Effects of genital prolapse surgery and hysterectomy on pelvic floor function

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Effects of genital prolapse surgery and hysterectomy on pelvic floor function

Gevolgen van genitale prolaps chirurgie en uterus extirpatie voor de functie van de bekkenbodem

(met een samenvatting in het Nederlands)

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Chapter *1*

Introduction

Both genital prolapse surgery and hysterectomy have been shown to effectively control the symptoms that led to their indication. Little attention has been paid to the effects of genital prolapse surgery and hysterectomy on micturition, defecation and sexuality. These three functions of the pelvic floor may be impaired due to damage of the pelvic floor innervation and pelvic fibromuscular structures during gynecological surgery.[1-4] Both genital prolapse surgery and hysterectomy can be performed either by vaginal or by abdominal approach. It is unknown whether either of these techniques causes more damage to the pelvic floor innervation and pelvic fibromuscular structures. If so, the prevalence of micturition symptoms, defecation symptoms and sexual dysfunction may differ between patients who have undergone vaginal surgery and patients who have undergone abdominal surgery.

Micturition symptoms, defecation symptoms and sexual dysfunction are all signs of impaired pelvic floor function that have been shown to negatively affect quality of life.[5-11] Information on the effects of different types of genital prolapse surgery and hysterectomy on pelvic floor function is, therefore, important.

Genital prolapse surgery

Prevalence of genital prolapse

In The Netherlands, every year approximately 8000 patients undergo a surgical correction because of genital prolapse. About 70 % of these operations involve the surgical correction of a decensus uteri or a vaginal vault prolapse whereas in the other 30% a single vaginal wall defect is repaired.[12] Almost 50 % of these 8000 patients are over age 65. The lifetime risk of undergoing an operation for pelvic organ prolapse and/or urinary incontinence is reported to be 11 %.[13] A population study performed among 641 women, aged 20 to 60 years, showed that the prevalence of any degree of prolapse was 31%.[14] Two percent of all women had a prolapse that reached the introitus. Prolapse symptoms, micturition symptoms and defecation symptoms were present in 10% of all women with any degree of prolapse. These symptoms were present in nearly all women in whom the prolapse reached to the introitus or beyond.

Anatomy of the pelvic floor

The pelvic floor is the lower border of the abdominal cavity and includes the levator ani muscles, the urethral and anal sphincter and the endopelvic fascia with the related condensations such as the sacrouterine, cardinal and pubourethral ligaments. The levator ani muscle forms an U-shaped sling that encircles the urogenital hiatus. This hiatus is the midline space through which the vagina and urethra pass. Another part of the levator ani

inserts into the rectum to form a sling around it, and is called the puborectalis muscle. The levator ani has two important functions. First, it provides a constant basal tone, thereby keeping the urogenital hiatus closed.[15] Second, the levator ani contracts reflexively in response to increased abdominal pressure, thereby supporting the related organs. Both actions contribute to the maintenance of continence.[16] The levator ani and the sphincter muscles of the pelvic floor are innervated by anterior sacral nerve roots S2-S4. Direct motor branches of these nerve roots migrate over the cranial surface of the pelvic floor, making them vulnerable to stretching and compression during parturition. The external anal sphincter muscle and the striated urethral sphincter are innervated by the pudendal nerve, which also arises from sacral nerve roots S2-S4.

Risk factors of genital prolapse

Several factors that increase the risk of developing genital prolapse have been identified. One of the major risk factors is stretching and laceration of the pelvic floor during vaginal delivery.[17] Such stretching and laceration may cause both direct damage to the pelvic floor and indirect damage resulting from pudendal neuropathy. Pudendal neuropathy is observed in 80% of all women in the first days after vaginal delivery.[18] A second factor that has been related to genital prolapse is gynecological surgery. Hysterectomy has been suggested to damage the supportive system of the vaginal vault. The incidence of vaginal vault prolapse following hysterectomy has been suggested to be as high as 43 %. [19] However, evidence has been provided that the risk on genital prolapse is increased in patients who undergo hysterectomy, because of genital prolapse.[20] In a study, evaluating the incidence of vault prolapse in 2670 patients who had undergone hysterectomy, an incidence of 11.6 % was observed when hysterectomy had been performed for genital prolapse and of 1.8 % when hysterectomy had been performed for other benign diseases. Gynecologic surgery may also increase the risk for prolapse by damaging the pudendal nerve. It has been shown that the pudendal nerve terminal motor latency is prolonged following pelvic surgery.[21] Possibly, pelvic floor supportive defects that have started to develop, become worse when gynecological surgery causes additional damage of the pudendal nerve.

A third factor that may lead to damage of the pelvic floor and neuropathy of the pelvic floor innervation, are expulsive forces present during chronic straining at stool[22], chronic coughing or heavy lifting.[23] Finally, aging is associated with decreased elasticity of the pelvic floor and worsened innervation and vascularization of the pelvic floor.[24] This may harm pelvic support of the genital organs and result in genital prolapse.

Symptoms of genital prolapse and indications for surgery

Genital prolapse may be restricted to complaints related to the anatomical defects itself, like feeling of protrusion or feeling of pelvic discomfort. In turn, genital prolapse may also affect micturition, defecation and sexuality. As a consequence, women may present themselves with any combination of prolapse symptoms (a sense of heaviness or dullness in the lower abdomen), micturition symptoms (urinary incontinence, overactive bladder symptoms, difficulty emptying bladder), defecation symptoms (fecal incontinence, difficulty emptying the bowel at defecation, sensation of anal blockage during defecation, incomplete evacuation at defecation) and sexual problems (decreased arousal, urinary incontinence during sexual activity, impossibility to have intercourse). These symptoms have been shown to negatively affect quality of life.[5-10]

The prevalence and experienced discomfort of micturition symptoms, defecation symptoms and sexual problems have not been shown to be correlated to the severity of anatomical abnormalities in patients with genital prolapse.[25] This variety in clinical expression, may be the most important reason that no consensus has been reached about the treatment of genital prolapse and associated pelvic floor dysfunction. Generally, gynecologists will propose surgery to patients in whom the genital prolapse reaches to the introitus or beyond and in whom this prolapse alters pelvic floor function so extensively that the patient's quality of life is negatively affected.

Diagnostic work-up

During the diagnostic work-up of a patient who is a candidate for surgical correction of a genital prolapse, gynecologists attempt to detect all present functional and anatomical abnormalities of the pelvic floor. A complete work-up, involving urodynamic investigation, defecography and anal manometry, is advocated by experts in the field of pelvic floor surgery.[26] However, one may question if there is a solid scientific basis for such a recommendation.

According to the recommendations of the International Continence Society (ICS), urodynamic investigation should include simple uroflowmetry with catheterized postvoid residual urine volume determination, retrograde provocative multi-channel urethrocystometry and passive and dynamic urethral pressure profilometry with the prolapse protruding and with the prolapse reduced.[27,28] If during urodynamic investigation evident loss of urine during straining with the prolapse protruding or with the prolapse reduced is visible, it is advised to combine the surgical correction of the prolapse with a bladder neck suspension.[29] Performing urodynamic investigation in patients who are candidate for genital prolapse surgery has been shown to be associated with improved outcome of treatment.[29-31]

Defecography allows detection of anatomical abnormalities such as enterocele and rectal intussusception that are frequently missed at pelvic examination.[32,33] Dynamic recordings of defecography allow a dynamic visualization of the process of defecation.[34] Little effort has been made to investigate which patients with genital prolapse are at increased risk to have abnormal findings at defecography.

Ano-rectal function tests are used to understand the pathophysiology of defecation symptoms.[35] Significant differences in ano-rectal function measurements between patients and healthy volunteers have been reported for several defecation symptoms.[36-39] Unfortunately, these studies may be biased by confounding because normal volunteers and patients with a defecation symptom may have differences, besides the defecation symptoms, that are not corrected for. In contrast to urodynamic investigation, it has not been proven that treatment decisions based on findings at defecography or ano-rectal function tests, positively affect outcome of treatment.

Surgical treatment of descensus uteri

In The Netherlands, vaginal hysterectomy combined with anterior and/or posterior colporraphy is the surgical treatment of choice in patients with descensus uteri. Studies reporting on recurrence rates of genital prolapse following this surgical technique vary from 2 % to 36 %.[40-43] All of these studies were of a retrospective design. The incidence of complications is low with this technique, and complications that occur are mild.[40,43]

In patients in whom a bladder neck suspension is indicated, the vaginal correction of a descensus uteri can be combined with a vaginal bladder neck suspension. Both the Stamey Pereyra bladder neck suspension[44] and the Raz bladder neck suspension[45] have been reported to have a cure rate between 50% and 90%.[46,47] The cure rate depends on the duration of follow-up and on the design of the study. Success rates based on retrospective data report higher cure rates in comparison to questionnaire-based outcomes studies.[46]

An alternative for the vaginal surgical correction of descensus uteri is the abdominal sacrocolpopexy with the use of a synthetic mesh. The technique of sacrocolpopexy that has been used during many years to surgically correct vaginal vault prolapse was first described by Rust.[48] Van Lindert and co-workers introduced a technique of sacrocolpopexy in The Netherlands that allows preservation of the uterus.[49] This technique has gained popularity over the years, although no superiority over the vaginal correction has been proven. Complications of the abdominal sacrocolpopexy with preservation of the uterus are reported to be low, but severe.[49]

In patients in whom a bladder neck suspension is indicated, the abdominal correction of a descensus uteri can be combined with a Burch colposuspension.[50] For the surgical

treatment of stress incontinence, randomized controlled trials have shown that the Burch colposuspension offers the best results.

A randomized controlled trial comparing vaginal hysterectomy combined with anterior and / or posterior colporraphy and abdominal sacrocolpopexy with preservation of the uterus as treatment of descensus uteri, has not yet been published. As a consequence, the decision for vaginal or abdominal approach in patients with descensus uteri is not based on scientific evidence but depends upon the experience of the surgeon and the familiarity with both procedures.

The only randomized controlled trial comparing vaginal and abdominal prolapse surgery was performed by Benson and co-workers.[51] In this trial, bilateral sacrospinous vault suspension and sacrocolpopexy were compared. It was found that the abdominal approach was more effective in the correction of significant pelvic supportive defects as compared to the vaginal approach. Unfortunately, about half of all abdominally operated patients in this study also underwent a vaginal surgical procedure to correct these defects.

Effects of genital prolapse surgery on pelvic floor function

So far the results of prolapse surgery have mainly been expressed as changes in findings at pelvic examination. However, genital prolapse surgery is not only intended to correct anatomical abnormalities but also to cure functional problems.

In 1998, guidelines for evaluating the outcomes of genital prolapse surgery were published.[52] The relief of symptoms and improvement of quality of life are advocated to be regarded as the most important outcomes. It is stressed that standardized and validated health-related quality-of-life instruments should be used to assess the effectiveness of genital prolapse surgery. At present, no studies applying these guidelines have been published.

Hysterectomy

History of hysterectomy

The vaginal hysterectomy procedure dates back to ancient times. The procedure was performed by Soranus of Ephesus 120 years after the birth of Christ. The many reports of its use in the middle ages were nearly always for the extirpation of an inverted uterus and the patients rarely survived.[53] The first abdominal hysterectomy was performed in 1843 by Charles Clay in Manchester.[53] Later, it was observed that leaving the cervix in situ reduced the risk of mortality and therefore subtotal abdominal hysterectomy became very popular. However in the 1950s, gynecologists tended to believe that the risk of cervical carcinoma in patients who had undergone subtotal hysterectomy was increased in comparison to

patients in whom the uterus was in situ.[54] Although not extensively studied, it was suggested that treatment of malignancy of the cervical stump was more difficult, when this subtotal hysterectomy was performed.[55] Nowadays, no overall increased risk of cervical cancer after subtotal hysterectomy is observed.[56]

In the Netherlands, every year approximately 20.000 women undergo a hysterectomy because of symptoms of benign disease.[57] Approximately 55 % of all hysterectomies are performed by abdominal approach. In about five percent of these abdominal cases a subtotal hysterectomy is performed. The remaining 45 % of all hysterectomies are performed by vaginal approach. More than half of these hysterectomies are combined with an anterior and/or posterior colporraphy. In case vaginal and abdominal removal of the uterus are both technically feasible, gynecologists will attempt to perform a vaginal hysterectomy because of the beneficial effects on duration of hospital stay, reduced complication rate and costs, compared with effects related to an abdominal hysterectomy.[58-60]

Effects of hysterectomy on pelvic floor function

The prevalence of micturition symptoms, defecation symptoms and sexual dysfunction is increased in patients who have undergone a hysterectomy.[61-68] The nature of this association is not clear. The increased prevalence of micturition symptoms, defecation symptoms and sexual dysfunction may have been present before hysterectomy.[68,69]

The changes in pelvic floor function that are caused by hysterectomy have been suggested to result from damage to pelvic floor innervation and pelvic fibromuscular structures during surgery.[1-4] The pelvic plexus is at risk in four areas during hysterectomy. First, the main branches of the plexus passing beneath the uterine arteries may be damaged during the division of the cardinal ligaments. Secondly, the major part of the vesical innervation, which enters the bladder base before spreading throughout the detrusor muscle, may be damaged during blunt dissection of the bladder from the uterus and cervix.[2] Thirdly, the extensive dissection of the paravaginal tissue may disrupt the pelvic neurons passing from the lateral aspect of the vagina.[4] Finally, the removal of the cervix may result in loss of a large segment of the plexus to which it is intimately related.[4] The dissection of the bladder from the vagina might be more extensive during vaginal hysterectomy[4] than during abdominal hysterectomy, leading to an increased prevalence of urinary incontinence among patients who have undergone vaginal hysterectomy.

Aside from damage to pelvic floor innervation and pelvic fibromuscular structures, hysterectomy may also result in impaired pelvic floor function because of altered anatomic position of the pelvic organs. The susceptibility to develop an enterocele and/or a vault prolapse is increased due to this altered anatomy.[70-72]

Aims of the thesis

At present, insight into the effects of genital prolapse surgery and hysterectomy on pelvic floor function is poor. There are several reasons for this oversight. First, most studies that have evaluated the effects of genital prolapse surgery and hysterectomy on pelvic floor function are of a retrospective design. In retrospective studies, limited information is available about the function of the pelvic floor before surgery. Second, studies comparing the effects of different techniques of genital prolapse surgery and hysterectomy on pelvic floor function are biased by confounding. Only a randomized controlled trial or a prospective study that accurately adjusts for all potential confounders can validly answer the question which technique of genital prolapse surgery and hysterectomy influences pelvic floor function most. Third, little is known about the optimal pre-operative diagnostic procedures that should be performed when planning genital prolapse surgery. Scientific evidence has been provided that performing urodynamic investigation may improve outcome of treatment in patients with genital prolapse. However, it is unknown whether performing defecography and ano-rectal function tests in patients undergoing genital prolapse surgery improves outcome of treatment. Before this can be established, the diagnostic characteristics of defecography and ano-rectal function tests have to be evaluated.

The aims of this thesis are threefold:

1. To compare the effects of vaginal and abdominal surgical correction on pelvic floor function in patients with descensus uteri grade II-IV.
2. To compare the effects of technique of hysterectomy on pelvic floor function.
3. To evaluate diagnostic characteristics of defecography and ano-rectal function tests.

Outline of the thesis

In *Part one* of this thesis (Chapter 2-5) the results are described of studies researching diagnostic characteristics of defecography and ano-rectal function tests. It may be valuable to include these two investigations in the diagnostic work-up of patients undergoing surgical correction of descensus uteri grade II – IV (ICS). The presented studies are performed as part of a multi-center randomized controlled trial comparing the abdominal and vaginal surgical correction of descensus uteri grade II – IV.

In *Chapter 2* a new instrument to score defecographic abnormalities is presented. In contrast to systems presented sofar, this system involves quantitative measurements and focuses on defecographic items that correlate well with clinical symptoms.

In *Chapter 3* the results are described of a study investigating whether discrimination of high and low probability of abnormal defecography is possible based on the quantified value of findings from patient history, pelvic examination and a validated questionnaire. Such a discrimination may improve the indication setting of defecography in the individual patient.

In *Chapter 4* it is studied whether a relation exists between findings at ano-rectal function tests and defecation symptoms in patients with descensus uteri grade II – IV (ICS). It is investigated whether abnormal findings at ano-rectal function tests can explain the presence of defecation symptoms in the studied population.

In *Chapter 5* the effects of prolapse surgery on bowel function are evaluated. Ano-rectal function tests and defecography are performed before and at six months after surgery in patients with a descensus uteri. The relation between changes in defecation symptoms and changes in results of ano-rectal function tests and defecographic findings will be evaluated. It is investigated whether there is a pathophysiological and anatomical explanation for the observed effects of genital prolapse surgery on bowel function.

In *Part two* of this thesis (Chapter 6-9) the vaginal and abdominal correction of descensus uteri grade II – IV (ICS) are compared. Both results of a retrospective study and results of a multi-center randomized trial are presented.

In *Chapter 6* a retrospective study is described comparing the effects of a combination of surgical procedures because of genital prolapse and coexisting stress incontinence, performed via unified vaginal and performed via abdominal approach. Micturition, defecation and prolapse symptoms as well as duration of hospital stay and complication rate are compared between patients undergoing a unified vaginal surgical correction and patients undergoing a unified abdominal surgical correction.

In *Chapter 7* the results are presented of a multi-center randomized controlled trial comparing vaginal hysterectomy combined with anterior and / or posterior colporraphy and abdominal sacrocolpopexy as surgical treatment for patients with descensus uteri grade II – IV (ICS). In case it is indicated to simultaneously perform a colposuspension, the abdominal operation is combined with a Burch colposuspension and the vaginal operation with a Stamey Pereyra or a Raz bladder neck suspension. Quality of life related to micturition and defecation is selected as primary outcome parameter in this study. Secondary outcome parameters involve changes in findings at pelvic examination, duration of hospital stay, complication rate and recurrence of genital prolapse.

In *Chapter 8* the effects of surgical correction of descensus uteri grade II – IV (ICS) on sexual function are evaluated. Differences between reported sexual satisfaction and frequency of intercourse before and after surgery are compared. Of patients who are sexually active before and one year after surgery, the prevalence of symptoms that remain

present or develop after surgery are calculated. Characteristics, pre-operative findings at pelvic examination and performed surgery, are compared between patients in whom sexual problems remain present or disappear.

In *Chapter 9* the results are reported of a randomized comparison of post-operative pain, quality of life and physical performance during the first 6 weeks after abdominal or vaginal surgical correction of descensus uteri. Participating patients are asked to fill out a general quality of life questionnaire before and six weeks after surgery and to keep a diary for the first six weeks after surgery. This diary assesses the pain perception, amount of administered pain medication per day, presence and experienced discomfort of limitations due to the surgery during hospital stay and performance of daily activities. A comparison of these outcomes is made between patients undergoing vaginal and abdominal prolapse surgery.

Part three of this thesis (Chapter 10-12) compares the effects of abdominal versus vaginal hysterectomy and of total versus subtotal hysterectomy on pelvic floor function. Both results of a retrospective study and results of a multi-center prospective study are presented. Confounding bias is accounted for by adjusting for all parameters in which patients undergoing vaginal, subtotal abdominal and total abdominal hysterectomy differ from each other.

In *Chapter 10* a retrospective study is presented, comparing the effects of vaginal, total abdominal and subtotal abdominal hysterectomy on micturition and defecation in patients with an uteral size of less than 10 centimeter. Observed differences in the prevalence of micturition and defecation symptoms are corrected for potential confounders.

In *Chapter 11* the results are presented of a prospective study that is performed in 13 hospitals. In this study, the effects of abdominal and vaginal hysterectomy on micturition and defecation are compared. Patients are selected in whom both approaches are technically feasible. Observed differences in the prevalence of micturition and defecation symptoms are corrected for potential confounders.

In *Chapter 12* the results of a prospective multi-center study are presented. This study compares the effects of vaginal, subtotal abdominal and total abdominal hysterectomy on sexuality. Of patients who are sexually active before and after hysterectomy, the prevalence of symptoms that remain present and develop after hysterectomy are calculated. Differences in symptoms that remain present or develop, are corrected for other differences between techniques of hysterectomy in prognostic factors for sexuality.

Chapter 13-15 of this thesis contain the general discussion, the summary in English and the summary in Dutch.

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Chapter 2

A new instrument to score abnormalities revealed by defecography.

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Abstract

Introduction: This study reports on a new system to score abnormalities revealed by defecography and on the inter-observer reproducibility of this new system. In contrast to systems presented thusfar, this system involves quantitative measurements and focuses only on defecographic items that correlate well with clinical symptoms.

Methods: Defecographies were collected from 77 patients participating in a multi-center randomized trial comparing vaginal and abdominal prolapse surgery. Two observers independently scored size of rectocele, grade and size of enterocele and grade and size of rectal intussusception, according to a newly developed instrument.

Results: The reproducibility of size of rectocele, quantification value of enterocele and quantification value of rectal intussusception was almost perfect with Intraclass Correlation Coefficients of 0.87 (95 % lower confidence interval (CI) 0.82), 0.98 (95 % lower CI 0.96), and 0.84 (95 % lower CI 0.63), respectively. The weighted Kappa values for grade of enterocele and grade of rectal intussusception were also almost perfect: 0.97 (95 % CI 0.93 to 1.00) and 0.91 (95 % CI 0.79 to 1.00), respectively.

Conclusion: The inter-observer reproducibility of both qualitative and quantitative measurements of defecographic abnormalities as measured with the proposed system is high. The diagnostic value of this scoring system needs to be studied, before this system can be used to ameliorate outcome of treatment.

Introduction

Defecography provides a dynamic assessment of the defecation process by recording the rectal expulsion of a barium paste that approximates the consistency of feces.[1] Defecography may play an important role in the diagnosis of rectoceles, enteroceles and rectal intussusceptions that are common in patients with genital prolapse.[2] This may contribute to surgical planning of these anatomical abnormalities.[3]

Until now, no consensus has been reached on the scoring of defecographic abnormalities. Several reasons may explain the absence of a widely accepted and used instrument to score defecographic abnormalities. First, studies evaluating the reproducibility of defecographic abnormalities have shown a high inter-observer inconsistency.[4-8] Such inconsistencies are likely to limit the diagnostic performance of defecography.[9] The reported high inter-observer inconsistency of defecographic abnormalities[5-8] may be explained by indistinctness among the observers about definitions, as these definitions are mostly not based upon precisely and consistently recognizable radiographic landmarks. Secondly, researchers have focussed for some time on defecographic abnormalities that correlate poorly with clinical symptoms.[4,6-8] Research has shown that only rectoceles of 2 centimeter or larger, enterocele and rectal intussusception are defecographic findings with clinical implications.[10] Thirdly, most instruments do not involve quantitative measurements.[4,6-8] Quantitative measurements enable insight into the severity of abnormalities and may enhance the diagnostic value of defecography, as they have a better discriminatory performance.

We felt the need to develop a new instrument to measure defecographic abnormalities. This new instrument involves quantitative measurements and focuses on defecographic abnormalities that correlate well with clinical symptoms. In this chapter this new scoring system is described and its inter-observer reproducibility of the measurements of defecographic abnormalities is evaluated.

Patients and Methods

Materials

Defecographies of 77 patients participating in a randomized controlled study comparing vaginal and abdominal prolapse surgery were evaluated in this study. All patients underwent a standardised urogynecologic interview before surgery, as well as a complete physical examination including a classification of the genital prolapse according to the

recommendations of the ICS[11] and an urodynamic multi-channel investigation.[12] All defecographies were performed 1 to 3 months before surgery at the Radiology Department of the University Medical Center Utrecht, the Netherlands, between January 1998 and December 1999.

Technique of defecography

The technique that was used was based on the method described by Mahieu et al.[1] To opacify the small bowel, all patients ingested 135 ml (340 g, 250% w/v) of liquid barium contrast (E-Z-HD, E-Z-EM Inc., Westbury, New York, USA) two hours prior to the examination. Then 120 ml of high density $BaSO_4$ contrast medium were introduced into the rectum with the patient in the left decubitus position, followed by thickened $BaSO_4$ contrast medium up to capacity, usually approximately 250 ml. Thickening was achieved by adding Metamucil® (Marion Merell Dow, Inc., Cincinnati, OH) to $BaSO_4$ contrast with a specific gravity of 1.2 g/cm^3, in a volume ratio of 1:30, to attain fecal viscosity. During withdrawal of the tube, a small amount of contrast is injected to delineate the anal canal. To coat the vagina, a contrast medium consisting of 30 ml amidotrizoic acid 50 % solution gel was applied by means of a syringe with a soft pediatric enema tip.

To assess the magnification factor a midline radiopaque ruler, made of a rubber tube with haleshots on every centimeter, was fixed between the buttocks. After sufficient filling of rectum and vagina, the patients were asked to sit on a radiolucent commode. This commode was covered by a water-filled motor scooter tube to cut out flare in the lower part of the image. Initially, the patient was screened at rest without consciously contracting any pelvic muscles. Then, the patient was asked to maximally contract the pelvic floor muscles ("squeeze") and finally the patient was asked to empty the rectum as completely as possible. The whole defecography was recorded on video. All recordings were taken from the lateral position.

Measurements

All defecographic recordings were analyzed by two independent observers who were trained to evaluate defecographies. No information about the patient was made available to them before observation of the recordings. Before the measurements were started, about 10 defecographies, that were not included in the analysis, were observed and discussed by both observers until consensus about all definitions was achieved.

A *rectocele* was defined as an outward bulge of the (usually anterior) rectal wall beyond the

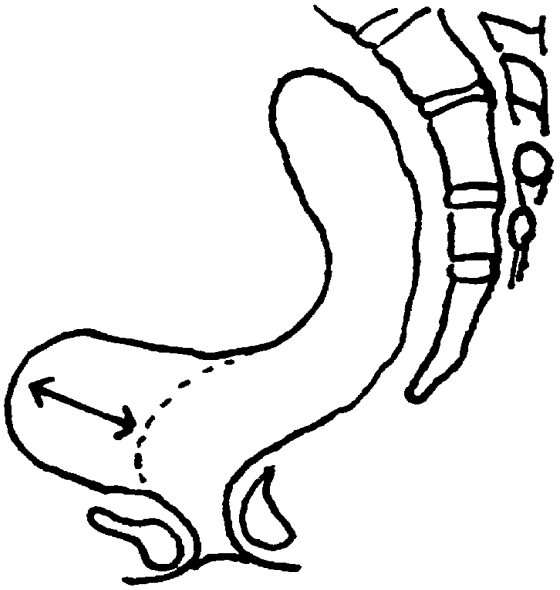

Figure 1
Measurement of size of rectocele : The distance between the most ventral part of the anterior rectal wall and the expected rectal lining is measured in centimeters.

extrapolated line of the expected rectal lining.[13] We quantified the size of a rectocele by measuring the distance between the most ventral part of the anterior rectal wall and the expected rectal lining in centimeters (Figure 1). Values were scored in half centimeters precise.

An *enterocele* was defined as a peritoneal sac, normally filled with loops of small bowel, that has herniated downwards along the ventral rectal wall.[3] Enteroceles were staged from 0 to 3, depending on the extension along the ventral rectal wall. The anal orifice (located at the lower margin of the anal canal) was considered as a fixed radiographic landmark that could consistently and precisely be identified. The radiographic position of the lowest part of the peritoneal sac was measured in centimeters above or proximal to the anal orifice (negative number) or in centimeters below or distal to the anal orifice (positive number) with the plane of the anal orifice being defined as zero. Values were scored in half centimeters precisely. In the scoring of an enterocele two other radiographic landmarks that could consistently and precisely be identified were used, namely the top of the vagina and the upper margin of the anal canal. As the length of the anal canal was considered to be 2 centimeter in all patients, the quantification value of the upper margin of the anal canal was -2.0 centimeter. The stage of enterocele was assigned according to the most severe extension of the peritoneal sac along the ventral rectal wall. The four stages of enterocele were as follows :

Stage 0: Two situations can occur: 1) No descent of a peritoneal sac along the ventral rectal wall is observed. 2) Descent is present, but during the whole recording the lowest point of the peritoneal sac does not descend below the level of the top of the vagina.

Stage I: The most distal part of the enterocele is below the level of the top op the vagina, but not below the upper margin of the anal canal (i.e., its quantification value is -2.0 centimeter.)

Stage II: The most distal part of the enterocele is below the upper margin of the anal canal, but not below the lower margin of the anal canal (i.e. quantification value is > -2.0 centimeter but 0 centimeter).

Stage III The most distal part of the enterocele protrudes out of the anal canal. (i.e., its quantification value is > 0 centimeter.)

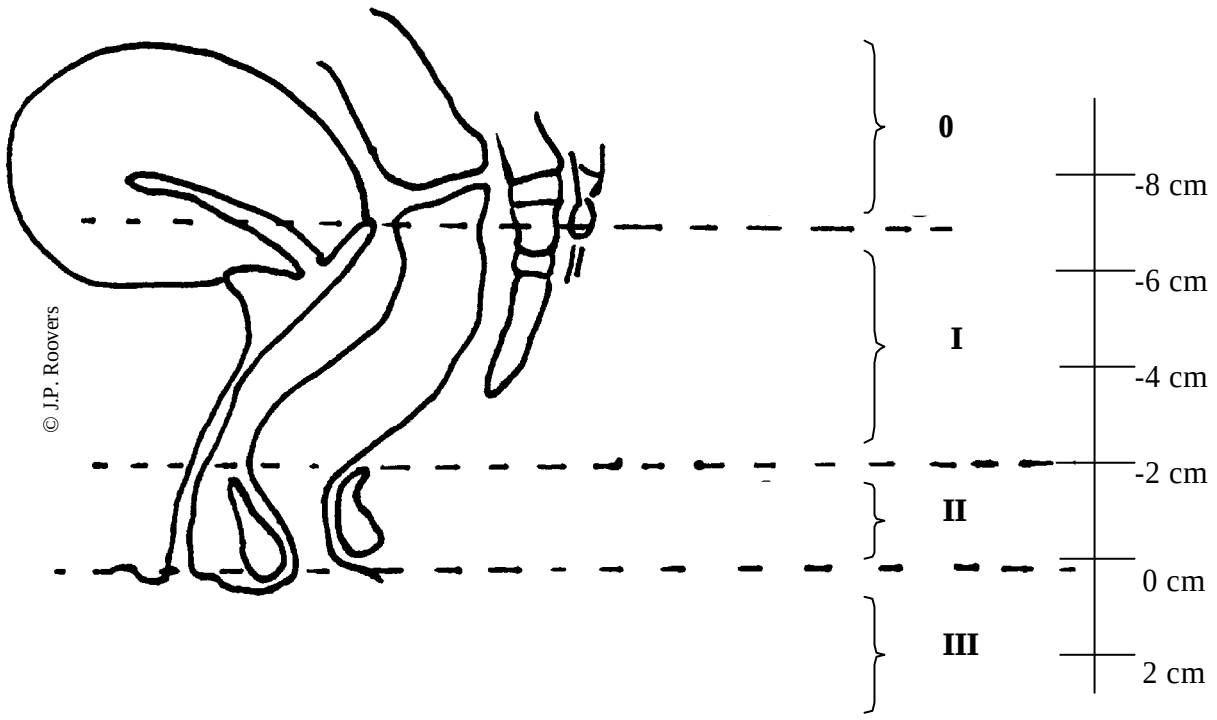

Figure 2. Radiographic landmarks, classification in grades and the method of quantification in centimeters.

Both the stage and the quantification value of an enterocele were recorded. For example, an enterocele that protruded 2.0 centimeter distal to the anal orifice would be scored as follows: enterocele stage III (+ 2.0). Figure 2 shows the radiographic landmarks, the classification in stages and the method of quantification in centimeters. Figure 3 shows the four different stages of enterocele.

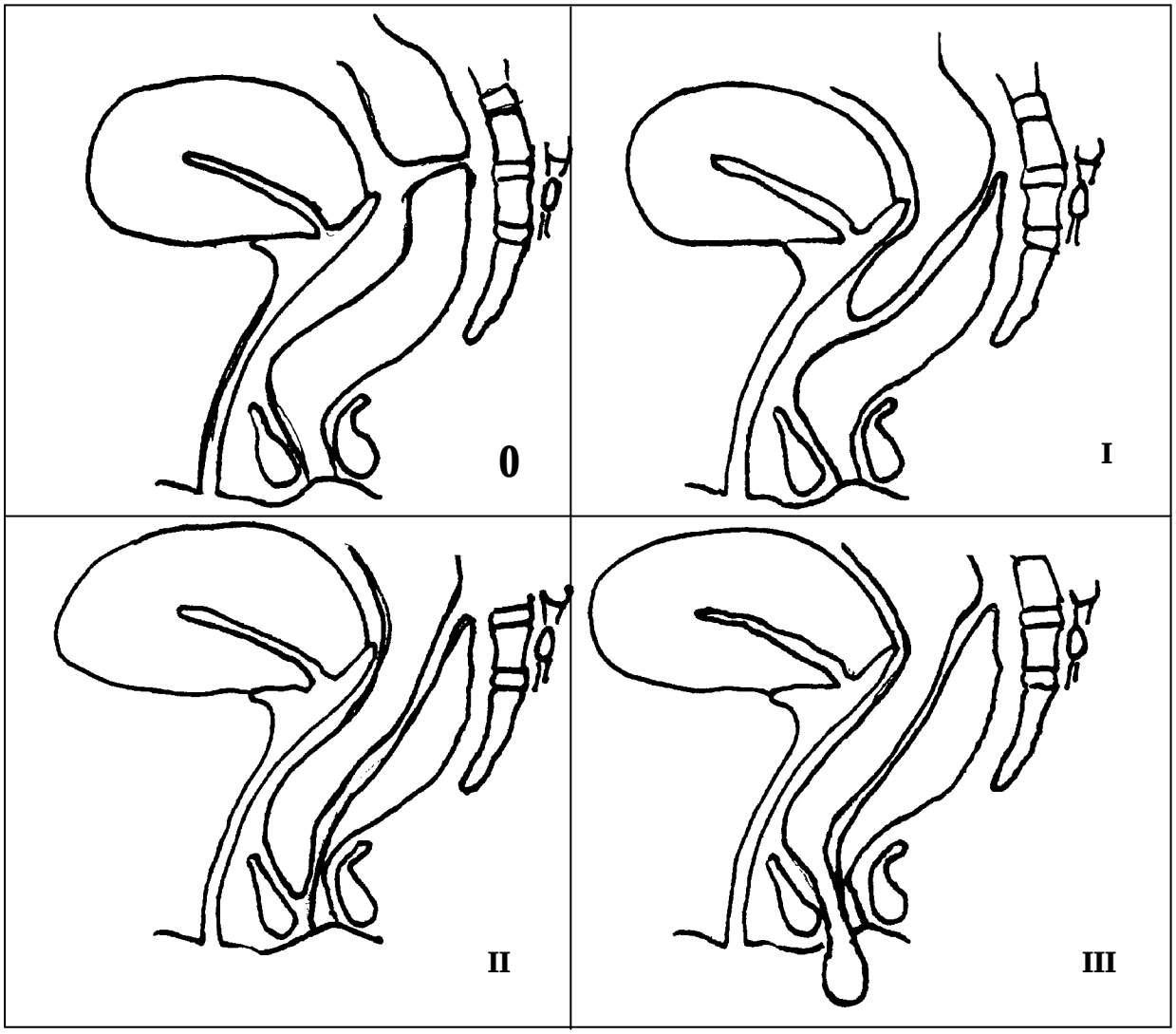

Figure 3. Four stages of enterocele.

Rectal intussusception, or internal procidentia, was defined as an intussusception of the rectal wall. The rectal intussusception begins as a circular fold 6 to 8 centimeter up in the rectum and develops into a condition in which the entire rectal wall folds in towards the rectal lumen.[14] During straining, the "infolding" progresses and deepens to form a ring pocket. Depending on the extension of the "infolding", intussusceptions were staged from 0 to 3. The anal orifice (located at the lower margin of the anal canal) was taken as a fixed radiographic landmark, conform the system developed to stage an enterocele. The radiographic position of the lowest part of the "infolding" was measured in centimeters above or proximal to the anal orifice (negative number) or centimeters below or distal to the anal orifice (positive number) with the plane of the anal orifice being defined as zero.

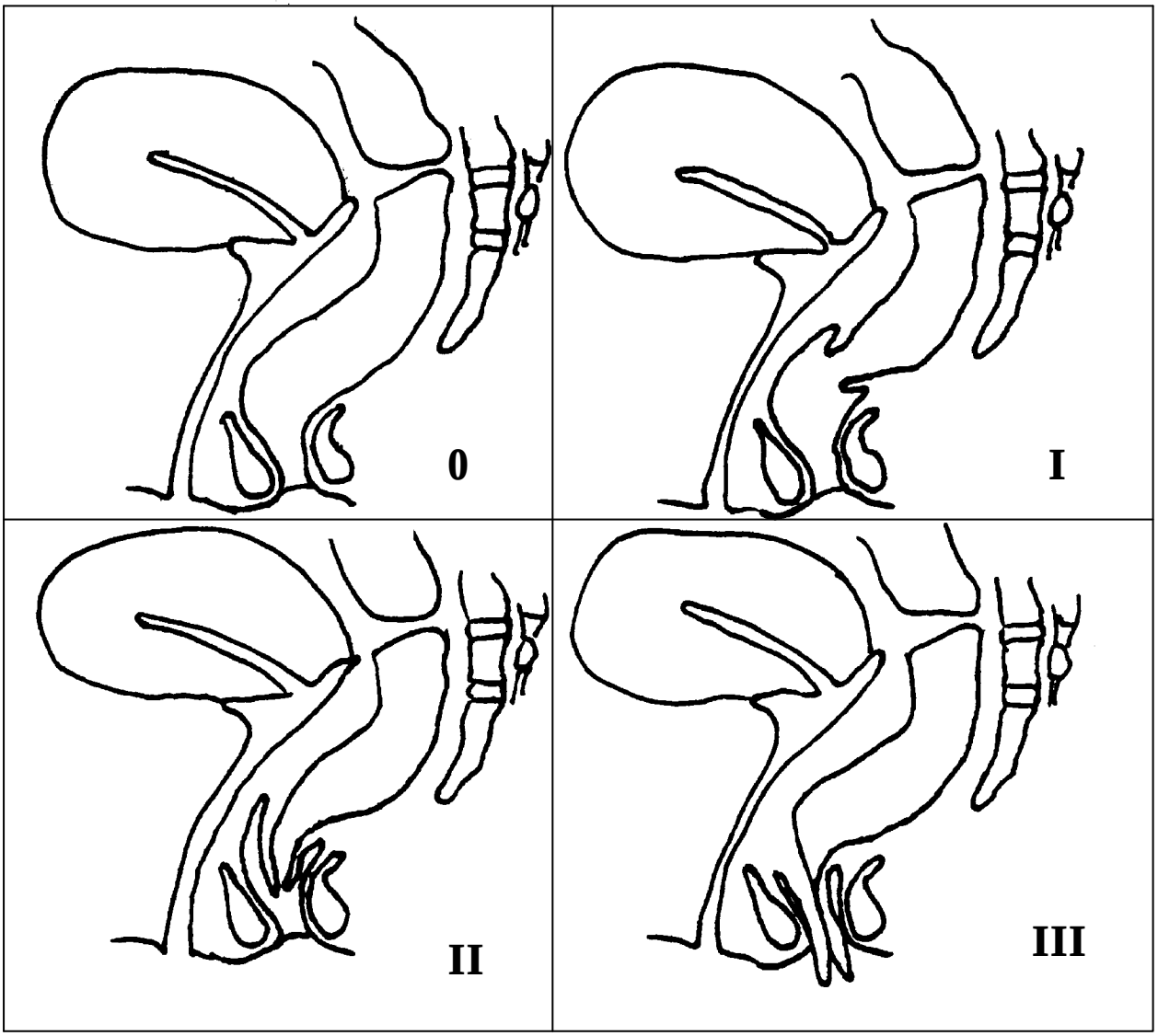

Figure 4. Four stages of rectal intussusception.

Values were scored in half centimeters precisely. The upper margin of the anal canal also served as radiographic landmark in the scoring of an intussusception. As the length of the anal canal was considered to be 2 centimeter in all patients, the quantification value of the upper margin of the anal canal was –2.0 centimeter. The stage of intussusception was assigned according to the most severe extension of the "infolding". The four stages of intussusception were as follows :

Stage 0: No development of a rectal intussusception is seen.

Stage I: "Infolding" of the rectal wall is present but the most distal part of the "infolding" does not descend to below the upper margin of the anal canal (i.e., its quantification value is -2.0 centimeter.)

Stage II: The most distal part of the "infolding" is below the upper margin of the anal

canal but not below the lower margin of the anal canal (i.e. quantification value is > -2.0 centimeter but 0 centimeter).

Stage III: The most distal part of the "infolding" protrudes out of the anal canal (i.e., its quantification value is > 0 centimeter). Both the stage and the quantification value of a rectal intussusception were recorded. Figure 4 shows the four different stages of a rectal intussusception.

Statistical analysis

Mean inter-observer differences (and 95 % confidence intervals) between measurements of size of rectocele, quantification value of enterocele and quantification value of rectal intussusception were calculated. The mean difference plus and minus 2 standard deviations were considered as 95 % limits of agreement.[15,16]

The inter-observer reproducibility for size of rectocele, quantification value of enterocele and quantification value of intussusception were expressed using Intraclass Correlation Coefficient (ICC) and lower confidence limits (95 % CL).[17] The ICC expresses the degree to which the total variance can be attributed to the true variance; true differences between subjects. It not only assesses the strength of correlation between two measurements but also detects systematic errors. Thus, if a set of estimates made by one observer is systematically lower or higher than the estimates made by another observer, the ICC is correspondingly reduced. Values of the ICC are interpreted as ê-statistics: from 0.00 to 0.20 'slight', from 0.21 to 0.40 'fair', from 0.41 to 0.60 'moderate', from 0.61 and 0.80 'substantial', and between 0.81 and 1.00 'almost' perfect.

To express the inter-observer reproducibility for stage of enterocele and stage of intussusception, weighted kappa-values and 95 % confidence intervals were calculated. A weighted kappa-value of 0 indicated no agreement beyond chance, a value of 1 indicated perfect agreement between observers. The classification of weighted kappa-values are interpreted as follows: from 0.00 to 0.20 'slight', from 0.21 to 0.40 'fair', from 0.41 to 0.60 'moderate', from 0.61 and 0.80 'substantial', and between 0.81 and 1.00 'almost' perfect.[18]

Results

Patient characteristics of all patients are shown in Table 1. Differences between (quantitative) measurements of size of rectocele, quantification value of enterocele and quantification value of rectal intussusception were plotted against the average of observations (figures 5 to 7), as described by Bland and Altman[15], to visualize the inter-

observer agreement on these measurements. Results of (qualitative) measurements of stage of enterocele and rectal intussusception of both observers are shown in Table 2.

Table 1. Characteristics of all patients (n=77).

Age (years)	57.1 (9.6)
Parity (number of children)	2.6 (1.1)
Body Mass Index (kg/m^2)	25.2 (3.3)
History of abdominal/pelvic surgery (n) *	17 (22.1 %)
Cholecystectomy	5
Appendectomy	6
Anterior and/or posterior repair	4
Burch colposuspension	1
Caesarian section	4
Findings at pelvic examination before surgery	
Descencus uteri (n)	
Grade II	63 (81.8 %)
Grade III	14 (18.2 %)
Cystocele (n)	
No cystocele	2 (2.6 %)
Grade I	7 (9.1 %)
Grade II	36 (46.8 %)
Grade III	32 (41.5 %)
Rectocele (n)	
No rectocele	16 (20.8 %)
Grade I	34 (44.2 %)
Grade II	23 (29.9 %)
Grade III	4 (5.2 %)

Values are means (standard deviation) or numbers (percentage).
* Some patients had undergone more than one surgical procedure.

Table 2. Qualitative scoring of enterocele and rectal intussusception by two independent observers on 77 defecographies.

	Observer 2 : Stage I	Observer 2 : Stage II	Observer 2 : Stage III	Total
Scoring of enterocele				
Observer I : Stage I	50 (65)			50 (65)
Observer I : Stage II		14 (18)	2 (3)	16 (21)
Observer I : Stage III			11 (14)	11 (14)
Total	50 (65)	14 (18)	13 (17)	77 (100)
Scoring of rectal intussusception	66 (86)	1 (1)		67 (87)
Observer I : Stage I		4 (5)		5 (5)
Observer I : Stage II			6 (8)	6 (8)
Observer I : Stage III	66 (86)	5 (6)	6 (8)	77 (100)
Total				

Values are numbers (percentage)

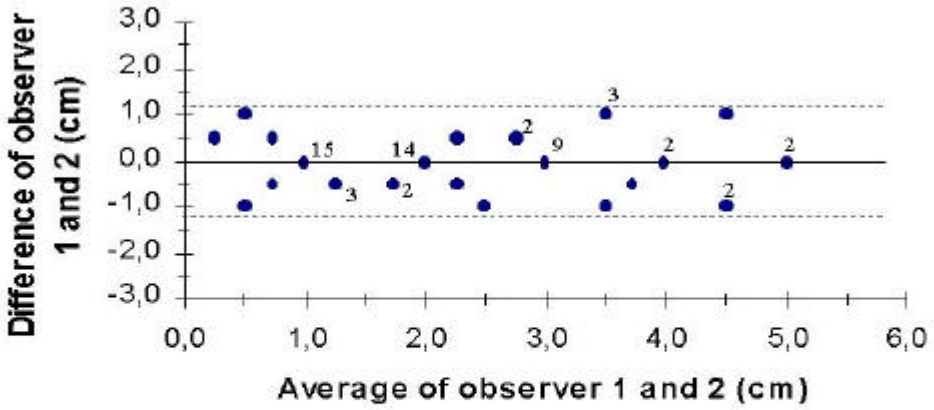

Figure 5. Difference between both observers according to size of rectoocele (cm).

Each number next to a dot indicates how many similar combinations of observations were made. In case no number is noted next to a dot, this dot represents one combination of observations.

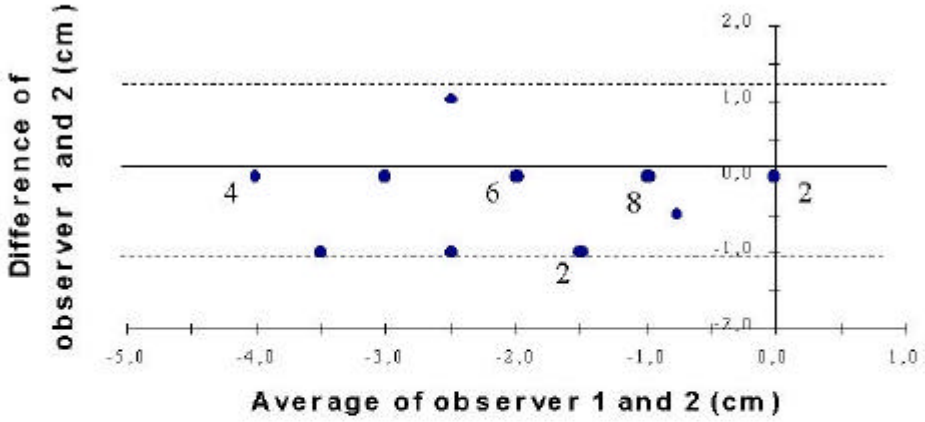

Figure 6. Difference between both observers according to quantification value of enterocele (cm).

Each number next to a dot indicates how many similar combinations of observations were made. In case no number is noted next to a dot, this dot represents one combination of observations.

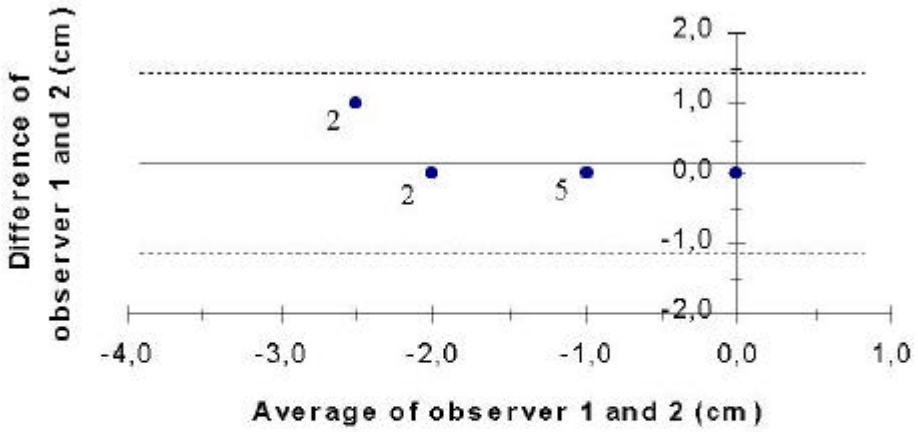

Figure 7. Difference between both observers according to quantification value of rectal intussusception (cm).

Each number next to a dot indicates how many similar combinations of observations were made. In case no number is noted next to a dot, this dot represents one combination of observations.

Weighted kappa-values, Intraclass Correlation Coefficients and mean differences between observers are shown in Table 3. Duration of fecal evacuation had a substantial reproducibility, with an ICC of 0.70 (95 % lower CI 0.60). The reproducibility of size of rectocele, quantification value of enterocele and quantification value of rectal intussusception was almost perfect with ICC's of 0.87 (95 % lower CI 0.82), 0.98 (95 % lower CI 0.96), and 0.84 (95 % lower CI 0.63), respectively. The weighted Kappa values for stage of enterocele and stage of rectal intussusception were also almost perfect: 0.97 (95 % CI 0.93 to 1.00) and 0.91 (95 % CI 0.79 to 1.00), respectively.

Table 3. Measurements of reproducibility: Weighted Kappa value and Intraclass Correlation Coefficients.

	Kappa-value (95 % CI)	ICC (lower 95 % CI)	Mean difference between observers (95 % CI)
Rectocele (in cm)		0.87 (0.82)	0.07 (- 1.1; 1.2)
Enterocele			
Stage	0.97 (0.93; 1.00)		
Distance from anal orifice (cm)		0.98 (0.96)	0.13 (- 1.0; 1.2)
Rectal intussusception			
Stage	0.91 (0.79; 1.00)		
Distance from anal orifice (cm)		0.84 (0.63)	0.20 (- 1.1; 1.5)

CI = Confidence interval; ICC = Intraclass Correlation Coefficient

Discussion

This study presents a new instrument to score abnormalities revealed by defecography. In contrast to earlier instruments, this instrument was based on fixed radiographic landmarks that could consistently and precisely be identified. The instrument had a high inter-observer agreement on measurements of size of rectocele, quantification value of enterocele and quantification value of rectal intussusception in patients with descensus uteri stage II (ICS) or more.

Some aspects regarding the radiographic landmarks, identified to allow precise measurements, need to be discussed. First, we assumed the anal canal to be 2 centimeter long in all patients. This assumption was made for practical reasons. Without this assumption an enterocele could, for example, be scored as stage II in a patient with an anal canal length of 3 centimeter and as stage I in a patient with an anal canal length of 2 centimeter. Second, it is known that the anal canal shortens during straining. This could have negatively influenced the inter-observer agreement on defecographic measurements. As we found a very good inter-observer agreement on all scored items we postulate that shortening of the anal canal during straining is not a major problem of our scoring system. A third problem of the selected radiographic landmarks may be variation in length of the vagina between patients. This could lead to inconsequent scoring of minimal enteroceles or rectal intussusceptions. An enterocele with a quantification value of -8 centimeter could for example be staged as stage 0 in a patient with a vaginal length of 7 centimeter and as stage 1 in a patient with a vaginal length of 9 centimeter. However, it is questionable whether this inconsequent scoring of minimal enteroceles or rectal intussusceptions is of any clinical relevance.

Investigators have studied the reproducibility of a wide variety of defecographic abnormalities.[4-8,19] The clinical relevance of most of these abnormalities is low, as they have a poor correlation with clinical symptoms.[20] In this study, only the reproducibility of defecographic items that correlate well with clinical symptoms was investigated[20,21].

A rectocele smaller than 2 centimeter may be a normal finding at defecography in asymptomatic subjects.[3,22-24] However, a rectocele of 2 centimeter or larger mostly causes defecation symptoms.[21] Inter-observer agreement on the presence of a rectocele is reported to be moderate-to-good.[4,5,8] Two studies have addressed the reproducibility of quantitative measurement of a rectocele.[7,19] Both of these studies reported a lower inter-observer agreement than we discovered, which may have two reasons. First, we used a midline radiopaque ruler that was fixed between the buttocks. This ruler allowed us not

only to assess the magnification factor, but also contributed to our insight into the location of the pelvic organs. Secondly, our definition of size of rectocele was not subject to interpretation.

Studies on systems scoring stage of enterocele or stage of rectal intussusception are lacking. Wiersma et al. suggested a system to stage an enterocele.[20] In this system a stage I enterocele reaches maximally to the distal half of the vagina, a stage II enterocele reaches maximally to the perineum and a stage III enterocele protrudes out of the anal canal. Studies evaluating the reproducibility or accuracy of this system to score an enterocele have not been published yet. Two scoring systems have been published to stage rectal intussusception.[13,20] Bartolo and co-workers proposed a scoring system from stage 1 to stage 7. Stages 1 and 2, according the system proposed by Bartolo and co-workers[13], involve folds of mucosa of 3 mm or less in thickness, and greater than 3 mm for stages 3 and above. The system proposed by Wiersma et all[20], basically scores rectal intussusceptions in a way that was also followed in this study. However, our scoring system adds a quantitative value of rectal intussusception to the scoring system as proposed by Wiersma. Reproducibility nor accuracy of the scoring of a rectal intussusception of either Bartolo's system or Wiersma's system have been evaluated.

We postulate that our scoring system has three advantages over systems presented until now. First, radiographic landmarks are used that can consistently and precisely be identified, allowing observers to agree upon the interpretation of defecographies. Secondly, only abnormalities that correlate well with clinical symptoms are scored. Thirdly, our scoring system allows exact quantification of defecographic findings. With ROC analysis, quantified measurements can be used to improve definitions of normal and abnormal defecographic findings. So far, these definitions have been based on defecographies performed in asymptomatic subjects.[1,23,24]

In conclusion, this study presents a new instrument that allows reproducible qualitative and quantitative measurements of clinically relevant defecographic abnormalities. The diagnostic value of this scoring system needs to be studied before this system can be used to ameliorate outcome of treatment.

Acknowledgement

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Chapter 3

Prediction of findings at defecography in patients with genital prolapse.

J.P.W.R. Roovers, J.G. van der Bom, C.H. van der Vaart, A.P.M. Heintz

Abstract

Objective: Defecography may be useful in surgical planning of patients with genital prolapse as it enables identification of enterocele and/or rectal intussusception. Although defecography is an invasive and embarrassing procedure for patients, little effort has been made to optimalize selection criteria to demand for defecography or not in the individual patient. We performed this study to investigate whether discrimination of high and low probability of abnormal defecography is possible based on the quantified value of findings from patient history, pelvic examination and a validated questionnaire.

Methods: Of 82 patients with descensus uteri stage II-IV (ICS classification) a history and quantitative measurement of the genital prolapse were obtained. A validated questionnaire was used to assess the presence of defecation and micturition symptoms. Using multivariate logistic regression analyses with Receiver Operating Characteristic (ROC) curves, a diagnostic model to predict the presence of an abnormal defecography was systematically constructed and validated.

Results: The most important predictors for an abnormal defecography were quantification value (QV) of rectocele, history of abdominal or pelvic surgery and constipation. With these variables a prediction rule (3 + 3*history of pelvic surgery + QV of rectocele + 3*constipation) could be constructed that confidently predicts the prevalence of an abnormal defecography (Area Under Curve = 0.73 (95 % CI : 0.61 – 0.83)).

Discussion: This study shows that a diagnostic model based on findings obtained from a non-invasive work-up can accurately predict the presence of an abnormal defecography. Such a model provides the possibility to better consider the decision to demand for defecography in the individual patient.

Introduction

Patients with prolapse of the uterus have a high prevalence of micturition and defecation symptoms.[1] These symptoms may be due to anatomical abnormalities of the anterior and posterior compartment associated with a descending uterus. Failure to identify these abnormalities in the diagnostic process, may lead to incomplete surgical repair. As a consequence, persistent or recurrent micturition and defecation symptoms may occur. Defecography can play an important role in the evaluation of posterior compartment abnormalities, as it enables identification of clinically unsuspected abnormalities and coexisting defecation disorders.[2,3] Defecography provides a dynamic assessment of the defecation process by recording the rectal expulsion of a barium paste that approximates the consistency of feces.[4]

Most studies evaluating the prevalence of defecographic abnormalities are performed in patients with common defecation symptoms, such as constipation or incomplete evacuation of the rectum. Studies evaluating defecographic abnormalities in patients with genital prolapse are scarce. Kelvin and co-workers have shown that the prevalence of defecographic abnormalities is high in patients with genital prolapse, especially in those patients who have defecation symptoms.[2,3] The authors concluded from these findings, that defecography is useful in the pre-operative evaluation of patients with genital prolapse.

Although defecography is an invasive and embarrassing procedure for patients, little effort has been made to optimize selection criteria for defecography in the individual patient. This study was performed to investigate whether the presence of an abnormal defecography in patients with genital prolapse can be predicted based on findings derived from a non-invasive diagnostic work-up.

Methods

Patients

This study is based on data obtained from a multi-center randomized controlled trial comparing vaginal and abdominal prolapse surgery in patients with descensus uteri grade II – IV (according to the classification of the International Continence Society[5] (ICS)). Eighty-two patients were enrolled in this trial between January 1998 and January 2000. The study protocol was approved by the institutional review boards of the three participating hospitals (University Medical Center in Utrecht, Diaconessenhuis in Utrecht

and St. Antonius Hospital in Nieuwegein) and informed consent was obtained from all patients.

Measurements

Each patient underwent before surgery a standardized urogynecologic interview and a complete physical examination, including a classification of the genital prolapse based on the recommendations of the ICS.[5] The ICS classification system involves quantitative measurements allowing a more precise description of the extent of the genital prolapse. These quantitative measurements are normally performed by assessing the distance between six defined points and one fixed reference point (the hymen). As using all six defined points was not very practical, in this study three defined points were used to assess the quantification value (QV) of respectively descensus uteri, cystocele and rectocele. These points were the following: 1) A point that represented the most distal edge of the cervix, 2) A point located in the midline of the anterior vaginal wall 3 cm proximal to the external urethral meatus, 3) A point located in the midline of the posterior vaginal wall 3 cm proximal to the hymen. Quantifications values were assessed by measuring the distance of these points in centimeters above or proximal to the hymen (negative number), or centimeters below or distal to the hymen (positive number), with the plane of the hymen being defined as zero. The ICS classification assigns stages of descensus uteri, rectocele and cystocele according to the measured QV. Stage 0 corresponds to a QV -3 cm, stage I corresponds to a QV > -3 cm but < -1 cm, stage II corresponds to a QV -1 cm but +1 cm, stage III corresponds to a QV > +1 cm but +6 cm and stage IV corresponds to a QV > +6 cm. By ICS definition, the QV of a rectocele and cystocele is between –3 cm and +3 cm. In this study, the QV of descensus uteri was -1 cm or more, as only patients with descensus uteri stage II or more were included.

All patients completed a questionnaire to assess the presence of defecation and micturition symptoms one to three weeks before surgery. The questionnaire consisted of questions selected from the Defecatory Distress Inventory (DDI) and from the Urogenital Distress Inventory. The DDI is a questionnaire developed by our group to assess the presence of defecation symptoms. The DDI consists of 15 items referring to symptoms of obstructive defecation, constipation, fecal incontinence and pain related to defecation. The questions were developed prior to this study and are based on literature and international definitions, interviews with patients who suffered from constipation or fecal incontinence, and on interviews with three experts in the field from the Department

of Surgery and Department of Obstetrics and Gynecology from the University Medical Center Utrecht, The Netherlands. Eventually, a structured interview using the 15 selected items was held with 20 female patients. Questions concerning micturition symptoms were selected from the Urogenital Distress Inventory (UDI).[6] In Appendix A the questions that were selected from the DDI and UDI to assess the presence of defecation and micturition symptoms are presented.

Technique of defecography

All defecographies were performed 1 to 3 months before surgery at the Radiology Department of the University Medical Center Utrecht, the Netherlands. The technique that was used was based on the method described by Mahieu et al.[4] In addition, the vagina was opacified by applying a contrast medium consisting of 30 ml amidotrizoic acid 50 % solution gel, using a syringe with a soft pediatric enema tip. To assess the magnification factor, a midline radiopaque metric ruler was fixed between the buttocks. After sufficient filling of rectum and vagina, the patient was asked to sit on a radiolucent commode. This commode was covered by a water-filled motor scooter tube to cut out flare in the lower part of the image. The whole defecography procedure was recorded on video. All recordings were taken from the left lateral position.

Scoring of defecographic items

All defecographic recordings were analyzed by two of the authors. No information about the patient was made available to them during observation of the defecographies. Before the measurements were started, 10 defecographies, that were not included in the analysis, were observed and discussed until consensus about all definitions was achieved. The inter-observer agreement of the defecographic items scored in this study had been recently studied by our group. The weighted Kappa values for quantification value of enterocele and rectal intussusception were respectively 0.97 (95 % CI 0.93 to 1.00) and 0.91 (95 % CI 0.79 to 1.00). In case of disagreement about the scoring of a defecography, both observers discussed their scorings and came to consensus.

In case an enterocele or rectal intussusception was found at defecography this defecography was considered to be abnormal. An *enterocele* was defined as a peritoneal sac (normally filled with loops of small bowel) that has herniated downwards along the ventral rectal wall.[2] To consider an enterocele present the peritoneal sac should extend to below the top of the vagina. *Rectal instussusception*, or internal procidentia, was defined as an intussusception of the rectal wall, which begins as a circular fold 6 to 8 cm up in the rectum and develops into a condition in which the entire rectal wall folds in towards the

rectal lumen[7]. During straining, the “infolding” progressess and deepens to form a ring pocket. When such a ring pocket is seen at defecography, a rectal intussusception is considered to be present.

Statistical analysis

The aim of the analysis was to investigate whether findings at pelvic examination and reported defecation symptoms can predict the presence of defecographic abnormalities. First, the association between each diagnostic variable and abnormal defecography was quantified using univariate logistic regression analyses. Continuous variables were initially included in the model without categorization as a linear relation was plausible, but various cut-off values and transformations (square root, log) were evaluated.[8] Subsequently, predictors that were univariately associated with the outcome (odds ratio with a p-value < 0.15) were included in a multivariate logistic regression model to evaluate their independent value in the prediction of outcome.[8] Model reduction from this overall model was then performed by excluding variables with p-value > 0.10. This yielded a reduced model. A multivariate model can be considered as one “combined diagnostic test” including several diagnostic findings, with the estimated probability of presence of abnormal defecography as its “test results”.

The reliability (goodness of fit) of the final diagnostic model was quantified by the Hosmer & Lemshow test[9] and the diagnostic ability was quantified using the area under the Receiver Operating Characteristic curve (ROC area).[8,10] An area under the ROC-curve of 0.5 implies that the diagnostic test under study has a discriminatory capacity that does not exceed chance, whereas an area under the ROC-curve of 1 implies that the discriminative capacity of the test under study is perfect. Differences in discriminative value between models were estimated by differences in ROC area with 95 % confidence interval (CI), taking into account the correlation between models as they were based on the same cases.[11]

Of the 82 enrolled subjects, 5 had missing values on one or more variables. To decrease bias and increase statistical efficiency[12], these missing values were filled in (imputed) using the expectation maximization method (SPSS, version 10.0). This method uses all available data to impute the missing values, based on the correlation between each variable with missing values and all other variables.

Next, random bootstrapping techniques were used[8,13] to validate the model and to adjust for overly optimistic estimates of the regression coefficients (or odds ratios) of the included predictors.[8] In this way, the prognostic ability of the model in future but similar

patients is estimated. The final model was then transformed into a scoring rule by dividing the regression coefficients of the included predictors by the smallest regression coefficient. To improve practical application of this rule, these coefficients were rounded to the nearest integer. As the ROC area reflects only the overall discriminative value of a model and not directly its clinical value in terms of absolute patient numbers[14], we additionally estimated the number of correctly and falsely diagnosed patients across various categories of the model's estimated probability.

Table 1. Characteristics of all patients (n=82).

Age (years)	56.4	(10.0)
Parity (number of delivered children)	2.6	(1.1)
Body Mass Index (kg/m^2)	25.2	(3.3)
Prior abdominal or pelvic surgery (n) *	17	(20.7 %)
Cholecystectomy	5	
Appendectomy	7	
Caesarean section	5	
Adnex extirpation	1	
Anterior and / or posterior repair	4	
Burch colposuspension	1	
Defecation Distress Inventory (n)		
Constipation	22	(26.8 %)
Feeling of incomplete evacuation	20	(24.4 %)
Incontinence for flatus	46	(56.1 %)
Incontinence for liquid or solid stools	14	(17.1 %)
Painful defecation	15	(18.3 %)
Difficulty emptying rectum	14	(17.1 %)
Urogenital Distress Inventory (n)		
Frequency	53	(64.6 %)
Urgency	55	(67.1 %)
Stress incontinence	45	(54.9 %)
Urge incontinence	40	(48.8 %)
Mixed incontinence	56	(35.4 %)
Difficulty emptying bladder	37	(45.1 %)
Findings at defecography (n)		
Normal defecography	56	(68.3 %)
Abnormal defecography	26	(31.7 %)
Enterocele	23	(28.0 %)
Rectal intussusception	9	(11.0 %)
Enterocele and rectal intussusception	6	(7.3 %)

Values are means (standard deviation) or numbers (percentage).

* Some patients had undergone more than one surgical procedure.

Results

Table 1 shows the baseline characteristics as well as the results of the DDI, UDI and defecography. Twenty-six (31.7 %) patients had an abnormal defecography. Six (7.3%)

patients had an enterocele and rectal intussusception at defecography. Findings at pelvic examination are shown in Table 2. Both stage and quantification value of descensus uteri, cystocele and rectocele are reported.

Table 2. Findings at pelvic examination before surgery

	Grade	Number of patients	Quantification Value	Number of Patients
Descencus of uterus	II	67	-1	13
			0	46
			1	8
	III	15	2	12
			3	3
Cystocele	0	2	-3	2
	I	8	-2	8
	II	38	-1	1
			0	22
			1	15
	III	34	2	25
			3	9
Rectocele	0	17	-3	17
	I	37	-2	37
	II	23	-1	5
			0	15
			1	3
	III	5	2	3
			3	2

Results of the univariate analyses are shown in Table 3. Odds ratios (ORs) for quantification values of descensus uteri, rectocele and cystocele as obtained from pelvic examination, express the increased odds for abnormal defecography per centimeter of prolapse. For example, the odds for abnormal defecography increases with about 40 % for every centimeter of additional descent of a rectocele. ORs for defecation symptoms express the odds that an abnormal defecography is found in a patient with a specific symptom in comparison to a patient without that symptom. In univariate analyses history of pelvic surgery, quantification value of rectocele and constipation were associated with the presence or absence of normal defecography. Other variables were not associated, neither when analyzed as continuous parameters nor after dichotomization at any value.
Multivariate analyses showed that all 3 (univariately) associated variables were predictors of abnormal defecography. None of the interactions between the determinants that were tested showed statistical significance in the multivariate analyses. The odds ratios and

Table 3. Univariable and multivariable analysis of the association of findings rom patient history, pelvic examination and DDI and UDI questionnaire with presence of rectocele or rectal intussusception at defecography.

	Univariable analysis			Multivariable analysis			
	OR	95 % CI	P-value	ß ¶	OR	95 % CI	P-value
Intercept				- 0.89			
Medical history							
Age (per year)	0.97	0.93 – 1.02	0.25				
BMI (per kg/m²)	1.04	0.90 – 1.20	0.62				
Parity (per child)	1.01	0.66 – 1.55	0.95				
History of abdominal or pelvic surgery	3.71	1.20 – 11.49	0.02	1.34	3.83	1.13 – 13.00	0.03
Pelvic examination							
QV of descensus uteri (per cm)	1.31	0.85 – 2.04	0.22				
QV of cystocele (per cm)	0.97	0.72 – 1.30	0.82				
QV of rectocele (per cm)	1.42	1.03 – 1.94	0.03	0.40	1.49	1.06 – 2.09	0.02
Defecation symptoms assessed by DDI							
Constipation	3.00	1.08 – 8.32	0.04	1.13	3.10	1.03 – 9.38	0.05
Feeling of incomplete evacuation	1.63	0.57 – 4.65	0.36				
Incontinence for flatus	0.88	0.34 – 2.23	0.78				
Incontinence for liquid and solid stools	0.84	0.24 – 2.97	0.78				
Painful defecation	1.57	0.49 – 4.99	0.45				
Difficulty emptying rectum	1.80	0.55 – 5.86	0.33				
Micturition symptoms assessed by UDI							
Frequency	0.96	0.37 – 2.60	0.96				
Urgency	0.89	0.33 – 2.43	0.82				
Stress incontinence	1.70	0.66 – 4.36	0.27				
Urge incontinence	0.59	0.23 – 1.51	0.27				
Mixed urinary incontinence	0.60	0.21 – 1.61	0.30				
Difficulty emptying bladder	1.49	0.57 – 3.86	0.42				

DDI = Defecatory Distress Inventory; UDI = Urogenital Distress Inventory; OR = odds ratio; CI = confidence interval;
QV = quantification value; ß = regression coefficient.

regression coefficients of these independent predictors are presented in Table 3. After bootstrapping the regression coefficients of history of abdominal or pelvic surgery, QV of rectocele and constipation wre respectively 1.20, 0.35 and 1.01. The ROC of the model (as calculated with the regression coefficients obtained by bootstrapping) including all 3 variables was 0.73 (95 % CI: 0.60-0.86). Exclusion of a variable from this model significantly decreased the ROC area. Re-entering univariate non-significant variables in the multivariate model did not statistically improve the ROC area. The reliability of the model was fair (p-value of the Hosmer & Lemeshow test > 0.30).

Table 4 shows for the model the distribution of patients with and without abnormal defecography across selected categories of the model's estimated probability. According to the developed prognostic model, 39% of all 82 patients had a probability of less than 20% to have an abnormal defecography. Sensitivity and specificity (reading Table 4 vertically), as well as predictive values (reading horizontally), can be obtained for different probability thresholds. For example reading the model vertically shows that in the probability group > 0.70, 19% of all 26 patients with abnormal defecography would be correctly classified (i.e. true positive rate or sensitivity). Whereas 2% of all 56 patients without abnormal defecography, would not (false positive rate). In the low probability group (p 0.20), 48% of all patients without abnormal defecography would be correctly classified (true negative rate or specificity), whereas 19% of all patients with abnormal defecography would be missed (false negative rate). Reading the model horizontally, in the high (p > 0.70) probability group 5 of the 6 patients had an abnormal defecography (i.e. the positive predictive value would be 83%), whereas in the low probability group 27 of the 32 patients did not have an abnormal defecography (i.e. the negative predictive value would be 84%).

Table 4. Absolute number of patients (%) with and without abnormal defecography according to the probability of abnormal defecography as estimated by the diagnostic model.

Score	Estimated probability	N	Abnormal defecography	Normal defecography
0 - 1	0.20	32 (39)	5 (19)	27 (48)
2 - 4	0.21 – 0.40	29 (36)	7 (27)	22 (39)
5 - 7	0.41 – 0.70	15 (18)	9 (35)	6 (11)
8 - 10	> 0.70	6 (7)	5 (19)	1 (2)
	Total	82	26	56

The model was transformed to a more easily applicable diagnostic rule by dividing the regression coefficient of each variable (Table 3) by 0.35 (the smallest regression coefficient) and rounding it to the nearest integer. By assigning points to each variable

present, a total score was computed for each individual patient using the following formula: 3 + 3*history of abdominal or pelvic surgery + QV of rectocele + 3*constipation. The three points were added to prevent a negative score in patients without a history of abdominal or pelvic surgery, who did not report constipation and had a QV of rectocele < 0 cm. Theoretically a patient can have a score from 0 to 12. For instance, a patient who did not undergo abdominal or pelvic surgery, had a rectocele descending until 1 centimeter above the hymen (QV = -1 cm) and reported constipation at the DDI received a score of 3 + 3*0 + -1 + 3*1 = 8. In our population the total score ranged from 0-10 and the ROC area of the rule was 0.73 (95 % CI : 0.61 – 0.83). The first column of Table 4 shows the score categories of the rule which corresponded to the probability categories of the prognostic model.

Sensitivity and specificity, for thresholds other than given in Table 4, can be obtained from Figure 1 which shows the cumulative distribution of patients with and without abnormal defecography across the entire score range of the rule. If one score-threshold would be used, for example a 2 (considering a score 2 a negative 'test'result indicating absence of abnormal defecography, and > 2 as a positive result indicating abnormal defecography presence), 23% of all patients with abnormal defecography would be missed (a sensitivity of 77%) and 52% of those without abnormal defecography would be correctly diagnosed (specificity of 52%).

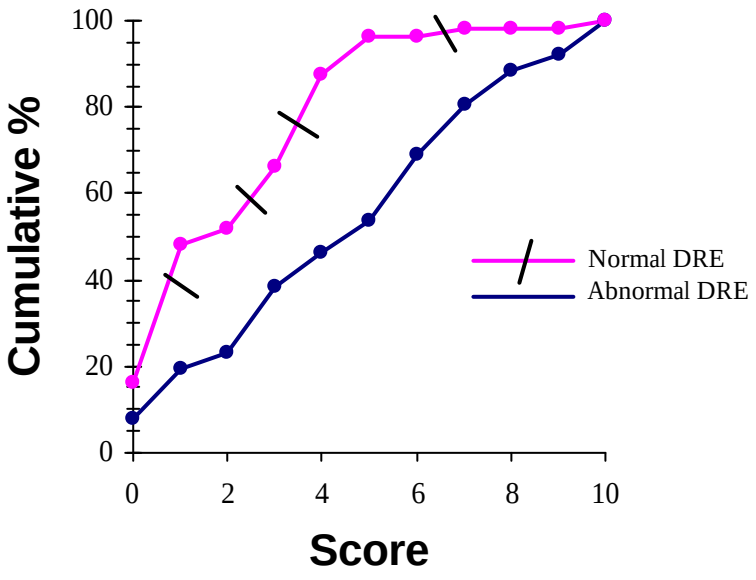

Figure 1. The cumulative distribution of patients with and without abnormal defecography, across all scores of the diagnostic rule including history of abdominal or pelvic surgery, quantification value of rectocele and constipation as assessed with the DDI.

Discussion

The aim of this study was to investigate whether the finding of an abnormal defecography in patients with descensus uteri stage II or more can be predicted by information obtained from less invasive assessments. We found that history of abdominal or pelvic surgery, QV of rectocele and constipation (as assessed by a questionnaire) are predictors of presence of abnormal defecography. The use of these few and simply obtainable parameters in the presented scoring rule enables the physician to identify a high probability group (probability > 70 % or score 8) in which 80 % have an abnormal defecography, and a low probability group (probability < 20 % or score 1) in which 84 % have a normal defecography. If gynecologists would decide not to demand a defecography for patients with a low risk of abnormal defecography (probability 0.20), in our population the number of defecographies would have been reduced by 39 %. A consequence of this decision is that in 5 (6 %) patients the diagnosis of abnormal defecography would have been missed.

Gynecologists planning surgery for a patient with genital prolapse perform defecography in case they prefer to be informed about the presence of an enterocele and/or rectal intussusception before surgery. Whether the detection of these anatomical abnormalities before surgery influences the treatment decision and improves outcome of treatment, has not been studied. As long as the exact diagnostic value of defecography has not been established, gynecologists may be expected to consider in which patients they demand for defecography and in which patients not. This consideration is also warranted because patients experience defecography as an embarrassing and bothersome procedure. To provide a tool that may help in the consideration to demand for defecography or not, we investigated whether the presence of defecographic abnormalities can be predicted in patients that are to be operated on for genital prolapse. All patients in this study had a descensus uteri grade II or more (according to the ICS classification). The observed prevalence of enteroceles (28 %) and rectal intussusception (11 %) in this study are similar to those reported by others who studied patients with genital prolapse.[2,15,16]

A defecography was defined as abnormal when an enterocele and/or rectal intussusception was detected. One may argue that a rectocele larger than 2 centimeter should also de defined as abnormal. Indeed, rectoceles of this size are considered to be an abnormal finding at defecography[17,18], but they are not likely to be missed at pelvic examination.[2,19] As a consequence, gynecologists will not have their patients undergo defecography to detect such a rectocele. Potential predictors of abnormal findings at

defecography were medical history, findings at pelvic examination, defecation and micturation symptoms. The predictive values of 19 parameters were studied. The predictive value of history of abdominal or pelvic surgery was studied as several studies have related the presence of an enterocele to previous abdominal or pelvic surgery.[20-22] We decided to analyze the quantification value of descensus uteri, cystocele and rectocele rather than their stage, as a quantified measurement is more precise. As pelvic examination has been shown to have a poor diagnostic performance to detect an enterocele or a rectal intussusception[2,3,23,24], we did not score the presence of either of these anatomical abnormalities at pelvic examination. The predictive value of defecation symptoms was evaluated, as many studies have shown a relation between these symptoms and abnormal defecography.[3,19,25-27] In contrast to these studies, we used a questionnaire to assess the prevalence of defecation symptoms. The main advantage of a questionnaire is that it assesses the presence of symptoms in a more standardized way than an interview does. The decision to study also the predictive value of micturition symptoms, was based on studies that have related the formation of an enterocele to damage of the pudendal nerve.[21,28] As micturition symptoms may result from damage of the pudendal nerve[29,30], the presence of micturition symptoms could predict the presence of abnormal defecographic findings.

A history of abdominal or pelvic surgery was an important predictor of abnormal defecography. It has been suggested that enterocele development following pelvic surgery may result from damage to the pudendal nerve and pelvic floor musculature.[21,28] Alternatively, abnormal defecography after abominal or pelvic surgery may result from constipation, which can be caused by damage to the pelvic floor innervation during surgery. The pelvic floor could then descend and become funnel-shaped, causing the anterior wall to incur most of the expulsive forces which may ultimately lead to rectal intussusception.[31,32]

Rectocele at pelvic examination appeared to be another important predictor of abnormal defecography. This confirms earlier findings that both enterocele and rectal intussusception are associated with a rectocele.[31,33] The observation that constipation was a predictor of abnormal defecography, confirms the findings of others who have related constipation to both the presence of an enterocele and a rectal intussusception.[2,19,25-27] As the questionnaire used in this study to assess the prevalence of defecation symptoms is new (results of validation studies have been recently submitted), one may question the validity of the measurements. However, all definitions used were based on the literature

and are widely accepted in the field.[34-36] None of the studied micturation symptoms appeared to importantly predict abnormal defecography.

Validation of the model by bootstrapping techniques demonstrated that the prediction rule is robust. However, before implementating the model in clinical practice, the actual performance of this scoring rule should be proven by using this rule in another group of women with descensus uteri.[13,37]

In conclusion, this study shows that a diagnostic model based on findings obtained from a non-invasive diagnostic work-up, can predict the presence of an abnormal defecography. Practitioners should realize that defecography is an invasive and embarrassing procedure to undergo. As a consequence, they are obliged to strongly consider for each individual case whether a defecography is warranted or not. Our prediction model may importantly contribute to this consideration.

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Chapter 4

Defecation symptoms and findings at ano-rectal function tests in patients with genital prolapse.

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Abstract

Objective: Defecation symptoms have been associated with abnormal findings at ano-rectal function tests. Some have suggested that ano-rectal function tests should be performed in all patients planned for surgical correction of genital prolapse. This study was performed to investigate whether constipation and fecal incontinence in patients with genital prolapse are associated with ano-rectal function tests.

Methods: In 83 patients with descensus uteri stage II-IV (ICS classification) ano-rectal function tests were performed and the presence of constipation and fecal incontinence was assessed by a validated questionnaire. The prevalence of these defecation symptoms was compared between different levels of the ano-rectal function tests.

Results: Constipation was present in 7 (8.4 %) patients and fecal incontinence in 16 (19.3 %) patients. The prevalence of constipation was 17.9 % in the upper tertile, 0 % in the middle tertile and 7.7 % in the lower tertile of threshold for rectal sensibility (÷² test $p < 0.05$). Defecation symptoms were not associated with any of the other ano-rectal function tests.

Conclusion: Except for the significant association between decreased rectal sensibility and constipation, other findings at ano-rectal function tests did not appear to be associated with constipation or fecal incontinence in patients with genital prolapse. Our results suggest that it is not recommendable to perform ano-rectal function tests in all patients with descensus uteri who are candidate for surgery and experience constipation and/or fecal incontinence.

Introduction

Women in the United States have a 11 % lifetime risk of undergoing an operation for genital prolapse or urinary incontinence.[1] Several combinations of pelvic floor defects may be present in patients with genital prolapse. Furthermore, any combination of impaired functioning of the urethra, bladder and anorectum, as well as impaired sexual functioning, may be observed in patients with genital prolapse.[2] Failure to identify anatomical and/or functional abnormalities in the diagnostic process may lead to incomplete surgical repair with subsequent persistence or recurrence of symptoms related to genital prolapse. It has been advocated to perform a complete diagnostic work-up, including urodynamic investigation, defecography and ano-rectal function testing, in patients undergoing genital prolapse surgery.[3,4] So far, a scientific base for this recommendation has not been provided.

Several studies are available that describe findings at urodynamic investigation and defecography in patients with genital prolapse[5-7], but studies that focus on ano-rectal function tests in patients with genital prolapse are lacking. So far, studies that have evaluated ano-rectal function tests, have been performed in patients with defecation symptoms. Most of these studies compare the results of ano-rectal function tests in patients with fecal incontinence or constipation with the results in healthy volunteers.[8-11] Based on these studies, hypotheses about the pathophysiology of constipation and fecal incontinence have been generated. An assumption in the field is that performing ano-rectal function tests in patients with genital prolapse can aid in distinguishing causes of defecation symptoms.[3] Such a distinction may help gynecologists to treat their patients optimally. However, it is unknown whether the observed associations between findings at ano-rectal function tests and defecation symptoms, are also present in patients with genital prolapse.

This study was performed to investigate whether constipation and fecal incontinence in patients with genital prolapse are associated with findings at ano-rectal function tests.

Patients and methods

Patients

The present study is based on data obtained from a randomized multi center trial comparing vaginal and abdominal prolapse surgery in patients with descensus uteri stage II - IV. Eighty-three patients were enrolled in this trial between January 1998 and January

2000. The study protocol was approved by the institutional review boards of all three participating hospitals (University Medical Center in Utrecht, Diaconessenhuis in Utrecht and St. Antonius Hospital in Nieuwegein) and written informed consent was obtained from all patients.

Measurements

Pre-operatively all 83 patients underwent a standardized urogynecologic interview and complete physical examination including a classification of the genital prolapse based on the recommendations of the ICS.[4] According to this classification descensus uteri, cystocele and rectocele were classified as follows: grade 0 – none; grade I – distal portion of the prolapse is > 1 cm above the hymenal ring; grade II – prolapse is between 1 cm proximal and 1 cm distal to the hymenal ring; grade III – prolapse is > 1 cm below the hymen, but no further than 2 cm or less than the total vaginal length; and grade IV – complete or near complete (within 2 cm) vaginal eversion.

Defecation symptoms were measured with the Defecation Distress Inventory (DDI) at one to three weeks before surgery. The DDI is a questionnaire developed by our group to assess the presence of defecation symptoms. The DDI consists of 15 items related to symptoms of constipation, obstructive defecation, painful defecation and fecal incontinence. The questions were developed after studying the literature and international definitions[12,13], interviewing patients who presented with defecation symptoms, and by interviewing three experts in the field from the Department of Surgery and Department of Obstetrics and Gynecology from the University Medical Center Utrecht, The Netherlands. Eventually a structured interview of the 15 selected items was held with 20 female patients. The following items were selected from the DDI: A patient was considered to have constipation when she replied positively to both the following questions: “Do you have less than 3 bowel movements a week?” and “Do you have to strain > 25 % of the time to have a bowel movement?”. A patient was considered to have fecal incontinence when she replied positively to at least one of the following questions: “Do you ever experience incontinence for liquid stools?” and “Do you ever experience incontinence for solid stools?”.

Anorectal function tests

Anorectal function tests were performed 1 to 3 months before surgery at the Gastro-Intestinal Research Unit of the University Medical Center Utrecht, The Netherlands. All patients were situated in the left lateral position. No enema was given. All measurements

were performed by one of the authors. After performing the ano-rectal function tests, the recordings were blinded and subsequently independently interpreted by two observers. No information about the patient was available to them during this interpretation. In case of disagreement about the interpretation, both observers analyzed the recordings together to reach consensus. Software for anal manometry and rectal compliance measurement was produced by Medical Measurement Systems, Enschede, The Netherlands.

Anal manometry

Vector manometry was performed using a radial eight-lumen water perfused catheter (Zynectics medical, Inc. Salt Lake City, UT). Seven side ports were situated in a longitudinal axis and 45 degrees apart around the circumference of the probe. Only four of the seven leads, situated at every 90 degrees around the circumference of the probe, were used for the measurements in this study. The eighth channel was connected to a rectal balloon at the tip.

After positioning the catheter the maximal basal pressure (MBP), a measurement for the internal sphincter, was noted as the highest recorded average of the four leads. Then the patient was asked to squeeze and the maximal squeeze pressure (MSP), a measurement for the external sphincter, was noted by calculating the average maximal increase in pressure. A pullout of the catheter was performed during rest at constant speed (1 mm/second), starting 8 cm from the anal verge, using an automated catheter puller (Medical Measurement Systems, Enschede, The Netherlands). The anal canal length was defined as the length (cm) over which a basal pressure was registered.

Rectal compliance

A catheter with an external diameter of 5 mm and a terminal rectal balloon to measure the intrarectal pressure was used. The lumen of the balloon was connected to a rolar pump. The catheter was introduced in the rectum of the patient, and the balloon was filled with 100 ml of water per minute. Volume at first sensation of filling, volume at first urge and maximum tolerated volume were noted. The compliance of the rectum was calculated by dividing the increase in rectal pressure by the maximum tolerated volume. Corrections were made for compliance of the balloon. During filling of the balloon the pressure in the anal canal was simultaneously measured. The recto-anal inhibitory reflex was considered to be present in case the anal pressure showed a considerable decrease. We also tested the presence of pelvic floor relaxation by fast inflating 30 ml of air into the balloon. Again the anal pressure had to show a considerable decrease in pressure to consider a recto-anal

inhibitory reflex to be present. In case this reflex was not observed the experiment was repeated with fast inflation of 60 ml of air into the balloon.

Electrosensibility tests

A specially constructed catheter with a diameter of 5 mm on which two electrodes were mounted, 1 cm apart, was used.[14] To measure anal sensibility, this probe was introduced into the anal canal. A constant current (square wave stimuli, 100 msec, 5 pulses per second) was increased gradually from 1 to 40 mAmp until threshold of sensation was indicated by the patient. The measurement was repeated two times, and the mean value was taken.

To measure rectal sensibility, the probe was then positioned in the rectum (about 6 cm from the anal verge). A constant current (square wave stimuli, 500 msec, 10 pulses per second) was increased gradually from 1 to 100 mAmp until threshold of sensation was indicated by the patient. The measurement was repeated two times, and the average value was taken.

Pudendal nerve terminal motor latency

A St Mark's electrode[15], with a stimulating electrode mounted at the tip and a recording electrode mounted at the base was used. The electrode had a constant distance of 50 mm between stimulation of the nerve and registration in the external anal sphincter (EAS). The finger was inserted into the rectum and the pudendal nerve on each side was stimulated. The latency was measured bilaterally from stimulation of the pudendal nerve to the start of the muscle motor potential. The fastest pudendal nerve terminal motor latency measured at both sides was scored as "best PNTML".

Statistical analysis

The aim of the analysis was to investigate whether abnormal findings at ano-rectal function tests can explain the presence of fecal incontinence and constipation in patients with descensus uteri. The findings obtained from ano-rectal function tests were divided in tertiles. For each tertile the prevalence of constipation and fecal incontinence was calculated. Distribution of the prevalence of constipation and fecal incontinence over the tertiles was compared using Chi-Square test. Fisher's exact test was used to test for statistically significant differences in the prevalence of constipation and fecal incontinence between patients with recto-anal inhibitory reflex and patients without this reflex.

Results

Table 1 shows the characteristics of all patients, findings at pelvic examination and results of the DDI. The prevalence of constipation was 8 % and of fecal incontinence 19 %.

Table 1. Characteristics, findings at pelvic examination and results of the Defecation Distress Inventory of all patients (n=83).

Patient characteristics		
Age (years)	56.4	(10.0)
Parity (number of children)	2.6	(1.1)
Body Mass Index (kg/m^2)	25.5	(3.4)
Pevious abdominal or pelvic surgery * (n)	16	(19.3)
Cholecystectomy	4	
Appendectomy	5	
Caesarean section	3	
Adnex extirpation	1	
Anterior and / or posterior repair	6	
Findings at pelvic examination		
Descensus uteri (n)		
Grade II	66	(79.5)
Grade III	17	(20.5)
Cystocele (n)		
Grade 0	2	(2.4)
Grade I	8	(9.6)
Grade II	39	(47.0)
Grade III	34	(41.0)
Rectocele (n)		
Grade 0	14	(16.9)
Grade I	40	(48.2)
Grade II	24	(28.9)
Grade III	5	(6.0)
De**fecation Distress Inventory (n)**		
Constipation	7	(8.4)
Fecal incontinence	16	(19.3)

Values are means (standard deviation) or numbers (percentage).

* Some patients had undergone more than one surgical procedure.

Table 2 shows findings at ano-rectal function tests. Data on the anal canal length can not be presented for 8 patients and data on the pudendal nerve terminal motor latency (PNTML) can not be presented for 12 patients. Of 8 patients the recording of anal canal length and PNTML have been lost due to problems with the recording of the measurements. Of 4 patients the PNTML is not presented because the pudendal nerve could not be detected at one of both sides. The characteristics of the patients with missing data were similar to those of patients without missing data.

Table 2.Findings at ano-rectal function tests of all patients (n=83).

	Missing data	Outcome of function test
Anal manometry		
Maximal basal pressure (mm Hg)	-	56 (39 ; 69)
Maximal squeeze pressure (mm Hg)	-	107 (83 ; 150)
Anal canal length (cm)	8	3.7 (2.8 ; 4.2)
Rectal compliance		
First sensation of filling (ml)	-	59 (40 ; 84)
Filled volume at first urge (ml)	-	108 (83 ; 163)
Maximum tolerated volume (ml)	-	170 (139 ; 214)
Rectal compliance (mm Hg/ml)	-	5.4 (3.7 ; 7.2)
RAIR present	-	70 (84.3)
Electrosensibility tests		
Anal sensibility (mAmp)	-	7 (6 ; 9)
Rectal sensibility (mAmp)	-	29 (22 ; 38)
PNTML		
Best PNTML (ms)	12	2.2 (2.0 ; 2.4)

Values are medians (interquartile range) or numbers (percentage).
PNTML = Pudendal nerve terminal motor latency

Table 3 shows the prevalence of constipation according to tertiles of ano-rectal function tests. Patients who had a decreased rectal sensibility (high threshold and thus belonging to the upper tertile) had a higher prevalence of constipation in comparison with patients who have a high rectal sensibility (lower tertile) or average rectal sensibility (middle tertile).

The prevalence of constipation was also higher in patients with a decreased anal sensibility and a delayed first sensation of filling. The prevalence of constipation in patients with an average maximal basal pressure, average maximal squeeze pressure or average anal canal length was lower than in patients in whom results of these function tests were above or below average. Rectal sensibility was the only ano-rectal function test in which the prevalence of constipation was statistically significantly unequally distributed. The prevalence of constipation was similar in patients in whom the recto-anal inhibitory reflex (RAIR) was present or absent (Fisher's exact Test: $p = 1.00$).

Table 4 shows the prevalence of fecal incontinence according to tertiles of ano-rectal function tests. The prevalence of fecal incontinence was increased in patients with a low or average maximal squeeze pressure (lower and middle tertile) in comparison with patients with a high maximal squeeze pressure (upper tertile). Patients who had a first sensation of filling at low volume (lower tertile) had a higher prevalence of fecal incontinence than patients who had not. Both patients with a low rectal compliance and high rectal compliance did have an increased prevalence of fecal incontinence in

Table 3. Prevalence of constipation (in %) by tertiles of ano-rectal function tests.

Ano-rectal function test	Tertile of ano-rectal function test			P value
	I	II	III	(÷² test)
Anal manometry				
Maximal basal pressure (mm Hg)	7.4	3.7	13.8	0.39
Maximal squeeze pressure (mm Hg)	10.3	-	14.8	0.13
Anal canal length (cm)	8.0	4.0	12.0	0.58
Rectal compliance				
First sensation of filling (ml)	3.7	7.4	13.8	0.39
Filled volume at first urge (ml)	3.7	10.2	10.7	0.56
Maximum tolerated volume (ml)	7.4	10.7	7.1	0.87
Rectal compliance (mm Hg/ml)	10.7	7.7	7.1	0.88
Electrosensibility tests				
Anal sensibility (mAmp)	-	9.1	14.3	0.19
Rectal sensibility (mAmp)	7.7	-	17.9	0.05
PNTML				
Best PNTML (ms)	8.0	5.0	7.7	0.91

Table 4. Prevalence of fecal incontinence (in %) by tertiles of ano-rectal function tests.

Ano-rectal function test	Tertile of ano-rectal function test			P value
	I	II	III	(÷² test)
Anal manometry				
Maximal basal pressure (mm Hg)	29.6	7.4	20.7	0.11
Maximal squeeze pressure (mm Hg)	27.6	22.2	7.4	0.14
Anal canal length (cm)	20.0	16.0	20.0	0.92
Rectal compliance				
First sensation of filling (ml)	33.3	11.1	13.8	0.08
Filled volume at first urge (ml)	25.9	21.4	10.7	0.34
Maximum tolerated volume (ml)	29.6	14.3	14.3	0.25
Rectal compliance (mm Hg/ml)	21.4	7.7	28.6	0.15
Electrosensibility tests				
Anal sensibility (mAmp)	13.6	24.2	17.9	0.60
Rectal sensibility (mAmp)	26.9	13.8	17.9	0.46
PNTML				
Best PNTML (ms)	8.0	35.0	23.1	0.08

Cut-off points of tertiles of ano-rectal function tests: Maximal basal pressure (mm HG): 43, 64; Maximal squeeze pressure (mm Hg): 92, 138; Anal canal length (cm): 3.1, 4.0; First sensation of filling (ml): 43, 73; Filled volume at first urge (ml): 93, 128; Maximum tolerated volume (ml): 149, 199; Rectal compliance (mm Hg/ml): 4.3, 6.6; Anal sensibility (mAmp): 6, 8; Rectal sensibility (mAmp): 25, 34; Best PNTML (ms): 2.0, 2.2.

comparison to patients with an average rectal compliance. Patients with a delayed or average PNTML at both sides (best PNTML in upper or middle tertile) had a higher prevalence of fecal incontinence than patients who had a relatively fast PNTML (lower tertile). None of the observed differences in prevalence of fecal incontinence between tertiles of findings at ano-rectal function tests were statistically significant. Patients without RAIR had an increased prevalence of fecal incontinence in comparison to patients with this reflex (Fisher's exact Test: $p = 0.27$).

Discussion

The relationships between findings at ano-rectal function tests and the presence of constipation and fecal incontinence were studied in a sample of patients with descensus uteri who are candidate for genital prolapse surgery. To the best of our knowledge, this is the first study evaluating ano-rectal function tests in a uniform population consisting of patients with genital prolapse. Weak associations between findings at ano-rectal function tests and the presence of constipation or fecal incontinence were observed.

To appreciate the results of our study, some issues need to be discussed. This study was focussed on constipation and fecal incontinence and not on other defecation symptoms. This selection was made, because hypotheses about the pathophysiology of defecation symptoms have only been generated for constipation and fecal incontinence.[8-11] We believe that we reliably assessed the prevalence of constipation and fecal incontinence, since a questionnaire was used that has been accurately validated and is based on the most widely accepted definitions of defecation symptoms.[12,13]

Constipation has been associated with a decreased rectal sensibility, decreased anal sensibility, delayed sensation of rectal distension, both decreased and increased rectal compliance and prolonged PNTML.[3,10,16,17] The results of this study confirm the association between the presence of constipation and a decreased rectal sensibility. Decreased sensibility suggests the presence of rectal sensory neuropathy.[16] The finding of decreased rectal sensibility in patients with constipation may be important because studies have shown that this finding is a good prognostic factor for the results of biofeedback therapy.[18] Therefore, in addition to the surgical correction of their genital prolapse, women with decreased rectal sensibility may benefit of biofeedback therapy. If this therapy will result in a better outcome of the overall treatment has to be evaluated.

Beside rectal sensibility, anal sensibility was also measured. A trend was observed towards a higher prevalence of constipation in patients with decreased anal sensibility. This is in

line with findings from other researchers in the field.[17] However, it has not been shown that the finding of decreased anal sensibility in patients with constipation does lead to treatment decisions of which the patient may ultimately benefit.

Fecal incontinence has been associated with a decreased maximal basal pressure, decreased maximal squeeze pressure, decreased anal canal length, both accelerated and delayed feelings of distension, decreased rectal compliance, absent recto-anal inhibitory reflex, decreased anal and/or rectal sensibility and prolonged PNTML.[3,9,15,17,19-24] It is obvious that the pathophysiology of fecal incontinence is complex and multi-factorial. No statistically significant associations between any of these measurements and the presence of fecal incontinence were observed in this study. A trend was observed towards a higher prevalence of fecal incontinence in patients with both decreased and increased rectal compliance. This finding is in agreement with the results of earlier studies. Decreased rectal compliance may result in fecal incontinence due to funneling of feces into the anus.[23] Conversely, increased rectal compliance, leading to excessive accommodation of the rectum, may produce fecal impaction and subsequent overflow incontinence.[24] The observed trend towards an increased prevalence of fecal incontinence in patients with accelerated first sensation of filling, may be the result of decreased rectal compliance. If the rectal compliance is decreased, the first sensation of filling will probably be accelerated, and the funneling of feces into the anus can not be controlled. Also a higher prevalence of fecal incontinence among patients with a prolonged PNTML was observed. This prolonged PNTML suggests that damage to the pudendal nerve has occurred in patients with genital prolapse who experience fecal incontinence.[15,25]

Two reasons can be given to explain the weak associations between defecation symptoms and abnormal ano-rectal function observed in this study. First, the sample size of our study may be too small to confirm the reported associations between abnormal findings at ano-rectal function tests and constipation or fecal incontinence. Second, studies that did show such associations compared the findings at ano-rectal function tests of patients who seek medical help because of a defecation symptom to the findings at ano-rectal function tests of healthy volunteers. These studies carry a substantial risk to be biased by confounding, meaning that other factors than the defecation symptom itself may be responsible for the existence of the difference. The finding in this study that the presence of defecation symptoms can be only minimally explained from abnormal findings at ano-rectal function tests may be explained by the uniformity of the population that was studied. Patients in our study underwent ano-rectal function tests independently of the presence of defecation symptoms, as they all participated in a randomized trial

(comparing abdominal and vaginal prolapse surgery).

Experts in the field of pelvic floor dysfunction recommend to perform ano-rectal function tests in patients with genital prolapse who report defecation symptoms.[3] Their argument is that patients may benefit of the physician's better understanding of the pathophysiology of defecation symptoms. The outcome of ano-rectal function tests appeared to influence treatment decisions[26,27], but have not been associated with improved outcome of treatment. An exception is the measurement of rectal sensibility. If rectal sensibility is decreased, patients with constipation may benefit of biofeedback therapy.[18] Further insight in the implications of abnormal findings at ano-rectal function tests for treatment is warranted, to justify the recommendation to perform these tests in patients with genital prolapse.

In conclusion, we do not recommend to perform ano-rectal function tests in all patients with genital prolapse who report defecation symptoms. Measurement of rectal sensibility in patients with genital prolapse who experience constipation may be valuable. Patients with decreased rectal sensibility could benefit of additional biofeedback therapy, but the effect of this therapy in this particular population needs to be evaluated.

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Chapter 5

The effects of prolapse surgery on bowel function.

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Abstract

Objective: Several surgical procedures have been shown to effectively correct descensus uteri. However, the effects of these procedures on bowel function are largely unknown. A prospective study was undertaken to evaluate the effects of genital prolapse surgery on bowel function and to provide a physiological and/or anatomical explanation for these effects.

Methods: All patients participated in a randomized trial comparing abdominal and vaginal surgical correction of descensus uteri grade II or more. Before and six months after surgery, patients filled out a validated questionnaire to assess the presence of defecation symptoms and underwent ano-rectal function tests and defecography. The relation between changes in defecation symptoms and changes in ano-rectal function and defecographic findings was tested for statistical significance, using Mann-Withney U Test and Fishers'exact Test.

Results: Except for constipation, all defecation symptoms reported before surgery persisted in about half of the patients. Feelings of distension of the rectum was accelerated in patients in whom soiling and flatus incontinence persisted, as compared to patients in whom these symptoms disappeared. The prevalence of de novo defecation symptoms was lower than 15 %. Incomplete evacuation and sensation of anal blockage developed in 24.5 % respectively 22.7 % of the patients who did not report these symptoms before surgery. In contrast to patients in whom these symptoms did develop, pudendal nerve terminal motor latency (PNTML) decreased after surgery in patients in whom these symptoms did not develop.

Discussion: Defecation symptoms (constipation excluded) persisted in about 50 % of the patients and developed (feeling of incomplete evacuation and sensation of anal blockage excluded) in less than 15 %. Changes in defecation symptoms appear to be associated with changes in ano-rectal function tests.

Introduction

Bowel dysfunction is often present in patients with genital prolapse, particularly when the posterior compartment is involved.[1] Bowel dysfunction and genital prolapse may have a common etiology. Childbirth is suggested to be such an etiologic factor. Damage to vaginal support during childbirth may be a primary event leading to defecation symptoms caused by stool sequestration.[2] Disordered bowel habits in younger life may be an other etiologic factor, as it could result in excessive straining and eventual deteriorate pelvic organ support.[1] It has been shown that the prevalence of defecation symptoms in patients with genital prolapse, is not related to the severity of prolapse of the posterior vaginal wall.[3]

The few studies that report on the effects of prolapse surgery on bowel function, are not consistent in their conclusions.[4-7] It has been suggested that performing ano-rectal function tests and defecography in patients with genital prolapse may provide insight in the pathophysiological and anatomical origin of defecation symptoms in patients with genital prolapse.[8] As far as known, no studies have been published that relate changes in bowel function occurring during prolapse surgery to changes in defecography and ano-rectal function tests.

We performed a prospective study to evaluate the effects of genital prolapse surgery on bowel function. A second aim was to provide a pathophysiological and/or anatomical explanation for observed effects.

Patients and methods

Study population

The study population consisted of 82 consecutive patients participating in a randomized multi-center trial comparing vaginal and abdominal prolapse surgery in patients with descensus uteri stage II – IV according to the classification of the International Continence Society (ICS).[9] All patients were enrolled in this trial between January 1998 and January 2000. Exclusion criteria were a uterus sized more than 12 weeks of gestational age, the presence of an adnexal mass, a history of more than two abdominal pelvic surgical procedures, extreme obesity (quetelet index > 35 kg/m^2), prior inflammatory bowel or pelvic disease, fecal incontinence because of internal or external anal sphincter defect and suspected enterocele at pelvic examination reaching to or beyond the introitus. The study protocol was approved by the local ethical committees of the three participating hospitals (University Medical Center in Utrecht, St. Antonius

Hospital in Nieuwegein, Diaconessenhuis in Utrecht) and written informed consent was obtained from all patients.

Pre-operative evaluation

All patients underwent before surgery a standardized urogynecologic interview, a classification of the genital prolapse according to the recommendations of the ICS[9] and an urodynamic investigation. Classification according to the recommendations of the ICS was in all participating patients performed by the first author. According this classification descensus uteri, cystocele and rectocele were classified as follows: grade 0 – none; I – distal portion of the prolapse is > 1 cm above the hymenal ring; grade II – prolapse is between 1 cm proximal and 1 cm distal to the hymenal ring; grade III – prolapse is > 1 cm below the hymen, but no further than 2 cm or less than the total vaginal length; and grade IV – complete or near complete (within 2 cm) vaginal eversion. Grading of the prolapse was performed at maximal straining in the 45 º supine position.

Surgical procedures

Vaginal correction of the genital prolapse involved vaginal hysterectomy combined with anterior and/or posterior colporrhaphy[10] if indicated. Abdominal correction of the genital prolapse involved sacrocolpopexy with preservation of the uterus.[11,12] After randomization for the vaginal or abdominal approach the surgeon was free to combine the surgical procedure with a colposuspension. A colposuspension was simultaneously performed in case of stress incontinence with the prolapse protruding or with the prolapse reduced as described by Bump.[13] When performing vaginal surgery either a Pereyra needle suspension[14] or a modification of this technique as described by Raz[15] was chosen. When performing abdominal surgery a Burch colposuspension as described by Tanagho[16] was chosen. All surgical procedures were performed by experienced gynecologists who were familiar with both techniques. All women received peri-operative deep vein thrombosis profylaxis and a single dose of intravenous prophylactic antibiotic during operation. All women had post-operatively a 14-French Foley indwelling bladder catheter which was removed after 2-5 days. A vaginal pack was placed and removed in approximately 24 hours in all patients who had vaginal surgery.

Measurement of defecation symptoms

Defecation symptoms were measured before surgery and at six months after surgery with the Defecation Distress Inventory (DDI). The DDI is a questionnaire developed by our group to assess the presence of defecation symptoms. The DDI consists of 15 items

related to symptoms of constipation, obstructive defecation, painful defecation and fecal incontinence. The questions were developed after studying the literature and international definitions[8,9,17], interviewing patients who presented themselves with defecation symptoms, and by interviewing three experts in the field from the Department of Surgery and Department of Obstetrics and Gynecology from the University Medical Center Utrecht, The Netherlands. Eventually a structured interview of the 15 selected items was held with 20 female patients. Appendix A shows which questions of the DDI were selected to assess the presence of defecation symptoms.

Defecography

All defecographies were performed one to three months before surgery and at six months after surgery, at the Radiology Department of the University Medical Center Utrecht, the Netherlands. Gynecologists were not informed about findings at defecography before surgery. The technique we used was based on the method described by Mahieu and co-workers[18] and is extensively described in Chapter 2 of this thesis.

Scoring of defecography items

All defecography recordings were analyzed by two independent observers. No information about the patient was available during observation of the defecographies. Both observers analyzed a defecography recording together in case of disagreement about the scoring to reach consensus. Before the measurements were started, 10 defecographies, that were not included in the analysis, were observed and discussed until consensus about all definitions was achieved. The inter-observer agreement of the defecographic items scored in this study had been recently studied by our group. The weighted Kappa values for quantification value of enterocele and rectal intussusception were respectively 0.97 (95 % CI 0.93 to 1.00) and 0.91 (95 % CI 0.79 to 1.00).

A *rectocele* was defined as an outward bulge of the anterior rectal wall beyond the extrapolated line of the expected rectal lining.[19] We quantified the size of a rectocele by measuring the distance between the most ventral part of the anterior rectal wall and the expected rectal lining in centimeters. Values were scored in half centimeters precise. We only scored the presence of rectoceles 2 cm, as smaller rectoceles are frequently observed in healthy volunteers.[20] An *enterocele* was defined as a peritoneal sac (normally filled with loops of small bowel) that has herniated downwards along the ventral rectal wall.[21] To consider an enterocele present the peritoneal sac should extent to below the top of the vagina. *Rectal instussusception* or internal procidentia was defined as an intussusception of the rectal wall which begins as a circular fold 6 to 8 cm up in the

rectum and develops into a condition in which the entire rectal wall folds in towards the rectal lumen.[22] During straining, the "infolding" progressess and deepens to form a ring pocket. When such a ring pocket is seen at defecography, a rectal intussusception is considered to be present.

Ano-rectal function tests

Anorectal function tests were performed one to three months before surgery and at six months after surgery, at the Gastro-intestinal Research Unit of the University Medical Center Utrecht, The Netherlands. Gynecologists were not informed about findings at ano-rectal function tests before surgery. All patients were situated in the left lateral position. No enema was given. All measurements were performed by one of the authors. After performing the ano-rectal function tests, the recordings were blinded and subsequently independently interpreted by two observers. No information about the patient was available during this interpretation. In case of disagreement about the interpretation, both observers analyzed the recordings together to reach consensus. Software for anal manometry and rectal compliance measurement was produced by Medical Measurement Systems, Enschede, The Netherlands.

Ano-rectal function tests were performed to measure maximal basal pressure, maximal squeeze pressure, anal canal length, first sensation of filling, filled volume at first urge, maximum tolerated volume, rectal compliance, presence of recto-anal inhibitory reflex, anal sensibility, rectal sensibility and the best pudendal nerve terminal motor latency (PNTML) of both sides. Chapter 4 of this thesis provides an extensive description of the methods used to perform these measurements.

Statistical analysis

The aim of the statistical analysis was to evaluate the effects of prolapse surgery on bowel function. A second aim was to investigate whether changes in ano-rectal function tests and defecography can provide an pathophysiological and/or anatomical explanation for the observed effects on bowel function.

For defecation symptoms that were present before surgery, we calculated how often these symptoms persisted and how often these symptoms disappeared. For defecation symptoms that were not present before surgery, we calculated how often these symptoms developed and how often these symptoms did not develop. The rationale to do discriminate between persisting and de novo defecation symptoms, was that both may have a different pathophsiology.

Changes in findings at ano-rectal function tests before and after surgery were compared between patients in whom a defecation symptom developed and patients in whom this symptom did not develop. We also compared changes in findings at ano-rectal function tests before and after surgery between patients in whom a defecation symptom persisted and in whom this defecation symptom disappeared. The observed differences were tested for statistical significance, using Wilcoxons' signed ranks test, as non-continuous distribution of the measured variables was assumed.

Subsequently, the prevalence of abnormal defecographic findings that had developed or disappeared after surgery, were compared between patients in whom a defecation symptom developed and patients in whom this symptom did not develop. A similar comparison was made between patients in whom a defecation symptom persisted and in whom this defecation symptom disappeared. These comparisons were tested for statistical significance, using Fishers' exact Test.

Results

Of the 82 patients who participated in the trial, ano-rectal function tests before and six months after surgery were performed in 73 patients. All these patients answered the DDI before and six months after surgery. Defecographies before and at six months after surgery were performed in 68 patients. Five patients who underwent ano-rectal function tests after surgery, refused to come for defecography, because they considered the latter procedure to be too bothersome. Table 1 shows the base-line characteristics of the 73 patients in whom data obtained from ano-rectal function tests and questionnaires were complete.

Table 1. Caracteristics and findings at pelvic examination before surgery of all patients (n=73).

Age (years)	56.6 (9.8)
Parity (n)	2.6 (1.1)
Body mass index (kg / m^2)	25.5 (3.4)
Prior prolapse surgery (n)	5 (6.8)
Findings at pelvic examination (n)	
Descensus uteri grade II or III	73 (100)
Cystocele grade 0 or 1	9 (12.3)
Cystocele grade II or III	64 (87.7)
Rectocele grade 0 or 1	47 (64.4)
Rectocele grade II or III	26 (35.6)

Values are means (standard deviation) or numbers (percentage).

Table 2 shows the prevalence of defecation symptoms before and at six months after surgery. For patients in whom a defecation symptom was present before surgery, it is shown how often this symptom persisted. For patients in whom this defecation symptom was not present before surgery, it is shown how often the symptom developed. Forty-seven (64.3 %) of all patients reported to have at least one defecation symptom before surgery, and 42 (89.4 %) of these patients reported to still have one or more defecation symptoms after surgery. De novo defecation symptoms were reported by 5 (6.8 %) of the 73 patients. “Feeling of incomplete evacuation” and “sensation of anal blockage” were the defecation symptoms with the highest incidence. All defecation symptoms disappeared in between 40.9 % and 60.0 % of the patients, except constipation that disappeared in all but one of the seven patients who reported this symptom before surgery.

Table 2. Defecation symptoms before and after surgery.

Before surgery		**Six months after surgery**
Reported defecation symptom	n	n (%)
Any defecation symptoms		
Yes	47	42 (89.4)
No	26	5 (19.2)
Constipation		
Yes	7	1 (14.3)
No	66	1 (1.5)
Feeling of incomplete evacuation		
Yes	20	11 (55.0)
No	53	13 (24.5)
Sensation of anal blockage		
Yes	29	17 (58.6)
No	44	10 (22.7)
Difficulty emptying rectum		
Yes	17	8 (47.1)
No	56	2 (3.6)
Painful defecation		
Yes	17	7 (41.1)
No	56	4 (7.1)
Soiling		
Yes	25	10 (40.0)
No	48	3 (6.3)
Fecal incontinence		
Yes	14	7 (50.0)
No	59	2 (3.4)
Flatus incontinence		
Yes	44	26 (59.1)
No	29	3 (10.3)

Medians of changes in results of ano-rectal function tests before and after surgery of patients in whom “feeling of incomplete evacuation” developed and did not develop and of patients in whom “feeling of incomplete evacuation” persisted and disappeared, are shown in Table 3. Pudendal nerve terminal motor latency was reduced in patients who did not develop “feeling of incomplete evacuation” and not in patients who did develop this symptom. This difference was statistically significant. Some other relevant differences that were not statistically significant were observed: Maximal basal pressure increased more in patients in whom “feeling of incomplete evacuation” developed than in patients in whom this symptom did not develop. Sensation of filling was accelerated in patients who developed “feeling of incomplete evacuation” and delayed in patients who did not develop this symptom. Patients in whom “feeling of incomplete evacuation” persisted, maximum tolerated volume decreased whereas in patients in whom this symptom disappeared, maximum tolerated volume increased. No major other differences in changes of ano-rectal function tests were observed.

Medians of changes in results of ano-rectal function tests before and after surgery of patients in whom “sensation of anal blockage” developed and did not develop and of patients in whom “sensation of anal blockage” persisted and disappeared, are shown in Table 4. PNTML did increase in patients who developed “sensation of anal blockage” and did not increase in patients who did not develop this symptom. The difference in changes of PNTML was statistically significant. A similar result was shown in patients in whom “sensation of anal blockage” persisted and disappeared. Patients in whom “sensation of anal blockage” persisted had unchanged PNTML, whereas PNTML reduced in patients in whom this symptom disappeared. This difference was not statistically significant. A trend was observed towards a different change in rectal sensibility between patients in whom “sensation of anal blockage” persisted and disappeared. Rectal sensibility remained unchanged in patients in whom this symptom persisted and decreased in patients in whom this symptom disappeared. Other relevant differences were not observed.

Table 5 shows medians of changes in results of ano-rectal function tests before and after surgery of patients in whom soiling developed and did not develop and of patients in whom soiling persisted and disappeared. Feelings of distension were after surgery more accelerated in patients in whom soiling persisted than in patients in whom soiling disappeared. Relevant differences in feelings of distension betwen patients in whom soiling developed and in whom not, were not observed.

Table 6 shows medians of changes in results of ano-rectal function tests before and after

Table 3. Medians of changes in results of ano-rectal function tests before and after surgery of patients in whom "feeling of incomplete evacuation" developed and did not develop and of patients in whom "feeling of incomplete evacuation" persisted and disappeared.

	Feeling of incomplete evacuation			***Feeling of incomplete evacuation***		
	developed	not developed	P value[1]	persisted	disappeared	P value[1]
Number of patients	13	40		11	9	
Anal manometry						
Maximal basal pressure (mm Hg)	9 (1; 26)	1 (-11; 10)	0.07	2 (-5; 28)	-2 (-8; 13)	0.47
Maximal squeeze pressure (mm Hg)	8 (-18; 15)	5 (-15; 20)	0.82	-1 (-23; 23)	-2 (-19; 29)	0.49
Anal canal length (cm)	0.3 (-0.2; 0.6)	0.3 (-0.3; 0.7)	0.57	0.3 (-0.1; 0.9)	0.2 (-0.3; 1.3)	0.82
Rectal compliance						
First sensation of filling (ml)	17 (-5; 24)	-19 (-39; 13)	0.08	10 (-7; 23)	11 (-18; 26)	0.85
Filled volume at first urge (ml)	6 (-60; 39)	-20 (-46; 21)	0.51	-2 (-24; 27)	23 (-8; 43)	0.11
Maximum tolerated volume (ml)	-15 (-56; 16)	-22 (-53; 28)	0.92	-16 (-34; 20)	26 (-14; 50)	0.10
Rectal compliance (mm Hg/ml)	-1.4 (-4.3; 0.7)	-0.7 (-2.6; 0.5)	0.37	0.7 (-1.6; 1.9)	0.1 (-0.9; 0.3)	0.97
PNTML						
Best PNTML (ms)	0.0 (0.0-0.2)	-0.1 (-0.4; 0.0)	0.05	0.1 (-0.2; 0.3)	0.0 (-0.2; 0.2)	0.43

Values are medians (interquartile range); PNTML = Pudendal Nerve Terminal Motor Latency; [1] Calculated with Mann-Withney U Test

Table 4. Medians of changes in results of ano-rectal function tests before and after surgery of patients in whom "sensation of anal blockage" developed and did not develop and of patients in whom "sensation of anal blockage" persisted and disappeared.

	Sensation of anal blockage			***Sensation of anal blockage***		
	developed	did not develop	P value[1]	persisted	disappeared	P value[1]
Number of patients	10	34		17	12	
Electrosensibility tests						
Anal sensibility (mAmp)	-1 (-5; 2)	0 (-2; 1)	0.50	-1 (-2; 3)	-2 (-4; 4)	0.51
Rectal sensibility (mAmp)	7 (-3; 3)	-1 (-15; 8)	0.25	1 (-10; 9)	8 (0; 23)	0.09
PNTML						
Best PNTML (ms)	0.2 (0.0-0.3)	0.0 (-0.3; 0.1)	0.03	0.0 (-0.2; 0.2)	-0.1 (-0.4; 0.0)	0.48

Values are medians (interquartile range); PNTML = Pudendal Nerve Terminal Motor Latency; [1] Calculated with Mann-Withney U Test

Table 5. Medians of changes in results of ano-rectal function tests before and after surgery of patients in whom soiling developed and did not develop and of patients in whom soiling persisted and disappeared.

	Soiling			***Soiling***		
	developed	did not develop	P value[1]	persisted	disappeared	P value[1]
Number of patients	3	45		10	15	
Rectal compliance						
First sensation of filling (ml)	-7 (-70; 25)	-4 (-28; 19)	0.69	-4 (-53; 14)	16 (2; 30)	0.06
Filled volume at first urge (ml)	1 (-70; 47)	-7 (-40; 30)	0.87	-28 (-45; 8)	20 (-8; 37)	0.04
Maximum tolerated volume (ml)	-15 (-72; 23)	-5 (-43; 40)	0.66	-31 (-58; -15)	-16 (-54; 38)	0.16
Rectal compliance (mm Hg/ml)	0.7 (-1.7; 1.8)	0.0 (-1.4; 1.4)	0.76	-1.3 (-2.4; 0.9)	-1.6 (-3.4; 0.1)	0.40

Values are medians (interquartile range); [1] Calculated with Mann-Withney U Test

Table 6. Medians of changes in results of ano-rectal function tests before and after surgery of patients in whom flatus incontinence develops or not develops and of patients in whom flatus incontinence remains present or disappears.

	Flatus incontinence			***Flatus incontinence***		
	developed	did not develop	P value[1]	persisted	disappeared	P value[1]
Number of patients	3	26		26	18	
Rectal compliance						
First sensation of filling (ml)	25 (6; 68)	11 (-24; 35)	0.39	-13 (-48; 13)	-1 (-24; 20)	0.19
Filled volume at first urge (ml)	47 (14; 58)	-1 (-48; 37)	0.15	-16 (-41; 3)	13 (-33; 39)	0.05
Maximum tolerated volume (ml)	30 (-15; 61)	-13 (-57; 40)	0.28	-25 (-47; -2)	8 (-29; 49)	0.03
Rectal compliance (mm Hg/ml)	1.9 (1.8; 2.0)	-1.1 (-3.0; 1.4)	0.03	-0.6 (-2.4; 0.8)	0.6 (-1.2; -2.4)	0.12
Electrosensibility tests						
Anal sensibility (mAmp)	0 (0; 1)	0 (-2; 2)	0.56	1 (-2; 4)	-1 (-5; 1)	0.12
Rectal sensibility (mAmp)	-20 (-33; -4)	0 (-10; 10)	0.03	3 (-3; 13)	5 (-9; 29)	0.65

Values are medians (interquartile range); [1] Calculated with Mann-Withney U Test

surgery of patients in whom flatus incontinence developed and did not develop and of patients in whom flatus incontinence persisted and disappeared. Rectal compliance had increased in patients who developed flatus incontinence and decreased in patients in whom this symptom did not develop. Rectal sensibility increased (i.e. the threshold decreased) in patients in whom flatus incontinence developed, and was unchanged in patients in whom flatus incontinence did not develop. Both the difference in rectal compliance and in rectal sensibility were statistically significant. Feelings of distension were accelerated in patients in whom flatus incontinence persisted, and not in patients in whom this symptom disappeared. No major other differences between both groups were observed.

For all other defecation symptoms that persisted or developed after surgery, no relevant relations with changes in ano-rectal function tests were observed. These data are not shown.

Table 7 shows the relation between changes in defecographic findings and the developing of "feeling of incomplete evacuation" and persistence of "sensation of anal blockage". Statistically significant relations were not observed. In patients who developed "feeling of incomplete evacuation" a rectocele larger than 2 centimeter developed more often than in patients who did not develop this defecation symptom. In patients in whom "sensation of anal blockage" persisted, an enterocele remained more often present, than in patients in whom this symptom disappeared.

Table 7. Changes before and after surgery in defecographic findings of patients in whom "feeling of incomplete evacuation" developed or did not develop and of patients in whom "sensation of anal blockage" persisted or disappeared.

	Feeling of incomplete evacuation			***Sensation of anal blockage***		
	developed	did not develop	P value[1]	persisted	disappeared	P value[1]
Number of patients	12	36		15	11	
Rectocele 2 cm						
Persisted	3 (25.0)	14 (38.9)	0.50	4 (26.7)	4 (36.4)	0.68
Developed	5 (41.7)	6 (16.7)	0.11	5 (33.3)	2 (18.2)	0.66
Enterocele						
Persisted	1 (8.3)	5 (13.9)	1.00	- -	2 (18.2)	0.17
Developed	- -	5 (13.9)	0.31	- -	- -	-
Rectal intussusception						
Persisted	- -	1 (2.8)	1.00	- -	- -	-
Developed	- -	- -	-	- -	1 (6.7)	1.00

Values are numbers (percentage); [1] Calculated with Fishers' Exact Test

Discussion

We conducted a multi-center prospective study to evaluate the effects of prolapse surgery on defecation symptoms and performed ano-rectal function tests and defecography before and after surgery to provide an pathophysiological and anatomical explanation for the observed effects. Feeling of incomplete evacuation and sensation of anal blockage developed in more than 20% of the patients and appeared to be associated with changes in pudendal nerve terminal motor latency. Patients in whom this latency reduced after surgery, developed less frequently these symptoms. Defecation symptoms (constipation excluded) reported before surgery, persisted in about 50 % of the patients. Symptoms of soiling and flatus incontinence remained more often present in patients in whom feelings of distension of the rectum were accelerated. No significant associations were observed between changes in defecation symptoms and changes in defecographic findings.

The patients participating in this study were selected from the outpatient clinic of three teaching hospitals in or around Utrecht, the Netherlands. All three hospitals have at least one gynecologist with special interest in the field of pelvic floor surgery. The presence of such a specialist may attract patients presenting themselves with genital prolapse, but this is not likely to have influenced the characteristics of these patients. Therefore, we believe that our study sample is representative for patients who undergo surgical correction of descensus uteri.

Our study was strengthened by the use of the same validated measurement instruments before and after surgery. By performing all ano-rectal function tests and defecographies in the same hospital, all investigations were performed on the same standardized method. This has reduced the variation in measurements that was not due to the performed surgery.

Most studies evaluating prolapse surgery report about the anatomical results and not about the effects on pelvic floor function. The few studies that did report on the effects of prolapse surgery on bowel function, were not consistent in their conclusions.[4,5] These reports have not provided a rationale to explain persistence or development of defecation symptoms after prolapse surgery.

The incidence of feeling of incomplete evacuation was 24.5 %. For patients in whom “feeling of incomplete evacuation” developed, the median PNTML remained unchanged, whereas the median PNTML reduced in patients in whom “feeling of incomplete evacuation” did not develop. We do not have a good explanation for the development of feeling of incomplete evacuation in patients in whom PNTML does not reduce. Possibly,

other changes occurring in patients who develop “feeling of incomplete evacuation”, like an increased maximal basal pressure and delayed first sensation, increase the risk on delayed bowel movement. If bowel movement is delayed, a feeling of incomplete evacuation is likely to exist. A reduction of PNTML, could allow the patient to have a better sensation of urge and could prevent delay of bowel movement. Pudendal nerve terminal motor latency has been reported to be prolonged in patients with pelvic floor dysfunction.[23] We hypothesize that this prolonged PNTML is the results of continuous stretching of the pudendal nerve by the weight of descending pelvic organs. After surgical correction of the genital prolapse, stretch of the pudendal nerve is no longer present. In some patients this may lead to normalization (and thus reduction) of the prolonged PNTML, whereas in other patients PNTML may not normalize or even worsen.

Patients who developed feeling of incomplete evacuation, showed a higher increase in maximal basal pressure than patients who did not develop this symptom. Feeling of incomplete evacuation suggests the presence of an increased tonus of the pelvic floor. Increased pelvic floor tonus has been related to a history of sexual abuse.[24] It is hypothesized that this increased tonus is a defense reaction to the trauma that has occurred to the pelvic floor. Possibly, the theory for this defense mechanism also accounts for prolapse surgery, and explains the increased basal maximal pressure in patients who developed feeling of incomplete evacuation.

The incidence of feeling of “sensation of anal blockage” was 22.7 %. A similar phenomenon with respect to changes in PNTML was observed in patients who developed “sensation of anal blockage”, as in patients who developed “feeling of incomplete evacuation”. An improved status of the pudendal nerve, may prevent the patient from developing “sensation of anal blockage”.

Rectal sensibility decreased in patients in whom sensation of anal blockage disappeared. Decreased rectal sensibility has been related to constipation[25] and fecal incontinence[26], but its relation with “sensation of anal blockage” has not yet been studied. If rectal sensibility is decreased, stronger stimulations are needed to experience a sensation. Several intra-rectal disorders (e.g. enterocele, rectal intussusception, hemorrhoids) may cause a “sensation of anal blockage”. Possibly, in patients with decreased rectal sensibility, the sensory input of these disorders is too low to experience a “sensation of anal blockage”.

Both the persistence of soiling and of flatus incontinence, were associated with accelerated feelings of distension. These accelerated feelings have been related to continuous funneling of feces into the anus during filling of the rectal reservoir.[27] In combination with decreased compliance of the rectum, this funneling may lead to

incontinence.[27] In the grading of fecal incontinence[28], the mildest types consist of incontinence for mucus and incontinence for flatus. Possibly, other mechanism monitoring continence for feces, prevent the presence of fecal incontinence in patients with accelerated feelings of distension.

No statistically significant associations between changes in defecographic findings and changes in defecation symptoms were observed. In patients in whom the "feeling of incomplete evacuation" persisted, more often a rectocele larger than two centimeter persisted, than in patients in whom this defecation symptom did not develop. It has been suggested that a large rectocele may be associated with impaired evacuation of the rectum, because of entrapment of feces in the rectocele. [29] This could explain why the persistence of an enterocele and the development of "feeling of incomplete evacuation" appeared to be associated. No other relevant associations between changes in defecation symptoms and changes in defecographic findings were observed.

Changes in bowel function in patients undergoing prolapse surgery were stronger associated with changes in ano-rectal function tests than with changes in defecographic findings. This suggests that the effects of prolapse surgery on bowel function depend more on altered pathophysiology than on altered anatomy of the pelvic organs. An other explanation might be that defecography does not provide optimal insight into the anatomical relations between the organs in the lower pelvis.

To the best of our knowledge, this is the first study evaluating the association between changes in bowel function and changes in ano-rectal function tests and defecographies, in patients undergoing genital prolapse surgery. Several hypotheses have been generated to explain the effects of prolapse surgery on bowel function. These hypotheses have to be further evaluated. By showing that changes in bowel function may be associated with changes in ano-rectal function, a base has been founded for future research.

In conclusion, this study shows that about half of the defecation symptoms, reported by patients undergoing prolapse surgery, persist. De novo feeling of incomplete evacuation and sensation of anal blockage are reported by one out of every four to five patients, without symptoms before surgery. Other defecation symptoms have an even lower incidence. Changes in defecation symptoms appear to be associated with changes in ano-rectal function tests.

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Part two

Effects of genital prolapse surgery on pelvic floor function

Chapter 6

Abdominal versus vaginal approach for the management of genital prolapse and coexisting stress incontinence

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Abstract

Objective: A retrospective observational study was performed to compare micturition, defecation and prolapse symptoms as well as complication rate and hospital stay between patients who underwent an unified vaginal or abdominal surgical correction of genital prolapse and coexisting stress incontinence.

Methods: Forty-seven consecutive patients who underwent a surgical correction of genital prolapse and coexisting stress incontinence between January 1995 and December 1997, were interviewed using a postal questionnaire about the prevalence of micturition, defecation and prolapse symptoms. Medical records were studied to compare complication rate and hospital stay.

Results Thirty-five patients were operated via the vaginal route, and twelve patients were operated via the abdominal route. Abdominal surgery was associated with a higher prevalence of difficulty emptying bladder (OR 9.2 (95% CI 1.7-48.8)), fecal incontinence during urge (OR 3.8, CI 0.8-18.4), fecal incontinence without urge (OR 11.0, CI 1.0-118.8) and soiling (OR 5.4, CI 1.3-22.3), as well as with a longer post-operative hospital stay (8.6 vs 7.3 days) and higher complication rate (25.0 % vs. 11.4 %) as compared to vaginal surgery. Painful defecation (OR 4.8, CI 0.5 – 48.2) was clinically significantly more often reported by vaginally operated patients. These differences were independent of pre-operative differences.

Conclusion: The unified vaginal surgical correction of genital prolapse and coexisting stress incontinence appears to be preferable as it is associated with a lower prevalence of bothersome defecation symptoms after surgery as well with a shorter hospital stay and lower complication rate as compared to the unified abdominal correction.

Introduction

Pelvic floor dysfunction is a major health issue for older women, as shown by the 11 % lifetime risk of undergoing an operation for pelvic organ prolapse or urinary incontinence. More than 150 surgical procedures have been described for the treatment of genital prolapse and urinary incontinence.[1] If both conditions are present, the gynecologist can decide to correct them at the same time, mostly using an unified abdominal or vaginal approach.

In The Netherlands, the vaginal approach mostly involves an anterior and posterior colporrhaphy in combination with a transvaginal Pereyra needle colposuspension.[2] Commonly a vaginal hysterectomy is performed simultaneously. The abdominal approach involves mostly a sacrocolpopexy with a modified Burch colposuspension.[2]

It is unknown whether the vaginal and abdominal approach are equally effective in the management of patients with genital prolapse and coexisting stress incontinence. With respect to stress incontinence, the abdominal procedure might be preferable as the Burch colposuspension has a higher cure rate than the Pereyra suspension.[3,4] With respect to prolapse symptoms, the abdominal procedure might also be preferable although there is only one randomized controlled study showing a beneficial effect of an abdominal approach in comparison to a vaginal approach.[5] On the other hand, a vaginal approach might be preferable, as gynecological abdominal surgical procedures have been associated with a higher complication rate and longer hospital stay[5-7], as well as with an increased prevalence of post-operative defecation symptoms.[8] Studies evaluating combined surgical procedures to manage genital prolapse and coexisting stress incontinence are scarce and inconclusive.

A retrospective study was performed to compare micturition, defecation and prolapse symptoms, as well as complication rate and hospital stay between patients who underwent vaginal or abdominal surgery for genital prolapse and coexisting stress incontinence.

Patients and methods

Study population

The study population consisted of 47 consecutive patients who underwent surgical correction of a genital prolapse in combination with a colposuspension via a unified abdominal or vaginal approach in the University Medical Center Utrecht or St. Antonius Hospital Nieuwegein between January 1995 and December 1997. Both centers are large

teaching hospitals that serve a population of mixed ethnicity in and around the city of Utrecht, The Netherlands.

Measurements

The following data were obtained from the medical files: pre-operative symptoms, findings at pelvic examination before surgery, age at surgery, obstetric history, history of abdominal/pelvic surgery, findings at multi-channel urodynamic evaluation, post-operative hospital stay (in days), performed surgical procedure and complication due to surgery. All patients had a standardised urogynecologic interview before surgery as well as a complete physical examination including a classification of the genital prolapse according to the recommendations of the ICS[9] and an urodynamic evaluation[10]. Urodynamic investigation included simple uroflowmetry with catheterized postvoid residual urine volume determination, retrograde provocative multi-channel urethrocystometry and passive and dynamic urethral pressure profilometry with the prolapse protruding and with the prolapse reduced.

A questionnaire in Dutch was sent to all patients, to assess the presence of micturition, defecation and prolapse symptoms. Questions concerning micturition and prolapse symptoms were selected from the Urogenital Distress Inventory (UDI)[11]. Questions about defecation symptoms were selected from the Defaecatory Distress Inventory (DDI). The DDI consists of 15 items related to symptoms of obstructive defecation, constipation, fecal incontinence and pain related to defecation. The questions were developed based on the available literature and international definitions, interviewing patients who presented with constipation or fecal incontinence, and by interviewing three experts in the field from the Department of Surgery and Department of Obstetrics and Gynaecology from the University Medical Center Utrecht, The Netherlands. Eventually, a structured interview of the 15 selected items was held with 20 female patients. Like the UDI, each question consists of two parts. The first part deals with whether or not a symptom is present. The questions that were selected from the UDI and DDI are presented in Appendix A. The second part of the question deals with the degree of discomfort that the woman experiences from that symptom. This was recorded on a four-point Likert scale: not at all, slightly, moderately or very much. A self-developed questionnaire(Appendix B) was used to assess the severity of stress incontinence before surgery, the type of sanitary towels that were used and the satisfaction about the outcome of surgery.

Surgical procedures

Vaginal correction of the genital prolapse involved an anterior and/or posterior colporrhaphy if indicated. In patients with a descensus uteri grade II or more (according ICS classification) a hysterectomy was simultaneously performed. Stress incontinence was managed by a Pereyra needle suspension[12] or a modification of this technique as described by Raz.[13] A colposuspension was considered to be indicated in case of evident loss of urine during straining with the prolapse protruding or with the prolapse reduced as described by Bump[14]. The abdominal correction involved a sacrocolpopexy[15] and a modified Burch colposuspension, as described by Tanagho.[16]

Each woman received a single dose of intravenous prophylactic antibiotic during the operation. A 14-French Foley indwelling bladder catheter with a 5 ml balloon was placed in all women post-operatively and removed after 5 days. In case of bladder retention (defined as twice a residual volume after voiding of more than 100 ml) the patient started clean intermittent catheterization.

Statistical analysis.

The characteristics of patients in the vaginal group and patients in the abdominal group were compared using an unpaired T test for continuous variables and a Pearson $\div^2$ test for dichotomous variables.

The prevalence of defecation, micturition and prolapse symptoms were compared between both groups using Fisher's Exact Test. Relative risks and 95 % confidence intervals (CI) were calculated. A relative risk expresses the risk to report a symptom of a patient who underwent abdominal surgery in comparison to a patient who underwent vaginal surgery.

Odds ratios (ORs) were calculated for symptoms with statistically significant ($p>0.05$) different prevalence between both groups using logistic regression analysis. The OR indicates the odds of an abdominally operated patient to report a symptom compared to the odds of a vaginally operated patient to report that symptom. The ORs were adjusted in a multivariate logistic regression analysis for differences in other prognostic factors. Other prognostic factors considered were age, number of delivered children, findings at pelvic examination before surgery, urodynamic findings before surgery and previous abdominal or pelvic surgery.

The results of the self-developed questionnaire were compared between both groups using Pearson $\div^2$ test.

Results

Forty-seven patients underwent a surgical correction of a genital prolapse combined with colposuspension via unified abdominal (n=12) or vaginal (n=35) approach at the University Medical Center Utrecht or St. Antonius Hospital Nieuwegein between January 1995 and December 1997. Forty-five (96 %) of these patients returned the questionnaire.

Table 1. Baseline characteristics according to surgical approavj.

	Abdominal approach (n = 12)	Vaginal Approach (n = 35)	P value
Age (years)	60.8 (12.2)	58.0 (12.0)	0.49 †
Follow-up (months)			
Median	18	24	0.66 †
Range	11-44	9-43	
Parity (number of children)			
Median	3	3	0.66 †
Range	1-5	1-6	
Findings at pelvic examination before surgery			
Cystocele (n)			
Not present	- -	- -	
Grade I	3 (25.0 %)	13 (37.1 %)	
Grade II	2 (16.7 %)	15 (42.9 %)	0.04 ‡
Grade III	7 (58.3 %)	7 (20.0 %)	
Rectocele (n)			
Not present	3 (25.0 %)	12 (34.3 %)	
Grade I	2 (16.7 %)	15 (42.9 %)	0.10 ‡
Grade II	3 (25.0 %)	5 (14.3 %)	
Grade III	4 (33.3 %)	3 (8.6 %)	
Descensus uteri/vault prolapse (n)			
Not present	1 (8.3 %)	16 (45.7 %)	
Grade I	3 (25.0 %)	10 (28.6 %)	0.01 ‡
Grade II	3 (25.0 %)	7 (20.0 %)	
Grade III	5 (41.7 %)	2 (5.7 %)	
Urodynamic findings before surgery			
Stress incontinence (n)	10 (83.3 %)	24 (68.6 %)	0.32 ‡
Masked stress incontinence (n)	2 (16.7 %)	11 (31.4 %)	0.32 ‡
Detrusor instabilities (n)	1 (8.3 %)	11 (31.4 %)	0.11 ‡
Maximal bladder capacity (cc)	537 (160)	466 (110)	0.22 ‡
History of abdominal/pelvic surgery (n) *	5 (41,7 %)	11 (31,4 %)	0.52 ‡
Hysterectomy	5	5	
Laparoscopic sterilization		4	
Anterior and posterior colporrhaphy	3		
Burch colposuspension		1	
Cesarean section		1	

Values are means (standard deviation) or numbers (percentage).

* Some patients had undergone more than one surgical procedure.

† Unpaired T test; ‡ Chi-Square Test

Table 1 shows baseline characteristics for both groups. Patients who had had abdominal surgery had more severe cystocele, rectocele and descensus of uterus (or vaginal vault prolapse), compared to patients who had had vaginal surgery. Although patients from both groups had a similar history of pelvic surgery, abdominally operated patients had undergone more often hysterectomy in comparison to vaginally operated patients. No major differences in any other baseline characteristics were observed between both groups.

Table 2 shows hospital stay, performed surgery and complications according to surgical approach. Abdominal surgery was associated with a longer hospital stay and higher complication rate in comparison to vaginal surgery. These differences were statistically not significant. Less than half of all vaginally operated patients simultaneously underwent hysterectomy.

Table 2. Hospital stay, performed surgery and complications according to surgical approach..

	Abdominal approach (n = 12)	Vaginal Approach (n = 35)	P value
Post-operative hospital stay (days)	8.6 (1.4)	7.3 (0.4)	0.21 †
Performed colposuspension			
Burch	12 (100 %)		
Stamey Pareyra		33 (94.3 %)	
Raz		2 (5.7 %)	
Performed prolaps surgery			
Sacrocolpopexy	12 (100 %)		
Only anterior colporrhaphy		6 (17.1 %)	
Only posterior colporrhaphy		4 (11.4 %)	
Anterior and posterior colporrhaphy		25 (71.4 %)	
Vaginal hysterectomy		15 (42.9 %)	
Complications	3 (25,0 %)	4 (11,4 %)	0.25 ‡
Bladder retention	2		
Blood transfusion needed		3	
Recurrence within 1 year of surgery	1	1	

Values are means (standard deviation) or numbers (percentage).
† Unpaired T test; ‡ Chi-Square Test

Table 3 shows the prevalence of micturition, defecation and prolapse symptoms according to surgical approach. Table 3 also shows the relative risk to report these symptoms of a patient who had undergone abdominal surgery, in comparison to a patient who had undergone vaginal surgery. Difficulty emptying bladder, fecal incontinence and soiling were statistically significantly more often reported by abdominally operated patients.

Table 3. Micturition, defecation and prolapse symptoms according to surgical route and relative risk to report these symptoms of a patient who underwent abdominal surgery in comparison to a patient who underwent vaginal surgery.

	Abdominal approach (n = 12)	Vaginal approach (n = 33)	Relative Risk (95 % CI)	P value *
Micturition symptoms				
Frequency	7 (58.3 %)	19 (57.6 %)	1.0 (0.6-1.8)	0.96
Urgency	6 (33.3 %)	14 (42.4 %)	0.6 (0.3-1.4)	0.31
Stress incontinence	7 (58.3 %)	20 (60.6 %)	1.0 (0.6-1.7)	0.89
Urge incontinence	6 (50.0 %)	14 (42.4 %)	1.2 (0.6-2.4)	0.65
Mixed incontinence	5 (41.7 %)	13 (39.4 %)	1.1 (0.5-2.3)	0.89
Dysuria	2 (16.7 %)	4 (12.1 %)	1.4 (0.3-6.6)	0.65
Difficulty emptying bladder	10 (83.3 %)	12 (36.4 %)	2.3 (1.4-8.4)	0.01
Defecation symptoms				
Constipation	4 (33.3 %)	17 (51.5 %)	0.6 0.3-1.5)	0.33
Feeling of incomplete evacuation	5 (41.7 %)	16 (48.5 %)	0.9 (0.4-1.8)	0.75
Fecal incontinence	5 (41.7 %)	4 (12.1 %)	3.4 (1.1-10.7)	0.04
Incontinence for gas	7 (58.3 %)	18 (54.5 %)	1.1 (0.6-1.9)	0.82
Incontinence for liquid stools	3 (25.0 %)	5 (15.2 %)	1.7 (0.5-5.9)	0.66
Incontinence for solid stools	1 (8.3 %)	- -	- -	0.26
Soiling	7 (58.3 %)	7 (21.2 %)	2.8 (1.2-6.2)	0.03
Painful defecation	1 (8.3 %)	10 (30.3 %)	0.3 (0.0-1.9)	0.24
Difficulty emptying rectum	2 (16.7 %)	9 (27.3 %)	0.6 (0.2-2.4)	0.70
Prolapse symptoms				
Feeling of genital prolapse	3 (25.0 %)	6 (18.2 %)	1.7 (0.5-5.9)	0.66
Protrusion of genital prolapse	- -	2 (6.1 %)	- -	1.00

Values are means (standard error) or numbers (percentage).

* Calculated with Fisher's Exact Test.

Table 4 shows the crude and adjusted odds ratios for difficulty with emptying of the bladder, fecal incontinence and soiling. The number of patients included in this study, allowed us to adjust for two other prognostic factors. We selected grade of descensus uteri and grade of cystocele, because the prevalence of these two variables was statistically significantly different between both groups. Adjustment of the odds ratio for difficulty emptying bladder and soiling for findings at pelvic examination, increased the crude odds ratio, indicating that surgical route was an independent risk factor for these symptoms.

Table 4. Odds ratio (OR) for micturition and defecation symptoms

	Crude OR (95 % CI)	Adjusted[1] OR (95 % CI)	Adjusted[2] OR (95 % CI)
Difficulty emptying bladder	8.7 (1.6-46.7)	17.8 (2.1-150.6)	22.7 (2.2-237.8)
Fecal incontinence	5.2 (1.1-24.5)	3.6 (0.6-21.6)	5.1 (0.6-47.3)
Soiling	5.2 (1.3-21.5)	6.9 (1.2-39.8)	7.4 (1.3-44.1)

[1] Adjusted for grade of descensus uteri

[2] Adjusted for grade of descensus uteri and grade of cystocele

The increased risk to report fecal incontinence of abdominally operated patients in comparison to vaginally operated patients decreased after adjustment for findings at pelvic examination and was not statistically significant. This indicates that surgical route was not an independent risk factor to report fecal incontinence after hysterectomy.
The results of the self-developed questionnaire are shown in Table 5. Patients that had undergone vaginal surgery considered themselves more often satisfied with the result of their surgery and complained less frequently about micturition and defecation symptoms that did not exist before they had surgery. No major differences in any of the other questions were observed between both groups.

Table 5. Severity of stress incontinence before surgery, sanitary towel use and satisfaction about result of surgery.

	abdominal approach (n = 11)	vaginal approach (n = 34)	P value
Severity of stress incontinence before surgery			
during coughing or straining	6 (54.5 %)	14 (41.2 %)	
during sitting, standing or walking	3 (27.3 %)	14 (41.2 %)	0.68
continuous incontinence	2 (18.2 %)	6 (17.6 %)	
Sanitary towel use before surgery	9 (81.8 %)	27 (79.4 %)	0.86
Sanitary towel use after surgery	7 (63.6 %)	18 (52.9 %)	0.54
Result of surgery with respect to stress incontinence			
Improved	4 (36.4 %)	17 (50.0 %)	
Unchanged	7 (63.6 %)	15 (44.1 %)	0.44
Worsened		2 (5.9 %)	
More active after surgery	3 (27.3 %)	10 (29.4 %)	0.89
Satisfied with result of surgery	6 (54.5 %)	25 (73.5 %)	0.24
New micturition and defecation symptoms following surgery	5 (45.5 %)	9 (26.5 %)	0.24

Values are number of patients (percentage).

Discussion

Vaginal and abdominal surgical correction of a genital prolapse and coexisting stress incontinence via an unified surgical route did not differ with respect to the prevalence of reported prolapse and stress incontinence symptoms after surgery. However, a clinically relevant increase in the prevalence of difficulty in emptying the bladder, fecal incontinence and soiling were observed in patients who had undergone abdominal surgery in comparison to patients who had undergone vaginal surgery. The observed differences in prevalence of difficulty to empty the bladder and soiling occurred independent from differences in other prognostic factors between both groups. This did not account for the observed difference in prevalence of fecal incontinence. The combination of surgical

procedures via the abdominal route was associated with a longer hospital stay and a higher complication rate in comparison to the combination via the vaginal route.

In general, a non-randomized study is considered to be less powerful as a randomized study in assessing valid relationships, mainly because it does not meet an important requirement for validity. This requirement is a random allocation of subjects to the intervention of interest. Indeed, patients undergoing abdominal surgery had more severe anatomical abnormalities at pelvic examination than those undergoing vaginal surgery. These differences could be an alternative explanation for the differences in micturition and defecation symptoms after surgery. However, adjustment for the pre-operative differences in findings at pelvic examination before surgery between both groups, did show that surgical route is an independent determinant of the presence of difficulty in emptying of the bladder and soiling after surgery.

The study design did not allow us to clinically assess the presence of the reported symptoms. However, as one might question the reliability of non-physiological bladder- and bowel function tests to determine the presence of pelvic floor symptoms, we preferred to focus on reported symptoms.

There are limited data on comparing the surgical outcome of a combined vaginal approach versus a combined abdominal approach in the treatment of genital prolapse and coexisting stress incontinence. In contrast to our findings, a retrospective study among 101 women reported that the combined abdominal approach was associated with a lower incidence of recurrent prolapse, urge incontinence and recurrent stress incontinence in comparison to the combined vaginal approach[17]. The age of the vaginally operated patients in this study was significantly higher, in comparison to the abdominally operated patients. Furthermore, no attempt was made to correct for differences in findings at pelvic examination before surgery. Another retrospective study that evaluated the results of vaginal and abdominal combination surgery in 22 patients, showed that the vaginal approach was associated with a shorter operating time and less blood loss in comparison to the abdominal approach[7]. No differences were observed in complication rate, micturition and defecation symptoms after surgery and recurrence rate between both groups.

In contrast to these findings, several studies have shown that post-operative voiding difficulties are more common following transvaginal needle suspension in comparison to Burch colposuspension[18-20]. The observed higher prevalence of difficulties in emptying the bladder in the abdominal group might be explained by the fact that we studied combined surgical procedures, instead of a single performed colposuspension. Another

explanation might be the difference in detrusor activity between both groups before surgery. The bladder volume measured during urodynamic investigation before surgery was larger in the abdominal group. As a large capacity bladder is associated with a low detrusor activity[21], the increased prevalence of voiding difficulties in the abdominal group may have existed before surgery.

The increased prevalence of fecal incontinence and soiling after abdominal surgery could be explained by a higher prevalence of enteroceles. Estimations about the prevalence of an enterocele following Burch colposuspension vary from 10 % to 30 %.[22,23] There has been no study describing a relationship between a needle suspension and the presence of an enterocele after surgery. Studies evaluating the correlation between patient's clinical symptoms and the radiological findings obtained by defecography have shown that an enterocele is often associated with defecation symptoms like fecal incontinence and soiling.[24,25] However, since in this study, no defecographies have been performed after surgery, one can only hypothesize the reason of the increased prevalence of fecal incontinence and soiling in the abdominal group.

The self-developed questionnaire that was used, showed that patients who had undergone vaginal surgery were more often satisfied with the result of their surgery. This may be due to the fact that they experienced less frequently micturition and defecation symptoms after surgery, that were not present before surgery.

Aside from the advantage with respect to micturition and defecation symptoms, this study showed that vaginal surgery was associated (as has been reported before[5-7]), with a shorter hospital stay and lower complication rate in comparison to abdominal surgery. All together, it can be concluded that when a surgical correction of genital prolapse and coexisting stress incontinence is performed via unified surgical route, the vaginal approach appears to be preferable to the abdominal approach.

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Chapter 7

A randomized trial comparing abdominal and vaginal prolapse surgery of patients with descensus uteri grade II – IV.

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Abstract

Objective: Descensus uteri can be corrected by either a vaginal hysterectomy combined with anterior and/or posterior colporraphy or an abdominal sacrocolpopexy with preservation of the uterus. Presently, it is not known which technique is superior. A randomized trial was performed to compare the anatomical effectiveness and effects on micturition and defecation of both techniques.

Methods: Patients were randomly selected for either vaginal or abdominal surgery. To measure the presence and discomfort of micturition and defecation symptoms, patients were asked to complete the urogenital distress inventory (UDI), defecation distress inventory (DDI) and incontinence impact questionnaire (IIQ), before and after surgery. Domain scores of the UDI, DDI and IIQ, ranging from 0 (no symptoms present) to 100 (all symptoms present and causing maximal bother) were calculated and compared between the vaginal and abdominal group, using repeated measurement analysis. Findings at pelvic examination at regular follow-up visits, number of doctor visits within the first year after surgery because of prolapse, micturition and defecation symptoms and repeated genital surgery for recurrent prolapse were also compared between both groups.

Results: Eighty-two patients, equally distributed over both groups participated in the trial. One year after surgery, scores on the discomfort/pain domain, overactive bladder domain, genital prolapse domain and obstructive micturition domain of the UDI were respectively 14, 18, 9 and 19 in the abdominal group and 7, 9, 5 and 9 in the vaginal group. The differences between both groups in these domain scores of the UDI were statistically significant. DDI domain scores, IIQ domain scores and findings at pelvic examination were similar in both groups. Twenty-five (61.0 %) patients of the 41 patients who underwent abdominal surgery visited a doctor within the first year after surgery because of prolapse, micturition or defecation symptoms in comparison to 13 (31.7 %) of the 41 patients who underwent vaginal surgery (Fishers Exact Test: $p=0.01$). Repeated prolapse surgery was performed or planned within the first year after surgery in 9 (22.9 %) patients who underwent abdominal surgery and in 1 (2.4 %) patient who underwent vaginal surgery (Fishers Exact Test: $p = 0.01$).

Conclusion: Vaginal hysterectomy with anterior and/or posterior colporraphy is the procedure of choice to surgically correct descensus uteri, when compared to abdominal sacrocolpopexy with preservation of the uterus.

Introduction

The prevalence of descensus uteri in the general female population has been shown to be approximately 5%.[1] Descensus uteri may negatively affect pelvic floor function, resulting in micturition symptoms, defecation symptoms and sexual dysfunction.[2] If the anatomical abnormalities and impaired pelvic floor function of patients with descensus uteri are severe enough, surgical correction is recommended. Several surgical procedures have been described to effectively correct descensus uteri.[3-6] In the Netherlands, gynecologists will either choose a vaginal hysterectomy combined with anterior and/or posterior colporraphy or an abdominal sacrocolpopexy with preservation of the uterus.[7] Retrospective studies have shown similar complication and failure rates of both techniques.[8-10] However, little is known about the efficacy of both techniques to correct functional problems of the pelvic floor. Because of this deficit, the decision to choose between a vaginal or an abdominal approach in patients with descensus uteri is based on the surgeon's inexplicit preferences.

A multi-center randomized trial was performed to compare the effects of abdominal and vaginal surgical correction of descensus uteri. Not only were the prevalence of micturition and defecation symptoms after both techniques evaluated, but also the effects on quality of life related to these symptoms.

Patients and methods

Study population

The study population consisted of 82 consecutive patients participating in a multi center randomized controlled trial, comparing vaginal and abdominal prolapse surgery in patients with descensus uteri stage II – IV according to the classification of the International Continence Society (ICS).[11] All patients were enrolled in this trial between January 1998 and January 2000. Exclusion criteria were a uterus sized more than 12 weeks of gestational age, the presence of an adnexal mass, a history of more than two abdominal pelvic surgical procedures, extreme obesity (quetelet index > 35 kg/m^2), prior inflammatory bowel or pelvic disease and fecal incontinence because of an internal or external anal sphincter defect. The study protocol was approved by the local ethical committees of the three participating hospitals (University Medical Center Utrecht, St. Antonius Hospital Nieuwegein and Diaconessenhuis Utrecht) and written informed consent was obtained from all patients.

Pre-operative evaluation

A standardized urogynecologic interview and a classification of the genital prolapse according to the recommendations of the ICS[11] was performed in all patients by the first author, before surgery and at 6 weeks, 6 months and 1 year after surgery. According to this classification descensus uteri, cystocele and rectocele were classified as follows: grade 0 – none; grade I – distal portion of the prolapse is > 1 cm above the hymenal ring; grade II – prolapse is between 1 cm proximal and 1 cm distal to the hymenal ring; grade III – prolapse is > 1 cm below the hymen, but no further than 2 cm or less than the total vaginal length; and grade IV – complete or near complete (within 2 cm) vaginal eversion. Grading of the prolapse was performed at maximal straining in the 45 º supine position.

The diagnostic work-up additionally included urodynamic evaluation, defecography and ano-rectal function tests. This work-up is in accordance with international standards.[11-13] Urodynamic investigation included simple uroflowmetry with catheterized postvoid residual urine volume determination, retrograde provocative multi-channel urethrocystometry and passive and dynamic urethral pressure profilometry with the prolapse protruding and with the prolapse reduced.[14] At defecography vagina, small bowel and recto-sigmoid were filled with barium contrast and the process of defecation was dynamically recorded.[15,16] Ano-rectal function tests were performed as previously described.[17-20]

Surgical procedures

Vaginal surgery consisted of a vaginal hysterectomy combined with anterior and/or posterior colporrhaphy if indicated.[3] After vaginal hysterectomy, the position of the vaginal vault was secured, by fixating it with absorbable sutures to the cardinal-uterosacral ligaments. A bladder neck suspension was simultaneously performed, in case of evident loss of urine during straining with the prolapse protruding or with the prolapse reduced as described by Bump[14], In this case either a Pereyra needle suspension[21] or a modification of this technique as described by Raz[22] was chosen. A vaginal pack was placed and removed after approximately 24 hours.

The abdominal correction involved a sacrocolpopexy with preservation of the uterus.[23] The abdomen is entered through a low midline or transverse incision. In contrast to most procedures that only identify the vaginal apex and attach graft material to this limited area, we start with a peritoneal incision, which is extended from the presacral area, across the cul-de-sac of Douglas, to the top of the vagina just next to the mesentery of the colon. The prolapsed uterus is replaced in its proper position by inserting a plastic stent in the

vagina, which is kept in place by an assistant. With the vagina distended, the vagina is dissected sharply from the bladder anteriorly and from the rectum posteriorly, over one-third of its length. Two Gore-Tex soft tissue patches, each measuring about 4 x 10 cm, are anchored along the anterior vaginal wall and the frontal aspect of the cervix respectively along the posterior vaginal wall and the dorsal aspect of the cervix. The rectum is lifted and fixated to the mesh with 2 to 3 non-absorbable sutures. In this way the recto-vaginal space is obliterated. The free part of the anteriorly placed implant is cut into two slings. The right and left sling are passed through the corresponding broad ligaments at an avascular point, about 1 cm medial from the external part of the isthmus tubae and are led to the dorsal side of the uterine cervix. Both slings are fixated here and secured to the dorsal patch. The periosteum of the sacrum is denuded with the sigmoid colon retracted sharply to the left. The implant is affixed transversely to the longitudinal ligament on the anterior surface of the sacrum by using three unresorbable sutures, approximately 4 cm below the promontorium. The patch is secured to the sacrum with minimal tension on the vagina. If a colposuspension is indicated, a modified Burch colposuspension, as described by Tanagho, is simultaneously performed.[24]
All surgical procedures were performed by gynecologists who had performed at least 50 procedures of each technique and were originally trained at the Medical Center Utrecht. All women received peri-operative deep vein thrombosis prophylaxis and a single dose of intravenous prophylactic antibiotic during operation. A 14-French Foley indwelling bladder catheter with a 5 ml balloon was placed in all women post-operatively and removed after 2-5 days. In case of bladder retention (defined as twice a residual volume after voiding of more than 100 ml) the patient started clean intermittent catheterization. Post-operative pain management was similar in both groups.

Measurements

The following information was collected from each patient: duration of surgery, amount of blood loss, complications during surgery, complications during hospital stay, duration of hospital stay, late complications due to surgery. During the first year after surgery, the number of doctor visits because of prolapse symptoms, micturition symptoms, defecation symptoms and other symptoms related to prolapse surgery were recorded for each patient. Recurrence of prolapse was scored for all patients and regarded to be present in case a patient had to undergo surgery again because of prolapse symptoms. All patients received a questionnaire 2 to 4 weeks before surgery, 6 weeks after surgery, 6 months after surgery and 1 year after surgery. This questionnaire consisted of the following modules :

1. Micturition and defecation symptoms were measured with the Urogenital Distress Inventory (UDI).[25] The UDI consists of 19 items and each item measures if a micturition or prolapse symptom is present and to what extent the patient is bothered by this symptom. The latter is measured on a four-point Likert scale ranging from not at all to greatly. After forward-backward translation, a factor analysis of the Dutch version of the UDI was performed. Data were used from a random population sample (n=2042) and from patients presenting themselves with urogenital dysfunction at the gynecologic outpatient clinic of the University Medical Center Utrecht, The Netherlands (n=196). Five domains were identified, namely: discomfort / pain, urinary incontinence, overactive bladder, genital prolapse and obstructive micturition. Cronbach's alpha's, a measurement of internal consistency, ranged between 0.74 and 0.82. One item (bed-wetting) had a low factor loading on all domains and was therefore excluded. The domain scores range from 0 to 100. A higher score indicates more bothersome symptoms on that particular domain.
2. Defecation symptoms were measured with the Defecation Distress Inventory (DDI). The DDI is a questionnaire in the same format as the UDI and was developed and validated by our group. It can be used to assess the presence and experienced discomfort of defecation symptoms. The questions were developed after studying the literature and international definitions, interviewing patients who presented themselves with constipation or fecal incontinence, and by interviewing three experts in the field from the Department of Surgery and Department of Obstetrics and Gynecology of the University Medical Center Utrecht, The Netherlands. Eventually a structured interview of the 15 selected items was held with 20 female patients. The DDI consists of 15 items that can be divided into 4 domains: constipation / obstructive defecation, fecal incontinence, painful defecation and incontinence for gas. Cronbach's alpha's of these domains ranged between 0.71 and 0.78. Similar to the UDI, the score of the domains ranged from 0 to 100, with a higher score indicating more bothersome symptoms.

Several questions were selected from the UDI and DDI to identify the presence of micturition, prolapse and defecation symptoms. These questions are presented in Appendix A.

3. Disease specific quality of life was measured with the Incontinence Impact Questionnaire (IIQ).[25] The IIQ consists of 30 items referring to the impact of urogenital symptoms on different aspects of quality of life. In addition to the

original four domains (mobility, physical functioning, social functioning and emotional functioning), factor analysis of the Dutch version identified a fifth domain of embarrassment. Cronbach's alpha's of these domains ranged between 0.83 and 0.93. Again, domain scores range from 0 to 100 with a higher score indicating more negative impact of symptoms on quality of life.

Outcome measurements

Several outcome measurements were selected. First, domain scores of the UDI, DDI and IIQ were measured at one year after surgery. Second, the reported prevalence of micturition and defecation symptoms at 6 weeks, 6 months and 1 year after surgery were measured. Third, the number of doctor visits within the first year after surgery because of prolapse, micturition and defecation symptoms were recorded. Finally, the number of patients in whom repeated surgery was performed or planned surgery because of recurrent genital prolapse was scored.

Power analysis

A difference between both surgical techniques of 10 points on the obstructive / pain domain of the UDI one year after surgery, was considered to be a clinically relevant difference between both groups. The standard deviation of the score on this domain was 15 points in a previously conducted study. With a power of 95% and an á level of 0.05, the calculated sample size necessary was 74 (37 in each group).

Randomization

Patients were assigned through balanced randomization, on the basis of a random number table, to have pelvic reconstructive surgery by either a vaginal or abdominal approach. The surgeon received the randomization assignment after the diagnostic work-up from the first author, who had sole access to the randomization table.

Statistical analysis

The aim of the statistical analysis was to calculate which of the two surgical procedures scored best with respect to the defined outcome measurements. To achieve this aim, an intention to treat analysis was performed. Outcome measurements of the two groups were compared and tested, for statistically significant differences. For continuous variables an unpaired T test was used, whereas for dichotomous variables a Chi-Square test was used. For differences in UDI, DDI, IIQ and RAND-36 domain scores a repeated measurement analysis was performed. In this analysis, variances between the

measurements were divided in variances due to differences between both treatments, variances due to differences between moment of interview and due to differences between subjects.

Table 1. Baseline characteristics of the patients according to surgical approach.

	Vaginal Approach (n=41)	Abdominal approach (n=41)
Age (years)	56.4 (10.9)	57.9 (8.8)
Parity (n)	2.5 (1.2)	2.9 (1.1)
Body mass index (kg / m^2)	26.0 (3.6)	25.1 (3.0)
History of prolapse surgery (n) *	2 (4.9)	4 (9.8)
Anterior colporraphy	1	3
Anterior and posterior colporraphy	2	1
History of other surgery (n) *	4 (9.8)	6 (14.6)
Heart transplantation	1	
Adnex extirpation		1
Cholecystectomy	2	2
Appendectomy	2	3
Sterilization		1
Co-morbidity (n) **	23 (56.1)	16 (39.0)
Rheumatoid arthritis	5	2
Hypertension	13	8
Diabetus mellitus	3	1
Hypercholesterolaemie	4	6
Hypothyreoidism	5	2
COPD	2	2
Transient ischemic attack	2	
Findings at urodynamic investigation		
Evident stress incontinence (n)	8 (19.5)	9 (22.0)
Masked stress incontinence (n)	3 (7.3)	7 (17.1)
Detrusor instabilities (n)	- -	2 (4.9)
Bladder capacity (ml)	483 (119)	455 (149)

Values are means (standard deviation) or numbers (percentage).
* Some patients had undergone more than one surgical procedure.
** Some patients had more than one disease.
COPD Chronic obstructive pulmonary disease

Results

A total of 82 patients participated in this trial. After randomization, both groups consisted of 41 patients. Of the 41 patients that were randomized for abdominal surgery, two patients requested afterwards to have vaginal surgery. All patients returned the questionnaire before surgery, 6 weeks after surgery and 6 month after surgery. One of the

questionnaires returned after 6 weeks could not be used because more than half of all questions was not answered. Two patients of each group refused further follow-up after six months after surgery. Table 1 shows the base-line characteristics of the study population. Prognostic factors were equally distributed among both groups.

Table 2. Comparison of clinical outcomes according to surgical approach.

	Vaginal approach (n = 41)	Abdominal approach (n = 41)	P value
Duration of surgery (min)	97 (23)	107 (30)	0.09
Amount of blood loss (ml)	244 (330)	248 (218)	0.95
Duration of admission (days)	7.7 (1.2)	7.6 (1.8)	0.77
Complications during surgery n)	3 (7.2)	1 (2.4)	0.62[1]
Bleeding needing transfusion	2	1	
Bowel lesion	1		
Complications during admission (n)	14 (24.4)	10 (34.1)	0.47[1]
Lower urinary tract symptoms	8	8	
Dullness upper leg	1		
Fever of unknown origin	3	1	
Wound infection		1	
Vault abscess	2		
Late complications (n)	1 (2.4)	3 (7.3)	0.62[1]
Development of vaginal stricture requiring excision	1		
Peritoneal hernia requiring surgery		1	
Infected implant requiring surgery		2	

Values are means (standard deviation) or numbers (percentage).
[1] Tested using Fisher's exact test

A comparison of the clinical outcome of both groups is listed in Table 2. There were no statistically significant differences between the groups in duration of surgery, amount of blood loss, duration of hospital stay and number of complications. The average surgery time in the vaginal group was longer than in the abdominal group, but the difference was not statistically significantly. Three of the abdominally operated patients and one of the vaginally operated patients had to be operated again because of a late complication which occurred.

Table 3 shows the findings of the pelvic examinations over time. No statistically significant differences between both groups were observed. The percentage of patients that had a grade II or grade III cystocele 6 weeks after surgery, was higher in the abdominal group than in the vaginal group. Other relevant differences in findings at pelvic examination were not observed.

Tabel 3. Findings at pelvic examination according to surgical approach.

	grade	Vaginal approach	Abdominal approach	P value (FE test)
Pre-operative		**(n = 41)**	**(n = 41)**	
Descensus uteri	2	41 (100)	41 (100)	1.00
Cystocele	1	6 (14.6)	5 (12.2)	1.00
	2	35 (85.4)	36 (87.8)	
Rectocele	1	26 (63.4)	28 (68.3)	0.82
	2	15 (36.6)	13 (31.7)	
6 weeks post-operative		**(n = 41)**	**(n = 41)**	
Descensus uteri	1	41 (100)	40 (97.6)	1.00
	2	- -	1 (2.4)	
Cystocele	1	38 (92.7)	33 (80.5)	0.19
	2	3 (7.3)	8 (19.5)	
Rectocele	1	39 (95.1)	38 (92.7)	1.00
	2	2 (4.9)	3 (7.3)	
6 months post-operative		**(n = 40)**	**(n = 40)**	
Descensus uteri	1	38 (95.0)	38 (95.0)	1.00
	2	2 (5.0)	2 (5.0)	
Cystocele	1	29 (72.5)	24 (60.0)	0.34
	2	11 (27.5)	16 (40.0)	
Rectocele	1	34 (85.0)	36 (90.0)	0.74
	2	6 (15.0)	4 (10.0)	
1 year post-operative		**(n = 39)**	**(n = 39)**	
Descensus uteri	1	37 (94.9)	37 (94.9)	1.00
	2	2 (5.1)	2 (5.1)	
Cystocele	1	24 (61.5)	25 (64.1)	1.00
	2	15 (38.5)	14 (35.9)	
Rectocele	1	33 (84.6)	37 (94.9)	0.26
	2	6 (15.4)	2 (5.1)	

Values are numbers (percentage)
FE Fisher's exact

Table 4 shows UDI, DDI and IIQ domain scores before surgery and one year after surgery for both groups. In both groups, all UDI and DDI domain scores reduced after surgery. The maximal reduction was observed in the score on the prolapse domain of the UDI. For all domains of the UDI, the reduction in score was higher in the vaginal group than in the abdominal group. Repeated measurement analysis of the UDI scores showed that throughout the total follow-up period statistically significant differences in domain scores between both groups were observed for the discomfort / pain domain, overactive bladder domain, genital prolapse domain and obstructive micturition domain.

At the one year follow-up point, the observed reductions in DDI domain scores were similar in both groups. Repeated measurements analysis of the DDI scores showed that over the entire follow-up period the abdominal group had a statistically significantly higher score on the constipation/obstructive defecation domain in comparison to the vaginal group. However, after correcting for differences before surgery, the scores on the constipation/obstructive defecation symptom were similar in both groups.

Reductions in IIQ scores were also similar in both groups. Over the complete follow-up period, no statistically significant differences in domain scores of the IIQ between both groups were observed, using repeated measurements analyses.

Table 4.Domain scores of urogenital distress inventory (UDI), defecation distress inventory (DDI) and incontinence impact questionnaire (IIQ) before surgery and one year after surgery according to surgical approach.

	Before surgery		***One year after surgery***		
	Vaginal Approach	Abdominal Approach	Vaginal Approach	Abdominal Approach	P value [1]
UDI domains	**n=41**	**n=41**	**n=40**	**n=38**	
Discomfort / pain	19.4 (2.7)	24.0 (3.0)	7.0 (1.9)	14.1 (2.4)	0.01
Urinary incontinence	24.7 (4.7)	21.8 (3.0)	7.2 (2.1)	13.2 (3.5)	0.19
Overactive bladder	28.0 (3.4)	31.7 (3.8)	9.4 (2.2)	18.1 (3.5)	0.02
Genital prolapse	58.0 (4.7)	68.3 (4.3)	5.1 (3.0)	9.2 (3.8)	0.02
Obstructive micturition	19.9 (4.3)	24.4 (4.7)	9.0 (2.5)	19.3 (4.2)	0.04
DDI domains	**n=41**	**n=41**	**n=40**	**n=38**	
Constipation/obstruction	8.1 (2.1)	15.6 (3.3)	6.2 (2.3)	9.3 (2.1)	0.02
Fecal incontinence	8.0 (2.3)	14.5 (3.6)	3.4 (1.9)	3.8 (1.5)	0.66
Painful defecation	6.1 (2.7)	12.9 (3.8)	5.4 (3.3)	5.0 (2.3)	0.10
Incontinence for gas	27.6 (5.6)	43.3 (6.5)	18.9 (4.8)	29.7 (6.0)	0.18
IIQ domain	**n=41**	**n=41**	**n=30**	**n=34**	
Mobility	20.7 (3.4)	23.2 (2.9)	6.7 (2.0)	11.3 (2.9)	0.65
Physical functioning	18.1 (2.9)	22.2 (2.8)	9.1 (2.6)	9.6 (3.1)	0.67
Social functioning	16.8 (2.3)	20.3 (3.1)	8.6 (2.4)	9.6 (2.7)	0.57
Emotional functioning	11.4 (3.1)	5.4 (1.7)	4.1 (2.0)	4.6 (1.9)	0.14
Embarrassment	6.5 (2.1)	8.6 (2.3)	1.7 (0.9)	7.1 (2.8)	0.16

Values are means (standard error)

[1] Calculated with repeated measurement analyses

Table 5 shows the prevalence of micturition and prolapse symptoms before surgery and at 6 weeks, 6 months and 1 year after surgery, according to surgical route. Statistically significant differences in the prevalence of micturition and prolapse symptoms between both groups were not observed before surgery. The prevalence of all these symptoms was higher in the abdominal group than in the vaginal group, with the exception of stress

incontinence. At six months and one year after surgery, the prevalence of urgency was statistically significantly higher in the abdominal group than in the vaginal group.

Table 5. Prevalence of micturition and prolapse symptoms according to surgical approach.

	Vaginal Approach	Abdominal Approach	P value (FE test)
Before surgery	**(n=41)**	**(n=41)**	
Frequency	24 (58.5)	28 (68.3)	0.42
Urgency	22 (53.7)	29 (70.7)	0.11
Stress incontinence	23 (56.1)	22 (53.7)	1.00
Urge incontinence	17 (41.5)	21 (51.2)	0.41
Dysuria	3 (7.3)	6 (14.6)	0.33
Difficulty emptying bladder	22 (53.7)	21 (51.2)	1.00
Feeling of genital prolapse	40 (97.6)	40 (97.6)	1.00
Protrusion of genital prolapse	27 (65.9)	26 (63.4)	1.00
6 weeks post-operative	**(n = 41)**	**(n = 40)**	
Frequency	15 (36.6)	22 (55.0)	0.12
Urgency	19 (46.3)	22 (55.0)	0.51
Stress incontinence	7 (17.1)	15 (37.5)	0.05
Urge incontinence	7 (17.1)	14 (35.0)	0.08
Dysuria	4 (9.8)	6 (15.0)	0.52
Difficulty emptying bladder	13 (31.7)	17 (42.5)	0.36
Feeling of genital prolapse	4 (9.8)	6 (15.0)	0.52
Protrusion of genital prolapse	4 (9.8)	3 (7.5)	0.82
6 months post-operative	**(n = 41)**	**(n = 41)**	
Frequency	13 (31.7)	15 (36.6)	0.82
Urgency	16 (39.0)	26 (63.4)	0.05
Stress incontinence	12 (29.3)	11 (26.8)	1.00
Urge incontinence	7 (17.1)	13 (31.7)	0.20
Dysuria	2 (4.9)	5 (12.2)	0.43
Difficulty emptying bladder	15 (36.6)	19 (46.3)	0.50
Feeling of genital prolapse	4 (9.8)	6 (14.6)	0.74
Protrusion of genital prolapse	4 (9.8)	5 (12.2)	0.84
1 year post-operative	**(n = 40)**	**(n = 38)**	
Frequency	10 (25.0)	12 (31.6)	0.62
Urgency	19 (47.5)	27 (71.1)	0.04
Stress incontinence	13 (32.5)	14 (36.8)	0.81
Urge incontinence	8 (20.0)	12 (31.6)	0.30
Dysuria	2 (5.0)	3 (7.9)	0.67
Difficulty emptying bladder	14 (35.0)	17 (44.7)	0.49
Feeling of genital prolapse	4 (10.0)	6 (15.8)	0.51
Protrusion of genital prolapse	2 (5.0)	5 (13.2)	0.26

Values are numbers (percentage)
FE Fisher's exact

Table 6 shows the prevalence of defecation symptoms before surgery and at 6 weeks, 6 months and 1 year after surgery, according to surgical route. All defecation symptoms had

a similar prevalence in both groups before surgery, except for constipation and difficulty emptying rectum. These two symptoms were more common in the abdominal group than in the vaginal group. The prevalence of sensation of anal blockage reported at 6 weeks and 1 year after surgery, was statistically significantly higher in the abdominal group than in the vaginal group.

Table 6. Prevalence of defecation symptoms according to surgical approach.

	Vaginal approach	Abdominal approach	P value (FE test)
Before surgery	**(n=41)**	**(n=41)**	
Constipation	2 (4.9)	6 (14.6)	0.11
Feeling of incomplete evacuation	9 (22.0)	13 (31.7)	0.34
Sensation of anal blockage	13 (31.7)	17 (41.5)	0.38
Difficulty emptying rectum	6 (14.6)	12 (34.1)	0.11
Painful defecation	6 (14.6)	11 (26.8)	0.20
Soiling	28 (68.3)	26 (63.4)	0.84
Fecal incontinence	6 (14.6)	8 (19.5)	0.60
Flatus incontinence	22 (53.7)	24 (58.5)	0.53
6 weeks post-operative	**(n = 41)**	**(n = 40)**	
Constipation	1 (2.4)	2 (5.0)	0.62
Feeling of incomplete evacuation	9 (22.0)	15 (37.5)	0.15
Sensation of anal blockage	9 (22.0)	17 (42.5)	0.06
Difficulty emptying rectum	4 (9.8)	8 (20.0)	0.23
Painful defecation	4 (9.8)	5 (12.5)	0.74
Soiling	3 (7.3)	5 (12.5)	0.48
Fecal incontinence	2 (4.9)	1 (2.5)	1.00
Flatus incontinence	16 (39.0)	14 (35.0)	0.82
6 months post-operative	**(n = 41)**	**(n = 41)**	
Constipation	- -	2 (4.9)	0.49
Feeling of incomplete evacuation	7 (17.1)	19 (46.3)	0.01
Sensation of anal blockage	11 (26.8)	17 (41.5)	0.24
Difficulty emptying rectum	2 (4.9)	8 (19.5)	0.09
Painful defecation	4 (9.8)	7 (17.1)	0.52
Soiling	5 (12.2)	8 (19.5)	0.55
Fecal incontinence	5 (12.2)	4 (9.8)	1.00
Flatus incontinence	17 (41.5)	16 (39.0)	1.00
1 year post-operative	**(n = 40)**	**(n = 38)**	
Constipation	- -	2 (5.3)	0.23
Feeling of incomplete evacuation	8 (20.0)	15 (39.5)	0.08
Sensation of anal blockage	6 (15.0)	15 (39.5)	0.02
Difficulty emptying rectum	7 (17.5)	9 (23.7)	0.58
Painful defecation	4 (10.0)	6 (15.8)	0.51
Soiling	5 (12.5)	5 (13.2)	1.00
Fecal incontinence	3 (7.5)	3 (7.9)	1.00
Flatus incontinence	18 (45.0)	18 (47.4)	1.00

Values are numbers (percentage)

FE Fisher's exact

The prevalence of feeling of incomplete evacuation was higher in the abdominal group than in the vaginal group at all measurements after surgery. This difference was statistically significant at six months after surgery. The prevalence of difficulty emptying rectum at six months after surgery was higher in the abdominal group than in the vaginal group (p = 0.09). Correction for the differences between both groups in prevalence of incomplete evacuation of the rectum and difficulty emptying the rectum before surgery, showed that no differences in the development of these symptoms after both techniques were present.

Table 7 shows the group comparison of doctor visits related to the performed genital prolapse surgery and prolapse surgery performed or planned within the first year after surgery because of recurrence of prolapse symptoms. Abdominally operated patients presented themselves more often with prolapse symptoms (p = 0.01), defecation symptoms (p = 0.10) and micturition symptoms (p=0.19) in comparison to vaginally operated patients. A second prolapse operation within the first year after the first prolapse operation, was performed in 5 patients and planned in another 4 patients who had undergone abdominal prolapse surgery. In these 9 patients, the indication to perform surgery was a cystocele in 5 cases and a recurrence of descensus uteri in 4 cases. In the vaginal group, a second prolapse operation within the first year after the first prolapse operation, was planned in only one patient. This patient had a vaginal vault prolapse reaching into the introitus.

Table 7. Number of doctor visits related to performed surgery and repeated prolapse surgery according to surgical approach.

	Vaginal Approach (n = 41)	Abdominal Approach (n = 41)	P value FE test
Visit because of symptoms related to surgery	13 (31.7)	25 (61.0)	0.01
Visit because of prolapse symptoms	5 (12.2)	16 (39.0)	0.01
Visit because of defecation symptoms	5 (12.2)	12 (29.3)	0.10
Visit because of micturition symptoms	3 (7.3)	8 (19.5)	0.19
Visit because of other symptoms	10 (24.4)	11 (26.8)	1.00
Second prolapse surgery performed	- -	5 (12.2)	0.05
Second prolapse surgery performed or planned	1 (2.4)	9 (22.0)	0.01

Values are numbers (percentage).
FE Fisher Exact

Discussion

In this multi-center randomized trial comparing the effects of abdominal and vaginal surgery in patients with descensus uteri grade II – IV, the quality of life related to

discomfort and pain during micturition, overactive bladder symptoms, genital prolapse symptoms and obstructive micturition symptoms improved more after vaginal surgery than after abdominal surgery. Vaginal and abdominal prolapse surgery appeared to have similar effects on defecation. Patients who had undergone abdominal surgery presented themselves more often with recurrence or persistence of their prolapse symptoms than patients who had undergone vaginal surgery, while anatomical results of both techniques were similar. Within the first year after prolapse surgery, repeated prolapse surgery was more often performed or planned in the abdominal group than in the vaginal group.

The patients participating in this study were selected from the outpatient clinic of three teaching hospitals in or around Utrecht, the Netherlands. All three hospitals had at least one gynecologist with special interest in the field of pelvic floor surgery. The presence of such a specialist may have attracted patients presenting themselves with genital prolapse, but there is no reason to believe that these patients differ from the average patient with genital prolapse. Therefore, our results are generelazable to all patients that fulfill our in- and exclusion criteria. All gynecologists who performed the surgical procedures in this study were familiar with both techniques. Furthermore, by including a detailed description of the surgical techniques in the study protocol, variations in the performance of surgery between gynecologists were assumed to be limited. Therefore, it is not believed that our results can be explained by differences in the gynecologists' skills to perform vaginal or abdominal surgery.

Clinical outcomes (complication rate, duration of surgery and hospital stay, amount of blood loss) observed in this study are comparable to those reported by others.[26-28] However, the anatomical results are more difficult to compare to those of others. Only a few studies have provided a detailed description of findings at pelvic examination obtained from regular follow-up visits in all patients. Marana and co-workers performed pelvic examination in 47 patients who had undergone vaginal hysterectomy with anterior and / or posterior colporraphy.[29] All patients but two presented with some degree of genital prolapse at the time of re-evaluation, which took place on average 5 years after surgery. Three out of every four patients had a grade II or grade III cystocele. Benson and co-workers performed a randomized trial comparing the surgical effectiveness of abdominal sacrocolpopexy with bilateral sacrospinous ligament fixation.[26] In this study, prolapse surgery was considered to be optimally effective if women remained free of prolapse symptoms, the vaginal apex remained supported above the levator plate, and no protrusion of any vaginal tissue beyond the hymen occurred. In 42 % of all sacrocolpopexies, the operation did not fulfill all requirements. A prospective study

evaluating sacrocolpopexy in 65 patients showed persistent anterior support defect in 29 % of the patients[30]. Follow-up of this study was 3 months.

The reported recurrence rates of genital prolapse surgery vary greatly. When using the definition for recurrence as was used in this study (requiring repeated prolapse surgery because of recurrent or persisting prolapse symptoms), reported recurrence rates varied between 2 % and 24 %.[26,27] Differences may be explained by different study designs. Prospective studies that involves regular follow-up visits to a gynecologist, are more likely to find high recurrence rates as compared to retrospective studies in which medical records are studied to determine if the patient underwent repeated prolapse surgery. The recurrence rates observed in this study, were in the range of those reported by others.

One of the strengths of our study, is that we focussed on the effects of prolapse surgery on health-related quality of life. Such an approach has been recommended by experts in the field of pelvic floor surgery.[13] Until now this recommendation has not been widely applied. We observed that patients experienced more discomfort of overactive bladder symptoms (urgency, frequency and nocturia) after abdominal surgery than after vaginal surgery. This could indicate that abdominal surgery causes more irritation of the bladder. Possibly, the tissue patche used for reconstruction in abdominal prolapse surgery, is responsible for this. Obsereved differences between groups in the prevalence of other micturition and prolapse symptoms and quality of life related to these symptoms, are more difficult to explain. Possibly, damage to the pelvic floor muscle and its innervation occur.

It was observed that repeated prolapse surgery was more often performed or planned in the abdominal group than in the vaginal group. This is a surprising finding, as findings at pelvic examination were similar in both groups. Patients who underwent abdominal surgery visited a doctor more often within the first year after surgery because of prolapse, micturition and defecation symptoms than patients who underwent vaginal surgery. At six months and one year after surgery, a cystocele grade II or more was present at pelvic examination in about 30 % to 35 % of patients. Gynecologists may recommend that patients with a cystocele grade II or more who present themselves with prolapse, micturition and defecation symptoms, undergo repeated prolapse surgery. We postulate that the difference in number of doctor visits within the first year after surgery, can be held responsible for the observed difference in repeated prolapse surgery between both groups.

It is difficult to explain why patients who underwent abdominal prolapse surgery returned to a doctor more often with prolapse symptoms compared with patients who underwent

vaginal prolapse surgery, since no differences in the pelvic examination results between both groups were observed. One explanation may be that vaginal and abdominal prolapse surgery have different effects on pelvic floor coordination. An impaired pelvic floor coordination may cause a sensation of genital prolapse. If this is true, biofeedback therapy, intended to re-educate pelvic floor coordination, may decrease the difference in frequency of doctor visits between both groups. Another explanation may be the fact that gynecologists were not blinded for the surgical procedure that was performed. A priori expectations of gynecologists about the effectiveness of vaginal and abdominal prolapse surgery may have influenced the treatment of patients who return with prolapse, micturition and defecation symptoms. If the expectations of both techniques are different, the treatment of patients who return with recurrent or persisting symptoms may also differ.

At one year after surgery, feeling of incomplete evacuation and sensation of anal blockage were more often observed in the abdominal group than in the vaginal group. However, the differences of these symptoms between both groups were already observed before surgery and discomfort related to these symptoms as expressed in domain scores of the DDI, was similar in both groups. Altogether, vaginal and abdominal prolapse surgery appear to have similar effects on the prevalence of defecation symptoms and the quality of life related to these symptoms.

In conclusion, this randomized trial shows that vaginal hysterectomy combined with anterior and/or posterior colporraphy is equally effective in treating the anatomical abnormalities of patients with descensus uteri grade II-IV in comparison to sacrocolpopexy with preservation of the uterus. However, abdominally operated patients experience more discomfort related to overactive bladder symptoms, prolapse symptoms and obstructive micturition symptoms. The frequency of doctor's visits and of repeated prolapse surgery was higher in abdominally operated patients than in vaginally operated patients. Our results suggest that, in comparison to sacrocolpopexy, vaginal hysterectomy combined with anterior and/or posterior colporraphy is the treatment of choice in patients with descensus uteri grade II or more.

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Chapter 8

Effects of genital prolapse surgery on sexuality

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Abstract

Objective: Problems with sexual function have been reported to occur commonly in women with genital prolapse. Effects of genital prolapse surgery on sexuality are largely unknown. We performed a prospective study to evaluate these effects. Additionally we investigated which factors increase the risk on persistedence or development of sexual problems after surgery.

Methods: All 82 patients participating in a randomized trial comparing vaginal and abdominal surgical correction of descensus uteri, were asked to fill out the Questionnaire for screening Sexual Dysfunctions (QSD) before surgery and six months and one year after surgery.

Results: Sixty-two patients participated in this study. General satisfaction was statistically significantly improved at six months after surgery but not at one year after surgery. Of 41 patients who were sexually active before surgery and at one year after surgery, 28 (68.3 %) patients reported sexual problems before surgery. In 13 (46.4 %) patients, all sexual problems disappeared. De novo sexual problems were reported by 2 patients of the 13 patients without sexual problems before surgery. Disappearance of sexual problems was associated with grade of cystocele. The relative risk of patients with cystocele grade 2 or 3 as compared to patients without cystocele grade 2 or 3 on disappearance of sexual problems was 1.5 (95 % confidence interval 1.1-2.1). Differences in other characteristics between patients in whom sexual problems persisteded and disappear were not observed.

Conclusion: Sexuality improved or did not change in most women after surgery for descensus uteri. The presence of a large cystocele before surgery enhances the “risk” on disappearance of sexual problems after prolapse surgery.

Introduction

Problems with sexual function have been reported to occur commonly in women with genital prolapse.[1] Some have suggested that this is mainly explained by the influence of age. After correction for the difference in age, measurements of sexual function between women with prolapse and women without prolapse did not differ from each other.[2]
Few studies have evaluated the effects of genital prolapse surgery on sexuality. Some studies have shown that sexual function and satisfaction improved or did not change after surgery[1,3], but studies reporting decrease of sexual function have also been published.[4] In one prospective study, vaginal dimensions were measured before and after surgery and it was concluded that preservation of vaginal length and caliber adequate for sexual intercourse is an achievable goal of prolapse surgery.[3] Studies evaluating factors that increase the risk on persistence or development of sexual problems after prolapse surgery, have not been published yet. Such studies would be very valuable, in the counseling of patients who are candidate for genital prolapse surgery.
We set out to assess the effects of genital prolapse surgery on sexuality. Additionally, we studied which factors increase the risk of persistence or development of sexual problems after surgery. This study was performed as part of a multi-center randomized trial comparing vaginal and abdominal surgical correction of descensus uteri.

Patients and methods

Study population
The present study is based on data obtained from a multi-center randomized trial comparing vaginal and abdominal prolapse surgery of descensus uteri stage II – IV (ICS). Patients were enrolled in this trial between January 1998 and January 2000. Exclusion criteria were a uterus sized more than 12 weeks of gestational age, the presence of an adnexal mass, a history of more than two abdominal pelvic surgical procedures, extreme obesity (quetelet index > 35 kg/m^2), prior inflammatory bowel or pelvic disease and fecal incontinence because of an internal or external anal sphincter defect. The study protocol was approved by the local ethical committees of the three participating hospitals (University Medical Center in Utrecht, St. Antonius Hospital in Nieuwegein, Diaconessenhuis in Utrecht) and written informed consent was obtained from all patients.

Surgical procedures

Vaginal correction involved a vaginal hysterectomy combined with anterior and/or posterior colporrhaphy if indicated.[5] In case the patient had evident loss of urine during straining with the prolapse protruding or with the prolapse reduced as described by Bump[6], a bladder neck suspension was simultaneously performed. If a colposuspension was indicated when performing vaginal surgery, either a Pereyra needle suspension[7] or a modification of this technique as described by Raz[8] was simultaneously performed. The abdominal correction involved a modification of the sacrocolpopexy[9] that allowed preservation of the uterus.[10] If a colposuspension was indicated, a modified Burch colposuspension, as described by Tanagho, was simultaneously performed.[11]

All surgical procedures were performed by experienced gynecologists who were familiar with both techniques. All women received peri-operative deep vein thrombosis prophylaxis and a single dose of intravenous prophylactic antibiotic during the operation. A 14-French Foley indwelling bladder catheter with a 5 ml balloon was placed in all women post-operatively and removed after 2-5 days. Pharmacologic post-operative pain management was similar in all patients.

Measurements

All patients underwent a standardized urogynecologic interview before surgery as well as a complete physical examination, including a classification of the genital prolapse according to the recommendations of the ICS.[12]

All participating patients were sent the Questionnaire for screening Sexual Dysfunctions (QSD)[13] before surgery and at six months and one year after surgery. This QSD is a validated questionnaire to assess the presence, frequency and experienced discomfort of sexual dysfunctions and consists of 36 questions. The first part of the question is concerned with whether a dysfunction is present or not, the second part refers to the frequency of occurrence of this symptom (measured with a five-point Likert scale ranging from hardly ever to always) and the third part refers to the experienced amount of discomfort of the dysfunction (measured with a five-point Likert scale ranging from not at all to severely). The first 16 questions concern the general perception of the patient's sexuality and the frequency of sexual activity. The following 18 questions concern different types of problems during sexual activity. From this part of the QSD, questions were selected to identify patients with problems with lubrication, orgasm, pain/sensation in genitals and arousal. In Appendix C the questions that were selected from the QSD are presented. We regarded a symptom to be present, when the experienced discomfort of

that symptom was scored as “I am bothered” or “I am much bothered“ or “I am severely bothered”. The rationale not to include the frequency of occurrence of the symptom in the analysis was twofold: first, frequency of occurrence depends on frequency of intercourse and is therefore difficult to interpret. Second, we think that a patient’s experience (as expressed by the experienced amount of discomfort) involves all aspects of a dysfunction, its frequency of occurrence included. The last two questions of the QSD concern the general satisfaction about sexuality and can be expressed in a score ranging from 0 to 10. A higher score indicates better satisfaction about sexuality.

Statistical analysis

The reported frequency of intercourse and general satisfaction before surgery, at six months after surgery and at one year after surgery, were compared to each other. Only patients that were sexually active were included in the further analysis. For problems during sexual activity that were present before surgery, we calculated how often these symptoms had persisted and how often these symptoms had disappeared, at one year after surgery. For problems during sexual activity that were not present before surgery, we calculated how often these symptoms had developed and how often these symptoms had remained absent, at one year after surgery. Problems during sexual activity that were considered included problems with lubrication, problems with orgasm, problems with pain/sensation in the genitals and problems with arousal. We also calculated in how many patients at least one sexual problem, persisted, disappeared, developed and did not develop.

Characteristics of patients who developed any problem during sexual activity after surgery and patients who did not, were compared. Subsequently, characteristics of patients that encountered any problem during sexual activity that persisted and of patients who’s problems disappeared, were compared. Differences in continuous variables were tested for statistical significance, using an unpaired T Test, or, in case of non-parametric distribution, a Mann-Whitney U Test. Differences in dichotomous variables were tested for statistical significance, using Fishers’ exact Test.

Results

Sixty-two (76 %) of the 82 patients participating in the randomized trial completed the Questionnaire for screening Sexual Dysfunctions (QSD) before surgery. Average age of patients who participated in the trial but were not willing to fill out the QSD was 64.2

years (standard deviation (sd) = 9.4) and the age of those who were willing to participate was 55.0 years (sd = 9.0). The difference was statistically significant ($p < 0.001$). Response rates after six months and one year were respectively 87 % and 82 %. Characteristics of patients responding before surgery and at six months and one year after surgery were similar.

Table 1. Patient characteristics, findings at pelvic examination and performed surgery.

	n = 62	
Patient characteristics		
Age (years)	55.0	(9.0)
Parity (number of children)	2.6	(0.9)
Body mass index (kg / m^2)	25.6	(3.5)
History of pelvic surgery (n) *	9	(14.5)
Anterior colporraphy	3	
Anterior and posterior colporraphy	2	
Adnex extirpation	1	
Cholecystectomy	1	
Appendectomy	4	
Co-morbidity (n)	29	(46.8)
Postmenopausal (n)	39	(62.9)
Sexual active (n)	48	(77.4)
Findings at pelvic examination		
Descensus uteri		
Grade II	52	(83.9)
Grade III	10	(16.1)
Cystocele		
Grade 0	1	(1.6)
Grade I	7	(11.3)
Grade II	29	(46.8)
Grade III	25	(40.3)
Rectocele		
Grade 0	11	(17.7)
Grade I	28	(45.2)
Grade II	20	(32.1)
Grade III	3	(4.8)
Performed surgery		
Vaginal prolapse surgery	31	(50.0)
Combined with colposuspension	9	(14.5)
Abdominal prolapse surgery	31	(50.0)
Combined with colposuspension	13	(21.0)

Values are means (standard deviation) or numbers (percentage).

* Some patients had undergone more than one surgical procedure.

Table 1 shows patient characteristics of the 62 patients that completed the QSD before surgery. Forty-eight (77.4 %) of these patients were sexually active before surgery. The percentage of patients who were sexually active at six months and one year after surgery was similar to the percentage of patients who were sexually active before surgery. Frequency of intercourse of the patients who were sexually active, was similar before and after surgery. General satisfaction about sexuality was 6.5 (Standard Error (SE): 0.3) before surgery, 7.3 (SE: 0.3) at six months after surgery and 7.0 (SE: 0.3) at one year after surgery. The reported satisfaction at six months after surgery was statistically significant higher than the reported satisfaction before surgery. The difference between the reported satisfaction before and one year after surgery was not statistically significant.

Table 2 shows the prevalence of problems with lubrication, orgasm, pain/sensation of genitals and arousal reported by sexually active patients, before and after surgery. The prevalence of problems with lubrication and pain/sensation of genitals had decreased with 13.6 % respectively 18.9 %, at one year after surgery. The prevalence of problems with orgasm and arousal had decreased with 5.4 % respectively 5.2 %, at one year after surgery. The prevalence of patients reporting at least one problem during sexual activity six months after surgery, had decreased with 6.3 % and with 22.7 % one year after surgery, compared to the prevalence before surgery. One year after surgery, 41.9 % of the patients experienced one or more problems during sexual activity.

Table 2. Reported problems during sexual activity before surgery, at six months after surgery and at one year after surgery.

	Before surgery	Six months after surgery	One year after surgery
Reported problem	**n=48**	**n=48**	**n=43**
Lubrication	21 (43.8)	13 (27.1)	13 (30.2)
Orgasm	16 (33.3)	15 (31.3)	12 (27.9)
Pain/sensation in genitals	18 (37.5)	11 (22.9)	8 (18.6)
Arousal	17 (35.4)	17 (35.4)	13 (30.2)
Any problem	31 (64.6)	28 (58.3)	18 (41.9)

Forty-one of the participating patients of who follow-up after one year was available, were sexually active before and one year after surgery.

Table 3 shows the prevalence of reported sexual problems before and one year after surgery among these patients. For patients who reported a sexual problem before surgery, it is presented how often this symptom persisted. For patients who did not report this sexual problem before surgery, it is shown how often the symptom developed. Problems with lubrication, orgasm and arousal reported before surgery, persisted in about 60 % of

the patients. Problems with pain/sensation of genitals had disappeared in more than 60 % of the patients. Sexual problems that were not reported before surgery, developed in 8.0 % to 11.5 % of the patients. In about half of the patients who reported one or more sexual problems before surgery, sexual problems persisted. Two of thirteen patients who did not report any sexual problem before surgery, developed one or more problems during sexual activity.

Table 3. Problems during sexual activity reported before and at one year after surgery.

Before surgery		**One year after surgery**
Reported sexual problem	n	n (%)
Lubrication		
Yes	19	11 (57.9)
No	22	2 (9.1)
Orgasm		
Yes	14	9 (64.3)
No	27	3 (11.1)
Pain/sensation of genitals		
Yes	16	6 (37.5)
No	25	2 (8.0)
Arousal		
Yes	15	9 (60.0)
No	26	3 (11.5)
Any problem		
Yes	28	15 (53.6)
No	13	2 (15.4)

Table 4 shows patient characteristics, pre-operative findings at pelvic examination and performed surgery of patients in whom sexual problems persisted and disappeared. No relevant differences between both groups were observed in patient characteristics and performed surgery. In all patients in whom problems during sexual activity disappeared, a grade II or grade III cystocele was observed during pelvic examination before surgery. A grade II or III cystocele was present in 66.7 % of the patients in whom problems during sexual activity persisted. This difference was statistically significant. The relative risk on the disappearance of sexual problems of patients with cystocele grade II or III in comparison to patients without cystocele grade II or III was 1.5 (95 % confidence interval 1.1-2.1).

No relevant differences between both groups in grade of rectocele, as measured at pelvic examination before surgery, were observed. Patient characteristics, findings at pelvic

examination and performed surgery were not compared between patients who developed sexual problems and patients who did not. The number of patients who developed sexual problems was too low to allow such comparison.

Table 4. Patient characteristics, pre-operative findings at pelvic examination and performed surgery, of patients in whom problems during sexual activity persisted and disappeared.

	Problem during sexual activity		
	Persisted (n=15)	Disappeared (n=13)	P value
Patient characteristics			
Age (years)	51.9 (2.3)	54.4 (2.0)	0.43 [1]
Parity (number of children)	2.7 (0.2)	2.8 (0.3)	0.77 [1]
Body mass index (kg/m²)	26.2 (1.2)	26.4 (0.9)	0.92 [1]
History of pelvic surgery (n)	1 (6.7)	- -	1.00 [2]
Co-morbidity (n)	7 (46.7)	7 (53.8)	1.00 [2]
Menopausal (n)	8 (53.3)	8 (61.5)	0.72 [2]
Findings at pelvic examination			
Grade II or III cystocele (n)	10 (66.7)	13 (100)	0.04 [2]
Grade II or III rectocele (n)	5 (33.3)	5 (38.5)	1.00 [2]
Performed surgery			
Abdominal prolapse surgery	7 (46.7)	6 (46.2)	1.00 [2]
Colposuspension performed	7 (46.7)	6 (46.2)	1.00 [2]

Values are means (standard error) or numbers (percentage).
[1] Calculated with Unpaired T Test
[2] Calculated with Fishers' exact Test

Discussion

Sexuality improved or did not change in most women after surgery for descensus uteri. Satisfaction about sexuality was improved after surgery. Problems with lubrication, orgasm and arousal during sexual activity, present before genital prolapse surgery, disappeared in about 40 % of all patients. Problems with pain/sensation of genitals during sexual activity disappeared in nearly 60 % of all patients. All together, a patient undergoing prolapse surgery who experienced one or more problems during sexual activity before prolapse surgery, had a chance of almost 50 % not to encounter any of these symptoms at one year after surgery. In patients, in whom sexual problems disappeared, a large cystocele before surgery was more often observed, than in patients in whom sexual problems persisted. Sexual problems developed occasionally after prolapse surgery. In our study, we could not identify risk factors of de novo sexual problems.

We performed a prospective observational study to examine the effects of genital prolapse surgery on sexuality and to evaluate which factors increase the risk that sexual

problems persist or develop after surgery. This study is limited by its observational design, which precludes definite conclusions about cause and effect of observed changes. Furthermore, the size of our study population may be too small to detect small differences between patients in whom sexual problems persist and disappear. However, the study is strengthened by the fact that the same standardized assessments of sexuality before and after surgery in each patient were used. In this study the Questionnaire for screening Sexual Dysfunctions (QSD)[13] was used to measure sexuality. We selected the QSD as it does not only include questions about the presence of a sexual problem but also about the experienced discomfort of that symptom. This allowed us to focus on symptoms that bother the patients.

We compared characteristics of patients in whom sexual problems persisted to characteristics of patients in whom sexual problems disappeared. Characteristics that were compared included age, body mass index, co-morbidity and menopausal status. All these factors have been shown to influence sexuality after hysterectomy.[14-17] Parity and history of pelvic surgery were studied as they have both been related to damage of the pelvic floor innervation.[18,19] Sexuality is an important function of the pelvic floor and could thus be influenced by parity and prior pelvic surgery. Findings at pelvic examination were compared, as severity of prolapse before surgery may be related to sexuality before and after surgery. Finally, performed surgery was studied as it may also influence sexuality. Vaginal procedures like posterior colporraphy and sacrospinous ligament fixation have been suggested to worsen sexual function caused by vaginal narrowing.[1,4,20] The combination of posterior colporraphy with colposuspension may negatively affect sexuality even more.[3]

Patient characteristics and performed surgery did not differ between patients in whom sexual problems persisted and patients in whom sexual problems disappeared. Patients in whom sexual problems persisted, had less often a large cystocele before surgery, in comparison to patients in whom sexual problems disappeared. Therefore, the data suggest that the beneficial effects of prolapse surgery for patients with sexual problems, are less likely to benefit patients with a small cystocele. The observed difference may be explained by a difference in narrowing of the vagina when performing prolapse surgery. Narrowing of the vagina during prolapse surgery has been related to sexual problems after surgery.[1,4,20] Patients who have a large cystocele, may be less susceptible to the results of narrowing of the vagina during prolapse surgery, in comparison to patients who do not have a large cystocele. Another explanation may be that sexual problems, reported by patients without a large cystocele, are likely to have an origin different from the genital

prolapse. Therefore, sexual problems reported by these patients, are not likely to disappear after genital prolapse surgery.

In conclusion, about half of all patients who have sexual problems before prolapse surgery, do not experience any sexual problem at one year after surgery. Patients without sexual problems are not likely to develop sexual problems within the first year after surgery. Patients who have a large cystocele before surgery, have a better chance that sexual symptoms disappear, compared to patients with a small cystocele.

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Chapter 9

A randomized comparison of post-operative pain, quality of life and physical performance during the first 6 weeks after abdominal or vaginal surgical correction of descensus uteri grade II - IV

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Abstract

Objective: Vaginal hysterectomy combined with anterior and/or posterior colporraphy and abdominal sacrocolpopexy with preservation of the uterus have both been shown to effectively correct descensus uteri. The effects of both procedures on post-operative recovery are largely unknown. We performed a randomized trial to compare pain, quality of life and physical performance during the first six weeks after surgery, between patients undergoing vaginal and abdominal surgical correction of descensus uteri.
Methods: All patients were asked to fill out the RAND-36 (a general quality of life questionnaire) before surgery and 6 weeks after surgery and to keep a diary for the first 6 weeks after surgery. This diary assessed the pain perception, amount of administered pain medication per day, presence and experienced bother of limitations due to the surgery during hospital stay and performance of daily activities. A comparison of these outcomes was made between both groups.
Results: Eighty two patients filled out the RAND-36 and 68 patients completed the diary. Patients who had undergone abdominal surgery had a statistically lower score on the health change domain (56 vs 68), bodily pain domain (63 vs 80) and mental health domain (74 vs 81) of the RAND-36, as compared to patients who had undergone vaginal prolapse surgery. During hospital stay, the abdominal group experienced on average more days of pain (4.5 vs 3.0) and impaired mobility (3.7 vs 2.9) as compared to the vaginal group. Pain medication during the first week of surgery was given longer (5.5 days vs 4.1 days) and in higher dosages (1943 mg of paracetamol daily vs 1334 mg) to patients who underwent abdominal surgery as compared to patients who underwent vaginal surgery.
Discussion: The vaginal operation to correct a descensus uteri grade is less morbid than the abdominal one. This conclusion is based on the finding that the vaginal approach is associated with less pain, better quality of life and better mobility during the first 6 weeks of the recovery period as compared to the abdominal approach.

Introduction

The prevalence of descensus uteri in the general female population has been shown to be almost 5%.[1] Descensus uteri may negatively affect pelvic floor function, resulting in micturition symptoms, defecation symptoms and sexual dysfunction.[2] When the anatomical abnormalities and impaired pelvic floor function of patients with descensus uteri are severe enough, surgical correction is recommended. Several procedures have been described to effectively correct descensus uteri.[3-6] In the Netherlands, gynecologists will either choose a vaginal hysterectomy combined with anterior and/or posterior colporraphy or an abdominal sacrocolpopexy with preservation of the uterus.[7] In relation to the success of anatomical correction of the prolapse, morbidity of the surgical procedure and risk on recurrence of genital prolapse, retrospective studies show similar results for both techniques.[8-10]However, the effects of vaginal and abdominal prolapse surgery on post-operative pain, quality of life and physical performance during the first six weeks of the recovery period are largely unknown.

Post-operative recovery after vaginal hysterectomy is faster than after abdominal hysterectomy.[11,12] This has been generalized to other gynecologic operations. However, recovery following vaginal hysterectomy combined with anterior and/or posterior colporraphy is not necessarily faster than recovery following abdominal sacrocolpopexy with preservation of the uterus. These surgical procedures do not only differ in relation to the chosen surgical approach but also regarding the removal of the uterus. Whereas the vaginal approach may be favorable because the abdomen is not opened, the abdominal approach may be favorable because the uterus is not removed.

A randomized trial was performed to compare post-operative pain, quality of life and physical performance, during the first 6 weeks after abdominal or vaginal surgical correction of descensus uteri.

Patients and methods

Study population

A randomized multi-center trial comparing vaginal and abdominal prolapse surgery was performed in 82 patients with descensus uteri stage II – IV (according to the International Continence Society (ICS).[13] All patients were included between January 1, 1998 and January 1, 2000. Exclusion criteria were a uterus sized more than 12 weeks of gestational age, the presence of an adnexal mass, a history of more than two abdominal pelvic

surgical procedures, extreme obesity (quetelet index > 35 kg/m^2), prior inflammatory bowel or pelvic disease and fecal incontinence because of internal or external anal sphincter defect. This study was approved by the ethical committees of the three participating hospitals (University Medical Center Utrecht, St. Antonius Hospital Nieuwegein and Diakonessenhuis Utrecht.). Patients were assigned through balanced randomization, on the basis of a random number table, to have pelvic reconstructive surgery by either a vaginal or abdominal approach. The surgeon received the randomization assignment, after an initial diagnostic work-up was performed, from the first author, who had sole access to the randomization table.

Measurements

All patients underwent before surgery a standardized urogynecologic interview and a physical examination, including a classification of the genital prolapse according to the recommendations of the ICS. We also performed an urodynamic investigation, which included simple uroflowmetry with catheterized postvoid residual urine volume determination, retrograde provocative multi-channel urethocystometry and passive and dynamic urethral pressure profilometry with the prolapse protruding and with the prolapse reduced.[14]

All patients were asked to answer the RAND-36 before surgery and 6 weeks after surgery.[15] The RAND-36 is a questionnaire that was developed in the United States in the late 1980's as part of the Medical Outcomes Study (MOS).[16-18] The MOS was a longitudinal investigation of the self-reported health status of patients with a range of chronic conditions. It consists of 36 items, organized into nine scales including the following: general health perceptions, health change, physical functioning, role limitations due to physical problems, role limitations due to emotional problems, social functioning, bodily pain, vitality and mental health. Each scale yields a score in the range from 0 (the worst possible score) to 100 (the best possible score). Patients answered the RAND-36 once before surgery and once six weeks after surgery.

Two months after the start of inclusion, participating patients were also asked to keep a diary, beginning the day before surgery until six weeks after surgery. This diary consisted of several questionnaires :

1. A self-developed questionnaire consisting of questions to evaluate the presence and experienced discomfort of bodily pain, having a bladder catheter, having food restrictions, being impaired in self-care, having intravenous infusion, undergoing investigations (e.g. X-ray, blood samples) and having impaired mobility after their

surgery. Each of these questions consisted of two parts. The first part asked whether or not a type of discomfort was present. The second part of the question asked about the degree of discomfort that was experienced from that symptom. The results were recorded on a four-point Likert scale: not at all, slightly, moderately or very much. This questionnaire was completed daily during the first week after surgery.

2. A questionnaire to assess activities of daily life (ADL) (getting in and out of bed, dressing and undressing, picking an object from the floor, walking). This questionnaire had been applied as part of a national health survey in a large sample of the Dutch population by the Central Bureau of Statistics.[19] The total ADL score expresses the ability of the patient to perform daily activities (minimum score 0, maximum score 100). This questionnaire was completed before surgery and one, two and six weeks after surgery.
3. A visual analogue scale ranging from 0 to 100 to assess the experienced pain was completed daily during the first week after surgery and at two and six weeks after surgery.

Patients were instructed to complete the questions in the evening as much as possible at a fixed time-point. During admission, the nursing staff daily scored whether or not and in what dosages analgesics were administered. Post-operative pain management was similar in both groups; all patients received intravenous morfine post-operatively from 24 to a maximum of 48 hours. Patients started to use paracetamol and/or diclofenac at the first day after surgery and administration of morfine was stopped as soon as possible. Patients were allowed to use a maximum of 4000 mg of paracetamol and/or 300 mg of diclofenac daily. Within these limitations patients were free to decide how much pain medication to take. After patients were discharged from the hospital, similar advice was given to them regarding usage of pain relievers. Patients were also instructed to avoid heavy lifting (more than 5 kg) and to avoid sexual intercourse for the first six weeks after surgery. With these restrictions, patients were allowed to resume daily activities after the operation when they felt comfortable.

Surgical procedures

Vaginal correction of the genital prolapse involved a vaginal hysterectomy combined with anterior and/or posterior colporrhaphy[3] as indicated. Abdominal correction of the genital prolapse involved a sacrocolpopexy with preservation of the uterus.[4,20] After randomization for the vaginal or abdominal approach, the surgeons were free to combine the surgical procedure with a colposuspension. A colposuspension was simultaneously

performed in case stress incontinence was present with the prolapse protruding or with the prolapse reduced as described by Bump.[14] Either a Pereyra needle suspension[21] or a modification of this technique as described by Raz[22], was chosen when vaginal surgery was performed. A Burch colposuspension as described by Tanagho[23], was chosen when abdominal surgery was performed.

All surgical procedures were performed by experienced gynecologists who were familiar with both techniques. All women received peri-operative deep vein thrombosis profylaxis and a single dose of intravenous prophylactic antibiotic during the operation. All women had post-operatively a 14-French Foley indwelling bladder catheter which was removed after two to five days. A vaginal pack was placed after the procudere and removed in approximately 24 hours in all patients who had vaginal surgery.

Statistical analysis.

The aim of the analysis was to compare pain, quality of life and physical performance between the abdominal and vaginal surgical correction of descensus uteri, during the first six weeks after surgery. An intention to treat analysis was performed.

RAND-36 and ADL scores were compared between both groups. For all seven types of discomfort related to the surgery, the number of days it was reported were calculated and compared between both groups. For each type of discomfort the distribution of reported degrees of discomfort was compared between both groups. The pain scores as assessed with the visual analogue scales were compared between groups. Administered pain medication during the first week after surgery and at two and six weeks after surgery were compared between both groups. Repeated measurements analyses were used to compare continuous variables that were compared at more than one time point. For those measurements that were not performed at more than one time point, an unpaired T test was used when comparing continuous variables and a Chi-square test when comparing dichotomous variables.

Results

A total of 82 patients participated in the randomized trial. After randomization both groups consisted of 41 patients. Of the 41 patients that were randomized for abdominal surgery, two patients requested vaginal surgery. The results of the RAND-36 before surgery and at six weeks after surgery were available for all patients. Seventy-two patients completed the RAND-36 questionnaire before surgery and at six weeks after surgery and

also kept the diary. Four patients did not keep their diary according to the instructions. Hence, full data collection was achieved in 68 (82.9 %) patients. Of these 68 patients, 35 underwent vaginal surgery and 33 underwent abdominal surgery.

Table 1. Baseline characteristics of the patients according to surgical approach.

	Vaginal approach (n = 41)	Abdominal approach (n = 41)
Age (years)	56.4 (10.9)	57.9 (8.8)
Parity (n)	2.5 (1.2)	2.9 (1.1)
Body mass index (kg / m^2)	26.0 (3.6)	25.1 (3.0)
History of prolapse surgery (n) *	2 (4.9)	4 (9.8)
Anterior colporraphy	1	3
Anterior and posterior colporraphy	2	1
History of other surgery (n) *	4 (9.8)	6 (14.6)
Heart transplantation	1	
Adnex extirpation		1
Cholecystectomy	2	2
Appendectomy	2	3
Sterilization		1
Co-morbidity (n) **	23 (56.1)	16 (39.0)
Rheumatoid arthritis	5	2
Hypertension	13	8
Diabetus mellitus	3	1
Hypercholesterolaemie	4	6
Hypothyreoidism	5	2
COPD	2	2
Transient ischemic attack	2	
Findings at pelvic examination (n)		
Descensus uteri grade 2	41 (100)	41 (100)
Cystocele grade 1	6 (14.6)	5 (12.2)
Cystocele grade 2	35 (85.4)	36 (87.8)
Rectocele grade 1	26 (63.4)	28 (68.3)
Rectocele grade 2	15 (36.6)	13 (31.7)
Findings at urodynamic investigation (n)		
Evident stress incontinence	8 (19.5)	9 (22.0)
Masked stress incontinence	3 (7.3)	7 (17.1)
Detrusor instabilities	- -	2 (4.9)
Bladder capacity (ml)	483 (119)	455 (149)

Values are means (standard deviation) or numbers (percentage).
* Some patients had undergone more than one surgical procedure.
** Some patients had more than one disease.
COPD Chronic obstructive pulmonary disease

Characteristics of all 82 participating patients are shown in Table 1. The prevalence of co-morbidity was higher in the vaginal group than in the abdominal group. No relevant differences in other characteristics were observed between both groups. Characteristics of

patients with complete data were (n=68) and incomplete data (n=14) were similar (data not shown).

Table 2 shows domain scores of the RAND-36 before surgery and at 6 weeks after surgery. The scores of the RAND-36 before surgery were similar in both groups. Six weeks after surgery, patients who underwent abdominal surgery had a statistically significant lower score on the health change domain, bodily pain domain and mental health domain in comparison to patients who underwent vaginal surgery. The score on the health change domain had increased in both groups compared to before surgery. The increase in the health change domain was higher in the vaginal group than in the abdominal group. Compared with before surgery, the score on the bodily pain domain had increased in the vaginal group and decreased in the abdominal group. The score on the mental health domain for the abdominal group at six weeks after hysterectomy was similar to the score before surgery. This score had increased in the vaginal group after the procedure. Statistically significant differences between both groups on the other domains of the RAND-36 were not observed.

Table 2. Domain scores of the RAND-36 questionnaire before surgery and 6 weeks after surgery according to surgical approach.

	Before surgery		**6 weeks after surgery**		
	Vaginal approach (n = 41)	Abdominal approach (n = 41)	Vaginal approach (n = 41)	Abdominal approach (n = 41)	P value[1]
General health perception	61 (2.7)	66 (2.6)	69 (2.2)	66 (2.6)	0.31
Health change	45 (3.9)	40 (4.1)	68 (3.9)	56 (4.9)	0.05
Physical functioning	71 (4.0)	67 (3.5)	72 (3.6)	71 (2.9)	0.71
RL due to physical problems	62 (7.7)	57 (8.2)	30 (5.8)	23 (5.8)	0.43
RL due to emotional problems	75 (7.1)	79 (7.1)	69 (6.4)	65 (7.1)	0.68
Social functioning	75 (4.3)	80 (3.5)	72 (3.5)	64 (3.8)	0.13
Bodily pain	72 (4.2)	76 (4.1)	80 (3.3)	63 (3.7)	0.001
Vitality	58 (3.7)	57 (3.3)	61 (3.1)	56 (2.9)	0.28
Mental health	73 (2.6)	74 (2.4)	81 (2.0)	74 (2.8)	0.04

Values are means (standard error).
RL = Role limitations
[1] Unpaired T Test of the differences in domain scores at 6 weeks after surgery.

Table 3 shows that patients who underwent abdominal surgery had statistically significant more days with bodily pain and impaired mobility compared with patients who underwent vaginal surgery. Abdominally operated patients also had more days with food restriction compared with vaginally operated patients, but this difference was not statistically significant. Pearson ÷² tests to compare the experienced discomfort of each symptom between both groups did not show relevant differences (data not shown).

Table 3. Number of days with different types of discomfort related to surgery according to surgical approach.

	Vaginal approach (n=35)	Abdominal approach (n=33)	P value
Days with bodily pain	3.0 (0.35)	4.5 (0.35)	0.01
Days with bladder catheter	3.2 (0.28)	3.3 (0.26)	0.88
Days with food restrictions	1.7 (0.18)	2.2 (0.20)	0.10
Days with impaired self-care	2.4 (0.24)	2.8 (0.19)	0.20
Days with intravenous infusion	1.3 (0.12)	1.7 (0.14)	0.22
Days with investigations	1.2 (0.24)	1.1 (0.18)	0.73
Days with impaired mobility	2.9 (0.28)	3.7 (0.25)	0.04

Values are means (standard error).

Table 4 shows the pain perception as assessed with visual analogue scales (VAS) and the administered pain medication according to surgical approach. During the total recovery period, patients who underwent abdominal surgery had higher VAS scores in comparison to patients who underwent vaginal surgery. However, this difference did not prove to be statistically significant. During the first week after surgery, patients who had undergone abdominal surgery used statistically significantly more days analgesics than patients who had undergone vaginal surgery.

During the first week after surgery, patients who underwent abdominal surgery received statistically significantly more days pain medication and used per day more milligrams of paracetamol in comparison to patients who underwent vaginal surgery. No statistically significant differences between the groups were observed in the daily dosage of paracetamol used at two weeks and at six weeks after surgery.

Table 4. Pain perception and pain medication according surgical approach.

	Vaginal approach (n=35)	Abdominal approach (n=31)	P value
VAS score during hospital stay	19.3 (2.5)	25.8 (3.1)	0.10 [1]
VAS score during 2 to 6 weeks after surgery	7.5 (1.7)	11.2 (2.1)	0.69 [1]
Days using pain medication during first week after surgery	4.1 (0.4)	5.5 (0.3)	0.003 [2]
Paracetamol use per day (mg)			
Average per day during first week after surgery	1334 (173)	1943 (162)	0.01 [1]
At 2 weeks after surgery	309 (127)	333 (117)	0.89 [2]
At 6 weeks after surgery	162 (96)	91 (46)	0.51 [2]

Values are means (standard error).
VAS visual analogue scale
[1] Calculated with Repeated Measurement Analysis
[2] Calculated with unpaired T Test

Table 5 shows daily activity scores before surgery, and at one, two and six weeks after surgery. Before surgery and at six weeks after surgery, scores were similar in both groups. One week and two weeks after surgery, scores were higher in the vaginal group in comparison to the abdominal group. Repeated measurement analyses showed that over the total recovery period no statistically significant difference in daily activity scores was observed between both groups (p=0.27).

Table 5. Daily activity scores (DAS) according to surgical approach.

	Vaginal approach (n=35)	Abdominal approach (n=33)	P value
DAS before surgery	93.8 (1.7)	93.3 (1.9)	0.87
DAS 1 week after surgery	83.1 (2.4)	78.9 (2.6)	0.24
DAS 2 weeks after surgery	86.2 (2.2)	82.7 (2.3)	0.27
DAS 6 weeks after surgery	97.5 (0.9)	97.0 (0.9)	0.66

Values are means (standard error).

Patients who were operated by vaginal approach did not resume daily activities any sooner than patients who were operated by abdominal approach (logrank test p=0.57). Kaplan-Meier curves presenting return to normal activity for both groups are shown in Figure 1.

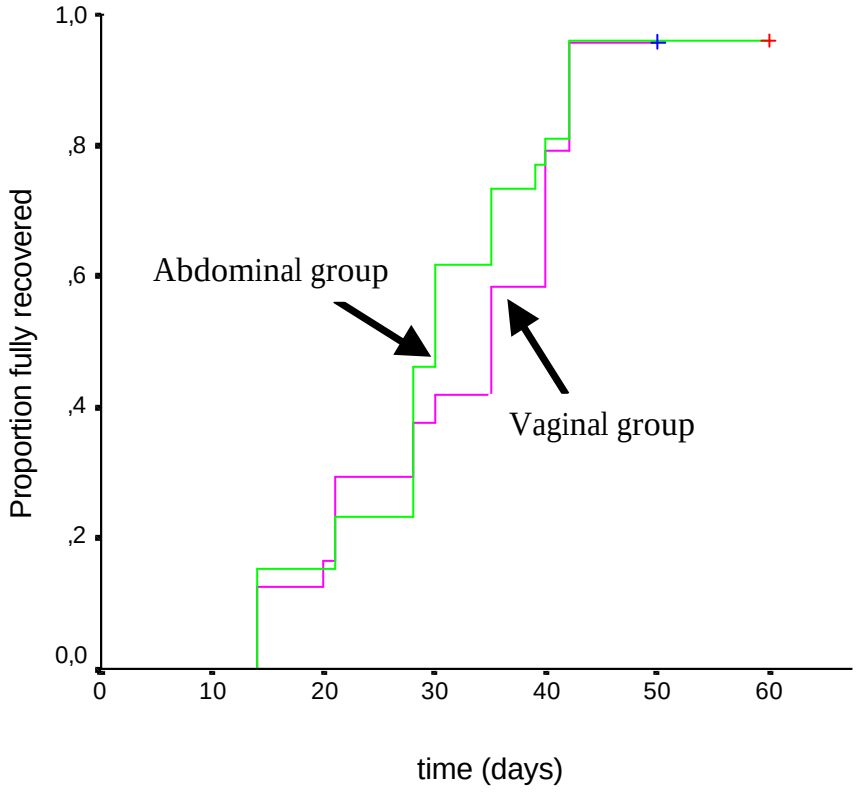

Figure 1. Kaplan-Meier curves for return to normal activity for patients operated on by abdominal approach and for patients operated on by vaginal approach.

Discussion

In this study, vaginal prolapse surgery was associated with less pain during the first 6 weeks of the post-operative period in comparison to abdominal prolapse surgery. Mobility, perception of mental health and perception of change of health were also higher in patients who underwent vaginal surgery than patients who underwent abdominal surgery.

To appreciate these results, several issues should be addressed. A multi-center randomized trial was performed to compare pain, quality of life and physical performance after vaginal and abdominal prolapse surgery. Co-morbidity was more frequent in the vaginal group than in the abdominal group. It may be argued that the difference in co-morbidity between both groups influenced our findings. However, the observed differences in outcome were in favor of the vaginal group and an equal distribution of co-morbidity over the groups may even have increased the observed difference between both groups.

The patients who were included within the first two months after the start of the trial, were not asked to keep a diary. As a result, in 14 patients no complete data collection could be achieved. As the patients who were asked to keep the diary were not selected, we do not think that incomplete data collection has affected the outcome of this study.

One of the strengths of our study is that we measured pain after surgery in several manners. Visual analogue scales were one of the used instruments to measure pain perception. An important advantage of this instrument is that it takes only a few seconds to obtain an impression of the experienced pain. However, the score is highly dependent on the moment of answering and on the intensity of use of analgesics. Although patients were instructed to keep their diary in the evening as much as possible at a fixed time point, patients may feel to fill out the visual analogue scale when at minimal pain. This could reduce the observed differences in pain perception between both groups.

The answer to the question whether the patient had been bothered by pain that day, may also be influenced by the moment of answering. However, this question is likely to provide a more reliable insight into pain perception than a visual analogue scale as this question concerns the experienced pain during the whole day.

We also performed a more objective measurement of pain by scoring the number of days analgesics were used and the daily dosage analgesics that was used. However, these measurements are only informative in case patients with more pain use more pain medication. The intensity of use of analgesics might be influenced by nursing staff. If the

nursing staff has the impression that abdominal surgery is more painful than vaginal surgery, they may have been more focussed on pain sympyoms in the abdominal group. If such differences in approach were to exist, it may have biased our results. As it was impossible to blind for treatment in this trial, it was not possible to prevent this bias. The questions of the domain of the RAND-36 that measure bodily pain ask the patient about the experienced pain and limitations caused by this pain in *the last four weeks*. Therefore, this measurement is less time depending. Furthermore, it provides a wider view of pain because also the limitations that are caused by pain are considered. All instruments that we used to score pain showed that abdominal prolapse surgery was associated with more pain as compared to vaginal prolapse surgery.

The statistically significant differences between both groups in other domains of the RAND-36 (health change and mental health) may be associated to the difference in pain. As patients who underwent abdominal surgery experienced more pain, their mental health may not have benefited of prolapse surgery and remained the same. Both after vaginal and after abdominal prolapse surgery an improved score on the health change domain of the RAND-36 was observed. However, the improvement in the vaginal group was more pronounced than in the abdominal group. The observed differences may be explained by a difference in experienced pain.

An other explanation for the difference in reported health changes may be found in the observed differences in daily activity scores at one and two weeks after surgery. Daily activity scores provide insight into the physical performance of the patient. The first weeks of the recovery period, patients who had vaginal surgery performed physically better as compared to patients who had abdominal surgery. This difference between both groups in physical performance was not observed at six weeks after surgery. However, the question of the RAND-36 concerning health change covers a period of several weeks. Therefore, the differences in daily activity scores at one and two weeks after surgery may have contributed to the observed difference between both groups in reported health change.

Patients were asked to keep a diary in order to get insight in the specific types of factors that bothered them during their stay in the hospital. Women who had undergone abdominal surgery were not only bothered by more days of pain but also by more days with food restrictions, impaired-self care, intravenous infusion and impaired mobility. All these types of discomfort may be related to an impaired bowel mobility that is inherently associated with abdominal surgery.[24] Because of the impaired bowel motility, patients are not allowed to eat or drink and are given intravenous infusion. Pain is a second factor that

negatively affects mobility. The longer impaired self-care after abdominal prolapse surgery as compared to after vaginal prolapse, does probably result of a combination of pain, impaired mobility and having intravenous infusion.

Daily activity scores were better in the vaginal group than in the abdominal group when measured at one or two weeks after surgery. This may be related to a combination of less pain and better mobility as explained before. The difference between both groups in daily activity scores was no longer present at six weeks after surgery. This may explain why we found that return to normal activity was similar following vaginal and abdominal prolapse surgery.

The overall results of this trial are consistent with the results of others. Studies comparing vaginal and abdominal hysterectomy showed that morbidity and changes in quality of life were in favor of the vaginal procedure.[11,25] These findings have raised the idea that abdominal surgery in general causes more discomfort than vaginal surgery. Retrospective studies reporting on outcome of vaginal and abdominal prolapse surgery describe similar morbidity, but do not report on pain and physical activity after surgery.[8-10] One randomized trial comparing vaginal and abdominal prolapse surgery has been published.[26] In this study bilateral sacrospinous ligament fixation was compared to sacrocolpopexy. No statistically significant difference in discomfort rating, complications and hospital stay between both groups was observed in this study. The authors did not describe how they measured discomfort.

We conclude that, based on the results of this study, the vaginal operation to correct a descensus uteri grade II or more is less morbid than the abdominal one. This conclusion is based on the finding that the vaginal approach is associated with less pain, better quality of life and better mobility during the first 6 weeks of the recovery period as compared to the abdominal approach.

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Part three

Effects of hysterectomy on pelvic floor function

Chapter 10

Does technique of hysterectomy influence micturition and defecation?

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Abstract

Objective: Hysterectomy may affect bladder and bowel function. A retrospective study was performed to compare the prevalence of micturition and defecation symptoms between different techniques of hysterectomy.

Methods: All pre-operatively asymptomatic patients, with uteral seize $\leq$ 10 cm, who underwent hysterectomy between 1988 and 1997 were interviewed about the prevalence of micturition and defecation symptoms and the experienced physical and emotional limitations of these symptoms. Using logistic regression analysis, odds ratio's (OR) were calculated for all symptoms in which the prevalence between techniques of hysterectomy differed more than 10 %. These odds ratios were adjusted for differences in other prognostic factors.

Results: Vaginal hysterectomy was performed in 68 patients, total abdominal hysterectomy in 109 patients and subtotal abdominal hysterectomy in 50 patients. An increased prevalence of urge incontinence (adjusted OR 1.5 (95 % CI 0.8-3.1)) and feeling of incomplete evacuation of the rectum (adjusted OR 1.9 (95 % CI 1.0-4.0)) was observed among patients who had undergone vaginal hysterectomy, as compared to patients who had undergone total abdominal hysterectomy. The prevalence of urge incontinence (adjusted OR 1.8 (95 % CI 0.8-4.2)) and difficulty emptying the rectum (adjusted OR 1.8 (95 % CI 0.7-4.4)) was higher among patients who had undergone vaginal hysterectomy than among patients who had undergone subtotal abdominal hysterectomy. Statistically significant odds ratios were not observed. Relevant differences in physical and emotional limitations related to micturition and defecation symptoms were not observed between groups.

Conclusion: Our results suggest that technique of hysterectomy may influence the prevalence of micturition and defecation symptoms following hysterectomy.

Introduction

Hysterectomy may affect bladder and bowel function.[1,2] It has been suggested that damage to pelvic floor innervation and pelvic fibromuscular structures during hysterectomy is responsible for these changes.[3-6] The pelvic plexus is at risk in four areas during hysterectomy.[4,6] It is unknown whether damage to the pelvic plexus depends on the technique of hysterectomy. Both surgical route and removal of the cervix may influence the amount of damage that is done to the pelvic plexus during hysterectomy. If such damage were to differ between techniques of hysterectomy, the prevalence of micturition and defecation symptoms among patients undergoing vaginal, total abdominal or subtotal abdominal hysterectomy may differ.

During the last decades, the vaginal approach of hysterectomy has gained an increased popularity. The decision of which technique of hysterectomy should be recommended in each specific case is not based on scientific grounds. The occurrence of pelvic floor symptoms is an important clinical issue. This issue should be enrolled in the decision of choosing the technique of hysterectomy and discussed with the patient prior to the operation. This study was undertaken to evaluate the difference in prevalence of micturition and defecation symptoms between patients who underwent vaginal, total abdominal or subtotal abdominal hysterectomy and to compare the physical and emotional limitations experienced due to these symptoms.

Patients and methods

Study population

The study population consisted of all consecutive patients who underwent a hysterectomy in the University Medical Center Utrecht between January 1988 and December 1997. This Center is a large teaching hospital that serves a population of mixed ethnicity in Utrecht, The Netherlands. Patients were included if they met the following criteria : 1) the patient was suffering from benign disease; 2) pre-operatively no micturition or defecation symptoms were noted in the medical file; 3) genital prolapse was not the indication for hysterectomy; 4) during hysterectomy no other surgical procedures were performed; 5) the maximal diameter of the uterus as assessed by ultrasound was 10 cm or less.

Vaginal hysterectomy was performed in all patients in whom this technique was technically feasible, with two exceptions. First, in patients who requested to preserve the cervix, subtotal abdominal hysterectomy was performed. Second, in case the gynecologist

was interested to inspect the abdomen, total abdominal hysterectomy was performed. In case of abdominal hysterectomy, the gynecologists discussed in nearly all cases with the patient whether the cervix was to be removed or not. During the study period, no changes occurred in peri-operative care of patients undergoing hysterectomy.

Measurements

All women received peri-operative deep vein thrombosis prophylaxis and a single dose of intravenous prophylactic antibiotic during the operation. A 14-French Foley indwelling bladder catheter with a 5 ml balloon, was placed in all women post-operatively and removed after about 24 hours. In case of bladder retention (defined as twice a residual volume after voiding of more than 100 ml), the patient started clean intermittent catheterization. Pharmacologic post-operative pain management was the same in all patients.

The following data were obtained from the patient's medical files: age at hysterectomy, obstetric history, history of abdominal surgery, indication for hysterectomy, duration of hospital stay (in days), surgical route (vaginal or abdominal), removal of the cervix (if abdominal hysterectomy was performed) and complications. Cystitis, as a complication of a hysterectomy, was only regarded to be present if verified by urine culture. Fever of unknown origin was regarded to be present if the patients temperature was more than 38.5 º C for more than 48 hours, without an obvious focus of infection.

A questionnaire was sent to all selected patients in December 1998. This questionnaire consisted of questions about micturition symptoms, defecation symptoms and experienced level of discomfort of micturition and defecation symptoms. The questions concerning micturition symptoms were selected from the Dutch version of the Urogenital Distress Inventory (UDI)[7]. This validated, health-related, quality of life questionnaire consists of 19 items and each item measures if a micturition symptom is present, and to what extent the patient is bothered by this symptom. The questions about defecation symptoms were selected from the Defecation Distress Inventory (DDI). The DDI is a Dutch validated questionnaire that was developed analogous to the UDI by our group and can be used to assess the presence and level of discomfort of defecation symptoms. The 15 questions were developed after studying the literature and international definitions, interviewing patients who presented themselves with constipation or fecal incontinence, and by interviewing three experts in the field from the Department of Surgery and Department of Obstetrics and Gynecology from the University Medical Center Utrecht, The Netherlands. Eventually, a structured interview of the 15 selected

items was held with 20 female patients. The questions which were selected from the UDI and DDI to assess the presence of the micturition and defecation symptoms are presented in Appendix A.

The Incontinence Impact Questionnaire (IIQ)[7] was used to measure experienced discomfort of present micturition and defecation symptoms. This questionnaire was originally developed to measure both physical and emotional limitations caused by micturition symptoms.[8] Validation of the Dutch version of the IIQ showed that all 30 items can be divided in to five domains : mobility / travel, emotional functioning, social functioning, physical activity and embarrassment. For every domain a score on a scale from 0 to 100 can be calculated. A high score on the IIQ domains indicates that the person's well being on that particular domain is more negatively affected. The IIQ total score ranges from 0 to 500. The IIQ was used to measure physical and emotional limitations caused by all present micturition and defecation symptoms.

Statistical analysis.

Patient characteristics, clinical outcome and prevalence of micturition and defecation symptoms were compared between techniques of hysterectomy. A difference of more than 10 % in the prevalence of a micturition or defecation symptom between two techniques of hysterectomy was considered to be clinically relevant. For symptoms with such a different prevalence, odds ratios (OR) and 95 % confidence intervals (CI) were calculated using logistic regression analysis. The OR expresses the increased risk that a patient who underwent one technique of hysterectomy reports a certain symptom compared to a patient who underwent another technique of hysterectomy. The ORs were adjusted for differences in other prognostic factors in a multivariable logistic regression analysis. Other prognostic factors considered were patient characteristics (age, parity, indication for hysterectomy, history of abdominal surgery) and clinical outcome parameters (duration of hospital stay, complications during surgery and during hospital stay). The IIQ scores of patients who experienced at least one micturition or defecation symptom, were compared between groups using analyses of variances.

Results

Nine-hundred-and-fifty-seven patients underwent an hysterectomy in the University Medical Center between January 1988 and December 1997. Of the 352 patients who met the inclusion criteria the addresses of 296 patients could be traced. Two-hundred-twenty-seven (77 %) of these patients returned a completed questionnaire. There were no

statistically significant differences between baseline characteristics of respondents and non respondents (data not shown). Of all responding patients 68 (30.0 %) had undergone a vaginal hysterectomy, 109 (48.0 %) had undergone a total abdominal hysterectomy and 50 (22.0 %) had undergone a subtotal abdominal hysterectomy.

Table 1. Patient characteristics according to technique of hysterectomy.

	vaginal hysterectomy (n=68)	total abdominal hysterectomy (n=109)	subtotal abdominal hysterectomy (n=50)
Age (years)	49.9 (8.0)	47.8 (4.7)	52.8 (9.3)
Follow-up (years)	6.5 (2.1)	5.9 (2.8)	6.9 (2.8)
Indication for hysterectomy (n)*			
Dysfunctional bleeding	51 (75.0)	65 (59.6)	42 (84.0)
Abdominal pain	15 (22.1)	37 (33.9)	10 (20.0)
Dysmenorroe	13 (19.1)	29 (26.6)	9 (18.0)
Other	13 (19.1)	11 (10.1)	5 (10.0)
Parity (n)			
0	4 (5.9)	27 (24.8)	8 (17.0)
1	64 (54.1)	82 (75.2)	39 (83.0)
History of abdominal surgery (n) **	40 (58.8)	74 (67.9)	23 (46.0)
Caesarean section	4	10	7
Appendectomy	20	22	5
Sterilization	19	27	12
Cholecystectomy	1	5	2
Adnex extirpation	3	2	1
Other	7	2	4

Values are means (standard deviation) or numbers (percentage).

* Some patients had more than one indication for hysterectomy.

** Some patients had undergone more than one surgical procedure.

Table 1 shows patient characteristics according to technique of hysterectomy. Patients who had undergone a total or subtotal abdominal hysterectomy, were more often nulliparous in comparison to patients who had undergone a vaginal hysterectomy. Patients who had undergone total abdominal hysterectomy had more often a history of abdominal surgery, in comparison to patients who had undergone subtotal abdominal hysterectomy. No major differences in any other patient characteristics were observed between both groups.

Table 2 shows the clinical outcome according to technique of hysterectomy. Subtotal abdominal hysterectomy was associated with a longer hospital stay in comparison to vaginal hysterectomy and total abdominal hysterectomy. Patients who had undergone total abdominal hysterectomy encountered complications more often in comparison to patients who had undergone vaginal hysterectomy or subtotal abdominal hysterectomy.

Table 2. Clinical outcome according to technique of hysterectomy.

	vaginal hysterectomy (n=68)	total abdominal hysterectomy (n=109)	subtotal abdominal hysterectomy (n=50)
Hospital stay (days)	7.1 (2.1)	8.3 (1.7)	9.2 (3.4)
Complications	3 (4.4)	15 (13.8)	4 (8.0)
Cystitis		4	2
Wound infection		3	
Blood transfusion needed		2	2
Vaginal vault abscess	1		
Peritoneal hernia		1	
Fever of unknown origin	2	3	
Bladder retention		2	

Values are means (standard deviation) or numbers (percentage).

Table 3. Prevalence of micturition and defecation symptoms according to technique of hysterectomy.

	vaginal hysterectomy (n=68)	total abdominal hysterectomy (n=109)	subtotal abdominal hysterectomy (n=50)
Micturition symptoms			
Frequency	31 (45.6)	46 (42.2)	24 (48.0)
Urgency	34 (50.0)	51 (46.8)	25 (50.0)
Stress incontinence	43 (63.2)	59 (54.1)	30 (60.0)
Urge incontinence	25 (36.8)	27 (24.8)	13 (26.0)
Dysuria	7 (10.3)	14 (12.8)	4 (8.0)
Difficulty emptying bladder	24 (35.3)	33 (30.3)	14 (28.0)
Defecation symptoms			
Constipation	11 (16.2)	13 (11.9)	9 (18.0)
Feeling of incomplete evacuation	25 (36.8)	24 (22.0)	15 (30.0)
Fecal incontinence	10 (14.7)	12 (11.0)	6 (12.0)
Flatus incontinence	19 (27.9)	37 (33.9)	18 (36.0)
Difficulty emptying rectum	22 (32.4)	25 (22.9)	11 (22.0)
Painful defecation	19 (27.9)	30 (27.5)	11 (22.0)

Values are numbers (percentage).

Table 3 shows the prevalence of micturition and defecation symptoms according to technique of hysterectomy. The prevalence of urge incontinence among patients who had undergone vaginal hysterectomy was more than 10 % higher than among patients who had undergone total abdominal hysterectomy (adjusted OR 1.5 (95 % CI 0.8-3.1)) or subtotal abdominal hysterectomy (adjusted OR 1.8 (95 % CI 0.8-4.2)). The prevalence of a feeling of incomplete evacuation at defecation was more than 10 % higher among patients who had undergone vaginal hysterectomy, in comparison to the prevalence among patients who had undergone total abdominal hysterectomy (adjusted OR 1.9 (95

% CI 1.0-4.0)). The prevalence of difficulty emptying rectum among patients who had undergone vaginal hysterectomy was more than 10 % higher than among patients who had undergone subtotal abdominal hysterectomy (adjusted OR 1.8 (95 % CI 0.7-4.4)). No other clinically relevant differences in the prevalence of micturition or defecation symptoms after surgery were observed between different techniques of hysterectomy.
No major differences in any of the IIQ domain scores were observed by analysis of variances, between different techniques of hysterectomy (data not shown).

Discussion

Our results show that different techniques of hysterectomy are not associated with statistically significant differences in the prevalence of micturition and defecation symptoms. Patients who have undergone vaginal hysterectomy tend to have an increased risk to report urge incontinence and feeling of incomplete evacuation after defecation in comparison to patients who have undergone total abdominal hysterectomy. Patients who have undergone vaginal hysterectomy tend to have an increased risk to report urge incontinence and difficulty emptying the rectum in comparison to patients who have undergone subtotal abdominal hysterectomy.
Before interpreting the data, some issues need to be addressed. We choose a retrospective study to investigate differences in micturition and defecation symptoms between different techniques of hysterectomy. All patients underwent a standardized gynecologic interview before surgery, as this was common practice in our hospital during the study period. Questions about micturition and defecation symptoms were an integral part of this interview. Based on these questions, we intended to exclude patients who experienced severe micturition or defecation symptoms before surgery. However, mild micturition or defecation symptoms present before hysterectomy may have been missed because of the retrospective design of this study. This indicates that the prevalence of micturition and defecation symptoms, as assessed in this study, does not only include de novo symptoms but also persistent symptoms.
Patients who undergo hysterectomy because they suffer from a genital prolapse have an increased risk of experiencing micturition and defecation symptoms. As patients with genital prolapse mostly undergo vaginal hysterectomy, these patients were excluded from the analysis. We were not informed about the extension of descensus of the uterus in patients that did not undergo hysterectomy because of genital prolapse. The more the uterus descends the more likely hysterectomy is performed by vaginal approach.[9] Differences in descensus of the uterus between vaginally and abdominally performed

hysterectomies are likely to have contributed to the observed differences in reported micturition and defecation symptoms. However, the odds ratios calculated in this study were adjusted for parity, that is known to be the most important predictor of descensus of the uterus.[10] We postulate that this adjustment largely corrects for the bias caused by (unknown) differences in descensus of the uteri before surgery between different techniques of hysterectomy.

One may argue that urinary incontinence should have been confirmed by pad test or urodynamic investigation. However, the association between clinical symptoms and urodynamic findings is poor.[11] Therefore, we question the relevance of the unphysiological procedure of urodynamic testing and focused rather on reported symptoms than on urodynamic findings.

Many investigators have reported that hysterectomy increases the risk for incontinence in later life, with relative risks ranging from 1.3 to 2.1.[2,8,12-14] However, few studies have evaluated whether there are differences in the prevalence of urinary incontinence and other micturition symptoms between patients undergoing vaginal or abdominal hysterectomy. Vervest et al. performed such a study in 554 patients who underwent non-radical hysterectomy and also reported an increased incidence of irritative bladder symptoms following vaginal hysterectomy, in comparison to following abdominal hysterectomy.[15]

An increased prevalence of constipation and feeling of incomplete evacuation after defecation has been reported in women who had undergone hysterectomy.[16-18] Most studies did not relate the prevalence of defecation symptoms to the route of hysterectomy. Van Dam et al. reported an increased prevalence of disturbed bowel function following vaginal hysterectomy, in comparison to abdominal hysterectomy.[18] This difference was not statistically significant. Unfortunately, the investigators did not compare the prevalence of disturbed bowel function for each symptom separately.

This study generates the hypothesis that vaginal hysterectomy may increase the risk for urge incontinence. Differences in damage of innervation and supportive structures of the pelvic floor between the vaginal and abdominal route may account for this. The pelvic plexus is at risk in four areas during hysterectomy. First, the main branches of the plexus passing beneath the uterine arteries may be damaged during the division of the cardinal ligaments.[4] Secondly, the major part of the vesical innervation, which enters the bladder base before spreading throughout the detrusor muscle, may be damaged during blunt dissection of the bladder from the uterus and cervix.[4] Thirdly, the extensive dissection of the paravaginal tissue may disrupt the pelvic neurons passing from the lateral aspect of

the vagina.[6] Finally, the removal of the cervix may result in loss of a large segment of the plexus, which is intimately related to it.[6] The dissection of the bladder from the vagina may be more extensive during vaginal hysterectomy than during total and subtotal abdominal hysterectomy, leading to an increased prevalence of urinary incontinence among patients who have undergone vaginal hysterectomy.

The autonomic supply to the lower bowel is closely related to the cardinal and uterosacral ligaments and the upper third of the vagina[19], and is therefore prone to injury during hysterectomy. Dissection of the paravaginal tissue leading to disruption of pelvic neurons passing from the lateral aspect of the vagina, may be more extensive during vaginal hysterectomy. This may explain the increased prevalent feeling of incomplete evacuation after defecation and difficulty to empty the rectum in the vaginal group.

Micturition and defecation symptoms are known to cause physical and emotional limitations.[20-24] This study used the IIQ[7] to measure these limitations and did not observe material differences in IIQ scores between different surgical techniques. This is not surprising as micturition and defecation symptoms are not expected to have different physical and emotional effects in patients who have undergone different techniques of hysterectomy.

Regarding hospital stay, complications and costs a vaginal hysterectomy is preferable.[25-27] Gynecologists are therefore motivated to perform a vaginal hysterectomy as often as possible.[28,29] Until now, little attention has been paid to possible differences in pelvic floor function and related quality of life of patients who underwent vaginal, total abdominal and subtotal abdominal hysterectomy. Due to its retrospective design, this study does not provide sufficient evidence that a total or subtotal abdominal hysterectomy is preferable over a vaginal hysterectomy with respect to pelvic floor function. However, it suggests that the prevalence of several micturition and defecation symptoms may be influenced by the technique of hysterectomy.

In conclusion, this study suggests that technique of hysterectomy may influence the prevalence of micturition and defecation symptoms following the procedure. Only a randomised controlled trial or a prospective study that accurately adjusts for all potential confounders, can validly answer the question whether technique of hysterectomy influences pelvic floor function.

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Chapter 11

Effects of vaginal and abdominal hysterectomy on micturition and defecation.

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Abstract

Objective: Differences in effects of vaginal and abdominal hysterectomy are largely unknown. It is currently believed that, with respect to morbidity, vaginal hysterectomy is preferable over abdominal hysterectomy. A multi-center prospective observational study was performed to compare morbidity, success, micturition and defecation symptoms after vaginal and abdominal hysterectomy.

Methods: Consecutive patients with benign disease in whom both vaginal and abdominal hysterectomy were technically feasible, were selected for this prospective cohort study. Before and after hysterectomy, they were interviewed about the prevalence of micturition and defecation symptoms. Using multivariate logistic regression analysis, adjusted odds ratio's (OR) were calculated to study whether surgical route is independently associated with micturition and defecation symptoms.

Results: Of the 194 participating patients, 112 (58 %) patients had a vaginal hysterectomy and 82 (42 %) patients had an abdominal hysterectomy. It was found that abdominal approach increased the risk to report dysuria at 6 weeks after hysterectomy as compared to vaginal approach (adjusted OR 3.0 (95 % CI 1.0-8.8)). This increased risk was not observed at 6 months after surgery. The vaginal approach increased the risk that stress incontinence was reported at 6 months after hysterectomy in comparison to the abdominal approach (adjusted OR 1.8 (95 % CI 0.8-3.7)). This increased risk was present in both patients with and without stress incontinence before hysterectomy. The prevalence of defecation symptoms, morbidity and reported success of hysterectomy were similar in both groups.

Discussion: In contrast to current thinking, morbidity and success of vaginal and abdominal hysterectomy appear to be similar in patients in whom both techniques are technically feasible. Our data suggest that vaginal hysterectomy increases the risk on persistence or development of stress incontinence in comparison to abdominal hysterectomy.

Introduction

Hysterectomy has been associated with an increased prevalence of micturition and defecation symptoms.[1-5] The pelvic plexus is at risk in four areas during hysterectomy.[6,7] Damage to the pelvic plexus and the pelvic fibromuscular structures during hysterectomy is held responsible for the changes in bladder and bowel function following hysterectomy.[6-9] Vaginal and abdominal hysterectomy may have different effects on the pelvic plexus and pelvic fibromuscular structures. Therefore, the incidence of micturition and defecation symptoms among patients undergoing one of either techniques may differ. With respect to morbidity, quality of life and costs, the vaginal hysterectomy is preferable.[10,11] However, the occurrence of pelvic floor symptoms is a very important clinical issue, that should also be considered in the decision of choosing the surgical route of hysterectomy. The present study was performed to study differences in the effects of vaginal and abdominal hysterectomy on micturition and defecation symptoms.

Patients and methods

Study population

A prospective observational study was performed among women undergoing hysterectomy for benign disease in 13 teaching and non-teaching hospitals. All gynecologists in these hospitals included patients in this study. The study was approved by all local ethical committees and written informed consent was obtained from all patients.

Patients in whom both vaginal and abdominal hysterectomy appeared to be feasible were selected. This was done by including those patients who met all of the following criteria : 1) maximal uteral length (cervix to fundus) as assessed by ultrasound 10 centimeter 2) descensus of the uterus during traction with a forceps to at least half-way of the vagina; 3) genital prolapse was not the indication for hysterectomy; 4) endometriosis was not the indication for hysterectomy; 5) no history of more than two caesarian sections present.

Measurements

All women received peri-operative deep vein thrombosis prophylaxis and a single dose of intravenous prophylactic antibiotic during operation. A 14-French Foley indwelling bladder catheter with a 5 ml balloon was placed in all women post-operatively and removed after about 24 hours. Pharmacologic post-operative pain management was the same in patients who underwent vaginal and abdominal hysterectomy.

Before hysterectomy, the gynecologist who had set the indication, completed a standardized form to score: obstetric history, history of abdominal surgery, indication for hysterectomy, duration of complaints, post-menopausal status, maximal diameter of the uterus as assessed by ultrasound, descensus of the uterus in centimeters above the hymen (expressed as a negative number) or below the hymen (expressed as a positive number), indication for vaginal or abdominal hysterectomy and indication for removal or preservation of the cervix. Furthermore, the gynecologist was asked to score whether the other route of hysterectomy than the one chosen, was also feasible.

After surgery, the gynecologist who had performed the hysterectomy, completed a standardized form to score the following potential confounders: age at hysterectomy, duration of surgery in minutes, amount of blood loss in ml, uteral size in centimeters as estimated by pelvic examination during anesthesia, descensus of the uterus in centimeters above the hymen (expressed as a negative number) or below the hymen (expressed as a positive number) as measured when pulling down the portio with a forceps under anesthesia, simultaneously performed surgery and complications during surgery. At the day of discharge, this form was completed by documenting the duration of hospital stay and complications during hospital stay.

Cystitis as complication of hysterectomy was only regarded to be present if verified by urine culture. Fever of unknown origin was regarded to be present if the patients temperature was > 38.5 º C for more than 48 hours, without a known focus of infection.

All standardized forms that were completed were sent to the research fellow in the University Medical Center who was responsible for the coordination of this study. After receiving the form that was completed after the indication setting, a questionnaire was sent to the corresponding patient. This questionnaire consisted of questions about micturition symptoms, questions about defecation symptoms and questions about experienced discomfort of present micturition and defecation symptoms. The questions concerning micturition symptoms were selected from the Dutch version of the Urogenital Distress Inventory (UDI).[12] This validated questionnaire consists of 19 items and each item measures if a micturition symptom is present and to what extent the patient is bothered by this symptom. The questions about defecation symptoms were selected from the Defecation Distress Inventory (DDI). The DDI is a Dutch validated questionnaire that was developed identical to the UDI by our research group and is used to assess the presence and experienced discomfort of defecation symptoms. The 15 questions were developed after studying the literature and international definitions, interviewing patients who presented with constipation or fecal incontinence, and by interviewing three experts

in the field from the Department of Surgery and Department of Obstetrics and Gynecology from the University Medical Center Utrecht, The Netherlands. Eventually, a structured interview of the 15 selected items was held with 20 female patients. In Appendix A, the questions that were selected from the UDI and DDI to assess the presence of the micturition and defecation symptoms, are presented.

The same questionnaire was sent to all patients at six weeks and six months after hysterectomy. The questionnaire at six months after surgery was extended with the question: "Have you experienced your operation as successfully?" The choices of answer were: "All problems have been solved", "Nearly all problems have been solved", "The problems have been partly solved" and "All problems are still present or have worsened". All questionnaires were accompanied by a return envelop to facilitate patients to return their questionnaire. Patients who had not returned their questionnaire after 4 weeks were sent a letter to remind them to the study. After six weeks, the patients who still had not responded were phoned to remind them to the study.

Statistical analysis

Sample size calculation was based on studies reporting that stress incontinence is present in 40 % of all patients who have undergone hysterectomy.[13,14] A difference in prevalence of stress incontinence of 20 % between the vaginal and abdominal group was considered to be clinically relevant. To detect such a difference with a power of 80 % and a significance level of 5 %, 83 patients were needed in each group.

The main analyses compared vaginal and abdominal hysterectomy with respect to the prevalence of micturition and defecation symptoms before the procedure and at six weeks and six months after the procedure. For the analysis of differences between both groups of continuous data we used unpaired t-tests, otherwise, if not normally distributed, non-parametric tests. The chi-square test, or if appropriate Fisher's exact test, was used to compare proportions. The significance level was 5 %. In case the prevalence of a symptom was significantly different between both groups, odds ratios (OR) and 95 % confidence intervals (CI) were calculated using logistic regression analysis. The OR expresses the increased risk that a patient who underwent hysterectomy by vaginal approach reports a symptom in comparison to a patient that was operated by abdominal approach. The ORs were adjusted for differences in other prognostic factors in a multivariable logistic regression analyses. Other prognostic factors considered were age, parity, body mass index, postmenopausal status, uteral size and descensus of the uterus under anesthesia. A stratified calculation of the ORs and adjusted ORs was made for patients who did not report the symptom to be present before hysterectomy.

Results

Four-hundred-and-seventy-seven patients underwent a hysterectomy in one of the participating hospitals between January 1, 1999 and June 1, 2000. Of the 194 patients who met the inclusion criteria and completed the questionnaire before surgery, 112 (58 %) patients underwent vaginal hysterectomy and 82 (42 %) patients underwent abdominal hysterectomy. Response rates after six weeks and six months were respectively 90 % and 92 %. The characteristics of the responding patients and non-responding patients were similar.

Table 1. Patient characteristics according to surgical approach.

	Vaginal Hysterectomy (n = 112)	Abdominal hysterectomy (n = 82)
Age (years)	43.5 (8.8)	43.6 (6.5)
Parity (n)	2.2 (1.1)	2.0 (1.1)
Body mass index (kg / m^2)	25.7 (3.0)	24.8 (3.2)
Maximal diameter of uterus (cm)	8.1 (1.4)	8.3 (1.2)
Descensus of uterus (cm) *	-2.5 (1.9)	-4.3 (0.9) †
Indication for hysterectomy (n)		
Menorrhagia	82 (73.2)	57 (69.5)
Metrorrhagia	50 (44.6)	25 (30.5)
Abdominal pain	25 (22.3)	32 (39.0) †
Dysmenorroe	29 (25.9)	27 (32.9)
Other	15 (13.4)	12 (14.6)
Duration of symptoms (months)	34.4 (27.8)	37.8 (37.8)
History of abdominal surgery (n)	44 (37.5)	36 (43.9)
Co-morbidity (n)	42 (36.6)	23 (28.0)
Postmenopausal (n)	13 (11.6)	10 (12.2)

Values are means (standard deviation) or numbers (percentage).
* Measured under anesthesia by pulling down the cervix with a forceps.
† $P < 0.05$

Table 1 shows patient characteristics categorized by surgical route of hysterectomy. The uterus could be pulled further downwards in patients who underwent vaginal hysterectomy than in patients who underwent abdominal hysterectomy. This difference was statistically significant. Metrorrhagia did more often lead to vaginal hysterectomy whereas abdominal pain did more often lead to abdominal hysterectomy. The difference between both groups in the prevalence of abdominal pain as indication for hysterectomy was statistically significant. Co-morbidity was more often present in patients who had undergone vaginal hysterectomy. Co-morbidity included diabetus, hypertension, hypercholesterolaemia, hyper- or hypothyreoidy, chronic obstructive pulmonary disease

and rheumatoid arthritis. Patients who underwent abdominal surgery had more often had abdominal surgery before. Prior abdominal surgery included cholecystectomy, appendectomy, adnex extirpation, diagnostic laparoscopy, laparoscopic sterilization and myoma enucleation.

Table 2. Clinical outcomes and reported success of hysterectomy according to surgical approach.

	Vaginal hysterectomy (n = 112)	Abdominal hysterectomy (n = 82)	P value
Duration of surgery (min)	55 (2.2)	60 (1.7)	0.08 [1]
Amount of blood loss (ml)	232 (14)	259 (21)	0.27 [1]
Duration of admission (days)	4.8 (0.1)	5.7 (0.2)	< 0.001 [1]
Simultaneously performed procedures (n)	9 (7.9)	14 (17.1)	0.05 [2]
Complications during surgery (n)	6 (5.3)	6 (7.3)	0.55 [2]
Blood transfusion due to bleeding	2	4	
Bleeding requiring surgical intervention	1	-	
Bladder lesion	2	-	
Abdominal haematoma	-	2	
Adnexal bleeding	1	-	
Complications during hospital stay (n)	5 (4.4)	7 (8.5)	0.23 [2]
Loss of sensibility in upper leg	1	-	
Bladder retention	1	2	
Cystitis	-	1	
Fever of unknown origin	-	3	
Vault abscess	3	-	
Vault haematoma	-	1	
Success of hysterectomy (n)			
All problems have been solved	74 (66.1)	53 (64.6)	0.82 [2]
Nearly all problems have been solved	28 (25.0)	25 (30.5)	
The problems have been partly solved	7 (6.3)	2 (2.4)	
All problems are still present or have worsened	1 (0.9)	2 (2.4)	

Values are means (standard error) or numbers (percentage).
[1] Unpaired T Test
[2] Chi-square Test

Table 2 shows clinical outcomes and reported success of hysterectomy, depending on surgical approach. No statistically significant differences in duration of surgery, blood loss and complication rate were observed between both groups. Patients who had undergone an abdominal hysterectomy stayed statistically significantly longer in the hospital than patients who had undergone a vaginal hysterectomy. Abdominal hysterectomy was more often combined with other surgical procedures than vaginal hysterectomy. Simultaneously performed surgical procedures included adnex extirpation at one or both sides, ovarial cyst puncture or extirpation, vaginal cyst extirpation and partial ovariectomy. The reported success of both vaginal and abdominal hysterectomy was similar.

Table 3. Prevalence of micturition symptoms according to surgical approach.

	Vaginal hysterectomy	Abdominal hysterectomy	P value
Before hysterectomy	(n = 112)	(n = 82)	
Frequency	44 (39.1)	26 (31.7)	0.28
Urgency	55 (49.1)	37 (45.1)	0.58
Stress incontinence	51 (45.5)	33 (40.2)	0.46
Urge incontinence	23 (20.5)	10 (12.2)	0.13
Dysuria	15 (13.4)	14 (17.1)	0.48
Difficulty emptying bladder	34 (30.4)	24 (29.3)	0.87
6 weeks post-operative	(n = 99)	(n = 75)	
Frequency	35 (35.4)	23 (30.7)	0.52
Urgency	48 (48.5)	32 (42.7)	0.45
Stress incontinence	34 (34.3)	24 (32.0)	0.75
Urge incontinence	12 (12.1)	10 (13.3)	0.81
Dysuria	13 (13.1)	19 (25.3)	0.04
Difficulty emptying bladder	31 (31.3)	26 (34.7)	0.64
6 months post-operative	(n = 105)	(n = 73)	
Frequency	38 (36.2)	21 (28.8)	0.30
Urgency	46 (43.8)	37 (50.7)	0.37
Stress incontinence	47 (44.8)	20 (27.4)	0.02
Urge incontinence	15 (14.3)	11 (15.1)	0.88
Dysuria	6 (5.7)	8 (11.0)	0.20
Difficulty emptying bladder	27 (25.7)	22 (30.1)	0.52

Values are numbers (percentage)

Table 3 shows the prevalence of micturition symptoms of both groups before hysterectomy and at six weeks and six months after hysterectomy. Before hysterectomy, no major differences between both groups were observed in the prevalence of micturition symptoms. Frequency and urge incontinence were more often reported by patients of the vaginal group, but the difference in prevalence was not statistically significant. At six weeks after surgery, the prevalence of dysuria was statistically significantly higher in patients who had undergone abdominal hysterectomy than in patients who had undergone vaginal hysterectomy. The prevalence of the other micturition symptoms was similar in both groups.

At six months after surgery, stress incontinence was statistically significantly more often reported by patients in the vaginal group than by patients in the abdominal group. In the vaginal group, the percentage of patients with stress incontinence six months after surgery was similar to the percentage before surgery. In the abdominal group the percentage of patients with stress incontinence was lower than before hysterectomy. Sub-analysis showed the following: Of the 91 patients who did not report stress incontinence before hysterectomy, 55 patients had a vaginal hysterectomy and 46 patients had an abdominal

hysterectomy. At six months after hysterectomy, stress incontinence developed in 11 (20.0 %) of the 55 patients who underwent a vaginal hysterectomy and in 4 (8.7 %) of the 46 patients who underwent an abdominal hysterectomy. Of the 75 patients who reported stress incontinence before hysterectomy, 48 patients had a vaginal hysterectomy and 27 patients had an abdominal hysterectomy. At six months after hysterectomy, stress incontinence was reported by 36 (75.0 %) of the vaginally operated patients and by 16 (59.3 %) of the abdominally operated patients. In conclusion, stress incontinence no longer existed in 40 % of the patients who underwent an abdominal hysterectomy and in only 25 % of the patients who underwent a vaginal hysterectomy.

No statistically significant differences between both groups were observed in the prevalence of any of the other micturition symptoms.

Table 4. Prevalence of defecation symptoms according to surgical approach.

	Vaginal hysterectomy	Abdominal hysterectomy	P value
Before hysterectomy	(n = 112)	(n = 36)	
Constipation	16 (14.3)	12 (14.6)	0.95
Feeling of incomplete evacuation	32 (28.6)	27 (32.9)	0.52
Sensation of anal blockage	44 (39.3)	37 (45.1)	0.42
Difficulty emptying rectum	23 (20.5)	14 (17.1)	0.54
Painful defecation	29 (25.9)	19 (23.2)	0.66
Soiling	18 (16.1)	15 (18.3)	0.68
Fecal incontinence	5 (4.5)	5 (6.1)	0.61
Flatus incontinence	35 (31.3)	33 (40.2)	0.20
6 weeks post-operative	(n = 99)	(n = 34)	
Constipation	16 (16.2)	10 (13.3)	0.60
Feeling of incomplete evacuation	33 (33.3)	24 (32.0)	0.85
Sensation of anal blockage	38 (38.4)	34 (45.3)	0.36
Difficulty emptying rectum	20 (20.2)	15 (20.0)	0.97
Painful defecation	36 (36.4)	25 (33.3)	0.68
Soiling	12 (12.1)	11 (14.7)	0.62
Fecal incontinence	5 (5.1)	4 (5.3)	0.93
Flatus incontinence	32 (32.3)	24 (32.0)	0.96
6 months post-operative	(n = 105)	(n = 34)	
Constipation	7 (6.7)	8 (11.0)	0.31
Feeling of incomplete evacuation	22 (21.0)	22 (30.1)	0.16
Sensation of anal blockage	31 (29.5)	25 (34.2)	0.51
Difficulty emptying rectum	18 (17.1)	13 (17.8)	0.91
Painful defecation	25 (23.8)	15 (20.5)	0.61
Soiling	22 (21.0)	10 (13.7)	0.22
Fecal incontinence	7 (6.7)	5 (6.8)	0.96
Flatus incontinence	29 (27.6)	25 (34.2)	0.34

Values are numbers (percentage).

Table 4 shows the prevalence of defecation symptoms of both groups before hysterectomy and at six weeks and six months after hysterectomy. No statistically significant differences in the prevalence of any of the reported defecation symptoms were observed between both groups. The prevalence of flatus incontinence was higher in patients who had undergone abdominal hysterectomy. At six weeks after surgery, no relevant differences in the prevalence of defecation symptoms were found between both groups. At six months after surgery, the prevalence of feeling of incomplete evacuation after defecation was higher in the abdominal group than in the vaginal group, but this difference was not statistically significant.

Table 5 shows odds ratios to report micturition symptoms. The adjusted odds for dysuria at six weeks after surgery was three times higher for patients who had undergone abdominal hysterectomy in comparison to patients who had undergone vaginal hysterectomy. Stratification for presence of dysuria before hysterectomy, showed that the increased risk to report dysuria six weeks after hysterectomy was observed in patients both with and without dysuria before hysterectomy.

Table 5. Odds ratios (95 % CI) of surgical route to report micturition symptoms .

	All patients		Patients without the symptom before surgery		Patient with the symptom before surgery	
Symptom	OR	(95 % CI)	OR	(95 % CI)	OR	(95 % CI)
Dysuria 6 weeks after surgery						
Crude OR (abdominal vs vaginal)	2.2	(1.0-4.9)	2.2	(0.7-6.5)	3.6	(0.5-23.9)
Adjusted OR (abdominal vs vaginal) [1]	3.0	(1.0-8.8)	3.0	(0.7-13.7)	- [2]	- [2]
S.I. 6 months after surgery						
Crude OR (vaginal vs. abdominal)	2.1	(1.1-4.1)	2.6	(0.8-8.9)	2.1	(0.8-5.6)
Adjusted OR (vaginal vs. abdominal) [3]	2.0	(1.1-4.0)	2.9	(0.8-11.2)	3.3	(1.1-10.5)
Adjusted OR (vaginal vs. abdominal) [1]	1.8	(0.8-3.7)	3.6	(0.7-13.3)	3.2	(0.8-12.2)

S.I. Stress incontinence

[1] Adjustment was made for age, parity, body mass index, menopausal status, uteral size and descensus uteri.

[2] Could not be calculated because of low number of patients with dysuria before hysterectomy.

[3] Adjustment was made for age, parity, body mass index, menopausal status.

The crude odds for stress incontinence at six months after surgery was two times as high for patients who had undergone vaginal hysterectomy in comparison to patients who had undergone abdominal hysterectomy. Adjustment of the odds ratio for differences in age, parity, body mass index and menopausal status (all four are known risk factors), left the

odds ratio for stress incontinence unchanged. This adjusted odds ratio was statistically significant. When adjusting also for differences in uteral length and descensus of the uterus, an odds ratio of 1.8 was calculated. This adjusted odds was not statistically significant. Stratification for presence of stress incontinence before hysterectomy, showed that the increased risk to report stress incontinence after vaginal hysterectomy in comparison to abdominal hysterectomy was independent of the presence of stress incontinence before hysterectomy.

Discussion

A prospective observational study was performed to compare the effects of vaginal and abdominal hysterectomy on micturition and defecation symptoms. Patients who underwent an abdominal hysterectomy more frequently reported dysuria at six weeks after surgery in comparison to patients who had a vaginal hysterectomy. This difference was no longer observed at six months after hysterectomy. The odds for stress incontinence at six months after surgery was two times as high for patients who had undergone vaginal hysterectomy in comparison to patients who had undergone abdominal hysterectomy. This increased odds was independent of differences in previously described other risk factors between both groups. However, after adjustment for differences in uteral length and descensus of the uterus, the increased odds slightly decreased. The prevalence of defecation symptoms did not seem to differ for the two surgical routes of hysterectomy. Morbidity and success of hysterectomy were similar in this selection of patients in whom both vaginal and abdominal hysterectomy were technically feasible.

Before interpreting the data, some issues need to be addressed. A prospective non-randomized comparison of the effects of vaginal and abdominal hysterectomy was performed. The non-randomized design may have effected validity of the results, due to prognostic incomparability of the patients undergoing either one of the two types of hysterectomy. In order to deal with this problem, two adjustments were made. First, only patients in whom both operation techniques would have been technically feasible were selected. Second, at baseline, all factors that are known to influence the outcome of interest were documented. Statistical techniques allowed for adjustment of these prognostics factors. Of course, unknown confounders were not assessed, and these may still bias our results. Our study is strengthened by use of the same standardized assessments of micturition and defecation symptoms before and after surgery in each patient.

Several studies have related hysterectomy to an increased prevalence of micturition and defecation symptoms.[2,3,14-16] Few studies report on the effect of surgical route on the prevalence of these symptoms. Vervest and co-workers performed a retrospective study in 554 patients who underwent non-radical hysterectomy and reported an increased incidence of irritative bladder symptoms following vaginal hysterectomy in comparison to following abdominal hysterectomy. They did not observe differences in other micturition symptoms between both groups. A retrospective study performed by Van Dam and co-workers reported an increased prevalence of disturbed bowel function following a vaginal hysterectomy compared with an abdominal hysterectomy.[4] This difference in this study was not statistically significant. The investigators did not provide results for each defecation symptom separately.

To the best of our knowledge, this study is the first to prospectively evaluate the effect of surgical route on the prevalence of micturition and defecation symptoms following hysterectomy. Differences in this prevalence may have been caused by differences in damage of innervation and supportive structures of the pelvic floor between the vaginal and abdominal approach. The pelvic plexus is at risk in four areas during hysterectomy. First, the main branches of the plexus passing beneath the uterine arteries may be damaged during the division of the cardinal ligaments.[6] Secondly, the major part of the vesical innervation, which enters the bladder base before spreading throughout the detrusor muscle, may be damaged during blunt dissection of the bladder from the uterus and cervix.[6] Thirdly, the extensive dissection of the paravaginal tissue may disrupt the pelvic neurons passing from the lateral aspect of the vagina.[7] Finally, the removal of the cervix may result in loss of a large segment of the plexus to which it is intimately related.[7] It is questionable whether the observed difference in dysuria between both groups at six weeks after hysterectomy should be sought in a difference in damage of the pelvic plexus between vaginal and abdominal hysterectomy. Such a difference in damage is likely to result in a different prevalence of dysuria at later follow-up. At six months after hysterectomy, the prevalence of dysuria in the abdominal group was still higher than in the vaginal group, but the difference in prevalence was small (5 %). The observed difference may be regarded as a short term effect of abdominal surgery. Possibly, abdominal hysterectomy is associated with more edema around the vaginal vault in comparison to vaginal hysterectomy. This edema could cause compression of the pelvic innervation and of the urethra and cause dysuria as a result of this compression. This theory needs to be further evaluated.

A difference in the prevalence of stress incontinence following vaginal and abdominal

hysterectomy was observed at 6 months after surgery. Patients both with and without stress incontinence before hysterectomy contributed to the observed difference in prevalence of stress incontinence at six months after surgery. The difference in the persistence and development of stress incontinence after hysterectomy may be the result of a different surgical trauma of the pelvic plexus. The branches of this plexus that innervate the striated urethral sphincter, may be more at risk during vaginal surgery than during abdominal surgery. An even more likely explanation for the difference in surgical trauma between both approaches may be the downwards directed traction of the uterus, performed during vaginal hysterectomy, that may cause damage to the pelvic plexus. As this downwards traction does not occur during abdominal hysterectomy, this procedure may be associated with less damage to the pudendal nerve. Previously described risk factors for stress incontinence are age, parity, body mass index and post-menopausal status.[15,17] The increased risk of vaginal approach at hysterectomy on the presence of stress incontinence, appeared to be independent of these risk factors. However, after adjustment for differences in uteral length and descensus uteri, the increased risk of vaginal approach on stress incontinence did slightly decrease and was on the border statistically significance. Uteral length and descensus uteri are not known risk factors on stress incontinence. We can not give an acceptable explanation for the reduced odds ratio after adjustment for these two factors. Maybe size of our study population was too small to allow adjustment of the odds ratio for six potential confounders. We are preparing a study to further evaluate the effects of uteral size and descensus of the uterus on bladder function.

Differences in the prevalence of defecation symptoms following vaginal and abdominal hysterectomy were not observed. It has been suggested that hysterectomy negatively effects defecation because of damage of the bowel innervation[3,4,8] and changes in the anatomy of the lower abdomen.[18] Apparently, this damage of innervation and altered anatomy caused by vaginal and abdominal hysterectomy are similar.

Studies comparing morbidity of vaginal and abdominal hysterectomy, have shown the vaginal approach to be preferable.[10,11,19] However, these studies were not limited to patients in whom both techniques were technically feasible. The observed similarity in morbidity of vaginal and abdominal hysterectomy in this study may be explained by the exclusion of patients with enlarged and/or non-descending uterus. Additionally, no differences were observed in reported success of hysterectomy. This suggests that vaginal and abdominal hysterectomy, if both techniques are technically feasible, are equally effective in curing benign disease. Nevertheless, based on studies comparing morbidity in

all patients undergoing hysterectomy[10,11,19], gynecologists are motivated to perform vaginal hysterectomy as often as possible. Studies have even been performed to evaluate how the number of vaginally performed hysterectomies may be increased.[20,21] When considering our findings of an increased risk on the persistence and development of stress incontinence after vaginal hysterectomy, we are concerned whether these studies pursue the correct goal.

In conclusion, morbidity and success of vaginal and abdominal hysterectomy appear to be similar in patients in whom both techniques are technically feasible. Our data suggest that a vaginal hysterectomy increases the risk on persistence or development of stress incontinence more so than an abdominal hysterectomy.

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Chapter 12

Effects of technique of hysterectomy on sexuality: preliminary results of a prospective multi-center study.

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Abstract

Objective: Hysterectomy has been shown to affect sexuality, but whether technique of hysterectomy affects sexuality is controversial. We performed a multi-center prospective study to compare the effects of vaginal hysterectomy, subtotal abdominal hysterectomy and total abdominal hysterectomy on sexual function.

Methods: All patients who underwent hysterectomy for benign disease in 13 participating hospitals were asked to complete the Questionnaire for screening Sexual Dysfunctions (QSD) before hysterectomy and at six months after hysterectomy. Differences between reported sexual satisfaction and sexual activity before and after hysterectomy were compared between techniques of hysterectomy. Of patients who were sexually active before and after hysterectomy, the prevalence of symptoms that persisted or developed after hysterectomy was calculated. Using logistic regression analysis, odds ratio's (OR) were calculated for all symptoms of which the prevalence between techniques of hysterectomy appeared to differ. These odds ratios were adjusted for differences in other prognostic factors.

Results: Four-hundred-and-thirteen patients participated in this study. Sexual satisfaction statistically significantly improved in all patients, independently of the performed technique of hysterectomy. Of patients who were sexually active before and six months after surgery, 89 patients underwent vaginal hysterectomy, 76 patients underwent subtotal abdominal hysterectomy and 145 patients underwent total abdominal hysterectomy. An increased prevalence of persisting problems with lubrication (adjusted OR 2.6 (95 % CI 0.6-10.2)) and problems with arousal (adjusted OR 2.1 (95 % CI 0.6-7.8)) were observed among patients who had undergone abdominal hysterectomy as compared to patients who had undergone vaginal hysterectomy. The prevalence of persisting problems with pain/sensation of the genitals (adjusted OR 1.8 (95 % CI 0.8-4.2)) was higher among patients who had undergone total abdominal hysterectomy than among patients who had undergone vaginal hysterectomy. No statistically significant differences between techniques of hysterectomy in the prevalence of symptoms that persisted or developed after hysterectomy were observed.

Conclusion: Removal of the cervix during abdominal hysterectomy does not appear to affect sexuality. Vaginal approach may have beneficial effects in patients who have sexual problems before hysterectomy.

Introduction

Hysterectomy may affect sexuality.[1-3] The exact effects of hysterectomy on sexuality are difficult to predict in the individual patient as both physical and psychological factors have varying and often unquantifiable influences on sexuality.

Whether removal of the cervix during hysterectomy affects sexuality after surgery is subject to debate. Total abdominal hysterectomy has been related to a significant decrease in number of orgasms at one year after surgery whereas this reduction was not observed in patients undergoing subtotal abdominal hysterectomy.[4] It has been suggested that total abdominal hysterectomy causes more damage of the autonomous innervation of the proximal vagina and cervix than subtotal abdominal hysterectomy. This was not confirmed in a study by Virtanen et al.[5] The lack of agreement between the results of these studies may have several reasons. Both studies did not use validated questionnaires to assess the presence of sexual problems. Even more important, confounding factors that could influence the reported sexual well-being were neglected in both studies.

If differences in sexuality after total and subtotal abdominal hysterectomy were to be caused by differences in damage of the pelvic innervation, differences in sexuality after vaginal and abdominal hysterectomy may also be expected. However, the difference in effect of vaginal and abdominal hysterectomy on sexuality has not been studied yet.

We performed a multi-center prospective study to compare the effects of vaginal hysterectomy, subtotal abdominal hysterectomy and total abdominal hysterectomy on sexual function.

Patients and methods

Study population

A prospective observational study was performed among women undergoing hysterectomy for benign disease in 13 teaching and non-teaching hospitals. All gynecologists in these hospitals included patients in this study. The study had been approved by all local ethical committees and written informed consent was obtained from all patients.

Surgical procedures

Peri-operative treatment was similar in all participating hospitals; All women received peri-operative deep vein thrombosis prophylaxis and a single dose of intravenous

prophylactic antibiotic during operation. A 14-French Foley indwelling bladder catheter with a 5 ml balloon was placed in all women post-operatively and removed after about 24 hours. In case of bladder retention (defined as twice a residual volume after voiding of more than 100 ml) the patient started clean intermittent catheterization. Pharmacologic post-operative pain management was the same in all patients.

Measurements

Before hysterectomy, the gynecologist who had set the indication completed a standardized form to score: age, obstetric history, history of abdominal surgery, indication for hysterectomy, duration of complaints, maximal diameter of the uterus as assessed by ultrasound, descensus of the uterus in centimeters above the hymen (expressed as negative number) or below the hymen (expressed as positive number), reason of indication for vaginal or abdominal hysterectomy, reason for removal or preservation of the cervix. Other data that were collected of all patients include duration of relation with partner and educational level.

Immediately after surgery, the gynecologist who had performed the hysterectomy completed a second standardized form to score the following parameters: duration of surgery in minutes, amount of blood loss in ml, descensus of the uterus in centimeters above the hymen (expressed as negative number) or below the hymen (expressed as positive number) as measured when pulling down the portio with a clamp under anaesthesia, simultaneously performed surgery and complications during surgery. This form was completed at the day of discharge by filling out the duration of hospital stay and complications during hospital stay.

All participating patients were sent the Questionnaire for screening Sexual Dysfunctions (QSD)[6] before hysterectomy and at six months after hysterectomy. The QSD is a validated questionnaire to assess the presence, frequency and experienced discomfort of sexual dysfunctions and consists of 36 questions. The first part of the question asks whether a dysfunction is present or not, the second part asks about the frequency of occurrence of this symptom (measured with a five-point Likert scale ranging from hardly ever to always) and the third part asks about the experienced amount of discomfort of the dysfunction (measured with a five-point Likert scale ranging from not at all to severely). The first 16 questions concern the general perception of the own sexuality and the frequency of sexual activity. The following 18 questions concern different types of problems during sexual activity. From this part of the QSD, questions were selected to identify patients with problems with lubrication, orgasm, pain/sensation in genitals and

arousal. In Appendix C the questions that were selected from the QSD are presented. We regarded a symptom to be present, in case the experienced discomfort of that symptom was scored as “I am bothered” or “I am much bothered“ or “I am severely bothered”. The rationale not to include frequency of occurrence of the symptom in the analysis was twofold: first, frequency of occurrence depends on frequency of intercourse and is therefore difficult to interpret. Second, we think that a patient’s experience (as expressed by the experienced amount of discomfort) involves all aspects of a dysfunction, its frequency of occurrence included. The last two questions of the QSD ask about the general satisfaction about sexuality and can be expressed in a score ranging from 0 to 10. A higher score indicates more satisfaction about sexuality.

Statistical analyses.

The aim of the statistical analysis was to study how often problems during sexuality persisted after different techniques of hysterectomy and how often problems during sexuality developed after different techniques of hysterectomy.

The number of patients sexually active, the reported frequency of intercourse and the general satisfaction about sexuality before hysterectomy and at six months after hysterectomy, were compared. Patient characteristics of all sexual active patients were compared between techniques of hysterectomy. Only patients that were sexually active were included in the further analysis.

The prevalence of problems during sexuality that persisted or had developed after surgery were compared between techniques of hysterectomy and tested for statistical significance, using chi-square test. For symptoms of which this prevalence between techniques of hysterectomy appeared to differ, odds ratios (OR) and 95 % confidence intervals (CI) were calculated using logistic regression analysis. The OR expresses the odds that a symptom remains present or develops in a patient who underwent a technique of hysterectomy in comparison to the odds of a patient who underwent an other technique of hysterectomy. The ORs were adjusted for differences in other prognostic factors in multivariable logistic regression analysis. Other prognostic factors considered were age, parity, body mass index, uteral size, descensus of the uterus, indication for hysterectomy, use of anti-depressive drugs, co-morbidity and duration of relation with partner.

Results

Of 477 patients who underwent a hysterectomy in one of the participating hospitals

between January 1, 1999 and June 1, 2000, 413 patients participated in this study. Of the 379 participating patients who had a male partner, 352 (93 %) responded at six months after surgery.

Table 1 shows the number of sexually active patients and the reported general satisfaction about sexuality before and after surgery, according to technique of hysterectomy, for these 352 patients. No statistically significant differences were observed in the number of patients sexually active before and after surgery, for any of the techniques of hysterectomy. For all three techniques, nearly all patients who were sexually active before hysterectomy, remained sexually active. More than half of the patients who were not sexually active before hysterectomy, became sexually active after hysterectomy, except when total abdominal hysterectomy was performed. The difference between techniques of hysterectomy in the number of patients that became sexually active after hysterectomy, was not statistically significant.

Table 2. Patient characteristics and reported sexual problems before hysterectomy, of patients who were sexually active before and after hysterectomy, according to technique of hysterectomy.

	vaginal hysterectomy (n=89)	subtotal abdominal hysterectomy (n=76)	total abdominal hysterectomy (n=145)
Patient characteristics			
Age (years)	43.1 (5.3)	43.4 (5.5)	44.4 (6.3)
Parity (n)	2.1 (0.8)	1.9 (1.1)	1.9 (1.2)
Body mass index (kg / m^2)	25.6 (4.1)	24.8 (3.9)	25.5 (4.0)
Maximal diameter of uterus (cm)	8.1 (1.4)	10.2 (3.8)	11.0 (3.4)
Descensus of uterus (cm) *	- 2.7 (1.9)	- 6.0 (2.4)	- 6.6 (2.4)
Indication for hysterectomy (n)			
Menorrhagia	63 (70.8)	60 (78.9)	88 (60.7)
Metrorrhagia	38 (42.7)	18 (23.7)	38 (26.2)
Abdominal pain	17 (19.1)	31 (40.8)	48 (33.1)
Dysmenorroe	25 (28.1)	22 (28.9)	31 (21.4)
Other	12 (13.5)	4 (5.3)	11 (7.6)
Duration of symptoms (months)	35.1 (28.1)	42.5 (41.7)	31.8 (31.5)
History of abdominal surgery (n)	34 (38.2)	31 (40.8)	55 (37.9)
Co-morbidity (n)	34 (38.2)	12 (16.7)	49 (35.3)
Use of anti-depressive drugs (n)	12 (13.5)	5 (7.1)	11 (8.0)
Duration of relation with partner (years)	20.0 (8.2)	19.0 (9.3)	20.5 (9.0)
Sexual problems before hysterectomy			
Lubrication	25 (28.1)	22 (28.9)	39 (26.9)
Orgasm	27 (30.3)	23 (30.3)	35 (24.1)
Pain/sensation in genitals	28 (31.5)	21 (27.6)	48 (33.1)
Arousal	30 (33.7)	26 (34.2)	44 (30.3)
Any problem	49 (55.1)	43 (56.6)	81 (55.9)

Values are means (standard deviation) or numbers (percentage).

* Assessed under anaesthesia

Table 1. Number of sexually active patients and reported general satisfaction about sexuality, before and after surgery, according to technique of hysterectomy.

	Vaginal hysterectomy (n=104)		Subtotal abdominal hysterectomy (n=84)		Total abdominal hysterectomy (n=164)	
	before hysterectomy	after hysterectomy	before hysterectomy	after hysterectomy	before hysterectomy	after hysterectomy
Sexually active[1]						
Yes	92	89 (96.7)	76	76 (100)	152	145 (95.4)
No	12	8 (67.7)	8	6 (75.0)	12	3 (25.0)
General satisfaction[2]	7.0 (0.3)	7.5 (0.2)	7.0 (0.2)	7.5 (0.2)	6.9 (0.2)	7.4 (0.2)

[1] Values are numbers (percentage)
[2] Values are means (standard error)

Table 3. Reported problems during sexual activity that persist or develop after surgery, according to technique of hysterectomy.

	Vaginal hysterectomy		Subtotal abdominal hysterectomy		Total abdominal hysterectomy		
	Before surgery	Problem present after surgery	Before surgery	Problem present after surgery	Before surgery	Problems present after surgery	
Reported sexual problem	n	n (%)	n	n (%)	n	n (%)	P value[1]
Lubrication							
Yes	25	9 (36.0)	22	12 (54.5)	39	22 (56.4)	0.25
No	64	5 (7.8)	54	6 (11.1)	106	41 (13.2)	0.56
Orgasm							
Yes	27	13 (48.1)	23	11 (47.8)	35	18 (51.4)	0.95
No	62	6 (9.7)	53	5 (9.4)	110	14 (12.7)	0.75
Pain/sensation of genitals							
Yes	28	9 (32.1)	21	8 (38.1)	48	22 (45.8)	0.49
No	61	8 (13.1)	55	6 (10.9)	97	8 (8.2)	0.61
Arousal							
Yes	30	12 (40.0)	26	14 (53.8)	44	23 (52.3)	0.50
No	59	4 (6.8)	50	2 (4.0)	101	10 (9.9)	0.42
Any problem							
Yes	49	29 (59.2)	43	23 (53.5)	81	45 (55.6)	0.85
No	40	9 (22.5)	33	8 (24.2)	64	12 (18.8)	0.80

[1] Calculated with $\div^2$ - Test.

Of the patients who were sexually active, frequency of intercourse was similar before and after hysterectomy, for all three techniques (data not shown). The general satisfaction about sexuality statistically improved after all techniques of hysterectomy. Differences in improvement between different techniques of hysterectomy were not observed.

Of the 352 patients who responded six months after hysterectomy, 310 patients reported to be sexually active both before and after surgery. These 310 patients, consisting of 89 (28.7 %) patients who underwent vaginal hysterectomy, 76 (24.5 %) patients who underwent subtotal abdominal hysterectomy and 145 (46.8 %) patients who underwent abdominal hysterectomy, were included in the further analysis. Their characteristics are shown in Table 2. Several differences were observed between patients who had undergone vaginal hysterectomy and patients who had undergone abdominal hysterectomy, whereas no major differences were observed within the abdominal group between patients who had undergone subtotal and total hysterectomy. In the vaginal group, the number of delivered children was higher, the uteral size was smaller, descensus of the uterus was further downwards, metrorrhagia was more often the indication for hysterectomy and abdominal pain was less often the indication for hysterectomy. Problems during sexuality reported before hysterectomy are also shown in Table 2. No major differences in the prevalence of these problems were observed between different techniques of hysterectomy. Over half of the patients reported at least one problem during sexual activity, prior to hysterectomy.

Table 3 shows the prevalence of problems during sexual activity that had persisted or developed, at six months after surgery, according to technique of hysterectomy. Statistically significant differences between techniques of hysterectomy were not observed. Problems with lubrication and arousal disappeared more often after vaginal hysterectomy, than after subtotal or total abdominal hysterectomy. Problems with pain/sensation in genitals disappeared more often after vaginal hysterectomy than after total abdominal hysterectomy. No major other differences between techniques of hysterectomy in the prevalence of problems during sexuality that persisted or developed after surgery were observed. More than half of the patients who reported sexual problems before hysterectomy, reported to still have sexual problems after hysterectomy. Sexual problems developed in between 18.2 % and 24.2 % of the patients who underwent hysterectomy, independent of the technique of hysterectomy that was chosen.

Table 4 shows odds ratios for the problems during sexual activity of which the prevalence differed between techniques of hysterectomy. These odds ratios were adjusted for differences in other prognostic factors. The adjusted odds to report that problems with

lubrication and arousal persisted was higher in patients who had undergone abdominal hysterectomy in comparison to patients who had undergone vaginal hysterectomy. Both adjusted odds ratios were not statistically significant. Patients who underwent total abdominal hysterectomy had an increased risk to keep problems with pain/sensation in genitals. The adjusted odds ratio was not statistically significant.

Table 4. Odds ratios (95 % CI) to report sexual problems at 6 months after surgery.

	Crude OR (95 % CI)	Adjusted OR (95 % CI) *
Abdominal vs vaginal		
Lubrication problems persist	2.2 (0.9-5.8)	2.6 (0.6-10.2)
Arousal problems persist	1.7 (0.7-4.0)	2.1 (0.6-7.8)
Total abdominal vs vaginal		
Problems with pain/sensation persist	1.8 (0.7-4.7)	3.4 (0.9-13.8)

Odds ratios were adjusted for age, parity, body mass index, uteral size, descensus of the uterus under anaesthesia and use of antidepressive drugs.

Discussion

We performed a prospective multi-center study to evaluate the effects of different techniques of hysterectomy on sexuality. Observed differences between techniques of hysterectomy were corrected for potential confounders. Technique of hysterectomy did not appear to be an independent risk factor for the remaining or development of problems during sexual activity.

The present study was based on a multi-center cohort study of 413 women undergoing vaginal, subtotal abdominal, or total abdominal hysterectomy. Data were prospectively collected; potential confounders were accurately documented; and a validated questionnaire was used to assess sexual function. Some limitations need to be discussed. First, the size of our study population may have been too small to detect small differences. Second, patients were not randomized for the technique of hysterectomy. Therefore, baseline differences in factors that influence sexual function may have confounded our results. To deal with this, we prospectively documented all potential confounders and our findings were adjusted for them with statistical techniques.

Quality of relation with the partner has also been associated with sexual function after hysterectomy.[7] In this study, we did measure this. We question whether this has biased our results, as no association between quality of relation and performed technique of hysterectomy is to be expected.

To measure sexuality we used the Questionnaire for screening Sexual Dysfunctions (QSD).[6] Out of other questionnaires developed to measure sexuality, we selected the QSD as it does not only ask about the presence of a symptom but also about the amount of discomfort experienced due to that symptom. This allows the possibility to focus on symptoms that bother the patient.

Studies evaluating the effects of type of hysterectomy on sexuality have mostly focussed on the effect of removal of the cervix.[4,5] A reduction in frequency of orgasms after total abdominal hysterectomy which was not observed after subtotal abdominal hysterectomy has been reported[4], but the presence of this reduction was not confirmed.[5] Preliminary results of a randomized trial comparing subtotal and total abdominal hysterectomy show that one year after hysterectomy intercourse was less frequent and dyspareunia was more common in patients who had undergone total hysterectomy in comparison to patients who had undergone subtotal hysterectomy.[8] In our study, no relevant differences in frequency of intercourse, sexual satisfaction or prevalence of problems during sexual activity were observed between patients who underwent subtotal and total abdominal hysterectomy.

To the best of our knowledge, this is the first study comparing the effects of vaginal and abdominal approach on sexuality after hysterectomy. A trend was observed towards a higher prevalence of problems with lubrication and arousal that persisted after subtotal or total abdominal hysterectomy than after vaginal hysterectomy. Problems with lubrication and arousal are related to each other.[9] Possibly, the differences in persistence of problems with lubrication and arousal can be explained by differences in characteristics between patients who udnerwent abdominal and vaginal hysterectomy. The prevalence of abdominal pain as indication for hysterectomy was higher in patients who underwent abdominal hysterectomy than in patients who underwent vaginal hysterectomy. Abdominal pain and sexual problems have been related to each other.[10] Possibly, these sexual problems are not solved by an abdominal hysterectomy as they are not related to the symptoms that led to the hysterectomy. Therefore a randomized trial will give a more valid answer to the question whether problems with lubrication and arousal persist as often after vaginal hysterectomy as after abdominal hysterectomy. The same accounts for the observed trend towards a higher prevalence of patients in whom problems with pain/sensation in genitals persisted after total abdominal hysterectomy than after vaginal hysterectomy.

In conclusion, we observed an increase in satisfaction about sexuality and decrease in prevalence of sexual problems after all surgical techniques of hysterectomy. Removal of

the cervix during abdominal hysterectomy does not appear to affect sexuality. A vaginal approach may have beneficial effects in patients who have sexual problems before hysterectomy. However, as long as studies confirming these beneficial effects have not been presented, we do not recommend to enroll them in the decision of choosing the technique of hysterectomy.

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Chapter 13

General discussion

In this thesis, several questions regarding characteristics of pre-operative diagnostic tools in women with genital prolapse and regarding the effects of genital prolapse surgery and hysterectomy on pelvic floor function are addressed.

Diagnostic characteristics of defecography and ano-rectal function tests

Several diagnostic tools are available to measure bladder and bowel function and to visualize the anatomy of the pelvic organs. Experts in the field of pelvic floor surgery have advocated a diagnostic work-up, including urodynamic investigation, defecography and ano-rectal function tests, in patients undergoing genital prolapse surgery.[1,2] With respect to urodynamic investigation, this recommendation is based on valid scientific evidence.[3,4]

In women with severe genital prolapse, descent of the pelvic organs may cause mechanical obstruction of the urethra.[3,5] In case the urethra is compressed during increased abdominal pressure, urinary incontinence may be masked. By redressing the prolapse during urodynamic investigation, such masked incontinence may be revealed.[5] Performing a colposuspension in addition to prolapse surgery in patients with masked incontinence, has been shown to improve outcome of treatment.[3] Masked incontinence is not only a risk in patients with cystocele or descensus uteri. A grade III posterior wall defect may also mask stress incontinence.[6] It may be clear that in all patients with genital prolapse who report urinary incontinence or in whom masked incontinence is suspected, urodynamic investigation is indicated. Because of the clarity about the role of urodynamic investigation in the diagnostic work-up of patients with genital prolapse, this diagnostic instrument was not evaluated in this thesis.

The value of defecography and ano-rectal function tests as diagnostic tools in patients with genital prolapse is less clear. In this thesis, several diagnostic characteristics of defecography and ano-rectal function tests were studied. The results of these studies may help to find out whether defecography and ano-rectal function tests provide information that will help gynecologists to better treat their patients.

Defecography provides a dynamic assessment of the defecation process by recording the rectal expulsion of a barium paste that approximates the consistency of feces.[7] There is no consensus about the scoring of defecographic abnormalities. We developed a new quantitative system to score abnormalities revealed by defecography and evaluated the inter-observer reproducibility of this new system (Chapter 2). The inter-observer reproducibility of all scored items was almost perfect. This good reproducibility was

achieved by basing the system on easily and consistently recognizable radiographic landmarks; the anal orifice, the upper margin of the anal canal and the top of the vagina. Furthermore, the fixation of a radiopaque metric ruler between the buttocks may have further enhanced the reproducibility of the new scoring system. One of the strengths of our system is that it includes only abnormal findings that correlate well with clinical symptoms and that in includes both qualitative measurements and quantitative measurements. The quantitative measurements may be especially valuable when studying the relation between defecographic abnormalities and clinical symptoms. After revealing these relations, the scoring system can be replaced by a grading system.

As defecography is a bothersome and embarrassing procedure from the patients point of view, we decided to study whether an a priori estimation of the risk on abnormal findings can be made with the use of non-invasive methods. It appeared to be possible to develop a prediction rule with which, based on the quantified value of the patient's history, findings at pelvic examination before surgery and a validated questionnaire, accurately can be predicted whether an enterocele and or rectal intussusception is present (Chapter 3). The use of this prediction rule may limit the number of defecographies performed in patients with genital prolapse. At present it is unclear whether the detection of defecographic abnormalities has any clinical implications. A randomized trial comparing treatment results with or without information about defecographic findings may validly answer the question whether performing defecography in patients with genital prolapse is recommendable.

Like defecography, the role of ano-rectal function tests, in the diagnostic work-up of patients with genital prolapse is unclear. Based on studies comparing the results of ano-rectal function tests in patients with fecal incontinence or constipation and in healthy volunteers[8-11], hypotheses about the pathophysiology of constipation and fecal incontinence have been generated. Some have suggested that performing ano-rectal function tests in patients with genital prolapse can aid in distinguishing causes of defecation symptoms.[2] We studied whether constipation and fecal incontinence in patients with genital prolapse are associated with findings at ano-rectal function tests (Chapter 4). Except for a statistically significant association between decreased rectal sensibility and constipation, other findings at ano-rectal function tests appeared to be only weakly associated with constipation or fecal incontinence in patients with genital prolapse. Because patients in our study underwent ano-rectal function tests independently of the presence of defecation symptoms, our study differs from previous studies. Possibly, the discrepancy between the results of these studies and our study accounts for the difference

in observed associations between findings at ano-rectal function tests and defecation symptoms.

The finding that constipation in patients with genital prolapse is associated with decreased rectal sensibility may have important implications. Studies have shown a beneficial effect of biofeedback therapy in constipated patients in whom decreased rectal sensibility is detected.[12] Possibly, constipated patients with genital prolapse also benefit of biofeedback therapy. Effect of biofeedback therapy in constipated women with decreased rectal sensibility and in constipated women without decreased rectal sensibility, need to be compared. If no difference in outcome of treatment is observed, the need to perform ano-rectal function tests in women with genital prolapse no longer exists.

We set out to understand changes in bowel function occurring during surgery. A prospective study was performed to evaluate whether performing ano-rectal function tests and defecography before and after prolapse surgery can provide a pathophysiological and/or anatomical explanation for the observed changes in bowel function (Chapter 5). Whereas changes in defecography appeared to be weakly associated with changes in bowel function, clear associations were observed between changes in ano-rectal function tests and changes in the persistence and development of defecation symptoms. These data suggest that the changes in bowel function due to prolapse surgery, have mainly a physiological etiology rather than an anatomical origin.

We observed that only two defecation symptoms ("feeling of incomplete evacuation" and "sensation of anal blockage") frequently developed after prolapse surgery, whereas all present defecation symptoms beside constipation, disappeared in about half of all patients. In patients who did not develop "feeling of incomplete evacuation" and "sensation of anal blockage", median pudendal nerve terminal motor latency was reduced. Possibly, in patients with genital prolapse, damage to the pudendal nerve occurs because of continuous stretching of the nerve by the force of descending pelvic organs. There is substantial evidence that genital prolapse surgery causes additional damage to the pudendal nerve.[13] Therefore, both the degree of pudendal nerve damage due to genital prolapse as well as due to its surgery, may be important in determining it's final function. If the pudendal nerve is in fair condition after surgery, this additional damage may not cause defecation symptoms. However, in patients in whom the function of the pudendal nerve has already been compromised, additional trauma due to surgery, may induce defecation symptoms. This theory could be further evaluated by investigating the association between pudendal nerve terminal motor latency and duration and severity of genital prolapse.

Both the persistence of soiling and flatus incontinence symptoms, were associated with accelerated feelings of distension. These accelerated feelings have been related to continuous funneling of feces into the anus during filling of the rectal reservoir.[14] In combination with decreased compliance of the rectum, this funneling may lead to incontinence.[14]

Genital prolapse surgery

Because vaginal and abdominal prolapse surgery have been shown to be equally effective with respect to correction of the anatomical abnormalities in patients with descensus uteri, the decision which technique is performed, mainly depends on the gynecologists experience and familiarity with different techniques. It is unclear whether both techniques have different effects on pelvic floor function. We studied the effects of two surgical techniques to correct descensus uteri, on bladder, bowel and sexual function. Historically gynecologists prefer vaginal hysterectomy combined with anterior and/or posterior colporraphy [15], but abdominal sacrcocolpopexy with preservation of the uterus is gaining popularity based on studies reporting fair treatment results.[16,17] It was decided to compare these surgical procedures and to focus on the effects that these procedures have on micturition, defecation and sexuality.

First, we performed a retrospective study, comparing the abdominal and vaginal surgical correction of descensus uteri and coexisting stress incontinence (Chapter 6). Abdominal surgery appeared to be associated with a higher prevalence of difficulty emptying bladder, fecal incontinence and soiling in comparison to vaginal surgery. It was hypothesised that the observed differences in “difficulty emptying bladder” may be caused by differences between the patients in bladder capacity before surgery. As a large capacity bladder is associated with a low detrusor activity[18], the increased prevalence of voiding difficulties in the abdominal group may have existed before surgery. This hypothesis was evaluated in a randomized trial. The difference in prevalence of fecal incontinence that was observed following abdominal and vaginal prolapse surgery, was explained by the theory that the Burch colposuspension performed during abdominal surgery was responsible for the formation of an enterocele. Estimations about the incidence of an enterocele following Burch colposuspension vary from 10 % to 30 %.[19,20,20] As far as we know, vaginal bladder neck suspension and the development of an enterocele have never been associated. We could not confirm our theory about the formation of an enterocele in a prospective study (Chapter 5). In this chapter it was reported that symptoms of fecal incontinence and soiling that had remained present or developed after prolapse surgery, were not associated

with the development of enteroceles. Possibly, this discrepancy visualizes the limitations of a retrospective study. However, follow-up of the study described in Chapter 5 may be too short to observe the formation of an enterocele. In some years, when long term follow-up of the presented studies is available, this issue can be further addressed.

A randomized multi-center trial was initiated in 1998 to compare the effects of abdominal and vaginal surgical correction of descensus uteri on micturition, defecation and sexuality. The generalazability of this trial may need some discussion. Not all patients who underwent surgical correction of descensus uteri, participated in the trial. Some patients felt uncomfortable by allowing fortune to decide whether their uterus was to be removed or not and whether they would spend the rest of their life with an abdominal scar or not. As a consequence, many patients felt they were responsible for their treatment decision, and decided not to participate. Furthermore, gynecologists felt sometimes uncomfortable to have fortune decide which surgical procedure they had to perform. Based on their personal experiences with both surgical techniques, they often had an opinion about which surgical procedures was to be preferred, although they were aware that this opinion was not evidence based. This could have resulted into a selection of patients to whom participation in this trial was proposed. This indicates that the results of our randomized trial are generalizable to patients with descensus uteri grade II-IV in whom the gynecologist does not have a strong opinion about which surgical procedure should be performed.

In Chapter 7 the effects of vaginal hysterectomy combined with anterior and/or posterior colporraphy and abdominal sacrocolopexy with preservation of the uterus on micturition and defecation are compared. Eighty-two patients, equally distributed over both groups participated in the trial. Bothersome urogenital symptoms related to discomfort/pain, overactive bladder (freqency, urgency, nightly frequency), obstructive micturition and prolapse symptoms, appeared to occur more frequently after abdominal prolapse surgery than after vaginal prolapse surgery. Differences in quality of life related to other micturition symptoms and to defecation symptoms were not observed between both groups.

The observation of more discomfort of overactive bladder symptoms after abdominal surgery suggests that abdominal surgery is associated with more irritation of the bladder than vaginal surgery. Possibly, the tissue patch inserted during abdominal prolapse surgery, causes irritation of the bladder. For the observed differences in discomfort related to other micturition and prolapse symptoms, an acceptable explanation is not immediately available. Possibly, differences in damage to the pelvic floor muscle and its

innervation account for the observed difference, but further research is needed to support this.

Doctor visits because of problems related to the surgery and performed or planned repeated prolapse surgery within the first year, were also addressed in Chapter 7. Patients who had undergone abdominal surgery visited more often a doctor within the first year after surgery because of prolapse, micturition or defecation symptoms in comparison to patients who had undergone vaginal surgery. Repeated prolapse surgery was more often performed or planned in the abdominal group than in the vaginal group. The latter finding was surprising, as differences in findings at pelvic examination performed at regular follow-up visits, were not observed. Therefore, the difference in performance of repeated surgery most likely results from the difference in number of doctor visits within the first year after surgery.

During pelvic examinations performed at regular follow-up visits it was observed that both vaginal and abdominal surgical correction of descensus uteri, do not always succeed in successfully correcting the anterior vaginal wall defects involved. Over 30 % of all patients had a grade II or more cystocele at six months after surgery. It is perceivable that gynecologists relate the prolapse and micturition symptoms in patients with a cystocele grade II or more to the anatomical abnormalities. As a consequence, patients with cystocele grade II or more who present themselves with dysfunctional problems of the pelvic floor, have a high risk to be indicated for surgical correction of their cystocele.

It is more difficult to explain why similar findings at pelvic examination were observed in the vaginal and abdominal group, whereas differences in the prevalence and experienced discomfort of pelvic floor symptoms were observed. A possible explanation is that vaginal and abdominal prolapse surgery have different effects on the pelvic floor coordination. If abdominal prolapse surgery more severely impairs pelvic floor function, it is imaginable that patients of the abdominal group experience more or more severe pelvic floor symptoms. Future research can evaluate whether biofeedback therapy, intended to teach the patient how to coordinate the pelvic floor, reduces post-operative functional problems of the pelvic floor. A randomized trial comparing post-operative biofeedback therapy and no post-operative treatment, may support or deny this theory.

Another explanation may be the fact that gynecologists were not blinded for the surgical procedure that was performed. A priori expectations of gynecologists about the effectiveness of vaginal and abdominal prolapse surgery may have influenced the treatment of patients who return with prolapse, micturition and defecation symptoms. If the expectations of both techniques are different, the treatment of patients who return

with recurrent or persisting symptoms may also differ.

In Chapter 8 we studied the effects of genital prolapse surgery on sexuality. Not all patients were willing to fill out the Questionnaire for screening Sexual Dysfunctions (QSD).[21] Some felt the questions were too intimate. This may have influenced the generalizability of our findings.

Sexuality improved or did not change in most women after surgery for descensus uteri. In patients in whom a large cystocele was present before surgery, sexual problems disappeared more often in comparison to patients without cystocele. Apparently, sexuality in patients with a large cystocele is severely impaired by this cystocele. Surgical correction of such cystocele may therefore improve sexuality.

The vaginal operation to correct a descensus uteri grade II or more appeared to be less morbid than the abdominal one (Chapter 9). This conclusion is based on the finding that the vaginal approach was associated with less pain, better quality of life and better mobility during the first 6 weeks of the recovery period in comparison to the abdominal approach. These advantages of the vaginal procedure were not necessarily expected before the trial was initiated because both surgical procedures do not only differ with respect to the chosen surgical approach but also with respect to the removal of the uterus. Whereas the vaginal approach may be expected to be favorable because the abdomen is not opened, the abdominal approach may be expected to be favorable because the uterus is not removed. Apparently, the effect of the removal of the uterus is associated with fewer side-effects than the opening of the abdomen.

From our findings it may be concluded that vaginal surgical correction of descensus uteri grade II or more is preferable to abdominal surgical correction with respect to quality of life related to micturition symptoms, prolapse symptoms and recovery after surgery.

Additionaly, the abdominal procedure may have advantages in some patients with genital prolapse. The effects of abdominal and vaginal prolapse surgery on pelvic floor function in patients with vaginal vault prolapse have not been studied in a randomized trial. Furthermore, in some cases it was decided by the gynecologist to perform sacrocolpopexy and not propose the patient to participate in the randomized trial. If the gynecologists were successful in selecting those patients in whom sacrocolpopexy was indeed more successful than vaginal surgery, there is still a group of patients with descensus uteri who are better of with an abdominal approach.

Hysterectomy

When performing hysterectomy, similar limitations in choosing the optimal technique are present. Vaginal, total abdominal and subtotal abdominal hysterectomy are equally effective in treating the symptoms that founded their indication. Until now, the decision to perform hysterectomy by vaginal or abdominal surgical approach has mainly been influenced by studies reporting faster convalescence and lower costs of vaginal hysterectomy. The decision whether to remove the cervix or not during abdominal hysterectomy, has been based on inconclusive data suggesting that sexuality may benefit of preservation of the cervix. We studied the effects of vaginal, total abdominal and subtotal abdominal hysterectomy on bladder, bowel and sexual function.

In a retrospective study we compared the prevalence of micturition and defecation symptoms after different techniques of hysterectomy (Chapter 10). An increased prevalence of “urge incontinence” and “feeling of incomplete evacuation of the rectum” were observed among patients who had undergone vaginal hysterectomy in comparison to patients who had undergone total abdominal hysterectomy. The prevalence of “urge incontinence” and “difficulty emptying the rectum” was higher among patients who had undergone vaginal hysterectomy than among patients who had undergone subtotal abdominal hysterectomy. We explained the differences in the prevalence of urge-incontinence following different techniques of hysterectomy by a more extensive dissection of the bladder from the vagina during vaginal hysterectomy. The difference in the prevalence of “feeling of incomplete evacuation” and “difficulty emptying the rectum” may be explained by a difference in damage to the autonomic supply to the lower bowel. This part of the pelvic innervation is closely related to the cardinal and uterosacral ligaments and the upper third of the vagina.[23] Dissection of the paravaginal tissue leading to disruption of pelvic neurons passing from the lateral aspect of the vagina, may be more extensive during vaginal hysterectomy.

Because of the methodological limitations that are clearly related to a retrospective study design we also performed a prospective observational study in 13 hospitals to compare the effects of different techniques of hysterectomy on pelvic floor function (Chapter 11-12). The non-randomized design may have affected the validity of our findings, due to prognostic incomparability of the patients undergoing either one of the three techniques of hysterectomy. In order to deal with this problem, we documented all factors that are known to influence our outcome of interest. Statistical techniques allowed us to adjust for these factors. Our study was strengthened by the use of the same standardized assessments of micturition, defecation and sexuality before and after surgery in each patient.

In Chapter 11 we compared the effects of vaginal and abdominal hysterectomy on micturition and defecation in patients in whom both techniques were technically feasible. Abdominal hysterectomy increased the risk to report dysuria at 6 weeks after hysterectomy in comparison to vaginal approach, but not after 6 months. Because the difference in prevalence of dysuria between both groups appeared to exist during a short period only, we did not consider this finding to be of high clinical relevance. In comparison to abdominal hysterectomy, vaginal hysterectomy increased the risk to report stress incontinence at 6 months after surgery. This increased risk was present in both patients with and without stress incontinence before hysterectomy. We hypothesized that downwards traction of the uterus during vaginal hysterectomy causes trauma of the pelvic innervation by stretching the pudendal nerve. Because the pudendal nerve innervates the external urethral sphincter, this damage may result into stress incontinence.

Our prospective study did not confirm the results of our retrospective study which had a longer follow-up (Chapter 10). In the retrospective study, an increased prevalence of stress incontinence following vaginal hysterectomy was not observed. We hypothesized that stretching of the pudendal nerve caused by traction during vaginal hysterectomy, accounts for the increased prevalence of stress incontinence. Possibly, this damage is reversible, like the damage to the pudendal nerve that occurs during vaginal childbirth is often reversible.[24] However, the first results of the follow-up at one year after hysterectomy, also show an increased risk to report stress incontinence in patients who have undergone vaginal hysterectomy in comparison to patients who have undergone abdominal hysterectomy. We think that differences between both groups before hysterectomy that could not be controlled for in the retrospective study, can be held responsible for the discrepancy between the retrospective and prospective study.

When designing a study comparing the effects of vaginal and abdominal hysterectomy on micturition and defecation, we first chose for a randomized trial. Only few gynecologists were willing to participate in such a trial. Most gynecologists thought it was unethical to randomize their patients for vaginal or abdominal hysterectomy in the presence of evidence about the advantages of vaginal approach and the absence of evidence about advantages of abdominal approach.[25,26] The idea for a randomized trial was therefore abandoned, and an observational study was designed. We have now provided scientific evidence that patients in whom vaginal hysterectomy is feasible, may benefit of abdominal hysterectomy. Our findings may help convincing gynecologists to participate in a randomized trial comparing the effects of vaginal and abdominal hysterectomy on pelvic floor function.

Chapter 12 reports on the effects of vaginal hysterectomy, subtotal abdominal hysterectomy and total abdominal hysterectomy on sexual function. It was known that hysterectomy may affect sexuality[27-29], but the effects of technique of hysterectomy on sexuality have not extensively been studied. We found that removal of the cervix during abdominal hysterectomy did not appear to affect sexuality. A trend towards a beneficial effect of vaginal approach was observed in patients who have sexual problems before hysterectomy. Possibly, the differences in persistence of problems with lubrication and arousal can be explained by differences in characteristics between patients who udnerwent abdominal and vaginal hysterectomy. The prevalence of abdominal pain as indication for hysterectomy was higher in patients who underwent abdominal hysterectomy than in patients who underwent vaginal hysterectomy. Abdominal pain and sexual problems have been related to each other.[10] Possibly, these sexual problems are not solved by an abdominal hysterectomy as they are not related to the symptoms that led to the hysterectomy. Therefore a randomized trial will give a more valid answer to the question whether problems with lubrication and arousal persist as often after vaginal hysterectomy as after abdominal hysterectomy. The same accounts for the observed trend towards a higher prevalence of patients in whom problems with pain/sensation of genitals persisted after total abdominal hysterectomy than after vaginal hysterectomy.

Recommendations for clinical practice

Based on the studies described in this thesis and available literature, we think that the diagnostic work-up of patients undergoing surgical correction of descensus uteri should include urodynamic investigation in all patients who report urinary incontinence and in patients who are suspected of masked stress incontinence. It is advisable to extent the diagnostic work-up with a measurement of the rectal sensibility in patients who report constipation. Constipated patients with decreased rectal sensibility may benefit of biofeedback therapy before and/or after prolapse surgery, although this has not sufficiently been supported by evidence. Performing other ano-rectal function tests does not add to the understanding of the pathophysiology of reported defecation symptoms. Extending the diagnostic work-up with defecography, will not help to make a better choice for abdominal or vaginal surgery. If the gynecologist wants to be informed about the presence of an enterocele and/or rectal intussusception before starting surgery, he/she might as well attempt to predict the risk on one or both of these abnormalities with the prediction rule described in Chapter 3. This prediction rule makes it possible to predict the presence of an enterocele and/or rectal intussusception with non-invasive

methods.

In patients with descensus uteri grade II or more, vaginal hysterectomy combined with anterior and/or posterior colporraphy appears to be the treatment of choice, when compared to abdominal sacrocolpopexy with preservation of the uterus. Vaginal hysterectomy combined with anterior and/or posterior colporraphy is associated with less bothersome symptoms of obstructive micturition, overactive bladder, genital prolapse and obstructive micturition, as well as with faster convalescence in comparison to sacrocolopexy. Effects on sexuality of both techniques are similar.

With respect to sexuality after prolapse surgery, patients who have sexual problems before undergoing prolapse surgery, have about 50 % chance that these symptoms will disappear. Patients without sexual problems are not likely to develop sexual problems. Patients who have a large cystocele before surgery, may have a better chance that sexual symptoms disappear, in comparison to patients without a large cystocele.

With respect to hysterectomy, it is questionable whether a vaginal approach should always be pursued. The advantages of vaginal hysterectomy in comparison to abdominal hysterectomy with respect to faster convalescence, do not appear to exist in patients in whom both procedures are technically feasible. Effects of vaginal and abdominal hysterectomy on the function of the pelvic floor should be enrolled in the decision of which technique of hysterectomy is to be performed. Vaginal hysterectomy may increase the risk on stress incontinence in comparison to abdominal hysterectomy. With respect to defecation, no difference following vaginal and abdominal hysterectomy are to be expected. With respect to sexuality, all techniques of hysterectomy appear to increase satisfaction about sexuality and decrease the prevalence of sexual problem. In patients who have sexual problems before hysterectomy, a vaginal approach may have beneficial effects. Removal of the cervix during abdominal hysterectomy does not appear to affect sexuality.

The prevalence of micturition and defecation symptoms among patients who have undergone prolapse surgery or hysterectomy is high. Since for most of these symptoms of pelvic floor dysfunction non-invasive treatments are available (physiotherapy, behavioral therapy, anti-incontinence drugs, sanitary pads), it may be valuable to add an additional follow-up visit at one year after genital prolapse surgery or hysterectomy.

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Chapter 14

Summary

This thesis aims to evaluate the effects of genital prolapse surgery and hysterectomy on pelvic floor function. A normal pelvic floor function is required to allow normal micturition, defecation, sexuality and vaginal delivery. Both vaginal delivery and surgical trauma to the pelvic floor can negatively affect pelvic floor function. Genital prolapse surgery and hysterectomy can both be performed by vaginal or by abdominal approach. It is unknown if, and to what extent, both techniques equally damage the pelvic floor innervation and pelvic fibromuscular structures. If there is a difference in surgical trauma, the prevalence of micturition symptoms, defecation symptoms and sexual dysfunction may differ among patients following vaginal and abdominal surgery. Micturition symptoms, defecation symptoms and sexual dysfunction are all signs of impaired pelvic floor function. These symptoms may negatively affect the patient's quality of life. Gynecologists may be expected to attempt to reduce the negative influence of gynecological surgery on quality of life as much as possible. This can only be established by studying the effects of different types of genital prolapse surgery and hysterectomy on pelvic floor function.
An additional aim of this thesis is to investigate diagnostic characteristics of defecography and ano-rectal function tests. Knowledge about these diagnostic characteristics may contribute in investigating whether defecography and ano-rectal function tests improve outcome of surgical correction in patients with descensus uteri. These investigations have not yet been incorporated in the standard diagnostic work-up of patients with genital prolapse. The diagnostic value of urodynamic investigation has already been assessed, and is therefore not subject to investigation in this thesis.

In Chapter 1, the introduction, the background of this thesis is illuminated. Furthermore, the aims and outline of this thesis are given. The aims of this thesis are threefold:

1. To compare the effects of vaginal and abdominal surgical correction on pelvic floor function in patients with descensus uteri grade II-IV (ICS).
2. To compare the effects of technique of hysterectomy on pelvic floor function.
3. To assess diagnostic characteristics of defecography and ano-rectal function tests.

In *Chapter 2* the inconsistency is addressed between researchers about the scoring of defecographic findings. A new system to score rectocele, enterocele and rectal intussusception is proposed. In contrast to systems presented thusfar, this system involves both qualitative and quantitative measurements and focuses only on defecographic items that correlate well with clinical symptoms. The inter-observer

agreement of the new system was studied, and appeared to be almost perfect for all scored items. Intra-class Correlation Coefficients for quantitative measurements of rectocele, enterocele and rectal intussusception were repectively 0.87 (95 % lower confidence interval (CI) 0.82), 0.98 (95 % lower CI 0.96), and 0.84 (95 % lower CI 0.63). The weighted Kappa values for grade of enterocele and grade of rectal intussusception were respectively 0.97 (95 % CI 0.93 to 1.00) and 0.91 (95 % CI 0.79 to 1.00). The use of consistently and precisely identifiable radiographic landmarks in our system, may have importantly contributed to the observed good reproducibility. The diagnostic value of this scoring system needs to be studied, before this system can be used to ameliorate outcome of treatment.

In *Chapter 3* we evaluated whether the presence of abnormal defecographic findings can be predicted with the quantified value of findings from patient history, pelvic examination and a validated questionnaire to assess the presence of defecation symptoms (Defecation Distress Inventory). We defined a defecography as abnormal in case an enterocele and/or rectal intussusception were detected. Using multivariate logistic regression analyses with Receiver Operating Characteristic (ROC) curves, a diagnostic model to predict the presence of an abnormal defecography was systematically constructed and validated. A prediction rule (3 + 3*history of pelvic surgery + quantification value (QV) of rectocele + 3*constipation) could be constructed that confidently predicts the presence of an abnormal DRE (Area Under Curve = 0.73 (95 % CI : 0.61 – 0.83)). This constructed diagnostic model provides the possibility to better consider the decision to demand for defecography in the individual patient.

In *Chapter 4* the associations are evaluated between defecation symptoms and findings at ano-rectal function tests in patients who are candidate for genital prolapse surgery. In 83 patients with descensus uteri grade II-IV (ICS classification) ano-rectal function tests were performed and the presence of constipation and fecal incontinence was assessed by a validated questionnaire. The prevalence of these defecation symptoms was compared between different levels of the ano-rectal function tests. Constipation was present in 7 (8.4 %) patients and fecal incontinence in 16 (19.3 %) patients. The prevalence of constipation was 17.9 % in the upper tertile, 0 % in the middle tertile and 7.7 % in the lower tertile of threshold for rectal sensibility ($\div^2$ test $p < 0.05$). Defecation symptoms were not associated with any of the other ano-rectal function tests. It was concluded that, except for the significant association between decreased rectal sensibility and constipation,

findings at ano-rectal function tests appeared to be weakly associated with constipation or fecal incontinence in patients with genital prolapse.

In *Chapter 5* the effects of genital prolapse surgery on bowel function are studied. In 73 patients participating in a randomized trial comparing vaginal and abdominal surgical correction of descensus uteri, defecography and ano-rectal function tests were performed before and at six months after surgery. Patients completed a validated questionnaire before and at six months after surgery, to assess the presence of persisting and developing defecation symptoms. Except for constipation, that disappeared in nearly all patients, all defecation symptoms reported before surgery disappeared in about half of the patients. Feelings of distension of the rectum were accelerated in patients in whom soiling and flatus incontinence persisted, in comparison to patients in whom these symptoms disappeared. The prevalence of all de novo defecation symptoms was lower than 15 %, except for incomplete evacuation and sensation of anal blockage which developed in 24.5 % respectively 22.7 % of the patients. In contrast to patients in whom these symptoms did develop, pudendal nerve terminal motor latency (PNTML) decreased after surgery in patients in whom these symptoms did not develop.

In *Chapter 6* the results are described of a retrospective study performed to compare micturition, defecation and prolapse symptoms among 47 patients who underwent a unified vaginal or abdominal surgical correction of descensus uteri and coexisting stress incontinence. A second aim of this study is to compare duration of hospital stay and complication rate between both groups. Abdominal surgery was associated with a higher prevalence of difficulty emptying bladder (odds ratio (OR) 2.3 (95% CI 1.4-8.4)), fecal incontinence (OR 3.4, CI 1.1-10.7) and soiling (OR 2.8, CI 1.2-6.2), as well with a longer post-operative hospital stay (8.6 vs 7.3 days) and higher complication rate (25.0 % vs. 11.4 %) in comparison to vaginal surgery. These results suggest that a unified vaginal surgical correction of genital prolapse and coexisting stress incontinence appears to be preferable to a unified abdominal surgical correction.

In *Chapter 7* we report on the results of a multi-center randomized trial comparing the effects of vaginal and abdominal surgical correction of descensus uteri on micturition and defecation. Additionally, the number of doctor visits within the first year after surgery and recurrence rates are compared between both groups. Vaginal surgery involved vaginal

hysterectomy combined with anterior and/or posterior colporraphy. Abdominal surgery involved sacrocolpopexy. Both procedures were combined with a bladder neck suspension in patients in whom evident or masked stress incontinence was observed at urodynamic investigation. To measure the presence and discomfort of micturition and defecation symptoms, 82 participating patients were asked to complete the urogenital distress inventory (UDI), defecation distress inventory (DDI) and incontinence impact questionnaire (IIQ), both before and after surgery. Scores on the UDI discomfort/pain domain ($p = 0.01$), overactive bladder domain ($p = 0.02$), genital prolapse domain ($p=0.02$) and obstructive micturition domain ($p=0.04$) of the UDI were during the first year after surgery higher in the abdominal group than in the vaginal group. DDI domain scores, IIQ domain scores and findings at pelvic examination were similar in both groups. Patients who had undergone abdominal surgery visited more often a doctor within the first year after surgery because of prolapse, micturition or defecation symptoms than patients who had undergone vaginal surgery. Repeated prolapse surgery was performed or planned in 9 (22.9 %) patients who had undergone abdominal surgery and in 1 (2.4 %) patient who had undergone vaginal surgery (Fishers Exact Test $p = 0.01$). It was concluded that vaginal hysterectomy with anterior and/or posterior colporraphy appears preferable above abdominal sacrocolpopexy with preservation of the uterus, as surgical correction of patients with descensus uteri.

In *Chapter 8* the effects of prolapse surgery on sexual function are evaluated. All patients participating in the previously described randomized trial (Chapter 7), were asked to complete the Questionnaire for screening Sexual Dysfunctions (QSD) before surgery and six months and one year after surgery. In 62 patients who participated in this study, general satisfaction was statistically significantly improved at six months after surgery but not at one year after surgery. Of 41 patients who were sexually active before surgery and at one year after surgery, 28 (68.3 %) patients reported sexual problems before surgery. In 13 (46.4 %) patients, all sexual problems disappeared. De novo sexual problems were reported by 2 patients of the 13 patients without sexual problems before surgery. Disappearance of sexual problems was associated with grade of cystocele. The relative risk of patients with cystocele grade II or III in comparison to patients without cystocele grade II or III on disappearance of sexual problems was 1.5 (95 % confidence interval 1.1-2.1). Differences in other characteristics between patients in whom sexual problems persisted and disappeared were not observed.

In *Chapter 9* a study is described comparing pain, quality of life and physical performance during the first six weeks after surgery, between patients undergoing vaginal and abdominal surgical correction of descensus uteri. Data were obtained from the randomized trial described in Chapter 7. All patients were asked to fill out the RAND-36 before surgery and 6 weeks after surgery. Additionaly, during the first 6 weeks after surgery, they answered questions to assess pain perception, amount of administered pain medication per day, presence and experienced bother of limitations during hospital stay and performance of daily activities. Patients who had undergone abdominal surgery had a statistically lower score on the health change domain (56 vs 68), bodily pain domain (63 vs 80) and mental health domain (74 vs 81) of the RAND-36, in comparison to patients who had undergone vaginal prolapse surgery. During hospital stay, the abdominal group experienced on average more days of pain (4.5 vs 3.0) and impaired mobility (3.7 vs 2.9) in comparison to the vaginal group. Pain medication during the first week of surgery was given longer (5.5 days vs 4.1 days) and in higher dosages (1943 mg of paracetamol daily vs 1334 mg) to patients who underwent abdominal surgery than to patients who underwent vaginal surgery. It was concluded that the vaginal operation to correct a descensus uteri grade II or more, is less morbid than the abdominal one.

In *Chapter 10* the results are described of a retrospective study comparing the effcts of different techniques of hysterectomy on micturition and defecation. Two-hundred-and-twenty-seven patients without micturition and defecation symptoms before surgery in whom uteral length was 10 cm or less, completed the UDI and DDI. All potential confounders were documented as completely as possible. Using multivariate logistic regression analysis, adjusted odds ratios (ORs) were calculated for all symptoms of which the prevalence between techniques of hysterectomy differed more than 10 %. An increased prevalence of urge incontinence (adjusted OR 1.5 (95 % CI 0.8-3.1)) and feeling of incomplete evacuation of the recrum (adjusted OR 1.9 (95 % CI 1.0-4.0)) was observed among patients who had undergone vaginal hysterectomy in comparison to patients who had undergone total abdominal hysterectomy. The prevalence of urge incontinence (adjusted OR 1.8 (95 % CI 0.8-4.2)) and difficulty emptying rectum (adjusted OR 1.8 (95 % CI 0.7-4.4)) was higher among patients who had undergone vaginal hysterectomy than among patients who had undergone subtotal abdominal hysterectomy. It was concluded that technique of hysterectomy may influence the prevalence of micturition and defecation symptoms following hysterectomy.

In *Chapter 11* the results are described of a multi-center prospective observational study comparing morbidity, success and prevalence of micturition and defecation symptoms after vaginal and after abdominal hysterectomy. Hundred-and-ninety-four patients in whom both techniques were technically feasible completed the UDI and DDI before surgery and at 6 weeks and 6 months after surgery. Using multivariate logistic regression analysis, adjusted odds ratio's (OR) were calculated to study whether surgical route is independently associated with micturition and defecation symptoms. Abdominal approach (n=112) increased the risk to report dysuria at 6 weeks after hysterectomy in comparison to vaginal approach (n=82) (adjusted OR 3.0 (95 % CI 1.0-8.8)), but not after 6 months. Vaginal approach increased the risk to report stress incontinence at 6 months after hysterectomy in comparison to abdominal approach (adjusted OR 1.8 (95 % CI 0.8-3.7)). This increased risk was present in both patients with and without stress incontinence before hysterectomy. The prevalence of post-operatively reported defecation symptoms, morbidity and reported success of hysterectomy were similar in both groups. It was concluded that vaginal hysterectomy may increase the risk on persistence or development of stress incontinence in comparison to abdominal hysterectomy.

In *Chapter 12* we report on a multi-center prospective observational study evaluating the effects of different techniques of hysterectomy on sexuality. All participating patients were asked to complete the Questionnaire for screening Sexual Dysfunctions (QSD) before and six months after hysterectomy. Sexual satisfaction statistically significantly improved in all patients, independently of the performed technique of hysterectomy. Of patients who were sexually active before as well as six months after surgery, 89 patients underwent vaginal hysterectomy, 76 patients underwent subtotal abdominal hysterectomy and 145 patients underwent total abdominal hysterectomy. An increased prevalence of persisting problems with lubrication (adjusted OR 2.6 (95 % CI 0.6-10.2)) and problems with arousal (adjusted OR 2.1 (95 % CI 0.6-7.8)) was observed among patients who had undergone abdominal hysterectomy in comparison to patients who had undergone vaginal hysterectomy. The prevalence of persisting problems with pain/sensation of the genitals (adjusted OR 1.8 (95 % CI 0.8-4.2)) was higher among patients who had undergone total abdominal hysterectomy than among patients who had undergone vaginal hysterectomy. It was concluded that removal of the cervix during abdominal hysterectomy did not appear to affect sexuality. Vaginal approach may have beneficial effects in patients with sexual problems before hysterectomy.

In Chapter 13, the general discussion, the most important findings of this thesis are discussed, questions for future research are pointed out and recommendations for clinical practice are given. The most important implications are the following: At moment, there is no evidence that defecography and ano-rectal function tests should be incorporated in the standard diagnostic work-up of patients undergoing surgical correction of descensus uteri. In patients with descensus uteri, gynecologists can use a diagnostic model, based on findings obtained from a non-invasive work-up, to accurately predict the presence of an enterocele and/or rectal intussusception.

Vaginal hysterectomy with anterior and/or posterior colporraphy appears to be preferable above abdominal sacrocolpopexy with preservation of the uterus, as surgical correction of patients with descensus uteri. Sexuality improves or does not change in most women after surgery for descensus uteri. The presence of a large cystocele before surgery may enhance the chance on disappearance of sexual problems after prolapse surgery. The observed differences between vaginal and abdominal surgery may be explained by a difference in surgical approach but also by a difference in whether the uterus is removed or not. A randomized trial comparing vaginal surgery with removal of the uterus and vaginal surgery with preservation of the uterus is planned.

Performing vaginal hysterectomy should not always be a goal when performing hysterectomy. Both data from a retrospective and of a prospective study suggest that abdominal hysterectomy may be beneficial with respect to the effects on bladder and bowel function in comparison to vaginal hysterectomy. A randomized trial comparing the effects of vaginal and abdominal hysterectomy on micturition and defecation is warranted. Removal of the cervix during abdominal hysterectomy does not appear to affect sexuality. Vaginal approach may have beneficial effects in patients who have sexual problems before hysterectomy.

Chapter 15

Samenvatting

Dit proefschrift handelt over de gevolgen van gynaecologische operaties voor de functie van de bekkenbodem. De gynaecologische operaties die worden bestudeerd zijn operaties vanwege een verzakking (vanaf nu prolaps operatie genoemd) en operaties waarbij de baarmoeder wordt verwijderd (vanaf nu uterus extirpatie genoemd). Een goede functie van de bekkenbodem is belangrijk voor een goede mictie, defaecatie, seksualiteit en vaginale baring. Zowel vaginale baring als chirurgische trauma's van de bekkenbodem kunnen de functie van de bekkenbodem nadelig beinvloeden. Prolaps operaties en uterus extirpaties kunnen via de vagina en via de buik worden uitgevoerd. Het is onbekend of, en in hoeverre, beide technieken in gelijke of ongelijke mate schade toebrengen aan de zenuw voorziening en aan bindweefsel structuren van de bekkenbodem. Indien er een verschil is, dan moet dit blijken uit de veranderingen in functie zoals problemen met het plassen, ontlasten en de seksualiteit. Problemen met het plassen, ontlasten en de seksualiteit zijn allemaal tekenen van een verstoorde bekkenbodem functie. Deze problemen kunnen de kwaliteit van leven negatief beinvloeden. Het mag van gynaecologen worden verwacht dat zij de negatieve invloed van problemen met het functioneren van de bekkenbodem op de kwaliteit van leven zoveel mogelijk trachten te beperken. Dit kan alleen maar bereikt worden door het bestuderen van de gevolgen die verschillende technieken van prolaps operaties en uterus extirpaties hebben voor de functie van de bekkenbodem.
Een ander doel van dit proefschrift is het bestuderen van diagnostische karakteristieken van defecografie en ano-rectaal functie onderzoek. Meer kennis over deze diagnostische karakteristieken kan bijdragen in het onderzoeken of defecografie en ano-rectaal functie onderzoek de behandel resultaten van prolaps operaties verbeteren. Defecografie en ano-rectaal functie onderzoek maken momenteel nog geen deel uit van het standaard diagnostisch onderzoek bij patiënten met een prolaps van de baarmoeder. Het nut van het verrichten van blaasfunctie onderzoek is reeds uitvoerig bestudeerd en wordt daarom niet nader bestudeerd in dit proefschrift.

In *Hoofdstuk 1*, de introductie, wordt de achtergrond van dit proefschrift uitgebreid uiteen gezet. Ook worden de doelstellingen en het plan van aanpak beschreven. De doelstellingen van dit proefschrift zijn drieledig:

1. Het vergelijken van de gevolgen die vaginale en abdominale operatieve correctie van een uterus prolaps graad II-IV (ICS) hebben voor de functie van de bekkenbodem.
2. Het vergelijken van de gevolgen die verschillende technieken van het verwijderen van de baarmoeder hebben voor de functie van de bekkenbodem.
3. Het onderzoeken van diagnostische eigenschappen van defecografie en ano-rectaal functie onderzoek.

In *Hoofdstuk 2* wordt een oplossing gezocht voor het gebrek aan eenduidigheid tussen wetenschappers over de classificatie van defecografische bevindingen. En nieuw systeem voor de classificatie van rectocele, enterocele en intussusceptie wordt gepresenteerd. In tegenstelling tot de bestaande systemen, bevat dit nieuwe systeem zowel kwalitatieve als kwantitatieve metingen en richt het zich alleen maar op klinisch relevante afwijkingen. Van dit nieuwe classificatie systeem wordt de reproduceerbaarheid van metingen door verschillende beoordelaars bestudeerd. Intra-class Correlatie Coefficienten voor kwantitatieve metingen van rectocele, enterocele en intussusceptie waren respectievelijk 0.87 (ondergrens 95 % betrouwbaarheids interval (BI) 0.82), 0.98 (ondergrens 95 % BI 0.96), en 0.84 (ondergrens 95 % BI 0.63). De gewogen Kappa waardes voor enterocele graad en intussuecptie graad waren respectievelijk 0.97 (95 % BI 0.93-1.00) en 0.91 (95 % BI 0.79-1.00). Het gebruik van consistent en precies identificeerbare radiologische herkennings punten, heeft mogelijk in belangrijke mate bijgedragen aan de gevonden goede reproduceerbaarheid. De diagnostische waarde van dit classificatie systeem moet worden bestudeerd, voordat dit systeem kan bijdragen aan een verbeterde uitkomst van behandeling.

In *Hoofdstuk 3* wordt onderzocht of de aanwezigheid van een afwijkend defecogram voorspeld kan worden aan de hand van gegevens die verkregen zijn via niet-invasieve methoden. Deze methoden zijn anamnese, gynaecologisch onderzoek en een vragenlijst om de aanwezigheid en ondervonden hinder van defaecatie symptomen te meten (Defaecatie Klachten Lijst (DKL). Een defecogram werd als afwijkend beschouwd indien deze een enterocele en/of intussusceptie liet zien. Met behulp van multivariate logistische regressie analyse met Receiver Operating Characteristics (ROC) curves, werd een diagnostisch model geconstrueerd en gevalideerd. Dit model kan de kans op een afwijkend defecogram voorspellen. Een predictie formule (3 + 3*voorgeschiedenis van bekken chirurgie (ja=1) + gekwantificeerde waarde van rectocele + 3*constipatie (ja=1)) kon worden gedefinieerd welke betrouwbaar de aanwezigheid van een abnormaal defecogram voorspelt (Oppervalk onder de ROC curve = 0.93 (95 % BI 0.61-0.83). Dit diagnostische model maakt het mogelijk om per patient te overwegen of een defecogram wel of niet wordt aangevraagd.

In *Hoofdstuk 4* worden de relaties tussen defaecatie symptomen en bevindingen bij ano-rectaal functie onderzoek onderzocht in patiënten die een prolaps operatie zullen ondergaan. In 83 patiënten met een uterus prolaps graad II-IV (ICS) werd ano-rectaal functie onderzoek verricht en werd met een vragenlijst vastgesteld of obstipatie en/of faecale incontinentie aanwezig waren. De prevalentie van deze defaecatie symptomen

werd vergeleken tussen verschillende niveaus in de resultaten van ano-rectaal functie onderzoek. Obstipatie was aanwezig bij 7 (8.4 %) patiënten en faecale incontinentie bij 16 (19.3 %) patiënten. De prevalentie van obstipatie was 17.9 % in het bovenste tertiel, 0 % in het middelste tertiel en 7.7 % in het laagste tertiel van drempel waarde voor rectale sensibiliteit (÷² test $p < 0.05$). Andere relaties tussen defaecatie symptomen en bevindingen bij ano-rectaal functie onderzoek werden niet gevonden. Wij concludeerden dat, buiten de statistische significante relatie tussen verminderde rectale sensibiliteit en obstipatie, geen duidelijke relaties bestaan tussen defaecatie symptomen en resultaten van ano-rectaal functie onderzoek. Het meten van rectale sensibiliteit bij geobstipeerde patiënten met een uterus prolaps zou zinvol kunnen zijn, omdat de bevinding van een verminderde rectale sensibiliteit mogelijk betekent dat biofeedback therapie een goed resultaat heeft.

In *Hoofdstuk 5* worden de gevolgen beschreven die prolaps operaties hebben voor de defaecatie. Bij 73 patiënten werden defecogrammen en ano-rectale functie onderzoeken verricht vóór en 6 maanden na operatie. Alle patiënten namen deel aan een gerandomiseerde trial waarin de vaginale en de abdominale operatieve correctie van een uterus prolaps werden vergeleken. Patiënten vulden voor en 6 maanden na operatie een vragenlijst in om vast te stellen hoe vaak defaecatie symptomen bleven bestaan of zich ontwikkelden na afloop van de operatie. Behalve obstipatie, dat in bijna alle patiënten verdween, verdwenen defaecatie symptomen die werden gemeld vóór de operatie in ongeveer de helft van de patiënten. Aandranggevoelens voor defaecatie waren, ten opzichte van voor de operatie, versneld bij patiënten bij wie symptomen van soiling en flatus incontinentie aanwezig bleven na de operatie, vergeleken met patiënten bij wie deze symptomen verdwenen. De prevalentie van alle de novo defaecatie symptomen was lager dan 15 %, behalve gevoel van incomplete evacuatie en gevoel van loze aandrang. Deze symptomen ontstonden in 24.5 % respectievelijk 22.7 % van de patiënten. In tegenstelling tot de patiënten bij wie deze symptomen zich post-operatief ontwikkelden, was de nervus pudendus geleidings tijd verkort in patiënten bij wie deze symptomen zich niet ontwikkelden.

In *Hoofstuk 6* worden de resultaten beschreven van een retrospectieve studie die als doel heeft om mictie, defaecatie en prolapse symptomen te vergelijken tussen patiënten die via de vagina en patiënten die via de buik worden geopereerd vanwege een uterus prolaps en stress incontinentie. Een tweede doel van deze studie is om de opname duur en complicaties te vergelijken tussen beide groepen. Abdominale chirurgie ging gepaard met het vaker voorkomen van moeizame blaas ontlediging (odds ratio (OR) 2.3 (95% BI 1.4-8.4)), faecale incontinentie (OR 3.4, CI 1.1-10.7) en soiling (OR 2.8, CI 1.2-6.2), en met

een langere opname duur (8.6 vs 7.3 dagen) en hoger complicatie percentage (25.0 % vs. 11.4 %) vergeleken met vaginale chirurgie. Deze resultaten suggereren dat patiënten die geopereerd worden vanwege een uterus prolaps in combinatie met stress incontinentie beter af zijn met een vaginale operatie dan met een abdominale operatie.

In *Hoofdstuk 7* worden de resultaten van een multi-center uitgevoerd gerandomiseerd onderzoek beschreven. In dit onderzoek worden de mictie, prolaps en defaecatie symptomen vergeleken tussen patiënten die een abdominale en vaginale operatieve correctie van een uterus prolaps hebben ondergaan. Tevens worden het aantal dokters bezoeken en het recidief percentage in het eerste jaar na de operatie vergeleken tussen beide groepen. Vaginale chirurgie bestond uit een vaginale uterus extirpatie met voorwand en/of achterwand plastiek. Abdominale chirurgie bestond uit een sacrocolpopexie. Beide ingrepen werden gecombineerd met een blaashals suspensie in patiënten bij wie urodynamisch onderzoek evidente of gemaskeerde stress incontinentie liet zien. Om het voorkomen en de mate van ondervonden hinder van mictie en defaecatie symptomen te meten, werd aan de 82 deelnemende patiënten gevraagd om de urogenitale klachten lijst (UKL), defaecatie klachten lijst (DKL) en incontinentie impact lijst (IIL) in te vullen voor en na operatie. Scores op het ongemak/pijn domein ($p=0.01$), overactieve blaas domein ($p=0.02$), prolaps domein ($p=0.02$) en obstructieve mictie domein ($p=0.04$) van de UKL waren gedurende het eerste jaar na de operatie hoger in de abdominale groep dan in de vaginale groep. DKL en IIL domein scores en bevindingen bij gynaecologisch onderzoek 6weken, 6 maanden en 1 jaar na operatie waren vergelijkbaar in beide groepen. Patiënten die abdominaal waren geopereerd bezochten in het eerste jaar na de operatie vaker een dokter vanwege prolaps, mictie en defaecatie klachten dan patiënten die vaginaal waren geopereerd. Een prolaps operatie was opnieuw uitgevoerd of gepland in 9 (22.9 %) van de patiënten die abdominaal waren geopereerd en in 1 (2.4 %) van de patiënten die vaginaal waren geopereerd (Fishers Eact Test $p=0.01$). Wij concludeerden dat vaginale uterus extirpatie met voorwand en/of achterwand plastiek is te prefereren boven sacrocolopexie met behoud van de uterus, als operatieve correctie van een uterus prolaps.

In *Hoofdstuk 8* worden de gevolgen van prolaps chirurgie voor de seksualiteit geëvalueerd. Alle patiënten die deelnamen aan de gerandomiseerde trial beschreven in hoofdstuk 7 werd gevraagd om de Vragenlijst voor het signaleren van Seksuele Disfuncties (VSD) in te vullen voor en 6 maanden en 1 jaar na operatie. De algemene tevredenheid over de seksualiteit was statistisch significant verbeterd in de 62 patiënten die deelnamen aan dit onderzoek. Van de 41 patiënten die seksueel actief waren vóór en 1 jaar na operatie, vermeldden vóór de operatie 28 (68.3 %) patiënten seksuele problemen te hebben. Bij 13 (46.4 %) van hen waren na de operatie alle seksuele problemen verdwenen. Seksuele

problemen ontstonden bij 2 van de 13 patiënten die geen seksuele problemen hadden voor de operatie. Het verdwijnen van seksuele problemen was gerelateerd aan de grootte van cystocele voor operatie. Het relatief risico op het verdwijen van seksuelen klachten van patiënten met een graad 2 of 3 cystocele vergeleken met patiënten die geen graad 2 of 3 cystocele hadden, was 1.5 (95 % BI 1.1-2.1). Er werden geen andere verschillen gevonden in karakteristieken van patiënten die seksuele problemen hielden en patiënten bij wie deze problemen verdwenen.

In *Hoofdstuk 9* worden pijn, kwaliteit van leven en fysiek functioneren gedurende de eerste 6 weken post-oparatief vergeleken tussen patiënten die via de buik of via de vagina werden geopereerd vanwege een uterus prolaps. Data voor deze vergelijking werden verkregen uit de gerandomiseerde trial beschreven in hoofdstuk 7. Aan alle patiënten werd gevraagd om de RAND-36 in te vullen voor de operatie en 6 weken na de operatie. Tevens beantwoordden deelnemende patiënten vragen over pijn perceptie, gebruikte pijn medicatie, ervaren beperkingen tijdens de opname en het vermogen om dagelijkse activiteiten te verrichten. Patiënten die abdominaal waren geopereerd hadden een statistisch significant lagere score op het gezondheids veranderingen domein (56 vs 68), pijn domein (63 vs 80) en mentale gezondheid domein (74 vs 81) van de RAND 36, vergeleken met patiënten die vaginaal waren geopereerd. Gedurende opname had de abdominale groep meer dagen pijn (4.5 vs 3.0) en verminderde mobiliteit (3.7 vs 2.9) dan de vaginale groep. Pijn medicatie werd door de abdominale groep langer gebruikt (5.5 dagen vs 4.1 dagen) en in hogere doseringen (1943 mg paracetamol per dag vs 1334 mg per dag), dan de vaginale groep. De conclusie werd getrokken dat reconvalescentie na de vaginale operatieve correctie van descensus uteri graad II of meer beter is dan na de abdominale behandeling.

In *Hoofdstuk 10* worden de resultaten beschreven van een retrospective studie naar de gevolgen van verschillende technieken van uterus extirpatie op mictie en defaecatie. De UKL en DKL werden door 227 patiënten ingevuld die een uterus extirpatie hadden ondergaan en bij wie de baarmoeder niet groter was dan 10 centimeter. Potentiele confounders werden zo compleet mogelijk gedocumenteerd. Door middel van multivariate logistische regressie analyse werden gecorrigeerde odds ratio's berekend voor alle mictie en defaecatie symptomen waarvan de prevalentie meer dan 10 % verschilden van elkaar. Een verhoogde prevalentie van urge incontinentie (gecorrigeerde OR 1.5 (95 % BI 0.8-3.1)) en een gevoel van incomplete blaas ontlediging (gecorrigeerde OR 1.9 (95 % BI 1.0-4.0)) werd waargenomen onder patiënten die een vaginale uterus extirpatie hadden ondergaan vergeleken met patiënten die een totale abdominale uterus extirpatie hadden ondergaan. De prevalentie van urge incontinentie (gecorrigeerde OR 1.8 (95 % CI

0.8-4.2)) en moeizame rectum ontlediging (gecorrigeerde OR 1.8 (95 % BI 0.7-4.4)) was hoger onder patiënten die een vaginal uterus extirpatie hadden ondergaan dan onder patiënten die een subtotale abdominale uterus extirpatie hadden ondergaan. Wij concludeerden dat de techniek van uterus extirpatie van invloed is op het voorkomen van mictie en defaecatie symptomen post-operatief.

In *Hoofdstuk 11* worden de resultaten van een multi-center uitgevoerd prospectief onderzoek beschreven. In dit onderzoek worden morbiditeit, succes en de gevolgen voor mictie en defaecatie van een vaginale en abdominale uterus extirpatie met elkaar vergeleken. De UKL en DKL werden voor en 6 weken en 6 maanden na de operatie ingevuld door 194 patiënten bij wie de vaginale en abdominale benadering beide technisch mogelijk waren. Door middel van multivariate logistische regressie analyse werden gecorrigeerde odds ratio's (OR) berekend die het mogelijk maken te bestuderen of de relatie tussen operatieve route en het voorkomen van mictie en defaecatie symptomen onafhankelijk is van andere factoren. Een abdominale operatieve benadering (n=112) verhoogde het risico op dysurie 6 weken na de operatie in vergelijking met de vaginale operatieve benadering (gecorrigeerde OR 3.0 (95 % BI 1.0-8.8)), maar niet na 6 maanden. De vaginale benadering verhoogde het risico op stress incontinentie 6 maanden na de uterus extirpatie vergeleken met een abdominale benadering (gecorrigeerde OR 1.8 (95 % BI 0.8-3.7)). Dit verhoogde risico bestond zowel in patiënten met als zonder stress incontinentie voor de uterus extirpatie. De prevalentie van post-operative defaecatie symptomen, de morbiditeit en het gerapporteerde succes van de ingreep waren vergelijkbaar tussen beide groepen. Er werd geconcludeerd dat een vaginale uterus extirpatie mogelijk het risico op het blijven bestaan of ontwikkelen van stress incontinentie vergroot, vergeleken met een abdominale uterus extirpatie.

In *Hoofdstuk 12* worden de gegevens van een multi-center prospectief onderzoek beschreven. Dit onderzoek bestudeert de gevolgen van verschillende technieken van uterus extirpatie voor de seksualiteit. Alle deelnemende patiënten werd gevraagd om de Vragenlijst voor het signaleren van Seksuele Disfuncties (VSD) in te vullen voor en 6 maanden na operatie. De algemene tevredenheid over de seksualiteit was statistisch significant verbeterd in alle patiënten, ongeacht de operatieve techniek die gebruikt was. Van de patiënten die seksueel actief waren voor en 6 maanden na de operatie ondergingen er 89 patiënten een vaginale uterus extirpatie, 76 patiënten een subtotale abdominale uterus extirpatie en 145 een totale abdominale uterus extirpatie. Een verhoogde prevalentie van persisterende problemen met lubricatie (gecorrigeerde OR 2.6 (95 % BI 0.6-10.2)) en problemen met de opwinding (gecorrigeerde OR 2.1 (95 % BI 0.6-7.8)) werd waargenomen onder patiënten die een abdominale uterus extirpatie hadden ondergaan in

vergelijking tot patiënten die en vaginale uterus extirpatie hadden ondergaan. Problemen met pijn/gevoel van de geslachtsdelen persisteerden vaker (gecorrigeerde OR 1.8 (95 % BI 0.8-4.2)) in patiënten die een abdominale uterus extirpatie hadden ondergaan dan in patiënten die een vaginale uterus extirpatie hadden ondergaan. Wij concludeerden dat het verwijderen van de cervix tijdens abdominal uterus extirpatie de seksualiteit niet beinvloedt. Vaginale uterus extirpatie heeft mogelijk een postief effect op de seksualiteit in patiënten die pre-operatief seksuele problemen hebben.

In *Hoofdstuk 13*, de algemene discussie, worden de belangrijkste bevindingen van dit proefschrift bediscussieerd, vraagstellingen voor toekomstig onderzoek uiteen gezet en aanbevelingen voor het klinisch handelen gegeven. De belangrijkste implicaties van ed beschreven studies zijn de volgende: Op dit moment is er geen bewijs dat het verrichten van een defecogram en van een ano-rectaal functie onderzoek onderdeel moet worden van het standaard diagnostisch onderzoek van patiënten die geopereerd worden vanwege een uterus prolaps. Bij patiënten die een uterus prolaps hebben, kunnen gynaecologen gebruik maken van een diagnostisch model, gebaseerd op bevindingen verkregen van niet-invasieve methoden, om nauwkeurig de kans op de aanwezigheid van een enterocele en/of rectal intussusceptie te voorspellen.
Vaginale hysterectomie met voorwand en/of achterwandplastiek is te prefereren boven sacrocolpopexy met behoud van de uterus, als operatieve behandeling van een uterus prolaps. Na een prolapse operatie verbetert de seksualiteit of blijft onveranderd bij de meeste vrouwen. De aanwezigheid van een grote cystocele voor de operatie kan de kans vergroten op het verdwijnen van seksuele problemen na prolaps operaties. De gevonden verschillen tussen vaginale en abdominale prolaps operaties kunnen te wijten zijn aan de gekozen operatieve route maar ook aan het wel of niet verwijderen van de baarmoeder. Een gerandomiseerd onderzoek om vaginale prolaps chirurgie met en zonder verwijderen van de baarmoeder te vergelijken wordt momenteel voorbereid.
Het altijd nastreven van een vaginale benadering bij het verrichten van een uterus extirpatie zou niet een doel op zich moeten zijn. Zowel gegevens uit retrospectief als prospectief onderzoek suggereren dat het verrichten van een abdominale uterus extirpatie voordelig zou kunnen zijn met betrekking tot de mictie en defaecatie, zelfs als een vaginale extirpatie mogelijk is. Het is aan te bevelen om in een gerandomiseerd onderzoek de gevolgen voor mictie en defaecatie die vaginale en abdominale uterus extirpaties hebben, te onderzoeken. Verwijdering van de cervix tijdens abdominal uterusextirpatie lijkt de seksualiteit niet te beinvloeden. Patiënten die vóór een uterus extirpatie seksuele problemen hebben zijn mogelijk beter af met een vaginale benadering.

Symptom	Domain	Question
Micturition symptoms		
Frequency	OAB	Do you experience frequent urination?
Urgency	OAB	Do you experience a strong feeling of urgency to empty your bladder?
Stress inconinence	Urinary Inc	Do you experience urine leakage related to physical activity, coughing or sneezing?
Urge incontinence	Urinary Inc	Do you experience urine leakage related to the feeling of urgency?
Dysuria	Discomfort	Do you experience pain when urinating?
Difficulty emptying bladder **	Obstructive	Do you experience difficulty emptying your bladder?
		Do you experience a feeling of incomplete bladder emptying?
Prolapse symptoms		
Feeling of genital prolapse	Prolapse	Do you experience a feeling of vaginal protrusion?
Protrusion of genital prolapse	Prolapse	Have you seen a vaginal protrusion?
Defecation symptoms		
Constipation *	Const / Obst	Do you have less than 3 bowel movements a week?
		Do you have to strain > 25 % of the time to have a bowel movement?
Feeling of incomplete evacuation	Const / Obst	Do you experience a feeling of incomplete evacuation after a bowel movement?
Sensation of anal blockage	Const / Obst	Do you ever experience a sensation of anal blockage when you have your bowel movement?
Difficulty emptying rectum **	Const / Obst	Do you ever have to remove feces manually out of the rectum?
		Do you ever have to push on the vaginal wall to have bowel movement?
Painful defecation **	Painful Def	Do you experience pain related to urgency for bowel movement?
		Do you experience pain during or shortly after a bowel movement?
Soiling	Fecal Inc	Do you experience signs of loss of feces in your underwear?
Fecal incontinence **	Fecal Inc	Do you experience incontinence for liquid stools?
		Do you experience incontinence for solid stools?
Flatus incontinence	Flatus Inc	Do you experience incontinence for gas?

A symptom is considered to be present if the corresponding question is answered positive.

* Symptom is considered to be present if both corresponding questions are answered positive.

** Symptom is considered to be present if at least one of the two corresponding questions is answered positive.

OAB : overactive bladder; Inc : incontinence; Const / Obst : constipation / obstructive defecation; Def : defecation

Appendix B

1. How bad would you say your urinary incontinence during straining was before you underwent surgery?
   - I was suffering from urinary incontinence during coughing or straining.
   - I was suffering from urinary incontinence during sitting, standing or walking.
   - I was suffering from continuous urinary incontinence.

2. Did you have to use sanitary towels because of urinary incontinence before you underwent surgery?
   - Yes
   - No

3. Do you have to use sanitary towels because of urinary incontinence at the moment?
   - Yes
   - No

4. How successful was your operation with respect to the urinary incontinence?
   - At the moment I experience less urinary incontinence than before surgery.
   - At the moment I experience urinay incontinence comparable to before surgery.
   - At the moment I experience more urinary than before surgery.

5. Do you consider yourself more active in comparison to before surgery?
   - Yes
   - No

6. Are you satisfied with the result of your operation?
   - Yes
   - No

7. Have you developed new micturition and / or defecation symptoms after your operation?
   - Yes
   - No

Sexual problem	Question
Lubrication problems	
No lubrication	Does it happen during sexual activity that your vagina does not get wet at all?
Decreased lubrication	Does it happen during sexual activity that your vagina gets less wet than you would like?
Decreased duration of lubrication	Does it happen during sexual activity that your vagina gets wet for shorter time than you would like?
Problems with orgasm	
No orgasm	Does it happen during sexual activity that you do not get an orgasm?
Orgasm comes later than desired	Does it happen during sexual activity that your orgasm comes later than you would like?
Orgasm is less intense than desired	Does it happen during sexual activity that your orgasm is less intense than you would like?
Orgasm comes faster than desired	Does it happen during sexual activity that your orgasm comes faster than you would like?
Problems with pain/sensation in genitals	
Pain in genitals	Does it happen before, during or after sexual activity that you experience pain in your genitals?
Decreased sensation in genitals	Does it happen before, during or after sexual activity that your genitals are less sensitive than you would like?
Problems with arousal	
No arousal	Does it happen during sexual activity that you are not aroused at all?
Decreased arousal	Does it happen during sexual activity that your are less aroused than you would like?
Decreased duration of arousal	Does it happen during sexual activity that you are aroused for shorter time than you would like?

A problem during sexual activity is considered to be present if at least one of the questions related to that problem, is answered positive.

Appendix D

J.G. van der Bom	Universitair Medisch Centrum, Utrecht
Y.A.J.M. Dabekausen	Streekziekenhuis Het Spittaal, Zutphen
M.J. Duk	Eemland Ziekenhuis, Amersfoort
E.J.M. van Erp	Leyenburg Ziekenhuis, Den Haag
J.F. ter Haar	TweeSteden Ziekenhuis, Tilburg
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H.M.M.H. Kerkhof	Carolus Ziekenhuis, ‘s Hertogenbosch
W.F.A. Mensink	Martini Ziekenhuis, Groningen
L.C. van Otterlo	Gelre Ziekenhuizen, Apeldoorn
A.A.F. Planken	Mesos Medisch Centrum, Utrecht (locatie Oudenrijn)
J.P.W.R. Roovers	Universitair Medisch Centrum, Utrecht
J.H. Schagen van Leeuwen	Antonius Ziekenhuis, Nieuwegein
P.C. Scholten	Diakonessenhuis, Utrecht
C.H. van der Vaart	Universitair Medisch Centrum, Utrecht
H.A.M. Vervest	St. Elisabeth Ziekenhuis, Tilburg
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Curriculum Vitae

De auteur van dit proefschrift werd geboren op 8 oktober 1971 te Sittard. Hij deed in 1989 eindexamen Gymnasium-â aan de Scholen Gemeenschap St. Ursula te Horn. In 1990 behaalde hij zijn propedeuse Medische Biologie aan de Universiteit te Utrecht en begon aan de studie Geneeskunde. Na het behalen van het doctoraal examen werd in 1994 gedurende 6 maanden onderzoek verricht naar de relatie tussen HIV infectie en cervix carcinoom. Dit onderzoek werd verricht in de University of California, Los Angeles, Verenigde Staten, onder begeleiding van Prof. Dr. J.S. Berek. In 1996 werd het artsexamen gehaald aan de Universiteit van Utrecht. Gedurende de laatste 2 maanden van de co-schappen en de eerste 3 maanden daarna, was de auteur werkzaam als house officer in een streekziekenhuis in Damongo, Ghana. In januari 1997 volgde een aanstelling als arts-onderzoeker gynaecologische oncologie. Van april 1997 tot en met september 1997 werden de in deze tijd opgestarte onderzoeken gecombineerd met werkzaamheden als AGNIO op de afdeling Obstretrie en Gynaecologie van het Academisch Ziekenhuis Utrecht (thans: Universitair Medisch Centrum Utrecht). Van oktober 1997 tot en met februari 2001 werden de studies beschreven in dit proefschrift opgezet en uitgevoerd. Tevens was de auteur gedurende deze tijd actief betrokken bij de diagnostiek en behandeling van patiënten met uro-genitale problematiek. Sedert maart 2001 is de auteur in opleiding tot gynaecoloog in het Cluster Utrecht (opleider: Prof. Dr. G.A.H. Visser). Momenteel is hij als zodanig werkzaam in het TweeSteden Ziekenhuis te Tilburg en Waalwijk (opleider: Dr. H.J.H.M. van Dessel).