Preservation of the uterus in vaginal prolapse surgery: the sacrospinous hysteropexy

Viviane Dietz

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Vaginale prolapse chirurgie met behoud van de uterus: de sacrospinale hysteropexie
(met een samenvatting in het Nederlands)

Proefschrift

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Chapter 1

Introduction and outline of the thesis

Introduction

With the enormous growth of the world population in the last decades and the higher life expectancy, pelvic organ prolapse has become a world wide health problem[1]. Thereby, with increasingly better health care facilities, older women remain more active in daily life. From population based studies, it was estimated that one in every 10 women will have had pelvic surgery by the age of 80, 29% will require a second operation because of recurrences[2]. In case of a uterine descent, a vaginal hysterectomy is a popular procedure to perform. In the Netherlands, it is considered to be the standard practice for correction of uterovaginal prolapse for decades. However, it is debatable whether removing the uterus is necessary. There are several uterine preserving surgical procedures in case of a uterine descent; vaginally (sacrospinous hysteropexy, Manchester procedure, posterior intravaginal slingplasty) as well as abdominally (sacrocolpopexy). The sacrospinous hysteropexy, in which the cervix is fixed to the sacrospinous ligament, has first been performed in 1989[3]. When starting this research in 2003, 7 reports, one prospective and 6 retrospective, were published on the results of this procedure[3-9]. In these studies, the focus has been on complications of the procedure and the anatomical outcomes, not on functional improvement and quality of life. Compared to a vaginal hysterectomy, preserving the uterus might be associated with better outcome on urogenital complaints and post operative recovery because of the less invasive nature of the procedure[6]. No randomized studies have ever been performed comparing the effects of sacrospinous hysteropexy with the more common vaginal hysterectomy on anatomical cure, urogenital symptoms and quality of life. More data are required on complications, recovery time, anatomical results, functional results and quality of life after a sacrospinous hysteropexy, especially in relation to a vaginal hysterectomy.

Pelvic organ prolapse

Anatomy

The pelvic floor is the lower border of the abdominal cavity and includes the levator ani muscles, the urethral and anal sphincter muscles and the endopelvic fascia with its related condensations like the sacrouterine, cardinal and pubourethral ligaments. The m. levator ani forms a U-shaped sling, encircling the urogenital hiatus, the midline space

through which the vagina and urethra pass. The part of the levator ani that inserts into the rectum wall to form a sling around it, is referred to as the puborectalis muscle. The levator ani has two important functions. First, it provides a constant basal tone, thereby keeping the urogenital hiatus closed[10]. If the basal tone is lost or diminished, the urogenital hiatus can widen, facilitating descent of the pelvic viscera. Secondly, the levator ani contracts reflexively in response to increased abdominal pressure, thereby supporting its related pelvic organs. This action most likely contributes to the maintenance of continence[11]. 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 travel over the cranial surface of the pelvic floor, making them vulnerable to stretching or 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.

Uterus and vagina are supported on three different levels[12]:

Level I suspension: The portion of the vagina adjacent to the cervix is suspended from above by the relatively long connective tissue fibres of the upper paracolpium (= tissue that attaches the vagina to the pelvic walls) and parametrium (= cardinal and uterosacral ligament complex).

Level II attachment: In the midportion of the vagina, the (lower) paracolpium becomes shorter and attaches the vaginal wall laterally to the pelvic wall. It consists of the pubocervical fascia and the rectovaginal fascia.

Level III fusion: Near the introitus the vagina infuses lateral to the levator ani muscles and posterior to the perineal body while anterior it blends with the urethra.

The three levels of support are continuous with one another and therefore interdependent.

Specific defects in the different levels of supports cause specific types of genital prolapse and call for specific operations to address each particular defect. In case of a uterine decent, we have to restore the level I support.

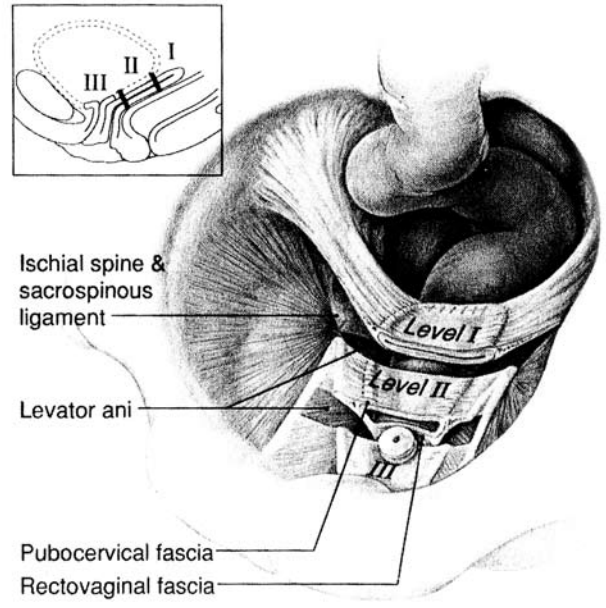

Figure 1: © DeLancey JO. Anatomic aspects of vaginal eversion after hysterectomy[12]

Prevalence and aetiology

In the Netherlands, in 2006, 12.702 uterus extirpations were performed[13]. Forty-five percent (5844) of these procedures were performed vaginally on benign indication including prolapse symptoms. The reported prevalence of symptomatic pelvic organ prolapse is estimated at 8% in a Swedish population based cohort study, which was comparable with other population studies e.g. 6% of a multiracial population in California (USA)[14,15]. The reported prevalence of pelvic organ prolapse estimated with gynecological examination is higher, about 41% of women over 50 years[16].

The aetiology of pelvic organ prolapse is complex with a variety of factors which are involved. It is related to some level of weakness in the supporting connective tissue of the pelvic structures which allows for the development of uterine descent secondary to multiparity, conditions related to high intra abdominal pressure (physical labour, chronic lung disease, chronic staining and obesity), age and post menopausal status[17].

Symptoms of pelvic organ prolapse

The aims of pelvic surgery for prolapse are to resolve the prolapse symptoms with the restoration or maintenance of bladder function, bowel/rectal function and sexual function. In case of pelvic organ prolapse, there are a variety of symptoms associated. Symptoms may only be related to the anatomical defect itself, the protrusion of the uterus outside the introitus such as feeling or seeing a bulge. It can also affect bladder function, defecation symptoms and sexual function. All of these dysfunctions can affect quality of life. Only a few symptoms have a high correlation with the extent of the prolapse at gynecological examination. Feeling or seeing a bulge out of the vagina had the highest correlation with the actual vaginal prolapse on gynecological examination[18]. Fifty percent of women with point C at -1 cm (stage 2 descent, POP-Q[19]) answered positive on this symptom. If point C exceeds the introitus, up to 85% of women answered positive to this symptom[20]. Therefore, it is difficult to predict if all symptoms which are experienced by a woman will disappear when the prolapse is surgically corrected.

Pelvic organ surgery

Vaginal hysterectomy and pelvic floor symptoms

Pelvic organ function (bladder function, bowel function and sexual function) may be affected after hysterectomy since it disrupts anatomical relationships and local nerve supply of the pelvic organs. In a review by Thakar and Sultan, the limited data available on the relation between a hysterectomy and bladder, bowel and sexual function, was collected[21]. They concluded that it is unlikely that a simple vaginal hysterectomy (on benign indication) causes bladder dysfunction, bowel dysfunction or sexual dysfunction. In a randomized study comparing the vaginal hysterectomy to the abdominal sacrocolpopexy (in which the uterus was preserved) in case of a uterine descent, urinary symptoms decreased after a vaginal hysterectomy[22]. However, these results may be distorted as urinary symptoms are related to prolapse and all women had at least a stage 2 prolapse before surgery. Sexuality improved or did not change in most women[23]. The presence of a large cystocele before surgery was associated with the disappearance of sexual problems after surgery[23]. Mild to severe dyspareunia symptoms were described in up to 14% of women after a vaginal hysterectomy for uterine prolapse[24].

Preserving the uterus in pelvic floor surgery

Although we know that the prolapsed uterus itself is not the cause but the result of weakening of the support systems, in the Netherlands the uterus is most commonly removed in prolapse surgery. Little or more attention is paid to level I support of the vagina after a hysterectomy (sacrospinous ligament fixation, Mc Call culdoplasty, Moschcowitz-type procedure and peritoneal closure). When level I support is diminished, we have to restore level I support, which does not necessarily mean removing the uterus. In most cases, the uterus itself is small and 'healthy'. By removing the uterus, the surgical procedure becomes more extent with entry into the abdominal cavity which might be associated with more complications and a longer recovery time. Level I support can also be restored by performing a sacrospinous hysteropexy in which the uterus is retained. Advantages of preserving the uterus can be preserving fertility, shorter recovery time because of the less invasive character of the procedure, psychological motives in retaining the uterus and possibly less new onset urinary, defecatory and sexual symptoms because the nerves and vessels were less damaged[3-9]. Maher et al and Hefni et al both performed non randomized studies comparing a vaginal hysterectomy combined with a sacrospinous ligament fixation to a sacrospinous hysteropexy[4,7]. Anatomical outcome was similar after both procedures but the operation time, blood loss and hospitalization was significantly longer after a vaginal hysterectomy.

The sacrospinous hysteropexy

The sacrospinous ligament fixation of the vaginal vault was first described by Richter[25] in 1968 for the treatment of vaginal vault prolapse and is associated with a success rate of 96.4% with regard to the apical support[26]. Richardson was the first to report about the sacrospinous hysteropexy, in young women with uterine descent[3]. The procedure can be combined with other prolapse surgery as anterior/posterior colporrhaphy and stress incontinence surgery. Two non-absorbable sutures are placed through the sacrospinous ligament, approximately 2 cm median to the ischial spine, and subsequently placed through the posterior side of the cervix in the midline. When tightening the sutures, the cervix is placed to the sacrospinous ligament above the levator plate.

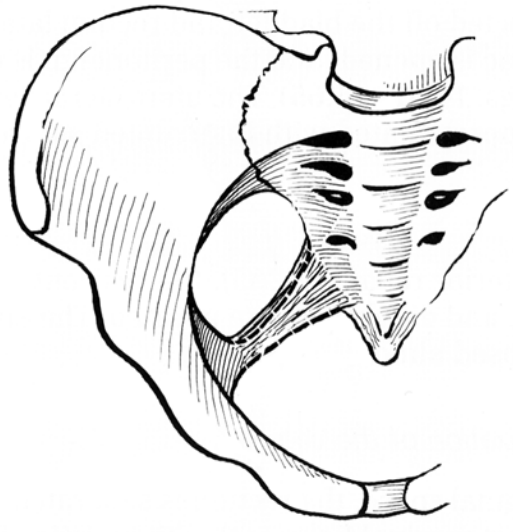

Figure 2: Female pelvis with sacrospinous ligament

Aims of the thesis

Although the vaginal hysterectomy is most commonly performed in case of uterine descent, data about the anatomical cure and symptomatic cure are scarce. Moreover, we do not know if this procedure is better as compared to other prolapse surgery such as the sacrospinous hysteropexy. Few studies were available on the sacrospinous hysteropexy. In 2003, at the start of this research, seven reports had been published[3-7]. From current literature, we know that recovery time might be shorter after a sacrospinous hysteropexy as compared to a vaginal hysterectomy[6]. In two reports comparing the sacrospinous hysteropexy with a vaginal hysterectomy
combined with a sacrospinous ligament fixation of the vault, comparable data on anatomical cure were found[4,7]. No randomized controlled trials comparing these procedures have ever been published.

The aims of the thesis are:

1. to study the sacrospinous hysteropexy in terms of anatomical outcomes, functional outcomes and quality of life compared to other vaginal prolapse procedures for uterine descent.
2. efficiency, safety, patient satisfaction and improvement on urogenital symptoms and quality of life.
3. Recovery time, anatomical outcomes, functional outcomes and quality of life compared to a vaginal hysterectomy.

Outline of the thesis

Section 1:
In *Chapter 2*, a systematic review of literature was performed on vaginal surgery for uterine descent. After a MEDLINE search, the following procedures were selected and investigated; the Manchester-Fothergill procedure, the vaginal hysterectomy, the sacrospinous hysteropexy and the posterior intravaginal slingplasty. Anatomical cure, symptomatic cure, complications and sexual function were described for each procedure.
Chapter 3 describes the anatomical cure, patient satisfaction and urogenital symptoms in 133 women after a sacrospinous hysteropexy. With validated questionnaires, urogenital symptoms and quality of life items were collected and all responding women were invited for gynecological examination.
In *Chapter 4* we report on urogenital symptoms, quality of life (assessed with validated questionnaires) and anatomical outcomes of 72 women before and after a sacrospinous hysteropexy.

Section 2:
Chapter 5 deals with postoperative recovery after a sacrospinous hysteropexy compared to a vaginal hysterectomy. We report on the results of a randomized study, performed by us, between a sacrospinous hysteropexy and a vaginal hysterectomy and compared complications, pain scores, use of analgesics and recovery time.
In *Chapter 6 and 7*, anatomical outcomes, urogenital symptoms and quality of life one year after a sacrospinous hysteropexy and vaginal hysterectomy were compared using questionnaires that were validated for the Dutch population. The need for second

prolapse surgery because of a recurrent prolapse was established.
The *Chapter 8* contains a general discussion, summary and recommendations for future research.

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Section 1

Chapter 2

Vaginal Surgery for Uterine Descent:
Which Options Do We Have?
A Systematic Literature Review.

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Abstract

Introduction and Hypothesis: Several vaginal procedures are available for treating uterine descent. Vaginal hysterectomy is usually the surgeon's first choice.
Methods: In this literature review, complications, anatomical and symptomatic outcomes, and quality of life after vaginal hysterectomy, sacrospinous hysteropexy, the Manchester procedure, and posterior intravaginal slingplasty are described.
Results: All procedures had low complication rates, except posterior intravaginal slingplasty, with a tape erosion rate of 21%. Minimal anatomical success rates regarding apical support ranged from 85% to 93% in favor of the Manchester procedure. Data on symptomatic cure and quality of life are scarce. In studies comparing vaginal hysterectomy with sacrospinous hysteropexy or the Manchester procedure, vaginal hysterectomy had higher morbidity.
Conclusions: Because no randomized, controlled trials have been performed comparing these surgical techniques, we can not conclude that one of the procedures prevails. However, one can conclude from the literature that vaginal hysterectomy is not the logical first choice.

Introduction

Pelvic organ prolapse is a common problem among aging women. About 40% of parous women have pelvic organ prolapse[1]. The lifetime risk at the age of 80 for surgical intervention is 11.1%[2]. Removal of the prolapsed uterus, eventually combined with preventive procedures for future vault prolapse, is considered the primary procedure in cases of uterine descent[3]. With a vaginal approach, combined vaginal repair methods, such as anterior or posterior colporrhaphy, are easy to perform. If one chooses a vaginal procedure to correct uterine descent, one can choose to retain and suspend the prolapsed uterus rather than removing it. Women have several reasons for wanting to preserve the uterus, such as retaining fertility and maintaining their personal identity. Other possible motivations may be the possibility that this kind of surgery might reduce operation time, blood loss, and postoperative recovery time[4,5]. The choice of operation for uterine prolapse depends on the preference of the woman and her surgeon, eg, the surgeon's expertise in different surgical techniques. The objective of this review is to outline the complication rate, anatomical success rate, functional outcomes, quality of life, and sexual function in women with uterine prolapse after a vaginal hysterectomy and 3 uterus-preserving vaginal techniques: sacrospinous hysteropexy, the Manchester procedure, and posterior intravaginal slingplasty.

Material and methods

Sources and search methods

After performing a MEDLINE search in November 2007 on vaginal surgical techniques for uterine descent, we selected 4 surgical procedures: vaginal hysterectomy (with or without prophylactic procedures for future vaginal vault prolapse) and 3 uterus-preserving procedures: sacrospinous hysteropexy, the Manchester procedure, and posterior intravaginal slingplasty. For each technique, a separate literature search was performed. The sacrospinous hysteropexy and posterior intravaginal slingplasty are relatively 'young' procedures (first publication in 1989 and 2006, respectively). Therefore, to make the groups of women who underwent the different procedures somewhat more comparable, we chose to only use data published over the last 20 years. The MEDLINE search was performed with the key words and phrases 'English', 'Human', 'Female', 'all adults 19+ years', and 'reports published between 1-nov-1987 - 1-nov-2007', and had the following results:

1. Prolapse AND vaginal hysterectomy (176 reports)
2. Prolapse AND sacrospinous hysteropexy OR sacrospinous ligament fixation OR sacrospinous colpopexy (71 reports)
3. Prolapse AND Manchester OR Fothergill OR cervical amputation (90 reports)
4. Prolapse AND intravaginal slingplasty OR posterior intravaginal slingplasty OR intravaginal sling OR infracoccygeal sacropexy (32 reports)

Also the following databases were searched: EMBASE, the Cochrane Central Register of Controlled Trials, Current Controlled Trials, and the Database of Abstracts on Reviews and Effectiveness. First, we searched for randomized trials. One randomized trial was found comparing vaginal hysterectomy with an abdominal procedure and one randomized trial was found comparing vaginal hysterectomy with sacrospinous hysteropexy[6,7]. After that, prospective cohort studies, prospective, case-controlled studies, retrospective studies and case reports were assessed. Finally, we included all different types of clinical research because in most cases no or little (randomized) data were available.

Study Selection

Titles and, if available, abstracts of all literature found after this search were assessed. The full report of each study likely to be relevant was than assessed, including the reference lists.

The vaginal hysterectomy search found 176 reports. However, most of these reports focused on outcome after vaginal hysterectomy (in most cases in comparison with abdominal hysterectomy) for benign diseases in general, not for the indication of prolapse separately. It is important to focus on this subgroup separately, because data on complications and outcome with regard to symptoms and anatomical recurrences will be different compared with complications and outcomes in a subgroup of women who underwent vaginal hysterectomy for other benign diseases like menorrhagia or leiomyoma. This is reflected in data published by Dallenbach et al in which the risk of prolapse repair after hysterectomy was 4.7 times higher in women whose initial hysterectomy was indicated for prolapse and 8.0 times higher if preoperative prolapse grade 2 or more was present[8]. When selecting only reports on women undergoing vaginal hysterectomy for uterine prolapse, we found 38 eligible reports. However,

many of these studies describe a prophylactic method for future vaginal vault prolapse in women without a uterus and in women in whom the uterus had to be removed at the time of this prophylactic procedure. In many reports, outcomes in these subgroups of women (in which a vaginal hysterectomy was performed) were not separately described. Therefore, 15 studies were excluded. 23 studies were available in which outcome data for 1764 women who underwent a vaginal hysterectomy for prolapse symptoms were analyzed separately, with a follow-up of between 9 and 60 months[4,5,6,9-28].

The sacrospinous hysteropexy search resulted in 71 reports. After selection and assessment of reference lists, 11 studies and one case report were found on women who underwent a sacrospinous hysteropexy (with preservation of the uterus)[4,5,7,16,17,21,29-33]. A total of 613 women who underwent a unilateral sacrospinous hysteropexy are described, with a follow-up of between 4 and 72 months. One study by Kovac and Cruikshank, in which 4 women with a unilateral sacrospinous hysteropexy and 15 women with a bilateral sacrospinous hysteropexy are described, was excluded for data on anatomical outcome and complication rate because this was the only report on the bilateral approach[32].

The Manchester procedure search found 90 reports. After assessment of these reports including reference lists of eligible studies, 4 studies and 2 case reports were found with data on 573 women[18-20,34-36]. All studies were retrospective. Follow-up varied from 12 to 43 months.

After assessment of the 32 reports and their reference lists, only 4 studies describing posterior intravaginal slingplasty in women preserving their uterus were available[37-40]. Because Mattox et al did not describe their subgroup of only 2 women with preservation of the uterus separately (21 women without a uterus), this report was excluded from the analyses of anatomical and functional outcomes[40]. A total of 143 women were analyzed with a follow-up of 6 to 30 months. In none of the studies were complications separately described for the subgroup of women in which the uterus was preserved. Therefore, for describing complications, we used data for women who underwent a posterior intravaginal slingplasty with and without preservation of the uterus[37-47].

Measurements

The following outcome measurements were reviewed: complications, anatomical outcomes, symptomatic outcomes, quality of life, sexual function, and pregnancy (after the 3 uterus-preserving techniques).

Surgical Procedures

Vaginal hysterectomy was first performed by Langenbeck in 1813[48]. The vaginal hysterectomy surgical technique is well described in surgical textbooks[49]. After removing the uterus, prophylactic procedures to prevent future vaginal vault prolapse, such as sacrospinous ligament fixation or McCall culdoplasty, can be performed[4,16,50].

The sacrospinous hysteropexy was first described by Richardson in 1989[29]. After opening the posterior vaginal wall, the right sacrospinous ligament is made visible through sharp and blunt dissection into the right para rectal space. The cervix is unilaterally attached to the right sacrospinous ligament, about 2 centimeters medial from the ischial spine with 2 nonabsorbable sutures.

In 1888, Archibald Donald of Manchester started treating women with uterovaginal prolapse with the combined operation of anterior and posterior colporrhaphy and amputation of the cervix, the Manchester procedure[51]. Edward Fothergill modified the procedure by including parametrial fixation[52]. The procedure consisted of the following elements: an anterior colporrhaphy including wide exposure of the parametria, suturing of the parametrial tissues in front of the cervix and lower uterine segment thereby shortening the ligaments and elevating the cervix, amputation of the cervix if necessary and a posterior colpoperineorrhaphy.

In 2001, the posterior intravaginal slingplasty was introduced by Petros[41]. It was a minimally invasive, transperineal technique providing Level I support, as described by deLancey, by making neo-sacrouterine ligaments using mesh[53]. Different materials have been used because the first nylon mesh had high rates of erosions. Later, polypropylene multifilament mesh was introduced.

In all reports of these 4 surgical techniques, concomitant surgery (anterior or posterior colporrhaphy or vaginal incontinence surgery) was performed when indicated.

Results

Complications

Table 1 shows the occurrence of complications. The vaginal hysterectomy complication rates reported in these studies are comparable to complication rates in large retrospective studies of vaginal hysterectomy for benign disease in general[54,55].

Vaginal hysterectomy was compared with the Manchester procedure in 2 studies in which

hysterectomy was associated with a significantly longer operating time and greater morbidity (blood loss, vaginal cuff abscesses)[19,20]. When comparing vaginal hysterectomy (in 2 studies combined with a prophylactic sacrospinous ligament fixation) with sacrospinous hysteropexy, also greater morbidity (longer operating time and recovery time and more blood loss) was seen after a vaginal hysterectomy [4,5,16].

After sacrospinous hysteropexy in 2 women (in one retrospective study), persistent buttock pain with the need for a second surgery occurred[33]. In one woman, the suture was removed and replaced one day after surgery, and she completely recovered. In the other woman, it was unclear whether the pain was caused by the sacrospinous hysteropexy or related to neurological problems in the lumbar region. After 3 years, the suture was removed, and the patient underwent a vaginal hysterectomy after which her pain decreased but did not resolve. In all other women, the buttock pain resolved within 6 weeks without any intervention. In one study, the Manchester procedure performed with patients under anaesthesia was associated with hematometra due to cervical stenosis with the need for dilatations in up to 11% of patients[34]. In one woman, after 4 dilatations of the cervix, an abdominal hysterectomy was performed. Hopkins et al reported on 3 patients with uterine disease (2 with cancer) after a Manchester procedure in women who thought that their uterus had been removed in prior prolapse surgery, which made the differential diagnosis difficult[35]. Therefore, after cervical amputation, a risk of stenosis is present, which could influence the occurrence of alarming symptoms (vaginal blood loss) in the development of adenocarcinoma of the uterus. Mesh erosion problems were seen in 0 to 21% of women after a posterior intravaginal slingplasty (with and without preservation of the uterus)[37-47]. Baessler et al described erosion problems in 13 women who were referred to their clinic after implantation of a multifilament mesh at other clinics[56]. Mesh infection, pain syndromes, and dyspareunia after a median time

of 24 months were the main indications for removing the mesh. Follow-up after mesh removal showed that symptoms in all women disappeared or decreased. Several explanations for the different amounts of mesh erosion were given. Achtari et al reported that women operated on by less-experienced surgeons had more erosion problems than women who were operated on by more experienced surgeons[57]. Hefni et al did not confirm these findings but reported that older age (>60 years) and diabetes mellitus were associated with a higher rate of mesh erosions[39]. Also the nature of the tape might play an important role. Farnsworth first had an erosion rate of 10% with nylon tape; after he started using polypropylene mesh, the erosion rate dropped to 0%[47]. In most subsequent studies, a multifilament polypropylene mesh was used, unfortunately still with erosion rates of up to 17%[39]. Removal of the uterus during the procedure did not alter the erosion rate[37].

No randomized trials were available comparing the surgical procedures with regard to complications. In comparative studies, vaginal hysterectomy was associated with greater morbidity compared with sacrospinous hysteropexy (aside from a short period of buttock pain) and the Manchester procedure (aside from cervical stenosis). All procedures were associated with a low complication rate. Because erosion rates after the posterior intravaginal slingplasty were high, this technique was not preferred.

Anatomical Cure

The anatomical outcome for apical support seems comparable to a minimum success rate of more than 85% (Table 2). Surgery for recurrent prolapse symptoms ranged from 0 to 7% (Table 2).

Low cure rates for the anterior and posterior vaginal wall have been reported after vaginal hysterectomy. These low cure data are described in a study with a follow-up of 5 years (which is relatively long in the prolapse surgery literature) in which all 47 women underwent gynecological examination[14]. None of these women had recurrent surgery because of prolapse symptoms. In the Dietz et al study (*Chapter 3*) in which women underwent gynecological examination regardless of symptoms, 38% of women after a sacrospinous hysteropexy had a recurrent cystocele (follow-up of 23 months)[33]. Recurrent surgery because of prolapse symptoms was performed in 2.3% (with regard to apical, anterior, and posterior recurrences).

The sacrospinous hysteropexy was compared (prospectively and retrospectively) with a vaginal hysterectomy with a prophylactic sacrospinous ligament fixation of the vaginal

vault [4,16]. In these studies, anatomical cure (also symptomatic cure and satisfaction) was comparable in both groups. The authors concluded that hysterectomy had no favourable effect. Anatomical outcomes after the Manchester procedure, with a mean follow-up of 12 to 43 months, were better than those for vaginal hysterectomy or sacrospinous hysteropexy. However, all studies included were of a retrospective design with data collected from medical charts or by sending questionnaires to women or surgeons.

Anatomical outcome data after posterior intravaginal slingplasty with preservation of the uterus were collected prospectively with follow-up between 6 and 30 months (143 women in 3 studies). Recurrent surgery in this group due to erosion problems occurred in up to 18%[39].

It is important to note that all studies reviewed were heterogenic in several aspects, such as follow-up time, selection of study group (eg, no stage 4 prolapse included, prior prolapse surgery), definition of recurrent prolapse, but most importantly in methods of collecting data. The vaginal hysterectomy procedures were also heterogenic due to the different procedures that were performed for preventing future vault prolapse[4,16,23]. However, in a study comparing the sacrospinous ligament fixation with the McCall culdoplasty as a prophylactic method for vaginal vault prolapse at the time of vaginal hysterectomy, no differences in apical recurrences were found[25].

Overall, we must conclude that the 4 surgical techniques were comparable in recurrent pelvic surgery for prolapse symptoms, regardless of the anatomical state at follow-up. The high rate of recurrent pelvic surgery after the posterior intravaginal slingplasty could be explained by erosion problems.

Symptomatic Cure and Quality of Life

Because hysterectomy can disrupt the local nerve supply and will disrupt the anatomical relationships of the pelvic organs, it has been thought that the functions of these organs may be adversely affected. To investigate these functions, validated questionnaires are useful. Roovers et al used validated questionnaires on urogenital symptoms and quality of life[27]. They found improvement in all urogenital domain scores (urinary incontinence, overactive bladder, pain, prolapse, and obstructive micturition) and quality of life (mobility, physical function, social functioning, emotional functioning, and embarrassment) after a vaginal hysterectomy. We have to acknowledge that prolapse itself can cause urogenital symptoms, so these symptoms will logically decrease after prolapse surgery. We do not know whether removal of the uterus negatively affected this outcome. It has been debated for many years that a vaginal hysterectomy possibly contributes to the development of urinary symptoms. In a prospective study, in which a vaginal hysterectomy was compared with endometrial ablation for the treatment of menorrhagia (not for prolapse symptoms), no differences in incontinence rates were found between the groups[58]. In a review of the literature, it was concluded that a vaginal hysterectomy is unlikely to cause bladder and bowel dysfunction[59]. The occurrence of de novo stress incontinence occurred in between 0 and 22% of women after a vaginal hysterectomy for uterine descent[6,14,17,23,24].

No reports were found of women developing de novo stress incontinence after sacrospinous hysteropexy, but recurrent stress incontinence occurred in up to 4%[4].

Van Brummen et al used validated questionnaires and found a higher percentage of women with urge incontinence and stress incontinence after a sacrospinous hysteropexy, 39% and 48%, respectively[5]. No data were available on improvement of urogenital symptoms and quality of life measured with validated questionnaires.

No published studies of the Manchester procedure report validated questionnaires being used to measure symptomatic cure or quality of life. No data on de novo stress incontinence were found. In the study of Dutta et al, a reduction of stress incontinence symptoms from 6 to 1% was described[18].

Neuman et al found “satisfaction with the posterior intravaginal slingplasty with preservation of the uterus” in 91.4% of women[37]. No other studies separately describe symptoms and quality of life in women preserving the uterus.

Therefore, although after a vaginal hysterectomy and a sacrospinous hysteropexy, urogenital symptoms decreased and quality of life improved, we could not conclude that one procedure is superior to the other with regard to symptomatic cure.

Sexual functioning

Sexual well-being may decrease after hysterectomy due to damage of the innervations and supportive structures of the pelvic floor. Many studies have been published about sexual function after a hysterectomy for benign conditions and show that a simple vaginal hysterectomy is not a risk factor for sexual dysfunction[59]. After surgery for uterine prolapse (including vaginal hysterectomy), sexuality improved or did not change in most women[60]. The presence of a large cystocele before surgery was associated with the disappearance of sexual problems after surgery[60]. Mild to severe

dyspareunia symptoms are described in up to 14% of women after a vaginal hysterectomy for uterine prolapse[25]. In a randomized study comparing women after a sacrospinous hysteropexy and a vaginal hysterectomy, no difference was reported in postoperative sexual functioning between women with and without preservation of the uterus at 6-month follow-up[7]. A decrease in the frequency of orgasm was reported after both procedures related to the fact that these women were afraid of wound disruption or disease recurrence. Pain during intercourse before and after surgery was equal in both groups (4% before surgery, 5% after surgery).
After a sacrospinous hysteropexy, dyspareunia was described in 0 to 7% of women[4,16]. Women who were sexually active before surgery were satisfied after surgery[17]. No information on sexual function in women after a posterior intravaginal slingplasty was found except for dyspareunia complaints that did not occur in women preserving the uterus[37]. After a posterior intravaginal slingplasty in women in which the uterus was removed, 5% of women had dyspareunia symptoms after surgery[45].
In conclusion, although vaginal hysterectomy is associated with the highest dyspareunia rate in retrospective studies, the only randomized study comparing sacrospinous hysteropexy and vaginal hysterectomy showed that the 2 procedures had the same effect on sexual function at 6-month follow-up.

Pregnancy
Tipton et al describe 5 women (total study group of 82 women) who desired pregnancy after the Manchester procedure[61]. Two of them had an uneventful pregnancy, one had a miscarriage at 3 months, and 2 had no pregnancy at all. There was no follow-up on these women. Also 3 unplanned pregnancies occurred in the total study group. The risk of premature delivery is unknown after the Manchester procedure but is possibly higher when cervical amputation is performed.
In the literature, pregnancy is described in 14 women after a sacrospinous hysteropexy (a total of 15 pregnancies one of which was a twin pregnancy)[4,30-32]. Six of these were vaginal deliveries, 9 were caesarean. After vaginal delivery, one woman needed second prolapse surgery (this patient delivered twice). After caesarean delivery, one woman also needed second prolapse surgery.
No data were available on pregnancies after a posterior intravaginal slingplasty.

Comment

All 3 uterus-preserving procedures appear to be equally effective with regard to anatomical apical cure and recurrent prolapse surgery, with less morbidity (operating time, blood loss, and recovery time), compared with vaginal hysterectomy, except for erosion rate. However, vaginal hysterectomy, combined with prophylactic methods for vaginal vault prolapse, is still the first choice procedure in many countries. Most likely, the morbidity associated with vaginal hysterectomy is considered mild by doctors and patients. The studies available were difficult to compare because of the major differences in data collection (retrospective, prospective) and defining recurrences. Examining all women after surgery will show higher recurrence rates compared with recurrence rates determined from medical records for the following reasons: First, some women with recurrent symptoms could have gone to another clinic for a second surgery. Second, some women with recurrent symptoms could have not wanted a second surgery and therefore did not return to the clinic. Third, some women could have been treated with a pessary. Fourth, in some women, recurrent prolapse on gynecological examination will be asymptomatic, and therefore the woman would not have returned to the clinic. Also other factors contributing to the heterogeneity have to be acknowledged, for example follow-up time, differences in baseline characteristics of the research groups (differences in age, preoperative stage of prolapse, or previous prolapse surgery), definition of recurrences and differences in surgical technique within the groups. Therefore, it was impossible to pool the data from all the studies. Finally, we have to acknowledge that there is publication bias that most likely would have influenced these results.
Because no randomized, controlled trials are available for the 4 surgical techniques (except for one trial containing data on sexual functioning), we can not state that one procedure is better than another[7]. Hopefully, this report will motivate researchers to perform such a trial.
In conclusion, we can state that, with the information from the current literature, it is not logical that many women worldwide will undergo vaginal hysterectomy when surgery for uterine descent is indicated. In comparative studies, sacrospinous hysteropexy and the Manchester procedure were, with regard to anatomical outcomes, equally effective with less severe morbidity compared with that of vaginal

hysterectomy for uterine descent. The use of mesh (posterior intravaginal slingplasty) needs to be investigated in a longer follow-up because the use of monofilament polypropylene mesh has only been recently introduced. Perhaps a monofilament polypropylene mesh, which was shown to be superior to the multifilament mesh in urinary incontinence surgery with regard to erosion rates, will decrease the high rate of erosion in posterior intravaginal slingplasty[62].

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Table 1: *Complications during and after surgery according to surgical approach*

	Vaginal hysterectomy[a]	Sacrospinous hysteropexy[b]	Manchester procedure[c]	Posterior intravaginal slingplasty[d]
Bladder injury	0-2%	0%	0-1%	0%
Rectal injury	0-2%	0-1%	0%	0-3%
Blood transfusion	0-11%	1%	0-3%	0-0.3%
Infection with the need for antibiotics	0-21%	0-2%	0-13%	0-0.3%
Lower urinary tract symptoms	up to 20%	up to 37%	up to 22%	0-6%
Vault abscess or haematoma	0-7%	0%	0%	0%
Cervical stenosis	not applicable	0%	0-11%	0%
Sensory Loss skin	0%	0-0.5%	0%	0%
Buttock pain	0%	3-27%	0%	0%
Mesh erosion	not applicable	not applicable	not applicable	0-21%
Mortality rate	0.4%	not available	not available	not available

[a] = references [4-6, 10,15, 16, 18-21, 23-26, 28]

[b] = references [4, 5, 7, 17, 21, 27, 28, 30, 32, 33]

[c] = references [18-20, 34]

[d] = references [37-47]

Table 2: *Anatomical cure rates and recurrent surgery according to surgical approach*

	Vaginal hysterectomy[a]	Sacrospinous hysteropexy[b]	Manchester procedure[c]	Posterior intravaginal slingplasty[d]
Cure rate:				
Apical support	88-100%	85-100%	93-100%	90-97%
Anterior support	28[e]-? %	62[e]-100%	95%	91-97%
Posterior support	36[e]-100%	97-100%	99-100%	97-100%
Recurrent surgery for				
apical prolapse:	0-7%	0-5%	0-4%	3%
any prolapse:	0-12%	0-7%	0-4%	3%
other conditions[f]	0%	0-4%	0-2%	0-18%

[a] = references [4, 9, 10, 13, 15,-18, 21, 23-28]

[b] = references [4, 5, 16, 17, 21, 28, 30-33]

[c] = references [18-20, 34]

[d] = references [37-39]

[e] = Data of studies in which all women underwent gynecological examination regardless of symptoms. Most of these recurrences were asymptomatic.

[f] = other conditions, eg menorrhagia, pain syndromes

Chapter 3

The effectiveness of the sacrospinous hysteropexy for the primary treatment of uterovaginal prolapse

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Abstract

The objective of this study was to assess the effectiveness of sacrospinous ligament fixation of the uterus as a primary treatment of uterovaginal prolapse. In this observational study, 133 women underwent a sacrospinous hysteropexy. Data were obtained from their medical records, and standardized questionnaires about urogenital symptoms and quality of life were used. All women were invited for gynecological examination, using the Pelvic Organ Prolapse Quantification score. Ninety-nine women responded by returning the questionnaire (mean age 59.2 y and follow-up time 22.5 months); 60 of these women underwent gynecological examination. Eighty-four percent of women were highly satisfied about the outcome of the procedure. Serious complications were rare. The recurrence rate of descensus uteri that needed surgical treatment was 2.3%. The recurrence rate of cystoceles was 38%, but there were no differences in urogenital symptoms between women with or without a cystocele.

Introduction

The last decades many studies showed that sacrospinous ligament fixation is an effective surgical procedure to correct post-hysterectomy vaginal vault prolapse[1,2]. Since it has proven its efficiency in vaginal vault prolapse surgery, it might be of interest to use it as a primary technique to correct a descensus uteri, the so-called sacrospinous hysteropexy. The anatomical outcome and complication rate of this operation was described in a few reports, but most authors do not focus on urogenital symptoms and quality of life after sacrospinous hysteropexy[3-8]. In a previous study by our group, we concluded that the sacrospinous hysteropexy is a promising technique for the correction of descensus uteri[9]. However, the mean follow-up of the study group was relatively short, the postoperative anatomical status was derived from the medical records, and differences in urogenital symptoms in relation to the anatomical outcome were not assessed.
We set out to assess the satisfaction, complications, urogenital symptoms and quality of life in a group of women after a sacrospinous hysteropexy.

Materials and methods

Patients
The study group consisted of 133 women who had a sacrospinous hysteropexy for uterovaginal prolapse in the period January 2000 and June 2004 in three large teaching hospitals in The Netherlands. All women wanted to preserve their uterus. Preoperative cytology of the cervix and ultrasound screening of the uterus and ovaries showed no abnormalities. Data on patient characteristics and perioperative events were collected retrospectively from medical files of all 133 women. All women received a standardized, validated questionnaire in 2005 that covered urogenital symptoms and quality of life aspects. They were invited to visit our clinic for a full gynecological examination and Pelvic Organ Prolapse Quantification (POP-Q) assessment[10]. The study was approved by the local ethics committee.

Surgery
All surgeries were performed by four senior surgeons. The sacrospinous hysteropexy is performed unilaterally to the right ligament. A midline incision in the posterior vaginal wall is extended to the posterior part of the cervix in the midline. Through sharp and blunt dissection the right sacrospinous ligament is made visible. Two non-absorbable sutures (Prolene 1) are placed through the sacrospinous ligament and subsequently placed through the posterior side of the cervix. An additional classical anterior and/or posterior colporrhaphy (fascia plication), with absorbable vicryl® 2-0 interruptered sutures, was performed when indicated by the judgment of the individual gynecologist. All women were given perioperative antibiotic and thrombosis prophylaxis, according to the guidelines of the individual hospitals.

Measurements
The following data were obtained from the patients' medical files: date of surgery, age at the time of surgery, peri- and postoperative complications, grade of prolapse before surgery and if additional anterior and/or posterior colporrhaphy was performed. In most cases the preoperative stage of genital prolapse was still classified according to the halfway system of Baden and Walker, noted as 0 = no prolapse, 1 = prolapse halfway to hymen, 2 = prolapse progressing to hymen, 3 = prolapse halfway through the hymen and 4 = total vaginal prolapse. In the analysis we dichotomized the grade of prolapse into stage 1 or less and stage 2 or more.
The women who underwent gynecological examination at follow-up were examined by an independent physician, trained in POP-Q assessment. The POP-Q score is a reliable and specific method to measure the pelvic organ support[10].
Partly the questionnaire consisted of the following items: satisfaction with the outcome of surgery, time span between surgery and complete recovery and recommendation to other patients. To assess satisfaction after surgery we asked: "Are you satisfied with the result of the surgery?" The answer was measured on a 5-point Likert scale ranging from very satisfied to very dissatisfied. In the analysis we dichotomized this into very satisfied / satisfied, and moderately satisfied / dissatisfied / very dissatisfied. We also asked patients if they would recommend the sacrospinous hysteropexy to other women with a prolapse. The answers could be yes, no or do not know. To evaluate the time until complete recovery we asked: "How quickly did you feel completely recovered from surgery?" The answer was measured on a 5-point Likert scale ranging from within 2 weeks, 2-4 weeks, 1-3 months, 3-6 months and more than 6 months.
Urogenital symptoms were measured with the Urogenital Distress Inventory (UDI),

which was validated for the Dutch population[11]. In this validation study on a large population-based sample, it was shown that the domain obstruction of the Dutch version was different from the original one. The following 5 domains were identified: urinary incontinence, overactive bladder, pain, obstructive micturition and prolapse. The scores of these domains vary from 0 to 100. A high score on a particular domain indicates more bothersome symptoms.
Disease-specific quality of life was measured with the Incontinence Impact Questionnaire (IIQ), also validated for the Dutch population[11]. These questions covered the following 5 domains: physical functioning, mobility, emotional functioning, social functioning and embarrassment. Again the score ranged between 0 (best quality of life) and 100 (worst quality of life).
We used information from the medical files to compare the baseline characteristics of the group of responders with the non-responders. We also compared the characteristics of the women who underwent gynecological examination with the group of responders who did not. By doing so we analyzed if there were differences in baseline or outcome parameters between responders and non-responders that could have influenced our findings.

Statistical analysis
Descriptive statistics were used for the whole population. To compare differences between groups, a Student t-test was used for continuous data and the χ^2-test for nominal or ordinal data. The significance level was set at an α of 0.05. Statistical analysis was performed with SPSS 12.0 for Windows.

Results

Of the 133 women a total of 99 women responded to the questionnaire. Sixty of these 99 women underwent a gynecological examination. Mean follow up was 22.8 months (3-55). In Table 1 the baseline characteristics of the responders and non-responders to the questionnaire are shown.
In Table 2, the complications during and after surgery are shown. Buttock pain occurred in 15% of women but resolved spontaneously in all but two women. One woman complained of severe buttock pain directly after surgery based on entrapment of branches of the ischiadic nerve. The suture from the sacrospinous ligament to the cervix

was replaced and the pain resolved. The other woman also had buttock pain after surgery. In this case, it was unclear if this pain was related to the surgery or related to her neurological problems in the lumbar region. After complete evaluation she chose to undergo a vaginal hysterectomy. After this surgery she still experienced buttock pain although it was less severe. One woman complained of numbness in the introitus probably based on damage to the posterior labial nerve. In one woman postoperative bleeding occurred which needed surgical intervention. A blood transfusion was not indicated.
Based on information of medical files, 3 women out of the 133 (2.3%) had surgical treatment because of a symptomatic recurrent prolapse (one cystocele, two descensus uteri). In one case an abdominal sacrocolpopexy of the uterus was performed. One patient had a colpocleisis (uterus in situ) and in one woman the recurrent prolapse was corrected by a colporrhaphy anterior. Another 3 women were also diagnosed with a recurrent prolapse of the uterus but did not need surgical treatment.
When we look at the results of the 60 women who underwent gynecological examination, 18 women (30%) had a cystocele stage 2 and 5 women (8%) had a cystocele stage 3. Only 2 of these 23 women (8.2%) had symptoms related to this prolapse. All women with a cystocele after surgery had an anterior wall colporrhaphy at their initial surgery. A total of 3 out of the 60 women (5%) had a recurrence of a descensus uteri stage 2, but all were asymptomatic. So in total (medical file information and gynecological examination) 8 women out of 133 (6%) were diagnosed with a recurrent descensus uteri. Of the 99 women who answered the questionnaire, 83 (84%) were (very) satisfied about the results of surgery, 91 (91%) would recommend the procedure to other women, 55 (56%) reported a total recovery within 3 months, and 77 (78%) reported to be completely recovered at 6 months.
In Table 3 the results of the UDI and IIQ scores are shown for all women who responded to the questionnaire, divided in those who had gynecological examination and those who did not. There were no statistically significant differences in UDI/IIQ scores and baseline characteristics between these groups. On a scale between 0 and 100, it is clear that both the UDI and IIQ scores are in the low range, indicating little bother.
In Table 4 we compare the results of the UDI and IIQ domains for women with (N = 23) or without (N = 37) a cystocele ≥ stage 2 at gynecological examination at time of follow-up. No statistically significant differences in UDI/IIQ scores and baseline characteristics between these groups were found.

Discussion

In this study we set out to assess the clinical outcome, complications, patients' satisfaction and quality of life after a sacrospinous hysteropexy. At a mean follow-up of 2 years, a recurrence of the descensus uteri was rare, the satisfaction rate high and almost all women would recommend the procedure to others. We did find a high percentage of recurrent cystoceles but surprisingly this did not result in a higher degree of bother from urogenital symptoms as compared to women without a recurrent cystocele. Especially complaints of genital prolapse symptoms did not differ between women with or without a recurrent cystocele.

After our initial study in which we retrospectively compared the sacrospinous hysteropexy with a vaginal hysterectomy as surgical procedure for descensus uteri, we now present more long-term follow-up data on a next consecutive group of patients[9].

The strength of our study is that we used validated questionnaires to assess urogenital symptoms and disease-specific quality of life. A potential draw back is that we did not have complete follow-up data on all women. As we have shown, women who responded to the questionnaire were significantly younger and had less urinary incontinence problems before surgery as compared to the non-responders. Age might be a factor that made women decide not to participate in the follow-up, but we cannot rule out that they had recurrent complaints. In this case, it would have been likely that the general practitioner had referred the woman, but it is also possible that the women were reffered to another hospital. Another source of bias could be that not all women who responded to the questionnaire appeared for gynecological examination. However, we showed that the results from baseline assessment and the questionnaires did not differ between these groups so we do not think these results are biased.

The recurrence rate of prolapse reported in the literature after sacrospinous ligament fixation of the vaginal vault is 18%[2]. Less information is available about prolapse after sacrospinous hysteropexy. Recurrence rates vary between 6.7 (only with regard to descensus uteri) to 26% (total recurrence of descesus uteri and cystocele/rectocele)[7,8,9,12]. In the group of 60 women who underwent gynecological examination, only 3 had a recurrent descensus uteri stage 2. As with the majority of women with a recurrent cystocele, these women did not experience symptoms of prolapse. Data from our clinical files and gynecological examination showed that a recurrence of symptomatic uterine prolapse needing surgical treatment is rare (2 out of 133 women).

In literature, several complications of sacrospinous ligament fixation are documented, especially buttock pain. In our study buttock pain occurred in 15% of the women which is also comparable with earlier studies[13]. In almost all cases this buttock pain resolved spontaneously within two weeks and could be treated with analgesics. Two women needed repeated surgery to release the suture.

Fifty-six percent of women completely recovered within 3 months, 78% within 6 months. This is comparable to the group of women who underwent a sacropinous hysteropexy in the study of van Brummen et al[9]. In this study, women who underwent a sacrospinous hysteropexy recovered significantly faster as compared to the women who underwent a vaginal hysterectomy.

When we assessed urogenital symptoms and disease-specific quality of life, the scores are low, suggesting a high quality of life and little complaints of urogenital problems after the sacrospinous hysteropexy. These data have to be viewed with caution because we have no information on the UDI and IIQ scores before surgery. So, if there has been a significant improvement in quality of life after surgery, this cannot be derived from our data. However, in contrast to our expectations, we found that women with a recurrent cystocele after a sacrospinous hysteropexy did not have more genital prolapse complaints. It is becoming more and more obvious that the prevalence of genital prolapse in the general population is high. In a recent Dutch population-based study, the prevalence of a stage 2 or higher genital prolapse was reported to be 40%[14]. Most of these women had no serious complaints and did not seek medical attention. Therefore, a 38% prevalence of recurrent cystoceles after surgery might well be comparable to the normal 'physiological' situation in the population.

Several potential limitations of our study need to be discussed. First, there might have been a selection bias. We tried to avoid this as much as possible by emphasizing the importance of the woman's cooperation, regardless the presence of symptoms. There might have been another selection bias in the group of patients appearing for gynecological examination. It is unclear if this group had the best anatomical results or had doubts about the anatomical results and therefore wanted this check up. However, as we have indicated, no differences in baseline and questionnaire outcomes were found between these groups.

Second, there might have been indication bias. Women who chose specifically for this operation instead of the more common vaginal hysterectomy probably had high

expectations of this procedure. This might have had influenced their answers. There also could have been indication bias of the gynecologist who selected the women for this procedure.
Third, although a mean follow-up of two years is reasonable, it could have been that some recurrences were not yet developed at time of gynecological examination or research of medical files. However, all women who were treated for their recurrent prolapse were diagnosed within 4 to 6 months after initial surgery. Fourth, our data on the recovery time after surgery were collected retrospectively and are therefore subject to recall bias by the patient. Therefore these data have to be interpreted with caution. Fifth, objective measures such as urodynamics or pad testing were not performed after surgery to confirm urinary incontinence and detrusor hyperactivity. However, these objective measures are known to correlate moderately with the reported symptoms[15-16]. Finally, a great part of our data was collected retrospectively from medical files.
We used an unilateral sacrospinous fixation and one could argue that a bilateral fixation might improve the results. However, one study showed that bilateral sacrospinous fixation was only possible in 73% of women with vaginal vault prolapse and in 56% of women who underwent a vaginal hysterectomy at the same procedure[17]. In addition, it is unclear if bilateral fixation will give better results and it might be associated with more complications and more postoperative buttock pain. Apart from the technical difficulty in attaching the cervix close to both ligaments, our results of the unilateral fixation show that the chance of symptomatic recurrence is very low. We therefore advocate to use the sacrospinous hysteropexy unilateral.
The number of recurrent cystoceles, although often asymptomatic, remains a point of concern in all classical prolapse surgical techniques. The use of synthetic or allograft implants might reduce the risk of recurrent cystoceles. Observational data are encouraging, but there is an urgent need for well-designed randomized trails, comparing classical reefing techniques with the use of implants.
We think that uterine preservation during prolapse surgery is a good option for women who desire this. Again, due to a lack of randomized trials, it is unclear if preserving the uterus gives better results and a higher quality of life compared to the traditional vaginal hysterectomy. The latter being the standard in Dutch practice for many years. At this time, a randomized trial between these two surgery methods is performed.
In conclusion, the sacrospinous hysteropexy is a safe procedure for the primary treatment of descensus uteri. Recurrence of an uterine prolapse is rare. The vast majority of women are highly satisfied with the outcome and would recommend this surgery to others. The majority of women with recurrent cystoceles do not have complaints about it, so re-intervention should not be based on anatomical grounds solely.

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Table 1: *Patient characteristics of responders and non-responders to the questionnaire*

Patient characteristics	Responders (N = 99)		Non-reponders (N = 34)		*P*-value
Age (years)*	59.2	(13.1)	68.3	(14.1)	0.001
Operation for prolapse in medical history	4	(4.4%)	3	(8.8%)	NS
Operation for urinary incontinence in medical history	1	(1.0%)	0	(0.0%)	NS
Urinary incontinence before surgery	36	(36.4%)	20	(58.8%)	0.002
Urge incontinence	8	(8.1%)	5	(14.7%)	NS
Stress incontinence	17	(17.2%)	10	(29.4%)	NS
Combination stress and urge incontinence	9	(9.1%)	3	(8.8%)	NS
Unknown type	2	(2.0%)	2	(5.9%)	NS
Faecal incontinence before surgery	4	(4.0%)	2	(6.1%)	NS
Gynecological examination before surgery					
Descensus uterus stage 2 or more	90	(91%)	32	(94%)	NS
Cystoceles stage 2 or more	79	(79.8%)	30	(88.2%)	NS
Rectoceles stage 2 or more	22	(23.9%)	16	(50%)	0.006
Enterocele	5	(5.4%)	5	(15.6%)	NS
SSF + anterior or posterior colporrhaphy	88	(88.9%)	32	(94.1%)	NS
Additional sugery for urinary stress incontinence	11	(11.1%)	3	(8.8%)	NS
Follow-up time in months*	22.5	(3-55)	23.6	(3-54)	NS

Data are numbers (%) or * mean (standard deviation)

NS = not significant (*P* >0.05)

Table 2: *Complications related to surgery assessed from medical files.*

Patient characteristics	Responders (N = 99)			Non-reponders (N = 34)		*P*-value
Complications during surgery	8	(8.1%)		3	(8.8%)	NS
• Blood loss > 500 cc	6	(6.1%)		2	(5.9%)	NS
• Lesion of the rectum wall	1	(1.0%)		0	(0.0%)	NS
Complications after surgery	42	(43.4%)		10	(29.4%)	NS
• Deep venous thrombosis	0	(0%)		1	(2.9%)	NS
• Buttock pain	16	(16.2%)		4	(11.8%)	NS
	11 °	(11%)	<	22	(25.9%)	NS
weeks	4	(4%)		1	(2.9%)	NS
	1 °	(1.0%)	>	02	(0.0%)	NS
weeks	0	(0.0%)		1	(2.9%)	NS
• Post spinal headache	12	(12.1%)		5	(14.7%)	NS
• Postoperative bleeding	25	(25.3%)		5	(14.7%)	NS
• Urinary tract infection	24	(24.2%)		4	(11.8%)	NS
• Retention bladder						
° Bladder catheterisation < 2 weeks	6	(6.1%)		2	(5.9%)	NS
° Bladder catheterisation > 2 weeks						

Data are numbers (%)

NS = not significant (*P* > 0.05)

Table 3: *Urogenital Distress Inventory and Incontinence Impact Questionnaire*

UDI	**Gynecological examination* (N = 60)**		**No gynecological examination* (N = 39)**		***P*-value**
Urinary incontinence	7.5	(11.4)	7.8	(14.4)	NS
Overactive bladder	14.6	(17.4)	16.5	(23.5)	NS
Pain	10.4	(15.7)	9.1	(16.1)	NS
Obstructive micturition	16.7	(22.5)	10.8	(20.9)	NS
Genital prolapse	8.2	(13.0)	8.1	(12.6)	NS
IIQ					
Physical functioning	10.6	(17.5)	4.5	(9.2)	NS
Mobility	12.6	(17.2)	9.0	(16.4)	NS
Emotional health	8.1	(15.6)	6.3	(10.4)	NS
Social functioning	6.1	(12.6)	4.9	(10.2)	NS
Embarrassment	6.9	(13.3)	5.0	(11.4)	NS

Mean (standard deviation).
NS = not significant ($P > 0.05$)
UDI: 0 = no bother, 100 = a lot of bother
IIQ: 0 = good quality of life, 100 = wordt quality of life

Table 4: *Urogenital Distress Inventory and Incontinence Impact Questionnaire for patients who underwent gynecological examination*

UDI	**Cystocele stage ≥ 2 (N = 23)**		**No cystocele (N = 37)**		***P*-value**
Urinary incontinence	7.5	(9.0)	7.5	(12.8)	NS
Overactive bladder	13.5	(17.7)	15.3	(17.4)	NS
Pain	12.1	(16.0)	9.3	(15.6)	NS
Obstructive micturition	18.1	(20.7)	15.8	(23.9)	NS
Genital prolapse	8.4	(13.7)	8.1	(12.8)	NS
IIQ					
Physical functioning	5.8	(10.8)	13.9	(20.5)	NS
Mobility	10.4	(11.5)	14.1	(20.2)	NS
Emotional health	6.1	(10.6)	9.5	(18.3)	NS
Social functioning	3.5	(8.0)	7.8	(14.8)	NS
Embarrassment	4.2	(8.4)	8.8	(15.6)	NS

Mean (standard deviation)
NS = not significant ($P > 0.05$)
UDI: 0 = no bother, 100 = a lot of bother
IIQ: 0 = good quality of life, 100 = worst quality of life

Chapter 4

Functional outcome after sacrospinous hysteropexy for uterine descensus

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Abstract

The study aimed to evaluate urogenital symptoms, defecatory symptoms and quality of life before and after a sacrospinous hysteropexy for uterovaginal prolapse. Seventy-two women with symptomatic uterovaginal prolapse were treated with sacrospinous hysteropexy. Before and after surgery urogenital and defecatory symptoms and quality of life were assessed with a validated questionnaire. Anatomical outcome was assessed by means of pelvic examination before and after surgery. The mean follow up time was 12.7 months. Scores on all domains of urogenital symptoms and defecatory symptoms, except for the pain and fecal incontinence domain, improved significantly. Also quality of life improved on all domains. No major complications were encountered.

Introduction

In the current debate on the optimal surgical treatment of a uterine descent, several vaginal and abdominal techniques have been described. In case of a vaginal vault prolapse, the sacrospinous ligament fixation has proven to be an effective treatment[1]. The sacrospinous ligament fixation can also be performed as primary treatment for a uterine descent, a technique that can be referred to as 'sacrospinous hysteropexy'. This procedure has been described in women who wanted to preserve the uterus to retain fertility[2,3]. Several studies have shown that the sacrospinous hysteropexy is anatomical efficient and safe and most women are highly satisfied about the procedure[4-10]. Outcome in these studies was mainly assessed in terms of anatomical results, and the majority of these studies did not evaluate urogenital symptoms and quality of life with validated questionnaires. So, although anatomical outcome of the sacrospinous hysteropexy appears to be good, we cannot conclude from current literature that this type of surgery is associated with a significant functional improvement of urogenital and defecatory symptoms. Measuring this functional outcome pre- and post-operatively was one of the recommendations for future research from a recent review on the subject[11]. The main objective of this study was to assess urogenital and defecatory symptoms and quality of life before and after sacrospinous hysteropexy. Secondary, we assessed anatomical outcome.

Materials and methods

Patients

In the period between December 2001 and April 2005, 72 women underwent a sacrospinous hysteropexy at the University Medical Center Utrecht, The Netherlands.
A woman was eligible for participation if she had a symptomatic pelvic organ prolapse and wanted surgical correction with preservation of the uterus. Exclusion criteria were; abnormal uterus or ovaries on ultrasound examination, abnormal bleeding pattern and abnormal cervical cytology. All women answered a standardized questionnaire covering urogenital symptoms, defecatory symptoms and quality of life before and after surgery. Urodynamic assessment was performed in all women preoperatively. We did not try to diagnose occult stress incontinence. The study was approved by the local ethics committee.

Surgery

Surgery was performed by two experienced surgeons who at least had performed 20 sacrospinous hysteropexies before start of the study. The sacrospinous hysteropexy was performed unilaterally to the right ligament. A midline incision in the posterior vaginal wall is extended to the posterior part of the cervix. Through sharp and blunt dissection, the right sacrospinous ligament is made visible with the use of three Breisky retractors. Two non-absorbable Prolene® sutures (Ethicon, Sommerville, NJ, USA) are placed through the right sacrospinous ligament, approximately 2 cm median to the ischial spine, and subsequently placed through the posterior side of the cervix in the midline. An additional anterior and/or posterior colporrhaphy (fascia plication), with absorbable Vicryl® 2-0 interrupted sutures (Ethicon, Sommerville, NJ, USA), was performed when indicated by the judgment of the individual gynecologist. In case of stress urinary incontinence, confirmed by urodynamic tests, a surgical procedure of the Tension-free Vaginal Tape (TVT, Ethicon, Sommerville, NJ, USA) was performed as described by Ulmsten[12]. All women received peri-operative thrombosis prophylaxis (anti-Xa) and a single dose of intravenous prophylactic antibiotic (amoxicillin/clavunalic acid). Post-operatively a 14-French Foley indwelling bladder catheter with a 5 ml balloon was placed in all women and removed after 1 day (in case of an additional anterior colporrhaphy after 3 days).

Measurements

Data collection took place in October/September 2005, at least 3 months after surgery of the last participating woman. The following data were collected: age at the time of surgery; medical history; hospital stay and peri- and postoperative complications. The anatomical outcome of all women was assessed with the Pelvic Organ Prolapse Quantification score (POP-Q), which is described by the International Continence Society as a reliable and specific method to measure the pelvic organ support[13]. Before surgery, POP-Q was performed by one of the two surgeons. After surgery, POP-Q was performed by one of three independent investigators. In the analysis, we dichotomized the POP-Q stage of prolapse into stage 1 or less and stage 2 or higher. Although we know that women with pelvic organ prolapse experience symptoms that do not necessarily correlate with the severity of prolapse, we have chosen this approach to try to separate potential clinical relevant from clinical irrelevant recurrences[14].

Urogenital symptoms were measured before and after surgery with a standardized questionnaire, the Urogenital Distress Inventory (UDI), which has been validated for the Dutch population[15]. In this validation study on a large population-based sample, it was shown that the domain obstruction of the Dutch version was different from the original one. The following 5 domains were identified: urinary incontinence, overactive bladder, pain, obstructive micturition and prolapse. The scores of these domains vary between 0 and 100. A high score on a particular domain indicates more bothersome symptoms. The incidence of urinary incontinence before surgery was measured as follows: a woman was considered to have stress urinary incontinence if she replied positively to the question "Do you experience urinary leakage related to physical activity, coughing or sneezing?" Urge urinary incontinence was scored if the question, "do you experience urinary leakage related to the feeling of urgency?" was answered positively.

All patients completed a questionnaire, the Defecatory Distress Inventory (DDI) to assess the presence of defecation symptoms before and after surgery. This questionnaire was developed by our research group to assess the presence of defecation symptoms[16]. The DDI consists of 15 items about symptoms related to obstructive defecation, constipation, fecal incontinence and pain related to defecation. The 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. The DDI was used as, at present, there are no other Dutch validated questionnaires to measure quality of life related to defecation symptoms. The design on the questions is identical to those of the UDI with domain scores between 0 and 100. Again, a high score on a particular domain indicates more bothersome symptoms. The DDI was used in previous studies at our department[4,17].

Before and after surgery, disease-specific quality of life was measured with the Incontinence Impact Questionnaire (IIQ), validated for the Dutch population[15]. These questions cover the following 5 domains: physical functioning, mobility, emotional functioning, social functioning and embarrassment. The score ranged between 0 (best quality of life) and 100 (worst quality of life).

Effect sizes were measured as a useful way to estimate whether an improvement on a particular domain was considered to have a small, moderate or large clinical relevance.

Statistical analysis

Descriptive statistics were used for the whole population. To compare scores on urogenital and defecatory symptoms before and after surgery a paired Student *t* -test was used. The significance level was set at a α of 0.05. The effect size was calculated by Cohen's d test which is defined as the difference between two means divided by the pooled standard deviation for those means[18]. An effect size of 0.2 was considered to be small, 0.5 to be median and 0.8 or higher to be large. Statistical analysis was performed in SPSS 12.0 for Windows.

Results

Table 1 shows the characteristics of the 72 women. The fast majority had a combination of sacrospinous hysteropexy with an anterior colporrhaphy (87.5%). Five women (6.9%) had a sacrospinous hysteropexy of a stage 1 uterine descent. In these women, the surgeon decided to perform a sacrospinous hysteropexy during surgery because the uterine descent under anaesthesia was stage 2. The mean follow up time was 12.7 months (median 11 months).

Peri- and postoperative complications are shown in Table 2. One woman needed repeated surgery for postoperative bleeding a couple of hours after the primary procedure. Total blood loss was estimated at 400 cc. There were no incidental bladder or rectal injuries. Of the twenty women (27.8%) who had urinary retention over 100 ml after removal of the indwelling bladder catheter, five women (6.9%) needed intermittent self catheterisation more than two weeks after surgery. However, at four weeks no women had significant urinary retention. This complication only occurred in women who underwent an anterior colporrhaphy. Seven women with cystitis received antibiotics and made an uneventful recovery. Five women (6.9%) developed right-sided buttock pain which persisted longer than two weeks. It resolved spontaneously within six weeks. No removal of the sacrospinal suture was required.

During the follow-up period, a total of sixteen women (22,2%) had a recurrent prolapse of one of the compartments. Five women (6,9%) had a recurrent prolapse of the uterus (four women stage 2, one woman stage 3). Ten women (13.9%) had a cystocele stage 2 or more (eight women stage 2, two women stage 3) and two women (2,8%) had a

prolapse of the posterior compartment stage 2. All the women with a recurrent cystocele had had surgery of the anterior compartment combined with the hysteropexy, so there were no de novo cystoceles. The two women with a recurrent rectocele did not have surgery of the posterior compartment combined with the sacrospinous hysteropexy, so these can be considered as de novo rectoceles.
Table 3 shows the results of the UDI, DDI and IIQ domain scores before and after surgery. On all urogenital domains, there was significant improvement as well as on all quality of life domains. Symptoms on domain constipation and obstructive defecation also improved significantly. Large effect sizes were found on domain pain (effect size = 0.92) and genital prolapse (effect size = 2.0) of the UDI. The domain physical functioning and emotional health of the IIQ also showed a large effect size (0.82 and 0.79 respectively).
In addition to the table we made a sub analysis for the fifteen women who had additional surgery for urinary incontinence (TVT). These women improved significantly on the urinary incontinence domain after surgery (mean score: 26.7 → 6.7, *P* =.009). This improvement was not significantly for the women without TVT surgery (mean score: 16.4 → 11.5, *P* =.162). On the other hand, the women with TVT surgery did not improve significantly on the overactive bladder domain (mean score: 24.3 → 16.23, *P* =.079) where the group without TVT did (mean score: 30.8 → 14.3, *P* <0.001).

Discussion

The objective of this study was to assess quality of life and urogenital and defecatory symptoms before and after sacrospinous hysteropexy. The results show that a sacrospinous hysteropexy significantly reduced all urogenital and several defecatory symptoms and significantly improved quality of life. Effect sizes were large on domain genital prolapse and pain (UDI), and on domain physical functioning and emotional health (IIQ). It also anatomically cured the uterine descent in 93.1% of women.
The sacrospinous ligament fixation was first described by Sederl (1958)[19]. Later it became more popular by Richter and Albright[20] (Europe) and Randall and Nichols[21,22] (USA). Several modifications of their techniques have been described since. The anatomical results of 2256 women after a sacrospinous ligament fixation of the vaginal vault were recently reviewed[1]. Objective cure rates varied between 67% and 96.8%, and subjective cure rates varied between 70% and 98%. Our findings are in line with these

results, although the review focussed on the sacrospinous fixation of a vault prolapse. Subjective outcomes are underreported in most studies on the sacrospinous ligament fixation. We have shown that bladder and bowel function improves significantly after a sacrospinous hysteropexy.
There are a variety of reasons why women want to preserve their uterus. Among those reasons are; keeping their fertility; personal identity, but also the possibility that this kind of surgery might reduce operation time, estimated blood loss and postoperative recovery time[4,23]. There are signs that removing the uterus may increase the risk of pelvic neuropathy, new onset urinary incontinence, bladder dysfunction and prolapse[24,25,26]. Several studies on the sacrospinous hysteropexy, as a technique in which the uterus is preserved, are available[3-6, 8-10, 27]. Among these studies, three were of prospective design[6,8,27], five were of retrospective design[3-5,9,10], and there was one case report[28]. One report described a different surgical technique and therefore cannot be compared with our study[2]. One study assessed risk factors for failure of sacrospinous hysteropexy[29], another study only assessed sexual functioning after sacrospinous
hysteropexy[30]. Anatomic success rates in these studies varied between 74% and 93.5%, which is comparable with our results. The main problems when comparing studies on the sacrospinous ligament fixation were recently debated by Morgan et al[11]. They showed that there is a variety in definition of failure of sacrospinous ligament fixation, due to differences in how anatomical outcomes are evaluated and which compartment of the vagina is considered. In our group, recurrent postoperative cystoceles stage 2 or higher were seen in ten women (13.9%). This percentage is slightly lower as the 21.3 % reported in the recent review[11]. However, our follow-up in the current study was
relatively short and some recurrences may not have been detected in this timeframe. In a previous retrospective study on the anatomical outcome of the sacrospinous hysteropexy by our group, we found a higher rate of recurrent cystoceles stage 2 or higher (38%)[9]. The follow-up period in this study was a mean of 23 months. The high rate of recurrent cystoceles may be related to the primary damage of neuromuscular support or may be the result of the retroverted axis of the vagina after sacrospinous hysteropexy. This last aspect, being regarded as an overcorrection, is held responsible for the high rate of cystoceles[27,31]. However, in a study by Smilen et al, the sacrospinous hysteropexy did not independently increase the risk of recurrent cystocele as

compared to other surgical techniques[32].
Apart from true genital prolapse symptoms, urogenital symptoms and also bowel symptoms improved after the sacrospinous hysteropexy. Since the majority of women in our study had their sacrospinous hysteropexy combined with an anterior colporrhaphy, one may argue that it was this anterior repair that relieved symptoms, and not the sacrospinous hysteropexy. However, it was shown that pelvic organ prolapse and urogenital symptoms were only slightly correlated to the site and severity of the prolapse[14]. This lack of a clear correlation between the site of the pelvic organ prolapse and symptomatology makes it very difficult in combination surgery to contribute functional improvement to a certain intervention. All we can conclude from our results is that surgical procedures that involve a sacrospinous hysteropexy show good functional outcome.
It was shown that overactive bladder symptoms disappear after anterior repair in 60-82% of women[33]. We also found a marked improvement of overactive bladder symptoms after surgery in our group. However, this significant improvement was confined to the women who did not have a combined TVT procedure with their sacrospinous hysteropexy. Women who did have a TVT combined procedure experienced more bother on overactive bladder domain after surgery as compared to women without TVT surgery. This finding is consistent with literature on the TVT in which the development of overactive bladder symptoms after TVT surgery is reported to occur in up to 15% of women[34]. We have to keep this in mind when placing a TVT (prophylactic) in case of occult stress incontinence.
After sacrospinous hysteropexy, postoperative complications occur, but none of them was life threatening. Most complications were self-limiting. The majority of postoperative complications were related to the bladder function. These complications did not occur in women who only had a sacrospinous hysteropexy. Therefore, it is likely that complications related to the bladder are the consequence of additional surgery and not the result of sacrospinous hysteropexy. The prevalence of buttock pain is estimated at 10 to 15 %[35]. This pain can be explained by injury to surrounding nerves of the sacral plexus and branches of the pudendal nerve. In an anatomical study, the relationship of the pudendal nerve to the sacrospinous ligament was found to be variable (one branch of the pudendal nerve piercing through the ligament was found in 11%)[36] . Barksdale et al. also showed that nerve tissue is present and widely distributed within the sacrospinous ligament[37]. Therefore, although the placement of the suture

two centimetres medial to the ischial spine protects against major nerve injuries, the complications of buttock pain cannot be prevented in all women. Fortunately, this buttock pain was shown to resolve spontaneously in most cases, as we also demonstrated in our series[9].
The strength of our study is that we measured urogenital and defecatory symptoms and quality of life in a large group of women who underwent a sacrospinous hysteropexy, with a validated questionnaire before and after surgery. There are some potential draw-backs that need to be discussed. First, there might be an indication bias. In our country, a vaginal hysterectomy is the standard surgical technique for correcting a uterine descent. Therefore, women that came to our hospital may have chosen specifically for this operation. They might have had high expectations of this procedure which could have influenced their outcome with respect to quality of life. Second, in some patients follow-up time was limited to three months. Possibly, some recurrences had not yet developed at that time. Third, the study was performed in a single university hospital. The sacrospinous ligament fixation has become rapidly popular in our center and is performed by two surgeons. They are highly trained in performing the procedure. This might have influenced the outcome. Fourth, we did not compare the sacrospinous hysteropexy with other surgical techniques to correct a uterine descent. Therefore, we cannot conclude that the sacrospinous hysteropexy is superior to other procedures. However, it is a safe and effective operation for women who wish to preserve their uterus at time of genital prolapse surgery.

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Table 1: *Patient characteristics*

Patient characteristics	**N = 72**	
Age (years) *	57.2	(11.9)
Surgery for prolapse in medical history	3	(4.2)
Surgery for urinary incontinence in medical history	4	(5.6)
Urinary incontinence before surgery †	40	(55.6)
• Urge incontinence	9	(12.5)
• Stress incontinence	21	(29.2)
• Combination stress ande urge incontinence	10	(13.9)
Gynecological examination before surgery		
• Descensus uteri stage 2 or more	67	(93.2)
• Cystoceles stage 2 or more	57	(79.2)
• Rectoceles stage 2 or more	19	(26.4)
• Enterocele	1	(1.4)
Surgery		
• Sacrospinous hysteropexy	8	(11.1)
• Sacrospinous hysteropexy + anterior colporrhaphy	54	(75)
• Sacrospinous hysteropexy + anterior and posterior colporrhaphy	9	(12.5)
• Sacrospinous hysteropexy + posterior colporrhaphy	1	(1.4)
• Additional TVT	15	(20.8)
Hospital stay (days) ††	3.5	(1-8)
Follow up in months ††	12.7	(3-33)

Data are numbers (%)

* mean (standard deviation),

† assessed with Urogenital Distress Inventory,

†† range

Table 2: *Complications related to surgery*

	N = 72	
Complications during surgery	0	(0)
Complications after surgery	32	(44.4)
• Second surgery because of bleeding	1	(1.4)
• Buttock pain	13	(18.1)
° Buttock pain < 2 weeks	8	(11.1)
° Buttock pain > 2 weeks	5	(6.9)
• Vaginal hematoma	2	(2.8)
• Urinary tract infection	7	(9.7)
• Retention bladder	20	(27.8)
° Bladder catheterisation < 2 weeks	15	(20.8)
° Bladder catheterisation > 2 weeks	5	(6.9)
• Vaginal adhesion	3	(4.2)

Data are numers (%)

Table 3: *Urinary Distress inventory (UDI), Defecatory Distress Inventory (DDI) and Incontinence Impact Questionnaire (IIQ).*

	Before surgery* (N = 72)		After surgery* (N = 72)		P-value	Effect Size
UDI						
• Urinary incontinence	18.5	(24.2)	10.5	(21.0)	.012	0.35
	29.5	• (26.7)	14.4	(18.6)	.000	0.66
Overactive bladder	30.1	(26.7)	9.5	(16.7)	.000	0.92
	27.0	• (28.3)	10.8	(19.7)	.000	0.66
Pain	56.6	(32.0)	5.6	(17.4)	.000	2.0
• Obstructive micturition						
• Genital prolapse	11.9	(18.8)	6.3	(9.8)	.021	0.37
DDI	13.3	(19.7)	8.3	(11.8)	.016	0.22
	4.5	• (16.3)	2.8	(8.3)	.498	0.13
Constipation	8.6	(20.7)	8.5	(14.4)	.955	0.01
• Obstructive defeca- t i on						
	26.0	• (24.4)	9.4	(15.1)	.000	0.82
Pain	25.0	(22.8)	12.6	(18.4)	.000	0.60
• Fecal incontinence	23.2	(23.3)	8.0	(14.2)	.000	0.79
IIQ	14.8	(19.1)	4.5	(11.8)	.000	0.65
• Physical functioning	11.2	(13.8)	6.7	(11.1)	.013	0.41
	•					
Mobility						
• Emotional health						
• Social functioning						
• Embarrassment						

* Mean (standard deviation)

Effect Size: 0.2 = small effect, 0.5 = medium effect, 0.8 = large effect

Section 2

Chapter 5

Postoperative Pain and Recovery Time After Vaginal Hysterectomy or Sacrospinous Hysteropexy: A Randomized Study

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Abstract

Introduction and hypothesis: The sacrospinous hysteropexy was associated with a shorter recovery time as compared to a vaginal hysterectomy in a retrospective study.
Methods: In this randomized study, 66 women with stage 2-4 uterine descent underwent a vaginal hysterectomy (31) or a sacrospinous hysteropexy (35). Complications, visual analogue scale scores, use of analgesics, hospital stay, and length of time to complete recovery and return to work were compared. Differences were tested with an unpaired Student *t* test or a chi-square test.
Results: Visual analogue scale scores, use of analgesics and complications did not differ significantly. Median hospital stay was shorter after a sacrospinous hysteropexy (3 versus 4 days, $P = 0.03$). Length of time to return to work was shorter after a sacrospinous hysteropexy (43 versus 66 days, $P = 0.02$).
Conclusions: The sacrospinous hysteropexy for uterine descent stage 2-4 is associated with a shorter median hospital stay and earlier return to work.

Introduction

Pelvic organ prolapse is a common health problem with a prevalence rate of 41% in women over 50 years of age[1]. One in every 10 women will have a pelvic organ prolapse that requires surgery. Unfortunately, the prolapse recurs in 29% of women, with the need for a second surgical intervention[2]. With increasingly better health care facilities, older women remain more active in daily life. Having pelvic organ prolapse interferes with daily life, and therefore treatment is desirable, irrespective of age.
In the Netherlands, a vaginal hysterectomy, combined with other prolapse surgery if necessary, is commonly performed for uterine descent. In 1989, Richardson was the first to report about sacrospinous hysteropexy in young women with uterine descent in which the uterus was preserved[3]. The uterus itself plays a passive role in the development of uterovaginal prolapse; therefore, it might be unnecessary to remove the uterus[4]. Preserving the uterus at the time of surgery for uterine descent might be accompanied with less morbidity and a shorter recovery time because of the less invasive nature of the procedure. Recovery time after a sacrospinous hysteropexy has been shown to be significantly shorter compared to vaginal hysterectomy[5]. No randomized studies between these 2 surgical techniques, describing complications and recovery time, have been published. We performed a randomized study comparing a vaginal hysterectomy with a sacrospinous hysteropexy for the treatment of uterine descent stage 2-4 in women with no medical history of pelvic surgery and normal uterus, cervix, and ovaries. Complications, postoperative pain, use of analgesics, length of hospital stay, and length of time to full recovery and return to work were compared.

Materials and Methods

This nonblinded, randomized study was approved by the ethics committees of the 6 participating hospitals (University Center Utrecht, Meander Medical Center Amersfoort, Rijnstate Hospital Arnhem, St. Antonius Hospital Nieuwegein, St. Elisabeth Hospital Tilburg and Twee Steden Hospital Tilburg). Women were referred to one of the hospitals by their general practitioner because of symptomatic pelvic organ prolapse. They were asked to participate between February 2004 and December 2006. Criteria for entry into the study were the presence of uterine descent stage 2-4, according to the classification of the International Continence Society[6], and the desire

for surgical correction. Other selection criteria were no medical history of pelvic surgery, normal uterus and ovaries on ultrasound examination, normal menstrual bleeding pattern (if premenopausal), and normal cervical cytology. Insulin-dependent diabetes mellitus was an exclusion criterion because it is related to bladder dysfunction. After informed consent, patients were randomly assigned to a vaginal hysterectomy or a sacrospinous hysteropexy by drawing sealed, opaque envelopes. Randomization was centralized. The gynecologist contacted the research nurse or the principal investigator for the randomization. The gynecologist was informed about the selected surgical procedure by phone and mail.

Measurements
Primary outcome of the study was recovery time after surgery including return to daily activities and resumption of work activities. Secondary outcome measurements were hospital stay, visual analogue scale (VAS) scores after surgery, use of analgesics after surgery, the need for professional home care after hospital stay, and complications during and after surgery, e.g., blood loss during surgery and the need for blood transfusion, bowel or bladder injuries, urinary tract symptoms after surgery, fever requiring antibiotics, and buttock pain. Data on anatomical and functional outcome 1 year after surgery will be described in *Chapter 6 and 7*.
Baseline characteristics were collected, and a gynecological examination was performed before surgery. Staging of the prolapse was preoperatively measured using the pelvic organ prolapse quantification system[6]. All women were asked to complete a diary during admission to the hospital, 1 week after surgery, 2 weeks after surgery, 6 weeks after surgery until the women could answer the questions considering recovery and, when applicable, returning to work. The questionnaire consisted of the following items:

1. A visual analogue scale ranging from 0-10 cm to assess the experienced pain during the first week, 2 weeks after surgery, and 6 weeks after surgery.
2. Use of pain medication during hospital stay, at 1 week and 2 and 6 weeks after surgery (which was also written down in the medical files).
3. Length of time to return to normal daily activities and, if applicable, length of time to return to (complete) functioning at work.
4. Days of having pain, having a bladder catheter, having food restrictions, being impaired in self-care, having intravenous infusion, and having impaired

mobility after surgery, during hospital stay.

5. The need for professional home care after hospital stay. This home care to support function at home was indicated during hospital stay by an independent assessor or arranged by the woman herself.

Women were asked to answer the questions about pain and use of analgesics in the evening at a fixed time point. Postoperative pain management in each hospital was done according to a protocol. All women had access to 4000 mg of paracetamol and 150 mg of diclofenac per day. The use of morphine was optional during the first 24-48 hours. Information about duration of surgery, amount of blood loss, complications during and after surgery, and length of hospital stay were collected in the clinical research file of all study participants. All women were counseled the same way about restrictions at home and at work regarding heavy lifting and exercise.

Surgical procedures

Experienced gynecologists from the 6 participating hospitals performed all vaginal hysterectomy procedures. Sacrospinous hysteropexy procedures were performed by experienced gynecologists with special skills in pelvic floor surgery who had performed at least 20 sacrospinous hysteropexy procedures before the start of the study. The vaginal hysterectomy and the sacrospinous hysteropexy were combined with an anterior or posterior colporrhaphy (fascia plication), or both, with absorbable Vicryl 2-0 interrupted sutures (Ethicon, Sommerville, NJ, USA) when indicated by the judgment of the individual gynecologist. In the vaginal hysterectomy group, the uterosacral ligaments were reattached with resorbable sutures (Vicryl 1, Ethicon, Sommerville, NJ, USA) to the vaginal cuff after removal of the uterus[7]. At the preference of the surgeon, a modified McCall culdoplasty was performed as described by McCall, except that a Vicryl 1 suture (Ethicon, Sommerville, NJ, USA) was used instead of the original suture[8]. The sacrospinous hysteropexy was performed unilaterally to the right sacrospinous ligament. A midline incision in the posterior vaginal wall was extended to the posterior part of the cervix. In 2 women, a transverse incision was made 2 cm below the fornix posterior because of the preference of the surgeon. Through sharp and blunt dissection, the right sacrospinous ligament was made visible with the use of 3 Breisky retractors. Two nonabsorbable Prolene 1 sutures (Ethicon, Sommerville, NJ, USA) were placed through the right sacrospinous ligament, approximately 2 cm median to the ischial spine, and subsequently placed through the posterior side of the cervix in the midline. In case of coexisting urinary stress incontinence, a surgical procedure using Tension-free Vaginal Tape (TVT, Ethicon, Sommerville, NJ, USA) was performed retropubic as described by Ulmsten[9] or by the transobturator route as described by de Leval[10]. All women received perioperative thrombosis prophylaxis and a single dose of intravenous prophylactic antibiotics before surgery. Postoperatively, an indwelling bladder catheter was placed in all women and removed 24 hours after surgery (except after an additional anterior colporrhaphy, in which case it was left in place for 3 days).

Sample size calculation

The sample size was calculated for the primary outcome measurement, recovery time. With an expected difference between groups of 25% (68% fully recovered within 3 months after a sacrospinous hysteropexy and 43% after a vaginal hysterectomy in a previous retrospective study),[5] a power of 80% and an alpha of 0.05, at least 61 women in each group were needed to be enrolled.

Statistic analysis

Descriptive statistics were used for interval (means and standard deviation) and categorical (numbers/percentages) data. Differences between the groups were analyzed with an unpaired Student *t* test for continuous variables and the chi-square test for categorized variables. Differences in VAS scores measured daily in the first week were calculated with repeated measurement analyses. A *P* -value of < 0.05 was considered significant. All statistical analyses were performed using SPSS 12.0.1 for Windows.

Results

Seventy-one women with symptomatic uterine descent stage 2-4 requiring surgery were randomized. A trial profile of subject enrollment is displayed in Figure 1. After randomization and before surgery, 5 women withdrew from further participation. In 3 of these 5 women, surgery was cancelled because the women stated that their complaints decreased. One woman was diagnosed with atypical endometrial hyperplasia after a diagnostic workup and therefore was treated differently. One woman refused to participate, because answering the questionnaires was regarded as too much bother. In the remaining 66 women, there were 6 protocol deviations;

2 women underwent a vaginal hysterectomy instead of a sacrospinous hysteropexy (one women because of inadequate visualization of the sacrospinous ligament, and in one women the reason for changing the procedure was not written down adequately in the clinical research file); 4 women had an exclusion criterion that was overlooked before randomization. Two of them were diagnosed with insulin-dependent diabetes mellitus (one in each group) and 2 of them had a medical history of pelvic surgery (one in each group, caesarean delivery and posterior colporrhaphy). All of these 66 women were included in the intention to treat analysis. Six women did not return the questionnaire (2 in the vaginal hysterectomy group, 4 in the sacrospinous hysteropexy group).

Table 1 shows the baseline characteristics of the 71 randomized women and the surgical procedures performed in the 66 analyzed women. The baseline table shows no incomparability in patient characteristics in the 2 groups, except age. The mean age of women who underwent a vaginal hysterectomy was about 2 years higher than the mean age in women who underwent a sacrospinous hysteropexy (P =0.3).

In Table 2, hospital stay, operating time, intraoperative blood loss, and complications during and after surgery according to surgical approach are described. The median hospital stay was one day shorter after a sacrospinous hysteropexy. Serious operative complications were rare in both groups. In both groups, no bladder or rectal injuries occurred, and no blood transfusions or intensive care admissions were needed. Urinary retention resolved within 6 weeks in all women. Five days after surgery, one woman who underwent a vaginal hysterectomy was diagnosed with a distal occlusion of the right ureter. Most likely, this was a result of a too-lateral placement of the Mc Call sutures. A nephrostomy catheter was placed that relieved the pain symptoms, and the patient was treated with antibiotics. At 4-month follow-up, normal ureter function returned, and the patient recovered completely.

Table 3 shows the use of paracetamol, VAS scores, and length of time to return to daily activities and work according to surgical approach. Not all women filled in the questions concerning the VAS scores and recovery time (N=29 and N=28). No statistical differences in pain perception, assessed by VAS scores during the first week after surgery, were seen. At 2 and 6 weeks, a borderline significant difference was found between the 2 groups in favor of the women with a vaginal hysterectomy. Use of

paracetamol after surgery was similar in both groups. Also no statistical differences in women after a sacrospinous hysteropexy or a vaginal hysterectomy were found in the first 3 days after surgery with regard to the use of diclofenac (respectively 23 mg/day, SD 41 versus 31 mg/day, SD 62, P =0.5) and morphine (respectively 2 mg/day, SD 3 versus 3 mg/day, SD 5, P =0.3). At 6 weeks, no women needed to use analgesics. One woman in the sacrospinous hysteropexy group had an epidural in the first 24 hours after surgery. Women returned to work 23 days earlier after a sacrospinous hysteropexy compared with women after a vaginal hysterectomy. In addition, significantly more women in the vaginal hysterectomy group needed professional home care after hospital stay compared with women in the sacrospinous hysteropexy group, 8 women (26%) versus 1 woman (3%) (P =0.01)
Days of having a bladder catheter, days with food restrictions, days with impaired self-care, days with intravenous infusion, and days with impaired mobility were similar between groups.
Adjustment for age did not alter our findings. Also analyzing the outcome measurements per protocol did not influence the results outlined except for the difference in median hospital stay (3 versus 4 days, P =0.09, in favor of the sacrospinous hysteropexy).

Discussion

This multi-center, randomized study showed that vaginal hysterectomy and sacrospinous hysteropexy for uterine descent stage 2-4 are comparable with respect to complication rate, postoperative pain scores, and use of analgesics after surgery. The median length of hospital stay was one day shorter in the sacrospinous hysteropexy group. Length of time to return to work was significantly shorter after a sacrospinous hysteropexy.

Significant differences were found between the 2 groups with regard to the resumption of work activities. In a retrospective study comparing a vaginal hysterectomy with a sacrospinous hysteropexy, women were asked about the length of time to complete recovery after surgery[5]. After a vaginal hysterectomy, 57% of women needed more than 3 months to recover compared with 32% of women after a sacrospinous hysteropexy, which was a statistically significant difference.

In our study, both groups needed almost 34 days to resume daily activities, which was also reported by Maher et al after a vaginal hysterectomy[11]. No other studies comparing the vaginal hysterectomy and sacrospinous hysteropexy were available with data on recovery time. When women were specifically asked about returning to work activities, the women in the vaginal hysterectomy group needed significantly more time. Moreover, women in the sacrospinous hysteropexy group not only returned to work 23 days earlier, but also were able to perform their work activities at their usual level 23 days earlier, but this finding was not statistically significant. These results indicate that morbidity in the long-term is higher after a vaginal hysterectomy. As previously mentioned, the vaginal hysterectomy procedure is more complex, accompanied by more damage to surrounding structures (vessels and nerves) and entry into the abdominal cavity. These differences in surgical techniques could be responsible for a shorter recovery time after a sacrospinous hysteropexy. It appears that these differences are also reflected in the median length of hospital stay, which was one day shorter after a sacrospinous hysteropexy. Aside the differences in surgical techniques, also other factors have to be considered. It is possible that the doctor released women earlier after a sacrospinous hysteropexy, because this procedure was considered less complex. Also women might have felt that after a sacrospinous hysteropexy recovery time would be shorter because surgery appeared less invasive to them. However, all women were counseled about recovery time after surgery in the same way so we do not think this had a major influence on the outcome. Although this study was not performed to evaluate the costs of these operations, the results could be of economic importance, because in 2006, in the Netherlands, 5819 vaginal hysterectomies were performed including those for uterine descent[12]. It is possible that this number will increase, because the incidence of prolapse will increase with longer life expectancy. Postoperative pain, measured with VAS scores, did not differ in the first week after surgery, and the use of analgesics was equally divided between the 2 groups. There appeared to be a trend that, after 2 to 6 weeks, women after a sacrospinous hysteropexy had higher VAS scores compared with women after a vaginal hysterectomy. An explanation for this trend could be that buttock pain, which is only related to a sacrospinous hysteropexy and occurred in 11% of women (which is comparable to reports in the literature) was responsible for the higher VAS scores[13,14]. Nevertheless, the groups were too small to make a subanalysis. We have to acknowledge that all VAS scores were low. The VAS scores and the use of analgesics

after a vaginal hysterectomy were comparable to those reported in the literature[15]. No data were available concerning a sacrospinous hysteropexy.

Some limitations of the study need to be addressed. First, the number of subjects fell short of the sample size that was calculated. A lot of women were reluctant to let a lottery decide whether their uterus was to be removed. This is reflected in our study flow chart (Figure 1). Only 17% of the potential women participated. Unfortunately, a lot of women had a preference for 1 of the 2 procedures. These women could be divided into 2 groups. When women were told that, at the time of the study, we did not know whether one procedure was superior to the other, some chose to retain their uterus ("why remove the uterus if not necessary"). Another group of women wanted to have their uterus removed because family members or friends had good experience with this procedure (first choice operation for decades). Therefore, many women argued that if the uterus is removed, it is impossible to have a recurrent prolapse. Also, the fact that a removed uterus cannot cause any health problems (eg, cancer of the cervix or uterus) in the future was a reason to prefer a vaginal hysterectomy. We do not think that the stage of prolapse or differences in symptoms was a reason for preferring 1 of the 2 procedures. Therefore, our results are most likely generalizable to all patients who meet the inclusion and exclusion criteria. Second, if the randomization was performed shortly before surgery or even in the operating room, fewer protocol deviations would have occurred. However, we had chosen to randomize earlier to have more time to inform the women about the procedure they were randomized to.

Based on the results of this study, a sacrospinous hysteropexy for the correction of uterine descent stage 2-4 is associated with earlier return to work activities and a shorter median hospital stay compared with a vaginal hysterectomy. If the data on anatomical and functional outcome of the 2 techniques prove to be comparable, the sacrospinous hysteropexy might be the first treatment of choice.

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Figure 1: *trial profile*

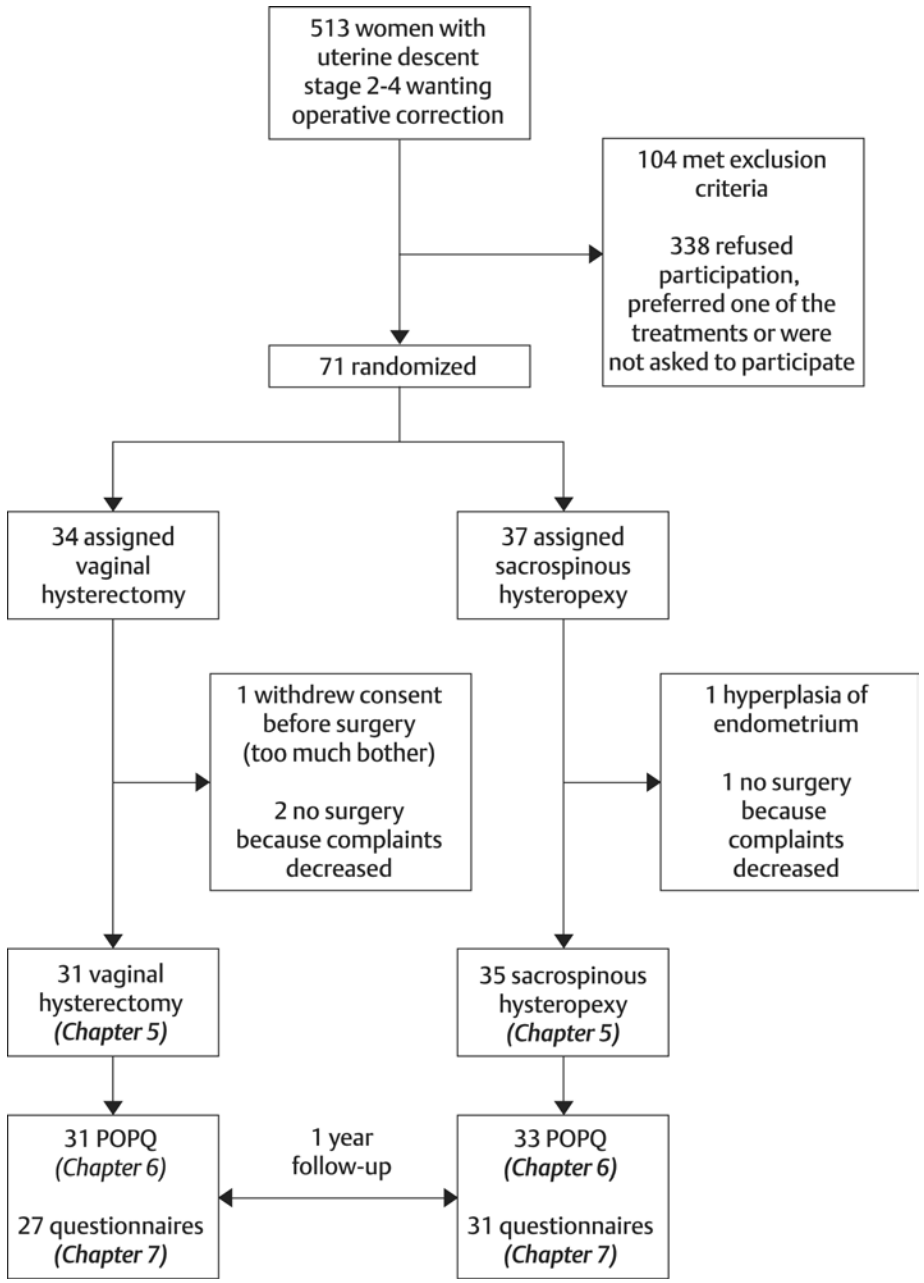

Table 1: *Baseline characteristics at randomization and surgical procedures performed.*

		Sacrospinous hysterpexy (N = 37)		Vaginal hysterectomy (N = 34)	
Age (mean years ± SD)		61.5	± 9.6	63.7	± 9.0
Body mass index (mean ± SD)		26.3	± 3.2	25.9	± 2.9
Parity [median (range)]		2	[0-5]	2	[1-7]
Postmenopausal		33	(89)	32	(94)
Prior surgery					
		4 •	(11)	5	(15)
Appendectomy		4	(11)	4	(12)
		1 •	(3)	0	(0)
Sterilization					
• Hemicolectomy (colon carcinoma)		1	(3)	1	(3)
Relevant comorbidity		1	(3)	2	(6)
• Insulin dependent diabetes mellitus		3	(8)	3	(9)
• Non-insulin dependent diabetes mellitus		0	(0)	2	(6)
• Chronic abstructive pulmonary disease					
		21 •	(57)	19	(60)
Rheumatoid arthritis		12	(32)	9	(27)
Stage of prolapse before surgery (POPQ)		4	(11)	6	(18)
• Uterine descent	Stage 2	1	(3)	1	(3)
		2	(5)	1	(3)
	Stage 3	14	(38)	9	(27)
		16	(43)	19	(56)
	Stage 4	4	(11)	4	(12)
• Cystocele	Stage 0	9	(24)	10	(29)
		5	(14)	8	(24)
	Stage 1	18	(49)	8	(24)
		2	(5)	5	(15)
	Stage 2	3	(8)	3	(9)
Stage 3					
	Stage 4				
• Rectocele	Stage 0				
	Stage 1				
	Stage 2				
	Stage 3				
	Stage 4				
Surgical procedures performed		**(N=35)**		**(N=31)**	
Sacrospinous hysteropexy		33	(94)	0	(0)
Vaginal hysterectomy		2	(6)	31	(100)
Mc Call sutures		0	(0)	5	(16)
Anterior colporrhaphy		28	(80)	31	(100)
Posterior colporrhaphy		20	(57)	15	(48)

Table 2: *Hospital stay, operating time, intraoperative blood loss, and complications during and after surgery according to surgical approach.*

	Sacrospinous hysteropexy (N = 35)		Vaginal hysterectomy (N = 31)		*P* -value
Operating time (min) (mean ± SD)	71	(18)	77	(25)	0.2
Estimated blood loss (cc) (mean ± SD)	185	(116)	183	(97)	0.9
Hospital admission (days):					
Median (range)	3	(3-7)	4	(3-14)	0.03*
Intraoperative complications:	1	(3)	2	(7)	0.5
Related to use antibiotics	0	(0)	1	(3)	0.3
Related to anaesthesia	0	(0)	1	(3)	0.3
Technical problems	1	(3)	0	(0)	0.3
Postoperative complications during admission:	8	(23)	4	(13)	0.3
Retention bladder	4	(11)	4	(13)	0.9
Fever requiring antibiotics	0	(0)	1	(3)	0.9
Buttock pain	4	(11)	0	(0)	0.05
ureter obstruction	0	(0)	1	(3)	0.3
Complications after admission till 6 weeks after surgery:	6	(17)	5	(16)	0.9
Retention bladder	3	(9)	3	(10)	0.9
Urinary tract infection	2	(6)	2	(7)	0.9
Buttock pain	1	(3)	0	(0)	0.3

Data are presented as n (%) unless otherwise noted. SD = standard deviation.
All *P* -values calculated with independent Student *t* test or chi-square test except for * which was calculated with Mann-Whitney U test.

Table 3: *Use of paracetamol, visual analogue scale scores, and length of time to return to daily activities and work according to surgical approach.*

	Sacrospinous hysteropexy (N = 34)		Vaginal hysterectomy (N = 31)		*P* -value
Use of paracetamol (mg/day)					
• In the first 3 days	2858	(873)	3032	(860)	0.4
	871	• (1155)	At 7931	(1271)	0.8
week	345	(857)	375	(824)	0.9
	0	•	At 02		1.0
weeks					
• At 6 weeks					

	Sacrospinous hysteropexy (N = 29)		Vaginal hysterectomy (N = 28)		*P* -value
	2.3	(2.1)	2.2	(1.8)	0.7*
VAS scores (0-10cm)	1.2	(1.9)	0.5	(0.8)	0.08
VAS score during first week after surgery	0.7	(1.2)	0.2	(0.3)	0.05
VAS score at 2 weeks after surgery					
VAS score at 6 weeks after surgery	34	(13)	33	(21)	0.9
Recovery time (days)	43	(21)	66	(34)	0.02
• Return to daily activities	57	(33)	80	(45)	0.08
• ~~Return tot working activities~~					
• Completely return to work					

Data are means (standard deviation)
All *P* -values calculated with independent Student *t* test except for * which was calculated with repeated measurements analysis
VAS = visual analogue scale

Chapter 6

One-Year Follow-Up of Anatomical Outcomes after a Sacrospinous Hysteropexy and Vaginal Hysterectomy for Uterine Descent: A Randomized Study

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Abstract

Objectives: Anatomical outcomes after a vaginal hysterectomy and a sacrospinous hysteropexy were compared.

Study Design: In this randomized study, 66 women with stage 2-4 uterine descent underwent a vaginal hysterectomy (31) or a sacrospinous hysteropexy (35). Anatomical outcomes were measured at 6 months and 1 year after surgery. The difference in risk of recurrent prolapse was calculated with the Confidence Interval Analysis.

Results: Nine women after a sacrospinous hysteropexy (27%) were diagnosed with a recurrent uterine descent. Only 1 recurrence was found after a vaginal hysterectomy (3%, *P* =0.01). The difference in risk for recurrent prolapse stage 2 or more of the apical compartment was 17% (95% CI: 2 to 30) in favor of the vaginal hysterectomy. All women with a pre operative prolapse stage 4, had a recurrent apical prolapse after a sacrospinous hysteropexy. No significant differences in risk were found in the anterior and posterior compartment.

Conclusions: The sacrospinous hysteropexy for uterine descent is associated with more recurrent apical prolapse at 1-year follow-up.

Introduction

Pelvic organ prolapse is a major health problem that will increase in the next decennia as the prevalence of pelvic organ prolapse increases with the aging population. In the Netherlands, a vaginal hysterectomy and concomitant repair of pelvic support defects is considered standard practice in case of uterine descent. In 1989, Richardson reported on the sacrospinous hysteropexy for uterine descent, a procedure performed in case of a uterine descent, in which the uterus could be preserved[1]. Today, it is unclear whether removing the uterus is necessary or leads to better anatomical results.
In several studies it has been shown that sacrospinous hysteropexy is anatomically efficient and safe, and most women have been highly satisfied with the procedure[2-6]. Only 3 studies have been published in which the sacrospinous hysteropexy was compared with a vaginal hysterectomy in terms of anatomical outcomes (in 2 of these studies the vaginal hysterectomy was combined with a prophylactic sacrospinous ligament fixation of the vault)[4-6]. None of these studies were randomized. In the study of van Brummen et al, anatomical outcomes were retrospectively collected from medical files that most likely underestimate the recurrence rates[6]. Hefni et al performed a prospective cohort study of women with a mean age of 74 years in which anatomical outcomes were not collected by an independent assessor[5]. The procedures were equally effective with regard to anatomical outcomes[4-6].
We performed a randomized study comparing the vaginal hysterectomy with the sacrospinous hysteropexy for the treatment of uterine descent stage 2-4 in women with no medical history of pelvic surgery, and with a normal uterus, cervix, and ovaries. Data on recurrent prolapse stage 2-4 and recurrent prolapse surgery at 1-year follow-up are presented.

Material and Methods

This nonblinded, randomized study was approved by the ethics committees of the 6 participating hospitals (University Center Utrecht, Meander Medical Center Amersfoort, Rijnstate Hospital Arnhem, St. Antonius Hospital Nieuwegein, St. Elisabeth Hospital Tilburg and Twee Steden Hospital Tilburg). This study reports the effect on anatomical outcomes.

Patients
Women were referred to one of the hospitals by their general practitioner because of symptomatic pelvic organ prolapse. Between February 1, 2004 and December 1, 2006, women were invited to participate. Criteria for entry into the study were the presence of a uterine descent stage 2-4 according to the classification of the International Continence Society and the desire for surgical correction[7]. Other selection criteria are described in *Chapter 5*. After informed consent, patients were randomly assigned to a vaginal hysterectomy or a sacrospinous hysteropexy by drawing sealed, opaque envelopes. Randomization was centralized. The gynecologist contacted the research nurse or the principal investigator for the randomization. The gynecologist was informed about the selected surgical procedure by phone and mail.

Measurements
At baseline and 1 year after surgery, women underwent a pelvic examination by the treating gynecologist. At 6-month follow-up, women were examined by an independent assessor. Pelvic organ prolapse was assessed using the pelvic organ quantification system (POP-Q)[7].
In the current study, we compared the recurrence rate stage 2-4 of the apical, anterior, and posterior compartment after a vaginal hysterectomy and a sacrospinous hysteropexy. A prolapse stage 2-4 on gynecological examination 1 year after surgery was considered a recurrence. The necessity for repeat surgery was indicated by the treating gynecologist.

Surgical procedures
Surgical procedures are described in *Chapter 5*.

Sample size
Sample size calculation was done for the primary endpoint of the study, the duration of the recovery period after surgery as described in *Chapter 5*. At least 61 women in each group had to be enrolled.

Statistical analysis
Descriptive statistics were used for continuous (means and standard deviation) and categorical (numbers/percentages) data. An intention to treat analysis was performed

to calculate the difference in risk and corresponding 95% confidence intervals of recurrent prolapse. The between group differences of the total vaginal length and point C, D, Ba, and Bp of the POP-Q were calculated with an unpaired Student *t* test. A regression analysis was performed to correct for age. A *P* -value of < 0.05 was considered significant. To handle the problem of missing data on POP-Q stage, we calculated 2 different scenarios. First, we used data on POP-Q stage of the last gynecological examination available, known as the Last Observation Carried Forward method (LOCF)[8]. Second, we used the worst-case scenario method in which all women who were not seen for gynecological examination 1 year after surgery were regarded as having a recurrent prolapse stage 4 on all compartments. All statistical analyses were performed using Confidence Interval Analysis[9] and SPSS.

Results

Seventy-one women with symptomatic uterine descent stage 2-4 requiring surgery were randomized between February 2004 and December 2006. A trial profile of subject enrollment is displayed in Figure 1 of *Chapter 5*. After randomization and before surgery, 5 women withdrew from further participation, in the remaining 66 women were 6 protocol deviations as described in the results section of *Chapter 5*.
At 1-year follow-up, 2 women of the sacrospinous hysteropexy group did not return for a gynecological examination. One woman was lost to follow-up 6 weeks after surgery for unknown reasons. The other woman was only examined at 6-month follow-up. None of these women had returned to their hospital because of recurrent prolapse symptoms at 1-year follow-up.

Table 1 of *Chapter 5* shows the baseline characteristics of the 71 randomized women and the surgical procedures performed in the 66 women who underwent 1 of the 2 procedures. The baseline table shows no significant differences in the patient characteristics except in age. The mean age of women who underwent a vaginal hysterectomy was about 2 years higher than the mean age of women who underwent a sacrospinous hysteropexy.

In Table 2, the mean total vaginal length (TVL) and point C, D, Ba, and Bp of the POP-Q in both groups is summarized. Women who underwent a sacrospinous hysteropexy had a higher mean TVL 1 year after surgery. Also, Point D was significantly higher. In some women, only POP-Q stage was written down in the clinical research file. This explains the number of missing data in Table 2.

In Table 3, the stages of pelvic organ prolapse 1 year after surgery are shown. The data at 1-year follow-up in Table 3 include the anatomical outcome of 3 women after a sacrospinous hysteropexy who already underwent repeat surgery because of recurrent prolapse (as described in Table 4). This means that at 1-year follow-up, 7 + 2 women (9/34, 27%) had had recurrent uterine descent stage 2 or more. Three women who underwent a sacrospinous hysteropexy had a stage 4 prolapse before surgery. All these women were diagnosed with a recurrent uterine descent within one year. Two of these women underwent repeat surgery.
The differences in risks for recurrent uterine descent or vault prolapse stage 2 or more at 1-year follow-up was 17% (95% CI, 2 to 30) in favor of the vaginal hysterectomy. The differences in risks for recurrent cystocele stage 2 or more was 15% (95% CI, 9 to 38) in favor of the sacrospinous hysteropexy. The differences in risks for recurrent rectocele stage 2 or more was 11% (95% CI, 30 to 9) in favor of the sacrospinous hysteropexy.
When we calculated the differences in risks per protocol (not intention to treat principle), the risk for recurrent apical prolapse was estimated at 25% (95% CI, 8-40) in favor of the vaginal hysterectomy.
The nature of the repeat surgery is described in Table 4. Surgery for prolapse after a sacrospinous hysteropexy was performed in 11% (4/35) of patients. Surgery for prolapse after a vaginal hysterectomy occurred in 7% (2/31) of patients (Risk difference: 5%, 95% CI = -9- 19).

Performing the analysis after correction for age showed no differences in all outcomes as described before.
No statistical subgroup analysis could be performed because of the small number of women in this study.

Discussion

The 2 procedures were comparable with regard to recurrences of the anterior and posterior compartment. At 1-year follow-up, women who underwent a vaginal hysterectomy for uterine descent stage 2 or more had considerably fewer recurrences (3%) of the apical compartment compared with women after a sacrospinous hysteropexy (27%). Especially high recurrence was noted in the preoperative high stage prolapse patients who underwent a sacrospinous hysteropexy.
The strength of this study was the randomization that made the groups of women comparable. So far, no randomized studies have been published comparing these 2 surgical procedures with regard to anatomical outcomes. We chose to perform a multicenter study to make the group of gynecologist who performed the surgery more generalizable compared with a 1-center study and to include a sufficient amount of patients. The anatomical outcomes were scored with the POP-Q system, which is considered to have high inter- and intraobserver validity[7]. The anatomical outcomes were not only scored by the gynecologist who performed the surgery, but also by an independent assessor 6 months after surgery.
Some limitations of this study need to be addressed. First, the number of subjects fell short of the sample size calculated in the methods paragraph. As mentioned before, the sample size was calculated for postoperative recovery time, not for difference in anatomical outcome. Up till now, in retrospective and prospective studies, no major differences in anatomical outcome have been seen between these 2 procedures. Therefore, we expected to find comparative anatomical results. Unfortunately, a lot of women were reluctant to let a lottery decide whether their uterus was to be removed. Reasons for not participating in the study were thoroughly described in the discussion section of *Chapter 5*. The stage of prolapse was most likely no reason for preferring 1 of the 2 procedures. Therefore, we consider our results as generalizable to all patients who meet the inclusion and exclusion criteria. Second, follow-up time for our study was relatively short. Data on longer follow-up (5 years) will follow. Third, if the randomization was performed shortly before surgery or even in the operating room, fewer protocol deviations would have occurred. However, we had chosen to randomize earlier to have more time to inform the women about the procedure they were randomized to. Finally, the use of a McCall procedure was not obligatory. As a consequence, one could state that our group of women who underwent a vaginal hysterectomy was heterogenic.

In the literature, recurrences of the apical compartment after a sacrospinous hysteropexy are described in 0% to 15% of patients[1-6,10-13]. After a vaginal hysterectomy for uterine descent, recurrences of the apical compartment varied between 0% and 12%.[4,5,10,14-23]. It should be noted that almost all of these studies were non-randomized.
An explanation for the variety of recurrence rates in the literature is the heterogeneity of data collection. Most studies were retrospective and based on medical files, not on gynecological examinations performed and regardless of symptoms. Although in some studies, the recurrence rates were high (0-15%), the rate of recurrent surgery for apical prolapse was low in all studies (0-7 % for a vault prolapse, 0-5% for a recurrent uterine descent)[1-6,10-23]. Recurrences of the anterior, posterior, and apical compartment after a vaginal hysterectomy in this study were comparable to that of Roovers et al, who performed a randomized study comparing anatomical outcome after a vaginal hysterectomy with an abdominal procedure for uterine descent[14]. Compared with nonrandomized prospective and retrospective studies, our recurrence rates of the apical compartment after the sacrospinous hysteropexy at 1-year follow-up were high. The number of women with and without a recurrent uterine descent was too small to make a statistical subanalysis. We did found that all women with a pre operative prolapse stage 4, had a recurrent apical prolapse after a sacrospinous hysteropexy. Two of these women had recurrent surgery. Lin et al described a correlation between a high rate of recurrent prolapse and a stage 3 or 4 prolapse preoperatively[11]. Based on their data, they advise against performing a sacrospinous hysteropexy in case of a stage 3 or 4 uterine descent. In our study, 44% of women who underwent a sacrospinous hysteropexy had a stage 3 or 4 uterine descent. This could have influenced our recurrence rates. In most reports on the sacrospinous hysteropexy, only a selected group of women were included into the study. Hefni et al described 109 women with a uterine prolapse of which 57 women (52%) had a stage 1 uterine descent and no women with a stage 4 uterine descent[5]. Maher et al also did not include women with a stage 4 uterine descent[4]. Therefore, these studies were not comparable to our study.
The uterine descent recurrences were already present at 6-month follow-up. After 6 weeks, women were instructed to expand their activities (but still not to perform heavy lifting). Possibly, after expanding activities, the Prolene sutures were torn from the cer-

vix. Apical prolapse after a vaginal hysterectomy is probably based on stretching of the tissue (sacrouterine ligaments) over time, and as a consequence, develop over time. Point D was calculated at a mean of 5.7 cm of the hymen with a mean total vaginal length of 7.3 cm. Longer follow-up will be necessary to examine whether these prolapses progress in time. TVL was significantly shorter after a vaginal hysterectomy which was associated with a higher risk of sexual dysfunction[24]. However, in a more recent publication these findings were not confirmed[25].

In the literature, it was stated that, after a sacrospinous hysteropexy is performed, the vaginal axis would become more horizontal with a higher risk of developing a cystocele[18]. Smilen et al could not confirm this hypothesis[26]. We also did not find more cystoceles after a sacrospinous hysteropexy compared with a vaginal hysterectomy.

Based on the anatomical results at 1-year follow-up, the vaginal hysterectomy had fewer recurrences, in the whole group of high and low grade prolapse, compared to the sacrospinous hysteropexy. A stage 4 prolapse preoperative, was associated with a high recurrence rate of uterine descent after a sacrospinous hysteropexy. Recurrent surgery because of prolapse symptoms was equally divided between the two procedures. Longer follow-up data and data on functional results will follow. A large cohort study will be needed to search for risk factors for having a recurrent prolapse after a sacrospinous hysteropexy.

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Table 2: *Pelvic organ prolapse quantification system: Point C, D, Ba, Bp, and TVL before surgery and 6 and 12 months after surgery*

		Sacrospinous hysteropexy (n = 30)	**Vaginal hysterectomy (n = 27)**	**Difference (95%CI)**	***P*-value**
Before surgery		n (SD)	n (SD)		
	TVL	8.1 (0.9)	7.8 (1.0)		
	C	1.5 (2.1)	1.6 (2.8)		
	D	-1.3 (4.2)	-0.7 (5.3)		
	Ba	1.8 (2.3)	2.2 (2.1)		
	Bp	-1.0 (2.1)	-0.1 (3.5)		
6 months after surgery		(n=33)	(n=29)		
	TVL	9.2 (1.4)	7.8 (1.6)	1.4 (0.7-2.1)	< 0.01
	C	-4.5 (3.7)	NA	NA	NA
	D	-7.6 (1.6)	-6.2 (1.5)	-1.4 (-2.2 - -0.6)	0.01
	Ba	-1.2 (1.4)	-0.8 (1.6)	-0.4 (-1.2 - 0.3)	0.3
	Bp	-2.7 (0.5)	-1.9 (1.1)	0.8 (-1.2 - 0.4)	0.0
1 year after surgery		(n=30)	(n=29)		
	TVL	8.8 (1.3)	7.3 (1.5)	1.5 (0.7 - 2.2)	<0.01
	C	-5.1 (3.6)	NA	NA	NA
	D	-7.4 (2.6)	-5.7 (1.9)	-1.7 (-2.9 - -4.4)	0.01
	Ba	-1.1 (1.9)	-0.7 (1.5)	-0.5 (-1.3 - 0.4)	0.4
	Bp	-2.2 (1.2)	-2.0 (1.3)	-0.2 (-0.9 - 0.4)	0.5

Data are numbers (standard deviation)

NA= not available

Table 3: Stage of prolapse 1 year after surgery according to surgical approach.

1 year after surgery		**Sacrospinous hysteropexy (n=34)**	**Vaginal hysterectomy (n=31)**	**Difference (95%CI)**	***P*-value**
LOCF		n(%)	n(%)	%	
Uterine descent/ vaginal vault descent	stage 0-1	27 (79)	30 (97)	17 (2 - 32)	0.03
	stage 2-4	7 (21)	1 (3)		
Cystocele	stage 0-1	17 (50)	11 (35)	-15 (-38 - 9)	0.2
	stage 2-4	17 (50)	20 (65)		
Rectocele	stage 0-1	28 (82)	22 (71)	-11 (-32 - 9)	0.3
	stage 2-4	6 (18)	9 (29)		
Worst-case scenario		(n=35)	(n=31)		
Uterine descent/ vaginal vault descent	stage 0-1	26 (74)	30 (97)	23 (7 - 38)	0.01
	stage 2-4	9 (26)	1 (3)		
Cystocele	stage 0-1	17 (49)	11 (36)	-13 (-37 - 11)	0.3
	stage 2-4	18 (51)	20 (64)		
Rectocele	stage 0-1	27 (77)	22 (71)	-6 (-27 - 15)	0.6
	stage 2-4	8 (23)	9 (29)		

LOCF = Last observation carried foreward

Table 4: Type and time span of second surgery in women with planned or performed recurrent surgery

Primary surgery: Sacrospinous hysteropexy		
Case	Second surgery	Time span till second surgery
1	Vaginal hysterectomy	13 months
2	Vaginal hysterectomy, Anterior colporrhaphy	6 months
3	Vaginal hysterectomy, Anterior colporrhaphy	10 months
4	Anterior colporrhaphy with a Mesh	6 months
Primary surgery: Vaginal hysterectomy		
Case	Second surgery	Time span till second surgery
5	Anterior colporrhaphy with a Mesh	16 months
6	Posterior colporrhaphy	12 months
7	TVT (de novo stress incontinence)	12 months
8	TVT (recurrent stress incontinence)	20 months

Chapter 7

Functional Outcomes and Quality of Life at One-Year Follow-Up after a Sacrospinous Hysteropexy and Vaginal Hysterectomy for Uterine Descent: A Randomized Study

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Abstract

Objectives: Functional outcomes and quality of life were compared after a vaginal hysterectomy and sacrospinous hysteropexy.
Study design: In this randomized study, 66 women with stage 2-4 uterine descent underwent vaginal hysterectomy (31) or sacrospinous hysteropexy (35). Validated questionnaires were used for measuring urogenital/defecatory symptoms and quality of life before and 1 year after surgery. Differences were tested with a paired- and unpaired Student *t* test and the Confidence Interval Analysis.
Results: Quality of life and urogenital domain scores improved significantly in all domains after both procedures, except for the obstructive micturition domain after a sacrospinous hysterectomy and the urinary incontinence domain after a vaginal hysterectomy. No differences were found in quality of life and urogenital/defecatory symptoms at 1-year follow-up between the 2 procedures.
Conclusions: The sacrospinous hysteropexy and the vaginal hysterectomy were equally effective in improving urogenital/defecatory symptoms and quality of life.

Introduction

Uterine descent is a common health problem of the aging woman. When uterine descent results in functional symptoms, a surgical intervention can be indicated. Several surgical interventions are available for uterine descent in which the uterus can be removed or retained. In the Netherlands, a vaginal hysterectomy and concomitant repair of pelvic support defects is considered standard practice. Sacrospinous hysteropexy, a vaginal procedure in which the uterus is retained and fixed to the sacrospinous ligament, was first described in 1989[1]. In prospective and retrospective studies, these 2 surgical procedures were proven to be equally effective[2-4]. However, these studies focused on anatomical results, not on functional outcomes. The correlation between anatomical outcomes and functional outcomes in case of pelvic organ prolapse was found to be poor[5]. When a uterine descent stage 2 or 3 was found on gynecological examination, this did not necessarily mean that functional symptoms were present. As a consequence, in the evaluation of pelvic organ prolapse surgery, functional outcomes would be of great importance. Van Brummen et al performed a retrospective study comparing vaginal hysterectomy with a sacrospinous hysteropexy in which functional outcomes were measured with validated questionnaires postoperatively[4]. The authors found that women who underwent a sacrospinous hysteropexy experienced a shorter recovery time and less urge incontinence. The only randomized study ever performed involving sacrospinous hysteropexy and vaginal hysterectomy focused solely on sexual function 6 months after surgery[6].
We performed a randomized study comparing the vaginal hysterectomy with the sacrospinous hysteropexy for the treatment of uterine descent stage 2-4 in women with no medical history of pelvic surgery, and with normal uterus, cervix, and ovaries. Data on functional outcomes and quality of life at 1-year follow-up are presented.

Material and Methods

This nonblinded, randomized study was approved by the ethics committees of the 6 participating hospitals (University Center Utrecht, Meander Medical Center Amersfoort, Rijnstate Hospital Arnhem, St. Antonius Hospital Nieuwegein, St. Elisabeth Hospital Tilburg and Twee Steden Hospital Tilburg). This study reports the effect on functional outcomes.

Patients
Women were referred to one of the hospitals by their general practitioner because of symptomatic pelvic organ prolapse. Between February 1, 2004 and December 1, 2006, women were invited to participate. Criteria for entry into the study were the presence of a uterine descent stage 2-4 according to the classification of the International Continence Society and the desire for surgical correction[7]. Other selection criteria were described in *Chapter 5*. After informed consent, patients were randomly assigned by drawing sealed, opaque envelopes for one of the 2 types of prolapse surgery. Randomization was centralized. The gynecologist contacted the research nurse or the principal investigator when randomization was needed. The gynecologist was informed about the surgical procedure by phone and mail.

Measurements
Domain scores of the Urinary Distress Inventory (UDI)[8], the Defecation Distress Inventory (DDI),[9] and the Incontinence Impact Questionnaire (IIQ)[8] were measured before surgery and 1 year after surgery. All women received a questionnaire consisting of the following items:

1. General medical history, height, and weight.
2. The Urinary Distress Inventory (UDI) questionnaire. This standardized questionnaire measuring urogenital symptoms was validated for the Dutch population. The scores of these domains vary between 0 and 100. A high score on a particular domain indicates more bothersome symptoms.
3. The Defecation Distress Inventory (DDI) questionnaire. The DDI consists of 15 items about symptoms related to obstructive defecation, constipation, fecal incontinence, and pain related to defecation. The design of the questions is identical to that of the UDI with domain scores between 0 and 100. Again, a high score on a particular domain indicates more bothersome symptoms. The DDI has been used previously in numerous studies[4,10,11].
4. The Incontinence Impact Questionnaire (IIQ). This questionnaire, which was validated for the Dutch population, measures disease-specific quality of life. It consists of 30 items referring to the impact of urogenital symptoms on different aspects of quality of life. It consists of 5 domains: mobility, physical functioning, social functioning, emotional functioning, and embarrassment. Domain scores range from 0 (best quality of life) to 100 (worst quality of life).

5. Sexual function was measured with selected items of the questionnaire for observing sexual dysfunction (VSD)[12].

A woman was considered to have stress incontinence when she answered positively to the question: "Do you experience urine leakage related to physical activity, coughing, or sneezing?" A woman was considered to have urge incontinence when she answered positively to the question: "Do you experience urine leakage related to the feeling of urgency?"

Surgical procedures

Surgical procedures are described in *Chapter 5*.

Sample size calculation

The sample size calculation was done for the primary endpoint of the study, the duration of the recovery period after surgery (*Chapter 5*). At least 61 women were required in each group.

Statistical analysis

An intention to treat analysis was performed to calculate which of the 2 surgical procedures scored best with respect to urogenital symptoms, defecatory symptoms and quality of life. Descriptive statistics were used for continuous (means and standard deviation) and categorical (numbers/percentages) data. Before and after surgery, domain scores were calculated with a paired and unpaired Student *t* test. The prevalence of symptoms after surgery was analyzed with a chi-square test. A regression analysis was performed to correct for age. A *P* -value of < 0.05 was considered significant. All statistical analyses were performed using Confidence Interval Analysis[13] and SPSS.

Results

Seventy-one women with symptomatic uterine descent stage 2-4 requiring surgery were randomized between February 2004 and December 2006. A trial profile of subject enrollment is displayed in Figure 1 of *Chapter 5*. After randomization and before surgery, 5 women withdrew from further participation. In the remaining 66 women, there were 6 protocol deviations as described in the results section of *Chapter 5*.

At 1-year follow-up, 4 women who underwent a vaginal hysterectomy and 4 women who underwent a sacrospinous hysteropexy did not return the questionnaire. One woman was lost to follow-up at 6 weeks after surgery for unknown reasons, and one woman did not fill in the questionnaires because she felt that this was too much of a bother because of her ill husband. The other 6 women were seen at 1-year follow-up by their gynecologist and reported no symptoms except recurrent stress incontinence (N=1). These women were left out of the analysis.

Table 1 shows the baseline characteristics of the 71 randomized women and the surgical procedures performed in the 66 analyzed women (*Chapter 5*, Table 1). The baseline table shows no incomparability in the patient characteristics in the 2 groups, except age. The mean age of women who underwent a vaginal hysterectomy was about 2 years higher than the mean age of women who underwent a sacrospinous hysteropexy.

In Table 2, domain scores (scale from 0 to 100) of the UDI, DDI, and IIQ are shown before and 1 year after surgery, according to surgical approach. No statistical differences in domain scores were found between the surgical procedures before surgery and 1 year after surgery, except for the constipation domain. When we calculated these domain scores per protocol, no differences were found among all the domains. Both procedures showed an improvement in symptoms in all domains of the UDI and IIQ at 1-year follow-up. These improvements were statistically significant except for the obstructive micturition domain, which was of borderline significance (*P* =0.06) in the sacrospinous hysteropexy group. In the vaginal hysterectomy group, there was no statistically significant improvement in the urinary incontinence domain (*P* =0.2).

In Table 3, prevalences of symptoms considering sexual function are shown before and 1 year after surgery according to surgical approach. Not all women wanted to fill in the questions about sexual function (N = 29, N = 27). No statistical differences in the prevalence of sexual symptoms were seen between the 2 surgical approaches.
De novo stress incontinence occurred in 2 women in each group (14% after a sacrospinous hysteropexy and 11% after a vaginal hysterectomy, *P* =0.7). Recurrent or ongoing stress incontinence occurred in 12 women (12/19, 63%) after a sacrospinous

hysteropexy and in 8 women (8/13, 62%) after a vaginal hysterectomy (*P* =0.7). De novo urge incontinence occurred in 4 women in both groups (15% after a sacrospinous hysteropexy and 17% after a vaginal hysterectomy, *P*=0.8). Recurrent or ongoing urge incontinence occurred in 3 women (50%) after a sacrospinous hysterectomy and in 4 women (57%) after a vaginal hysterectomy (*P* =0.6). Five of 6 women who underwent a TVT procedure were continent at 1-year follow-up. When the prevalence of all symptoms reported on the questionnaire was calculated, no differences were found. Performing the analysis after correction for age showed no differences in all outcomes as described before.

At 1-year follow-up, 3 women after a sacrospinous hysteropexy had had repeat surgery for prolapse symptoms. No repeat surgery was performed in the group of women who underwent a vaginal hysterectomy before 1-year follow-up.

Discussion

The sacrospinous hysteropexy and the vaginal hysterectomy for uterine descent stage 2 to 4 were equally effective with regard to functional outcomes and quality of life. Domain scores on urinary symptoms, defecatory symptoms, and quality of life did not differ between the 2 surgical techniques at 1-year follow-up.
The strength of this study was the randomization that made the 2 groups of women comparable except for age. We did not only focus on anatomical outcome, which will be described in another report, but also measured functional outcomes and quality of life. We used questionnaires, validated for the Dutch population, before and after surgery[8,9].
Some limitations need to be addressed. The number of subjects fell short of the sample size that was calculated. As mentioned in the methods section, the sample size was calculated for postoperative recovery time, not for difference in functional outcomes. Unfortunately, a lot of women were reluctant to let a lottery decide whether their uterus was to be removed. Reasons for not participating in the study were thoroughly described in the discussion section of *Chapter 5*. We do not think that the stage of prolapse or differences in symptoms was a reason for preferring 1 of the 2 procedures. Therefore, our results are most likely generalizable to all patients who meet the inclusion and exclusion criteria. If randomization was performed just before

surgery or even in the operating room, fewer protocol violations would have occurred. However, we had chosen to randomize earlier to have more time to inform women about the procedure they were randomized to.
In the literature, only a few other studies describe functional outcomes after a sacrospinous hysteropexy[2,3,4,11,14]. Validated questionnaires were only used in 3 studies, all with a retrospective design[4,11,14]. In only one of these studies were preoperative functional outcomes described[14]. Our domain scores were comparable to the domain scores in these studies. Roovers et al also used validated questionnaires in a study comparing a vaginal hysterectomy for uterine descent with an abdominal approach[10]. The domain scores on urogenital symptoms and quality of life were comparable to our results after a vaginal hysterectomy. In all of these studies, a large improvement in prolapse symptoms was shown. The impact on urinary symptoms and defecatory symptoms was smaller, but we can conclude that both procedures provided significant improvement in urogenital symptoms and quality of life. In one retrospective study of van Brummen et al, after correction for age, body mass index, and follow-up time, a difference was found in urge incontinence symptoms in favor of the sacrospinous hysteropexy (OR 3.4, CI 1.0-12.3)[4]. It was postulated that these symptoms were possibly related to nerve damage during bladder dissection, which is not necessary when a sacrospinous hysteropexy is performed. We could not confirm these findings. Thereby, because the vaginal hysterectomy and the sacrospinous hysteropexy were performed concomitantly with an anterior colporrhaphy in (almost) all cases, we do not know which surgical procedure contributed the most to the improvement in urogenital symptoms. In the literature, no profound evidence was available to underscore that a vaginal hysterectomy would be associated with more urogenital symptoms[15]. Moreover, in a study comparing a hysterectomy with an endometrial ablation for heavy bleeding, no differences were seen in urogenital symptoms after surgery[16]. Only one randomized study was available comparing sexual function 6 months after a vaginal hysterectomy to sacrospinous hysteropexy[6]. As in our study, no postoperative differences in sexual function at 6-month follow-up between the procedures were found.

De novo stress incontinence occurred in 2 women after a sacrospinous hysteropexy which was comparable to findings of Maher et al[3]. We found a high prevalence of recurrent stress and urge incontinence in both groups, but apparently women did not

experience much discomfort from it, which was reflected in the low domain scores. Hefni et al found recurrent stress incontinence in only 20% of women after a sacrospinous hysteropexy[17]. Our domain scores on urine incontinence before and after surgery show that although there might be some urge or stress incontinence, bothersome symptoms are very low. Indication for incontinence surgery is related to the degree of bothersome symptoms. This explains the low rate of incontinence surgery in this study.

We can conclude from this study that a vaginal hysterectomy and a sacrospinous hysteropexy for uterine descent stage 2 or more were equally effective with regard to functional outcomes and quality of life at 1-year follow-up. To be completely informed about all differences between these 2 procedures, it will be necessary to obtain data on longer follow-up and anatomical outcomes.

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Table 2: Domain scores of the Urinary Distress Inventory (UDI), Defecatory Distress Inventory (DDI), and Incontinence Impact questionnaire (IIQ) before and after surgery according to surgical approach.

	Before surgery		1 year after surgery			
	SSH N = 34	VH N = 31	SSH N = 31	VH N = 27	Difference (95%CI)	*P*-value
UDI domain scores:						
Overactive bladder	22 (20)	25 (24)	11 (18)	12 (17)	0.5 (-10.1 -11.1)	0.9
Urinary incontinence	11 (14)	10 (16)	6 (8)	6 (11)	0.3 (-4.8 - 5.4)	1.0
Obstructive micturition	11 19)	23 (26)	3 (9)	8 (16)	-5.0 (-13.6 - 3.6)	0.1
Genital prolapse	55 (30)	64 (32)	2 (5)	4 (13)	-2.5 (-7.9 - 2.9)	0.5
Pain	22 (19)	24 (25)	11 (18)	7 (21)	2.5 (-7.3 - 12.4)	0.4
DDI domain scores:						
Constipation	10 (17)	6 (12)	8 (16)	1 (4)	6.1 (0.3 - 11.9)	0.03
Obstructive defecation	9 (13)	9 (14)	7 (12)	4 (7)	2.6 (-2.1 - 7.3)	0.3
Pain	4 (13)	4 (14)	4 (12)	1 (6)	1.1(-4.1 - 6.2)	0.4
Fecal incontinence	6 (16)	5 (12)	4 (10)	6 (20)	-1.9 (-9.6 - 5.9)	0.7
IIQ domain scores:						
Physical functioning	17 (23)	23 (23)	3 (9)	12 (22)	-9.9 (-18.5 - - 1.3)	0.06
Mobility	20 (18)	26 (17)	7 (13)	12 (15)	-3.6(-10.5 - 3.3)	0.3
Emotional health	13 (15)	12 (19)	5 (8)	6 (11)	-2.0 (-6.9 - 3.0)	0.5
Social functioning	6 (12)	14 (18)	2 (7)	3 (8)	-0.9 (-4.7 - 2.8)	0.6
Embarrassment	10 (14)	16 (14)	4 (11)	6 (16)	-2.6 (-9.4 - 4.2)	0.5

SSH = sacrospinous hysteropexy VH = vaginal hysterectomy

UDI and DDI: 0 = not bothersome, 100 = most bothersome

IIQ: 0 = best quality of life, 100 = worst quality of life

Data are numbers (standard deviation)

Table 3: Prevalence of sexual symptoms (measured with the VSD) according to surgical approach

	Sacrospinous hysteropexy	Vaginal hysterectomy	Difference (95%CI)	*P*-value
Before surgery	**N = 29**	**N = 27**		
Sexual symptoms				
Sexual intercourse	19 (59)	20 (69)		
Urinary incontinence during intercourse	4 (21)	3 (15)		
Pain during intercourse	4 (21)	7 (35)		
Feeling of narrow vagina	1 (5)	0 (0)		
1 year after surgery	**N = 28**	**N = 26**		
Sexual symptoms				
Sexual intercourse	17 (61)	19 (75)	-12 (-37 - 12)	0.7
Urinary incontinence during intercourse	1 (6)	1 (5)	-0.2 (-10 - 10)	0.9
Pain during intercourse	4 (24)	5 (25)	-5 (-25 - 15)	0.9
Feeling of narrow vagina	0 (0)	2 (10)	-8 (-18 - 3)	0.2

Data are numbers (%)

Chapter 8

General discussion and summary

Our primary motivation for performing the studies included in this thesis was twofold: First, we asked why it is necessary to remove all those 'healthy' uteri? The prolapsed uterus is the result of a diminished level 1 support, not the cause of pelvic organ prolapse. Because the sacrospinous hysteropexy restores level 1 support (suspension), this procedure is a logical alternative for the hysterectomy[1]. Second, what is the efficiency of the sacrospinous hysteropexy? Data on this topic are lacking, although this procedure has been associated with shorter recovery time and less incontinence compared with vaginal hysterectomy[2]. These findings were retrospective and based on only a single study. Randomized trials comparing sacrospinous hysteropexy and other surgical procedures for vaginal prolapse were not available when our investigation began.

Comparison with Other Vaginal Prolapse Procedures

In *Chapter 2*, we reported that it is difficult to compare studies performed to evaluate surgeries for vaginal prolapse because of differences in inclusion criteria, follow-up time, definition of recurrence, and data collection methods. For evaluation of treatment strategies, well-defined cohorts of patients with specific symptoms should be the starting point. Based on the available literature from 1987 to November 2007, sacrospinous hysteropexy was equally effective in anatomical and functional outcomes compared with a vaginal hysterectomy and was associated with less morbidity. No information on improvement of quality of life after sacrospinous hysteropexy was available. Despite these positive findings for sacrospinous hysteropexy, most gynecologists in the Netherlands perform a vaginal hysterectomy for uterine descent.

Efficiency, Safety, and Patient Satisfaction

The results of sacrospinous hysteropexy performed in 133 women were evaluated retrospectively and are described in *Chapter 3*; this study is the largest ever done on women after this operation. In accord with the available literature, a low rate of recurrent uterine descent (6%) and a low rate of recurrent surgery for prolapse (2.3%) were found. Of the women who underwent the procedure, 83% were satisfied or very satisfied with the procedure, and 91% would recommend it to other women.
The rate of recurrent cystoceles was high (38%); however, this high recurrence rate can

be attributed to the method of data collection. Specifically, women were invited for gynecologic examination regardless of the presence or absence of symptoms. As a consequence, asymptomatic prolapses were found, whereas in other studies only symptomatic cystoceles were reported. In a cohort study on pelvic organ prolapse, 40% of women were diagnosed with a genital prolapse[3]. Therefore, our group of postoperative women was comparable to the general population. We found that women both with and without a recurrent cystocele had the same rate of urogenital symptoms. These findings show the need for evaluating functional outcomes before and after surgery regardless of anatomical outcomes. Anatomical abnormalities are poorly related to functional symptoms. Ellerkman and colleagues concluded that women with pelvic organ prolapse experience symptoms that do not necessarily correlate with compartment-specific defects[4]. Increasing severity of pelvic organ prolapse was weakly to moderately associated with several specific symptoms, such as urinary incontinence and voiding, defecatory symptoms, and sexual dysfunction. Only one question about the finding of a bulge in the vagina had a high correlation with anatomical findings for all compartments (anterior, apical, posterior). So the indication for performing surgery to correct prolapse should be specifically related to prolapse symptoms or other related functional symptoms combined with anatomical abnormalities. Mild anatomical abnormalities without complaints are not an indication for surgery.

Serious complications were rare after a sacrospinous hysteropexy. Buttock pain occurred in 15% of women and resolved spontaneously in all but two women. In these two women, the suture was removed and the complaints decreased. Buttock pain was thoroughly described in reports on the sacrospinous ligament fixation and occurred in 10% to 15%[5]. The buttock pain can be explained by injury to surrounding nerves, that is, the pudendal nerve and the levator ani nerve. The levator ani nerve originates directly from the sacral plexes and courses on the superior surface of the coccygeus muscle-sacrospinous ligament complex toward the superior surface of the levator ani muscle. On its trajectory, it crosses the sacrospinous ligament 0 to 4 cm medial to the ischial spine. The pudendal nerve lies inferior to the sacrospinous ligament, only 4 to 11 mm from the levator ani nerve[6]. Also, in the ligament itself, nerve tissue is widely distributed[7]. Although placing the sutures 2 cm medial from the ischial spine is recommended to prevent damage to surrounding vessels (internal pudendal vessels and internal gluteal vessels) and nerves (pudendal nerve), this placement might not be optimal. Placing the sutures in the lateral third part of the ligament was shown to be a better region for preventing neurovascular complications in a cadaver study[7].

Improvement in Functional Outcomes and Quality of Life

Because no data were available in the literature on improvement of urogenital symptoms and quality of life after a sacrospinous hysteropexy, we asked 72 women to answer a validated questionnaire before and after surgery (see *Chapter 4*). A major improvement in prolapse symptoms was shown after a sacrospinous hysteropexy (domain score: 56 → 5.6, *P* -value < .001). All our studies confirmed these important improvements. Also, on other urogenital domain scores, including quality of life domain scores, significant improvements were found. Because sacrospinous hysteropexy was combined with other prolapse surgery (Tension-free Vaginal Tape, colporrhaphy anterior/posterior), it remains unclear which procedure contributed most to resolving functional symptoms and improving quality of life.

Comparison with Vaginal Hysterectomy

A randomized, controlled trial is the best way to address differences between two surgical procedures. Therefore, we chose to set up a randomized study, although we were aware that randomizing women into the study in which a lottery decided whether their uterus was to be removed or not could be a difficult process. Calculation of a sample size should be based on outcome differences generated by prior studies. Only three studies existed in which these two procedures were compared: two retrospective studies and one prospective study[2,8,9]. No differences in anatomical outcomes were found. Recovery time after sacrospinous hysteropexy was significantly shorter (68 % versus 43% of women fully recovered within 3 months)[2]. Sample size calculation was based on the difference in recovery time in this retrospective study. The ideal trial is the double-blinded, randomized trial. Unsatisfactorily but obviously, blinding was impossible. The surgeon needs to know what procedure to perform, and the patient must know whether her uterus has been removed or not for managing future health problems (cervix cytology, bleeding abnormalities). Postoperative complaints such as buttock pain will be noticeable on recovery. Also, performing a gynecologic examination will reveal the cervix in women after a sacrospinous

hysteropexy. To answer the question of whether a sacrospinous hysteropexy is superior to a vaginal hysterectomy on morbidity, anatomical outcomes, functional outcomes, and quality of life, a randomized study was performed (see Section 2).
Although time until return to daily activities was equal after the two procedures, women who had a sacrospinous hysteropexy with either paid or unpaid jobs were able to participate significantly earlier in their jobs (*Chapter 5*). Hospital stay was 1 day shorter after a sacrospinous hysteropexy. Although this study was not designed to calculate economic benefits, one could speculate that being able to return to work 23 days earlier after prolapse surgery would be quite beneficial economically. With an increasing population of older active women and a lifetime risk for requiring prolapse surgery of 11%, the sacrospinous hysteropexy is the better procedure from a societal point of view[11].

Based on all the studies available in the literature, we did not expect to find differences in anatomical outcomes between a sacrospinous hysteropexy and a vaginal hysterectomy (*Chapter 2*). However, our recurrence rates of uterine descent after the sacrospinous hysteropexy at 1-year follow-up were substantially higher (27%, *Chapter 6*), as described in the literature (between 0% and 15%)[2,9,10,12-18]. Because this was the first
randomized study to compare vaginal hysterectomy and sacrospinous hysteropexy, no comparable data were available.
Nonetheless, a few explanations for the high recurrence rate should be considered.
First, we performed a multicenter study in which all women with a symptomatic uterine descent stage 2 to 4, normal ovaries and uterus, and no previous pelvic surgery were eligible for inclusion. This most likely reflects the general population in which also women with atrophic vaginas and a stage 4 prolapse undergo surgery. In some reports, only a select group of women who went to a tertiary center were included in the study, which makes the studies biased. Hefni and colleagues described 109 women with a uterine prolapse, of which 57 (52%) had a stage 1 uterine descent and only seven (6%) had a stage 3 uterine descent[10]. No women were treated in which a stage 4 uterine descent was identified. Maher and associates also did not include women with a stage 4 uterine descent[9]. Lin and colleagues performed a study to find the risk factors for
failure of the sacrospinous hysteropexy, and they concluded that an elongated cervix and a third-degree uterine prolapse were the two main risk factors for recurrent

uterine prolapse[16]. In our randomized study, 44% of women who underwent a sacrospinous hysteropexy had a stage 3 or 4 prolapse. Our groups of women were too small to make a statistical subanalysis, as described in *Chapter 6*. The high percentage of women with a stage 3 or 4 uterine descent estimated before surgery could be responsible for the higher rate of recurrences compared with those reported from other studies. It seems likely that when a uterus is situated outside the vagina for a long time, the cervix becomes fragile and erosive. This might be a risk factor for tearing the suture out of the cervix. Also, the strength of the sacrospinous ligament was
designated a risk factor. One cadaver study considering the strength of the sacrospinous ligament was available in which the authors concluded that the
resistance of the sacrospinous ligament was weak in some cases (20 N = 2 kg) and that the strength was variable between individuals[19]. No information is available on the risk factors for having a weak sacrospinous ligament. Second, when a multicenter study like this one is performed and a larger group of surgeons will perform the procedures, which is more in line with reality compared with one-surgeon studies performed in a tertiary center, more generalizable results can be obtained. However, the larger group of surgeons also carries the risk of quality differences, with a negative effect on the results of the group. In the Netherlands, all gynecologists are trained to perform a vaginal hysterectomy. Currently, a sacrospinous hysteropexy is performed only by gynecologists who have special interest and experience in urogynecology. All the gynecologists participating in the trial who performed the sacrospinous hysteropexy were trained the same way and had performed at least 20 procedures, but they
differed in their frequency of performing this procedure. It is therefore possible that in the randomized study, aside from patient factors, factors relating to the surgeons could have played a role in the anatomic outcomes. In the study by Hefni and colleagues, one surgical team performed all the procedures[10]. Although the procedure does not seem to be complicated, the exact placement of the sutures in the sarospinous ligament could be of greater importance than we initially realized. No learning curve is recognized with sacrospinous hysteropexy.

When this higher rate of recurrence of prolapse after sacrospinous hysteropexy results in a greater number of recurrent surgeries, the economic benefit of the sacrospinous hysteropexy from earlier working activities will weaken. At 1-year follow-up, no statistical differences in recurrent surgery were found (*Chapter 6*), nor were statistical

differences found in functional outcomes (*Chapter 7*). As described in *Chapter 3*, a recurrent cystocele was not associated with more bothersome symptoms. Aside from the low correlation between functional symptoms and anatomical abnormalities, as mentioned, it remains unclear why women experience fewer symptoms after surgery when an anatomic recurrence is noted. Other studies need to be performed to clarify these phenomena.

Two concerns were expressed in literature about the sacrospinous hysteropexy. First is the change in the vaginal axis that results from stretching of the vagina to the right side in a more horizontal position. This anatomic deviation has been held responsible for a high recurrence of cystoceles[17]. Smilen and colleagues showed that the risk of cystocele is not greater after a sacrospinous hysteropexy[20]. Based on our results, we agree with Smilen and colleagues. We did not find differences in the rate of recurrent prolapse in the anterior or posterior compartment.
Second, some gynecologists are concerned about future development of carcinoma of the uterus or cervix. In the Netherlands each year, about 600 women are diagnosed with cervical cancer, about 1400 women with endometrial cancer[21]. Women who undergo sacrospinous hysteropexy can be evaluated the same way as are women who have not undergone this procedure (i.e., through Pap smear, endometrial biopsy, hysteroscopic evaluation); a prophylactic hysterectomy for oncologic reasons is not justified. This concern applies more to difficulties in diagnostic workup after a Manchester procedure in which the alarm symptom of blood loss in endometrial cancer can be absent due to the amputation of the cervix[22].

Conclusions

Our studies showed that sacrospinous hysteropexy is a safe procedure with no major complications and a significant improvement in urogenital symptoms and quality of life accompanied by low anatomic recurrence rates in observational studies. Compared with vaginal hysterectomy, hospitalization was 1 day shorter and women were able to return to work earlier. Although urogenital symptoms and quality of life scores after both procedures were comparable a year after surgery, anatomical outcomes differed. At 1-year follow-up, the recurrence rates for the anterior and posterior compartment were comparable. Of all women with a stage 2-4 prolapse pre operative, a lower

recurrence rate was found of the apical compartment after vaginal hysterectomy compared to women who had a sacrospinous hysteropexy. Especially high recurrence was noted in the preoperative high stage prolapse patients who underwent a sacrospinous hysteropexy. However, recurrent surgery was not significantly higher after a sacrospinous hysteropexy.

Recommendations

Both procedures, a sacrospinous hysteropexy and a vaginal hysterectomy, are safe and good anti-prolapse procedures which should be standard technique for every well trained pelvic floor surgeon. Although the sacrospinous hysteropexy was associated with more apical recurrences for the pre operative (high stage) prolapses, it seems a good alternative for women who wish to preserve their uterus. This seems most appropriate for patients with a prolapse stage 2 and 3 pre operative.
Due to the follow-up of 1-year of this study, no data on the frequency of recurrence on a longer term are available. Longer follow up is needed to provide solid data on the frequency of recurrence after both procedures. We hope to be able to provide these data after a longer follow up of the patients in this study.
Also a long term follow up cohort study of a large patient group is needed to identify the risk factors for both procedures, especially for recurrent prolapse and procedure specific low incidence complications.

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Appendices

Questionnaires used in this thesis

Appendix I

Urogenital Distress Inventory

1. a. Vindt u dat u vaak moet plassen?
   1. ja 2. nee (ga door met vraag 2)
   b. Zo ja, hoeveel last heeft u hier van?
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

2. a. Als u moet plassen voelt u dan altijd een sterke aandrang?
   1. ja 2. nee (ga door met vraag 3)
   b. Zo ja, hoeveel last heeft u hier van?
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

3. a. Heeft u ongewenst urineverlies als u aandrang voelt om te plassen?
   1. ja 2. nee (ga door met vraag 4)
   b. Zo ja, hoeveel last heeft u hier van?
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

4. a. Heeft u ongewenst urineverlies bij lichamelijke inspanning, hoesten of niezen?
   1. ja 2. nee (ga door met vraag 5)
   b. Zo ja, hoeveel last heeft u hier van?
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

5. a. Heeft u wel eens ongewenst urineverlies zonder dat u aandrang voelt of zonder dat u zich lichamelijk inspant?
   1. ja 2. nee (ga door met vraag 6)
   b. Zo ja, hoeveel last heeft u hier van?
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

6. a. Verliest u ongewenst wel eens kleine hoeveelheden urine (druppels)?
   1. ja 2. nee (ga door met vraag 7)

b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

7. a. Verliest u ongewenst wel eens grote hoeveelheden urine?
1. ja 2. nee (ga door met vraag 8)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

8. a. Moet u 's nachts meerdere keren plassen?
1. ja 2. nee (ga door met vraag 9)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

9. a. Plast u wel eens in uw bed?
1. ja 2. nee (ga door met vraag 10)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

10. a. Heeft u moeite uw blaas leeg te plassen?
1. ja 2. nee (ga door met vraag 11)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

11. a. Heeft u wel een het gevoel dat de blaas na het plassen niet helemaal leeg is?
1. ja 2. nee (ga door met vraag 12)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

12. a. Heeft u wel eens een drukkend gevoel onder in de buik?
1. ja 2. nee (ga door met vraag 13)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

13. a. Heeft u wel eens pijn tijdens het plassen?
1. ja 2. nee (ga door met vraag 14)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

14. a. Heeft u wel eens pijn onder in de buik of in de schaamstreek?
1. ja 2. nee (ga door met vraag 15)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

15. a. Heeft u wel eens een zwaar of drukkend gevoel in het bekkengebied?
1. ja 2. nee (ga door met vraag 16)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

16. a. Heeft u wel eens het gevoel dat er iets uit de vagina stulpt?
1. ja 2. nee (ga door met vraag 17)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

17. a. Heeft u wel eens gezien dat er iets uit de vagina stulpt?
1. ja 2. nee (ga door met vraag 18)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

18. a. Heeft u wel eens een ongemakkelijk gevoel in het bekken gebied als u staat of als u zich lichamelijk inspant?
1. ja 2. nee (ga door met vraag 19)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

19. a. Moet u wel eens tegen de vaginawand drukken om uw ontlasting kwijt te raken?
1. ja 2. nee

b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

Appendix II

Defecation Distress Inventory

1. a. Heeft u minder dan driemaal per week ontlasting?
1. ja 2. nee (ga door met vraag 2)

b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

2. a. Moet u om ontlasting te krijgen in meer dan een kwart van de keren persen?
1. ja 2. nee (ga door met vraag 3)

b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

3. a. Heeft u na de ontlasting het gevoel dat u niet leeg bent?
1. ja 2. nee (ga door met vraag 4)

b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

4. a. Heeft u wel eens aandrang tot ontlasting terwijl er dan op het toilet geen ontlasting komt?
1. ja 2. nee (ga door met vraag 5)

b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

5. a. Moet u de ontlasting wel eens met de vingers via de anus verwijderen?
1. ja 2. nee (ga door met vraag 6)

b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

6. a. Moet u wel eens via de vagina meedrukken om ontlasting te krijgen?
1. ja 2. nee (ga door met vraag 7)

b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

7. a. Heeft u wel eens het gevoel dat er iets uit de anus hangt of er iets voor zit?
1. ja 2. nee (ga door met vraag 8)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

8. a. Ervaart u pijn tijdens de aandrang tot ontlasting?
1. ja 2. nee (ga door met vraag 9)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

9. a. Ervaart u pijn tijdens of vlak na de ontlasting?
1. ja 2. nee (ga door met vraag 10)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

10. a. Treft u wel eens sporen van ontlasting in uw ondergoed aan?
1. ja 2. nee (ga door met vraag 11)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

11. a. Komt het wel eens voor dat u het toilet te laat bereikt als u aandrang voelt?
1. ja 2. nee (ga door met vraag 12)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

12. a. Merkt u wel eens dat u ontlasting hebt verloren zonder dat u aandrang voelde?
1. ja 2. nee (ga door met vraag 13)

b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

13. a. Laat u wel eens winden zonder dat u daar controle over heeft?
1. ja 2. nee (ga door met vraag 14)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

14. a. Verliest u wel eens dunne ontlasting zonder dat u daar controle over heeft?
1. ja 2. nee (ga door met vraag 15)
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

15. a. Verliest u wel eens vaste ontlasting zonder dat u daar controle over heeft?
1. ja 2. nee
b. Zo ja, hoeveel last heeft u hier van?
1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

Appendix III

Incontinence Impact Questionnaire

Hoeveel invloed heeft ongewenst urineverlies en/of verzakking en/of problemen met de ontlasting op:

1. Uw vermogen om huishoudelijk werk te doen (koken, schoonmaken, wassen)
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

2. Uw vermogen om klein onderhoud of reparaties te verrichten in en om het huis
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

3. Boodschappen doen en winkelen
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

4. Hobby's en vrijetijdsbesteding
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

5. Actieve ontspanning zoals wandelen, zwemmen of andere activiteiten
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

6. Activiteiten zoals naar de film, theater of concert gaan
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

7. Reizen met auto of openbaar vervoer over een afstand van minder dan 20 minuten
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

8. Reizen met auto of openbaar vervoer over een afstand van meer dan 20 minuten
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

9. Ergens naar toe gaan als u niet helemaal zeker weet of er daar toiletten zijn
   1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

10. Op vakantie gaan
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

11. Naar de kerk, moskee of synagoge gaan
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

12. Vrijwilligerswerk
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

13. Betaald werk buitenshuis
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

14. Bezoek krijgen van vrienden en kennissen
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

15. Deelnemen aan sociale activiteiten buitenshuis
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

16. Relaties met vrienden en kennissen
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

17. Relaties met familie en gezin behalve uw partner / echtgenoot
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

18. Vermogen om een seksuele relatie te hebben
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

19. Keuze van kleding
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

20. Geestelijke / emotionele gezondheid
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

21. Lichamelijke gezondheid
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

22. Slapen
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

23. Wordt u in uw activiteiten beperkt door angst dat anderen u ruiken?
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

24. Beperkt de angst om in verlegenheid gebracht te worden u in uw activiteiten?
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

Heeft u als gevolg van uw probleem de volgende gevoelens ?

25. Nervositeit of ongerustheid
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

26. Angst
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

27. Frustratie
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

28. Boosheid
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

29. Depressie
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

30. Zich gegeneerd voelen
    1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

Appendix IV

Uit vragenlijst seksuele dysfuncties

Heeft u wel eens seksueel contact met uw partner? (Denk hierbij aan *alle vormen* van seksueel contact en niet alleen aan geslachtsgemeenschap)

1. Ja (beantwoord ook vraag b) 2. Nee (beantwoord ook vraag c)

b. Zo ja, hoe tevreden bent u daarover?

1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

c. Zo nee, hoe vervelend vindt u dat?

1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

Hoe vaak heeft u geslachtsgemeenschap?

1. Nooit
2. minder dan 1 keer per maand
3. 1 tot 2 keer per maand
4. 1 keer per week
5. meerdere keren per week

Verliest u wel eens urine tijdens de geslachtsgemeenschap?

1. Ja 2. Nee 3. niet van toepassing (geen gemeenschap)

Zo ja, hoeveel last heeft u hier van?

1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

Ervaart u pijn tijdens de geslachtsgemeenschap?

1. Ja 2. Nee 3. niet van toepassing (geen gemeenschap)

Zo ja, hoeveel last heeft u hier van?

1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

Is de vagina zo nauw dat geslachtsgemeenschap daardoor niet mogelijk is?

1. Ja 2. Nee 3. niet van toepassing (geen gemeenschap)

Zo ja, hoeveel last heeft u hier van?

1. Helemaal niet 2. Een beetje 3. Nogal 4. Heel erg

Nederlandse samenvatting

Verzakkingen van de baarmoeder zijn een toenemend gezondheidsprobleem ten gevolge van het bereiken van hogere gemiddelde leeftijden en het steeds langer actief blijven van vrouwen. Naast leeftijd spelen ook andere factoren een rol bij het ontstaan van een verzakking, zoals verhoogde druk in de buik (bijvoorbeeld door chronische obstipatie, chronisch hoesten of overgewicht) en het baren van kinderen. Een verzakking bij de vrouw wordt ingedeeld in drie compartimenten: het voorste compartiment (verzakking van de blaas), het achterste compartiment (verzakking van laatste deel dikke darm) en het middelste compartiment (verzakking van de baarmoeder). Uit onderzoek is gebleken dat het risico van een vrouw om op haar 80e jaar een operatie voor een verzakking te hebben ondergaan 10% is. Helaas moet bijna 30% van deze vrouwen daarna opnieuw geopereerd worden, omdat de verzakking weer terug gekomen is. Blijkbaar is er nog geen ideale techniek gevonden om deze vrouwen voorgoed van hun klachten af te helpen.

In Nederland wordt, indien er een verzakking van de baarmoeder is, meestal gekozen om de baarmoeder te verwijderen via de schede (de vaginale uterus extirpatie). De baarmoeder zelf is echter meestal klein en niet de oorzaak, maar het gevolg van de verzakking. De oorzaak ligt in het verzwakte ophangsysteem van de baarmoeder. Vandaar dat sommige gynaecologen ervoor kiezen om niet de baarmoeder te verwijderen maar om dit insufficiënte ophangsysteem te verbeteren. Een voorbeeld van zo'n ingreep is de sacrospinale hysteropexie waarbij de baarmoedermond wordt opgehangen aan een bindweefselstreng in het bekken van de vrouw, het sacrospinale ligament. Aan het begin van onze studies was deze operatie nog weinig onderzocht. Uit enkele onderzoeken bleek dat in vergelijking met het verwijderen van de baarmoeder, de sacrospinale hysteropexie geassocieerd was met minder complicaties rondom de operatie en een sneller herstel na de operatie. Mogelijk dat vrouwen na deze operatie ook minder plasklachten hadden. Voor het opheffen van de verzakking leken beiden methoden even effectief.

Om de effectiviteit van de sacrospinale hysteropexie te onderzoeken, hebben we, naast het analyseren van complicaties en het vaststellen van het anatomische resultaat (dat wat je ziet bij gynaecologisch onderzoek), gebruik gemaakt van vragenlijsten. Met de vragenlijsten, die gevalideerd waren voor de Nederlandse populatie, hebben we de mate van hinder van plasklachten, verzakkingsklachten en stoelgangklachten berekend op verschillende domeinen. Dit noemen we verder functionele klachten. Deze berekening geeft een getal tussen de 0 en 100 aan, waarbij 0 helemaal geen klachten

betekent en 100 de meest denkbare hinder van de klachten. Kwaliteit van leven werd ook gescoord met een gevalideerde vragenlijst, waarbij de 0 de beste kwaliteit van leven aangeeft en 100 de slechtste kwaliteit van leven. Tegenwoordig wordt steeds meer waarde gehecht aan de functionele uitkomsten en kwaliteit van leven na een operatie. Het anatomisch resultaat kan misschien wel goed zijn, maar als een patiënt daarbij veel klachten heeft of een slechtere kwaliteit van leven ervaart, is de operatie niet succesvol gebleken.
In dit proefschrift worden de resultaten beschreven van studies naar de sacrospinale hysteropexie (het ophangen van de baarmoeder) en wordt deze operatie vergeleken met het verwijderen van de baarmoeder (meest verrichte operatie in Nederland bij een verzakking van de baarmoeder).

In **hoofdstuk 2** wordt het verwijderen van de baarmoeder via de schede vergeleken met drie andere operaties die verricht kunnen worden in geval van een baarmoederverzakking, waarbij de baarmoeder niet verwijderd wordt: sacrospinale hysteropexie, de Manchester-procedure en de IVS posterior. Alle beschikbare publicaties tussen 1987 en november 2007 over deze vier operaties zijn verzameld en vergeleken met betrekking tot complicaties, anatomisch resultaat, functioneel resultaat, kwaliteit van leven, seksuele functie en het optreden van zwangerschappen. Uit de beschikbare literatuur kon geconcludeerd worden dat er maar weinig vergelijkende studies beschikbaar waren tussen de procedures, maar dat het verwijderen van de baarmoeder niet de meest logische keuze was. Het was geassocieerd met meer complicaties rondom de operatie, een langere herstelperiode met vergelijkbare anatomische resultaten in vergelijking met de baarmoedersparende operaties.

In **hoofdstuk 3** worden data gepresenteerd van 133 vrouwen die een sacrospinale hysteropexie hebben ondergaan in drie Nederlandse ziekenhuizen. Er werden weinig ernstige complicaties gezien, echter een aantal vrouwen had pijn in de rechterbil na de operatie. Dit is het gevolg van het ophangen van de baarmoeder aan een bindweefselstreng in het bekken, het sacrospinale ligament, die omringt wordt door zenuwen. Deze pijn werd aangegeven door 15% van de vrouwen, maar was meestal van voorbijgaande aard. Echter twee vrouwen ondergingen een tweede operatie in verband met deze pijn in de bil. 99 Vrouwen vulden de vragenlijst in over functionele klachten en kwaliteit van leven, gemiddeld 23 maanden na de operatie. Het bleek dat ze weinig

klachten hadden en uit statusonderzoek bleek dat het anatomisch resultaat ook goed was. 60 Vrouwen werden opnieuw gynaecologisch onderzocht. Verrassend was dat 38% van deze vrouwen een lichte tot ernstige verzakking van de blaas had, terwijl ze hier meestal geen klachten van hadden. In totaal had 6,7% van de vrouwen opnieuw een verzakking van de baarmoeder gekregen, slechts 1,5% (2/133) had zich opnieuw laten opereren. 84% Van de vrouwen was (zeer) tevreden over het resultaat van de operatie.
Conclusie van de studie is dat de sacrospinale hysteropexie een veilige en effectieve operatie is bij vrouwen met een baarmoederverzakking met een laag risico op een tweede verzakkingsoperatie. De vrouwen die een voorwandverzakking hadden na deze operatie, hadden hier weinig hinder van.

In alle studies die verricht zijn naar de sacrospinale hysteropexie, waren er geen studies die het functionele resultaat en kwaliteit van leven voor en na de operatie beschrijven, gemeten met gevalideerde vragenlijsten. In **hoofdstuk 4** worden 72 vrouwen beschreven die voor en na de operatie de vragenlijsten hebben ingevuld en gynaecologisch zijn onderzocht. De follow-up duur was 12,7 maanden. De scores op alle domeinen van de functionele klachten verbeterden, met uitzondering van het domein pijn en incontinentie voor ontlasting. Kwaliteit van leven verbeterde significant na deze operatie. Geconcludeerd kan worden dat de sacrospinale hysteropexie eventueel gecombineerd met andere verzakkingsoperaties (bijvoorbeeld een vagina voor of achterwandplastiek) een significante verbetering geeft in functionele klachten en kwaliteit van leven.

De beste manier om uit toe zoeken of een bepaalde operatie beter is dan een andere, is het verrichten van de gerandomiseerde studie. In zo'n studie bepaalt het lot (het trekken van een lootje) welke operatie iemand ondergaat. Op deze manier hebben zowel de dokter als de patiënt geen invloed op de keuze van operatie. Dit wordt beschouwd als de meest zuivere manier van onderzoek. In **deel 2** van dit proefschrift (hoofdstuk 5, 6 en 7) wordt een gerandomiseerde studie beschreven tussen de sacrospinale hysteropexie en het verwijderen van de baarmoeder via de schede bij vrouwen met een baarmoederverzakking. 66 Vrouwen participeerden in deze studie.

In **hoofdstuk 5** worden de resultaten van complicaties, pijn, gebruik van pijnstillers, post-operatief herstel en werkhervatting beschreven van de vrouwen na een vaginal uterus extirpatie en na een sacrospinale hysteropexie. Ernstige complicaties waren zeldzaam in beide groepen, pijnscores en gebruik van pijnstillers waren gelijk. Echter vrouwen na een sacrospinale hysteropexie verbleven 1 dag korter in het ziekenhuis en gingen gemiddeld 23 dagen eerder aan het werk. Mogelijk zou het economisch aantrekkelijker zijn om in geval van een baarmoederverzakking een sacrospinale hysteropexie te verrichten.

In **hoofdstuk 6** wordt dezelfde gerandomiseerde groep vrouwen beschreven, maar wordt er gekeken naar anatomisch resultaat. Zowel voor als 6 en 12 maanden na de operatie werden deze vrouwen op een gestructureerde manier gynaecologisch onderzocht. Vrouwen na een sacrospinale hysteropexie hadden een langere totale vaginalengte. Er zijn aanwijzingen dat dit ten gunste komt aan het seksueel functioneren. Het aantal vrouwen dat 1 jaar na de operatie een verzakking van de voor- of achterwand van de vagina had, was gelijk verdeeld tussen de groepen. Echter het verschil in risico op het opnieuw verzakken van de baarmoeder of het verzakken van de top van de vagina (het middelste compartiment, indien de baarmoeder verwijderd is heet dit de top van de vagina) was 17% ten gunste van het verwijderen van de baarmoeder. Aangezien de groep vrouwen die we onderzocht hadden als klein kan worden beschouwd, kunnen we geen subanalyse doen naar risico's voor het optreden van dit recidief. Wel was opvallend dat met name vrouwen die een zeer ernstige verzakking van de baarmoeder voor de operatie hadden (graad 4), een hoog risico hadden om een recidief te krijgen na een sacrospinale hysteropexie. De conclusie van deze studie was dat het anatomisch resultaat na het verwijderen van de baarmoeder beter is na een vaginale uterus extirpatie bij 1 jaar follow-up. Echter het aantal vrouwen dat opnieuw geopereerd moet worden was gelijk tussen de groepen. Mogelijk dat de sacrospinale hysteropexie geschikt is voor een selecte groep vrouwen die geen zeer ernstige verzakking van de baarmoeder hebben.

Naast het anatomisch resultaat is het nog belangrijker dat patiënten tevreden zijn over het functionele resultaat; de klachten op het gebied van verzakkingsgevoel, plassen, stoelgang en seksueel functioneren. Bovendien is het belangrijk dat er een goede kwaliteit van leven bestaat na de operatie. In **hoofdstuk 7** worden deze resultaten van

functionele klachten beschreven tussen de gerandomiseerde groepen vrouwen. Er blijken geen verschillen te bestaan in klachten 1 jaar na de operatie. Beide ingrepen waren geassocieerd met een significantie verbetering op bijna alle klachten genoemd in de vragenlijsten. Kwaliteit van leven verbeterde ook significant na beide operaties. We kunnen concluderen dat beide operaties even effectief waren in het verbeteren van de functionele klachten en kwaliteit van leven.

In **hoofdstuk 8** worden de resultaten bediscussieerd en worden aanbevelingen gedaan voor toekomstig onderzoek. Veel onderzoek naar verzakkingsoperaties hebben een beperkte follow-up terwijl we weten dat verzakkingen en recidief verzakkingen in de tijd ontstaan. Het is zeer waarschijnlijk dat er meer recidieven gaan ontstaan in de onderzochte groep vrouwen beschreven in dit proefschrift. We zullen deze groep vrouwen daarom bij 5 jaar follow-up nogmaals benaderen voor verder onderzoek. Ook is het belangrijk op zoek te gaan naar risicofactoren voor het krijgen van een recidief verzakking van de baarmoeder of top van de vagina. Mogelijk is het verrichten van een sacrospinale hysteropexie met name geschikt voor vrouwen met een matig ernstige verzakking van de baarmoeder. Misschien dat bij zeer ernstige verzakkingen het weefsel waarmee de baarmoeder opgehangen wordt minder stevig is geworden doordat het langere tijd buiten de vagina heeft gehangen. Daardoor zou de hechting minder stevig kunnen zitten en gemakkelijk afscheuren bij uitbreiding van activiteiten na de operatie. Een studie hiernaar zou de indicatiestelling voor de sacrospinale hysteropexie scherper kunnen stellen.

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Curriculum Vitae

Viviane Dietz werd op 3 juli 1974 geboren te Nuenen als jongste van twee dochters. Zij deed in 1992 eindexamen Voorbereidend Wetenschappelijk Onderwijs aan het Eckart college te Eindhoven. Vervolgens behaalde zij haar propedeuse en eerste fase van Medische Biologie aan de Rijksuniversiteit Utrecht. In 1995 begon zij aan de studie Geneeskunde aan de Rijksuniversiteit Utrecht en ontving zij haar artsdiploma in 2000. In 2000 werkte de auteur als arts-assistent gynaecologie in het Diakonessenhuis te Utrecht (opleider Dr. M.V.A.M. Kroeks) waarna zij in 2001 kon toetreden in de opleiding tot gynaecoloog. Van 2002 tot 2005 vervolgde zij haar opleiding in het Universitair Medisch Centrum Utrecht (opleider Prof. Dr. A.P.M. Heintz). In deze periode kon zij starten met het onderzoek in samenwerking met Dr. C.H. van der Vaart en Dr. S.E. Schraffordt Koops dat leidde tot deze dissertatie. Het laatste deel van haar specialisatie werkte zij in het Twee Steden Ziekenhuis in Tilburg/Waalwijk (opleider Dr. H.J.H.M. van Dessel) waarna zij terugkeerde naar het Universitair Medisch Centrum Utrecht (opleider Prof. Dr. G.H.A. Visser). Sinds 2008 is zij werkzaam als gynaecoloog in vervolgopleiding tot urogynaecoloog en endoscopist in het Catharina Ziekenhuis Eindhoven.

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