Chapter 2

Prospective analysis of complications of Tension-free Vaginal Tape (TVT) from The Netherlands TVT Study

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American Journal of Obstetrics and Gynecology 2005, July 193: 45-52

Abstract

Objective: The intra- and postoperative anatomical complications, frequency, and influence of risk factors of the tension-free vaginal tape are described.

Study Design: This was a prospective cohort study of 809 patients.

Results: The total intraoperative complication rate was 6.2%. Previous prolapse surgery was a risk factor for complications (odds ratio, 2.86; 95% CI, 1.15 - 7.11). We found more intraoperative complications in patients with general anesthesia than with local analgesia with sedation (odds ratio, 4.14; 95% CI, 2.01- 8.53). In teaching hospitals the postoperative complication frequency was higher than in non-teaching hospitals (odds ratio, 0.55, CI 0.35- 0.85). The learning curve is short and more postoperative complications were found in the second ten patients operated by 1 surgeon (odds ratio, 1.94; 95% CI, 1.14 – 3.29). Spinal analgesia gives fewer postoperative complications than local analgesia with sedation (odds ratio, 0.35; CI, 0.13 – 0.92).

Conclusion: Tension-free vaginal tape is a relative safe procedure; concomitant pelvic surgery can be performed safely. Several risk factors for complications were identified: menopausal state, previous prolapse surgery, mode of anesthesia, teaching hospital, and the second ten procedures of each surgeon.

INTRODUCTION

Stress urinary incontinence (SUI) is a common health problem among women[1]. Besides physiotherapy, incontinence surgery is the cornerstone in the treatment of these women. Many different surgical techniques have been introduced for the treatment of SUI. The techniques not only differ with regard to success, but they also have different complication rates. These complications can be anatomic (eg, bladder perforation) or functional (eg, voiding dysfunction).

Currently, tension-free vaginal tape (TVT) is a well-established therapy for SUI in women. The procedure was introduced by Ulmsten et al[2,3] in 1995, and has replaced most other forms of anti-incontinence surgery, with > 500,000 devices sold worldwide. TVT is a minimally invasive procedure and is based on the concept of mid urethral support. The TVT has proved to be as successful as any other incontinence procedure[4]. Reasons for its popularity are the minimally invasive nature of the procedure and its high success rate. Nevertheless, minor and major complications have been reported[5]. Operative bladder or urethral perforation has been reported to be up to 15% of cases[6]. Several other severe intra- and postoperative complications like urethral erosion, injury to large vessels, hematoma, wound infection, and complete urinary retention have been described[5-9].

Several possible risk factors for complications have been described[5-9]. The operative history of the patient, the learning curve of the surgeon, concomitant surgery, and the different sorts of anesthesia, may all play a role in the occurrence of complications. To be able to prevent complications, knowledge of these possible risk factors is needed. No prospective study has ever been performed to establish insight into these risk factors. The study of Ward et al[4] was a trial that compared the TVT and the Burch procedures. The study reports the incidence of complications but does not report on the possible risk factors for complications. The results of the Austrian registry, as reported by Tamussino et al[8], described the complications of TVT in a large group (N=2795). Participating centers in that study were asked to complete a single-page questionnaire for every patient who underwent a TVT procedure. It is not clear from the article whether this was done prospectively for every patient. All other studies also have described the complications and its rate retrospectively, which gives a subjective insight in the real amount and severity of the complications.

The aim of this study was to describe the anatomic complications, their frequency, and the influence of several risk factors (such as the operative history, concomitant surgery, learning curve and type of anesthesia) on the complication rate of the TVT procedure. Furthermore, a survey of complications of the TVT procedure, as published in the English scientific literature, is presented.

MATERIALS AND METHODS

This study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg, as primary research center, and all other co-working hospitals, as required by Dutch law. Written informed consent for this study was obtained from all the women. Between March 2000 and September 2001, all patients with an indication for the TVT procedure were asked to participate in this study. The procedures took place in 41 different hospitals, in which 54 gynecologists and urologists performed the TVT procedure. Among the 41 hospitals, there were 3 university hospitals, 25 teaching hospitals, and 13 local hospitals. All participating gynecologists and urologists were qualified to perform vaginal surgery and had a short training in performing TVT procedure by an experienced surgeon.

Inclusion criteria were SUI that was proved at urodynamics or at history/physical examination with an indication for surgery. The urodynamic investigations were performed according to the standards recommended by the International Incontinence Society[10]. Exclusion criteria were recurrent and difficult-to-treat urinary tract infections, significant symptoms of urge urinary incontinence, a history of detrusor overactivity at cystometry, post voiding bladder retention (>150 ml), bladder capacity < 200ml or physical/mental impairment.

The TVT was performed as described by Ulmsten[2]. The operation was carried out with local anesthesia with 0.25% prilocaine with adrenalin and sedation, spinal analgesia, or general anesthesia.

A standardized history, physical examination, and urine culture was accomplished before the operation and at 2, 6, 12, and 24 months. The registration of intraoperative and direct postoperative complications was done by the surgeon.

The following complications were recorded: blood loss > 300 ml, bladder perforation, urethral lesion, major vessel lesion, and other intra operative complications. Post operative complications considered were the need for catheterization > 24 hours, the need for self-catheterization, postoperative bleeding, hematoma, wound infection, urinary tract infection, tape rejection, tape erosion, temperature rise > 38 °C. The number of TVT procedures that every surgeon performed and the complications per surgeon were counted. Groups were formed of the first 10 TVT procedures, 11-20 TVT procedures and over 20 TVT procedures that the surgeon performed.

Statistical analysis

All data were anonymous processed by a research physician (TMB) and the secretary of the research team. Statistical analysis was performed with SPSS 10.0 for Windows (SPSS Inc, Chigago, **I**11. The X^2 test was used to compare proportions that related to subjects in different groups. Categorical variables were compared with a 2-sided Fisher exact test. The Student t-test was used as a statistic to compare interval variables. Univariate odds ratios (ORs) and 95% confidence intervals (CI) and the probability values were calculated for risk factors.

Subsequently, multivariate logistic regression analysis was used to construct a prediction model to determine preoperative and postoperative factors that independently

influenced the complication rate. Logistic regression is a technique that can be used to evaluate the performance of multiple variables in a diagnostic model. The selection of variables usually is performed with a significance level of 5%. However, the incorrect exclusion of a factor would be more deleterious than including too many factors. Multivariate analysis included therefore all variables with a probability value $< .30$ in the univariate analysis.

RESULTS

In total 809 women participated in the study. Their mean age was 51.3 ±10.4 (range, 20-82) years and mean parity was 2.4 ±1.1. Of all patients, 46.6% were postmenopausal, and 34% of the postmenopausal women used hormone replacement therapy. The mean operating time for only the TVT procedure was 32.4 ± 11.2 minutes (range, 14 - 120 minutes). The incidence of intraoperative complications was 6.2% (n = 50 women; Table 1). Bladder perforation was the most common complication (n = 28 women; 3.5%). In all cases it was diagnosed during the procedure. In all but 1 case, the tape was reinserted, and an indwelling catheter was placed; at follow-up examination, none of these patients had any problems. There were no urethral lesions. Severe blood loss (>300ml) occurred in 10 cases. In 1 case, the internal iliac vein was lacerated, and a laparotomy performed. There was 2500-ml blood loss; the tape was left in place, and the patient recovered completely.

The total incidence for postoperative complications was 20.9% (n = 169 cases; Table 1). In this group there were 30 patients (3.7%) with a combination of > 1 complication. These complications were counted separately in the total incidence. Abdominal, vaginal, or retropubic hematoma was seen in 28 patients (3.4%). A temperature rise (> 38°C) was diagnosed in 1 case (0.1%). Tape erosion was found in 2 cases (0.2%) within the two-year follow-up examination. In 121 cases (14.9%), an indwelling bladder catheter was needed for > 24 hours. In 13 of these patients (1.6%), because of voiding difficulty, the TVT tape had to be cut. After reopening the midline incision, the tape was identified and cut laterally of the urethra. In one case, the tape was cut in the midline, a lesion arose in the urethra during surgery, which was closed. Afterwards a urethral-vaginal fistula developed which was closed vaginally. The patient recovered completely. Of the 13 patients in whom the TVT had to be cut, 5 patients were reported to be continent. All these 13 patients were able to void without residual volumes of > 150 ml at 12 months after the tape was cut. Three women required either self-catheterization or a suprapubic catheter.

There were 131 women with an operative history for incontinence or prolapse. In the group with previous incontinence surgery (n = 50 women), there was no significant difference in sort of complications. In this group, there were 9 patients who had undergone 2 previous incontinence procedures, and 1 patient who had undergone 3 previous incontinence procedures (Burch, re-Burch and hysterectomy with concomitant Raz sling procedure). In this group of 9, there were no intra- and postoperative complications; 1 patient had worsening of pre-existing urge incontinence.

A statistical difference was found in the intraoperative complication rate of the group who had a history of prolapse surgery (OR, 2.86, 95% CI, 1.15 - 7.11; Table 2). There were only 16 cases (2%) with a history of both prolapse and incontinence surgery. No significant difference in complication rate was found in this group. Women with a rectocele before surgery had statistically a lower chance at postoperative complications. General anesthesia was found to give more complications intra- operatively than local analgesia with sedation (OR, 4.14, 95% CI, 2.01- 8.53).

In 59 cases (7.3%) concomitant surgery was performed: vaginal hysterectomy for

uterine descent, 7 cases; anterior repair, 15 cases; posterior repair, 28 cases; and anterior and posterior repair, 9 cases. The intra- and postoperative complication rates in this group did not differ significantly (Table 2 and 3). The complication rate in the group with concomitant non-pelvic surgery was 9.5% (not significant).
The postoperative complication rate in the in the 25 teaching hospitals was 24% and 16% in the 13 local hospital. This indicates a significant difference in postoperative complication rate among the different types of hospitals (OR, 0.55, 95% CI, 0.35-0.85). In the group of premenopausal women, we found fewer postoperative complications (OR 0.67, 95% CI, 0.46 – 0.99). The multivariate regression analysis showed a significant difference for spinal anesthesia (OR 0.35, 95% CI, 0.13 – 0.92). The results of the learning curve are shown in tables 2 and 3. In the second ten procedures performed by the same surgeon, statistically most of the postoperative complications occur (OR 1.94, 95% CI, 1.14 – 3.29).

COMMENT

This study comprises 30% of all TVT procedures that were performed in the Netherlands during the inclusion period of our study. It analyzes the intra- and postoperative complications that are associated with the TVT procedure. We tried to get a clear view in the origin of these complications. Is there a learning curve? Does concomitant surgery complicates the procedure? Is a history of previous surgery the main factor in causing complications? Several studies report about the complication rates with different kinds of incontinence surgery (Table 1). However, to our knowledge, apart from the comparative study of Ward et al[4], a large prospective study of complications with the TVT procedure has never been published.

Different kinds of incontinence procedures result in different complications and different complication rates. The complications presented in this study do not differ much from, and in general occur less frequent than, the complications described with other incontinence procedures[11-14]. Table 1 shows the observations from several other studies on complications with the TVT procedure[4-9].

It appears that the rate of intra- and postoperative complications does not differ significantly among these studies. However, in a number of these studies, the data were collected retrospectively. Hence, under or over reporting and other sources of bias may have been introduced unwittingly.

The introduction of the TVT needles is relatively "blind", and no visual control is possible for the retropubic part of the introduction. Despite this, the number of complications (eg, hemorrhage, urinary, or visceral tract injuries) is low. Most common is a bladder perforation (2.7%-15%). In our study, all complications were reported by the surgeon. We found no obturator nerve and no urethral injury. Nevertheless, we did report 1 case of iliac vessel injury. Analysis of this case did not reveal any special circumstance for this complication to have happened. This is in concordance with literature, because case reports about these complications are limited[15-18]. One may conclude that serious complications are uncommon after TVT procedure.

In addition, complications that are seen often with the use of foreign body material (such as fever, erosion, or infection) are low with the TVT procedure. In our study, 2 tapes had to be removed because of infection or erosion within the 2-years follow-up examinations. Whether these cases could be attributed to real infection or to erosion or to a defective wound healing is unknown. Tape removal has been reported more often in the international literature[19, 20] and is especially seen in few cases in which the vaginal wall did not close completely over the tape. This might be due to extreme atrophy of the vaginal mucosa. In our study, this is reflected in the occurrence of more postoperative complications in postmenopausal women.

The learning curve is associated with complication rates in many medical procedures. Two studies in the English literature report about the learning curve of the TVT procedure [5, 21]. Kuuva et al[5] found a decline in the number of complications per surgeon after 15 procedures. Groutz et al[21] found 5 bladder injuries in the first 20 patients underwent operation by an experienced urogynecologist. These authors state: "We believe these injuries represent the learning curve because no further

injuries occurred subsequently". In our cohort, the complication rate was increased in the second 10 patients who underwent operation by 1 surgeon. We cannot explain the reason that the number of complications is higher in the second 10 procedures as compared to the first 10 procedures for each surgeon. We should emphasize that all gynecologists and urologists who participated in this study were trained in the procedure by experienced peers. Furthermore, they were able to carry out cystoscopy procedures to detect bladder injury, which is of paramount importance for a safe TVT procedure. Nevertheless, we conclude that, as compared to other incontinence procedures, the TVT procedure has a short learning curve. Related to the subject of experience, we observed significantly more postoperative complications in teaching hospitals. In these hospitals, procedures were carried out by residents and registrars who were supervised by experienced consultants. The increased number of complications in these hospitals may be the result of the fact that the retropubic part of the procedure is difficult to supervise. However, when this is true, one might expect more intra- than postoperative complications. Nevertheless, this observation strengthens the fact that, although short, there is a learning curve.

Simultaneous surgery may affect the complication rate. We found no differences in intra- or postoperative complication rates between isolated TVT procedures or TVT procedures in combination with prolapse surgery. To our surprise a pre-existing rectocele was associated with fewer postoperative complications. We do not have a clear explanation for this observation, and it may merely be a coincidence. Previous prolapse surgery was attributed to more intra-operative complications, predominantly bladder perforations. Others before have described this. Moss et al[22] found 3 bladder perforations in 154 primary TVT procedures. Ten bladder perforations occurred in a group of 163 patients with previous pelvic surgery. However, this was not significantly different. Moss et al did not make a difference between previous prolapse surgery and previous incontinence surgery because the last group was too small to analyze separately. In contrast, Daraï et al[23], who studied the outcome of 40 TVT procedure with and 41 procedures without simultaneous hysterectomy, found significant differences among women with previous incontinence surgery. They found no intra- and postoperative differences in complication rates between the 2 groups who were studied, except for de novo urge symptoms. Nevertheless, they did find a significant difference in complication rate among patients with previous incontinence surgery. Daraï et al claim that this occurred because of the scarification of Retzius space. Our data, however, did not associate incontinence surgery before the TVT procedure with an increase in intra- or postoperative complications.

Finally, the mode of anesthesia may influence the complication rate of the TVT procedure. Multivariate regression analysis for intraoperative complications and the type of anesthesia showed a significant difference for general anesthesia. This analysis corrects for confounding factors such as concomitant surgery and history of pelvic surgery. Spinal anesthesia was found to give fewer postoperative complications, especially no postoperative urinary obstruction. One might think that when the cough test that was described by Ulmsten et al[2] is not performed, more obstruction could have been encountered. Possibly the surgeons who performed the TVT with spinal anes-

thesia are aware of the possibility of this complication and left the tape lose under the urethra. In contrast, Bodelsson et al[6] found a higher incidence of bladder perforations in the spinal group.

In conclusion, this study shows that the TVT is a relatively safe procedure with a low complication rate. Several risk factors for complications were identified: menopausal state, previous prolapse surgery, general anesthesia, teaching hospital, and the second ten procedures performed by each surgeon. The TVT procedure has a short learning curve; however, good cystoscopic skills are essential for everyone performing the TVT procedure.

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Table 1. Complications of TVT's performed (N = 809) in comparison with other studies

Sort study	This study prospective	Ulmsten (7) retrospective	Kuuva (5) retrospective	Ward (4) prospective	Bodelsson (6) retrospective	Meschia (9) retrospective	Tamussino (8) retrospective
Only TVT	**no N=809**	**yes N=50**	**no N=1455**	**no N=170**	**no N=174**	**yes N=404**	**no N=2795**
intra-operative complications							
bladder perforation	3.5%	NA	3.8%	8.8%	13.8%	6%	2.7%
blood loss>300ml	1.2%	0%	1.9%⋆	0.6%#	4% ##	0.5%	2.3%‡
urethral lesion	0%	0%	0.1%	NA	1.2%	NA	NA
lesion of the iliac vessels	0.1%	0%	0.1%	0.6%	NA	NA	NA
other	1.4%		0.2%⋆⋆			0.2%¶	2.4%‡‡
post-operative complications							
hematoma	3.4 %	NA	2.4%	1.8%†††	0.6%	1.5%	NA
persisting complete retention	NA	0%	2.3%	2.9%	2.8%	NA	NA
need of catheter>24 hours	14.9 %	10%	NA	11.2%††	20%	4%	NA
tape rejection	0.2%	0%	0%	0.6%	1.7%	0.5%	NA
urinary infection	0.7%	0%	4.1%	22.3%†	7%	NA	17%
fever (>38 degrees Celsius)	0.1%	NA	0.8%	0.6%	NA	NA	NA
other				Vaginal perforation 2.9%			
remarks	1.6% adhaesiolysis of tape	No significant other complications were noted		This is a prospective study comparing TVT with Burch			

NA: not available
†: in 6 weeks postoperative
††: > 7 days
†††: retropubic hematoma
#: Obturator artery injured requiring laparotomy and bllod transfusion (4 units)
⋆: >200 ml.
⋆⋆: 1x obturator nerve lesion, 1x vaginal hematoma
##: amount of blood loss unknown, vaginal pack needed
¶: 1 obturator nerve lesion
‡: increased bleeding amount not stated
‡‡: needed reoperation

Table 2. Univariate and Multi variate Analysis of Riskfactors influencing Intra-operative Complications

		Univariate Analysis						Multivariate analysis			
	missing values	**no complications** (n = 759)		**complications** (n =50)		**OR[95% CI]**	***p***	**β**	**OR**	**[95% CI]**	***p***
General Data											
age (years ± sd)	6	51.31	± 10.3	50.7	± 11.6		0.690				
parity	75										
nulliparity		15	(88%)	2	(12 %)	0.5 [0.1 - 2.3]	0.378				
multiparity		671	(94 %)	46	(6 %)						
menopausal status	69										
premenopausal		370	(94 %)	25	(6 %)	1.0 [0.5 - 1.8]	0.979				
postmenopausal		323	(94 %)	22	(6 %)						
Urogynecological History	0										
no previous urogynecological surgery		641	(95 %)	37	(5 %)	+					
previous prolapse surgery		58	(89 %)	7	(11 %)	2.1 [0.9 - 4.9]	0.083	1.05	2.86	[1.15-7.11]	**0.02**
previous incontinence surgery		46	(92 %)	4	(8 %)	1.5 [0.5 - 4.4]	0.452	0.36	1.44	[0.46-4.51]	0.54
previous incontinence and prolapse surgery		14	(88 %)	2	(12 %)	2.5 [0.5 - 11.3]	0.227	1.31	3.72	0.77-17.94]	0.10
Pelvic Floor Status prior to TVT											
cystocele	121										
no cystocele		337	(93 %)	24	(7 %)	1.1 [0.6 - 2.0]	0.722				
cystocele		303	(93 %)	24	(7 %)						
rectocele	103										
no rectocele		501	(93 %)	39	(7 %)	0.6 [0.2 - 1.3]	0.17	-0.96	0.38	[0.15-0.96]	**0.04**
rectocele		159	(96 %)	7	(4 %)						
prolaps of uterine cerix of vaginal vault	94										
no prolapse of cervix of vaginal vault		522	(94 %)	32	(6 %)	1.4 [0.7 - 2.8]	0.29	0.29	1.34	[0.64-2.80]	0.44
prolapse of cervix of vaginal vault		148	(92 %)	13	(8 %)						
urethral hypermobility	192										
no hypermobility		98	(94 %)	6	(6 %)	0.8 [0.3 - 2.0]	0.694				
hypermobility		478	(93 %)	35	(7 %)						
type of hospital setting	0										
no. of TVT in teaching hospitals		439	(94 %)	30	(6 %)	0.9 [0.5 - 1.6]	0.764				
no. of TVT in non-teaching hospitals		320	(94 %)	20	(6 %)						

Simultaneous Procedures	0										
TVT only		643	(94 %)	44	(6 %)	+					
TVT with prolapse surgery		55	(94 %)	4	(6 %	1.1 [0.4 - 3.1]	0.91				
TVT with other surgical procedures		61	(97 %)	2	(3 %)	0.5 [0.1 - 2.0]	0.306				
Type of Anesthesia	64										
local anesthesia (with sedation)		564	(95 %)	32	(5 %)	+					
spinal analgesia		59	(95 %)	3	(5 %)	0.9 [0.3 - 3.0]	0.859	-1.09	0.34	[0.04-2.55]	0.29
general anesthesia		72	(83 %)	15	(17 %)	3.7 [1.9 - 7.1]	**0.001**	1.42	4.14	[2.01-8.53]	**0.01**
Surgeon's Experience	0										
learning curve effect											
first 10 procedures for each surgeon		265	(94.0%)	17	(6%)						
next 10 procedures for each surgeon		145	(92%)	13	(8%)	1.4[0.7-3.0]	0.432				
more than 20 procedures for each surgeon		349	(95%)	20	(5%)	0,9[0.5-1.7]	0.736				

Values are mean (SD). number (%) and Odds Ratio [95% CI]
A Fisher exact Tes was performed for catergorical variables
Student-t test was performed for interval variables
(+) Reference group
statistically significant differences are highlighted
p= p-value

Table 3.Univariate and Multivariate Analysis of Riskfactors influencing Postoperative Complications

		Univariate Analysis						Multivariate Analysis		
	missing values	no complicatior (n = 640)		complicatior (n = 169)		OR [95% CI]	*p*	β	OR [95% CI]	*p*
General Data										
age (years ± sd)	7	50.9	± 10.4	52.6	± 10.4		0.055			
parity	75									
nulliparity		13	(76 %)	4	(24 %)	0.9 [0.3 - 2.7	0.816			
multiparity		565	(79 %)	152	(21 %)					
menopausal status	69									
premenopausal		321	(81 %)	74	(19 %)	0.7 [0.5 - 0.9	**0.041**	-0.4	0.67[0.45-0.99	**0.044**
postmenopausal		259	(75 %)	86	(25 %)					
Urogynecological History	0									
no previous urogynecological surgery		543	(80 %)	135	(20 %)	+				
previous prolaps surgery		46	(71 %)	19	(29 %)	1.7 [0.9 - 2.9]	0.077			
previous incontinence surgery		38	(76 %)	12	(24 %)	1.2 [0.6 - 2.5]	0.487			
previous incontinence and prolaps surgery		13	(81 %)	3	(19 %)	0.9 [0.3 - 3.3]	0.908			
Simultaneous Procedures	0									
TVT only		532	(77 %)	155	(23 %)	+				
TVT with prolaps surgery		52	(88 %)	7	(12 %)	0.5 [0.2 - 1.04]	0.056	-0.64	0.53[0.21-1.33]	0.17
TVT with other surgical procedures		56	(89 %)	7	(11 %)	0.4 [0.2 - 0.96]	**0.035**	-0.25	0.78[0.33-1.87]	0.58
Pelvic Floor Status prior to TVT										
cystocele	121									
no cystocele		274	(76 %)	87	(24 %)	0.9 [0.6 - 1.2	0.401			
cystocele		257	(79 %)	70	(21 %)					
rectocele	103									
no rectocele		411	(76 %)	129	(24 %)	0.6 [0.4 - 0.9	**0.016**	-0.49	0.61[0.36-1.0]	0.07
rectocele		141	(85 %)	25	(15 %)					
prolaps of uterine cerix of vaginal vault	94									
no prolaps of cervix of vaginal vault		429	(77 %)	125	(23 %)	0.8 [0.5 - 1.2	0.287			
prolaps of cervix of vaginal vault		131	(81 %)	30	(19 %)					
urethral hypermobility	192									
no hypermobility		83	(80 %)	21	(20 %)	1.1 [0.7 - 1.9	0.679			
hypermobility		400	(78 %)	113	(22 %)					

type of hospital setting	0									
no. of TVT in teaching hospitals		355	(76 %)	114	(24 %)	0.6 [0.4 - 0.8(	**0.005**	-0.60	0.55[0.35--0.8!	**0.01**
no. of TVT in non-teaching hospitals		84	(84 %)	55	(16 %)					
Type of Anesthesia	64									
local anesthesia (with sedation)		462	(77 %)	134	(23 %)	+				
spinal analgesia		56	(90 %)	6	(10 %)	0.4 [0.2 - 0.9]	**0.019**	-1.1	0.35[0.13-0.92]	**0.03**
general anesthesia		65	(75 %)	22	(25 %)	1.2 [0.7 - 2.0]	0.561	0.27	1.31[0.71-2.42]	0.40
Surgeon's Experience	0									
learning curve effect										
first 10 procedures for each surgeon		233	(83%)	49	(17%)	+				
next 10 procedures for each surgeon		112	(71%)	46	(29%)	2.0 [1.2-3.1]	**0.005**	0.66	1.93[1.14-3.29]	**0.02**
more than 20 procedures for each surgeon		295	(80%)	74	(20%)	1.2 [0.8-1.8]	0.736	0.09	1.09[0.67-1.77]	0.73

Values are mean (SD). number (%) and Odds Ratio [95% CI]
A Fisher exact Tes was performed for catergorical variables
Student-t test was performed for interval variables
(+) Reference group
statistically significant differences are highlighted
p= p-value