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Cost-analyzes based on a prospective, randomized study comparing laparoscopic colposuspension with a tension-free vaginal tape procedure

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Background. The aim of this study was to compare laparoscopic colposuspension with tension-free vaginal tape (TVT) in terms of costs to the county.

Methods. In a prospective, randomized study, we approached 270 consecutive women presenting for evaluation of stress urinary incontinence symptoms at one university hospital. Preoperatively, and at 1-year follow-up, the women underwent urodynamic evaluation, an ultra-short pad-test and completed a lower urinary tract symptoms questionnaire. We randomized 79 consenting, eligible women to either procedure; a 1-year follow-up examination was performed on 68/71 (96%) women that were available. The procedures were performed as described previously. Main outcome measures were all relevant costs for goods and services associated with the procedures.

Results. The baseline characteristics of the two groups were similar. The TVT procedure was performed significantly faster than the laparoscopic colposuspension, i.e. 44.9 ± 14.2 min compared with 60.5 ± 13.4 min ($p < 0.0001$). Even so, procedural costs were significantly lower for laparoscopic colposuspension than for TVT (€1273.4 compared with €1342.8 $p < 0.001$). At the 1-year follow-up visit, three women operated on with TVT and one operated on with laparoscopic colposuspension required re-operation for continuous stress urinary incontinence. One woman operated on with TVT had her sling cut for bladder-emptying problems. Total costs, including re-operations were €1462.6 for a TVT procedure and €1314.5 for a laparoscopic colposuspension.

Conclusion. In our hands, the laparoscopic colposuspension was less expensive to the county than the TVT procedure.

Key words: female stress incontinence; laparoscopic colposuspension; tension-free vaginal tape

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During the last decade, several less invasive modifications of the traditional surgical procedures for female stress urinary incontinence have been developed (1–4). Mostly, the open Burch colposuspension procedure has been used as a reference method because it is well documented and effective (5–7). Two of the relatively new procedures are

laparoscopic colposuspension and the modification of the suburethral sling procedure named tension-free vaginal tape (TVT). Either of these two procedures can be used for the same patients, i.e. those with primary incontinence, a hypermobile bladder neck with normal urethral closing pressure and without concomitant, severe, uterovaginal prolapse. The reported short-term results of the procedures are encouraging and seem to be in the same range (4, 8–15). However, no study has

Abbreviations:

TVT: tension-free vaginal tape; €: Euro; SEK: Swedish crowns.

directly compared the two methods with each other. We therefore designed this prospective, randomized study to compare the TVT and laparoscopic colposuspension procedures. The present report, based on a subset of all patients projected to be enrolled, focuses on costs to the county accrued by the two procedures.

Materials and methods

The Ethical Committee of the Lund University approved the study. Consecutive women presenting to the Department of Obstetrics and Gynecology, University Hospital of Lund, Sweden, between December 1998 and September 2000 with significant symptoms of stress urinary incontinence, were candidates for the study. Some patients, who had been similarly evaluated before that period and were waiting for surgery, were also candidates for the study. All patients underwent urodynamic investigation and performed an ultra-short pad-test (16). Inclusion criteria were urethral closing pressure ≥ 20 cm H₂O, urethral functional length ≥ 25 mm, hypermobility of the bladder neck (≥ 45 degrees of down rotation at valsalva manoeuvre), and five or more ml leaking at the pad test.

The pad-test was performed in the following way: the patient was allowed to empty her bladder. Any remaining urine was tapped using a catheter without anesthetic gel. We then filled the bladder with 300 ml sterile water at room temperature. The woman was handed a preweighed sanitary napkin to put inside her underwear. She was instructed to perform a standardized physical activity during 1 min at submaximal level. The details of the physical activity were explained and demonstrated by the study nurse. The pad was weighed after the manoeuvre to estimate the leaked volume.

We excluded women who predominantly had urge incontinence, had previously been operated on for stress urinary incontinence, were incontinent after previous vaginal repair, or had grade two or more uterovaginal prolapse (17). Women not having completed childbirth, needing additional gynecologic surgery, or having a contra-indication to incontinence surgery were excluded. We also excluded women regarded to be at increased risk for complications during general anesthesia or laparoscopic surgery, i.e. those with cardiovascular disease, known or suspected intra-abdominal adhesions, or abdominal obesity. Preoperatively, we obtained a medical history using a standardized protocol that included questions concerning parity, concomitant disease, medication, former surgery, lower urinary tract symptoms and former non-surgical treatment of stress urinary incontinence.

Eligible patients, who gave informed consent, were randomized in a proportion of 1:1 to either TVT or laparoscopic colposuspension. Randomization was performed as follows: before start of the study, the research nurse prepared equal numbers of assignments, indicating TVT ($n = 140$) or laparoscopic colposuspension ($n = 140$). She folded the pieces of paper with the assignments several times, mixed them, put them in opaque envelopes that were sealed, mixed, and then numbered. The patients were consented and randomized at the time of urodynamic evaluation. Patients already evaluated were consented and randomized at the time of admission to the hospital the day before surgery. The number of assignments was in accordance with a sample-size analysis based on the desire of being able to identify a 10% difference in 1-year cure rate with 80% power and an α -error of $< 0.05\%$. We did not have relevant data available to estimate the number of patients needed for the economic analyzes presented in this paper. Therefore, we arbitrarily chose to base analyzes on the first 25% (70) of the 280 patients that were planned to be enrolled.

The laparoscopic colposuspension procedure and the TVT procedure are described in detail elsewhere (1, 4, 8, 9, 14, 15). Briefly, laparoscopy was performed under general anesthesia. After having entered the abdominal cavity, the space of Retzius was dissected and the vaginal fascia lifted against the Cooper ligament with two single-bite polytetrafluoroethylene sutures on each side of the urethra (Gore-Tex[®], CV 2, W. L. Gore Inc., Flagstaff, AZ, USA). The sutures were placed approximately 2 cm lateral to the urethra and 2 cm distal to the bladder neck. For the TVT procedure, we used the commercially available TVT device (Medscand Medical AB, Malmö, Sweden and Ethicon Inc., Somerville, NJ, USA). After a short longitudinal incision was made under the mid-urethra, we placed the graft as a sling around the urethra using the disposable needles in the TVT kit as described by Ulmsten et al. (4, 8, 9). The TVT procedure was performed under local anesthesia, with the addition of 50–75 μ g of fentanyl intravenously and 30–100 mg of propofol intravenously at onset of surgery and before administration of local anesthesia. Shortly before the graft was placed, another 25–50 μ g of fentanyl and 20–50 mg of propofol were given intravenously. All patients underwent cystoscopy during the procedures to rule out bladder perforation. Any adverse events were recorded.

After surgery, the indwelling catheter was immediately removed. We controlled the urinary bladder for any residual urine repeatedly and daily using ultrasound-equipment (BladderScan[®] BVI 2500, Diagnostic Ultrasound Corporation,

Redmond, WA, USA). Patients were scheduled for hospitalization until the first postoperative day. Thereafter, they were discharged when residual urine was less than 100 ml on one or less than 150 ml on two repeated measurements. However, women not able to empty their bladder sufficiently until the second postoperative day were discharged and evaluated as outpatients every second day until fulfilling the above-mentioned criteria. We recorded adverse events or complications delaying discharge.

Two to five months after surgery, the women were telephone interviewed according to a standardized questionnaire. Also, the charts from the outpatient clinics were reviewed for adverse events related to the procedures. Any events occurring within the first 2 months postoperatively were recorded. Patients were scheduled for a follow-up examination after 1 year. Shortly before the examination, the patients were mailed a questionnaire that included questions regarding continuous stress urinary incontinence symptoms (cured, much improved, little improved, unimproved). Then, the urodynamic examination and the same ultra-short pad-test used before surgery were performed. According to protocol, the follow-up examination was to be performed by a study nurse blinded as to which surgical procedure the patients had been operated with. To achieve blinding, the study nurse was instructed not to read the hospital chart, to initially tell the patient not to talk about her surgery or any abdominal scars, and to have the patient keeping a towel over the abdomen during the examination to cover the scars.

The main outcome measures were subjective change in stress-induced urinary leakage evaluated by the questionnaire, and objective cure evaluated by the relation of leaking between the pre- and postoperative pad-tests. Objective cure was defined as no leaking at postoperative pad-test, improvement as less than one third of the preoperative leakage and un-improvement as one-third or more than the preoperative leakage at the postoperative pad-test. The decision to re-operate required a statement from the woman of being unsatisfactorily improved (unimproved or little improved) and continuous leaking at pad-test (one woman was unable to perform the follow-up pad-test but leaked at stress-test in the upright position).

For the economic analyzes, we decided to estimate the costs from the aspect of the hospital owner (the county). The reason for not estimating the societal costs was that decisions on sick leave were made by one of the investigators at the time of discharge from hospital. The length of sick leave was decided according to the estimated workload the patients were exposed to during regular work,

and not according to the surgical procedure they had been through. Procedural costs were calculated from estimates of the quantity of goods and services used in performance of the procedures, peroperative and postoperative hospital care, and outpatient medical care. These quantities were derived in part from interviews with operating room staff, the economists of our department and of the department of anesthesiology, in part from recordings of procedure-related time-periods. Anesthesia time was derived from the anesthesiology record made for each patient. Moreover, estimates of use of outpatient medical services were derived from patient interviews and chart reviews. We have defined costs as salaries attributable to the procedure, actual costs (i.e. for instruments), charges by our department to the county for inpatient care, charges by the department of anesthesiology to our department, and charges to the county for outpatient visits. The charges used have previously been arrived at by the county to reflect the actual attributable costs for different services. All costs are expressed in Euro (€): [1 € ≈ 9.0 Swedish Crowns (SEK)].

We arrived at time-dependent costs in the following way: the basic costs were those accrued by rent of the operating theatre and the salaries for operating room staff during the time the operating theatre was assigned to each procedure, i.e. from preparations started to the room was cleared and ready for another procedure. The theatre rent was estimated to be €0.04 per min. The theatre staff consisted of one nurse and one nurse's aide at an estimated cost per minute of €0.53, giving a total basic cost of €0.57 per min. Anesthesia costs were estimated by multiplying average anesthesia time with the standardized minute costs of €3.28 charged by the department of anesthesiology. Anesthesia time was defined as the time from when anesthesiologists received the patient outside the operating room until they could wheel her out of the room. Surgical time was defined as the time from injection of local anesthetics during TVT or first cut during the laparoscopic procedure until the last stitch was tied and cystoscopy had been performed. Surgical costs were estimated by multiplying average surgical time by the minute costs for a gynecologist. One gynecologist, assisted by the nurse, usually performed both procedures. During two laparoscopic procedures and one TVT, an additional gynecologist was recruited as an assistant, adding costs to the procedures. Based on average monthly salary of a certified specialist in our department, the surgical costs were estimated to €0.56 per min. To these costs, we added costs for the extra gynecologist needed during two of the 33 laparoscopic procedures (€0.03) and one of the

37 TVTs (€0.015). The above-mentioned different cost types were added to estimate the total time-dependent procedural costs. Hospital costs were those charged by our department for inpatient care. The department charges €343.9 for the admission day and €187.5 for each further day of inpatient care. The standard charge for an out-patient visit to a doctor is €58.3 and to a nurse €23.2.

We arrived at fixed costs in the following way: for the laparoscopic colposuspension, we used laparoscopic video equipment that otherwise was used for a number of different procedures. We estimated the investment cost for a study procedure by dividing the total annual investment cost by the average number of procedures for which the equipment was used each year. Assuming a 5-year depreciation time of the equipment, we arrived at a cost of €18.0 per procedure. The instruments used for the laparoscopic procedure were arbitrarily estimated to last for 300 procedures. Thus, we estimated the investment costs for laparoscopic instruments to €17.4. We also included the costs for gloves, gowns, drapes, and sterilization of the instruments used during each procedure. For TVT procedures, we included the cost for the TVT device (€351). Due to bladder perforation with the TVT needle in one of the 38 patients, we added €9.2 for an estimated average need of an additional TVT device.

In sensitivity analyzes, we examined cost implications of variations in surgical time. During surgery, basic costs, anesthesia costs and surgical costs are always accrued. Thus, a 1-min increase or decrease in surgical time will alter the time-dependent costs by €0.57 (basic cost) plus €3.28 (anesthesia cost) plus €0.58 or €0.59 (surgical cost for TVT or laparoscopic procedure, respectively). Assessing the effects of variations in surgical time, we assumed that pre- and postoperative anesthesia care, and pre- and postoperative work in the operating theatre was unchanged.

Data were entered in the StatView® (SAS Institute Inc., Cary, NC, USA) database. To compare categorical variables, we used the chi-square test and to compare continuous variables we used the Mann–Whitney rank sum test.

Results

Surgical treatment was indicated in 156 of 270 consecutive women presenting for evaluation of presumed stress urinary incontinence symptoms. The main reasons for ruling out surgery were mild stress incontinence symptoms and/or women without previous physiotherapy ($n=64$), and urge incontinence or mixed incontinence with dominating

urge symptoms ($n=41$). Sixty-eight of the 156 planned for surgery were ineligible for the study for one or more of the following reasons: recurrence after previous incontinence surgery ($n=10$), vaginal prolapse ($n=23$), leaking less than 5 ml during pad-test or inability to perform the test ($n=7$), urethral functional length less than 25 mm and/or urethral closing pressure less than 20 cm H₂O ($n=14$), non-hypermobility urethra ($n=19$), needing additional gynecologic abdominal surgery ($n=3$), cardiovascular disease ($n=3$), known or suspected intra-abdominal adhesions ($n=2$), or extreme abdominal obesity ($n=2$). In addition to the 88 remaining women, we approached five women already on the waiting list for incontinence surgery and who were eligible for the study. Of the altogether 93 eligible women, 79 gave their informed consent and were randomized. As of November 2000, 71 randomized women had been operated on, that is 38 with the TVT procedure and 33 with laparoscopic colposuspension. One of the 33 women operated on with laparoscopic colposuspension was excluded from analyzes based on surgical and immediate postoperative data because she erroneously was operated on for training purposes by a gynecologist not participating in the study. All included laparoscopic procedures were performed by one of the authors (JP). The TVT procedures were performed by either two of the authors (PT and JP), depending on who was on duty. There was no steering of certain patients to the one or other gynecologist.

As shown in Table I, women randomized to the one or the other procedure did not differ significantly regarding demographic characteristics or obstetric history. Moreover, median leakage during the ultra-short pad-test also was similar between the groups. None of the preoperative urodynamic characteristics differed significantly between the two groups (residual urine, urethral closing pressure

Table I. Basic data from women randomized to laparoscopic colposuspension or tension-free vaginal tape (TVT) procedures

Characteristics	Laparoscopic colposuspension $n=32$	TVT $n=38$	p
Age (in years)*	51 (30–68)	48 (28–68)	0.33
Body mass index*	23.8 (20.1–32.4)	25.8 (20.5–35.6)	0.08
Parity*	2 (2–4)	2 (1–5)	0.49
Postmenopausal women without HRT	5 (15%)	1 (3%)	0.06
Years of incontinence*	6.0 (1–28)	9.0 (2–40)	0.30
Cysto- or rectocele \leq grade one	5 (12%)	6 (16%)	0.90

*Values are shown as median (range) or n (%) as appropriate.

HRT: hormonal replacement therapy.

Table II. Intraoperative and postoperative characteristics associated with costs for TVT and laparoscopic colposuspension procedures

Characteristics	Laparoscopic colposuspension <i>n</i> = 32	TVT <i>n</i> = 38	<i>p</i>
Basic time (min)*	128.0 ± 20.6	96.3 ± 17.8	< 0.0001
Anesthesia time (min)	117.6 ± 22.8	77.3 ± 16.0†	< 0.0001
Surgical time	59.9 ± 13.4	44.9 ± 14.2	< 0.0001
Discharge on the first postoperative day	19 (59%)	29 (76%)	0.06
Outpatient postoperative visits to a physician‡	0.15 (0–1)	0.19 (0–3)	0.67
Outpatient postoperative visits to a nurse‡	0.36 (0–4)	0.03 (0–1)	0.003

*Time period when the theatre staff was engaged with the procedure, i.e. from they started to prepare the theatre to they had cleaned it after surgery. Values are shown as mean (± 1 standard deviation) or median (range).

†Data available for 36 women.

‡Two women operated on with TVT could not be reached, values are shown as mean (range)

Table III. Reasons for hospital stay for more than 1 postoperative day and for visits to physicians or nurses within 2 postoperative months among women operated on with laparoscopic colposuspension or TVT procedures

Reason	Extended stay		Outpatient visits	
	Laparoscopic colposuspension <i>n</i> = 32	TVT <i>n</i> = 32	Laparoscopic colposuspension <i>n</i> = 38	TVT <i>n</i> = 36*
Insufficient bladder emptying	13 (41%)	3 (8%)	3 (9%)	2 (6%)
Pain/discomfort	0	2 (5%)	1 (3%)	5 (14%)
Anxiety/social reasons	1 (3%)	2 (5%)	0	0
Control of urination according to protocol (by a nurse)	–	–	12 (38%)	1 (3%)
Bleeding/hematoma	0	1 (3%)	0	0
New onset of prolapse	–	–	1 (3%)	–

*Two women operated on with TVT could not be reached for a telephone interview.

ure, urethral functional length, and continence area).

As shown in Table II, the TVT was performed significantly faster than the laparoscopic colposuspension. For example, mean anesthesia time was 77.3 min compared with 117.6 min ($p < 0.001$), and mean surgical time was 44.9 min compared with 60.5 min ($p < 0.0001$). The difference between basic time and surgical time, i.e. the time for preparing the operating room, also tended to be larger for patients operated on by laparoscopic colposuspension (128.0–60.5 = 67.5 min) than for those operated on with TVT (96.3–44.9 = 51.4 min). There was no significant difference in median surgical time between the two surgeons performing the TVT procedures ($p = 0.09$).

The following complications were noted: in one woman operated on with TVT, the bladder was perforated during surgery. She was discharged on the first postoperative day, but had an indwelling catheter for 7 days. Another woman operated on with TVT had bladder retention immediately postoperatively. This was resolved by reducing the tension of the tape. Using a Hegar's dilator the urethra was gently pulled down to stretch the graft. The stretching was performed on the gynecologic

ward the day after surgery under local anesthesia. The time needed for this manoeuvre was not recorded, but is estimated to 10 min. However, 10 months later, the sling had to be divided for continuous bladder emptying problems. For that procedure, the patient was hospitalized for 1 day and operated on for 48-min under local anesthesia adding a cost of €11 for each TVT in the study. In four women (11%) operated on with TVT, sedation had to be converted to general anesthesia due to pain or restlessness. In another three women (8%) operated on with TVT, severe pain during surgery had to be resolved with additional analgesics.

All women were scheduled to be discharged on the first postoperative day. Actual postoperative stay in mean numbers of days was 1.2 days for those operated on with TVT and 1.5 days for those operated on with the laparoscopic procedure ($p = 0.14$). There was a non-significant tendency that women operated on with TVT more often were discharged on the first postoperative day (78% compared with 58%, $p = 0.06$). In Table III, reasons for extended hospital stay beyond the first postoperative day and outpatient visits are shown. Insufficient bladder emptying of patients operated on with the laparoscopic procedure was the most

Table IV. One-year subjective and objective cure rates among women randomized to either TVT or laparoscopic colposuspension procedures

Subjective cure	TVT n = 37	Laparoscopic colposuspension n = 31	Objective cure	TVT n = 37	Laparoscopic colposuspension n = 31
Cured	21 (57%)	16 (52%)	Cured	33 (89%)	27 (87%)
Much improved	10 (27%)	14 (45%)	Improved	2 (5%)	4 (13%)
Little improved	3 (8%)	1 (3%)	Unimproved	2 (5%)	0
Unimproved	3 (8%)	–			

Three women with TVT and one woman with laparoscopic colposuspension were re-operated for non-cure. One woman with TVT was re-operated with division of the tape because of persistent bladder emptying problems.

common reason for extended stay. Some discharged women attended a doctor's or a nurse's office beyond what was scheduled. The main reason for visits to a nurse after discharge was control of residual urine among women operated on with the laparoscopic procedure and the main reason for visits to a physician was suprapubic pain and discomfort among those operated on with TVT procedure. During one of these visits, a woman operated on with TVT had the subcutaneous part of the sling removed at one side for persistent suprapubic pain. We did not regard this to be associated with costs beyond the regular costs for attending a physician.

Sixty-eight of the 71 women (96%) agreed to participate in the 1-year follow-up examination. Subjective and objective follow-up results are shown in Table IV. As shown in Table IV, three women operated with TVT were re-operated: two

with a new TVT and the third with conventional Burch colposuspension. One woman operated with laparoscopic colposuspension was re-operated with a synthetic suburethral sling (GoreTex® soft tissue patch, W. L. Gore Inc.). Nevertheless, for the economic analyzes we have estimated costs for a reoperation to be the same as the estimated costs for the original operation.

In Table V, all relevant procedural costs are shown. Basic costs, anesthesia cost, and surgical costs are based on the means of the different time periods recorded for the study procedures. Surgical costs are based on the salary for the main surgeon and for one assistant if needed (in this series during three laparoscopic and one TVT procedure). For estimations of hospital costs, we multiplied average days of inpatient care after surgery with above-mentioned charges, adding admission costs, and arrived at average hospital costs of €569.1 for those operated on with TVT and €625.2 for those operated on with laparoscopy. Physicians or nurses employed by the county performed outpatient medical care. Therefore, the costs for their services were included in the analyzes. As shown in Table V, in our hands the TVT procedure was significantly more expensive than the laparoscopic procedure, i.e. the procedure cost €69.4 (5.4%) more than the average laparoscopic colposuspension. When costs for reoperations were included, the difference in procedural costs increased to €148.1.

As demonstrated in Fig. 1, the needed surgical time for the two procedures hardly changed during the study, even though we took up the TVT procedure mainly to perform this study. By contrast, as shown previously from this department, the surgical time for laparoscopic colposuspension was clearly reduced with experience (14). We therefore performed a sensitivity analysis to see how surgical time influenced the costs relationship between the two procedures (cost for reoperations not included). Keeping the TVT time constant at the mean surgical time in this study, we estimated the surgical time needed for the laparoscopic pro-

Table V. Total costs in Euro (€) to the county associated with laparoscopic colposuspension and TVT procedures

Economic parameters	Laparoscopic colposuspension n = 32	TVT n = 38
Basic costs* (€0.57 per min)	72.8	54.7
Anesthesia costs* (€3.28 per min)	385.2	254.8
Surgical costs:*		
TVT (€0.59 per min)		25.8
Laparoscopic colposuspension (€0.59 per min)	35.7	
Surgical materials†	102.0	426.7
Hospital care‡	625.2	569.1
Depreciation of video equipment	18.0	0
Depreciation of laparoscopic instruments	17.4	
Outpatient visits to a physician (€58.3 per visit) or to a nurse (€23.2 per visit)	17.1	11.7
Average total cost per procedure§	1273.4	1342.8
Total costs including re-operations	1314.5	1462.6

*Mean times from Table III are multiplied with the specific costs per minute.

†Includes drapes, gloves, gowns, packing and sterilization of instruments.

‡Includes cost for postoperative analgesics.

§ $p < 0.001$.

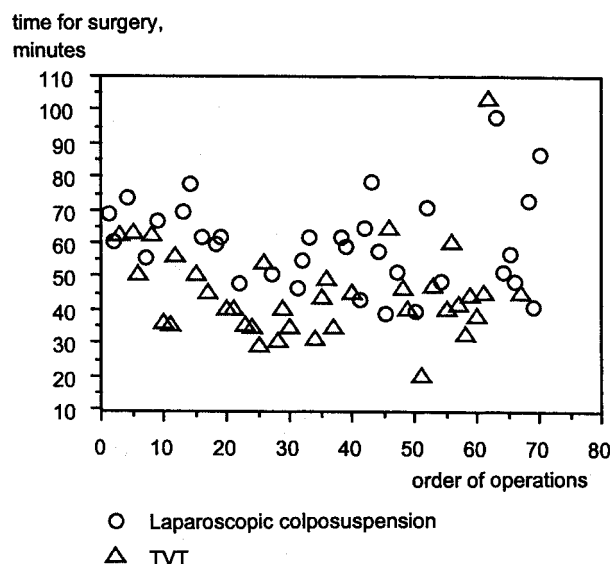


Fig. 1. Surgical times for the laparoscopic colposuspension and tension-free vaginal tape (TVT) procedures in relation to the order of operation.

cedure to cost the same as the TVT procedure. The mean surgical time for the laparoscopic procedure had to be increased from 60.5 min to 76.1 min to achieve break-even, that is, a prolongation of laparoscopic time more than one standard deviation above the time spent for the procedure in this study. On the other hand, keeping the laparoscopic time constant at the mean for this study and reducing the surgical time for the TVT procedure by 15.7 min the costs for that procedure would be the same as for the laparoscopic procedure.

Discussion

This study shows that the TVT procedure is significantly more expensive to perform than the laparoscopic colposuspension. Sensitivity analyzes showed that surgical time and anesthesia fees were major cost-deciding factors, but not even the relatively long surgical time for laparoscopic colposuspension outweighed the high investment costs for the TVT kit.

In the original description of the TVT method, Ulmsten et al. stated that the procedure was performed under local anesthesia (4). As shown in the present analyzes, the procedural costs were in a large part dependent on anesthesia charges and would be significantly reduced if anesthesiologists were not involved. However, the patients in the Ulmsten study (Dr Per Johnson, personal communication, 2000), as in this study, needed sedation during the operation and thus required full attention by anesthesiologists.

For the economic analyzes in this study, we

chose to take the standpoint of the hospital owner. An alternative approach would be to estimate the societal costs. Costs for sick-leave would be the main cost differences between the two analyzes. However, sick-leave was prescribed according to type of employment, not according to which surgical method the patient had been operated on with. Women estimated to have a physically heavy job were prescribed 3 to 4 weeks, the remaining 1 to 2 weeks of sick-leave. Therefore, costs to the society would not add anything to the economic comparison between the surgical methods.

The TVT procedure is now widely used. The first 3-year follow-up study by the inventors showed an unchanged cure rate between the first and 3-year follow-up examinations (9). By contrast, Liapis et al. (A. Liapis et al. in Abstracts of the 30th Annual Meeting of the International Continence Society, Tampere, Finland, 2000) demonstrated a decline in cure rate from 93% to 84% between the 1 and 2-year follow-up visits after the TVT procedure. Recently, Nilsson and Kuuva reported a cure rate of 88% after 6–24 months follow-up (12). Similar cure rates have been described for laparoscopic colposuspension (14). However, no previous study has directly compared the two methods. Strengths of this study, apart from the randomized, prospective design, include recording of pertinent time periods by independent staff, i.e. anesthesiology nurses and surgical nurses. Finally, the study nurse performing the follow-up urodynamic evaluations and pad-tests was instructed to perform the procedures in such way as to keep her blinded regarding the surgery the patients had been operated on with.

An obvious, but unavoidable, weakness of the study is the unblinded design. Regarding the outcome measures, the blinded approach of the study nurse might have guaranteed an unbiased evaluation. Regarding the economic analyzes, these were in a large part based on time-dependent costs associated with the unblinded performance of the surgical procedures. Gynecologists in our department introduced laparoscopic colposuspension early in 1994. Since then, the co-author (JP) performing the laparoscopic procedures has performed a large number of these procedures. TVT was introduced to perform this study. Thus, one might speculate whether the study was biased in disfavor of TVT. However, the operating gynecologists were experienced with suburethral sling procedures in general and performed some TVT procedures before the study was started. There was no significant difference in surgical time between the first 19 and the last 18 TVT procedures performed in the study ($p=0.8$), arguing against a technical bias against TVT. Moreover, there was

no significant difference in surgical time for TVT procedures between the two gynecologists. Even so, the mean operating time for TVT was clearly longer in this study than in the studies reported by Ulmsten et al. (44.9 min compared with 29 min) or by Nilsson and Kuuva (median 22 min) (22). Other investigators report a mean surgical time ranging between 22 and 42 min for TVT (4, 8, 10, 11, 18). For laparoscopic colposuspension, surgical times of 49–110 min are reported (15, 19–22). To account for different expertise among gynecologists performing one or the other procedure, and for different charges for anesthesia, we performed sensitivity analyses. As shown, surgical time and anesthesia charges have a large impact on procedural costs. Thus, other investigators might arrive at different cost estimates than we did, depending on how rapid they can perform the surgical procedure or how much they are charged for anesthesia.

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