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ORIGINAL ARTICLE

Patient satisfaction after retropubic and transobturator slings: first assessment using the Incontinence Outcome Questionnaire (IOQ)

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Abstract
Introduction and hypothesis The aim of the Incontinence Outcome Questionnaire (IOQ) is to assess quality of life and patient-reported outcome after midurethral slings.
Methods In this retrospective study, 626 patients with a minimum follow-up period of 1 year were sent the IOQ. Four hundred twenty-two of 626 (67.4%) patient responses were evaluated.
Results The mean IOQ QoL extended score was 33.7±17.5 and comparable for tension-free vaginal tape (TVT), outside-in transobturator tape (TOT), and inside-out transobturator vaginal tape (TVT-O). Evaluation of IOQ question about readmission revealed a total of 32 patients (18 TVT, 12 TOT, and 2 TVT-O) who underwent a subsequent operation due to sling-related complications. Freedom from reoperation for recurrent SUI at 1, 2, and 5 years was 100%, 99.7±0.3%, and 99.7±0.3% for TVT, 100% for TVT-O, and 94.2±2.5%, 91.9±2.9%, and 89.9±3.5% for TOT, respectively ($p<0.001$).
Conclusions Patient satisfaction, assessed using the IOQ, is high after retropubic and transobturator slings. In our collective, relapse incontinence is higher after TOT.

Keywords Incontinence Outcome Questionnaire (IOQ) · Patient satisfaction · TOT · TVT · TVT-O · Stress urinary incontinence (SUI)

Introduction

Urinary incontinence defined as any involuntary loss of urine has a negative impact on the social, physical, and psychological life of women affected [1, 2]. The current evidence base for the surgical treatment of stress urinary incontinence (SUI) suggests that the insertion of a midurethral tape will become the treatment of choice [3]. For the retropubic route—first introduced as tension-free vaginal tape (TVT) by Ulmsten and Petros in 1995—long-term results of up to 11 years are well documented and continence rates of 90 % are reported [4, 5]. In 2001, Delorme introduced an outside-in transobturator tape (TOT) [6] and in 2003, de Leval introduced the inside-out transobturator vaginal tape (TVT-O) [7]. Subsequent publications for transobturator slings cover only short- to mid-term follow-up of a maximum of 3 years [8]. Overall, all tapes establish continence effectively and can be considered as safe and durable surgical procedures for SUI [5, 9].

Operations for urinary incontinence seldom lead to severe morbidity and the primary impact is on improved quality of life (QoL) and patient satisfaction. The ICS standardization committee emphasizes the importance of postoperative survey on subjective outcome, patient satisfaction, and health-related quality of life parameters

Cornelia Betschart and David Scheiner contributed equally to this study.

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measured by specific questionnaires [8]. In the fourth edition of the International Consultation on Incontinence, self-completed patient questionnaires are considered to represent the best clinical review of symptom impact and treatment benefit. QoL after sling procedures was the objective of several trials using different incontinence-specific questionnaires like the Urogenital Distress Inventory (UDI-6) [10], Incontinence Impact Questionnaire (IIQ-7) [5, 11, 12], Incontinence Severity Index (ISI), Pelvic Floor Distress Inventory, Short Form-20 (PFI-20), Pelvic Floor Impact Questionnaire-Short Form-7 (PFIQ-7), and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-Short Form (PISQ-12) [13]. Significant improvements of QoL after sling procedures have been shown for retropubic and transobturator slings and are persistent for up to 11 years. In order to evaluate QoL and postoperative patient satisfaction without preoperative baseline data, a specific one-point measurement instrument is needed. Therefore, a detailed 27-item Incontinence Outcome Questionnaire (IOQ), validated for the German language, was constructed to assess patient-reported outcome and QoL after insertion of a midurethral tape [14]. The IOQ is considered as a valid and reliable instrument when baseline or preoperative data is unavailable because of the partial correlation with objective clinical parameters such as continence. Our study was designed to answer the following primary question: How is the patient satisfaction 1 year or more after midurethral sling procedure using the IOQ? Secondary questions were the applicability of the IOQ 1 year and more after operation and differences in outcome parameters among different sling types.

Material and methods

Patient and preoperative evaluation

In this retrospective study, 626 women who underwent midurethral sling surgery at two medical centers (one university hospital and one district hospital) between January 1999 and December 2007 were identified as follows using a computerized medical record system: 452 (72.2 %) TVT, 119 (19.0 %) TOT (Monarc), 36 (5.8%) TVT-O, 9 (1.4 %) intravaginal sling (IVS), and 10 (1.6 %) readjustable sling system (Remeex). The minimal follow-up after operation was determined as 1 year. All patients were evaluated preoperatively by means of a patient history, gynecological examination with a positive cough test, and urine control (dipstick) to exclude a urinary tract infection. All subjects had a clinical SUI. The inserted TVT and TVT-O were manufactured by Ethicon, Neuchâtel, Switzerland and distributed by Gynecare Switzerland; the TOT Monarc® was manufactured by American Medical Systems, Minnetonka, USA and distributed by Promedics, Switzerland. Ten surgeons, trained in urogynecological surgery, performed the operations according to the original methods. Every surgeon was carrying out all three sling procedures. The anesthesia was usually local anesthesia or dependent on concomitant surgery.

Ethical approval was obtained from the ethics committees of Zurich University Hospital and Altdorf District Hospital, Canton Uri. This clinical trial has been registered at http://www.clinicaltrials.gov, and the identification number is NCT01042275.

Outcome measures

The IOQ consisting of 27 questions were sent by mail to all patients identified. Patients who did not respond to the first mailing received a second mail. The IOQ consists of 27 questions comprised as follows: four related to symptoms [pain, postoperative symptoms, preoperative overactive bladder (OAB), and change in OAB symptoms pre or postoperatively], four about complications (urinary or other infection, hospital readmission, and residual urine), seven about QoL (felt tired/drained/lacking energy, felt irritable/snappy, felt depressed/tearful, general evaluation of health, limitations in daily activities, change in sexual activity, and change in body perception), five about satisfaction (changes of symptoms pre and postoperatively, time of recovery, satisfaction with information, improvement in well-being, and recommending the operation), one about problems with urinary incontinence before surgery, and six address demographic and treatment-related information (age, occupation, living arrangements, reason for operation, hormone replacement therapy, and time interval to operation). Each item is rated onto a 0–100 scale (0=minimum, 100=maximum impairment), from which two scores are calculated: one for the seven QoL and the five satisfaction questions, and an extended score which includes additional questions about postoperative symptoms, post-void residual urine volume, and change in OAB symptoms as well. A visual analogue scale was added (VAS, where 0 means no urinary problems and 10 means unbearable urinary problems) to assess the subjective grade of discomfort for urine loss pre and postoperatively. Further analysis of the answers related to readmission (IOQ4) was carried out by cross-checking patient answers and remarks with our clinical information system.

Statistics

All patients who completed the questionnaire following TVT, TOT Monarc, or TVT-O procedure were included for statistical analysis. Statistic evaluation was carried

out with the Kruskal–Wallis, chi-square, or Fisher's exact test as appropriate, using Intercooled Stata 10.0. Continuous data are presented as mean±standard deviation. Two-sided p values≤0.05 are considered statistically significant. Readmission and reoperation due to relapse incontinence was examined with the Kaplan–Meier analysis and log-rank test. The time analysis was measured in years, expressing the time period between the sling insertion and readmission, respectively, the second sling operation. No power analysis was performed due to the retrospective design.

Results

Five hundred twenty (83%) of the 626 questionnaires sent were returned, of which 434/626 (69.1%) were completed IOQ questionnaires, 55 (8.8%) were returned by the post office (address not known in the electronic telephone directory and no addendum in the internal address system), 21 (3.4%) women had died, 6 (1%) patients returned a blank IOQ, 4 questionnaires (0.6%) could not be properly evaluated because of serious cognitive disorders, and 108 (17.3%) were not returned by the patients. IVS and Reemex interventions were excluded from further evaluation because of the small number of patients (<2% of all operations) and the different material of the sling. The following analysis included the 422 patients who had TVT, TOT, or TVT-O. Among this group, patient compliance was good with a maximum of 2.7% (1.3–5.7%) of missing data per item.

The distribution of the slings during the observation period is shown in Fig. 1. Two hundred seventy-eight of the 422 eligible patients had a preoperative urodynamic evaluation (65.9%). Table 1 shows the basic characteristics. With the exception of the lower age of the TVT group and the higher age in the TOT group, the three groups TVT, TOT, or TVT-O did not differ significantly in relation to preoperative basic characteristics such as body mass index, parity, history of smoking, hormone replacement therapy, and urodynamic parameters such as maximum urethral closure pressure, volume at first desire to void, and bladder capacity, where these data was available. Twenty-five patients had previous incontinence surgery, showing no statistically significant difference among the three groups (p=0.19, Fisher's exact test). Concomitant prolapse surgery was performed in a total of 63 patients with clinical SUI (p=0.11, Fisher's exact test).

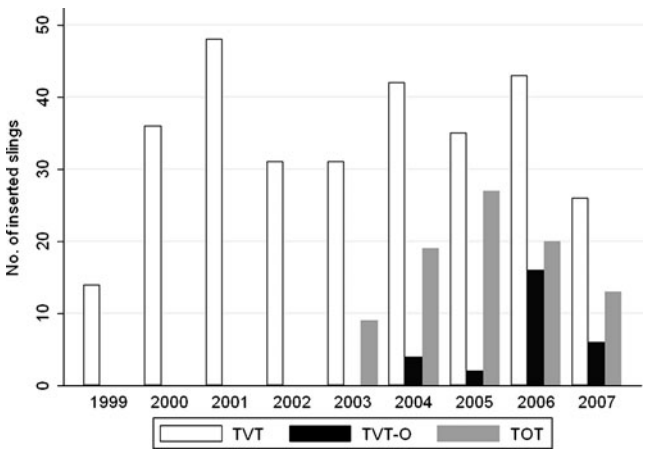

Fig. 1 Distribution of the sling types inserted during observation period 1999–2007 in the 422 eligible patients

At the time of completion of the IOQ, the overall mean follow-up was 4.9±2.3 years. The mean follow-up of the TVT group (5.5±2.4 years) was significantly longer than of the TOT (3.6±1.1 years) or TVT-O (2.9±1.0 years) group (p<0.001), due to the gradual introduction of these different sling techniques.

The total impact of postoperative incontinence on QoL, as measured by means of VAS and IOQ scores, did not differ for the sling types, as shown in Table 2. With the exception of the IOQ5 score (feeling tired/drained/lacking energy), the subjective outcomes were comparable between the groups. The postoperative change in the sex life of the respondents shows a tendency in favor of the TVT and TVT-O sling, but is not statistically significant (p=0.056).

The evaluation of question IOQ4 about readmission revealed a total of 32 patients who underwent a second sling-related operation [18 TVT (5.9%), 12 TOT (13.6%), 2 TVT-O (7.1%)]. The percentage of patients without a second intervention after 1, 2, and 5 years is described as freedom from reoperation. Freedom from reoperation at 1, 2, and 5 years was 95.8±1.1%, 95.4±1.2% and 93.9±1.5% for TVT, 92.9±4.9% for TVT-O, and 93.1±2.7%, 88.3±3.5%, and 86.1±4.0% for TOT, respectively (p=0.029, log-rank test) (Fig. 2). Partial tape excision or resuturing of the vaginal wall due to tape erosion was performed in ten patients (seven TVT (2.3%), three TOT (3.4%), and zero TVT-O). Complete tape incision was performed on 12 patients due to bladder outlet obstruction, recurrent urinary tract infections, or de novo urge [ten TVT (3.3%), one TOT (1.1%), and one TVT-O (3.6%)]. Owing to relapse of stress urinary incontinence, ten patients (one TVT (0.3%), eight TOT (9.0%), and one TVT-O (3.6%)) received a second tape (nine TVT, one Remeex). One patient underwent an intravesical injection of botulinum toxin due to urge incontinence 15 months after insertion of a TOT and an antecedent tape incision. None of the patients with a repeat incontinence procedure had a prior incontinence surgery. Freedom from reoperation for recurrent SUI at 1, 2, and 5 years was 100%, 99.7±0.3% and 99.7±0.3% for TVT, 100% for TVT-O, and 94.3±2.5%, 91.8±3.0%, and 89.9±3.7% for TOT, respectively (p<0.001) (Fig. 3).

Table 1 Basic characteristics including preoperative urodynamic data of the 422 eligible patients. Data is expressed as mean±standard deviation (eligible patients in parenthesis) or number of patients (percentage)

N	TVT (pts.) 306 (72.5%)	TOT Monarc (pts.) 88 (20.9%)	TVT-O (pts.) 28 (6.6%)	*p* Value –
Age at operation (years)	59.7±12.2	65.0±12.9	62.2±13.8	0.003[a]
Body mass index (kg/m^2)	26.8±4.9	26.2±4.4	27.7±4.6	0.32[a]
	(286)	(78)	(28)	
Parity	2.5±1.1	2.6±1.3	2.5±1.0	0.85[a]
	(277)	(76)	(22)	
History of smoking	103/300	27/86	5/27	0.24[a]
	(34.2%)	(31.4%)	(18.5%)	
Hormone replacement therapy	71/300 (23.7%)	17/85 (20.0%)	7/28 (25.0%)	0.60[a]
Urodynamic data				
Maximum urethral closure pressure (cmH_2O)	43.3±23.3 (203)	38.6±19.1 (45)	51.7±26.9 (19)	0.18[a]
Volume at first desire to void (ml)	244.9±108.0 (208)	234.3±120.3 (46)	264.0±104.5 (19)	0.41[a]
Maximum bladder capacity (ml)	452.9±104.8 (208)	424.4±128.4 (48)	479.1±108.7 (20)	0.21[a]
Preoperative post-void residual urine volume (ml)	19.6±41.3 (180)	28.1±64.8 (37)	28.2±30.3 (19)	0.13[a]
Short-pad test (g)	67.8±68.2 (207)	60.4±66.0 (44)	107.5±137.2 (18)	0.25[a]
Previous incontinence surgery				0.19[b]
Abdominal colposuspension	11	0	3	
Vaginal colposuspension	5	0	3	
Sling insertion	0	1	0	
Botulinum toxin intravesical	1	0	0	
Sling and botulinum toxin	0	0	1	
Concomitant prolapse surgery	39	19	5	0.11[a]
Hysterectomy	19	9	2	0.42[b]
Colporrhaphia anterior	28	10	4	0.47[b]
Colporrhaphia posterior	23	11	2	0.36[b]
Sacrospinous ligament fixation	4	6	0	0.02[b]
Botulinum toxin intravesical	1	3	1	0.02[b]

TVT tension-free vaginal tape, *TOT* outside-in transobturator tape, *TVT-O* inside-out transvaginal tape, *Pts* number of eligible patients

[a] Kruskal–Wallis

[b] Fisher's exact test

Discussion

In order to determine the efficacy of any treatment modality, the impact of the procedure on patient's quality of life and long-term satisfaction must be evaluated and reported. This information needs to be provided in order for patients to make an accurately informed decision regarding their therapy. To the best of our knowledge, this is the first clinical application of the IOQ for assessing patient satisfaction in a clinical trial. An advantage of the IOQ is that it is applicable for posttreatment assessment of QOL following surgery for incontinence within the scope of clinical studies or as a quality control tool when preoperative questionnaires are not collected.

The IOQ provides information on QoL, patient satisfaction, and complication rate in an accurate and comprehensive way after more than 1 year after operation. Up to now, no long-term data for acceptability, reliability, and validity of the IOQ were available [15].

Patient compliance was excellent as in the original publication, with less than 4% missing data [15]. This was achieved in a collective study where 26.1% of patients were older than 70 years.

Mean follow-up for TVT (5.4 years) was obviously longer than for TOT (3.5 years) and TVT-O (2.9 years), as these were introduced subsequently in our clinic.

Outcome parameters for QoL and subjective continence are similar for all three sling types, showing no time-related decrease. This finding is corresponding with other studies providing subjective outcomes using validated questionnaires like the UDI-6 and IIQ-7, where the scores for retropubic and transobutrator slings were similar. Notably, retropubic slings were followed by significantly higher objective continence rates [15]. As

Table 2 Postoperative subjective long-term results. Data are expressed as mean±standard deviation (range)

	TVT (306)	TOT Monarc (88)	TVT-O (28)	*p* Value
Follow-up (time interval between operation and completion of IOQ, in years)	5.5±2.3 (1.2–10.0)	3.6±1.1 (1.7–6.2)	2.9±1.0 (1.7–4.9)	<0.001[a]
VAS preoperative (0–10)	7.9±1.8	7.9±1.8	7.7±2.3	0.97[a]
VAS postoperative (0–10)	2.4±2.6	2.1±2.9	2.3±2.9	0.21[a]
Symptoms				
Pain (IOQ1)	9.9±21.9	7.5±15.3	8.9±16.0	0.97[a]
Symptoms preoperative (IOQ8)	76.7±23.4	75.0±24.0	71.4±28.6	0.65[a]
Symptoms postoperative (IOQ9)	18.1±26.7	22.1±30.4	15.2±25.8	0.51[a]
OAB preoperative (IOQ20)	74.4±43.7	80.0±40.2	85.2±36.2	0.30[a]
Change in OAB symptoms pre or postoperative (IOQ21)	30.1±27.5	27.8±29.3	22.3±22.1	0.33[a]
Complications				
Urinary infection (IOQ2)	37.4±48.5	29.9±46.0	33.3±48.0	0.42[a]
Other infection (IOQ3)	19.1±39.4	12.9±33.8	21.4±41.8	0.38[a]
Hospital readmission (IOQ4)	7.1±25.7	14.8±35.7	7.1±26.2	0.08[a]
Residual urine (IOQ19)	28.7±25.3	31.2±28.8	26.8±26.3	0.81[a]
Quality of life				
Felt tired/drained/lacking (IOQ5)	42.2±28.3	41.2±28.0	23.2±25.4	0.003[a]
Felt irritable/snappy (IOQ6)	38.1±28.0	34.1±24.7	28.6±31.7	0.13[a]
Felt depressed/tearful (IOQ7)	38.1±29.9	36.6±27.0	35.7±35.6	0.83[a]
Global evaluation of health (IOQ10)	43.8±21.5	44.2±22.6	46.4±26.1	0.64[a]
Limitations in daily activities (IOQ12)	30.9±30.2	31.2±32.7	28.6±28.6	0.95[a]
Change in sex life (IOQ13)	52.6±35.7	63.2±35.8	55.1±37.6	0.06[a]
Change in feeling about body (IOQ14)	25.3±30.2	27.9±33.1	23.2±28.8	0.82[a]
Satisfaction				
Symptoms changes pre and postoperative (IOQ11)	14.1±25.5	17.7±30.2	17.9±30.3	0.73[a]
Time of recovery (IOQ15)	33.7±30.6	38.8±37.2	32.1±33.9	0.67[a]
Satisfaction with information (IOQ16)	50.0±15.3	54.9±18.6	46.4±18.9	0.02[a]
Improvement in well-being (IOQ17)	19.9±27.9	21.6±29.6	15.2±25.8	0.57[a]
Recommending operation (IOQ18)	15.2±29.6	19.4±32.1	14.3±30.7	0.35[a]
IOQ QoL Score (0-100)	33.6±17.2	35.3±18.6	30.8±18.1	0.57[a]
IOQ QoL extended score (0–100)	31.9±16.9	33.7±18.9	27.9±17.9	0.35[a]

TVT tension-free vaginal tape, *TOT* outside-in transobturator tape, *TVT-O* inside-out transvaginal tape, *IOQ* Incontinence Outcome Questionnaire, *VAS* visual analogue scale, *OAB* overactive bladder, *QoL* quality of life

[a] Kruskal–Wallis test

short-term results of the TVT procedure are encouraging [16] and were supported by several authors [17, 18], long-term results after sling insertion have been published in the last few years [5, 12–14, 19]. Like the Burch colposuspension, there seems to be a surgical success decline with TVT procedure after 5- and 7-year follow-up [20].

Objectively, we found an increased recurrence rate of incontinence in the TOT group leading to a significantly smaller freedom from reoperation. This might be a reason why women with a TOT were the less satisfied with the preoperative information (IOQ16). The informed consent forms for all sling operations were the same and can be downloaded from the homepage of the Swiss Society of Obstetrics and Gynecology.

Repeated procedures for incontinence are known to increase the risk of surgical failure after incontinence surgery [21, 22]. Although it might be expected that recurrent incontinence could result from previous incontinence surgery, none of our patients with a recurrence of SUI after sling procedure had had any prior incontinence surgery, and the preoperative MUCP did not differ among the groups [23]. There is a lack of data and guidelines for treatment of recurrent SUI and there is no clear guidance regarding the approach for secondary surgery which would offer the best result [24]. In our observational study, all

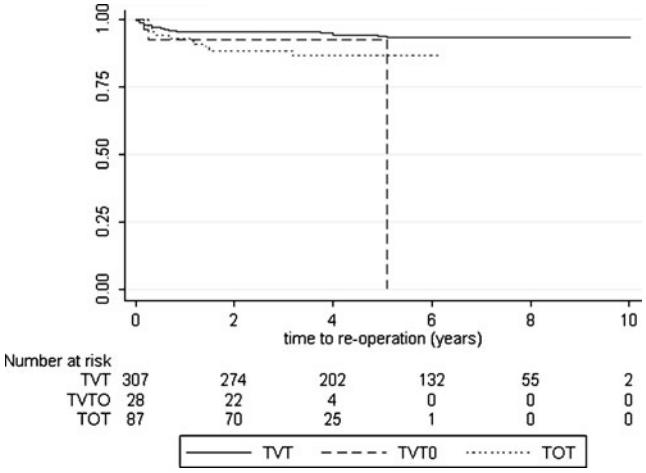

Fig. 2 Kaplan–Meier curve for reoperation depending on sling type. Log rank (Mantel–Cox) test for equality of readmission functions $p=0.029$

secondary inserted slings were inserted by the retropubic route (11 TVT, 1 Remeex). Recently, lower failure rates following retropubic slings have been published and there is some evidence to consider the insertion of a retropubic sling in the case of primary failure [25, 26].

There was no difference in the reporting of voiding difficulties (IOQ19) in our midterm follow-up, in contrast to a recent meta-analysis, where TOT and TVT-O caused less voiding difficulties [27]. However, the readmission rate for sling release because of voiding difficulties (1 day–45 months after operation) as controlled by the clinical information system, was higher in the TVT group but not yet statistically significant.

Weaknesses of the study are the not uniform sample size with a majority of TVT, the varying length of follow-up,

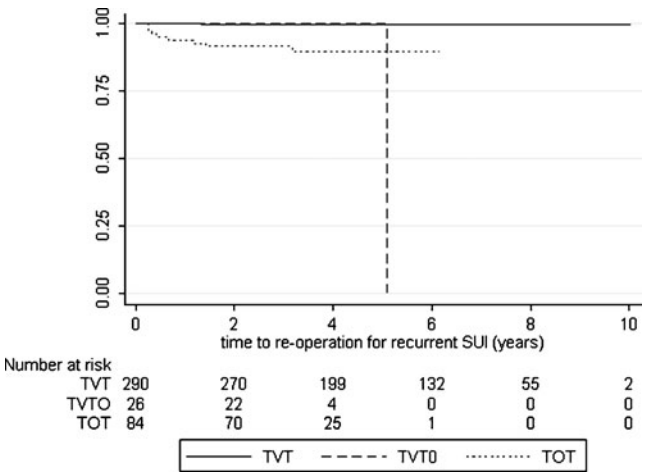

Fig. 3 Kaplan–Meier curve for second sling insertion due to relapse incontinence depending on sling type. Log rank test (Mantel–Cox) for equality of relapse incontinence functions $p=<0.001$

the differences in age, and the inhomogeneous distribution of concomitant procedures due to the retrospective design of this study. Another flaw is the possible incorrect completion of questions like IOQ4 about readmission (yes/no and the cause of the readmission). To avoid misinterpretation, patient remarks about the reason for readmission must be checked against a clinical information system. After cross-checking, the patients answer with the clinical information system, we state that most patients reported the diagnosis of relapse incontinence correctly, whereas voiding difficulties resulting as a consequence of too tense slings or tape erosions were reported by related symptoms such as urinary tract infection or incomplete bladder emptying. As the IOQ was designed for application 3 months after operation, some questions like IOQ5 (felt tired/drained/lacking) and IOQ6 (felt irritable/snappy) are not appropriate questions in a follow-up longer than 3 months. The symptoms of fatigue and irritability are mostly dependent on a short date back operation or anesthesia.

The slightly lower age in the TVT group is explained by a possible selection bias. In the early stage, we preferred the transobturator route for older patients based on the rationale that this technique is less obstructive, while later the established retropubic route was preferred for younger and sexually active patients in order to avoid pain-related sexual dysfunction caused by the TO passage [28, 29].

Most of the recurrent cases were in the TOT group. Except the older age of these patients, we do not have an explanation for this observation and cannot exclude bias.

The retrospective design of this study is a further weakness due to missing preoperative data such as the VAS for incontinence distress symptoms. The VAS for preoperative incontinence distress symptoms was collected by the IOQ at time the questionnaire was completed, and this might be a recall bias and not represent the real discomfort the incontinence caused to the patient preoperatively. Nevertheless, the VAS has been proven to be a reliable and reproducible method for the assessment of quality of life in urogynecological research [30].

The IOQ is categorized as a level C grade of recommendation by the fourth edition of the International Consultation on Incontinence, which implies that a questionnaire is in the early development stage and has future potential but that further work is required and encouraged [10]. In our analysis, the IOQ proved to be a valuable and proper instrument to assess the subjective patient mid- to long-term outcome on various emotional, physical, and social states, as well as on symptom distress data and readmission rate following sling surgery. Further studies are required to affirm our results.

Conclusion

Patient assessment using the IOQ showed that all sling procedures restore continence effectively with comparable mid-term outcome in relation to quality of life in women with stress urinary incontinence. In our survey, a higher postoperative incontinence rate was shown with TOT slings compared to TVT, and this occurred within a shorter observational interval. This raises the question whether TOT will maintain comparable long-term efficacy as TVT.

Conflicts of interest None.

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