ORIGINAL ARTICLE

Resolution of urge urinary incontinence with midurethral sling surgery in patients with mixed incontinence and low-pressure urethra

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Received: 21 December 2011 / Accepted: 30 January 2012 / Published online: 17 February 2012 © Springer-Verlag 2012

Abstract The aim of the study was to determine the rate of persistence of urgency or urge urinary incontinence following midurethral sling surgery compared to standard medication treatment in patients with mixed incontinence and ISD urethra. A prospective study was conducted at a tertiary referral Urogynecology Center. One hundred five women with stress urinary incontinence (SUI) and urgency were identified. Fifty-four consecutive women with SUI and urgency who underwent midurethral sling were compared to 51 women with SUI and urgency but treated with medications first. Women with persistent urgency or urge urinary incontinence (UUI) at 6-month follow-up following a TVT sling procedure were compared with those whose symptoms had resolved, to determine the risk factors for persistent symptoms. Forty out of 54 patients in the operation group also underwent a prolapse repair, either a colpopexy or a colpocleisis. All patients had demonstrated a mean urethral closure pressure of 20 mmHg or lower, indicating an intrinsic sphincteric deficiency. Persistent urgency (6 of 54, 11%) and UUI (3 of 54, 5.5%) were found in patients with mixed incontinence who underwent a sling operation. All 51 patients (100%) persisted with some urgency and urge incontinence despite anticholinergic medication treatment, only (7 of 51, 13.7%) reporting improvement of symptoms. Concomitant prolapse surgery, especially apical correction

(OR 0.55, 95% CI 0.37–0.65), decreased the risk of urgency persistence, while age (OR 1.04, 95% CI 1.02–1.05), detrusor overactivity (OR 1.66, 95% CI 1.28–2.53), baseline symptom severity (OR 1.77, 95% CI 1.48–2.36), and previous incontinence surgery (OR 2.08, 95% CI 1.38–3.60) increased the risk of persistent urgency in the operated cohort. Women were happier in the operated cohort (45 of 54, 83.3% cure rate). A sling itself decreased the risk of persistent urge or UUI (OR 0.33, 95% CI 0.15–0.70). The most significant improvement was UUI at night. Urodynamic parameters, baseline urgency symptom severity, age, and concomitant prolapse operation are important predictors of persistent urgency or UUI following midurethral sling for mixed incontinence patients.

Keywords Mixed incontinence · Midurethral sling urethropexy · Intrinsic sphincter deficiency

Introduction

Mixed urinary incontinence is defined as the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing, or coughing [1]. Involuntary leakage associated with urgency was initially thought to cause failure in surgery for stress incontinence [2], and surgery was therefore only considered appropriate when a cystometrogram showed no detrusor overactivity [3]. The measurement of intrinsic sphincter deficiency is best understood as the urodynamic criteria of mean urethral closure pressure (MUCP) of <20 cm H₂O or valsalva leak point pressure (VLPP) of <60 cm H2O [4].

However, several studies show a reduction in urge incontinence symptoms and detrusor overactivity after successful surgery for stress incontinence [5]. Rezapour and Ulmsten

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N. Agarwala (⊠) 910 Robin Road, State College, PA 16801, USA e-mail: neena.agarwala@gmail.com found 85% of their mixed incontinent women to be cured after tension-free vaginal tape (TVT) [6] while Schiotz et al. report 72% success rates for such patients [7]. Similarly, Debodinance et al. report lower, yet reasonable, cure rates for mixed incontinent patients at 2 years after a sling operation when compared to pure stress incontinent patients [8].

This raises the question as to how does one select patients to offer stress incontinence surgery over medical treatment, at what risks and what cure rate should be expected. In the longest follow-up by Nisson et al., reporting an 11-year follow-up for genuine stress incontinent patients who underwent a TVT sling showing a 90% cure rate objectively by using a stress test and a pad test was noted [9]. The aim of our study was (1) to investigate subjective and objective outcomes after TVT operations in mixed incontinent women particularly the elderly population with severe quality of life issues and (2) to evaluate factors that predict poorer surgical outcome.

Materials and methods

From January 2008 to June 2009, 105 women bothered with both stress and urge incontinence symptoms, low urethral closure pressures, and valsalva leak point pressures on urodynamics were identified and followed at a tertiary referral Urogynecology Center. Initial evaluation included urodynamic testing and validated questionnaires.

All patients underwent urodynamic evaluation, using Medtronics equipment, performed by our nurse practitioner in office, prior to surgery or medical treatment based on symptoms. Preoperatively, they also demonstrated urodynamic leakage with valsalva (VLPP) and low MUCP. They were asked, preoperatively, to decide their predominant symptom—stress or urge incontinence—or whether they were equally bothered by stress and urge incontinence. Women who found urge incontinence to be the predominant symptom were chosen for this study and offered either treatment with bladder training and an anticholinergic drug or surgical treatment with TVT sling first. Before and after the TVT operations, the following objective variables were recorded: standardized stress test (three coughs with 300 ml bladder volume), residual urine, and maximum urinary flow.

A short-form disease-specific questionnaire which has been validated and found reliable was used pre- and post-operatively [10]. A stress incontinence index was constructed from the questionnaire by three subindices: when, how often, and to what extent was stress incontinence experienced? An urge incontinence index is constructed by two questions: How often and to what extent is urge incontinence experienced? Urge incontinence index 0 means that the woman is not urge incontinent. Urge incontinence index 8 (the highest possible) means that the woman experiences a sudden

and imperious need to void, and urinary leakage before she reaches the toilet more than once per day, and that the urine runs down her legs or onto the floor. Four items constructed the quality of life index: (1) How many pads are used? (2) How often do they avoid activities due to fear of leakage? (3) How often do they avoid places or situations due to fear of no toilet available? and (4) How does leakage influence vacations, family life, social life, and sleep? The women were defined as mixed incontinent if they admitted to both stress and urge incontinence symptoms.

Postoperatively, the women recorded their degree of satisfaction with the operation. Their choices were: very satisfied, some satisfaction, neither satisfied nor unsatisfied, slightly unsatisfied, and very unsatisfied. For all questions, the scores ranged from 0 to 4. An increasing score meant a less favorable outcome. The urge incontinence, stress incontinence, and the quality of life indices range from 0 to 8, 12, and 16, respectively. The questionnaire was completed by the women preoperatively and at the follow-up consultation, 6 months postoperatively.

Fifty-four patients had a TVT operation and a follow-up 6 months after the operation. Fifty one stayed on anticholinergic therapy and were also followed up at 6 months. A hundred percent of the patients were followed at 6–8 months. All women except the ones who had a colpopexy laparoscopically had the TVT operation (Gynecare, Ethicon, Johnson & Johnson, Sommerville, NJ) performed under propofol sedation and local anesthesia. Ten of the 54 women (19%) that had concomitant colpopexy had general anesthesia. All patients were treated primarily in our outpatient clinic, and they were all seen in 2 days to evaluate residual urine. One surgeon performed the TVT operations. Before the follow-up visit in the outpatient clinic at 6 months, the women completed a voiding diary. "Cure" was defined as a condition where the women were very satisfied with the TVT operation and had a negative stress test. A subjective cure was obtained from the questionnaire and was defined as: no stress or urge incontinence and very satisfied. Methods, definitions, and units conform to the standards recommended by the International Continence Society.

Preoperatively, all of the women who considered urge incontinence to be the predominant bother and had low urethral closure pressures <20 cm H_2O and valsalva leak point pressures <60 cm H_2O were offered both treatment options. The women's presumptions of their predominant urge bother agreed well with the results of the mean stress (9.2 ± 1.7) and urge (6.6 ± 1.2) indices. The index 9.2 is out of 12 and 6.6 is out of 8; therefore, the urge index was higher.

Fifty-four women chose to go through the TVT sling procedure prior to trying anticholinergics. They were counseled that they may need anticholinergics after the procedure, and there is a chance that their urgency may



worsen. They were also thoroughly counseled on the risks and benefits of the procedure. The risks of a TVT operation were thoroughly discussed including but not limited to: risk of retention, graft exposure or erosion, prolonged catheterization, repeat surgery, infection, injury to bladder, bowel and other organs, and bleeding. Patients agreed to the possibilities and signed consents. They also agreed to a 6-month follow-up and questionnaire as they were aware that this is not standard protocol for selection of this surgery. They were also made aware that the sling was going to be placed slightly snug than a TVT sling recommendation since they had sphincter deficiency on urodynamic testing; therefore, they may have a higher risk of voiding dysfunction postoperatively. Intraoperatively, this sling placement was tested by "crede" maneuver producing no leakage in a 300-cm³ filled bladder. All patients were also made aware that the age-related lower bladder capacity would not improve post surgery.

Statistical methods: When comparing changes in a continuous variable from before and after operation in the same patient group and in two patient groups, two-sided Wilcoxon and Mann–Whitney tests, respectively, were used. When comparing percentages in groups of patients, a chi-square test was used. A significance level of 5% was used.

Results

The mean age of patients in both groups was 74.2 and 76.7 years, respectively. Forty of the 54 patients in the sling group (74%) and 24 of 51 (47%) had symptomatic prolapse either apical or anterior compartment. All the patients with prolapse in the TVT group also underwent correction of the prolapse. Thirty out of 40 (75%) had a colpocleisis, and 10 out of 40 (25%) had apical correction in the form of a laparoscopic colpopexy. Most patients with prolapse in the medication group were fitted with a pessary (Table 1).

During follow-up, 83% (45 of 54) of the women were very satisfied with the TVT operation due to resolution of their urgency symptoms; 91% (49 of 54) did not leak during stress test. Persistent urgency (3 of 54, 5.5%) and urge urinary incontinence (UUI) (6 of 54, 11%) were found in patients with mixed incontinence who underwent a sling operation. All 51 patients (100%) persisted with some urgency and urge incontinence despite anticholinergic medication treatment; only 7 of 51 (13.7%) reported improvement of any symptoms.

Concomitant prolapse surgery, especially apical correction (OR 0.55, 95% CI 0.37–0.65), decreased the risk of urgency persistence, while age (OR 1.04, 95% CI 1.02–1.05), detrusor overactivity (OR 1.66, 95% CI 1.28–2.53), baseline urge symptom severity (OR 1.77, 95% CI 1.48–2.36), and previous incontinence surgery (OR 2.08, 95% CI 1.38–3.60) increased

Table 1 Characteristics of 105 patients

| | TVT surgery (54) | Medicational therapy (51) | |
|---|------------------|---------------------------|--|
| Mean age, years (range) | 74.2 (63–86) | 76.7 (60–90) | |
| Mean parity (range) | 3.1 (0-7) | 3.2 (0-8) | |
| Mean body mass index, kg/m² (range) | 24.8 (19–32) | 26.8 (21–33) | |
| Prolapse | 40 | 24 | |
| No. urgency | 35 | 38 | |
| No. associated urge incontinence | index | | |
| 1–2 | 3 | 5 | |
| 3–4 | 13 | 18 | |
| 5–6 | 26 | 20 | |
| 7–8 | 12 | 13 | |
| No. concomitant prolapse repair | 40 | 0 | |
| Mean urodynamic parameters: | | | |
| Peak urinary flow, ml/s (range) | 25.3 (15–70) | 23.8 (13-69) | |
| Voided volume, ml (range) | 293.5 (78–467) | 301.2 (87–438) | |
| Post-void residual, ml (range) | 15.2 (0-81) | 18.5 (0-89) | |
| Maximum cystometric capacity, ml (range) | 382.6 (202–420) | 367.6 (221–433) | |
| Maximum detrusor pressure, cm H ₂ O (range) | 44.3 (22–78) | 47.8 (26–79) | |
| VLPP, cm H ₂ O (range) | 55.2 (18-60) | 50.2 (17-60) | |
| MUCP, cm H ₂ O (range) | 15.2 (9–20) | 16.4 (11–20) | |
| No. detrusor overactivity (%) | 44 | 43 | |
| Mean stress incontinence index (max 12, range) | 10 (9–12) | 11 (9–12) | |
| Mean quality of life index (max 16, range) | 13 (10–16) | 14 (11–16) | |

the risk of persistent urgency in the operated cohort. A sling itself decreased the risk of persistent urgency or UUI (OR 0.33, 95% CI 0.15–0.70). Most significant improvement was UUI at night.

Postoperatively, 5.5% (3 of 54) of the women were still bothered by urinary urgency, 11% (6 of 54) were bothered by urge incontinence, and 83% (45 of 54) were not bothered at all. Women were happier in the operated cohort.

The percentage of very satisfied women decreased with increasing preoperative urge incontinence index (Table. 2). A significant increase in bother regarding postoperative stress incontinence, urge incontinence, and quality of life indices was seen with increasing preoperative urge incontinence index (Table 2).

Median, 25 and 75 percentile ages were 72 years (65, 84) and 73 years (61, 89), respectively, in the surgical and medication groups. Women with mixed incontinence were significantly older than women with pure genuine stress incontinence in our practice (72.5 vs. 44.6 years) (P<0.005). Therefore, the patients participating in this study were elderly based on the presence of this symptom complex.



Table 2 Relationship of cure/stress, urge, QOL indices to preoperative urge incontinence index

| Preoperative urge incontinence index | Number of patients | Number of cured | % cured | Post-op stress index | Post-op urge index | Post-op QOL index |
|--------------------------------------|--------------------|-----------------|------------|----------------------|--------------------|-------------------|
| 1–2 | 3 | 3 | 100 | 0 | 0 | 0 |
| 3–4 | 13 | 12 | 92 | 0 | 1 | 2 |
| 5–6 | 26 | 21 | 80 | 2 | 3 | 5 |
| 7–8 | 12 | 9 | 75 | 3 | 4 | 7 |

Subjective cure was 83% and 14%, respectively, in the surgical and medication groups. Significantly more patients were subjectively cured in the TVT group than the medication group (P<0.001).

Two bladder perforations (3.7%) and 5 (9.2%) urinary tract infections were recorded in the post-surgical period. If the patients had more than 100 ml residual urine twice on the first or second postoperative day, a Foley catheter was left for an additional 2 days in 15 of 54 (28%) patients. Persisting residual urine was treated with self-catheterization in one patient (1.8%) for 2 weeks postoperatively. No long-term catheterizations were needed, and no sling cutting was needed in any patient (Table 3).

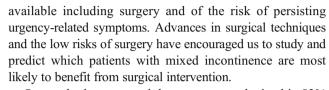
Discussion

Surgery is a known and common intervention for SUI and is now increasingly considered as an option for those with mixed urinary incontinence (MUI). However, success rates tend to be lower for those with mixed than with pure stress incontinence [11, 12]. Women with mixed incontinence with a clearly positive stress test and urethral hypermobility will almost certainly have the stress incontinence element of the condition cured by surgery, but they may require ongoing anticholinergic agents for urgency and related symptoms [13].

On the contrary, women with mixed incontinence with a predominant urgency element create some difficulty in predicting the benefits of surgery. It is important not to create unreasonable patient expectations, and women with urge-predominant incontinence need to be aware of options

Table 3 Complications after tension-free vaginal tape procedure

| | No. (%) of 54 |
|--|---------------|
| Bladder perforation | 2 (3.7%) |
| Urinary tract infection in 6 weeks | 5 (9.2%) |
| Short-term voiding difficulty (2 days) | 15 (28%) |
| TVT release or cutting | 0 (0%) |
| Persistent pain | 0 (0%) |
| Clean intermittent catheterization (2 weeks) | 1 (1.8%) |
| Leg weakness | 0 (0%) |



Our study demonstrated that a cure was obtained in 83% of our mixed incontinent women after TVT. This compares with Rezapour and Ulmsten, who found 85% of their mixed incontinent women to be cured after TVT [6]. After 1 and 2 years, Debodinance et al. found 91% and 83% of stress incontinent and 85% and 60% of mixed incontinent women to be cured, respectively [8]. Laurikainen and Kiilholma found 97% of stress incontinent and 69% of mixed incontinent women to be cured [14]. Objective cure and subjective cure were found to be, respectively, 91% and 69% in stress incontinent and 83% and 54% in mixed incontinent women by Jeffry et al. [15]. Holmgren et al. found that stress incontinent women after TVT were cured or almost completely cured in 80-90% after 1-9 years. However, women who were stress incontinent and subjectively urge incontinent were cured or almost completely cured in 60% after 3 years and only 30% after 6-8 years [16]. All these articles have different definitions of cure. In this current study, we used the definition of cure as a condition where the women were very satisfied with the TVT operation and had negative stress test.

The success rates of the TVT procedure in women with MUI, however, are not consistent. One study showed similar results in the two types with overall subjective cure rate at 6 months of 91% for GSUI, whereas the subgroup with MUI had a cure rate of 89% [17]. At present, the measurement of intrinsic sphincter deficiency has not been standardized. However, MUCP <20 cm $\rm H_2O$ or VLPP <60 cm $\rm H_2O$ has been the urodynamic criteria for the diagnosis of intrinsic sphincter deficiency [4]. According to Paick et al., the overall cure rate of TVT 10 months after surgery was significantly lower in patients with low VLPP (<60 cm $\rm H_2O$) than in those with higher VLPP (\geq 60 cm $\rm H_2O$; 82.0% vs. 93.1%) [18].

The study from Rezapour and Ulmsten had a similar cure rate for mixed incontinent women after TVT compared to ours and the above-mentioned articles [6, 7]. Our study compares mixed incontinent patients with significant urge symptoms who undergo initial medical treatment for urge



first with patients who undergo treatment for stress first. Our study shows that mixed incontinent women with significant urge incontinence have a poorer outcome with urge incontinence treatment alone compared with women with stress incontinence treatment followed by treatment of urgency if needed. Previous reports of mixed incontinence surgery often report the outcome of stress incontinence, but not of urge incontinence [8, 15].

As part of our analysis, we wanted to use a cure outcome value, which consisted of stress test, and satisfaction with the operation. This was chosen because a cure outcome value makes it easier to evaluate the outcome of the two groups. There were no missing values in our subjective outcomes either pre- or postoperatively. Our subjective cure rate of 83% was slightly lower than the objective cure rate of 91%. Ward and Hilton found that women reported no leakage under any circumstances after TVT in 36% [19].

Postoperatively, 5.5% of our patients were still bothered by urgency, and 11% were bothered by urge incontinence. Other studies have also reported similar improvements in urgency [14, 19–21]. In our study, only 7% of the women who were bothered by stress and urge incontinence improved with medication treatment as a start while 83% improved with surgical intervention. Nearly two thirds of the women who were still bothered by urge incontinence after the TVT operation had had a previous incontinence operation, were significantly older, and had a higher preoperative urge score.

Karram and Bhatia, and Colombo et al. were unable to find any preoperative cystometric parameters that could predict the success of colposuspension in mixed incontinent women [22, 23]. However, Lose et al. found that in women with a detrusor instability index ≤ 0.4 , the cure rate was significantly better compared to women with an index >0.4 [24]. We concur that the higher the detrusor instability, the greater the risk of failure from surgery as seen by the correlation with the preoperative urge incontinence index. In our present study, women with severe preoperative urge incontinence were found to have several associated outcomes. These women were postoperatively less satisfied, leaked more during the stress test, were more bothered by urge and stress incontinence, and had a poorer quality of life when compared to women with less severe preoperative urge incontinence.

The preoperative stress test did not predict the postoperative outcome of the TVT operations. The TVT operation appears to be particularly successful in women with stress incontinence as the predominant problem. Ninety-one percent of our patients did not leak during the postoperative stress test.

Our complication rate was similar to rates established for the TVT procedure. Bladder perforation is one of the most frequently observed complications after the TVT procedure estimated to occur in 5.8% of women [25]. We observed a similar rate (3.7%, 2 of 54 patients), although most of these patients needed an indwelling catheter for a short period of time

Some studies have reported an increase in the prevalence of symptoms of urgency and urge incontinence after the TVT procedure [26]. In an analysis of the changes in urge incontinence and overactive bladder symptoms after the TVT procedure at a mean follow-up of 7.1-8.1 months, 4.3% and 9.1% of patients with pure SUI had developed de novo urgency and de novo incontinence, respectively [27]. Of the patients with MUI, the urge component resolved in 63.1%, whereas preoperative overactive bladder symptoms resolved in 57.3% of patients after the TVT procedure. In our study, at 6 months after surgery, objectively and subjectively, preoperative urgency and urge incontinence improved in 91.0% and 83.0% of patients, respectively. We did not see an increased incidence of de novo urge incontinence and urgency after the TVT procedure as all our patients had preexisting urgency symptoms. But, the proportion of patients who persisted with urgency or urge incontinence postoperatively was relatively low meaning that the perceived urgency could in fact be stress incontinence or stress-induced urgency. This may be due to recognition of such patients, their prolapse correction, and placement of the sling in a slightly tighter fashion to correct the low mean urethral closure pressures. We believe that patients with lower closure pressures develop urgency and urge incontinence due to the urethral stimulation by a few drops of urine that are released from the urethral sphincter. We did not follow the patients on a longterm basis, a lack in our study, but if their symptoms would even gradually worsen with time, we believe that it is worthwhile to provide these patients improved quality of life for some period of time.

We have found no other study which analyses mixed incontinence separately in two groups as we have done. The subdivision appears to be of practical interest. The relatively large differences in cure between the two mixed incontinent groups suggest that women in the different groups should be given additional information before a choice for treatment of incontinence. Offering surgical treatment to mixed incontinent women predominantly bothered by stress incontinence is today not controversial. To offer a TVT operation to women significantly bothered by urge incontinence or those with low-pressure urethras is, in our opinion, appropriate provided the women are informed about what they risk and what they can achieve. Though Griffith et al. and Kulseng-Hanssen et al. stated that cystometry has low diagnostic sensitivity in evaluating mixed incontinence patients, we used the cystometric criterion to specifically choose the patients that are not normally considered surgical candidates for sling surgery and have shown a definite benefit [7, 28].



Conclusions

The high success rate of the TVT procedure for elderly mixed incontinent patients with low closure pressures shows that this surgery is effective and safe for the treatment of SUI and MUI. After TVT operations, mixed incontinent women with significant urge incontinence appear to have a better cure rate than those who are offered medical therapy alone. The TVT procedure may have an obstructive effect on voiding and may thereby reduce the provocative urge. Interestingly, patients experienced decreased nighttime urinary urge incontinence episodes despite the fact that their bladders did not become larger; they just did not have the urgency induced by urine in the urethra.

We did find that mixed incontinent women with very high urge incontinence and urge symptom score and prior surgery had the poorest outcome. The relatively large difference in cure rates between the two groups—surgery vs. medical therapy, indicates that mixed incontinent women should receive thorough education and information according to their main bother symptom before offering just medical therapy as the only treatment option.

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