Female Urology – Incontinence

Functional Results After the Suburethral Sling Procedure for Urinary Stress Incontinence: A Prospective Randomized Multicentre Study Comparing the Retropubic and Transobturator Routes

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Abstract


Population and methods: This prospective, multicentre study involved 88 women undergoing suburethral sling procedure for stress urinary incontinence (SUI). The retropubic route (RPR) and the transobturator route (TOR) were used in 42 and 46 women, respectively. No difference in epidemiologic and preoperative urinary functional status (SUI stage, and pollakiuria, nocturia, and urgency rates) was found between the groups. Functional results and quality of life were evaluated before surgery and at 1, 3, 6, and 12 mo postoperatively. Urodynamic examinations were performed before and 3 mo after surgery.

Results: The mean follow-up was 10 mo. No difference in the rate of de novo urge incontinence and immediate and late voiding dysfunction was noted between the groups. No difference in the cure rate was observed between the groups (89.3% in the RPR group and 88.6% in the TOR group). RPR was associated with a significant decrease in maximum urinary flow and an increase in residual urine volume. Quality of life was significantly improved after surgery without difference between the groups.

Conclusions: Retropubic and transobturator routes for treatment of female SUI have similar high cure rates and quality of life improvement. Because of advantages in the rate of complications and postoperative pain previously demonstrated on the same population, the transobturator route appears to be the best option for the treatment of urinary incontinence.

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1. Introduction

In the 10 yr since the first description of tension-free vaginal tape (TVT) procedure by Ulmsten et al. in 1996 [1], TVT has become one of the most popular procedures worldwide for female stress urinary incontinence (SUI) [2]. However, potential immediate surgical complications include bladder perforation [3], and injury to the pelvic vessels [4], the bowel [5,6], and the ilioinguinal nerve [7]. Moreover, de novo urge incontinence and voiding dysfunction may occur after overcorrection associated with the retropubic approach and/or the use of elastic polypropylene tape [3].

In 2001, Delorme et al. [8,9] advocated the use of the transobturator route (TOR) to avoid bladder injury, which was estimated to occur in 7.34% of 12,280 women treated with the retropubic route (RPR). Delorme et al. [8] also showed that the TOR gave a similar success rate and avoided bladder injury. These results were recently confirmed in a large series of women treated with nonelastic polypropylene tape, in which the rate of bladder injury was 0.3% [10]. In a randomized study comparing TOR with RPR [11], TOR was associated with a risk of vaginal injury but not of bladder injury. TOR was also associated with less postoperative pain than RPR. The functional results of TOR and RPR for SUI have not been compared by using the same nonelastic polypropylene tape. Therefore, the aims of this prospective randomized multicentre study were to compare the short-term functional outcomes of TOR and RPR.

2. Population and methods

This prospective randomized multicentre study involved three gynaecology units and two urology units, and was conducted in France from March 2004 to May 2005. All the surgeons had lengthy experience with RPR and had performed at least 30 procedures by TOR.

Inclusion criteria were women older than 18 yr with SUI proven by clinical and urodynamic examinations. Exclusion criteria were women with previous history of radio- or chemotherapy, women with anticoagulant or antipsychotic treatment, and pregnant women. Women with mixed incontinence were not excluded from the study. Women with SUI were randomized to undergo the suburethral sling procedure by either RPR or TOR, by using a predetermined computer-generated randomization code. Our institutional ethics committee approved the study protocol, and all the women gave their written consent after receiving full information on the study.

The power calculation used to estimate the required study size assumed that the incidence of de novo urge incontinence and immediate and late voiding dysfunction after the suburethral sling procedure by retropubic route was 60%, and that this figure would be halved by using the transobturator route, with an α (type I) error of 0.05 and a β (type II) error of 0.2. On this basis it was necessary to recruit at least 40 women to each study arm. Forty-two and 46 women were enrolled in the RPR and TOR groups, respectively.

The epidemiologic characteristics and surgical histories of the women in the RPR and TOR groups were not significantly different: mean age, mean body mass index (BMI), mean parity, the proportion of menopausal women, and the proportion of women with prior surgery for SUI were respectively 58.8 ± 12 and 53.4 ± 10.5 yr, 25 ± 4 and 26 ± 4 kg/m², 2.1 ± 0.9 and 2 ± 1 children, 66.7% and 58.7%, and 21.4% and 26.1%. No difference in the rate of women with obesity (BMI ≥ 30 kg/m²) (8 vs. 5 in TOR and RPR groups, respectively). Moreover, no difference in the rate of women with previous hysterectomy was noted between the groups (12 vs. 9 in TOR and RPR groups, respectively). None of the women had diabetes.

The preoperative workup included a standardized history taking and physical examination, and a urodynamic evaluation. Urinary incontinence was classified as recommended by the International Consultation on Incontinence [12]. The preoperative SUI grades were not significantly different between the groups. Women in the RPR group had SUI stages 1, 2, and 3 in respectively 8 (19%), 30 (71.4%), and 4 (9.5%) cases (72.7%). Women in the TOR group had SUI stages 1, 2, and 3 in respectively 6 cases (13.6%), 33 (72.7%), and 7 cases (13.6%). No significant difference in SUI stage distribution was observed between the groups. Urodynamic parameters in the two groups are summarized in Table 1. The rates of preoperative pollakiuria and nocturia were also similar: 19 (45.2%) and 19 (41.3%), and 17 (40.5%) and 14 (30.4%) in the RPR and TOR groups respectively. Preoperative urgency tended to be more frequent in the RPR group (25 [59.5%] vs. 18 cases [39.1%], p = 0.06).

Patients were considered cured (success) if they had no stress incontinence by clinical and urodynamic examinations, no incontinence during the stress provocation test, and no urinary retention or a residual urine volume of less than 150 ml. Patients were considered cured (improved) if no incontinence occurred during stress provocation test. All other cases were considered failures.

All the women completed validated questionnaires on quality of life (Urinary Distress Impact Questionnaire [UDI]) [13], and on the social and emotional impact of SUI (Incontinence Impact Questionnaire [IIQ]) [13], before surgery, at the first postoperative visit (4–6 wk after surgery), and 3, 6, 12, and 24 mo postoperatively. In addition, all the women underwent a systematic urodynamic evaluation at the 3-mo postoperative visit. This preliminary report describes urodynamic and functional results in women with at least 6 mo of follow-up.

The I-STOP device (CL Medical, Lyon, France) was used for both the RPR and the TOR procedures to avoid bias linked to different tapes. The tape consisted of macroporous (>75-micron pore size), nonelastic, monofilament, polypropylene mesh.

All the procedures were performed in the modified dorsal lithotomy position. Blood pressure, electrocardiogram,
transcutaneous oxygen saturation were continuously monitored. The RPR procedure was performed as described by Ulmsten et al. [1] and the TOR procedure as described by Delorme et al. [8]. The choice between general and regional anesthesia was made in each centre. The prosthetic implant was placed under the midurethra. A vertical 15-mm vaginal incision was made 10 mm below the urethral meatus. Dissection of the paraurethral space on each side of the incision was performed with scissors, towards the ischiopubic ramus.

For RPR, ancillary was similar to that used for the TVT procedure.

In the TOR approach, the needle of the device was introduced on each side through a 5-mm incision in the genitofemoral fold, on a horizontal line passing through the clitoric hood and facing the transobturator membrane. The needle was exteriorized in the vagina, and the tape was "clipped" to the needle tip before being withdrawn through the genitofemoral incision.

Regardless of the route, tension-free tape adjustment was performed under the midurethra. Cystoscopy was always performed before vaginal and skin closure with resorbable sutures.

The procedure was timed from the vaginal incision to the last skin suture, including cystoscopy.

Intraoperative and immediate postoperative complications, febrile morbidity, pain (numerical rating scale: 0 = no pain, 10 = unendurable pain), and the postoperative hospital stay were systematically recorded. The women were discharged when the residual urine volume was <150 ml and were seen again 4–6 wk after surgery.

The type of anaesthesia, the mean operating time, mean residual urine volume, intra- and postoperative complications, and postoperative pain in the RPR and TOR groups are shown in Table 2.

Statistical analysis was based on the Student t test and the Mann-Whitney test for parametric and non-normally distributed continuous variables, respectively, and the chi square test or Fisher exact test, as appropriate, for categoric variables. p < 0.05 was considered to denote statistical significance.

### Results

#### 3.1. Incidence of de novo urge incontinence and immediate and late voiding dysfunction after the suburethral sling procedures

The mean follow-up was 10 mo, with 37 women having 6 mo of follow-up and 51 women having at least 12 mo of follow-up. The proportion of women with follow-up exceeding 1 yr was similar in the two groups (23 women in the RPR group and 28 women in the TOR group).

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**Table 1 – Pre- and postoperative urodynamic parameters**

<table>
<thead>
<tr>
<th>Urodynamic parameters</th>
<th>RPR (n = 42)</th>
<th>TOR (n = 46)</th>
<th>p value</th>
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</thead>
<tbody>
<tr>
<td>UCP (cm H₂O)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>46 ± 22 (6–90)</td>
<td>60 ± 31 (23–144)</td>
<td>0.02</td>
</tr>
<tr>
<td>Postoperative</td>
<td>58 ± 24 (15–86)</td>
<td>45 ± 24 (19–120)</td>
<td>0.2</td>
</tr>
<tr>
<td>p value</td>
<td>0.25</td>
<td>0.76</td>
<td></td>
</tr>
<tr>
<td>Q_max (ml/s)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>30 ± 16 (8–79)</td>
<td>25 ± 9 (3–47)</td>
<td>0.17</td>
</tr>
<tr>
<td>Postoperative</td>
<td>20 ± 9 (6–38)</td>
<td>24 ± 11 (7–47)</td>
<td>0.14</td>
</tr>
<tr>
<td>p value</td>
<td>0.001</td>
<td>0.73</td>
<td></td>
</tr>
<tr>
<td>Residual urine volume (ml)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>13 ± 40 (0–200)</td>
<td>11 ± 46 (0–300)</td>
<td>0.80</td>
</tr>
<tr>
<td>Postoperative</td>
<td>43 ± 45 (0–100)</td>
<td>28 ± 49 (0–260)</td>
<td>0.10</td>
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<tr>
<td>p value</td>
<td>0.03</td>
<td>0.64</td>
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Q_max: maximum urinary flow rate; RPR: retropubic route; TOR: transobturator route; UCP: urethral closure pressure.

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**Table 2 – Success, improvement, and failure rates of retropubic and transobturator sling placement for urinary incontinence**

<table>
<thead>
<tr>
<th></th>
<th>1-mo postoperative visit</th>
<th>3-mo postoperative visit</th>
<th>6- and 12-mo postoperative visits</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>RPR (n = 42)</td>
<td>TOR (n = 46)</td>
<td>RPR (n = 46)</td>
</tr>
<tr>
<td>Success</td>
<td>39 (92.9)</td>
<td>43 (93.5)</td>
<td>38 (90)</td>
</tr>
<tr>
<td>Improvement</td>
<td>2 (4.8)</td>
<td>1 (2.2)</td>
<td>4 (7.1)</td>
</tr>
<tr>
<td>Failure</td>
<td>1 (2.4)</td>
<td>2 (4.3)</td>
<td>0</td>
</tr>
</tbody>
</table>

RPR: retropubic route; TOR: transobturator route.
No difference in the rate of de novo urgency was observed between the groups (Fig. 1).

The rate of postoperative dysuria was similar in the RPR and TOR groups. In contrast, at the 6-mo visit, dysuria was present in 4.9% of the women in the RPR group and in none of the women in the TOR group (not significant).

Whatever the group, about 10% of women reported de novo pollakiuria at the first and second postoperative visits, at 1 and 3 mo (Fig. 2). After 6 mo of follow-up the rate of de novo pollakiuria fell significantly in the RPR group but not in the TOR group ($p = 0.01$).

3.2. Success rate and urinary symptoms before and after the suburethral sling procedure

Among women with more than 6 mo of follow-up, the success rates in the RPR and TOR groups were 88.5% and 86.5%, respectively ($p = \text{ns}$, Fig. 3). The proportions of women who were dry, improved, and unimproved did not differ between the groups (Table 2).

No tape erosion or infection occurred during follow-up. No additional surgery was required, even when the procedure was considered to have failed.

3.3. Urodynamic parameters before and after the suburethral sling procedure

All the women underwent a urodynamic evaluation before and 3 mo after the procedure.

Preoperative urethral closure pressure (UCP) was significantly higher in the TOR group ($p = 0.02$; Table 1). After surgery, no difference in the UCP was observed between the groups. The pre- and postoperative UCP values did not differ significantly in either group.

No difference in pre- or postoperative maximum urinary flow ($Q_{\text{max}}$) was noted between the groups (Table 1). A significant decrease in $Q_{\text{max}}$ was observed in the RPR group ($p = 0.001$) but not in the TOR group.

No difference in the pre- or postoperative residual urine volume was noted between the groups (Table 1). A significant increase in residual urine volume was observed in the RPR group ($p = 0.03$) but not in the TOR group.

3.4. Quality of life before and after the suburethral sling procedure

Semi-quantitative evaluation showed a significant improvement in global discomfort, and in emotional and social discomfort in both groups (Table 3). These improvements were noted at the first postoperative visit and remained stable thereafter.

The UDI and IIQ questionnaires showed a significant improvement in quality of life in both groups (Table 4). These improvements were noted at the first postoperative visit and remained stable thereafter.

4. Discussion

This prospective study shows that RPR and TOR offer similar de novo urge incontinence and immediate and late voiding dysfunction, as well as similar
cure rates and significantly improved quality of life in women undergoing the suburethral sling procedure for stress urinary incontinence. The RPR was associated with a significant change in urodynamic parameters.

The choice between the retropubic and transobturator routes for the treatment of female urinary incontinence is controversial, owing to the absence of prospective randomized studies comparing the two routes and using the same polypropylene mesh. This is the first prospective randomized study with ethical approval. De novo urinary symptoms such as pollakiuria, nocturia, and urgency are associated with patient dissatisfaction after surgical treatment of urinary incontinence. The rate of de novo pollakiuria was about 10% with both the retropubic and transobturator approaches in our study. This rate fell significantly after 6 mo in the RPR group but not in the TOR group, but the difference between the two groups never reached statistical significance. It should be noted that mictional disorders have a bigger psychosocial impact than incontinence in women [14]. Long considered psychogenic, these disorders may in fact be a symptom of a severe underlying disease or follow physiologic (e.g., hormonal) changes. We have no clear explanation for the relatively high rate of de novo pollakiuria in our study. Among the patients who had a follow-up of more than a year, about 15% of women in the RPR group reported de novo urgency, without significant difference between the groups. This complication can have a major impact on quality of life and represents a huge economic burden [15]. Our rate of de novo urgency was in keeping with that reported by Segal et al. [16] in a chart review of women undergoing the TVT procedure. These latter authors found that de novo urge incontinence and overactive bladder symptoms occurred in 9.1% and 4.3% of women, respectively, and that 8.7% of women required anticholinergics for the first time. In addition to the use of synthetic mesh, Cetinel and Demirkesen [17] suggested that old age might be a risk factor for postoperative overactive bladder symptoms. A previous study showed that the rate of urgency was lower with TOR than with RPR [18].

Both the retropubic and the transobturator routes offered high success rates, in keeping with the results of a recent meta-analysis of sling procedures [19]. However, controversy exists on criteria to define success, improvement, and failure after SUI treatment. In accordance with Deval et al. [20], success rate was defined by both clinical and urodynamic parameters, allowing an adequate evaluation of objective cure rate. However, Roumégue`re et al. [21] used a cough test and the need of pad to evaluate the success of SUI treatment. In contrast to the RPR, few data are available on the TOR approach described by Delorme et al. [8], who reported a high success rate and no bladder injury. However, Krauth et al. [10], in a longitudinal study of

<table>
<thead>
<tr>
<th>Table 3 – Pre- and postoperative numerical rating scores of global discomfort, and emotional and social discomfort</th>
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<tr>
<td>Scores (mean ± SD [range])</td>
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<td>-----------------------------------------------</td>
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<tr>
<td><strong>Global discomfort</strong></td>
</tr>
<tr>
<td>RPR</td>
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<tr>
<td>TOR</td>
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<tr>
<td><strong>Emotional and social discomfort</strong></td>
</tr>
<tr>
<td>RPR</td>
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<td>TOR</td>
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</table>

RPR: retropubic route; TOR: transobturator route.

<table>
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<tr>
<th>Table 4 – Pre- and postoperative quality-of-life scores (UDI questionnaire) and social and emotional scores (IIQ questionnaire)</th>
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<tr>
<td>Scores (mean ± SD [range])</td>
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<td>-----------------------------------------------</td>
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<tr>
<td><strong>UDI</strong></td>
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<td>TOR</td>
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<td><strong>IIQ</strong></td>
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<td>RPR</td>
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more than 600 women, observed a bladder injury rate of 0.3% with TOR. In accordance with a previous anatomic study performed by Delmas [22], we confirmed that TOR avoids bladder injury, obviating the need for routine intraoperative cystoscopy [11]. In a nonrandomized study, Fischer et al. [18] showed that outside-in TOR was as effective as RPR but had fewer intraoperative and postoperative complications, including de novo urgency. Moreover, these authors found that TOR was more rapid than the RPR procedure, and was also less costly because cystoscopy was not necessary. Finally, thanks to the absence of major complications and less postoperative pain after TOR compared with RPR, with similar success rates with the two routes, our data support the view that the outside-in transobturator approach is the best option. Owing to the lack of studies comparing the RPR and inside-out TOR, our conclusions cannot be extended to this latter route, initially described by de Leval [23]. Further studies are required to compare the inside-out and outside-in transobturator procedures.

In addition to the impact on SUI itself, quality of life is a major criterion in this setting. Although Munir et al. [24] reported a strong correlation between the surgeons’ and patients’ perceptions regarding outcome and changes in symptoms after TVT sling placement, validated questionnaires are the best tools for assessing patient satisfaction. Few teams have assessed quality of life by using validated questionnaires, even after the popular TVT procedure [25]. Recently, with the same validated questionnaires as those used here, Schraffordt Koops et al. [26] observed an improvement in quality of life after the TVT procedure, and noted that a subjective improvement could occur as late as 2 yr postoperatively. In our study, both RPR and TOR significantly improved global discomfort, emotional and social discomfort, and quality of life, to similar extents. The improvement was noted 1 mo after surgery and remained stable during more than 1 yr of follow-up.

Urodynamic analysis is important to understand potential adverse effects of sling procedures. In our study, neither RPR nor TOR affected UCP. However, RPR was associated with a decrease in $Q_{\text{max}}$ and an increase in residual urine volume. Our data are in keeping with those of previous studies [27,28]. Indeed, Lukacz et al. [27] showed that $Q_{\text{max}}$ fell by up to 43% after the TVT procedure. Moreover, although these authors reported no clinical difference in postvoid residuals, residual urine volume was doubled postoperatively. Wang et al. [28] reported similar results after TVT sling placement, with a decrease in free $Q_{\text{max}}$ and in detrusor pressure at $Q_{\text{max}}$, but an increase in urethral resistance, particularly in women with dysfunctional voiding. Therefore, this side-effect of RPR observed here could be relevant in specific clinical situations.

Certain limitations of this study should be underlined. First, despite the prospective and randomized nature of the present study, a difference in the preoperative UCP values was observed between the groups underlying the limited sample size. Second, despite the absence of major postoperative complications in the TOR group, the sample size was too small to demonstrate the potential superiority of this approach. Likewise, power was lacking to show the potential advantage of TOR over RPR as regards the rate of de novo dysuria, whereas the TOR approach was associated with a higher rate of pollakiuria. Fourth, longer-term results are required to confirm the superiority of TOR. Finally, as elastic polypropylene tape is most frequently used for the treatment of urinary incontinence, additional studies are required to compare elastic and nonelastic tapes.

5. Conclusions

The results of this prospective randomized study confirm that the retropubic and transobturator routes for female SUI have similarly high cure rates and postoperative dysuria. Owing to advantages in the rate of complications and postoperative pain previously demonstrated on the same population, TOR appears to be the best option for the treatment of urinary incontinence in women, although this observation needs to be confirmed by longer follow-up.

References


[26] Schraffordt Koops SE, Bisseling TM, Heintz AP, Vervest HA. Quality of life before and after TVT, a prospective multicentre cohort study, results from the Netherlands TVT database. BJOG 2006;113:26–9.

Editorial Comment
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Since the introduction of the trans-obturator route for midurethral slings in 2001, the question of which midurethral sling procedure is the “better” procedure has persisted in the minds of surgeons worldwide. To respond to this as yet unresolved question, a number of comparative studies have been reported or are underway. Most, if not all, of the already published studies suffer from inadequate sample size, nonrandomised methods, or other limitations.

Darai and colleagues report the results of a randomised, controlled trial (RCT) conducted among three gynaecology and two urology centres in which a single type of mesh was used to compare the retropubic and trans-obturator routes. The authors report similar efficacy between the two routes but higher morbidity (decreased flow rates...
and increased postvoid residual) in the retropubic route; they therefore conclude that the trans-obturator route is “the best” method of surgical treatment for women with stress urinary incontinence (SUI). (Interestingly, the authors used postoperative urgency as the primary outcome instead of objective or subjective cure).

Regrettably, inherent limitations of the current study do not support the authors’ conclusions, for several reasons. First, the severity of SUI was not equal between the two groups with mean urethral closure pressure lower in the retropubic group. Second, the retropubic group had higher levels of urgency preoperatively. Finally, the study suffers from lack of adequate sample size and power to arrive to such conclusions.

I am aware of at least three other RCTs that are investigating questions similar to those posed by the authors. The largest one is being conducted by the Urinary Incontinence Treatment Network (UITN) of the US National Institutes of Health. It plans to have a sample size of 294 in each arm (total of 588). Using a two-sided equivalence test of proportions for assessment of objective and subjective cure, the UITN trial would consider 8 to 12 percentage points of range of equivalence for the power of 70–90%, respectively (personal communication with Dr Michael Albo, San Diego, CA). The two other studies—one being conducted in the United States and the other in the United Kingdom—have each a sample size of 180–200 in each arm of their studies. In all three studies the primary outcome comprises objective or subjective measures of cure.

The focus of authors on comparing the two routes of midurethral slings based on the rate of their complications, and not on their efficacy, is innovative and warrants recognition. This is so because I suspect that in the era of highly effective anti-incontinence procedures, the choice of the “better” procedure would, in fact, ultimately be based not on its effectiveness but rather on its fewer number of complications. My suspicion is based on the fact that treatment of a quality-of-life condition such as SUI should presumably lead to improved quality of life, in which complications such as bothersome urgency or urge incontinence should have no place.