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ORIGINAL ARTICLE

Long-term results of two different trans-obturator techniques for surgical treatment of women with stress and mixed urinary incontinence: a 10-year randomised controlled study follow-up

Tamara Serdinšek[1] · Igor But[1]

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Abstract

Introduction Our aim was to compare the long-term results and complications of the outside-in (Monarc®) versus inside-out (TVT-O®) trans-obturator approaches.

Methods We performed a 10-year follow-up of our randomised study from 2007 in which we compared short-term outcomes of both procedures in 120 women. Patients were examined at our department in a tertiary centre between March and December 2016. The primary aim of the study was to compare the cure and satisfaction rates of both procedures. The secondary aim was to determine the incidence of vaginal tape exposures, dyspareunia and LUTS.

Statistical analysis was performed using SPSS Statistics Programme 21.0. Descriptive statistics were calculated based on basic patient characteristics. Non-parametric tests were used for comparisons of numerical and Pearson's chi-square for categorical data. Statistical significance was set at $p < 0.05$.

Results Of 114 living patients, 82.5% responded. Average follow-up time was 10.2 years. There were no statistically significant differences between the objective (84.6% for Monarc vs. 94.6% for TVT-O) and subjective cure rates (67.9% vs. 68.3%) or satisfaction rates (83.9% vs. 78.7%). We found no cases of vaginal tape exposure; 6.4% of all (10.3% of sexually active) patients reported dyspareunia and 34% reported LUTS with no significant differences between groups.

Discussion According to our study, both the inside-out and outside-in procedures showed comparable long-term efficacy with low complication rates. To our knowledge, this is the longest randomised study follow-up comparing the cure and satisfaction rates of these two techniques.

Keywords Long-term follow-up · Midurethral slings · Tension-free vaginal tape · Trans-obturator tape · Urinary incontinence

Introduction

Stress urinary incontinence (SUI) is the most common form of UI in women and can seriously affect patients' quality of life [1–4]. Different surgical procedures are available for SUI management and they have become less invasive over the last decades [3]. Midurethral slings (MUS) are a recognised minimally invasive surgical treatment for SUI with a good safety profile. They involve placement of a tape underneath the urethra either behind the pubic bone (retropubic MUS) or through the groin (trans-obturator MUS) [3]. Retropubic (RP) MUS can be further divided into the "bottom-up" and "top-down" and trans-obturator (TOT) into the "inside-out" and "outside-in" approach [1, 3]. The principle of MUS is to provide a tension-free support of the mid-urethra and act as a replacement of the pubourethral ligament [1, 3, 5]. When the patient strains, the urethra compresses to the tape, leading to an increase in intra-urethral pressure and prevention of urinary leakage [1, 3]. Because the procedure is minimally invasive, the patient's hospital stay is reduced and recovery is faster. Nevertheless, possible complications such as vaginal tape erosion, pain and the risk of vessel/nerve injury need to be taken into account [1].

Although the first MUS was introduced into clinical practice back in 1996 [1], there is still an ongoing debate about their safety and efficacy and an increasing need for high-

✉ Tamara Serdinšek
todorovic.tamara@gmail.com

[1] Department of General Gynaecology and Urogynaecology, Clinic for Gynaecology and Perinatology, University Medical Centre Maribor, Maribor, Slovenia

quality long-term results of these procedures. With that in mind, we performed a follow-up of our randomised controlled study from 2007, in which we analysed the short-term results of two different trans-obturator techniques for surgical treatment of women with SUI or mixed urinary incontinence (MUI) [6]. The aim of our present study was to determine women's satisfaction rate with both procedures approximately 10 years after the primary surgery, to determine the objective and subjective cure rates, and the incidence of dyspareunia, vaginal tape exposures and lower urinary tract symptoms (LUTS) in both procedures.

Patients and methods

We performed a follow-up of our prospective, randomised, head-to-head comparative study from 2007 in which we compared the short-term results of two different TOT techniques. The primary study included 120 women with SUI or MUI with a predominant stress component. Patients were operated between January 2005 and June 2007 by the same experienced surgeon. Either the inside-out (TVT-O®, Ethicon, USA) or the outside-in (Monarc®, AMS, USA) approach was used [6].

The primary outcome of this study was to compare the cure and satisfaction rates of both procedures. The subjective cure rate was defined as the absence of complaints about any involuntary leakage of urine on effort, exertion, sneezing, coughing or laughing. The objective cure rate was defined as a negative stress test. The satisfaction rate was evaluated by patients on a scale from 0% (not satisfied at all) to 100% (complete satisfaction). The secondary outcome was to determine the incidence of vaginal tape exposures, dyspareunia and LUTS.

The study was performed in accordance with the ethical standards laid down by the Declaration of Helsinki. Institutional review board ethical approval was obtained, approval no. UKC-MB-KME-18-20/16. The clinical and functional terminology used was in concordance with the International Continence Society's (ICS) and International Urogynecology Association's guidelines [4].

Patients were invited to a follow-up via regular mail. If they did not respond, we invited them once again via telephone. If they could not be reached after this, they were considered untraceable. Prior to the visit, they evaluated their satisfaction with the procedure on a scale from 0% (not satisfied at all, no improvement compared with the time prior to the treatment) to 100% (complete satisfaction, no subjective problems) and filled out the "*Incontinence impact questionnaire*" (IIQ) and "*Urogenital distress inventory*" (UDI). The IIQ, UDI and stress component of the UDI (UDIs) scores were calculated.

For each patient, a detailed history, gynaecological examination, pelvic organ prolapse evaluation using the POP-Q system, gynaecological ultrasound, stress test and uroflowmetry were performed. The examination was performed by a trained urogynaecologist or by a gynaecology resident directly supervised by the urogynaecologist.

The gynaecological examination was performed in the dorsal lithotomy position with an empty bladder. The vaginal mucosa underneath the urethra was examined to detect possible tape exposure. Gynaecological ultrasound was performed to visualise the position of the tape underneath the urethra. POP-Q system measurements were determined as described in the International Consultation on Incontinence [7]. A stress test was performed by instilling 250 ml saline into the bladder. A pre-weighted pad was placed in the patient's underwear. The patient had to cough, perform squats and jump on the spot. The test was considered negative if the pad remained dry. The average urine flow (Q_{ave}), maximal urine flow (Q_{max}) and post-voiding residual volume (PVR) were determined during urinary flowmetry.

Statistical analysis was performed using SPSS Statistics Programme 21.0. Descriptive statistics were calculated based on basic patient characteristics. Non-parametric Mann-Whitney and Wilcoxon signed rank tests were used for comparisons between and within groups, respectively. Pearson's chi-square was used to compare categorical data between groups. Based on our primary study, we also compared the average age at the procedure and the satisfaction rate 3 months after the procedure between responding and untraceable patients. Statistical significance was set at $p < 0.05$.

Results

One hundred twenty women were included in the primary study. Thirty-one (25.8%) were diagnosed with SUI and 89 (74.2%) with MUI. Eight (6.7%) had at least one previous continence procedure. Six (5%) patients passed away prior to the follow-up. Of the remaining 114 women, 94 (82.5%) responded.

Twenty of 114 women (17.5%) were untraceable. There was no statistically significant difference between the average age at the procedure and the patient-reported satisfaction rate at the 3-month follow-up compared with the responding patients (52.9 ± 15.3 years vs. 51.8 ± 9 years, $p = 0.718$; $84.8\% \pm 27.3\%$ vs. $90.8\% \pm 14.7\%$, $p = 0.279$, respectively). According to our hospital computer database, only two of these patients visited our clinic after surgery (one because of LUTS and the other because of osteomuscular pelvic pain).

Responding women were examined at our office between March and December 2016. Eighty-six (91.4%) women agreed to a full work-up, four (4.3%) to a work-up with gynaecological examination and ultrasound only, and four (4.3%) to history taking and questionnaire evaluation only. A stress test was performed in 89 patients and urinary flowmetry in 86. The most common reason for rejection of

clinical examination or testing was the fear of discomfort during the examination. The UDI questionnaire was fully completed by 92 and the IIQ by 89 patients. Figure 1 represents a flowchart of the patient enrolment and follow-up process.

Fifty-three (56.4%) women underwent the Monarc and 41 (43.6%) the TVT-O procedure. The average follow-up period was 10.2 ± 0.6 years (range 8.5–11.3 years). There were no statistically significant differences between groups in the follow-up period ($p = 0.732$) or basic patient characteristics (Table 1).

The objective cure rate was 88.8% (84.6% for Monarc vs. 94.6% for TVT-O, $p = 0.259$, RR = 0.314, 95% CI = 0.063–1.575) and subjective cure rate 68.1% (67.9% vs. 68.3%, respectively, $p = 1.000$, RR = 0.991, 95% CI = 0.411–2.389). Patients' satisfaction rates in the primary study were 90.8% ± 14.7 and 81.6% ± 29.1% at the follow-up ($p = 0.03$). For Monarc, satisfaction rates were 90.1% ± 15.9 and 83.9% ± 27.6% ($p = 0.185$) and for TVT-O 91.6% ± 13.1 and 78.7% ± 31% ($p = 0.007$), respectively. There was no difference in the follow-up satisfaction rates between groups ($p = 0.377$).

LUTS were present in 32 (34%) of all women. Twenty-seven (28.7%) of the participating patients were diagnosed with pure SUI in the primary study. Of these patients, nine (33.3%) complained of urgency or urgency UI at the follow-up. Of all women, 58 (61.7%) still had sexual intercourse and only six (6.4%) reported dyspareunia (10.3% of sexually active patients). No vaginal tape exposures were found. Sixty (63.8%) patients did not have to use protective pads. Only one patient in the outside-in group needed another continence procedure for SUI. In

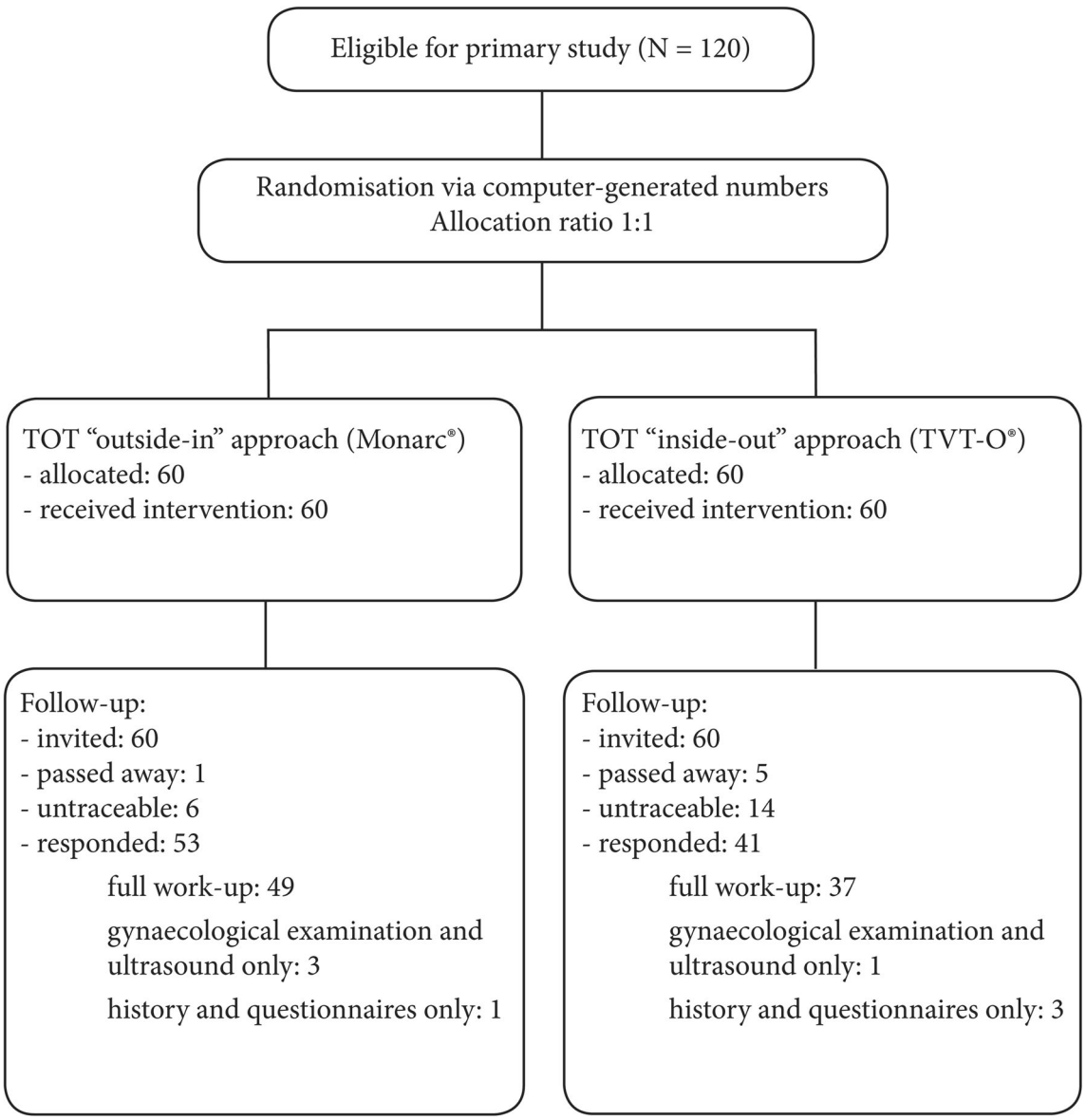

Fig. 1 Flowchart of the patient enrolment and follow-up process

Table 1 Comparison of basic patient characteristics between groups

Variable	All patients	Monarc	TVT-O
Age [years±SD]	61.9 ± 9.0	61.3 ± 9.4	62.8 ± 8.6
Body mass index [kg/m^2 ± SD]	27.6 ± 7.0	27.7 ± 6.2	27.5 ± 8
Menopause: yes [%]	85.1	90.6	80.5
Number of pregnancies [no. ± SD]	2.6 ± 1.3	2.6 ± 1.4	2.6 ± 1.1
Number of vaginal deliveries [no. ± SD]	1.9 ± 0.8	1.8 ± 0.9	1.9 ± 0.7
Accompanying medical issues: yes [%]	68.1	67.9	73.0
Gynaecological surgeries prior to the procedure: yes [%]	27.7	30.2	24.4
Hormone replacement therapy: yes [%]	13.8	15.1	12.2

her case, an RP MUS was performed. Comparison of patients' outcomes, results of the POP-Q system and questionnaire scores between groups is presented in Table 2. There were no statistically significant differences between groups when comparing these variables (Table 2).

Comparing patients' questionnaire scores with results of the primary study, there was a significant increase in the UDIs (8.8 ± 18.9 vs. 27.1 ± 32.5, $p < 0.001$), UDI (26.8 ± 42.3 vs. 60.9 ± 60.9, $p < 0.001$) and IIQ scores (36.5 ± 70.1 vs. 67.5 ± 91.9, $p < 0.001$). The difference was also statistically significant when comparing scores within the Monarc (UDIs 10.2 ± 20.2 vs. 27.1 ± 34.6, $p = 0.001$, UDI 27.2 ± 41 vs. 54.1 ± 58.9, $p < 0.001$, IIQ 38 ± 79.5 vs. 63.4 ± 90.2, $p = 0.004$) and TVT-O group (UDIs 6.9 ± 17.1 vs. 27.1 ± 30.1, $p = 0.002$, UDI 26.3 ± 44.4 vs. 69.7 ± 61.6, $p < 0.001$, IIQ 34.6 ± 58.7 vs. 72.8 ± 95, $p = 0.03$).

In the primary study, there were three cases of vaginal wall perforations in the Monarc group. Additionaly, we had five cases of vaginal mucosal tears in the Monarc and one in the TVT-O group. Overall, there were three failures of the procedure, one in the TVT-O group and two in the Monarc group. One patient presented with defective healing under the urethra after the Monarc procedure in the postoperative period and was treated in a conservative manner. Eleven of these 13 women attended the follow-up visit. Four of them had a 100% satisfaction rate and did not have any urogynaecological problems. One patient was 100% satisfied with the procedure, but had the complaint of recurrent UTIs. Another patient was also 100% satisfied with

Table 2 Comparison of patients' outcomes and questionnaire scores between groups

Variable	All patients	Monarc	TVT-O	*p* value
Objective cure rate [%]	88.8	84.6	94.6	0.259
Subjective cure rate [%]	68.1	67.9	68.3	1.000
Satisfaction rate [% ± SD]	81. ± 29.1	83.9 ± 27.6	78.7 ± 31	0.377
LUTS any time after the procedure: yes [%]	34	30.2	39	0.294
Dyspareunia [%]	6.4	7.5	4.9	1.000
Vaginal tape exposures [%]	0	0	0	1.000
POP-Q values:				
• Aa [cm ± SD]	−1.6 ± 1.1	−1.4 ± 1.1	−1.9 ± 1	0.067
• Ba [cm ± SD]	−1.6 ± 1.1	−1.4 ± 1.1	−1.9 ± 1	0.058
• C [cm ± SD]	−5.6 ± 1.2	−5.6 ± 1.4	−5.7 ± 0.8	0.875
• Ap [cm ± SD]	−2 ± 1.5	−2.1 ± 1.2	−1.8 ± 1.9	0.868
• Bp [cm ± SD]	−2 ± 1.3	−2 ± 1.3	−2 ± 1.3	0.967
Number of pads used per day [no. ± SD]	0.8 ± 1.5	0.8 ± 1.6	0.9 ± 1.5	0.401
Daytime frequency [no. ± SD]	6.5 ± 2.3	6.6 ± 2.1	6.2 ± 2.5	0.306
Nocturia [no. ± SD]	1.6 ± 1.1	1.5 ± 1.2	1.7 ± 1.1	0.346
Stress test [g ± SD]	5.7 ± 28.5	7.7 ± 36.1	2.4 ± 11.5	0.158
Q_{ave} [ml/s ± SD]	8.8 ± 3.0	9.2 ± 3.3	8.5 ± 2.6	0.268
Q_{max} [ml/s ± SD]	17.7 ± 6.4	18.5 ± 7	16.6 ± 5.3	0.256
PVR [ml ± SD]	14.5 ± 22.9	14.8 ± 23.2	13.5 ± 22.4	0.767
UDI [mean score ± SD]	60.9 ± 60.9	54.1 ± 58.9	69.7 ± 61.6	0.164
UDIs [mean score ± SD]	27.1 ± 32.5	27.1 ± 34.6	27.1 ± 30.1	0.735
IIQ [mean score ± SD]	67.5 ± 91.9	63.4 ± 90.2	72.8 ± 95	0.677

the procedure, but had a symptomatic pelvic organ prolapse and was considered for surgical management. Three patients had satisfaction rates of 80–90% and had a complaint of LUTS and/or dyspareunia. Two patients had a positive stress test and were considered for further diagnostics and treatment.

Discussion

The first MUS was introduced into clinical practice more than 20 years ago [1]. It used an RP approach and provided very good cure rates [5]. Aiming to avoid bladder perforation, TOT approaches were developed: the outside-in technique by Delorme in 2001 and the inside-out technique by De Laval in 2003 [5, 8, 9]. The main difference between the TOT and RP MUS approaches was that the tape passed through the obturator foramen [10]. By avoiding blind entry into the retropubic space, the possibility of bladder, vessel and nerve injuries was reduced [10, 11]. Meta-analyses show that all of these techniques are highly effective in the short and medium term, and some of the evidence even demonstrated their effectiveness in the long term [3]. Moreover, they also seem to be equally effective in patients with recurrent SUI [12], even in the long term, which was shown in a study by Abdel-Fattah et al. from 2017. In their work, the patient-reported success rate based on the Patient's Global Impression of Improvement (PGI-I) 9 years after the procedure was 62.1% [13, 14].

Comparing both TOT techniques, there is no current evidence to support the use of one approach over another [3, 10, 14]. For example, a randomised study from 2007 found an objective cure rate of 87% for the inside-out and 90% for the outside-in procedure 1 year after surgery. The subjective cure rates were 80 and 77%, with no significant differences between groups [5]. The prospective randomised controlled trial E-TOT by Abdel-Fattah et al. recruited 341 patients and showed a patient-reported success rate of 80% and objective cure rate of 91% 1 year after surgery [15]. When following these women 3 and 9 years after surgery, there were again no differences between groups, but there was a significant drop in patient-reported success rates compared with the original study [16, 17]. However, the drop in success rate when comparing results 3 and 9 years after the initial procedure was clinically insignificant [17]. A 2–4-year follow-up study by Houwert et al. also found no differences in the efficacy and safety of the two approaches [18]. A randomised controlled trial by Park et al. reported an 85.7 and 84.6% 3-year cure rate for the outside-in and inside-out approach [19].

Our findings are comparable to the results of these studies. Our objective cure rate was 84.6% for Monarc vs. 94.6% for TVT-O, subjective cure rate 67.9% vs. 68.3% and satisfaction rate 83.9% vs. 78.7%, respectively. Although the objective cure rate of TVT-O at the follow-up was higher than for the Monarc, the differences between groups were not significant. There was a significant reduction in the overall satisfaction rate compared with the primary study. Nevertheless, the overall satisfaction was still very high, as 79.8% of patients reported a $\geq$ 80% satisfaction rate. When comparing satisfaction rates within groups, we discovered that the drop in satisfaction rate was significant for the inside-out, but not for the outside-in group. Unfortunately, we could not identify any factors that could explain these results, as there were no statistically significant differences between the two groups when comparing variables that could affect patients' satisfaction with the procedure such as daytime frequency, nocturia, number of pads used per day, results of the stress test, flowmetry and questionnaire scores.

To our knowledge, our study is the first long-term follow-up to compare both the cure and satisfaction rates of two different TOT approaches. The only other study comparing both procedures in a similar period was the previously mentioned 9-year follow-up of the E-TOT study. Their follow-up achieved an adjusted response rate of 67.8%. The overall patient-reported success rate was 71.6%, with an additional 14% of patients reporting "improvement." Similar to our study, they found no statistically significant differences in success rates between the two groups and noticed a significant reduction in success rates compared with the results obtained 1 year after the procedure. The percentage of women requiring further continence surgery in the E-TOT trial was 7.96 and 1.1% in our study [17].

However, some other long-term results of TOT procedures have also been published. In 2017, Serati et al. published their 10-year results for the inside-out TOT procedure. They included 168 women with pure urodynamic SUI and achieved a 95% response rate. The authors reported 97% subjective and 92% objective cure rates and identified a history of failure of previous anti-incontinence procedures as the only predictor for SUI recurrence. They found no late complications of the procedure [20]. Although our objective cure rate for TVT-O was comparable, their subjective cure rate was higher than in our study. This might be due to differences in definitions of the subjective cure rate. We defined it as the absence of complaints of any involuntary leakage of urine on effort, exertion, sneezing, coughing or laughing, while Serati et al. defined it as both a Patient Global Impression of Improvement scale score $\leq$ 2 and a patient satisfaction score $\geq$ 8 on a patient satisfaction scale of 0–10 [20]. A systematic review from 2017 found long-term objective and subjective cure rates of TOT procedures to be 64.4 and 81.3%, respectively, with no significant difference between the outside-in and inside-out approach [21]. A comparison of the long-term results of TOT and RP MUS can also be made based on our results and results of other studies in this field. For example, a recent study by Schauer et al. described long-term results of surgical UI treatment and included retropubic slings performed in their facility at that time. The study included 256 women, operated

between 1999 and 2004, and achieved a 54.5% response rate. After 10 years, 62.6% of patients had a high degree of treatment satisfaction, 88.5% of women reported use of only 0–1 pad per day, and more than 95% reported no SUI, comparable to the results of our study. Advanced age, the presence of urgency, nocturia and a decreased baseline bladder capacity were identified as risk factors for unsatisfactory outcome [22].

The most commonly reported adverse events of TOT procedures are vaginal tape exposures, dyspareunia and voiding disorders [5, 10, 11]. Vaginal tape exposures occur in up to 7.6%, de novo dyspareunia in up to 9%, newly onset urgency and bladder overactivity in up to 14% and voiding difficulties in up to 5% of patients [5, 11, 18–20, 22]. In our study, there were no cases of vaginal tape exposures; 6.4% of patients complained of dyspareunia and 34% of LUTS. We found no statistically significant differences in complication rates between groups, which is similar to the results of other studies in this field [3, 5, 17, 23]. A few studies have suggested that voiding difficulties and vaginal tape exposures might be more frequent with the outside-in approach; however, our results did not confirm this [10, 11].

In general, vaginal tape exposures can even be diagnosed a long time after the procedure. While some can be asymptomatic, patients generally present with excessive vaginal discharge/bleeding, groin pain and complaints of dyspareunia. Tape exposure usually requires surgical exploration with or without complete/partial tape removal [11]. At our facility, we had a few cases of tape exposure when we first started using TOT procedures [24]. We believe that this was due to lack of experience at the beginning of the learning curve. With further improvement of our technique, we reduced the number of tape exposures to a minimum and found no such cases in the cohort of patients included in the present study.

Dyspareunia is of great importance when discussing continence procedures, because it can significantly affect patients' quality of life. One study showed that sexual dysfunction rates might be higher with the outside-in procedures [13, 14]; however, other studies could not confirm this finding [18, 19]. In our case, the incidence of patient-reported dyspareunia was slightly higher than in other studies. In our opinion, this might be due to procedure-unrelated causes such as osteomuscular pain, pelvic organ prolapse or vaginal atrophy after menopause. The incidence of LUTS in our study was 34%. Serati et al. reported only 14% of de novo detrusor overactivity 10 years after the TVT-O procedure, but their study only included patients with pure urodynamic SUI [20]. In comparison, Schauer et al. discovered that 41.7% of their patients had the complaint of urgency 10 years after RP MUS [22]. It is also important to emphasise that because of the higher incidence of voiding disorders after menopause, it is possible that de novo LUTS symptoms occurring so late after the procedure could be a natural course of ageing rather than the consequence of tape procedures. However, this can be said with confidence only if a similar long-term study with a control arm of women without surgery has been performed. In this way, it would be possible to establish the percentage of women who would develop a complaint of dyspareunia and LUTS within 10 years and compare it to the percentage of women with these symptoms after the TOT procedure.

In our original study, there were three cases of primary procedure failure, six cases of vaginal mucosal tears and three cases of vaginal wall perforation during surgery. There was also one case of defective healing under the urethra in the postoperative period. We performed a separate analysis of these 13 patients. Eleven of them attended the follow-up visit and were generally satisfied with the results of the procedure. Two had positive stress tests and were considered for further management.

This study has a number of strengths. First, it was a long-term follow-up of a randomised study in which patients were allocated to different intervention groups using computer-generated numbers. We also achieved a good response rate, and the assessment was standardised using validated questionnaires. A potential limitation is that only one surgeon performed all surgeries, so we were not able to assess the impact of surgical experience on the results. Furthermore, 17.5% of the patients were lost to follow-up, but the satisfaction rate of non-responders 3 months after surgery did not significantly differ from the satisfaction rate of responders. Since we are the only urogynaecological centre in our part of the country, these patients would most probably be referred to us if they had any procedure-related complications. Moreover, our study did not address all the reported adverse events of TOT procedures, for example groin pain. Since it can be a consequence of several different medical conditions (e.g. hip problems, nerve entrapment syndromes, hernia, lumbar disk pathology, etc.), we believe that groin pain incidence could be overestimated because of possible medical comorbidities. Another limitation is that there was no power analysis performed in the original study. However, because of the structured patient work-up and high response rate, we believe that present work will add some new important insights into the long-term outcomes of TOT procedures.

In conclusion, in our randomised controlled trial follow-up comparing two different TOT techniques, we found no significant differences in cure or satisfaction rates 10 years after the procedure. Both approaches show high long-term efficacy with relatively few complications.

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Compliance with ethical standards

Conflicts of interest Serdinšek T: none; But I: none.

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