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ORIGINAL ARTICLE

What is the optimal length for single-incision tape?

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Abstract

Introduction and hypothesis The aim of this study was to assess the length of adjustable single-incision midurethral tape (SIMS; Ajust), which is needed to fix this tape to the obturator membrane. From these data, we can deduce the optimal length of the SIMS.

Methods For this study, we employed the intra-operative data of patients included in a single-center randomized trial comparing the efficacy of Tension free vaginal tape obturator (TVT-O) and Ajust. The length of the Ajust tape was calculated using the formula: total length of the tape minus the length of the stylet used for the tape lock, minus the length of the lock minus the width of the two anchors. The length of the obturator tape was calculated using the formula: total tape length minus the snipped parts of the tape. The correlation coefficient of the tape length to basic biometric parameters, such as height, weight, and body mass index, was calculated.

Results For this study, data from 50 women from each group, TVT-O and Ajust, were used. The mean length of the Ajust tape inside the body is 11.6 cm (SD 0.9), with a minimum length of 9.6 cm and a maximum length of 14.6 cm. The mean length of TVT-O tape inside the body is 20.3 cm (SD 2.1), with a minimum of 14.8 cm and a maximum length of 24.5 cm.

Conclusions This study demonstrates that to achieve continence it is necessary to use different lengths of single-incision tape. Inappropriate SIMS length could cause failure related to the tape itself and not to the TVT technique.

Keywords Stress urinary incontinence · TVT-O · Ajust · Surgical treatment · Single-incision midurethral sling

Introduction

Tension-free vaginal tape (TVT or midurethral sling, MUS) is a method frequently used in the treatment of stress urinary incontinence (UI). The procedure is regarded as minimally invasive and highly effective [1]. However, owing to the retropubic trajectory of the tape insertion, the first generation of MUS introduced in 1995 was associated with some major peri-operative complications, such as major vessel and bowel injury, sometimes with fatal consequences [2–5]. The next generation of MUS featured the transobturator approach, first the outside-in route (TOT) [6] and then the inside-out approach (TVT-O) [7]. Transobturator tapes achieved the same efficacy as retropubic tapes [1, 8, 9], but for patients with intrinsic sphincter deficiency (ISD), the retropubic approach could be more efficient [10]. The most frequent complication resulting from transobturator tapes is transient groin pain; persistent groin pain due to irritation of the obturator nerve is a rare complication [11, 12]. In 2006, the first generation of single-incision midurethral slings (SIMS), TVT-Secur (TVT-S), was introduced onto the market, but there were no clinical studies dealing with the safety and efficacy of this procedure. These tapes were expected to be less invasive, the surgical procedure would require fewer tissue dissections, and there would be less post-operative pain, while maintaining a similar degree of efficacy. However, several randomized trials and meta-analyses showed lower efficacy than expected [13–19], and accounts of some serious complications were published [20]. Anatomical studies proved that the major reason for the failure of this procedure is the inadequate length of the tape, preventing the anchoring part from reaching the proper fixation structure [21, 22]. Consequently,

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the tape did not provide adequate restriction of urethral descent [23]. Afterward, anchored SIMS were introduced, followed later by anchored slings with adjustable length (Ajust). Anchored tapes could achieve better results, but in some kits the results are highly variable [15]. We suppose that the reason for this is the fixed length of anchored SIMS. The adjustable length of the tape makes it possible to reach adequate fixation structures [24] and analyses focusing on such devices have proved the same efficacy as transobturator tapes [25]. In recent years, the use of SIMS has been widely discussed; some kits are no longer available on the market, and in some countries there is a ban on the usage of such devices. The aim of this study was to assess the length of adjustable SIMS (Ajust), which is needed to fix this tape to the obturator membrane in real patients and prove our hypothesis: that to reach proper fixation structures and maintain efficacy, different tape lengths are required. Fixed length of SIMS is not adequate for reaching proper fixation structures in some patients, and this could be the major reason for lower SIMS efficacy. For the purposes of a comparison, we also assess the length of transobturator tape in-out (TVT-O), which stays in the patient's body after the procedure. From these data, we deduce the optimal length for SIMS and suggest whether it might be possible to successfully use a single-incision tape with a fixed length for all patients.

Materials and methods

For this study, the intra-operative data of patients included in a single-center randomized trial comparing the objective and subjective efficacy of TVT-O and Ajust was used (this is a secondary analysis of the data). The study was approved by the ethics committee of the General University Hospital in Prague (IRB 000021705), approval number 0080/12. The recruitment period for the study started in January 2010 and ended in March 2012. The sample size of the prospective randomized study was determined to be 90 women. To compare the probabilities of successful surgeries, we can use the Chi-squared test of the hypothesis pTVT-O = pAjust™. The sample size was derived from the requirement to detect actual probabilities (successful surgeries) pTVT-O = 90%, pAjust™ = 70% with the probability (power) of 80% (those probabilities were derived from our previous randomized trial comparing TVT-O and TVT-S procedures, where the objective cure rate following TVT-O was 92.6%, for the TVT-S hammock 68.8%, and for TVT-S U approach 69.2%, subjective cure rates were 85.3%, 68.8%, and 61.5% respectively [16]; thus, for this study we expected a cure rate for TVT-O of 90% and for Ajust™ a cure rate of 70%). We determined the randomization sequence for assigning women to two intervention groups (classical surgery, TVT-O, and Ajust™). Based on this pre-study statistical

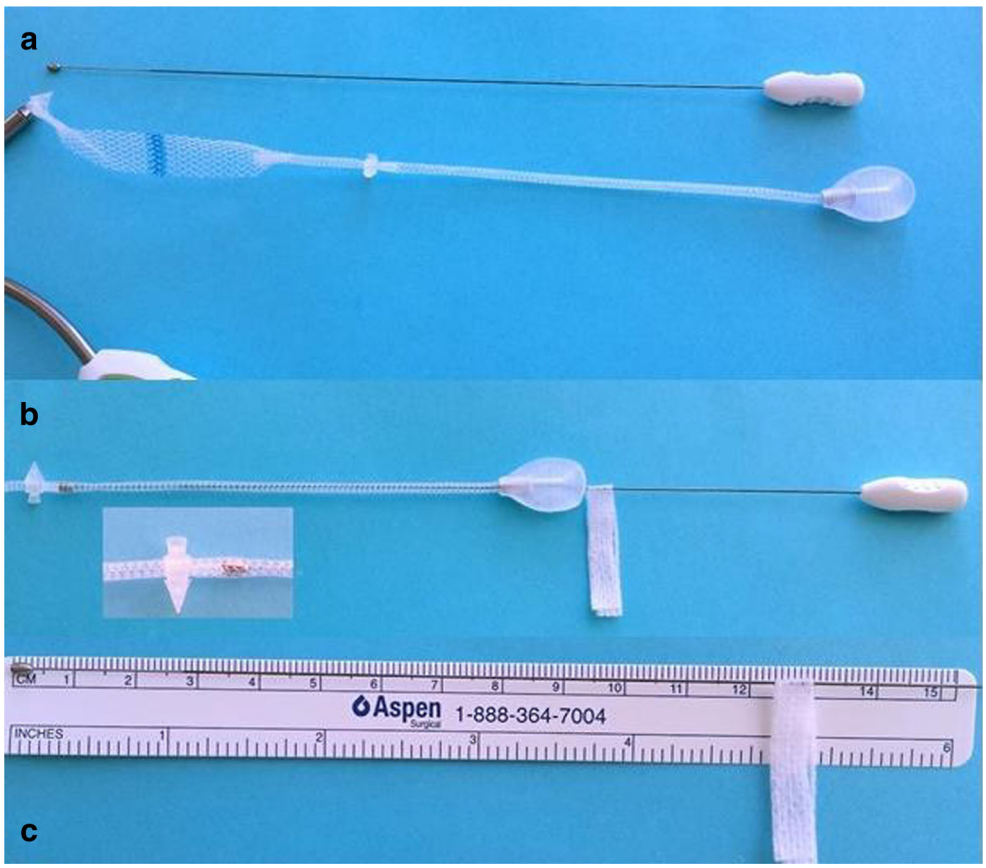

Fig. 1 Description of the measurement of the Ajust tape, which needs to be properly fixed to the obturator membrane. **a** Ajust tape. **b** Lock of the anchor and marker of the stylet length. The tape lock was pushed into the proper place at the adjustable anchor; we put the marker (Steri-Strips) on the flexible stylet. **c** Measurement of the inserted part of the stylet. After the procedures, the length of the inserted part of the stylet was measured

Table 1 Pre-operative patient characteristics

	TVT-0	Ajust	*p*
N	50	50	
Ethnics: Caucasian (*N*)	50	50	
Age, years	58.9 ± 12.4	55.8 ± 10.2	11.5*
Height, mean, m	164.1 ± 6.6	164.3 ± 6.085.1[b]	
Height, median, m	164	164.5	71.8*
Weight, kg	74.9 ± 10.2	73.8 ± 13.8	66.1**
Weight, median, kg	73	71.5	47.9*
BMI, mean, kg/m^2	27.9 ± 4.4	27.3 ± 4.8	50.9**
BMI, median, kg/m^2	27.1	26.8	45.4*
Parity	2.0 ± 0.6	2.0 ± 0.9	67.3*
Previous hysterectomy, *n*/%	17 (34)	16 (32)	100***
Previous vaginal wall repair	9 (18)	6 (12)	57.7***
Mixed UI, *n* (%)	23 (46)	22 (44)	100***
Urgency, *n* (%)	31 (62)	27 (54)	54.4***
Sexually active	28 (56)	34 (68)	30.3***
MUCP, cm H_20	54.0 ± 20.8	55.5 ± 22.5	81.7*
Maximum flow rate, mL/s	26.8 ± 13.8	23.5 ± 11.7	29.0*
ICIQ	14.6 ± 2.5	14.7 ± 2.5	72.0*
IQOL	41.0 ± 17.8	38.5 ± 18.4	51.0*

Values are given as mean ± SD or number of patients/%

MUCP maximal urethral closure pressure, *ICIQ* International Consultation on Incontinence Questionnaire, *IQOL* incontinence quality of life, *BMI* body mass index, *UI* urinary incontinence

*Mann–Whitney test

**Student's *t* test

***Fisher's test

calculation (power analysis), it was indicated that the required sample size for the final statistical analysis in each group was 45 patients (allocation ratio 1:1). We calculated a drop-out rate of 10%; thus, it was planned to enroll 50 patients into each group. Interim analysis was not planned. We implemented randomization by placing pieces of paper containing the randomization allocation in sealed envelopes, which were arranged for sequential opening (these envelopes were prepared by an external statistician and marked from 1 to 100, put into the box, and opened in order sequentially from the first one (marked with a 1). A comprehensive description of study methodology and surgical procedure description was published in a previous study [26]. The length of the obturator tape that remains in the patient's body was calculated using the formula: total tape length minus the snipped parts of the tape. The Ajust procedure was performed according to the company's recommendation; this technique has been described previously [27]. After insertion of the adjustable anchor at the obturator membrane on the left-hand side, Metzenbaum scissors were placed between the tape and urethra, and the appropriate tension of the sling was set. Finally, the tape lock was pushed into the proper place at the adjustable anchor; we put the marker (Steri-Strips) on the flexible stylet (Fig. 1). After the procedures, the length of the inserted part of the stylet was measured. The length of the Ajust tape required for proper fixation to the obturator membrane was calculated using the formula: the total length of the tape minus the length of stylet used for the tape lock, minus the length of the lock minus the width of the two anchors. The correlation coefficient of the tape length with basic biometric parameters, such as height, weight, and body mass index (BMI), was calculated.

Table 2 One-year objective and subjective follow-up

	TVT-O	Ajust	*p*
ICIQ	2.4 ± 3.6	2.2 ± 3.6	NS*
Subjective stress negative, *n* (%)	43 (91.5)	44 (89.8)	NS
IQOL	91.5 ± 11.2	88.5 ± 12.8	NS*
Stress test negative, *n* (%)	41 (87.2)	44 (89.8)	NS**

*Mann–Whitney test

**Fisher's test

Results

For this study, data from 100 women with proven USI who were randomized into two groups were used: TVT-O (50) and Ajust (50). There were no differences in each group regarding pre-operative characteristics (Table 1). At a 1-year follow-up, there were no differences in subjective and objective outcomes between the two groups (Table 2). The mean length of the Ajust tape inside the body was 11.6 cm (SD 0.9), with a minimum length of 9.6 cm and a maximum of 14.6 cm. The mean length of TVT-O tape that remained in the patient's body was 20.3 cm (SD 2.1), with a minimum length of 14.8 cm and a maximum length of 24.5 cm (Table 3). In both procedures, there is no relationship between the tape length and the patient's height, weight or BMI (Tables 4, 5).

Table 3 Length of the tape inside the body

	Ajust	TVT-O
Mean (cm)	11.6	20.3
Median (cm)	11.5	20.4
SD (cm)	0.9	2.1
Minimum (cm)	9.6	14.8
Maximum (cm)	14.6	24.5
Q1 (cm)	11.0	19.0
Q3 (cm)	12.1	21.8

Length is in centimeters

Length of the Ajust tape is without the anchors

Q quartile

Table 4 Correlation coefficients of the length of the Ajust tape with basic biometric parameters

	Weight	Height	BMI
Correlation coefficient	0.240	0.267	0.148
p value	0.093	0.061	0.306

Discussion

In our study, we have demonstrated that to achieve continence with single-incision tape comparable to transobturator tape, there is a need for SIMS tapes in a range of lengths. These differences are probably due to the high variability of the female pelvis, differences in surgical technique, and different tape tensioning, tape placement, and tape biomechanical properties. Using the same type of single-incision tape with the possibility of adjusting it, we found in different women a range of up to 5 cm (4.9 cm) in the tape length needed to achieve a proper fixation structure. In previous anatomical studies, high physiological variability of the individual structures in the lesser pelvis was proven. Ridgeway et al. published a study that focused on the variability of the bony pelvis, in which the interobturator foramina distance varied from 4.3 to 6.9 cm (mean 5.7 ± 0.5), so the absolute variability was 2.6 cm. They concluded that there is considerable variability in the bony architecture of the obturator foramen and pubic arch of the female pelvis [28]. Very similar variability in interobturator foramina distance (from 37.2 to 74.1 mm, mean 56.5 ± 6 .3mm) was described by Bogusiewicz et al. [29]. The high degree of variability in terms of the distance from the mean urethra to the obturator foramina was also confirmed using magnetic resonance imaging of the lesser pelvis [30]. The mean distance from the mid-urethra to the obturator membrane in the cases examined here was 31.8 mm (left) and 32.1 mm (right), with a range from 25.9 to 42.0 mm; thus, the absolute difference was 32.1 mm. The strength of our study is that clinical practice has proven that the difference in the tape length that is needed to reach the fixation structure is much greater than the differences in distance between fixation structures in anatomical studies. This could be because during surgery, the most direct pathway is not possible. Another important factor could be the surgeon, with each individual using a slightly different trajectory of tape insertion during the same procedure. It should be mentioned that tape tensioning could also influence the overall tape length. The tape tensioning could be influenced by the tape's mechanical properties [31]. In this context, there should also be a discussion about whether the use of single-incision tapes with a predefined length is appropriate, because the kit itself could be the reason for failure (if it is not possible to reach a proper fixation point). The surgeon could avoid the use of a kit of this type at the beginning of the surgery; by using scissors for tunneling, the depth of the fixation structures could be estimated. In cases where it seems to be too large, single-incision tape should be avoided. Another possibility is to use single-incision tape with adjustable length. Compared with the first generation of single-incision tape, anchored tapes could achieve better results, but in some kits the results are highly variable [15]. The best results are reached using single-incision tapes with adjustable length [25], and it certainly seems questionable whether the pre-defined length of the mini-tape is appropriate for all patients. Current evidence is not sufficient to establish a difference in incontinence rates with single-incision slings (excluding TVT-S) compared with inside-out or outside-in transobturator slings [32].

Table 5 Correlation coefficients of the length of the TVT-O tape with basic biometric parameters

	Weight	Height	BMI
Correlation coefficient	0.088	−0.027	0.104
p value	0.542	0.851	0.473

Conclusion

This study demonstrates that to achieve continence it is necessary to use different lengths of single-incision tape. These differences are probably due to the high variability of the female pelvis, differences in surgical technique, and different tape tensioning, tape placement, and tape biomechanical properties. A single-incision tape with a set length will not fit all patients, and failure related to the tape rather than the surgical method could occur.

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Compliance with ethical standards

Conflicts of interest A. Martan is a preceptor for Meditrade. None of the other authors has any conflicts of interest to declare.

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