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Original Article

Are complications of stress urinary incontinence surgery procedures associated with the position of the sling?Jacek Kociszewski,¹ George Fabian,¹ Susanne Grothey,¹ Andrzej Kuszka,¹ Aneta Zwierzchowska,² Wojciech Majkusiak² and Ewa Barcz²¹Department of Gynecology and Obstetrics, Evangelical Hospital Hagen-Haspe, Hagen, Germany, and ²1st Department of Obstetrics and Gynecology, Medical University of Warsaw, Warsaw, Poland**Abbreviations & Acronyms**

ICS = International Continence Society
IVS = intravaginal sling
LSM = longitudinal smooth muscle
OAB = overactive bladder
SUI = stress urinary incontinence
TOT = transobturator tape
TVT-O = transvaginal tape obturator
TVT = tension-free vaginal tape
US = ultrasound

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Objectives: To evaluate whether the sling position is associated with particular types of complications in patients undergoing suburethral sling placement for stress urinary incontinence.

Methods: Data from 100 women diagnosed at the Evangelical Hospital Hagen-Haspe with complications after suburethral sling insertion were analyzed. All patients underwent pelvic floor ultrasound to assess: urethral length, sling location in relation to the urethral length (%) and the sling distance to the longitudinal smooth muscle complex of the urethra (the sling–longitudinal smooth muscle distance).

Results: The shortest median sling–longitudinal smooth muscle distance was observed in patients with recurrent urinary tract infections, urinary retention and overactive bladder: 0.9, 1.1 and 1.75 mm, respectively ($P < 0.05$). In women with persistent stress urinary incontinence and sling erosion, the sling–longitudinal smooth muscle distance was 3.6 and 4.6 mm, respectively ($P < 0.05$). Persistent stress urinary incontinence was connected with the position of the sling in relation to the bladder neck – in these patients, the sling was closer to the bladder neck.

Conclusions: Sling location plays a pivotal role in the occurrence of certain complications. The sling position in the proximal part of the urethra or between the middle and proximal urethra appears to be connected with a high rate of unsuccessful stress urinary incontinence treatment. A sling–longitudinal smooth muscle distance below 2 mm is often connected with sling complications, such as overactive bladder, urinary retention and recurrent urinary tract infections.

Key words: overactive bladder, postoperative complications, stress urinary incontinence, suburethral slings, ultrasound imaging.

Introduction

SUI occurs in approximately 30% of adult women.¹ The treatment methods most commonly utilized in these cases are sling procedures, which involve inserting a suburethral tape to support the urethra on exertion.² Despite being considered the gold standard in modern SUI treatment, these techniques are not free of complications. The primary complications after sling operations are: voiding dysfunction (approximately 5–7%),³ OAB (10–30%),⁴ tape erosion (2–3%),⁵ pain (3%) and dissatisfaction with treatment results (10–30%).⁶

It is currently believed that postoperative complications depend on the operative technique, the sling type and approach chosen to insert it. Urinary retention and OAB are considered to occur more often after the insertion of retropubic tapes, whereas erosion and postoperative pain are more frequently experienced with retropubic slings.⁵ There is, however, no unanimous opinion with regard to the cause of these clinical problems.

Recently, US has been proving increasingly useful in the diagnosis of complications of sling procedures. In the literature, various techniques of ultrasonographic presentations are used to define different parameters (mobility of the urethra, levator ani, localization of the synthetic materials).^{7,8} Furthermore, trials using US have compared the clinical outcomes according to different types of slings.⁹ Some reports correlate the occurrence of urinary tract symptoms, such as urinary retention and de novo OAB, with the position of the suburethral tape assessed using US.^{10,11}

The aim of the present study was to assess the localization of the slings with US, and evaluate whether certain positions are associated with particular complications.

Methods

The present study was a retrospective analysis of data regarding 100 women with postoperative complications after sling procedures, diagnosed in Evangelical Hospital Hagen-Haspe in the years 2010–2012. All surgeries were carried out between the year 2000 and 2010 at different units in Germany. The time to the occurrence of complications after the procedure varied. The mean time interval was 13.5 months (SD 24.4). In 48% of the patients, complications occurred immediately after the procedure; whereas in 30%, complications occurred earlier than half a year after sling implantation. The majority of the patients presented more than one complication at the same time.

For all patients diagnosed with a complication of the sling procedure, pelvic floor US examination was carried out in a standardized manner, with the patient on the gynecological chair in a semi-sitting position with their bladder filled to 300 mL. The probe (a 3.6- to 8.3-MHz vaginal transducer with a beam angle of 160°) was placed in the vaginal introitus at the level of the external urethral orifice. With the probe in this position, the urinary bladder, urethra, suburethral vagina and pubic symphysis with the interpubic disc were visualized in the median sagittal plane, according to the Interdisciplinary S2k Guideline: Sonography in Urogynecology.¹² The US examination was always carried out by two specialists, and the results that differed by more than 10% were excluded.

In all cases, the 3-day bladder diary was analyzed. The diary included intake of fluids (volume, type and time), time and volume of micturition, urinary incontinence episodes, urgency, and pads used. A stress cough test was carried out on the gynecological examination chair with bladder volume of approximately 300 mL (measured with ultrasound). The 1-h pad test was carried out for all cases according to ICS recommendations. Uroflowmetry and profilometry were carried out in a normal manner.

OAB was diagnosed according to ICS recommendations on the basis of symptoms (pollakisuria, nocturia and urgency). In all cases, the bladder diary was analyzed to objectify the symptoms. The intensity of urgency was quantified on the basis of the 10-point visual analog scale score.

According to the study protocol, the following parameters were assessed:

- 1 Length of the hypoechoic core of the urethra
- 2 Tape position:
 - a its location in relation to the urethral length (%)
 - b the sling–LSM distance (mm) – determination of the distance between the sling and the echolucent part of the urethra (consisting of mucosa, submucosa and smooth muscle layers).

After the above examination, US scan was carried out in order to assess the residual volume.

The statistical significance of the difference in medians of measurement results in patients with different complications was assessed using the Mann–Whitney–Wilcoxon rank sum test. The normality of distributions of tape position was verified using the Shapiro–Wilk test. The computer software utilized for statistics was STATA 11.1 SE (STATA Data Analysis and Statistical Software, Lake Drive, TX, USA), licence number: 40110544729.

The study was approved by the ethics committee of the University Hospital (no. AKBE/38/13).

Results

The mean age of the patients at the time of diagnosis was 57.2 years (SD 11). The youngest woman was aged 37 years, the oldest was aged 77 years.

In the majority of cases, more than one complication occurred.

The most common complication was OAB, which occurred in 64 women (64%). Women diagnosed with bladder instability fulfilled the criteria established by ICS in 2003 (urgency, frequent urination defined as at least eight micturitions per day and at least one micturition during the night).¹³

All women with OAB suffered from nocturia (3.28 micturitions per night on the average), whereas the mean number of urinations was 13.3 ± 2.35 , the mean micturition volume was 131.7 ± 36.9 mL and the mean severity of urgency in a 10-degree visual scale was 8.78.

The second most common complication, persistent SUI or insufficient treatment effect, was observed in 59 patients (59%). It was diagnosed on the basis of the patient's statement on continence, a positive cough test and the result of the 1-h pad test (mean result $100.9 \text{ g} \pm 65.4$).

A total of 40 patients suffered from pain associated with the tape: dyspareunia (29%), spontaneous pain (27%), pain on walking (3%) and dysuria (2%).

Urinary retention occurred in 40% of patients. In 16%, overflow incontinence accompanying retention was observed. The mean residual volume was 206 ± 129.5 mL. The residual volume was even greater in women with accompanying overflow incontinence – 286 mL (SD 151 mL).

Vaginal erosion of the sling was observed in 25 women (25%).

The patients enrolled in the study had two types of tapes: retropubic (52 cases; TVT 44, TVT-Exact 4, TVT-Seraxis 2, IVS 2) and transobturator slings (45 cases; TVT-O 18, TOT- 15, TOT Obtape 6, TOT-Monarc 4, TOT-Aris 1, TVT-O Abrevo 1). Three women underwent two sling procedures, and different tapes were used at each procedure.

Table 1 presents median tape–LSM distances and median sling positions relative to the urethral length.

In the whole group, the median tape–LSM distance was 1.9 mm. The shortest distance was observed in patients who were diagnosed with recurrent bladder infections and urinary retention (0.9 and 1.1 mm, respectively). The differences were statistically significant. Women with OAB were also

Table 1 Median tape–LSM distances and median sling positions relative to the urethral length

	Whole group <i>n</i> = 100	OAB <i>n</i> = 64	Persistent SUI <i>n</i> = 59	Pain <i>n</i> = 40	Urinary retention <i>n</i> = 40	Lower urinary tract infections <i>n</i> = 40	Tape erosion <i>n</i> = 25
Tape–LSM distance (mm)	1.9 (3.8)	1.75 (3.6)	3.6 (4.2)	2.4 (4.4)	1.1 (1.9)	0.9 (2.7)	4.6 (3.7)
		<i>P</i> = 0.019	<i>P</i> < 0.001	<i>P</i> = 0.982	<i>P</i> < 0.001	<i>P</i> = 0.001	<i>P</i> = 0.006
Tape position in % relative to the urethral length (from the bladder neck)	45.5 (0.37)	46.0 (0.37)	37.8 (0.34)	55.1 (0.42)	49.2 (0.27)	53.0 (0.34)	47.3 (0.36)
		<i>P</i> = 0.943	<i>P</i> = 0.014	<i>P</i> = 0.055	<i>P</i> = 0.078	<i>P</i> = 0.055	<i>P</i> = 0.550

Data are given as median (interquartile range).

characterized by a close tape–LSM distance – in this group the median was 1.75 mm, statistically significantly closer than in the cases of other complications. In contrast, in the other subgroups of complications, persistent SUI and tape erosion, the tape–LSM distance was longer, 3.6 and 4.6 mm, respectively.

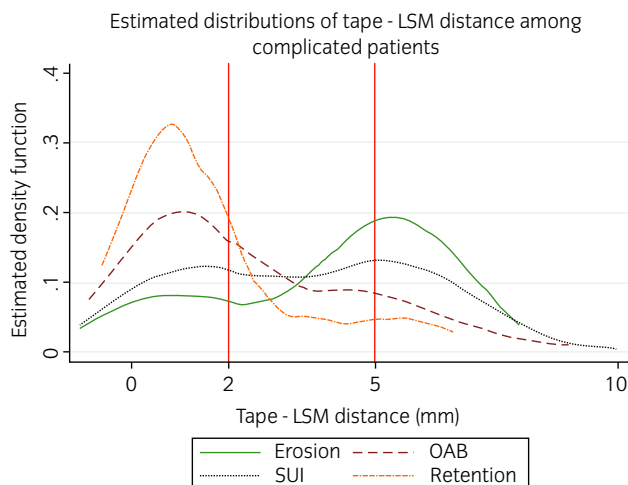
The only complication that differed significantly from the others with regard to the average position of the sling in relation to the bladder neck was persistent SUI. Patients suffering from this adverse effect had the sling located closer to the bladder neck than the others.

Neither tape–LSM distance, nor relative position of the sling varied significantly between women with postoperative pain and others.

Figure 1 presents estimated distributions of tape–LSM distance for patients manifesting various complications.

In case of retention and OAB, the distribution is shifted to the left, in the direction of short tape–LSM distances. The distribution for erosion, in contrast, is nearly a mirror reflection of the distribution for OAB – distances longer than average favor this complication. Patients with persistent SUI usually had their tape localized further from the urethra, but for this group the distribution was the most even.

Figure 2 presents estimated distributions of relative distances of the slings from the bladder neck for patients manifesting various complications.

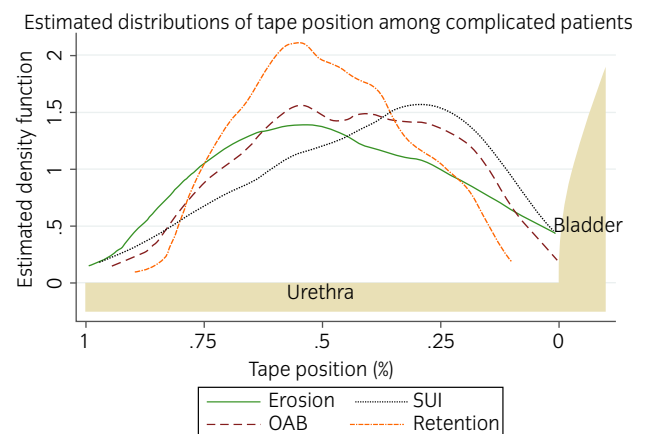
**Fig. 1** Estimated distributions of tape–LSM distance.

For the three groups of complications: erosion, OAB and urinary retention, the conditional distributions seem to be normal according to the Shapiro–Wilk test. Only for SUI was the distribution strongly asymmetrical – women manifesting this adverse effect had their tape fixed too proximal to the bladder neck; that is, 37.8% of the total urethral length on average.

No differences in average sling locations between transobturator and retropubic slings were found. We separately analyzed retropubic and transobturator slings, finding no differences between the two types of tapes as far as connection between sling location and complications are considered.

Discussion

Suburethral slings have become the gold standard in the surgical treatment of SUI. Although the technique is effective and safe, there exists a group of patients who suffer from postoperative complications. Brubaker *et al.* carried out a randomized study assessing 597 cases of SUI treated with a retropubic or transobturator tape. Complications were observed in 42% of the operated women; 20% suffered from adverse effects that were classified as severe (such as persistent SUI, OAB de novo, urinary retention, pain).¹⁴ This high incidence of complications implicates the necessity of considering them seriously when making decisions about surgical or

**Fig. 2** Estimated distributions of relative distances of the slings from the bladder neck.

conservative management of SUI. The risk should always be discussed with the patient.¹⁵

The causes of complications or unsatisfying results of surgical treatment of SUI are being widely discussed. Researchers focus mainly on seeking a relationship between certain types of slings, sling material and the route utilized to insert them, and particular complications.¹⁶

Recently, US examination has become more important in the diagnosis of postoperative complications. Most authors assess the tape position in relation to the urethral length, as well as its distance from the urethral lumen. In a research study carried out by Reich *et al.*, the localization of the sling in patients with complications did not differ from those without complications.⁹ However, the existing data regarding tape position and its correlation with postoperative complications are inconclusive and often contradictory.

This is one of the most extensive studies regarding US findings in patients with complications after sling procedures. The results of the current study show that the complications of SUI surgery procedures are indeed associated with the position of the sling, and that US assessment of the distance between the tape and the bladder neck is highly suitable for the diagnosis of ineffective SUI treatment. In the analyzed material regarding 59 women with persistent SUI, the problem occurs statistically significantly more often among patients with the tape localized closer to the bladder neck. Similar results were obtained by our group in previously carried out studies, which investigated both cases with and without complications.^{17,18} The results of the current study also confirm the findings of a Taiwanese research group, who showed that SUI recurs more often in patients who have their tape located near/at the level of the bladder neck.¹⁹

On the contrary, no such correlation was proved by de Tayrac *et al.*, who studied the results of US examination in women who had undergone the TVT or TOT procedure.²⁰ It should be stressed, however, that the analyzed group was too small (seven patients) to draw reliable conclusions from the

study. Results similar to those presented in the current study were described by Bogusiewicz *et al.* The authors utilized a 3-D probe, and proved that proximal localization of the tape is associated with a higher incidence of persistent SUI.²¹

In the analyzed material, the position of the sling in relation to the total urethral length correlated only with persistent SUI – no correlation with other complications of sling procedures was proved. The other aspect associated with unsatisfying treatment results (that is persistent SUI) was the distance between the tape and urethral lumen. In these patients, the tape–LSM distance was slightly greater than in those cured (negative cough test, 1-h pad test <2 g). This probably results from the fact that a greater urethra–sling distance provides insufficient support for the urethra on exertion.

OAB and urinary retention were the most common complications diagnosed in the study group. It appears that these two complications are associated with a shorter distance from the tape to LSM complex (<2 mm). Similar results were

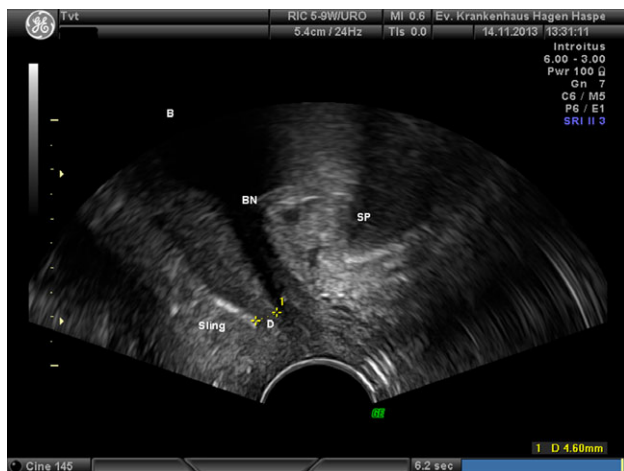


Fig. 3 Optimal sling location relative to the urethral length and proper distance from the urethral lumen. B, bladder; BN, bladder neck; D, tape–LSM distance; SP, symphysis pubis; U, urethra.



Fig. 4 Tape located under the bladder neck. B, bladder; BN, bladder neck; SP, symphysis pubis; U, urethra.

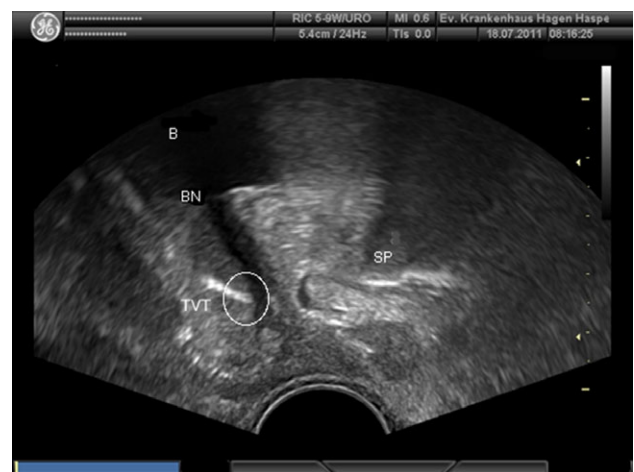


Fig. 5 Tape located too close to the urethral lumen. B, bladder; BN, bladder neck; SP, symphysis pubis; TVT, tension-free vaginal tape.

obtained in our previous study.²² In research carried out by Mouracade *et al.*, cases of 31 patients who underwent suburethral tape placement for stress urinary incontinence and developed lower urinary tract symptoms were analyzed. In those women in whom incorrect localization of the tape caused distortion of the urethra, obstructive complications, such as de novo OAB or urinary retention, occurred. Tape lysis resulted in resolution of the symptoms in the majority of them.¹⁰

In the group studied, OAB and urinary retention were strictly correlated with the distance between the sling and urethral lumen. The occurrence of these complications coexisted with a distance smaller than 2 mm.

Urinary retention can also be caused by detrusor underactivity. Unfortunately, we do not have information about preoperative detrusor characteristics, as all the patients were admitted from other centers, usually several years after the first sling was implanted and the complications occurred. During the complication diagnostics, all the patients underwent urodynamic examination to exclude underactivity of the detrusor. However, it is worth underlining that prolonged urinary retention with bladder outlet obstruction can lead to secondary detrusor underactivity.

Vaginal erosion of the sling is observed in 25% of patients after sling procedures. In the present research, erosion was diagnosed in those women whose tape–LSM distance was >4 mm. In these cases, vaginal exposure of the mesh was observed not only directly under the urethra, but also laterally, in the vaginal fornices. Similar localization of erosion complicated with an abscess was described in 2013.²³

The results of the current analysis strongly suggest that the localization of the tape, both in relation to the bladder neck and its distance from the urethral lumen, is significant in the context of postoperative complications. Similar conclusions arise from studies assessing US localization of the tape, also in other publications; that is, when a 3-D probe is utilized.²⁴

The limitations of the study included the relatively small sample size and, to a certain degree, subjectivity of US assessments. Also, the results cannot be compared with women who had no complications post-sling implantation, as only complicated cases were taken into consideration. In our previous study it was shown, however, that among cured patients (with no persistent SUI), approximately 10% had the tape implanted in proximal urethra. In contrast, we had not found women without complications in case of too tight tape–LSM complex distance (<2 mm).⁹ The obtained results have significant clinical implications, as they help to make the proper decision regarding further management. On the basis of tape location, it is possible to define whether the complication is connected to the sling implantation or if it is a coexisting, independent problem. When the wrong position of the tape is visualized, it is easier to confirm the cause and relationship, and counsel the patients to undergo further surgery. In our departments, in the case of wrong tape location, we prefer vaginal sling excision and repeated sling implantation.

Figures 3–5 present US imaging of tapes located correctly (Fig. 3), too close to the bladder neck (Fig. 4) and too close to the LSM complex (Fig. 5).

In summary, the analysis of 100 cases of patients presenting complications associated with sling procedures showed that tape positioning plays a pivotal role both in the effectiveness of treatment and the occurrence of complications, such as OAB, urinary retention and vaginal erosion. The sling position in the proximal part of the urethra or the border between the middle and proximal portions of the urethra appears to be connected with a high rate of unsuccessful SUI treatment. The sling–LSM distance below 2 mm often correlates with sling complications, such as OAB, urinary retention and recurrent urinary tract infections.

Conflict of interest

None declared.

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