Archives of Gynecology and Obstetrics (2019) 299:1015–1022
https://doi.org/10.1007/s00404-019-05077-0

GENERAL GYNECOLOGY

Comparison of two retropubic tension-free vaginal tape procedures in women with stress urinary incontinence: a randomized controlled multicenter trial

Juliane Marschke[1] · Christl Reisenauer[2] · Tomi S. Mikkola[3] · Frank Schwab[4] · Ralf Tunn[1] · Markus Huebner[2,5]

Received: 14 August 2018 / Accepted: 1 February 2019 / Published online: 25 February 2019

Abstract

Purpose Midurethral slings are a well-established treatment option in women suffering stress urinary incontinence. Various different products and methods are used, therefore, the aim of our study was to compare two inside-out retropubic slings (TVT exact® vs. RetroArc®) inserted in two different ways regarding perioperative and mid-term outcomes.

Methods In this prospective randomized controlled non-inferiority multicentre trial, primary endpoint was postoperative cure rate, both objective (negative cough test) and subjective (absence of leakage during physical activity using the UDI-6 questionnaire). Secondary endpoints were patients' satisfaction (Likert scale; ICIQ-UI-SF questionnaires). In addition, intra- and postoperative complications were evaluated. The TVT®-group was operated with an empty bladder, a 18 CH catheter was used with a straight inserter as instructed. Patients randomized into the RetroArc®-group were operated without inserter leading to a reduced catheter size (14 CH), bladder was filled (200 ml) during the procedure.

Results Of the 303 women, 152 were randomized to the TVT® and 151 to the RetroArc® operation. At 3 months, $n=288$ (95.0%) and at 12 months $n=229$ (75.6%) were assessed. In postoperative objective cure the RetroArc®-procedure was not inferior to TVT® ($p=0.144$). In subjective cure, however, the TVT exact® procedure achieved significant better results (TVT® 76.1%, RetroArc® 54.3%, $p=0.002$). Perioperative complications were in majority voiding difficulties and lower after the TVT exact®-procedure.

Conclusions Retropubic sling procedures are safe and successful to treat female stress urinary incontinence. However, different materials and techniques result in differences between outcomes also experienced surgeons should be aware of.

Keywords Bladder inserter · Cough test · Operative variations · Retropubic sling · Stress urinary incontinence · Tension-free vaginal tape

Introduction

The introduction of the tension-free vaginal tape (TVT), a midurethral sling supporting the urethra in women with stress urinary incontinence (SUI), revolutionized the surgical treatment of this common condition [1]. After 20 years we have good evidence of success rates around 80–90% and the perioperative complications are commonly known [2, 3].

With the introduction of the sling, its inaugurator, Professor Ulmsten, also provided a detailed cook-book-like instruction, which made this operation a standardized procedure [1]. This step-by-step-instruction included an intraoperative cough test to avoid postoperative retention. Another aspect was to reduce iatrogenic injury by emptying the bladder and using urethral inserter during the procedure to lateralize the urethra and bladder.

✉ Juliane Marschke
j.marschke@alexianer.de

1 Department of Urogynecology, German Pelvic Floor Centre, St. Hedwig Hospital, Große Hamburger Strasse 5-11, 10115 Berlin, Germany

2 Department of Women's Health, University Hospital of Tuebingen, Tüebingen, Germany

3 Department of Obstetrics and Gynecology, Helsinki University Hospital, Helsinki, Finland

4 Department of Hygiene and Environmental Medicine, Charité, Universitätsmedizin Berlin, Berlin, Germany

5 Women´s Center Bern, Lindenhofgruppe, Bern, Switzerland

The TVT® (Gynecare, Ethicon Inc., Johnson & Johnson, Somerville, NJ, USA) is at present gold standard of a retropubic midurethral tension-free sling commonly used in women's SUI surgery [4, 5]. Nonetheless, with the overabundance of products and the fast-changing medical product industry it is essential to conduct well-designed clinical studies before integrating new products into the surgeons' portfolio. At the time of our trial design, RetroArc® (AMS, Minnetonka, MN, USA) was available as a retropubic sling with the recommended mesh quality (polypropylene, macroporous) [4, 5]. However, the RetroArc®-sling has a higher elasticity compared to the TVT®-sling, and also the needles are of a different thickness and differ in its covering. These differences in the sling material and variance in the surgical technique may affect the outcomes and thus, should be assessed.

Therefore, the aim of this prospective randomized non-inferiority-trial was to compare RetroArc®-sling to the golden standard TVT regarding their immediate, i.e., perioperative and mid-term outcome. In addition, the surgical procedure with special regards to the benefit of urethral inserter and an empty bladder and its variations was analyzed.

The trial was designed according to the requested standards proposed by IUGA [6].

Materials and methods

This is a prospective randomized controlled non-inferiority trial with three participating centers (Department of Urogynecology, German Pelvic Floor Centre, St. Hedwig Hospital, Berlin, Germany; Department of Women's Health, University Hospital of Tuebingen, Germany; Department of Obstetrics and Gynecology, Helsinki University Hospital, Finland). Women were consecutively enrolled opting for surgical treatment of SUI with a suburethral sling. Recruitment period was 04/2014–01/2016, follow-up visits were scheduled at three and 12 months. Patients were randomized into two groups by closed, non-transparent envelopes in order of recruitment.

All participating surgeons were beyond their learning curve for retropubic slings and familiar with the TVT®-procedure. It was mandatory to have performed five RetroArc®-procedures before participating.

Inclusion criteria were defined as legal age and the ability for an informed consent. SUI had to be diagnosed both clinically (positive cough test) as well as in urodynamic testing. Regarding urodynamics, only patients with pure SUI and a bladder capacity > 300 ml were included. Surgical therapy had to be indicated as defined in national and international guidelines [4, 5].

Women with a clinical and urodynamic diagnoses of overactive bladder syndrome (detrusor contractions during cystometry) were excluded as well as women with pelvic organ prolapse greater or equal POP-Q stage II [7]. A history of any surgical incontinence procedure, radio-, anticoagulation or immunosuppressive therapy was an exclusion criteria as well.

Primary endpoint was the postoperative cure rate (on every follow-up examination), both objective cure, defined by negative cough test with filled bladder and subjective cure, defined by the absence of leakage during physical activity using the UDI-6 questionnaire [8].

Secondary endpoints were patients' satisfaction using a Likert scale and the ICIQ-UI-SF questionnaire [9, 10]. In addition, intra- and postoperative complications such as blood loss, signs of infection, bladder-, urethra or bowel perforation, thromboembolic complications, post void residual volumes and interventions, intraoperative and postoperative pain measured on a Visual Analog Scale (VAS), operating time, and length of hospital stay were evaluated.

Ulmsten used the urethral inserter to push urethra and bladder to the contralateral side for injury protection and described palpation of the urethra for better estimation of urethral length and sling positioning.

TVT exact®-group was operated with an empty bladder, a 18 or 20 Charrière catheter was used with a straight inserter as instructed. Patients randomized into the RetroArc®-group were operated without inserter which can lead to a reduction in catheter size. Bladder was filled (200 ml). Both groups got local infiltration of a mixture of Lidocaine 0.5%/Adrenaline 1:250,000 for hydrodissection up to the retropubic space.

There were variations of operative procedures in the three centers: Helsinki and Tuebingen both performed the operation under local anesthesia to include the intraoperative cough test; Helsinki until just a drop of urine leakage was detectible, Tuebingen placed the sling until there was just no leakage visible. In Berlin majority of patients were operated under general anesthesia, therefore, none of them did the cough test.

The postoperative care also varied within centers. The Finnish study group measured residual volumes after the first time patients went to urinate. Patients were released home with postvoid residual of < 200 ml. In Germany, retropubic sling procedure is an inpatient procedure, patients usually stay one to two nights. To reduce swelling, some patients get a transurethral catheter for 12 h followed by instruction for bladder training and regular check-ups.

Statistical analysis

For power calculations we used a one-sided equivalence test. Success rate of TVT exact® is 90% and we aim to prove non-inferiority of RetroArc®-procedure (significance-level $\alpha = 0.05$) using limit of equivalence of $\delta = 0.10$ (P2 = 80%

is to be tolerated) with 80% power ($\beta = 0.20$); thus, 111 per treatment group was needed.

Based on these assumptions, 140 patients were included in each treatment group, total 280 patients; with a corresponding drop-out rate of 26%. The relative high drop-out rate is due to secondary analysis of the endpoints (success rate with no signs or symptoms of SUI) after surgical procedure. The expected drop-out rate at 1 year after the operation procedure was 10% (123 in each treatment group/arm, 246 total).

Differences and its significances were tested using Fisher's exact *T* test, Chi-square test, *T* test and/or Wilcoxon rank-test (depending on distribution of parameters).

To analyze postoperative cure rates adjusted odds ratios (OR) including logistic regression to consider further confounders were used.

Ethical approval

The study was approved by the local ethical committee (Eth 12/13), the study follows the CONSORT guidelines [11, 12].

Results

A total of 303 women were randomized with 151 in the TVT® arm and 152 in the RetroArc® arm. Table 1 shows centers' distribution. Patient characteristics and preoperative data on subjective and objective SUI are shown in Table 2.

At 3 months and at 12 months $n = 288$ (95.0%) and $n = 229$ (75.6%), respectively, of the data/women were available. Regarding the objective outcome parameters (Table 3) there was a tendency towards favoring the TVT exact®-procedure, however, the differences did not reach significance. The TVT exact® procedure achieved significantly better results in both ICIQ-UI-SF and UDI-6 questionnaires (Table 3).

The complications are shown in Table 4. We found significant less pain on a VAS in patients operated with the RetroArc®-method.

There were no bowel or urethra injury, or postoperative infection or impaired healing. One uncomplicated bladder lesion occurred (RetroArc®-group), without prolonged treatment or hospitalization. Three Patients (TVT exact® $n = 1$, RetroArc® $n = 2$) had retropubic hematoma resulting in surgical revision, one requiring blood transfusion.

Of the Finnish patients, $n = 8$ patients showed > 100 ml residual (27.6%), $n = 19$ patients 100 ml residual. $n = 1$ patient required surgical intervention day 14 after surgery. Patients of the Tuebingen-group showed least postoperative urinary retention, measured the day after surgery ($n = 4$, 3%). Berlin had $n = 26$ (18.7%) patients with postvoid residual > 100 ml, evaluated on day two after surgery.

The RetroArc®-group suffered from outlet obstruction and reoperation in a significant higher number (3.4% reoperation, 17.5% postvoid residual > 100 ml) compared to 6.0% of residual > 100 ml in the TVT®-group. Transient catherisation occurred in $n = 7$ (4.7%) TVT®-group versus $n = 17$ (11.3%) RetroArc®-group ($p = 0.035$).

Intervention for postvoid residual does not influence patients' satisfaction; Table 5 shows descriptive follow-up data of patients after intervention due to urinary retention.

Table 1 Patients' distribution regarding center and surgical technique

$N = 303$ (100%)	TVT®	RetroArc®
	152 (50.2)	151 (49.8)
Tuebingen ($n = 135$, intraoperative cough test: tape adjustment till no leakage)	72	63
Helsinki ($n = 29$, intraoperative cough test: tape adjustment till leakage)	15	14
Berlin ($n = 139$, no intraoperative cough test)	65	74

Table 2 Patient characteristics: preoperative SUI-data (SEST: supine empty stress test)

	TVT®	RetroArc®	*p* value
Age mean (IQR)	51 (43–76)	57 (33–81)	0.014
Parity > 1 *n* (%)	145 (96)	141 (93.4)	0.445
Previous prolapse surgery *n* (%)	32 (21.1)	35 (23.2)	0.656
Current smoker *n* (%)	21 (14)	25 (16.6)	0.53
BMI mean (IQR)	25.4 (22–49)	25.7 (23–27)	0.717
Pre-operative urinary incontinence			
Cough test positive ($N = 303$) *n* (%)	152 (100)	151 (100)	1
SEST positive *n* (%)	106 (70.2)	102 (68.0)	0.68
ICIQ-SF total mean (IQR)	12 (11–14)	12 (11–14)	0.953
UDI-6 total mean (IQR)	16 (14–17)	16 (14–17)	0.308

IQR interquartile range: (25–75%percentile)

Discussion

In this prospective randomized controlled trial, we present data of a large group of women with SUI treated with two different midurethral slings with intraoperative variation in technique. Our results showing after 12 months an objective cure rate of 92% (TVT exact®) and 85.8% (RetroArc®), respectively, are in line with previous data [13].

Interpretation of main findings

Regarding our primary endpoints, there were no statistically significant differences between the RetroArc® and the TVT

Table 3 Summary of objective and subjective results

Parameter	3 months follow-up (N_{max}=288)			12 months follow-up (N_{max}=229)		
	TVT® (N_{max}=144)	RetroArc® (N_{max}=144)	*p* value*	TVT® (N_{max}=113)	RetroArc® (N_{max}=116)	*p* value*
Cough Test positive, % (*n*/*N*)	6.9 (10/144)	13.9 (20/144)	0.054	8.0 (9/112)	14.2 (16/113)	0.144
Objective cure rate, % (*n*/*N*)	93.1 (134/144)	86.1 (124/144)	0.054	92.0 (103/112)	85.8 (97/113)	0.144
UDI-6: "Leakage related to physical activity" ≥ 1, % (*n*/*N*)	13.2 (19/144)	30.6 (44/144)	< 0.001	23.9 (27/113)	45.7 (53/116)	0.001*
Subjective cure rate % (*n*/*N*)	86.8 (125/144)	69.4 (100/144)	< 0.001	76.1 (86/113)	54.3 (63/116)	0.002*
ICIQ-UI-SF total, median (IQR)	0 (0–4)	2.5 (0–7)	0.004[a]	0 (0–5)	4 (0–8)	0.004*[a]
ICIQ-UI-SF: "Leaks when you cough or sneeze", % (*n*/*N*)	4.9 (7/144)	16.0 (23/144)	0.002	10.6 (12/113)	26.7 (31/116)	0.002*
Likert scale ≤ 1, % ("much better") (*n*/*N*)	88.6 (117/132)	81.8 (108/132)	0.117	88.5 (100/113)	79.3 (92/116)	0.059

IQR interquartile range: (25–75%percentile)

**p* value, Chi-square test if no other indicated

Table 4 Perioperative results and complications

Parameter	TVT® (N_{max} = 144)	RetroArc® (N_{max} = 144)	*p* value*
Blood loss 0–50 ml	148	151	0.083
Blood loss 50–200 ml	3	0	0.083
Bladder perforation	0	1	0.315
Retropubic hematoma resulting in surgical revision	1	2	0.51
Post void residual volume (> 60 ml)	22	32	0.119
Sling loosening	1	5	0.97
Suprapubic catheterization	0	3	0.81
Postoperative pain (VAS 0–10)	2 (1–3)	1 (0–2)	0.0117
Operating time	20 (15–23)	20 (15–25)	0.328
Prolonged hospitalization> two nights after surgery	8	18	0.038*

IQR interquartile range: (25–75%percentile); the following adverse events did not occur in this study sample (blood loss > 200 ml, infection, urethral and bowel perforation, thromboembolic complications) (up to two nights is regular hospitalization time after sling procedure in Germany)

**p* value, Chi-square test if no other indicated

[a]Wilcoxon-ranksum test

[b]Fisher's exact test

Table 5 Follow-up data of patients which received immediate intervention for postoperative urinary retention

Parameter	12 months follow-up					
	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Sling loosening	Yes	Yes	Yes	Yes	Yes	Yes
Intermittent suprapubic catheter	No	No	Yes	Yes	No	Yes
Cough test	Negative	Negative	Positive	Negative	Negative	Negative
Postvoidal residual volume	No	Yes (150 ml)	Yes (100 ml)	No	No	No
UDI-6: "Leakage related to physical activity" (1 = no leakage)	1	1	3	1	1	2
ICIQ-UI-SF total	1	0	14	5	0	3
ICIQ-UI-SF: "Leaks when you cough or sneeze"	0	1	1	0	0	1
Likert scale satisfaction (1–10)	1	1	1	1	1	1

exact® group, indicating non-inferiority. However, in the secondary endpoints, the RetroArc® treatment was inferior to the TVT exact® operation.

Our aim was to compare a new product to the well-established golden standard in order to evaluate if a "similar" product would be non-inferior. Furthermore, we wanted to compare the different techniques used with the products. Despite our good experiences with the TVT exact® we were interested in expanding our sling portfolio and furthermore, economical pressure warrant reducing costs.

Even though during the follow-up period RetroArc® was withdrawn from the market [14–16], we believe that our results are important to women that have received the product, as well as for future development of new products.

Complications

Complication rates in both groups were small and are in line with international register-studies indicating that both methods are safe surgical procedures to treat female SUI [17–20].

Retropubic hematoma is a rare but known risk with retropubic sling operation. In our study, retropubic hematoma occured only three times. Although this can potentially be a very serious complication, when detected and dealt with immediately it can be resolved without sequelae [21], as was the situation with our patients. Bladder perforation is a typical learning curve incident ranging up to 20% in the first 50 slings operated [22, 23]. Nonetheless it can be classified similar to retropubic hematoma regarding its lack of long-term effect on quality of life after appropriate and immediate dealing with it [21]. Whilst all surgeons in this trial were very experienced in the TVT exact®-procedure they had not performed as many RetroArc®-slings. This could have had an influence on the bladder lesion that occurred during the first three RetroArc®-procedures performed in the study and thus, highlights the relationship of the learning curve not only to new techniques but also to new products.

Surgical variations

Regarding variations of the surgical technique, the urethral inserter does not seem to have an influence on urethral injury. As described by Ulmsten [1] he is also using the catheter with the inserter to detect the bladder neck region and bring the sling to the correct position. We found this as feasible without inserter just using a blocked catheter. Not using the inserter gives us the opportunity to reduce catheter size, which can be necessary in some patients.

Challenging the cook-book of having an empty bladder being pushed contralateral to prevent lesions showed the feasibility of performing the operation with a filled bladder. We first started to place the devices with a filled bladder after having perforated the bladder. After detection during intraoperative cystoscopy, we would usually replace the device keeping the bladder filled. With the results of this study, we now use this variation in patients having had previous surgery in the retropubic space. This variation can offer protection for bowel perforation.

Despite differences between the two techniques there was no difference in mean operation time. Subjectively (with remarks the surgeons were asked to give) RetroArc®-Kit seemed to be less easy to apply compared to TVT. However, this was likely not clinically relevant since we presume that in general surgeons are familiar with the transvaginal inside-out-technique.

The needles in RetroArc® are of a different design compared to the TVT®/TVT exact®: thicker and the absence of a cover around the metal might result in less friction explaining less postoperative pain.

As described in other publications there are various anaesthetical options, ranging from local anesthesia to regional and general anesthesia [23]. Our data support all available options nonetheless we advise not to use regional (spinal) anesthesia after we had a delayed detection of retropubic hematoma due to the prolonged anesthetic effect.

The difference between both groups in blood loss might be of the same reason as the reduction in pain in the RetroArc®-group, with less friction of the needles, however, with bleeding below 200 ml this finding seems not to be of clinical relevance.

Postoperative voiding dysfunction

The cough test was modified based on clinical experiences (from placing it as tight as no leakage occurred to just a dropwise leakage is detectable) without being revised leading to a greater variety of this former standardized operation technique. Critics state the lack of evidence for this maneuver; surgical condition is not comparable to physical stress in real life. Interestingly, we found the least numbers of postvoid residual occurred when the sling was applied using the cough test until no leakage is detected, opposite to the center which let patients cough to just detect a dropwise leakage, with a high number of (uncomplicated) transient voiding problems. These results show the low predictive value of the intraoperative cough test. We presume the artificial situation of coughing in a supine position in the surgery room is not reflecting day-to-day-life. Kang et al. found a significantly increased urinary retention in their sample when the cough test was used as proposed by Professor Ulmsten [1]. Without the cough test, they reported no cases of post void residual [24].

We analyze and discuss postoperative voiding dysfunction in greater detail, since this complication is handled controversial internationally but is of great interest for the patients` care. Persistent postvoid residual may have a major

impact on quality of life. Surgical intervention for postoperative outlet obstruction was performed in 1.9% of our patients, which is within the range of published numbers: 2.3% Finnish, 1.4% Austrian register study, other reports have up to 7% of persistent voiding dysfunction [25–27].

In both groups most voiding dysfunction resolved without intervention. However, the high number in the RetroArc®-group is concordant to 20% retention during learning curve reported earlier [23].

In addition to the statistical difference it seems of high clinical relevance showing that a new product has a learning curve. It is likely that this influence is not only caused by the technique itself but also by material quality as elasticity and width. Novara et al. found in their meta-analysis a better outcome (parameter: reoperations, voiding difficulties) for transvaginal (inside out) slings compared to pubovaginal slings [21], with our findings it is as likely differences in mesh quality causing the problems as surgical technique. Surgeons should be aware of this fact. Even with fixed criteria for quality of medical devices there seems to be a variety in quality and handling resulting in learning-curve-complications.

This awareness promotes standards for each procedure and avoidance of change to often between different products. It is also promoting collaboration with industry and supporting them with our knowledge and requirements. A standardized approach is not only a protection of complications due to a learning curve but also provides a well-grounded teaching practice.

Since outlet obstruction is a risk of the suburethral sling procedure resulting in reoperation in 1–4% [26] over a period of up to several month of insufficient conservative treatment it is of great interest to determine patients with persistent residual volume better. Ideally this leads to a surgical intervention restoring full bladder emptying earlier.

The national medical system determines the standard of care. The Finnish study group measured residual volumes after 1–2 h after the operation, which has been the first time patients went to urinate. If they were able to urinate with postvoid residual of < 200 ml they were released home. Therefore, there was a high number of measured residual volumes without clinical relevance due to the quite short time interval after the intervention itself. Patients in Germany usually stay over one to two nights. Some of them get a catheter for one night to reduce swelling, followed by a period of bladder training. Others leave the operating room without catheter. In either case, there is still enough time within 24–48 h after surgery to evaluate postvoid residuals. This practice results in less postvoid residual volume measured on day one or two after surgery. In addition, in case there is a significant residual volume, patients requiring further intervention can be detected immediately. In contrast to possible problems caused by a delayed reaction there is the risk of intervene to early having unnecessary procedures. With the presented data we can show that early intervention does not reduce the one year success rate of retropubic slings. Whether or not postsurgical mild voiding difficulties cause longer term problems need to be analyzed further.

Strengths

One of the strengths of this study is its prospective randomized multicenter design, allowing a detailed analysis of primary and secondary endpoints, clearly defined prior to the start. Whereas many studies have reproduced the well-established cure rates suburethral slings can achieve in the treatment of SUI in women, it was the aim of this study, not only to reproduce these cure rates, but also to define the significant value of an alternative product, prior to its inclusion into our SUI treatment portfolio. This should be the common approach for any new product. In addition, since the original step-by-step procedure of the TVT operation [1] has never been reviewed, potential intraoperative variations of the technique were subject to analysis. These variations could be shown to be feasible, allowing the surgeon to include these variations whenever necessary.

Limitations

Nevertheless, several limitations need to be addressed. First, regarding age distribution, even with performing a randomized controlled trial there was a significant difference in the two treatment arms. Women being operated on with the RetroArc® method were significantly older. However, since age is not known to be a relevant risk factor for lower cure rates in the published literature, this difference might be of less clinical relevance. Song et al. could not show any differences in different age groups regarding overall cure rates [28]. Another limitation is the combination of different material and different surgical technique in two arms only. The authors are aware of the fact, that a four-arm design (TVT® with and without filled bladder and inserter vs. RetroArc® with and without filled bladder and inserter) could have eliminated a potential bias. However, we are confident that variation and material can be distinguished in our two-arm design. Finally, even after the RetroArc® being no longer available, there is still a plurality of available and commonly used retropubic slings. Besides the fact that publishing these data goes along with ethical principles of publication processes, this study highlights the importance of critical questioning before expanding or changing the medical device portfolio.

In addition, describing the intraoperative variations can be clearly separated from the withdrawal of one of the products.

Female sexual function and quality of life is of major importance, as described by Elzevier et al. [29]. Unfortunately, we did not specifically ask for these items besides our primary and secondary endpoints. Ongoing and future projects will include both quality of life and female sexual outcome. In addition, clitoral blood flow measurements could have helped to gain more insights in female sexual function after surgery for SUI as described by Matarazzo et al. and Caruso et al. [30, 31].

In summary, the retropubic sling procedure is a safe and successful procedure to treat female stress urinary incontinence. However, there is an influence of different products on the outcome also experienced surgeons must be aware of. Despite this learning-curve-bias which is likely to have influenced this study, we can show that variations of the original cook-book are feasible and may be used if clinically appropriate offering individual treatment options. Whenever new products are developed, their use should be based upon strong evidence rather than business plans. Intra-and postoperative complications are rare and with good standards to handle them still leading to good results.

Acknowledgements The authors acknowledge the initial support by a clinical trial grant from AMS. In addition, all contribution in recruitment is acknowledged.

Author contributions JM: Protocol/project development, data collection or management, data analysis, and manuscript writing/editing. CR: Protocol/project development, data collection or management, and manuscript writing/editing. TSM: Protocol/project development, data collection or management, and manuscript writing/editing. FS: Data collection or management, data analysis, and manuscript editing. RT: Protocol/project development, data collection or management, data analysis, and manuscript writing/editing. MH: Protocol/project development, data collection or management, data analysis, and manuscript writing/editing.

Funding Initially supported by a clinical trial grant from AMS. After having stopped producing mesh products the study continued without funding. AMS was not involved in study setup, design, data acquisition, data analysis, data interpretation or editing of this study.

Compliance with ethical standards

Conflict of interest Juliane Marschke: (speaker honorar) AMS, Astellas. Christl Reisenauer: (speaker honorar) Astellas, AMS, Allergan, Medtronic, Coloplast. Tomi S Mikkola: Unrestricted grant from Contura, speaker for Astellas and Mylan. Ralf Tunn: (speaker honorar) AMS, Astellas, Allergan, Promedon. Markus Huebner: None.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

References

1. Ulmsten U, Henriksson L, Johnson P, Varhos G (1996) An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 7(2):81–85 **(discussion 85–86)**
2. Nilsson CG, Kuuva N, Falconer C, Rezapour M, Ulmsten U (2001) Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 12(Suppl 2):S5–S8
3. Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C (2013) Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 24(8):1265–1269. https://doi.org/10.1007/s00192-013-2090-2
4. Reisenauer C, Muche-Borowski C, Anthuber C, Finas D, Fink T, Gabriel B, Hubner M, Lobodasch K, Naumann G, Peschers U, Petri E, Schwertner-Tiepelmann N, Soeder S, Steigerwald U, Strauss A, Tunn R, Viereck V, Aigmuller T, Kolle D, Kropshofer S, Tamussino K, Kuhn A, Hofner PD, Kirschner-Hermanns R, Oelke M, Schultz-Lampel D, Klingler C, Henscher U, Kowing A, Junginger B (2013) Interdisciplinary S2e guideline for the diagnosis and treatment of stress urinary incontinence in women: short version—AWMF registry no. 015-005, July 2013. Geburtshilfe und Frauenheilkunde 73(9):899–903. 10.1055/s-0033-1350871
5. National Collaborating Centre for Women's and Children's Health (UK): National Institute for Health and Clinical Excellence (NICE) Clinical guidelines (2013) Urinary Incontinence: The Management of Urinary Incontinence in Women. RCOG PMID 25340217
6. Ghoniem G, Stanford E, Kenton K, Achtari C, Goldberg R, Mascarenhas T, Parekh M, Tamussino K, Tosson S, Lose G, Petri E (2008) Evaluation and outcome measures in the treatment of female urinary stress incontinence: International Urogynecological Association (IUGA) guidelines for research and clinical practice. Int Urogynecol J Pelvic Floor Dysfunct 19(1):5–33. https://doi.org/10.1007/s00192-007-0495-5
7. Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P, Shull BL, Smith AR (1996) The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 175(1):10–17
8. Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA (1995) Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. Neurourol Urodyn 14(2):131–139
9. Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P (2004) ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol Urodyn 23(4):322–330. https://doi.org/10.1002/nau.20041
10. Wolfle D, Likert R et al (1949) Standards for appraising psychological research. Am Psychol 4(8):320–328
11. Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P, Group CN (2017) CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update and a consort extension for nonpharmacologic trial abstracts. Ann Intern Med 167(1):40–47. https://doi.org/10.7326/M17-0046
12. Schulz KF, Altman DG, Moher D, Group C (2010) CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. Obstet Gynecol 115(5):1063–1070. https://doi.org/10.1097/AOG.0b013e3181d9d421
13. Lucas MG, Bosch RJ, Burkhard FC, Cruz F, Madden TB, Nambiar AK, Neisius A, de Ridder DJ, Tubaro A, Turner WH,

Pickard RS, Association European, of U, (2012) EAU guidelines on surgical treatment of urinary incontinence. Eur Urol 62(6):1118–1129. https://doi.org/10.1016/j.eururo.2012.09.023
14. Mock S, Angelle J, Reynolds WS, Osborn DJ, Dmochowski RR, Gomelsky A (2015) Contemporary comparison between retropubic midurethral sling and autologous pubovaginal sling for stress urinary incontinence after the FDA advisory notification. Urology 85(2):321–325. https://doi.org/10.1016/j.urology.2014.10.017
15. Mucowski SJ, Jurnalov C, Phelps JY (2010) Use of vaginal mesh in the face of recent FDA warnings and litigation. Am J Obstet Gynecol 203(2):103.e101–103.e104. https://doi.org/10.1016/j.ajog.2010.01.060
16. Reynolds WS, Gold KP, Ni S, Kaufman MR, Dmochowski RR, Penson DF (2013) Immediate effects of the initial FDA notification on the use of surgical mesh for pelvic organ prolapse surgery in medicare beneficiaries. Neurourol Urodyn 32(4):330–335. https://doi.org/10.1002/nau.22318
17. Kuuva N, Nilsson CG (2002) A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand 81(1):72–77
18. McLennan MT, Barr SA, Melick CF, Gavard JA (2012) Bladder perforation during tension-free vaginal tape procedures: abdominal versus vaginal approach. Female Pelvic Med Reconstr Surg 18(1):25–29. https://doi.org/10.1097/SPV.0b013e318240d3f6 **(discussion 29–31)**
19. Tamussino KF, Hanzal E, Kolle D, Ralph G, Riss PA, Austrian Urogynecology Working G (2001) Tension-free vaginal tape operation: results of the Austrian registry. Obstet Gynecol 98(5 Pt 1):732–736
20. Tseng LH, Wang AC, Lin YH, Li SJ, Ko YJ (2005) Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women. Int Urogynecol J Pelvic Floor Dysfunct 16(3):230–235. https://doi.org/10.1007/s00192-004-1248-3
21. Novara G, Artibani W, Barber MD, Chapple CR, Costantini E, Ficarra V, Hilton P, Nilsson CG, Waltregny D (2010) Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol 58(2):218–238. https://doi.org/10.1016/j.eururo.2010.04.022
22. Groutz A, Gordon D, Wolman I, Jaffa AJ, David MP, Lessing JB (2002) Tension-free vaginal tape for stress urinary incontinence: Is there a learning curve? Neurourol Urodyn 21(5):470–472. https://doi.org/10.1002/nau.10056
23. Lebret T, Lugagne PM, Herve JM, Barre P, Orsoni JL, Yonneau L, Saporta F, Botto H (2001) Evaluation of tension-free vaginal tape procedure. Its safety and efficacy in the treatment of female stress urinary incontinence during the learning phase. Eur Urol 40(5):543–547
24. Kang J, Gou X, Zhao QH, He WY, Xiao MZ, Wang M, Deng YZ (2013) Cough test during tension-free vaginal tape procedure in preventing postoperative urinary retention. Adv Urol 2013:797854. https://doi.org/10.1155/2013/797854
25. Glavind K, Glavind E (2007) Treatment of prolonged voiding dysfunction after tension-free vaginal tape procedure. Acta Obstet Gynecol Scand 86(3):357–360. https://doi.org/10.1080/00016340601124227
26. Klutke C, Siegel S, Carlin B, Paszkiewicz E, Kirkemo A, Klutke J (2001) Urinary retention after tension-free vaginal tape procedure: incidence and treatment. Urology 58(5):697–701
27. Rardin CR, Rosenblatt PL, Kohli N, Miklos JR, Heit M, Lucente VR (2002) Release of tension-free vaginal tape for the treatment of refractory postoperative voiding dysfunction. Obstet Gynecol 100(5 Pt 1):898–902
28. Song PH, Kim YD, Kim HT, Lim HS, Hyun CH, Seo JH, Yoo ES, Park CH, Jung HC, Gomelsky A (2009) The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence. BJU Int 104(8):1113–1117. https://doi.org/10.1111/j.1464-410X.2009.08504.x
29. Elzevier HW, Putter H, Delaere KP, Venema PL, Lycklama a Nijeholt AA, Pelger RC (2008) Female sexual function after surgery for stress urinary incontinence: transobturator suburethral tape vs. tension-free vaginal tape obturator. J Sex Med 5(2):400-406. https://doi.org/10.1111/j.1743-6109.2007.00671.x
30. Caruso S, Rugolo S, Bandiera S, Mirabella D, Cavallaro A, Cianci A (2007) Clitoral blood flow changes after surgery for stress urinary incontinence: pilot study on TVT Versus TOT procedures. Urology 70(3):554–557. https://doi.org/10.1016/j.urology.2007.04.045
31. Matarazzo MG, Cianci S, Rampello L, Presti LL, Caruso S (2013) Urethral sphincter innervation and clitoral blood flow after the transobturator (TOT) approach. Int Urogynecol J 24(4):621–625. https://doi.org/10.1007/s00192-012-1891-z