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Patient goals after incontinence procedures: does the single-incision sling satisfy them?

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ABSTRACT

Objective: This study was undertaken to describe short-term postoperative achievement of subjective preoperative goals for single-incision MiniArc slings, in comparison with tension-free vaginal tape (TVT).
Method: Patients submitted to mid-urethral sling (TVT and MiniArc) procedures for stress urinary incontinence (SUI) in two centers were included in this prospective study. Before surgery, the patients completed a preoperative open-ended questionnaire, in which they described their personal outcomes goals for SUI surgery and the degree of severity of their symptoms. At the first postoperative check, they were asked to assess the degree to which their goals had been met and the degree of postoperative incontinence symptoms; their grade of satisfaction was evaluated with IIQ-7, UDI-6 and a 0–10 visual analog scale.
Results: One hundred and eight patients (TVT $n = 51$, MiniArc $n = 57$) were included in this study. Incontinence symptom relief and improvement of quality of life were the most commonly described preoperative goals. Six to eight weeks after surgery, 47 patients (92.1%) after TVT and 53 (92.9%) women after single-incision slings were objectively cured ($P = 1$). After surgery, more than 90% of the patients in both groups achieved their preoperative goals. Symptom scores improved significantly and were comparable in both groups.
Conclusion: Our results show that self-reported achievement of preoperative goals of patients submitted to single-incision slings are comparable at the first follow-up with patients who have undergone the classic mid-urethral sling.

1. Introduction

Patient goals can range from specific symptom relief to general lifestyle improvement. The evaluation of surgical outcomes remains a complex, non-standardized by-product of the opinion of the patient and physician. Patient expectations for surgery may be particularly important when surgery is being performed simply to improve quality of life (QoL).

Usually the surgical success of the mid-urethral sling has been assessed using objective outcome measures and instruments. After surgery for stress urinary incontinence (SUI), however, patient satisfaction is influenced more by the achievement of patient-stated goals than objective improvement [1,2]. For the physician, it is important to know exactly what the patient expectations are in order to plan interventions to achieve those goals.

The MiniArc single-incision sling belongs to the new generation of mid-urethral slings for female SUI: it uses a single-incision vaginal approach and self-fixating anchoring tips in the obturator membrane. The objective cure rate of MiniArc is described in literature at 84–93.5% after 1 year [3–7], and 82–93% after 2 years of follow-up [8–11], comparable with the results of conventional mid-urethral tapes.

Our first aim was to assess if the new generation of mid-urethral sling satisfies the subjective expectations of women undergoing SUI surgery, in comparison with traditional procedures. A secondary aim included determining the patient's view of her surgical experience.

2. Materials and methods

In this dual-center, prospective cohort study, we recruited patients submitted to a tension-free vaginal tape (TVT) and mini-sling (MiniArc) for female SUI between January and October 2008 in the Department of Obstetrics and Gynecology at the University

Abbreviations: TVT, tension-free vaginal tape; IIQ-7, Incontinence Impact Questionnaire short form-7; UDI-6, Urogenital Distress Inventory short form-6; VAS, visual analog scale; QoL, quality of life; SUI, stress urinary incontinence; MUI, mixed urinary incontinence; CST, cough stress test.

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Table 1
Patient questions for preoperative evaluation.

1. Describe your most important goal/expectation from the proposed incontinence operation:

Answer:

2. How do you describe the severity of your urinary incontinence symptoms?

Very severe	Severe	Moderate	Mild	Not severe
☐	☐	☐	☐	☐

in Mainz, Germany, and in the Pelvic Floor Center Hospital in Suhl, Germany. All surgeons had adequate experience in sling surgery. Once a patient gave informed consent to proceed with surgery, she was approached for participation in this trial. There were no changes in the women's routine clinical care, and care during and after surgery was performed according to usual clinical practice.

The following exclusion criteria were considered: urge incontinence, mixed urinary incontinence, neurogenic bladder (multiple sclerosis, meningomyelocele, spinal cord injury), previous incontinence and prolapse surgery, severe mental illness, severe physical handicap, poor knowledge of German language and refused consent.

Preoperatively, the patients were asked to list their personal outcome goals for surgery, which were subsequently classified in three categories: relief of urine leakage symptoms, resumption of sport activity and quality of life improvement. The participants also completed a questionnaire on how they judge the severity of urinary incontinence using a 5-point scale (Table 1).

At the first postoperative check-up (6–8 weeks after surgery), an objective test for SUI is performed: the patient is asked to cough with a full bladder in lying and standing positions. Objective cure of SUI required no urine leakage in both positions. As part of this check, the participants completed the same 5-point scale questionnaire on their personal judgment of the severity of the urinary incontinence. At this point, they reviewed personal goals and finally assessed their goal attainment, describing the degree to which those goals have been met by using a 5-point scale (1 = goal absolutely not achieved, 5 = goal completely achieved).

In addition, they postoperatively completed the short form of the Incontinence Impact Questionnaire 7 (IIQ-7) and Urogenital Distress Inventory 6 (UDI-6), approved tools for the evaluation of quality of life after surgery. The IIQ-7 and UDI-6 were scored according to established protocols. The mean value for all IIQ and UDI items completed (item range 0–3) was calculated.

Women also provided details of their surgical experience: how much pain they felt during the surgery, with a 3-point scale (1 = painful, 2 = moderately painful, 3 = painless); whether they would have the same surgery again. Finally they described their grade of satisfaction with a 100 mm visual analog scale (VAS) [12].

All nomenclature conforms to current standards advocated by the International Continence Society [13].

Age, follow-up period, objective outcomes, intraoperative and peri-operative complications were obtained and analyzed using the Excel program (Microsoft Office Excel 2007). Statistical analysis was performed using GraphPad Prism, version 4.03 for Windows (GraphPad Software, San Diego, CA). Normality testing (D'Agostino and Pearson omnibus normality test) was performed to determine if data were sampled form a Gaussian distribution. The *t* test and Mann–Whitney *U* test were performed to compare continuous parametric and non-parametric variables respectively. The proportion of categorical variables was analyzed for statistical significance by using Fisher's exact test. Statistical significance was considered to have been reached when *P* value was less than 0.05.

Table 2
Patient characteristics and surgical complications.

	TVT ($n=51$)	Single-incision sling ($n=57$)	*P*
Age (years)	52 (34–80)	56 (39–72)	0.67
Follow-up (weeks)	7 (2–6)	6 (3–6)	0.71
Intraoperative complications (n)	0	0	1
Peri-operative complications (n)	2	1	0.6

Table 3
Preoperative patient goals.

	TVT ($n=51$)	Single-incision sling ($n=57$)	*P*
No urinary leakage	30 (58.8%)	35 (61.4%)	0.84
Practicing sport	4 (7.8%)	11 (19.2%)	0.10
Improvement in QoL	15 (29.4%)	11 (19.2%)	0.26

3. Results

One hundred and eight patients were enrolled in this study: 51 women underwent TVT at Mainz University and 57 underwent MiniArc at the Hospital of Suhl. All the incontinence surgeries were performed under local anesthesia and sedation. The two groups are comparable in age, follow-up, intraoperative and peri-operative complications (Table 2). No intraoperative complication (bladder lesion, bleeding >500 ml, nerve lesions) occurred in either group. No conversion to general anesthesia was required. A transurethral catheter was placed postoperatively and removed the day after surgery. Two patients in the TVT group and one patient in the single-incision sling group had residual urine volume >100 ml over 72 h. No cases had prolonged urinary retention requiring sling release.

Incontinence symptom relief and improvement in quality of life were the most commonly described preoperative goals in both groups (Table 3). Most women in both groups preoperatively described their urinary incontinence as very severe/a severe problem (94.1% before the TVT and 94.6% before single-incision sling); 3.9% in the TVT group and 5.2% in the single-incision sling group defined it as moderate; only 1.9% in the TVT group defined it as not a severe problem. Preoperatively, the severity of the urinary incontinence was comparable between the two groups (Table 4).

Forty-seven patients (92.2%) after TVT and 53 (93.0%) women after single-incision slings were objectively cured ($P=1$). Two

Table 4
Preoperative subjective severity of the urinary incontinence.

	TVT ($n=51$)	Single-incision sling ($n=57$)	*P*
Not severe	1 (1.9%)	0	0.47
Mild	0	0	1
Moderate	2	3 (5.2%)	1
Severe	19 (37.2%)	25 (43.8%)	0.55
Very severe	29 (56.8%)	29 (50.8%)	0.19