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# Results of sling surgery in a non-selected population

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## Introduction

Urinary incontinence is a condition that affects women worldwide and reduces quality of life (QoL) (1). Stress urinary incontinence (SUI) is the most common type of urinary incontinence and is described as the involuntary loss of urine on effort or exertion, sneezing, or coughing (2). SUI can be treated either conservatively or surgically. The most common conservative treatment options for SUI include lifestyle changes, pelvic muscle exercises (Kegel exercises), physical therapy, biofeedback therapy, or the use of a pessary (3). If conservative treatment fails, the physician and patient can opt for surgical treatment. The European Association of Urology recommends the use of mid-urethral slings (MUSs) as the initial surgical intervention for women with uncomplicated SUI (grade A recommendation) (4). First- and second-generation MUSs, the tension-free vaginal tape (TVT), tension-free vaginal tape-obturator (TVT-O) and trans-obturator tape (TOT), have led to reported cure rates ranging from 84 to 100%, with few complications after a minimum follow-up of 1 year (5-8).

When considering surgery, patients are provided with brochures that usually describe high success rates with few complications on the basis of previous results. Nevertheless, despite vast research on sling surgery over the past decade, studies often lack sufficiently large and representative populations (9-12). Moreover, objective and subjective definitions of cure and improvement often prove variable, and standardized means of evaluation pre- and post-MUS surgery continue to be optional. The aim of the present study was to evaluate MUS surgery in terms of effectiveness and QoL in a non-selected population, and describe the influence of different coexisting medical conditions on the results of surgery.

## Materials and methods

A retrospective cohort study was performed at the specialized pelvic floor center of the Albert Schweitzer Medical Center, Dordrecht, the Netherlands. Women who underwent sling surgery as a result of symptoms of urinary incontinence that were predominantly or solely associated with SUI between January 1, 2010, and January 31, 2012, and who had completed a preoperative questionnaire were eligible for inclusion. No restrictions were made regarding age, body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters), type of MUS, symptom severity, obstetric or surgical history, or concomitant pelvic organ prolapse (POP). The study protocol was approved by the medical ethics review board of the Albert Schweitzer Hospital, Dordrecht. Participants provided written informed consent.

Before surgery, patients underwent a routine preoperative assessment consisting of a bladder diary, evaluation of urethral mobility and POP, uroflowmetry, a cough stress test, and cystoscopy. As part of the routine preoperative procedure, patients completed a standardized questionnaire. The questionnaire was designed by the Dutch Association for Obstetrics and Gynecology in cooperation with the Dutch Association of Urology to evaluate the impact of urinary incontinence. The questionnaire consisted of an initial QoL scale to evaluate general QoL, the five-dimensional EuroQol instrument (EQ-5D) (13), and a visual analog scale. Subsequent parts evaluated the distress caused by urogenital related symptoms using sections of the Urogenital Distress Inventory (UDI) and the impact of the incontinence on normal daily functioning using the Incontinence Impact Questionnaire (IIQ) (14).

All procedures were performed by one of five experienced pelvic floor surgeons (four gynecologists, one urologist). The slings used were the TVT (Ethicon Gynecare, Cincinnati, OH, USA), TVT-O (Ethicon Gynecare, Cincinnati, OH, USA), TOT (Cousin Inc., Wervicq-Sud,France), and Pelvilace suburethral sling (C. R. Bard Inc., Murray Hill, NJ, USA). The decision regarding which sling to use was made solely on the basis of the physicians' preference and not on patient characteristics. After surgery, a request to use data from the preoperative questionnaire and a postoperative questionnaire were sent to patients by post. The postoperative questionnaires were sent at two points during follow-up (January 2012 and July 2012) to limit differences in time since surgery. In addition to the scales included in the preoperative questionnaire, the postoperative questionnaire included the Patient Global Impression of Improvement (PGI-I) (15). Patients with repeat sling surgery before completion of the postoperative questionnaire or who had died at the time of follow-up were excluded.

For further analysis, the study population was divided into four groups. Patients in group A had no history of either POP or MUS surgery and were solely treated for their SUI; this group was considered to be affected by the fewest confounding variables of the four and was used as the reference group in the later analysis. Patients in group B had a history of POP surgery or vaginal hysterectomy; those in group C had had previous MUS surgery; and those in group D had concomitant POP surgery. Patients could qualify for inclusion in more than one group. The final stage of the analysis evaluated BMI as a possible confounding variable.

Primary outcome measures were the effects of surgery as assessed by the UDI, IIQ, and QoL scales. Patients scoring 0 in the UDI stress symptoms section were considered cured (as recommended by the International Continence Society (16;17)). The subjective improvement or deterioration in symptoms were scored using the PGI-I. If a patient stated her incontinence status as either being "very much improved" or "much improved" after surgery, symptoms were considered improved. The UDI and IIQ were scored using the different subscales as described by van der Vaart et al. (18); outcomes were converted

to a scale from 0–100, with higher values correlating to more severe symptoms. The QoL scale score was converted to a scale from 0–10, with 10 being the highest QoL possible. Statistical analysis was performed using SPSS release 20.0 for Windows (IBM, Armonk, NY, USA). Outcomes were considered significant at the 95% level (P ≤ 0.05).

## Results

Of the 301 women who underwent MUS surgery between January 2010 and January 2012, 255 (84.7%) were included in the present study. Of the 46 patients excluded, 36 had failed to complete the preoperative questionnaire, seven had a second procedure before the postoperative questionnaire was completed, and three were deceased (natural causes). Baseline characteristics are shown in Table 1. No significant differences were found in baseline characteristics between participants and non-participants (data not shown). Among participants, the procedures had been performed under spinal anaesthesia in 109 patients (42.7%) and under general anaesthesia in 146 patients (57.3%).

**Table 1** Patient characteristics (N=255)[a]

| | |
|---|---|
| Age (years) | 53.2 ± 12.1 (27.0-85.8) |
| Body Mass Index[b] | 28.3 ± 6.0 (18.9-62.5) |
| Mixed urine incontinence[c] | 204 (79.4) |
| Concomitant POP surgery (Group D) | 98 (38.4) |
| Vaginal hysterectomy | 5 (2.0) |
| Anterior colporrhaphy | 41 (16.1) |
| Posterior colporrhaphy | 62 (24.3) |
| Sacrospinous fixation | 5 (2.0) |
| Anterior mesh | 5 (2.0) |
| Posterior mesh | 7 (2.7) |
| Manchester fothergill | 1 (0.4) |
| Type of MUS | |
| TVT | 31 (12.2) |
| TVT-O | 55 (21.6) |
| TOT | 158 (62.0) |
| Pelvilace suburethral sling | 11 (4.3) |

Abbreviations: POP, pelvic organ prolapse; MUS, midurethral sling; TVT, tension-freevaginal tape; TVT-O, tension-free vaginal tape-obturator; TOT, trans-obturator tape.
a Values are given as mean ± SD (range) or number (percentage).
b Calculated as weight in kilograms divided by the square of height in meters.
c As described in Urogenital Distress Inventory.

Adverse events were seen in 25 (9.8%) of the 255 patients. Six patients needed surgical release of their sling as a result of evident obstructive micturition (four cases), graft erosion (one case), or serious groin pain (one case). Two cases of perioperative bladder-wall perforation and one case of urethral injury were noted. Postoperatively, a para-urethral abscess was found in one patient, and short-term catheterization because of retention or residual volume was necessary in 15 patients. De novo urge urinary incontinence, as assessed by the relevant section in the UDI, was not noted.

The postoperative questionnaire was completed and returned by 228 (89.4%) patients (although three patients did not complete the PGI-I).The mean time since surgery was 14.9 months (range 2–32). UDI, IIQ, and QoL scores all improved significantly after surgery (Table 2). At the time of follow-up, 158 (69.3%) patients were deemed to have been cured according to the UDI. On the PGI-I, 155 (68.9%) of 225 patients reported that their symptoms were very much or much improved, whereas 70 (31.1%) reported only a slight improvement, no difference, or a deterioration (Table 3).

**Table 2** Pre- and postoperative scores[a]

| | Preoperative N=255 | Postoperative N=228 | P value[b] |
|---|---|---|---|
| Urogenital symptoms related distress (UDI) total[c] | 34.8 ± 16.3 | 14.9 ± 14.1 | <0.001 |
| Discomfort/pain | 34.0 ± 28.8 | 16.2 ± 21.3 | <0.001 |
| Urinary incontinence | 61.9 ± 24.1 | 18.6 ± 24.3 | <0.001 |
| Overactive bladder | 41.5 ± 29.9 | 21.4 ± 25.6 | <0.001 |
| Obstructive micturition | 24.1 ± 27.0 | 17.0 ± 21.9 | <0.001 |
| Genital prolapse | 12.8 ± 22.5 | 2.6 ± 8.7 | <0.001 |
| Impact on everyday functioning (IIQ) total[c] | 30.5 ± 22.0 | 13.4 ± 17.5 | <0.001 |
| Mobility | 37.3 ± 27.8 | 19.7 ± 24.6 | <0.001 |
| Emotional | 33.5 ± 26.3 | 15.4 ± 21.6 | <0.001 |
| Physical | 26.4 ± 28.4 | 9.8 ± 19.1 | <0.001 |
| Social | 18.7 ± 22.6 | 8.7 ± 16.9 | <0.001 |
| Embarrassment | 38.0 ± 29.8 | 15.7 ± 23.4 | <0.001 |
| QoL scale[d] | 4.6 ± 1.1 | 4.8 ± 1.1 | 0.014 |

a: Values are given as mean ± standard deviation. b: Paired-samples t-test for continuous data; Pearson X2 test for categorical data. c: Scaled from 1 (no complaints) to 100 (several complaints). d: Scaled from 1 (very bad) to 6 (excellent).

The next phase of the analysis divided the total study population into four groups. Among the 255 patients, 96 (37.6%) were treated for SUI only and did not have a history of either POP or MUS surgery (group A), 81 (31.8%) had a history of POP surgery (group B), 24 (9.4%) had a second MUS (group C), and 98 (38.4%) underwent concomitant POP surgery (group D).

**Table 3** Outcomes on the UDI and PGI-I scales

| Outcome | No. (%) |
|---|---|
| UDI (n = 228) | |
| Cure | 158 (69.3) |
| Failure | 70 (30.7) |
| PGI-I (n = 225)[a] | 72 (32.0) |
| Very much improved | 83 (36.9) |
| Much improved | 37 (16.4) |
| A little improved | 12 (5.3) |
| No difference | 13 (5.8) |
| A little worse | 4 (1.8) |
| Much worse | 4 (1.8) |
| Very much worse | 4 (1.8) |

Abbreviations: UDI, Urogenital Distress Inventory; PGI-I, Patient Global Impression of Improvement.
a: Three patients failed to complete the PGI-I postoperatively.

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The first sub-analysis compared the group of patients with a history of either POP surgery or hysterectomy (group B) and group A, and showed significantly worse scores regarding both improvement and the UDI score, although cure rates did not differ (Table 4). Compared to patients in group A, those in group B had a higher mean age (59.4 vs 50.5 years; P ≥0.05) and a higher prevalence of pre-existent mixed urinary incontinence (70 [86.4%] of 81 vs 71 [74.0%] of 96; P ≥0.05).

**Table 4** Postoperative outcomes in the four subgroups[a,b]

| Outcome | Group A | Group B | Group C | Group D |
|---|---|---|---|---|
| | (n = 79) | (n = 78) | (n = 22) | (n = 90) |
| UDI total[c] | 11.3 ± 11.1 | 19.3 ± 15.7[d,e] | 23.5 ± 14.7[d,e] | 14.7 ± 13.3 |
| IIQ total[c] | 12.3 ± 17.7 | 17.8 ± 19.5 | 26.9 ± 22.8[d,e] | 13.1 ± 17.0 |
| QoL scale[f] | 4.8 ± 1.1 | 4.6 ± 1.1 | 4.3 ± 1.3 | 4.9 ± 1.0 |
| EQ-5D[g] | 88.0 ± 16.4 | 85.6 ± 18.6 | 82.3 ± 17.5 | 87.7 ± 14.4 |
| VAS[h] | 77.8 ± 16.0 | 75.3 ± 17.3 | 70.5 ± 16.7 | 76.7 ± 14.8 |
| Cure[i] | 56 (70.9) | 49 (62.8) | 8 (36.4)[d,j] | 68 (75.6) |
| Improvement[k] | 57 (74.0) | 44 (57.1)[d,j] | 6 (28.6)[d,j] | 65 (72.2) |

Abbreviations: UDI, Urogenital Distress Inventory; IIQ, Incontinence Impact Question- naire; QoL, Quality of life; EQ-5D, EuroQol-5 Dimensions; VAS, Visual Analog Scale.
a: Values are given as mean ± standard deviation or number (percentage). b: Group A, reference group; group B, patients with a history of prolapse surgery or hysterectomy; group C, patients with previous midurethral sling surgery; group D, patients undergoing concomitant pelvic organ prolapse surgery. c: Scaled from 1 (no complaints) to 100 (a lot of complaints). d: Comparison with group A: P <0.05. e: Independent-samples *t*-test. f: Scaled from 1 (very bad) to 6 (excellent). g: Based on Dutch values: utility score from 1 (very bad) to 100 (excellent). h: Scaled from 1 (very bad) to 100 (excellent). i: Score of 0 on UDI. j: χ2 test. k: Incontinence status "very much improved" or "much improved" according to the PGI-I.

Comparison between groups C (repeat sling surgery) and A showed significantly lower cure and improvement rates in group C (P < 0.001) as well as higher scores on both the UDI (P = 0.018) and IIQ (P = 0.017) (Table 4). Patients in group C were also older (56.1 vs 50.5 years; P = 0.048) and had a higher BMI (30.0 vs 27.6), although the difference was not significant.

The postoperative scores of group D (patients with concomitant POP surgery) showed no significant differences in patient-reported cure and improvement rates when compared with group A (Table 4). Postoperative UDI, IIQ, and QoL scores of Group D did not differ significantly from those of group A (Table 4). No differences in demographics were seen between groups A and D (data not shown).

The final analysis compared patients with regard to BMI, showing that women with a BMI of at least 35 scored significantly worse in several sections of the questionnaire, although the cure rate did not differ significantly (Table 5).

**Table 5** Postoperative outcomes of patients according to BMI[a,b]

| Outcome | BMI <35 | BMI ≥35 | P value[c] |
|---|---|---|---|
| | (n = 189) | (n = 17) | |
| UDI[d] | 12.9 ± 13.1 | 24.0 ± 12.1 | 0.005 |
| IIQ[d] | 12.1 ± 15.6 | 16.7 ± 24.4 | 0.448 |
| QoL scale[e] | 4.8 ± 1.0 | 4.3 ± 1.2 | 0.076 |
| EQ-5D[f] | 89.1 ± 14.1 | 69.7 ± 29.1 | 0.015 |
| VAS[g] | 78.1 ± 15.4 | 66.5 ± 14.8 | 0.008 |
| Cure[h] | 139 (73.5) | 11 (64.7) | 0.409 |
| Improvement[i] | 141 (74.6) | 8 (47.0) | 0.041 |

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); UDI, Urogenital Distress Inventory; IIQ, Incontinence Impact Questionnaire; QoL, Quality of life; EQ-5D, EuroQol-5 Dimensions; VAS, Visual Analog Scale.
a: Values are given as mean ± SD or number (percentage), unless indicated otherwise. b: Patients who underwent secondary midurethral sling surgery were excluded. c: Paired-samples *t*-test for continuous data; Pearson χ2 test for categorical data. d: Scaled from 1 (no complaints) to 100 (a lot of complaints). e:Scaled from 1 (very bad) to 6 (excellent). f: Based on Dutch values: utility score from 1 (very bad) to 100 (excellent). g: Scaled from 1 (very bad) to 100 (excellent). h: Score of 0 on UDI. i: Incontinence status "very much improved" or "much improved" according to the Patient Global Impression of Improvement.

## Discussion

The present study has evaluated MUS surgery in a non-selected population using a combination of standardized, validated questionnaires both before and after surgery.

Overall, approximately 70% of the study population reported positive effects of the intervention (either cure or improvement). Moreover, nearly all incontinence-related symptoms improved after surgery. Subgroup analysis showed multiple differences between the patient groups with and without confounding variables. It was observed that patients with prior sling surgery benefited significantly less from an intervention than did those in the reference group. Moreover, patients with a history of POP surgery showed significantly less improvement postoperatively, although cure rates did not differ. The analysis of patients with concomitant POP surgery showed comparable scores in all outcome parameters postoperatively. Further analysis showed that, although a higher BMI influences improvement rates and several other aspects of SUI postoperatively, it does not have a negative effect on the success of surgery.

The present study found slightly lower cure rates than those described in a meta-analysis by Schimpf et al. (8), which presented subjective cure rates ranging from 43 to 100%. One explanation for the lower cure rates observed is the fact that no restrictions were made regarding age, BMI, type of MUS, symptom severity, obstetric or surgical history, or concomitant POP. Lower cure rates have also been observed in other studies using similar inclusion criteria (10;19). Moreover, cure rates defined by validated subjective measures tend to be lower than those defined by objective measures (20).

In recent years, there has been ongoing discussion regarding whether to combine MUS and POP surgery (21). The present study suggests that simultaneously performing POP and MUS surgery has no negative effect on the outcome in terms of SUI-related symptoms. Several previous studies have described simultaneous POP surgery and MUS placement (21-23). All authors supported the combined procedures, as they provided significant improvements in both urinary symptoms and QoL. In the review by van der Ploeg et al. (21), the authors conclude that combined surgery (POP and MUS) is beneficial and should be considered in women with both POP and SUI, although the number of adverse events could be higher.

The analysis of patients with repeat sling surgery showed that this group performed significantly less than women receiving a primary MUS. Other studies have also observed low success rates after repeat sling surgery (24;25); however, the success rates found in the present investigation are the lowest. This discrepancy could be due to the fact that in the present study women had a higher BMI and age or had genuine urethral sphincter deficiency instead, although this was not specifically analysed.

The European Association of Urology guidelines on the surgical treatment of urinary incontinence (4) indicate that both age and BMI are possible confounding variables determining the success of a surgical intervention. Studies on MUS surgery frequently exclude patients with a BMI of more than 35 because an intervention is expected to be less effective in this group (26;27). This expectation is supported by several parts of the

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present analysis, although not with regard to the success rate; however, because only 17 patients had a BMI of over 35, no conclusions can be drawn.

The main strength of the present study is the use of multiple questionnaires, with a response rate of 89.4% at the time of follow-up. This contributed to an extensive results section in which multiple confounding variables could be analysed separately. The major limitation of the present study was the fact that no objective methods were used to determine the effects of surgery and, although a cough stress test or pad test merely represent a measurement at one point in time, these would have objectified the findings. Future research should therefore include both objective and subjective measurements that should then be analysed separately and in combination. The second limitation is the fact that several types of MUS (TVT, TVT-O, and TOT) and techniques (retropubic and trans-obturator) were used but were not analysed separately. Although this limitation could possibly bias the results, the meta-analysis conducted by Schimpf et al. (8) does recommend either retropubic or obturator slings for cure outcomes. Finally, because the postoperative questionnaires were sent at only two points, the range of time since surgery is large. Although this large range makes results more difficult to interpret, the overall mean follow-up period of 14.9 months should ensure reliable information.

In conclusion, MUS surgery is both efficient and effective in curing SUI. However, the present study shows that patient characteristics and confounding variables can greatly influence the outcome of surgery. The use of multiple validated questionnaires results in a multifaceted database that can then be used by physicians to provide optimal informed consent before MUS surgery.

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