



Patients lost to follow-up after midurethral sling surgery: How are they?

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ABSTRACT

Purpose: To assess the ratio of patients lost to follow-up (FU) after midurethral sling surgery, to evaluate their success rate and current status, and to identify the reasons for FU loss.

Materials and Methods: Two-hundred thirty-eight patients who received trans-obturator tape (TOT) surgery were reviewed. For patients lost to FU within 3 months, Stamey's outcome questionnaire and questions regarding the reasons for FU loss were submitted via phone interview.

Results: One hundred forty-three (60.1%) patients (FU loss group) were lost to FU within 3 months postoperatively. In the FU loss group, phone interviews were conducted with 117 (81.8%) patients. Aside from the urgency rate (59.3% vs. 72.3%, $p=0.049$), there were no significant statistical differences in preoperative profiles between two groups. The success rate of the FU loss group (80.3%, 94 of 117 patients) was lower than that of the FU group (95.8%, 91 of 95 patients) ($p=0.001$). The success rates in the FU loss group with mixed urinary incontinence (MUI) were significantly lower than in the FU group with MUI. As for the reason for FU loss, 74 patients (62.7%) were lost due to incontinence improvement, 19 patients (16.1%) cited personal problems, and 5 patients forgot the next follow-up date. Only 10 patients gave up further treatment despite their persisting incontinence.

Conclusions: In our study, more than half of patients were lost to follow-up after midurethral sling surgery. The FU loss group showed a lower surgical success rate, particularly with MUI. Close FU is recommended for better consultation of patients' incontinence.

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INTRODUCTION

Stress urinary incontinence (SUI) is a widespread problem estimated to affect over 26% of middle-aged women in America and it induces social, sanitary, and psychological problems related to the patients' quality of life (1). Recently, considerable progress has been made toward treatments of SUI stemming from advances in understanding the pathogenesis (2-5). Various new surgical tre-

atments that are safe, convenient, and less invasive have been introduced (6-8). In particular, the mid-urethral sling surgeries (MUSSs) substitute for other previous treatments and have emerged as the new gold standard (9).

The MUSS was initially described as a Tension-free vaginal tape (TVT) procedure by Ulmsten et al. in 1995 (6). Afterwards, the Suprapubic arc (SPARC) and Trans-obturator vaginal tape (TOT) procedures were introduced to lessen the compli-

cations such as bladder or bowel injuries. In less than ten years, these MUSs spread worldwide. Various studies have demonstrated that all types of MUSs have equivocally high long-term treatment rates, as well as low complication rates (10-13).

In clinical practice, however, it has been our empiric observation that a considerable fraction of SUI patients are lost to follow-up after MUSs. Most previous reports have disregarded the results of those lost to regular follow-up (14-17), and there is relatively little information in the literature regarding missing patients after MUSs. We hypothesized that these follow-up loss patients may have different results after MUSs.

To test this hypothesis, we contacted our follow-up loss patients by telephone. We investigated the reasons for follow-up loss and the treatment success rate in these patients.

MATERIALS AND METHODS

A retrospective analysis was conducted of all patients who underwent outside-in type TOT (Monarc®; AMS Inc., MN, USA) by single surgeon (Son H) between January 2003 and December 2008 for SUI. The study group included 238 women with a mean age of 55.8 (± 9.7 , SD) years. The protocol of the current study was approved by the Institutional Review Board of SMG-SNU Boramae Medical Center, Seoul, Korea (IRB No. 06-2009-28).

The operative technique was modified from DeLorme et al. (18, 19). The patients were put in lithotomy position. A vertical midline vaginal incision was made and the peri-urethral tissue was dissected laterally from the incision. Bilateral puncture incisions were made lateral to the ischiopubic ramus. The tunneller was introduced through the skin incision and crossed the obturator membrane. The index finger was placed into the vaginal incision to guide the tunneller. The end of the tape was introduced into the eye of the needle and then pulled through to place it behind the urethra without tension. The vaginal incision was repaired, and the Foley catheter and the vaginal gauze packing were indwelling until the first postoperative day.

Based on follow-up records, patients were divided into two groups: the follow-up loss group

(FU loss group) with loss within 3 months after the surgery and the follow-up group (FU group) with current follow-up. The following preoperative parameters were collected from the clinical records: age, body mass index (BMI), comorbidity, previous gynecologic surgery, symptom duration, symptom severity, International Prostate Symptom Score (IPSS), voiding diary, urinalysis, uroflowmetry (UFM) with post-void residual volume (PVR), 1hr pad test and Q-tip, and urodynamic study findings, including valsalva leak point pressure (VLPP) and cough leak point pressure (CLPP).

The routine interval for follow-up was 1, 3, 6 and 12 months after the surgery. Careful interviews, UFM and PVR measurement were performed in the FU group. Additional telephone interviews were conducted for the FU loss group. The questionnaires used in the phone interview were written at our institute (Table-1). Questionnaires were designed in previous studies to determine the following: the current states of SUI, the reason for follow-up loss, subjective satisfaction, and complications after the surgery in the FU loss group (20-24).

Surgical outcomes were grouped into 3 categories according to the continence grading described by Stamey (25). These were as follow: cure, defined as a no leakage of urine; improvement, defined as minimal leakage without subjective discomfort; and failure, defined as no change in incontinence or with subjective discomfort. Treatment success was defined as the cure or improvement of presenting symptoms by the time of this survey.

The patients' baseline characteristics, preoperative data, and surgery outcomes were compared between the two groups. We also analyzed the reasons for the follow-up loss in the FU loss group by referring to the results of questionnaire. Comparisons between the two groups were made with the Student's t-test or paired t-test for continuous variables, chi-square or Mann-Whitney U test for nominal variables using SPSS® (version 21.0; IBM, NY, USA). All p-values were two-sided with significance considered at $p < 0.05$.

RESULTS

Of the 238 treated patients, 143 (60.1%) were allocated to the FU loss group and 95 (39.9%)

Table 1 - Telephone interview questionnaire for follow-up loss group.

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- 1. Why didn't you return to the hospital after the surgery?**
 - A. Symptom improvement.
 - B. Private problems
 - C. Abandonment of additional treatments
 - D. Others
 - 2. What is your current SUI status after the surgery?**
 - A. No leakage
 - B. Minimal leakage, without subjective discomfort.
 - C. Leakage is decreased, but discomfort.
 - D. No change after the surgery.
 - E. Deterioration after the surgery
 - 3. Do you think the SUI surgery improved your incontinence symptoms?**
 - A. Yes
 - B. No
 - 4. Are you satisfied with the outcomes after the surgery?**
 - A. Yes.
 - B. No.
 - 5. Did you have any other complications after the surgery?**
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to the FU group. Mean time from surgery was 19.6 (± 9.9) months for FU loss group vs. 26.7 6 (± 12.7) for FU group. There were no significant differences between the two groups in baseline characteristics and preoperative findings except in the comorbid urgency rate. The compared parameters included age, BMI, symptom duration, symptom severity, comorbid urgency or urge incontinence, previous surgery, IPSS, preoperative UFM with PVR, 1hr pad test, and urodynamic study findings. Detailed data for the two groups are shown in Table-2.

120 (83.9%) of the 143 FU loss patients were contacted for the telephone interview. Two patients refused to respond, and one patient had died before the interview for reasons unrelated to the TOT procedure. Consequently, 117 patients (81.8%) in the FU loss group were interviewed. The overall treatment success rate in the FU group was 95.8% [91 of 95 patients, "cure" in 78 (82.1%) and "improvement" in 13 (13.7%)]. FU group showed significant improvement of IPSS-total (sum of question 1 to 7; 20.5 vs. 6.9, $p < 0.001$), IPSS-voiding (sum of question 1, 3, 5, and 6; 10.0 vs. 2.5, $p < 0.012$), IPSS-storage (sum of question 2, 4, and 7; 10.5 vs. 2.5, $p < 0.001$), and IPSS-QoL (quality of life question score; 4.8 vs. 1.5, $p < 0.001$), respectively (table was not given). According to the

interview responses from the FU loss group, the success rate was 80.3% [94 of 117 patients, cure in 82 (70.1%) and improvement in 12 (10.2%)]. There was a statistical difference in treatment success rates between the two groups ($p = 0.001$) (Table-3).

The status of SUI could be determined in 212 patients (95 in the FU group, and 117 in the FU loss group). In 204 of the 212 patients, the presence of preoperative urgency and urge incontinence was identified through review of medical records. The 204 identified patients were classified into two subgroups: stress type incontinence and mixed type incontinence. In each subgroup, the treatment success rates for the FU group and the FU loss group were compared. Among the 131 patients in the mixed type incontinence subgroup, there was a significant difference in success rate (95.5% in FU group vs. 76.6% in FU loss group, $p=0.002$). However, among the 73 patients in the stress type incontinence subgroup, there was no statistically significant difference (96.3% in FU group vs. 82.6% in FU loss group, $p=0.086$) (Table-4).

In the FU loss group, the reasons for follow up loss were identified for 118 patients (117 responders plus one deceased person) (Table-5). Seventy-four patients (62.7%) did not follow up

Table 2 - Baseline characteristics and preoperative findings.

	FU loss group	FU group	P*
No. of patients	143	95	-
Mean age (\pm SD, years)	55.8 (\pm 9.6)	55.9 (\pm 9.8)	0.929
BMI (\pm SD, kg/m ²)	25.3 (\pm 3.4)	25.2 (\pm 3.1)	0.800
DM, HTN (%)	44 (30.8%)	37 (38.9%)	0.192
Gynecologic operation (%)	18 (12.6%)	12 (12.6%)	0.992
Symptom duration (\pm SD, months)	56.3 (\pm 56.4)	65.9 (\pm 63.8)	0.250
Median Stamey grade (range)	2 (1-3)	2(1-3)	0.987
Urgency (%)	80 of 135 (59.3%)	68 of 94 (72.3%)	0.042
Urge incontinence (%)	65 of 135 (48.1%)	57 of 94 (60.6%)	0.062
IPSS-total (\pm SD)	15.5 (\pm 9.3)	17.8 (\pm 8.1)	0.464
IPSS-voiding (\pm SD)	7.9 (\pm 6.5)	9.1 (\pm 5.4)	0.193
IPSS-storage (\pm SD)	7.5 (\pm 4.0)	8.7 (\pm 3.8)	0.115
IPSS-QoL (\pm SD)	4.0 (\pm 1.6)	4.2 (\pm 1.3)	0.367
MUCP (\pm SD, cm H ₂ O)	56.5 (\pm 22.9)	52.8 (\pm 21.4)	0.213
MCC (\pm SD, mL)	407.0(\pm 85.3)	384.6 (\pm 100.6)	0.133
VLPP (\pm SD, cm H ₂ O)	85.9 (\pm 32.7)	85.1 (\pm 27.6)	0.838
CLPP (\pm SD, cm H ₂ O)	101.5 (\pm 36.5)	104.1 (\pm 34.0)	0.590
Q-max (\pm SD, mL/sec)	33.5 (\pm 29.2)	31.7 (\pm 19.9)	0.577
Q-tip >30° (%)	59 of 140 (42.1%)	30 of 94 (31.9%)	0.131
1hr Pad test (\pm SD, gm)	48.8 (\pm 58.5)	39.3 (\pm 37.7)	0.152
Voided volume (\pm SD, mL)	228.8 (\pm 102.7)	243.2 (\pm 98.4)	0.278
PVR volume (\pm SD, mL)	21.4 (\pm 63.2)	23.0 (\pm 37.3)	0.825
FBC (\pm SD, mL)	379.9 (\pm 131.7)	380.6 (\pm 136.6)	0.972

FU loss group = follow-up loss group; **FU group** = follow-up group; **BMI** = Body mass index; **IPSS** = International Prostate Symptom Score; **IPSS-total** = sum of question 1 to 7; **IPSS-voiding** = sum of question 1, 3, 5, and 6; **IPSS-storage** = sum of question 2, 4, and 7; **IPSS-QoL** = quality of life question score; **MCC** = maximal cystometric capacity; **VLPP** = valsalva leakage point pressure; **CLPP** = cough leakage point pressure; **Q-max** = peak flow rate on uroflowmetry; **PVR** = volume, post-void residual urine volume; **FBC** = functional bladder capacity; * = by Student's t-test (continuous variable), chi-square test (binary categorical variable), and Mann-Whitney U test (categorical variable more than three)

Table 3 - Outcome of the surgical procedure in two groups.

Outcome	FU loss group	FU group
Cure	82 (70.1%)	78 (82.1%)
Improvement	12 (10.2%)	13 (13.7%)
Failure	23 (19.7%)	4 (4.2%)
Total	117 (100%)	95 (100%)

FU loss group = follow-up loss group; **FU group** = follow-up group

Table 4 - Treatment success rate for the two groups stratified by accompanying symptoms.

	FU loss group	FU group	P
Mixed type incontinence	76.6% (n=64)	95.5% (n=67)	0.002
Stress type incontinence	82.6% (n=46)	96.3% (n=27)	0.086

FU loss group = follow-up loss group; **FU group** = follow-up group

Table 5 - Reasons for follow-up loss after the mid-urethral sling surgery.

Reason	N	Percent
Symptom improvement	74	62.7%
Personal problem	19	16.1%
Abandonment of additional treatment	10	8.5%
Oblivion of the follow-up date	5	4.2%
Death	1	0.8%
Other reasons	9	7.6%
Total	118	100

because of symptom improvement. Other patients were lost due to private matters, including 19 (16.1%) patients with financial or private problems and 10 patients (4.2%) who abandoned additional treatment despite their ongoing incontinence. Five patients (4.2%) forgot the follow-up dates. Among the 117 responders in the FU loss group, 98 patients (83.8%) thought that TOT improved their symptoms, and 85 patients (72.6%) were satisfied with the outcome of the surgery. Two patients (1.7%) experienced de novo urgencies after surgery.

DISCUSSION

This study showed that 60.1% of patients with TOT for SUI were lost to follow-up within 3 months. There are not many reports about follow-up loss after MUSs, but a few studies reported 27 to 31% loss rate within 3 months (26, 27). Ou et al. [28] performed systematic review of 58 prospective SUI surgery series and reported 36% follow-up loss at 36 months after surgery. Our loss rates were higher than those of previous reports. The

cultural differences, the educational and financial statuses of local populations, the differences in the medical systems, and the intensity of follow-up recommendation between clinical studies and real practices could be reasons for the differences in follow-up rates. In real-life practice, stress urinary incontinence is not a life-threatening disease; thus the discrepancy of follow-up compliance may be exaggerated.

Many factors may have influenced the patients who did not follow-up. Symptom improvement after surgery is postulated as the major cause. Indeed, our findings show that 62.7% patients are lost to follow-up because of symptom improvement (Table-5). These results are in close agreement with Ballert et al. (26), suggesting that a substantial portion of patients lost to follow-up were satisfied with treatment and discontinued the planned follow-up by their own decision. In the current study, personal problems such as busyness or financing problems were the second largest (16.7%) causes. However, a considerable fraction of these patients may have experienced symptom improvement. Such improvement might

have promoted the follow-up loss because of their private problems. Even though the number of such cases was low, some patients (4.2%) were lost to follow-up because they had forgotten their next appointment dates. In practice, patients could be reminded of the next follow-up appointment. However, a considerable portion of patients abandoned their further treatment despite their remaining symptoms. Some may have visited other hospitals.

Evidence continues to accumulate indicating that the overall outcomes of MUSs are excellent. In outside-in type TOT, well-designed prospective studies have shown that the treatment success rate is 86% to 94% in up to 4-year follow-up (14-16). However, all these studies reported some fraction of follow-up loss (4% to 14%) and missing data were excluded from the analyses (complete case analysis). However, processing the missing data is a complicated issue. Karl et al.(29) recommended considering the full range of best (all cases are successes) and worst (all cases are failures) scenarios in handling loss of follow-up data. In this manner, Ward et al.(30, 31) reported an extremely broad range of success rates after TVT: 63% to 85% in 2 years and 33% to 82% in 5 years. Ou et al. (28) pointed out that only 7 of 58 SUI prospective studies considered the missing data as failure. This exclusivity of complete case analysis may exaggerate the outcomes of MUSs.

In our analysis, the overall treatment success rate was 95.8% in the FU group (Table-2). This result is consistent with previous TOT series. However, we found a significant difference in the treatment success rates between the FU group and FU loss group, (95.8% vs. 80.3, $p=0.001$). In a previous study, Ballert et al. (26) concluded that there are no significant differences in success rates (follow-up loss vs. follow-up: 73% vs. 81%, $p=0.39$). However, they were only able to contact about two-thirds of follow-up loss patients. We had a higher response rate of follow-up loss patients (81.8%). The results of the present study correspond with the results from Minassian et al.(27), which reported that follow-up loss patients had lower success rates (72.4% vs. 92.4%, $p=0.006$).

SUI subtypes were not considered in previous studies (26, 27). To clarify this point, the patients were classified in two subgroups: mixed

type incontinence and stress type incontinence. In mixed type incontinence, there was a statistically significant difference in success rates between the two groups (95.5 % vs. 76.6%, $p=0.002$). In stress type incontinence, however, there was no significant difference ($p=0.086$). These results are in agreement with those of a previous study reporting that more than half of treatment failure patients in the follow-up loss group had a higher urge score ratio than stress score ratio based on the Medical, Epidemiological and Social Aspects of Aging (MESA) questionnaire [26]. We postulated that, in the FU group, the remnant urgency or urge incontinence after MUS may be settled by additional treatment; on the other hand, in the FU loss group, these supplementary aids were not utilized. With these findings, we suggest that the mixed type incontinence patients need to be followed more closely than simple stress type incontinence patients.

In our experience with the telephone interview with follow-up loss patients, in the event of successful contact, nearly all patients responded well to the survey (98.3% 117 of 119). The merit of the telephone interview is that the current states of follow-up loss patients were determined with ease. We simplified the questionnaires to optimize the response. However, our study design has an important limitation in that the results are dependent on the patients' replies, without any objective findings. Another limitation of the current study is the relatively high rate of follow-up loss. Possible reasons for this higher incidence were mentioned above. The retrospective study is also a pitfall. However, by simplifying the study design, we could identify the current status of most patients who were lost to follow-up after MUS and thus fulfill our initial purpose. Patients lost to follow-up after MUSs are often excluded because of the difficulty in identifying their current status. As a result, there is relatively little information in the literature regarding these follow-up loss patients. Our current study reconsidered these neglected patients. Further long-term and intensive studies are required to assess these follow-up loss patients. Furthermore, the status of FU loss patients must be considered in order to study the long-term outcomes of the MUSs.

CONCLUSIONS

The current study demonstrated that a considerable fraction of patients were lost to follow up 3 months after MUSSs. Moreover, there was a significant difference in treatment success rate, especially between the FU and FU loss groups in the mixed type incontinence subgroup. Based on these findings, we recommend that mixed type incontinence patients should be followed up more closely.

ABBREVIATIONS

SUI = stress urinary incontinence
 MUSS = mid-urethral sling surgery
 SPARC = suprapubic arc
 TOT = trans-obturator vaginal tape
 FU = follow-up
 BMI = body mass index
 UFM = uroflowmetry
 PVR = post-void residual volume
 VLPP = Valsalva leak point pressure
 CLPP = cough leak point pressure
 MESA = Medical, Epidemiological and Social Aspects of Aging

CONFLICT OF INTEREST

None declared.

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