

# Outcomes of Patients Lost to Followup After Mid Urethral Synthetic Slings—Successes or Failures?

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**Purpose:** We classified patients lost to followup after mid urethral synthetic sling placement as examples of treatment success or failure based on the Patient Global Impression of Improvement, and compared the outcomes of those who followed up to the outcomes of those who did not.

**Materials and Methods:** We reviewed the charts of 217 patients who underwent mid urethral synthetic sling placement. Telephone interviews including the Patient Global Impression of Improvement and the Medical, Epidemiological, and Social Aspects of Aging questionnaires were conducted for patients lacking 3-month followup.

**Results:** Based on the Patient Global Impression of Improvement of the 48 patients who responded 13 (27.1%) were failures. The overall failure rate of patients with at least 3-month followup was 19% (23 of 124).

**Conclusions:** In our study success rates for patients lost to followup were similar to the rates for those who had routine followup. However, it is uncertain if these data can be applied to other study populations, especially in a randomized controlled trial.

**Key Words:** urinary incontinence, stress; suburethral slings; outcome assessment

THERE IS NO reliable means to our knowledge of handling missing data when reporting patient outcomes for anti-incontinence procedures. Options for handling missing data include assuming patients lost to followup are failures, assuming they are successes, performing a Last Observation Carried Forward analysis or simply disregarding the patients lost to followup. Performing a last observation carried forward analysis is an appealing option but its use is limited in long-term studies because it does not account for the decrease in cure rates over time. Most studies simply report the data from patients who have complete followup, disregarding the data from those who do not. Analyzing the data in this manner is based on the

assumption that those lost to followup were lost at random and the reason for the lack of followup was not related to outcome. Ward et al analyzed 2 and 5-year data on TVT vs colposuspension using each of these assumptions, and obtained wide ranges of cure rates for both procedures, demonstrating that the assumption made can greatly affect the outcomes reported.<sup>1,2</sup>

We classified treatment outcomes of patients lost to followup after MUSS placement as subjective successes or failures based on the PGI-I, a single question, global, patient reported outcome. We also used the MESA questionnaire and questions regarding complications experienced to determine

## Abbreviations and Acronyms

MESA = Medical, Epidemiological, and Social Aspects of Aging

MUSS = mid urethral synthetic sling

PGI-I = Patient Global Impression of Improvement

RCT = randomized controlled trial

SUI = stress urinary incontinence

TVT = tension-free vaginal tape

UUI = urinary urge incontinence

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Study received institutional review board approval.

Supplementary material for this article can be obtained at <http://urology.med.nyu.edu/node/1031>.

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whether failure was related to recurrent or persistent SUI, UII or complications experienced. Lastly we compared the outcomes of patients who followed up to the outcomes of those who did not.

**METHODS**

Using an institutional review board approved protocol we reviewed the charts of 217 women who underwent placement of a MUSS by the retropubic approach (TVT) or the obturator approach (TVT obturator) for the primary complaint of stress incontinence from December 2001 to July 2007. Patients who underwent concomitant procedures at the time of MUSS placement were not included in the study. Patients with stress predominant mixed urinary incontinence were included in study. Before the procedure patients had a comprehensive history and physical examination as well as a urodynamic evaluation performed according to International Continence Society standards and guidelines.<sup>3</sup> The mid urethral synthetic slings were placed by 2 surgeons at a single academic institution. All patients were instructed to follow up at 1 to 2 weeks, at 3 and 6 months postoperatively, and then annually. Patients were given the PGI-I at the 3 and 6-month followup visits as well as at the annual visits thereafter.

We identified patients who did not follow up at 3 months or beyond and attempted to contact them by telephone. We chose 3 months because this was the appointment at which they were given the initial postoperative PGI-I. We did not give patients the PGI-I at the 1 to 2-week appointment because we believed that it was too early to provide a reliable postoperative assessment. Telephone interviews included the PGI-I and the MESA questionnaire. In addition, patients were asked the reason for not following up, whether or not followup was sought with a different physician, if they experienced any complications and, if so, did the complication resolve and did it require treatment. Telephone interviews were conducted during a 3-month period.

Success was defined by a PGI-I of very much improved or much improved. Those patients reporting outcomes of a little better, no change, a little worse or much worse were classified as having treatment failure. Using data from the MESA questionnaires a total urge score, an urge score ratio (total urge score/18×100), a total stress score and a stress score ratio (total stress score/27×100) were calculated for each patient. Data were recorded and analyzed using JMP® Statistical Analysis Software.

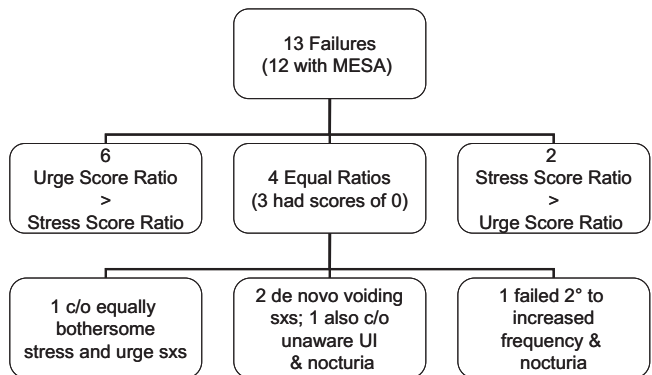
**RESULTS**

Of the 217 women who underwent MUSS there were 73 (34%) who did not return for followup at 3 months or beyond. Mean age of patients lost to followup was 54.3 years. Of the 73 patients lost to followup 50 (68.5%) were able to be reached by telephone. Two patients refused to participate and 2 completed only the PGI-I. Mean age of those who completed the PGI-I was 55.4 years (range 32 to 82) with a mean time from surgery of 30.1 months (range 4.5 to 70).

Based on the PGI-I of the 48 patients who responded 13 (27.1%) had treatment failure (7 of these patients had outcomes of a little better). Mean time from surgery was 32.2 months for cases of treatment failure vs 29.3 months for treatment success. Of the 13 patients in whom treatment was considered a failure 12 completed the MESA questionnaire. Of these patients 6 had a higher MESA urge score ratio than stress score ratio, while only 2 patients had a higher stress score ratio (fig. 1). The stress and urge score ratios were equal in 4 of the patients in whom treatment failed. One patient reported equally bothersome stress and urge symptoms, and 3 had stress and urge score ratios of zero. Of the 3 failures with stress and urge score ratios of zero, 1 reported worsening frequency and nocturia after MUSS, and 2 reported de novo voiding symptoms. One of the patients with de novo voiding symptoms also complained of unaware incontinence and nocturia.

The most common reason cited for not returning for followup among the 48 patients contacted was that the patient was satisfied and did not believe she needed to follow up (fig. 2, A). When only analyzing patients with treatment failure the most common reason cited for not following up was dissatisfaction (fig. 2, B). Of those patients who did not follow up at our institution 18% sought followup elsewhere. Only 4 of the women contacted reported a specific complication. One patient with treatment success reported an uncomplicated urinary tract infection. One patient with treatment failure reported de novo voiding symptoms, and 2 of the patients in whom treatment failed reported postoperative urinary retention. Of these 2 patients 1 with urinary retention required loosening of the MUSS after which SUI recurred, while the other reported persistent voiding symptoms as well as unaware incontinence and nocturia.

Of the initial 217 charts reviewed 144 patients had at least 3 months of followup. Mean patient age was 60.5 years (range 21 to 88) and mean followup



**Figure 1.** Treatment failures stratified by urge and stress score ratios. c/o, complained of. sx's, symptoms. UI, urinary incontinence.

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