

PATIENTS LOST TO FOLLOW-UP IN LEVEL I/II EVIDENCE-BASED STUDIES IN THE SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN: THE ELEPHANT IN THE ROOM!

Hypothesis / aims of study

Stress urinary incontinence (SUI) is a common condition affecting up to 30% of women. A large amount of publications report optimistic outcomes after different incontinence surgeries. One harsh reality that should not be overlooked when reviewing these results is that lost data are seldom considered in the final analysis. To evaluate the significance of this outcome bias, a literature review of high-level (I/II) evidence-based publications was conducted to determine the percentage of patients lost to follow-up (LTF) after anti-incontinence surgeries.

Study design, materials and methods

Publications on the surgical treatment of SUI in women from January 1995 to November 2009 were searched on PUBMED. Keywords included "stress urinary incontinence", "treatment", "randomized clinical trial", and "prospective study". Inclusion criteria were randomized clinical trials (level I) or non-randomized but prospective studies (level II) related to anti-incontinence surgeries. Data reviewed included type of study, number of participating centers or hospitals, sample size, surgical technique, power calculations, estimated dropout rate, duration of follow-up, rate and reasons of LTF. Surgical techniques included TVT, SPARC, TOT, sling procedures, Burch urethropexy, MMK and laparoscopic colposuspension.

Results

Of 664 publications, 71 articles (11007 women) met the inclusion criteria, with 47 randomized clinical trials and 24 non-randomized prospective studies. Twenty of the 71 trials resulted from multi-center cooperation (3 from 2 centers, 7 from 3 centers, 2 from 4 centers, 1 from 5 centers, 1 from 6 centers, 4 from 7 centers, 1 from 12 centers, and 1 from 14 centers). Mean patient sample size was 155 (range: 20-913). Thirty-three articles gave details on sample size calculations, and 20 reported on their dropout rate. Mean length of follow-up was 24.7 months (range: 1.5-192). Percentages of LTF patients were 8.1% (587/7213) at or less than 12 months in 58 articles, 28.1% (813/2890) at 24 months in 13 articles, 35.7% (248/694) at 36 months in 5 articles, 32.9% (233/708) at 36-60 months in 5 articles and 32.4% (722/2227) at or more than 60 months in the remaining 10 articles. Only 16 articles provided some specific reasons for lost to follow-up (e.g. relocation, travel, death, working duty or even decline) and this information came from reaching the LTF patients by mail or telephone. Some patients, although not LTF, returned for scheduled visits but provided incomplete data (9 articles). Only 4 articles defined the LTF patients as treatment failure and reported outcomes accordingly. The rest of the articles simply drew conclusions without considering the effect of lost data.

Interpretation of results

This extensive review of the best evidence-based literature in the surgical treatment of SUI in women indicates that the LTF problem increases with duration of follow-up (range 28-34% LTF at 2-5 years post-operatively). Although such a high drop-out rate can induce serious conclusion flaws, few articles address this issue (16/71). In addition, some authors reached patients at the scheduled follow-up, but incomplete data was gathered during the visit, thus further compromising the conclusions. Far more concerning is that many articles did not take the LTF data into consideration despite adequate sample size calculation.

Concluding message

According to this contemporary literature review, we found that the longer the follow-up, the worse the attrition and the softer the conclusions on the leftover patient population in each study. Furthermore, a minority of reports (4/71) treated the LTF data as failures and made appropriate adjustments to avoid this bias. Remedial options include better adherence to the CONSORT guidelines, designing more effective patient retention tools for studies on quality of life conditions such as urinary incontinence, and methodological statistical consensus in reporting LTF to achieve a more realistic estimate of surgical outcome results.

<i>Specify source of funding or grant</i>	None
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	NONE