Comparison of retropubic vs transobturator approach to midurethral slings: a systematic review and meta-analysis

CRD summary
The authors concluded that the transobturator approach is associated with a lower risk of complications than the retropubic approach to midurethral slings for stress incontinence, but there was insufficient evidence to compare the effects on other outcomes. The evidence appears to support this conclusion. However, limitations of the review make it difficult to determine the reliability of the results.

Authors' objectives
To compare the retropubic (RP) and transobturator (TO) approach to midurethral slings for the treatment of stress incontinence.

Searching
PubMed, Ovid, EMBASE, CINAHL, POPLINE, Web of Science, the Cochrane Library, DARE, TRIP, Global Health, ClinicalTrials.gov and CRISP were searched from 1990 to April 2006; the search terms were reported. In addition, reference lists of selected studies, reviews and texts and abstracts from meetings of four relevant named societies were screened, and experts in the field contacted. No language restrictions were applied to the searches.

Study selection
Comparative studies with clearly defined follow-up times were eligible for inclusion in the review. The duration of follow-up in the included studies ranged from 1 to 15 months.

Specific interventions included in the review
Studies that compared the RP and TO approach to midurethral polypropylene slings were eligible for inclusion in the review. The included studies evaluated a variety of different types of devices (details were reported).

Participants included in the review
Studies of patients with stress incontinence were eligible for inclusion in the review. All participants in the included studies were female. Some studies were in women with either stress or mixed incontinence.

Outcomes assessed in the review
Studies that assessed and clearly defined objective and/or subjective outcome measures were eligible for inclusion. The review assessed the following outcomes: cough stress test, objective failure, subjective success (defined as dry or improved), subjective failure (defined as unchanged or worse), quality of life, peri-operative complications, post-operative de novo irritative voiding symptoms and voiding dysfunction requiring reoperation.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The studies were apparently assessed for blinding. The authors did not state how the validity assessment was performed.

Data extraction
Two reviewers independently extracted the data. Any discrepancies were identified by a third reviewer and were resolved by consensus between the three reviewers. Data on the outcomes of interest were extracted, and odds ratios (ORs) either extracted or calculated.

Methods of synthesis
How were the studies combined?
The studies were grouped by study design (RCT or cohort) and outcome measure, and pooled using the random-effects model of DerSimonian and Laird where sufficient data on similar outcome measures were available and in a narrative synthesis otherwise. Pooled ORs with 95% confidence intervals (CIs) were calculated. Publication bias was assessed using a funnel plot and tested using the Begg and Egger test. Characteristics of additional trials that would be required to change the review findings were determined (details were reported).

How were differences between studies investigated?
Statistical heterogeneity was assessed using the Cochran Q statistic. Sensitivity analysis were conducted by excluding studies with short-term (less than 1 year) follow-up; changing event counts in each treatment arm; after omitting each study in turn; and using a different definition for subjective failure. There were insufficient data to undertake the planned subgroup analyses for women with mixed incontinence and women with intrinsic sphincter deficiency.

Results of the review
Eighteen studies (n=2,591) were included: 6 randomised controlled trials (RCTs; n=492) and 12 studies reporting 11 cohorts (n=2,099).

One RCT reported blinding of the patients and outcome assessors.

Objective outcomes.

One RCT assessed the results from a cough stress test; the results were not reported in the review. In cohort studies, objective failure (defined variously) was reported in 12.8% of women in the TO group and 13.7% of women in the RP group (based on 4 cohort studies, n=860).

Subjective outcomes.

There was no statistically significant difference in the risk of subjective failure between women in the TO and RP groups when using data from RCTs or cohort studies: OR 0.85 (95% CI: 0.38, 1.92; 5 RCTs) and OR 0.73 (95% CI: 0.38, 1.4; 8 cohort studies), respectively. Two RCTs reported improvement in quality of life scores post-operatively in both treatment groups. Three cohort studies assessed quality of life using validated measures. Two studies reported similar rates of post-operative improvement in both treatment groups and one reported 90% of all patients improved.

Peri-operative complications.

Complications were significantly less common among women in the TO group than among those in the RP group when using data from RCTs or cohort studies: 0.8% (2 out of 241) versus 12.2% (30 out of 246), OR 0.40 (95% CI: 0.19, 0.83; 6 RCTs) and 0.8% (7 out of 830) versus 5.5% (56 out of 1,024), OR 0.21 (95% CI: 0.10, 0.44; 10 cohort studies), respectively. For all studies combined, the most common complications were bladder perforation (3.5% in RP group versus 0.2% in TO group), haematoma (1.6% in RP group versus 0.08% in TO group) and infection (less than 1% in both groups).

De novo irritative voiding symptoms.

When using data from RCTs, there was no statistically significant difference in de novo irritative voiding symptoms between women in the TO and the RP groups (OR 0.54, 95% CI: 0.26, 1.1; 5 RCTs). When using data from cohort studies, de novo irritative voiding symptoms were significantly less common among women in the TO group than among those in the RP group (OR 0.44, 95% CI: 0.24, 0.80; 8 cohort studies).

Voiding dysfunction requiring reoperation.

One RCT and 6 cohort studies assessed this outcome. The authors stated that, overall, this outcome was rare and there were insufficient data for pooling.

The findings were robust to the sensitivity analyses, and there was no evidence of either statistical heterogeneity or
publication bias in any of the analyses.

**Authors' conclusions**
The TO approach is associated with a lower risk of complications than the RP approach to midurethral slings for the treatment of stress incontinence, but there was insufficient evidence to compare the effect of surgical approaches on objective and subjective outcomes.

**CRD commentary**
The review addressed a clear question that was defined in terms of the intervention, participants, outcomes and study design; inclusion criteria for the outcomes and study design were broad. The strategy undertaken to identify studies was extensive and no language restrictions were applied to the search. The authors stated that only published data were included, which raises the potential for publication bias; however, no evidence of it was found. Methods were used to minimise reviewer errors and bias in the extraction of data, but it was unclear whether similar steps were taken in the selection of studies or assessment of blinding. The validity assessment, being apparently limited to the blinding of RCTs, was inadequate and this makes it difficult to determine the reliability of the evidence presented. The methods used to combine the studies appear appropriate, and limitations of the review and the evidence were discussed. The evidence appears to support the authors’ conclusion, but incomplete reporting of review methods and an inadequate assessment of study quality make it difficult to determine the reliability of the results.

**Implications of the review for practice and research**
*Practice:* The authors did not state any implications for practice.

*Research:* The authors stated that good-quality trials are needed to compare RP and TO approaches to midurethral slings for the treatment of stress incontinence. Future studies should report manufacturers’ information; assess long- and short-term outcomes separately, including an assessment of long-term mesh erosion; use clearly defined and standardised objective and subjective outcome measures; and systematically assess post-operative complications.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.