

# OHTAC Recommendation: Midurethral Slings for Women with Stress Urinary Incontinence

Ontario Health Technology Advisory Committee

Revised January 2013 (Original Recommendation February 2006)

# Background

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The Ontario Health Technology Advisory Committee (OHTAC) met on February 21, 2006, and reviewed the effectiveness of midurethral slings for women with stress urinary incontinence (SUI). This report began as an update of a previous review, completed in February 2004 by the Medical Advisory Secretariat (the predecessor of Health Quality Ontario) on tension-free vaginal tape (TVT). As part of the recommendations for the TVT review, guidelines on the most appropriate use of TVT were to be developed. Since completion of the TVT review, many other midurethral slings have become available, and it was decided to conduct a review of all available midurethral slings, rather than TVT alone, to develop the guidelines.

## OHTAC Findings

The midurethral sling procedure is a minimally invasive procedure that is highly effective at reducing the symptoms associated with stress urinary incontinence (SUI) in women who have failed conservative treatments such as pelvic floor muscle therapy and behaviour modification.

There are over 15 different midurethral slings licensed by Health Canada. However, not all have been reported on in high-quality trials in peer-reviewed journals. Seven randomized controlled trials (RCTs) were identified. These compared midurethral slings to colposuspension (open or laparoscopic), which has historically been the gold standard surgical intervention for SUI.

Based on the results of these 7 RCTs, which all had consistent results, midurethral slings appear to be as effective as open colposuspension and more effective than laparoscopic colposuspension. The time required to insert a midurethral sling is significantly shorter than that required for colposuspension. In addition, the midurethral sling procedure is an outpatient procedure in Ontario, while colposuspension is an inpatient procedure. The cost of the midurethral sling procedure is about \$2,600 including professional fees, hospital costs, and the cost of the device. Colposuspension costs approximately \$3,700.

In addition, there does not appear to be one type of midurethral sling that is superior to another in terms of effectiveness for patients or hospital outcomes (procedure time and length of stay). However, since the RCTs contained too few subjects to definitively exclude the possibility that one type was superior to another, it is unclear at this time if there are substantial differences in effectiveness between devices.

There may be differences between the types of midurethral slings in terms of complication rates, although it is difficult to fully assess because of their novelty. The suprapubic and retropubic route slings have a rate of bladder perforation of 5% to 6%. The transobturator route slings have a rate of bladder perforation of less than 1% and a rate of accidental vaginal perforation of approximately 1%. However, according to a clinical expert in Ontario the perforations are minor complications that heal naturally without any intervention. If a bladder perforation is recognized at the time of the procedure, it can be managed by repositioning the needle—without any long-term consequence. However, if unrecognized at the time of the procedure, a perforation with the sling mesh still in the bladder can cause more serious complications, including pain.

The rate of device problems is about 1% to 6% across the sling types. These estimates of complications are based on those reported in the RCTs and are limited by the detail of complications each study reported.

The incidence of pain is unknown, though pain can be a long-term complication. Treatment of the cause of pain can be simple and effective in some situations, whereas in others it may be more complicated. Expert opinion indicates that simple solutions include a course of pain medication, local injection of local anesthetic, or the application of local vaginal estrogens. More complex solutions include attempts to remove the mesh, which may be difficult or impossible, and referrals to pain-management services for more aggressive approaches to pain control.

Conversely, there is a significantly higher reoperation rate in women undergoing colposuspension compared to the sling procedure (Table 1).

**Table 1. Summary Table of Complications Associated with Midurethral Slings and Colposuspension**

Complication	Number of RCTs, N (Number of subjects, N)	Odds Ratio (95% CI)	Summary
Bladder / vaginal perforation	6 (653)	5.35 (2.27–12.63)	Significantly higher rate in slings
Hematoma	4 (533)	1.16 (0.37–3.66)	No significant difference
Urinary tract infection	5 (650)	1.65 (0.72–3.81)	No significant difference
Storage LUTS	7 (768)	1.31 (0.90–1.90)	No significant difference
Voiding LUTS	8 (812)	0.81 (0.54–1.22)	No significant difference
Reoperation	2 (416)	0.29 (0.10–0.80)	Significantly higher in colposuspension

Abbreviations: CI, confidence interval; LUTS, lower urinary tract symptoms; RCT, randomized control trial.

Source: Novara et al, 2008

# Conclusions

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There is high-quality evidence that the midurethral sling procedure is a minimally invasive procedure that is effective at reducing the symptoms associated with stress urinary incontinence (SUI) in women. However, despite good short-term results, the long-term implications of the slings ( > 20 years) are unknown.

Based on evidence from a high-quality systematic review, there is a significantly higher rate of bladder perforations in women undergoing midurethral sling procedures compared to colposuspension, and conversely, there is a significantly higher reoperation rate in women undergoing colposuspension compared to the sling procedure.

# OHTAC Recommendations

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## Original 2006 OHTAC Recommendation:

- Explore the introduction of unique Canadian Classification of Health Interventions (CCI) codes so that midurethral slings can be tracked according to retropubic and transobturator routes through administrative databases—to assess, in particular, variation in complication rates (*Note: new CCI codes were added in 2006 to track management and removal of the midurethral slings*)

## Update 2013:

- Please note the Notice to Hospitals from Health Canada ([http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/\\_2010/surgical-mesh\\_nth-aah-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2010/surgical-mesh_nth-aah-eng.php)) that highlights the need for physicians to: 1) review warnings on devices; 2) inform patients of adverse events; 3) watch for signs of intraoperative and postoperative complications; and 4) maintain training for procedure and management of complications.