

# Midurethral Minimally Invasive Sling Procedures for Stress Urinary Incontinence

This technical update was prepared by the Sub-Committee on Urogynaecology and approved by the Executive of the Society of Obstetricians and Gynaecologists of Canada.

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Disclosure statements have been received from all members of the committee.

to the guidelines developed by the Canadian Task Force on Preventive Health Care.

**Values:** This update is the consensus of the Sub-Committee on Urogynaecology of the Society of Obstetricians and Gynaecologists of Canada.

**Benefits, Harms, and Costs:** Counselling for the surgical management of urinary incontinence should consider all benefits, harms, and costs of the surgical options.

## Recommendations

1. Tension-free vaginal tape can be offered as an alternative of equal efficacy to the Burch procedure for the surgical management of stress urinary incontinence. (I-A)
2. Transobturator tape can be offered as an alternative to tension-free vaginal tape that eliminates the risks of intra-abdominal organ injury. It should be offered with the proviso that its long-term effectiveness and safety relative to tension-free vaginal tape remain to be determined. (II-B)
3. Midurethral sling procedures performed through a single suburethral incision should be used only in the setting of a clinical trial until their effectiveness and safety are proven. (III-C)
4. Despite the suggested simplicity of pre-packaged surgical kits for midurethral procedures, specific training is recommended prior to performing any of these surgical procedures. (III-C)

**Validation:** This technical update has been approved by the Subcommittee on Urogynaecology and Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

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## INTRODUCTION

Over 200 surgical procedures to treat stress urinary incontinence have been reported in the medical literature.<sup>1</sup> With the advent of the TVT surgical kit there has been a shift in practice towards more minimally invasive procedures. Previously, the Burch procedure was offered to patients with stress urinary incontinence as the gold standard primary procedure. When compared with the outpatient minimally invasive procedures, the Burch has the obvious drawbacks of an abdominal incision and a hospital stay. Laparoscopic Burch repair has demonstrated high subjective cure rates, but objective cure varies. Success with

## Abstract

**Objective:** To provide an update on currently used minimally invasive surgical treatments for stress urinary incontinence in women: tension-free vaginal tape (TVT) procedure, transobturator tape (TOT) procedure, and other midurethral sling devices.

**Options:** The discussion is limited to minimally invasive surgical management of stress urinary incontinence in women.

**Evidence:** A search of PubMed and Cochrane library for articles published in English before the end of February 2008 identified the most relevant literature. Recommendations were made according

**Key Words:** Urinary incontinence TVT, TOT, midurethral sling

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**Table 1. Long-term outcomes of the TVT procedure**

Author	N	Patient group	Duration of follow-up (years)	Treatment outcomes (subjective/objective) % cured
Rezapour et al. <sup>13</sup>	34	Recurrent SUI	4	82
Rezapour et al. <sup>14</sup>	80	Mixed UI	4	85
Rezapour et al. <sup>15</sup>	49	Intrinsic sphincter deficiency	4	74
Deffieux et al. <sup>16</sup>	51	SUI	6.9	80
Nilsson et al. <sup>12</sup>	80	SUI	7	81.3
Moran et al. <sup>17</sup>	40	genuine SUI	2	95

laparoscopic Burch repairs is very dependent upon the surgeon's experience and surgical technique.<sup>2</sup> Because of shorter operating room time and greater simplicity, the midurethral slings have supplanted the laparoscopic Burch as the preferred minimally invasive procedure.

The TVT procedure developed by Ulmsten et al. in the early 1990s, a midurethral sling, has been shown to have long-term effectiveness and equivalent efficacy of TVT to Burch.<sup>3-5</sup> Studies have shown TVT to be a safe and effective surgical procedure for managing female stress urinary incontinence.

The transobturator approach to midurethral slings was developed in 2001<sup>6</sup> with the following proposed advantages:

- It avoids the retropubic area, thus decreasing the risk of bowel perforation and vascular injury.
- It requires less operating room time.
- It is believed to mimic the natural support system in the pelvic floor better than the TVT.<sup>6</sup>

In 2006, a surgical device requiring only one suburethral incision was introduced.<sup>7</sup> Its purported advantages over existing midurethral procedures were the following:

- Complications associated with suprapubic and groin incisions will be eliminated.
- Cystoscopy will not be necessary.
- Operating room time will be shorter than with other midurethral sling techniques.

There is insufficient evidence to permit an evaluation of the advantages of outside-in versus inside-out transobturator routes, as long-term studies with significant results have yet

to be published. Both TVT and TOT surgeries are minimally invasive, both have specialized instrumentation, both minimize morbidity, and both reduce costs and recovery time.

### **TVT PROCEDURE**

TVT is a minimally invasive midurethral sling that is passed through the retropubic space and that was designed to replace functionally deficient pubourethral ligaments.<sup>8,9</sup> The TVT kit consists of two curved stainless steel needles attached to a prolene mesh sling sheathed in plastic, a detachable handle to facilitate retropubic passage of the needles, and a guide to make a Foley catheter rigid. Variations include needles designed to be passed from the suprapubic incisions into the vaginal incision, where the tape is picked up and passed through the space of Retzius. Three small incisions are made: two suprapubic and one on the anterior vaginal wall at the midurethra. The TVT needles are then passed from the vagina through retropubic space, exiting through the suprapubic incisions. Cystoscopy is performed to ensure there have been no bladder perforations. The tape is adjusted to an appropriate snugness. Excess sling is then trimmed and the incisions closed with sutures. Originally, the TVT procedure was performed using local anaesthesia, with the woman in the lithotomy position, to allow for intraoperative cough testing. Recent literature has shown that the type of anaesthesia and the use of the cough test do not affect postoperative voiding function or surgical success.<sup>10,11</sup>

### **TVT outcomes**

There is now a significant body of literature showing the success of TVT for the treatment of stress urinary incontinence.

A number of prospective observational trials have been conducted to evaluate the effectiveness of the TVT procedure (Table 1).<sup>12-17</sup> The results of this procedure for the treatment of primary stress incontinence and mixed

### **ABBREVIATIONS**

TOT	transobturator tape
TVT	tension-free vaginal tape

**Table 2. TVT complications**

Author	N	Bladder perforations (%)	Postop voiding difficulty (%)	Postop urge (%)	Vascular injuries (%)	Urethral erosion (%)	Vaginal erosion (%)	Postop infection (%)	Nerve damage (%)
Huang et al. <sup>20</sup>	106	2	11	10	–	–	–	–	–
Azam et al. <sup>21</sup>	67	19	–	–	–	–	–	–	–
Neuman <sup>22</sup>	75	8	5	–	4 (intraop)	–	–	2.7	–
Karram et al. <sup>23</sup>	350	4.9	4.9	–	0.9 (major bleed)	0.9	10.9	0.9	1.7

**Table 3. TOT cure rates**

Author	N	Patient group	Duration of follow-up	Treatment outcomes (% cured)
Giberti et al. <sup>33</sup>	108	stress urinary incontinence due to urethral hypermobility	2 years	80
Cindolo et al. <sup>34</sup>	80	stress urinary incontinence with urethral hypermobility	4 months	92
Roumeguere et al. <sup>35</sup>	120	Urodynamic stress	1 year	80
Waltregny et al. <sup>36</sup>	91		3 year	88

incontinence are comparable to the published results for both the Burch and the pubovaginal sling.<sup>18</sup> For patients with recurrent incontinence, the results are similar<sup>13</sup> to those achieved with a primary procedure; for those with a fixed urethrovesical junction, the outcome is poor, as it is with other surgical procedures.<sup>15,19</sup> A prospective study comparing the TVT procedure with the open Burch procedure has found after two-year follow-up that the effectiveness of the two procedures is almost the same (TVT: 81%; Burch: 80%).<sup>3</sup> Holmgren conducted a long-term study, published in 2005, concluding that initial cure rates of TVT were good for mixed incontinence but did not persist after four years.<sup>4</sup>

**Complications of TVT**

Concerns about the safety of retropubic midurethral slings have been prompted by a growing number of case reports of complications, including injury to the bowel, major vessels, and bladder, and urethral perforation.

Complications with retropubic slings include bleeding, hematoma, erosion of the mesh into the urethra or vagina, bladder perforation, de novo urge symptoms, voiding dysfunction, and infection (Table 2).<sup>20–23</sup> Rarer case reports include delayed bowel erosion, bowel injury, bowel obstruction, urethral diverticulum, vesical calculi, paraurethral abscess, necrotizing fasciitis, fistulas, urethral erosions, and nerve damage.<sup>24–29</sup> However, Ammendrup et al. note that TVT procedure complication rates are low, with very few serious complications.<sup>30</sup> Azam et al. note that an excellent three-dimensional working knowledge of the retropubic area is vital for a safe performance of the TVT.<sup>21</sup> Further long-term prospective studies evaluating TVT outcomes still need to be conducted.

**TOT PROCEDURE**

The TOT procedure is performed under general or regional anaesthesia with a woman in the dorsal lithotomy position with thighs flexed at a 120° angle.<sup>31</sup> Three incisions are made: two small incisions in the groin lateral to inferior pubic ramus, and one vaginal incision in the midurethral area. For the TOT procedure, the needles are inserted in the groin incision and passed into the midurethral incision. With TVT-O, the needles are passed from the vaginal incision to the thigh incision. Once the tape is in place, it is adjusted to the appropriate tension. The sheath is then removed, the excess mesh trimmed from the surgical site, and the incisions closed with sutures.

TOT was developed to eliminate the need for intraoperative cystoscopy. However intraoperative bladder injury has been reported and routine cystoscopy is recommended.<sup>32</sup>

**TOT Outcomes**

Long-term studies have yet to be done on the effectiveness and outcomes of the TOT procedure. Giberti et al. conducted a two-year follow-up study of women with stress urinary incontinence managed with TOT and found an objective cure rate of 80%.<sup>33</sup> Cindolo et al. observed a 92%

**Table 4. TOT complications**

Author	N	Postop urge (%)	Dyspareunia (%)	Vaginal erosions (%)	Sling rejection (%)	High thigh pain (%)	Retention (%)	Postop void dysfunction (%)
Giberti et al. <sup>33</sup>	108	14.8	7.3	6.4	3.8	—	—	—
Meschia <sup>43</sup>	231	—	—	—	—	5	—	—
Waltregny et al. <sup>36</sup>	91	—	—	—	—	—	4	—
Delorme <sup>6</sup>	32	6.25	—	—	—	—	3.13	15.63
Dobson et al. <sup>42</sup>	52	—	—	9.6	—	26	—	—

objective cure rate,<sup>34</sup> Roumeguere et al. found an 80% cure rate,<sup>35</sup> and Waltregny et al. found an 88% cure rate<sup>36</sup>(Table 3).

### Complications of TOT

Postoperative groin pain is reported at higher levels than most other complications and is usually resolved within two months of follow-up.<sup>37</sup> Although transobturator approaches avoid the retropubic area, there is a higher risk of damage to the obturator vessel tributary and the vagina.<sup>38,39</sup> Juma and Brito found lower rates of persistent urge incontinence (21/130 [16%]) and de novo urge incontinence (1/130 [2%]).<sup>40</sup> There is a higher risk of vaginal erosion with the TOT than with the TVT approach. Groin abscesses have been reported with TOT<sup>41</sup> and are more common with certain types of sling material.<sup>42</sup> See Table 4 for summary of complications.

### SUMMARY OF COMPARATIVE OUTCOMES AND RESULTS FOR TVT VERSUS TOT MIDURETHRAL SLINGS

There have been no long-term studies published of the surgical outcomes of the transobturator approach. Silva, in a study published in 2007, reviewed four randomized controlled trials comparing TVT and TOT, noting no significant differences in complications and success.<sup>44</sup> A recent randomized controlled trial of TOT versus TVT with a 12-month follow-up showed that TOT is as safe and effective as TVT in treating women with stress urinary incontinence.<sup>45</sup> Objective cure rates were 71.4% for TVT and 77.3% for TOT. Table 5 shows outcomes for TVT versus TOT, and Table 6 shows complications.

### ALTERNATIVE MIDURETHRAL SLING KITS

TVT SECUR (Gynecare) is a new short midurethral sling tape with a novel securing mechanism. It is a modification of the TVT and TVT-O, with the ends of the tape held in place initially by friction between the tissue and a PDS/Vicryl pledget. It can be placed in a “U” (like the TVT) or hammock (like the TOT) orientation. Initial results suggest a steep learning curve and lower success rates than the traditional TVT.<sup>7,48</sup>

There are so far no published data on Miniarc (AMS), another new short midurethral tape.

### DISCUSSION

Since their introduction, minimally invasive midurethral procedures used to treat stress incontinence have been aggressively marketed to surgeons and, in many cases, have supplanted the gold standard Burch procedure. While the evidence now supports the substitution of the TVT procedure for the Burch, it provides very little support for other midurethral procedures. TOT was introduced as a purportedly safer procedure of equal effectiveness to TVT. In considering the rationale for the introduction of TOT it must be remembered that serious retropubic complications from the TVT are rare. While the use of TOT has eliminated the serious retropubic risks, it has introduced a new set of complications. Rates for more minor complications appear to be similar for the two procedures. Therefore, the effectiveness of the procedure should guide selection and patient counselling. TVT has undergone the most rigorous testing; it must therefore be considered superior to the other midurethral procedures until further scientific evidence demonstrates equivalency for another procedure. TOT has demonstrated good short-term results. Other midurethral procedures are currently unsupported by any reliable evidence.

### Recommendations

Recommendations were made according to the guidelines developed by the Canadian Task Force on Preventive Health Care.<sup>49</sup>

1. Tension-free vaginal tape can be offered as an alternative of equal efficacy to the Burch procedure for the surgical management of stress urinary incontinence. (I-A)
2. Transobturator tape can be offered as an alternative to the tension-free vaginal tape that eliminates the risks of intra-abdominal organ injury. It should be offered with the proviso that its long-term effectiveness and safety relative to the tension-free vaginal tape remain to be determined. (II-B)

**Table 5. TVT versus TOT cure**

Author	N	Patient group	Follow-up duration (months)	Objective cure (%)	Subjective cure (%)
Poranea et al. <sup>45</sup>	148	SUI	12	TVT 71 TOT 77	TVT 90 TOT 91
Falkert et al. <sup>46</sup>	105	SUI	12	TVT 90 TOT 96	TVT 48 TOT 74
Laurikainen et al. <sup>37</sup>	267	SUI	2	TVT 98 TOT 95	–
Schierlitz et al. <sup>47</sup>	162	SUI & ISD	6	TVT 84 TOT 72	TVT 77 TOT 79

**Table 6. TVT versus TOT complications**

Complication	TVT (%)	TOT (%)
Hemorrhage	3.75	8.5
Postop urethral catheterization	8.75	3.7
Intermittent self-catheterization	2.5	1.2
Tape release	3.7	2.4
Vaginal perforation	0	4.8
Bladder injury	5	2

3. Midurethral sling procedures performed through a single suburethral incision should be used only in the setting of a clinical trial until their effectiveness and safety are proven. (III-C)

4. Despite the suggested simplicity of pre-packaged surgical kits for midurethral procedures, specific training is recommended prior to performing any of these surgical procedures. (III-C)

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