Tension-Free Vaginal Tape for Stress Urinary Incontinence

Health Technology Literature Review

Completed February 2004
TVT for stress urinary incontinence

Disclaimer

This health technology scientific literature and policy review was prepared by the Medical Advisory Secretariat, Ontario Ministry of Health and Long-Term Care for the Ontario Health Technology Advisory Committee and developed from analysis, interpretation and comparison of scientific research and/or technology assessments conducted by other organizations. It also incorporates, when available, Ontario data, and information provided by experts and applicants to the Medical Advisory Secretariat to inform the analysis. While every effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of the review.

Please contact MASInfo@moh.gov.on.ca if you are aware of scientific research findings that should inform the report or would like further information.

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Executive Summary

Purpose

In October 2003, the Ontario Technology Advisory Committee requested an evidence-based analysis on the effectiveness and cost-effectiveness of tension-free vaginal tape for stress urinary incontinence in women. A systematic literature review of this technology was synthesized with health system information so that recommendations for the provision of this technology in Ontario could be made.

The Technology

Created by a Swedish team in 1996, the tension-free vaginal tape (TVT) is a minimal access surgical procedure for the treatment of SUI in women who are past childbearing age. The tape is inserted underneath the urethra with minimal tension. A tissue reaction with a subsequent collagen scar is thought to create a support that enables the urethra to be stabilised at moments of stress, such as laughing, coughing or strenuous exercise. TVT has been available as one surgical intervention for the treatment of female SUI in Canada since 1998.

It is estimated that about 6,000 to 7,000 TVT procedures have been performed in Canada since its availability in 1998. In Ontario 62 devices were sold in 2000, about 1,200 in 2001 and over 1,900 in 2002 (personal communication, October 2003). A report from the United Kingdom in 2003 indicated that the number of TVT procedures rose from 214 in 1998/1999 to 2,706 in 2000/2001, making up one third of all surgical procedures for UI in women in 2000/2001.

Review Strategy

The objective of this review was to summarize the current evidence regarding the safety, clinical and cost-effectiveness of TVT compared with more traditional surgical procedures for SUI in Canada.

The leading international organizations were scanned for previous HTAs on TVT. The Cochrane Library Database and the Cochrane Incontinence Group Database were also scanned. To augment these HTAs, the peer-reviewed literature was searched from 2002 to 2003. Case studies, review articles, editorials and letters were not included. The search was limited to studies on humans.

For the most recent RCTs found in this literature search, relative cure and complication risk rates and 95% confidence intervals were calculated.

Summary of Findings

There is Level 1 evidence from randomized control trials (RCTs) and systematic reviews that TVT is as effective as more invasive treatments for SUI with decreased hospital length of stay and post surgical morbidity. However, there are currently no trials with follow-up longer than two years and therefore, long-term effectiveness and complication rates of TVT have yet to be determined. High complication rates are noted to be associated with lack of surgical training in the TVT procedure.

This technology is already in use in Ontario and will likely continue to diffuse rapidly. Currently, the number of TVTs performed in Ontario is increasing. Early data suggest that TVT is replacing other SUI treatments, rather than increasing the number of existing procedures being performed. However, as TVT becomes more widely available, its use may become additive. For example, women who would not otherwise be eligible for invasive surgery may consider TVT as a less invasive option. Since long term
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outcomes are not known, there may be subsequent health services necessary if long-term complications arise.

Accurate estimates of SUI prevalence and acuity are not known. Economic and budget impact estimates cannot be accurately developed until this information is ascertained.

Issue

In October 2003, the Ontario Technology Advisory Committee requested an evidence-based analysis on the effectiveness and cost-effectiveness of tension-free vaginal tape for stress urinary incontinence in women. A systematic literature review of this technology was synthesized with health system information so that recommendations for the provision of this technology in Ontario could be made.

Urinary incontinence (UI) is extremely common. Broad prevalence estimates of UI range from 10% to 52% in adult women in the United Kingdom.(1) About 8 million American women and an estimated 250,000 women over the age of 65 in Canada have reported UI.(2;3) The extent of underreporting of this condition is unknown because associated psychosocial stress may preclude some persons from reporting their condition or seeking the advice of a physician. Moreover, variations in populations sampled and survey methods used to determine prevalence add to the lack of accuracy.

Stress urinary incontinence (SUI) is characterized by a weakening of the pelvic tissue surrounding the urethra (urethral hyper-mobility and/or intrinsic sphincter deficiency) caused by strenuous exercise, childbirth, loss of pelvic muscle tone, loss of estrogen, obesity and gynecologic surgery. The prevalence of SUI is estimated to be from 18% to 34% of women aged 40 and over.(1) A more recent international study suggests that 24% of women aged 18 to 44 years and 37% of women 45 and over years experience symptoms of SUI.(6) About 2% of women with SUI are reported to exhibit symptoms “most of the time”.(4)

There are over 200 reported treatments for SUI.(7) Following the failure of conservative treatment, surgical procedures may be indicated. Since 1998, TVT has been available in Canada as one minimal access surgical intervention for the treatment of female SUI (Health Canada licence #59).

Created by a Swedish team in 1996,(5) the TVT is a minimal access surgical procedure for the treatment of stress urinary incontinence in women. The tape is inserted underneath the urethra with minimal tension. A tissue reaction with a subsequent collagen scar is thought to create a support that enables the urethra to be stabilised at moments of stress.(1)

About 6,000 to 7,000 TVT procedures have been performed in Canada since its availability in 1998, with just over 60 sold in 2000, 1,500 sold in 2001 and over 1,900 sold in Ontario in 2002 (personal communication, October 2003). A report from the United Kingdom indicated that the number of TVT procedures rose from 214 in 1998/1999 to 2,706 in 2000/2001, making up one third of all surgical procedures for UI in women in 2000/2001.(1)

In effectiveness studies and extensive systematic reviews, TVT has been shown to be as effective as more invasive surgical procedures for SUI with decreased hospital length of stay and post surgical morbidity. However, there have been few well-designed RCTs with long-term follow-up and therefore, definitive effectiveness of this procedure has yet to be determined.
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International health technology assessments (HTAs) and appraisals evaluating the clinical and cost effectiveness of TVT have been performed since 2001, the most recent in August 2003. This report will synthesize and update the conclusions from previous HTAs in the Ontario context.

It is important to note that women may choose TVT as a primary surgical procedure or may have this procedure performed in conjunction with another gynecological procedure. This HTA focuses on women who may opt for TVT as their primary treatment for SUI. Further and most importantly, accurate Ontario SUI prevalence estimates are not known.

Background

Clinical Need: Target Population and Condition

Normal continence is maintained through the constant co-ordination between bladder, urethra, urethral sphincter and pelvic floor, controlled by the nervous system. Incontinence occurs when the relationship between the above components is compromised, either due to physical damage or nerve dysfunction.(1) SUI is the most common form of urinary incontinence in women. It is characterised by the “complaint of involuntary leakage on effort or exertion, or on sneezing or coughing” when there is increased abdominal pressure without detrusor (bladder wall) contraction.(7) There are two distinct characterisations that comprise the symptoms known as SUI: a weakening in the support of the proximal urethra, causing urethral hyper-mobility (in an otherwise healthy urethra) and deficiency in the sphincter, thereby causing urethral leakage. Increasingly, both types are thought to co-exist.(1) Accurate tests are not available to distinguish these two types of SUI. Guidelines for the diagnosis and management of SUI have recently been adopted in Canada.(7;8)

UI is estimated to affect approximately 8 million American women and an estimated 250,000 Canadian women aged 65 and over.(2;3) The prevalence of SUI is very difficult to measure because of its associated psychosocial sequelae and because many women with this condition do not consult a physician. A cross-sectional postal survey of 15,904 adults aged 40 and over who were registered with a local GP in Leicestershire, United Kingdom revealed that between 18% and 34% of respondents exhibited symptoms of stress incontinence.(4) Just over 9% reported symptoms “sometimes” while almost 3% reported symptoms “most of the time”. SUI was most common for women in their fifties. A more recent study suggests that 24% of women aged 18 to 44 years and 37% of women 45 and over years experience symptoms of SUI.(6)

SUI has been associated with a broad range of psychosocial stress and disablement, such as difficulties with activities of daily living, avoidance of social activities, fear of unpleasant odour and embarrassment.(9) Economic burden may include cost of pads, drugs, devices and inability to participate in work force in severe cases. Risk factors for SUI include vaginal prolapse due to increased parity and obesity.

Existing Treatments Other Than Technology Being Reviewed

According to the Society of Obstetricians and Gynaecologists of Canada (SOGC), there are over 200 treatment options for SUI.(7) They range from non-invasive, conservative management to invasive surgical procedures, such as colposuspension (also called retropubic urethroplexy) performed both through open surgery and laparoscopy. Conservative techniques are the first line of treatment and include Kegel exercises (with or without weighted vaginal cones), lifestyle modification (e.g., weight loss), limitation of fluid intake, behavioural interventions (such as bladder retraining) and urethral plugs.
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Alternative treatments such as biofeedback devices or electrical stimulation have also been used with limited success. Drug therapy has also been used. (1) A new drug called duloxetine has recently completed phase III clinical trials but is not yet available in Canada. (10;11) The utility of this drug in treating women with moderately severe or severe SUI is as yet unknown. Surgery is an option when other treatments fail. Aside from TVT, these treatments are summarized below:

Open colposuspension: Deemed the ‘gold standard’ for primary SUI,(7) this procedure is most commonly used when conservative methods have failed. During this procedure, the bladder neck is surgically elevated to behind the anterior pubic bones. This procedure is performed under general or regional (e.g., spinal) anesthesia and requires approximately 2 to 4 hospital days for recovery.(1;12) Subjective cure rates of have been estimated at 82% to 95% at 1 year after surgery.(12)

Laparoscopic colposuspension: This procedure is the same as open colposuspension; however, minimal access techniques are guided laparoscopically.

Traditional suburethral ‘slings’: This procedure inserts a hammock-like device (fascia or synthetic mesh) under the urethra and attaches it to the rectus wall or anterior pubic bones. This provides bladder support when the rectus muscles are tightened. This procedure has been shown to be as effective with similar short-term cure rates as colposuspension, with typical hospital stay of about 3 to 5 days.(1) TVT is considered to be a minimally invasive sling procedure.

Injection of bulking materials: Bulking material can be injected into the walls of the urethra with a spinal needle or other special device to provide extra pressure on the urethra to better resist pressure from the abdomen. Materials used include autologous fat, silicone, polytetrafluoroethylene and collagen. Two-day hospital stays may be required (1) and cure rates range from 33% to 63% for autologous fat, 60% to 70% for silicone, 40% to 78% for collagen and 34% to 70% for polytetrafluoroethylene. This is most commonly performed on an outpatient basis.

Needle suspensions and anterior repairs: A long needle is inserted either vaginally or through the abdomen into the retropubic space blindly. Sutures are looped through the paraurethral tissue on each side of the bladder neck to provide support.

Tension free vaginal tape

Created by a Swedish team in 1996,(5) the TVT is a minimal access surgical procedure for the treatment of SUI in women. The tape is inserted underneath the urethra with minimal tension. A tissue reaction with a subsequent collagen scar is thought to create a support that enables the urethra to be stabilised during moments of stress.(1) TVT technology proposes that SUI is caused by a laxity in the connective tissue of the vagina itself or in its supporting ligaments, for which the pelvic muscles are unable to compensate. The urethra, therefore, cannot maintain closure. The tape simulates the support mechanism of the pubourethral ligament providing a firm anchoring point for the 3 muscles associated with urethral closure. Collagen forms around the mesh or tape and holds it in place.

The tape, covered by a plastic sheath, is inserted under local, regional or general anaesthesia over the mid-urethra through a small incision in the vaginal wall. Two needles are subsequently inserted through the retropubic space into the abdomen to hold the tape in place. The plastic covering and the needles are removed once the tape is in place. The tape then replaces the defective ligaments and acts to retain urine.
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during a cough or sneeze. Cystoscopy is conducted to make sure that the bladder wall has not been perforated.

The cited advantages of TVT over the other technologies are as follows:

- Use of regional or local anesthesia
- The procedure takes 30 to 45 minutes to perform and requires about 3 days fewer hospital stay and less recovery time than more invasive procedures
- Women who are not eligible for surgery may be eligible for TVT.

Literature Review on Effectiveness

Objective

To summarize the current evidence regarding the safety, clinical and cost-effectiveness of TVT compared with more traditional surgical procedures for SUI in Canada.

Methods

The first stage of this review scanned the leading international HTA organizations for previous HTAs on TVT, including the Canadian Coordinating Office of Health Technology (CCOHTA), International Network of Agencies for Health Technology Assessment (INAHTA), National Institutes of Clinical Excellence (NICE) and Database of Abstracts of Reviews of Effectiveness (DARE). The Cochrane Library Database and the Cochrane Incontinence Group Database were also scanned.

The peer-reviewed literature was searched, including the following databases: MEDLINE, EMBASE, PREMEDLINE (MEDLINE citations in process) and the Cochrane Library Database from 2002 to 2003. Case studies, review articles, editorials and letters were not included. The search was limited to studies on humans.

Key words for the initial search included TVT, tension-free vaginal taping and vaginal taping. More explicit key words for the search on EMBASE and MEDLINE were as follows:

- TVT
- Tension-free vaginal tape
- Vaginal tape, SUI
- Stress incontinence and outcomes

Other Web-based information, such as clinical position papers and guidelines for clinical management of SUI, were gleaned from clinical societies’ or patient care Web sites.

Inclusion criteria for this HTA were as follows:

- Population: general population of women with SUI
- Procedure: TVT alone and/or in comparison with other procedures for SUI
- Date: articles and reports published in 2002, but not included in the NICE HTA; reports and articles published in 2003
- Language: publication in English
- Published HTAs and guidelines
TVT for stress urinary incontinence

For the most recent RCTs found in this literature search, relative risks of cure and complication rates and 95% confidence intervals were calculated.

Results of Literature Review

Our search strategy produced 120 relevant articles published from January 1, 2002 to September 2003. All articles were read by a reviewer and included for analysis based on the above criteria. Exclusions in this analysis were for the following reasons:

- 31 non-English abstracts/journals
- 6 were not explicitly about SUI or were analyses of combinations of urinary incontinence types
- 9 articles were included in the NICE HTA
- 10 were about new methods of inserting TVT procedure
- 6 were about TVT in combination with other procedures
- 2 were duplicates
- 5 were commentaries or essays or editorials
- 12 dealt with special populations (e.g., the elderly or obese patients)
- 4 studies had fewer than 10 cases
- 1 was a physician practice management questionnaire
- 2 were about non-living subjects
- 2 were incorrect citations

Ninety articles were excluded from this search. Two guidelines and 4 systematic reviews (one comprehensive appraisal published in August 2003) were found from the search. These are described in the section below. Twenty-five peer-reviewed studies were examined. These are described later in this report.

Summary of Existing Health Technology Assessments

Appendix B summarises the findings from the 4 systematic reviews. The reviews recognised that TVT cure rates are similar to those achieved with more invasive procedures. However, the reviews collectively were cautious in their full endorsement of this technology due to the lack of long-term trials. With the recognition that women may prefer this procedure because it is minimally invasive with faster recovery times (despite the surgical risks and the possibility of post-surgical complications), the most recent reviews from the National Institute for Clinical Excellence and Agencee Nationale d’Accréditation de Santé recommended multi-centre registries for long term evaluation.

The most recent and comprehensive appraisal of TVT was developed by NICE in the United Kingdom. The objective of this appraisal was to evaluate the effectiveness and cost effectiveness of TVT in comparison with the standard surgical interventions currently used. They searched the electronic literature from January 1, 1966 to May 2002. Additional searches of the Internet, conference proceedings and advice from experts in the field were conducted. Table 1 illustrates the results of the articles included in their review. A standardized data extraction and quality assessment form for each study was used. The primary outcomes were subjective cure rates and quality of life at least 24 months after surgery and peri-operative and short-term complications post-surgery. Cost effectiveness was also examined and is discussed later in this report.
Table 1: Results of the NICE Health Technology Assessment literature review

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Level of Evidence</th>
<th>Number of Eligible Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large RCT, systematic reviews of RCTs</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Large RCT unpublished, but reported to an international scientific meeting</td>
<td>1(g)</td>
<td>9</td>
</tr>
<tr>
<td>Small RCT</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Small RCT unpublished, but reported to an international scientific meeting</td>
<td>2(g)</td>
<td></td>
</tr>
<tr>
<td>Nonrandomised study with contemporaneous controls</td>
<td>3a</td>
<td></td>
</tr>
<tr>
<td>Nonrandomised study with historical controls</td>
<td>3b</td>
<td></td>
</tr>
<tr>
<td>Nonrandomised study presented at international conference</td>
<td>3(g)</td>
<td></td>
</tr>
<tr>
<td>Surveillance (database or register)</td>
<td>4a</td>
<td>2</td>
</tr>
<tr>
<td>Case series with more than 2 year of follow-up (multi-site)</td>
<td>4b</td>
<td>17</td>
</tr>
<tr>
<td>Case series with less than 2 years of follow-up</td>
<td>4c</td>
<td>49</td>
</tr>
<tr>
<td>Retrospective review, modelling</td>
<td>4d</td>
<td></td>
</tr>
<tr>
<td>Case series presented at international conference</td>
<td>4(g)</td>
<td></td>
</tr>
</tbody>
</table>

g=grey literature

The NICE authors evaluated the Level 1 evidence (randomised control trials, RCTs) from 1966 to May 2002. Table 2 illustrates the effectiveness from the RCTs gleaned from the NICE review. There were few differences in the cure rates between TVT and other procedures.

Table 2: Effectiveness of TVT versus comparators based on randomized controlled trials gleaned from NICE review

<table>
<thead>
<tr>
<th>Study</th>
<th>Follow-up (months)</th>
<th>Comparator</th>
<th>Subjective cure rates:</th>
<th>Subjective cure rates:</th>
<th>Relative Risk (95% CI)</th>
<th>Objective cure rates:</th>
<th>Objective cure rates:</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>TVT</td>
<td>Comparator</td>
<td></td>
<td>TVT</td>
<td>Comparator</td>
<td></td>
</tr>
<tr>
<td>RCTs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cucinella – 2001</td>
<td>6-24</td>
<td>Lap Colpo</td>
<td>53/57 (93%)</td>
<td>45/56 (80%)</td>
<td>1.16 (1.00-1.34)</td>
<td>NR</td>
<td>NR</td>
<td>NA</td>
</tr>
<tr>
<td>Halaska – 2001</td>
<td>6</td>
<td>Burch Colpo</td>
<td>NR</td>
<td>NR</td>
<td>NA</td>
<td>NR</td>
<td>NR</td>
<td>NA</td>
</tr>
<tr>
<td>Han – 2001</td>
<td>6</td>
<td>Burch Colpo</td>
<td>NR</td>
<td>NR</td>
<td>NA</td>
<td>NR</td>
<td>NR</td>
<td>NA</td>
</tr>
<tr>
<td>Liapis – 2002</td>
<td>22</td>
<td>Burch colpo</td>
<td>30/36 (83.3%)</td>
<td>30/35 (85.7%)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NA</td>
</tr>
<tr>
<td>Ward – 2002</td>
<td>6</td>
<td>Burch colpo</td>
<td>103/159 (64.8%)</td>
<td>90/127 (70.9%)</td>
<td>0.91 (0.78-1.07)</td>
<td>128/156 (82.1%)</td>
<td>109/131 (83.2%)</td>
<td>0.99 (0.89-1.10)</td>
</tr>
</tbody>
</table>

The NICE report also synthesised the complications found in the RCTs, as illustrated in Table 3. Note that wide confidence intervals accompany the large relative risks. This may be in part due to the small number of complications overall and the fact that, in some cases, there were no complications at all in the comparison groups.
Bladder perforation was the most commonly reported complication. The Ward and Hilton trial(13) was the only one that reported a statistically significant difference in complications between TVT and Burch colposuspension. The case series studies found similar complications rates to those found in the RCTs: bladder perforation was the most common complication. Other complications seen were new urge symptoms, voiding dysfunction and post-operative pain. Tape erosion or rejection was seen in 1% of women involved in case series studies.

Disease-related Quality of life (QOL) is an important outcome of treatment for SUI. Three of the RCTs assessed this using validated instruments. Ward and Hilton(13) found no significant difference in QOL between TVT and Burch colposuspension at 6 weeks and no increased functional and emotional QOL at 6 months.

The trial by Ward and Hilton(13) is the most important study contributing to Level I evidence to date. In this prospective, multi centre trial, 344 women with SUI were recruited from 13 centres in England and 1 centre in Ireland. In this unblinded trial, women were randomised to receive open colposuspension or TVT over a 15-month period. Objective outcomes, measured by urodynamic testing and 1-hour pad test and subjective outcomes, measured by questionnaires and interviews, were assessed at 6 weeks and 6 months post-surgery. The authors found that TVT was as effective as colposuspension. The objective and subjective cure rates ranged from 65% to 82% for TVT compared with 71% to 83% for colposuspension. Women who received TVT had shorter decreased hospital stays than those who received colposuspension and quicker return to normal activities for women who underwent TVT.

Although there were more operative complications in the TVT group (12%) compared with the colposuspension group (2%), there were fewer post-surgical complications in the TVT group (27%) compared with the colposuspension group (42.5%) (Table 4). Limitations acknowledged by the authors included a smaller than calculated sample size due to limited time and resources and a lower cure rate than other studies, attributed due to a more stringent definition of cure. Finally, there was a higher attrition rate for women who were randomised to the colposuspension group; however, the authors used an intention-to-treat analysis.
Table 4: Complication rates from Ward and Hilton Trial

<table>
<thead>
<tr>
<th>Complications</th>
<th>TVT group (n=170)</th>
<th>Open Colposuspension group (n=146)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder injury</td>
<td>15 (9)</td>
<td>3 (2)</td>
<td>0.013</td>
</tr>
<tr>
<td>Vaginal perforation</td>
<td>5 (3)</td>
<td>0</td>
<td>0.06</td>
</tr>
<tr>
<td>Wound infection</td>
<td>4 (2)</td>
<td>10 (7)</td>
<td>0.06</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>1 (1)</td>
<td>3 (2)</td>
<td>0.10</td>
</tr>
<tr>
<td>Incisional hernia</td>
<td>N/A</td>
<td>3 (2)</td>
<td></td>
</tr>
<tr>
<td>Retropubic hematoma</td>
<td>3 (2)</td>
<td>0</td>
<td>0.25</td>
</tr>
<tr>
<td>Vascular injury</td>
<td>1 (1)</td>
<td>0</td>
<td>1.0</td>
</tr>
<tr>
<td>Tape erosion</td>
<td>1 (1)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Urinary tract infection (6 weeks post surgery)</td>
<td>38 (22)</td>
<td>46 (32)</td>
<td>0.74</td>
</tr>
<tr>
<td>Total complications</td>
<td>67 (39)</td>
<td>65 (44.5)</td>
<td>0.36</td>
</tr>
</tbody>
</table>


Overall, external validity in the randomised and non-randomised RCTs assessed by NICE was difficult to ascertain. Generalizability of the patients and the facilities in which the patients were receiving their treatment could not be determined in 96% of the studies. Most of the studies (91%) did not explicitly state whether persons who measured outcomes were blind to the intervention. Only 1 RCT stated its blinding procedures.

The NICE appraisal also identified 9 comparative trials that involved 677 patients. Follow-up ranged from 3 to 4 weeks to 44 months. Two population-based registries were included in the review. One based in Finland, included 1,455 women in 38 hospitals who were followed from between 2 weeks to 2 months. The second was based in Austria, with 2 published reports involving 806 and 2,795 patients, respectively.

Case series reports involved 1,369 patients (range, 25 to 206) with a mean or median follow-up period of 24 to 60 months. Other case series reports followed 3,336 patients for less than 2 years. The case series data revealed cure rates similar to those found in the RCTs and comparative trials above (75% – 95%). Sixteen per cent of women reported an improvement in their symptoms.

The NICE appraisal findings were:

- The main findings from case series (Level 4 evidence) are 2-year cure rates of 74% to 95% and improvement in symptoms for 3% to 16% of women.
- Injectable agents appear to have lower cure rates than TVT (Level 4 evidence).
- A concern is the potential erosion of tape into the vagina or urinary tract over time, the rate of which current evidence cannot yet evaluate.
- TVT is less invasive than other surgical procedures, may be performed under local or regional anesthesia and requires shorter length of hospital stay.
- The principal complication from TVT is bladder perforation, which occurs in 1 of 25 procedures. Very rare complications include major vessel or nerve injury.
- Few RCTs have been done comparing TVT with other procedures. High-quality data with longer than 2-year follow-up are not available.
- TVT is cost-effective compared with other procedures.

Based on their review, the authors made the following conclusions:
TVT for stress urinary incontinence

- Long-term effectiveness is not yet known, both in terms of cure rates and complications. However in the short and medium-terms, TVT cure and complication rates appear to approach those of the currently used procedures.
- Since TVT is less invasive than other procedures for SUI, it costs less; however, women who are not eligible for invasive surgery will be eligible for TVT, and this may increase the current utilization and overall cost of treatment for SUI.
- Additional, qualified surgeons will be necessary if TVT is widely adopted. Some of the observed variations in rates of complications and cure rates may be because of a lack of adequate surgical training in this procedure.

The authors made the following recommendations:

- RCTs and analyses of population-based registries with longer follow-up are needed.
- More information from scientifically rigorous trials using standard outcome measures and more intense evaluation are needed before extending the use of TVT to women who are currently managed non-surgically.

The authors noted the following limitations in the published literature:

- There are very few long-term trials (> 2 years).
- Few studies compare treatments.
- Some studies included heterogeneous populations (i.e., mixed continence or coexisting vaginal prolapse) without analytic stratification, so interpretation needs to be cautious.
- Review was limited to women whose incontinence was treated surgically and did not include those who were managed conservatively.

Summary of Medical Advisory Secretariat Review

The NICE review of TVT effectiveness was augmented by a review by the Medical Advisory Secretariat from January 1, 2002 to September 15, 2003 (excluding articles included in the NICE appraisal). Table 5 summarises the Medical Advisory Secretariat systematic review of TVT. Overall there were 25 studies in this review, including the RCT portion of the NICE appraisal, 4 RCTs, and 20 case series or restrospective chart reviews.

As Table 6 illustrates, there were few differences in the SUI cure rates comparing TVT with another procedure. None of the above differences were statistically significant. Note that the subjective cure rates were higher than the objective rates in the 2 studies that provided both measures. As Table 6 illustrates, there were few differences in the SUI cure rates comparing TVT with another procedure. None of the above differences were statistically significant. Note that the subjective cure rates were higher than the objective rates in the 2 studies that provided both measures.
TVT for stress urinary incontinence

Table 5: Quality of Evidence from systematic review, January 1 2002 to September 15, 2003

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Level of Evidence</th>
<th>Number of Eligible Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large RCTs, systematic reviews of RCTs</td>
<td>1</td>
<td>1 HTA (separate analysis of RCTs) 3 RCTs in 2003</td>
</tr>
<tr>
<td>Large RCT unpublished but reported to an international scientific meeting</td>
<td>1(g)</td>
<td>1</td>
</tr>
<tr>
<td>Small RCT</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Small RCT unpublished but reported to an international scientific meeting</td>
<td>2(g)</td>
<td>0</td>
</tr>
<tr>
<td>Nonrandomised study with contemporaneous controls</td>
<td>3a</td>
<td>0</td>
</tr>
<tr>
<td>Nonrandomised study with historical controls</td>
<td>3b</td>
<td>0</td>
</tr>
<tr>
<td>Nonrandomised study presented at international conference</td>
<td>3(g)</td>
<td>0</td>
</tr>
<tr>
<td>Surveillance (database or register)</td>
<td>4a</td>
<td>0</td>
</tr>
<tr>
<td>Case series (multi-site)</td>
<td>4b</td>
<td>3</td>
</tr>
<tr>
<td>Case series (single site)</td>
<td>4c</td>
<td>12</td>
</tr>
<tr>
<td>Retrospective review, modelling</td>
<td>4d</td>
<td>4</td>
</tr>
<tr>
<td>Case series presented at international conference</td>
<td>4(g)</td>
<td>1</td>
</tr>
</tbody>
</table>

* g=grey literature

The most common operative complications of TVT were bladder perforation and hematoma. Table 7 summarizes these complications from the 4 RCTs gleaned from this review.

The complication rates in these studies were very low. One study had no surgical complications at all. None of the differences were statistically significant. These complication rates were lower than those cited in the NICE report and the reason for this is not clear. It may be that the surgeons performing the procedure in the more recent studies had the benefit of more experience and hence better outcomes than surgeons performing in the earlier trials.

The rest of the articles were case series and retrospective chart reviews. There were 3 case series studies(14-16) that took place across multiple centres (Level of evidence 4b). The studies examined 112, 162 and 245 women with SUI, with a follow-up of 22 months (2 studies) and 4 weeks, respectively. The subjective cure rates were 86.6% and 92.2% in 2 studies(14;16). The study with 162 subjects(15) focussed on quality of life (QOL) instead of cure rate, using validated survey instruments. The authors concluded that QOL was elevated after TVT.(15)
Table 6: Summary of cure rates from randomized controlled trials, January 2002 to September 2003

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>142</td>
<td>90</td>
<td>121</td>
<td>57</td>
</tr>
<tr>
<td>Follow-up, months (median)</td>
<td>6-24 (12)</td>
<td>12-36 (22)</td>
<td>6 weeks</td>
<td>3-24 (24)</td>
</tr>
<tr>
<td>Comparator</td>
<td>Porcine dermal sling</td>
<td>Burch Colpo</td>
<td>Laparoscopic mesh colposuspension</td>
<td>Pubovaginal sling</td>
</tr>
<tr>
<td>Subjective cure rate (TVT)</td>
<td>58/68 (85%)</td>
<td>45/49 (92%)</td>
<td>Not reported</td>
<td>25/29 (86%)</td>
</tr>
<tr>
<td>Subjective cure rate (comparator)</td>
<td>66/74 (89%)</td>
<td>38/41 (93%)</td>
<td>Not reported</td>
<td>20/28 (72%)</td>
</tr>
<tr>
<td>Relative risk (95% CI*)</td>
<td>0.956 (0.36, 2.57)</td>
<td>0.99 (0.21, 4.66)</td>
<td>Not applicable</td>
<td>1.21 (0.32, 4.56)</td>
</tr>
<tr>
<td>Objective cure rates (TVT)</td>
<td>Not reported</td>
<td>40/49 (82%)</td>
<td>65/70 (93%)</td>
<td>20/29 (69%)</td>
</tr>
<tr>
<td>Objective cure rates (comparator)</td>
<td>Not reported</td>
<td>31/41 (76%)</td>
<td>45/51 (88%)</td>
<td>13/28 (46%)</td>
</tr>
<tr>
<td>Relative risk (95% CI*)</td>
<td>Not applicable</td>
<td>1.08 (0.39, 2.96)</td>
<td>1.05 (0.30, 3.63)</td>
<td>1.5 (0.51, 4.42)</td>
</tr>
</tbody>
</table>

* CI – confidence interval

Table 7: Summary of RCT complication rates gleaned from systematic review January 1, 2002 to September 15, 2003

<table>
<thead>
<tr>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>142</td>
<td>90</td>
<td>121</td>
<td>57</td>
</tr>
<tr>
<td>Follow-up, months (median)</td>
<td>6-24 (12)</td>
<td>12-36 (22)</td>
<td>6 weeks</td>
<td>3-24 (24)</td>
</tr>
<tr>
<td>Comparator</td>
<td>Porcine dermal sling</td>
<td>Burch Colpo</td>
<td>Laparoscopic mesh colposuspension</td>
<td>Pubovaginal sling</td>
</tr>
<tr>
<td>Bladder perforation (TVT)</td>
<td>0/68</td>
<td>Not reported</td>
<td>1/70 (1.4%)</td>
<td>6/29 (21%)</td>
</tr>
<tr>
<td>Bladder perforation (comparator)</td>
<td>0/74</td>
<td>Not reported</td>
<td>1/51 (2%)</td>
<td>5/28 (18%)</td>
</tr>
<tr>
<td>Relative Risk of Bladder perforation (95% CI)</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>0.74 (0.05, 11.80)</td>
<td>1.16 (0.31, 4.33)</td>
</tr>
<tr>
<td>Hematoma (TVT)</td>
<td>0</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Hematoma (comparator)</td>
<td>0</td>
<td>Not reported</td>
<td>1/51 (2%)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative Risk of Hematoma (95% CI)</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

* CI – confidence interval

Twelve single-centre case series studies (Level 4c) were found and were categorized based on the number of patients in the studies (below 50, 50 – 100; and > 100 patients). Three studies (17-19) had very few study patients (20, 22 and 30) with cure rates of 80%, 91% and 100%, respectively. The range of follow-up for all patients combined was between 5 and 22 months. Four Level 4c studies (20-23) had patient...
TVT for stress urinary incontinence

numbers between 50 and 100 (51, 63, 69, and 92). Follow-up was between 6 weeks and 3 years. Reported subjective cure rates were between 85% and 92%. Five studies had patients numbering over 100 (112, 158, 177, 193 and 375) with follow-up times of between 6 weeks and 3 years. Subjective cure rates ranged from 83% to 95%. Bladder perforation (range, 3%–10%) and hematoma rates (range, 0.4%–3%) were reported. (24;25)

Four studies were retrospective chart reviews (Level 4d). One study (26) had only 20 patients with a follow-up of 10 months and a subjective cure rate of 100%. One study (27) (n=153) examined factors associated with normal voiding after TVT. Another study(27) (n=245) compared outcomes of TVT in women with primary versus secondary SUI. In the latter study, similar cure rates (87% and 85%, respectively) were observed after about 38 weeks. The last one (28) examined bladder perforation in 140 women who underwent TVT and found a rate of about 4%.

Summary of Findings on Effectiveness

Stress urinary incontinence may pose a considerable quality of life burden for affected women. Conservative therapies are recommended as the first line of treatment for SUI (for example, pelvic floor exercises or limitation of fluids). For eligible patients, surgery is recommended when conservative strategies fail. The limited evidence suggests that TVT is as effective as the more invasive procedures used for women with SUI. The complication rate seems to be indirectly related to the level of surgical training. Most of this evidence comes from just a few well-conducted studies. Outcomes longer than 2 years have still not been adequately examined. Further, the available evidence has centred around women with SUI who were eligible for surgery – evidence regarding the effectiveness of women with less severe SUI who may be willing to undergo a less invasive procedure than previously available, or women who were not eligible for surgery has not been examined. TVT is therefore not recommended for this group of women.

Economic Analysis

Literature Review: Objectives and Methods

An economic evaluation of TVT was undertaken. A literature search was conducted using the following key words: TVT and cost; SUI and cost.

Articles that compared the cost of TVT with another treatment option for SUI were included. Fifty-eight articles were found that evaluated the cost of treatment for SUI. Eleven articles were found that focussed on costs for TVT. Of these 69 articles, 2 were eligible for inclusion in this review.

The four HTAs discussed previously contained some cost information. However, only the NICE report had comprehensive cost-effectiveness analyses. These are summarised later in this report.

Results of Literature Review on Economics

Two articles(28;29) based on RCT data were found. Table 8 illustrates the unit costs, converted to Canadian dollars ($Cdn) from Euro dollars (€) and British pound sterling (£GBP), for selected items used in these 2 studies.
Table 8: Costs from Persson 2002(28) and Manca 2003 (29) reviews of TVT and comparator technology

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(costs in $Cdn converted from Euros €; OECD 2002)</td>
<td>(costs in $Cdn converted from £GBP; OECD 2002)</td>
</tr>
<tr>
<td>TVT (N=38)</td>
<td>Lap colposuspension (N=32)</td>
<td>TVT (N=117)</td>
</tr>
<tr>
<td>Total cost</td>
<td>Total costs</td>
<td>Mean total cost</td>
</tr>
<tr>
<td>Theatre (OR) costs</td>
<td>1317.60</td>
<td>431.88</td>
</tr>
<tr>
<td>Hospital ‘hotel’ cost</td>
<td>51.24</td>
<td>139.08</td>
</tr>
<tr>
<td>Other post-operative costs</td>
<td></td>
<td>135.24</td>
</tr>
<tr>
<td>Follow up cost at 6 months</td>
<td></td>
<td>1936.14</td>
</tr>
<tr>
<td>Total cost per patient</td>
<td>1317.60</td>
<td>431.88</td>
</tr>
<tr>
<td>Differential cost</td>
<td>-444.69</td>
<td>-444.69</td>
</tr>
<tr>
<td>Basic costs</td>
<td>73.30</td>
<td>97.55</td>
</tr>
<tr>
<td>Anesthesia costs</td>
<td>341.43</td>
<td>516.17</td>
</tr>
<tr>
<td>Surgical costs</td>
<td>34.57</td>
<td>47.84</td>
</tr>
<tr>
<td>Surgical materials</td>
<td>571.78</td>
<td>136.68</td>
</tr>
<tr>
<td>Hospital care</td>
<td>762.59</td>
<td>837.77</td>
</tr>
<tr>
<td>Depreciation of instruments</td>
<td>0</td>
<td>47.44</td>
</tr>
<tr>
<td>Outpatient visits to physician or nurse</td>
<td>15.67</td>
<td>22.90</td>
</tr>
<tr>
<td>Average cost/procedure</td>
<td>1799.35</td>
<td>1706.36</td>
</tr>
<tr>
<td>Total costs including re-operations</td>
<td>1959.88</td>
<td>1761.43</td>
</tr>
</tbody>
</table>

(1.34 EUR = 1 CAD; 1.83 GBP = 1 CAD based on 2002 purchasing power parity estimates; OECD 2003)

The total average patient cost for TVT in the Persson trial (without re-operations) was Cdn $1799.35 compared with Cdn $1936.14 in the Manca trial. The Persson trial compared costs of TVT with those of laparoscopic colposuspension while the Manca trial compared TVT with open colposuspension. The total average cost for TVT was Cdn $92.99 higher than laparoscopic colposuspension; average costs for TVT was Cdn $444.69 lower than open colposuspension.

The costs derived in these studies were not directly comparable because different aggregate costs were used in their calculation. Nonetheless, the main cost saving in the Manca trial was due to the postsurgical hospital costs associated with open colposuspension (length of hospital stay post-TVT was 2.29 days compared with 6.67 days in the open colposuspension group). There were also a higher number of re-admissions to hospital in the colposuspension group that would factor into the higher cost of colposuspension in this trial (2 days for TVT vs. 12 days for colposuspension). This was not taken into account in the Persson trial, however Persson did factor in re-operations (Cdn $160.53 for TVT and $55.07 in the laparoscopic colposuspension group).
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Only the Manca trial estimated cost effectiveness. TVT had a mean improvement in outcomes of 0.01 quality adjusted life-years (QALYs) per patient over the six-month period. Manca et al found that using a wide range of values for added QALYs, the effectiveness of TVT over colposuspension remained over 80%. The authors contended, however, that a longer follow up was needed.

The NICE report(1) produced a very detailed cost effectiveness analysis comparing TVT and open colposuspension. A Markov modeling technique was used to determine cost-effectiveness based on resource use and costing, as gleaned from the review. The model used a probabilistic analysis to estimate costs and QALYs for up to 10 years post-surgery. Economic modeling suggested that at 5 years post-surgery, TVT had a lower mean cost (£267 or $Cdn 488.61) than open colposuspension for the same or more QALYs (+0.00048).

Ontario-Based Economic Analysis or Budget Impact Analysis

Diffusion

Currently, the delivery of TVT in Ontario is controlled through the hospital. Professional cost (including anesthetist costs) for TVT is $593 (this is also for other more invasive sling procedures) compared with $454 for open colposuspension (Ontario Schedule of Benefits physician claims). According to the manufacturer of TVT, the unit cost of TVT device is Cdn $730.00

Figure 1 shows the number of procedures performed for SUI in the United Kingdom (based on hospital data) and in Ontario (based on estimates from OHIP) from 1998/99 to 2002/03. Administrative data does not capture TVT alone (it is included in the sling procedure category in both the Ontario and United Kingdom data) and therefore, the manufacturer’s sales figures were used as a proxy for TVT utilization. The number of open colposuspension procedures declined over the time period in both jurisdictions while the number of sling procedures rose. During this time, it appeared that TVT was replacing other SUI treatments, rather than adding to the already existing procedures being performed. In terms of diffusion, we are uncertain where we are currently on these curves; that is, although TVT is currently substituting the more traditional procedures, we are unsure whether more women will opt or be eligible for TVT because it is less invasive.
TVT for stress urinary incontinence

Demographics

The prevalence of SUI is unknown, ranging broadly from study to study. A UK cross-sectional survey of 5,544 women aged 40 and over who visited their family physician identified about 35% who had urinary incontinence. About 50% of women with incontinence are deemed to have stress urinary incontinence. The cross-sectional survey identified 9.5% of their sample with stress incontinence who sometimes had symptoms and 2.8% of women with SUI who most of the time had symptoms. These estimates were used to determine the clinical need for surgery for women with SUI in Ontario.

In 2001, there were about 2,755.3 million women in Ontario aged 40 and over.

To get relevant estimates for potential TVT recipients in Ontario, the UK estimates are used.

Ontario women with SUI:

2,755,300 women aged 40 and over * 35% with UI= 96,436 women in Ontario who have UI;
96,436 women with UI * .50 with SUI = 482,178 women with SUI;

High estimate of need for SUI surgery

9.5% women with SUI who “sometimes” have symptoms:
9.5% * 482,178 women with SUI = 45,807 women who sometimes have SUI symptoms.

Low estimate of need for SUI surgery

2.8% women with SUI who “most of the time” have symptoms:
2.8% * 482,178 = 13,500 women who most of the time have SUI symptoms.

Overall there may be between 13,500 and 45,807 women who may be candidates for TVT in Ontario. Given that there are currently about 5,000 SUI procedures for SUI performed in Ontario annually, the point-in-time backlog of those seeking treatment for SUI is estimated to be between 8,500 and 40,807 women.

Costs

Interim results from a small, unpublished case-costing study in Ontario calculated the costs (in-hospital costs and professional fees) of seven patients who underwent the TVT procedure and compared this to a cohort of patients who underwent open Burch colposuspension. The study found an average total cost of the TVT procedure was Cdn $3,032 (in-hospital costs of Cdn $1,876 and professional fees of Cdn $1,156). The average cost of the Burch colposuspension was Cdn $6,047 (in-hospital costs of Cdn $5,014 and professional fees of Cdn $1,033). The difference in total costs between the two procedures was Cdn $3,015 and the difference in hospitalization costs was Cdn $3,138.

Based on an analysis of Resource Intensity Weights for Ontario, the per diem hospitalisation cost of an inpatient procedure for stress urinary incontinence (ICD-9 625.6) was Cdn $486.50. Given an average

---

1 The Case Mix Group for ICD-9 625.6 (female stress incontinence) is 596 and the Routine and Ancillary Per -diem Weight (component of the RIW score) for CMG 596 (complexity level 1) in 2001 was 0.1390. Using a unit weight = $3,500, the dollar value of a recovery day for colposuspension or TVT is (0.1390 * $3,500) = Cdn $486.50. Multiplying this per-diem dollar figure by the difference in lengths of stay between colposuspension and TVT provides an approximate difference in the inpatient costs for the two procedures.
TVT for stress urinary incontinence

Length of stay of approximately 5 days for colposuspension and potentially no hospitalisation days for TVT, the difference in hospitalisation costs is estimated to be Cdn $2,433. Assuming that the surgical costs are approximately equivalent, the total difference in per-capita inpatient costs can be conservatively estimated using this method at Cdn $2,433 – Cdn $730 (cost of TVT device) = CDN $1,7002

A recently published study from the UK found that TVT was £243 less expensive than colposuspension (£1,058 vs. £1,301).(29) Based on purchasing power parity (PPP) figures from OECD (1.83 $Cdn per £UK), this savings translates to approximately Cdn $445. (OECD, 2003)

Even though cost savings per case accruing to the hospital would be in the range of Cdn $445 – Cdn $3,138, it is possible that adoption of TVT would not be budget-saving due to concerns over diffusion associated with a less invasive procedure. We estimate that approximately 1,000 extra TVT procedures province-wide could be funded by hospitals entirely from the savings achieved by replacing 2,000 colposuspension procedures with TVT as a standard surgical intervention for stress urinary incontinence.3

The cost to the Ontario Ministry of Health and Long-term Care (MOHLTC) would be an estimated $870,000 in OHIP physician fees. However, clearing the entire backlog of cases in the province through direct MOHLTC funding of procedures at approximately $5,000 per procedure + OHIP costs may be from approximately Cdn $47.8 million to Cdn $228.5 million.4

**Cost-effectiveness**

Given successful cure rates of between 68% and 91% for TVT and colposuspension procedures, the incremental cost per cure ratio for TVT is undefined since the denominator is likely not different from zero. TVT would economically “dominate” colposuspension because of the costs savings achieved. In terms of cost per quality adjusted life year (QALYs), TVT added approximately 0.01 QALYs compared to colposuspension in a 2003 study.(29) Since TVT dominates in terms of costs and effects (i.e., lower costs, higher effects over standard treatments), incremental cost-effectiveness ratios are not applicable to this situation. The authors of this study state that the probability of tension-free vaginal tape being more cost effective than colposuspension was 94.6% if the decision-maker was willing to pay £30,000/QALY (approximately, Cdn $50,000/QALY). Given current practice, TVT is 100% certain to be cost-saving and as long as average length of stay is at least two days longer following colposuspension, TVT will remain the less costly procedure.

Intangible/unmeasured costs and cost/effectiveness

Given the uncertainty about long-term effectiveness, a number of costs may not be reflected in this analysis. Although TVT is cost-saving relative to open colposuspension in the short term, it may not necessarily be budget-saving in the long term if TVT is rapidly adopted as the surgical procedures of choice for women with SUI. Downstream health care costs due to potential long term complications are also not estimated.

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2 This is probably a conservative estimate since colposuspension is an invasive procedure in which operating room costs are probably higher than for a minimally invasive procedure like TVT.

3 This figure is based on the assumption that approximately 2,000 colposuspension procedures currently being performed annually would be replaced with TVT and the savings would be used to fund the extra TVT procedures. The distribution of colposuspension among the 43 centres currently performing the procedure is not necessarily uniform nor would TVT be uniformly distributed among the hospitals. As a result, the ability of each centre to fund TVT out of savings would vary depending on the centre.

4 (8,500*5,000 per procedure) + $5.3 million OHIP costs = $47.8 million (40,800*5,000 per procedure + $24.5 million OHIP costs = $228.5 million. The $5,000 per procedure cost was based on the Mount Sinai cost estimates of colposuspension (most expensive procedure available.)
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Existing Guidelines for Use of Technology

There are two recent guidelines for the use of TVT for stress urinary incontinence.


Recommendations from this guideline report included:

1. “The Burch procedure (colposuspension) should be offered as the gold standard. The TVT procedure is promising but currently under evaluation in trials that will establish its efficacy and safety.
2. Proper training is recommended prior to performing TVT procedures.
3. Long-term trial results are needed before the TVT procedure can be offered to patients as an equal alternative to the Burch procedure. “

Technology Appraisal Guidance No. 56. Guidance on the use of tension-free vaginal tape (Gynecare TVT) for stress incontinence. NICE, February 2003.

This NICE guideline recommended that:

1. TVT be used as one treatment option for SUI where non-surgical treatments have failed;
2. The operation should be carried out by a trained surgeon who regularly treats women with SUI;
3. Women considering surgery for SUI should be fully informed regarding the advantages and risks associated with each procedural options.

Overall Summary of Findings

Conservative treatment management is recommended as the first line of treatment for SUI (for example, pelvic floor exercises). For eligible patients, surgery is recommended when conservative strategies fail. The limited evidence suggests that TVT is as effective as the more invasive procedures used for women with SUI. The complication rate seems to be indirectly related to the level of surgical training. Most of this evidence comes from just a few well-conducted studies. Outcomes longer than 2 years have still not been adequately examined. Further, the available evidence has centred around women with SUI who were eligible for surgery – evidence regarding the effectiveness of women with less severe SUI who may be willing to undergo a less invasive procedure than previously available, or women who were not eligible for surgery has not been examined. TVT is therefore not recommended for this group of women.

TVT appears to be more cost-effective than open colposuspension (the gold standard for surgical treatment of SUI), mainly attributed to cost-savings due to longer hospital stays for colposuspension.

This technology is already in use in Ontario and its utilisation is increasing. Early data suggest that TVT is displacing other SUI treatments rather than increasing the existing number of invasive procedures. While Level 1 evidence suggests that TVT is as effective as other more invasive procedures for SUI, the 5-year effectiveness and complication rates are unknown. This is a concern given the possible wider use and rapid diffusion of this device. The use of TVT may increase rapidly due to its reduced invasiveness, and may be more attractive to patients than more invasive surgical options. Women who would not have otherwise opted for invasive surgery may all opt for TVT. Further, women who would not otherwise be eligible for invasive surgery may be eligible for TVT. Finally, since long term outcomes are
TVT for stress urinary incontinence

not known, the possibility for long-term complications adds uncertainty about future related health service demands.

Appraisal/Policy Development

Policy Considerations/Implications

Recommendations for the provision of TVT in Ontario should be predicated on the considerations outlined below.

Patient Outcomes – Medical, Clinical

- SUI predominantly affects women 40 and over
- Improved quality of life is the primary treatment outcome for women with severe SUI.
- There are a variety of treatment options for women with SUI.
- SUI should initially be managed using conservative treatments as outlined by clinical guidelines; most women respond to these treatments.
- When conservative treatments fail, TVT could be considered as an alternative to currently used surgical procedures for women with SUI who are past the childbearing age.
- TVT should not be used as an alternative to conservative therapies.
- Effectiveness and procedure related complications associated with TVT are dependent on surgical training.
- While cure rates of TVT are similar to that of colposuspension (the current ‘gold standard’ for surgical treatment for SUI) in clinical trials, follow-up longer than 2 years has not been effectively examined.
- Peri operative complication rates of TVT are higher than colposuspension, but post operative complication rates (such as infection) are lower. TVT complication rates in more recent studies are lower than in the older studies perhaps owing to the expanded experience of surgeons; long term complication rates have not been adequately evaluated.
- Overall patient satisfaction levels are about the same as other procedures post surgery.
- The effectiveness of TVT for other types of urinary incontinence has not been fully evaluated.

Demographics

- Accurate estimates of SUI prevalence and acuity are not known.
- Based on survey data from the United Kingdom, between 13,500 and 45,807 women may be eligible for TVT in their treatment of SUI in Ontario.

Diffusion

- It appears that TVT is replacing some of the more invasive surgeries for TVT in Ontario.
- If TVT becomes more widely accessible, women may opt for TVT when less-invasive conservative treatment is indicated.

Cost

- The surgical component of TVT is more expensive than colposuspension; however, there is cost saving per patient when taking into account the higher number of hospital bed-days associated
TVT for stress urinary incontinence

with recovery of more invasive surgery. If TVT diffuses rapidly it may cost the system more due to additional procedures for SUI being performed.

- Economic and budget impact estimates cannot be accurately developed until accurate estimates of prevalence and acuity are ascertained.
- Hospitals currently pay for TVT from their global budget and therefore control the dissemination of TVT.
- There is no way of distinguishing hospital costs of TVT from other traditional sling procedures using administrative data.
- There is no distinct professional code for TVT; there is currently no way of distinguishing professional costs of TVT from other sling procedures.
- Complications arising from TVT are associated with lack of surgical training.
- Because there are no distinguishing codes in the current health administrative databases for TVT, the only way to examine the utilisation of TVT in the province is through the manufacturer’s sales figures.

System pressures

- Up to 43 hospitals in Ontario perform TVT; hospital TVT volumes are not currently known.
- The precise utilisation of TVT in Ontario is not known; manufacturer’s sales figures currently provide a proxy for actual utilisation.
- The characteristics of patients receiving TVT are not known.
- The specialty/training of physicians and the number of cases per provider performing TVT are not known.
Appendices

Appendix A: Clinical management for women with SUI

(Source: Canadian Continence Foundation; 2001)
# Appendix B: Systematic Review on TVT - Summary

<table>
<thead>
<tr>
<th>Organization</th>
<th>National Institute for Clinical Excellence (NICE)</th>
<th>Agencee Nationale d'Accreditation et d'Evaluation en Sante</th>
<th>Canadian Coordinating Office for Health Technology Assessment (CCOHTA)</th>
<th>Australian Safety and Efficacy Register of New Interventionsal Procedures – Surgical. The Royal Australian College of Surgeons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country of origin and publication date</td>
<td>United Kingdom 2003</td>
<td>France 2002</td>
<td>Canada 2002</td>
<td>Australia 2001</td>
</tr>
<tr>
<td>Review dates</td>
<td>1966 to May 2002</td>
<td>Not stated in report</td>
<td>Not stated; pre-assessment</td>
<td>1966 to August 2000</td>
</tr>
<tr>
<td>Population/inclusion criteria</td>
<td>Women diagnosed with SUI stratified:</td>
<td>-Women diagnosed with SUI</td>
<td>-Not explicit</td>
<td>-Women diagnosed with incontinence</td>
</tr>
<tr>
<td></td>
<td>-secondary intervention</td>
<td>-TVT or TVT vs colposuspension</td>
<td></td>
<td>-TVT vs intravaginal slingplasty</td>
</tr>
<tr>
<td></td>
<td>-co-existing prolapse</td>
<td></td>
<td></td>
<td>-TVT vs Burch colposuspension (open)</td>
</tr>
<tr>
<td></td>
<td>-mixed incontinence</td>
<td></td>
<td></td>
<td>-all articles including letters, essays, and background material</td>
</tr>
<tr>
<td></td>
<td>Women diagnosed with SUI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcomes reviewed</td>
<td>Study validity</td>
<td>-Study validity</td>
<td>-Not explicitly stated</td>
<td>-Mortality</td>
</tr>
<tr>
<td></td>
<td>-Complications</td>
<td>-Complications</td>
<td></td>
<td>-Complications</td>
</tr>
<tr>
<td></td>
<td>-Quality of life</td>
<td>-Cure rates</td>
<td></td>
<td>-Cure rates</td>
</tr>
<tr>
<td></td>
<td>-Economic analysis</td>
<td>-French health services review attempted</td>
<td></td>
<td>-Intra-operative and hospital factors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Brief economic analysis</td>
<td></td>
<td>-recovery</td>
</tr>
<tr>
<td>Conclusions</td>
<td>-TVT as effective as other more invasive procedures</td>
<td>-Poor design of clinical and economic evaluations to date</td>
<td>-Publication of Ward and Hilton trial will provide needed information</td>
<td>-TVT yields lower infection rate with lighter sedation used</td>
</tr>
<tr>
<td></td>
<td>-TVT is more cost-effective than more invasive procedures</td>
<td>-1 long-term case study (5 years)</td>
<td>-HTAs from NICE and ASERNIP-S will shed further light</td>
<td>-No reported rejection to date</td>
</tr>
<tr>
<td></td>
<td>-Not recommended for women who are not eligible for surgery because of lack of long term outcome data</td>
<td>-TVT replacing colposuspension as treatment of choice</td>
<td></td>
<td>-TVT cure rate similar to colposuspension</td>
</tr>
<tr>
<td></td>
<td>-Population-based registry recommended</td>
<td>-TVT sometimes used for invalidated indications; this trend could continue</td>
<td></td>
<td>-Variation in definitions and patient composition of studies make comparisons difficult</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-experienced surgeon required</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-large, multi-centred cohort registry with annual followup for at least 5 years required</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>-Standard coding</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
TVT for stress urinary incontinence

<table>
<thead>
<tr>
<th>Limitations of Review</th>
<th>necessary to evaluate utilization</th>
<th>Summary of clinical effectiveness adapted from Agence Nationale d’Accreditation et d’Evaluation en Sante, March 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>-Comprehensive</td>
<td>-No parameters around data collection</td>
<td>-Parameters of review are stated but information sparse – 1 RCT, costing reference from manufacturer</td>
</tr>
<tr>
<td>-No indication of the type/quality of articles assessed</td>
<td>-Economic analysis methods not explicit</td>
<td>-Early review of new technology</td>
</tr>
<tr>
<td></td>
<td>-No attached bibliography</td>
<td>-Developer of the technology on the advisory panel</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure duration:</th>
<th>Burch procedure</th>
<th>TVT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>72 ±23.5 minutes</td>
<td>22 to 47 minutes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-operative catheterization:</th>
<th>7 ±2 days</th>
<th>3 to 16% requiring this (where specified)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of hospital stay:</td>
<td>2-5 days</td>
<td>8 hours to 3 days</td>
</tr>
<tr>
<td>Objective cure rate:</td>
<td>84-100% (&lt;12 months); 25-89% (1-3 years); 84% (up to 47 months); 72-82% (3 years); 84% (4 years – meta analysis)</td>
<td>95-100% (&lt;1 year); 86-90% (3 years); 84.7% (5 years)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality of Life:</th>
<th>-</th>
<th>on a 10-point scale, QOL increased by 6.3; on a 100 point scale, discomfort decreased from 75 pre-op to 0 post-op</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety:</td>
<td>5.6%</td>
<td>0-7% of cases</td>
</tr>
<tr>
<td>Bladder perforation:</td>
<td>134.3 ±102 ml</td>
<td>reported in 1% of cases (TVT should be avoided in patients using anticoagulation therapy)</td>
</tr>
<tr>
<td>Bleeding:</td>
<td>2.2%</td>
<td>0.8-17%</td>
</tr>
<tr>
<td>Urinary tract infection:</td>
<td>4.3%</td>
<td>0-7.8%</td>
</tr>
<tr>
<td>Dysuria:</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>Rejection of materials:</td>
<td>-</td>
<td>0</td>
</tr>
</tbody>
</table>

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References


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