

# **Tension-Free Vaginal Tape for Stress Urinary Incontinence**

**Health Technology Literature Review**

**Completed February 2004**

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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 Gynecare TVT\* Tension Free Vaginal Tape (\*trademarked by Ethicon Inc.) for stress urinary incontinence (SUI) 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, 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 stabilized at moments of stress, such as laughing, coughing, or strenuous exercise. TVT has been available as a 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 urinary incontinence in women in 2000/2001.

## Methods

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

The leading international organizations were scanned for previous health technology assessments on TVT. The Cochrane Library Database and the Cochrane Incontinence Group Database were also scanned. To augment these assessments, the peer-reviewed literature from 2002 to 2003 was searched. Case studies, review articles, editorials, and letters were excluded. The search was limited to studies on humans.

For the most recent randomized controlled trials (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 RCTs and systematic reviews that TVT is as effective as more invasive treatments for SUI and is associated with a decreased length of hospital stay and postsurgical morbidity. However, there are currently no trials with follow-up longer than 2 years; therefore, the long-term effectiveness and complication rates of TVT have yet to be determined. High complication rates have been 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. The number of TVT procedures 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

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otherwise be eligible for invasive surgery may consider TVT as a less invasive option. Because long-term outcomes are not known, subsequent health services may be 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 Gynecare TVT \*Tension Free Vaginal Tape (\*trademarked by Ethicon Inc.) for stress urinary incontinence (SUI) 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 is extremely common. Broad prevalence estimates 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 urinary incontinence. (2;3) The extent of underreporting of this condition is unknown because associated psychosocial stress may preclude some people 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.

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 a 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 SUI in women. During the procedure, 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 stabilized 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 urinary incontinence 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; therefore, definitive effectiveness of this procedure has yet to be determined.

International health technology assessments and appraisals evaluating the clinical and cost-effectiveness of TVT have been performed since 2001, most recently in August 2003. This report will synthesize and update the conclusions from previous health technology assessments 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 assessment 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, and is controlled by the nervous system. Incontinence occurs when the relationship among 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 characterized 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 2 distinct characterizations 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 2 types of SUI. Guidelines for the diagnosis and management of SUI have recently been adopted in Canada. (7;8)

Urinary incontinence is estimated to affect about 8 million American women and 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 18% to 34% of respondents had symptoms of SUI. (4) Just over 9% reported symptoms “sometimes,” while almost 3% reported symptoms “most of the time.” SUI was most common for women in their 50s. A more recent study suggests that 24% of women aged 18 to 44 years and 37% of women aged 45 and over have 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 the cost of pads, drugs, and devices, and the inability to participate in the work force in severe cases. Risk factors 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 noninvasive, 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.

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.,

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spinal) anesthesia and requires 2 to 4 hospital days for recovery. (1;12) Subjective cure rates 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 a typical hospital stay of 3 to 5 days. (1) TVT is considered 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 resist pressure from the abdomen better. 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.

## The Technology Being Reviewed: Tension-Free Vaginal Tape

Created by a Swedish team in 1996, (5) Gynecare TVT\* Tension Free Vaginal Tape (trademarked by Gynecare, a division of Ethicon, Inc., Somerville, NJ) 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 stabilized 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 then inserted through the retropubic space into the abdomen to hold the tape in place. The plastic covering and the needles are removed when the tape is in place. The tape then replaces the defective ligaments and acts to retain urine during a cough or sneeze. Cystoscopy is done 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 and 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 health technology assessment organizations for previous assessments 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 from 2002 to 2003, including the following databases: MEDLINE, EMBASE, PREMEDLINE (MEDLINE citations in process) and the Cochrane Library Database. 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 health technology assessment; reports and articles published in 2003
- Language: publication in English
- Published health technology assessments and guidelines

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 yielded 120 relevant citations for 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:

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- 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., elderly people or obese patients)
- 4 studies had fewer than 10 cases
- 1 was a physician practice-management questionnaire
- 2 were about nonliving subjects
- 2 were incorrect citations

Ninety articles were excluded from this search. Two guidelines and 4 systematic reviews (1 comprehensive appraisal published in August 2003) were found. 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 summarizes 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 owing to the lack of long-term trials. With the recognition that women may prefer this procedure because it is minimally invasive and has faster recovery times (despite the surgical risks and the possibility of postsurgical complications), the most recent reviews from the National Institute for Clinical Excellence (NICE) and Agence Nationale d'Accréditation de Santé recommended multicentre registries for long-term evaluation.

The most recent and comprehensive appraisal of TVT was developed by NICE in the United Kingdom. (1) 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 information was obtained from the Internet, conference proceedings, and advice from experts in the field. 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 perioperative and short-term complications postsurgery. Cost-effectiveness was also examined and is discussed later in this report.

**Table 1: Results of the NICE Health Technology Assessment Literature Review**

Study Design	Level of Evidence	Number of Eligible Studies
Large RCT, systematic reviews of RCTs*	1	5
Large RCT unpublished, but reported to an international scientific meeting	1(g)	9
Small RCT	2	
Small RCT unpublished, but reported to an international scientific meeting	2(g)	
Non-RCT with contemporaneous controls	3a	
Non-RCT with historical controls	3b	
Non-RCT presented at international conference	3(g)	
Surveillance (database or register)	4a	2
Case series with more than 2 years of follow-up (multisite)	4b	17
Case series with less than 2 years of follow-up	4c	49
Retrospective review, modelling	4d	
Case series presented at international conference	4(g)	

g=grey literature

\*RCT represents randomized controlled study.

The NICE authors evaluated the Level 1 evidence (randomized controlled 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 the NICE Review\***

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

\*Reprinted from Health Tech Assess 2003, Vol. 7(21); Cody J, Wyness L, Wallace S et al; Systemic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence, with permission from National Coordinating Centre for Health Technology Assessment.

The NICE report also synthesized 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.

**Table 3: Complications From Randomized Controlled Trials Gleaned From the NICE Review\***

Study	Comparator	Bladder Perforation TVT	Bladder Perforation Comparator	Relative risk (95% CI) / Risk Difference (95% CI)	Hematoma TVT	Hematoma Comparator	Relative risk (95% CI) / Risk Difference (95% CI)
RCTs							
Cucinella - 2001	Lap Colpo	3/57 (5%)	0/56 (0%)	6.88 (0.36-130.21); 0.05 (0.01-0.12)	0/57 (0%)	2/56 (4%)	0.20 (0.01-0.02); -0.04 (-0.9-0.02)
Han – 2001	Burch Colpo	1/25 (4%)	0/25 (0%)	3.00 (0.13-70.3); 0.04 (-0.06-0.14)	NR	NR	NR
Ward – 2002	Burch Colpo	15/170 (9%)	31/146 (2%)	4.29 (1.27-14.54)	3/170 (1.8%)	0/146 (0%)	6.02 (0.31-15.55); 0.02 (-0.01-0.04)

*\*Reprinted from Health Tech Assess 2003, Vol. 7(21); Cody J, Wyness L, Wallace S et al; Systemic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence, with permission from National Coordinating Centre for Health Technology Assessment.*

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 found similar complications rates to those reported in the RCTs; bladder perforation was the most common complication. Other complications seen were new urge symptoms, voiding dysfunction, and postoperative pain. Tape erosion or rejection was seen in 1% of women involved in case series.

Disease-related quality of life (QOL) is an important outcome of treatment for SUI. Three of the RCTs assessed QOL 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, multicentre trial, 344 women with SUI were recruited from 13 centres in England and 1 centre in Ireland. In this unblinded trial, women were randomized to receive either open colposuspension or TVT over 15 months. Objective outcomes, measured by urodynamic testing and 1-hour pad tests; 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 hospital stays than those who received colposuspension, and there was 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 postsurgical 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, due to a more stringent definition of cure. Finally, there was a higher attrition rate for

women who were randomized to the colposuspension group; however, the authors used an intention-to-treat analysis.

**Table 4: Complication Rates From Ward and Hilton Trial\***

Complications	TVT group (n=170) N (%)	Open Colposuspension group (n=146) N (%)	P value
Bladder injury	15 (9)	3 (2)	.013
Vaginal perforation	5 (3)	0	.06
Wound infection	4 (2)	10 (7)	.06
Deep vein thrombosis	1 (1)	3 (2)	.10
Incisional hernia	N/A	3 (2)	
Retropubic hematoma	3 (2)	0	.25
Vascular injury	1 (1)	0	1.0
Tape erosion	1 (1)	N/A	
Urinary tract infection (6 weeks after surgery)	38 (22)	46 (32)	.74
Total complications	67 (39)	65 (44.5)	.36

\*Reproduced from *British Medical Journal* 2002,325(7355); p. 367-373: Ward K, Hilton P et al; Prospective multicentre randomized trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence;; with permission from BMJ Publishing Group.

Overall, external validity in the RCTs and non-randomized trials 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 those 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 had 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 involved 1,369 patients (range, 25 to 206) with a mean or median follow-up period of 24 to 60 months. Other case series 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 as follows:

- 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.

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- 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:

- 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 summarizes the Medical Advisory Secretariat's review. Overall, there were 25 studies, including the RCT portion of the NICE appraisal, 4 RCTs, and 20 case series or retrospective 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.

**Table 5: Quality of Evidence From Systematic Review, January 1, 2002 to September 15, 2003**

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

g=grey literature

\*RCT represents randomized controlled trial; HTA, health technology assessment

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 (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) focused on 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**

<b>RCTs</b>	<b>Arunkalaivanan 2003</b>	<b>Wang 2003</b>	<b>Valpas 2003</b>	<b>Kondo 2003 (unpublished)</b>
N	142	90	121	57
Follow-up, months (median)	6-24 (12)	12-36 (22)	6 weeks	3-24 (24)
Comparator	Porcine dermal sling	Burch Colpo	Laparoscopic mesh colposuspension	Pubovaginal sling
Subjective cure rate (TVT)	58/68 (85%)	45/49 (92%)	Not reported	25/29 (86%)
Subjective cure rate (comparator)	66/74 (89%)	38/41 (93%)	Not reported	20/28 (72%)
Relative risk (95% CI*)	0.956 (0.36, 2.57)	0.99 (0.21,4.66)	Not applicable	1.21 (0.32, 4.56)
Objective cure rates (TVT)	Not reported	40/49 (82%)	65/70 (93%)	20/29 (69%)
Objective cure rates (comparator)	Not reported	31/41 (76%)	45/51 (88%)	13/28 (46%)
Relative risk (95% CI*)	Not applicable	1.08 (0.39, 2.96)	1.05 (0.30, 3.63)	1.5 (0.51, 4.42)

\* CI – confidence interval

**Table 7: Summary of RCT Complication Rates Gleaned From Systematic Review January 1, 2002 to September 15, 2003**

<b>RCTs</b>	<b>Arunkalaivanan 2003</b>	<b>Wang 2003</b>	<b>Valpas 2003</b>	<b>Kondo 2003 (unpublished)</b>
N	142	90	121	57
Follow-up, months (median)	6-24 (12)	12-36 (22)	6 weeks	3-24 (24)
Comparator	Porcine dermal sling	Burch Colpo	Laparoscopic mesh colposuspension	Pubovaginal sling
Bladder perforation (TVT)	0/68	Not reported	1/70 (1.4%)	6/29 (21%)
Bladder perforation (comparator)	0/74	Not reported	1/51 (2%)	5/28 (18%)
Relative Risk of Bladder perforation (95% CI)	Not applicable	Not applicable	0.74 (0.05, 11.80)	1.16 (0.31, 4.33)
Hematoma (TVT)	0	Not reported	Not reported	Not applicable
Hematoma (comparator)	0	Not reported	1/51 (2%)	Not applicable
Relative Risk of Hematoma (95% CI)	Not applicable	Not applicable	Not applicable	Not applicable

\* CI – confidence interval

## TVT for Stress Urinary Incontinence

Twelve single-centre case series (Level 4c) were found and 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 from 5 to 22 months. Four Level 4c studies (20-23) had patient numbers between 50 and 100 (51, 63, 69, and 92). Follow-up was from 6 weeks to 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 6 weeks to 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 cure rate of about 4%.

### **Summary of Findings on Effectiveness**

Stress urinary incontinence may pose a considerable QOL 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 still have not been adequately examined. Further, the available evidence has centred on women with SUI who were eligible for surgery. Evidence on the effectiveness for 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 these groups 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 focused on costs for TVT. Of these 69 articles, 2 were eligible for inclusion in this review.

The four health technology assessments discussed previously contained some cost information. However, only the NICE report had comprehensive cost-effectiveness analyses. These are summarized later.

### **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\*†**

	<b>Persson – 2002</b> (costs in \$Cdn converted from from Euros €; OECD 2002)		<b>Manca – 2003</b> (costs in \$Cdn converted from £GBP; OECD 2002)	
	TVT (N=38) Total cost	Lap colposuspension (N=32) Total costs	TVT (N=117) Mean total cost	Open colposuspension (N=97) Mean total
• OR costs			1317.60	799.71
• Hospital cost			483.12	1396.29
• Follow up cost at 6 months			135.24	184.83
• Total cost per patient			1935.96	2380.83
• Difference			-444.87	
• Basic costs	73.30	97.55		
• Surgical + anesthesia costs	376.00	564.01		
• Surgical materials	571.78	136.68		
• Hospital care	762.59	837.77		
• Depreciation	0	47.44		
• Outpatient visits to physician or nurse	15.67	22.90		
• Average cost/procedure	1799.34	1706.35		
• Total costs including re- operations	1959.88	1761.43		

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

\* From Persson J, Teleman P, Eten-Bergquist C, Wolner-Hanssen P. Cost-analyses based on a prospective randomized study comparing laparoscopic colposuspension with a tension-free vaginal tape procedure. *Acta Obstetrica et Gynecologica Scandinavica* 2002; 81:1066-1073.

† From: Manca A, Sculpher MJ, Ward K, Hilton P. A cost-utility analysis of tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence. *BJOG: an International Journal of Obstetrics & Gynaecology* 2003; 110(3):255-262.

All results are in Canadian currency unless otherwise noted. The total mean patient cost for TVT in the Persson trial (without reoperations) was \$1799.35 compared with \$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 \$92.99 higher than laparoscopic colposuspension; average costs for TVT was \$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 more readmissions to hospital in the colposuspension group, which 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 reoperations (\$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 6 months. 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.

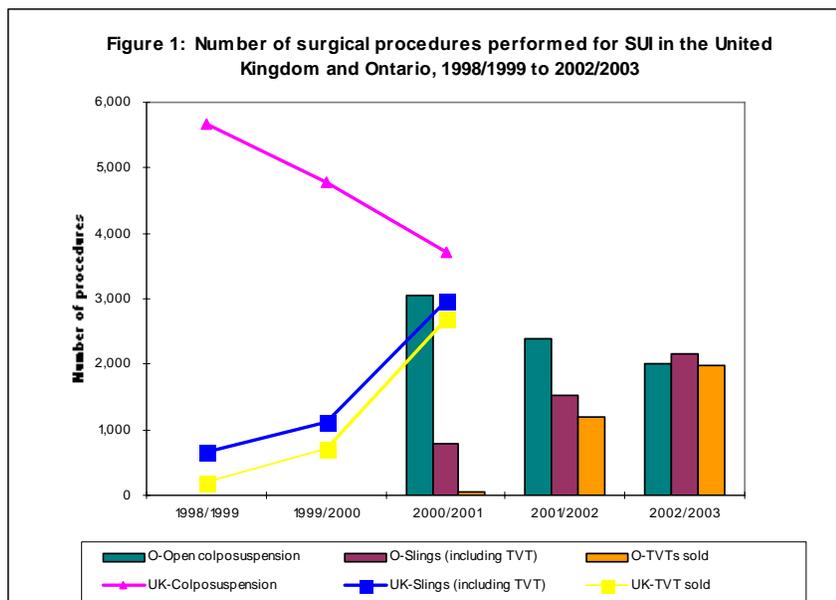
The NICE report (1) produced a detailed cost-effectiveness analysis comparing TVT with open colposuspension. A Markov modeling technique was used to determine cost-effectiveness based on resource use and costing, as gleaned from the review. The model used a probabilistic analysis to estimate costs and QALYs for up to 10 years post-surgery. Economic modeling suggested that at 5 years postsurgery, 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/Budget Impact Analysis

#### Diffusion

Currently, the delivery of TVT in Ontario is controlled through the hospital. Professional cost (including anesthetist costs, all in Canadian currency) 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 a TVT device is \$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 do not capture TVT alone (it is included in the sling procedure category in both the Ontario and United Kingdom data); 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.



### **Figure 1: Stress Urinary Incontinence Procedures in Ontario and the United Kingdom Demographics**

The prevalence of SUI is unknown. It ranges broadly from study to study. A United Kingdom cross-sectional survey of 5,544 women aged 40 and over who visited their family physician identified about 35% who had urinary incontinence. (4) About 50% of women with incontinence are deemed to have SUI. (9;30) The cross-sectional survey identified 9.5% of their sample with SUI 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 United Kingdom estimates are used.

#### **Ontario women with SUI:**

2,755,300 women aged 40 and over \* 35% with urinary incontinence = 964,355 women in Ontario;  
- 964,355 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 are between 13,500 and 45,807 women who may be candidates for TVT in Ontario. Given that there are currently about 5,000 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**

All costs are in Canadian currency unless otherwise noted.

Interim results from a small, unpublished case-costing study in Ontario calculated the costs (in-hospital costs and professional fees) of 7 patients who underwent the TVT procedure and compared this to a cohort of patients who underwent open Burch colposuspension. (Schachter, J, Mount Sinai Hospital presentation to manufacturer, 2000) The study found an average total cost of the TVT procedure was \$3,032 (in-hospital costs of \$1,876 and professional fees of \$1,156). The average cost of the Burch colposuspension was \$6,047 (in-hospital costs of \$5,014 and professional fees of \$1,033). The difference in total costs between the two procedures was \$3,015 and the difference in hospitalization costs was \$3,138.

Based on an analysis of Resource Intensity Weights for Ontario, the per diem hospitalization cost of an inpatient procedure for SUI (ICD-9 625.6) was \$486.50.<sup>1</sup> Given an average length of stay of about 5 days

<sup>1</sup> 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

## TVT for Stress Urinary Incontinence

for colposuspension and potentially no hospitalization days for TVT, the difference in hospitalization costs is estimated to be \$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 \$2,433 to \$730 (cost of TVT device) = \$1,700<sup>2</sup>

A recently published study from the United Kingdom 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 about \$445. (OECD, 2003)

Even though cost savings per case accruing to the hospital would range from \$445 to \$3,138, it is possible that the adoption of TVT would not be budget-saving because of concerns over diffusion associated with a less invasive procedure. We estimate that about 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 SUI.<sup>3</sup> The cost to the Ontario Ministry of Health and Long-term Care would be an estimated \$870,000 in OHIP physician fees. However, clearing the entire backlog of cases in the province through direct ministry funding of procedures at about \$5,000 per procedure + OHIP costs may be from about \$47.8 million to \$228.5 million.<sup>4</sup>

### Cost-Effectiveness

Given successful cure rates ranging from 68% to 91% for TVT and colposuspension procedures, the incremental cost-per-cure ratio for TVT is undefined, because the denominator is likely not different from zero. TVT would economically “dominate” colposuspension because of the costs savings achieved. In terms of cost per QALY, TVT added about 0.01 QALYs compared to colposuspension in a 2003 study. (29) Because 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 TVT being more cost-effective than colposuspension would be 94.6% if the decision-maker is willing to pay £30,000/QALY (about 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 2 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 procedure of choice for women with SUI. Downstream health care costs due to potential long-term complications were also not estimated.

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colposuspension or TVT is  $(0.1390 * \$3,500) = \text{Cdn } \$486.50$ . 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.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup>  $(8,500 * \$5,000 \text{ per procedure}) + \$5.3 \text{ million OHIP costs} = \$47.8 \text{ million}$   $(40,800 * \$5,000 \text{ per procedure} + \$24.5 \text{ million OHIP costs} = \$228.5 \text{ million}$ . The \$5,000 per procedure cost was based on the Mount Sinai cost estimates of colposuspension (most expensive procedure available.)

## Existing Guidelines for Use of Technology

There are 2 recent guidelines for the use of TVT for SUI.

Farrell SA for the Society of Obstetricians and Gynaecologists of Canada. Tension-free vaginal tape (TVT) procedure. *J Obstet Gynaecol Can* 2003;25(8):692-4.

Recommendations from this guideline report included the following:

- “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.
- Proper training is recommended prior to performing TVT procedures.
- 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 the following:

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

## 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 on women with SUI who were eligible for surgery. Evidence on the effectiveness for 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 these groups of women.

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

This technology is already in use in Ontario and its use 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 it may be more attractive to patients than more invasive surgical options. Women who would not have otherwise opted for invasive surgery may 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 unknown, 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 and Clinical

- SUI predominantly affects women aged 40 and older.
- Improved QOL 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.
- Perioperative complication rates of TVT are higher than for colposuspension, but postoperative 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 greater experience of surgeons; long-term complication rates have not been adequately evaluated.
- Overall patient satisfaction levels are about the same as for other procedures after 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, 13,500 to 45,807 women in Ontario may be eligible for TVT to treat their SUI.

#### 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 a cost savings per patient when taking into account the higher number of hospital bed-days associated with recovery of more invasive surgery. If TVT diffuses rapidly it may cost the system more due to additional procedures for SUI being performed.

## TVT for Stress Urinary Incontinence

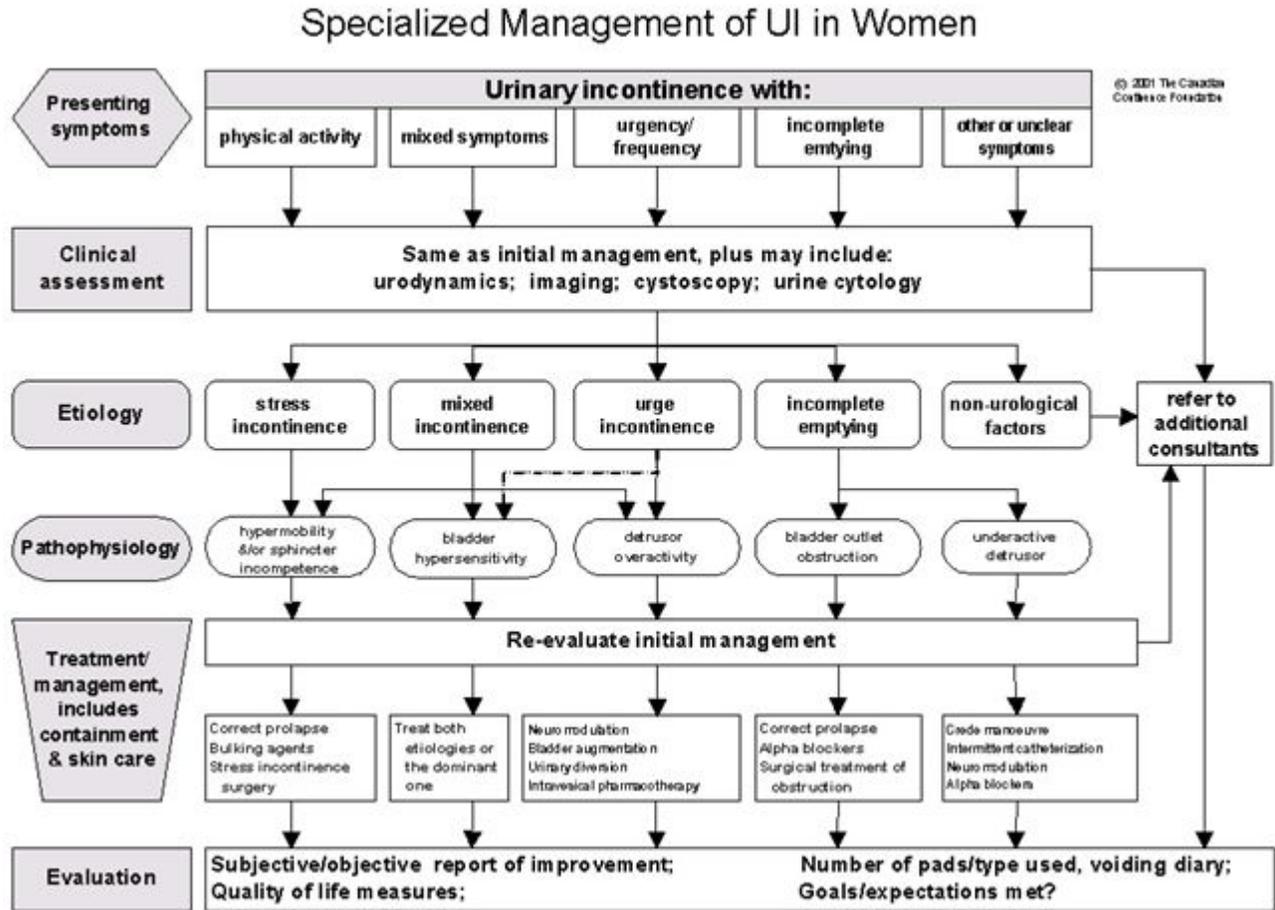
- Economic and budget impact estimates cannot be accurately developed until accurate estimates of prevalence and acuity are ascertained.
- Hospitals pay for TVT from their global budget and therefore control its dissemination.
- There is no way to differentiate the hospital costs of TVT from other traditional sling procedures using administrative data.
- There is no distinct professional code for TVT; therefore, there is no way of differentiating professional costs of TVT from other sling procedures.
- Complications arising from TVT are associated with a lack of surgical training.
- Because there are no distinguishing codes in the health administration databases for TVT, the only way to examine the use 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 use of TVT in Ontario is not known; manufacturer's sales figures currently provide a proxy for actual use.
- The characteristics of patients receiving TVT are not known.
- The specialty/training of physicians and the number of cases per provider of TVT are unknown.

# Appendices

## Appendix A: Clinical management for women with SUI\*



\*Image retrieved from <http://www.continence-fdn.ca/consensus/figure2.htm>, reprinted with permission from the Canadian Continence Foundation, 2001

**Appendix B: Systematic Review on TVT - Summary**

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

## TVT for Stress Urinary Incontinence

		evaluate utilization		
Limitations of Review	-Comprehensive	-No parameters around data collection -No indication of the type/quality of articles assessed -Economic analysis methods not explicit -No attached bibliography	-Parameters of review are stated but information sparse – 1 RCT, costing reference from manufacturer	-Early review of new technology -Developer of the technology on the advisory panel

### Summary of Clinical Effectiveness Adapted From Agence Nationale d'Accreditation et d'Evaluation en Sante, March 2002

	Burch procedure	TVT
Procedure duration:	72 ±23.5 minutes	22 to 47 minutes
Post-operative catheterization:	7 ±2 days	3 to 16% requiring this (where specified)
Duration of hospital stay:	2-5 days	8 hours to 3 days
Objective cure rate:	84-100% (< 12 months); 25-89% (1-3 years) 84% (up to 47 months) 72-82% (3 years) 84% (4 years – meta analysis)	95-100% (<1 year) 86-90% (3 years) 84.7% (5 years)
Quality of Life:	-	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
Safety:	5.6%	
Bladder perforation:	134.3 ±102 ml	0-7% of cases
Bleeding:		reported in 1% of cases (TVT should be avoided in patients using anticoagulation therapy)
Urinary tract infection:	2.2%	
Dysuria:	4.3%	0-7.8%
Rejection of materials:	-	0.8-17%
		0

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