Ontario Health Technology Assessment Series 2006; Vol. 6, No. 3

Midurethral Slings for Women with Stress Urinary Incontinence

An Evidence-Based Analysis

February 2006

Ontario

Medical Advisory Secretariat
Ministry of Health and Long-Term Care

Suggested Citation

This report should be cited as follows:

Medical Advisory Secretariat. Midurethral slings for women with stress urinary incontinence: an evidence-based analysis. *Ontario Health Technology Assessment Series* 2006; 6(3)

Permission Requests

All inquiries regarding permission to reproduce any content in the *Ontario Health Technology Assessment Series* should be directed to MASinfo@moh.gov.on.ca

How to Obtain Issues in the Ontario Health Technology Assessment Series

All reports in the *Ontario Health Technology Assessment Series* are freely available in PDF format at the following URL: www.health.gov.on.ca/ohtas

Print copies can be obtained by contacting MASinfo@moh.gov.on.ca

Conflict of Interest Statement

All analyses in the Ontario Health Technology Assessment Series are impartial and subject to a systematic evidence-based assessment process. There are no competing interests or conflicts of interest to declare.

Peer Review

All Medical Advisory Secretariat analyses are subject to external expert peer review. Additionally, the public consultation process is also available to individuals wishing to comment on an analysis prior to finalization. For more information, please visit http://www.health.gov.on.ca/english/providers/program/ohtac/public_engage_overview.html

Contact Information

The Medical Advisory Secretariat
Ministry of Health and Long-Term Care
20 Dundas Street West, 10th floor
Toronto, Ontario
CANADA
M5G 2N6
Email: MASinfo@moh.gov.on.ca
Telephone: 416-314-1092

ISSN 1915-7398 (Online)
ISBN 1-4249-1974-6 (PDF)

About the Medical Advisory Secretariat

The Medical Advisory Secretariat is part of the Ontario Ministry of Health and Long-Term Care. The mandate of the Medical Advisory Secretariat is to provide evidence-based policy advice on the coordinated uptake of health services and new health technologies in Ontario to the Ministry of Health and Long-Term Care and to the healthcare system. The aim is to ensure that residents of Ontario have access to the best available new health technologies that will improve patient outcomes.

The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

The Medical Advisory Secretariat conducts systematic reviews of scientific evidence and consultations with experts in the health care services community to produce the *Ontario Health Technology Assessment Series.*

About the Ontario Health Technology Assessment Series

To conduct its comprehensive analyses, the Medical Advisory Secretariat systematically reviews available scientific literature, collaborates with partners across relevant government branches, and consults with clinical and other external experts and manufacturers, and solicits any necessary advice to gather information. The Medical Advisory Secretariat makes every effort to ensure that all relevant research, nationally and internationally, is included in the systematic literature reviews conducted.

The information gathered is the foundation of the evidence to determine if a technology is effective and safe for use in a particular clinical population or setting. Information is collected to understand how a new technology fits within current practice and treatment alternatives. Details of the technology's diffusion into current practice and information from practicing medical experts and industry, adds important information to the review of the provision and delivery of the health technology in Ontario. Information concerning the health benefits; economic and human resources; and ethical, regulatory, social and legal issues relating to the technology assist policy makers to make timely and relevant decisions to maximize patient outcomes.

If you are aware of any current additional evidence to inform an existing Evidence-Based Analysis, please contact the Medical Advisory Secretariat: MASInfo@moh.gov.on.ca. The public consultation process is also available to individuals wishing to comment on an analysis prior to publication. For more information, please visit
http://www.health.gov.on.ca/english/providers/program/ohtac/public_engage_overview.html

Table of Contents

Abbreviations

CI	Confidence interval
IVS	Intravaginal slingplasty
PFMT	Pelvic floor muscle therapy
RCT	Randomized controlled trial
SOGC	Society of Obstetricians and Gynaecologists of Canada
SPARC	Suprapubic arc
SUI	Stress urinary incontinence
TVT	Tension-free vaginal tape
UTI	Urinary tract infection

Glossary

Cystocele	A cystocele occurs when the wall between the bladder and the vagina weakens and allows the bladder to droop into the vagina. A cystocele is mild (grade 1) when the bladder droops only a short way into the vagina. With more severe (grade 2) cystocele, the bladder sinks far enough to reach the opening of the vagina. The most advanced (grade 3) cystocele occurs when the bladder bulges out through the opening of the vagina.
Pelvic prolapse	Pelvic prolapse is the relaxing or dropping of the pelvic organs into the vagina. Women may experience prolapse of the uterus, urethra, vagina, bladder, or rectum.
Stress urinary incontinence	Weakening of the pelvic tissue surrounding the urethra so that urine loss occurs when coughing, sneezing, laughing. Etc.
Uterine prolapse	Uterine prolapse is a descent or herniation of the uterus into or beyond the vagina. In first-degree prolapse, the cervix remains within the vagina; in second-degree prolapse, the cervix is at or near the introitus; and in third-degree prolapse (procidentia), most or all of the uterus lies outside the vaginal opening. Uterine prolapse always is accompanied by some degree of vaginal wall prolapse.
Vaginal vault prolapse	Vaginal vault prolapse occurs when the upper portion of the vagina loses its normal shape and sags or bulges down into the vaginal canal or outside of the vagina.

Executive Summary

Objective

The objective of the current review was to evaluate the safety, efficacy, and cost-effectiveness of midurethral slings compared with traditional surgery.

Background

This assessment was undertaken in order to update and expand upon the health technology & policy assessment of tension-free vaginal tape (TVT, Gynecare Worldwide, a division of Ethicon Inc, a Johnson & Johnson company, Somerville, New Jersey) sling procedure for stress urinary incontinence published by the Medical Advisory Secretariat in February 2004. Since the publication of the 2004 assessment, a number of TVT-like sling alternatives have become available which employ the same basic principles as TVT slings: minimally invasive, midurethral placement, self-fixing, and tension-free. This update will evaluate the efficacy and safety of midurethral slings.

Clinical Need

Normal continence is controlled by the nervous system and involves co-ordination between bladder, urethra, urethral sphincter, and pelvic floor. Incontinence occurs when the relationship among the above components is compromised, either due to physical damage or nerve dysfunction. (1) Stress urinary incontinence 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. (2) There are 2 factors which define stress urinary incontinence: a weakening in the support of the proximal urethra, causing urethral hyper-mobility and deficiency in the sphincter, causing urethral leakage. Both factors are thought to co-exist. (1) Accurate tests are not available to distinguish these 2 types of stress urinary incontinence.

Urinary incontinence is estimated to affect about 250,000 Canadian women and 8 million American women aged 65 and over. (3;4) The prevalence of stress urinary incontinence is very difficult to measure because women with stress urinary incontinence may not tell their health practitioner about their symptoms due to embarrassment associated with stress urinary incontinence. 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. (5) Just over 9% reported symptoms "sometimes," while almost 3% reported symptoms "most of the time." Stress urinary incontinence 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 stress urinary incontinence. (6)

Stress urinary incontinence 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. (7) Economic burden may include the cost of pads, drugs, and devices, and the inability to participate in the work force in severe cases.

Midurethral Slings

Suburethral slings differ according to several criteria including placement, approach, method of fixation, and sling material. This review will evaluate slings which fulfill all of the following criteria:

- Midurethral placement (as opposed to bladder neck placement)
- Self-fixing (no sutures, bone anchors, etc.)
- Minimally invasive (using local, epidural, or general anesthesia)
- "Tension-free" placement

The different types of midurethral slings available vary according to 3 main parameters:

- Implant material, i.e., monofilament, multifilament, elastic, non-elastic, smooth, serrated, etc.,
- Delivery instruments, i.e., needles, curved trocars, disposable, reusable, etc.,
- Surgical approach

As any one, or any combination of these parameters may vary across the different sling brands, it is difficult to ascribe observed differences in efficacy and safety across slings to any one factor.

Review Strategy

The literature published between January 2000 and February 2006 was searched in the following databases: OVID Medline, In Process and Other Non-Indexed Citations, Embase, Cochrane Database of Systematic Reviews and CENTRAL, INAHTA. The database search was supplemented with a search of relevant Web sites, and a review of the bibliographies of selected papers. The search strategy can be viewed in Appendix 1.

Inclusion Criteria

- General population with SUI
- Randomized controlled studies, health technology assessments, guidelines
- Female subjects
- Midurethral, self-fixing, and minimally invasive slings/tapes
- English language

The search strategy yielded 391 original citations. Studies were excluded for a variety of reasons, such as using traditional, suburethral slings as opposed to midurethral slings, not including patients with stress urinary incontinence, including males in the study, case reports, and not reporting the outcomes of interest.

There were 13 randomized controlled trials identified that compared midurethral slings to other midurethral slings or traditional surgery. (8-20) (Table 1) Three of the randomized controlled trials (15;17;20) have had subsequent updated articles of longer term results. (21-23) The results of the randomized controlled trials have been stratified into 2 groups: TVT versus colposuspension and comparisons of midurethral slings. No randomized controlled trials were identified that compared a midurethral sling other than TVT to colposuspension.

Summary of Findings

Effectiveness

At this time, there does not appear to be one procedure that is more effective than another at curing stress urinary incontinence. TVT appears to have similar cure rates to open colposuspension; and the various midurethral sling types seem to have similar cure rates.

Procedure Time and Length of Hospital Stay

The procedure time and the length of hospital stay for TVT are significantly shorter than the procedure time and length of stay for colposuspension.

The procedure time and length of hospital stay for all midurethral slings appears to be similar.

Complications

The most frequently reported complications were bladder perforations, de novo voiding difficulties and device problems.

Quality of Life

Quality of life was not consistently reported in all of the randomized controlled trials. In the studies that reported quality of life there does not appear to be a significant difference in quality of life scores between the sling procedures.

Objective

The objective of the current review was to evaluate the safety, efficacy, and cost-effectiveness of midurethral slings compared with traditional surgery.

Background

This assessment was undertaken to update and expand upon the health technology and policy assessment of tension-free vaginal tape (TVT, Gynecare Worldwide, a division of Ethicon Inc, a Johnson & Johnson company, Somerville, New Jersey) sling procedure for stress urinary incontinence (SUI) published by the Medical Advisory Secretariat in February 2004. Since the publication of the 2004 assessment, a number of TVT-like sling alternatives have become available. These adhere to the same basic principles as the TVT procedure: minimally invasive, midurethral placement, self-fixing, and tension-free. This update will evaluate the efficacy and safety of midurethral slings.

Clinical Need: Target Population and Condition

Normal continence is controlled by the nervous system and involves coordination between bladder, urethra, urethral sphincter, and pelvic floor. Incontinence occurs when the relationship among the above components is compromised, either due to physical damage or nerve dysfunction. (1) Stress urinary incontinence 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. (2) There are 2 factors that define SUI: a weakening in the support of the proximal urethra, causing urethral hypermobility, and deficiency in the sphincter, causing urethral leakage. Both factors are thought to co-exist. (1) Accurate tests are not available to distinguish these 2 types of SUI.

Urinary incontinence is estimated to affect about 250,000 Canadian women aged 65 years and over. (3) The prevalence of SUI is difficult to measure because women with SUI may not tell their health practitioner about their symptoms owing to embarrassment associated with SUI. A cross-sectional postal survey of 15,904 adults aged 40 years and over who were registered with a local general practitioner 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." Stress urinary incontinence 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 years and over have symptoms of SUI. (5)

A grading scale that provides an estimation of the degree of incontinence experienced by the patient was developed by Stamey in 1979. (23)

The Stamey grade criteria are as follows:

- Grade 0: Continent.
- Grade 1: Loss of urine with sudden increases in abdominal pressure, such as coughing, sneezing,

aerobic exercise, etc.; not in bed at night.
- Grade 2: Incontinence with walking, rising from a chair, or climbing stairs.
- Grade 3: Total or near-total incontinence occurs without relation to physical activity or position.

Stress urinary incontinence 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. (6) Economic burden may include the cost of pads, drugs, and devices; and, in severe cases, the inability to participate in the work force.

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. (2) They range from noninvasive, conservative management to invasive surgical procedures, such as colposuspension (also called retropubic urethroplexy) performed through either open surgery or laparoscopy. Conservative techniques are the first line of treatment and include pelvic floor muscle therapy (PFMT) (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 including biofeedback devices, radiofrequency, and electrical stimulation have also been used with limited success. Drug therapy has also been used, as have injectable and bulking agents.

Colposuspension: Deemed the gold standard for primary SUI, (2) 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 2 to 4 hospital days for recovery. (1;24) In a systematic review of the literature published in 2005, Lapitan et al. (25) reported an overall continence rate of 85% to 90% within the first year of surgery, with about 70% of patients dry at 5-year follow-up. Colposuspension can be performed through an open procedure or 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 using sutures or bone anchors. This provides bladder support when the rectus muscles are tightened. This procedure has been shown to be as effective as colposuspension. (1)

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.

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.

New Technology Being Reviewed

Suburethral slings differ according to several criteria including placement, approach, method of fixation, and sling material. This review will evaluate slings that fulfil all of the following criteria:

- Midurethral placement (as opposed to bladder neck placement)
- Self-fixing (no sutures, bone anchors, etc.)
- Minimally invasive (using local, epidural, or general anesthesia)
- "Tension-free" placement
    - Tension-free refers to the nature of the mesh sling in that it is not sutured into place, and there is no rigidity holding the sling in place. The purpose is for the sling to provide sufficient support to the urethra when coughing, jumping, laughing, etc so that leakage does not occur. However, if there is too much tension on the sling pulling on the urethra, normal micturition is not possible.

History

Treatment of stress incontinence generally involves increasing outlet obstruction, either through suspension of the bladder neck to its original position, or creation of a platform against which the urethra is compressed during stress.(26) While considered the gold standard, colposuspension is an invasive procedure. Needle suspension procedures were developed to achieve the same surgical correction in a less invasive fashion. However, these procedures displayed significant long-term failure rates. These needle suspensions were the basis for modern sling procedures.

Although the first pubovaginal sling operation was performed in 1907, the procedure was not popularized until the 1970s. (26) These early operations utilized fascia from the patient's own leg or abdomen to create urethral support. These slings were placed under the urethra at the bladder neck in order to "suspend" the bladder neck in the same way as colposuspension and needle suspension procedures. Given the added surgical morbidity of using autologous tissue, other options have been utilized, including cadaveric, porcine, bovine, and synthetic sources, each which their own unique advantages and disadvantages.

The notion of placing support at the midurethra without tension rather than "suspending" the bladder neck was pivotal in the evolution of incontinence slings. In 1990, Ulmsten described his integral theory of incontinence, suggesting that continence was maintained by integral function of the pubourethral ligaments that attach the urethra to the pubic bone. (27) He proposed 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.

Based on the integral theory, intravaginal slingplasty (IVS) was developed, and out of this evolved what is now called the tension-free vaginal tape (TVT) sling procedure. Tension-free vaginal tape slings simulate the support mechanism of the pubourethral ligament, providing a firm anchoring point for the 3 muscles associated with urethral closure. The tape is inserted underneath the midurethra with minimal tension. The tape/sling material passes through several layers of pelvic tissue between the vaginal and abdominal incisions, and this is what holds it in place. 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.

Tension-free vaginal tape slings were the first commercially available midurethral sling; hence, the bulk of the available literature evaluates TVT slings either alone or in comparison with other, more traditional treatments for SUI. However, since the introduction of TVT slings, numerous midurethral sling variations have been introduced including the transobturator approach, a significant modification in surgical approach, which was introduced by Delorme in 2001. (28)

The different types of midurethral slings available vary according to 3 main parameters:

- Implant material (e.g., monofilament, multifilament, elastic, non-elastic, smooth, serrated, etc.)
- Delivery instruments (e.g., needles, curved trocars, disposable, reusable, etc.)

- Surgical approach

As any one, or combination, of these parameters may vary across the different sling brands, it is difficult to ascribe observed differences in efficacy and safety across slings to any one factor.

Implant Material

Although synthetic slings have higher reported rates of erosion and infection than do biomaterial slings, synthetic materials offer a number of advantages including low cost; easily modifiable in size, weave, and fibre type; durable over time; and no risk of infectious agent transmission. (29)

Almost all commercially available midurethral slings licensed by Health Canada are made of polypropylene, with the exception of Stratasis, a porcine material, and the hybrid sling, BioArc, which allows the surgeon to choose the preferred biomaterial. The type of polypropylene used in the synthetic slings differs substantially across manufacturers, and it has been suggested (29;30)that the differing efficacy and tolerability observed across products may be due to variations in the propylene material.

Fibre type (monofilament versus multifilament), pore size, and weaving vary considerably in synthetic slings. Monofilaments tend to be more elastic, hence affecting the degree of tension provided by the sling material. Pore size is important as it influences permeation of fibroblasts, which are theoretically critical to the success of midurethral sling procedures given that they regenerate collagen. (29) Pore size also affects the migration of leukocytes and macrophages, which affect tissue regrowth, infection, etc. The optimal pore size will permit collagen regeneration while minimizing infection risk.

Delivery Instruments

The nature and shape of the delivery instruments used to insert the sling can theoretically affect efficacy and safety. Manufacturers have developed delivery instruments with ergonomic handles, non-skid surfaces, rims that facilitate tactile feedback, curved needles that assist the surgeon in maintaining contact with the pubic bone, and blunt tips that reduce the risk of perforation. Some manufacturers have provided coloured protective sheaths with tensioning aids, while others have dispensed with the protective sheath altogether.

Surgical Approach

There are 3 surgical approaches used to insert midurethral slings: suprapubic, retropubic and transobturator. Some sling systems can be inserted through more than one approach, usually through a change in delivery device. At least one sling system, Uretex, allows for a combined approach. The suprapubic and retropubic approaches both pass the device through the retropubic space in order to pull the tape between the vaginal and abdominal incision.

Each of the 3 surgical approaches is described below (see Appendix 1 for figures).

Suprapubic

The suprapubic approach is also referred to as top down, antegrade, descending retropubic, or craniocaudal. It involves passing the delivery device through the small abdominal incisions made above the pubic bone, and drawing the tape through the retropubic space downward and out through the vaginal incision in a U-shape. Cystoscopy (visual examination of the urinary tract with a cytoscope) is performed once to identify bladder perforation. Although the retropubic space is penetrated as in the transvaginal approach, it has been suggested that the natural downward angle of the delivery instrument offers the

surgeon greater control, and minimizes the potential for bowel and vascular injury. (31;32) The suprapubic approach tends to require a larger vaginal wall incision than in the transvaginal procedure and more paraurethral dissection.

Retropubic

The retropubic approach is also referred to as bottom up, ascending retropubic, retrograde, or caudocranial. The delivery device is inserted into an incision made in the anterior vaginal wall, then passed blindly into the retropubic space up and out through 2 small suprapubic incisions in a U-shape. Cystoscopy is performed after each pass of the needle to identify bladder perforation. This approach theoretically holds the most potential for bladder, urethral, bowel, nerve and vessel in injury due to the blind retropubic passage of the delivery instruments.

Transobturator

The transobturator approach is a relatively recent midurethral sling insertion method. The selected implant is inserted through the obturator foramens from inside to outside, or vice versa. Both techniques require a vaginal incision at the midurethral level, similar to the retropubic procedures. Two small incisions are also made at the front of the obturator membrane (at the thigh fold). A tunneller is introduced into the either the vaginal (inside-out) or skin (outside-in) incision, and the implant exits through the opposite incision. Cytoscopy is not required with the transobturator approach as the retropubic space is bypassed. There are no major blood vessels, nerves, or viscera along this anatomical route. While this approach is theoretically safer than the retropubic approach, improper placement of the tunneling device may increase the risk of vesical or vaginal perforation. In the transobturator procedure the sling lies flat, as compared to the U-shape of retropubic slings.

Benefits

Midurethral slings require smaller incisions, minimal dissection, and minor manipulation compared to traditional slings, colposuspension, and needle suspension procedures. (33)

Because the procedures are minimally invasive, they can be performed under local anesthetic; however, regional or general anesthetic may also be used. Midurethral sling procedures can be performed on an outpatient basis, resulting in shorter hospital stays than traditional continence surgeries, less surgical morbidity, and faster resumption of normal activities compared with the more invasive surgeries.

Regulatory Status in Canada

There are more than 15 different midurethral slings licensed by Health Canada. As noted, all of the midurethral slings vary slightly based on implant material, delivery instruments, and surgical approach. Peer-reviewed, published, high-quality (e.g., from randomized controlled trials) evidence is not available for all types of midurethral slings. The majority of the high quality evidence is focused on a handful of midurethral sling types. Not all midurethral slings available in Canada have published RCTs measuring their effectiveness.

Other Jurisdictions

United States

Coverage policy has been issued by major coverage providers such as AETNA and CIGNA for TVT

slings only.

AETNA (United States)

Aetna considers the TVT slings procedure medically necessary for the treatment of SUI when patients are refractory to behavioural and pharmacological treatments. (34)

CIGNA (United States)

CIGNA indicated that studies comparing the TVT sling procedure to colposuspension (Burch procedure) have provided objective outcome results comparable to those of the already well-established surgical interventions for the treatment of urinary incontinence.(35) They concluded that the results support the use of the TVT sling procedure as a surgical intervention for the treatment of urinary incontinence, as long as there is documentation of incontinence refractory to medical management.

Literature Review on Effectiveness

Research Questions

- Are midurethral slings more effective and safer compared with traditional surgery for SUI (i.e., colposuspension)? If so, which midurethral sling is most effective and the safest?
- Are midurethral slings cost-effective compared with traditional surgery? If so, which midurethral sling is most cost-effective?

Outcomes of interest are cure rates, hospital outcomes (length of stay, procedure time), quality of life, and complications.

Methods

The literature published between January 2000 and February 2006 was searched in the following databases: MEDLINE, MEDLINE In Process and Other Non-Indexed Citations, EMBASE, Cochrane Database of Systematic Reviews, and CENTRAL, INAHTA. The database search was supplemented with a search of relevant Web sites, and a review of the bibliographies of selected papers. The search strategy can be viewed in Appendix 2.

Inclusion criteria

- General population with SUI
- Randomized controlled studies, health technology assessments, guidelines
- Female subjects
- Midurethral, self-fixing, and minimally invasive slings/tapes
- English language

Exclusion criteria

- Special groups (i.e., elderly, obese)
- Focus on mixed and urge incontinence
- Prolapse requiring surgical intervention

- Abstracts
- Non-RCTs, cohort studies (except as pertained to the examination of complications; where there were not many RCTs, large cohort studies (> 100), published in 2005 or later were included to assess complications.)

Results of Literature Review

The search strategy yielded 391 original citations. Studies were excluded for a variety of reasons, such as using traditional, suburethral slings as opposed to midurethral slings, not including patients with SUI, including males in the study, case reports, and not reporting the outcomes of interest. The details of the studies included in the review are reported in more detail below.

Summary of Existing Health Technology Assessments

Five health technology assessments were identified; 4 evaluating TVT slings, and 1 evaluating the transobturator approach.

Appendix 3 summarizes the findings from 4 health technology assessments of TVT slings. The reviews reported that TVT sling cure rates were 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 Coordinating Centre for Health Technology Assessment (NCCHTA) (1) and Agence Nationale d'Accréditation de Santé (ANAES) (24) recommended multicentre registries for long-term evaluation.

Apart from the health technology and policy assessment by the Medical Advisory Secretariat in 2004 (of which this is an update), the most recent and comprehensive appraisal of TVT slings was developed by the NCCHTA in the United Kingdom. (1) The objective of this appraisal was to evaluate the effectiveness and cost-effectiveness of TVT slings compared 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 and conference proceedings, along with advice from experts in the field. 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 after surgery. Cost-effectiveness was also examined and is discussed further in this report.

The NCCHTA concluded that TVT slings were an effective surgical option for women with uncomplicated SUI, and should be considered among other options for women with SUI. They added the caveat that there is little long-term follow-up data on the effectiveness and safety of TVT slings, and that further research is needed. They also indicated that women need to be informed about the advantages and disadvantages of the procedure (e.g., that it is minimally-invasive, but that there are complications associated with the procedure). Finally, they concluded that surgeons need adequate training using TVT slings to maximize the effectiveness and decrease the risks associated with TVT slings. Appendix 2 describes the outcomes of this health technology assessment.

In 2004, the National Institute for Clinical Excellence (NICE) (36) in the United Kingdom published guidance based on a health technology assessment evaluating transobturator tape insertion for SUI. However, this guidance was subsequently retracted from the NICE Web site in 2005 when the RCT on

which the majority of the health technology assessment was based, was retracted from the journal in which it was published. The RCT by deTayrac et al. (37) comparing transobturator approach slings to TVT slings was voluntarily retracted by the authors due to a failure to obtain proper ethics review and approval before conducting the study.

Summary of Medical Advisory Secretariat Review

There were 13 RCTs identified that compared midurethral slings to other midurethral slings or traditional surgery. (7-19) (Table 1) Three of the RCTs (14;16;19) have had subsequent updated articles of longer-term results. (20-22) The results of the RCTs have been stratified into 2 groups: TVT slings versus colposuspension and comparisons of midurethral slings. No RCTs were identified that compared a midurethral sling other than TVT slings to colposuspension.

Table 1: Results of This Health Technology Assessment Literature Review*

Study Design	Level of Evidence	Number of Eligible Studies
Large RCT, systematic reviews of RCTs (N > 100)	1	4
Large RCT unpublished, but reported to an international scientific meeting	1(g)	
Small RCT	2	9
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	
Case series with more than 2 years of follow-up (multisite)	4b	
Case series with less than 2 years of follow-up	4c	
Retrospective review, modeling	4d	
Case series presented at international conference	4(g)	

*RCT represents randomized controlled study; g, grey literature

Retropubic Route (TVT Slings) Versus Colposuspension

Quality of RCTs Comparing Retropubic Route to Colposuspension

The RCTs comparing TVT slings to colposuspension have strengths and limitations. Table 3 outlines the quality of each of the RCTs. Based on the criteria in Table 2, the quality of the RCTs overall ranges from low to moderately high. Two of the RCTs have published updated results of their trials (Ward and Hilton (22) and Valpas et al. (21)).

Table 2: Quality of Randomized Controlled Trials Comparing Retropubic Route Midurethral Slings to Colposuspension*†

Study, Year	Randomization Method	Adequate Sample Size	Allocation Concealment/ Blinding	Reliability of Method To Measure Outcome	ITT Analysis	Lost to Follow-Up	Overall Quality
Bai, 2005 (8)	- NR - Balanced at baseline	Unclear	No	Yes	N/A	No patients	Low-moderate
El-Barky, 2005 (9)	- NR - Balanced at baseline	Unclear	No	Yes	N/A	No patients	Low-moderate
Paraiso, 2004 (13)	- NR - Balanced at baseline	Unclear	No	Yes	No	6/72 (8.3%)	Low
Valpas, 2004 (21) Valpas, 2003 (16)	Computer-generated randomization list	Yes*	No	Yes	Yes	7 dropouts	Moderate-high
Ward, 2004 (22) Ward, 2002 (19)	Computer generated randomization in block of 4 and 6	Yes*	No	Yes	Yes	99 dropouts at 2 years	Moderate-high
Ustun, 2003 (17)	- NR - Balanced at baseline	Unclear	No	Yes	Yes	2 patients	Low-moderate
Liapis, 2002 (18)	- NR - Balanced at baseline	Unclear	No	Yes	N/A	None lost	Moderate

*The RCT by Valpas et al. (16;21) indicated that for a cure rate of 95% among patients receiving TVT slings and a cure rate of 80% among patients receiving laparoscopic colposuspension, the sample size should have been 176 patients. The sample size for their study was 128 patients. Thus, Valpas et al. did not meet their a priori sample size requirement; however, they did detect a significantly higher cure rate among patients receiving TVT slings compared to the patients receiving laparoscopic colposuspension. Valpas et al. conducted a post-hoc power calculation and reported a power of 0.917 to detect a significant difference between the groups. Similar to the RCT by Valpas et al., the RCT by Ward and Hilton did not meet its recruitment target, but in the case of Ward and Hilton they reported inconsistent results using various intent-to-treat models.
†ITT refers to intent-to-treat; N/A, not applicable; NR, not reported.

Characteristics of RCTs Comparing Retropubic Route to Colposuspension

There was substantial variability in the inclusion and exclusion criteria for the RCTs identified that compared TVT slings to colposuspension; most notably the inclusion or exclusion of women with prolapse requiring additional surgery. Some studies specifically excluded women who required additional surgery, while some studies did not, and others did not specify either way whether women who required concomitant surgery were to be included. Another difference among the studies regarding eligibility criteria was whether or not women were included if they had had previous incontinence surgery. Table 3 lists the inclusion and exclusion criteria of the RCTs included in this review. Table 4 lists the characteristics of patients included in the RCTs.

Table 3: Inclusion and Exclusion Criteria of Randomized Controlled Trials Comparing Retropubic Route Midurethral Slings to Colposuspension*

Study, Year	Inclusion Criteria	Exclusion Criteria
Bai, 2005 (8)	- Grade 1 or 2 Stamey	- Grade 3 Stamey - Detrusor overactivity - UTI - Intrinsic sphincter deficiency - Pelvic organ prolapse more severe than stage II
El-Barky, 2005 (9)	- Women with SUI	- Presence of uninhibited detrusor contraction during bladder filling more than 15 cm H_2O - Incompetent internal urethral sphincter - More than grade I cystocele - Previous failed repair of SUI
Paraiso, 2004 (13)	- Urodynamic SUI with abdominal leak-point pressures > 60 cm H_2O - No anterior vaginal wall prolapse to or beyond hymen - Willingness to complete follow-up	**Not reported**
Valpas, 2004 (21) Valpas, 2003 (16)	- History of SUI - Positive stress test - Urodynamic confirmation of SUI	- $\geq$ 70 years - Previous incontinence surgery - > 3 UTIs within past 2 years - Coincident gynecological surgery - BMI > 32 - Urethral closure pressure < 20 cm H_2O - Residual volume > 100 ml in preoperative urodynamic evaluation
Ward, 2004 (22) Ward, 2002 (19)	- Unresponsive to pelvic floor muscle exercise - Completed childbearing	- Vaginal prolapse requiring treatment - Previous surgery for incontinence or prolapse - Neurologic disease - Known bleeding diathesis, current anticoagulant therapy - Allergy to local anesthetic - Detrusor overactivity - Voiding difficulty
Ustun, 2003 (17)	- Previous incontinence surgery okay	Not reported
Liapis, 2002 (18)	- Stage I anterior wall prolapse or less - No previous operation for urinary incontinence - Absence of urge incontinence - Competent intrinsic urethral sphincter	- Prolapse more than first degree - Previous surgery for SUI - Detrusor instability

* BMI indicates body mass index; SUI, stress urinary incontinence; UTI, urinary tract infection.

Table 4: Characteristics of Randomized Controlled Trials Comparing Retropubic Route Midurethral Slings to Colposuspension*

Study	Treatment Groups	N	Mean (SD) Age, Years (range)	Parity	Median Follow-Up, Months	Local or General Anaesthesia	Follow-up Periods
Bai, 2005 (8)	Burch colposuspension	33	56.5 ± 3.1	2.7 ± 1.2	> 12	NR	3, 6, 12 months
	Pubovaginal sling	28	56.3 ± 2.9	3.1 ± 1.3			
	TVT slings	31	58.2 ± 3.3	2.9 ± 1.8			
El-Barky, 2005 (9)	Burch colposuspension	25	50 ± 12	3–4	> 24	NR	Followed every 3–6 months for a minimum of 2 years
	TVT slings	25	50 ± 14	2–5		Local	
Paraiso, 2004 (13)	Laparoscopic colposuspension	33	54.8 ± 9.3 (38–76)	2 (0–5)	20.6 ± 8 (12–43)	General	6 months,1 year, and 2 years
	TVT slings	33	53.3 ± 9.5 (40–80)	2 (0–7)	20.6 ± 8 (12-43)	Local, regional, or general	
Valpas, 2004 (21) Valpas, 2003 (16)	Laparoscopic colposuspension	51	48 (29–68)	NR	> 12	General	6 weeks, 12 months
	TVT slings	70	50 (33–67)			Local	
Ward, 2004 (22) Ward, 2002 (19)	Colposuspension	169	50 (45–59)	2 (2–3)	> 24	NR	6 weeks, 6, 12, 24 months
	TVT slings	175	50 (42–56)	2 (2–3)		local	
Ustun, 2003 (17)	Laparoscopic colposuspension	23	45.8 ± 11.4	3 (0–5)	13.4 (3–24)	General	1, 3, 6, 12, 18 months
	TVT slings	23	45.6 ± 10.0	3 (1–7)	11.3 (3–24)	Local, spinal, or general	
Liapis, 2002 (18)	Burch colposuspension	35	48.4 (35–64)	1.9 ± 0.8	> 24	NR	24 months
	TVT slings	36	46.5 (32–62)	2.1 ± 1.1		NR	24 months

* NR indicates not reported; TVT, tension-free vaginal tape.

Outcomes of RCTs Comparing Retropubic Route to Colposuspension

Six of the 7 RCTs comparing TVT slings to colposuspension reported procedure time. (9;13;17;18;21;22) All 6 found the TVT sling procedure to be significantly shorter than the procedure for colposuspension. The mean procedure times reported for TVT slings ranged from 20 to 79 minutes, while the mean procedure times reported for colposuspension ranged from 47 to 132 minutes.

Five studies reported length of hospital stay. (9;13;17;18;21) Four of the 5 reported that patients undergoing the TVT sling procedure had a significantly shorter hospital stay than did patients undergoing colposuspension. The other study, by Paraiso et al., (13) reported that there was no significant difference in the length of stay between the patients undergoing the TVT sling procedure compared to those receiving colposuspension. Table 5 outlines the procedure time and the length of hospital stay reported in the RCTs comparing TVT slings to colposuspension.

Table 5: Operative Outcomes of Randomized Controlled Trials Comparing Retropubic Route Midurethral Slings to Colposuspension*

Study	Treatment Groups	No. of Patients	Mean Procedure Time (range)	Mean Length of Hospital Stay (range)
Bai, 2005 (8)	Burch colposuspension	33	NR	NR
	Pubovaginal sling	28		
	TVT slings	31		
El-Barky, 2005 (9)	Burch colposuspension	25	57 min (46–70)	6.2 ± 2.2 days
	TVT slings	25	20 min (16–25) $P < .05$	3.1 ± 1.2 days $P < .05$
Paraiso, 2004 (13)	Laparoscopic colposuspension	36	132 (107–156) min	33 hours (6–131)
	TVT slings	36	79 (22–266) min $P = .003$	29 hours (19–37) $P = .86$
Valpas, 2004 (21) Valpas, 2003 (16)	Laparoscopic colposuspension	51	47 (19–120) min	1.8 days
	TVT slings	70	29 (14–153) min $P < .001$	0.7 days $P < .001$
Ward, 2004 (22) Ward, 2002 (19)	Colposuspension	169	50 (35–60) min	NR
	TVT slings	175	40 (30–48) min $P < .001$	
Ustun, 2003 (17)	Laparoscopic colposuspension	23	82.4 ± 25.5 min	3.4 ± 2.1 days
	TVT slings	23	31.1 ± 9.5 min $P = .001$	2.0 ± 1.8 days $P = .003$
Liapis, 2002 (18)	Burch colposuspension	35	58 min	5.7 ± 2.2 days
	TVT slings	36	20 min $P < .05$	2.1 ± 1.1 days $P < .05$

*NR refers to not reported; TVT, tension-free vaginal tape

The overall cure rates ranged among the 7 studies from 51% to 97%. It is important to note that each study defined cure differently. Some relied solely on objective data, while others incorporated subjective data into the cure rate. Definitions of subjective and objective cure rates varied considerably across studies. Table 6 lists the cure rates and the definition used to define cure in each study.

Table 6: Cure Rates Reported in Randomized Controlled Trials Comparing Retropubic Route Midurethral Slings to Colposuspension*

Study, Year	Treatment Groups	N	Cure, %	Improved, %	Definition of Cure	Power
Bai, 2005 (8)	Burch colposuspension	33	87.8 at 12 months	NR	• Absence of subjective complaints of leakage • Absence of urinary leakage on stress test	No explanation regarding the sample size.
	Pubovaginal sling	28	92.8† *P* < .05			
	TVT slings	31	87.0			
El-Barky, 2005 (9)	Burch colposuspension	25	72	16	• No SUI 3–6 months after surgery • Improved: less SUI than prior to surgery	No explanation regarding the sample size.
	TVT slings	25	72 *P* = NS	20		
Paraiso, 2004 (13)	Laparoscopic colposuspension	36	81.2	NR	• No evidence of leakage during urodynamic studies	Study was designed to enroll 130 women; only 72 women were enrolled.
	TVT slings	36	96.8 *P* = .056			
Valpas, 2004 (21) Valpas, 2003 (16)	Laparoscopic colposuspension	51	56.9 at 12 months (stress test)	NR	• Stress test • 48-hour pad test (*P* = .105) at 12 months	Study was designed to enroll 176 women; only 121 women were enrolled.
	TVT slings	70	85.7 *P* = .000			
Ward, 2004 (22) Ward, 2002 (19)	Colposuspension	169	51 at 24 months	NR	• Negative 1-hour pad test • Subjective cure OR 1.67; 95% CI; 1.09–2.58	Study was designed to enroll 436 women; only 344 women were enrolled.
	TVT slings	175	63			
Ustun, 2003 (17)	Laparoscopic colposuspension	23	82.6	NR	• No requirement for pads • No leakage on urodynamic evaluation	No explanation regarding the sample size.
	TVT slings	23	82.6 *P* = NS			
Liapis, 2002 (18)	Burch colposuspension	35	86 at 24 months	6	• 1-hour pad test < 1g • Improvement: 50% reduction in 1-hour pad test	Reported post hoc statistical power calculations that are not reproducible by Medical Advisory Secretariat based on the data in the study.
	TVT slings	36	84 *P* = NS	7 *P* = NS		

* NR indicates not reported; TVT, tension-free vaginal tape.
† In the RCT by Bai et al. (8), the women who had received the pubovaginal sling reported significantly higher cure rates than women who had received TVT or colposuspension (*P* < .05).

There were varying results of cure rates among the 7 studies that compared TVT slings to colposuspension. Four studies (8;9;17;18) reported that there was no significant difference in cure rates between TVT slings and colposuspension. The RCT by Paraiso et al. (13) reported a marginally significant difference between the cure rates of TVT slings versus colposuspension (*P* = .056). It is important to note that this study was assessed to be of low quality earlier in this report, and it may not have been powered to detect a significant difference between the groups. The studies by Valpas et al. (16;21) and Ward and Hilton (19;22) reported conflicting results. Valpas et al. reported a significant

difference in the results of the stress test at 12 months, favouring TVT slings (P = .000); however, there was not a significant difference between the groups in the 48-hour pad test at 12 months (P = .105).

The RCT by Ward and Hilton (22) reported 2-year follow-up data on patients included in their RCT. At the study's onset there were 344 patients randomized to receive either a TVT sling or colposuspension. At 2 years, 73% of the patients in the TVT sling group and 62% of patients in the colposuspension group remained in the study and had completed pad test results. Of the patients with completed pad test results, 81% were negative (i.e., cured) in the TVT sling group, and 80% were negative in the colposuspension group. Based on these results there was no significant difference between the 2 groups. However, if it is assumed that patients who were lost to follow-up failed treatment, then the results would favour TVT slings. This is because there were more dropouts in the colposuspension group. Table 7 describes the results based on various intent-to-treat analysis scenarios. As can be seen, depending on which intent-to-treat analysis is chosen, results vary considerably.

Table 7: Results of Randomized Controlled Trial Based on Various Intent-to-Treat Scenarios*

Assumption	TVT Slings		Colposuspension		Odds Ratio	95% Confidence Interval	*P*
	No. of Patients/Total Patients	%	No. of Patients/Total Patients	%			
Patients with data at 24 months follow-up	111/137	81	86/108	80	1.09	0.59–2.06	.870
Assuming all withdrawals are failures	111/175	63	86/169	51	1.67	1.09–2.58	.020
Assuming all withdrawals are cured	149/175	85	147/169	87	0.86	0.47–1.58	.640
Last observed result carried forward	136/175	78	115/169	68	1.64	1.01–2.65	.052
Assuming presugery withdrawals are cured, and last postoperative result carried forward	141/175	81	138/169	82	0.93	0.54–1.60	.890

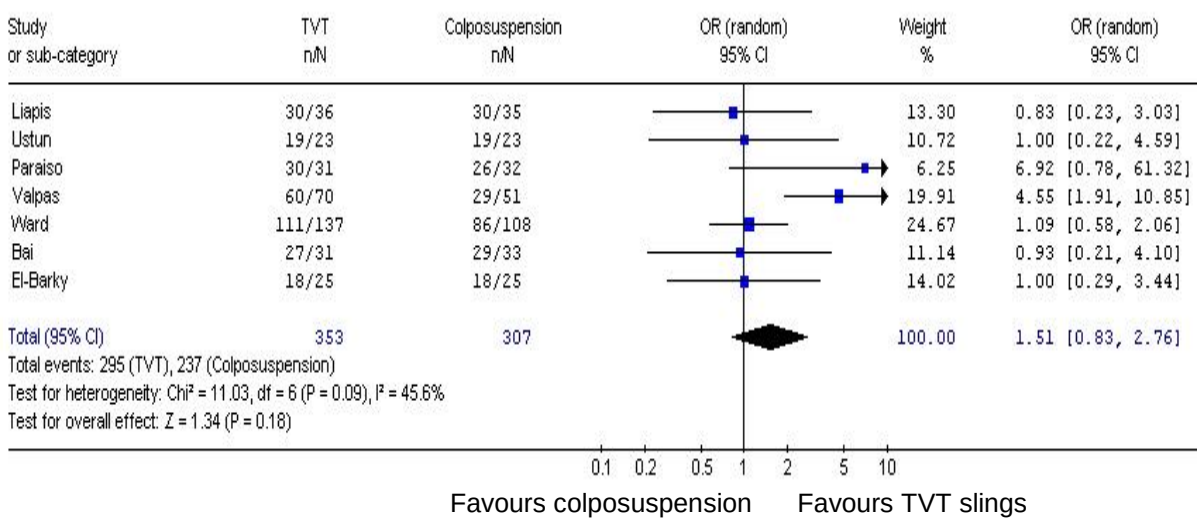
* From Ward and Hilton; (22) TVT indicates tension-free vaginal tape.

Figure 1 outlines the results of the pooled cure rates among the RCTs comparing TVT slings to colposuspension. There are some limitations of the pooled results that need to be acknowledged. First, the studies reported different follow-up times; however, each of the 7 RCTs reported follow-up of at least 12 months after surgery. Second, the cure rates for open colposuspension were combined with the rates for laparoscopic colposuspension. Third, as noted previously, the definition of cure varied among the studies. Finally, some studies reported cure rates and rates of improvement, while others only reported cure rates. Figure 1 includes only cure rates. The improved rates were not incorporated into the pooled analysis.

The pooled analysis indicates there is no significant difference between the cure rates for TVT and colposuspension (odds ratio 1.1; 95% CI, 0.83–2.76). To assess whether TVT and colposuspension are equivalent, boundaries around the odds ratio need to be defined. A conservative boundary would be 0.3.

Thus, if the 95% confidence interval of the summary statistic falls between 0.7 and 1.3, it would be reasonable to assume that TVT and colposuspension were equivalent in terms of effectiveness. The 95% confidence interval is 0.83 to 2.76. Since the 95% confidence interval falls outside the equivalence range, it is not possible to assume equivalence. However, because the lower end of the 95% confidence interval is greater than 0.7, it is possible to assume that TVT is not inferior to colposuspension.

Figure 1: Pooled Cure Rates Among Randomized Controlled Trials Comparing Retropubic Route Midurethral Slings to Colposuspension



Quality of life was reported by only 3 of the 7 RCTs. All 3 of these studies used different measures to assess quality of life (Table 8). Overall, quality of life does seem to improve after surgery for SUI; however, it is unclear if there is a significant difference between patients receiving TVT slings and colposuspension in terms of quality of life.

Table 8: Quality of Life Outcomes Reported in Randomized Controlled Trials Comparing Retropubic Route Midurethral Slings to Colposuspension*

Study, Year	Treatment Groups	No. of Patients	Quality of Life
Bai, 2005 (8)	Burch colposuspension	33	Not reported
	Pubovaginal sling	28	
	TVT slings	31	
El-Barky, 2005 (9)	Burch colposuspension	25	Not reported
	TVT slings	25	
Paraiso, 2004 (13)	Laparoscopic colposuspension	36	- IIQ score and satisfaction (0–10) not significantly different between groups at 2 years
	TVT slings	36	
Valpas, 2004 (21) Valpas, 2003 (16)	Laparoscopic colposuspension	51	King's College Health Questionnaire - Reported 95% CI for the difference between the groups change in scores from baseline to 12-month follow-up. - Reported that there was a significant difference in patient preference favouring TVT (no statistical values reported).
	TVT slings	70	
Ward, 2004 (22) Ward, 2002 (19)	Colposuspension	169	- Compared baseline SF-36 scores to scores at 24 months within same treatment arm—there were no across-arm comparisons. - Both groups had significant improvements in the following dimensions: role emotional (P = .028) and mental health (P = .007).
	TVT slings	175	
Ustun, 2003 (17)	Laparoscopic colposuspension	23	Not reported
	TVT slings	23	
Liapis, 2002 (18)	Burch colposuspension	35	Not reported
	TVT slings	36	

*TVT refers to tension-free vaginal tape.

Comparisons of Midurethral Slings

Suprapubic Versus Retropubic Slings

Quality of RCTs Comparing Suprapubic to Retropubic Slings

The RCTs comparing suprapubic to retropubic slings have various strengths and limitations. Table 11 outlines the quality of each of the RCTs. Based on the criteria in Table 9, the RCTs have overall quality ranging from moderate to high.

Table 9: Quality of Randomized Controlled Trials Comparing Suprapubic to Retropubic Slings*

Study, Year	Randomization Method	Adequate Sample Size	Allocation Concealment/ Blinding	Reliability of Method To Measure Outcome	ITT Analysis	Lost to Follow-Up	Overall Quality
Andonian, 2005 (7)	Sealed envelopes	Yes	Patients blinded	Yes	No	1 patient died due to MI in TVT group	Moderate-high
Lim, 2005 (10)	NR - Balanced at baseline	Unclear	Patients blinded	Yes	Yes	24 pts lost	Moderate
Tseng, 2005 (11)	Computer-generated randomization code	Yes	Yes Follow-up clinician and patients	Yes	N/A	No patients lost	High

* ITT refers to intent-to-treat; MI, myocardial infarction; N/A, not applicable; NR, not reported; TVT, tension-free vaginal tape.

Characteristics of RCTs Comparing Suprapubic to Retropubic Slings

There was substantial variability in the inclusion and exclusion criteria for the RCTs investigating suprapubic versus retropubic slings. Table 10 lists these criteria. Table 11 describes the characteristics of the patients.

Table 10: Inclusion and Exclusion Criteria of Randomized Controlled Trials Comparing Suprapubic to Retropubic Slings*

Study, Year	Inclusion Criteria	Exclusion Criteria
Andonian, 2005 (7)	- SUI with or without prolapse - Women with prolapse received surgery - Women with previous failed incontinence surgery - Women with mixed incontinence	- Obstructive, unstable bladder functions - Neurogenic bladder - UTI was a temporary exclusion criteria
Lim, 2005 (10)	- Failed conservative treatment for SUI or required prophylactic incontinence surgery during prolapse repair	- History of urogenital malignancy, fistula, pelvic radiotherapy
Tseng, 2005 (11)	- If required, patients underwent surgery for prolapse.	- Pelvic prolapse greater than stage II - Previous incontinence surgery

*SUI indicates stress urinary incontinence; UTI, urinary tract infection.

Table 11: Characteristics of Patients in Randomized Controlled Trials Comparing Suprapubic to Retropubic Slings*

Study, Year	Treatment Groups	N	Mean Age, Years	Mean Parity	Median Follow-up, Months	Local or General Anesthesia	Follow-Up Periods
Andonian, 2005 (7)	TVT slings (retropubic)	43	60.4 (range 56.5–64.2)	NR	> 12	Mostly spinal (some local or general)	1, 6, 12 months
	SPARC slings (suprapubic)	41	62.6 (range 59.4–65.9)				
Lim, 2005 (10)	TVT slings (retropubic)	61	56.4 ± 11.9	2.6 ± 1.3	> 6–12 Weeks	Mostly General	6–12 Weeks
	IVS (retropubic)	60	58.4 ± 11.8	2.7 ± 1.3			
	SPARC slings (suprapubic)	61	58.2 ± 11.6	2.9 ± 1.6			
Tseng, 2005 (11)	TVT slings (retropubic)	31	51 ± 11.7	3 (range 0–7)	25 (range 24–30)	Local or regional	24 months
	SPARC slings (suprapubic)	31				Local or regional	

* IVS refers to intravaginal slingplasty; SPARC, suprapubic arc; TVT, tension-free vaginal tape.

Andonian et al. (7) and Tseng et al. (11) reported procedure time and length of stay, but Lim et al. (10) did not report these outcomes. Neither Andonian et al. nor Tseng et al. found a significant difference in the procedure time. Andonian et al. reported that there also was not a significant difference in length of hospital stay, however, Tseng et al found that patients receiving the suprapubic slings had a significantly longer length of stay than did patients receiving the retropubic slings (P = .03) (Table 12).

Table 12: Operative Outcomes of Randomized Controlled Trials Comparing Suprapubic to Retropubic Slings*

Study, Year	Treatment Groups	No. of Patients	Mean Procedure Time	Mean Length of Hospital Stay
Andonian, 2005 (7)	TVT slings (retropubic)	43	35.6 min (range 27.2–44.1)	1 day (range 0–3)
	SPARC slings (suprapubic)	41	32.3 min (range 26.2–38.4) P = NS	1 day (range 0–7) P = NS
Lim, 2005 (10)	TVT slings (retropubic)	61	NR	NR
	IVS (retropubic)	60		
	SPARC slings (suprapubic)	61		
Tseng, 2005 (11)	TVT slings (retropubic)	31	32.7 ± 8.4 min	3.1 ± 1.4 days
	SPARC slings (suprapubic)	31	40.8 ± 13.3 min P = .78	4.0 ± 1.4 days P = .03

* IVS refers to intravaginal slingplasty; NR, not reported; SPARC, suprapubic arc; TVT, tension-free vaginal tape.

None of the 3 RCTs comparing suprapubic and retropubic slings found a significant difference in cure rate. The overall cure rates ranged from 69.2% to 95%. It is important to note that each study defined cure differently. Some studies relied solely on subjective data, while others incorporated objective data into the cure rate. Table 13 lists the cure rates and the definition used to define cure in each study.

Table 13: Cure Rates Reported in Randomized Controlled Trials Comparing Suprapubic to Retropubic Slings*

Study, Year	Treatment Groups	N	Cure, %	Improved, %	Definition of Cure
Andonian, 2005 (7)	TVT slings (retropubic)	43	At 12 months, 95	NR	• 1-hour pad test < 2 g
	SPARC slings (suprapubic)	41	83 $P \leq .1$		
Lim, 2005 (10)	TVT slings (retropubic)	61	(ITT) 73.8	NR	• Subjective cure rates
	IVS (retropubic)	60	72.3		
	SPARC slings (suprapubic)	61	69.2 $P = .84$		
Tseng, 2005 (11)	TVT slings (retropubic)	31	87.1	12.9	• 1-hour pad test < 1g • Improvement: 50% reduction in 1-hour pad test
	SPARC slings (suprapubic)	31	80.7 $P = .71$	19.3	

* ITT refers to intent-to-treat; IVS, intravaginal slingplasty; SPARC, suprapubic arc; TVT, tension-free vaginal tape.

Quality of Life

Only the RCT by Andonian et al. (7) reported quality of life among the 3 RCTs comparing suprapubic to retropubic slings. Andonian and colleagues did not find a significant difference between the groups in terms of quality of life using the Incontinence Impact Questionnaire ($P = .46$).

Retropubic Slings

Quality of RCTs Comparing 2 Types of Retropubic Slings

Two RCTs were identified that compared one type of retropubic sling to another. In this case, both studies compared TVT slings to IVS. Table 14 outlines the quality of each of the RCTs. Based on the criteria in Table 14, the quality of each study was rated as moderate.

Table 14: Quality of Randomized Controlled Trials Comparing 2 Types of Retropubic Slings*

Study, Year	Randomization Method	Adequate Sample Size	Allocation Concealment/ Blinding	Reliability of Method to Measure Outcome	ITT Analysis	Lost to Follow-Up	Overall Quality
Lim, 2005 (10)	- Not reported - Balanced at baseline	Unclear	Patients blinded	Yes	Yes	24 patients	Moderate
Rechberger, 2003 (15)	Simple randomization using pseudo-random numbers, computer generated (1:1 ratio)	Unclear	Blinding of the follow-up physician (not the physician performing the procedure)	Yes	N/A	No patients	Moderate

* ITT refers to intent-to-treat; N/A, not applicable.

Characteristics of RCTs Comparing 2 Types of Retropubic Slings

Inclusion and exclusion criteria for the RCTs comparing 2 types of retropubic slings varied. Rechberger

et al. (15) excluded women who required concomitant surgery, while it is not clear from the article by Lim et al. (10) whether women who required concomitant surgery were eligible. Table 15 lists the inclusion and exclusion criteria of the RCTs. Table 16 describes the characteristics of the patients.

Table 15: Inclusion and Exclusion Criteria of Randomized Controlled Trials Comparing Two Types of Retropubic Slings*

Study, Year	Inclusion Criteria	Exclusion Criteria
Lim, 2005 (10)	- Failed conservative treatment for SUI or required prophylactic incontinence surgery during prolapse repair	- History of urogenital malignancy, fistula, pelvic radiotherapy - Intrinsic sphincter deficiency
Rechberger, 2003 (15)	- Stage I or II prolapse - Previous surgery for incontinence was acceptable	- Gynecological disease (uterine myoma [benign tumour], ovarian cyst, severe uterine or vaginal prolapse) - Concomitant surgery required

* SUI indicates stress urinary incontinence.

Table 16: Characteristics of Patients in Randomized Controlled Trials Comparing Two Types of Retropubic Slings*

Study	Treatment Groups	N	Mean Age, Years	Mean Parity	Median Follow-up, Months	Local or General Anesthesia	Follow-Up Periods
Lim, 2005 (10)	TVT slings	61	56.4 ± 11.9	2.6 ± 1.3	> 6–12 weeks	Mostly general	6–12 weeks
	IVS	60	58.4 ± 11.8	2.7 ± 1.3			
	SPARC slings	61	58.2 ± 11.6	2.9 ± 1.6			
Rechberger, 2003 (15)	TVT slings	50	54.0 ± 9.1	3 (range 1–6)	13.5 (range 4–18)	Spinal anesthesia	1, 4, 6, 12, 18 months
	IVS	50	55.9 ± 9.7	2 (range 0–6)			

*IVS refers to intravaginal slingplasty; SPARC, suprapubic arc; TVT, tension-free vaginal tape.

Neither RCT reported a significant difference in cure rate. The overall cure rates ranged from 69.2% to 88% across studies. It is important to note that each study defined cure differently. Lim et al. relied on subjective data, while Rechberger et al. incorporated objective measures into their definition. Table 17 lists the cure rates and the definition of cure in each study.

Table 17: Cure Rates Reported in Randomized Controlled Trials Comparing Two Types of Retropubic Slings*†

Study, Year	Treatment Groups	N	Cure, %	Improved, %	Definition of Cure
Lim, 2005 (10)	TVT slings	61	(ITT) 73.8	NR	• Subjective cure rates
	IVS	60	72.3		
	SPARC slings	61	69.2 *P* = .84		
Rechberger, 2003 (15)	TVT slings	50	88	10	• No longer require pads • Negative cough test • Improvement: cough test was negative, but still had to change pad during the day
	IVS	50	80 *P* = .21	18 *P* = .19	

*Neither the study by Lim et al., (10) nor the study by Rechberger et al. (15) included hospital outcomes such as

procedure time or length of stay. The studies also did not include outcomes for quality of life in their analyses.
† ITT refers to intent to treat; IVS, intravaginal slingplasty; NR, not reported; SPARC, suprapubic arc; TVT, tension-free vaginal tape.

Transobturator Compared to Retropubic or Suprapubic Slings

Quality of RCTs Comparing Transobturator to Retropubic or Suprapubic Slings

The RCTs comparing transobturator versus retropubic or suprapubic slings had strengths and limitations. Table 18 outlines the quality of each of the RCTs. Based on the criteria in Table 18, the quality of the RCTs is moderate to high. It is important to note that the study by David-Montefiore et al. (38) used devices that were not licensed by Health Canada at the time of this assessment. A decision was made to include this trial because it is the only RCT to date that compared retropubic to transobturator slings.

Table 18: Quality of Randomized Controlled Trials Comparing Transobturator to Retropubic or Suprapubic Slings*†

Study, Year	Randomization Method	Adequate Sample Size	Allocation Concealment/ Blinding	Reliability of Method to Measure Outcome	ITT Analysis	Lost to Follow-Up	Overall Quality
David-Montefiore, 2006 (38)*	Computer-generated randomization code	Yes	No	Yes	N/A	No patients	Moderate-high
Wang, 2005 (39)	Computer-generated randomization code	Yes	Patients and clinician blinded	Yes	No	2 patient moved over-seas	Moderate-high

* Devices used in this study (I-STOP) were not licensed by Health Canada at the time of this assessment.
† ITT refers to intent-to-treat; N/A, not applicable.

Characteristics of RCTs Comparing Transobturator to Retropubic or Suprapubic Slings

There was variability in the inclusion and exclusion criteria for the RCTs comparing transobturator to retropubic or suprapubic slings. Table 19 lists the inclusion and exclusion criteria of the RCTs included in this review. Table 20 describes the characteristics of the patients included in the RCTs.

Table 19: Inclusion and Exclusion Criteria of Randomized Controlled Trials Comparing Transobturator to Retropubic or Suprapubic Slings*

Study, Year	Inclusion Criteria	Exclusion Criteria
David-Montefiore, 2006 (38)*	- Stress urinary incontinence, any stage (pts mostly stage II, 72%) - Previous stress urinary incontinence surgery acceptable	Not reported
Wang, 2005 (39)	- Stress urinary incontinence	- Women with bladder outlet obstruction - Previous anti-incontinence surgery - Pelvic prolapse greater than stage II

* Devices used in this study (I-STOP) were not licensed by Health Canada at the time of this assessment.

Table 20: Characteristics of Patients of Randomized Controlled Trials Comparing to Retropubic or Suprapubic Slings*†

Study, Year	Treatment Groups	N	Mean Age, Years	Mean Parity	Median Follow-up, Months	Local or General Anesthesia	Follow-up Periods
David-Montefiore, 2006 (38)*	Retropubic route	42	56.8 ± 12.0	2.1 ± 0.9	> 1 month	Regional or general	1, 3, 6, 12, 24 months
	Transobturator route	46	53.4 ± 10.5	2.0 ± 1.0			
Wang, 2005 (39)	SPARC slings	29	50.0 ± 10.7	4 (range 1–8)	9 (range 6–14)	Spinal	1 week, 1 month, 5 months, 12 months, annually
	MONARC slings	31					

* Devices used in this study (I-STOP) were not licensed by Health Canada at the time of this assessment.

Both of the studies reported procedure time. Wang et al. reported that there was no significant difference in procedure time between the transobturator and suprapubic sling groups. The RCT by David-Montefiore et al. reported that the transobturator route procedure time was significantly shorter than the procedure time for the retropubic route. Both David-Montefiore et al and Wang et al found no significant difference between the groups for length of stay (Table 21).

Table 21: Operative Outcomes of Randomized Controlled Trials Comparing Transobturator to Retropubic or Suprapubic Slings*†

Study	Treatment Groups	No. of Patients	Mean Procedure Time	Mean Length of Hospital Stay
David-Montefiore, 2006 (38)*	Retropubic route	42	21 ± 9.5	1.8 ± 1.7
	Transobturator route	46	17 ± 6.6 *P* = .03	1.4 ± 0.5 *P* = NS
Wang, 2005 (39)	SPARC slings	29	39.7 ± 12.2	3.92 ± 1.4
	MONARC slings	31	33.8 ± 8.4 *P* = .77	3.44 ± 1.5 *P* = NS

* Devices used in this study (I-STOP) were not licensed by Health Canada at the time of this assessment.

None of the RCTs identified that compared transobturator slings to retropubic or suprapubic slings found a significant difference in cure rates. The overall cure rates were fairly high. It is important to note that each study defined cure differently. Some studies relied solely on objective data, while other incorporated subjective data. The study by Wang et al. did not report cure rate as a percentage; rather, they reported the actual pad test score. Both groups had a statistically significant improvement from before the sling procedure to afterward; however, there was not a significant difference between the groups' postoperative pad test scores. Table 22 lists the cure rates and the definitions used to define cure.

Table 22: Cure Rates Reported in Randomized Controlled Trials Comparing Transobturator to Retropubic or Suprapubic Slings*†

Study, Year	Treatment Groups	N	Cure, %	Improved, %	Definition of Cure
David-Montefiore, 2006 (38)*	Retropubic route	42	92.9	4.8	• Subjective cure
	Transobturator route	46	93.5 *P* = .71	2.2	
Wang, 2005 (39)	SPARC slings	29	8.2 ± 21.0	NR	• 1 hour pad test score
	MONARC slings	31	8.6 ± 21.4 *P* = .15		

* Devices used in this study (I-STOP) were not licensed by Health Canada at the time of this assessment.

Quality of Life

Only the RCT by David-Montefiore et al. reported outcomes for quality of life. They found that both groups had significant improvements in quality of life scores from before surgery to after surgery based on the urinary distress impact questionnaire.

Bayesian Analysis of Failure Rate

Using a Bayesian random effects logistic regression model, the Medical Advisory Secretariat attempted to identify which treatment option was best for patients in terms of failure rate. This model allowed for direct and indirect comparisons between the interventions for SUI. Because the RCTs did not make all of the possible comparisons between the studies, this model allowed for all comparisons. Data from 25 arms of 12 RCTs (1 RCT had 3 arms) were used in the analysis. Each RCT included TVT slings in 1 arm of the trial. The other arms were laparoscopic colposuspension, open colposuspension, SPARC slings, IVS, and transobturator slings. Table 23 summarizes the data.

Odds ratios were computed using a logistic regression model. In addition, the probability that a given intervention would reduce the failure rate by more than one-half in relation another intervention was also computed (i.e., the probability that one intervention is better than the other). Similarly, the probability that a given intervention would more than double the failure rate in relation to another intervention was computed as well (i.e., the probability that one intervention is worse than another). This model is based on a publication by Caldwell et al. (40)

Table 23: Data Incorporated Into Bayesian Analysis

	TVT Slings	Laparoscopic Colposuspension	Open Colposuspension	SPARC Slings	IVS	Transobturator Slings
Bai, 2005 (8)	27/31	—	29/33	—	—	—
El-Barky, 2005 (9)	18/25	—	18/25	—	—	—
Paraiso, 2004 (13)	35/36	29/36	—	—	—	—
Valpas, 2004 (16;21)	60/70	29/51	—	—	—	—
Ward, 2004 (22)	110/175	---	86/169	—	—	—
Ustun, 2003 (17)	19/23	19/23	—	—	—	—
Liapis, 2002 (18)	30/36	—	30/35	—	—	—
Andonian, 2005 (7)	41/43	—	—	34/41	—	—
Lim, 2005 (10)	45/61	—	—	42/61	43/60	—
Tseng, 2005 (11)	27/31	—	—	25/31	—	—
Rechberger, 2003 (15)	44/50	—	—	—	40/50	—
David-Montifiore, 2006 (38)	39/42	—	—	—	—	43/46

* IVS refers to intravaginal slingplasty; SPARC, suprapubic arc; TVT, tension-free vaginal tape.

The results of the Bayesian analysis are detailed in Table 24. The results suggest that laparoscopic colposuspension is significantly inferior to TVT slings (odds ratio 4.11; 95% credible region, 1.47–9.30). Moreover, there was a 0% probability that laparoscopic colposuspension was better than TVT slings, and a 92% probability that it was worse than TVT slings. Even though all of the other credible regions for the odds ratios for the other comparisons crossed 1.0, there were some high probabilities favouring one intervention over another. For instance, there was a 74% probability that the transobturator sling was better than laparoscopic colposuspension, and only a 3% probability that the transobturator sling was worse than laparoscopic colposuspension.

It is important to note that the accuracy of the Bayesian model is dependent upon the accuracy of the results of the RCTs, which had varying levels of quality.

Table 24: Results of Bayesian Analysis Comparing Treatment Options

Comparison: X vs. Y	Odds Ratio (95% CR)	Probability That X Is Better Than Y, %	Probability That X Is Worse Than Y, %
Laparoscopic colposuspension vs. TVT slings	4.11 (1.47–9.30)	0.0	92.0
Open colposuspension vs. TVT slings	1.35 (0.60–2.36)	1.2	6.7
SPARC slings vs. TVT slings	2.01 (0.83–4.37)	0.2	40.0
IVS vs. TVT slings	1.66 (0.63–3.78)	1.0	24.0
Transobturator sling vs. TVT slings	1.54 (0.11–6.64)	26.0	21.0
Open colposuspension vs. laparoscopic colposuspension	0.40 (0.10–1.02)	75.0	0.2
SPARC slings vs. laparoscopic colposuspension	0.61 (0.15–1.79)	52.0	1.8
IVS vs. laparoscopic colposuspension	0.51 (0.11–1.53)	64.0	1.3
Transobturator sling vs. laparoscopic colposuspension	0.47 (0.02–2.19)	74.0	3.0
SPARC slings vs. open colposuspension	1.70 (0.53–4.79)	1.8	24.0
IVS vs. open colposuspension	1.40 (0.41–3.98)	5.0	15.0
Transobturator sling vs. open colposuspension	1.31 (0.08–5.95)	36.0	15.0
IVS vs. SPARC slings	0.92 (0.29–2.16)	14.0	3.0
Transobturator sling vs. SPARC slings	0.92 (0.05–4.15)	50.0	9.0
IVS vs. transobturator sling	1.17 (0.06–5.31)	42.0	14.0

*CR refers to credible region; IVS, intravaginal slingplasty; SPARC, suprapubic arc; TVT, tension-free vaginal tape.

Complications

The cure rates reported among all of the studies comparing various slings were quite high; thus, it is not possible to identify which sling systems are more effective based on cure rate alone. Therefore, the complication rates were analyzed for each of the RCTs included in this review. In addition, where there were fewer RCTs, large cohort studies (N > 100) published in 2005 or later reporting complication rates were included.

Various complications were reported. The most frequently reported were bladder perforations, de novo voiding difficulties, and device problems. Bladder perforations generally heal without any intervention. The de novo voiding difficulties ranged from transient urinary retention after surgery to longer-term difficulties such as urge incontinence or urgency. The issue of de novo voiding difficulties may be related to the accuracy of the original diagnosis. Midurethral slings are designed to treat genuine SUI; they are not designed to treat other types of incontinence, particularly urge incontinence. Thus, if a patient had mixed incontinence (stress + urge) prior to surgery, after the sling procedure the patient would still have urge incontinence. The device problems usually required a reoperation to adjust or remove the sling. Also, there was a fairly high rate of urinary tract infections (UTIs) postoperatively. Some studies indicated that patients suffered from recurrent UTIs; however, most did not indicate if the UTIs recurred.

Table 25 lists the complication rates for the SPARC sling system, which is a type of suprapubic sling system. Table 26 lists the complication rates for the IVS system, which is a type of retropubic sling system. Table 27 lists the complication rates for the TVT slings system, which is another type of

retropubic sling system. Table 28 lists complication rates for the MONARC sling, Table 29 lists the complications for the various transobturator slings system (various manufacturers systems are included). Finally, Table 30 lists the complication rates for colposuspension.

Table 25: Complication Rates for Patients Receiving the Suprapubic Arc Sling System (Suprapubic Sling)

	Wang, 2005 (39)	Andonian, 2005 (7)	Lim, 2005 (10)	Tseng, 2005 (11)	Hodroff, 2005 (41)*
Total no. of patients	29	41	58	31	445
Bladder perforation, %	3.4	24.4	6.9	12.9	6.7
Urinary retention, %	—	4.9	—	—	3.4
Infection, %	—	2.4	—	—	—
Hematoma, %	3.4	—	—	9.7	0.2
Urinary tract infection, %	—	—	—	—	0.2
Device problem (erosion, removal, protrusion), %	—	2.4	13.8	6.5	6.1
De novo voiding dysfunction, %	—	—	24.1	100†	6.1
Other, %	3.4	2.4	5.2	3.2	—
Overall complication rate, %	10.2	36.6	50.0	100	22.7
Patients with complications resolved at 6 weeks, %	10.2	36.6	27.8	32.2	10.1
Patients requiring re-admission or subsequent surgery, %	0	9.8	10.3	6.5	6.5

* The study by Hodroff et al. (41) was specifically designed to investigate complications in a large cohort of women who had received a SPARC sling system; this was not a randomized trial.
† Unclear if patients suffered from voiding dysfunction prior to surgery.

Table 26: Complication Rates for Patients Receiving the Intravaginal Sling System (Retropubic Sling)

	Lim, 2005 (10)	Rechberger, 2003 (15)
Total no. of patients	54	50
Bladder perforation, %	3.7	8.0
Urinary retention, %	—	4.0
Infection	—	—
Hematoma	—	—
Urinary tract infection, %	—	2.0
Device problem (erosion, removal, protrusion), %	1.9	—-
De novo voiding dysfunction, %	24.1	8.0
Other, %	—	2.0
Overall complication rate, %	29.6	24.0
Patients with complications resolved at 6 weeks, %	5.6	16.0
Patients requiring readmission or subsequent surgery, %	1.9	0.0

Table 27: Complication Rates for Patients Receiving the Tension-Free Vaginal Tape Sling System (Retropubic Sling)*

	Andonian, 2005 (7)	Lim, 2005 (10)	Tseng, 2005 (11)	Rechberger, 2003 (15)	Bai, 2005 (8)	El-Barky, 2005 (9)	Paraiso, 2004 (13)	Valpas, 2004 (21) Valpas, 2003 (16)	Ward, 2004 (22) Ward, 2002 (19)	Ustun 2003 (17)	Liapis, 2002 (18)
Total no. of patients	43	58	31	50	31	25	33	70	175	23	36
Bladder perforation, %	23.3	1.7	—	4.0	—	8.0	—	1.4	8.6	8.7	11.1
Urinary retention, %	9.3	—	—	20.0	12.9	20.0	—	2.9	—	—	—
Infection, %	—	—	—	—	—	—	—	1.4	—	—	—
Hematoma, %	—	—	16.1	2.0	---	—	3.0	—	1.7	—	—
Urinary tract infection, %	—	—	—	—	—	20.0	—	4.3	21.7	—	13.9
Device problem (erosion, removal, protrusion), %	—	3.4	19.4	—	—	—	9.1	—	2.3	—	—
De novo voiding dysfunction, %	—	13.8	54.8*	16.0	—	8.0	—	2.9	—	—	22.2
Other, %	—	—	9.7	4.0	—	—	18.2	—	10.3	—	—
Overall complication rate, %	32.6	25.9	100	46.0	12.9	56.0	30.3	12.9	44.6	8.7	47.2
Patients with complications resolved at 6 weeks, %	32.6	5.2	41.9	30.0	0	48.0	21.2	10.0	30.3	8.7	25.0
Patients requiring re-admission or subsequent surgery, %	4.7	3.4	19.4	0	0	0	6.1	2.9	3.4	0	0

* Unclear if these patients suffered from voiding dysfunction prior to sling procedure

Table 28: Complication Rates for Patients Receiving a MONARC Sling System (Transobturator Sling System)

	Wang, 2005 (39)	Davila, 2005 (42)	Fischer, 2005 (43)
Total no. of patients	31	200	220
Bladder perforation, %	—	—	0.5
Vaginal perforation, %	12.9	—	—
Urinary retention	—	—	—
Infection	—	—	—
Hematoma, %	—	0.5	—
Urinary tract infection	—	—	—
Device problem (erosion, removal, protrusion), %	—	1.0	1.8
De novo voiding dysfunction, %	—	20.5	1.4
Other, %	12.9	4.5	—
Overall complication rate, %	25.9	26.5	3.7
Patients with complications resolved at 6 weeks, %	25.9	6.0	2.3
Patients requiring readmission or subsequent surgery, %	0.0	0.0	0.0

Table 29: Complication Rates for Patients Receiving Transobturator Sling Systems*†

	David-Montefiore, 2006 (38)*	Wang, 2005 (39)	Davila, 2005 (42)	Palma, 2005 (44)	Fischer, 2005 (43)	Roumeguere 2005 (45)	Spinosa, 2005 (46)
Total no. of patients	46	31	200	100	220	120	117
Device name	I-STOP slings	MONARC slings	MONARC slings	SAFYRE slings	MONARC slings	URATAPE slings and OBTAPE slings	OBTAPE slings
Bladder perforation, %	—	—	—	—	0.5	0.8	—
Vaginal perforation, %	10.9	12.9	—	—	—	10.8	—
Urinary retention, %	—	—	—	—	—	1.7	—
Infection, %	—	—	—	1.0	—	—	—
Hematoma, %	—	—	0.5	—	—	—	—
Urinary tract infection, %	—	—	—	—	—	4.2	—
Device problem (erosion, removal, protrusion), %	—	—	1.0	6.0	1.8	—	2.6
De novo voiding dysfunction, %	—	—	20.5	10.0	1.4	9.2	6.0
Other, %	—	12.9	4.5	3.0	—	6.7	0.8
Overall complication rate, %	10.9	25.9	26.5	20.0	3.7	33.3	9.4
Patients with complications resolved at 6 weeks, %	10.9	25.9	6.0	20.0	2.3	33.3	5.1
Patients requiring re-admission or subsequent surgery, %	0.0	0.0	0.0	6.0	0.0	2.5	2.6

* The randomized controlled trial by David-Montefiore et al. used a transobturator sling system that was not licensed for use in Canada at the time of the assessment.

Table 30: Complication Rates for Patients Receiving Colposuspension

	Bai, 2005 (8)	El-Barky, 2005 (9)	Paraiso, 2004 (13)	Valpas, 2004 (21) Valpas, 2003 (16)	Ward, 2004 (22) Ward, 2002 (19)	Ustun, 2003 (17)	Liapis, 2002 (18)
Total no. of patients	33	25	33	51	169	23	35
Bladder perforation, %	—	—	—	2.0	1.8	—	—
Urinary retention, %	—	12.0	—	3.9	—	—	8.6
Infection, %	—	8.0	—	2.0	5.9	—	—
Hematoma, %	—	—	3.0	2.0	1.8	—	5.7
Urinary tract infection, %	—	12.0	—	2.0	27.2	—	5.7
De novo voiding dysfunction, %	12.1	12.0	—	—	2.4	—	17.1
Other, %	—	—	33.3	5.9	15.4	8.7	11.4
Overall complication rate, %	12.1	44.0	36.3	17.8	54.5	8.7	48.6
Patients with complications resolved at 6 weeks, %	0.0	32.0	36.3	17.8	40.8	8.7	20.0
Patients requiring re-admission or subsequent surgery, %	0.0	0.0	6.1	3.9	10.1	8.7	0.0

Economic Analysis

Disclaimer: This economic analysis represents an estimate only, based on assumptions and costing methodologies that have been explicitly stated. These estimates will change if different assumptions and costing methodologies are applied for the purpose of developing implementation plans for the technology.

Literature Review: Objectives and Methods

An economic evaluation of midurethral slings was undertaken.

Articles that compared the cost of midurethral slings with another treatment option for SUI were included. Two studies were identified that compared TVT slings to colposuspension. (48;49)

Results of Literature Review on Economics

Two studies (48;49) based on RCT data were found. Table 32 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 31: Costs from Persson 2002 (48) and Manca 2003 (49) Reviews of TVT Slings and Colposuspension

Study/Variable	**Persson, 2002** (costs in $CDN converted from Euros €; OECD 2002)*		**Manca, 2003** (costs in $CDN converted from £GBP; OECD 2002)*	
Intervention	TVT slings (N=38) Total cost	Lap colposuspension (N=32) Total costs	TVT slings (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)

All results are in Canadian currency unless otherwise noted. The total mean patient cost for TVT slings in the Persson (48) trial (without reoperations) was $1799.35 compared with $1936.14 in the Manca (49) trial. The Persson trial compared costs of TVT slings with those of laparoscopic colposuspension while the Manca trial compared TVT slings with open colposuspension. The total average cost for TVT slings was $92.99 higher than laparoscopic colposuspension; average costs for TVT slings 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 sling procedure 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 slings procedures versus 12 days for colposuspension). This was not taken into account in the Persson trial; however, Persson did factor in reoperations ($160.53 for TVT slings and $55.07 in the laparoscopic colposuspension group).

Only the Manca trial estimated cost-effectiveness. TVT slings had a mean improvement in outcomes of 0.01 quality adjusted life-years (QALYs) per patient over the 6 months. Manca et al. (49) found that using a wide range of values for added QALYs, the effectiveness of TVT slings over colposuspension remained over 80%. The authors contended, however, that a longer follow-up was needed.

The NCCHTA report (1) produced a detailed cost-effectiveness analysis comparing TVT slings 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 slings had a lower mean cost (£267or $CDN 488.61) than open colposuspension for the same or more QALYs ($\pm$0.00048).

Ontario-Based Economic Analysis/Budget Impact Analysis

Prevalence of stress urinary incontinence (SUI)

In 2004, the Medical Advisory Secretariat surveyed 1365 women in Ontario and found that 28% of these women suffered from some degree of stress urinary incontinence. Of the women with SUI, 9% reported that their quality of life was affected a lot by their incontinence. A clinical expert, who has conducted research with women regarding their decision to undergo surgery, estimated that 25% of the women with severe SUI would choose slings to treat their incontinence.

Population of Ontario women $\geq$20 years	4,588,175 women in Ontario
28% suffer from some degree of SUI	1,284,689 women in Ontario
9% have quality of life affected 'a lot' by SUI	115,622 women in Ontario
25% would choose sling procedure to treat SUI	28,906 women in Ontario

Therefore, there are potentially approximately 29,000 women in Ontario who could potentially benefit from a midurethral sling procedure. It is important to note that 75% of women who are affected a lot by SUI will not choose to undergo surgery, implying that a large proportion of women are managing their SUI with pads. In addition, it should be noted that surgical options for SUI are 'last resort' options. First line treatment options include behavior therapy, pelvic floor muscle therapy (PFMT) and possibly drug therapy. Currently in Ontario, PFMT is not an insured service. However, there are some facilities where PFMT are offered for a fee, in addition, there are some continence programs in the province that provide PFMT to women without a fee.

A Cochrane Systematic Review on PFMT first published in 2001 was updated in November 2005. (50) The original systematic review was broken down into 5 parts for the update because the scope and complexity of the original review was "unwieldy". This systematic review published in November 2005 specifically compared PFMT to no treatment. The other reviews will compare: PFMT versus other forms

of PFMT; PFMT versus other treatments (physical therapy, medication, surgery); PFMT with other therapies versus other therapies alone.

The systematic review comparing PFMT to no treatment concluded, with some limitations, that PFMT is better than no treatment or placebo. They identified 13 RCTs comparing PFMT (defined as repeated, voluntary PFMT taught and supervised by a health care professional) to no treatment. There was heterogeneity across the studies in terms of inclusion criteria (including women with any type of incontinence, or women with stress urinary incontinence only), definition of cure, inconsistency in the reporting of results. They did not identify any economic analyses to include in their systematic review.

In terms of duration of effect, they identified 1 study from 1991 that had 5 year follow-up data. (51) This study included women with all types of incontinence, not just stress urinary incontinence. At 5 years they contacted 88 of 110 women from the original study. Approximately the same proportion of women who were continent after the original study were continent 5 years later (25%). However, the number of women with severe incontinence had significantly increased from 3% to 16%, and the number of leakage episodes also significantly increased ($P<.01$). Women with SUI were less likely to report that their condition had worsened at 5 years compared to women with urge or mixed incontinence. The authors of the 5 year follow-up study reported the results of a logistic regression at 5 years including the following variables: age, parity, anxiety, incontinence severity, adherence to treatment and treatment success. They found that among the women with SUI the only factor associated with a better outcome at 5 years was continued PFMT ($P=.04$).

Costs

All costs are estimates and are in Canadian currency unless otherwise noted.

Total hospital costs for colposuspension = $3,200
Total hospital costs for midurethral slings = $1,533

Total physician costs for colposuspension = $516
Total physician costs for midurethral slings = $518

Estimated device costs for midurethral sling = $600

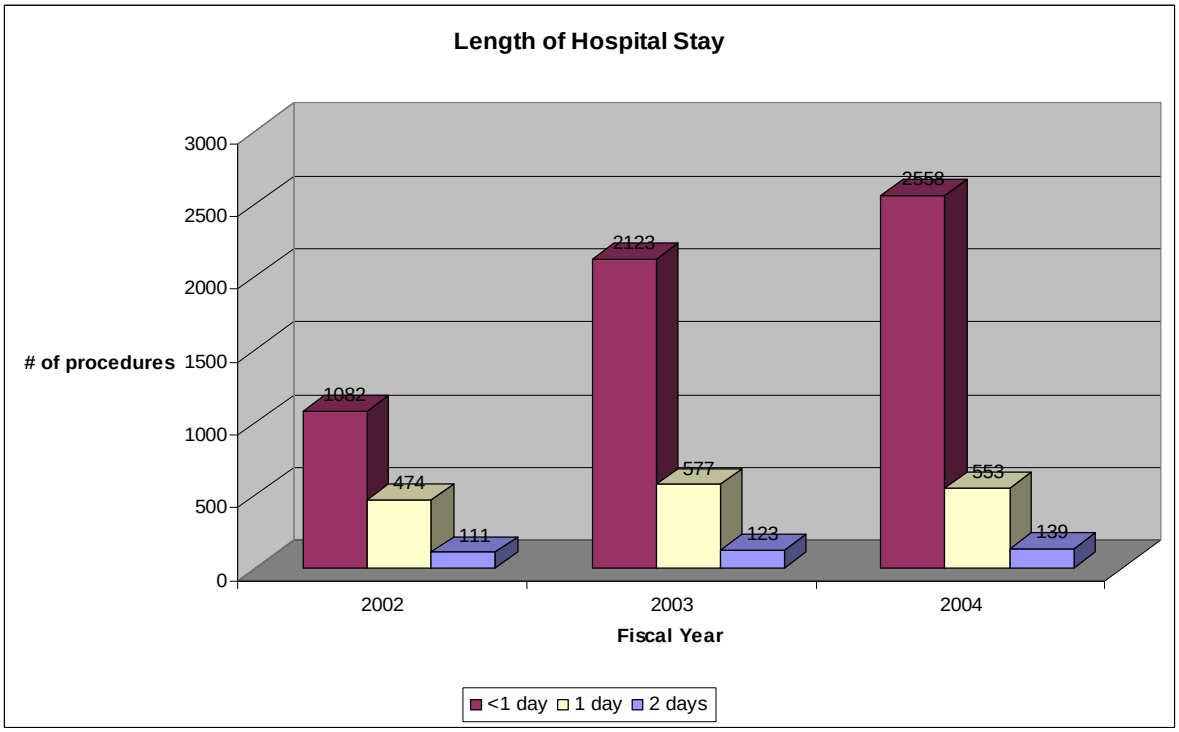
Total cost for colposuspension procedure = $3,716
Total cost for midurethral sling procedure = $2,651

Even though cost savings per case are approximately $1,667, it is possible that the adoption of midurethral slings would not be budget-saving because of concerns over diffusion associated with a less invasive procedure. In 1998/99 there were approximately 2,000 procedures to treat women with SUI and in 2004/05 there were almost 4,000 procedures performed to treat SUI in women in Ontario.

Length of Hospital Stay

There was some discrepancy among the studies regarding length of stay. The average length of stay for midurethral sling procedures ranged from 0.7 days to 4.0 days across the RCTs included in this review. When the Medical Advisory Secretariat conducted an analysis using the administrative databases they found that the majority of the patients were being treated on an outpatient basis (Figure 2). As experience with midurethral slings increases, more patients seem to be treated on an outpatient basis.

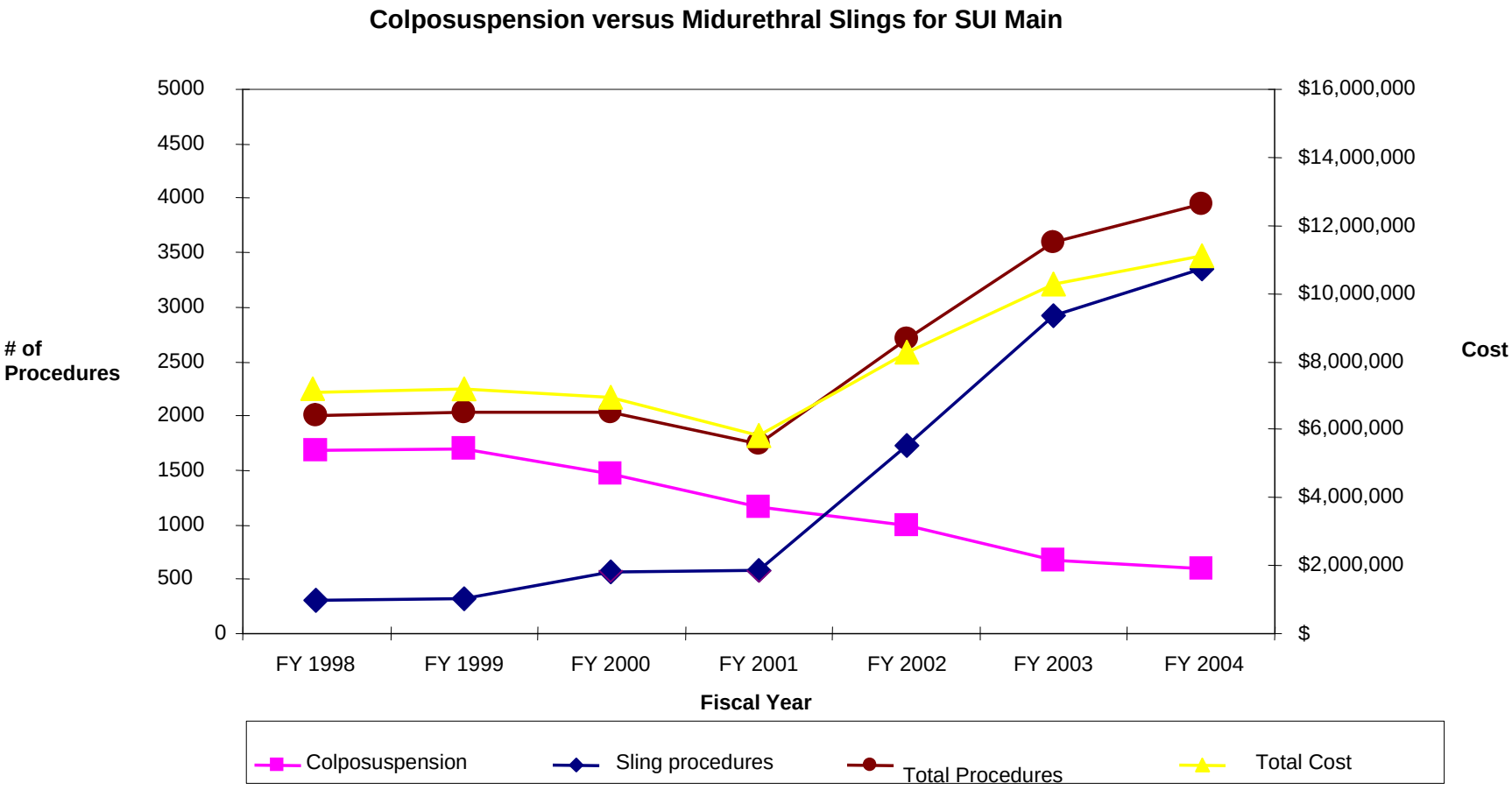
Figure 2: Length of Hospital Stay for Women Undergoing Midurethral Sling Procedures in Ontario Between Fiscal Year 2002-2004



Diffusion

Figure 3 shows the number of colposuspension procedures versus the number of sling procedures performed for women with stress urinary incontinence (main diagnosis) between 1998/99 and 2004/05. Administrative data do not capture unique types of midurethral slings individually. From the figure the trend towards using midurethral slings instead of colposuspension is evident. There has been approximately a $4 million increase in the cost of treating women stress urinary incontinence from 1998/99 to 2004/05, however, almost twice as many women were treated in 2004/05 than were treated in 1998/99. The slight decrease in the number of procedures in 2001/02 is possibly due to the change over in coding systems in that year from Canadian Classification for Procedures (CCP) codes to the Canadian Classification for Interventions (CCI) codes.

Figure 3: Comparison of Colposuspension Versus Midurethral Slings in Ontario From Fiscal Year 1998-2004



Cost-Effectiveness

Given the high cure rates for midurethral slings and colposuspension procedures, the incremental cost-per-cure ratio for midurethral slings is undefined, because the denominator is likely not different from zero. Midurethral slings economically "dominates" colposuspension because of the costs savings achieved.

In terms of cost per QALY, TVT slings added about 0.01 QALYs compared to colposuspension in a 2003 study. (49) Because TVT slings dominate 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 slings 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, the TVT sling procedure is 100% certain to be cost-saving and, as long as average length of stay is at least 2 days longer following colposuspension, TVT slings 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 midurethral slings are cost-saving relative to open colposuspension in the short term because the downstream health care costs due to potential long-term complications were not estimated.

Existing Guidelines for Use of Technology

Canada

The Society of Obstetricians and Gynaecologists of Canada (SOGC) have published guidelines on surgeries for SUI in October 2005. (52) TVT slings are recommended as a primary surgery based on Level 1-A evidence, with the proviso that the technique has not been rigorously tested for long-term equivalency. The SOGC reported insufficient evidence with sufficient follow-up to permit informed recommendation concerning other sling procedures, including the transobturator approach. This guidance updates previous SOGC guidance published in 2003 (2) which recommended colposuspension as the gold standard, and indicated that TVT slings could not be recommended due to a lack of trials establishing long-term efficacy and safety.

United Kingdom

In October 2003 guidance was published by the Royal College of Obstetricians and Gynaecologists, which assessed TVT slings. They found that TVT slings had similar objective and subjective continence rates to colposuspension with a shorter hospital stay, but cited a need for long-term outcome studies.(53) They emphasized that newer slings based on similar technology to TVT slings, but using different materials, do not have the same evidence base and should be subjected to RCTs.

National Institute for Clinical Excellence

TVT Slings

The National Institute for Clinical Excellence (NICE) published guidance on the use of TVT slings in February 2003 (37). They recommended that:

- TVT slings be used as one of a surgical options for uncomplicated SUI where nonsurgical treatments have failed
- The operation should be carried out by a trained surgeon who regularly carries out surgery on women with SUI
- Women considering surgery for SUI should be fully informed regarding the advantages and risks associated with each procedural option, particularly the lack of long-term follow-up on the TVT procedure, concomitant surgery requirements, and future conception plans

Of interest, a retrospective audit of patient care provided by the Oxford Radcliffe NHS Trust over 3 years, against the NICE guidelines, was conducted.(54) Overall performance was considered satisfactory. For all women, the type of incontinence was confirmed by urodynamic investigation and in 92% of cases, conservative management had been tried and failed before surgery was considered. A high subjective cure rate was reported, with 95% either fully cured or substantially improved. Complications were statistically low: bladder/urethral perforation 4%; hemorrhage 1%; long-term voiding dysfunction 2%; de novo urine retention 12%. However, it was noted that ¼ of patients were not provided with enough information fully informed about the TVT procedure (i.e., provide informed consent), or it was not documented.

Transobturator Slings

As mentioned previously in this review, NICE published guidance in January 2005 for transobturator slings for SUI. (55) Unfortunately the guidance has been withdrawn, given the retraction of the main trial upon which the guidance was based. (38) The article in question was retracted because the authors had not sought ethical committee approval before commencing the trial. (56) NICE will be reviewing its decision and, based on a revised overview, will incorporate the relevant available evidence.

Conclusions

Effectiveness

At this time, there does not appear to be one procedure that is more effective than another at curing stress urinary incontinence. The cure rates for TVT slings are not inferior to the cure rates of the gold standard, colposuspension. There does not appear to be one type of midurethral sling that has substantially higher cure rates than any other midurethral sling.

Procedure Time and Length of Hospital Stay

The procedure time and the length of hospital stay for TVTslings are significantly shorter than the procedure time and length of stay for colposuspension.

The procedure time and length of hospital stay for all midurethral slings appear to be similar.

Complications

The most frequently reported complications were bladder perforations, de novo voiding difficulties and device problems.

Quality of Life

Quality of life was not consistently reported in all of the RCTs. In the studies that reported quality of life there does not appear to be a significant difference in quality of life scores between the sling procedures.

Cost

Midurethral sling procedures cost approximately $1100 less than the cost of colposuspension (estimated $2650 versus $3715).

Appraisal

Implications

Recommendations for the provision of midurethral slings 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, including pelvic floor muscle therapy (PFMT) as outlined by clinical guidelines; most women respond to these treatments.
- PFMT is currently not an insured service in Ontario
- When conservative treatments fail, midurethral slings could be considered as an alternative to currently used surgical procedures for women with SUI who are past the childbearing age.
- Overall patient satisfaction levels are about the same as for other procedures after surgery.

Diffusion

- In Ontario there are an estimated 29,000 women who could potentially benefit from a midurethral sling procedure, currently, approximately 4,000 women are being treated per year.
- To manage the prevalence over 5 years, an additional 1,800 procedures per year would be required.
- Midurethral slings are replacing colposuspension for SUI in Ontario.
- If midurethral slings become more widely accessible, women may opt for midurethral slings when less invasive, conservative treatment is indicated, especially when pelvic floor muscle therapy is not an insured service.

Cost

- The surgical component of midurethral slings 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 midurethral slings diffuse rapidly it may cost the system more due to additional procedures for SUI being performed.
- Hospitals pay for midurethral slings from their global budget and therefore control its dissemination.
- There is no distinct professional code for midurethral slings; therefore, there is no way of differentiating professional costs of midurethral slings from other sling procedures.

System Pressures

- The characteristics of patients receiving midurethral slings are not known.
- The specialty/training of physicians and the number of cases per provider of midurethral slings are unknown.

Other Considerations

As mentioned previously, this HTPA is an update of the TVT Slings HTPA from February 2004. At that time OHTAC made recommendations on the usage of TVT slings. Their recommendations were as follows:

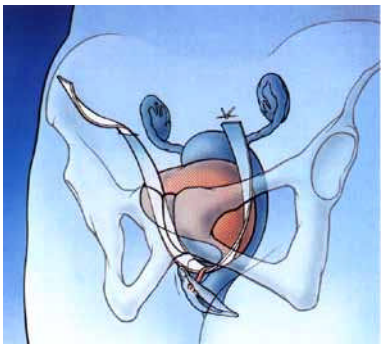
- Conduct a population based survey of women in Ontario to assess SUI
    - Survey was completed in 2004 with the Women's Health Council and York University

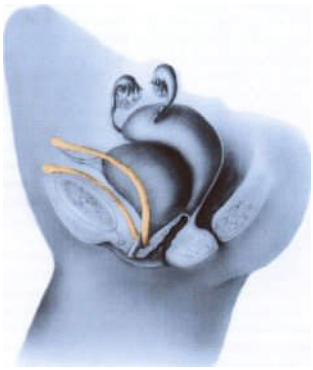
- Develop guidelines on the appropriate usage of TVT slings
    - Process was initiated, chair of the guideline committee requested an update to the TVT Slings HTPA to incorporate other midurethral slings
- Collect data on the delivery of TVT to get a sense of the budgetary and resource implications of TVT slingsCase-costing methodology has been completed through major health science centres in Ontario.
- Introduce new OHIP and CCI codes so that TVT slings can be tracked through administrative databases
    - New CCI and ICD-10 codes issued for 2006, including new codes for complication and removal of sling
    - TVT slings are one of the 6 pilot technologies that are being tracked by the Medical Advisory Secretariat

Appendices

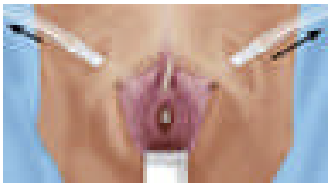
Appendix 1:

Retropubic midurethral sling placement

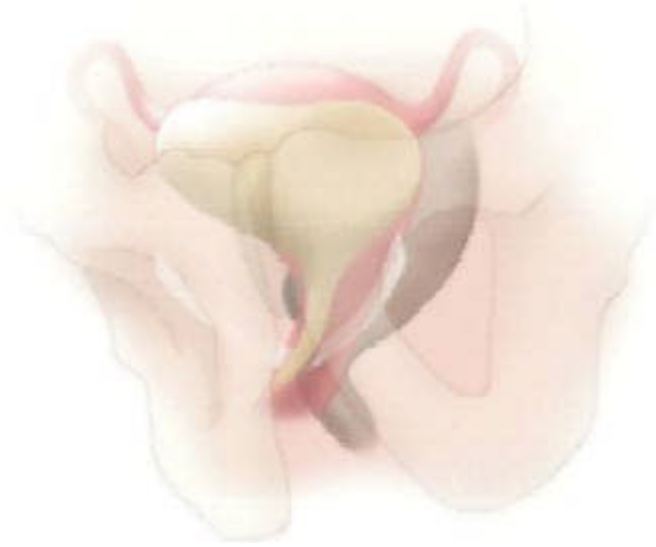




Transobturator midurethral sling placement



Available at Boston Scientific
http://www.bostonscientific.ie/med_specialty/deviceCategoryList.jsp?task=tskCategoryList.jsp&sectionId=4&relId=8,386,2026



From http://www.TVTsling.com/TOT.php

Appendix 2: Literature Search Strategies

Database: Ovid MEDLINE(R) <1966 to February Week 1 2006>
Search Strategy:
---
1 exp Urinary Incontinence, Stress/ (5518)
2 ((mid-urethral or midurethral) and (sling$ or tape$ or taping)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (31)
3 (suprapubic arch sling or SPARC).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (563)
4 (tension free vaginal tap$ or TVT).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (527)
5 (transobturator or trans-obturator).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (55)
6 ((intravaginal or transvaginal) adj3 (sling$ or tape$ or taping)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (76)
7 ((aris or MONARC or safyre or stratasis or MONARC or obtape or advantage or bioarc or obtryx or lynx or IVS or t-sling or tsling) adj3 (sling$ or tape$ or taping or mesh)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (56)
8 (polypropylene adj3 (sling$ or tape$ or taping)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (70)
9 or/2-8 (1250)
10 1 and 9 (483)
11 limit 10 to (humans and english language and yr="2000 - 2006") (362)
12 limit 11 to (meta analysis or review, academic or review, tutorial) (21)
13 systematic review$.mp. (7731)
14 11 and (12 or 13) (25)
15 11 (362)
16 limit 15 to (case reports or comment or editorial or letter or "review" or "review literature" or review, multicase or "review of reported cases") (119)
17 15 not 16 (243)
18 14 or 17 (267)

Database: EMBASE <1980 to 2006 Week 5>
Search Strategy:
---
1 exp Stress Incontinence/ (4934)
2 exp Tension Free Vaginal Tape/ (352)
3 ((mid-urethral or midurethral) and (sling$ or tape$ or taping)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (39)
4 (suprapubic arch sling or SPARC).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (522)
5 (tension free vaginal tap$ or TVT).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (637)
6 (transobturator or trans-obturator).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (64)
7 ((intravaginal or transvaginal) adj3 (sling$ or tape$ or taping)).mp. [mp=title, abstract, subject

headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (94)
8 ((aris or MONARC or safyre or stratasis or MONARC or obtape or advantage or bioarc or obtryx or lynx or IVS or t-sling or tsling) adj3 (sling$ or tape$ or taping or mesh)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (65)
9 (polypropylene adj3 (sling$ or tape$ or taping)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (82)
10 or/2-9 (1327)
11 1 and 10 (546)
12 limit 11 to (humans and english language and yr="2000 - 2006") (415)
13 exp "Systematic Review"/ (7381)
14 Meta Analysis/ (23824)
15 (systematic review$ or meta-analysis or metaanalysis).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (35335)
16 12 and (13 or 14 or 15) (10)
17 12 (415)
18 limit 17 to (editorial or letter or note or "review") (87)
19 Case Report/ (864903)
20 17 not (18 or 19) (258)
21 16 or 20 (267)

Appendix 3: Summary of Health Technology Assessments*

Organization	The National Coordinating Centre for Health Technology Assessment (NCCHTA) (1)	Agencee Nationale d-Accreditation et d'Evaluation en Sante (24)	Canadian Coordinating Office for Health Technology Assessment (CCOHTA) (3)	Australian Safety and Efficacy Register of New Interventional Procedures-Surgical. The Royal Australian College of Surgeons (56)
Country of origin and publication date	United Kingdom 2003	France 2002	Canada 2002	Australia 2001
Review dates	1966 to May 2002	Not stated	Not stated; pre-assessment	1966 to August 2000
Population and inclusion criteria	Women diagnosed with SUI stratified: - secondary intervention - co-existing prolapse -mixed incontinence	- Women diagnosed with SUI - TVT slings or TVT slings vs. colposuspension	Not explicit	- Women diagnosed with incontinence - TVT slings vs. intravaginal slingplasty - TVT slings 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 stated - Brief report on complications, cure rates, and economic evaluation	- Mortality - Complications - Cure rates - Intraoperative and hospital factors - Recovery
Conclusions	- TVT slings as effective as other more invasive procedures - TVT slings are more cost-effective than are more invasive procedures - Not recommended for women who are ineligible 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 slings replacing colposuspension as treatment of choice - TVT slings sometimes used for invalidated indications; this trend could continue - Experienced surgeon required - Large, multicentre cohort registry with annual follow-up for at least 5 years required - Standard coding necessary to evaluate utilization	- Publication of Ward and Hilton trial will provide needed information - Health technology assessments from NICE and ASERNIP-S will shed further light	- TVT slings yield lower infection rate with lighter sedation used - No reported rejection to date - TVT slings' cure rates similar to those for colposuspension - Variation in definitions and patient composition across studies make comparisons difficult
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

*ASERNIP-S indicates Australian Safety and Efficacy Register of New Interventional Procedures-Surgical; NICE, National Institute for Clinical Excellence; RCT, randomized controlled trial; SUI, stress urinary incontinence; TVT, tension-free vaginal tape.

References

(1) Cody J, Wyness L, Wallace S, Glazener C, Kilonzo M, Stearns S et al. Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence. Health Technol Assess 2003; 7(21):iii-189.

(2) Farrell SA, Beckerson LA, Epp A, Flood CG, Lajoie F, MacMillan JB et al. Tension-free vaginal tape (TVT) procedure. J Obstet Gynaecol Can 2003; 25(8):692-694.

(3) Canadian Coordinating Office for Health Technology Assessment. Pre-assessment. Tension-free vaginal tape for urinary incontinence [report on the Internet]. 2002. Ottawa, Canadian Coordinating Office for Health Technology Assessment (CCOHTA). 3-15-2006.

(4) Perry S, Shaw C, Assassa P, et al. An epidemiological study to establish the prevalence of urinary symptoms and felt need in the community: the Leicestershire MRC Incontinence study. J Public Health Med 2003; 22(3):427-34.

(5) PR Newswire. Stress urinary incontinence (SUI): a problem for many women of all ages [Web page]. PR Newswire . 2003. 4-4-2006.

(6) Newman D. Stress urinary incontinence in women. Am J Nurs 2003; 108(8):46-55.

(7) Andonian S, Chen T, St Denis B, Corcos J. Randomized clinical trial comparing suprapubic arch sling (SPARC) and tension-free vaginal tape (TVT): one-year results. Eur Urol 2005; 47(4):537-541.

(8) Bai SW, Sohn WH, Chung DJ, Park JH, Kim SK. Comparison of the efficacy of Burch colposuspension, pubovaginal sling, and tension-free vaginal tape for stress urinary incontinence. Int J Gynaecol Obstet 2005; 91(3):246-251.

(9) El Barky E, El Shazly A, El Wahab OA, Kehinde EO, Al Hunayan A, Al Awadi KA. Tension free vaginal tape versus Burch colposuspension for treatment of female stress urinary incontinence. Int Urol Nephrol 2005; 37(2):277-281.

(10) Lim YN, Muller R, Corstiaans A, Dietz HP, Barry C, Rane A. Suburethral slingplasty evaluation study in North Queensland, Australia: the SUSPEND trial. Aust N Z J Obstet Gynaecol 2005; 45(1):52-59.

(11) Tseng LH, Wang AC, Lin YH, Li SJ, Ko YJ. Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women. Int Urogynecol J Pelvic Floor Dysfunct 2005; 16(3):230-235.

(12) Wadie BS, Edwan A, Nabeeh AM. Autologous fascial sling vs polypropylene tape at short-term followup: a prospective randomized study. J Urol 2005; 174(3):990-993.

(13) Paraiso MF, Walters MD, Karram MM, Barber MD. Laparoscopic Burch colposuspension versus tension-free vaginal tape: a randomized trial. Obstet Gynecol 2004; 104(6):1249-1258.

(14) Arunkalaivanan AS, Barrington JW. Randomized trial of porcine dermal sling (Pelvicol implant) vs. tension-free vaginal tape (TVT) in the surgical treatment of stress incontinence: a questionnaire-based study. Int Urogynecol J Pelvic Floor Dysfunct 2003; 14(1):17-23.

(15) Rechberger T, Rzezniczuk K, Skorupski P, Adamiak A, Tomaszewski J, Baranowski W et al. A randomized comparison between monofilament and multifilament tapes for stress incontinence surgery. Int Urogynecol J Pelvic Floor Dysfunct 2003; 14(6):432-436.

(16) Valpas A, Kivela A, Penttinen J, Kauko M, Kujansuu E, Tomas E et al. Tension-free vaginal tape and laparoscopic mesh colposuspension in the treatment of stress urinary incontinence: immediate outcome and complications--a randomized clinical trial. Acta Obstet Gynecol Scand 2003; 82(7):665-671.

(17) Ustun Y, Engin-Ustun Y, Gungor M, Tezcan S. Tension-free vaginal tape compared with laparoscopic Burch urethropexy.[erratum appears in J Am Assoc Gynecol Laparosc. 2003 Nov;10(4):581]. J Am Assoc Gynecol Laparosc 2003; 10(3):386-389.

(18) Liapis A, Bakas P, Creatsas G. Burch colposuspension and tension-free vaginal tape in the management of stress urinary incontinence in women. Eur Urol 2002; 41(4):469-473.

(19) Ward K, Hilton P, United Kingdom and Ireland Tension-free Vaginal Tape Trial Group. Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. Br Med J 2002; 325(7355):67.

(20) Abdel-Fattah M, Barrington JW, Arunkalaivanan AS. Pelvicol pubovaginal sling versus tension-free vaginal tape for treatment of urodynamic stress incontinence: a prospective randomized three-year follow-up study. Eur Urol 2004; 46(5):629-635.

(21) Valpas A, Kivela A, Penttinen J, Kujansuu E, Haarala M, Nilsson CG. Tension-free vaginal tape and laparoscopic mesh colposuspension for stress urinary incontinence. Obstet Gynecol 2004; 104(1):42-49.

(22) Ward KL, Hilton P, UK and Ireland TVT Trial Group. A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. Am J Obstet Gynecol 2004; 190(2):324-331.

(23) Stamey TA. Urinary incontinence in the female. In: Harrison JH, Guittes RF, Perlmutter AD, editors. Campbell's urology. Philadelphia: WB Saunders, 1979.

(24) Agence Nationale d'Accreditation et d'Evaluation de Sante, Corbillon E, Poullie A. Assessment of TVT (Tension-Free Vaginal Tape) in female stress urinary incontinence [report on the Internet]. 2002. France, Agence Nationale d'Accreditation et d'Evaluation de Sante (ANAES). 5-3-2006.

(25) Lapitan MC, Cody DJ, Grant AM. Open retropubic colposuspension for urinary incontinence in women. Cochrane Database Syst Rev 2005; Issue 3(Art. No.: CD002912. DOI: 10.1002/14651858.CD002912.).

(26) Morley R, Nethercliffe J. Minimally invasive surgical techniques for stress incontinence surgery. Best Pract Res Clin Obstet Gynaecol 2005; 19(6):925-940.

(27) Atherton MJ, Stanton SL. The tension-free vaginal tape reviewed: An evidence-based review from inception to current status. BJOG 2005; 112(5):534-546.

(28) Rodrigues Palma PC. Which sling for which patient? Int Urogynecol J Pelvic Floor Dysfunct 2004; 15(6):369-372.

(29) Shindel AW, Ruiz AC, Klutke CG. Transobturator approch to suburethral sling placement in the treatment of stress urinary incontinence in women. Expert Rev Med Devices 2005; 2(5):613-622.

(30) Hermieu JF, Milcent S. Synthetic suburethral sling in the treatment of stress urinary incontinence in women. Prog Urol 2003; 13(4):636-647.

(31) Kohli N, Kleeman SD, Noblett K, Walter A. A critical review of mid-urethral slings: a roundtable discussion. OBG Management 2005; 17(Suppl):1-8.

(32) Stanton SL. Mid-urethral tapes: Which? Review of available commercial mid-urethral tapes for the correction of stress incontinence. BJOG 2004; 111(SUPPL. 1):41-45.

(33) Lo T-S, Horng S-G, Liang C-C, Lee S-J, Huang H-J, Lin C-T. Ultrasound and urodynamic comparison between caudocranial and craniocaudal tension-free vaginal tape for stress urinary incontinence. Urology 2005; 66(4):754-759.

(34) AETNA. Urinary incontinence treatments [report on the Internet]. AETNA Clinical Policy Bulletins . 7-12-2005. 2-1-2005.

(35) CIGNA. CIGNA healthcare coverage position. Surgical interventions for urinary incontinence [report on the Internet]. CIGNA . 5-15-2005. 2-1-2006.

(36) National Institute for Clinical Excellence. Guidance on the use of tension-free vaginal tape (Gynecare TVT) for stress incontinence [report on the Internet}. Technology Appraisal #56. 2003. London, National Institute for Clinical Excellence (NICE). 3-3-2006.

(37) deTayrac R, Deffieux X, Droupy S, Chauveaud-Lambling A, Calvanese-Benamour L, Fernandez H. A prospective randomized trial comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of stress urinary incontinence.[retraction in Am J Obstet Gynecol. 2005 Feb;192(2):339; PMID: 15695968]. Am J Obstet Gynecol 2004; 190(3):602-608.

(38) David-Montefiore E, Frobert JL, Grisard-Anaf M, Lienhart J, Bonnet K, Poncelet C et al. Peri-operative complications and pain after the suburethral sling procedure for urinary stress incontinence: A French prospective randomised multicentre study comparing the retropubic and transobturator routes. Eur Urol 2006; 49:133-138.

(39) Wang AC, Lin Y-H, Tseng L-H, Chih SY, Lee CJ. Prospective randomized comparison of transobturator suburethral sling (Monarc) vs suprapubic arc (Sparc) sling procedures for female urodynamic stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2005; Dec. 3;: 1-5(Epub ahead of print).

(40) Caldwell DM, Ades AE, Higgins JPT. Simultaneous comparison of multiple treatments: combining direct and indirect evidence. Br Med J 2005; 331:897-900.

(41) Hodroff MA, Sutherland SE, Kesha JB, Siegel SW. Treatment of stress incontinence with the SPARC sling: intraoperative and early complications of 445 patients. Urology 2005; 66(4):760-762.

(42) Davila GW, Ghoniem GM, Kapoor DS, Contreras-Ortiz O. Pelvic floor dysfunction management practice patterns: A survey of members of the International Urogynecological Association. Int Urogynecol J Pelvic Floor Dysfunct 2002; 13(5):319-325.

(43) Fischer A, Fink T, Zachmann S, Eickenbusch U. Comparison of retropubic and outside-in transoburator sling systems for the cure of female genuine stress urinary incontinence. Eur Urol 2005; 48(5):799-804.

(44) Palma P, Riccetto C, Herrmann V, Dambros M, Thiel M, Bandiera S et al. Transobturator SAFYRE sling is as effective as the transvaginal procedure. Int Urogynecol J Pelvic Floor Dysfunct 2005; 16(6):487-491.

(45) Roumeguere T, Quackels T, Bollens R, De Groote A, Zlotta A, Bossche MV et al. Trans-obturator vaginal tape (TOT) for female stress incontinence: one year follow-up in 120 patients. Eur Urol 2005; 48(5):805-809.

(46) Spinosa JP, Dubuis PY. Suburethral sling inserted by the transobturator route in the treatment of female stress urinary incontinence: preliminary results in 117 cases. Eur J Obstet Gynecol Reprod Biol 2005; 123(2):212-217.

(47) Persson J, Teleman P, Eten-Bergquist C, Wolner-Hanssen P. Cost-analyzes based on a prospective, randomized study comparing laparoscopic colposuspension with a tension-free vaginal tape procedure. Acta Obstet Gynecol Scand 2002; 81(11):1066-1073.

(48) 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 2003; 110(3):255-262.

(49) Hay-Smith E, Dumoulin C. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database Syst Rev 2006; Issue 1(Art. No.: CD005654. DOI: 10.1002/14651858.CD005654).

(50) Lagro-Janssen TLM, Debruyne FMJ, Smits AJA, van Weel C. Controlled trial of pelvic floor exercises in the treatment of urinary stress incontinence in general practice. Br J Gen Pract 1991; 41:445-449.

(51) Robert M, Farrell SC. Choice of surgery for stress incontinence. SOGC clinical practice guideline. J Obstet Gynaecol Can 2005; 27(10):964-971.

(52) Royal College of Obstetricians and Gynaecologists. Surgical treatment of urodynamic stress incontinence. [report on the Internet]. RCOG Guidance #35. 2003. Royal College of Obstetricians and Gynaecologists (RCOG). 2-3-2006.

(53) Price N, Jackson SR. Clinical audit of the use of tension-free vaginal tape as a surgical treatment for urinary stress incontinence, set against NICE guidelines. J Obstet Gynaecol 2004; 24(5):534-538.

(54) National Institute for Clinical Excellence. Transobturator foramen procedures for stress urinary incontinence [report on the Internet]. NICE Interventional Procedure Guidance 107. 2005. London, National Institute for Clinical Excellence (NICE). 3-15-2006.

R

(55) Comment on notice of retraction.[retraction of de Tayrac R, Chevalier N, Chauveaud-Lambling A, Gervaise A, Fernandez H. Am J Obstet Gynecol. 2004 Jul;191(1):90-4; PMID: 15295347]. Am J Obstet Gynecol 2005; 192(2):339.

(56) Merlin T, Arnold E, Petros P, MacTaggart P, Tulloch A, Faulkner K et al. A systematic review of tension-free urethropexy for stress urinary incontinence: intravaginal slingplasty and the tension-free vaginal tape procedures. BJU Int 2001; 88(9):871-880.