

Quantifying cost avoidance possibilities by investing in the minimally-invasive mid-urethral sling surgical treatment of stress urinary incontinence

D. Wayne Taylor, PhD, F.CIM, Director, Health Leadership Institute, McMaster University, wtaylor@mcmaster.ca
Elisabeth Fowler, MBA, Vice-President, World Health Advocacy, efowler@whadvocacy.com

Abstract

Urinary incontinence is one of the most prevalent, untreated chronic conditions for individuals living in Canada. The impact of incontinence on an individual's quality of life is significant as it negatively affects a person's physical, psychological, sexual, social and overall quality of life (QOL). Due to the stigma associated with this condition, many individuals do not seek treatment for their incontinence, even though 80% of incontinence cases can be managed or cured. A variety of treatment options exist for those living with incontinence. Women in Canada choosing to undergo treatment via surgery face long wait times of up to two years. An increase in funding for the treatment of incontinence is desperately needed; however, treating incontinence may also provide significant savings to government funders in the long run due to delayed admissions to long term care facilities. This report investigated possible cost savings to the Ontario Ministry of Health and Long Term Care if future admissions to long-term care facilities were delayed by 6 months, 1 year, or 4 years, and assuming that 10%, 25% and 40% of those living with stress urinary incontinence (SUI) are reached and treated with the minimally invasive mid-urethral sling (TVT). The sensitivity analysis performed found that a modest investment on the part of the Ministry in the treatment of SUI (\$3.6-\$14.5 million) could reap significant rewards (\$29.8 million – \$1.1 billion) through delayed admissions to long term care facilities. Calculated as a return on investment (ROI) the net savings produce an ROI ranging from 8:1 up to 74:1. These are conservative financial gain calculations as they do not take into consideration indirect savings that may accrue to the health care system or improved quality of life. Treatment and management of SUI as proposed will help thousands of women living with incontinence remain independent, able and productive members of society.

Introduction

Many Canadian women are living with incontinence and the consequences of urinary incontinence are varied and important. The impact on a person's quality of life must not be discounted. Urinary incontinence is associated with a loss of self esteem, the avoidance of social activity and interaction, restricted sexual activity, a decreased ability to maintain an independent lifestyle, and increased dependence on caregivers for activities of daily life. According to Thom *et.al.* "(t)he most frequently cited and most costly consequences of incontinence include admissions to a nursing home or long term care (LTC) facility, injurious falls and fractures, and urinary tract infections."¹ The onset of incontinence is often the "straw that breaks the camel's back" and initiates admittance to long term care facilities². Further, a study found that the risk of nursing home admission is 2 to 3.2 times higher, for women and men respectively, with incontinence compared to those without that diagnosis³. One-half of resident admissions to long-term care facilities are individuals with incontinence.⁴ Other consequences of incontinence include an increased propensity for falls; and many hip fractures in elders can be traced to nocturia.

Thus, urinary incontinence is an important factor that contributes to the admission of older adults to long-term institutional health care centres in Canada and the United States. According to a study by McDowell, for seniors in institutions, daily urinary incontinence was nine to ten times higher (men 36.8% and women 36.9%) than among seniors residing in the community.⁵ As the population ages, the cost of incontinence to the healthcare system is

¹ Thom D.H., Hann M.N., Van den Eeden S.K. *Medically recognized urinary incontinence and risks of hospitalization, nursing home admission, and mortality.* Age Ageing 26 (1997) 367-374.

² Dr. Harold Drutz, quoted at the *Power to the Patient Forum*, Toronto ON Canada, April 4, 2006.

³ Op.cit.

⁴ Viktrup L, Koke S, Burgio KL, Ouslander JG, *Stress Urinary Incontinence in Active Elderly Women* S Med J 2005, Vol 98 No 1, 79-89.

⁵ McDowell I, *Analysis of urinary and faecal incontinence in the Canadian population using data from the Canadian Study of Health and Aging*, Faculty of Medicine, University of Ottawa, 1998 as prepared for the Public Health Agency of Canada, Division of Aging and Seniors.

expected to increase proportionately unless action is taken. Any delay in the onset of incontinence can have the concomitant effects of delaying admission to long term care facilities and off-setting falls and fractures.

There are many treatments available to treat urinary incontinence in general, and stress urinary incontinence in particular. These treatments range from conservative (bladder retraining, exercises), to more invasive (surgery). While surgery should be considered a treatment of last resort, for women suffering from stress urinary incontinence who have failed on more conservative treatments, surgery represents their chance for reasonable quality of life.

However, women will often have to wait 6-9 months before they will see a specialist, another 4-6 month wait is generally required to assess their incontinence, and if surgery is an option, patients can wait up to two years to receive the surgical treatment that they require.⁶ These long wait times for appropriate treatment are another burden for women living with stress urinary incontinence (SUI).

Given that the only prospective randomized controlled trial comparing two surgical techniques, the mid-urethral sling and colposuspension, identified the sling as being less expensive and equally effective as colposuspension⁷, this paper set out to discover possible future cost avoidances related to an increase in government funding for the minimally-invasive surgical treatment of stress urinary incontinence using the mid-urethral sling. The paper begins with a brief discussion of the prevalence of the condition in order to determine the number of women and men affected followed by a discussion of treatment options. Conservative, mid-range and aggressive options were examined to discover possible cost avoidances related to deferred admittance to long-term care facilities. The paper concludes with a discussion of the financial feasibility of an increased investment in the treatment of SUI.

Types of Incontinence

The bladder is the urine storage reservoir, the urethra is a passage through which the bladder is emptied, and supportive structures and pelvic and periurethral muscles are responsible for preventing leakage. Incontinence has been defined by the International Continence Society as the "complaint of any involuntary leakage of urine"⁸. There are numerous types of incontinence, the most common type amongst women both young and elderly being Stress Urinary Incontinence (SUI).^{9,10,11,12,13} SUI refers to the leaking of urine, due to insufficient urethral closure, caused by coughing, sneezing, straining, exercise or any other type of exertion; fifty percent (50%) of individuals with incontinence have SUI. Urge Incontinence (UI), is leaking of urine associated with the sudden uncontrollable urge to empty the bladder. The urge to empty the bladder cannot be delayed and leakage occurs. UI is a key symptom of the overactive bladder syndrome. Overflow incontinence is constant leaking or dribbling from a full bladder. Finally, mixed incontinence (MUI) is a combination of stress and urge incontinence. Overall, urinary incontinence has a significant adverse effect on an individuals' quality of life.¹⁴

SUI is associated with a number of causes, including pregnancy and childbirth, increased body mass index (BMI), and abnormal metabolic factors. A study by Van der Vaart *et.al.* examined the effect on quality of life of various types of incontinence in community dwelling young women (ages 20-45 years). The study found that SUI was the most prevalent type of incontinence in this age group and that both SUI and overactive bladder have a similar detrimental effect on quality of life as urge incontinence¹⁵. As women age, the number of cases of incontinence in general

⁶ Carr L, Urologist, Sunnybrook Health Sciences, presentation, *Shedding light on a neglected women's health issue stress urinary incontinence*, September 22, 2006.

⁷ Ontario Health Technology Advisory Committee, *Midurethral Slings for Women with Stress Urinary Incontinence* Ministry of Health and Long Term Care, Government of Ontario, Feb 21, 2006.

⁸ Abrams P, Cardozo L, Fall M, et al. The standardisation of terminology of lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. *Neurourol Urodyn* 2002;21:167-78

⁹ Hunskar S, Arnold EP, Burgio K et al., *Epidemiology and natural history of urinary incontinence* Int Urogynecol J Pelvic Floor Dysfunct 2000, Vol 11, 301-319.

¹⁰ Maral I, Ozkardes H, Peskircioglu L et al., *Prevalence of stress urinary incontinence in both sexes at or after age 15 years: a cross-sectional study* J Urol 2001, Vol 165, 408-412.

¹¹ Nygaard IE, Lemke JH, *Urinary incontinence in rural older women: prevalence, incidence and remission* J Am Geriatr Soc 1996, Vol 44, 1049-1054.

¹² Payne CK, *Epidemiology, pathophysiology, and evaluation of urinary incontinence and overactive bladder* Urology 1998, Vol 53, 3-10.

¹³ Sandvik H, Hunskar S, Vanvik A, et al., *Diagnostic classification of female urinary incontinence: an epidemiological survey corrected for validity* J Clin Epidemiol 1995, Vol 48, 339-343.

¹⁴ Viktrup L, Koke S, Burgio KL, Ouslander JG, *Stress Urinary Incontinence in Active Elderly Women* S Med J 2005, Vol 98 No 1, 79-89.

¹⁵ Van der Vaart CH, de Leeuw JR, Roovers, JP, Heintz AP *The effect of urinary incontinence and overactive bladder symptoms on quality of life in young women* BJU Int. 2002 90(6):544-9.

increases, but the proportion of cases of urge incontinence also rises. Age itself does not cause incontinence; normal changes that occur in the urinary and genital systems as people age make this condition more common in the elderly. For example, the bladder and muscles that support the urinary system tend to sag with age, making it more difficult to store urine. Urge incontinence is the most common type in older adults in institutions¹⁶. However, studies have found that urge and stress incontinence are intimately associated with each other.¹⁷ Finally Wattanayingcharoenchai et.al¹⁸ found that women with a combination of SUI and OAB have the greatest impairment of quality of life (compared to SUI or OAB alone).

If incontinence is treated when it is diagnosed – at whatever age - it will significantly improve the person’s quality of life, help save resources (fewer costs related to pads and other incontinence products), and will also aid symptoms of possible future incontinence episodes that occur as the individual ages.

Prevalence of Incontinence

Accurate statistics on the prevalence of incontinence are difficult to determine¹⁹. The stigma of the condition, reluctance on the part of patients to discuss the problem with friends, family and physicians, as well as discrepancies in the definition of incontinence have led to significant disparities among prevalence studies and their results.

Estimates of urinary incontinence in the literature vary from 4% to 50%²⁰. In 1997 a telephone survey of urinary incontinence was conducted in Canada among a random and representative sample of adult women²¹. Nearly 9% of all respondents reported urinary incontinence, 56% of whom were below 55 years of age. Over half of the respondents had never consulted a physician about their incontinence, which illustrated the poor self-reporting of the problem. For the female population, the prevalence of urinary incontinence can conservatively be estimated to range between 10% and 20%.²² The prevalence of incontinence increases significantly with age.

According to the Canadian Urinary Bladder Survey (CUBS), 8% of all respondents initially acknowledged having a bladder problem. However, 52% responded “yes” to having one or more bladder symptoms. The commonest symptoms were nocturia (38%), urgency (16%), frequency (14%), stress incontinence (13%), and urge incontinence (7%).²³

Table 1 shows the percentage of males and females with any degree of incontinence stratified by age as determined by the Canadian Urinary Bladder Survey.

TABLE 1: Percent of men and women with any degree of incontinence

	Age (years)		
	18-40	41-64	≥65
Male	10%	16%	30%
Female	16%	33%	55%

Canada has ten provinces. For the purpose of this study only the Province of Ontario was investigated. Ontario is Canada’s second largest province geographically and its largest province based on population accounting for nearly 40% of the country’s inhabitants. Table 2 highlights Ontario’s population by age and sex in 2006.

¹⁶ Resnick NM, Yalla SV, Laurino E, *The pathophysiology of urinary incontinence among institutionalized elderly persons*. N Engl J Med 1989; 320:1-7.

¹⁷ Teleman PM, Lidfeldt J, Nerbrand C, Samsioe G, Mattiasson A, *Overactive Bladder: prevalence, risk factors and relation to stress incontinence in middle-aged women*. BJOG 2004 Jun; 111(6):600-4.

¹⁸ Wattanayingcharoenchai R, Manonai J, Vannatim N, Saritapirak S, Imsomboon C, Chittacharoen A. *Impact of stress urinary incontinence and overactive bladder on quality of life in Thai women attending the urogynecology clinic*. J Med Assoc Thai 2007 90(1):26-31.

¹⁹ Ward Health Strategies (2007) *Incontinence A Canadian Perspective* www.continence-fdn.ca

²⁰ Thom D. Variation in estimates of urinary incontinence prevalence in the community: effects of differences in definition, population characteristics, and study type. J Am Geriatr Soc 1998; 46: 473–80.

²¹ Fedorkow DM. Prevalence of urinary incontinence, pelvic organ prolapse and anal incontinence in women. In: Drutz HP, Herschorn S, Diamant NE, eds. *Female pelvic medicine and reconstructive pelvic surgery*. London: Springer, 2003; 11–24

²² Brolmann, HAM *Pelvic Floor Disorders: Diagnosis, Management and New Developments*, Gynaecology Forum 2004; Vol 9, Issue 1

²³ Herschorn S, Corcos J, Gajewski J, Schulz J, Ciu E *Canadian Urinary Bladder Survey: Population-Based Study of Symptoms and Incontinence* Neurology and Urodynamics, 2003, Vol 22, Part 5.

TABLE 2: Ontario Population by Age & Gender, 2006²⁴

	Age (years)		
	20-39	40-64	>=65
Male	1,792,700	2,158,900	718,000
Female	1,781,700	2,198,900	923,400

Table 3 tabulates the number of Ontario residents with any degree of incontinence stratified by age, and gender, excluding those aged over 85 years.

TABLE 3: Ontario Population by Age & Gender with any degree of incontinence

	Age (years)		
	20-39	40-64	65-84
Male	179,270	345,424	197,370
Female	285,072	725,637	436,810
Totals:	464,342	1,071,061	634,180
Total:	2,169,583		

As the average age of individuals being placed into long term care facilities is approximately 85 years²⁵, it was assumed that those individuals (85+ years of age, living in Ontario) would not be treated for incontinence in order to delay entrance into long term care facilities. In 2007 the number of individuals in Ontario who were over the age of 85 years was 189,300 (60,100 men, and 129,200 women).²⁶ Table 4 calculates the number of Ontarians aged 65-84 who were eligible for the study.

TABLE 4: Individuals over the age of 65 years eligible for inclusion in the study

	Men	Women
Ontarians over 65 years	718,000	923,400
Ontarians over 85 years	60,100	129,200
Ontarians 65 – 84 years eligible for the study	657,900	794,200
Total:	1,452,100	

Costs Associated with Urinary Incontinence

It has been over a decade since the costs of treating urinary incontinence were first calculated for individuals 65 years of age and older in the United States. In 1995 the diagnostic, treatment, routine care, *sequelae* and home care costs of urinary incontinence for the U.S. totalled \$26.3 billion.²⁷ In 2003, the Canadian Urinary Bladder Survey (CUBS) estimated that urinary incontinence costs Canadians \$1.5 billion per year.²⁸ The results of five cost studies are shown in Table 5.

In determining *cost avoidance* from the treatment of SUI the overall cost of SUI to the system must also be determined. There are both direct and indirect costs associated with the condition. Indirect costs are much harder to quantify, particularly as the impacts on an individual's quality of life are so great with SUI.

Direct Costs

According to Birnbaum et.al, the average direct medical cost for treating SUI was US\$5,642 per person in 1998.²⁹ Direct costs associated with SUI include physician care expenditures, drug expenditures, hospital care expenditures, long term care expenditures, and individual expenses.

²⁴ Ontario Ministry of Finance, Ontario Population Projections, 2007.

²⁵ PricewaterhouseCoopers LLP, Report of a Study to Review Levels of Service and Responses to Need in a Sample of Ontario Long Term Care Facilities and Selected Comparators, December 2001.

²⁶ Ontario Ministry of Finance, Ontario Population Projections Update, Spring 2007.

²⁷ Wagner TH, Hu T. *Economic costs of urinary incontinence in 1995*. Urology 1998; 51:355-361.

²⁸ Herschorn S, Corcos J, Gajewski J, Schulz J, Cui E, *Canadian Urinary Bladder Survey: Population-Based Study of Symptoms and Incontinence*. Neurourology and Urodynamics 2003, Vol 22 Issue 5 – Proceedings of the International Continence Society 33rd Annual Meeting paper 49.

²⁹ Birnbaum H, Leong S, Oster E, Kinchen K, Sun P *Cost of Stress Urinary Incontinence: A Claims Data Analysis*. Pharmacoeconomics. 22(2):95-105, 2004.

TABLE 5: Comparative Costs of Urinary Incontinence

Study & Date	Country & Population (2003)	Total Annual Cost (CDN\$)	Notes
Wagner & Hu (1995)	United States 288.4 million	\$26.3 billion (prorated to be \$2.9 billion for Canada)	Costs of urinary incontinence for individuals over 65 years of age.
Levy & Muller (2000)	United States 288.4 million	\$37.5 billion (prorated to be \$4.1 billion for Canada)	Majority of costs are management costs & expenses associated with nursing home admissions
Tediosi, et. al. (2000)	Italy 56.3 million	\$277 million (prorated to be \$154 million for Canada)	Study considers the cost of drugs and diapers only
Doran, Chiarelli & Cockburn (2001)	Australia 19.5 million	\$651 million (prorated to be \$1 billion for Canada)	\$309 million in treatment costs & remainder in personal costs
Canadian Urinary Bladder Survey (CUBS, 2003)	Canada 31.4 million	\$1.5 billion	

Indirect Costs

Indirect costs include a loss of productivity (absenteeism and presenteeism), costs to family caregivers, and costs related to treatment for depression.

Quality of Life Issues

The human toll of this condition is significant as it negatively affects a person’s physical, psychological, sexual, social and overall quality of life (QOL). Women living with incontinence are much more likely to suffer from depression than their continent peers.³⁰ In fact, in one study, urinary incontinence, Alzheimer’s disease, and stroke are the three chronic health conditions that most adversely affect an individual’s health-related quality of life³¹.

Vigod and Stewart³² found that incontinence is associated with nearly double the occurrence of depression for women with the problem than those without. Younger women with incontinence are also more likely to be depressed than older women with the condition, and the combination of incontinence and depression were found to be associated with many negative effects (stress, increased visits to the physician, and lost days from work).

Incontinence has also been shown to restrict an individual’s activities; limiting physical fitness (reluctance to exercise due to potential triggering of the condition); limiting ability to work (due to potential triggering of condition and social perception); and limiting social engagement.

All of the above QOL issues bear associated costs from not treating incontinence.

Table 6 identifies various piecemeal costs associated with SUI as reported in previous studies.

Treatment Options

A variety of treatment options exist for individuals living with incontinence, and up to 80% of incontinence cases can be treated or managed – once incontinence has been appropriately diagnosed. One of the main issues with the treatment of incontinence lies in the fact that the stigma of the condition stops many men and women living with the condition from mentioning it to their physician. Shame and embarrassment are the key deterrents of seeking help.

³⁰ Vigod SM, Stewart DE, *Major Depression in Female Urinary Incontinence* Psychosomatics 47:147-151, April 2006

³¹ Schultz SE, Kopec JA. *Impact of chronic conditions*. Health Rep. 2003;14:41–53

³² Vigod SM, Stewart DE, *Major Depression in Female Urinary Incontinence* Psychosomatics 47:147-151, April 2006

According to the Canadian Urinary Bladder Survey (CUBS) only 26% of those with any bladder problem had seen a doctor or health care professional³³.

TABLE 6: Various Costs Associated with SUI*

Average Direct Medical Costs/person	\$5,642 ³⁴
Increased visits to family physician	\$56.10/visit ³⁵
Increased nursing home costs	\$4,957 annually ³⁶
Daily LTC Facility rate (basic)	\$133.75/resident/day ³⁷
<ul style="list-style-type: none"> • Nursing & Personal Care: \$73.69 • Program & Support Services: \$7.12 • Raw Food: \$7.00 • Other Accommodation: \$ 45.94 	
Individual Expenses	\$1,500 annually ³⁸

* At the time of writing the Canadian dollar was at par with the U.S. dollar.

However, a wide range of treatment options exist for those living with incontinence. New concepts in continence mechanisms, behavioural treatments and new medications have led to advances in treatment. Conservative treatments such as behavioural treatments and pelvic floor exercises are the cornerstone of continence treatment, but are not always effective for all individuals. Once an individual has not been helped by the conservative treatments they may wish to consider a more 'aggressive' treatment option.

Diapers or pads are used throughout many treatments. Patients who are treated successfully may still require diapers, but to a lesser extent. The following section describes various incontinence treatment options.

Non-Surgical Treatments

Bladder Retraining

Bladder retraining combines education on healthy bladder behaviours with positive reinforcement and a scheduled voiding routine.

Healthy bladder behaviours include³⁹:

- Limiting or avoiding caffeine/alcohol (coffee, tea, carbonated drinks);
- Drinking non-caffeinated fluids – up to six to eight cups (1.5-2.0 litres) per day;
- Trying to avoid getting up more than twice a night;
- Not “pushing” when urinating;
- Maintaining a healthy weight;
- Not smoking (the chronic cough associated with smoking is a risk factor for incontinence); and,
- Eating more fibre to avoid constipation which strains and weakens the pelvic floor

Pelvic Floor Retraining

Kegel exercises, often taught to pregnant women, are useful in managing SUI too. This technique of physical training may lead to behaviour changes that will also help to improve continence.

Intermittent Self-Catheterization

In some cases women are unable to void their bladder completely. In severe cases, especially amongst the inactive elderly, the pressure from a large amount of urine left in the bladder causes frequent urination and, possibly, overflow incontinence. Intermittent self-catheterization can be used in cases such as these. This involves passing a small

³³ Herschorn S, Corcos J, Gajewski J, Schulz J, Ciu E *Canadian Urinary Bladder Survey: Population-Based Study of Symptoms and Incontinence* Neurourology and Urodynamics 2003, Vol 22, Issue 5.

³⁴ Ibid. - assuming a Canadian dollar at par

³⁵ Ministry of Health and Long Term Care, *Schedule of Benefits for Physician Services under the Health Insurance Act*, 2007.

³⁶ Shih YC, Hartzema AG, Tolleson-Rinehart S *Labor costs associated with incontinence in long term care facilities* Urology 2003, Sept;62(3):442-6.

³⁷ Verleyen C, Lutheran Homes, Kitchener ON Canada, 2008, personal communication.

³⁸ Subak, LL, Brown JS, Kraus SR, Brubaker L, Lin F, Richter HE, Bradley CS, Grady D, *The “Costs” of Urinary Incontinence for Women* Obstetrics & Gynecology 2006:107:908-916.

³⁹ Adapted from Viktrup L, Koke S, Burgio KL, Ouslander JG, *Stress Urinary Incontinence in Active Elderly Women* S Med J 2005, Vol 98 No 1, 79-89.

disposable catheter, several times a day, through the urethra and into the bladder to empty it and thus keep the bladder from getting too full. Infection is a risk if universal precautions are not taken.

Estrogen Treatment

While it has been used as a treatment, there is no compelling, objective evidence that exogenous estrogen is effective in treating urge or stress incontinence. Topical vaginal estrogen may improve urogenital aging symptoms such as vaginal dryness and some sensory bladder symptoms.

Injectables

Injecting bulking agents, such as collagen, to narrow the urethral walls has been shown to be successful and is minimally invasive. Overall, up to 75% of women with SUI may benefit from injectable treatment for short periods of time. There are various agents available (collagen, silicone rubber particles, ethylene vinyl alcohol, non-animal stabilized hyaluronic acid).

Compared to surgical options, research studies have shown limited efficacy for bulking agents since after 3 years following the treatment, fewer than half of the women who underwent the procedure maintain continence. Another barrier to this approach in Canada is that the cost of the injectable is usually borne by the patient, and this can be as much as \$2000.

Pessary

A vaginal pessary is a nonsurgical way to treat stress urinary incontinence. A pessary is made of medical grade rubber and is inserted into the vagina. The knob of the pessary or the wide bell-shaped portion of the pessary provides support to the urethra through the vaginal wall and holds up the bladder in place, much like surgery. It is not necessary to remove the pessary to urinate. Studies have shown that pessaries can be as effective as surgery in the treatment of SUI⁴⁰.

Surgical Treatments

Retropubic suspension technique (also called colposuspension & the Burch procedure, MM)

During this procedure, stitches are placed into the vaginal wall lateral to the urethra and sutured to either the periosteum of the symphysis pubis (MMK) or to Cooper's ligament (Burch) to provide support to the urethra. These techniques have been shown to have good long-term efficacy.

Slings

This technique involves using a graft of abdominal fascia (strong tissue lining muscles), or an artificial material that is placed under the urethra for support. The sling is fastened to the abdominal wall.

Mid-urethral sling (TVT)

The mid-urethral sling procedure is a minimally-invasive procedure which is highly effective at reducing the symptoms associated with stress urinary incontinence in women who have failed conservative treatments for SUI, such as pelvic floor muscle therapy and behaviour modification.⁴¹

This technique involves the use of a loose-weave polypropylene mesh ribbon placed under the urethra. This procedure requires three incisions, two suprapubic and one suburethral. There is a limited vaginal dissection and the procedure is usually performed using regional or local anaesthetic. A polypropylene mesh is applied around the mid-urethra in order to hold it securely. This provides support without fixation of the bladder neck.

Transobturator sling approach

Rather than passing the tape through the abdominal wall, French surgeons devised a technique to pass the tape out into the groin through the obturator membrane. This allows the surgeon to stay out of the abdominal cavity, thereby reducing the small risk of bladder perforation and eliminating the risk of bowel and pelvic blood vessel injury.

Surgical Treatments Compared

Surgical techniques have been compared with each other and in 1997 Leach et al⁴² showed the Burch and sling techniques had fairly good durability. The less invasive alternatives (Needle Suspensions) had better safety profiles and morbidity but the long-term outcomes were poorer.

⁴⁰ Farrell SA, Baydock S, Amir B, et.al. *Effectiveness of a New Self-Positioning Pessary for the Management of Urinary Incontinence in Women* Am J Obstet Gynecol 2007:196, 474e1-474e8.

⁴¹ OHTAC, *Midurethral Slings for Women with Stress Urinary Incontinence* MOHLTC, Government of Ontario, Feb 21, 2006.

Colposuspension (either through an open procedure or laparoscopically) was historically the gold standard surgical intervention for stress urinary incontinence. Trial results demonstrate that midurethral slings are as effective as open colposuspension, and more effective than laparoscopic colposuspension. The time required for the procedure of insertion of a midurethral sling is significantly shorter than for colposuspension. In addition, the midurethral sling procedure can be and often is an outpatient procedure while colposuspension is an inpatient procedure⁴³.

In Ontario the trends in the surgical interventions for the treatment of stress urinary incontinence between 1998/99 and 2004/05 indicate a shift away from the use of colposuspension in favour of the more economical midurethral slings. There has been approximately a 55% increase in the cost of treating female stress urinary incontinence from 1998/99 to 2004/05; however, almost 70% more women were treated in 2004/05 than were treated in 1998/99⁴⁴.

Mid-urethral slings were first introduced 10-15 years ago. There have been many series of patients treated with this technique but it was with the publication of the first prospective randomized trial of tension-free vaginal tape (TVT) used in mid-urethral slings versus colposuspension (Burch) that it became much more widely accepted⁴⁵. The study compared TVT with Burch at 6 months and again at 2 years in the same groups of patients and found the durability and effect on SUI were equivalent. However, the overall patient morbidity and quality of life was better with the TVT compared to the Burch procedure. At the time of writing the cost of the midurethral sling procedure was estimated to be \$2,600 including professional fees, hospital costs and the cost of the device. Colposuspension was estimated to cost approximately \$3,700.⁴⁶

Therefore, in terms of direct costs, the cost of using the mid-urethral sling is 30% less expensive than colposuspension yielding a direct saving of \$1,100 per procedure. Also, mid-urethral slings are inserted on an outpatient basis, SUI recurs less frequently with TVT, depression is less frequently observed, and the time required of the patient to be under treatment is less, thus yielding significant indirect savings to both provider and patient.

TABLE 8: Summary of Comparative Costs/Savings of Mid-urethral Sling versus Colposuspension

	Direct Costs	Indirect Savings
Colposuspension	\$3,700.00	
Mid-urethral sling	\$2,600.00	Outpatient Quicker Better QOL Less morbidity
Cost Avoidance	\$1,100.00	significant

Recently, there have been a number of modifications of the TVT procedure including the ability of introducing the device either through the vaginal approach or via the abdominal wall and the concept of stabilization of the tape laterally through the obturator foramen.

According to the Cochrane Collaboration Systematic Review completed in May 2005⁴⁷:

“Muscle-strengthening exercises can help incontinence, and there are surgical techniques to improve support, or correct problems. Open retropubic colposuspension involves lifting the tissues around the junction between the bladder and the urethra. The review of trials found that this is an effective surgical technique for stress and mixed urinary incontinence in women, resulting in long term cure for most women. New techniques, particularly sling operations (including the use of TVT - tension-free vaginal tape) and

⁴² Leach GE, Dmochowski RR, Appell RA, Blaivas JG, Hadley HR, Luber KM, et al. *Female Stress Urinary Incontinence Clinical Guidelines Panel summary report on surgical management of female stress urinary incontinence*. *J Urol* 1997; 158:875– 80.

⁴³ OHTAC, *Midurethral Slings for Women with Stress Urinary Incontinence* MOHLTC, Government of Ontario, Feb 21, 2006.

⁴⁴ *ibid*

⁴⁵ Ward K, Hilton P. *Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence*. *BMJ* 2002; **325**: 67–73

⁴⁶ *ibid*

⁴⁷ Lapitan MC, Cody DJ, Grant AM, *Open retropubic colposuspension for urinary incontinence in women* Cochrane Database of Systematic Reviews 2005, Issue 3, Art no CD002912.

keyhole (laparoscopic) colposuspension, look promising but need further research particularly on long term performance.”

Financial Sensitivity Analysis

Given the lack of awareness of incontinence coupled with sufferers' reticence in discussing their problem and treatment options, incontinence remains one of the most prevalent untreated chronic conditions in Ontario. If the Ontario Ministry of Health and Long Term Care (the Ministry) were to provide additional funding for incontinence treatment in order to reach those individuals currently living with incontinence, the possible cost avoidances to the Ministry could be significant. An investment in incontinence can take many forms, but the most advantageous to both funder and patient is through investment in minimally invasive surgical treatment options, particularly in the use of mid-urethral slings for women suffering from SUI.

General Assumptions

- Using the CUBS data, the number of Ontarians under the age of 85 years with any degree of incontinence was 2,169,583; of that number 1,447,519 were women.
- Given that 50% of people with incontinence will have Stress Urinary Incontinence (SUI), the number of Ontario women with SUI eligible for inclusion in the study was estimated to be 723,760.
- In 2006, 2.4% of Ontario women under the age of 85 were 80-84 years old therefore 17,370 of Ontario women with SUI were 80-84 years old.
- 80% of SUI can be treated or managed therefore 13,896 women may be aided by incontinence interventions.
- SUI interventions can take the form of bladder retraining, pelvic floor exercises, pessaries, injectables, self-catheterization, and surgery. The sensitivity analysis below is only for surgical options. Surgery is most often performed in women from the ages of 40-60 years. However, if incontinence is treated early, as discussed previously, there will be advantages to these women when they reach their 80's. Therefore cost savings will not be seen immediately, but will accrue over time.
- The average age of individuals being placed in Ontario long term care facilities is approximately 85 years. If Ontario women 80-84 years of age living with SUI were given help for their incontinence *prior* to admission to a long term care facility potential cost savings to the Ministry can be calculated if future admissions were delayed by 6 months, 1 year or 4 years.
- Given the stigma associated with the condition, it is not reasonable to expect that physicians, nurse continence advisors, physiotherapists and/or patient organizations will be able to reach every eligible woman in Ontario who is currently living with incontinence. Savings have been calculated assuming that 10%, 25% and 40% of those living with SUI are reached and aided.
- The basic daily cost for a resident in a Ontario government-funded long-term care facility is \$133.75

Assumptions regarding the mid-urethral sling

- The cost of the mid-urethral sling procedure is estimated to be \$2,600 including professional fees, hospital costs and the cost of the device.⁴⁸
- The age of individuals receiving the sling ranges from the 30's to the 80's.
- While not everyone who has SUI will be eligible for receiving the sling, the procedure is indicated for all forms of SUI.
- For those individuals who have undergone the procedure, there is an overall 97% success rate, with an 86% cure rate and an 11% improvement rate.
- The procedure is designed to last the life of the patient. There is however, a reasonable expectation of re-operation as the individuals' body changes with age. As the sling has only been on the market for 10 years, there have been few re-operations to date.
- A recent study by Campeau et.al⁴⁹ examined quality of life and levels of satisfaction for women who had undergone the surgery. The authors concluded that after six months, “the group of elderly women who underwent TVT surgery showed a significant improvement in QOL [Quality of Life], patient satisfaction, and less urinary problems compared to the group...waiting for the same surgery.”

⁴⁸ Ward K, Hilton P. *Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence.* BMJ 2002; **325**: 67–73

⁴⁹ Campeau L, Lemieux M.C., Naud A, Karsenty G, Schick, E, Corcos J. (2007) *A Multicenter, Prospective, Randomized Clinical Trial Comparing Tension-Free Vaginal Tape Surgery and No Treatment for the Management of Stress Urinary Incontinence in Elderly Women.* Neurourology and Urodynamics 26:990-994.

- The mid-urethral sling has been recommended for use in Ontario by the Ontario Health Technology Advisory Committee (OHTAC): “The time required for the procedure of insertion of a midurethral sling is significantly shorter than for colposuspension. In addition, the midurethral sling procedure is an outpatient procedure in Ontario, while colposuspension is an inpatient procedure”⁵⁰.
- Surgery is one of many options available to women for the treatment of incontinence. However surgery is a treatment that is easily quantifiable with well defined success rates, therefore, mid-urethral slings were used as an example for the calculation of cost avoidance possibilities.

Based upon the above assumptions a financial sensitivity analysis was performed to identify the cost avoidances that could be realized if 10%, 25% and 40% of the targeted women with SUI were reached and treated with TVT, and placement into long-term care could be delayed by 6 months, 1 year and 4 years (see Table 10). The cost of each incremental TVT treatment would be \$2,600.00; a day of long-term care delayed per person would save \$133.75. As more women are reached and treated with TVT, and placement in long-term care is delayed, the costs avoided increase significantly.

TABLE 9: Summary of Assumptions

# of Ontarians under the age of 85 with incontinence:	2,169,583
# of Ontario women under the age of 85 with incontinence:	1,447,519
# of Ontario women under the age of 85 with SUI:	723,760
# of Ontario women 80-84 years old with SUI	17,370
80% of Ontario women 80-84 years old with SUI who can be treated or managed:	13,896
Savings per person per day if not placed in a LTC facility	\$133.75
Cost of TVT	\$2,600

TABLE 10: Financial Sensitivity Analysis: Cost avoidances for the Ontario Ministry of Health and Long Term Care by Funding the Increased Use of Mid-Urethral Slings reaching 10%, 25% and 40% of the targeted population and delaying placement in LTC facilities by 6 months, 1 year and 4 years (n=13,896)

Increased Investment Delayed LTC Placement	10% reached (1,390) @ \$2,600 each = \$3,614,000	25% reached (3,474) @ \$2,600 each = \$9,032,400	40% reached (5,558) @ \$2,600 each = \$14,450,800
6 months (180 days) delayed placement @ \$133.75/day	\$33,464,250 - 3,614,000 \$29,850,250	\$83,636,550 - 9,032,400 \$74,604,150	\$133,808,850 - 14,450,800 \$119,358,050
1 year (365 days) delayed placement @ \$133.75/day	\$67,858,062 - 3,614,000 \$64,244,062	\$169,596,330 - 9,032,400 \$160,563,930	\$271,334,610 - 14,450,800 \$256,883,810
4 years (1,460 days) delayed placement @ \$133.75/day	\$271,432,250 - 3,614,000 \$267,818,250	\$678,385,350 - 9,032,400 \$669,352,950	\$1,085,338,400 - 14,450,800 \$1,070,887,600

⁵⁰ OHTAC, *Midurethral Slings for Women with Stress Urinary Incontinence* MOHLTC, Government of Ontario, Feb 21, 2006.

Conclusion

A modest investment on the part of the Ontario Ministry of Health and Long Term Care in the minimally invasive surgical treatment of stress urinary incontinence (\$3.6-\$14.5 million) using the mid-urethral sling could reap significant rewards (\$29.8 million – \$1.1 billion) through delayed admissions to long term care facilities.

Calculated as a return on investment (ROI) the net savings would produce an ROI ranging from 8:1 up to 74:1. These are conservative financial gain calculations as they do not take into consideration other savings that may accrue to the health care system through avoided physician visits, a decrease in prescriptions, and decreases in emergency room visits.

Furthermore there are significant quality of life issues, associated with incontinence, which have gone unquantified. An investment in the surgical treatment of SUI would help alleviate the long wait times that women currently experience waiting for surgery. Although the federal and provincial governments in Canada have tackled wait times in several areas, women's health and urology have not been targeted, and given the information produced above, this situation should be investigated in the future.

Treatment and management of SUI as proposed above will help thousands of women living with incontinence remain independent, able and productive members of society.

This study was made possible by an unrestricted grant from Johnson & Johnson.