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ERECTILE DYSFUNCTION IN SPINAL CORD INJURY: A COST-UTILITY ANALYSIS

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Background: **There is a high incidence of erectile dysfunction after spinal cord injury. This can have a profound effect on quality of life. Treatment options for erectile dysfunction include sildenafil, intracavernous injections of papaverine/alprostadil (Caverject®), alprostadil/papaverine/phentolamine ("Triple Mix"), transurethral suppository (MUSE®), surgically implanted prosthetic device and vacuum erection devices. However, physical impairments and accessibility may preclude patient self-utilization of non-oral treatments.**

Methods: **The costs and utilities of oral and non-oral erectile dysfunction treatments in a spinal cord injury population were examined in a cost-utility analysis conducted from a government payer perspective. Subjects with spinal cord injury ($n = 59$) reported health preferences using the standard gamble technique.**

Results: **There was a higher health preference for oral therapy. The cost-effectiveness results indicated that sildenafil was the dominant economic strategy when compared with surgically implanted prosthetic devices, MUSE® and Caverject®. The incremental cost-utility ratios comparing sildenafil with triple mix and vacuum erection devices favoured sildenafil, with ratios less than CAN $20,000 per quality adjusted life year gained.**

Conclusion: **Based on this study, we conclude that sildenafil is a cost-effective treatment for erectile dysfunction in the spinal cord injury population.**

Key words: erectile dysfunction, spinal cord injury, cost-utility analysis.

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INTRODUCTION

There are currently 36,000 people in Canada living with a spinal cord injury (SCI) (1). SCI refers to injury within the neural canal below the level of the foramen magnum up to and including the cauda equina. The distribution of spinal cord impairment has been reported as 31% incomplete tetraplegia, 21% complete tetraplegia, 21% incomplete paraplegia and 27% complete paraplegia (2). SCI affects predominantly young adults with a 4 : 1 ratio of men to women (3). Fifty-five percent of persons are injured between the ages of 16 and 30 years, 32 years being the average age of injury.

Erectile dysfunction is a common complication in patients with SCI. Erectile dysfunction is defined as the consistent or recurrent inability of a man to attain and/or maintain an erection sufficient for sexual performance (4). Erectile dysfunction is characterized by disorders of self-esteem and deterioration partner relationships that impact seriously on patients' quality of life (QoL) (5). The impact of erectile dysfunction on the QoL of individuals with SCI may be even more profound as the SCI population is comprised primarily of young men between the ages of 16 and 30 as shown in recent studies. For example, individuals with SCI have ranked sex-life fifth out of 12 in terms of importance in one's life, with health, family relationships, emotional well-being and money being ranked higher. In contrast, when rating their satisfaction with these life areas, sex-life ranked the lowest and family relationships and housing the highest (6). Phelps et al. (7) reported that 42% of men with SCI were dissatisfied with their sex lives, 50% had a weak or very weak sense of sexual adequacy and 20% reported that their sexual desire was weak. Concern about not satisfying their partner was the primary concern in a study of 79 men with SCI (6).

Interventions for erectile dysfunction have a significant impact on the relationships, self-esteem and perceived QoL of individuals with SCI. Treatment options for erectile dysfunction include intracavernous injections (ICI) of papaverine prostadil (Caverject®), alprostadil (Prostin VR®) given in combination with papaverine and phentolamine ("triple mix"), transurethral

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suppository (MUSE®), a surgically implanted rigid, semi-rigid, or inflatable prosthetic device (PPS), vacuum erection devices (VED) and oral phosphodiesterase inhibitors (sildenafil citrate, tadalafil and vardenafil). All treatment modalities have advantages and disadvantages. The advantages of non-oral compared with oral treatments include their relatively low cost (injection and VED) and absence of drug interactions as compared to oral phosphodiesterase inhibitors and nitrates. Limitations for some non-oral treatments (injection, suppository, VED) include physical impairments, namely limited hand function and obesity, reluctance to have invasive procedures (PPS), complications (PPS), lack of accessibility (injections), concurrent use of anti-coagulants (VED) and overall lack of convenience. Taking both the advantages and disadvantages into consideration, oral treatments for erectile dysfunction may be the most appropriate strategy in an SCI population with limited hand function.

The primary objective of this research was to compare the utilities/health preferences and costs associated with oral and non-oral erectile dysfunction treatments in a Canadian population of individuals with SCI. At the time of study, sildenafil (SILD) was the only approved oral erectile dysfunction treatment in Canada. The study was conducted from a government payer perspective over a period of 1 year. It was hypothesized that a cost-utility analysis would favour oral agents compared with non-oral treatments. Secondary objectives were to describe the socio-demographics of a population with SCI in Canada and to assess their QoL and erectile function using 2 validated questionnaires.

METHODS

A cost-utility evaluation was conducted at the Toronto Rehabilitation Institute (Toronto, Canada) to compare the costs and utilities/health preferences associated with erectile dysfunction treatments in a population of SCI individuals. This study received ethics approval from the Toronto Rehabilitation Institute Research Ethics Board.

Based on previous utility studies (8–10) a sample size of 60 patients was set *a priori*. Study subjects were recruited through a poster campaign to participate in a 90-minute interview. In exchange for their participation, subjects were given a CAN$50 honorarium. Subjects gave written informed consent before participating in the study. If written consent was not available due to physical barriers, then verbal consent was accepted.

Potential participants were screened for the following inclusion criteria: (i) men aged 18–55 years with a documented history of traumatic SCI C2–L5 (ASIA A–D) at least 6 months prior to screening; and (ii) erectile dysfunction attributable solely to SCI (based on the investigators' clinical opinion). Subjects were recruited into 4 impairment strata: complete tetraplegics, incomplete tetraplegics, complete paraplegics and incomplete paraplegics. During the interview, baseline demographics, impairment characteristics and previous experience with erectile dysfunction treatments were recorded for each subject. Subjects completed the standardized validated International Index of Erectile Function (IIEF) (11) and the SF-36. During these interviews, subjects were invited to indicate their utilities/health preferences *vis à vis* each treatment option for erectile dysfunction. The interviews were conducted by research assistants with SCI.

This cost-utility evaluation included 3 analyses: a cost-analysis, a utility/health preference analysis and an incremental cost-utility analysis. The economic evaluation was conducted from the Canadian provincial government payer perspective over a period of 1 year assuming that all treatments for erectile dysfunction were publicly reimbursed for patients with SCI, which is not currently the case. The treatment options for erectile dysfunction that were examined included: (i) oral SILD; (ii) ICI of Caverject; (iii) "Triple Mix"; (iv) MUSE; (v) PPS; and (vi) VED.

In the cost analysis, the 1-year cost of treatment associated with each treatment for erectile dysfunction was calculated using clinical scenarios approved by a Delphi panel composed of physiatrists, urologists, methodologists and pharmacists ($n = 5$). These clinical pathways were based on the current standard of care in the Toronto Rehabilitation Institute, a tertiary care spinal cord rehabilitation centre. The assumptions used in the cost-analysis are listed in Table I. Direct medical costs in Canadian dollars (2001) were included in the analysis from a number of public sources including Ontario drug formularies and physician billing codes. Direct medical costs included drug acquisition cost, dispensing fee, mark-up, physician fees, laboratory, supplies and caregiver costs (nursing and attendant). Non-medical costs (e.g. patient travel to clinic) and indirect costs (e.g. time off work) were not considered in this analysis due to the study perspective. Discounting was not used given the 1-year period considered in this study. For SILD, a mark-up of 10% and a dispensing fee of CAN$4.47 were considered in addition to the cost of drug acquisition.

In this cost-analysis, a frequency of sexual intercourse of 8 times a month was assumed for individuals with SCI. This frequency was based on a number of scientific, non-scientific and pharmacological studies. Giuliano et al. (12, 13) and Mayton et al. (14) reported a utilization of 8 SILD tablets per month in which patients with SCI were provided SILD at no cost and without the hurdle of completing a script in public in a pharmacy. Since patients with SCI reported higher frequencies of sexual intercourse when SILD was provided free of charge and without the hurdle of completing a script, it was assumed that this frequency would be the approximated desired frequency of sexual relationships if SILD was provided at no charge and if the individual did not have to undergo the normal process of completing a script in a public pharmacy. This frequency also corresponded to the results of an international market research of 18,500 sexually and non-sexually active non-SCI adults aged 16–55 years conducted by Durex. According to this survey, which was conducted by telephone, non-SCI individuals claimed to have sexual intercourse on average 8.08 times per month (15). Given the utilization of SILD reported in patients with SCI and the frequency of sexual intercourse in a general population, a frequency of sexual intercourse of 8 times a month was used in this analysis. However, other studies indicated that there is considerable variation in the reporting of sexual frequency of SCI individuals, from 3 to 6 times a month, when using different treatments or devices (16–18). A sensitivity analysis using a frequency of sexual intercourse of 4 times a month was conducted to examine the impact of lower sexual frequencies on the results.

In the utility/health preference analysis, the utility or health preferences associated with each treatment for erectile dysfunction were derived from the standard gamble theory. In this method, 2 alternatives were offered to each subject. The first, alternative 1, is a treatment with 2 possible outcomes: (i) either the individual is returned to normal health and lives for additional years or (ii) the patient dies immediately. Alternative 2 has a certain outcome of a state of chronic ill-health for life (i.e. having erectile dysfunction). The probability of each alternative is varied until the respondent is indifferent between alternative 1 and alternative 2. This probability, in which the individual is indifferent between the 2 alternatives, indicates the level of risk an individual is willing to take to return to normal life. Once the risk was determined for each treatment option, the utility associated with each treatment is derived by using formula the 1 – risk. Visual aids, provided for each treatment option to describe the treatment, were used to supplement the standard gamble method. The visual aids were reviewed and approved by the Delphi panel. The utility analysis assumes that the utility remains constant over the 1-year period and that all erectile dysfunction products had the same efficacy in patients with SCI. In cost-utility analyses, utility values for particular clinical scenarios are generally weighted by the amount of time an individual spent in that clinical scenario to calculate a quality adjusted life year (QALY). QALYs are widely used and provide an indication of the benefits gained from a particular treatment. Since it was assumed that erectile

Table I. *Study assumptions*

Variable/assumptions
Physician
• Patients would be treated by a physical medicine and rehabilitation specialist (physiatrist).
• Patients visited a physiatrist at 6-month intervals. One visit was categorized as a medical specific re-assessment and the other visit was categorized as a partial assessment, which included counselling. Patients would receive rehabilitation counselling at each visit.
• Sexuality is one component of the annual physiatry check-up. Patients would discuss erectile dysfunction during the course of a regular check-up with their physiatrist.
• Upon discussion of erectile dysfunction, referral to an urologist would be made.
• The initial urologist visit would be a consultation. This visit would involve the following laboratory test work-up: complete blood count (CBC), diabetes mellitus, male hormonal profile. A prescription for a treatment would occur during this visit[1].
• A clinic nurse would train and supervise the initial administration of an injectable or suppository treatment in 20% the cases (expert opinion – personal communication).
• Patients would follow up with another visit to the urologist upon prescription of treatment.
Surgical information
• Pharmacological and mechanical treatment failures would result in penile prosthesis surgery. A surgery consultation would occur after 3 visits to the urologist.
• Patients would undergo penile prosthesis surgery. An additional surgeon assists and an anaesthesiologist would be present during surgery. Patients would be hospitalized for 1 day post-operatively. An urologist would assess the patient during hospitalization (prior to discharge).
• A post-surgery/hospitalization follow up visit to the urologist would occur.
• There would be no post-surgery analgesia due to lack of sensation of the patients.
• There is a 10% failure rate for penile prosthesis surgery (expert opinion – personal communication). Failure would result in revision and replacement of the implant.
• All surgeries would take place during regular surgery hours and did not consider the costs of emergency services or after hour fees.
Drug information
• SCI patients received 100 mg dose of SILD[2,3].
• SCI patients received 10 μg of alprostadil intracavernous injection[4].
• SCI patients received 250 μg of MUSE[4].
• Triple mix consisted of papavarine 17.64 mg/ml (CAN$3.02), phentolamine 0.65 mg/ml (CAN$9.01), alprostadil 5.88 mg/ml (CAN$10.77) and sodium chloride (CAN$0.03). A pharmacy technician spent 20 minutes, at CAN$0.55/minute, preparing the mixture ($11.00). A vial of 4 ml is dispensed. The average volume for injection is 0.1 ml[5].
• Triple mix has a shelf life of 1 month once the vial is punctured. A new prescription would be requested monthly. This would involve a dispensing fee with each prescription. A new syringe is required for each injection.
• Alprostadil intracavernous injection is sold in packages of 5 pre-filled syringes. Based on intercourse frequency data, we assumed that patients would require 95 syringes in 1 year. This would amount to 19 kits.
• It was assumed that patients would receive a prescription every 3 months. The Ontario provincial formulary will only fund 3 months worth of prescriptions at one time.
Adverse events
• Priapism (prolonged erection >6 hours) may occur in patients receiving pharmacological treatments. Priapism was not reported as an adverse event in any of the sildenafil pre-marketing clinical trials. However, priapism has been reported during post-marketing surveillance of SILD. The incidence of priapism cannot be determined from voluntary adverse drug reaction monitoring programs but can be assumed to be rare.
• For this study, a conservative estimate of the rate of priapism for SILD of $<1/10{,}000$ was used.
• Priapism with alprostadil intracavernous injection was 0.4% and alprostadil suppository 0.1% and triple mix at 1%[6].
• Patients with priapism would present to the emergency room. The patient would receive an emergency consultation and urology consultation upon admission. A protocol for detumescence would be conducted. The patient would be hospitalized for a minimum of 24 hours An urologist would assess the patient during hospitalization.
Laboratory information
• Upon visiting the urologist, patients would undergo the following laboratory tests: glucose tolerance test (blood and urine glucose), male hormonal profile (testosterone, progesterone) and complete blood count.
Sexual frequency
• Given the utilization of SILD reported in SCI patients and the frequency of sexual intercourse in a general population, a frequency of 8 intervals of sexual intercourse was used in this analysis.
• A sensitivity analysis was conducted to examine the impact of other sexual frequencies.

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SILD: sildenafil; SCI: spinal cord injury

Table II: *Demographic Information for Study Subjects*

Variable	Frequency (%) (N = 59)	Frequency (%) Complete paraplegic (N = 15)	Frequency (%) Complete tetraplegic (N = 16)	Frequency (%) Incomplete paraplegic (N = 15)	Frequency (%) Incomplete tetraplegic (N = 13)
Level of Injury					
-C6	10 (16.9)		6 (37.5)		4 (30.7)
-C5	8 (13.6)		6 (37.5)		2 (15.4)
-C4	7 (11.9)		4 (25.0)		3 (23.1)
-T12	7 (11.9)	5 (33.3)		2 (13.3)	
-C7	4 (6.8)				4 (30.7)
-T4	3 (5.1)	3 (20.0)			
-T5	3 (5.1)	2 (13.3)		1 (6.7)	
-T10	3 (5.1)			3 (20.0)	
-T6	2 (3.4)	1 (6.7)		1 (6.7)	
-T11	2 (3.4)	1 (6.7)		1 (6.7)	
-Missing	1 (1.7)			1 (6.7)	
-T7	1 (1.7)	1 (6.7)			
-T8	1 (1.7)			1 (6.7)	
-T9	1 (1.7)	1 (6.7)			
Primary Cause of Injury					
-MVA	15 (25.4)	4 (26.7)	3 (18.8)	2 (13.3)	6 (46.1)
-Diving accident	11 (18.6)		8 (50.0)	2 (13.3)	1 (7.7)
-Fall	10 (16.9)	5 (33.3)		3 (20.0)	2 (15.4)
-Motorcycle accident	5 (8.5)	3 (20.0)	1 (6.25)	1 (6.67)	
-Other sports accident	5 (8.5)		4 (25.0)		1 (7.7)
-Recreational MVA	3 (5.1)	2 (13.3)			1 (7.7)
-Bullet wound	3 (5.1)	1 (6.67)		2 (13.3)	
-Vascular	3 (5.1)			3 (20.0)	
-Medical complications	2 (3.4)			1 (6.67)	1 (7.7)
-Osteoporosis fracture	1 (1.7)			1 (6.67)	
-Spinal cord compression	1 (1.7)				1 (7.7)

MVA = motor vehicle accident.

dysfunction was a chronic condition and as the time period was 1 year, a QALY equals the utility score multiplied by 1.

In the cost-utility analysis, costs and utilities associated with non-oral treatments were compared with those of SILD through incremental cost-effectiveness ratios (ICER) to determine the relative economic attractiveness of oral treatment with SILD vs non-oral treatments. The formula: ICER = (cost of oral−cost of comparator)/(utility of oral−utility of comparator) was used to derive the relative cost-effectiveness of SILD vs each non-oral treatment (i.e. comparator).

RESULTS

Out of the total of 69 subjects screened, 59 were male. Ten subjects were excluded from participating in the study for the following reasons (3 unavailable, 2 required translator, 1 no erectile dysfunction, 1 non-traumatic erectile dysfunction, 2 changed mind about participating, 1 cancelled interview). The average age of the subjects with SCI was 40.25 years (SD 10.43; range 23–65 years). The time since injury was 10.30 years (SD 9.35; range 1–36 years) and the most frequent levels of injury were C6 (16.9%), C5 (13.6%) and C4 (11.9%). Motor vehicle accidents were the most common cause of injury (25.4%), followed by diving accidents (18.6%). Table II presents this information in more detail.

In terms of socio-economics, more than half of the subjects had a monthly income of less than CAN$2500. The main sources of income were government programs (27%), followed by employment (25%), private insurance benefits (13%), investments (11%) and spouse/partner (8%). Private insurance (42%) was the primary source of payment for medication, followed by government payers (Ontario Drug Benefit (ODB)/Ontario Drug Special Programs (ODSP)) (29%). Approximately 1 out of 5 subjects (21%) indicated that they were paying for their medication themselves and 8% reported other sources of payment.

More than half of subjects indicated having a sexual partner at the time of interview and 41% indicated that they were single. Forty-one percent (41%) of the subjects had had previous experience with sildenafil, 22% with injections, 9% with a vacuum erection device, 5% with MUSE and 3% with a penile implant. Only 21% of the subjects had no prior experience of treatment for erectile dysfunction. Our population was suffering from moderate erectile dysfunction at the time of the interview, as indicated by the scores to the Erectile Function domain of the IIEF. A score of 11–16 indicates a moderate erectile dysfunction and a score of less than 10 a severe erectile dysfunction. Out of a maximum of 30, the mean score for Erectile Function was 12.27 ± 10.64 (range 0–30) for the entire population, 13.93 ± 11.31 for the strata complete paraplegia, 10.75 ± 10.92 for complete tetraplegia, 11.40 ± 10.85 for incomplete paraplegia and 13.23 ± 10.16 for incomplete tetraplegia. The mean scores for the other domains of the IIEF for the

Table III: *Total Annual Costs of Treatments in Erectile Dysfunction*

Cost Variables	Sildenafil (Viagra®)	Alprostadil ICI (Caverject®)	Alprostadil Suppository (MUSE®)	Triple Mix ICI	Vacuum Erection Device	Penile Prosthesis Surgery
Drug	$1205.88	$1572.18	$2278.78	$363.24	$0	$0
Physician	$259.45	$259.45	$259.45	$259.45	$259.45	$336.45
Laboratory	$68.24	$68.24	$68.24	$68.24	$68.24	$68.24
Surgery	$0	$0	$0	$0	$0	$3765.03
Nurse	$0	$6.00	$6.00	$6.00	$0	$72.00
Device Equipment	$0	$0	$0	$96.00	$402.00	$0
Adverse Event-Priapism	$0.06	$2.59	$0.65	$64.75	$0	$0
Failure of Penile Implant	$0	$0	$0	$0	$0	$3633.13
Total Cost	$1533.64	$1908.46	$2613.12	$857.68	$729.69	$7874.85

entire population were 2.32 (±2.71) for orgasmic function, 6.46 (±2.19) for sexual desire, 4.44 (±4.00) for intercourse satisfaction and 4.81 (±2.54) for overall satisfaction with sex.

In addition to their erectile dysfunction, our population of 59 patients with SCI had a low QoL as indicated by the results of the SF-36. Out of a maximum of 100, the scores were 41.1 (±41.2) for physical functioning, 45.3 (±25.8) for physical role, 60.6 (±24.0) for bodily pain, 55.5 (±20.5) for general health, 66.7 (±23.5) for vitality, 63.2 (±41.8) for social functioning, 69.5 (±18.8) for emotional role and 62.3 (±25.3) for mental health.

The results of the cost-analysis indicated that the annual cost of treatments for erectile dysfunction ranged from CAN$729.69 (VED) to CAN$7874.85 (PPS). The annual cost of treatment with SILD (CAN$1534) was cheaper than the costs associated with Caverject (CAN$1908), MUSE (CAN$2613) and surgery (CAN$7875), but more expensive than Triple Mix (CAN$858) and VED (CAN$730). Aggregate costs for each treatment option and costs associated with drugs/devices, physicians, nurses, laboratory, adverse events and surgery variables are presented in more detail in Table III. The utility/health preference analysis using the standard gamble method confirmed our research hypothesis that patients with SCI have a preference for oral SILD compared with non-oral interventions. The utilities associated with treatments for erectile dysfunction ranged from 0.82 (PPS) to 0.92 (SILD). The utility associated with the "no treatment" alternative was 0.84.

According to the results of the incremental cost-utility analysis, oral treatment with SILD is either a dominant or a cost-effective treatment in patients with SCI. As reported in Table IV which lists the costs and utilities associated with each treatment for erectile dysfunction, SILD is the dominant economic strategy compared with Caverject, MUSE and surgery, as SILD is less expensive and has a higher utility than the other treatments. When compared with Triple Mix and VED, the ICERs for SILD were CAN$9656 and CAN$13,399, respectively, per QALY (Table IV).

A sensitivity analysis considering a frequency of sexual intercourse of 4 times a month instead of 8 times a month indicated that SILD was still the dominant economic strategy compared with MUSE, Caverject and surgery. However, the incremental cost-utility ratios were even more favourable for SILD when compared with Triple Mix.

DISCUSSION

Subjects in this analysis were comparable to populations evaluated in other studies of erectile dysfunction post-SCI with respect to age, time since injury and level of injury (19–21). The sample size was also similar to that of other studies in SCI men (8–10). The scores for the Erectile Domain of the IIEF in our population with SCI (12.2) were comparable to the scores at baseline (9.2) of 41 patients with SCI enrolled in a clinical trial to evaluate the efficacy and safety of SILD in patients with SCI. The scores for the other domains of the IIEF were similar to the results regarding satisfaction with intercourse (4.5 vs 4.4 in our study) and overall satisfaction with sex (4.2 vs 4.8 in our study) (22). Results also confirmed that, due to their injury, patients with SCI with erectile dysfunction have a low QoL as illustrated by the low scores on the SF-36 questionnaire.

A certain number of limitations were associated with the economic evaluation. The results of this study are based on the assumption that all treatments for erectile dysfunction in SCI have equal efficacy since very few studies have examined the efficacy and safety of each treatment considered in this analysis for a population with SCI. In addition, there are no direct comparative studies between treatments for erectile dysfunction in men with SCI. Given the lack of clinical evidence and in order to minimize bias, it was assumed that all treatments for erectile dysfunction have similar efficacy. The study research assumption was that a cost-utility analysis would favour oral treatments. However, at the time of the study, SILD was the only oral treatment for erectile dysfunction available in Canada. Therefore, subjects could not evaluate clinical scenarios with other oral treatments. Future research is warranted to determine the economic profile of new oral treatment for erectile dysfunction (i.e. tadalafil, vardenafil) in SCI patients.

Secondly, this economic analysis did not consider all direct medical costs and the long-term costs associated with the administration of treatments for erectile dysfunction. For example, the cost associated with the administration of injectable agents by a healthcare worker was excluded from the

Table IV. *Overall costs and utility measurements*

Variable	Overall cost (CAN$)	Overall utility Mean (SD)/Range/	Incremental cost-utility ratio (ICUR)
Sildenafil (SILD)	1533.64	0.92 (0.17)/0.00–1.00/	–
Alprostadil ICI – Caverject®	1908.46	0.85 (0.20)/0.00–1.00/	SILD vs alprostadil: SILD is less expensive than alprostadil ICI. SILD has a higher QALY than alprostadil ICI. SILD is the dominant economic strategy.
Alprostadil suppository (MUSE®)	2613.12	0.85 (0.18)/0.00–1.00/	SILD vs MUSE®: SILD is less expensive than alprostadil suppository. SILD has a higher QALY than alprostadil suppository. SILD is the dominant economic strategy.
Triple Mix ICI (triple mix)	857.68	0.85 (0.20)/0.00–1.00/	SILD vs triple mix: SILD is more expensive than triple mix ICI. SILD has a higher QALY than triple mix ICI. The ICUR is favourable for SILD. SILD costs CAN$9656 per additional life year.
Vacuum erection device (VED)	729.69	0.86 (0.20)/0.00–1.00/	SILD vs VED: SILD is more expensive than VED. SILD has a higher QALY than VED. The ICER is favourable for SILD. SILD costs CAN$13 399 per additional life year.
Penile prosthesis surgery (PPS)	7874.85	0.82 (0.20)/0.00–1.00/	SILD vs PPS: SILD is less expensive than surgery. SILD has a higher QALY than surgery. SILD is the dominant economic strategy.

QALY = quality-adjusted life years, ICI = intracavernous injection

analysis. Given the private and personal nature of treatment for erectile dysfunction, it was considered unlikely that patients would ask the healthcare worker to administer the injections before sexual intercourse. This economic evaluation did not examine the long-term economics of treatments for erectile dysfunction and did not adjust for the natural decrease in sexual activity over time associated with age. A 1-year time period was chosen for this analysis because the utilization and frequency data over time were unavailable and the long-term outcomes and costs of treatments for erectile dysfunction were unknown. Due to the 1-year time period, it was assumed that the utility associated with treatments for erectile dysfunction remained constant over time, which may not be true in the long term.

This study sought to evaluate health preferences associated with treatments for erectile dysfunction in patients with SCI experience according to the standard gamble theory. In this assessment, although each individual may not have had experience with each specific treatment, each subject was presented with standardized information on the benefits and limitations of each treatment modality. This includes efficacy, adverse events, administration and timing information presented by the interviewer. Since almost 80% of our study population had experienced at least 1 treatment for erectile dysfunction, it is believed that an objective assessment of health preferences for treatment for erectile dysfunction in SCI patients was captured.

There is also uncertainty surrounding the frequency of utilization of oral treatment in patients with SCI. The base case analysis incorporated a frequency of intercourse of 8 times a month. Given the uncertainty surrounding the frequency of intercourse and the potential impact of frequency on the outcome, a frequency of 4 times a month was used in the sensitivity analysis. The interpretation of the results did not change.

Despite these limitations, the economic results presented in this paper are comparable with 2 other cost-utility economic evaluations of SILD conducted in different settings and for non-SCI populations (9, 23, 24). The results of this research conducted with 59 SCI individuals recruited in Toronto indicate that oral treatment with SILD is the dominant strategy when compared with Caverject, MUSE and surgery in terms of cost and utility. When compared with Triple Mix and VED, the ICERs indicated that SILD was cost-effective, with ICERs less than CAN$20,000 per year. In Canada, cost-effectiveness values less than CAN$20,000 per QALY are considered to be excellent value for money (25). It is important to note that not all individuals have access to the "triple mix" formulation. Only a limited number of pharmacies in Ontario were able to formulate the "triple mix" combination. Individuals with SCI outside of these locations would not have access to this medication.

In Canada, oral treatments for erectile dysfunction are not reimbursed by public plans. However, the current annual financial burden on provincial governments for reimbursing oral treatments for erectile dysfunction to an appropriate patient population, such as SCI individuals, would not be great, due to the low prevalence of SCI and considering that almost 42% of our study population of 59 men with SCI reported having private insurance coverage for medications. While treatments for erectile dysfunction may be reimbursed by private insurance, they are not covered by provincial formularies. This leaves more than half of the population with SCI paying for their own erectile dysfunction treatment.

In conclusion, this is the first Canadian analysis to examine both the costs and utility associated with SCI and treatments for erectile dysfunction. Results indicate that SILD is the dominant economic strategy when compared with intracavernous injections, suppositories and surgery. Incremental cost-utility ratios for sildenafil when compared with vacuum erection devices and triple mix are considered economically attractive. In light of these results and considering the low prevalence of SCI and the poor QoL of SCI men with erectile dysfunction, SILD should be considered for reimbursement for SCI patients as the clinical effect of oral SILD is derived at a cost saving or at a reasonable cost.

In general, treatments for erectile dysfunction are considered to be "lifestyle" drugs and much controversy surrounds their formulary addition. Governments must define "lifestyle" before reimbursement decisions are made and should revisit their actual expenditures in the area of intervention for erectile dysfunction to ensure equitable access for special populations of patients and the optimal use of resources.

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