A Cost-Utility Analysis of Nonsurgical Treatments for Stress Urinary Incontinence in Women

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Objective: The objective of this study was to perform a cost-utility analysis of nonsurgical treatments for stress urinary incontinence (SUI) in healthy adult women with a health system perspective over a 1-year time horizon.

Methods: A decision tree model was constructed to evaluate the following nonsurgical treatment options for SUI in a simulated healthy adult female cohort who had failed Kegel exercises: pelvic floor muscle therapy (PFMT), a disposable tampon device (Impressa), a self-fitting intravaginal incontinence device (Uresta), and a traditional incontinence pessary. Published data and consultation with health care providers were used to estimate efficacies and costs. Health utility estimates were derived from existing literature. Deterministic sensitivity analyses were performed as well as Monte Carlo probabilistic sensitivity analysis to account for the impact of parameter uncertainty on costs and efficacies for each treatment. Our primary outcome was the highest net monetary benefit (NMB), which represents the monetary value of the health benefits less the treatment costs. The standard willingness-to-pay threshold of US $50,000 per quality-adjusted life year was used.

Results: The utility of SUI in an otherwise healthy patient was 0.81 ± 0.16 and for subjective cure was 0.93 ± 0.08. Using base-case estimates, PFMT was the most cost-effective treatment with an NMB of US $44,098. The Impressa tampon, Uresta, and traditional pessary had NMBs of US $43,970, $43,785, and $42,846, respectively. The probabilistic sensitivity analysis confirmed PFMT to be the most cost-effective treatment option at a willingness to pay of US $50,000 per quality-adjusted life year.

Conclusions: The findings of our cost-utility analysis favor PFMT as the most cost-effective nonsurgical treatment option for SUI. Cost-effectiveness for 1 year of treatment was also favorable for Impressa and Uresta. In jurisdictions where there is no public funding for PFMT, Impressa or Uresta are alternatives for women wishing to avoid surgery.

Key Words: urinary incontinence, cost-effectiveness, stress incontinence, nonsurgical management

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Nonsurgical treatments include strengthening the pelvic floor muscles with self-initiated Kegel exercises,6 formal pelvic floor muscle training (PFMT) with a physiotherapist,7 and mechanical devices that are placed in the vagina and support the bladder neck. Mechanical devices include incontinence pessaries that are fitted by health care providers,7 self-fitting reusable intravaginal devices that are placed and removed by the patient,5,9 and disposable incontinence tampons.10,11 National guidelines recommend Kegels for all women presenting with SUI.12 The other available treatments involve different costs and efficacies, and therefore, an economic evaluation may be useful in guiding decision-making for providers and patients.

The purpose of our study was to perform an economic evaluation of nonsurgical treatments for SUI in healthy adult women who failed treatment with Kegel exercises. We used a health system perspective, including all direct health care expenditures irrespective of payer, and a 1-year time horizon.

MATERIALS AND METHODS

A health system perspective was taken for our cost-utility analysis (CUA) because the management of SUI may involve public and private (self-pay and personal insurance) payers, depending on the jurisdiction. Our theoretical population consisted of healthy adult women (age, >18 years) presenting to a family physician or gynecologist with predominant symptoms of SUI. In this simulated cohort, patients required sufficient manual dexterity to perform self-management of all modalities, had no prior surgical treatment for SUI, had failed Kegels as a first-line therapy, and were highly motivated to avoid surgical treatment. A total time horizon of 1 year was used to reflect follow-up data available in the literature and clinical practice and because most costs are incurred within the first year of treatment for many of these strategies.

A decision tree model was developed using TreeAge software (TreeAgePro 2017; TreeAge Software Inc, Williamstown, Mass) to compare the costs and outcomes of nonsurgical treatments for SUI (Fig. 1). The treatment strategies evaluated in our model were PFMT, disposable tampon (Impressa), self-fitting (Uresta) pessary, or incontinence pessary. Information on costing and efficacies was derived from existing literature (Table 1).

Treatment success was defined as subjective cure, and failure as continued subjective symptoms of SUI. We chose to use patient-reported efficacy measures, because the treatment success of SUI is dependent on improvements in QoL. Systematic literature reviews and meta-analyses were used to derive efficacy values where available. If unavailable, existing literature was used to establish the range of clinical effects. If no randomized studies existed for a treatment, the best available literature was used to obtain estimates.

Efficacy estimates for PFMT were derived from a Cochrane review.7 For Impressa, the available literature was limited to a 28-day trial10; therefore, we used data for a similar disposable tampon device manufactured in another country for the same indication to estimate longer-term efficacy,12 and estimated the range of effects using other literature where disposable tampon devices were used for SUI.13 Furthermore, for Uresta, there exists only 2
studies, one which was performed by the manufacturer\textsuperscript{8} and was felt to have an inflated probability of cure as per expert opinion. Therefore, to obtain a more objective efficacy value, expert opinion was obtained from a urogynecologist who treats 150 to 190 patients with pure SUI annually. A randomized controlled trial was used to derive efficacy estimates for the pessary.\textsuperscript{13}

Costing information was obtained from the supplying company and publicly available data for the mechanical devices,\textsuperscript{9,11} as well as 2 experts in the field for PFMT (Table 1). Amounts were obtained in Canadian dollars and then converted to 2017 American dollars (US $) (conversion rate, Can $1.00 = US $0.74). Although PFMT, Uresta, and the incontinence pessary incurred all costs up front in our model, the Impressa tampon incurs monthly costs as long as it is being used. Hence, in our model, individuals only incurred the monthly costs of Impressa for the time that they were using this device.

The cost of each individual treatment is presented in Table 1. For PFMT, cure of SUI symptoms typically requires 4 to 6 sessions. Costing ranges from US $74 to $104 (Can $100 to $140) for an initial session and US $56 to $71 (Can $75 to $95) for a 30-minute follow-up session. There may be additional costs associated with the use of equipment for biofeedback or muscle stimulation. The cost of a vaginal probe is US $22 to $37 (Can $30 to $50) plus purchase of a muscle stimulation unit (US $178 for 3 months [Can $240]). Hence, the base-case estimate for PFMT was US $534 ± 105.45 (Can $715 ± 142.50). For the mechanical devices, costing of the Impressa tampon is US $7.40 (Can $10) for the initial sizing kit and then US $37 per month (Can $50/mo) if 1 tampon is used every day. Over the course of a year, Impressa costs US $451.40 ± 6.85 (Can $610 ± 9.25). Uresta is available at a cost of US $223 per year (Can $299/y) as per the manufacturer and is replaced after 2 years.\textsuperscript{9} Pessaries range from US $37 to $75 (Can $50 to $100); the manufacturers do not specify a timeline after which they must be replaced, but in clinical practice, they can last for up to 5 years. The cost of the incontinence pessary in our base case analysis was US $55.50 ± 9.25 (Can

FIGURE 1. Simplified decision tree for the nonsurgical treatment options. Patients who have failed self-directed Kegel exercises have the option of PFMT, a mechanical device, or no further treatment. If Impressa or Uresta fails, another mechanical device is tried before terminating treatment.

TABLE 1. Costing and Base Case Estimates for Probability of Cure Derived From the Literature and Publicly Available Data for Each Treatment

<table>
<thead>
<tr>
<th>Treatment Option</th>
<th>Cost (US $) for 1 y ± SD (Can $)</th>
<th>Probability of Cure ± SD</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>No further treatment</td>
<td>0</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>PFMT*</td>
<td>534 ± 105.45 (715 ± 142.50)</td>
<td>0.60 ± 0.19</td>
<td>7</td>
</tr>
<tr>
<td>Uresta*</td>
<td>221.26 (299)</td>
<td>0.40 ± 0.05</td>
<td>8,9</td>
</tr>
<tr>
<td>Impressa</td>
<td>451.40 ± 6.85 (610 ± 9.25)</td>
<td>0.48 ± 0.06</td>
<td>10,11</td>
</tr>
<tr>
<td>Pessary*</td>
<td>55.50 ± 9.25 (75 ± 12.50)</td>
<td>0.40 ± 0.1</td>
<td>1,13</td>
</tr>
</tbody>
</table>

Values are displayed in 2017 American dollars; values in parentheses are Canadian dollars.

*May be covered by private insurance.

SD, standard deviation.
The probability of cure for each strategy is derived from the best available literature and ranged from 40% cure with the incontinence pessary and UrgoTite, 48% for the Impressa tampon, and 60% for PFMT. The widest variability in the probability of cure was seen for PFMT.

We used health utility estimates (HUES) that have been validated in the literature. Health utility estimates are derived from large population-based studies with validated measures of self-rated health in individuals; they provide a single value to describe the overall utility of an individual living with a specific health condition. Values range from 0 to 1, with 0 representing the worst possible health state and 1 representing perfect health. They are used by economists and researchers in CUA's and health care decision-making. Harvie et al. estimated a mean HUE score of 0.81 ± 0.16 (mean ± SD) for individuals living with SUI based on the EQ-5D, which demonstrated significant correlation with the Pelvic Floor Distress Inventory, a commonly used QoL measurement tool for SUI. Similar HUES for SUI have been reported in other studies. The mean HUE for SUI cure was valued at 0.93 ± 0.8 based on National Population Health Survey evaluating individuals without any of 20 chronic health conditions, including SUI. To put this into context, women living with cancer report utilities of 0.82 and individuals living with the effects of having had a stroke report HUES of 0.80. The low utility score is likely reflective of the effects of living with a condition that infers daily symptoms, which are likely especially pronounced in young women. Because HUES are subjective and may change with time and disease severity, we limited our analysis to presence or absence of SUI and did not evaluate improvement only of SUI symptoms.

Utilities were weighted based on the number of months spent in the failure and cure states for each strategy.

In our model, the patients had the following decision pathways: no further nonsurgical treatment, PFMT, disposable tampon (Impressa), self-fitting (Uresta) pessary, or incontinence pessary. If a patient had no further nonsurgical treatment, the associated cost was US $0 and they were given the utility of failure for the full year. If they chose PFMT and were successful, they incurred the entire cost of PFMT and the utility of success for the full year. If they chose PFMT and failed, they were given an equal option of all mechanical devices, and 2 devices were tried before terminating conservative treatment. The first decision path in our model closely resembles the current guidelines set by the National Institute for Health and Care Excellence pathway for SUI in women, where PFMT is considered first-line therapy. In our model, each mechanical device was tried for 3 months and PFMT was tried for 6 months, because the literature demonstrates maximal benefit of PFMT at 6 months and, in clinical practice, most treatments would be tried for at least 3 months before trying an alternative modality. Treatment failure was defined as no subjective cure of SUI.

Consistent with clinical practice, we assumed that some women would not want to choose PFMT as a treatment modality and hence included other decision paths directly to mechanical devices (Impressa, Uresta, or pessary) after failure of Kegel exercises. One to 2 mechanical devices were tried before treatment was terminated owing to treatment failure. The Uresta and Impressa devices were treated equally in the treatment pathway. If pessary was chosen at any point and failed, treatment was terminated, because pessaries are traditionally considered the final treatment option in clinical practice before surgery is offered. Treatment pathways are calculated in TreeAge to reflect the probability of requiring more than 1 treatment, and the costs and utilities for various time periods while using each treatment.

Our primary outcome was the treatment pathway with the most favorable net monetary benefit (NMB). The NMB reflects the value of each intervention in monetary terms at the designated willingness-to-pay (WTP) threshold; it is a useful measure in decision analyses such as this one, where more than 2 strategies are compared. The most cost-effective strategy is the one with the highest NMB. We used the standard WTP of US $50,000 per quality-adjusted life year (QALY). We also evaluated the treatment pathway with the most favorable incremental cost-effectiveness ratio (ICER).

One-way sensitivity analyses were performed to determine at what threshold the optimal strategy changed for each parameter. Two-way sensitivity analyses were performed to understand interactions between parameters of interest. A Monte Carlo probabilistic sensitivity analysis (PSA) was performed to account for parameter uncertainty. For clinical utility and efficacy, beta distributions were used. Gamma distributions were used for costing. As Uresta is a fixed one-time annual cost (only available through the manufacturer), a single value was used. When not provided in the literature, calculations of standard deviations for the sensitivity analysis were calculated as per recommendations by Hozo et al. A total of 10,000 samples were run for the PSA.

RESULTS

Treatment costs and efficacies derived from the literature are presented in Table 1. A simplified decision tree is outlined in Figure 1, demonstrating the three primary decision pathways: initial treatment with PFMT, a mechanical option, or no further treatment. Using TreeAge, the decision tree was populated with the associated costs and efficacies for each strategy, as well as the probability that patients would require a trial of more than one treatment in each pathway.

The cost of each decision pathway based on the initial treatment tried is presented in Table 2. Costs and effectiveness take into account the probability of success, as well as the costs of requiring a trial of another option. For example, the cost of PFMT is US $609.50 as this treatment pathway accounts for the possibility that a patient who tries PFMT initially will continue to have symptoms and go on to try one or more mechanical options with their associated costs and efficacies. Incremental costs are described relative to the prior less expensive option. Effectiveness was derived from each pathway, and incremental effectiveness is described relative to the prior less effective option.

Incremental cost-effectiveness ratios are displayed in Table 2. Pelvic floor muscle therapy was the most cost-effective option, followed by Impressa, Uresta, and the incontinence pessary. The ICER comparing pessary to no further treatment was US $1156 per QALY. Uresta compared with pessary had an ICER of US $10,470 per QALY. Impressa compared with Uresta had an ICER of US $9440 per QALY. Pelvic floor muscle therapy compared with Impressa had an ICER of US $33,579 per QALY. Although pessary had the lowest cost and ICER, it was not the preferred method owing to its low efficacy. The NMB for PFMT was the highest at US $44,098; however, the NMB for Impressa and Uresta was US $43,970 and $43,785, respectively (Table 2), indicating a small margin between these 3 most cost-effective options.

One-way sensitivity analyses were performed to determine at what parameter value the most cost-effective option changes (Fig. 2). The model was most sensitive to the probability of success with PFMT. For Uresta, if the probability of SUI cure was above 48.3%, it was the most cost-effective option; below this threshold, PFMT was the most cost-effective option. Our analyses also showed that PFMT was the most cost-effective strategy above an efficacy threshold of 57.3%, below which Impressa became the most cost-effective strategy. The Impressa tampon would be the most cost-effective option over 1 year if its annual cost was US $75 ± 12.50.
**TABLE 2.** Base Case Cost-effectiveness Rankings for 1 Year of Use for Each Treatment Pathway

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<tbody>
<tr>
<td>No further treatment</td>
<td>0</td>
<td>N/A</td>
<td>0.8100</td>
<td>N/A</td>
<td>N/A</td>
<td>40,500</td>
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<td>Pessary</td>
<td>55.50</td>
<td>55.50</td>
<td>0.8580</td>
<td>0.0480</td>
<td>1156</td>
<td>42,846</td>
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<td>(75)</td>
<td>(75)</td>
<td></td>
<td></td>
<td></td>
<td>(1563)</td>
<td></td>
</tr>
<tr>
<td>Uresta</td>
<td>304.27</td>
<td>248.77</td>
<td>0.8818</td>
<td>0.0238</td>
<td>10,470</td>
<td>43,785</td>
</tr>
<tr>
<td>(411.17)</td>
<td>(336.18)</td>
<td></td>
<td></td>
<td></td>
<td>(14,149)</td>
<td></td>
</tr>
<tr>
<td>Impressa</td>
<td>347.31</td>
<td>43.04</td>
<td>0.8863</td>
<td>0.0045</td>
<td>9440</td>
<td>43,970</td>
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<tr>
<td>(469.34)</td>
<td>(58.18)</td>
<td></td>
<td></td>
<td></td>
<td>(12,757)</td>
<td></td>
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<tr>
<td>PFMT</td>
<td>609.50</td>
<td>262.19</td>
<td>0.8941</td>
<td>0.0078</td>
<td>33,579</td>
<td>44,098</td>
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<tr>
<td>(823.65)</td>
<td>(354.31)</td>
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<td>(45,377)</td>
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</table>

Cost-effectiveness rankings are based on treatment pathways, and the initial treatment indicates which modality was tried first. Incremental cost, effectiveness, and ICERs are expressed relative to prior less expensive/costly option. Values are displayed in 2017 American dollars; values in parentheses are Canadian dollars.

Incr., incremental; Eff., effectiveness.

**FIGURE 2.** One-way cost-effectiveness sensitivity analyses. One-way sensitivity analyses are used to determine cost or efficacy thresholds at which each modality becomes the optimal treatment strategy; they are helpful for interrogating parameter uncertainty. A, Probability of Uresta success, demonstrating a threshold of 48.3%. Below this threshold, Impressa is the most cost-effective strategy. Above this threshold, PFMT is the most cost-effective strategy. B, Probability of PFMT success, demonstrating a threshold of 57.3%, below which Impressa is the most cost-effective strategy. C, Annual cost of Impressa. If priced at US $218.57 or lower, it would be the most cost-effective option. D, Cost of PFMT. If priced at US $662.21 or lower, it remains the most cost-effective option. c indicates cost, p, probability.
$218.47 (Can $380.14) or lower. Pelvic floor muscle therapy remains the most cost-effective option if its annual cost were US $662.21 (Can $1152.25) or lower; if its cost were above this threshold, then Impressa becomes the most cost-effective. Two-way sensitivity analyses were performed to examine the sensitivity of the model to the adjustment of pairs of parameter estimates for Impressa, Uresta, and PFMT (Fig. 3).

A Monte Carlo PSA was run for 10,000 samples (Table 3). The cost-effectiveness plane based on the PSA is presented in Figure 4. Cost-effectiveness planes plot the cost and effectiveness for each treatment. The WTP threshold is also plotted, and the optimal strategy is determined by finding the intersection between the WTP line and the cost-effectiveness frontier. At a WTP of US $50,000 per ICER, PFMT is the most cost-effective treatment, followed by tampon, Uresta, pessary, and no further treatment.

DISCUSSION

Pelvic floor muscle therapy was the most cost-effective non-surgical treatment for SUI in this CUA, closely followed by Impressa and Uresta. The literature supports the use of PFMT for SUI, and the American College of Physicians' Clinical Practice Guideline and National Institute for Health and Care Excellence recommend PFMT before any other modalities, which we modeled in our first decision pathway. We did not model PFMT as a necessary component of all decision pathways; because it is not the standard of care in Canadian or American national guidelines, some patients may not want or be eligible for PFMT and PFMT can be prohibitively expensive in patients without private coverage. Proceeding to mechanical devices without PFMT is reflective of clinical practice in a jurisdiction where universal coverage is not available for this service. In an equitable system, PFMT should be an option for any woman who is motivated to try non-surgical management options.

The margin between the top 3 options (PFMT, Impressa, and Uresta) was small; however, we only modeled a 1-year time horizon, during which all the costs of PFMT were incurred, and costs would continue monthly with Impressa and biannually with Uresta. Hence, the cost of each treatment beyond the first year must be considered when discussing these alternative treatments with patients.

Impressa and Uresta had the most uncertainty around efficacy data, owing to a paucity of well-designed studies. We relied on expert opinion for efficacy estimates, and our model was very sensitive to changes in these parameters. There is a need for more well-designed studies to establish the true efficacy of these mechanical devices. A Cochrane review comparing mechanical devices

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**TABLE 3.** Monte Carlo PSA Simulation Results (N = 10,000)

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<tr>
<td>No further treatment</td>
<td>0</td>
<td>N/A</td>
<td>0.8078</td>
<td>N/A</td>
<td>N/A</td>
<td>40,390 ± 8050</td>
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<td>Pessary</td>
<td>55.50 ± 9.33</td>
<td>55.50</td>
<td>0.8568</td>
<td>0.0490</td>
<td>1133</td>
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<td>(75 ± 12.61)</td>
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<td></td>
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<td>(57,815 ± 7022)</td>
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<td>Uresta</td>
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<td>248.78</td>
<td>0.8811</td>
<td>0.0243</td>
<td>10,209</td>
<td>43,753 ± 4025</td>
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<td>(411.19 ± 11.69)</td>
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<td></td>
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<td>(13,796)</td>
<td>(59,125 ± 5439)</td>
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<tr>
<td>Impressa</td>
<td>347.50 ± 12.96</td>
<td>43.22</td>
<td>0.8859</td>
<td>0.0048</td>
<td>9078</td>
<td>43,948 ± 3884</td>
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<td></td>
<td></td>
<td></td>
<td>(12,268)</td>
<td>(59,389 ± 5249)</td>
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<td>PFMT</td>
<td>609.98 ± 111.89</td>
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<td>0.8935</td>
<td>0.0076</td>
<td>34,677</td>
<td>44,064 ± 4026</td>
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<tr>
<td>(824.30 ± 151.20)</td>
<td>(58.41)</td>
<td></td>
<td></td>
<td></td>
<td>(46,861)</td>
<td>(59,545 ± 5441)</td>
</tr>
</tbody>
</table>

Values are displayed in 2017 American dollars; values in parentheses are Canadian dollars. ICER is expressed relative to prior less expensive option. Incr., incremental; Eff., effectiveness; SD, standard deviation.
for SUI concluded that the value of mechanical devices in the management of SUI remains uncertain, and the optimal device remains unknown. The authors commented that an intravaginal tampon may perform as well as other mechanical devices and have the additional benefit of familiarity to women. In our model, Impressa would be cost-effective over the course of a year at US $18.21 per month (Can $31.69) or less.

The pessary performed poorly, with the lowest probability of cure, and the lowest cost-effectiveness. From an economic standpoint, pessary should not be considered a first-line treatment for SUI. Although not the preferred option in this decision analysis, pessaries have clinical utility for SUI in women with financial constraints or medical conditions where they cannot participate in PFMT and surgical management is not an option.24 Of note, all patients in our simulated population were able to perform self-management of all SUI treatment modalities to enable equal comparison of these options.

Our model has several limitations. We did not model treatment complications for several reasons: first, the complications for all these modalities are typically minor (vaginal candidiasis, spotting, discomfort, or pain) and resolve with discontinuation.1,25 Second, for the mechanical devices, some studies reported high rates of complications such as patient discomfort, but this did not always translate into device discontinuation.10 No disutility was applied for complications in our model. Third, complication rates associated with some mechanical devices are poorly reported in the literature,8 making estimates unreliable. We did not consider or model efficacy for combined treatments (such as PFMT and a mechanical device). Although commonly performed in the real world setting, these data are lacking in the literature. There is also a paucity of data on patient and physician preference for each device, and we therefore modeled an equal chance of each treatment pathway.

Our model also has several strengths. First, our model is clinically accurate and relevant to current practice where PFMT is not universally covered, and many patients will try mechanical devices owing to inability to afford PFMT. Second, all treatment pathways in our model are within the scope of a family physician and in many cases may avoid referral to a specialist, which could confer economic benefits to the health care system. This makes our model more relevant to a larger number of health care providers and patients. Third, we adopted a health payer perspective to determine overall costing regardless of the payer to determine the overall economic impact on the public health care system should they cover some of these treatments.

Our model demonstrated that PFMT is the most cost-effective nonsurgical SUI treatment option and Uresta and Impressa were cost-effective mechanical options for women who are unable to afford or do not wish to participate in PFMT. The findings of our economic evaluation support improving access to PFMT through public funding to allow women to avoid surgical treatment and its associated risks.

ACKNOWLEDGMENTS

The authors thank Angelique Montano-Bresolin (Proactive Pelvic Health Centre) and Nelly Faghani (Pelvic Health Solutions) for providing information on costing for PFMT; Dr Rebecca Hancock-Howard at the Institute for Health Management, Policy and Evaluation for her contributions to this study as well; and Josie Chundamala, scientific grant editor, funded by the Department of Obstetrics and Gynaecology at Mount Sinai Hospital, for assistance in editing and preparing this article for submission.

The authors have presented the findings of this study at the University of Toronto Obstetrics and Gynaecology Research Day, April 28, 2017 (Toronto, Canada), and have also been accepted to present this study at the International Urogynaecology Association Annual Meeting on June 22, 2017 (Vancouver, Canada).

REFERENCES


