Paclitaxel-Coated Balloon Dilation for Adults With Recurrent Bulbar Urethral Stricture

Recommendation

Month 20XX

Ontario Health

Draft Recommendation

Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding paclitaxel-coated balloon dilation for adults with recurrent bulbar urethral stricture.

Rationale for the Recommendation

The Ontario Health Technology Advisory Committee considered the clinical, economic, and patient preferences and values evidence reported in the health technology assessment (HTA).[1]

Committee members acknowledged that surgical urethroplasty remains the gold standard treatment for recurrent bulbar urethral stricture, though some patients may be reluctant to undergo this surgical procedure. They also noted that direct visual internal urethrotomy (DVIU) is currently the standard endoscopic treatment in Ontario and is generally effective. However, the committee also recognized the challenges in managing recurrent bulbar urethral strictures, particularly among people who decline urethroplasty or who experience frequent recurrences with existing endoscopic treatment options, such as DVIU.

The committee acknowledged that the current evidence for paclitaxel-coated balloon dilation is limited to 1 randomized controlled trial that compared the treatment with a control group that comprised 3 different endoscopic techniques (uncoated balloon, DVIU, and rigid dilator). Committee members acknowledged uncertainty related to the results of this study and highlighted potential bias in the study that may lead to an overestimation of the effectiveness of paclitaxel-coated balloon dilation for the outcome of freedom from reintervention.

The committee considered the economic evidence, which suggested that publicly funding paclitaxel-coated balloon dilation for adults with recurrent bulbar urethral strictures could potentially be cost saving to Ontario. While acknowledging the limitations of currently published clinical evidence and a possible overestimation of the effectiveness, committee members found the economic analysis results relatively robust and noted the potential for improved outcomes and savings compared with usual care.

Committee members took into account the lived experience of patients with urethral strictures who described the impact of their condition on their quality of life. In particular, the committee noted that people with urethral strictures valued the noninvasive nature of paclitaxel-coated balloon dilation and expressed their hesitancy in undergoing urethroplasty.

In making their recommendation, the committee recognized the need for paclitaxel-coated balloon dilation in people who have been unsuccessfully treated with multiple endoscopic management procedures and in those who would wish to delay or avoid urethroplasty (the surgical option). However, they also expressed concerns that a broader use and an expansion of eligibility criteria beyond what was considered in the HTA could challenge implementation and budget planning.

Committee members also recognized that paclitaxel-coated balloon dilation would be in the scope of subspecialty care (done by urologists with additional training, including a fellowship or subspecialty training) to ensure appropriate use of this treatment in the management of recurrent bulbar urethral

strictures. However, the committee considered that limiting access to specialized centres potentially perpetuates geographic and systemic inequities. It was also noted that the technology is already available privately in Ontario, which introduces further disparities.

Decision Determinants for Paclitaxel-Coated Balloon Dilation for Adults With Recurrent Bulbar Urethral Stricture

Overall Clinical Benefit

Effectiveness

How effective is the health technology/intervention likely to be?

There is currently no evidence for head-to-head comparison between paclitaxel-coated balloon dilation and direct vision internal urethrotomy – the most common endoscopic treatment method for bulbar urethral stricture in Ontario. Evidence is limited to 1 trial in which paclitaxel-coated balloon dilation was compared with different endoscopic methods combined. This trial showed a statistically significant difference in freedom from repeat intervention at 1 year, favouring the intervention (paclitaxel-coated balloon dilation) group (Grading of Recommendations, Assessment, Development and Evaluations [GRADE]: Low). However, this estimate was skewed by the fact that there were participants in the intervention group who failed the treatment but did not undergo reintervention. These cases were excluded (censored) from the analysis, which made the intervention look more effective than it might actually be. There is some evidence that paclitaxel-coated balloon dilatation improves urinary symptoms and urine flow rate better than other endoscopic treatment methods (GRADE: Low).

Safety

How safe is the health technology/intervention likely to be?

Treatment with paclitaxel-coated balloon dilation causes more hematuria and dysuria during the first month compared with other endoscopic treatments (GRADE: Moderate). Treatment with paclitaxel-coated balloon dilation does not adversely affect sexual function (GRADE: Moderate). Paclitaxel is a genotoxic and cytotoxic drug and its effect on semen is not yet known.

Burden of Illness

What is the likely size of the burden of illness pertaining to this health technology/intervention?

The prevalence of urethral stricture is reported as 229 to 627 per 100,000 men (~0.6%).[2] A large study reported that urethral strictures were in the anterior urethra in 92.2% and in the posterior urethra in 7.8% of people seeking treatment for urethral stricture. Within the anterior section, 46.9% were in the bulbar segment, 30.5% in the penile segment, and 9.9% in the bulbar plus penile segments, while 4.9% were panurethral.[3]

Need

How large is the need for this health technology/intervention?

Urethroplasty surgery is generally the preferred and most effective treatment for recurrent bulbar urethral strictures, offering superior long-term patency compared to endoscopic methods. However, the best choice is made in collaboration with the patient, considering their symptoms, preferences, the stricture's complexity, and the long-term effectiveness and potential risks of each option.

Patient Preferences and Privacy

Patient Preferences and Values

Do patients have specific preferences, values, or needs related to the health condition, health technology/intervention, or life impact that are relevant to this assessment?

People we spoke with valued having minimally invasive treatment options for recurrent urethral strictures, especially given the sensitivity of the area and the recovery involved. Those who underwent paclitaxel-coated balloon dilation reported being able to fully empty their bladder after the initial recovery period. They also described improvements in related symptoms, such as a stronger urine stream, as well as positive impacts on their mental health. Participants who experienced a recurrence noted that it helped them feel more comfortable with the idea of undergoing urethroplasty.

Autonomy, Privacy, Confidentiality, and/or Other Relevant Ethical Principles as Applicable

Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles that are relevant to this assessment?

Participants saw paclitaxel-coated balloon dilation as supporting shared decision-making. They valued having the autonomy to make informed health decisions in consultation with their health care provider.

Equity and Patient Care

Equity of Access or Outcomes

Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved or worsened that are relevant to this assessment?

In Ontario, access to paclitaxel-coated balloon dilation is currently available in a limited number of hospitals and private clinics. Those accessing the procedure in private clinics pay out of pocket for the procedure.

Patient Care

Are there challenges in the coordination of care for patients or other system-level aspects of patient care (e.g., timeliness of care, care setting) that might be improved or worsened that are relevant to this assessment?

Paclitaxel-coated balloon dilation is a minimally invasive, outpatient treatment option that could potentially delay urethroplasty in people who would not opt for an invasive surgical option. Urethroplasty is an open surgery that requires specialized surgeons and requires a longer recovery.

Cost-Effectiveness

Economic Evaluation

How efficient is the health technology/intervention likely to be?

From the Ontario Ministry of Health perspective, compared with usual care over 5 years, paclitaxel-coated balloon dilation is less costly (mean: −$1,476.44 per person; 95% credible interval [CrI]: −$3,217.15 to $112.40) and more effective (a decrease in the recurrence of urethral strictures at 5 years [mean: 69%; 95% CrI: 68%–70%] where the recurrence was defined by the clinical outcome *freedom from reintervention*). In the reference case, paclitaxel-coated balloon dilation was highly likely to be cost-saving (about 97% of the time).[4] However, these results are uncertain and ought to be interpreted with caution because of the limitations and the low quality of the currently published clinical evidence that informed the economic modelling. In scenarios, the cost-effectiveness results were sensitive to changes in the effectiveness of the intervention, duration of the time horizon, and device cost.

Feasibility of Adoption Into Health System

Economic Feasibility

How economically feasible is the health technology/intervention?

The estimated cost of paclitaxel-coated balloon dilation for the treatment of recurrent and symptomatic bulbar urethral strictures in adult males is about $4,546 per person (including the costs of the device [list price: $2,800] and consumables [about $72]). Assuming a high rate of uptake from 50% in year 1 to 100% in year 5 (for a total of 2,747 eligible males in Ontario), we may expect additional costs of about $0.28 million in the first year of funding and annual savings for the remaining 4 years, starting with $0.02 million in year 2, increasing to $0.58 million in year 5. The overall 5-year budget impact of publicly funding paclitaxel-coated balloon dilation in Ontario is a cost savings of about $0.74 million.

Organizational Feasibility

How organizationally feasible is it to implement the health technology/intervention?

Paclitaxel-coated balloon dilation is used in private clinics (paid out of pocket) and in some hospitals in Ontario (paid by research foundations or through the hospital global budget). Based on expert consultation, use of this procedure ideally would be restricted to sub-specialty care, and the procedure would be used one-time only and not as a first-line option for the treatment of recurrent bulbar

strictures in adult males. An Ontario Health Insurance Plan (OHIP) fee code may need to be established for this procedure. Changes to the schedule of benefits are jointly negotiated between the Ministry of Health and the Ontario Medical Association.

References

1) TBD
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