

CADTH Health Technology Review

# Urethral Inserts for the Management of Adult Male Urinary Incontinence

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## Key Messages

- No evidence was identified regarding the clinical effectiveness of male urethral inserts for the management of male urinary incontinence.
- No evidence was identified regarding the cost-effectiveness of male urethral inserts for the management of male urinary incontinence.

## Context and Policy Issues

Urinary incontinence refers to the involuntary leakage of urine.<sup>1</sup> With increasing age, urinary incontinence can occur in both men and women, and affects the quality of life. This condition is associated with social and economic impacts.<sup>2</sup> For men aged more than 65 years, the prevalence of urinary incontinence has been reported to range between 11% and 34%.<sup>1</sup> The prevalence of incontinence increases with age. In Canada, according to a 2014 report, the estimates for the prevalence of incontinence in men were 6.4%, 11.6, and 18.7% in the age ranges 65 to 74 years, 75 to 84 years, and greater than 85 years, respectively.<sup>3</sup> There are various types of urinary incontinence; these include urge urinary incontinence, stress urinary incontinence, mixed incontinence (combination of urge urinary incontinence and stress urinary incontinence), overflow incontinence, post-void dribbling, functional incontinence, and incontinence after prostrate treatment.<sup>1</sup> Treatment and management options for urinary incontinence include pelvic floor muscle exercise, pharmacotherapy, urethral inserts, catheters, and surgical interventions.<sup>1-3</sup> Generally, if conservative treatments (such as exercises) are not effective, other less conservative treatment modalities may be considered.<sup>3</sup> Pharmacotherapy may be effective but may be associated with side effects.<sup>1,3</sup> Surgical interventions are invasive and may be associated with complications.<sup>2,3</sup> As urethral inserts may be less invasive, there is growing interest in this management option for controlling urinary incontinence. The Contino is an example of a self-administered urethral insert to control urinary incontinence in male adults. It is inserted into the distal portion of the male urethra, inhibiting the flow of urine, and can be removed before urination and reinserted after urination.<sup>4</sup> The Contino is made from medical-grade polymer and has been tested for biocompatibility.<sup>4</sup>

The purpose of this report is to summarize the evidence regarding the clinical effectiveness and cost-effectiveness of male urethral inserts for the management of male urinary incontinence.

## Research Questions

1. What is the clinical effectiveness of male urethral inserts for the management of male urinary incontinence?
2. What is the cost-effectiveness of male urethral inserts for the management of male urinary incontinence?

## Methods

### Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the international HTA database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine’s MeSH (Medical Subject Headings), and keywords. The main search concept was urethral insert. No search filters were applied to limit retrieval. No language or date limits were applied.

### Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

### Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1.

### Critical Appraisal of Individual Studies

Not applicable, as no relevant studies were identified.

## Summary of Evidence

### Quantity of Research Available

A total of 40 citations were identified in the literature search. Following the screening of titles and abstracts, 35 citations were excluded and 5 potentially relevant reports from the

**Table 1: Selection Criteria**

Criteria	Description
Population	Adult males aged ≥ 18 years with urinary incontinence for any reason (e.g., post-surgery [radical prostatectomy], sphincteric incompetence, hyperactive bladder)
Intervention	Urethral insert or blocking device (e.g., brand name Contino) for male urinary incontinence
Comparator	Penile clamp; external or intermittent catheter or catheter in general No comparator (safety studies only)
Outcomes	Q1: Clinical effectiveness (e.g., quality of life, bladder leakage); safety Q2: Cost-effectiveness
Study designs	HTAs, SRs, RCTs, non-randomized studies, and economic evaluation

HTAs = health technology reviews; Q = question; RCTs = randomized controlled trials; SRs = systematic reviews.

electronic search were retrieved for full-text review. No potentially relevant publications were retrieved from the grey literature search for full-text review. Of these potentially relevant articles, 5 publications were excluded for various reasons, and no publication met the inclusion criteria and was not included in this report. Appendix 1 presents the PRISMA<sup>5</sup> flow chart of the study selection.

## Summary of Findings

As no relevant evidence on the clinical effectiveness and cost-effectiveness of urethral inserts for the management of adult male urinary incontinence was identified, a summary of evidence cannot be provided.

## Limitations

To our knowledge, there appears to be lack of relevant published evidence regarding the clinical effectiveness and cost-effectiveness of urethral inserts for the management of adult male urinary incontinence.

## Conclusions and Implications for Decision- or Policy-Making

No evidence was identified regarding the clinical effectiveness or the cost-effectiveness of male urethral inserts for the management of male urinary incontinence.

One unpublished, prospective, open-label, single arm study (NCT04165408)<sup>4</sup> was identified; this study investigated the safety and clinical efficacy of Contino for the control of urinary incontinence. Of note, as no published report of this study was available, this study was not included in the main text and a critical appraisal of the study was not conducted. The estimated study completion date was December 30, 2020.<sup>4</sup> This study included 25 male adults, with evidence of sphincteric incompetence, as assessed by the investigator.<sup>4</sup> Some results of this study were available from the 2020 Canadian Urological Association (CUA) meeting abstracts collection.<sup>6</sup> The study duration was 30 days and 15 patients completed the study. With the use of the Contino device, there was a reduction in the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) score (mean [standard deviation]) from 16.5 (3.7) at baseline to 12.2 (5.5) at the end of the study;<sup>6</sup> the higher the ICIQ-SF score, the greater the severity of urinary incontinence.<sup>7</sup> Adverse events with use of Contino were generally mild and not serious. Another prospective, open-label, single arm study (the COMFORT STUDY: NCT03605459) investigated the safety and clinical efficacy of the Comfort Plug for the control of urinary incontinence.<sup>8</sup> This study included 30 male adults with evidence of moderate to severe urinary incontinence, as assessed by the investigator; study duration was 30 days. The study was completed on April 3, 2018, but no results have been published. Considering the lack of relevant published evidence regarding the use of urethral inserts for the management of urinary incontinence in male adults, definitive conclusions are not possible.

Comparative studies involving larger patient numbers and investigating long-term effects and economic evaluations are needed to understand the clinical effectiveness and cost-

effectiveness of urethral inserts, relative to alternatives, for the control of adult male urinary incontinence.

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## Appendix 1: Selection of Included Studies

Figure 1: Selection of Included Studies

