

Effectiveness of Technologies for Management of Continence Difficulties

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Background

- **Urinary Incontinence (UI)** is defined by the involuntary leakage of urine from the bladder. The most common types of UI are stress incontinence (caused by insufficient strength of the pelvic floor) and urge incontinence (spastic contractions of the detrusor muscle).
- An **Assistive Technology Device (ATD)** is “any item, piece of equipment, or product system, whether acquired commercially, modified, or customized, that is used to increase, maintain or improve functional capabilities” (Assistive Technology Act, 2004).
- In Canada, there is currently 1.5 million inhabitants suffering with UI.
- Annually, \$17.5 billion is spent in the USA on the direct or indirect medical costs of UI.
- High prevalence in seniors (1/5), women (1/4) and patients suffering from stroke, radical prostatectomy, urethral sphincter injury, paralysis and other post-surgical conditions.
- Strong psychosocial impacts on UI sufferers including social stigmas, social barriers, physical activity barriers, embarrassment and overall decreased quality of life (QoL).

Methodology

An extensive literature search using multiple databases was conducted to find studies including all forms of ATDs for incontinence management including behavioural, pharmaceutical, surgical, and device oriented interventions.

Scope:

- Men and women with UI over the age of 65
- English references published between 1985-2011
- PubMed, Medline, Embase and Cochrane Collaboration databases were searched
- Studies were included if the research topic was the evaluation of an assistive device used for the management of incontinence.
- Exclusion took place if the study did not evaluate a continence device in adults, or if the paper was an editorial, theoretical, or opinion piece.
- Systematic reviews and randomized control trials (RCT) were preferred

Determining Study Quality

The studies were evaluated using three sets of criteria.

Criteria	Evaluation	Scoring System	
Methodological Quality	Downs and Black (1998)	Excellent (26-28) Fair (15-19)	Good (20-25) Poor (≤14)
Level of Evidence	Sackett's Levels of Evidence (2005)	RCT (I) Cohort (II) Case control (III)	Case series (IV) Expert opinion (V)
Strength of Evidence Level	Adaptation of method used in the Evidence-Based Review of Stroke Rehabilitation project (Foley, Teasell, Bhogal, & Speechley, 2003).	<ul style="list-style-type: none"> ▪ Level 1a (Very Strong): Findings supported by ≥1 study of excellent quality ▪ Level 2b (Limited): Supported by ≥1 study of good quality ▪ Level 2c (Weak): Supported by ≥1 study of fair or poor quality ▪ Level 3 (Consensus): In the absence of evidence, agreement by a group of experts on the appropriate treatment course ▪ Level 4 (Conflicting): Disagreement between findings 	

Results

- First literature search, 308 articles were retrieved. After verifying abstract relevance, 36 ATD articles were subjected to evaluations specifically adapted for the topic of UI. Currently, 14 studies are included in the manuscript, 8 of which are RCTs.
- During the UROP, a second literature search was conducted with a total of 432 articles retrieved. Out of 12 sustainable articles, 2 dealt with a new ATD for incontinence, 3 articles were systematic reviews and 7 were recent studies concerning ATDs.
- These 12 studies have not been evaluated for quality and evidence level to date. The results below are based on the original 14 studies.

Objective

How effective are current ATD intervention methods in improving incontinence issues in adults 65 or older?

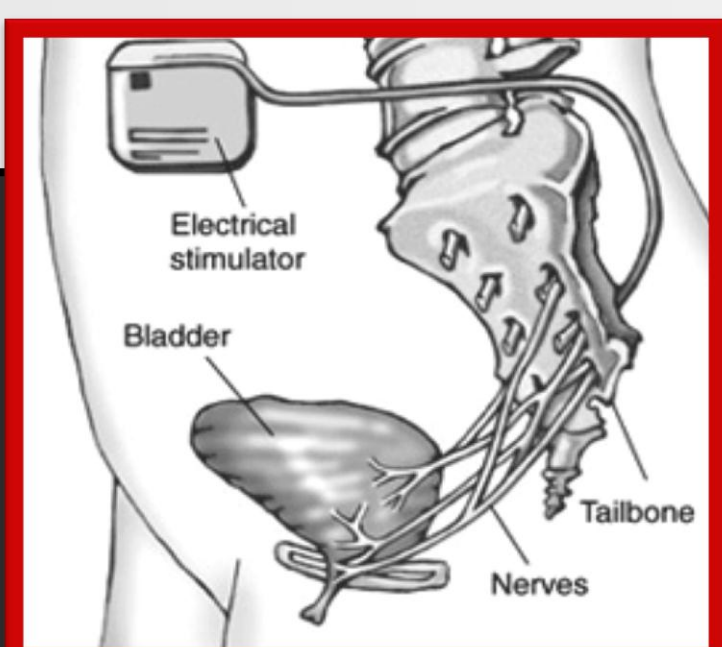
Decreasing levels of study quality and evidence →

Electrical Stimulation

Low frequency impulses cause contractions to strengthen the pelvic floor muscles

Results: Barroso et al., (2003) showed a 96.4 ml increase in maximum bladder capacity and a 2.8 ml decrease in leakage scores. Contrarily, O'Reilly et al. (2007) did not find statistically significant results in a similar experimental design.

Complications: Contradictory effectiveness, new technology, cumbersome structure, difficulty traveling, expensive.

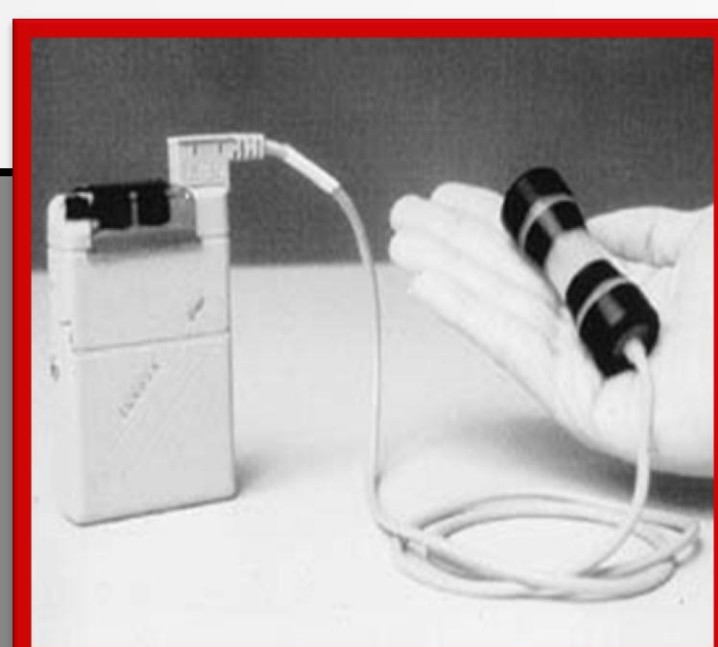


Biofeedback

Device informs the user of muscle contraction to convey a sense of awareness and promote urinary control.

Results: An effective way of improving continence when coupled with pelvic floor training. (Aukee et al., 2003). Pad weight testing decreased from 5.56 g to 3.38 g with fewer incontinence incidences (Seo et al., 2004).

Complications: Used in conjunction with other UI interventions.



Artificial Sphincter Implantation

Implantation occurs around urethra of the penis. Device filled with fluid to provide support and pressure, closing the sphincter and allowing for urinary flow control. Deflate sphincter to void bladder

Results: Average pad usage decreased from 2.27 pads to 0.36 pads per day. Pad weight testing also decreased significantly from 153.1 g to 25.9 g post-treatment (Fleshner and Herschorn, 1996).

Complications: Difficulty traveling, negative impact on QoL

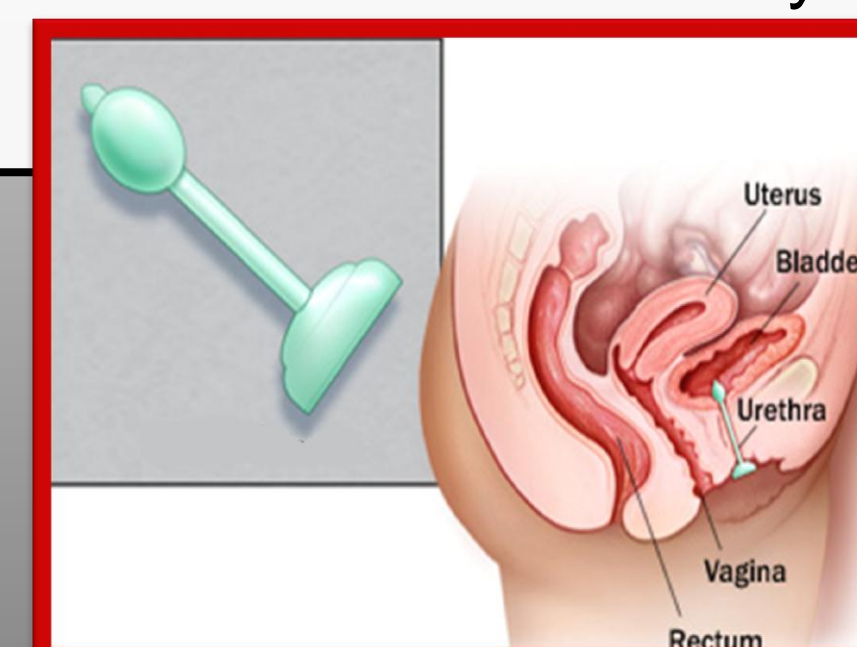


Urinary Insert

Inflated balloon tip blocks the release of urine. Remove device like a tampon for normal voiding, then replace with a new one.

Results: 80% decrease in unwanted urine loss amongst 94% of patients with 27% of patients reported being subjectively cured on incontinence. (Sand et al., 1999). Average pad weight test showed a decrease from 41.5 g to 5.3 g.

Complications: Frequent changing to prevent infection and promote efficiency, QoL questionnaires contradictory

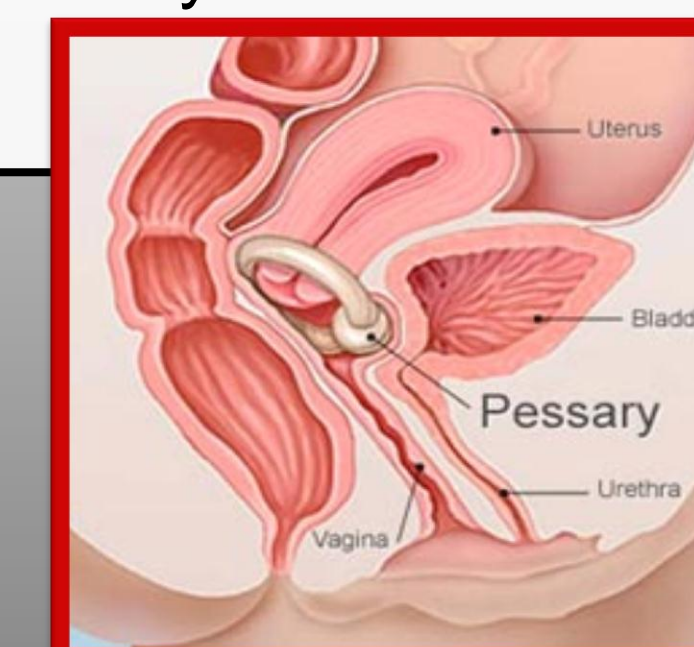


Pessary

Ring-shaped device is inserted into the vagina and compresses the urethra against the bladder wall while lifting the bladder neck.

Results: Clemons et al. (2003) showed a 92% satisfaction rate among the participants, a 45% improvement in stress, a 46% improvement in urge incontinence, and 53% experienced improvement in voiding capability.

Complications: Vaginal erosion, proper fitting necessary.



Reusable Undergarment

Absorbent layers draw moisture away from the body, promote evaporation of wetness, and disperse moisture evenly.

Results: Gallo and Staskin (1997) measured patient satisfaction using a self-report questionnaire. Rated good comfort by 83% of users, effective dryness by 52%, prevented wetness to outer clothes by 75%, good odor control by 80% of the patients.

Complications: None

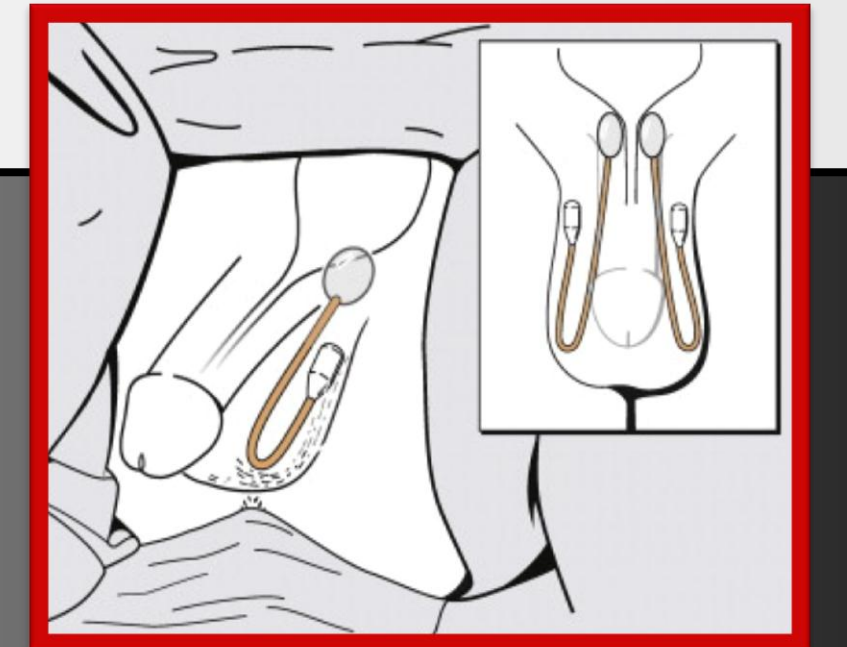


Adjustable Continence Therapy

Device is bilaterally implanted to provide support to the urethrovesical junction and urethra. Two balloons are inflated with isotonic solution to provide support to the urinary structures.

Results: Over 80% of women experienced a decrease in pad weight of more than 50% (Aboseif et al., 2009). Quality of life scores in all QoL domains improved in over 80% of patients after implantation.

Complications: Erosion of tissue, balloon migration and urinary retention



Discussion

- The articles found were mostly of weak or moderate quality according to Sackett's levels of evidence.
- Only articles about electrical stimulation belonged to the strong evidence level group.
- More recent articles found during the UROP experience validate adjustable continence therapy and artificial sphincter implantation as an effective device for incontinence management. The studies are RCTs and may improve the quality of evidence.
- Articles relating to the most commonly used UI devices such as reusable undergarments showed low study quality and low study numbers.
- This result demonstrates that the current quality of research on the subject of incontinence ATDs is not at an adequate level.
- As populations begins to age, there will be a greater demand for these types of ATDs for incontinence management. Subsequently, the research to support these UI interventions will be crucial.

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- Manuscript to be submitted for publication. Special thanks to Dr. Jeffrey Jutai and his team at Bruyère Continuing Care for their invaluable help and mentorship.
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