

The subjective and objective benefits of a remote-controlled intraurethral device for managing the female acontractile bladder

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OBJECTIVE

To determine the subjective and objective benefits of the Inflow™ (SRS Medical Systems, N. Billerica, MA, USA) intraurethral device for managing acontractile bladders in women.

PATIENTS AND METHODS

Twenty women with acontractile bladders who had been managed unsuccessfully by the usual methods were recruited. All patients were asked to complete a quality-of-life (QoL) questionnaire and were assessed with urine flowmetry and urine culture; to measure the

postvoid residual urine (PVR) in the bladder, ultrasonography was used after activating the device.

RESULTS

There was a decrease in the QoL score from a mean of 59.6 before insertion to means of 11.2, 8.8, 6.3 and 5.0 at 1, 3, 6 and 12 months afterward. The mean (range) urinary flow rate was 10.7 (9–16) mL/s and the PVR 3 (0–17) mL. Three patients had temporary asymptomatic bacteriuria and two a single infection after the device was inserted that settled readily with antibiotics.

CONCLUSION

This study shows that the Inflow device provides an effective method of bladder drainage, with few side-effects and a significant improvement in QoL.

KEYWORDS

acontractile bladder, intraurethral device, flow rate

INTRODUCTION

Managing the acontractile bladder invariably requires mechanical emptying as no medication or operation can re-establish detrusor contraction. A few patients will regain adequate detrusor contraction for bladder emptying, although the exact nature of this phenomenon is unknown. The standard methods of managing the condition include inserting a permanent indwelling urethral catheter, or a suprapubic catheter, or the patient may learn the technique of intermittent self-catheterization (ISC). Whilst none of these methods could be regarded as major procedures, nevertheless patient acceptance of these management options is often poor. Indwelling catheters have the ongoing risk of infection and over time many women develop a patulous urethra, which becomes a major management issue. It has therefore become the norm for most women with an acontractile bladder to have a permanent suprapubic catheter inserted, or use ISC. As many of these women have other comorbidities the suprapubic technique is often the only available option.

In 1994 a remote-controlled intraurethral device (the Inflow™, (SRS Medical Systems, N. Billerica, MA, USA) was developed for bladder drainage, with none of the disadvantages of the previous methods. The device consists of a short silicone catheter sheath of differing lengths to allow for variance in the length of the urethra. Six silicone fins maintain its position at the bladder neck. An outer flange is positioned flush with the urethral meatus, and allows finer positioning for comfort after insertion, as well as providing orientation for the fitted Inflow device. There is an inner valve pump consisting of a neodymium-iron-boron magnet shaped like a turbine (Fig. 1a,b). When exposed to a magnetic field the inner turbine spins and the catheter valve opens, drawing urine from the bladder and therefore emptying it. When the magnetic field is removed or reversed the valve closes and the turbine stops spinning, maintaining continence. An activator powered by two 3 V lithium batteries generates the magnetic field (Fig. 1c).

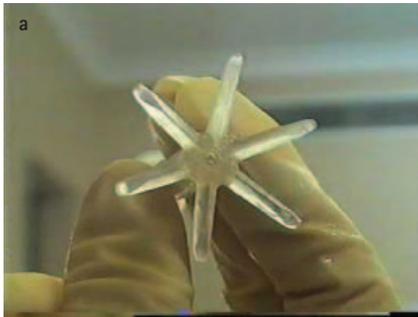
The aim of the present study was to examine any potential benefits, subjective and objective, that this device may offer women

with an acontractile bladder. Specific objectives were to show effective and complete bladder drainage and to evaluate any effect that the device has on the quality of life of the patients in the study. A secondary objective was to determine the incidence of bacteriuria and whether this was symptomatic or not.

PATIENTS AND METHODS

Twenty women were recruited for this study (mean age 64.5 years, range 37–87). The causes of their condition varied and included two patients who developed acontractile bladders after surgery for spinal tumours, two who had recently undergone gynaecological procedures, seven who had 'idiopathic' hypocontractility with large-capacity bladders and chronic retention leading to recurrent UTIs, and the remaining nine had a neurological condition (cerebrovascular accident, congenital mental impairment). All patients had no evidence of effective detrusor contraction during urodynamic assessment.

FIG. 1. The Inflow device, showing the inner valve pump (a,b) and the activator powered by two 3-V lithium batteries (c).



their particular method of bladder drainage, and were thus enrolled in this study.

The Inflow device was inserted in the standard fashion as previously described [1]. Patients received detailed instruction in the use of the device and were provided with a 24-h help-line for support in becoming familiar with the use of the Inflow system. The first Inflow catheter was changed at 4 weeks, with subsequent periods of exchange extended in 2–4 week increments according to patient comfort and the appearance of the device at the time of exchange.

Patients were asked to complete the 34-point validated Wagner quality-of-life (QoL) questionnaire [2] (Appendix 1) with reference to their original bladder drainage method, and then at 1, 3, 6 and 12 months after inserting the Inflow. Urinary flow rates were measured after the first exchange catheter was inserted to allow the patients to learn the technique of operating the Inflow catheter. The postvoid urinary residual (PVR) was measured by transabdominal ultrasonography, and urine samples cultured at each catheter exchange. Any symptoms suggesting UTI were reported and samples subsequently cultured.

RESULTS

The QoL scores (Table 1) showed a significant improvement after insertion. The mean (range) flow rate was 10.7 (9–16) mL/s and the PVR 3 (0–17) mL. Two patients had a single UTI after the initial insertion of the Inflow; these responded to standard antibiotic therapy and did not recur. Three patients had asymptomatic bacteriuria on one occasion at the time of catheter exchange. The patient who had had recurrent UTIs before inserting the Inflow interestingly had no further infections after establishing adequate bladder drainage. One patient only had recurrent UTIs from the time she was placed on parenteral nutrition to treatment an unrelated condition. One patient died from an unrelated condition; the device was working well to her satisfaction at the time.

Seven patients discontinued the treatment; one (as described) died from unrelated causes, three eventually re-established normal bladder function, one had recurrent catheter obstruction from a blood clot (she had severe radiation cystitis after radiotherapy for a

gynaecological malignancy), one developed a high-pressure bladder that eventually required augmentation cystoplasty and one could not tolerate the catheter and withdrew, although she had used the device successfully for 4 months with no apparent problems.

On a few occasions the Inflow catheters were exchanged earlier than planned, invariably in patients who were having their exchange time extended. Two reasons were accidental expulsion or intraluminal leakage because of the formation of sediment within the catheter.

DISCUSSION

The management of women with chronically and poorly emptying bladders is often very unsatisfactory. Ideally, all patients would be managed with ISC, which is safe and effective for bladder drainage [3]. However, many patients are elderly and incapable of mastering the technique; body habitus, arthritis, poor eyesight, neurological conditions and Parkinson's disease can all make it impossible for the patient to use ISC. It is impractical in most cases for carers to perform ISC for the patient. Many women also find the idea of ISC repugnant and refuse to learn the technique. The mentally impaired patient also finds it difficult to use and so it is not an option in their management.

Long-term indwelling urethral catheterization is not a well regarded solution, as bacteriuria is soon established [4] and most patients eventually develop symptomatic infections. There is also the added risk of developing a patulous urethra in those patients who remain catheterized for a considerable time. This condition, once developed, requires a major surgical intervention to remedy.

The remaining alternative of permanent suprapubic catheterization is often not acceptable to the body image of the patient and frequently requires some attention to the suprapubic penetration site. It is this group of patients who find the standard alternatives unsatisfactory, for whatever reason, who potentially stand to benefit from the Inflow intraurethral device.

There have been an attempts to establish similar devices in the past; such devices have not been readily available in Australia and there is little information available on their use. One such device, the Autocath 100 (HK

TABLE 1 The QoL scores during the follow-up

Follow-up, months	Mean (range)
Baseline	59.6 (35–91)
1	11.2 (1–29)
3	8.8 (0–29)
6	6.3 (4–10)
12	5.0 (1–9)

All patients had used the standard bladder drainage techniques; most had tried more than one of the alternatives. At the time of enrolment the techniques used were ISC in five, indwelling urethral catheter in eight and suprapubic catheterization in seven. All patients had expressed dissatisfaction with

Medical Technologies, San Antonio, USA), was similar to the Inflow device in configuration. The main difference was that there was no mechanism for assisted drainage of the bladder. The valve system in that device was released by abdominal pressure which was a disadvantage, and incomplete emptying was a common problem. There were two main concerns about this device. First, it required some residual detrusor contractile ability to function (often a paradox in appropriate patients). Second, it was made of metal and thus quite heavy, and it was felt that it would contribute to the incidence of patulous urethra and urgency. The Autocath 100 is no longer available.

The present small study shows that patients felt they had a significant improvement in their QoL when using the Inflow to effect their bladder drainage. If provided with appropriate support while the catheter was established even the mentally impaired can achieve effective and adequate bladder emptying. The side-effect profile is low and the risk of infection seems minimal.

No patient has yet developed a patulous urethra; interestingly, in two patients who had begun to develop a patulous urethra from long-term urethral catheterization the condition seemed to resolve after 2 months of using the Inflow. There is no ready explanation of this, although it is possible that the main stimulus for the formation of the patulous urethra is the relatively constant pressure from the balloon. The Inflow catheter is held in place via six silicone fins that are only a few millimetres wide, and therefore exert no pressure on the internal urethra.

This study also highlighted the range of patients who could be treated with this device. Whilst the original recommendations for selecting patients were that they should be self-motivated, mentally and physically agile with bladder capacities of > 150 mL, the present patients included the elderly, the confused, and the mentally and physically impaired. Some patients also had UTIs and some bladder capacities were < 150 mL. With hindsight, the patient who developed a high-pressure bladder was undoubtedly poorly selected. It would seem prudent that patients with such bladders be adequately controlled with anticholinergic medication before inserting the device, to improve the chances of successful implantation. Urge incontinence

must be regarded as a relative contraindication. There seem to be no real contraindications for the use of this device in patients with acontractile bladders.

Several issues still need to be adequately addressed. Whilst it is impossible to assess the cost in different parts of the world, the cost of the Inflow will invariably be significantly higher than the cost of Silastic catheters used in the other techniques. For instance, in Australia the estimated annual cost of the device, including consultation and nursing time, is ≈AU\$ 1800 and similar to the cost of insertion and maintenance of a suprapubic catheter for 1 year (assuming the patient is admitted as a day-case for insertion under anaesthetic). This can be compared to ≈AU\$ 1000 for a patient with an indwelling catheter and AU\$ 600 for a patient using ISC. Whilst the Inflow device potentially offers a lower side-effect profile than either a permanent indwelling urethral or suprapubic catheterization, and therefore the 'real' cost to the patient may be much less, no information is yet available on these aspects. A cost-effectiveness study should be conducted. ISC has a low cost and low side-effect profile, and must still be considered the ideal solution for bladder emptying in these terms. The ideal selection criteria have yet to be determined.

In conclusion, the Inflow device offers effective bladder emptying at low risk for those patients who find ISC or its alternatives unsatisfactory. Currently it cannot be regarded as a treatment alternative for either stress or urge incontinence, but warrants further investigation and can reasonably be considered an alternative therapy for managing the acontractile bladder.

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Abbreviations: ISC, intermittent self-catheterization; PVR, postvoid residual; QoL, quality of life.

APPENDIX 1

The QoL questionnaire: all questions are answered with a tick box for the appropriate response, i.e. 0, Very much; 1, Moderately; 2, A little; 3, Not at all.

1. I am satisfied with the overall comfort provided by my current type of catheter
2. I am satisfied with the dryness provided by my current type of catheter during the day
3. I am satisfied with the dryness provided by my current type of catheter during the night
4. I am satisfied with the amount of time it takes me to completely empty my bladder with my current type of catheter
5. I am satisfied with the comfort during sexual intercourse provided by my current type of catheter
6. I am satisfied with the ease of use of my current type of catheter
7. I am satisfied with the urinary flow rate of my current type of catheter
8. I am satisfied with the way my current type of catheter allows me to be in control of my urine drainage
9. I am satisfied with the way my current type of catheter allows me to drain my bladder in public restrooms
10. I am satisfied with the way my current type of catheter lets me go about my normal daily and social activities
11. All in all, I am satisfied with my current type of catheter
12. All in all, I am satisfied with my quality of life using my current type of catheter

- 13. I worry about wetting myself
- 14. I worry about coughing or sneezing because of my urinary condition
- 15. I have to be careful standing up after sitting down because of my urinary condition
- 16. I worry about where toilets are in new places
- 17. I feel depressed because of my urinary condition
- 18. Because of my urinary condition, I don't feel free to leave my home for long periods.
- 19. I feel frustrated because my urinary condition prevents me from doing what I want
- 20. I worry about others smelling urine on me
- 21. My urinary condition is always on my mind
- 22. It's important for me to make frequent trips to the toilet
- 23. Because of my urinary condition it's important to plan every detail in advance
- 24. I worry about my urinary condition getting worse as I grow older
- 25. I have a hard time getting a good night's sleep because of my urinary condition
- 26. I worry about being embarrassed or humiliated because of my urinary condition
- 27. My urinary condition makes me feel like I'm not a healthy person
- 28. My urinary condition makes me feel helpless
- 29. I worry about not being able to get to the toilet in time
- 30. I get less enjoyment out of life because of my urinary condition
- 31. I feel like I have no control over my bladder
- 32. I have to watch what I drink because of my urinary condition
- 33. My urinary condition limits my choice in clothing
- 34. I worry about having sex because of my urinary condition