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New device for intermittent emptying of the bladder in female children and adolescents: A pilot study

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Summary

Introduction
Urinary incontinence (UI) is a challenging problem for the urological community. Clean intermittent catheterization (CIC) is the most commonly used method to restore bladder emptying to the state close to the physiological condition. This procedure can cause negative aspects such as pain and possible urethral injury. In addition, there is a negative impact on self-image and decline in quality of patient's life. The aim of the present study was to evaluate the safety and efficacy of a new intraurethral self-retaining device (ISRD), in female children and adolescents, as an attractive alternative to CIC.

Materials and methods
A prospective clinical pilot study was performed, in a single-institution, including female children and adolescent patients with urinary incontinence secondary to myelomeningocele who were already in an intermittent bladder catheterization program. Assessments included the use of a visual analogue scale in diagnosis of UI, reported adverse events, and the King's Health Questionnaire (KHQ) to evaluate quality of life, which was answered by patients and the caregivers of younger patients before and 6 months after enrolment.

Discussion
The device was efficient and well tolerated by most patients (84%). The ISRD significantly improved quality of life in children and adolescents ($p < 0.0001$ for both) (Table). The safe insertion and removal of the ISRD can be considered an advantage compared with CIC as eventual urethral trauma is significantly minimized. It was found that one of the main advantages of the ISRD is the possibility of management as an outpatient procedure both for initial insertion and replacement. The autonomy of patients to perform the bladder emptying process by themselves indicates the importance of this study, especially for school life and social interaction. ISRD use showed a tendency to improve the QoL.

Conclusions
This new bladder-draining device (ISRD) was effective and secure in terms of insertion technique, and improved QoL of patients with urinary retention and incontinence, according to domains evaluated in the KHQ.

Table Results summary

Clinical symptoms	Clinical indexes (%)				Quality of life (KHQ score)				KHQ domains
	Children ($n = 13$)		Adolescents ($n = 12$)		Children ($n = 13$)		Adolescents ($n = 12$)		
	Before	After	Before	After	Before	After	Before	After	
Frequency	43.3	10.0	43.3	3.3	70.0	12.5	77.5	15.0	General health perception
Nocturia	50.0	13.3	66.7	10.0	90.0	36.7	93.3	36.7	Incontinence impact
Urgency	33.3	6.7	56.7	3.3	93.3	26.7	100.0	20.0	Role limitations
Incontinence during sexual intercourse[a]	_	_	58.3	4.2	100.0	10.0	100.0	20.0	Physical and social limitations
Recurrent urinary tract infections	66.7	16.7	66.7	6.7	90.0	56.7	73.3	33.3	Personal relationship
_	_	_	_	_	66.7	10.0	100.0	53.3	Emotions
_	_	_	_	_	100.0	43.3	100.0	36.7	Sleep/energy
_	_	_	_	_	_	_	100.0	33.3	Severity measures

[a] This applied to only two cases ($N = 5$).

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Introduction

Urinary incontinence (UI) is caused by an imbalance between anatomical structures and their functions [1—5]. The lack of coordination between the bladder and sphincter promotes urinary disorders, such as urinary retention, which in turn cause residual urine accumulation, leading to recurrent infections and deterioration of the upper urinary tract.

According to the International Continence Society guidelines, the prevalence of UI in the female population varies (5—69%) according to age, education level, and disease severity [6,7].

UI is a persistent challenge for the urological community, especially in cases where the use of surgically implantable devices is contraindicated because of the presence of severe comorbidities such as diabetes mellitus, neurological injury, cerebral palsy, and increasing age [1,8—10]. Clean intermittent catheterization (CIC) is the most commonly used method to restore physiological function, and is also considered a satisfactory drainage method for the urinary reservoir, especially in neurogenic patients [11,12]. However, adherence to the CIC program by patients and their caregivers is influenced by negative aspects such as pain during the procedure and possible urethral injury. The high cost of materials may also influence quality of life (QoL) [13—16].

The aim of the present study was to evaluate the safety and efficacy of a new intraurethral self-retaining device (ISRD), in female children and adolescents, as an attractive alternative to CIC.

Material and methods

Design

A prospective clinical pilot study was performed, in a single-institution, including female child and adolescent patients with UI secondary to myelomeningocele who were already in an intermittent bladder catheterization program. Patients were selected from a convenience sample.

The institutional review board approved the study protocol (number: 728.793) and all patients provided written informed consent.

Population

Twenty-five female patients were recruited between July and October 2014 and followed up for 6 months. The present study enrolled volunteers who met the inclusion criteria: female children (age range: below 12 years old) or adolescents (age range: 12—18 years old), who suffered from neurogenic bladder secondary to myelomeningocele (MMC) and that were already included in an intermittent bladder catheterization program (CIC).

Exclusion criteria included patients with history of critical urethral trauma or genital anomalies which create any obstacle that could make the procedure unviable. Patients o antibiotic prophylaxis and/or using anticholinergics were kept on the same regimen.

Materials

The ISRD was made of medical grade silicone and is available from 10 to 20Fr in diameter with four different sizes, 3, 3.5, 4, and 4.5 cm, of distance between disks. The structure of the new device was formed by two disks (one proximal or fixed and the other mobile or distal), six collectors of urine, and a cover connected to the lumen of the catheter. The fixed disk was positioned at the bladder neck from the inside. The mobile disk was positioned at the level of the external urethral meatus (Fig. 1A). The device had a specific pusher to provide adequate resistance at the moment of introduction (Fig. 1B).

The ISRD was manufactured by Medicone Innovation for Health Ltd. (Cachoeirinha, RS, Brazil).

The idea for this new device was inspired by similar catheters that use sliding disks to adjust or fix tubes used to drain the bladder or stomach [14—17].

Intervention

The technical procedures were initiated from the antisepsis of the perineal region and subsequent introduction of the device through the external urethral meatus. Consequently, patients underwent local anesthesia with lidocaine gel 20 mg/mL applied intraurethrally. There were five specific child cases who received light sedation.

The urethra was dilated up to 26 Fr when necessary to facilitate introduction of the proximal disk that was positioned in the inner portion of the bladder neck. The mobile disk was adjusted to the external meatus by sliding it along the ISRD.

After initial training, patients or caregivers were advised to empty the bladder at regular intervals according to bladder capacity. No systematic antibiotic prophylaxis was administered.

Measures

Assessments included visual analog scale for diagnosis of UI, quality of life analysis, and reported adverse events. For diagnosis of UI, patients were asked, as part of their clinical assessment, to indicate the severity of urinary symptoms by marking a 10 cm analogue scale. The mark was scored from 0 to 10 (0 for no incontinence and 10 for total incontinence) [18].

All patients had already undergone a complete urological evaluation that included ultrasonography, urodynamics, and cystography. Data collected from previous treatments included tolerance of the device (unless an ISRD had been inserted and remained), urine sterility, time since treatment, and total number of devices used. No patient had previously used other types of indwelling catheter.

Side effects and any adverse events encountered at home or noted by the physician were also reported. The daily number of used diapers was also counted.

The complications were defined through CTCAE (Common Terminology Criteria for Adverse Events) considering the system organ class (SOC) accompanied by descriptions of adverse events [19]. In case of adverse events associated with the ISRD (technical difficulties, discomfort, pain,

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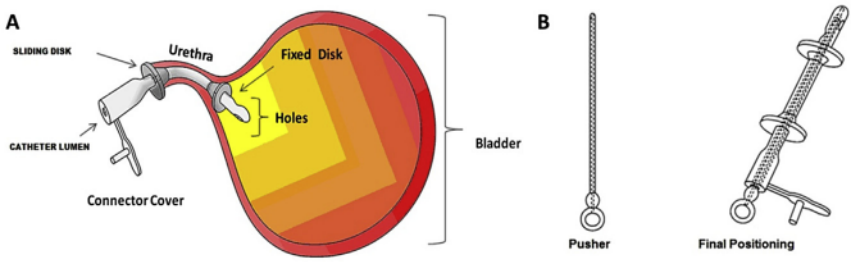

Figure 1 Technical drawing containing the probe inserted into the urethra and bladder. (A) Panoramic view of the device in situ. (B) Technical drawing of the device pusher and its positioning inside catheter.

urinary leakage, anatomical anomalies, and infection signs), the treatment was re-evaluated.

The QoL was evaluated using the King's Health Questionnaire (KHQ) [20], and was performed in two stages: before and 6 months after implantation of the ISRD. The questionnaire was answered by the adolescent patients and by the caregivers of younger patients. Caregivers (with close relationship with the child) were chosen to answer the questionnaire on behalf younger patients for ease of communication and higher response accuracy.

The QoL questionnaire consists of 21 items in eight domains (1: General health perception; 2: Incontinence impact; 3: Role limitations; 4: Physical and social limitations; 5: Personal relationship; 6: Emotions; 7: Sleep/Energy; 8: Severity measures) and one sub-domain in independent scales (presence and intensity of urinary symptoms). Item responses are based on Likert scales with scores standardized to a scale of 0—100 points, of which lower scores correspond to better health states [20]. Each domain has been independently validated.

The parameters (clinical UI and QoL) were evaluated before and after implantation of the ISRD.

Outcomes

The primary end-point was to evaluate the safety and efficacy of the device for UI. QoL was the second point addressed in the study, as well as daily number of diapers used per day. The complications (adverse events) were monitored to review study performance (data validity and integrity).

Statistical analysis

Data were evaluated by analysis of variance (ANOVA) or, alternatively, by the Kruskal—Wallis test whenever the data did not fit a normal distribution. Differences were tested by two-tailed Student's *t*-test or Mann—Whitney *U* test. Proportions were evaluated by the chi-square test or, alternatively, by the Fisher exact test. Statistical analysis was performed using the GraphPad Prism 5.0 program (GraphPad Software Inc., USA), and a difference was considered to be statistically significant at $p < 0.05$.

Results

The patients' ages ranged from 5 to 18 years (mean 11.2; median 12). They were categorized into two groups: children (below 12 years old; $n = 13$) and adolescents (12—18 years old; $n = 12$). All patients had neurogenic bladder secondary to myelomeningocele and were already participating in the CIC program.

At the initial clinical evaluation, most patients described their incontinence as a 4 on the analog scale. There was a drop in the number of diapers, to a mean of two per day, when compared with the use of eight a day before entering the ISRD program. All patients continued to use pads for ongoing fecal incontinence.

Clinical symptoms (nocturia, urgency, and incontinence) were significant before ISRD use, but were reduced after entering the program (Fig. 2). Symptomatic urinary tract infection was also decreased (50%) after ISRD use.

The device was well tolerated by 21 patients (84%), who retained the device without any reports of complication after 6 months of use. Adverse events were observed in four patients (16%) using the ISRD (Fig. 3). The first patient presented with febrile UTI and pain at the site of implantation of the device. Another presented a case of catheter obstruction after an interval of 1 month secondary to calcification. The third patient reported difficulties with manipulating (opening and closing) the ISRD. And the last case presented vulvar irritation near the mobile disk. Side effects and adverse events such as urethral erosion, bleeding, or infection signals were not encountered.

QoL analysis was based on the perception of how much the bladder malfunction had affected the patient's life. Results showed that the ISRD significantly reduced the intensity of the impact in both children and adolescents ($p < 0.0001$), (Fig. 4).

Data analysis concerning the questionnaire's domain means showed an improvement for the analyzed parameters before and after use of the device (1: General health perception; 2: Incontinence impact; 3: Role limitations; 4: Physical and social limitations; 5: Personal relationship; 6: Emotions; 7: Sleep/Energy; 8: Severity measures), with statistical significance for adolescents ($p = 0.0233$) (Fig. 5).

Discussion

Chronic urinary retention requires the bladder to be emptied several times per day to prevent urinary tract infection and impairment of renal function [4,6]. CIC has been used for this purpose; however, this has adverse effects such as discomfort, difficult handling, and worsening of self-esteem [12—14].

The safe insertion and removal of the ISRD can be considered as an advantage when compared with CIC as

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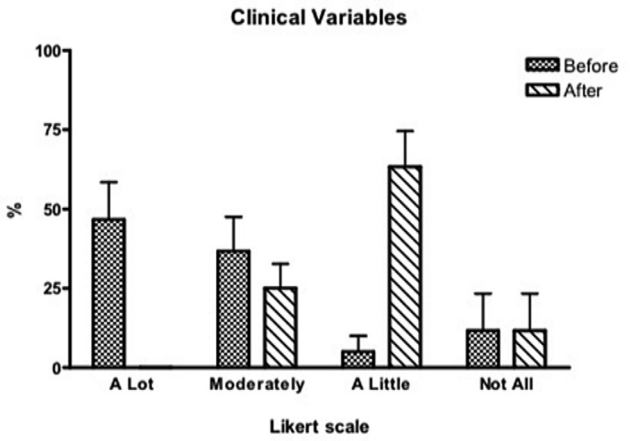

Figure 2 Clinical variables before and after introduction of the ISRD. Values are percentage answers of the scores by Likert scale. *p*-value by chi-square test <0.0001, for children and adolescents.

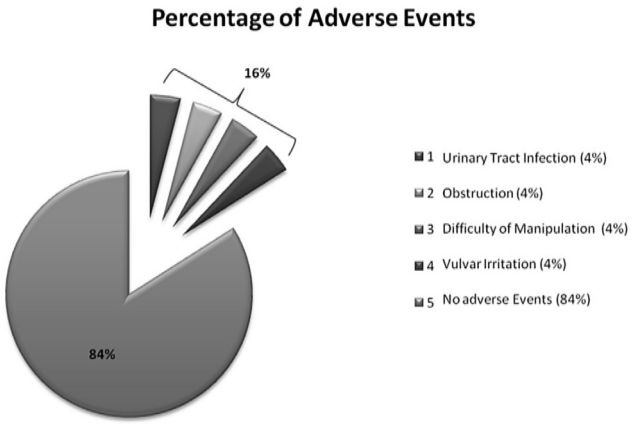

Figure 3 Pie chart depicting the percentage of adverse events related in the total sample.

eventual urethral trauma is minimized significantly. Incontinent patients, because of reduced or absent urethral resistance, also seem to benefit from the use of the new device by improving their ability to store urine and empty the bladder as desired. This is an important argument for reduction in symptomatic UTI as patients are not always able to empty the bladder because of conditions such as a suitable place to perform the emptying or problems related to the material and local antisepsis.

The observations made in this pilot study showed that 6 months was an adequate time interval to exchange the device when in routine clinical use. As the device is manufactured of medical grade silicone, the same as that used in implants and catheters, the safe use of this material is assured. Similar devices previously proposed required monthly removal and involved complex and expensive technology [13,14]. To our knowledge there is no similar technology that has been proposed for use in children [21,22].

In the observation period of this study, it was found that one of the main advantages of the ISRD is the possibility of management as an outpatient procedure both for initial insertion and replacement. The autonomy of patients to perform the bladder emptying process by themselves indicates the importance of this study, especially for school life and social interaction. Previous studies have shown an ambiguous response of CIC in QoL. In contrast to the results obtained with the KHQ, in the present study, ISRD use showed a tendency to improve the QoL [23,24].

The adverse events found in the present study are similar to previous ones, which are related to a different population groups and, as such, deserve limited attention [14].

Our study has some limitations that are related to the small size of the patient group and the limited period of observation. However, even given such limitations, our study challenges the limitations of previous work by attempting to resolve the problem with simplicity. Similar studies, to our knowledge, are few. The sensation of being able to empty the bladder by just going to the toilet without the need of help from someone or something is one of the main findings for QoL during the present study. Devices previously proposed with the same objective lacked

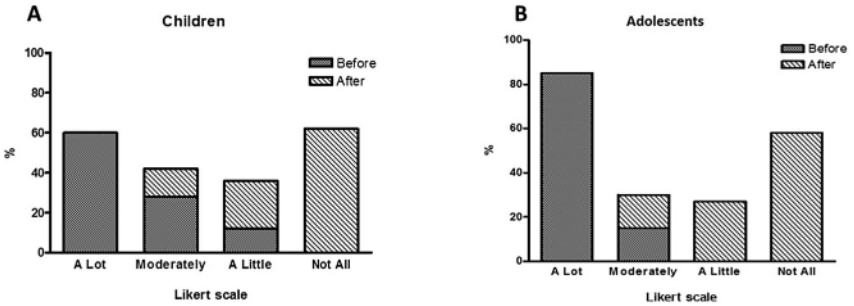

Figure 4 Perception of how the urological problem affected quality of life. Values are percentage answers of the scores standardized to a scale of 0—100 points. (A) Children. (B) Adolescents. *p*-value by chi-square test <0.0001, for children and adolescents.

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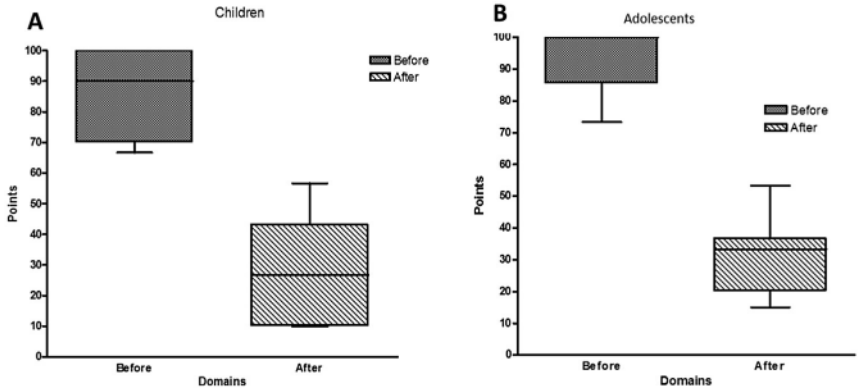

Figure 5 Analysis of the areas of King's Health Questionnaire (KHQ). Values are mean of the scores standardized to a scale of 0—100 points. (A) Children. (B) Adolescents. *p*-value by chi-square test <0.0001, for children and adolescents.

practicality and involved complex technology, although having been proposed more than 10 years ago, these seem to have been abandoned [15,25].

Conclusions

The new bladder-draining device (ISRD) was safe and effective in terms of its insertion and improved the QoL of patients with urinary retention and incontinence, according to domains evaluated in the KHQ. However, additional studies with a larger number of patients and with longer follow-up to test the permanent effectiveness of the device are needed.

Conflict of interest

None.

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