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A New Device for Intermittent Emptying of the Bladder in Children and Adults: A Long-Term Follow-Up

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Abstract

Contextualization: Emptying the bladder is a challenging problem for the urological community. Intermittent catheterization is the most widely used method to restore bladder emptying mechanism. However, this procedure can have a negative impact on self-image and result in a decline in the quality of life of patients. In this context, the use of a bladder emptying device (SVCATH3D) proposes to be effective and have a positive impact on the quality of life of different patients. **Objective:** The objective of the study was to evaluate the functionality of a new device for both intermittent and controlled emptying of the bladder in both sexes and ages. **Materials and methods:** A randomized clinical trial was conducted with 251 patients, with different bladder problems, from March 2013 to January 2023. After randomization, the patients were divided into two groups: Group I (SVCATH3D) and Group II (Clean Intermittent Catheterization). The primary outcome was defined as the impact on quality of life. Data on episodes of urinary tract infection, adverse effects, number of diaper use and treatment costs were analyzed. **Results:** The apposition of the SVCATH3D was performed on an outpatient basis, with no complications during the procedures. The patients were followed up for 10 years. There was a significant improvement in quality of life when comparing the moments before and after the use of SVCATH3D ($p < 0.001$), as well as there was a significant reduction in the number of episodes of urinary tract infection ($p < 0.001$), absent serious adverse effects and a reduction in the number of diapers or daily protectors. **Conclusion:** The study using SVCATH3D showed promising results in relation to functionality, showing improvement in quality of life with a reduction in episodes of urinary in-

fection and amount of diapers/day. This allows us to conclude that SVCATH3D can represent an important step in the treatment of patients suffering from various bladder problems both incontinence and affecting emptying mechanism.

Keywords

Clean Intermittent Catheterization, Neurogenic Bladder, New Device, Quality of Life

1. Introduction

Previous studies [1] about this new bladder-emptying device have been presented in different places and periods, showing the continued evolution of the results (**Figure 1**).

Neurogenic bladder is characterized by lower urinary tract dysfunction due to neurological impairment [2]. One of the available treatment options is clean intermittent catheterization (CIC), which aims to maintain bladder function as similar as possible to the physiological state in relation to filling and emptying phases [3] [4]. CIC is done at regular intervals that vary according to age, bladder capacity, residual urine volume, and time free from involuntary urine leakage as well as finding a suitable place to perform it. The purpose is to restrain postvoid residual volume by mimicking normal voiding. These measures result in the reduction of risk of urinary tract infection (UTI) [5] [6]. However, to be effective, CIC requires regularity, therefore impacting on daily life activities and generating fixed costs to patients and caregivers [7] [8]. Adherence rate is influenced by negative aspects such as the need of preserved cognition, the presence of pain, and the possibility of urethral injury. For this reason, CIC could impact daily life activities in some patients [9] [10]. To solve these problems, the present study aimed to evaluate the performance of a new intraurethral self-retaining device (SVCATH3D) in both male and female patients with neurogenic bladder or other emptying-impairing diseases, as a possible alternative to CIC. New data shows how well-adjusted the patients were after a long-term follow-up of 10 years.

2. Materials and Methods

2.1. Design and Sample Selection

A prospective, single institution with the same team of researchers, randomized clinical study was performed, including female and male subjects aged from 5 to 30 years, with neurogenic bladder diagnosis and currently in use of CIC. From March 2013 to January 2023, all patients admitted to our urologic outpatient clinic who met inclusion criteria were enrolled. Exclusion criteria included symptomatic UTI and history of urothelial tumors. Subjects were randomized to two groups, either to use the SVCATH3D (experimental group [GI]) or to continue

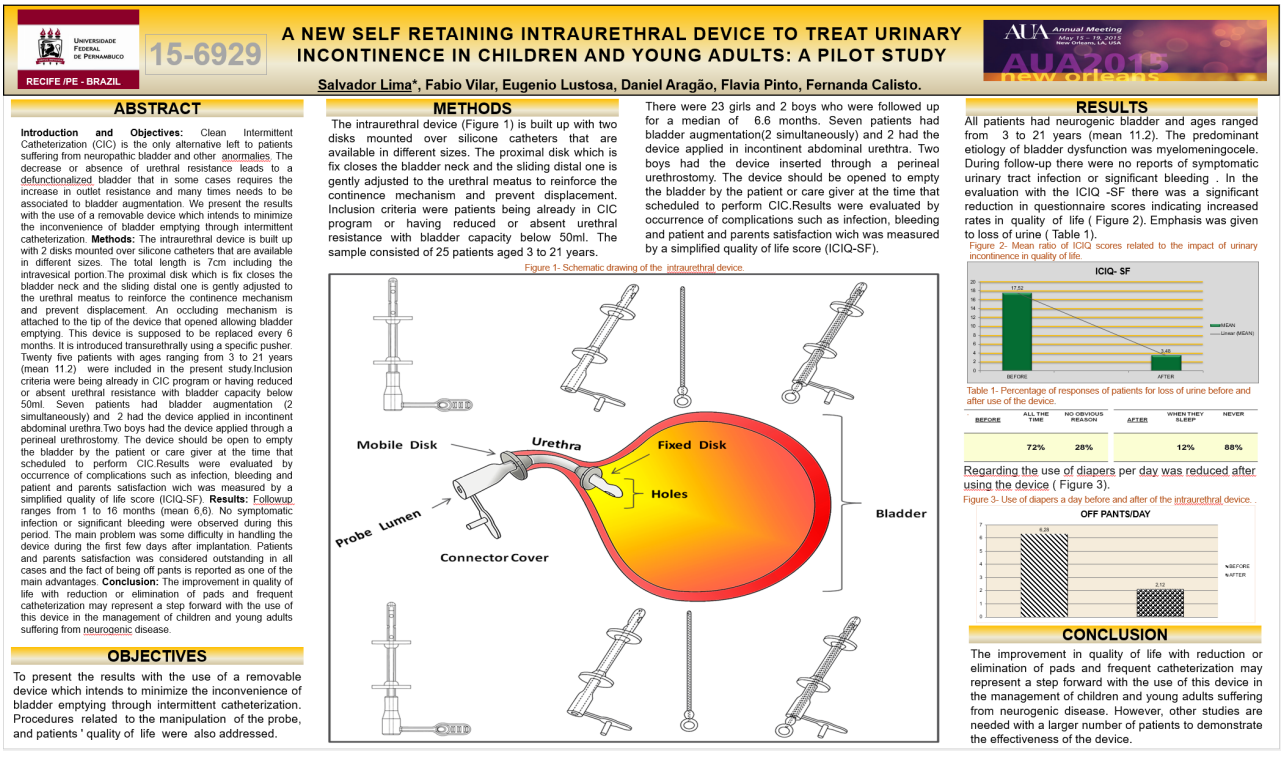


Figure 1. The continued evolution of this new bladder-emptying device has been shown in different places and periods [1].

using CIC (control group [GII]). The participants were separated into the groups using a list of random numbers that had been generated using Random Allocation Software, version 1.0. The list was drawn up by a member of the team who was not involved in collecting the data. One researcher determined the group to which the participants would be allocated by consulting the randomization list. The analysis was conducted by protocol and baseline and posttreatment assessments were compared between (SVCATH3D vs CIC) and within groups (pre-post analysis) according to the trial profile. The institutional review board approved the study protocol (number: 728.793) and all patients provided written informed consent. The sample size followed determinations of National

Agency of Sanitary Surveillance (ANVISA) directed to the type of clinical research phase II: "First controlled studies in patients to demonstrate the potential effectiveness of the medical device (100 to 200 volunteers)." In addition to ANVISA determination, the sample size formula was used to describe the population represented by a quantitative variable, comparing two groups. To satisfy all dimensions, the minimum sample estimated was 94 patients (47 individuals per group). In both groups, all patients had been using oral anticholinergics and this regimen was maintained all the period. None has submitted to botulinum toxin application or another way to control detrusor overactivity.

2.2. Materials

The SVCATH3D was made with medical grade silicone and is available from 13 to 23 Fr in diameter with two different sizes (7 cm, used for children, and 8 cm for adults). Details on manufactured, structure and insertion have been published in previous pilot study [11]. The device structure was formed by three disks (1 proximal, fixed and 2 others mobile, used to accommodate the device to the patient's urethra), and a cover connected to the lumen of the catheter (**Figure 2** and **Figure 3**). This new device structure, changed from the 2-disk model of 2018, proved to be better at reducing periurethral leakage. The fixed disk was positioned at the bladder neck from the inside. The mobile one is positioned at the level of the external urethral meatus and can be adjusted to completely occlude the bladder neck. The urinary catheter used in CIC was typically made of plastic (PVC). The sizes variations were between 8 and 12 Fr, in accordance with the age and urethral size.

2.3. Insertion Technique

The size of SVCATH3D was chosen according to the anatomy of each patient, urethra size, and age. SVCATH3D was inserted by simple technique and with local anesthesia, in an outpatient setting and without the need for optical instruments or sedation. The technique of routine asepsis of the genital and perineal

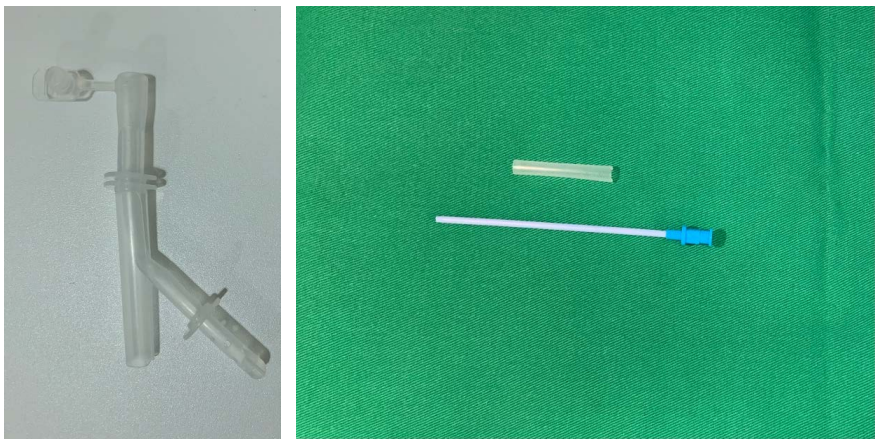


Figure 2. SVCATH3D with insertion guides, which can be done in an outpatient setting.

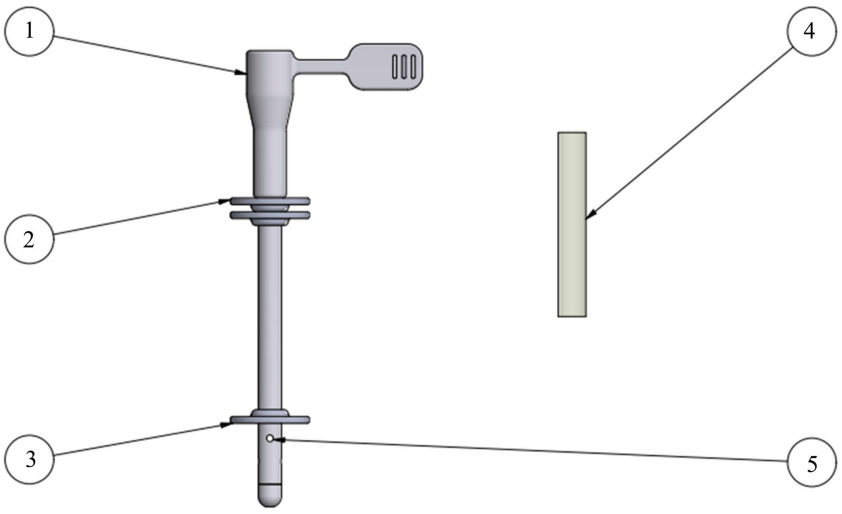


Figure 3. External portion of the catheter, sealed by a plastic lid. (2) Outer discs; (3) Inner disc, which occludes the bladder neck; (4) Insertion device; (5) Inner portion of the catheter, with holes for urine drainage.

region, then urethral lubrication with lidocaine 1% in the form of gel and direct introduction of SVCATH3D coupled in the rigid pusher. After that, the pusher was removed sequentially, and the distal discs were adjusted to the size of the urethra [11].

In the male candidates, the SVCATH3D can be inserted either through a small perineal urethrostomy or through a suprapubic incision (**Figure 4** and **Figure 5**).

2.4. Follow-Up

Patient follow-up was performed through presential visits in the third and sixth months previously scheduled, in addition to extra evaluation in cases of intercurrences or during the device exchanges which is recommended after 2 months [12].

3. Results

The results have been previously disclosed in a previous study [1]: a total of 177 subjects were included, 91 children (11 ± 6 years) and 86 adults (41 ± 17 years). The most prevalent conditions at baseline evaluation and demographic characteristics were shown in the previous study. Preliminary studies with a larger patient base and longer follow-up are being held.

3.1. Quality of Life Analysis

QOL data was homogeneous between groups at baseline evaluation. In the intergroup analysis at 6 months, the following mean values and standard deviation of the scores were observed for each domain: limitation GI = 2 ± 0.7 and GII = 7 ± 0.67; fear G1 = 2.5 ± 1 and GII = 8 ± 0.61; feeling G1 = 2 ± 0.71 and GII = 6 ± 0.98; impact on daily life G1 = 2.5 ± 0.89 and G2 = 8 ± 0.4.

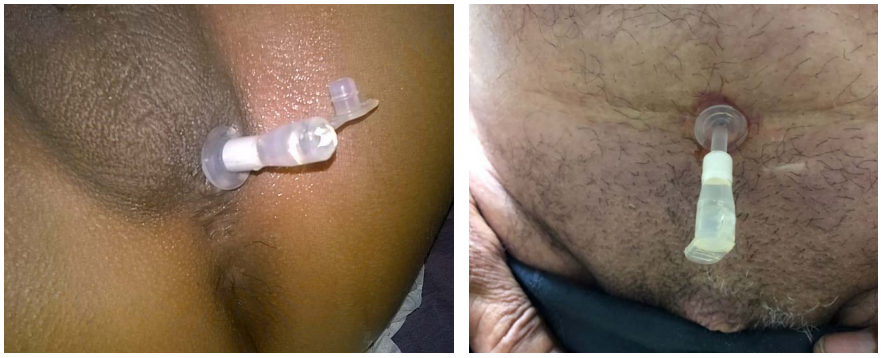


Figure 4. (1) Perineal Insertion of the Catheter; (2) Insertion through Suprapubic incision, both in males.

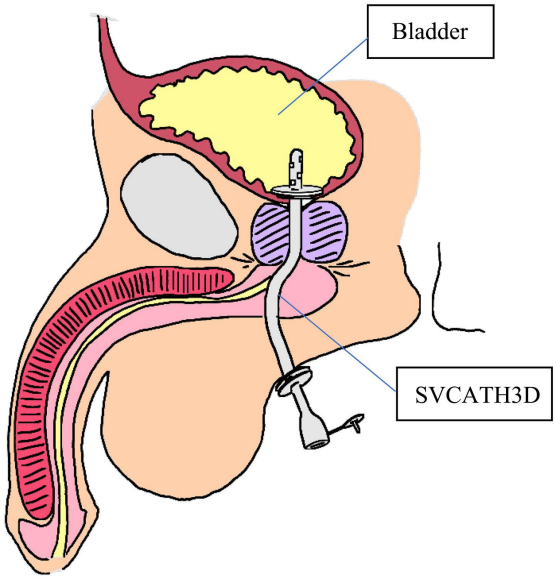


Figure 5. Perineal positioning of the SVCATH3D.

3.2. Number of Catheters Used

The SVCATH3D showed a clear advantage against CIC when taking the number of catheters used into consideration. One single SVCATH3D can be exchanged after 2 months of usage, while CIC used a mean of 6 catheters per day, representing 360 urethral catheters used in the same period as a single SVCath3D.

3.3. Urinary Tract Infection Episodes

The number of UTI episodes was compared between groups (GI and GII) at 6 months, with a significant statistical difference between groups. We found that the SVCATH3D group presented a significant reduction (rate of reduction of two episodes) in the number of episodes after the use of the device (intragroup analysis; Figure 6). Infection reduction was also found in CIC, but less significant than in the other group. The most frequently described pathogen was Escherichia coli in both groups.

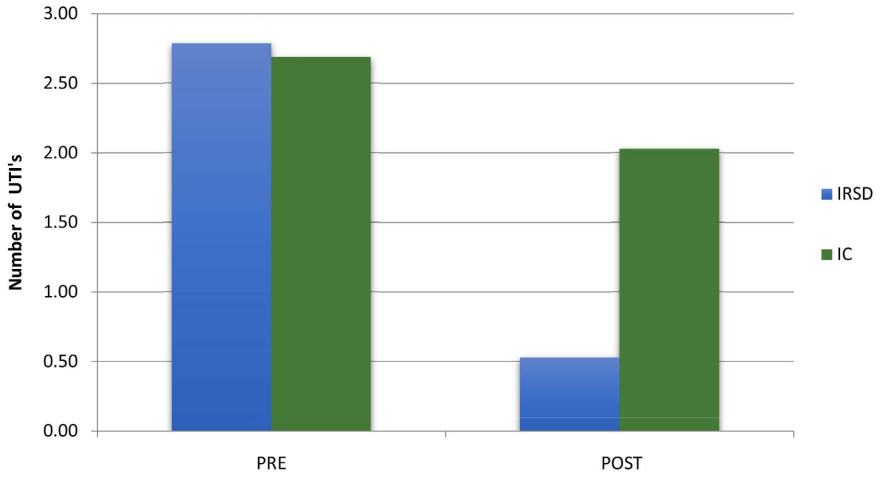


Figure 6. Analysis of the number of UTI episodes. IC, intermittent catheterization; ISRD, intraurethral self-retaining device; UTI, urinary tract infection.

3.4. Urodynamic Parameters

Bladder capacity and compliance were assessed. In the intragroup analysis (SVCATH3D group) there was a statistically significant increase in bladder capacity when comparing the mean values of baseline evaluation (202 mL) with the post-intervention evaluation (282 mL); representing a mean difference of 80 mL or a 40% increase in relation to the initial bladder capacity. No difference was observed in the intragroup analysis of the CIC group. In the intergroup analysis, at 6 months post-intervention, the SVCATH3D group presented higher bladder capacity and compliance as compared with those who followed the CIC protocol, with $p = 0.001$ and $p < 0.001$, respectively.

3.5. Adverse Effects

According to the previous categorization, the intergroup analysis of adverse effects was performed. Among all adverse effects, the SVCATH3D group presented an incidence of 41%, while the CIC group presented with 83% ($p < 0.01$).

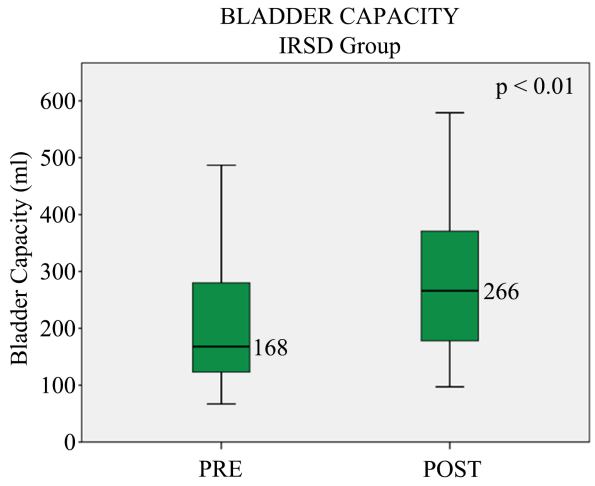
3.6. Number of Daily Diapers or Daily Protectors

Both groups presented a mean use of 7 ± 2 diapers per day at baseline evaluation. At 6 months (intergroup analysis), the SVCATH3D group presented a significant reduction of diaper use with 2 units per day, while CIC group maintained the use of 6 units/day ($p < 0.01$).

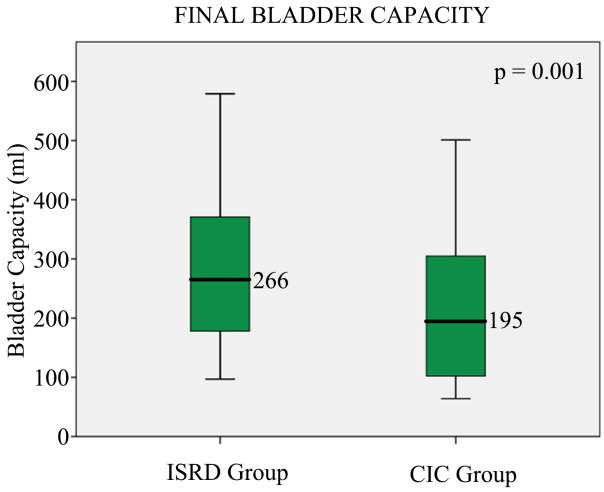
4. Discussion

CIC represents the main treatment alternative for patients with neurogenic bladder who are unable to perform bladder emptying adequately [6]. However, the practicality of this technique is influenced by a negative impact on QOL, compromising patients' self-esteem [11]. In this context, SVCATH3D presents advantages as an alternative to CIC, such as the possibility of management as an

outpatient procedure both for initial insertion and replacement. Such advantages result in greater autonomy of patients that perform bladder emptying, which significantly affects social interaction. One of the most relevant reports by patients and caregivers was the fact that they could empty their bladders at the precise moment they wanted without having to look for an adequate place to do so. Adults reported how pleasant was the sensation of emptying their bladders at the toilet without anyone's help. This improvement in QOL was reflected by a significant score reduction on the SF-QUALIVEEN questionnaire, both in the intergroup comparison (post-SVCATH3D vs post-CIC moment) and intragroup temporal comparison. Among the reported benefits, adult patients have mentioned resumption of active sexual life without constraints, reduction of social isolation, and increase of autonomy. Child patients have reported reintroduction in school dynamics and the freedom to participate in social activities. The possible placebo effect could not be assessed by the study method. In relation to the incidence of UTIs, SVCATH3D promoted a reduction in the number of episodes in 6 months. Previous reports have shown that CIC-related UTIs are frequent, with the incidence of 70% to 80% [13] [14] [15] [16]. It is important to emphasize that the practicality in the handling of the device also interferes in this outcome, because patients can open the device anywhere, while intermittent catheterization requires specific setting and conditions. Our hypothesis is that by reproducing the physiological voiding reducing the accumulation of residue plus raising the frequency of emptying (therefore improving bacterial elimination), the device has promoted this improvement. This benefit may be explained by the directions given for patients how to execute the catheterization. Regarding urodynamic data, the SVCATH3D presented an expressive gain in bladder capacity and compliance (**Figure 7**). This can be attributed to mechanisms of distension and contention of the bladder, which are enabled by the attainment of maximum cystometric capacity. This can be explained by the fact that by emptying the bladder at a more appropriate time and not depending on availability of a new catheter and adequate place to perform CIC the bladder tends to behave closer to a normal pattern. Risks of deterioration of upper tracts should not exist because by doing bladder emptying at shorter intervals for the same reasons upper and lower tract tend to behave more physiologically. These results are in agreement with data from the previous reports that showed bladder capacity gain due to the reduction of urinary loss [17] [18]. Experimental studies have also presented an improvement of bladder compliance after detrusor musculature distension [19] [20] [21]. The proportion of total adverse events in the SVCATH3D group was approximately half of those found in the CIC group, while more than 50% of the patients in the SVCATH3D group did not present any side effects. This result agrees with the data obtained in the pilot study [12] and with previous studies that idealized alternative devices to CIC [22]. Regarding the number of diapers used daily by subjects, both the SVCATH3D and CIC groups used an average of 7 units per day at baseline evaluation, but only the SVCATH3D



(a)



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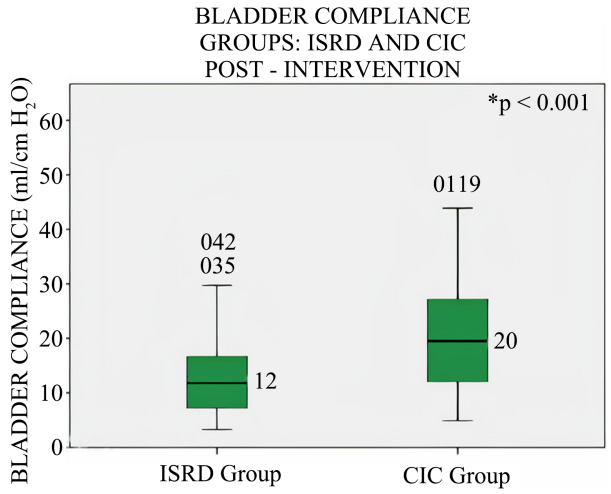

(c)

Figure 7. (a) Intragroup analysis (ISRD) of bladder capacity; (b) Intergroup analysis of the bladder capacity; (c) Intergroup analysis of the bladder compliance. ISRD, intraurethral self-retaining device.

promoted a significant reduction after 6 months (2 units per day). This reduction is in disagreement with two recent reports by Jeong *et al.* [23] and Renard *et al.* [24], in which authors reported no difference in urine leakage and diaper use after the intervention. In the pilot study conducted by our group [12], the SVCATH3D demonstrated safety and handling suitability. The present study provides new data that reinforces the SVCATH3D as a viable alternative to intermittent catheterization with significant advantages concerning all analyzed parameters. Currently, studies with larger population and longer follow-up are being held.

5. Conclusion

The new bladder-draining device (SVCATH3D) has previously been shown to be a safe and promising alternative for adequate bladder emptying in both male and female patients. The present studies reinforced the safety and ease of handling of the device as well as demonstrated a positive impact on the clinical and psychosocial parameters of the subjects involved.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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