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CLEAN INTERMITTENT CATHETERIZATION IN MULTIPLE SCLEROSIS PATIENTS: AN ADHERENCE AND LONG-TERM FOLLOW-UP STUDY

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Abstract

Introduction: Clean Intermittent Catheterization (CIC) is considered as a gold standard of treatment for bladder emptying disorders. A large amount of literature on CIC for patients suffering from neurological disorders is available, but there is a lack of research specifically concerning multiple sclerosis (MS) patients. Our primary outcome was to determine the characteristics of our population (sex, EDSS and age when CIC was introduced). Our secondary outcomes were to determine adherence of CIC.
Method: As part of a multicenter, observational, retro-prospective study, data was collected from neuro-urologist consultation reports, and extracted from bladder diaries between 01/01/2000 and 31/03/24. MS patients, over 18 years, with the indication of CIC were included.
Results: 195 patients (72.3% women) were included, with a mean age of 49 years old. The median of follow-up was 9 years. Median EDSS at the start of the study was 5.5. There was an adherence rate of 65.1%. Urinary leakage was present in 74.2% of patients prior to CIC and 31.6% following CIC.
Conclusion: Catheterization is mainly offered to patients with an EDSS between 0 and 7. Rate of adhesion is encouraging, with most patients still continuing to use CIC by the end of follow-up. During the follow-up, we observed a reduced leakage rate but CIC alone can not explain this improvement. Following studies should include a list of constraints and reasons of halted CIC.

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Résumé

Introduction : Le sondage intermittent propre est considéré comme le traitement de choix pour les troubles de vidange vésicale. Il existe encore peu de littérature traitant spécifiquement du sondage intermittent propre chez les patients atteints de Sclérose en Plaques (SEP). Nous avons analysé notre expérience du recours au sondage intermittent propre dans une population exclusivement atteinte de SEP. Notre objectif principal est de déterminer les caractéristiques épidémiologiques de notre population (sexe, EDSS, âge, le moment auquel le sondage intermittent est proposé). Notre objectif secondaire est de déterminer l'adhérence à la technique.
Méthode : Il s'agit d'une étude observationnelle rétrospective multicentrique. Les données ont été collectées dans les rapports de consultations de neuro-urologie et extraites des calendriers mictionnels, du 01/01/2000 jusqu'au 31/ 03/2024. Les patients majeurs, atteints de SEP avec indication de pratiquer le sondage intermittent propre ont été inclus.
Résultats : 195 patients ont été inclus, leur âge moyen est de 49 ans (72,3% sont des femmes) la durée médiane du suivi est de 9 ans. L'EDSS médian avant de débuter le traitement par sondage intermittent propre était de 5,5. L'adhérence est de 65,1%. 74,2% de notre cohorte présentait des fuites urinaires avant l'inclusion et 31,6% à la fin du suivi.
Conclusion : Le sondage intermittent est principalement proposé pour les patients ayant un EDSS entre 0 et 7. L'adhérence est satisfaisante car la majorité des patients inclus pratique encore le sondage à la fin du suivi. Par ailleurs, nous avons observé une diminution de l'importance des fuites urinaires. Il est désormais important de compléter nos données par la liste des contraintes et motifs d'arrêt rapportés par les patients.

1. Abbreviations

ANLUTD	Adult Neurogenic Lower Urinary Tract Dysfunction
CIC	Clean Intermittent Catheterization
CISC	Clean Intermittent Self Catheterization
DO	Detrusor Overactivity
EAU	European Association of Urology
MS	Multiple Sclerosis
PVR	Post-void residual
SCI	Spinal Cord Injury

2. Introduction

The current prevalence of multiple sclerosis (MS) in Europe is 83/ 100,000 [1]. In this population, 75 to 80% of patients will develop Adult Neurogenic Lower Urinary Tract Dysfunction (ANLUTD) within 6 to 10 years of disease onset [1,2]. In 10% of cases, neuro-urological symptoms are the first manifestation of the disease and lead to a diagnosis. [1,3]. This is correlated with higher severity of symptoms and urodynamic abnormalities [4]. These symptoms affect the patient's quality of life and pose a particular risk to the upper urinary tract (infections, uretero- hydronephrosis, . . .) [2,3].

Presentation of ANLUTD are not segmented according to lesion topography. In particular, they may be the result of the neurogenic lesion, but may also be linked to cognitive, motor impairment or iatrogenic causes (use of anti-cholinergic treatments or intra-detrusor injection of botulinum toxin) [3,5].

Detrusor overactivity (DO) leads to urgency associated with urinary incontinence, increased urinary frequency and nycturia, and affects 37 to 99% of patients with MS [1,2,4]. Detrusor sphincter dyssynergia affects 35% of patients while under contractility, with a risk of urinary retention, is found in 25% of cases [1,3,4]; and low bladder compliance (2 to 10%) [4].

CIC is considered a gold standard for treating neurogenic or non- neurogenic bladder voiding dysfunction (like urinary retention, symptomatic post-void residual (PVR)), but can help to relieve storage symptoms (urgency). CIC can be performed by a third person or the patient themselves [3,6].

In MS patients, detrusor pressures are often lower, so the presence of a PVR is not always as problematic as in spinal cord injury (SCI). Increased PVR is correlated with a higher risk of urinary tract infection but there is no consensus on the volume at which catheterization is required [3,4].

The first description of Self Clean Intermittent Catheterization (CISC) in an MS female patient was reported by Lapides et al. in 1970 [7]. The study was later expanded to patients with various urological clinical signs (such as frequency, urgency, urinary infections, incomplete bladder voiding, . . .). All participants reported improvements in various aspects, including a complete and easy bladder emptying, a reduced urgency, less leakage and an increased quality of life [7].

The European Association of Urology (EAU) has developed guidelines for managing bladder and bowel neurogenic disorders but none specifically for MS [1].

There are many evidence-based treatments that can be used in combination, that can be more or less invasive [1,6]. First, it is important to apply dietary measures (management of fluid intakes) and rehabilitation (such as pelvic floor muscle training or electro-stimulation, biofeedback). Following this, it is then possible to start drug treatment, such as anticholinergics and alpha-blockers, associated or not with minimally invasive techniques such as CIC. The latter, is the gold standard method for voiding disorders [1,6].

Minimally invasive treatment also includes intravesical oxybutynin for patients intolerant to the oral form, detrusor botulinum toxin injections in MS or spinal cord injury patients (SCI) when anticholinergic therapy is insufficiently effective; and for refractory neurogenic DO, surgical treatments such as bladder augmentation can be considered. Surgical treatment can be associated with an autologous urethral sling or artificial sphincter [1,6].

While SCI patients have a high risk of upper tract injury (25%) due to detrusor sphincter dyssynergia and DO with higher detrusor pressure (>40cmH2O), these complications are less common in MS patients [810]; thus, the therapeutic objectives differ. In MS, the priority is to relieve storage symptoms and prevent urinary infection [10]. Indeed, by reducing PVR, catheterization improves bladder filling. In addition, Castel-Lecanal et al. have shown an improvement in quality of life when MS patients use CIC [11].

Therefore, the primary outcome of this study was to determine adherence and symptom comparison prior to and after 9 years of follow- up of using CIC. The secondary outcomes was to determine adherence to CIC.

3. Materials and method

3.1. Design, recruitment, participants

This retrospective multicentric observational study was carried out at the Liège University Hospital and the Regional Hospital of Huy (Belgium). This study has been approved by both local ethic committees (local reference number is 2024/91).

MS patients who are over 18 of age with an indication for CIC for voiding management were enrolled in this study. This included patients who had urgency, hesitancy, symptomatic PVR.

We excluded patients that were pregnant at baseline.

217 patients from 1 January 2000 to 31 March 2024 were included in the study. Data was extracted from neuro-urologist consultation reports and through analysis of bladder diaries in patients' medical files.

Data pertaining to age, sex, EDSS, urinary symptom, treatments and bladder diaries (including the number of catheterizations, leaks and spontaneous micturition for at least 2 consecutive days) were collected.

3.2. Statistical analyses

Given the observational nature of the study and the lack of previous data in this category of patients, a sample size calculation was not performed.

Statistical analyses were performed using R software (version 4.2.0 for Windows). Normality of quantitative variables was tested with the Shapiro-Wilk test ($P < 0.05$). Results were expressed as mean and standard deviation (SD) for variables following a normal distribution or as median with interquartile range (Q1-Q3) for asymmetric distributions. Qualitative variables were described using counts and percentages. Pearson's x^2 test was used to assess the homogeneity of distribution between groups. One-way ANOVA or Kruskal-Wallis non-parametric tests were used to determine statistical differences between groups for continuous variables. Results were considered significant at the level of a = 5% ($P<0.05$).

In addition, a Kaplan-Meier analysis was used to evaluate the rate of patients continuing CIC over time.

4. Results

Sample At baseline, CIC was proposed to 217 patients: 9 patients refused to participate, and 13 patients accepted to learn the CIC technique but immediately stopped the practice. Finally, a total of 195 patients were enrolled in this study. There was no significant difference in disease severity (evaluated by EDSS; P = 0.53) between the group who practiced CIC and the group who refused to or never practiced it. The socio- demographic and medical characteristics of the final sample are presented in Table 1. There is a greater proportion of women in this study (72.3% of the sample) and 49.2% of the sample has an EDSS > 5.5 at baseline.

4.1. Evaluation of incontinence and suggestion of CIC

Baseline urinary incontinence rate is 74.2% and does not differ according to sex (P = 0.173). Table 1 shows that CIC is more frequently suggested 5 years after MS diagnosis. Nevertheless, the time at which CIC is offered varies depending on the type of MS (P < 0.001). CIC was offered more frequently, 5 years before diagnosis in the relapsing-remitting MS
group (25%). Delay to start CIC after diagnosis does not differ according to sex (*P* = 0.22).

There is a significant difference (P <0.01) between the continence rate before and during the CIC period: 25.8% of patients were continent at recruitment against 68.4% at the end of the follow-up.

Incontinence rates also differ by sex at follow-up, with proportionally more women being incontinent (36.2% while is of 19.2% for men) (*P* = 0.024).

4.2. Evaluation in relation to the severity of the disease

The disease was divided into 3 groups of severity (Table 1): "independent walker" patients (group 1, EDSS 0 to 5.5: 50.8% of the patients), walker with aid (group 2, EDSS 6.0 to 7.0: 40.6%) and non-walker (group 3, EDSS 7.5 to 10: 8.60%). Different parameters were evaluated based on these groups (Table 2).

At baseline, age is significantly (P = 0.007) different between disease severity groups. Post hoc analysis showed that patients in groups 2 and 3 were significantly older than patients in group 1. The distribution of men and women within each severity group was not significantly different (*P* = 0.284). Time between diagnosis and the start of CIC differs according to disease severity. In particular, patients in group 1 were more likely to be offered CIC within 5 years of diagnosis, in contrast to patients in group 3 who were offered CIC only after 5 years post diagnosis.

The frequency of CIC also differed (P = 0.001) between groups of disease severity. Post hoc analysis showed that patients in group 3 were less likely to use CIC than patients in groups 1 and 2.

Finally, urinary incontinence at baseline (P = 0.094) and cessation of CIC before the end of the study (P = 0.081) did not differ between disease severity groups.

Table 1

Socio-demographic and medical characteristics of the population (N = 195).

Variable	*n*	*n* (%)	Mean ± SD or Median (P25–P75)
Baseline			
Sex	195		
Women		141 (72.3%)	
Men		54 (27.7%)	
Age at the start of CIC (years)	194		49.1 ± 11.1
Type of MS	190		
Relapsing-remitting		84 (44.2%)	
Progressive secondary		84 (44.2%)	
Progressive primary		22 (11.6%)	
EDSS at the start of CIC (score from 0 to 10)	187		5.50 (4.00–6.50)
EDSS at the start of CIC	187		
Group 1 (score from 0 to 5.5)		95 (50.8%)	
Group 2 (score from 6.0 to 7.0)		76 (40.6%)	
Group 3 (score from 7.5 to 10)		16 (8.60%)	
Urgency urinary incontinence	163		
Yes		121 (74.2%)	
Women	118	91 (77.1%)	
Men	45	30 (66.7%)	
No		42 (25.8%)	
MS duration before suggesting of CIC	191		
Less than 5 years		27 (14.1%)	
More than 5 years		164 (85.9%)	
Follow-up			
Frequency of CIC (times per day)	193		4.00 (2.00–5.00)
Age at end of follow-up (years)			59.1 ± 10.6
EDSS at the end of follow-up (score from 0 to 10)	191		6.50 (5.00–7.00)
EDSS at the end of follow-up	191		
Group 1 (score from 0 to 5.5)		65 (34.0%)	
Group 2 (score from 6.0 to 7.0)		79 (41.4%)	
Group 3 (score from 7.5 to 10)		47 (24.6%)	
Follow up duration (years)	195		9.00 (4.00–14.0)
Urgency urinary incontinence at the end of follow-up	190		
Yes		60 (31.6%)	
Women	138	50 (36.2%)	
Men	52	10 (19.2%)	
No		130 (68.4%)	
Death during follow-up	195		
Yes		32 (16.4%)	
No		163 (83.6%)	
Halted CIC before the end of study	195		
Yes		68 (34.9%)	
No[a]		127 (65.1%)	

[a] Patients who died and were still practicing CIC until their death were counted in this group.

Table 2
Parameter analysis in relation to severity of the disease.

Variable	EDSS			*P*-value
	Group 1	Group 2	Group 3	
	(score from 0 to 5.5)	(score from 6.0 to 7.0)	(score from 7.5 to 10)	
Age (years; mean ± SD)	46.8 ± 11.8	50.8 ± 9.79	55.0 ± 9.82	0.007*
Sex [*n* (%)]				
Women	70 (51.5%)	52 (38.2%)	14 (10.3%)	0.284
Men	25 (49%)	24 (47.1%)	2 (3.9%)	
MS duration before suggesting CIC				
Less than 5 years	19 (73.1%)	7 (26.9%)	0 (0.00%)	0.029*
More than 5 years	75 (46.9%)	69 (43.1%)	16 (10%)	
Urgency urinary incontinence at baseline				
Yes	54 (67.5%)	53 (81.5%)	12 (85.7%)	0.094
No	26 (32.5%)	12 (18.5%)	2 (14.8%)	
Frequency of CIC (times per day)	5.00 (2.00–5.00)	4.00 (2.00–5.00)	2.00 (1.00–3.25)	0.001*
Halted CIC before the end of study				
Yes	28 (29.5%)	30 (39.5%)	9 (56.3%)	0.081
No	67 (70.5%)	46 (60.5%)	7 (43.7%)	

*: Significant results (P<0.05)

4.3. Voiding method

Voiding methods are listed in Table 3. In most cases, patients used CISC alone (49%) or CISC and spontaneous voiding (24.5%).

Moreover, 4% of the cohort had surgery for enterocytoplasty during the follow-up and still used voiding by catheterization, with the exception of two patients: one who underwent indwelling transurethral catheterization and bricker surgery for the other one. For both, follow-up was stopped. In this cohort, none of the patient underwent stress incontinence surgery.

In addition, with regard to the treatment of DO, 73% of our patients had received anticholinergic treatment prior to commencing CIC, and 31% continued at the end of follow-up period. 42.5% of patients received detrusor botulinum toxin injection prior to starting CIC and 38.7% at the end of follow-up.

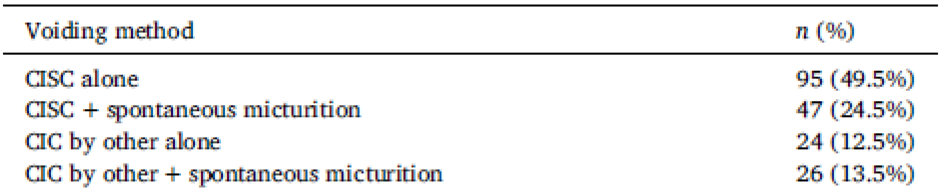
4.4. Adherence

In terms of adherence, at the end of the follow-up period, 45.1% stopped (due to death or other reasons) and 54.9% still performed CIC. The median duration of follow-up was 9 years. The Kaplan-Meier analysis (Fig. 1) shows that there is a 72.2% chance (95% CI: 65.3-77.9) that patients will continue CIC for more than 5 years. At 10 years, this chance decreases to 45.4% (95% CI: 38.2-52.2).

Among the 31 deceased patients, 20 of them continued CIC until their death. Taken into account adherence rate is of 65.1%.

There were no significant difference in EDSS between patients who continued CIC and those who stopped (P = 0.081). In the total population, the reasons that have led patients to stopping catheterization were as follows: Bricker (3.1%), indwelling transuretral catheter (3.1%), indwelling suprapubic catheter (1.5%). 21,5% did not specify the of stoping. These patients were included but follow-up ceased on the date of micturition mode modification.

Table 3
Voiding method.



Voiding method	*n* (%)
CISC alone	95 (49.5%)
CISC + spontaneous micturition	47 (24.5%)
CIC by other alone	24 (12.5%)
CIC by other + spontaneous micturition	26 (13.5%)

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5. Discussion

There are very few studies about CIC in MS patients. Patients with symptomatic PVR were included but unfortunately, this data was not available prior to the commencement of CIC. This needs be considered for future recruitment.

Various statistical measures of disease severity showed a negative correlation between disease severity and the frequency of CIC. In fact, the higher the EDSS, the lower the frequency of CIC ($P < 0.05$), which is probably related to the deterioration of abilities (cognitive and physical) to accept CIC. However, CIC frequency did not change with the type of MS.

Type of MS has no influence on urinary disorders [4], and regardless of the type of MS, most patients started CIC 5 years after diagnosis (Table 3). However, patients with relapsing-remitting MS, were offered CIC earlier.

The current study is based on bladder diaries. In these diaries, patients were asked to record over 2 days the frequency of CIC, the number of micturition and leakage but unfortunately it lacked data about urinary infection and others clinical signs of DO (patients with DO signs were included but there was no report in the diaries). It seems that for future research, it is better to fill diaries over a longer period of time, such as 7 days [12]. However, MS patients are not the most reliable patients to keep diaries. As shown by Menoux et al. in a study requiring 3 days of completion, only 25% of patients completed it correctly [5]. This variability is not only related to low adherence but also to the higher variability of urinary symptom in this population (influenced by hormonal fluctuations, spasticity, constipation, . . .) [5].

Bladder diaries provide information regarding voiding technique. It seems that spontaneous micturition and CISC seem to be the safer techniques to protect the upper urinary system, whereas CIC by a third person is associated with more risk [4]. In this cohort, the micturition mode is, in most cases, safer. Future studies could confirm this by adding urodynamic data.

With regard to satisfaction, difficulties and adherence to this treatment patients could have been asked patients to fill in different questionnaires, such as the InCaSaq, the ICDQ and I-Cas. [13-15]. Luoto et al. have studied CIC practice in 70 MS patients, 79% of whom reported an improvement in their quality of life [16].

Fig. 1. Survival curve of the time of cessation of CIC.

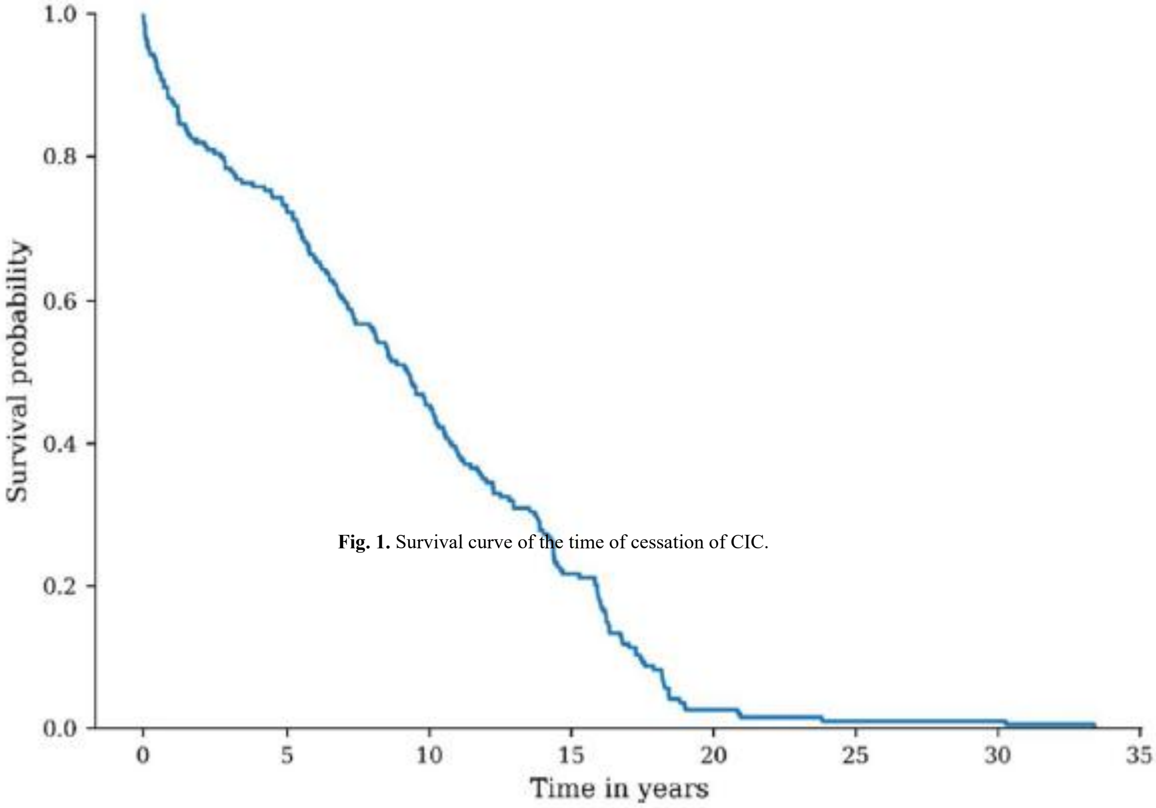

Fig. 1. Survival curve of the time of cessation of CIC.

To refine our inclusion criteria, tools such as the pencil and paper test (PP test) could have been used. This test is validated for neurological patients (including MS patients) and helps to determine with high accuracy ability to undergo a CISC [17]. To evaluate acceptance, another tool called I-CAT could have been used. This questionnaire, developed by Guinet-Lacoste et al. [14], is useful to identify the psychological barrier and fear associated with CISC, and is a good tool to identify patients' fears, reassure them and reduce anxiety [14]. It is validated for both neurological and non-neurological patients [14].

Similar EDSS scores were found in patients who continued catheterization, to those who stopped. It seems that the reasons why patients quit are not only related to their abilities: in the study by Krebs et al, the reasons for abandoning the technique were: increasing age, decreasing cognitive abilities and loss of upper limb function [8]. In several studies, patients quit because of an improvement in their symptoms (reduction in PVR, reduction in symptoms of overactivity) [16,18,19]. Unfortunately, in this study there was not enough data to list the reasons that lead the patients to quit. In this study, 78.3% of patients that quits did not provide a reason. Different questionnaires could be helpful in this situation: technical constraints can be assessed by the LUTS-TCA questionnaire, validated for neurological patients [20]. It evaluates patients' opinions in different domains such as: economic, environmental, social, psychological, daily organization, medical follow up required. [20].

As for the limitations of this study, neither patient satisfaction nor quality of life was assessed. There are several tools, very easy and quick to use, that take into account patients' feelings, which is essential to promote adherence in the long term.

This study has shown a significant improvement in continence over the course of 9 years follow-up. This is paramount as leakage leads to a deterioration in self-image and quality of life. Continence has been described as the main adhesion factor over time in SCI or MS [21]. However, this cannot be attributed solely to the CIC. Indeed, there are a number of potential causes of incontinence, including medical treatment modification during follow-up, cross-talk with the rectum and body mass index. This data was not available in this study, and future studies should take this into considerations [22]. Obesity also plays a part in urinary incontinence by increasing bladder pressure, but also with hormonal changes, dysfunction of bladder vascular endothelium . . . [23].

Furthermore, the majority of patients included in this study were medicated with anticholinergics both prior to and throughout the follow- up period; however, this study does not present accurately the rate of botulinum toxin injections. This could be further investigated in future studies.

Corona et al. looked at how CIC only and anticholinergic drugs only affect quality of life and the rate of urinary infections in MS patients. They found that the CIC option increased the risk of infection, while anticholinergics are linked to better urinary symptom improvement [24]. In our cohort, CIC was not initiated as a first-line treatment for urinary symptoms. Indeed, prior to initiating CIC, 73% of patients had already been treated with anticholinergics, and CIC was initiated due to the insufficient efficacy of pharmacologic treatments. 4% of patients had enterocystoplasty, which could also influence the rate of continence.

The principal strength of our study is the size of the sample of our population which lends itself to further investigation. Another strength of the study was the length of follow-up and the specificity of this population. To the best of our knowledge, there are very few studies that look at CIC in MS patients and none have as long a follow-up as the current study. It would be interesting to continue the follow-up of our patients and extend the recruitment phase with additional data, including urodynamic, PVR, CIC indication, associated treatment, and questionnaires.

6. Conclusion

CIC is considered as the gold standard for voiding dysfunction, but due to the variability of symptoms in MS patients, it is difficult to collect accurate data. We have shared our experience and found that, firstly, the higher the EDSS, the lower the frequency of CIC, CIC is often starting more 5 years after diagnosis. Secondly, adherence is quite satisfactory in our MS population but we need to be more specific about the reasons for stopping.

The best option to facilitate bladder voiding must be decided by a multidisciplinary team and needs to take into account the global function of our patients (considering cognitive, physical abilities, socio-cultural aspects, cost). Moreover, MS is a progressive disease, so patients' abilities (cognitive or physical) may deteriorate over time, which requires regular assessment.

Disclosure of Interest

The authors declare that they have no competing interest.

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