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ORIGINAL ARTICLE

Efficacy and security of continent catheterizable channels at short and middle term for adult neurogenic bladder dysfunction

Efficacité et complications des cystostomies continentes à court et moyen terme chez le patient neuro-urologique

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KEYWORDS
Neurogenic bladder;
Functional efficacity;
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Urinary diversion;
Intermittent catheterization

Summary
Aims. — The objective of this study was to assess the effectiveness and the complications rate following continent cutaneous channels (CCC) procedures, at short and medium term follow-up (FU).
Materials & Methods. — A continuous retrospective case series (2008—2018): all patients who have undergone a CCC for neurogenic bladder were included in our department. The primary outcome was the effectiveness of CCC defined by the status of catheterizability (by the patient or a care-giver), continence of the tube, and absence of reintervention at 3 and 12 months FU. The secondary outcome was the prevalence of postoperative complications at 3 and 12 months FU.
Results. — Fifty-three patients were included during the study period in our department. Median follow up was 3,3 years (1.5—6.1). The overall effectiveness of CCC was 67.9% ($n = 36/53$) at 3 months FU and 45,3% ($n = 24$) at 12 months FU. The global rate of complications was 60.4%

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($n = 32/53$) at 3 months, and 73.6% ($n = 39/73$) at 12 months FU. The statistical analysis showed no statistical differences on efficacy and complications in the different subgroups of CCC.
Conclusions. — In the current series, the effectiveness and the complications rates following CCC were comparable across the procedure types.
Level of evidence.— 4.

MOTS CLÉS
Cystostomie ;
Efficacité ;
Complications ;
Vessie neurologique ;
Sondage intermittent

Résumé
But. — Apporter des informations sur l'efficacité et les complications des techniques de cystostomie continentes à court et moyen terme.
Matériel et méthode. — Nous avons étudié rétrospectivement les dossiers médicaux de tous les patients adultes atteints de troubles neurologiques, ayant bénéficié d'une cystostomie continente entre 2008 et 2018 dans notre centre. Le critère de jugement principal était l'efficacité de la cystostomie (cathéterisable, continente et absence de réintervention) à 3 et 12 mois. Les critères de jugement secondaires étaient les complications à 3 et 12 mois. Nous avons également comparé ces critères entre les différents types de cystostomies.
Résultats. — Cinquante-trois patients ont été inclus pendant la période étudiée. La médiane de suivi était de 3,3 ans (0,5—6,1). Les cystostomies continentes réalisées ont été : 47 % de Mitrofanoff ($n = 25$), 25 % de Monti ($n = 13$), 22 % de Casale ($n = 12$), et 6 % d'autres procédures($n = 3$). L'efficacité des cystostomies étaient de 67,9 % ($n = 36$), et 45,3 % ($n = 24$) à 3 et 12 mois respectivement. Le nombre de complications était de 32 (60,4 %) à 3 mois, et 39 (73,6 %) à 12 mois. Il n'a pas été retrouvé de différence statistiquement significative d'efficacité ou de complications entre les techniques de cystostomies.
Conclusion. — Notre étude présente des résultats fonctionnels et de complications pour un effectif important de patients. Il n'a pas pu être mis en évidence de différence entre les différents types de procédure, mais nos résultats permettent d'apporter des données supplémentaires à la littérature sur ce sujet peu étudié.
Niveau de preuve.— 4.

Introduction & Objectives

Keeping a low-pressure bladder in neurogenic detrusor hyperactivity is essential to prevent urinary upper tract complications, such as urinary tract infections, lithiasis, and renal dysfunction.

Since the first description of bladder intermittent self-catheterization, ruled by Lapidus [1] in 1972, Continent cutaneous channels (CCC) appeared to be a helpful alternative for patients having difficulties to perform urethral catheterisation. Either these difficulties came from urethral traumas, neurological arms limitations, or difficulties to reach the urethra. Moreover, urinary continence may be obtained, in case of intra-bladder hyper pressure.

CCC procedures are usely associated at the same time by a sus-trigonal cystectomy and bladder augmentation by enterocystoplasty for those who show refractory detrusor over-activity or low bladder compliance. It rarely can be performed without associated enterocystoplasty if the bladder hyperactivity and capacity is corrected under pharmacologic treatments, and the indication of the CCC is the difficulty to catheterize the urethra.

However, CCC are major invasive surgeries with high risk of post-operative complications in short and long term, such as urinary sepsis, digestive occlusion, tube stenosis, or urinary stones [2—4].

They are complex surgeries, mainly performed in centre of expertise, which explain that few data are available in literature.

Thus, it is essential to be able to give the best information about surgery to patients, so we need more data about effectiveness and complications of CCC, as well as trying to obtain a better knowledge of the differences between the major CCC procedures.

The objective of this study was to assess effectiveness of these stomas in short and middle term (3 and 12 months), considering catheterizability, continence of CCC (provided that detrusor hyperactivity is considered as controlled), and absence of reintervention.

We also studied short and mid-term complications of CCC.

Materials & Methods

It was a monocentric retrospective study in a reference center of neurourology between 2008 and 2018.

Table 1 Characteristics of patients.

		Total	Mitrofanoff	Yang-Monti	Casale	Others
Number of patients, *n* (%)		53 (100)	25 (47%)	13 (25%)	12 (22%)	3 (6%)
Gender	Male, *n* (%)	23 (43.4)	13 (52%)	5 (38%)	3 (25%)	2 (66%)
	Female, *n* (%)	30 (56.6)	12 (48%)	8 (62%)	9 (75%	1 (33%)
Mean age, years (IQR)		46 (32—54)	45 (31—59)	38.5 (35—42)	45(39.5—50.5)	53.7 (48—57)
Mean BMI (IQR)		26.0 (18.8—29.5)	24 (18—32)	25.5 (21—30)	25 (22—28)	25.7 (22—33)
Neurological disease						
Multiple sclerosis		4 (7.5%)	4 (100%)	0	0	0
Spina bifida		7 (13.2%)	1 (14.29%)	3 (42.9%)	3 (42.9%)	0
Spinal cord injury	Cervical	15 (28.3%)	8 (53.4%)	3 (20%)	2 (13.3%)	2 (13.4%)
	Thoracic	10 (18.9%)	6 (60%)	3 (30%)	1 (10%)	0
	Lumbar	2 (3.8%)	1 (50%)	0	0	1 (50%)
Equina cord syndrome		3 (5.7%)	0	0	3 (100%)	0
Cerebral palsy		2 (3.8%)	0	1 (50%)	1 (50%)	0
Others		10 (18.9%)	0	10 (100%)	0	0
Associated procedures						
Enterocystoplasty		34 (64.2%)	16 (64%)	11 (84.6%)	7 (53.3%)	—
Bladder neck surgery		17 (32.1%)	6 (60%)	7 (53.8%)	4 (33.3%)	0

BMI: Body mass index; IQR: inter-quartile range.

We included in our study every patient, 18 years or older, undergoing continent urinary diversion (every type of CCC procedures), with or without associated bladder augmentation, for neurogenic bladder in our department.

Patients were excluded in case of non-neurological bladder disease or congenital low urinary tract malformation.

Primary outcome was effectiveness of CCC defined by the association of catheterizability (by the patient or a care-giver), continence of the tube, and absence of reintervention at 3 and 12 months.

All the information was obtained by screening the patient electronic medical file.

Secondary outcomes were postoperative complications at 3 and 12 months. Complications were classified in different categories: tube stenosis, incontinency, lithiasis, urinary tract infections, other surgical complications, necessity of reinterventions and need of complementary treatment.

We described major and minor complications according to the Clavien-Dindo classification.

We considered any outcome as positive if it was reported in any medical report until 3 or 12 months postoperative.

We decided to realise statistical analysis on the difference of effectiveness and complications between the different types of cystostomy, at short and middle term.

Statistical significance tests were performed with the Logical R, 3.4.0, using the Fisher's exact test. It analysed contingency tables of the different groups of stomas, for primary and secondary outcomes.

We decided not to present other data about preoperative treatment, urodynamic and precise associated treatments, because of the large amount of missing data.

Results

Fifty-three patients were included in the study period in our department (Table 1). All of the 53 patients presented a follow-up equal or superior to 12 months.

Median follow up was 3,3 years (1,5—6,1).

The different types of neurological diseases relative to the bladder dysfunction were presented in the Table 1.

No major differences seem to be observed in the patients' characteristics between the different types of procedure, instead of an inversion of the ration male/female in Mitrofanoff group, with a rate of male lightly superior in this group.

CCC procedure was Mitrofanoff in 47% ($n = 25/53$) of patients, Monti in 25% ($n = 13/53$), Casale in 22% ($n = 12/53$) and other types (Miami, Mayence and Koch pouch) in 6% ($n = 3/53$). Augmentation enterocystoplasty was realized in 64,2% of patients ($n = 34/53$) and 32,1% ($n = 17/53$) of patients underwent associated bladder neck procedure (Table 1). We considered as bladder neck surgery the following procedure: urethral sling, artificial urinary sphincter (AUS) and bladder neck closure.

Primary and secondary outcomes are presented in Table 2. Comparisons between the different types of CCC are also presented in this table (statistical analysis were only performed on outcomes at 3 and 12 months, not between 3 and 12 months).

The overall effectiveness of CCC was 67,9% ($n = 36/53$) at 3 months postoperative, and 45,3% ($n = 24/53$) at 12 months.

The global rate of complications was 60,4% ($n = 32/53$) at 3 months, and 73,6% ($n = 39/53$) at 12 months.

To separate patients who presented complication before 12 months for the first time, from the patients who recidivate complication after 3 months, we also presented in Table 2 the rate of complications occurring in the period 3—12 months, excluding patients which didn't present complications before 3 months.

For 39 patients (73.6%) who presented a complication in the first 12 months, 19 (35.8%) didn't present it before 3 months. In other terms, 20 patients (37.8%) presented a complication before 3 months, and recidivate after 3 months.

Table 2 Continent Catheterizable Cystostomy efficacy (continent, catheterizable and no need of reintervention) and complications at 3 and 12 months, according to the type of stoma (Statistical analysis using Fisher exact test).

Type of stoma	Efficacy 3 months	*P*-value	Complications at 3 months	*P*-value	Efficacy 12 months	*P*-value	Complications at 12 months	*P*-value	Complications 3—12 months
Mitrofanoff	16 (66.7%)	0.298	16 (66.7%)	0.81	13 (52%)	0.0911	19 (76%)	0.33	7 (28%)
Monti	11 (78.6%)	0.298	7 (50.00%)	0.81	7 (53.8%)	0.0911	9 (69%)	0.33	4 (30.8%)
Casale	6 (50%)	0.298	7 (58.30%)	0.81	2 (16.7%)	0.0911	8 (66.7%)	0.33	7 (53.3%)
Others	3 (100%)	0.298	2 (66.7%)	0.81	2 (66.7%)	0.0911	3 (100%)	0.33	1 (33%)
Total	36 (67.9%)		32 (60.4%)		24 (45.3%)		39 (73.6%)		19 (35.8%)

Table 3 Separated elements of the composite criteria at 3 and 12 months according to the type of stoma.

Type of stoma	Catheterizable 3 months	Continence 3 months	Reintervention 3 months	Catheterizable 12 months	Continence 12 months	reintervention 12 months
Total	44 (83%)	49 (92.4%)	9 (17.0)	41 (77.3)	45 (84.9)	16 (30.2%)
Mitrofanoff	20 (80%)	21 (84%)	2 (8%)	18 (72%)	21 (84%)	4 (16%)
Monti	13 (100%)	13 (100%)	3 (23.0%)	12 (92.3%)	13 (100%)	5 (38.5%)
Casale	8 (66.7%)	11 (91.7%)	4 (33.3%)	8 66.7%)	9 (75%)	6 (50%)
Others	3 (100%)	3 (100%)	0	3 (100%)	2 (66.7%)	1 (33.3%)

Table 4 Complications according to Clavien-Dindo classification at 3, 12 and after 12 months.

Complications	Total	Mitrofanoff	Monti	Casale	Others
Clavien 1—2 < 3 months	23 (43.4%)	13 (52%)	5 (38.5%)	3 (25%)	2 (66.7%)
Clavien ≥3, < 3months	9 (17%)	3 (12%)	2 (15.4%)	4 (33.3%)	0
Clavien 1—2, 3—12 months	18 (34%)	7 (28%)	3 (23.1%)	7 (58.3%)	1 (33.3%)
Clavien ≥ 3, 3—12 months	1 (2%)	0	1 (7.7%)	0	0
Clavien 1—2, ≥ 12 months	30 (57%)	12 (63.2%)	6 (46.2%)	2 (17%)	1 (33.3%)
Clavien ≥ 3, ≥ 12 months	1 (2%)	0	0	1 (8.3%)	0

The statistical analysis showed no statistical differences on efficacy and complications in the different groups of CCC.

We also presented results of separated criteria from the primary outcome and rate of reinterventions (Table 3).

Major complications (≥ Clavien 3) occurred in 17% of patients during the first 3 months, 2% between 3 and 12 months and 2% after 12 months. Digestive occlusion, digestive fistula, gastro-intestinal bleeding, pulmonary embolism, acute lung injury, septic shock was considered as major complications (Table 4).

Thirteen point one percent ($n = 6/53$) of patients underwent non-continent trans-ileal urinary diversion during the follow-up.

Outcomes after 12 months are presented in Table 5.

At the date of last follow-up for each patient, 76,2% ($n = 32/42$) of patient were able to catheterize the CCC, 69% ($n = 29/42$) were continent, and 33,3% ($n = 19/42$) needed a reintervention. The efficacy, as define as the primary outcomes was achieved in 26 patients (61.9%). Causes of catheterisation failure found in this population were stoma abscess, stoma channel necrosis, stoma malposition, or stoma polyp.

Reintervention was realized in 25.8% of patients (30.2% ≤ 1 year; 33,3% > 1 year). The reinterventions performed were stoma dilatation, stoma closure, stoma plasty, cystostomy catheter repositioning, abscess drainage, bladder neck closure, urethral sling, enterocystoplasty, urethrovesical fistula treatment by muscular transposition, AUS removal, uretroplasty, non-continent cystostomy, digestive diversion, digestive adhesiolysis, vesicotomy for lithiasis treatment.

Discussion

This study brings several interesting data about efficacy at short and middle term in adult neurologic patients with CCC.

Population of the study

One strength of this study is the evaluation of a large homogeneous population including only adult neurological patients.

Indeed, we included 53 patients in our study. Therefore, we would be a part of the largest adult populations available in the literature. Redshaw et al. evaluated 61 adults undergoing CCC creation, and Shpall's in 2004, included 39 patients in his study, [5,6] Szymanski et al. report on the results of 510 patients, however it included patients only under 21 years old [7].

Table 5 Results of efficacy and security of continent cutaneous channels, according to the type of stoma, between 1 year and the last follow-up for each patient.

	Mitrofanoff	Monti	Casale	Others	Total
Caracteristics					
n patient	19	13	8	2	42
Average time of follow-up	4.3	5.0	2.1	3.2	3.6
Efficacy	14 (73.7%)	6 (46.2%)	5 (62.5%)	1 (50%)	26 (61.9%)
Catheterizable stoma, *n* (%)	14 (73.7%)	9 (69.2%)	7 (87.5%)	2 (100%)	32 (76.2%)
Stoma continency, *n* (%)	14 (73.7%)	10 (76.9%)	4 (50%)	1 (50%)	29 (69%)
Security/complication					
Complications >1year, *n* (%)	12 (63.2%)	6 (46.2%)	3 (37.5%)	1 (50%)	22 (52.4%)
Reintervention > 1year, *n* (%)	5 (26.3%)	6 (46.2%)	2 (25%)	1 (50%)	14 (33.3%)
Stoma stenosis >1 year, *n* (%)	6 (31.6%)	9 (69.2%)	6.00	1 (50%)	20 (47.6%)
Catheterizable stoma stenosis > 1year, *n* (% stenosed stoma)	4 (66.7%)	7 (77.8%)	3 (50%)	1 (100%)	15 (75%)

Also, this study differs from a large number of articles mixing neurological and non-neurological bladder dysfunction, by focusing only on neurogenic bladder [8].

The neurologic diseases distribution seems to be similar between the different types of stoma, and doesn't seem to influence the choice of CCC surgical technique.

As in previous study, with a proportion of 47% of this population, rate of Mitrofanoff procedure is slightly higher than the others procedures whenever the appendix remains [8]. It can be explained by the fact that it is the first type of cystostomy described, and it had revealed a lower rate of stoma revision, and complications, especially metabolic and gastro-intestinal side effects [9].

The mean age was 46 (32—54). We observed a superior rate of women included.

The characteristics of our population are more balanced than the data shown in Phé's systematic review [8], considering the sex repartition, and the range of age.

The higher rate of women can be explained by a higher difficulty for women to catheterize the urethra. However, the effectives are small and prevent us from being certain about the comparability of the population.

The mean time of follow-up was 3.3 years, which is congruent with previous studies presenting results on 1.8—8.7 years of follow-up [8].

Primary and secondary outcomes

It appears in our study that CCC showed a moderate efficacy. Approximately the half of the population was simultaneously catheterizable, continent and did not need any reintervention.

We decided to choose a composite primary outcome because it seemed more relevant to define the efficacy of the CCC by including results of catheterizability, continence and absence of reintervention. We considered that these criteria reflect an optimal result of CCC for the patient. This is a difficult goal to achieve and this rate of efficacy is quite acceptable, knowing that a patient can present an absence of efficacy but still two over three of the items positives.

However, this assertion is purely speculative, but consistent with the results of the separate criteria. We didn't find any other study in the literature using the same composite criteria.

In our study, results of stoma continence and ability to catheterize the channel at 12 months were 84.9% and 77.3% respectively. These data remain consistent with the results of previous studies, which had reported a rate of 84% (58.3—100) for catheterizability and 75% (75—100) for stoma continency [8]. In some studies, stoma incontinence can reach 9 to 22% [2,3].

Rate of complications were 60.4% ($n = 32/53$) at 3 months, and 73.6% ($n = 39/53$) at 12 months.

Comparing to some articles in literature, we obtained a higher rate of complications and reintervention at any time of the follow-up [8].

However, it can be explained partially by the assessment of the complications and reintervention, which included all kind and gravity of complications and intervention. Considering only major complication, these rates appeared to be equivalent or lower to literature (17% at most for period before 3 months, and then 2% between 3 and 12 months, and after 12 years) [8].

Szymansky et al. showed a rate of complications from 18 to 26%, and including only stoma complications [6].

Also, these high rates of complications can be related, in part, to the associated surgical procedures performed in over 50% of the population (enterocystoplasty and bladder neck surgeries), which are high-risk surgeries. Unfortunately, no statistical analysis was performed in these studies because of the small groups obtained, no statistical differences would have been observed.

Additional results

In our study, channel stenosis occurred in 47.6% of patients after one year, in contrast with the rate of 4 to 33% cases described in the systematic review of Phé et al. [8]. Fifteen of the 20 patients (75%) with stoma stenosis were able to catheterize their stoma (Table 5).

These results may be explained by the fact that in our study, we considered as stoma stenosis any modification of the stoma size, even if it was still catheterizable without any difficulty. We decided to realize this strict assessment

show any clinical difference recorded by the physician or felt by the patient himself.

We diagnosed fewer urinary stones occurrences, with only 6 events in 6 patients (11.32%). The rate of urinary stone in CCC is usually around 20—25% [10—12]. However, lithiasis complications occurred hugely after 5 years of follow-up. Thus, these short-term observations cannot be analysed.

There were 3 bladder neck closures realised in our population, and it concerned only early cases.

According to Nguyen et al., bladder-neck closure is an irreversible procedure that should be reserved for cases of persistent severe stress incontinence after failure of prior procedures. Moreover, they reported a high rate of stoma stenosis (30%) and bladder stone (40%) after bladder-neck closure. His study was performed in a paediatric population [4]. Moreover, it has been suggested that the bladder neck and urethra were left open to preserve a ''pop-off mechanism'', which prevents the development of high intra-vesical pressure in case of CCC technical problem and allows easier access to the bladder if there are difficulties with catheterization or during endoscopic examinations [7].

Limitations of the study

We decided to study the events at 3 and 12 months as a primary and secondary outcome to avoid a large amount of loss to follow-up.

It is unfortunately shorter comparing to the longest time of follow-up in some studies performed, especially those performed in paediatric populations [10,11,13—21].

Our study was non-comparative and retrospective, and the results of our statistical analyses were non-significant.

However, we brought new data to this rarely studied topic.

We didn't show a significant difference of efficacy or complication between the different types of CCC but Mitrofanoff and Monti surgeries seemed to have better results.

It may be related to a lack of strength in this study, due to the small number of patients in every group.

That also limits us in the analysis of difference of efficacy and complications considering preoperative treatment on bladder capacity that influence the outcomes of continence, and associated surgeries that can impair the complications results.

Initially, we hoped for analyzing data about amelioration of urodynamic outcomes, and quality of life. Unfortunately, these informations weren't reported systematically in every medical report.

Detrusor hyperactivity status should be integrated to the analysis of CCC continence. Despite the high rate of missing data, we considered in this study, that patients presented a controlled detrusor hyperactivity (either they had an enterocystoplasty to treat that issue, either they didn't get that surgery if they already have been well controlled by medical treatments).

It has been well described that enterocystoplasty provides a long-term low-pressure reservoir with adequate volume, allowing less catheterization per day (4—6), increasing compliance, providing long-term upper-urinary-tract protection and continence, with few major complications [22].

However, we didn't include in the statistical analysis the association to bladder augmentation surgery, so we cannot highlight the implication of these associated surgeries on the efficacy or complications of CCC.

Another bias of our study is the retrospective design. Indeed, it would be necessary to have a larger prospective study running over at least 15 years. A long study managed by Liard during over 20years of follow-up showed the occurrences of complications of CCC even after 15 years [23].

Concerning the after-one-year data, the different criteria were considered as absent if the criteria weren't specified until the last medical visit recorded. This allocation method may have underestimated the rate of complications or overestimate the rate of efficacy.

Perspectives

We decided to assess information about body-mass index because we believe, as a morphologic index, it is a factor of decision between the different type of procedures, and related to the risk of postoperative complications, however these cofactors weren't included in the analysis, as well as bladder neck procedures and associated enterocystoplasty [24]. It would be interesting in a future study to analyse the impact of these cofactors on efficacy and complications of CCC surgeries.

We proposed an innovative composite criterion as primary outcomes, which seemed to us more clinically relevant. Being the only one in the literature to use these criteria, it was harder to compare our results to others, but we hope that future research teams will be interested in using these criteria.

It would be interesting to develop and share a standard report file, in every center performing these surgeries, to get strong data to analyze. And then, elaborate a shared protocol, for inclusion and follow up information's. It would facilitate the creation of a prospective, large and comparative study, or at least ease the comparability between different studies.

Conclusions

This study on a population of adult neuro-urological patients in a center of reference, confirm that CCC are an effective solution for these patients. However, the risk of complications is high with these surgeries and may require specific resources to manage them. That's why it probably should be performed preferentially by trained surgeons, and the medical care by experienced teams, to improve the results of the surgery.

It is one of the largest studies available, and it contributes to the knowledge of CCC by adding information to a topic rarely studied. It would be beneficial to perform a large prospective study, potentially multi-centric to regroup small effectives, based on a standard report file, to improve our knowledge on the CCC.

Disclosure of interest

The authors declare that they have no competing interest.

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