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Bulking agent treatment of incontinent catheterizable channels in pediatric patients and young adults

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Summary

Background
Catheterizable continent channels (CCC) provide means for urinary continence when urethral catheterization is not feasible. However, some patients present with stomal incontinence warranting further interventions. The purpose of this study is to evaluate the effectiveness of endoscopic injection (EI) of bulking agent (Deflux©) as a minimally invasive treatment for CCC incontinence and to explore patient-specific variables influencing outcomes in a pediatric cohort.

Methods
Hospital's pediatric urology procedure registry was retrospectively reviewed to identify all patients with a CCC and at least one EI of bulking agent for the leakage of the stoma at our institution between 2001 and 2021. The postoperative outcomes were assessed three months after the procedure and annually thereafter.

Results
A total of 21 children and young adults were included with CCC indications including neurogenic bladder (n = 13), bladder or cloacal exstrophy (n = 5) and other conditions (n = 3). The most common channel type was appendicovesicostomy (n = 7) followed by Monti tube (n = 5), spiral Monti (n = 3), ureter (n = 3), and other types (n = 3). The median age at first EI was 9.7 years (IQR 8.2—15.1) with a median follow-up time of 4.0 years (IQR 1.2—6.7). At follow-up, 11 patients (52 %) achieved continence. Surgical correction was ultimately required in nine patients (43 %) due to incontinence and in three patients for other reasons. No patient (0 %) experienced long term benefit from >1 injections.

Conclusion
Endoscopic injections offer a minimally invasive option and can be considered a first-line approach for treating CCC incontinence. However, surgical correction remains necessary for some patients. In our material, re-injections were ineffective.

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Introduction

Patients with neurogenic bladder or with severe structural anomalies face a lifelong burden of frequent investigations and interventions aimed at protecting the kidneys and managing urinary function. Clean intermittent catheterization (CIC) is a cornerstone of bladder management and has been associated with fewer bladder dysfunction symptoms compared to other techniques [1]. However, for patients with anatomical challenges, orthopedic deformities, or impaired motor function, performing CIC via the urethra may become difficult or impossible. In such cases, catheterizable channels (CCCs) provide a valuable alternative, allowing bladder access through a surgically created conduit [2].

Despite their utility, CCCs are prone to complications such as stomal stenosis and leakage, which can significantly impair health and affect quality of life. Reported rates of stomal incontinence range from 1 to 47 %, difficulty with catheterization from 5 to 32 %, and the need for surgical revision from 18 to 58 %, depending on follow-up duration and channel type [2—4]. Stomal incontinence, often resulting from inadequate valve function, poses a particular challenge and traditionally requires invasive surgical correction, further increasing the patient's surgical burden [5].

Minimally invasive approaches, such as endoscopic injections of bulking agents, offer a potential alternative to surgical revision for treating stomal incontinence [6]. While results from small series have been variable, no significant differences in outcomes have been observed between the different bulking agents used, including Teflon©, Deflux©, Bulkamid© and Macroplastique© [6—9]. Given the significant impact of urinary incontinence on health-related quality of life (HRQoL) [10—12], refining minimally invasive treatments is crucial to improving outcomes and reducing the need for surgical revisions. However, the existing literature is limited by several factors. Many previous studies have involved small patient cohorts and short follow-up periods, and few to none have analyzed outcomes based on patient-specific characteristics. These limitations impede a comprehensive understanding of which patients may benefit most from these interventions and underscore the need for further investigation into optimizing treatment strategies for stomal incontinence.

This study aims to evaluate not only the effectiveness of endoscopically injected bulking agent as a minimally invasive treatment for stomal incontinence, but also comparing the results to patient-specific variables focusing on outcomes related to continence and complications. Our primary outcome measure is urinary continence with the secondary outcome measure being surgical revision rate.

Materials and methods

With approval from the institutional review board, we reviewed the hospital's pediatric urology procedure registry to identify all patients with catheterizable channels (CCCs) and at least one bulking agent injection treatment for the leakage of the channel at our institution between 2001 and 2021. Data was collected from the hospital medical records and every incontinent CCC case was retrospectively reviewed. Collected data included demographics, underlying diagnosis, age at CCC surgery, site for stoma creation, tissue used, age at injections, number of injections and sessions, injectable substance amount, augmentation history, duration of follow up and outcomes. The study was approved by the institutional review board (HUS/180/2020).

We identified 25 patients, three of whom were excluded because of unknown results and a fourth one since having a catheter constantly in the channel leaving a total of 21 patients for retrospective analysis. Every patient was seen at our hospital during their annual treatment visits for CCC. Each channel was originally constructed with the aim of achieving a standard 3 cm anti-reflux channel in the bladder wall or relying on the natural anti-reflux mechanism when ureters were utilized. Bulking agent injection treatment was offered to patients reporting disturbing urinary leakage. The treatment decision was guided by the patient's CIC diary, verbal report, and subjective experience of the leakage. A urodynamic study was performed for all patients prior to the injections to confirm an age-appropriate bladder size and normal pressure.

The endoscopic injection technique was standardized. A flexible needle (Cook Williams Cystoscopic Injection Needle, 3.7 F 23G, Cook Medical, Bloomington, IN, USA) was inserted under the channel mucosa 1—2.5 cm outwards from the bladder junction and an average of 3 injections (range 2—5 injections) with a median instilled volume of 3.5 mL (range 2—5 mL) were performed and positioned side by side. Injection substance was dextranomer/hyaluronic acid copolymer (Dx/HA, Deflux©). The procedure was performed using pediatric cystoscopes with a working channel and a 0-degree lens. Patients were under general anesthesia during the treatment and an indwelling catheter was left in the channel for 3—5 days after the procedure. The majority of the endoscopies were done through the channel, but in a few cases, a cystoscopy via urethra had to be combined for achieving an adequate result. The continence immediately after the procedure was ascertained with manual compression of the half full bladder.

Pre-operative continence was categorized as daily incontinence or rare incontinence and postoperative continence was categorized as fully continent, rarely incontinent and daily incontinent. Postoperative outcomes were assessed three months after the procedure and during annual follow-up visits from then on. Patients provided CIC diary and verbal reports on the level of leakage (or absence thereof) which were supplemented by routine ultrasound examinations of the urinary organs. In unresponsive cases, injection treatment was typically repeated 1—2 times, after which revision surgery was discussed. Our classification aligns with the International Children's Continence Society (ICCS) guidelines, where 'rare incontinence' corresponds to a partial response (50—99 % reduction in leakage episodes) and 'fully continent' corresponds to a complete response (100 % resolution of incontinence) [13]. This standardization facilitates comparability with existing literature and future studies.

Descriptive statistics were used to summarize the data. Continuous variables, such as age at initial channel surgery and follow-up duration, were reported as medians and interquartile ranges. Categorical variables were presented

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as frequencies and percentages, including patient demographics, channel types, and treatment outcomes. No formal hypothesis testing was conducted except for Fisher's Exact Test, which was used to compare the effectiveness of repeat injections to the primary injection. A p-value <0.05 was considered statistically significant.

Results

We identified 21 patients, ten males and 11 females, with ten ambulatory and 11 wheelchair-bound. Indications for CCC creation were diverse. 13 patients had a pure neurogenic bladder, six patients a structural disease and two patients had both structural disease and a neurogenic bladder. The median age at initial channel surgery was 8.2 years (IQR 6.6–11.8). The most common channel type was an appendicovesicostomy (7/21), followed by Monti tube (5/21), spiral Monti (3/21), ureter (3/21), and other types (3/21). In most cases, the channel orifice was in the lower abdomen (19/21), with two exceptions having umbilical orifices. Additionally, 15 patients (71 %) had undergone prior bladder augmentation, including enterocystoplasty (12/15), autoaugmentation (2/15), and ureterocystoplasty (1/15). The demographics are summarized in Table 1.

The median age at the first Deflux© injection was 9.7 years (IQR 8.2–15.1), with a median interval of 1.2 years (IQR 0.7–2.8) between the original stoma surgery and the injection. Patients were followed after EIs for a median of 4.0 years (IQR 1.2–6.7), with a minimum one-year follow-up post-injection or until surgical revision in each case. The median age at the last stoma evaluation was 15.4 years (IQR 12.9–20.9) (Table 1).

Following the initial Deflux© injection, 6/21 patients achieved full continence, while 5/21 experienced rare episodes of incontinence after the follow-up. For both groups, the treatment was considered successful. Among these 11 patients with satisfactory results, three did not achieve optimal continence immediately after the injection but showed gradual improvement over time. One of these patients with rare incontinence underwent repeat EI once, from which he did not receive additional help and remained rarely incontinent.

Ten of the 21 patients experienced unsatisfactory long-term results following the initial Deflux© injection with four of them having adequate primary response but only up to 6 months. Among those with persistent leakage, seven patients underwent repeat EIs (4 patients once, 2 patients twice and one patient four times). However, repeat EIs did not result in long-term continence for any of these patients, and all seven patients eventually required revision surgery. The overall results are presented in Fig. 1.

Altogether, 11 patients (52 %) achieved satisfactory outcomes with endoscopic injections, including five patients who became fully continent and six who experienced rare incontinence. In contrast, ten patients (48 %) continued to experience daily incontinence, prompting nine of them to undergo surgical correction of their catheterizable channel. One patient did not have revision surgery despite continuing disturbing incontinence. Another patient with ureterocystoplasty started to void naturally, and the rarely leaking CCC was subsequently closed.

Table 1 Demographics

Demographics	
Study cohort	21
Gender, female	11 (52 %)
Ambulatory status, walking	10 (45 %)
Stomal age, y	8.2 (IQR 6.6–11.8)
Bladder augmentation, total	15 (71 %)
Enterocystoplasty	12 (57 %)
Autoaugmentation	2 (9 %)
Ureterocystopalsty	1 (5 %)
Type of channel	
Appendix	7 (33 %)
Montitube	5 (24 %)
Spiral Monti	3 (14 %)
Ureter	3 (14 %)
Other	3 (14 %)
Orifice	
Lower abdomen	19 (91 %)
Umbicus	2 (9 %)
Injections	
Age at 1st injection, y	9.7 (IQR 8.2–15.1)
Time between stoma and 1st injection, y	1.2 (IQR 0.7–2.8)
Injection route, number	
Channel	26
Bladder and channel	4
Bladder	1
Unclear	3
No of injection sessions per patient	
1	13 pts (62 %)
2	5 pts (24 %)
3	2 pts (9 %)
5	1 pts (5 %)
Amount of dfl in one session, mL	3 [2–5]
Number of injections in one session	3 [2–5]
Follow up time, y	4.0 (IQR 1.2–6.7)
Age at final (stoma) control visit, y	15.4 (IQR 12.9–20.9)

Additionally, two patients underwent CCC revision due to increasing difficulties with catheterization, increasing the total surgical revision rate to 57 % when all indications are included. The detailed results are presented in Table 2.

Due to the small sample size and cohort heterogeneity, definitive conclusions regarding the influence of patient characteristics on the outcomes of endoscopic injections are limited. However, some patterns were observed (Table 2). The efficacy of re-injections was poor compared to the primary injection, as the continence achieved was lower (0 % vs 52 %, $p = 0.01$) and the surgical revision rate remained higher (100 % vs 57 %, $p = 0.03$) after follow-up. Patients with appendicular channels exhibited the lowest continence rates (29 %) and the highest surgical revision rates (86 %) compared to other channel types, where Monti tubes and ureter-based channels achieved higher continence rates (60–67 %) and lower revision rates (33–40 %). Bladder augmentation did not appear to improve continence rates (53 % vs. 50 % without augmentation), but it

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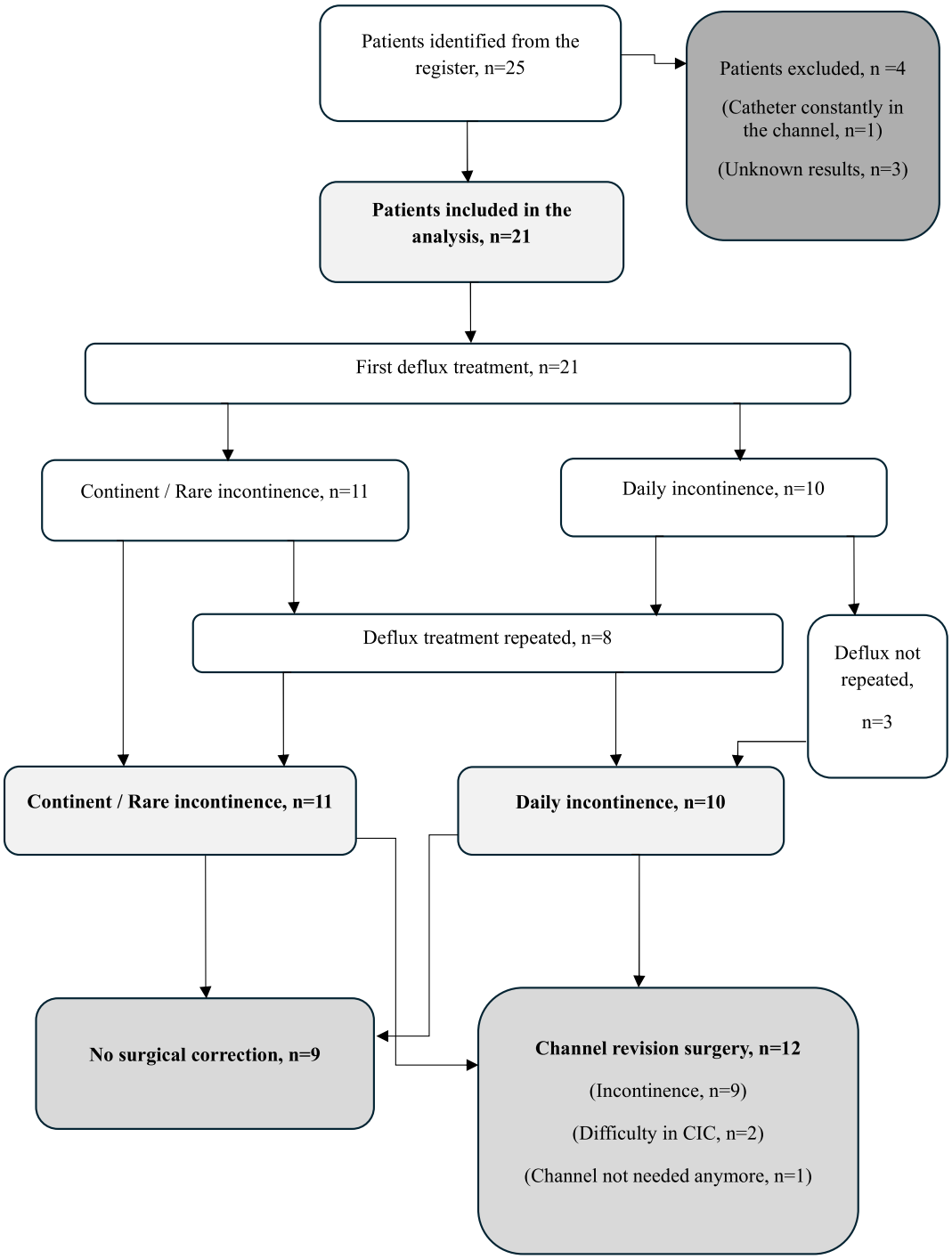

Fig. 1 Patient identification and treatment outcomes

was associated with a higher revision rate (67 % vs. 33 % without augmentation).

Diagnoses such as MMC showed better outcomes (70 % continence, 30 % revision), while cloacal malformations had poorer continence rates and higher revision rates. These findings suggest that anatomical factors, including the type of catheterizable channel, may influence outcomes. However, more extensive studies are required to confirm these associations.

Discussion

Catheterizable channels provide a valuable alternative for patients unable to perform urethral catheterization, but complications such as stomal incontinence frequently necessitate additional interventions [3]. Our study examined the outcomes of minimally invasive Deflux© injections as a treatment for stomal incontinence within this population. Overall, 52 % of patients achieved full continence or

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Table 2 Results of injections

	n	Continent	Rare incontinence	Daily incontinence	Surgical revision
Diagnosis					
MMC	10	5	2	3[d]	3[a] (30 %)
Cloacal exstrophy	4	0	1	3	4[a] (100 %)
Cloaca	2	0	0	2	2 (100 %)
Bladder exstrophy	1	1	0	0	0 (0 %)
Caudal regression	1	0	1	0	0 (0 %)
Paraplegia and diastrofic dysplasia	1	0	0	1	1 (100 %)
Sacrocoggygeal teratoma	1	0	0	1	1 (100 %)
Posterior urethral valves	1	0	1	0	1[b] (100 %)
Augmentation					
Bladder augmentation	15	4	4	7	10[c] (67 %)
No augmentation	6	2	1	3[d]	2 (33 %)
Type of channel					
Appendix	7	1	1	5	6[b] (86 %)
Monti tube	5	1	2	2	2 (40 %)
Spiral Monti	3	1	1	1	1 (33 %)
Ureter	3	2	1	0	1[a] (33 %)
Other	3	1	0	2[d]	2[a] (67 %)
Injections					
One Deflux injection	21	6	5	10[d]	12[c] (57 %)
Repeat Deflux injections	8	0	1	7	8[b] (100 %)
Level of incontinence before Deflux					
Daily incontinence	18	5	4	9[d]	11[c] (61 %)
Rare incontinence	3	1	1	1	1 (33 %)

[a] Surgical revision for one patient because of difficulty in CIC.
[b] Surgical closure for one patient because the channel was not needed anymore.
[c] Surgical revision for two patients because of difficulty in CIC and for one because the channel was not needed anymore.
[d] One patient did not have surgical revision despite daily incontinence.

rare incontinence through Deflux© injections alone, supporting the role of minimally invasive options as a possible management for selected patients. However, repeat injections offered no additional benefit for patients who remained incontinent after the first treatment. The incontinence rates were similar regardless of bladder augmentation status. Appendicular channels showed a higher rate of persistent incontinence (71 %) compared to channels constructed from small intestine (Monti) (33—40 %). While 57 % of patients (43 % due to incontinence) eventually required surgical correction, our findings emphasize that minimally invasive treatment can provide benefits for a subset of patients, reducing the need for surgical intervention.

Our long-followed material, while limited, represents one of the largest pediatric series reported thus far. The results differ in many respects from those previously reported. Prieto et al. had a success rate of 71 % continence after a single endoscopic bulking agent injection in carefully selected adult and pediatric patients (n = 14) [6]. In material comparable to ours (n = 22), but with retrograde endoscopic approach, Riachy et al. reported a successful primary injection of a bulking agent in only 20 % of patients, whereas the second injection increased the success rate to near 75 % [8]. Kass-iliyya et al. in turn observed in their adult patient material (n = 24), that patients with appendiceal channels and colonic reservoirs had higher rates of continence following endoscopic injections than patients with Monti channels and ileal reservoirs [9]. In a small series of eight patients with nine incontinent CCC and ACE stomas together, Roth et al. reported a success rate as high as 86 % after a single bulking agent injection treatment [7]. In a dataset of the same size, Koivusalo et al. also studied the effectiveness of bulking agents in the treatment of ACE incontinence and found that after an average of 2 endoscopic injection procedures, all patients achieved continence. Unfortunately, this response was not durable, and only 38 % of patients reported improved continence at 2 months [14].The literature on Deflux© treatment for incontinence of catheterizable channels remains scarce, underscoring the need for further studies to establish its long-term efficacy.

Although varying, our findings, together with previously reported results suggest, that while minimally invasive interventions offer benefits and should be considered as a first-line approach, surgical correction remains a valuable option for those whose continence needs are not fully met by Deflux© alone. Approaches to achieving continence in this population thus include both minimally invasive and traditional surgical options, depending on individual patient needs and anatomical factors.

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Our study has limitations. First, we have not been able to measure the amount of incontinence and hence the results are categorical and based on the CIC diaries and patient's own report without measuring the volumes of the leakage. In addition, compliance with treatment varied and potentially influenced the results. Insufficient urinary diary keeping was rather common between control visits. It is possible that without enough compliance the catheterization has not been performed with adequate frequency promoting urinary incontinence. Future studies with larger cohorts may elucidate the impact of these variables better.

The use of proper patient reported outcome measures and urination diaries, along with methods to quantitatively measure incontinence, could yield more unambiguous and comparable data in the future. While objective measurements can enhance precision of treatment outcomes, patient-reported experiences remain paramount, as it is ultimately the patient who determines the success of the intervention based on their level of bother from leakage. Incorporating both perspectives would enhance our understanding of treatment efficacy and support more tailored, patient-centered management approaches for this complex patient population. Ultimately, treatment must remain patient-oriented, addressing the individual's subjective experience and needs.

Conclusion

Incontinent CCC significantly impacts a patient's health and quality of life. Our reported continence rate of 52 % together with those previously established suggest that while EI of a bulking agent provides a convenient first-line approach in treating incontinent CCC, surgical correction remains an important option for those whose continence needs are not met by EI alone. In our material, re-injections offered no additional benefit for patients who remained incontinent after the first treatment. Definitive conclusions regarding the influence of patient characteristics on the outcomes of endoscopic injections remained otherwise limited. Future studies with larger cohorts may elucidate the impact of patient specific variables better.

Availability of data and materials

The dataset supporting the conclusions of the current study is available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The study was approved by the institutional review board (HUS/180/2020). All methods were carried out in accordance with the Declaration of Helsinki.

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Conflict of interest

None of the authors have conflicts of interest to declare.

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