Journal of Pediatric Urology (xxxx) xxx xxx

Medium- and long-term results of botulinum toxin injection in patients with bladder augmentation: A retrospective study and literature review

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Keywords
Neurogenic bladder; Augmentation bladder; Overactive bladder; Botulinum toxin; Botox; Exstrophy epispadias complex

Received 7 November 2024
Revised 22 April 2025
Accepted 16 May 2025
Available online xxx

Summary

Objective
To determine the medium and long-term results and safety of botulinum toxin treatment in enlarged patients with incontinence secondary to overactive bladder and compared it with literature review.

Materials and methods
a prospective study was performed analysing the results of 41 procedures performed between 2010 and 2023 in a total of 14 patients with a history of bladder augmentation and clinical or urodynamic findings suggestive of overactive bladder or low compliance.

Results
A total of 41 procedures were performed on 14 patients. 71 % of patients received previous oral treatment, the average between the bladder augmentation and the first injection was 20 years. The re-injection rate was 71 % with a mean time between procedures of 19 months. 61 % of the patients presents clinical response. No differences were found in terms of underlying pathology, epidemiological factors, urodynamic parameters or combined vs single bladder patch injections. Differences were found regarding previous use of anticholinergic treatment.

Conclusions
Botulinum toxin treatment is safe and effective for patients with cystoplasty and may avoid a major procedure in those patients than show symptomatology or urodynamic findings with overactive bladder or a low accommodation.

https://doi.org/10.1016/j.jpurol.2025.05.017

Introduction

The first line treatment of both, idiopathic and neurogenic overactive bladder is medical treatment and in case of failure, the next therapeutic step includes botulinum toxin injection [1,2].

When all previous treatments fail, or the scenario shows a high risk bladder, the gold standard treatment is a bladder augmentation (AB) whose main objective is to increase bladder capacity, avoid renal damage and improve continence, as well as the patients' quality of life.

Although the success rate of AB is around 70—90 %, in 20—36 % of cases, symptomatology or changes suggestive of therapeutic failure may reappear. Although there is no protocolized treatment for this group of patients, there is a dichotomy between a more extensive treatment such as bladder reagumentation or a more conservative treatment such as botulinum toxin injection [3,4].

Materials and methods

A retrospective study was made of patients with a history of bladder augmentation who underwent treatment with botulinum toxin injection between 2010 and 2023. This study was approved by the Ethics Committee of Fundació Puigvert (Approval number: O2024/50).

Treatment efficacy was defined as improvement or disappearance of urinary symptoms and improvement of urodynamic parameters detected in the postoperative urodynamic study, the urodynamic parameters assessed were: maximum bladder capacity (BCmax), compliance or DLPP, volume infused in the first contraction and pDetmax. Additionally, questionnaires (TBS, treatment Benefit scale) (Table 1) were used to establish the patients' perception of their clinical improvement. The safety of the procedure was assessed using the Clavien Dindo classification to describe the adverse effects secondary to treatment.

Table 1 TBS scale.

Well Improved	1
Improved	2
No changes	3
Worse	4

All patients with clinical urgency with or without incontinence or OD previously demonstrated by urodynamic study were offered oral treatment with detrusolytic drugs (anticolinergic or beta 3 adrenergic) until the maximum dose was reached according to tolerance and response, for at least 8—12 weeks, after which the patient was reassessed. Patients who did not respond to the treatment or rejected it and the patient with low compliance, were proposed for treatment by injection of botulinum toxin. The contraindications for the botulinum toxin injection were: hypersensitivity to botulinum toxin or any of its excipients, active urinary infection, a medical history of myasthenia gravis or Eaton-Lambert disease, as well as prior botulinum toxin injection within the 6 months prior to the proposed treatment.

The procedure was performed in all cases under antibiotic prophylaxis with cephalosporin in case of previous negative urine culture or under targeted antibiotic treatment in case of positive urine culture 7 days prior to the procedure. Under general anesthesia and with a rigid cystoscope of 20 Ch or a pediatric cystoscope of 9.5 Ch, urethral or transmitrofanoff route according to the characteristics of each patient, 100 and 300U of botulinum toxin (Botox®) diluted in 10 ml of saline were injected. Until 2017 the injections were performed only in the bladder remnant, from there until today the punctures were performed in both patches: bladder and bowel and since then the distribution was attempted by 5 or 10 punctures in intestinal patch and 5—10 punctures in bladder patch (0.5 ml or 1 ml) always respecting the trigonal area (Fig. 1).

For Botox injection in patients with bladder augmentation, we use the InjeTAK® cystoscopic injection needle from Laborie Medical Technologies, as it allows adjusting the needle depth between 1 and 5 mm (Fig. 2). For the injection in the intestinal patch, there are two points that the authors consider important: the first is that the bladder should not be completely full, and the second is to reduce the needle length to 3 mm, as the wall of the intestinal patch is usually thinner than the wall of the bladder patch, for which we use a needle length of 4 mm.

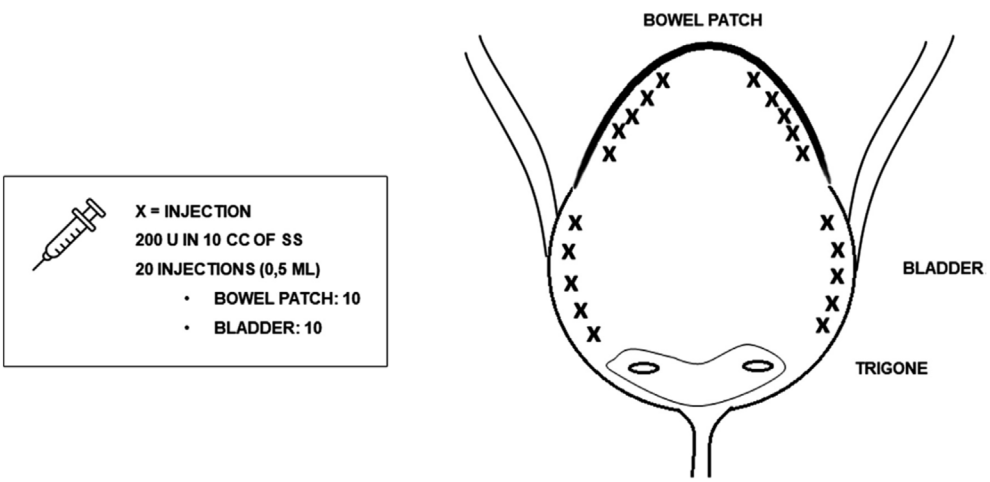

Fig. 1 Distribution of Botox puncture sites in AB.

Please cite this article as: Jiménez-Corro R et al., Medium- and long-term results of botulinum toxin injection in patients with bladder augmentation: A retrospective study and literature review. Journal of Pediatric Urology. https://doi.org/10.1016/j.jpurol.2025.05.017

Fig. 2 InjeTAK cystoscopic injection needle.

Subsequently, a clinical control was performed 3 months after surgery to evaluate complications and efficacy using the TBS questionnaire. An UDS under the effect of Botox® treatment was considered in those cases in which there was no clinical improvement, presented a high risk bladder or an ultrasound showed dilatation of the upper urinary tract. The urodynamic parameters assessed were: maximum bladder capacity (BCmax), compliance or DLPP, volume infused in the first contraction and pDetmax.

Statistical analysis

The data analysis was performed with STATA 17 using descriptive statistics; a bivariate statistical analysis was performed using Pearson's chi-square test, Fisher's exact test, and Student's t-test. Fisher's exact test was used to analyze categorical variables, while Student's t-test was applied to compare continuous variables between two groups.

Results

From 1995 to 2023, a total of 133 bladder augmentations were performed at our center. Of these, starting in 2010 (when the use of botulinum toxin was approved for patients with bladder augmentation), 14 patients (10.5 %) underwent botulinum toxin injection due to symptoms of overactive bladder or poor bladder compliance. A total of 41 procedures performed in 14 patients from 2010 to 2023 were analyzed, with a median age of 30.45 years (11—50 years). Descriptive data regarding sex, type of urinary diversion, clinical record and age are summarized in Tables 2 and 3.

All patients had urgency with incontinence, and one had severe low compliance (15 ml/cm H2O) with high pressure bladder [5]. Of the 14 patients, 10 (71.4 %) were under medical treatment with anticholinergic or beta-3-adrenergic at full dosage for at least 8—12 weeks without response, the other 4 refused oral treatment due to severe constipation or lack of previous efficacy. All patients followed a CIC protocol, with catheterization recommended every 3—4 h and a maximum of 400 mL per void. For high-pressure bladder cases, the frequency was increased to every 2 h. Following botulinum toxin injection, no significant changes were observed in the CIC frequency.

The median time of symptom onset since AB was 102 months (6—336 months), and the median time between AB and the first Botox® injection was 20 years (1.7—32 years).

Ten of the 14 patients (71.4 %) had Botox re-injected with a median of 4.37 injections (2—10). The mean time between Botox injection and recurrence of symptoms was 8.82 months (2—24 months).

Table 2 Epidemiologic data.

Pacient	Sex	Clinical record	Type of augmentation	Age at AB (years)	Time symptoms onset (years)	Previous treatment	Drug
1	F	Epispadias	Colocistoplasty + mitrofanoff	20	15	Sí	Solifenacin/Fesoterodin
2	M	MMC	Colocistoplasty + Mitrofanoff	32	7	No	
3	M	ECC	Ileocistoplasty + Mitro + bilateral reimplantation	8	5	Sí	Oxibutinin/Fesoterodin/ Fesoterodin + Mirabegron
4	F	MMC	Colocistoplasty	24	1	Sí	Mirabegron/Oxibutinin
5	M	Ochoa Syndrom	Colocistoplasty + Right Reimplantation	26	2	No	
6	F	ECC	Ileocistoplasty + Reimplantation	7	16	No	
7	M	MMC	Colocistoplasty	22	9	No	
8	F	ECC	Colocistoplasty + bilateral reimplantation + BNR + mitrofanoff	9	3	No	
9	F	MMC	Colocistoplasty + bilateral reimplantation + AUE	15	31	Sí	Mirabegron
10	F	MMC	Colocistoplasty + left reimplantation + mitrofanoff + RT	11	5	Sí	Solifenacin
11	F	ECC	Colocistoplasty + left reimplantation + mitrofanoff	17	23	Sí	Solifenacin
12	M	MMC	Colocistoplasty	22	10	Sí	Solifenacin
13	F	MMC	Colocistoplasty + bilateral reimplantation + Casale	4	28	Sí	Solifenacin
14	M	ECC	Colocistoplasty + Mitrofanoff	31	19	Sí	Solifenacin

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Table 3 Summary of epidemiological, clinical and surgical data.

Item	Number/Percentage
Sex	6 ♂/8 ♀
Median age	30.45y (11—50)
Clinical Record	6 EEC/7 MMC/1 Ochoa Sd
Symptoms	13 urge-incontinence/1 low accomodation
Previous treatment	10 (71.4 %) anticol or β3-adr.
Mean time from AB to symptoms	8.5 y (0.5—28)
Mean time betwen AB and botox	20 y (1.7—32)
Reinjection	10 (71.4 %)
Complications *(Clavien — Dindo)*	3 (7.3 %) UTI
Clinical improvement	61 %
TBS score	1-2 86 %/3 14 %

The most recent patient is still in follow-up pending duration of response to consider a new injection.

Until 2017, injections were performed only in the bladder remnant; since then, punctures were performed in both the bladder and bowel patch, 31 procedures out of 41 (75.6 %).

Regarding complications according to the Clavien-Dindo system, no systemic effects were observed; 3 non-febrile urinary tract infections (Clavien-Dindo II) resolved with oral antibiotic treatment (7.3 %), and no other complications were observed.

Urodynamic changes were performed only in those patients in whom radiological or clinical changes were evident, with no statistically significant findings in any of the parameters analysed: BMC, pDetmax, first contraction volume or accommodation.

Discussion

AB is an effective alternative for patients with bladder dysfunction refractory to medical treatment [6,7]. Despite high success rates of up to 90 %, it is a surgery that is not free of complications, the most frequent of which are: voiding difficulty, UTI, bladder lithiasis and metabolic disorders [8—12].

In addition, clinical or urodynamic failure may also occur, depending on the series, between 26 and 30 % [13,14]. The most frequent clinical manifestation is either the persistence or appearance of urinary incontinence or urodynamic changes, the most common being changes in accommodation bladder. Despite the limitations of our study, such as its retrospective design and the fact that not all patients underwent urodynamic studies following botulinum toxin injection, our results are in line with those previously reported in the literature. In our series, the most frequent symptom at both debut and follow-up was clinical manifestation in the form of urge incontinence; only one case presented low compliance without clinical repercussions.

According to Martínez [14], the clinical expression may occur early, which would be due to a failure in the surgical technique: either by choosing a very short intestinal segment with tension of the mesentery or by a very large bladder remnant with persistence of the previous overactivity, or delayed, in which case it is hypothesised that it may be due to chronic ischaemia of the mesentery causing fibrosis of the intestinal patch or by de novo overactivity. All bladder augmentations performed at our center followed standard, well-established surgical techniques within the accepted range of clinical care. In our series, the mean interval between bladder augmentation and the onset of symptoms was 8.5 years. Only one of the 14 patients (7 %) developed symptoms within two years post-augmentation, while the remaining cases occurred between 6 and 31 years after surgery.

Based on classical techniques for bladder augmentation [15—17], the intestinal segment must be detubulated and configured in a spherical shape to increase its surface area, and thus achieve greater bladder capacity at a lower pressure; however, it has been described that the intestinal segments used may retain their intrinsic contractile properties [17]. The question that arises in these cases is whether, on urodynamic study, the presence of uninhibited contractions is due to de novo overactivity or to the intestinal segment's own contractions. Whatever the cause, it is postulated that the use of botulinum toxin may be useful as a treatment in symptomatic patients [13,4,18].

The first study on botulinum toxin puncture in neurogenic patients was published by Shcurch in 2000 and in paediatric patients with spina bifida in 2002 [19,2]; however, there are not many references in the literature on botulinum toxin puncture in patients with bladder augmentation [20]. The first publication on the subject was reported by Apostoilidis in 2007 [1] and the largest series described to date has been the Enterotox study [13].

Regarding the results in these patients, Hascoet et al. [21,22] reported a better clinical response (66 %) than urodynamic response (38 %); Eight of the fourteen patients (57 %) underwent urodynamic studies within four months following the botulinum toxin injection; the urodynamic response being defined as an improvement in accommodation parameters and MBC. Similar with these results, our series shows a clinical response of 61 % compared to a urodynamic response which, according to the parameter assessed, was as follows [23] (Table 4).

Since McGuire [24,25] established a DLPP >40 cm H2O as a risk for renal impairment, several studies have been conducted to more accurately establish this risk [26,27]: Tanaka publishes the results of a multicentre study

Table 4 Urodynamic response following botulinum toxin injection in the present study, according to the parameter assessed.

UDS (8 patients, 14 procedures)	Percentage	Mean
Compliance	53.8 %	9.6 cm H2O
MBC	30.7 %	−77 ml
Volume first contraction	69 %	122 ml
pDetmax	77 %	−11.6 cm H2O

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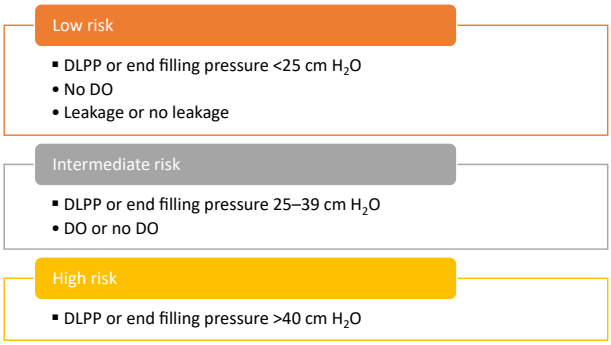


Fig. 3 Risk stratification for renal deterioration in children with spina bifida, according to Tanaka et al. [28] DLPP, detrusor leak point pressure; DO, detrusor overactivity.

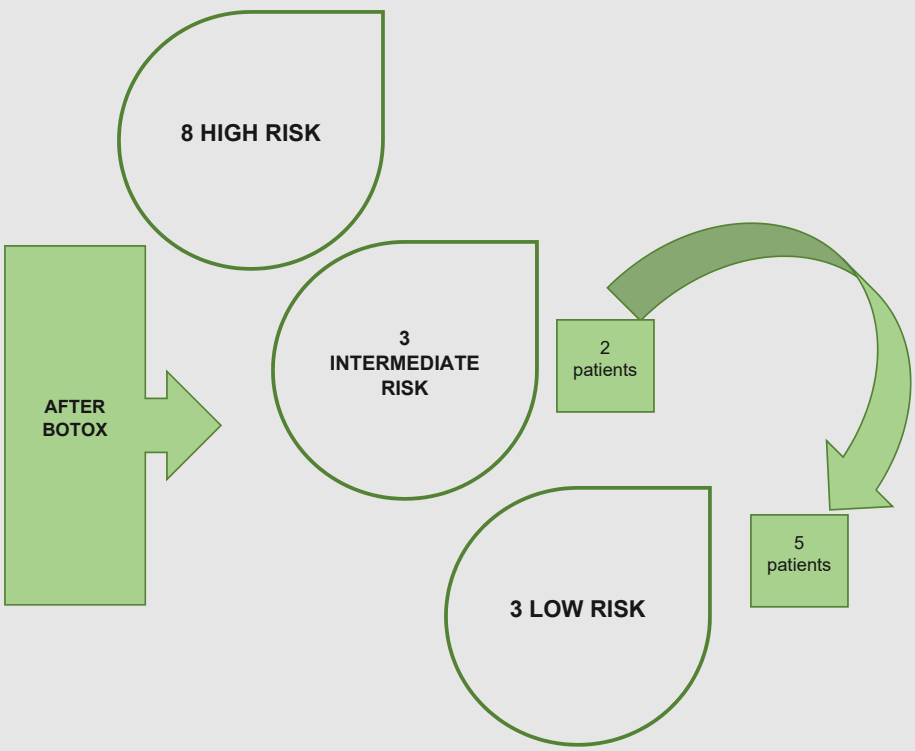
(UMPIRE) [28] that stratifies patients with spina bifida at risk for developing renal failure (Fig. 3).

Bowen [3] attempted to unify clinical and urodynamic criteria in order to establish which neurogenic patients would be candidates for more conservative surgery such as botulinum toxin injection and which for augmentation bladder: of a total of 16 patients at risk for AB according to the NBPSR classification, only 3 became intermediate risk, and 10 according to the LCH classification; the intermediate risk patients remained the same, showing improvement in accommodation in all cases. In our series, using the UMPIRE study classification: 8 patients meet high-risk criteria, 3 intermediate-risk and the other 3 low-risk. After botox puncture, there were no changes in the high-risk patients, but the 3 patients belonging to the intermediate risk group showed an improvement in accommodation, with only one patient remaining in this group and 5 in the low risk group (Table 5). The improvement in accommodation was seen in 53.8 % of patients.

In the same study, it is analysed how many patients end up in AB despite botulinum toxin injection: 43 % with a median time between botox injection and AB of 3.7 years versus 38 % who continued with periodic punctures. In our series, to date, all patients follow a programme of periodic injection of botulinum toxin, paying special attention to the patient with high-pressure bladder.

Regarding botulinum toxin injection in the bladder remnant or combined (bladder remnant + bowel patch), there are no significant differences, both options being safe [13,14,30]. In our series, 10 of the 41 (24.4 %) procedures were performed before 2017 in the bladder patch, after that combined injection was performed in a total of 31 (75.6 %); in 3 patients both techniques were performed. In agreement with other series, no significant differences were found in our study in terms of duration, recurrence of symptoms or complications including those patients who underwent both techniques. Although no significant differences were found between the two techniques in our small series, the rationale for continuing to inject both bladder and intestinal patches remains. Dr. Pope's study suggests that, despite proper surgical technique, some augmented bladders—especially those with ileal or ileocaecal segments—can retain segment-specific contractions. Specifically, up to 16 % of these

Table 5 Flowchart according bladder risk after treatment with Botox®.



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bladders exhibit large amplitude contractions, which may lead to urge incontinence, and up to 6 % may present with contractions >40 cm H2O, increasing the risk of upper urinary tract complications. For this reason, we continue injecting both patches to address potential overactivity from both the bladder and intestinal segments. Additionally, Gourcerol's work supports the safety and effectiveness of rectal pouch injections for fecal incontinence secondary to rectal overactivity [31]. To further investigate any differences, we are conducting a larger study with a broader patient sample.

Although there is no protocol for treatment failure in patients with AB, it is proposed that those who do not wish to undergo major surgery or who respond well to a first injection of botulinum toxin may be offered further treatment and those who wish a more definitive solution should be offered major surgery such as bladder reaugmentation [16].

Conclusions

Botulinum toxin treatment is safe and effective for patients with bladder augmentation and may avoid major surgery in those patients in whom symptomatology or a high-pressure bladder appears or recurs.

In our series, combined puncture has been shown to be as safe and effective as puncture of the bladder remnant alone.

Prospective studies are needed to establish risk factors in order to know which patients may be candidates for major treatment such as bladder enlargement in the first instance and which are candidates for more conservative treatment.

Conflict of interest

None.

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