Arab Journal of Urology (2013) **11**, 344–349

Arab Journal of Urology
(Official Journal of the Arab Association of Urology)

www.sciencedirect.com

VOIDING DYSFUNCTION / FEMALE UROLOGY
ORIGINAL ARTICLE

The satisfaction of patients with refractory idiopathic overactive bladder with onabotulinumtoxinA and augmentation cystoplasty

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Received 20 May 2013, Received in revised form 10 July 2013, Accepted 13 July 2013
Available online 12 August 2013

KEYWORDS

Refractory;
Overactive bladder;
Botulinum toxin;
Augmentation cystoplasty

ABBREVIATIONS

OAB, overactive bladder;
oBTX, onabotulinumtoxinA;
DO, detrusor overactivity;
AC, augmentation ileocystoplasty;
UDI-, Urogenital Distress Inventory;

Abstract ***Objective:*** To assess the satisfaction of patients with refractory idiopathic overactive bladder (OAB) with two treatment methods, onabotulinumtoxinA (oBTX) and augmentation ileocystoplasty (AC).

Patients and methods: This prospective study included patients with refractory idiopathic OAB for >6 months and a urodynamic diagnosis of OAB. Oral pharmacotherapy had failed in all patients. Patients with any suspected neurological disorder were excluded. Before the procedure, patients completed the Urogenital Distress Inventory (UDI-6) and modified Incontinence Impact Questionnaire (IIQ-7), a neurological evaluation, a urodynamic study and their postvoid residual urine volume was measured. Patients were assigned to receive oBTX or AC, depending on patient's preference. Follow-up visits were at 6 weeks and 3 and 6 months after the procedure. The OAB Satisfaction questionnaire (OAB-SAT-q) was used to assess satisfaction after the procedure.

Results: In all, 31 patients with refractory OAB were included, 16 in the oBTX group and 15 in the AC group. There was no significant difference between the groups in mean age, baseline OAB symptoms and urodynamic values. There were significant improvements in urinary symptoms (UDI-6) and quality of life (IIQ-7) after both procedures (except in the domain enquiring about difficulty, which significantly worsened after AC). Of the 16 patients, 15/16 and seven of 15 were com-

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Peer review under responsibility of Arab Association of Urology.

Production and hosting by Elsevier

http://dx.doi.org/10.1016/j.aju.2013.07.003

IIQ-7, modified Incontinence Impact Questionnaire;
OAB-SAT-q, OAB Satisfaction questionnaire;
CIC, clean intermittent self-catheterisation;
QoL, quality-of-life;
PVR, postvoid residual urine volume;
NE, nocturnal enuresis

pletely dry after AC and oBTX, respectively. The overall and individual scores of the OAB-SAT-q were significantly higher among patients treated with AC than with oBTX. The incidence of the de novo need to use clean intermittent catheterisation after oBTX and AC was two of 16 and four of 15, respectively.

Conclusions: Both procedures are effective in improving the symptoms of OAB and of quality of life, but patients were more satisfied with AC than oBTX therapy.

Introduction

The refractory overactive bladder (OAB) represents one of the most challenging problems in general urological practice. The effects on an individual's quality of life in the physical and psychosocial domains are significant. Although the efficacy and specificity of antimuscarinic agents have improved in the last decade, many patients do not tolerate or fail to respond to oral therapy. Of those who respond to antimuscarinic agents, $<30\%$ remain on this therapy at 1 year after starting therapy for OAB [1]. Alternatives for patients with refractory OAB include sacral neuromodulation, intradetrusor injection of onabotulinum toxin A (oBTX), posterior tibial nerve stimulation and augmentation cystoplasty (AC). Sacral neuromodulation has been confirmed as a long-term successful method of treatment for refractory OAB [2]. There is also a good level of evidence that posterior tibial nerve stimulation is effective for treating the symptoms of OAB, with no side-effects, but the follow-up is short [3]. Since it was introduced into clinical practice by Schurch et al. [4] in 2000, oBTX therapy has been effective for treating patients with detrusor overactivity (DO), whether neurogenic or idiopathic. AC is an invasive and irreversible procedure, and can be associated with long-term adverse events. This procedure increases the bladder capacity and reduces the storage pressure, but many patients subsequently require regular clean intermittent self-catheterisation (CIC) for effective bladder emptying. This procedure can be associated with adverse events on the short and long-term. A review of previous reports showed that the success rate of AC for refractory OAB is 75–100% [5].

Patient satisfaction is a subjective, personal assessment of the effectiveness of treatment, based on the fulfilment of the expectations of patients [6]. Satisfaction is different from quality-of-life (QoL) measures, and its measure allows healthcare providers to assess the appropriateness of treatment according to patients' expectations. In addition, an assessment of patient satisfaction provides feedback from patients that can be used to alter and improve the quality of healthcare delivery [7]. Many surveys intentionally avoid asking patients how they feel about the quality of specific healthcare given to patients [8]. Treatment might be effective but it does not suit the social and economic character of the community. The primary aim of the present study was to assess the satisfaction of patients with refractory OAB after treatment with two methods, oBTX or AC.

Patients and methods

This was a prospective study that included patients of either sex with refractory idiopathic OAB symptoms for >6 months and a urodynamic diagnosis of DO. In all patients behavioural therapy and oral pharmacotherapy (high-dose combined anticholinergics) had failed (due to poor efficacy or tolerability). A requisite for inclusion was the confirmation of DO with standard cystometry. Excluded from the study were patients with any suspected neurological disorder, pregnant or lactating women, patients on anticoagulant therapy, patients with myasthenia gravis, interstitial cystitis, associated stress incontinence, associated schistosomiasis, those with renal impairment, those with upper tract dilatation due to poor compliance and those with a poor bladder outlet. The study was approved by the local ethics committee of the University.

All consecutive patients who met the inclusion criteria were invited to participate in the study. After signing the informed consent and extensive patient counselling, eligible patients were required to complete the Urogenital Distress Inventory (UDI-6) and modified Incontinence Impact Questionnaire (IIQ-7) questionnaires [9]. Patients then had a focused neurological evaluation, urine analysis and culture, a multichannel urodynamic study and their postvoid residual urine volume (PVR) was assessed. Follow-up visits were at 6 weeks and 3 and 6 months after the procedure. If the PVR was $\geqslant 150$ mL during any of these follow-up visits, CIC was recommended. Patients were assigned to receive oBTX or AC, but not randomly, the selection of therapy depending on the patient's preference. Patients treated with oBTX were injected with 200 or 100 U of oBTX (Allergan, Irvine, CA, USA), and each 100 U was diluted in 1 mL of saline. The injection comprised

0.1 mL containing 10 U of oBTX into the detrusor muscle, using a cystoscopic injection needle (5 mm, 23 G needle tip, on a 5-F sheath; Contigen Injection Needle, C.R. Bard, Murray Hill, NJ, USA) introduced through a 22-F rigid cystoscope. Typically, the dome, posterior and lateral walls were injected using 20 injection sites, sparing the trigone. For AC we used a 20-cm ileal segment. In young unmarried women, the operation was done through a Pfannenstiel incision without using a suprapubic tube, and the bladder drained by a Foley catheter alone.

The primary endpoint was a comparison between the scores from the satisfaction questionnaires after AC or oBTX therapy. The secondary endpoint was the change in symptoms from the baseline, as assessed by the UDI-6. Patients were considered cured if they scored 0 in the postoperative evaluation on the UDI-6, i.e. reported no urge incontinence episodes.

Satisfaction with treatment

We used the OAB Satisfaction Questionnaire (OAB-SAT-q), a valid and reliable tool, to assess patient satisfaction with their treatment for OAB [10]. The questionnaire assesses whether subjects were satisfied or not but does not assess the reasons for being dissatisfied. Thus, after administering the questionnaire, patients were also asked to list their reasons for being dissatisfied. We produced a translated version in a lay Egyptian language, validated linguistically, that was conceptually equivalent to the original version, and clear and easy to understand. The linguistic validation required three steps, i.e., two forward translations, a backward translation and patient testing [11]. The questionnaire was administered during the 3-month follow-up visits after each treatment.

We used two-sample paired *t*-tests when the relevant variables were normally distributed. Significance tests were two-sided and a $P < 0.05$ was considered to indicate significant differences.

Results

Between February 2009 and June 2012, 31 patients with refractory OAB were included in the study, 16 in the oBTX group and 15 in the AC group. There was no significant difference between the groups in mean age, baseline OAB symptoms and urodynamic variables (Table 1).

There were significant improvements in the urinary symptoms (individual and overall scores on the UDI-6) and in QoL (individual and overall scores in the IIQ-7) after both treatments (except in the domain enquiring about difficulty, which significantly worsened after AC). The degree of improvement in symptoms and QoL was significantly better after AC than after oBTX (Table 2). Fourteen of 15 patients were completely dry after AC, but only one had no improvement after AC. Three patients had nocturnal enuresis (NE) after AC, all categorised by the patients as mild (infrequent episodes of NE). However, half the patients were completely dry after oBTX, whilst six were improved and in two the treatment was considered to have failed. After oBTX 11 patients had their NE completely cured but five had persistent NE, two of them categorising the NE as moderate.

The overall scores on the OAB-SAT-q were significantly higher among those treated with AC than among those treated with oBTX (Table 3). The mean score of the Overall Satisfaction question (No. 1) was significantly higher for patients treated with AC (4.4, corresponding to 'being very satisfied') than those treated with oBTX (3.0, corresponding to 'being satisfied'; $P = 0.002$). Respectively, two and six patients were 'very satisfied' to 'satisfied' in the oBTX group, compared to five and seven in the AC group ($P = 0.041$). However, two patients were not satisfied with AC, compared to eight after oBTX therapy. Patients were less satisfied with oBTX therapy because of the need to regularly re-inject oBTX, and the high cost of this therapy. The mean age of patients who were dissatisfied did not differ from those who were satisfied (31.4 vs. 30.1 years, $P = 0.413$). Patients who were emptying their bladder without the use of CIC were more likely to be satisfied than those who used CIC (16/20, 78%, vs. six of 11) although this was not statistically significant ($P = 0.09$).

The incidence of the need for de novo CIC in patients treated with oBTX was two of 16 patient, vs. four of 15 of those treated with AC. Patients who did not need CIC after AC had a significantly greater maximum urinary flow rate than those who needed CIC (28.5 vs. 20 mL/s, $P = 0.034$) and a greater detrusor pressure during voiding (83.6 vs. 39 cm H_2O, $P = 0.07$).

Two patients after AC reported repeated episodes of epididymo-orchitis due to CIC, but this was controlled with antibiotic therapy. Another two patients in the AC group, who were voiding without CIC, developed an acute abdomen soon after surgery, at 6 and 9 weeks after removing the catheters. Imaging studies showed a mild free intraperitoneal collection, with suspected minute bladder leakage. They were managed conservatively with catheter drainage for 3 weeks. No long-term complications were recorded after either procedure (Fig. 1).

Discussion

Despite many studies investigating the clinical and urodynamic efficacy of different treatments for OAB, few to date have attempted to examine any therapy from the patients' perspective [12,13]. These former studies did not assess the satisfaction with oBTX therapy, but measured the QoL, and satisfaction per se was not measured directly. The only study, by Sussman et al. [14], assessed the satisfaction of patients who had neurogenic DO

Table 1 The preoperative baseline patient characteristics.

Variable	oBTX	AC	P
No. of patients	16	15	
Gender, n			0.149*
Male	9	4	
Female	7	11	
Mean (SD) age (years)	24.5 (8.3)	28.2 (7.6)	0.208†
Symptoms (UDI-6), n			
Severe frequency	14	9	0.188*
Severe urge incontinence	10	10	0.324*
NE	13	10	0.160*
Mean (SD) urodynamic variables			
MCC (mL)	156.8 (73.2)	212.2 (98.6)	0.085
Amplitude of UDC	78.3 (25.8)	78.1 (17.5)	0.965
Q_{max} (mL/s)	18.2 (6.0)	19.5 (10.9)	0.696
$PdetQ_{max}$ (cm H_2O)	56.0 (28.4)	60.9 (33.6)	0.662

MCC, maximum cystometric capacity; UDC, unstable detrusor contraction; Q_{max}, maximum urinary flow rate; $PdetQ_{max}$, detrusor pressure at Q_{max}.
* Chi-square test.
† Independent sample *t*-test. Severe urge incontinence was based on self scoring by patients on UDI-6.

Table 2 The change in patients' symptoms (UDI-6) and QoL (modified IIQ-7) after oBTX or AC.

Mean (SD) scores	oBTX		AC		*P* before	*P* after
	Before	After	Before	After		
UDI-6						
1. Frequency	2.8 (0.36)	1.1 (0.9)	2.5 (0.63)	0.33 (0.61)	0.071	0.005
2. UI	2.5 (0.80)	0.96 (0.97)	2.6 (0.47)	0.21 (0.51)	0.357	0410
3. SUI	1.0 (1.35)	0.60 (1.1)	1.0 (0.95)	0.20 (0.54)	1.0	0.165
4. Incontinence	2.07 (1.1)	0.96 (.97)	2.30 (1.01)	0.21 (0.51)	0.459	0.002
5. Difficulty	0.62 (0.79)	0.81 (0.92)	0.56 (1.0)	1.70 (1.2)	0.805	0.004
NE	2.60 (0.67)	1.20 (1.0)	2.6 (0.78)	0.47 (0.73)	0.780	0.006
IIQ-7						
1. Prayer	1.3 (1.2)	0.18 (0.48)	2.1 (0.9)	0.16 (0.38)	0.033	0.892
2. Work	1.03 (1.0)	0.57 (0.80)	1.3 (1.0)	0.13 (0.34)	0.369	0.018
3. Entertainment	1.8 (1.0)	0.80 (0.80)	1.4 (1.3)	0.21 (0.67)	0.009	0.029
4. Social	1.9 (0.95)	1.1 (0.92)	2.1 (0.79)	0.34 (0.71)	0.504	0.360
5. Car	0.34 (0.62)	0.11 (0.32)	0.65 (0.77)	0.13 (0.62)	0.134	0.915
6. Anxiety	2.25 (0.98)	1.8 (1.09)	2.6 (0.55)	0.69 (1.18)	0.066	0.001
7. Depression	2.59 (0.79)	1.8 (1.09)	2.69 (0.55)	0.69 (1.18)	0.605	0.001
Misbehaviour	1.07 (1.1)	0.37 (0.79)	0.82 (1.2)	0.13 (0.45)	0.457	0.206
Barrier to marriage	1.03 (1.1)	0.30 (0.67)	1.4 (1.4)	0.21 (0.73)	0.248	0.557
Affect marital relation	0.25 (0.67)	0.08 (0.27)	0.26 (0.86)	0.13 (0.45)	0.962	0.643

Each item is a domain of the UDI and IIQ questionnaires. *P* values are from an independent sample *t*-test. UI, urinary incontinence; SUI, stress UI.

(spinal cord injury and multiple sclerosis) and were treated with placebo, 200 and 300 U of oBTX in a double-blind placebo-controlled well-designed study. They used a structured validated 16-item OAB Patient Satisfaction with Treatment questionnaire to assess satisfaction. They concluded that patients with neurogenic DO treated with oBTX have greater satisfaction with treatment than with placebo, with no clinical difference in satisfaction between the oBTX doses of 200 and 300 U [14]. The present study is the first to compare the satisfaction of patients who have refractory idiopathic OAB when treated with two different therapies, oBTX or AC, using a structured validated questionnaire. Both procedures have comparable beneficial effects in improving the symptoms and QoL in patients with refractory idiopathic DO. However, the present patients were more satisfied with AC. Patients were less satisfied with oBTX because of the need to inject oBTX regularly, and the high cost of this therapy. These two points were discussed extensively with patients during preoperative counselling, and patients were well aware of the cost and the need for maintenance with oBTX therapy.

Table 3 The scores from the OAB-Sat questionnaire among patients treated with oBTX or AC; higher scores indicate better satisfaction.

Mean (SD) score	oBTX	AC	P
Q1	3.0 (1.2)	4.4 (1.0)	0.002
Q2	3.2 (1.1)	4.7 (1.1)	0.002
Q3	3.1 (1.7)	4.6 (1.1)	0.018
Q4	3.3 (1.1)	4.4 (1.2)	0.131
Q5	2.1 (.70)	2.0 (1.1)	0.461
Q6	4.2 (.67)	3.8 (1.3)	0.066
Q7	4.0 (1.0)	3.8 (1.4)	0.467
Q8	3.6 (.95)	4.8 (.50)	< 0.001
Q9	2.6 (.71)	3.6 (.73)	0.001
Q10	3.0 (.85)	3.6 (.56)	0.001
Q11	3.5 (1.0)	5.1 (.94)	< 0.001

However, patients treated with AC were satisfied because they considered the procedure to be a final therapy, and with good continence status. AC was conducted using a Pfannenstiel incision in young unmarried women with idiopathic DO. We did not place suprapubic tube in such patients, to improve the cosmesis after surgery. These patients mostly did not need postoperative CIC.

AC is an invasive procedure and can be associated with long-term adverse events. The procedure effectively improves LUTS and QoL. Many centres, especially in Western communities, have abandoned the use of AC for refractory OAB [15]. Many less invasive but more expensive procedures have been used to manage these patients. In the present study, all urinary symptoms and QoL domains significantly improved after AC, and complete urinary continence was established in most patients. There were occasional episodes of NE after AC, in three of 15 patients, that did not affect their activities but markedly impaired their QoL. NE, especially among young unmarried women, is a very distressing symptom, as it precludes these women from marriage.

Voiding dysfunction is not uncommon after AC and oBTX therapy. In the present study, the rate of de novo CIC after oBTX was two of 16, comparable to rates reported previously [16,17]. The rate of de novo CIC after AC was four of 15, and a review of previous studies showed a rate of de novo CIC of 40–70% after AC, but most of these studies were of patients with neurogenic DO. Peak urinary flow rates and the detrusor pressure during voiding were significantly lower among patients who required CIC after AC than in those who did not require CIC. In addition, the pattern of the urodynamic voiding cystometry curve might aid in predicting patients who might require CIC after AC.

In conclusion, both AC and oBTX are effective in improving the symptoms of OAB, and for improving QoL. However, the present patients were more satisfied with AC than with oBTX therapy. AC remains an excellent alternative for refractory OAB, especially in developing countries, and all previous reports to downgrade this procedure are not evidence-based. Patient satisfaction should be measured in the long-term to assess whether satisfaction remains high or might diminish due to the emergence of complications.

Conflict of interest

None.

Source of funding

None.

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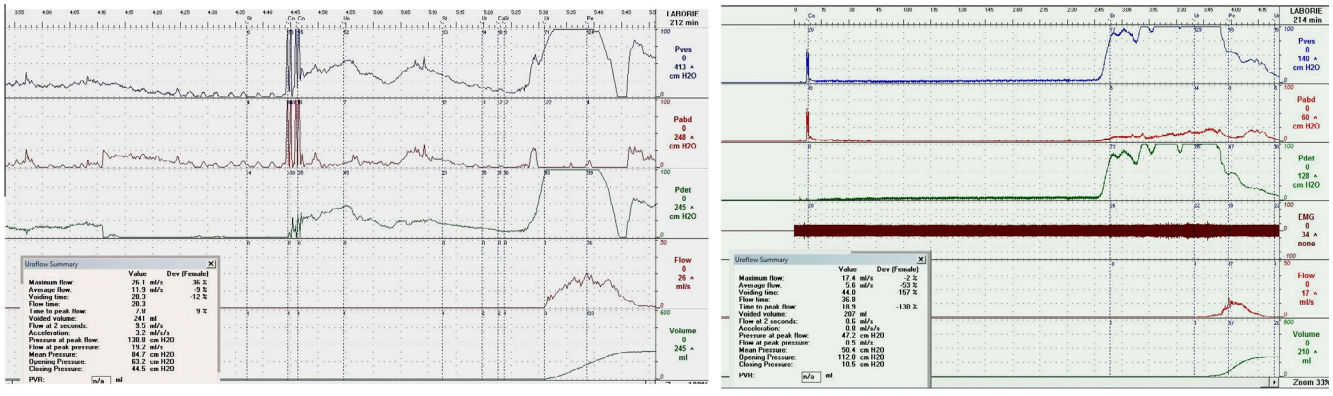

Figure 1 A typical cystometry curve of a patient (A) who did not require CIC after AC and another (B) who did. The flow rates and the strength of detrusor contraction were lower in those who required CIC. The peak flow rate (Q_{max}) in patient A coincides with the peak of the Pdet curve, whilst in curve B the Qmax occurs during the downward limb of the Pdet curve.

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