331

Raut N[1], Arunkalaivanan A[1]
1. *City Hospital*

RANDOMISED COMPARISON OF FLEXIBLE WITH RIGID CYSTOSCOPIC INTRADETRUSOR INJECTION OF BOTULINUM TOXIN A IN WOMEN WITH INTRACTABLE DETRUSOR OVERACTIVITY (DO)

Hypothesis / aims of study

Botulinum Toxin A (Dysport™) injections into the detrusor muscle have been shown to provide significant improvement in women with intractable detrusor overactivity. Most published reports of intradetrusor Botulinum injection describe intraoperative techniques using rigid cystoscopy and general or spinal anesthesia, or light sedation with intravenous medications(1). For patients who require chronic intradetrusor injection therapy with botulinum toxin having to undergo treatment under general anaesthetic would be a financial and time burden on the service. There were also studies confirming the feasibility of flexible cystoscopic injections under local anaesthetic (2). However, there is a paucity of randomized comparison between flexible and rigid cystocopic injections in the literature.

Our aim was to evaluate the tolerability, efficacy and safety between rigid and flexible cystoscopic intradetrusor injections of DYSPORT™ – Botulinum toxin-A in women with Intractable detrusor overactivity (Idiopathic-IDO or Neurogenic-NDO).

Study design, materials and methods

A total of 63 women were prospectively randomised for either flexible (30) or rigid (33) cystoscopic procedure based upon their choice of anaesthetic to either flexible (under local anaesthesia) or rigid cystoscopy (under general anaesthesia). Power calculation suggests that estimated minimum sample size for an unpaired two sample Student t test should be 23 experimental subjects.
However, acknowledging the possibility of loss to follow-up, poor RNIE data collection and withdrawal of consent, our minimum target was 30 women. This project was approved by the clinical effectiveness department and drug & therapeutics committee (DTC). An informed consent was obtained in all cases. They should be tried on at least three anticholinergic drugs as approved by the DTC, unless contraindicated. All women were taught clean intermittent self-catheterisation should the need arise. Urine analysis was done to exclude any infection. Multichannel urodynamics (UDS) were performed prior to therapy.

All women received intravenous injection of 1.2 gm of Co-amoxiclav if not allergic to Penicillin. If allergic to Penicillin, a three day course of Trimethoprim was given. In the flexible group, eleven ml of Instillagel™ was instilled into the urethra . After about 5 minutes a Storz™ 14Fr flexible cystoscope with a 2.2 mm working channel was introduced through the urethra and into the bladder. For the rigid Cystoscope group a 22Ch rigid cystoscope was used under a general anaesthesia. Bladder was drained in both groups. The bladder was then distended with 100 to 200 ml 0.9% normal saline . For both groups, a 27G flexible Olympus injection needle with a 4mm working length, in IDO 500 units of Dysport™ were injected in a Bladder mucosa at 20-25 sites supratrigonally .For NDO 750-1000 units of Dysport were injected. The tolerability was assessed using VAS for pain during flexible cystoscopy. The efficacy was assessed using the ICIQ questionnaire. Complications such as UTI and the need for CISC were recorded. Response was assessed using a validated questionnaires(International Consultation on Incontinence -ICIQ), medical history with physical exam at 2-6 months and at 12 months. Statistical analysis was done using SPSS™ release 16.0.

Results

30 women underwent flexible cystoscopic intradetrusor injection of DYSPORT™. 33 women had rigid cystoscopy. 3 women (10%) developed retention needing CISC in flexible cystoscopy while 5 women (15.1%) needed CISC in the rigid cystoscopy group for the same reason. In the flexible group, the mean VAS score for pain was 1.17±1.3 with a median score of 1 (0-8). Infection rate was similar in both of the groups.

Table 1: Demography

Variable	Flexible Median & range	Rigid Median & range	P value
Age	59.50 (23-78)	59(25-80)	0.125
Parity	3(1-5)	3(0-7)	0.4
BMI	32(18-51)	27(14-41)	0.34
IDO	24(80%)	29(87.9%)	0.2
NDO	6(20%)	4(12.1%)	0.15

Table 2 : Complications

Variable	Flexible	Rigid	PValue
CISC	3(10%)	5 (15.2%)	0.41
UTI	3(10%)	3(9.1%)	0.54

Table 3 :Efficacy

Variable	Flexible	Rigid	P value
ICIQ Pre Procedure	18.1+/-1.69	17.5+/- 5.2	0.79
ICIQ Post Procedure	7.03 +/- 4.2	7.20 +/- 4.8	0.62
Cost of anaesthesia*	£1.58	£119	<0.05

* Cost obtained from the finance department

Interpretation of results

The demographic features of age, parity, BMI and the indications needing the procedure were matched for both groups. The number of patients requiring CISC were similar in both groups. In both groups the botulinum toxin injection therapy was effective by the ICIQ analysis ($p<0.05$). However, there is no siginificant difference between the flexible and the rigid cystoscopy groups. VAS analysis during flexible cystoscopy suggests that this procedure is well tolerated and cost effective

Concluding message

Botulinum toxin-A injection using flexible or rigid endoscopy is safe and effective in women with intractable detrusor overactivity. However, flexible cystoscopic injection of botulinum toxin done under local anaesthetic has the added advantages of good tolerability and cost effectiveness.

References

1. Sahai A, Khan MS, Dasgupta P. Efficacy of botulinum toxin-A for treating idiopathic detrusor overactivity: results from a single center, randomized, double-blind, placebo controlled trial. J Urol. 2007 Jun;177(6):2231-6.,
2. Cohen BL, Rivera R, Barboglio P, Gousse A. Safety and tolerability of sedation-free flexible cystoscopy for intradetrusor botulinum toxin-A injection. J Urol. 2007 Mar;177(3):1006-10.

Specify source of funding or grant	**Nil**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**This project was approved by the clinical effectiveness department and drug & therapeutics committee (DTC).**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**