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Grise P[1], Ruffion A[2], Chartier Kastler E[3], Denys P[4], Egon G[5]
1. *Hopital Charles Nicolle,* ***2.*** *Hospices civils de Lyon,* ***3.*** *Hopital Pitie salpetriere Paris,* ***4.*** *Hopital de Garches,* ***5.*** *Centre de l'Arche Le Mans*

IMPACT ON CONTINENCE OF ONLY BLADDER BOTULINUM TOXIN INJECTION WITHOUT ANTICHOLINERGICS IN NEUROGENIC PATIENTS

Aims of study

Botulinum toxin bladder injection is an established treatment of neurogenic detrusor hyperactivity refractory to anticholinergics (1). Its efficacy is demonstrated but in most of the publications, it is associated with an anticholinergic treatment during a variable period of time. The aim of the study was to evaluate the effect on continence of two doses of Dysport toxin without any anticholinergic treatment.

Materials and methods

A prospective randomized multi-centre clinical study was conducted. Injections were extratrigonal in the détrusor muscle, the dose of injection of Dysport botulinum toxin was 500 US versus 750 US. The total number of patients were 77 (mean age 40 years). All were neurogenics (spinal cord injury: 49, multiple sclerosis: 18, other causes: 10) and most (64%) were paraplegic patients.
Inclusion criteria were: urinary incontinence due to detrusor hyperactivity (bladder tumor, lithiasis, urinary infection were excluded). A 14 days wash-out period without anticholinergic treatment was required, then no anticholinergic were authorized during the study period. The follow-up period was 1 year. The onset of urinary incontinence was considered as a failure of the treatment and end of the study. Preoperative evaluation included clinical study questionnaire, bladder diary, uroculture, urodynamics. Post-operative evaluations were at day 30, day 90, day180, day360, day at the end of the study, using the same evaluation.

Results

The results on cumulative rate of continence are summarized in the table. No statistical difference was observed (Chi2 test at 5%) between the two dosages. No difference (Fisher test) was found concerning the aetiology or the initial amount of urine leakage. For the 54 patients with a complete continence observed after the injection (25 in the 500 group 500, 29 in the 750 group), the onset of secondary incontinence was 162 days. Even if a the duration was longer with 750 US, the Log rank test was no statistically different, 161 days in 500 group versus 168 days in 750 group.

	Cumulative rate of incontinence		
	Dose 500	***Dose 750***	
day30	16 (41%)	10 (26 %)	26 (34%)
day90	24 (62%)	21 (55%)	45 (58%)
day180	29 (74%)	26 (70%)	55 (72%)
day360	36 (92%)	35 (97%)	71 (95%)

Interpretation of results

The continence rate observed of treatment of neurogenic détrusor hyperactivity with only botulinum toxin without any anticholinergic treatment was less than the continence rate of 80% reported when toxin is associated to anticholinergics, nevertheless 66% of the patients were continent at one month and 42% at three months. This study documented the real efficacy of the toxin. Patients benefited from the absence of adverse effects of anticholinergics, a secondary prescription may be an option when happens a decrease in efficacy of toxin effect. No difference was observed in the two doses of the Dysport toxin but a larger population could be more informative.

Concluding message

The botulinum toxin without anticholinergics in neurogenic patients has 5.4 months mean duration of efficacy on continence. The continence rate seems better with 750 US than 500 US but the results were not statistically significant.

References

1- J Urol. (2000) 164 ; 692-697
2- BJU Int. (2006) 97 ;(5): 1030-1034

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
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