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ON LABLE TREATMENT OF INTRADETRUSOR BOTULINIUM TOXIN IS LESS EFFECTIVE THAN PREVIOUS USED OFF LABEL DOSAGES

Hypothesis / aims of study

Clinical use of the intradetrusor botulinum toxin proved a viable alternative for treating neurogenic overactive bladder in not responsive or not tolerant to antimuscarinic treatment patients.
The aim of this study was to evaluate in our sample the effectiveness of the two types of botulinum toxin A used till now in practice (abobotulinumtoxin A vs onabotulinumtoxin A) in their different dosages.

Study design, materials and methods

120 patients (70 male; 50 female; mean age: 44 y.o.; 32 with Multiple Sclerosis; 26 with tetraplegia; 62 with paraplegia) were subjected to detrusor injection with botulinum toxin in 2 different occasions (abobotulinumtoxin A – abTOX A- 750 U and 500 U or onabotulinumtoxin A – onTOX A- 300 U and 200 U in first administration, then only onabotulinumtoxin A – onTOX A- in second administration). Therefore we evaluated the effectiveness of treatement by analyzing it in terms of duration compared to toxin types and dosages used

Results

Considering the whole sample, we obtained the following results:

Tot= 120	Patients n°.	Mean Duration in days
750U abTOX A	71	608
500 U abTOX A	17	588
300 U onTOX A	10	551
200 U onTOX A	22	350

Stratifying the sample to pathology we obtained:

Paraplegia= 62	Patients n°.	Mean Duration in days
750U abTOX A	50	608
500 U abTOX A	--------	-------
300 U onTOX A	6	575
200 U onTOX A	6	350

Multiple Sclerosis= 32	Patients n°.	Mean Duration in days
750U abTOX A	10	661
500 U abTOX A	12	507
300 U onTOX A	-------	--------
200 U onTOX A	366	199

Tetraplegia= 26	Patients n°.	Mean Duration in days
750U abTOX A	11	565
500 U abTOX A	5	629
300 U onTOX A	4	598
200 U onTOX A	6	357

None of the patients recruited in this sample has presented adverse events following the detrusor infiltration, especially side effects requiring hospitalization.

Interpretation of results

Since two years our Operative Unit of Neuro-Urology has complied with the instructions for use of intradetrusor botulinum toxin on label: in patients with neurogenic overactive bladder onabotulinumtoxin A is now used at 200 U for administration. The entire sample analysis showed that the time range, passed from the first and the second administration, is reduced in patients treated with onabotulinumtoxin A at 200 U, compared both to the higher dose of 300 U and to the abobotulinumtoxin A 750 U or 500 U (with statistical significance in our sample of: p (750-200) =0.01; p (500-200) =0.006; p (300-200) =0.05).
The same result has been obtained analyzing the recovered data by stratifying patients to pathology:
-Paraplegia: p (750-200) = 0.02; p (300-200) =0.008
-Tetraplegia: p (750-200) = 0.02; p (500-200) =0.05
-Multiple Sclerosis: p (750-200) = 0.02; p (500-200) =0.05

Concluding message

From this sample analysis, it's clearly showed that the clinical use of onabotulinumtoxin A in 200 U (BOTOX ®), as the recommended dosage of this only type of botulinum toxin suggested in intravesical use for detrusor overactivity treatment, is less effective in terms of duration compared to the higher dose (300 U, already employed in past times) and specially among the abobotuliumtoxin A (750 U and 500 U, employed in past times too). Reducing the effectiveness times obviously involves the enforcement's need of a new invasive maneuver with possible complications attached (hematuria, infection) and with an incrase of sanitary and social charge.

Disclosures

Funding: no grants **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** approved dosage of treatment **Helsinki:** Yes **Informed Consent:** Yes