731

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THE USE OF OXYBUTYNIN IN PATIENTS TREATED BY MEANS OF BOTULINUM NEUROTOXIN A (BONT-A) FOR NEUROGENIC DETRUSOR OVERACTIVITY: AN OBSERVATIONAL STUDY

Hypothesis / aims of study

Botulinum NeuroToxin A (BONT-A) is highly recommended (grade of recommendation A) for the treatment of neurogenic detrusor overactivity (NDO), especially in spinal cord injury (SCI) patients (1). In the majority of the published studies, the use of antimuscarinics (or drugs with mixed action as Oxybutynin) after BONT-A administration, was allowed, provided that no dosage escalation was permitted. In few study the percentage of patients who discontinued the treatment with antimuscarinics was reported and varied from 28 to 58%, with many other patients who reduced the dose (2). Nevertheless, no study has been published, specifically investigating how many patients, in a clinical (non investigational) setting, discontinue the antimuscarinics or reduce their dosage after BONT-A administration. Aim of this observational study was to investigate the use of Oxybutynin after BONT-A administration in NDO patients.

Study design, materials and methods

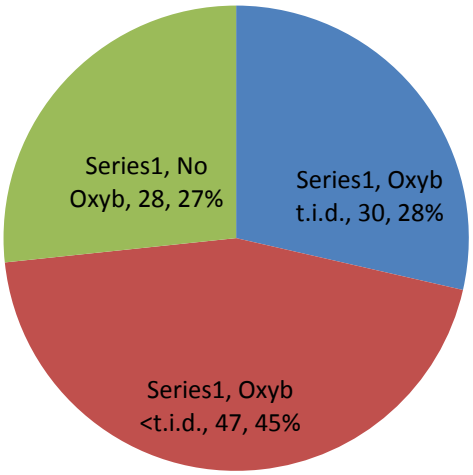
MATERIALS AND METHODS

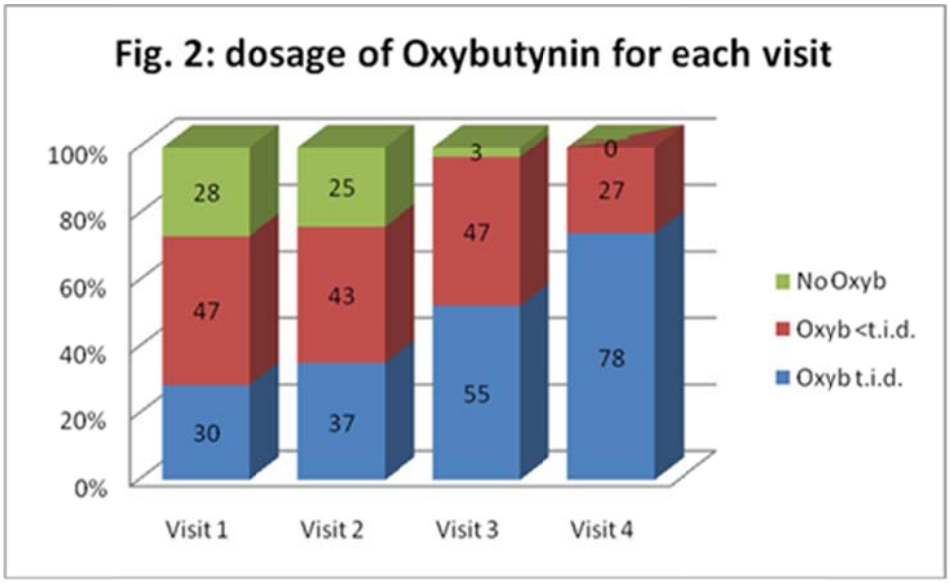
All patients who received intradetrusor injections of BONT-A for NDO in two Centres between January and December 2009 were considered in this observational studies. Inclusion criteria were: use of BONT-A (Botox, Allergan Inc., Irvine, CA, USA) at the dosage of 300 U; previous and ongoing unsuccessful treatment with high dosage mixed action drugs (Oxybutynin). These inclusion criteria were decided to diminish the number of variables. Patients were followed up at 30 days (visit 1), by means of bladder diaries and (in some cases) urodynamic examination. After this visit, patients were suggested to continue or reduce or interrupt the oral treatment (Oxybutynin) on the basis of the physician opinion (based only on clinical/urodynamic findings, without a pre-established strategy). Visit 2, 3 and 4 were performed 120, 180 and 270 days after BONT-A administration. The use of Oxybutynin was registered during every visit.

Results

On 174 patients treated in both Centres, during the study period, 105 were included in this observational study. Ninety five were suprasacral SCI patients, whilst the remaining 10 were multiple sclerosis patients. All patients had been taking Oxybutynin tablets 5 mg, 1 t.i.d. All patients were on intermittent catheterization regimen. At visit 1, only 30 patients (28,5%) were suggested to stay on Oxybutynin t.i.d., whilst 47 (44,8%) reduced the dosage and 28 (26,7%) stopped the oral therapy (see Fig. 1). Globally, a reduction of 158 tablets/day (around 1,5 tablets/day per patient, 50% less than the starting dose) was registered.
At visit 2, 68/75 (90,7%) of patients who had reduced Oxybutynin intake, maintained the dosage decided at visit 1. At visit 3 (180 days), 55 patients (52,3%) returned to Oxybutynin t.i.d., 47 (44,8%) were on a reduced dosage of 1 (14, 13,3%) or 2 (33, 31,4%) tablets/day and only 3 (2,9%) were not assuming the drug. At visit 4 (270 days), data were available only for 75/105 patients (71,4%). 15 of the patients lost (14,3%) had been retreated with BONT-A before visit 4. Only 27 patients (25,7%) were assuming less than Oxybutynin t.i.d. In figure 2 the number of patients using each dosage at each visit is reported.

Fig. 1: Oxybutynin dosage after visit 1





Interpretation of results

This observational study was able to show that, in a clinical setting, 71,5% of patients reduce Oxybutynin after BONT-A detrusor infiltration (Botox 300 U), with 26,7% stopping oral drug administration. Globally, a 50% reduction of the starting dose was registered. This reduction of dosage was maintained at 120 days in 90,7% of patients. Progressively, an increase of Oxybutynin dosage is than observed, with only 25,7% still assuming less than Oxybutynin t.i.d at visit 4 (270 days).

Concluding message

Our observations suggests that, in an economic evaluation of BONT-A for NDO, the reduction (or interruption) of oral agents should be considered. On the other hand, efficacy results obtained after BONT-A detrusor injection are often observed in patients still using antimuscarinics or mixed action drugs for NDO and these drugs can exert a role of adiuvant therapy.

References

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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	**It is an observational study**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**