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INTRADETRUSOR INJECTIONS OF BOTULINUM TOXIN A IN ADULT PATIENTS WITH SPINAL DYSRAPHISM: FINAL RESULTS OF THE SPINATOX STUDY

Hypothesis / aims of study

The DIGNITY randomized controlled trials have led botulinum toxin A to be licensed for neurogenic detrusor overactivity (NDO) but included only spinal cord injured and multiple sclerosis patients. To date, no data has been published regarding the efficacy of intradetrusor botulinum toxin injections (IDBTI) in patients with spinal dysraphism while these patients are injected in numerous centers in daily practice. The aim of the present study was to report the outcomes of IDBTI in spina bifida patients.

Study design, materials and methods

All patients with spinal dysraphism who had undergone at least one IDBTI from 2002 to 2016 in 14 centers were included retrospectively. Patients below the age of 16 years old were excluded to focus on an adult population. The primary endpoint was the success of injections, defined as the combination of urgency, urinary incontinence and detrusor overactivity resolution. Data collected included patients' characteristics, adverse events, and urodynamics parameters before and 6 weeks after IDBTI. The impact of poor compliance (defined as bladder compliance < 20 ml/cm H₂O) and type of spinal dysraphism on outcomes was assessed through univariate analyses.

Results

After exclusion of 53 children, 125 patients who underwent a total of 561 IDBTI courses were included (1 to 17 courses per patient). The urodynamic patterns were detrusor overactivity in 48.6% of patients, isolated poor compliance in 33.6% of patients and combination of poor compliance and detrusor overactivity in 17.8%. The toxin used was in the vast majority onabotulinum toxin A at a dosage of 200 U in 43 patients (34.7%) and 300 U in 62 patients (49.2%). Twenty patients (16.1%) received initially abobotulinum toxin A 750 injections. Global success rate of the first injection was 68.8% with resolution of urinary incontinence in 73.5% of patients. Ninety-six patients (76.8%) underwent a second injection and the mean interval between the first and second injections was 7.5 months. Success rate was significantly lower in case of poor compliance (49% vs. 87%; $p < 0.0001$). In contrast, success rates did not differ significantly between open and closed spinal dysraphism (66.7% vs. 72.3%; $p = 0.51$). The two other predictors of success were female vs. male gender (83.3% vs. 51.7%; $p = 0.0002$) and age (OR=0.1; $p = 0.005$). Out of 561 injections, 20 adverse events were noted (3.6%) including three fatigue/muscular weakness.

Interpretation of results

Low compliance spina bifida bladders may be poorly sensitive to IDBTI.

Concluding message

IDBTI seems effective in spina bifida patients showing detrusor overactivity regardless of the type of spinal dysraphism (open or closed). In contrast, the effectiveness is much lower in spina bifida patients with poor compliance bladder. The safety of IDBTI in patients with spinal dysraphism is satisfactory

Disclosures

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