INTRADETRUSOR INJECTIONS OF BOTULINUM TOXIN A IN PATIENTS WITH SPINAL DYSRAPHISM: RESULTS OF A MULTICENTER STUDY

Hypothesis / aims of study
The DIGNITY randomized controlled trials have lead 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 6 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 5 children, 82 patients who underwent a total of 420 IDBTI courses were included (1 to 17 courses per patient). The urodynamic patterns were detrusor overactivity in 48.8% of patients, isolated poor compliance in 35.9% of patients and combination of poor compliance and detrusor overactivity in 15.3%. The toxin used was in the vast majority onabotulinum toxin A to a dosage of 200 U in 35 patients (41.4%) and 300 U in 42 patients (49.4%). Eight patients (9.5%) received initially obobotulinum toxin A 750 injections. Global success rate of the first injection was 63.4% with resolution of urinary incontinence in 72.2% of patients. Seventy two patients (84.7%) underwent a second injection and the mean interval between the first and second injections was 9.1 months. Success rate was significantly lower in case of poor compliance (31.9% vs. 82.1%; p<0.0001). In contrast, success rates did not differ significantly between open and closed spinal dysraphism (66.7% vs. 61.5%; p=0.80). Secondary resistance to botulinum toxin occurred in one patient (from the seventh injection with failures of the three following injections). Out of 420 injections, 12 adverse events were noted (2.9%): two muscular weakness, two prolonged bladder pain, two gross hematuria and six urinary tract infections.

Interpretation of results
Low compliance spina bifida bladders are poorly sensitive to IDBTI.

Concluding message
ICBTI 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
Funding: none Clinical Trial: No Subjects: HUMAN Ethics Committee: Locals ethics committees Helsinki: Yes Informed Consent: Yes