

(Long-term) treatment of drooling in children with neurological disorders using botulinum toxin

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Objectives: Injections of BoNT into the salivary glands offer an efficient treatment option to reduce drooling in children with chronic neurological disorders. The objective of this study was to investigate the long-term efficacy as well as the optimal dosage and differential effects of the preparations BoNT/A (Botox®) and BoNT/B (NeuroBloc®).

Methods: Retrospective data assessment was carried out using a database containing all information about therapy procedure. Three subgroups were formed: *group A:* patients with one injection (n=15), *group B:* 2-4 injections (n=10), *group C:* >4 injections (n=9). A parental drooling frequency and severity scale was assessed prior to and 4-8 weeks after injection. Secondly a parent questionnaire was developed to sample therapy related effects on daily life and care.

Results: For the period of December 2004- october 2007 34 patients received 106 injections of BoNT (mean age during their first session 9y 10mo, range 1,5-25y; mean sessions per patient 3,1, range 1-9). Mean total dose of BoNT/A 95 Units (range 42-160 U; n=33). Mean total dose of BoNT/B 2383 U (range 1000-5000 U; n=70). Re-injections interval averaged at 21 weeks and did not change during long-term use.

Measurement of drooling frequency and severity scores showed distinct reductions for all treatment groups (mean reduction 8,1 to 4,4). Group C showed the least reduction (8,1 to 4,7). Mean reduction of drooling frequency and severity scores was 8,4 to 4,1 after BoNT/B and thus better than that following BoNT/A (7,4 to 5,4).

19 of 32 questionnaires were answered (60%). From group A, 4/13 (31%) parents replied (group B: 6/10; 60%, group C: 9/9; 100%). In total 17 parents found their child's quality of life improved and its need for care reduced (90%). Social interactions were relieved in 16 children (84%). 15 parents rated the therapeutic procedure as valuable (79%).

Most mentioned adverse events were described as dry mouth (n=3) or dysphagia (n=2), one of ever lead to discontinuation of treatment. Oral soor and pain at the injection sites was each mentioned once.

Antibody formation against BoNT/B was proven in two children, antibody formation against both BoNT/A and BoNT/B in one child, what also lead to discontinuation of treatment.

Conclusions: BoNT injections offer an effective option in the long-term therapy of drooling without serious side effects. BoNT/B was more successful in reducing sialorrhea never the less antibody formation seems to be an important issue for discontinuation of therapy.