Safety of NT 201 (Xeomin(R); Botulinum neurotoxin type A free from complexing proteins) for the treatment of upper limb spasticity: a pooled data analysis

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Objectives
To assess the safety of NT 201 (Xeomin®; Botulinum neurotoxin type A, free from complexing proteins) in the treatment of patients with upper limb spasticity, using a pooled data analysis.
Methods
Data were pooled from two randomised clinical studies. In one study, patients with upper limb post-stroke spasticity (n=148) received one set of injections with either NT 201 or placebo (double-blind). In the other study, patients with upper limb spasticity of various aetiologies (n=192) received one set of injections with NT 201 at either 50 U/ml or 20 U/ml dilution (observer-blind). Post-injection, patients in both studies were followed for up to 20 weeks. Upper limb muscles were treated as clinically indicated; maximum intended dose, 400 U. Safety was assessed by the incidence rates of adverse events (AEs).
Results
The pooled safety population consisted of 340 patients (NT 201, n=265; placebo, n=75). The median dose of NT 201 was 300 U (maximum 495 U). AEs were reported by 35.5% (94/265) of patients receiving NT 201, and 26.7% (20/75) of patients receiving placebo. In the NT 201 group, 7.6% (20/265) of patients had AEs judged to be related to the study medication, most commonly injection site haematoma (1.5%, 4 patients) and muscular weakness (1.1%, 3 patients). No serious AEs, or AEs leading to study drop-out, were judged as medication-related.
Conclusions
Pooled data from two clinical studies demonstrate the good safety and tolerability of NT 201, at doses up to 495 U, in the treatment of upper limb spasticity.

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