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Title **Botuls: A Multicentre Randomized Controlled Trial to Evaluate the Clinical Effectiveness and Cost Effectiveness of Treating Upper Limb Spasticity due to Stroke with Botulinum Toxin Type A**

Agency **NETSCC, HTA, NIHR Evaluation and Trials Coordinating Centre**
Alpha House, University of Southampton Science Park, Southampton, SO16 7NS, United Kingdom;
Tel: +44 2380 595 586, Fax: +44 2380 595 639; hta@soton.ac.uk, www.hta.ac.uk

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Aim

To compare the clinical and cost effectiveness of treating upper limb spasticity due to stroke with botulinum toxin type A plus an upper limb therapy program versus the upper limb therapy program alone.

Conclusions and results

There was no significant difference between the study groups (intervention: botulinum toxin type A plus upper limb therapy; control: upper limb therapy alone) for the primary outcome of improved arm function at 1 month. This was achieved by 30/154 (19.5%) in the control group and 42/167 (25.1%) in the intervention group ($p = 0.232$). No significant differences in improved arm function were seen at 3 or 12 months. In terms of secondary outcomes, muscle tone/spasticity at the elbow was decreased in the intervention group compared with the control group at 1 month. The median change in the Modified Ashworth Scale was – 1 in the intervention group compared to zero in the control group ($p < 0.001$). No difference in spasticity was seen at 3 or 12 months. Participants treated with botulinum toxin type A showed improvement in upper limb muscle strength at 3 months. The mean change in strength from baseline (upper limb component of the Motricity Index) was 3.5 (95% CI 0.1 to 6.8) points greater in the intervention group compared to the control group. No differences were seen at 1 or 12 months. Participants in the intervention group were more likely to undertake specific basic functional activities, eg, dress a sleeve, clean the palm, and open the hand for cutting fingernails. At 1 month, 109/144 (75.7%) of the intervention group and 79/125 (63.2%) of the control group had improved by at least 1 point on a 5-point Likert scale for at least one of these tasks ($p = 0.033$). At 3 months the corresponding proportions were 102/142 (71.8%) of the intervention group and 71/122 (58.2%) of the control group ($p = 0.027$). Improvement was sustained at 12 months for opening the hand to clean the palm and opening the hand to cut the nails, but not for other activities. Pain rating improved by 2 points on a 10-point severity rating scale in the intervention group versus zero points in the control group ($p=0.004$) at 12 months, but no significant differences were seen at 1 or 3 months. The base case incremental cost effectiveness ratio was 93 500 pounds sterling (GBP) per quality adjusted life year (QALY) gained. Estimation of the cost effectiveness acceptability curve for botulinum toxin type A plus the upper limb therapy program indicated that there was only a 0.36 probability of its being cost effective at a threshold ceiling ratio of GBP 20 000 per QALY (willingness to pay for a QALY by NHS decision makers).

Recommendations

This randomized controlled trial suggests that most stroke patients with upper limb spasticity will not achieve enhanced improvement in active upper limb function by the addition of botulinum toxin to an upper limb therapy program. However, botulinum toxin type A may improve the ability of some patients to undertake basic upper limb functional tasks and may reduce pain at 12 months. Despite some clinical benefits, the addition of botulinum toxin type A to an upper limb therapy program does not appear to be a cost-effective treatment for the patients included in this study.

Methods

See Executive Summary link www.hta.ac.uk/project/1408.asp.

Further research/reviews required

See Executive Summary link www.hta.ac.uk/project/1408.asp.

Written by Professor Helen Rodgers, Newcastle University, NETSCC, United Kingdom

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