Response to Letter by Munin et al Regarding Article, “Botulinum Toxin for the Upper Limb After Stroke (BoTULS) Trial: Effect on Impairment, Activity Limitation, and Pain”

Response:

We thank Dr Munin et al1 for their interest in the Botulinum Toxin for the Upper Limb after Stroke (BoTULS) trial, a multicenter, randomized, controlled trial evaluating the clinical effect of botulinum toxin type A in addition to an upper limb therapy program for the treatment of poststroke upper limb spasticity.2

We agree that localization of muscles for injection using ultrasound or electromyography guidance may result in more accurate placement of botulinum toxin type A. However, we are not aware of any publications that report enhanced clinical benefit from guided placement compared to localization of muscles using surface anatomy. Injection site placement by surface anatomy is considered acceptable in national and international guidelines for the use of botulinum toxin to treat spasticity3,4 and is widely used in clinical practice.

We agree that the median doses of botulinum toxin type A used in BoTULS were lower than those used in other upper limb spasticity trials, but the decrease in spasticity 1 month after injection was similar to other studies.5 In BoTULS, some patients had less severe spasticity than participants in other trials (Modified Ashworth Scale score at the elbow at baseline was 2 in BoTULS compared with >2 in many of the previous trials); therefore, in accordance with clinical guidelines, the dose of botulinum toxin type A was adjusted according to level of spasticity.3 The choice of muscles for injection was according to the pattern of spasticity of individual participants. Dr Munin et al report that the majority of BoTULS participants had spasticity affecting the hand, wrist, elbow, and shoulder, but spasticity in all 4 arm areas was only present in 47.6% of the intervention group participants. Of the 164 participants in the intervention group who received an initial set of botulinum toxin type A injections, 98 of 164 (60%) received treatment to all 4 arm areas was only present in 47.6% of the intervention group participants. Of the 164 participants in the intervention group who received an initial set of botulinum toxin type A injections, 98 of 164 (60%) received treatment to >1 area of the arm when the arm was divided as hand (flexor digitorum superficialis and/or (flexor digitorum profundus and/or flexor pollicis longus); wrist (flexor carpi ulnaris and/or (flexor carpi radialis), elbow (biceps and/or brachioradialis), and shoulder (pectoralis major).6

BoTULS enrolled 184 of 333 (55%) patients with a baseline Action Research Arm Test score of 0 to 3. We agree that patients with poorer initial arm function are likely to show less improvement. This was the reason for definition of a lower “successful” outcome in patients with a baseline Action Research Arm Test score of 0 to 3 than for those with a baseline Action Research Arm Test score of >3.

We fully agree that measurement of upper limb function is challenging and different measures give different information about the effects of treatment. We certainly support the need for more research to answer the question, “which measures are best for measuring changes in upper limb spasticity after stroke?”

Disclosures

Ipsen provided the botulinum toxin type A (Dysport) used by the study free of charge. The design, analysis, and reporting of the study were undertaken independently of Ipsen. M.P.B. uses botulinum toxin regularly in clinical practice and has received sponsorship from Ipsen to attend and teach at conferences. He has no personal financial interest in botulinum toxin or any related product.

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