INCOBOTULINUM TOXIN FOR UPPER LIMB SPASTICITY PAIN

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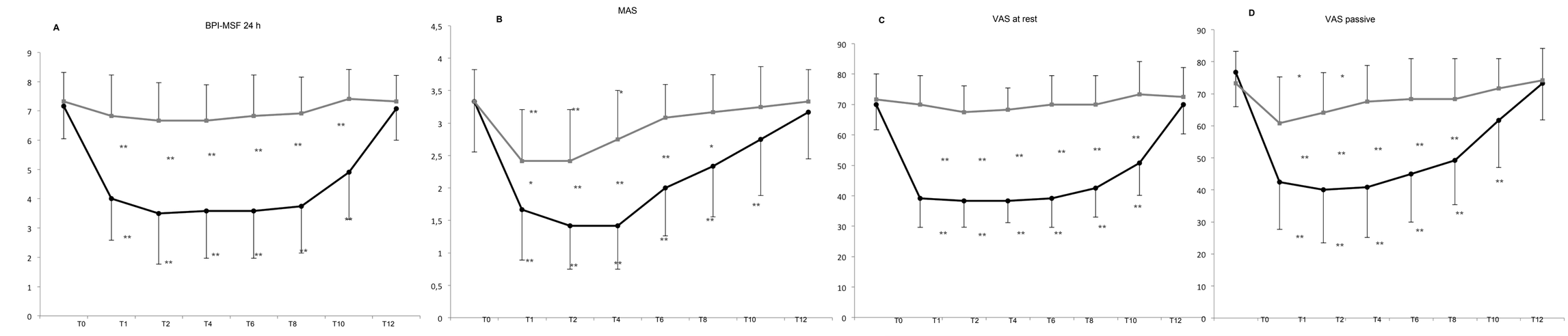
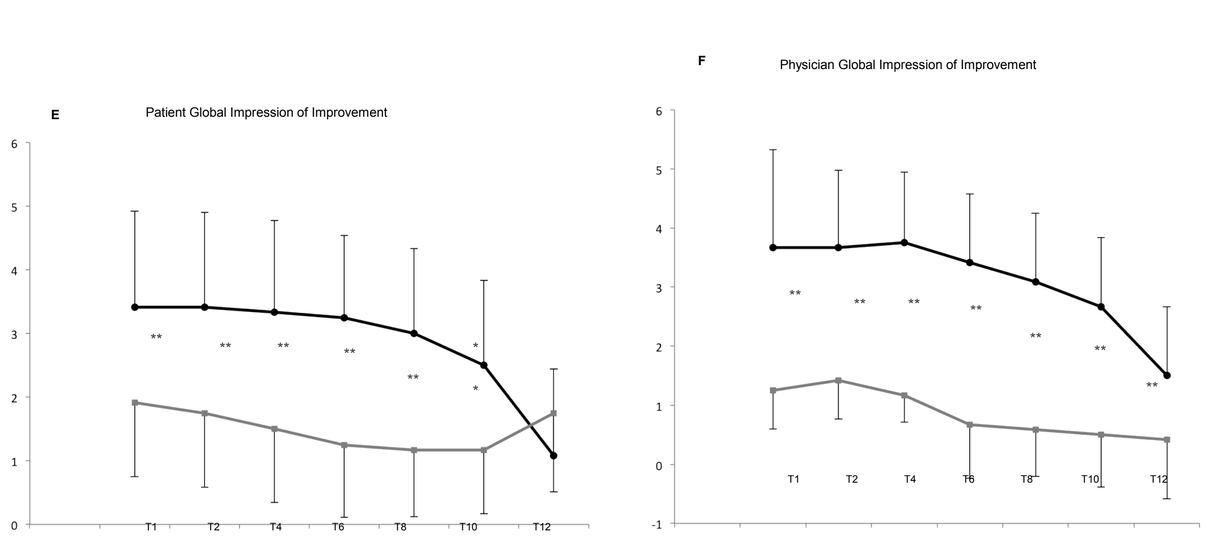
Introduction: spasticity is often associated with pain and spasms. Pain may significantly worsen spasticity and increase the severity of disability. Spasticity-related pain may be due to the vascular compression by focal muscle hyperactivity with consequent ischemic pain. Botulinum toxin A (BoNT/A) injected into the spastic muscles has shown to be effective in reducing muscle tone, but only few studies reported pain relief as additional benefit. Moreover, in most of them, pain evaluation was one of the secondary outcomes and consequently, it was evaluated marginally. The aim of the present study was to investigate the effects of local incobotulinum toxin A treatment in reducing upper-limb spasticity pain.

Patients and methods: 24 patients (mean age: 68.9 ± 7 years); with acute (< 2 months) post-stroke upper-limb spasticity pain in at least 2 joints were randomized into two groups: 1) 12 patients received BoNT/A injections plus a 4-week program of upper-limb therapy; 2) 12 patients underwent upper limb therapy program alone. Based on the involved joint(s), a dose of incobotulinum toxin (xeomin 100 units; diluition: 2Ml ; Mertz Pharma; Germany) ranging from 100U to 200U/joint (maximal total dose 400U) was injected. Primary outcome: Brief Pain Inventory Modified Short Form (BPI-MSF) 24-hours average pain change. Secondary outcomes: 1) BPI-MSF 24-hours changes at week 1 (first treatment period) comparing the 2 groups; 2) variations in the mean intensity of pain measured by a 0-100 visual analogue scale (VAS) at rest and after passive joint movements; 3) the Physician Global Impression of Improvement Score; 4) the Patient Global Impression of Improvement Score, 5) the modified Ashworth Scale (MAS). Patients were evaluated at baseline, and at 1, 2, 4, 6, 8, 10, and 12 weeks after treatments. Moreover, within the first week of evaluation, the primary outcome and the MAS were also evaluated at day 2, 4, and 6 after BoNT/A injections. For Statistical analysis evaluation, for all of the outcomes, the Wilcoxon signed rank test was used to compare the baseline values with the data of each treatment time, whereas Mann-Whitney U test was used for mean differences between the 2 groups for each session measurements. Level of significance: $p < 0.05$.

Results: The primary outcome decreased over the sessions, reaching the maximum reduction (51% - 50%) as compared to baseline, from T2 to T6. High statistical differences were also observed at T8 and T10, until a complete recovery was gained at T12. The BPI-MSF showed significant changes already over the first week. Similar patterns of changes were observed for the secondary outcomes. The comparison of mean values between groups at each session showed statistical differences from T2-T10 for all of the parameters except for MAS and VAS passive with differences between T2 and T8. The effect of BoNT/A on BPI-MSF appeared earlier (Day 2) than the effect on spasticity (Day 6).





Conclusions: local infiltrations of BoNT/A into the upper limb in post-stroke patients can be a safe and promising treatment of spasticity-associated pain. In consideration of the earlier analgesic effect of BoNT/A as compared to the anti-spasticity effect, it can be hypothesized that the improvement of spasticity pain induced by BoNT/A may be due to a specific analgesic effect of botulinum neurotoxin different from its effect on spasticity

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