뇌신경재활
발표일시 및 장소 : **10 월 26 일(금) 13:35-13:45 Room C(5F)**

OP2-1-3

A randomized controlled trial to determine dose-response relationship for BTX in finger spasticity

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Objectives
Long finger flexor is one of the most commonly injected muscles with botulinum toxin A (BTX-A) in the management of spasticity. However, how much units of toxin should be injected for appropriate decrease in spasticity has not been reported. To our knowledge no randomized placebo-controlled trial has been reported. This study aimed to investigate dose-dependent efficacy and safety of BTX-A for post-stroke finger flexor spasticity. Study design: A double-blind randomized placebo-controlled design

Methods
Participants with post-stroke finger flexor spasticity (modified Ashworth scale [MAS] 2 and higher) were enrolled in this randomized, placebo-controlled study. After randomization, subjects were injected with placebo (0), 30, 60, 100, or 150 units of BTX-A (halves into flexor digitorum profundus and flexor digitorum sublimis) by ultrasound guided technique. The BTX-A used in this study was Nabota® (Daewoong Pharm. Inc). The primary efficacy endpoint was MAS, and the secondary outcomes were Fugl-Myer upper extremity assessment, Wolf motor assessment, and hand grip strength of the affected hand at 2, 4, 8, and 12 weeks after the initial treatment visit. Adverse events were also recorded.

Results
Eighty-five participants were recruited and 78 were randomized (21 women, age 60.6 ± 9.5 years) to one of the 5 groups. After six participants were dropped during follow-up, 72 subjects were analyzed as per protocol. Finger flexor spasticity decreased more with injections of BTX-A than with placebo at weeks 2 (100 units) and 4 (150 units) ($P = 0.031$). A dose-dependent response was generally observed in tone reduction but not in upper extremity functions and hand grip strength. There were no serious adverse events of BTX-A injections.

Conclusion

BTX-A reduced post-stroke spasticity in a dose-dependent manner in finger flexor but did not appear to affect upper extremity functional outcomes and hand grip strength.

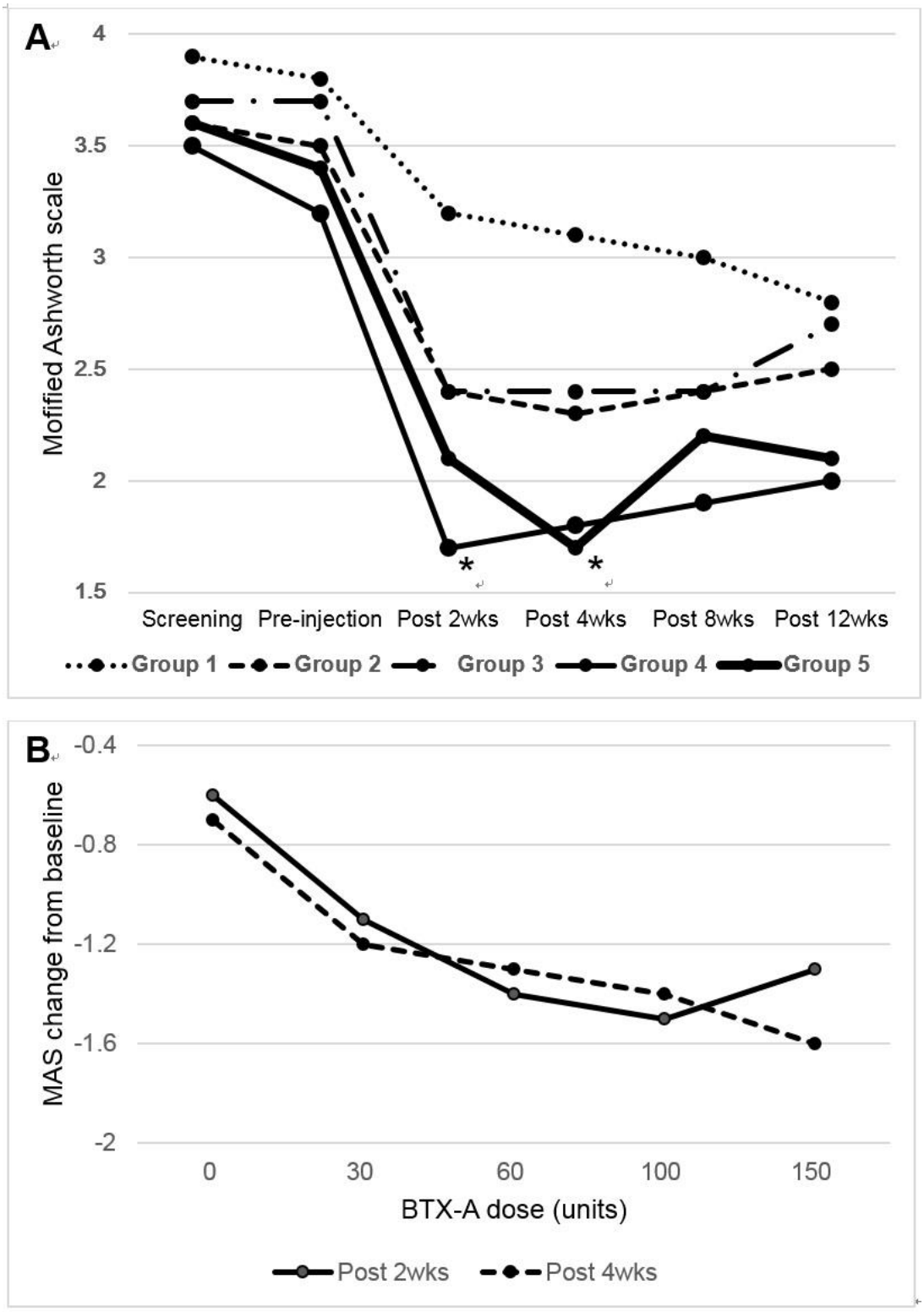

Figure 1. Dose–response analysis of finger flexor spasticity measured by modified Ashworth Scale (MAS): (A) MAS measured at each point, (B) MAS changes from baseline depending on BTX-A dose at 2 and 4 weeks after BTX-A injection. * $P < 0.05$ compared with group 1 at each measure point (by ANOVA test with post-hoc analysis of Tukey HSD)

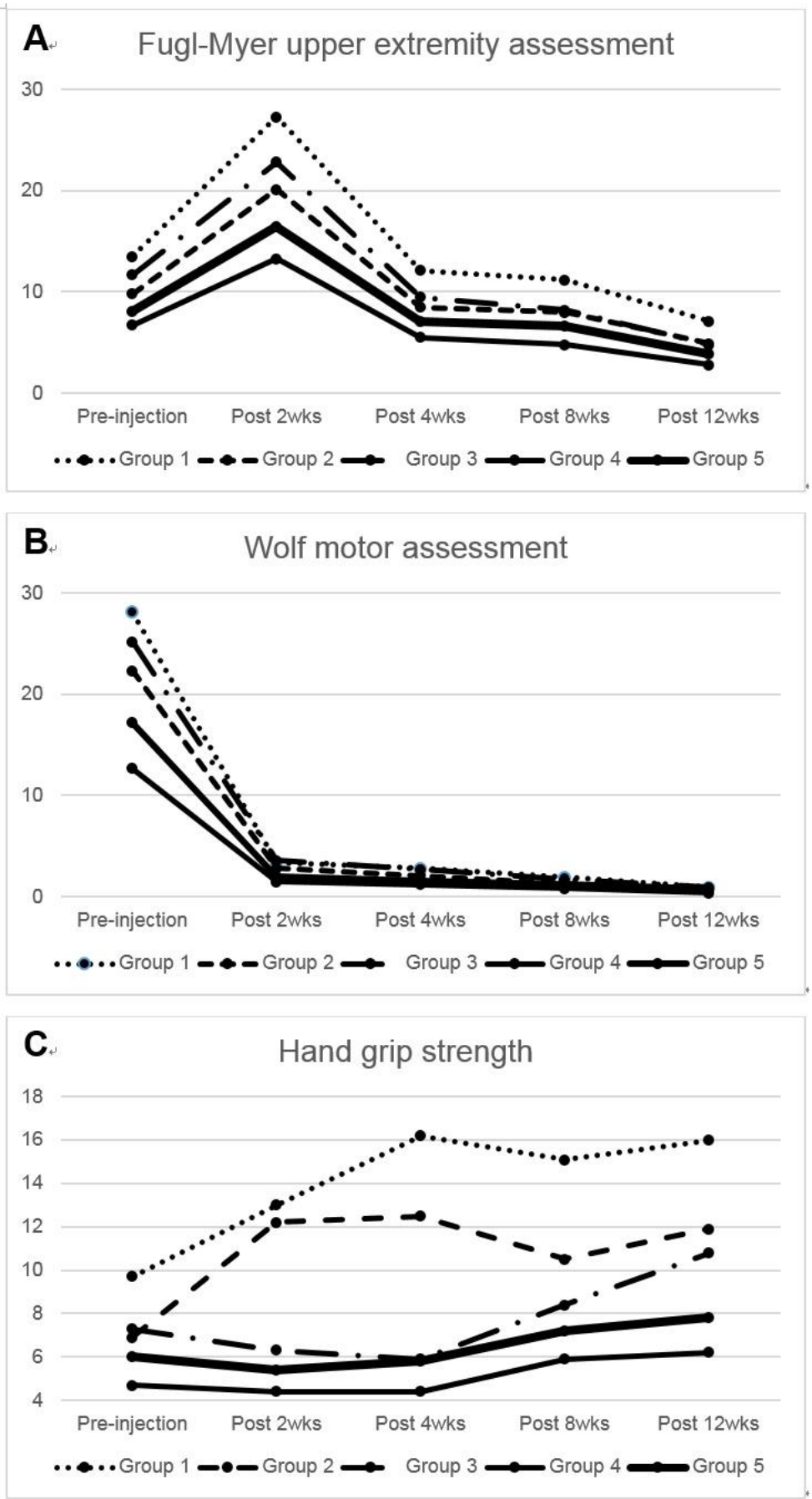

Figure 2. Dose–response analysis of upper extremity functional assessments measured by (A) Fugl-Myer upper extremity assessment, (B) Wolf motor assessment, and (C) Hand grip strength.