Kyung Hee Do et al., J Neurol Neurophysiol 2017, 8:4(Suppl)
DOI: 10.4172/2155-9562-C1-053

Efficacy and safety of a new botulinum toxin a from strain CBFC26 (NTC, letibotulinumtoxinA, BOTULAX®) for the treatment of post-stroke upper limb spasticity

Kyung Hee Do[1], **Min Ho Chun**[2], **Nam-Jong Paik**[3, 4], **Yoon Ghil Park**[5], **Shi-Uk Lee**[3, 6], **Min-Wook Kim**[7], **Don-Kyu Kim**[8] and **Changjin Lee**[9]
[1]Veterans Health Service Medical Center, South Korea
[2]University of Ulsan College of Medicine, South Korea
[3]Seoul National University, South Korea
[4]Seoul National University Bundang Hospital, South Korea
[5]Yonsei University, South Korea
[6]Seoul National University Boramae Medical Center, South Korea
[7]St. Mary's Hospital, Catholic University of Incheon, South Korea
[8]Chung-Ang University, South Korea
[9]Hugel Inc., South Korea

Objectives: Botulinum neurotoxin type A (BoNT/A) has been widely used to decrease spasticity and enhance function in stroke patients with upper limb spasticity. In the current study, we investigated a new botulinum neurotoxin type A, termed as letibotulinumtoxinA (Botulax®) and compared its efficacy and safety for post-stroke upper limb spasticity with that of onabotulinumtoxinA (Botox®).

Methods: Two kinds of botulinum neurotoxin type A (Botulax® and Botox®) were used. One set of injection were performed and total injected doses were 309.21±62.48U (Botulax group) and 312.64±49.99U (Botox group) ($p>0.05$). Main measures: Primary outcome was measured using the modified Ashworth scale for wrist flexors at week four and secondary outcome was measured using modified Ashworth scale for wrist flexors, elbow flexors, finger flexors, and thumb flexors as well as global assessment in spasticity, disability assessment scale, and caregiver burden scale at baseline, 4, 8, and 12 weeks. Safety measures including adverse events, vital signs and physical examination, and laboratory tests were also monitored.

Results: The mean ages for the Botulax group were 56.81±9.49 and which for the Botox group were 56.93±11.93. In primary outcome, the change in modified Ashworth scale for wrist flexors was -1.45±0.61 in the Botulax group and -1.40±0.57 in the Botox group, and the difference between the two groups was -0.06 (95% CI: -0.23–0.12, $p>0.05$; $p=0.5253$). In secondary outcome, both groups also demonstrated significant improvements with respect to modified Ashworth scale, global assessment in spasticity, disability assessment scale, and caregiver burden scale during the study periods ($p<0.05$), and no significant difference was observed between the two groups ($p>0.05$). In addition, safety measures showed no significant differences between the two groups ($p>0.05$).

Conclusions: The efficacy and safety of Botulax were comparable with those of Botox in treatment of post-stoke upper limb spasticity.

khdo79@gmail.com

Notes: