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Evaluation of the diffusion characteristics of LetibotulinumtoxinA in comparison to Ona- and AbobotulinumtoxinA in a double-blind, randomized split-face study

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Introduction & Objectives:

The targeted diffusion and migration of different BotulinumtoxinA (BoNTA) formulations has been repeatedly discussed as one of the factors that may influence the overall therapeutic outcome1. Therefore, the diffusion characteristics of LetibotulinumtoxinA (Leti-BoNTA), the market leader in South Korea, was compared with OnabotulinumtoxinA (Ona-BoNTA) and AbobotulinumtoxinA (Abo-BoNTA) in a randomized, double-blind, intra-individual split-face comparison.

Materials & Methods:

Subjects:

30 healthy subjects aged 24-64 years with symmetrical forehead wrinkles were enrolled. Subjects suffering from symmetric dynamic forehead lines and having not received any treatment with BoNTA in the previous 6 months.

Treatment Regime:

All patients were randomized to receive two of the three BoNTA formulations, Leti-BoNTA guaranteed. The subjects were injected in the frontal muscle with an intramuscular application of a total of 2 injection points per forehead side. Each point treated with 4 U Leti-/ Ona-BoNTA or 10 U Abo-BoNTA (1:2.5 conversion rate2), with the same technique and identical volume.

Outcome:

Evaluation of diffusion characteristics was performed before and within 6 months after treatment using the iodine starch test3. Standardized photographic documentation was captured with the VisioFace® 1000 D (Courage+Khazaka electronic GmbH, Cologne, Germany) to determine the size of the anhidrotic area.

Results:

A total of 26 subjects successfully completed the observation period and demonstrated a positive response to treatment with BoNTA (Fig. 1). A significant difference in anhidrotic areas with Leti-BoNTA compared to Ona-BoNTA and Abo-BoNTA was demonstrated within 6 weeks (maximal area of anhidrosis; primary outcome) and 6 months (area under the curve (AUC); secondary outcome). Leti-BoNTA showed an overall smaller anhidrotic halo than Ona- and Abo-BoNTA.

Conclusion:

Leti-BoNTA exhibits precise and predictable diffusion while achieving the same clinical efficacy as Ona- and Abo-BoNTA4. Due to the significant differences in diffusion characteristics, treatment protocols should take product-specific behaviour into account, especially when changing formulations. Selection of the appropriate formulation is critical, as diffusion properties can influence therapeutic outcomes. Further research is needed to investigate the relationship between anhidrotic area, muscle relaxation and therapeutic index of different formulations.

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DISCLOSURE: THE AUTHORS DECLARES NO CONFLICT OF INTEREST.