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Pilot study comparing the diffusion characteristics of two formulations of botulinum toxin type A in forehead hyperhidrosis

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Background: The diffusion characteristics of different formulations of botulinum toxin type A (BoNTA) are not identical.
Methods: Patients were eligible for inclusion in this study if they had excessive forehead sweating and had not received treatment with BoNTA in the preceding 12 months. All patients received two injections of BoNTA1 on one side of their forehead (forehead side was determined by random assignment) and two injections of BoNTA2 on the other side of their forehead. For BoNTA1, each injection was 3 U for all patients. For BoNTA2, patients were randomly assigned to one of the following doses per injection: 7.5 U, 9 U, or 12 U. Therefore patients received treatment at one of the following dose ratios of BoNTA1 to BoNTA2: 1:2.5, 1:3, or 1:4. On each forehead side, one injection was lateral and one was medial. All injections were of identical volume. The injections were administered after marking each patient's forehead with a template showing four injection sites 3 cm apart horizontally and 3 cm above the orbital rim. Patients were evaluated at baseline and at least monthly for 6 months. The area of any forehead anhidrosis was highlighted using starch and iodine and assessed using the Canfield Mirror DPS Imaging System.
Results: A total of 20 patients were enrolled (14 women and 6 men, 18-61 years old). The mean area of forehead anhidrosis was significantly larger with BoNTA2 than BoNTA1 for each of the dose ratios ($P < .001$).
Conclusions: Across a range of dose ratios, BoNTA2 has a greater area of diffusion in the forehead than BoNTA1 even with identical injection volumes. This may hinder accurate localization of clinical effect, thereby increasing the potential for adverse events. BoNTA1 is the formulation from Allergan, Inc. BoNTA2 is the formulation from Ipsen Ltd. in the United Kingdom. Dosing and results reported in this study are specific to each formulation. Botulinum toxin products are not interchangeable and cannot be converted by using a dose ratio.

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