N_03 DOI: https://doi.org/10.5114/reum/219181

Botulinum toxin for microstomia in systemic sclerosis: a literature review

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Key words: systemic sclerosis, scleroderma, microstomia, botulinum toxin, oral aperture

Introduction: Systemic sclerosis (SSc) often causes perioral fibrosis leading to microstomia, which impairs speech, nutrition, and oral hygiene. Conventional stretching, physiotherapy, and surgery provide limited and inconsistent benefit. Botulinum toxin (BoNT) has been proposed to relax perioral muscles and improve mouth opening.

The study aims to review published clinical trials, prospective studies, case series, and case reports on the use of BoNT for SSc-related microstomia, summarise, and to critically appraise the available evidence regarding its efficacy and safety.

Material and methods: A literature review was conducted in major biomedical databases and a clinical trial registry (inception – 2023). Eligible reports included clinical trials, prospective studies, case series, and case reports evaluating BoNT injections with outcomes related to mouth opening and/or oral function in patients with SSc.

Results: Of 677 records identified, four studies met the predefined inclusion criteria, namely: studies involving patients with systemic sclerosis; administration of BoNT as an intervention; evaluation of outcomes related to microstomia or oral aperture; and original clinical study design (clinical trials, prospective studies, or case series). These comprised one small prospective interventional study, one registered clinical trial with unpublished results, one case series, and one case report. Across studies, perioral BoNT type A (most commonly 16–20 units) was associated with short-term increases in maximal interincisal distance and improvements in patient-reported oral function. Reported adverse events were minimal and transient, with no serious complications described.

Discussion: The evidence suggests a consistent signal of short-term benefit, but certainly is low due to small samples, heterogeneity, and limited controlled data. Optimal formulation, dosage, injection mapping, and retreatment intervals remain unclear, and durability beyond about 3 months is insufficiently studied.

Conclusion: Botulinum toxin appears to be a promising adjunctive option for SSc-related microstomia; however, adequately powered randomised trials with standardised outcomes are needed before routine clinical use can be recommended.