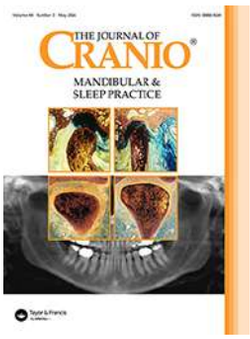

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Botulinum toxin in orofacial pain: A clinician's perspective on what we know, what we do, and what we get wrong

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EDITORIAL

Botulinum toxin in orofacial pain: A clinician's perspective on what we know, what we do, and what we get wrong

Let us be direct: botulinum toxin (BTX) is being injected into the orofacial region far more often than the evidence warrants. Within several dental and medical communities, it has quietly shifted from "promising adjunct" to de facto first-line therapy – a transition that has not been drawn from the literature, but seems more based on fashion, market, and social media boosts. As clinicians who have spent decades working at the intersection of temporomandibular disorders (TMDs), orofacial pain (OFP), bruxism and neuromodulatory treatment [1,2], we try offer an appraisal of where BTX treatment stands today, what the evidence actually supports, and where the field is headed – or should be.

The muscle story: Solid ground, but not holy ground

The strongest case for the use of BTX in the orofacial region is built on its well-understood mechanism: acetylcholine blockade at the neuromuscular junction, resulting in temporary muscle paralysis. For TMDs of prevalently myogenous symptoms driven primarily by masticatory muscle hyperactivity, this is genuinely useful. The literature summarized in a recent systematic review [3] suggested that BTX injections into the masseter and temporalis can reduce pain scores and improve jaw function in selected patients. This is not in dispute.

What is in dispute – and what too many practitioners seem to ignore – is the diagnosis. The paradox is that even injecting BTX in the masseter and temporalis muscles of a patient with arthrogenous TMDs, albeit not addressing the symptoms, may help reducing the cause of joint overload. On the other hand, it may mask pain while the structural problem progresses. In our own proof-of-concept investigation combining intramuscular BTX with arthrocentesis and viscosupplementation [4], we observed meaningful added benefit – but only when the treatment was tailored to patients with a mixed clinical picture, not in patients with "pure" TMJ arthritis. The lesson is not that BTX works broadly; it is that BTX works specifically, when applied to the right target in the right patient.

The bruxism issue deserves a separate and even more critical paragraph. The market for BTX in bruxism is booming – equally driven by patient demand and financial considerations. Unfortunately, the scientific premise is shaky. Bruxism is a behavior, and it is a symptom, not a disorder by itself. Reducing masseter bulk in case of hyperthrophy may help aesthetics, but it does not eliminate bruxism; it reduces one of its potential unpleasant consequences. The confusion between reducing bruxism itself and managing its sequelae is not semantic – it has real implications for treatment planning and informed consent. Patients need to understand that they are receiving a palliative, time-limited intervention, not a cure [5].

Beyond the muscle: The antinociceptive promise

The more intellectually exciting frontier – and the one that is most vulnerable to overreach – is the use of BTX as an antinociceptive agent. Beyond its muscular effects, BTX inhibits the release of substance P, glutamate, and calcitonin gene-related peptide (CGRP) from peripheral sensory neurons. This mechanism has driven its FDA approval for chronic migraine, and has sparked interest in its use for other orofacial pains such as trigeminal neuralgia (TN), post-herpetic neuralgia (PHN), and burning mouth syndrome (BMS), amongst the others.

In our systematic review of BTX for orofacial neuropathic pains [2], we found preliminary supportive evidence that far from conclusive. For TN, randomized controlled trials indicate meaningful pain reduction and decreased attack frequency in refractory cases [6,7]. For PHN and BMS, the data are thinner and the sample sizes smaller. What is worrying from a clinical perspective is the temptation to extrapolate the single case to generalization of outcomes: because BTX helps some patients with TN, clinicians are beginning to use it for poorly characterized facial pain syndromes where diagnosis is uncertain and placebo response is high. That is a recipe for wasted resources, patient frustration, and delayed appropriate care.

Chronic migraine with orofacial referral is perhaps the most clinically relevant crossover condition. Jaw and neck pain in chronic migraineurs is common, and the neuromodulatory activity of BTX appears to address both the primary headache and its orofacial satellite symptoms [8]. This is an area where closer collaboration between neurologists and orofacial pain specialists is urgently needed – and rarely happens.

The elephants in the room: Protocols, dosing, and the wild west of clinical practice

Here is the uncomfortable truth: there is no agreed-upon protocol for BTX injection in the orofacial region. Dosages range from 10 to over 100 units per masseter across published studies [9]. Products vary. Injection sites vary. Treatment intervals vary. Outcome measures vary. This heterogeneity is not a minor methodological inconvenience – it makes head-to-head comparison of studies nearly impossible and clinical replication unreliable.

From a practical standpoint, the clinician at chairside is essentially flying blind with regard to dosing. The cosmetic literature, from which many orofacial practitioners have borrowed their protocols, is not an appropriate reference frame for pain management [9]. It's like comparing the use of hyaluronic acid for lips contouring and its use for joint lubrication. Cosmetic contouring of the masseter and therapeutic reduction of muscle hyperactivity are different goals requiring different doses, depths, and follow-up strategies. Making them converge to the same discipline or technicalities of usage is a clinical mistake with real consequences, including unwanted facial asymmetry, difficulty to chew, and patient dissatisfaction.

The financial dimension cannot be ignored either. BTX is expensive. Its cost limits both patient access and research design, since adequately powered, long-term randomized trials remain scarce. In systems without reimbursement for orofacial BTX, the treatment gravitates toward patients who can afford it, not necessarily toward those most likely to benefit. This creates a selection bias that skews the "clinical experience" practitioners cite when advocating for the therapy.

What actually needs to happen

We are not arguing against BTX. We use it in our own clinical practice. It should be used selectively, after a sound diagnostic work-up, as part of a multimodal strategy – not as a stand-alone shortcut. The field needs to move in that direction, and several specific steps are necessary.

First, diagnosis must precede treatment. This sounds obvious, but it is violated constantly. The DC/TMD criteria [10] may help providing a theoretical framework for a "validated" diagnosis, but are we sure that patients with myalgia are clinically different from myofascial pain, just to cite a concrete taxonomic example? Are we sure that categorizing patients based on the axis I is enough, given the amount of evidence suggesting that the psychosocial component is leading prognostic factor? The same considerations apply to neuropathic pain conditions: BTX for TN is not a short-cut for neurological workup.

Second, the field urgently needs standardized, condition-specific injection protocols. Professional societies – including those governing orofacial pain, oral medicine, and maxillofacial surgery – should collaborate to develop evidence-based guidelines with minimum acceptable diagnostic thresholds, dosing ranges, and follow-up intervals. The current situation, in which it seems that a practitioner may base practice on his/her own ideas, is professionally untenable.

Third, as anticipated above, psychosocial factors must be incorporated into patient selection of any clinical trials and evaluated as a treatment predictor. OFP is not purely a peripheral phenomenon. Central sensitization, catastrophizing, anxiety, and depression all influence treatment outcomes [11,12]. A patient with high pain catastrophizing and widespread sensitization is unlikely to respond durably to a peripheral injection, regardless of its mechanism. The Axis II component of orofacial pain assessment is not optional. Indeed, evidence from viscosupplementation trials has shown that Axis II psychosocial findings are significant predictors of treatment outcome [13].

Finally, long-term data are lacking and must be generated, also to understand the safety of procedures, which are sometimes depicted as either miraculous or as a boogeyman for bone density and the immune system. The sustained clinical benefit of BTX beyond 6 months remains poorly characterized in most OFP conditions, and so is the use of repeated injections or that of specific "follow the pain" techniques [14–17]. We need pragmatic trials – conducted in real-life clinical environments, with appropriate control arms and patient-reported outcomes including quality of life, function, and psychosocial impairment – not just pain VAS scores.

Conclusion

Botulinum toxin is a genuinely useful tool in the orofacial pain clinician's armamentarium. It is not, however, a universal solution, and its uncritical adoption – driven by market forces, patient demand, and the seductive simplicity of an injection – risks doing more harm than good. The evidence, read honestly, supports targeted use in prevalently myogenous TMDs, selected neuropathic conditions, and as an adjunct in carefully appraised combined therapy protocols. It does not support the kind of compulsive prescribing that is becoming increasingly common.

The future of BTX in OFP management depends on the discipline leaders to keep the highest scientific and ethical standard: accurate diagnosis, standardized protocols, honest informed consent, and rigorous outcome tracking. Anything less is not evidence-based medicine – it is clinical improvisation dressed up in a scientific costume and masked as a novelty that is a couple of decades old.

Author contributions

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