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Original article

Effect of intra-articular Botulinum toxin injections on temporo-mandibular joint pain☆

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ABSTRACT

Temporo-mandibular joint dysfunction can be painful and disabling. In some cases, it is refractory to classical treatment. Intra-articular Botulinum toxin injections have been shown to have an anti-inflammatory and analgesic effect. The aim of this study was to evaluate the effectiveness of such injections on severe, refractory temporo-mandibular joint pain. This was a retrospective study. Patients were included if they still had joint pain ≥ 5 on a Visual Analogue Scale following completion of all other treatments. A complete treatment protocol (including physiotherapy, tongue splints, intra muscular injections of Botulinum toxin and injections of hyaluronic acid, excluding surgery) having being done before the injection of 30 Botox* units (Botulinum toxin A), the treatment being considered clinically successful if the Visual Analogue Scale decreases by at least 2 points. Seventy-seven patients were included. Sixty-six percent of patients have a significant reduction in pain at 1 month which lasted at least until 3 months. Mouth opening and quality of life also improved. Moreover, no complications were reported. Further randomized, controlled studies are needed to confirm the results, however this study suggests intra-articular injection of Botulinum toxin is a safe and effective treatment for severe, refractory temporo-mandibular joint pain, avoiding surgery.

1. Introduction

According to the Public Health Code, temporomandibular joint (TMJ) dysfunction is a cause of disability. The prevalence varies from 15 to 80% depending on the study. Associated symptoms are varied and complex but patients principally complain of pain. Pain may be periarticular and muscular and can be severe, long lasting and disabling. Many patients can experience relief with oral medication, physiotherapy and splints. If these treatments are ineffective, intramuscular injections of Botulinum toxin type A (BoNTA) can be carried out. Intramuscular BoNTA has been used for the treatment of TMJ disorders for over 20 years [1], [2]. The most frequently injected muscles are the masseter and the temporal muscles. These injections have been shown to be effective for the treatment of TMJ disorders with a predominantly muscular component or mixed [3], as well as for pain relief in the case of hypertonicity of the masticating muscles [4] and bruxism [5]. If patients still experience significant pain, an intra-articular injection of hyaluronic acid can be carried out.

In 2007 when this study began, studies in rats suggested that BoNTA could reduce nociceptive joint pain [6] by its inhibition of neurotransmitter release from primary sensory neurons [7]. This led to trials of intra-articular BoNTA injections for the treatment of joint pain in human subjects. One of the first studies by Mahowald carried out in 2006 [8], involved a case series of 12 patients with different types of arthritis, mainly in the knee or shoulder, who had refractory pain despite intra-articular injections of steroids or viscosupplement injections. Significant reductions in pain were found following intra-articular BoNTA injections.

We then began to carry out intra-articular BoNTA injections in the TMJ in patients who had undergone the total battery of treatments, but still had persistent pain. We trialled different

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doses, finding that 20U was insufficient, 30U was effective and 50U did not provide better results than 30U. We therefore concluded that the minimal effective dose was 30U.

The aim of the present study was therefore to evaluate the effect of the intra-articular injection of 30U of BoNTA for the treatment of severe, refractory TMJ pain up to 3 months post injection.

2. Materials and methods

2.1. Patients

A standardized protocol of intra-articular injections of BoNTA injections was generated from the collective experience of all authors. We retrospectively reviewed data for all patients with severe, chronic TMJ pain, who did not respond to conventional medical treatment, undergoing intra-articular injections in the TMJ at a single academic medical center between 2007 and 2016. Patients were identified from institutional database after the study was approved by the Institutional Review Board of the University of Montpellier (France).

The inclusion criteria were as follows: patients over the age of 18 who had had TMJ pain for at least 1 year, with a pain score with the mouth shut of 5 or more following at least 1 year of a complete battery of treatment (described below). The exclusion criteria included allergy to Botulinum toxin, myopathy, central neuropathy, pregnancy and breast-feeding. These are all contraindications to Botulinum toxin injection. Patients with uncontrolled diabetes, who were immuno-depressed, had coagulation disorders or were on strong doses of anticoagulants were also excluded because of the risk of hemarthrosis or septic arthritis. Patients who had undergone surgical interventions (traumatology or oncology related) in the joint region were also excluded. Patients with systemic diseases were not injected during inflammatory flare-ups.

Pain was defined as severe if the score was 5 or more out of 10 on the Visual Analogue Scale (VAS). It was considered as refractory if it persisted after complete treatment (except surgery) for one year. The treatment involved an increasing therapeutic strategy going from analgesic, muscle relaxant and anti-inflammatory medication, to physiotherapy (massage, mouth opening exercises, mandibular mobilisations, repositioning of the tongue and postural correction), followed by the provision of an occlusion splint (correction of bite alignment). If these strategies were insufficiently effective, patients underwent intra-muscular injection of BoNTA to relax the muscles. If significant pain persisted, viscoelastic intra-articular injections of sodium hyaluronate (Arthrum H 2% - 2 mL–LCA Pharmaceutical, Chartres, France) were carried out. Patients who were not sufficiently relieved by this complete battery of treatment were included.

2.2. Outcome measures

Outcomes were measured at baseline (before injection), day 15, 1 month and 3 months.

The primary outcome measure was the pain score measured on a Visual Analogue Scale (VAS) Pain was rated on the left and right sides. The patients self-rated their pain on a scale of 0 to 10 where 0 = no pain and 10 = the worst imaginable pain.

The secondary outcome measures were amplitude of mouth opening and quality of life, in order to determine the psychosocial impact of the disorder. Pain in the contralateral TMJ was also evaluated on a VAS. Mouth opening was measured with a short ruler. The result is in centimetres. Quality of life was evaluated using our own version of the short form of the SF36 questionnaire. It evaluates physical and mental health, including physical and social function and the accomplishment of different activities of daily living (disability). Seven of the 12 items were selected in order to simplify the questionnaire (grouping of similar questions).

2.3. Procedure

A standardized injection protocol for the intra-articular injection of BoNTA was defined in order to ensure reproducibility. The injections were carried out in an aseptic room (with resuscitation equipment), with the assistance of a nurse. Mouth opening and VAS pain scores were measured before the injection. Intra-articular BoNTA injections were carried out a minimum of 4 months following hyaluronic acid injection or intramuscular botulinum toxin injection.

Patients with a ≥ 5 in both TMJs underwent bilateral injections. The same concentration and dose were used for all patients. The molecule used was Botulinum toxin type A Botox (Allergan Pharmaceuticals, Westport, Ireland), conditioned in vials of 100 units.

The patient's head was rotated contralaterally to the TMJ to be injected. Detersive cleaning was carried out and a sterile operating field was put in place. Local subcutaneous anaesthesia was carried out with 1% non-diluted lidocaine in the TMJ zone. The BoNTA was diluted in 1 mL of 9% isotonic injectable saline solution in a graduated syringe to make up 100U/mL. The solution was taken-up using a graduated 1 mL syringe. A total of 30U were injected for each joint. The anatomical reference points (the posterior border of the ramus to the condyle and the inferior border of the zygomatic arch) were palpated during a movement of rotation and sliding of the joint with the mouth maximally opened (Fig. 1).

A 23G needle of 0.6 mm diameter and 25 mm length was introduced in the posterior-superior border of the condyle in the joint space. The piston was depressed for security and the product was injected. Mouth opening was measured a second time. An increase in amplitude signified a successful intra-articular injection. The injected product has the effect of flushing the joint (Fig. 2).

2.4. Ethical considerations

All patients were given a clear information letter regarding the intra-articular injections and the inclusion criteria, including the secondary effects and risk factors relating to BoNTA injection. All patients signed an informed consent in their medical file prior to participation. A traceability form was filled out for each BoNTA injection, including the patient's identity, the date, name of the injector, the dose injected per joint and the batch number of the injected BoNTA.

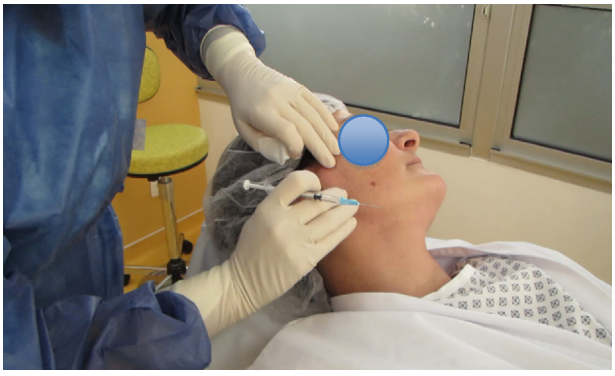

Fig. 1. Palpation of anatomical reference points for the TMJ before intra-articular injection: palpation of the ramus of the mandible and the condyle with the mouth closed.

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