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Systematic Review
TMJ Disorders

A systematic review of different substance injection and dry needling for treatment of temporomandibular myofascial pain

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Abstract. Temporomandibular myofascial pain presents a major challenge in the diagnosis of temporomandibular disorders (TMD). Due to the characteristics of this condition, intramuscular injection procedures are often needed for adequate control of symptoms and treatment. Thus, the aim of this systematic review was to evaluate the effectiveness of dry needling and injection with different substances in temporomandibular myofascial pain. Electronic databases PubMed, EMBASE, CENTRAL/Cochrane, Lilacs, Scopus, Web of Science and CAPES Catalog of Dissertations and Theses were searched for randomized clinical trials until January 2018. Manual search was performed in relevant journals and in the references/citations of the included studies. The selection of studies was carried out by two independent reviewers according to eligibility criteria. From 7128 eligible studies, 137 were selected for full-text analysis and 18 were included. Due to the heterogeneity of the primary studies it was not possible to perform a meta-analysis. The narrative analysis of the results showed that most of the studies had methodological limitations and biases that compromised the quality of the findings. Dry needling and local anaesthesic injections seem promising, but there is a need to conduct further randomized clinical trials, with larger samples and longer follow-up times, to evaluate the real effectiveness of the technique and evaluated substances.

Key words: myofascial pain dysfunction syndrome; temporomandibular joint disorders; local anaesthetics; botulinum toxins; dry needling.

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Myofascial pain is part of muscle temporomandibular disorder (TMD), and its diagnosis and treatment are a constant challenge for the professional. Estimates indicate that 42% of TMD diagnoses correspond to temporomandibular myofascial pain[1]. In relation to the prevalence, there are rates ranging from 5 to 10%, with greater involvement of the female gender[2–4].

This condition is characterized by the presence of painful trigger points in com-

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pression and may give rise to referred pain[5], irradiated to other structures distant from the place of origin. Clinical characteristics may be accompanied by muscle fatigue and decreased joint movements[6], as well as headaches[7], more commonly affecting the masseter and temporalis muscles in the orofacial region.

Trigger-point needling is a treatment modality that involves inserting a needle into trigger points to inactivate them. Stimulation of the needle in these points produces an analgesic effect as a consequence of affecting somatosensory thresholds. Satisfactory results are achieved in the alleviation of local and referred pain[8]. Needling can be performed dry or wet, using substances such as local anaesthesic, botulinum toxin and corticosteroids[8–10]. Myofascial trigger-point injections are widely used in Medicine, with randomized controlled trials (RCTs) evaluating different substances and presenting satisfactory results[9,10]. The realization of adequate primary studies in Medicine has made it possible to perform systematic reviews[11,12] and meta-analysis[13] that evaluated the effectiveness of the technique and of different substances. In Dentistry, the literature analysis indicates the existence of randomized clinical trials, evaluating different substances[8,14] and dry needling[15,16], but there are no systematic reviews and meta-analyses of RCTs, designs associated with the highest indexes of scientific evidence[17]. Thus, due to the comorbidity that myofascial pain causes and the absence of studies with the design proposed by this paper, the objective of this systematic review was to evaluate the effectiveness of the injection of different substances and dry needling in the treatment of temporomandibular myofascial pain.

Material and methods

Protocol and registration

The methodology applied in the conduction of the present study is available in the registration protocol on the International prospective register of systematic reviews (PROSPERO) platform under the code CRD42014014141[18]. This systematic review was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement[19].

Definition of the research question

The research question was: what is the effectiveness of injections with different substances and dry needling in the treatment of temporomandibular myofascial pain?

Search strategy

Electronic searches were performed in PubMed, EMBASE, CENTRAL/Cochrane, Lilacs, Scopus and Web of Science databases until January 2018 with no language restrictions. Also, during the same period, a search was performed in the CAPES Catalog of Dissertations and Theses. Citations and references of the included studies were consulted. In addition to the electronic search, a manual search was also performed in six journals relevant to temporomandibular disorders over the last 10 years. The periodicals were: *Journal of Orofacial Pain*; *Journal of Oral Rehabilitation; Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontology; CRANIO: The Jounal of Craniomandibular Practice; Journal of Oral and Maxillofacial Surgery*; and *Pain*.

Descriptors were extracted from Medical Subject Headings (MeSH) and free terms. Subsequently, a search strategy was set up, divided into phases 1 (outcome) and 2 (intervention), according to the Cochrane Handbook for Systematic Review of Interventions[20]. The basic search strategy, which was applied to the different research bases consulted, respecting their particularities, was:

((((((((((((((((((((((((((''Temporomandibular Joint Disorders''[Mesh] OR ''Temporomandibular Joint''[Mesh] OR ''Craniomandibular Disorders''[Mesh] OR ''Temporomandibular Joint Dysfunction Syndrome''[Mesh] OR ''Myofascial Pain Syndromes''[Mesh]) OR ''Trigger Points''[Mesh])) OR ''Myofascial Pain Syndrome'') OR ''Pain Syndrome, Myofascial'') OR ''Pain Syndromes, Myofascial'') OR ''Syndrome, Myofascial Pain'') OR ''Syndromes, Myofascial Pain'') OR ''Myofascial Trigger Point Pain'') OR ''Trigger Point Pain, Myofascial'') OR ''Myofascial Pain Dysfunction Syndrome, Temporomandibular Joint'') OR ''Myofascial Pain Dysfunction Syndrome'') OR ''temporomandibular joint'') OR ''TMJ Syndrome'') OR ''Costen's Syndrome'') OR ''Costens Syndrome'') OR ''Costen Syndrome'') OR ''Temporomandibular Joint Syndrome'') OR ''Temporomandibular disorder$") OR ''Temporomandibular disorder'') OR ''craniomandibular disorder'') OR ''trigger point'') OR ''Joint Syndrome, Temporomandibular'') OR ''Syndrome, Temporomandibular Joint'') OR ''Temporomandibular Joint Dysfunction Syndrome'') OR ''Temporomandibular Joint Disorders'') OR ''Myofascial Pain Syndromes'')) AND ((((((((((((((((((((((((((''Prilocaine'' [Mesh] OR ''Anesthetics, Local''[Mesh] OR ''Bupivacaine''[Mesh] OR ''Anesthesia, Local''[Mesh]) OR ''Procaine'' [Mesh]) OR ''Mepivacaine''[Mesh]) OR ''Lidocaine''[Mesh]) OR ''Botulinum Toxins''[Mesh]) OR ''Botulinum Toxins, Type A''[Mesh]) OR ''Injections'' [Mesh]) OR ''Adrenal Cortex Hormones''[Mesh])) OR ''anesthesia local'') OR ''anesthetic local'') OR ''local anesthetic'') OR ''local anesthetic'') OR ''Anesthesia, Local'') OR ''Anesthetics, Local'') OR ''lidocaine'') OR ''prilocaine'') OR ''procaine'') OR ''mepivacaine'') OR ''bupivacaine'') OR ''ropivacaine'') OR ''botulinum toxin'') OR ''Botulinum Toxins'') OR ''Botulinum Toxins, Type A'') OR ''injection'') OR ''injections'') OR ''corticosteroid'') OR ''corticoesteroid'') OR ''dry needling'') OR ''needling'') OR ''Adrenal Cortex Hormones'')

Selection of studies and data extraction

The studies were evaluated by two independent reviewers (E.M. and P.C.) and eligible articles were analysed according to established eligibility criteria. The eligibility criteria for study selection were as follows: (1) studies should be categorized as RCTs; (2) with patients of any age and gender with clinical diagnosis of temporomandibular myofascial pain; (3) evaluating effectiveness (pain intensity – assessed by Visual Analog Scale or similar, pressure pain threshold (PPT) – measured by algometer, or maximum mouth opening (MMO) – measured by millimetre rule or similar) of dry or wet needling (with injection of substances as local anaesthetics, botulinum toxin, corticosteroids or other drugs). In the first stage, the titles and abstracts were read and studies that met the eligibility criteria were selected for full-text reading. In the following stage, the complete versions of the articles were evaluated and the studies that satisfed the eligibility criteria were included. If there was disagreement among the independent reviewers, there would be a consensus attempt or a third evaluator (P.M.) would be required to determine inclusion or exclusion of the study. The data were extracted independently by the reviewers.

Evaluation of biases

After the final selection of the papers, the primary studies were evaluated for biases according to the Cochrane risk of bias tool[21,22]. The articles were classified as having low risk of bias, high risk of bias

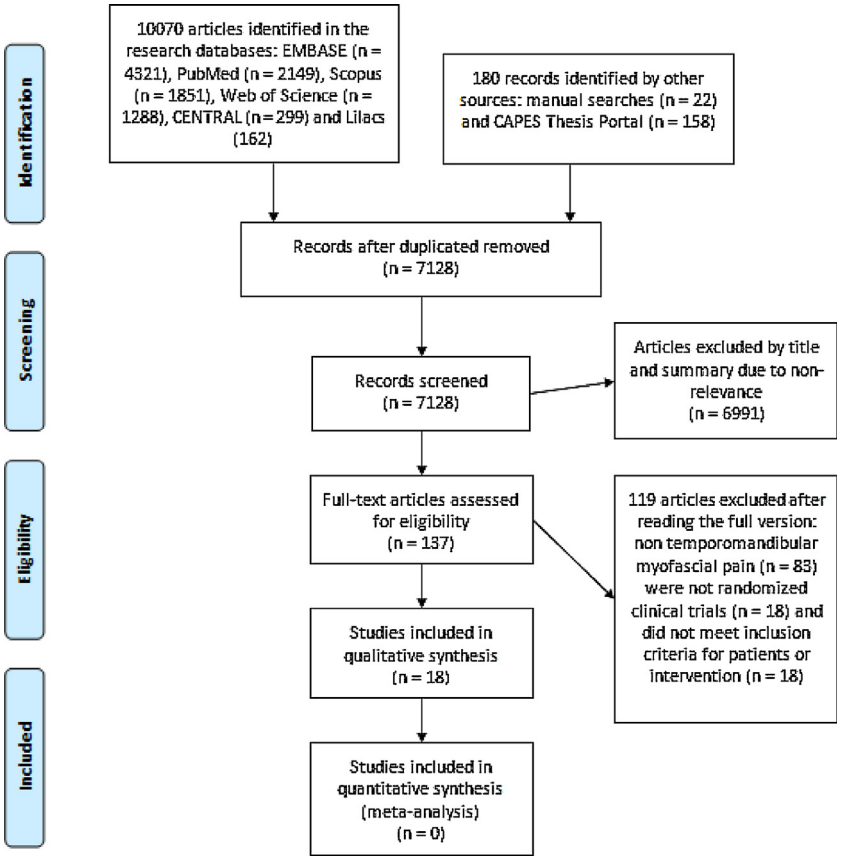

Fig. 1. Flowchart of studies search.

or unclear risk of bias for the following items: generation of allocation sequence, allocation secrecy, blinding, incomplete data, selection of the outcomes differently to the research protocol or if all possible outcomes were correctly explored, and potential bias as calibration, bias in the study design and others. This step was performed by two independent reviewers (E.M. and P. C.). Evaluation of bias was based on the data available in the studies. E-mail contact with the corresponding authors was attempted on two occasions, with 15 days of interval when there was unclear bias, and there was no reply in any of the requested cases.

Data analysis

A narrative summary of the findings of the included studies was performed, structured in the type of intervention, characteristics of the target population and type of outcome with subsequent discussion of the findings. Outcome results were presented as mean and standard deviation.

Results

Search

After the removal of the duplicated studies, 7128 articles were identified. Of these records, 137 were considered eligible for full-text reading. In the titles and abstracts selection step, the interexaminer agreement (Kappa) was 0.99. In the full-text reading step, Kappa was 1.00. There was no need for evaluation by a third reviewer during the selection steps. Figure 1 illustrates the selection process.

Included studies

Eighteen studies met the inclusion criteria of this systematic review[8,14–16,23–36]. The characteristics of the included studies are presented in Table 1. Table 2 shows the primary outcomes evaluated and results of the studies. Studies were divided according to the comparisons: Dry needling × Substance injection, Dry needling × Substance injection × False needling × Other treatments, Dry needling × False needling, Dry needling × - Other treatments, Substance injection and Substance injection × Other treatments.

In relation to the analysed interventions, seven studies evaluated botulinum toxin[14,23,24,27,28,30,31], six evaluated local anaesthetics[8,26,29,30,32,33], seven evaluated dry needling[8,15,16,29,30,32,33], one evaluated corticosteroid[29] and one evaluated granisetron[25].

Eight studies used the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD)[14,15,26–28,31–33], one used the criteria of the American Academy of Orofacial Pain[25], one the classification of the International Headache Society[8], one reported consistent criteria to RDC/TMD[23] and four did not specify a standardized and validated method[16,24,29,30].

Risk of bias

The evaluation of bias is presented in Fig. 2 and Table 3. Only six studies presented low risk of bias for most parameters[14–16,25,28,35], while the other studies presented unclear risk of bias for most evaluated parameters[8,23,24,26,27,29–34,36].

Main findings

Dry needling × Substance injection

Although there were favourable results for pain intensity, frequency and duration, none of the evaluated studies showed statistical difference between the groups for the evaluated outcomes.

Dry needling × Substance injection × False needling x Other treatments

One study evaluating laser therapy, needling with lidocaine on one side and dry needling on the other side and false laser application concluded that both lidocaine injection and laser therapy were effective for deactivation of trigger points[33].

Dry needling × False needling

Fernandez-Carneiro et al.[15] observed that dry needling was efficient in improving the PPT and MMO parameters, while Diraçoglu et al.[16] observed improvement only for PPT and no significant differences for pain intensity and MMO.

Dry needling × Other treatments

Gonzalez-Perez et al.[34] showed reduction in pain intensity at rest and on mastication for dry needling in comparison with a methocarbamol/paracetamol combination, but no significant improvement in MMO was observed.

Substance injection

Five studies[14,23,24,27,28] compared botulinum toxin with saline solution. Only Von Lindern et al.[24] and Guarda-Nardini et al.[27] observed reduction in pain intensity for botulinum toxin; the other studies showed no differences between the groups for pain intensity, MMO and PPT. Two studies compared Ganisetron with saline solution: Christidis et al.[25] observed no reduction in the pain intensity and improvement in PPT for Ganisetron, and Christidis et al.[35] showed a reduction in

Table 1. Characteristics of included studies.

Author, year and design	Sample data	Diagnostic criteria and muscles involved	Treatment and control groups	Follow up and particularities (number of sessions)
Dry-needling × Substance injection LA				
McMillan et?al. (1997)[8]. RCT, double-placebo-controlled, double-blind, parallel	30 individuals, aged 23–53 years. No other sample information	Based on the Classification of the International Headache Society. Masseter and temporal	Groups: tt in the active TP in the right or left masseter and PL in point without symptoms in the same patient. Gauge: 27-gauge hypodermic needle and disposable syringe. (A) 0.5 ml of procaine 1% without VC (tt) and dry needling (PL) (n = 10); (B) dry needling (tt) (acupuncture needle: SeirinKasei, Shimizu City, Japan) left in situ for 1–2 min and simulated LA (SS) (n = 10); (C) dry needling (PL) and LA (PL) (n = 10)	Three sessions, separated by a week, with follow up of 24 h Patients could not use medications or adjuvant treatments during the study Treatment was given on three occasions 1 week apart
Venâncio et?al. (2008)[29]. RCT, parallel. OBS: authors considered the dry-needling group as control	45 patients (40 F and 5 M, aged 18–65 years)	It was not specified whether any standardized and validated criteria were used. Masseter, temporal, trapezius and occiput	Each patient was injected in one to three TPs, in accordance with headache reproduction at the time of physical exam with disposable syringes (BD) 13 × 4.5, 26G 1/2, 5 ml and BD Precision Glide 0.45 × 13, 26G 1/2 needles (BD, Franklin Lakes, NJ), after the skin had been cleaned with alcohol 70. The needle was inserted 1–2 cm away from the TP and advanced into the TP at an acute angle of 30° to the skin. Group 1 (control, n = 15): dry needling; Group 2 (tt, n = 15): 0.2 ml lidocaine 0.25% without VC Group 3 (tt, n = 15): 0.2 ml of lidocaine 0.25% without VC + 0.2 ml of corticoid (Decadron 4 mg/ml).	12 weeks Ibuprofen was allowed if needed
Silva et?al. (2012)[32]. RCT, double-blind, parallel	No information	RDC/TMD with minor modifications. Masseter	The injections were performed using 3-ml disposable syringes (BD Plastipak™), Luer Lock® with disposable needles 0.45 × 13 26G 1/2 (BD PrecisionGlide™). Group 1: injection with 0.5% lidocaine 1 ml (n = 8); Group 2: dry needling (n = 8). No other information and no placebo group.	30 days They could not have used analgesics or anti-inflammatories in the previous 72 h Only one application session
LA and botulinum toxin				
Venâncio et?al. (2009)[30]. RCT, parallel. OBS: authors considered the dry-needling group as control	45 patients (40 F and 5 M, aged 18–65 years)	It was not specified if any standardized and validated criteria were used. Masseter, temporal, trapezius and occiput	The needle was inserted 1–2cm away from the TP and advanced into the TP at an acute angle of 30° to the skin. The injections were given with disposable syringes (BD) 13 × 4.5, 26G 1/2, 5 ml and BD Precision Glide 0.45 × 13 26G 1/2 needles (BD, Franklin Lakes, NJ). Each patient was injected in one to three TPs, selected in accordance with headache reproduction at the time of physical exam. Group 1 (control, n = 15): dry needling; Group 2 (tt, n = 15): 0.2 ml lidocaine 0.25% without VC; Group 3 (t,t n = 15): 0.2 ml of botulinum toxin 25–50 U (unspecified label).	12 weeks Ibuprofen was allowed if needed

Dry-needling × Substance injection × False needling × Other treatments				
Uemoto et?al. (2013)[33]. RCT, placebo-controlled, parallel	21 patients (all F, aged 20–52 years)	RDC/TMD. Masseter	Laser group (n = 7): infrared laser with wavelength of 795 nm at 80 mW power (Model Three Light, Clean Linebrand, São Paulo, Brazil) at a dose of 4 J/cm^2 in the right masseter of each patient and 8 J/cm^2 to the left side. Dry needling group on one side and 0.25 ml 2% lidocaine without VC on the other side (n = 7); Dental carpules with reflux and short 30G (Unoject Nova DFL brand, Rio de Janeiro, Brazil) disposable needles. The needle was inserted to a depth of 1–2 cm at an acute angle of 30° to the skin, in various directions, with movement into the tissue. Control group (n = 7) with false laser application. All therapies with four sessions.	8 days The use of analgesics, muscle relaxants, anti-inflammatories and/or benzodiazepines was not allowed Four sessions with intervals ranging between 48 and 72 h.
Dry-needling x False needling				
Fernandez-Carneiro et?al. (2010)[15]. RCT, Placebo-controlled, double-blind, crossover (washout of at least 7 days)	12 patients (all F, aged 20–41 years)	RDC/TMD. Masseter	tt group: dry needling (acupuncture needle 0.26 × 25 mm). Control group: false needling (short needle 0.26 × 13 mm). For both interventions, needles used for this experiment were stainless steel, manufactured by Novasan (Maraca ''Ener-Qi'' CE0197).	5min after the intervention No analgesic or anti-inflammatory drugs were allowed 48 h prior to the sessions Each patient attended two treatment sessions on two separate days and received one intervention assigned in a random fashion
Diraçoglu et?al. (2012)[16]. RCT, placebo-controlled, double-blind, parallel	50 patients (aged 18–57 years)	It was not specified whether any standardized and validated criteria were used. Masseter and temporal	tt group (n = 25) (standard single-use sterile acupuncture needles (0.22 mm × 30 mm) with plastic guide tubes (three times with 7-day intervals)). Control group (n = 25) with false needling (region without TP, acupuncture needle and the same sessions as the tt group).	1 week No report on drug use
Dry-needling × Other treatments Methocarbamol + paracetamol				
Gonzalez-Perez et?al. (2015)[34]. RCT, parallel	DDN group (5 M and 19 F, mean 34.3 SD ± 13.8 years) and control group (5 M and 19 F, 35.5 ± 11.2 years)	RDC/TMD. Lateral pterygoid	tt group: deep dry needling (once per week for 3 weeks). Sterile stainless-steel needles (length 40 mm/caliber 0.25 mm, with a cylindrical plastic guide; Agu-punt®). Control group: methocarbamol (380 mg) and paracetamol (300 mg) combination drug therapy, at a dose of two tablets every 6 h for 3 weeks.	8weeks
Substance injection Botulinum toxin × SS				
Nixdorf et?al. (2002)[23]. RCT, placebo-controlled, double-blind, crossover (4-week washout)	15 patients (all F, aged 18–45 years) started the study; 10 completed the study	Reported that the diagnostic criteria would be consistent with RDC/TMD. Masseter and temporal	tt group: 0.2 cm^3 (25–50 U according to muscle) of botulinum toxin (Botox/Allergan, Markham ON, Canada). Control group: 0.2 cm^3 of saline solution 0.9% per point. A 27-gauge, Teflon-coated needle (King Medical, King City, ON, Canada) attached to an audioamplified electromyographic (EMG) machine (Allergan, Markham ON, Canada) was used to confirm placement within the appropriate muscle and deliver the drug.	8 weeks for therapy Patients could not initiate or change medical or physical therapies during the study

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Table 1 (*Continued*)

Author, year and design	Sample data	Diagnostic criteria and muscles involved	Treatment and control groups	Follow up and particularities (number of sessions)
Von Lindern et?al. (2003)[24]. RCT, placebo-controlled, blind (patient), parallel	No information	It was not specified whether any standardized and validated criteria were used. Masseter, temporal and medial pterygoid	tt group: botulinum toxin (Botox, Allergan, Ettlingen, Germany) (mean 35 U diluted in 0.7 ml SS) (n = 60). Control group: 0.7 ml saline solution (n = 30). No information about the needling and number of sessions.	4 weeks Patients oriented to cease treatments for pain 7 days before injection
Guarda-Nardini et?al. (2008)[27]. RCT, placebo-controlled, double-blind, parallel	20 patients (10 F and 10 M, aged 25–45 years)	RDC/TMD. Masseter and temporal	tt group: Botulinum toxin (three injections of 20 U on temporalis muscle and 30 U on masseter muscle for a total treatment of 100 U) (Botox, Allergan, Inc. Irvine, CA) (n = 10). Control group: saline solution (n = 10). The injections were made during a single appointment under anatomo-topographic and/or ultrasonographic control. No information about the needling.	Baseline and at three follow-up appointments at 1 week, 1 month and 6 months. No report on the use of other drugs
Kurtoglu et?al. (2008)[28]. RCT, placebo controlled, double-blind, parallel	Botulinum toxin group: n = 12, 10 F and 2 M, aged 16–53 years and control group (saline solution): n = 12, 10 F and 2 M, aged 20–34 years	RDC/TMD. Masseter and temporal	tt group: 10 U of botulinum toxin (Allergan Pharmaceuticals, Ltd, Mayo, Ireland) diluted in 2 cc of SS (n = 12). Control group: 2 cc of saline solution (n = 12). Two injections were given 1 cm apart, where the muscle is most active during palpation. Whether the subject's complaint was unilateral or bilateral, injections were given bilaterally. Three points in two masseter muscles and two points in two anterior temporal muscles, for a total of 10 points, were injected with botulinum toxin.	Subjects were evaluated at baseline, and on 14 and 28 days Patients received no medication (analgesics, anti-inflammatories, muscle relaxants) or adjuvant therapies during the study
Ernberg et?al. (2011)[14]. RCT, placebo-controlled, double-blind, crossover (washout of at least 4weeks)	21 patients (19 F and 2 M and aged 26–50 years)	RDC/TMD. Masseter	tt group: 0.2 ml of botulinum toxin 50 U per muscle (and a maximum dose of 100 U to the patient if both muscles) (Botox; AllerganNorden AB, UpplandsVäsby, Sweden) diluted in 1 ml of SS (n = 12). Control group: 1 ml SS (n = 9). After crossing: Botulinum toxin group (n = 9) and SS group (n = 11:1 loss) A 1-mL syringe with a 19-mm-long needle (diameter 0.4 mm) was used for injections. The solution was injected at a depth of approximately 15 mm after careful aspiration. Injection in three points of each masseter (0.1 ml into the deep portion and 0.2 ml into the origin and attachment portions).	3 months The use of muscle relaxants or aminoglycoside antibiotics was not allowed
Granisetron × SS Christidis et?al. (2007)[25]. RCT, placebo-controlled, double-blind	18 patients (14 F and 4 M, mean age 36.9 years ± 12)	American Academy of Orofacial Pain. Masseter	On one side the patient received the tt group: 1 ml of granisetron (Kytril, 1 mg/ml, Roche, Stockholm, Sweden); and in another the control: 1 ml of saline solution. The injections were made perpendicular to the skin surface with a 19-mm-long needle (diameter 0.4 mm) by a 1-ml syringe at a depth of approximately 15 mm, during 10 s. The order of injections was the same for all participants, always starting on the right side, immediately followed by an injection on the left side.	Up to 30 min after infiltration No patient used analgesics on the study day

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Christidis et?al. (2015)[35]. RCT, placebo-controlled, double-blind, parallel	tt group, n = 20: 18 F and 2 M, 38.3 (15.1) years; and control group, n = 20: 19 F and 1 M, 39.1 (16.1) years	RDC/TMD. Masseter and temporal	tt group: granisetron (KYTRIL®; 1 mg/mL, Roche, Stockholm, Sweden) was used as active treatment (GRA-group). Control group: isotonic saline (NaCl; 0.9 mg/ml, Fresenius Kabi, Uppsala, Sweden) was used as control treatment. Injections were repeated after 1 and 2 weeks in the most painful tender-points at that time. The injections were made perpendicular to the skin surface over the chosen tender-point with an angle of 90° using a 19-mm-long needle (diameter 0.4 mm) from a 2-mL syringe. The solution was administered into each tender-point as a single shot during 10 s.	6 months No patient used any kind of centrally acting medication prior to or during the study
Ketamine × SS				
Castrillon et?al. (2008)[26]. RCT, placebo controlled, double-blind, crossover (12.2 ± 1.9 days washout)	14 patients (10 F/28.7 ± 2.0 years and 4 M/ 26.3 ± 2.5 years)	RDC/TMD. Masseter	tt group: 0.2 ml ketamine (Ketalar 10 mmol/l; pH7.0, Park Davis). Control group: 0.2 ml of saline solution. Each subject participated in two sessions (separated by an interval of 12.2 ± 1.9 days), with the same experimenter in which they received either a single injection of 0.2 mL of ketamine (Ketalar 10 mmol/l; ∼pH7.0; Park Davis) or placebo (buffered isotonic saline NaCl 155 mmol/l, Alcon Lab) into the deep masseter muscle. One injection per session was given into the same masseter muscle by the same experimenter. The injection was made into the most painful point (as determined by palpation) of the masseter muscle over a 10-s period with a 27-gauge hypodermic needle and a disposable syringe.	24 h Patients could not make chronic use of analgesic, psychiatric or other drugs that influence the response to pain
Substance injection × Other treatments				
Botulinum toxin × Fascial manipulation				
Guarda-Nardini et?al. (2012)[31]. RCT, parallel	30 patients (22 F and 8 M, aged 23–69 years)	RDC/TMD. Masseter and temporal	Group A (n = 15): Botulinum toxin 150 U per treated side (Dysport, Ipsen, Ltd., UK) in a single session in the temporalis and masseter muscles. Injections were performed by the same expert operator using a 0.7-mm 30G needle and with full respect of current standards for sterility. Group B (n = 15): multiple sessions of fascial manipulation. Each patient underwent three (±1) 50-min sessions of fascial manipulation on a weekly basis, for a total of 150 (±50) min over a 2- to 4-week span. No placebo group.	3 months No report on the use of other drugs
Botulinum toxin × Laser				
De Carli et?al. (2016)[36]. RCT, blind, parallel	n = 15 (13 F and 2 M, mean age 38 years and no specification between groups)	Diagnosis of myofascial pain without further information. Masseter and temporal	Laser group (n = 8): low-level device (Photon Lase III, DMC equipment, São Carlos, SP, Brazil) was used with GaAlAs (Gallium Arsenide and Aluminum) active medium, 100 mW of power, at a continuous emission mode, wavelength of 830 nm, and dose of 80 J/cm^2 per application point. Seven applications were performed at 48-h intervals between each application (session). Toxin group (n = 7): 500 U of botulinum toxin type A was used. In the first session, 30 U were applied per point. Fifteen days later, 15 U were applied per point, as in the first session. Toxin injection proceeded with the insulin syringe of ultrathin, sterile, 23-gauge, and 12-mm length needle.	30 days

DDN, deep dry needling; F, female; LA, local anaesthetic; M, male; OBS, observation; PL, placebo; RCT, randomized clinical trial; RDC/TMD, Research Diagnostic Criteria for Temporomandibular Disorder; SD, standard deviation; SS, saline solution; TP, trigger point; tt, treatment; U, units; VC, vasoconstrictor.

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YJOM-3945; No of Pages 13

Table 2. Results of included studies.

Author and comparator	Primary outcomes and measurement scale	Results - MD (SD)	*p*-Value between therapies	Adverse effects
Dry needling × Substance injection				
LA				
McMillan et?al. (1997)[8]: LA (A) vs dry needling (B) vs LA/simulated dry needling (control)	(1) Pain intensity (VAS: mm) (2) PPT (kg)	(1) Baseline: Group A 28 (28), group B 32 (29) and control group 17 (22); 24 h: Group A 28 (32), group B 25 (25) and control group 19 (20) (2) Baseline: Group A 0.80 (0.20), group B 0.9 (0.5) and control group 0.70 (0.20); 24 hours: Group A 1.00 (0.30), group B 1.0 (0.6) and control group 0.7 (0.2)*	(1) NS (2) NS	No information available in the study
Venâncio et?al. (2008)[29]. Dry needling vs lidocaine without VC vs lidocaine without CV + corticosteroid	Intensity, frequency and duration of pain (SSI)	Baseline: Group 1 (DN): 0.52 (0.09), Group 2 (L): 0.60 (0.21) and Group 3: (L + C) 0,51 (0.10); 12 weeks: Group 1 (DN): 0.36 (0.17), Group 2 (L): 0.46 (0.24) and Group 3: (L + C) 0.33 (0.12)	(1) NS	No information available in the study
Silva et?al. (2012)[32]. Dry needling vs lidocaine without VC	(1) Pain intensity (VAS) (2) PPT (kgf)	(1) Baseline: Group 1 (DN): 9.4, Group 2 (L): 9.6; 30 days: Group 1 (DN): 0.12, Group 2 (L): 0 (2) Baseline: Group 1 (DN): 1.081 (0.237), Group 2 (L): 1.063 (0.133); 30 days: Group 1 (DN): 1.604 (0.164), Group 2 (L): 1.56 (0.088)	(1) NS (2) NS	No information available in the study
LA and botulinum toxin				
Venâncio et?al. (2009)[30]. Dry needling vs lidocaine without VC vs botulinum toxin	Intensity, frequency and duration of pain (SSI)	Baseline: Group 1 (DN): 0.52 (0.09), Group 2 (L): 0.60 (0.21) and Group 3: (BT) 0.44 (0.19); 12 weeks: Group 1 (DN): 0.36 (0.17), Group 2 (L): 0.46 (0.24) and Group 3: (BT) 0.44 (0.19)	(1) NS	No information available in the study
Dry-needling × substance injection × False needling × Other treatments				
Uemoto et?al. (2013)[33]. Laser vs dry needling/lidocaine without VC vs false laser	(1) Pain intensity (VAS) (2) PPT (kgf)	It did not clearly or tabulate values of mean, SD, RR and CI for assessment	No comparisons between study groups	No information available in the study
Dry-needling × False needling				
Fernandez-Carneiro et?al. (2010)[15]. Dry needling vs false needling	(1) PPT (kPa) (2) MMO (mm)	(1) Baseline: tt group: 98.5 (30.57) and control group 108.7 (30.66); 5 min: tt group 176.5 (34.19) and control group 100.0 (34.28) (2) Baseline: tt group 30.9 (8.21) and control group 36.2 (10.95); 5 min: tt group 41.5 (11.04) and control group 36.1 (11.04)**	(1) $p < 0.001$ in favour of the tt group (2) $p < 0.001$ in favour of the tt group	No information available in the study
Diraçoglu et?al. (2012)[16]. Dry needling vs false needling	(1) PPT (kPa) (2) Pain intensity (VAS) (3) MMO (mm)	(1) Baseline: tt group 2.64 (1.05) and control group 2.69 (0.38); 1 week: tt group: 3.21 (1.06) and control group 2.75 (0.35) (2) Baseline: tt group 6.32 (1.54) and control group 5.68 (1.37); 1 week: tt group 3.88 (1.69) and control group 3.80 (1.47) (3) Baseline: tt group 41.20 (7.69) and control group 39.50 (4.72); 1 week: tt group 40.08 (6.10) and control group 39.60 (4.18)	(1) $p < 0.001$ in favour of the tt group (2) NS (3) NS	No information available in the study. Two withdrawals: difficulty in going to the clinic (1) and without treatment benefit (1)
Dry-needling × other treatments				
Methocarbamol + paracetamol				

Gonzalez-Perez et?al. (2015)[34]. Deep dry needling vs methocarbamol/paracetamol combination	(1) Pain intensity at rest (VAS) (2) Pain intensity on mastication (VAS) (3) MMO (mm)	(1) Pain at rest: tt group baseline 5.65 [4.65–7.17] and day 70 1.80 [0.30–3.40]; control group baseline 5.10 [2.92–6.80] and day 70 1.90 [0.30–3.92] 2) Pain on mastication: tt group baseline 6.75 [5.77–8.30] and day 70 2.10 [0.50–5.00]; control group baseline 6.15 [1.15–8.17] and day 70 1.75 [0.20–4.27] (3) MMO: tt group baseline 42.00 [35.00–46.75] and day 70 43.00 [40.00–46.00]; control group baseline 40.00 [36.50–48.75] and day 70 45.50 [39.75–49.75]	(1) Statistically significant values of p in pain reduction at rest in favour of the tt group (2) Statistically significant values of p in pain reduction at mastication in favour of the tt group (3) No signifcant improvement in MMO	Control group: 10 patients with adverse effects due to drug use
Substance injection Botulinum toxin × SS				
Nixdorf et?al. (2002)[23]. Botulinum toxin vs saline solution	(1) Pain intensity (VAS: mm) (2) MMO (mm)	(1) Baseline: mean of 56 (range from 30 to 73); 8weeks: tt group mean reduction of 19 (31) and control group 1 (16) (2) Baseline: mean of 43 (range from 27 to 56); 8weeks: tt group worsening of 3 (5) and control group improvement of 5 (7)	(1) NS (2) NS	Five dropouts: pain worsened (3) and paralysis (2)
Von Lindern et?al. (2003)[24]. Botulinum toxin vs saline solution	Pain (modified VAS but not specified)	It did not clearly or tabulate values of mean, SD, RR and CI for assessment	p <0.010 in favour of the tt group	Difficulty in swallowing/paralysis in one patient
Guarda-Nardini et?al. (2008)[27]. Botulinum toxin vs saline solution	(1) Pain during mastication (VAS) (2) Voluntary MMO (mm)	(1) Baseline: tt group 6.2 (2.78) and control group 4.10 (2.92); 6 months: tt group 3.60 (2.37) and control group 4.70 (2.79) (2) Baseline: tt group 46.30 (8.74) and control group 43.80 (9.40); 6 months: tt group 48.40 (7.63) and control group 43.50 (9.11)	(1) p <0.023 in favour of the tt group (2) NS	No information available in the study
Kurtoglu et?al. (2008)[28]. Botulinum toxin vs saline solution	Pain (bio-behavioural questionnaire: no further information)	Baseline: tt group 56.10 (17.10) and control group 58.90 (14.70); 28 days: tt group 43.90 (25.20) and control group 51.40 (23.00)	NS	There was no apparent adverse effect
Ernberg et?al. (2011)[14]. Botulinum toxin vs saline solution	(1) Pain intensity (VAS: mm) (2) PPT (kPa) (3) MMO (mm)	(1) Baseline: tt group: 69 (11) and control group 67 (14); 3months: tt group 58 (14) and control group 65 (11) (2) Baseline: tt group 112 (33) and control group 107 (31); 3 months: tt group 111 (44) and control group 116 (31) (3) Baseline: tt group: 42.70 (11.30) and control group 43.40 (7.30); 3 months: tt group 44.30 (7.20) and control group 44.20 (8.70)	(1) NS (2) NS (3) NS	One withdrawal. Adverse effects not related to treatments
Ganisetrom × SS				
Christidis et?al. (2007)[25]. Granisetron vs saline solution	(1) Pain intensity (VAS: mm) (2) PPT (kPa)	It did not clearly or tabulate values of mean, SD, RR and CI for assessment	(1) NS (2) p <0.016 in favour of the tt group	No information available in the study

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Table 2 (*Continued*)

Author and comparator	Primary outcomes and measurement scale	Results - MD (SD)	*p*-Value between therapies	Adverse effects
Christidis et?al. (2015)[35]. Granisetron vs saline solution	(1) Pain intensity (VAS: mm) (2) MMO (mm) (3) PPT (kPa)	(1) tt group baseline 52 (29) and 6 months 24 (35); control group baseline 57 (24) and 6months 34 (31) (2) tt group baseline 41.1 (9.3) and 6 months 47.2 (10.8); control group baseline 44 (10.9) and 6months 46.1 (6.2) 3) There was no change in PPT after treatment with any of the substances	(1) $p = 0.031$ in favour of the tt group (2) NS (3) NS	Four patients in both groups reported mild, short lasting adverse events, such as nausea, constipation, dizziness, haematoma and itching after the first injection of substance. These adverse events did not occur after the second and third injections
Ketamina × SS				
Castrillon et?al. (2008)[26]. Ketamine vs saline solution	(1) Pain intensity (VAS: cm) (2) PPT (kPa) (3) MMO (mm)	It did not clearly or tabulate values of mean, SD, RR and CI for assessment	(1) NS (2) NS (3) p <0.047 in favour of ketamine	No information available in the study
Substance injection × Other treatments				
Botulinum toxin × fascial manipulation				
Guarda-Nardini et?al. (2012)[31]. Botulinum toxin vs fascial manipulation	(1) Pain (VAS) (2) MMO (mm)	(1) Baseline: BT group: 7.3 (1.1) and Group FM 6.0 (2.0); 3 months: BT group 4.8 (2.0) and control 2.5 (2.2) (2) Baseline: BT group 48.7 (8.3) and FM group 52.0 (9.5); 3 months: BT group 51.4 (without SD) and FM group 52.40 (without SD)	(1) NS (2) NS	No relevant adverse effects, only mild discomfort to chewing
Botulinum toxin × laser				
De Carli et?al (2016)[36]. Laser vs botulinum toxin	(1) Pain (VAS) (2) MMO (mm)	It did not clearly or tabulate values of mean, SD, RR and CI for assessment	(1) NS (30 days) (2) NS	No information available in the study

BT, botulinum toxin; C, corticoid; CI, confidence interval; DDN: deep dry needling; DN, dry needling; FM, fascial manipulation; kgf, kilogram-force; L, lidocaine; LA, local anaesthetic; MD, mean; MMO, maximum mouth opening; NS, not significant; PPT, pressure pain threshold; RR, relative risk; SD, standard deviation; SSI, Symptom Severity Index; tt, treatment; VAS, visual analogue scale; VC, vasoconstrictor.

[*] Results based on the baseline of the third treatment session for PPT in the masseter muscle.

[**] Imputed standard deviation results from 95% confidence interval data.

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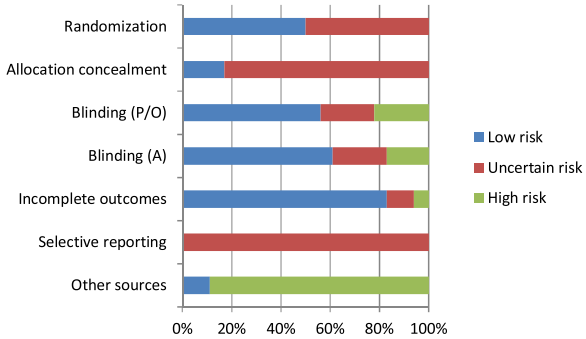

Fig. 2. General risk of bias. A, outcome assessor; O, operator; P, patient.

the pain intensity for Ganisetron, but no improvement for MMO and PPT parameters. The only study comparing ketamine with a saline solution[26] did not show difference between the groups for pain and MMO parameters.

Substance injection × Other treatments

Guarda-Nardini et al.[31] showed no differences between botulinum toxin and fascial manipulation for pain and MMO parameters. De Carli et al.[36] observed no differences between botulinum toxin and laser for pain symptoms and MMO.

Discussion

A systematic review requires a thorough knowledge not only of the evaluated research question, but also of the design, methodology and statistics. Due to the large number of studies available, this design is an important tool for the condensation of the best available evidence. The objective of this study was to obtain validated scientific conclusions regarding the effectiveness of needling (dry or with different substances) in temporomandibular myofascial pain. However, the findings were limited due to lack of primary studies of acceptable scientific quality.

The critical analysis of the evidences show that the selected studies presented different diagnostic criteria for myofascial pain. It should also be noted that RDC/TMD is now the most used criterion, but it presents limitations as only two diagnoses are considered for muscle dysfunctions: myofascial pain and myofascial pain with limited opening. The diagnostic heterogeneity limited and made it difficult to compare the results obtained in the included studies.

Considering the Cochrane risk of bias tool[21] (Table 3), it is verified that only nine studies presented low risk of bias for randomization[14–16,23,25,28]. It is more alarming when the allocation concealment is evaluated, in which only three studies presented a low risk of bias[14,28]. Failures in randomization and in the allocation concealment can introduce serious biases and compromise the quality of the evidence generated[17]. In relation to blinding of the patient and outcome evaluator, nine studies had a low risk of bias[8,14–16,25,26,28,32,35], four presented an unclear risk of bias for patient blinding and outcome evaluator[23,27,29,30] and one study had a low risk of bias for patient blinding and a high risk for outcome evaluator[24]. Still, in two studies, blinding was not possible due to the nature of the proposed treatments[31,33].

The overall risk of bias, as verified in Fig. 2, was quite significant. It was found that 83% of the studies had unclear risk of bias for allocation concealment and 50% for randomization, which may have been reflected in selection biases. Regarding blinding of the outcome evaluator, 39% of the studies presented an unclear or high risk of bias. Also, 89% of the studies had other sources of bias that could compromise the quality of their findings. Faced with this situation, the interpretation of the results obtained in the primary studies is compromised and must be carried out with caution, since the general risk of bias was quite present.

In evaluating the therapeutic options available for the treatment of temporomandibular myofascial pain, some considerations become important. In relation to botulinum toxin, eight included studies evaluated its effectiveness and showed diverse results. Three studies found that injection of botulinum toxin was ineffective for the outcome assessed[14,23,28], while five found little benefit in its use[24,27,30,31]. In the five studies that found positive results, all presented important limitations: lack of blinding of the outcome evaluator[24,31] and of the patient[31], small

Table 3. Individual evaluation of biases by the Cochrane tool.[21]

Author and year	Randomization	Allocation concealment	Blinding (P/O)	Blinding (A)	Incomplete outcomes	Selective reporting	Other sources
McMillan et?al. (1997)[8]	?	?	+	+	+	?	–
Nixdorf et?al. (2002)[23]	+	?	?	?	–	?	–
Von Lindern et?al. (2003)[24]	?	?	+	–	+	?	–
Christidis et?al. (2007)[25]	+	?	+	+	+	?	–
Castrillon et?al. (2008)[26]	?	?	+	+	+	?	–
Guarda-Nardini et?al. (2008)[27]	?	?	?	?	+	?	–
Kurtoglu et?al. (2008)[28]	+	+	+	+	+	?	–
Venâncio et?al. (2008)[29]	?	?	?	?	+	?	–
Venâncio et?al. (2009)[30]	?	?	?	?	+	?	–
Fernandez-Carneiro et?al. (2010)[15]	+	?	+	+	+	?	–
Ernberg et?al. (2011)[14]	+	+	+	+	+	?	+
Diraçoglu et?al. (2012)[16]	+	?	+	+	+	?	–
Guarda-nardini et?al. (2012)[31]	?	?	–	–	+	?	–
Silva et?al. (2012)[32]	?	?	+	+	+	?	–
Uemoto et?al. (2013)[33]	?	?	–	–	?	?	–
Gonzalez-Perez et?al. (2015)[34]	+	?	–	+	+	?	–
Christidis et?al. (2015)[35]	+	+	+	+	+	?	+
De Carli et?al. (2016)[36]	+	?	–	+	?	?	–

+, low risk of bias; –, high risk of bias; ?, unclear risk of bias. A, outcome assessor; O, operator; P, patient.

sample size[27,30,31], short follow-up time[24] and unclear risk of bias regarding randomization and allocation concealment[24,27,30,31]. The three studies that did not find an effective use of botulinum toxin were those that presented the greatest methodological care, but also contained, to a lesser extent, limitations such as small samples[23,28] and short follow-up times[23,28]. Due to the cost of the botulinum toxin and results that suggest that it does not present effectiveness, the current context requires the realization of new well-conducted RCTs, with larger samples and longer follow-up times, in order to evaluate its real effectiveness.

Regarding dry needling, two studies with low risk of bias showed benefits of the technique in comparison with false needling for PPT and MMO[15,16]. Dry needling therapy does not use any substance injection and is based on intramuscular stimulation and mechanical disruption of muscle fibres and nerve endings[30]. Another suggested mechanism is by the reduction of the electrical activity[37]. Similar results to therapies with injections of local anaesthetics and botulinum toxin were found in three studies[29,30,32]; in one the dry needling was inferior in relation to injection with local anaesthetics and laser application[33], and in one there were no significant differences from local anaesthesic/false dry needling or false dry needling/false local anaesthesic[8]. The use of local anaesthetic reduces the discomfot felt by the patient after needling[38]. Another study found that the dry needling procedure was more effective than the combination of methocarbamol and paracetamol[34]. The results are suggestive of a certain effectiveness of the therapy, which presents a lower cost when compared to other techniques, but the results should be interpreted with caution, considering the small sample size evaluated[15,16,32,33] and short follow-up time,[8,15,16,32,33] as well as limitations and methodological biases.

The injection of other substances such as local anaesthetics, corticosteroids or other drugs was also evaluated in the present study. Some studies have found benefits in the use of injections with local anaesthetics[29,30,32,33]. Only one study[29] evaluated corticosteroid use associated with lidocaine and found results similar to injection of lidocaine alone. The use of ketamine[26] was not effective in the control of myofascial pain. The use of granisetron showed positive results[35] and lack of effectiveness[25]. Studies that found positive associations presented serious methodological limitations in sample size and follow-up times, which greatly compromised the quality of the information generated, but the results are suggestive of the effectiveness of the technique. The use of granisetron seems promising, but it needs further studies to confirm its true effectiveness.

The methodological limitations and biases of the included studies compromise the achievement of definitive results. In general, results suggestive of effectiveness were verified only in the injection of local anaesthetics[29,30,32,33] and with dry needling[15,29,30,32]. The other therapies did not present reliable evidence to support their use.

The follow-up time in an RCT is extremely important to evaluate the effects of therapy on the outcome of interest. Four studies followed patients for hours or only 1 day[8,15,25,26], five studies for 2–30 days,[16,24,28,33,36] seven for 1–3months[14,23,29–32,34] and two for 6 months[27,35]. Thus, only the studies of Guarda-Nardini et al.[27] and Christidis et al.[35] presented long follow-up times, while the others included studies presenting limitations on the follow-up time, which compromised the evaluation of the desirable and adverse effects of the therapy in question in the medium and long term.

In the same way as the follow-up time, the sample size of the included studies presented important limitations. Among the selected studies, only four presented for consideration the sample size calculation[8,14,26,35]. The other studies did not perform a sample size calculation or did not report it. Some authors reported the small sample size among the limitations of their studies, requiring studies with larger samples[15,16,23,27,28,31].

The adverse effects of the applied therapies were only present in the studies involving botulinum toxin[23,24,31], due to the characteristics and actions of the injected substance. In these studies, there was an increase in pain[23], paralysis[23,24], difficulty in swallowing[24] and discomfort in chewing[31]. In other botulinum toxin studies, such as that by Ernberg et al.[14], there was a withdrawal, but it was not associated with the treatment, while in the study of Kurtoglu et al.[28], there were no evident adverse effects. In the study by Christidis et al.[35], some adverse effects were reported for both the treatment (granisetron) and control groups and only after the first session. For all the other selected studies, involving the other therapies, information about the occurrence of adverse effects was not reported. More importantly, adverse effects should also be evaluated in the medium and long term, which did not occur in most of the included studies, as previously discussed.

All studies included in this systematic review were found to have limitations of varying degrees. Within the temporomandibular myofascial pain research line, new randomized controlled clinical trials evaluating needling with the different substances analysed in this study, as well as dry needling, need to be conducted and their results presented based on rigorous methods of evidence. They should adopt standardized, validated and universal diagnostic criteria, guiding their results in samples with representativeness and power, as well as with longer follow-up times, in order to evaluate the real effectiveness of the techniques under evaluation. Also, it is important to evaluate the patient's perception of the improvement of the intervention in their quality of life.

It can be concluded that definitive conclusions about the therapies evaluated can not be made due to the lack of adequate quality of the selected studies. There is a need for new RCTs, with rigorous methodological criteria, standardized diagnostic methods and larger samples and longer follow-up times to evaluate the real effectiveness of the treatments analysed in this study, so that a future meta-analysis can be carried out within this research question.

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Competing interests

The authors declare that there are no conflicts of interest.

Ethical approval

Not required.

Patient consent

Not required.

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