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Bruxism and oral splints

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Abstract

Objectives: to evaluate the clinical-effectiveness of oral splints for patients with TMD or bruxism for the primary outcomes: pain (TMD) and tooth wear (bruxism).

Data selection and extraction: Randomised controlled trials comparing all types of splints versus no/minimal treatment for patients with TMD or bruxism were eligible. Standard Cochrane review methods were used. Standardised mean differences (SMD) were pooled for the primary outcome of pain, using random effects models in TMD patients.

Data synthesis: Thirty-seven trials were included and the evidence identified was of very low certainty using GRADE assessments. When all subtypes of TMD were pooled into one global TMD group, there was no evidence that splints reduced pain: SMD (up to 3 months) -0.18 (95% CI -0.42 to 0.06); 13 trials, 1,076 participants. There was no evidence that any other outcomes improved when using splints. There was no evidence of adverse events associated with splints, but reporting was poor regarding this outcome. No trials measured tooth wear in patients with bruxism. There was a large variation in diagnostic criteria, splint types and outcome measures used and reported. Sensitivity analyses based on these factors did not indicate a reduction in pain.

Conclusions: The very low-certainty evidence identified did not demonstrate that splints reduced pain in TMD as a group of conditions. There is insufficient evidence to determine whether splints reduce tooth wear in patients with bruxism.

Keywords: bruxism, oral splint, temporomandibular disorders

Introduction

Temporomandibular disorders (TMD) are the second most common cause (after dental pain) of orofacial pain, characterised by pain in the temporomandibular joint area and in the facial muscles. Apart from pain, patients may experience other signs and symptoms, such as clicking of the joint and restricted mouth-opening. Around 5% to 12% of the population have TMD symptoms to some degree, varying by age group and gender [1]. One of the most common ways in which dentists, particularly in primary care, manage symptomatic TMD is the provision of oral splints [2].

Splints are also provided to help manage tooth wear caused by bruxism. The prevalence of bruxism ranges from 8% to 31% within the general population [3], and it is estimated globally that sleep bruxism affects 16%, and awake bruxism 24%, of the adult population [4].

There is continuing debate about the exact mechanism of action of oral splints. Mechanisms include: muscle relaxation/habit-breaking for patients with increased parafunctional or muscle-tightening habits; protection of teeth and jaws, particularly where teeth clenching and grinding may lead to damage of teeth; normalising periodontal ligament proprioception, by utilising a splint to spread the forces placed on individual teeth; and repositioning of the jaws and condyles into centric relation.

Methods

We undertook the review using Cochrane methods [5], which are described in greater detail elsewhere (in press).

Eligibility criteria

Randomised controlled trials were included (crossover studies were excluded as deemed inappropriate). We included children (over 11 years old) and adults who had either TMD or bruxism, in either primary or secondary care.

We included trials where any type of splint was compared with a non-splint group. This group also included watchful waiting or minimal treatment (advice/counselling, education or self-performed exercises).

The primary outcomes were pain and harms. For bruxism patients, tooth wear was also considered a primary outcome. Secondary outcomes included clicking of the temporomandibular joint, change in restricted mouth opening, frequency of headaches and reduced quality of life. Patient satisfaction and adherence to treatment were collected whenever possible. For bruxism, the index and frequency of bruxism activity was also to be recorded.

Follow-up periods for the outcome data were divided into short-term follow-up (0 to 3 months), medium-term (>3 to 6 months), or long-term (>6 to 12 months).

Results

Characteristics of included studies

Thirsty-seven studies were included; 34 on patients with TMD and two on patients with bruxism, with a further study on patients with both TMD and bruxism. All studies, with the exception of one, were conducted in universities or public hospitals/clinic.

For the studies evaluating the effectiveness of splints for people with TMD, the diagnostic criteria for TMD varied. However, the predominantly used criteria were the RDC [6], used in 17 studies [11, 12, 13, 14, 15, 16, 17, 18, 19], The DC criteria [7]

were used in two studies, and an additional three studies used criteria that approximated to the RDC (either by citing the instrument and/or their description matched a similar process). No studies used the AAOP criteria [8].

The remaining studies used criteria that we had not pre-specified in our protocol or that were undefined/unclear:

- Three had used the Helkimo index
- Two used arthrography
- One used MRI
- Six used diagnostic systems that were not possible to classify.

The two studies examining the effects of splints on bruxism used the Lobbezzo *et al* [9]. criteria for likelihood of a bruxism diagnosis: 'possible' self-report of bruxism; 'probable' clinical evidence of bruxism with or without self-report; and 'definite' defined by polysomnography. We classified both studies as examining 'probable' bruxism.

The study that examined bruxism with co-morbid TMD used the Fonseca index for TMD and examined 'probable' bruxism.

Thirty-five studies compared splints against no splints for TMD patients. Ten of these studies used a no treatment control group [14]. Twenty had a co-intervention in each arm, with 13 having a 'minimal' co-intervention of usual treatment, counselling, information or exercise, [11, 12, 13, 15, 16, 17, 18, 19] while 7 had a 'non-minimal' co-intervention of 'acuhealth', manipulative and physical therapy, massage, Prozac, microcurrent electrical nerve stimulation, physical therapy with vapocoolant spray, arthrocentesis and sodium hyaluronate The remaining six studies had minimal treatment controls: three were self-exercises, and three were information-based.

One trial that has been referenced twice above had four arms with which we made two separate pairwise comparisons: 1) splint + co-intervention vs co-intervention alone; and 2) splint vs minimal treatment.

Nineteen studies used a stabilisation splint, 14 of which were in the upper jaw (Michigan-style splints), [11, 13, 14, 19] but not clearly reported in the other five [16].

Seven studies compared more than one splint against no splint in this comparison, and were included twice in any meta-analysis as two separate pairwise comparisons.

Patients with TMD

There was consensus with clinicians and methodologists that 0 to 3 months was an appropriate time point to use for the primary analysis of the data. The primary pain outcome was any continuous scale that was sensible to combine (for example, Visual Analogue Scale (VAS), Numerical Rating Scale (NRS), Characteristic Pain Intensity (CPI)).

Thirteen trials of 16 pairwise comparisons, all at high risk of bias and with 1,076 patients, contributed to the results for the main comparison at three months. There was considerable heterogeneity and the overall SMD was -0.18 (95% CI -0.42 to 0.06). Using a rule of thumb for SMD effect estimates [5], 0.18 would be considered a small effect and, as this was not statistically significant, there is no evidence that oral splints reduce pain. Due to differences in splint type, the control group with no/minimal interventions and different types of TMD diagnoses between the individual studies, we were unable to investigate the heterogeneity any further. There were fewer studies and patients for the other time periods (>3 to 6 months: 2 trials, 160 patients and >6 to 12 months: 2 trials, three pairwise comparisons, 246 patients) and the effect sizes also failed to demonstrate that oral splints reduced pain.

Patients with bruxism

Only one of the studies focusing on patients with bruxism provided usable outcome data at 0 to 3 months [15]; however, no studies looked at the primary outcome tooth wear. The aforementioned study on 78 patients looked at the other primary outcome pain on a 0 to 10 scale and indicated that splints reduced pain MD -2.01 (95% CI -2.62, -1.40).

Discussion

Summary of main results

Despite the inclusion of 35 studies comparing oral splints to no splints or a minimal intervention in patients with TMD, the body of evidence was assessed as being at very low certainty (see Summary of findings table in online-only Supplementary Appendix 5). There was no evidence that oral splints improved the following outcomes: pain; clicking of the temporomandibular joint; restricted mouth opening; or quality of life.

For patients with bruxism, there was insufficient evidence to conclude whether the provision of oral splints reduced tooth wear, as no studies reported this. Although a small number of studies reported pain and other outcomes, there was also insufficient evidence to conclude whether or not oral splints were beneficial. We were unable to undertake any sensitivity analyses due to the lack of outcome data.

For the TMD patients, we undertook three separate sensitivity analyses restricted to trials where: a) the inclusion criteria were based on, or could be clearly mapped to, specific pre-determined sets of diagnostic criteria; b) only stabilisation splints were used; and c) current pain was measured on a 0 to 100 visual analogue scale or numerical rating scale. There were no differences in the results based on these factors.

For both patients with TMD and bruxism, due to differences in the diagnoses of the included trial participants and differences in the types of splints and control groups used, the applicability of the evidence is questionable and certainly incomplete for patients with bruxism.

Pain was reported in numerous different ways, at different times, and this reduced the number of studies that could be combined in a meta-analysis to produce a pooled estimate. The use of an agreed measure for pain and how and when this is measured would enable the pain data from all studies to contribute to a single pooled estimate. It is also important to consider what would be a clinically important reduction in pain. It is suggested that a reduction of around 20% represents a minimally important decrease, 30% a moderately important decrease and 50% a substantial decrease.

Numerous studies reported on some of our outcomes but did not report the data in a suitable format for inclusion in our meta-analyses (including missing standard deviations). This can mean that meta-analyses are biased due to missing information. This highlights the need for standardisation in both 'what to measure' and 'how to measure it' in clinical trials within this area of research; otherwise, there will continue to be research waste, with data that we are unable to pool in data syntheses. Initiatives such as IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials), COMET (Core Outcome Measures in

Effectiveness Trials) and COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) could help with these issues.

Alternative treatment options for TMD

Other recent research into treatment options for the management of TMD has included orthognathic surgery, TMJ lavage, physiotherapy, low-level laser therapy, exercise therapy, pharmacological treatment, and acupuncture. However, results are mixed and generally unconvincing.

Conclusions

Implications for healthcare

From this systematic review, there is no clear evidence to support the provision of splints for the various sub-types of TMD or bruxism. However, the body of evidence that this conclusion is based on is of very low certainty. The studies included in this review differed in three important factors: 1) diagnoses, 2) splint type, and 3) outcome measurement/reporting. This made it difficult to draw clear and definitive conclusions.

Recommendations for future research

Further well-conducted randomised controlled trials are urgently needed to determine whether the use of splints is clinically effective, generates meaningful patient benefit and whether splints offer an efficient use of resources in both Bruxism and TMD. Multiple trials will be required to concentrate on specific sub-types of TMD in order to facilitate future, more focused meta-analyses. The need for further trials is perhaps more pronounced in bruxism patients, as there were no trials measuring tooth wear.

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