BMC Medical Research Methodology

RESEARCH

Open Access

Spin Bias in randomized controlled trials of botulinum toxin for bruxism management: a meta-epidemiologic study

Graziela De Luca Canto[1,2,3,4], Patrícia Pauletto[5*], Cristine Miron Stefani[1,6], Thais Marques Simek Vega Gonçalves[2], Nelson Carvas Junior[3], Carlos Flores-Mir[8], Ana Carolina Pereira Nunes Pinto[3,4,9,10] and Virginia Fernandes Moça Trevisani[3,4,7]

Abstract

Objective To perform a quantitative and qualitative analysis of spin bias in randomized clinical trials (RCTs) focusing on botulinum toxin (BTX-A) for managing bruxism.

Study design and protocol This is a meta-epidemiologic study. The protocol was registered on the Open Science Framework.

Study selection We included RCTs that evaluated the effectiveness of BTX-A for managing bruxism, associated or not with signs and symptoms of temporomandibular disorders. The outcomes were changes in pain and bruxism events. Spin bias was investigated in abstract and main text. The frequency of spin bias was assessed, and a qualitative analysis was conducted. The study was classified as effective if the outcome analyzed was statistically significant (*p*-value 0.05) and reached the minimum important difference of 20% and ineffective if the reported outcome was statistically nonsignificant or the study did not report the p-value or the results did not reach the minimum important difference of 20%.

Results An overall frequency of 59.4% spin bias was identified in eight included RCTs. The conclusion in the main text (87.5%) was the section with the highest frequency of spin bias. In the qualitative analysis, the most common strategies identified were inadequate extrapolation to a large population (30.61%), inadequate implication for clinical practice (20.41%), and misleading reporting (12.25%).

*Correspondence:
Patrícia Pauletto
patricia.pauletto.p@gmail.com
[1] Brazilian Centre for Evidence-Based Research, Federal University of Santa Catarina, Florianopolis, Brazil
[2] Department of Dentistry, Federal University of Santa Catarina, Florianopolis, Brazil
[3] Postgraduate Program in Evidence Based Medicine, Federal University of São Paulo, São Paulo, Brazil
[4] Emergency Medicine and Evidence-Based Medicine, Federal University of São Paulo, São Paulo, Brazil
[5] School of Dentistry, Universidad de Las Americas, Quito, Ecuador
[6] Department of Dentistry, University of Brasilia, Brasilia, Brazil
[7] Medicine, Santo Amaro University, São Paulo, Brazil
[8] Mike Petryk School of Dentistry, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Canada
[9] Iberoamerican Cochrane Centre - Biomedical Research Institute Sant Pau (IIB Sant Pau), Barcelona, Spain
[10] Biological and Health Sciences Department, Federal University of Amapa, Macapá, Brazil
Full list of author information is available at the end of the article

Conclusion There is a high frequency of spin bias in RCTs that evaluated BTX-A for bruxism management. Close to 90% of the selected RCTs presented spin bias in the main text's conclusion. The most common spin was the inadequate extrapolation of the results.

Clinical Significance Applying BTX into the temporalis did not reduce muscle activity and the results for masseter injections remain controversial. It seems that BTX-A injections can reduce pain from two weeks to one year. It is not possible to have certainty about the efficacy and safety of using BTX-A to reduce pain and bruxism events.

Keywords Spin bias, Bruxism, Botulinum toxin, Controlled trials

Introduction

Randomized Controlled Trials (RCTs) are widely considered the gold standard for evaluating the efficacy of health interventions [1]. Various methodologies have been developed to optimize the design, execution, analysis, reporting, and critical evaluation of RCTs [2–4]. However, despite rigorous efforts to enhance their methodological integrity, RCTs remain vulnerable to biases that undermine the accurate interpretation of results [5].

The CONSORT guidelines for RCTs emphasize the importance of precise and transparent reporting and interpretation based on the available evidence [6]. Accurate reporting is essential for disseminating knowledge, guiding future research, and informing clinical practice guidelines [6]. However, reporting can be complex, as there is a risk of both conscious and unconscious misinterpretation of results, which may introduce "spin" into the narrative. Spin bias refers to the distortion of result interpretation, potentially misleading readers. This bias can arise from a lack of understanding of the scientific subject, unconscious biases, or even a deliberate intent to mislead [5].

The BMJ introduced the concept of spin bias in biomedical research in 1995 [7]. Boutron et al. [8] initially defined spin bias as specific reporting tactics that, regardless of intent, present an experimental treatment as beneficial despite statistically non-significant primary outcomes or divert attention from such outcomes. More recently, spin bias has been further defined as the intentional or unintentional misrepresentation of study findings [9], with different forms identified, such as emphasizing statistically significant but clinically irrelevant results or interpreting non-significant findings as positive [10]. The prevalence of spin in abstracts has been explored across various fields of medicine [11] and dentistry [12–17], as a reminder for readers to critically evaluate new treatment options that may seem too good to be true.

In recent years, growing interest has been shown in the therapeutic potential of Botulinum toxin type A (BTX-A) for bruxism management. This toxin inhibits acetylcholine release from presynaptic nerve endings in striated muscle, causing temporary muscle paralysis [18, 19]. Numerous trials have investigated its effects on pain and bruxism event reduction [20–27]. Given the promising nature of this intervention and the possible commercial interests involved, researchers may be inclined to accentuate its benefits when interpreting RCTs findings. To our knowledge, no study has examined spin in RCTs assessing BTX-A use in bruxism management. Hence, this study aims to identify the frequency of spin bias in such studies and conduct a qualitative analysis of spin bias in publications of RCTs evaluating botulinum toxin use for bruxism management to reduce pain and bruxism events. Also, we aimed to analyze whether the studies are effective from a statistical and clinical point of view.

Methods

Study design and setting

This meta-epidemiological study was conducted at the Universidade Federal de São Paulo, Brazil. The study adhered to a pre-established protocol accessible through the Open Science Framework (OSF) under Doi: 10.17605/OSF.IO/QASC9.

Criteria for including publications

Types of studies

We considered only published RCTs evaluating the effectiveness of BTX-A for managing bruxism, with no restrictions on time or language. To be included, the study must have evaluated pain and/or bruxism events as outcomes. BTX-A could have been applied alongside other therapies (co-interventions) if its effect could be isolated.

Types of participants

We included studies comprising patients diagnosed with bruxism. Bruxism may manifest as an isolated condition or be accompanied by signs and symptoms of temporomandibular disorders. Participants of any age, sex, race, or socioeconomic status were eligible. We accepted studies involving sleep or awake bruxism management. The bruxism could have been identified by different methods: sleep/wake bruxism based solely on positive self-report; probable sleep/wake bruxism based on positive clinical

inspection, with or without positive self-report; definitive sleep/wake bruxism based on positive instrumental assessment (polysomnography-PSG or electromyography-EMG), with or without positive self-report and/or positive clinical inspection, adhering to the criteria outlined by Lobbezoo et al. (2018) [28].

Types of interventions

We considered any form of BTX-A used for therapeutic purposes for bruxism. The drug should have been administered into the masseters and/or temporalis muscles, employing various administration protocols and follow-up periods.

Types of comparators

The effects of the intervention should have been assessed through any of the following comparisons: versus sham therapy or placebo; no treatment; other interventions alone (e.g., occlusal splints, medication use); or BTX-A plus other interventions versus other interventions alone.

Types of outcomes

We considered only RCTs in which the outcomes were in pain and/or bruxism events. The pain must have been measured using a Visual Analog Scale (VAS) or another validated instrument. In case more than one scale was used, the results from the VAS were prioritized for the analysis to improve the consistency and comparability of our analysis. The bruxism events must have been measured by EMG or PSG and expressed as masticatory muscle activity or number of bruxism episodes per hour.

Exclusion criteria

1. Study types other than published RCTs (observational studies, non-randomized clinical trials, pilot studies, and study protocols).
2. Studies that do not present the outcome of interest.
3. Studies in which the sample was composed only of people presenting congenital abnormalities, cerebral palsy, orofacial or craniocervical dystonia, Parkinson's disease, autism, etc.
4. Studies involving patients with secondary bruxism (caused by or associated with neurological disorders or medication use).
5. Studies in which BTX-A was applied for another purpose than bruxism.
6. Studies that analyzed BTX-A in different administration doses in both groups and/or studies without a control group that did not receive BTX-A.

Identification and selection of publications

The Cochrane Highly Sensitive Search Strategy [29] was used in the string strategy on MEDLINE (via PubMed) to identify RCTs that evaluated BTX-A for bruxism. We applied this string, and one author (GDC) read the titles, abstracts, and keywords of the identified references to collect terms to improve the search strategy. Afterward, with the assistance of a Health Science Librarian, appropriate word combinations were adapted in new search strategies for each electronic database: MEDLINE (via PubMed), Cochrane (Central), Embase, and LILACS (via BVS), from inception to June 10th, 2024, when the strategies were applied. No language or publication date restrictions were set. The final strategy for each database is available in Appendix A.

Study selection process

The reference files of each database were imported into a reference software manager (EndNote X9®; Thomson Reuters, Philadelphia, PA, USA). EndNote initially managed duplicate removal, which was then manually reviewed using Rayyan® Online Software (Qatar Computing Research Institute, Qatar).

The Rayyan® Online Software (Qatar Computing Research Institute, Qatar) was used throughout the study selection process. Two authors (GDC; PP) were calibrated by reading ten abstracts, according to the eligibility criteria, before the selection process. Then, these authors (GDC; PP) participated in the study selection process. If any disagreements arise, the third author (TMSVG) was involved in reaching a final decision. The selection process was conducted in two phases. During phase 1, the identified RCTs underwent an initial screening process based on their titles and abstracts. In phase 2, RCTs that passed the initial screening stage underwent a full-text assessment.

Data extraction

One author (GDC) collected data from the selected articles using standardized spreadsheets previously prepared by the authors. A second author (TMSVG) cross-checked all the data.

Spin bias analysis

Quantitative analyses of spin bias (Frequency)

Spin bias was investigated in four sections of the publication: the abstract results, abstract conclusions, main text results, and main text conclusions.

Based on the concept of spin bias, "the intentional or unintentional misrepresentation of study findings [9]," two independent authors (GDC and TMSVG) classified the sections with spin (yes) or without (no) to identify

spin bias. After that, the two authors (GDC and TMSVG) held a consensus meeting to decide on the presence or absence of spin in each section. Then, we determined the spin frequency in each section and across the sample of the included studies.

The proportion of spin in each section was calculated considering the number of spin × 100, divided by the total of RCTs included in the analysis. The proportion of spin in all studies was calculated considering the sum of spins × 100, divided by the total of RCTs included in the analysis.

Qualitative analysis

A qualitative analysis of spin bias was conducted by quoting sentences related to the identified spin bias and offering plausible explanations for any disagreements with the original wording. If spin bias was detected, it was classified by two authors (GDC and TMVG) into categories as recommended by Lazarus [30] (Appendix B). A third author (CMS) crosscheck the data. Descriptive statistics were used to summarize the frequency and characteristics of the spin, and they were categorized into three types: (1) misleading reporting, (2) inadequate interpretation, and (3) inadequate extrapolation [30].

Statistical analysis and clinical applicability

We tabulated the p-values for the differences between the groups described in each article. This data was also used to calculate the change in mean values after the intervention (across different follow-up periods) compared to baseline, with the differences expressed as percentages. We defined the minimum important difference (MID) as the smallest meaningful change in the scores of both outcomes. For our study, we defined the Minimum Important Difference (MID) as a 20% improvement for both pain and bruxism events. Given the absence of established MID values for bruxism events in the literature, we based our decision on Calixtre et al [31]. Calixtre et al [31]. found that the MID for general chronic pain, measured using the Visual Analog Scale (VAS), ranges from 1.5 to 3.2 cm, and a pain reduction of 3.2 cm on the VAS may not be necessary to demonstrate clinically meaningful improvement in TMD patients [31].

Based on this threshold, we classified the study results as either effective or ineffective. The study was classified as effective if the analyzed outcome was statistically significant (p-value < 0.05) and achieved a 20% improvement (MID). It was classified as ineffective if the reported outcome was statistically non-significant, the p-value was not provided, or the results did not reach the 20% improvement threshold.

Results

Study selection

We identified 211 references, of which 125 remained after duplicate removal to begin phase 1. Based on the eligibility criteria, 110 references were excluded, leaving 15 studies for the full-text analysis in phase 2. At the end of phase 2, eight articles were included in the final analysis. A flowchart outlining the study selection process is presented in Fig. 1. The excluded references, along with the reasons for their exclusion, are provided in Appendix C.

Study characteristics

The studies were published between 2010 [22] and 2024 [23], with sample sizes ranging from 12 [22] to 73 patients [23], totaling 244 participants. Six studies were conducted in Asia [20–23, 25, 26], one in the Americas [24], and one in Turkey [27]. The main characteristics of the included studies are summarized in Table 1.

Most of the studies focused on sleep bruxism. One study [23] included patients with both awake and sleep bruxism, while in another, this information was unclear [27]. Bruxism diagnosis was made using a variety of methods, including questionnaires [22], questionnaires combined with clinical assessment [20, 21, 23, 25, 26], or EMG/PSG [24]. One study relied solely on clinical assessment to identify bruxism patients [27].

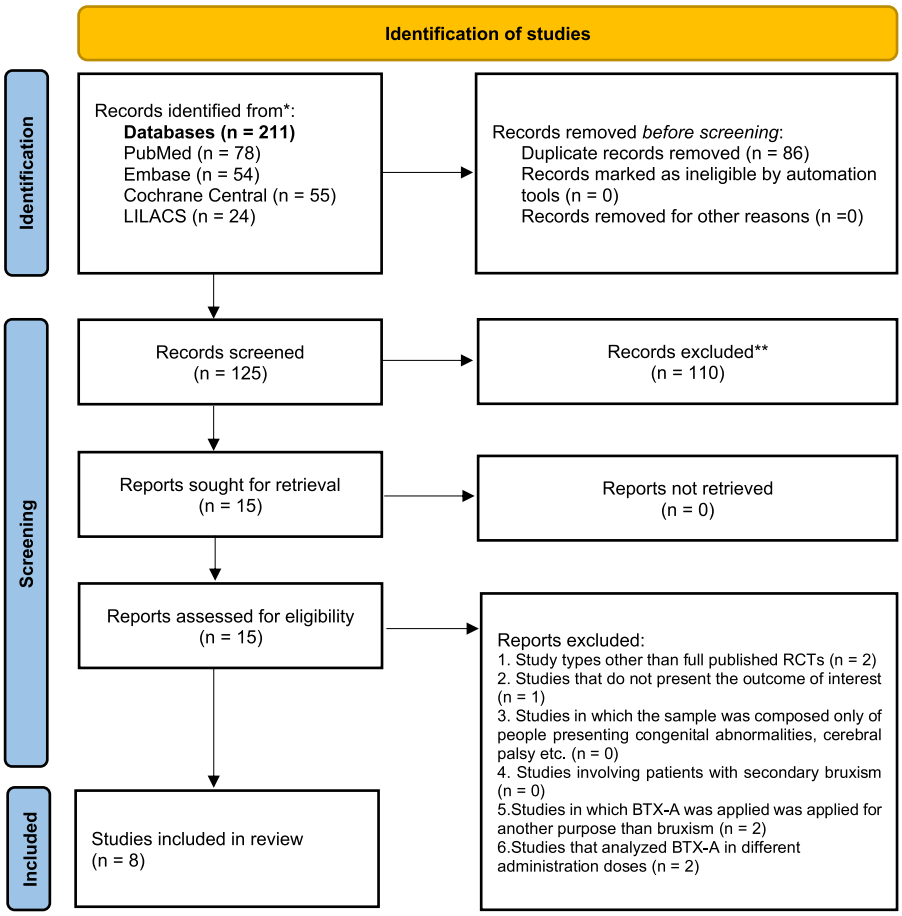
The BTX-A was injected bilaterally in the masseter muscle [20, 22, 23] or in the masseter and temporalis [21, 24, 27].

Of the eight included studies, only two [25, 27] reported using the CONSORT guidelines [6], and just four studies provided a flow diagram outlining the participant selection process [23, 25–27]. Two studies were funded by the pharmaceutical industry [24, 26]. Only two studies included a sample size calculation [23, 25]. Three studies used a random number generator program for randomization [24, 25, 27], while one used the slot method [23]. The bibliometric characteristics of the included studies are detailed in Table 2 and Appendix D.

Spin bias analysis

Quantitative analyses of spin bias (Frequency)

We identified spin bias in all of the included articles. Across the four sections analyzed in the eight RCTs, 59.4% exhibited spin bias. When considered individually, a high frequency of spin bias was observed in each section. The section with the highest frequency of spin bias was the conclusion in the main text, which occurred in 87.5% of the studies (Fig. 2/Appendix E).



Source: Page MJ, et al. BMJ 2021;372:n71. doi: 10.1136/bmj.n71.

Fig. 1 Flow diagram

Qualitative analysis

The most common spin strategies identified were inadequate extrapolation to a larger population (30.61%), inadequate implications for clinical practice (20.41%), and selective reporting (12.25%). Table 3 presents the qualitative analysis of the spin bias and the classification of the identified spin types. Table 4 shows the frequency of each spin classification, while Fig. 3 illustrates the most frequent forms of spin.

Clinical and Statistical Effectiveness

Pain (Fig. 4 / Appendix F):

Five studies evaluated pain [20, 21, 23, 25, 27], considering different types of pain: pain at rest and during chewing, pain upon palpation of the chewing muscles, perceived pain, and unspecified pain types.

The results for BTX-A application were statistically significant and led to a reduction of more than 20% in pain, meeting the MID at various time points: two weeks [23, 25], one month [25], two months [20], three months [25], four months [25], six months [20, 25, 27], and one year [20]. However, Al-Wayli (2017) [20] did not show effectiveness for three weeks. The studies by Al-Wayli (2024) [23] and Jadhao et al. (2017) [21] were classified as non-effective because they did not report the p-value.

Among these five studies, two exhibited 25% spin bias [21, 25], one showed 50% spin bias [27], and two had 100% spin bias [20, 23], meaning spin bias was present in all four sections analyzed for these studies.

Bruxism (Fig. 5/ Appendix G):

Four studies evaluated bruxism events using different measures: muscular activity (microvolts) [25], the number of bruxism events [22, 24], and rhythmic masticatory muscle activity (RMMA) episodes per hour [26].

The results of BTX-A application to the masseter were statistically significant, reducing muscle activity by more than 20%, and meeting the MID at two weeks [25] and

Table 1 Main characteristics of included studies ($n = 8$)

Author, year, country	Sample size	Age (SD)	Bruxism Diagnosis/type	Intervention	Muscle injections	Comparison	Follow up	Outcome Pain	Outcome Bruxism Events	Adverse effects
Al-Wayli 2017, Saudi Arabia [20]	50	45.5 (SD 10.8)	Clinical inspection and questionnaire Sleep bruxism	20 units of BTX, (BOTOX; Allergan Inc.) per side	Masseter muscle bilaterally (3 points)	Traditional methods to treat bruxism	3 weeks, 2 months, 6 months, and 1 year	Pain, assessed by VAS (0 to 10 cm)	-	None of the patients reported any adverse effects
Alwayli et al. 2024, India and Saudi Arabia [23]	40	No reported	Clinical inspection with a positive self-report Sleep/Awake	100 units BTX-A (BOTOX; Allergan) reconstituted with 2 ml of sterile preservative-free saline. Forty units were injected	Masseter muscle bilaterally (4 points)	Placebo (saline injections)	2, 4, 8, 12, 16, 18, and 24 weeks	Pain at rest and chewing, assessed by VPS (0 to 10)	-	Not reported by the authors
Jadhao et al. 2017, India [21]	24	Not reported	Clinical inspection with a positive self-report Sleep bruxism	Four BTX-A (BOTOX; Allergan) intramuscular injections for each side (30 U) within the masseter muscles and 3 injections (20 U) within the anterior temporalis muscles, for a treatment total of 100 U	Masseter (4 points)/Temporalis (3 points)	Placebo (saline injections)/ control group	1 week, 3 months, and 6 months	Pain at rest and at chewing assessed by VAS (0 to 5)	-	Not reported by the authors
Lee et al. 2010, Korea [22]	12	Control = 24.8 (SD 1.47) BTX-A = 25.0 (SD 2.28)	Questionnaire Sleep bruxism	80 MU of BTX- A diluted in 0.8 ml of saline	Masseter (3 points)	Placebo (saline injections)	4, 8, and 12 weeks	-	Number of bruxism events per hour assessed by EMG / The EMG data of both masseter and temporalis muscles were collected for 3 consecutive nights at home	None of the patients reported any adverse effects

Table 1 (continued)

Author, year, country	Sample size	Age (SD)	Bruxism Diagnosis/type	Intervention	Muscle injections	Comparison	Follow up	Outcome Pain	Outcome Bruxism Events	Adverse effects
Ondo et al. 2018, United States [24]	22 for pain 21 for bruxism	Placebo = 45.8 (SD 19.6) BTX-A = 48.6 (SD 13.6)	PSG Sleep bruxism	100 U/mL of Onabotulinum toxin-A. Sixty units were injected bilaterally into the masseter muscles and 40 units into the bilateral temporalis	Masseter muscles (2 points)/ Temporalis (3 points)	Placebo	4 to 8 weeks	Pain assessed by VAS (0–10 cm)	Number of bruxism events per hour assessed by PSG/EMG/ signals from the temporalis and masseter	The injections were well tolerated. Adverse events were limited to 2 participants with a cosmetic change in their smile. No participant reported dysphagia, masseter weakness, or dry mouth
Shehri et al. 2022, Syria [25]	20	29.81 (SD 7.12)	Clinical inspection and questionnaire Sleep	100 MU of BTX-A diluted in 2 ml of saline solution. Patients were injected with 10 MU of BTX-A per side	Masseter muscle bilaterally (2 points)	Sham therapy (stinger pen used in the blood glucose meter)	2 weeks, 3 and 4 months	Perceived pain assessed by VAS (0–10 cm)	Muscular activity recorded by EMG in right and left masseter muscles	Four patients had pain in the injection points in the first week of injection, and two patients had discomfort at the injection site. No side effects were reported by the rest of the included patients

Table 1 (continued)

Author, year, country	Sample size	Age (SD)	Bruxism Diagnosis/type	Intervention	Muscle injections	Comparison	Follow up	Outcome Pain	Outcome Bruxism Events	Adverse effects
Shim et al. 2020, Korea [26]	23	Placebo = 28,90 (SD 8,13) BTX = 32.46 (SD 9.94)	Clinical inspection with a positive self-report, accordingly American Academy of Sleep Medicine Sleep Bruxism	BTX (NABOTA, prabotulinum-toxin A) supplied as a freeze-dried powder of 100 U and reconstituted with 2 mL of sterile normal saline to a concentration of 5 U/0.1 mL. A dose of 25 U was injected into each masseter muscle	Masseter muscle bilaterally (2 points)	Placebo (saline injections)	before, at 4 weeks after, and at 12 weeks after injection	-	Number of RMMA episodes per hour of sleep assessed by EMG/ submental and bilateral tibialis anterior muscles, as well as from the bilateral masseter muscles	Not reported by the authors
Yurttutan et al. 2019, Turkey [27]	73	Group A = 31 (SD 7.33) Group B = 30.5 (SD 9.95) Group C = 30.2 (SD 8.63)	Unclear	100-U of freeze-dried BTX-A (BOTOX; Allergan) with 1.0 mL of sodium chloride, for a dose of 1.0 U/0.1 mL. Each participant received 90 U of BTX-A: 15 U into each temporalis muscle and 30 U into each masseter muscle	Masseter (5 points)/ Temporalis (3 points)	Occlusal splint occlusal splint and BTX-A injections	7 days, 3 months, and 6 months	Pain at palpation of the chewing muscles, assessed by VAS (0–10)	-	None of the patients reported any adverse effects

Legend: *BTX-A* Botulinum toxin type A, *EMG* Electromyography, *PSG* Polysomnography, *RMMA* Rhythmic Masticatory Muscle Activity, *SD* standard deviation, *U* unit, *VAS* Visual Analog Scale, *VPS* Visual Pain Scale

Table 2 Summary of bibliometric characteristics of the included studies

Description	% (n)
Presence of flow diagram	No = 50% (4) Yes = 50% (4)
Consort adherence	No = 75% (2) Yes = 25% (2)
Report the sample calculation	No = 37,5% (3) Yes = 25% (2) Unclear = 37,5% (3)
Randomization method	Not reported = 50% (4) Slot = 12,5% (1) Computer generation numbers = 37,5% (3)
Blinding	Unclear = 25% (2) Single = 12,5% (1) Double = 50% (4) Triple = 12,5% (1)
Continent	Asia 75% (6) America 12,5% (1) Euro Asia 12,5% (1)
Number of authors	1 author = 12,5% (1) 3 authors = 25% (2) 5 authors = 25% (2) 6 authors = 37,5% (3)
Journal	American Journal of Physics 12,5% (1) Cranio 12,5% (1) Cureus 12,5% (1) Indian Journal Dental Research 12,5% (1) J Clin Exp Dent 12,5% (1) Journal of Oral and Maxillofacial Surgery 12,5% (1) Neurology 12,5% (1) Toxins 12,5% (1)
Funding	Unclear 12,5% (1) Declared without conflict 12,5% (1) No funding declared 25% (2) University's financial support 25% (2) Pharmaceuticals 25% (2)

two months [22]. The results were inconsistent at one and three months, and by six months, no effects were observed [25].

On the other hand, applying BTX-A to the temporalis muscle was ineffective and did not reduce muscle activity [22], regardless of the follow-up period.

Among these four studies, two exhibited 25% spin bias [25, 26], one showed 50% spin bias [22], and one had 100% spin bias [24].

Discussion

This study aimed to identify the frequency of spin bias in RCTs evaluating BTX-A use for bruxism management and conduct a qualitative analysis of the spin bias present in these publications. We found that 100% of the included RCTs exhibited spin bias in at least one section analyzed. The frequency of spin bias was particularly high in the conclusions of the main text.

Numerous studies have examined spin bias in dentistry, revealing a high frequency of spin bias in the dental literature [12–17]. The prevalence of spin bias in dental articles' abstracts has been reported to range from 31% [16] to 60% [12]. Spin bias has been observed across various dental specialties, with 62.2% in orthodontics [14], 69% in periodontology and oral implantology [17], 78.4% in pediatric dentistry [15], 79% in dental caries [32], and 85% in endodontics [13]. In the field of sleep medicine, Guo et al. (2023) [15] evaluated the prevalence and characteristics of spin in RCT abstracts, finding that 78.1% contained at least one form of spin bias, with 57.9% exhibiting spin in the results section and 71.9% in the

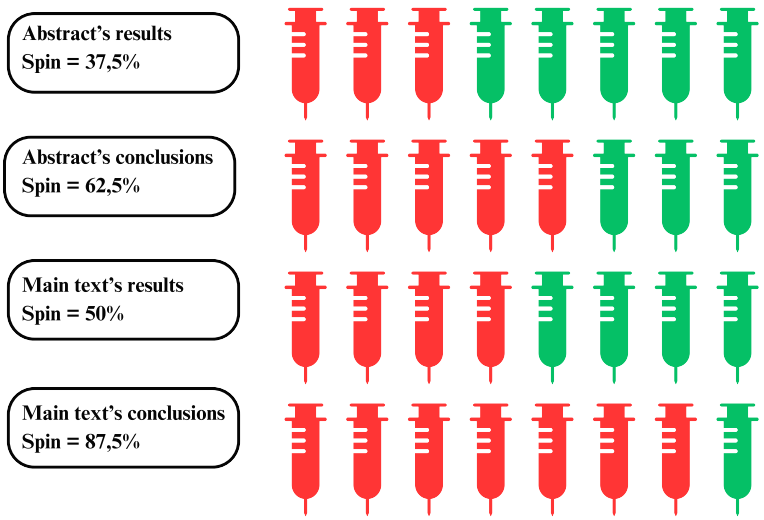


Fig. 2 Frequency of spin bias in the included studies

Table 3 Qualitative and categorical analysis of included publications where spin bias was detected

Author, year, country	Quoted text	Categories of spin accordingly Lazarus et al. [30]	Spin Analysis
Al-Wayli 2017 [20]	**Results in the abstract** "Mean pain score due to Bruxism events in the masseter muscle decreased significantly in the botulinum toxin injection group A (P = 0.000, highly significant)."	2 K, 3 M	The study did not evaluate bruxism events. Then the conclusion is not supported by the results In the main text, the statistical analysis did not evaluate the changes in both the control and the BTX-A group, only compared the difference between both groups. In the abstract, on the other hand, the authors inform the before and after results for each group and not the comparison between them The results did not show that the reapplication is necessary because the patients were not reevaluated after 15 days and there is no information on reapplication. Also, according to the results the improvement in the pain was stable in 6 months and one year The authors use linguistic spin ("highly significant") to emphasize the results
	Conclusion in the abstract "Our results suggest that BTX injection reduced the mean pain score and number of bruxism events, most likely by decreasing the muscle activity of masseter rather than affecting the central nervous system."	2 J, 3 M, 3O	
	Results in the main text "There was highly significant difference in mean pain score post-operatively at 3 weeks in group I and group II ($p = 0.000$). The mean pain score at 2nd month post-operatively in group I was 2.5 ± 0.59 and in group II was 4.3 ± 0.48. There was highly significant difference in mean pain score at post-operative 2nd month in group I and group II."	1D, 2 K, 2 J, 3 M, 3O	
	Conclusion in the main text "20 UI per side BTX injection in the masseter muscles is an effective and safe means of intervention in cases of moderate to severe chronic myofascial and TMJ pain associated with bruxism. The patient should be evaluated 15 days after the application and return for control after three or four months after the application for a new evaluation and another application, if needed."	3 M, 3N	
Alwayli et al. 2024 [23]	**Results in the abstract** "The study included 24 females and 16 males aged 21 to 52 years (mean 33.9 ± 31.0). The mean VPS score on the first day was 5.75 (± 1.9), significantly decreasing after two weeks to 0.44 (± 0.727). The mean difference of VPS from 8 weeks up to 24 weeks gradually increase from 0.69 at 8 weeks to 2.00 at 24 weeks."	1B, 2G	The results are not clearly reported. The outcomes are described as "Pain at rest and chewing, assessed by using a VPS from 0 to 10, with the extremes being no pain and pain as bad as the patient has ever experienced, assessed at baseline and follow-up appointments, i.e., at 2 weeks, 4, 8, 12, 16, 18, 20, and 24 weeks." However, in the results the authors have presented two different measurements. The first one is "the mean subjective VPS". For this outcome, only results from the BTX-A group were reported at 2 weeks, 4, 8, 12, 16, 18, 20, and 24 weeks. The second is "the mean pain score". For this one, the authors have presented the results for both groups only at 2, 8 and 24 weeks. Also, it is important to highlight that the results from the control group can be correct, but they are exactly the same in the three follow-up points Besides that, the BTX-A was evaluated alone, then, cannot be considered "a useful adjunct" treatment So, we considered that this study has selective reporting, claims of significant difference despite lack of statistical test and the conclusion cannot not be supported by the results. Also, the authors use linguistic spin ("highly significant") to emphasize the results
	Conclusion in the abstract "This study provides evidence that BTX-A could reduce the pain of nocturnal bruxism in affected patients."	1B, 3 M, 3N	
	Results in the main text "This study shows that BTX-A could reduce the pain of nocturnal bruxism in affected patients. The VPS scores showed significant decrease of pain initially. Very mild pain returned after 12 weeks; however, tolerability and subjective efficacy of treatment were rated by most as either good or excellent."	1B, 2G, 2 J, 3 M	
	Conclusion in the main text "It can be concluded that injectable BTX-A is a useful adjunct in the management of bruxism."	1D, 3 M, 3N	
Jadhao et al. 2017 [21]	**Results in the abstract** No spin	-	The results of the statistical analysis for "Duration of clenching and releasing" are not presented anywhere in the main text "To determine the precision of the occlusal analysis system" was not described as a purpose of the study. Therefore, the conclusion should not consider this variable The authors use linguistic spin ("obvious advantages") in the conclusion
	Conclusion in the abstract No spin	-	
	Results in the main text No spin	-	
	Conclusion in the main text "We also achieve that the occlusal analysis system precisely imitates the characteristics of occlusal force during treatment of bruxism." "BTX-A has obvious advantages for the treatment of bruxism in terms of tumbling the occlusal force."	1D, 3 M, 3O	

Table 3 (continued)

Author, year, country	Quoted text	Categories of spin accordingly Lazarus et al. [30]	Spin Analysis
Lee et al. 2010 [22]	**Results in the abstract** No spin	-	The results for this study were positive only for masseter muscle, not for temporalis So, we considered that this study has selective reporting, claimed an effect for non-statistically significant results (temporalis) and the conclusion cannot not be supported by the results. Therefore, we considered a spin interpreting statistically nonsignificant results of the temporalis muscle as showing treatment equivalence or comparable effectiveness
	Conclusion in the abstract "Our results suggest that BTX injection reduced the number of bruxism events, most likely mediated its effect through a decrease in muscle activity rather than the central nervous system."	1B	
	Results in the main text No spin	-	
	Conclusion in the main text "Our results showed that the injection of BTX in the masseter muscle reduced the number of bruxism events during sleep, most likely mediated through its effect on muscle tone rather than central nervous system. BTX injection can be used as an effective treatment for nocturnal bruxism."	1B, 2G, 3 M, 3N	
Ondo et al. 2018 [24]	**Results in the abstract** "CGI ($p < 0.05$) and VAS of change ($p < 0.05$) favored the BTX-A group. None of the exploratory endpoints changed significantly, but total sleep time and number/duration of bruxing episodes favored the BTX-A group. Two participants randomized to BTX-A reported a cosmetic change in their smile. No dysphagia or masticatory adverse events were reported."	1B	There is selective reporting in the abstract, because the results did not report the number of bruxism events in both groups The results for pain and bruxism (assessed by VAS) were not described and they were only presented in "Table 1—Demographics and efficacy points" Also, the results for Bruxism Quest score, which shows that there was no difference in the changes from baseline to four weeks between both groups (p = 0.11), were not described in the text We also considered that the study did not evaluate efficacy, presented a selective reporting and claimed for a significant difference despite the lack of statistical test. Moreover, inadequate extrapolation and inadequate implication for clinical practice were also detected
	Conclusion in the abstract "BTX-A effectively and safely improved sleep bruxism in this placebo-controlled pilot trial."	3 M, 3N	
	Results in the main text Table 1 Demographics and efficacy points	, 2 K	
	Conclusion in the main text Not described in the main text	3 M, 3N	
Shehri et al. 2022 [25]	**Results in the abstract** No spin **Conclusion in the abstract** No spin **Results in the main text** Table 2 (no comparison between different follow up points and the baseline – the statistically significant difference may be misleading) **Conclusion in the main text** No spin	3O	Table 2 presents comparisons for each evaluation time with the previous one. The existence of statistical significance from 3 months onward means a worsening of the condition, but since there is no comparison with the baseline, it is difficult to interpret and may be misleading to the reader
Shim et al. 2020 [26]	**Results in the abstract** No spin	-	The authors state that the study evaluated "long-term effect" when 3 months is the usual duration of the botulinum toxin The study did not evaluate occlusal splints and therefore, this conclusion was not supported by the results
	Conclusion in the abstract "The injection decreased the peak amplitude of EMG bursts during SB only in the treatment group for 12 weeks (p < 0.0001). A single BTX-A injection cannot reduce the genesis of SB. However, it can be an effective management option for SB by reducing the intensity of the masseter muscle."	3 M, 3N	
	Results in the main text No spin	-	
	Conclusion in the main text "This study is significant for evaluating the long-term effect of BTX-A for SB using PSG evaluation in a randomized, placebo-controlled trial." "Changing the concept of SB, i.e., from disorder to behavior, we can use BTX-A as an effective modality in reducing the intensity of masticatory muscle during SB along with occlusal splints. In the future, we need randomized, double-blind, placebo-controlled clinical studies with an accurate SB diagnosis by several consecutive PSG recordings and large sample size."	1D, 3 M, 3N, 3O	

Table 3 (continued)

Author, year, country	Quoted text	Categories of spin accordingly Lazarus et al. [30]	Spin Analysis
Yurttutan et al. 2019 [27]	**Results in the abstract** No spin	-	In the main text, the conclusion is not clear. In fact, the results showed that the combined therapy is more effective in comparison to the other treatments. However, the authors concluded that the BTX therapy and combined occlusal splint and BTX therapy were more effective Thus, we considered that the authors claimed equivalence for non-statistically significant results, and there is an inadequate interpretation of the results and, consequently, inadequate implications for clinical practice
	Conclusion in the abstract "Occlusal splints might not be necessary for patients treated with botulinum toxin injections."	3 M, 3N	
	Results in the main text No spin	-	
	Conclusion in the main text "According to our findings, the use of an occlusal splint will benefit patients." although BTX therapy and combined occlusal splint and BTX therapy were more effective. BTX therapy effectively improved myofascial pain with or without the use of an occlusal splint."	3 M, 3N	

BTX botulinum toxin, *PSG* polysomnography, *SB* sleep bruxism, *VAS* visual analog scale, *VPS* visual pain scale

conclusions section. These findings align with the results of our study, which identified approximately 59% of spin bias across the included studies.

Our comprehensive literature search identified only eight RCTs that compared patients who received BTX-A with those who did not (control, sham, placebo, or other treatment) for bruxism management. These studies included a total of 244 patients, with 143 receiving BTX-A. The studies were highly heterogeneous, which made it challenging to synthesize results and draw meaningful comparisons. Despite several attempts to group the findings in systematic reviews [33–45], only three of these reviews conducted a meta-analysis to synthesize the results [34, 35, 44]. Recently, Coelho et al. [46] published an overview protocol, highlighting that these systematic reviews yield controversial results, underscoring the need for further clarification.

For over 100 years, the results of scientific research have been primarily analyzed by focusing on the p-value, using an arbitrary threshold of < 0.05 as a "magic" cutoff to determine statistical significance [47]. A new concept has recently emerged in the literature that encourages

Table 4 Categorization of Spin according to Lazarus [30]

Type	Category of Spin	Strategy Used	Definition	Quantity	Frequency(%)
3 M	Inadequate extrapolation	Inadequate extrapolation to larger population	Results are generalized to another population, intervention or outcome than those of the study (such as surrogate outcomes)	15	30.61
3N	Inadequate interpretation	Inadequate implication for clinical practice	Authors recommend the use of therapeutic intervention for clinical practice	10	20.41
1B	Misleading reporting	Selective reporting	Only a subset of the original outcomes or analysis planned in a study is fully reported	6	12.25
3O	Inadequate extrapolation	Other	Evidence of spin not classified under other criteria	5	10.21
1D	Misleading reporting	Use of linguistic spin	Any word or expression emphasizing the beneficial effect of the therapeutic intervention	4	8.16
2G	Inadequate interpretation	Claim an effect for non-statistically significant results	Therapeutic intervention is presented as effective despite a non-statistically significant result	3	6.12
2 J	Inadequate interpretation	Causal language or causal claim	Results are presented with a sentence implying a cause-and- effect link between the intervention and the outcome	3	6.12
2 K	Inadequate interpretation	Claim of any significant difference despite lack of statistical test	Therapeutic intervention and comparator are compared despite no proper statistical test reported	3	6.12

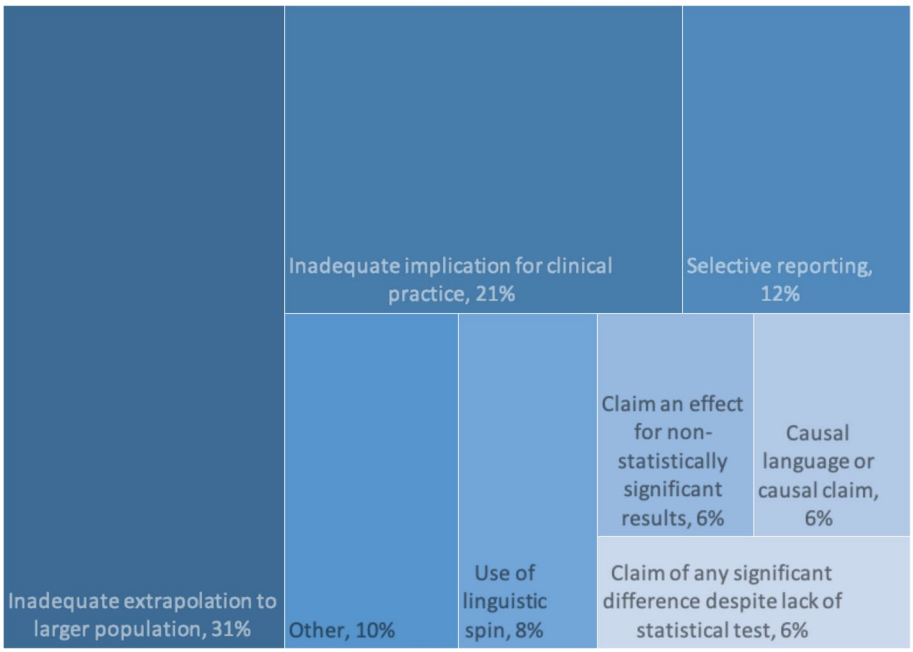


Fig. 3 Types of spin and frequency

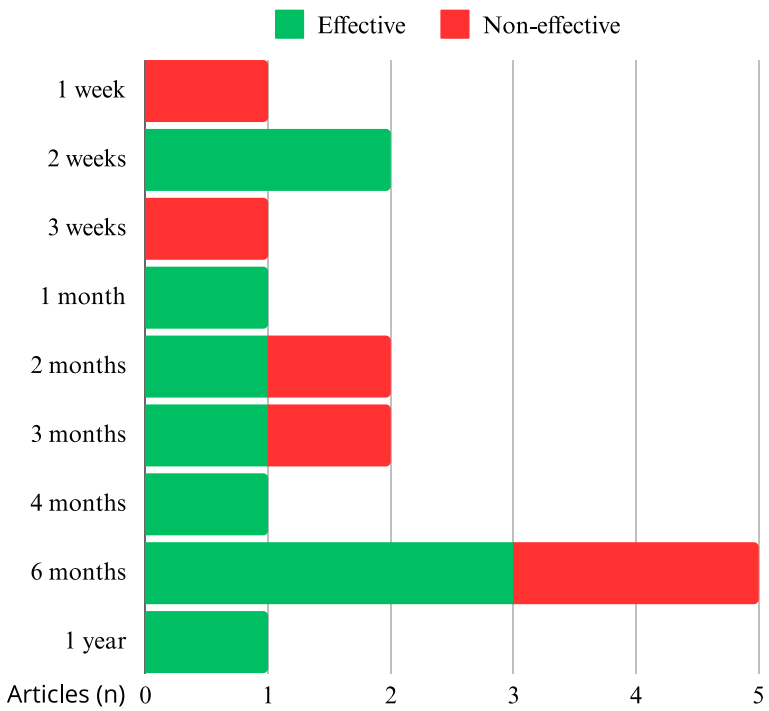


Fig. 4 Results for pain outcome in different follow-ups ($n = 4$)

a more critical analysis of clinical study results. This approach emphasizes that, beyond statistical significance, an intervention must also be clinically meaningful for patients. Schünemann and Guyatt (2005) [48] defined exhibited less than 50% spin bias [25]. Furthermore, these RCTs had a significant conceptual flaw. Most of the studies evaluated pain and bruxism events as outcomes, yet bruxism itself does not directly cause pain. Bruxism

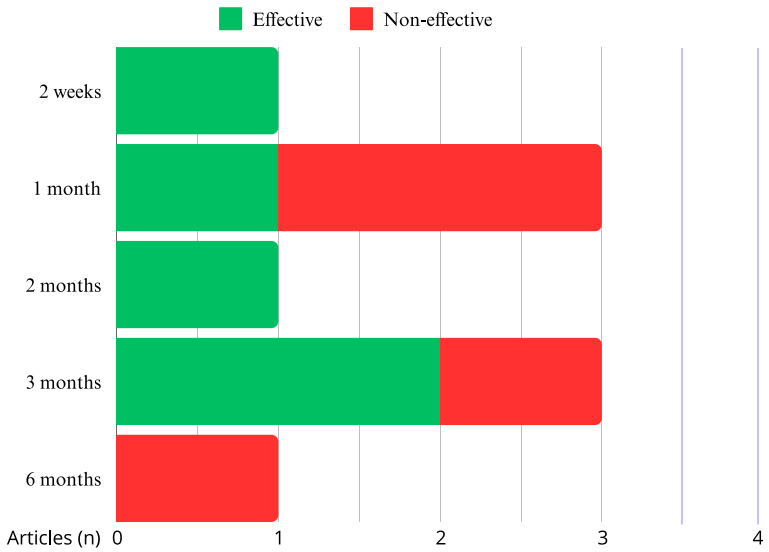


Fig. 5 Results for bruxism events in different follow-ups

the Minimum Important Difference (MID) as the smallest difference in an outcome that patients or their proxies perceive as important, either beneficial or harmful, and which would lead to a change in clinical management. Therefore, the interpretation of research results should go beyond just the numbers. As illustrated by the qualitative analysis in our study, many authors [20–22, 26, 27, 49] tend to exaggerate the significance of their findings, offering overly assertive conclusions that, in some cases, are not based on actual data but on assumptions [8]. This highlights the importance of critically evaluating both statistical and clinical relevance in research.

The qualitative analysis in our study revealed that more than half of the identified spin bias involved the inadequate extrapolation of results—either to a larger population or to clinical practice. This type of spin can mislead inattentive readers, potentially prompting them to apply ineffective therapies based on a cursory reading of only the abstracts of scientific articles.

In this context, we must consider the importance of the linguistic perspective [7]. Authors should be trained to report only what is directly supported by the results, avoiding strategies that exaggerate or extrapolate the findings [7]. Similarly, readers should be equipped with the necessary tools to identify the author's intentions in their writing [7]. When spin bias goes unnoticed by readers, it can lead to clinical misconduct by adopting ineffective or unproven interventions [50]. To reduce spin bias, training journal reviewers to detect it is crucial [8].

For clinicians, it is important to recognize that although BTX-A has been used for bruxism treatment for over 15 years [22], its efficacy and safety remain unproven. The articles included in our study have significant limitations: only two RCTs reported sample size calculations [25, 48]; only two [25, 27] adhered to CONSORT guidelines [6], and two studies were funded by the pharmaceutical industry [24, 26], raising potential conflicts of interest. Of the eight studies, only five evaluated adverse effects [20, 22, 24, 25, 27], with three reporting no adverse effects [20, 22, 27], one mentioning cosmetic changes in two patients [22], and another citing pain and discomfort at the injection sites in some patients [25]. Additionally, all the RCTs focused on young adults, primarily in Asia, which limits the generalizability of the results to global clinical practice. These limitations reduce the study's external validity, as bruxism was assessed using varying eligibility criteria and detection methods.

Regarding bruxism events, the results showed that BTX-A had no lasting effect after six months [25], and injections into the temporalis did not reduce muscle activity [22]. The results for masseter injections were inconsistent, based on only four studies [22, 24–26], which collectively analyzed just 76 patients.

In terms of pain, there is a common belief that BTX-A reduces pain. However, these conclusions are based on just four studies, with a total sample of 183 patients [20, 25, 27, 49]. In addition to the small sample size, it is important to note that only one of these studies

is a central-origin activity characterized by repetitive jaw-muscle movements, including clenching or grinding of the teeth, and/or bracing or thrusting of the mandible [51, 52]. While bruxism can be correlated with painful temporomandibular disorder (TMD) [53], a definitive causal relationship between bruxism and TMD has yet to be conclusively established [54]. The prevalence of spin in studies of botulinum toxin A (BTX-A) for bruxism suggests potential weaknesses in the design and execution of these clinical trials. These methodological shortcomings may contribute to difficulties in conducting the research and subsequently complicate the reporting of findings.

The main strength of this study lies in the robust methodology employed, with the selection and analysis process carried out by two independent evaluators, reducing the potential for bias. However, there are some limitations. One is the subjectivity inherent in qualitative analysis. Additionally, our research does not allow us to determine the underlying reasons for the spin biases identified—whether they were intentional, a lack of knowledge, or a combination of both. The small number of included studies also limited our ability to conduct more sophisticated quantitative analyses.

Clear, transparent, and objective reporting of research results is crucial for ensuring the accurate reflection of data and preventing misinterpretations that could negatively impact clinical practice. Inadequate reporting can lead to poor clinical decisions and potentially harm patients. Our study revealed spin bias in 87.5% of main text conclusions and 62.5% of abstract conclusions, a finding particularly concerning given that clinicians may rely solely on these conclusions when making treatment decisions. To mitigate this risk, clinicians should receive training in critically appraising published research, including education on study design, potential biases, and conflicts of interest. This is especially important in therapeutic areas with substantial industry funding, such as botulinum toxin therapies.

Given the current state of the literature, more RCTs are needed to establish the efficacy and safety of BTX-A for reducing pain and bruxism events, as there is insufficient evidence to draw definitive conclusions.

Conclusion

This study suggests that spin bias is highly prevalent in RCTs evaluating BTX-A for bruxism management. Specifically, nearly 90% of the reviewed RCTs showed spin bias in their conclusions, with excessive extrapolation of results being the most common issue.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12874-025-02547-9.

Supplementary Material 1: Appendix A. Databases and search strategies.

Supplementary Material 2: Appendix B. Spin bias categories as defined by Lazarus et al., 2015.

Supplementary Material 3: Appendix C. Articles excluded and the reasons for exclusion ($n=7$).

Supplementary Material 4: Appendix D. Bibliometric characteristics of the included studies ($n=8$).

Supplementary Material 5: Appendix E. Frequency of Spin Bias.

Supplementary Material 6: Appendix F. Results of included studies for pain in all groups and different follow-ups.

Supplementary Material 7: Appendix G. Effectiveness of botulinum toxin in bruxism at different follow-ups.

Acknowledgements
The authors would like to thank the librarian MSc Karyn Munyk Lehmkuhl for her support in developing the search strategy. Graziela De Luca Canto is supported by the National Council for Scientific and Technological Development (CNPq).

Authors' contributions
Conceptualization: Graziela De Luca Canto; Virginia Fernandes Moça Trevisani Data curation: Graziela De Luca Canto; Patrícia Pauletto; Cristine Miron Stefani; Thais Marques Simek Vega Gonçalves Formal analysis: All authors Investigation: Graziela De Luca Canto; Patrícia Pauletto; Cristine Miron Stefani; Thais Marques Simek Vega Gonçalves Methodology: All authors Writing original draft: Graziela De Luca Canto Writing review and editing: All authors Supervision: Virginia Fernandes Moça Trevisani.

Funding
This research received no specific grant from any funding agency, commercial or not-for-profit sectors.

Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]Brazilian Centre for Evidence-Based Research, Federal University of Santa Catarina, Florianopolis, Brazil. [2]Department of Dentistry, Federal University of Santa Catarina, Florianopolis, Brazil. [3]Postgraduate Program in Evidence Based Medicine, Federal University of São Paulo, São Paulo, Brazil. [4]Emergency Medicine and Evidence-Based Medicine, Federal University of São Paulo, São Paulo, Brazil. [5]School of Dentistry, Universidad de Las Americas, Quito, Ecuador. [6]Department of Dentistry, University of Brasilia, Brasilia, Brazil. [7]Medicine, Santo Amaro University, São Paulo, Brazil. [8]Mike Petryk School of Dentistry, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Canada. [9]Iberoamerican Cochrane Centre - Biomedical Research Institute Sant Pau (IIB Sant Pau), Barcelona, Spain. [10]Biological and Health Sciences Department, Federal University of Amapa, Macapá, Brazil.

Received: 12 December 2024 Accepted: 1 April 2025
Published online: 08 May 2025

References

1. Hariton E, Locascio JJ. Randomised controlled trials—the gold standard for effectiveness research. BJOG Int J Obstet Gynaecol. 2018;125:1716. https://doi.org/10.1111/1471-0528.15199.
2. JBI Institute, Checklist for randomized controlled trials-Critical Appraisal tools for use in JBI Systematic Reviews. Jbi, 1–5, (2020).
3. Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions version 6.5 (updated August 2024). Cochrane, 2024. Available from www.training.cochrane.org/handbook.
4. Schulz KF. The quest for unbiased research: Randomized clinical trials and the CONSORT reporting guidelines. Ann Neurol. 1997;41:569–73. https://doi.org/10.1002/ana.410410504.
5. Heneghan C, Mahtani KR, Goldacre B, Godlee F, Macdonald H, Jarvies D. 2017 Evidence based medicine manifesto for better healthcarehttps://doi.org/10.1136/ebmed-2017-j2973
6. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials, Bmj 340 (2010). https://doi.org/10.1136/bmj.c869.
7. Horton R. The rhetoric of research. BMJ. 1995;310:985–7. https://doi.org/10.1136/bmj.310.6985.985.
8. Boutron I, Dutton S, Ravaud P, Altman DG. Reporting and interpretation of randomized controlled trials with statistically nonsignificant results for primary outcomes. JAMA. 2010;303:2058–64. https://doi.org/10.1001/jama.2010.651.
9. Aromataris E, Lockwood C, Porritt K, Pilla B, Jordan Z, editors. JBI Manual for Evidence Synthesis. JBI; 2024. Available from: https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-24-01.
10. Chellamuthu G, Muthu S, Damodaran UK, Rangabashyam R. "Only 50% of randomized trials have high level of confidence in arthroscopy and sports medicine"—a spin-based assessment. Knee Surg Sports Traumatol Arthrosc. 2021;29:2789–98. https://doi.org/10.1007/s00167-021-06614-8.
11. O'Leary R, La Rosa GRM, Vernooij R, Polosa R. Identifying spin bias of nonsignificant findings in biomedical studies. BMC Res Notes. 2023;16:50. https://doi.org/10.1186/s13104-023-06321-2.
12. Eleftheriadi I, Ioannou T, Pandis N. Extent and prevalence of spin in randomized controlled trials in dentistry. J Dent. 2020;100:103433. https://doi.org/10.1016/j.jdent.2020.103433.
13. Fang X, Hua F, Riley P, Chen F, Zhang L, Walsh T, Chen Z. Abstracts of published randomized controlled trials in Endodontics: reporting quality and spin. Int Endod J. 2020;53:1050–61. https://doi.org/10.1111/iej.13310.
14. Guo F, Fang X, Li C, Qin D, Hua F, He H. The presence and characteristics of 'spin'among randomized controlled trial abstracts in orthodontics. Eur J Orthod. 2021;43:576–82. https://doi.org/10.1093/ejo/cjab044.
15. Guo F, Zhao T, Zhai Q, Fang X, Yue H, Hua F, He H. "Spin" among abstracts of randomized controlled trials in sleep medicine: a research-on-research study. Sleep. 2023;46:zsad041. https://doi.org/10.1093/sleep/zsad041.
16. Roszhart JI, Kumar SS, Allareddy V, Childs CA, Elangovan S. Spin in abstracts of randomized controlled trials in dentistry: a cross-sectional analysis. J Am Dent Assoc. 2020;151:26–32. https://doi.org/10.1016/j.adaj.2019.08.009.
17. Wu X, Yan Q, Fang X, Hua F, Shi B, Tu Y. Spin in the abstracts of randomized controlled trials in periodontology and oral implantology: A cross-sectional analysis. J Clin Periodontol. 2020;47:1079–86. https://doi.org/10.1111/jcpe.13340.
18. Nigam PK, Nigam A. Botulinum toxin. Indian J Dermatol. 2010;55:8–14. https://doi.org/10.4103/0019-5154.60343.
19. Serrera-Figallo MA, Ruiz-De-León-Hernández G, Torres-Lagares D, Castro-Araya A, Torres-Ferrerosa O, Hernández-Pacheco E, Gutierrez-Perez JL. Use of botulinum toxin in orofacial clinical practice, Toxins. 2020;12. https://doi.org/10.3390/toxins12020112.
20. Al-Wayli H. Treatment of chronic pain associated with nocturnal bruxism with botulinum toxin. A prospective and randomized clinical study. J. Clin. Exp. Dent. 2017;9: e112–e117. https://doi.org/10.4317/jced.53084.
21. Jadhao VA, Lokhande N, Habbu SG, Sewane S, Dongare S, Goyal N. Efficacy of botulinum toxin in treating myofascial pain and occlusal force characteristics of masticatory muscles in bruxism, Indian J. Dent. Res. Off. Publ. Indian Soc. Dent. Res. 2017;28: 493–497. https://doi.org/10.4103/ijdr.IJDR_125_17.
22. Lee SJ, McCall WD Jr, Kim YK, Chung SC, Chung JW. Effect of botulinum toxin injection on nocturnal bruxism: a randomized controlled trial. Am J Phys Med Rehabil Assoc Acad Physiatr. 2010;89:16–23.
23. Alwayli HAM, B.I. Abdulrahman BI, Rastogi S. Does botulinum toxin have any role in the management of chronic pain associated with bruxism? Cranio. 2024;42:215–222. https://doi.org/10.1080/08869634.2021.1949536.
24. Ondo WG, Simmons JH, Shahid MH, Hashem V, Hunter C, Jankovic J. Onabotulinum toxin-A injections for sleep bruxism. Neurology. 2018;90:e559–64. https://doi.org/10.1212/WNL.0000000000004951.
25. Shehri ZG, Alkhouri I, Hajeer MY, Haddad I, Abu Hawa MH. Evaluation of the Efficacy of Low-Dose Botulinum Toxin Injection Into the Masseter Muscle for the Treatment of Nocturnal Bruxism: A Randomized Controlled Clinical Trial., Cureus. 2022;14: e32180. https://doi.org/10.7759/cureus.32180.
26. Shim YJ, Le HJ, Park KJ, Kim HT, Hong IH, Kim ST. Botulinum toxin therapy for managing sleep bruxism: A randomized and placebo—controlled trial, Toxins. 2020;12. https://doi.org/10.3390/toxins12030168.
27. Yurttutan ME, Tütüncüler Sancak K, Tüzüner AM. Which Treatment Is Effective for Bruxism: Occlusal Splints or Botulinum Toxin?, J. Oral Maxillofac. Surg. 2019;77: 2431–2438. https://doi.org/10.1016/j.joms.2019.06.005.
28. Lobbezoo F, Ahlberg J, Raphael KG, Wetselaar P, Glaros AG, Kato T, Santiago V, Winocur E, De Laat A, De Leeuw R. International consensus on the assessment of bruxism: Report of a work in progress. J Oral Rehabil. 2018;45:837–44. https://doi.org/10.1111/joor.12663.
29. Robinson KA, Dickersin K. Development of a highly sensitive search strategy for the retrieval of reports of controlled trials using PubMed. Int J Epidemiol. 2002;31:150–3.
30. Lazarus C, Haneef R, Ravaud P, Boutron I. Classification and prevalence of spin in abstracts of non-randomized studies evaluating an intervention. BMC Med Res Methodol. 2015;15:85.
31. Calixtre, et al. What is the minimal important difference of pain intensity, mandibular function, and headache impact in patients with tempo-romandibular disorders? Clinical significance analysis of a randomized controlled trial. Musculoskeletal Science and Practice. 2020;46:102108. https://doi.org/10.1016/j.msksp.2020.102108.
32. Su N, Van Der Linden MW, Faggion CM Jr, Van Der Heijden GJ. Assessment of spin in the abstracts of randomized controlled trials in dental caries with statistically nonsignificant results for primary outcomes: A methodological study. Caries Res. 2023;57:553–62.
33. Ågren M, Sahin C, Pettersson M. The effect of botulinum toxin injections on bruxism: A systematic review. J Oral Rehabil. 2020;47:395–402. https://doi.org/10.1111/joor.12914.
34. Chen Y, Tsai C-H, Bae TH, Huang C-Y, Chen C, Kang Y-N, Chiu W-K. Effectiveness of Botulinum Toxin Injection on Bruxism: A Systematic Review and Meta-analysis of Randomized Controlled Trials. Aesthetic Plast Surg. 2023;47:775–90. https://doi.org/10.1007/s00266-023-03256-8.
35. Cheng Y, Yuan L, Ma L, Pang F, Qu X, Zhang A. Efficacy of botulinum-A for nocturnal bruxism pain and the occurrence of bruxism events: a meta-analysis and systematic review. Br J Oral Maxillofac Surg. 2022;60:174–82. https://doi.org/10.1016/j.bjoms.2021.03.005.
36. De la Torre Canales G, Câmara-Souza MB, do Amaral CF, Garcia RCMR, Manfredini D. Is there enough evidence to use botulinum toxin injections for bruxism management? A systematic literature review. Clin. Oral Investig. 2017;21: 727–734. https://doi.org/10.1007/s00784-017-2092-4.
37. Fernández-Núñez T, Amghar-Maach S, Gay-Escoda C. Efficacy of botulinum toxin in the treatment of bruxism: Systematic review. Med Oral Patol Oral Cirugia Bucal. 2019;24:e416–24. https://doi.org/10.4317/medoral.22923.
38. Long H, Liao Z, Wang Y, Liao L, Lai W. Efficacy of botulinum toxins on bruxism: An evidence-based review. Int Dent J. 2012;62:1–5. https://doi.org/10.1111/j.1875-595X.2011.00085.x.
39. Miron MI, Ciora E, Vedinas T, Mocuta DE. Therapeutic approaches to nocturnal bruxism—a systematic review, Arch Balk Med Union. 2022;57: 372–383. https://doi.org/10.31688/ABMU.2022.57.4.06.

40. Patel J, Cardoso JA, Mehta S. A systematic review of botulinum toxin in the management of patients with temporomandibular disorders and bruxism. Br Dent J. 2019;226:667–72. https://doi.org/10.1038/s41415-019-0257-z.
41. Rajamoorthy SN. Botulinum toxin-A injections into facial muscles for the treatment of temporomandibular disorders and bruxism: a systematic review, J Popul Ther Clin Pharmacol. 2023;30: 229–240. https://doi.org/10.53555/jptcp.v30i16.2244.
42. Sendra LA, Montez C, Vianna KC, Barboza EP. Clinical outcomes of botulinum toxin type A injections in the management of primary bruxism in adults: A systematic review. J Prosthet Dent. 2021;126:33–40. https://doi.org/10.1016/j.prosdent.2020.06.002.
43. Sposito MM DE M, Teixeira SAF. Toxina Botulínica Tipo A para bruxismo: analise sistemática. Acta Fisiátrica. 2014;21: 201–204.
44. Zhang A-B, Zhang J-Y, Zhou X, Sun L-S, Li T-J. Can botulinum toxin injection alleviate the pain of bruxism? A Bayesian network analysis and a single-arm analysis. J Dent Sci. 2024;19:885–93. https://doi.org/10.1016/j.jds.2023.08.001.
45. Manfredini D, Ahlberg J, Winocur E, Lobbezoo F. Management of sleep bruxism in adults: a qualitative systematic literature review. J Oral Rehabil. 2015;42:862–74. https://doi.org/10.1111/joor.12322.
46. Coelho MS, de Oliveira JMD, Polmann H, Pauletto P, Stefani CM, Maciel LCDL, Canto GDL. Botulinum toxin for the management of bruxism: an overview of reviews protocol. BMJ Open. 2024;14: e082861.
47. Goel H, Raheja D, Nadar SK. Evidence-based medicine or statistically manipulated medicine? Are we slaves to the P-value?, Postgrad. Med. J. 2024: qgae012. https://doi.org/10.1093/postmj/qgae012.
48. Schünemann HJ, Guyatt GH. Commentary—Goodbye M(C)ID! Hello MID, Where Do You Come From? Health Serv Res. 2005;40:593–7. https://doi.org/10.1111/j.1475-6773.2005.0k375.x.
49. Alwayli HM, Abdulrahman BI, Rastogi S. Does botulinum toxin have any role in the management of chronic pain associated with bruxism? Cranio J Craniomandib Pract. 2024;42:215–22. https://doi.org/10.1080/08869634.2021.1949536.
50. IPereira LN, Hassan, H. toxin A in dentistry and orofacial surgery: an evidence-based review - part 1: therapeutic applications., Evid. Based Dent. 2022. https://doi.org/10.1038/s41432-022-0256-9.
51. Lobbezoo F, Ahlberg J, Glaros AG, Kato T, Koyano K, Lavigne GJ, De Leeuw R, Manfredini D, Svensson P, Winocur E. Bruxism defined and graded: an international consensus. J Oral Rehabil. 2013;40:2–4. https://doi.org/10.1111/joor.12011.
52. Lobbezoo F, Naeije M. Bruxism is mainly regulated centrally, not peripherally. J Oral Rehabil. 2001;28:1085–91. https://doi.org/10.1046/j.1365-2842.2001.00839.x.
53. Chattrattrai T, Blanken TF, Lobbezoo F, Su N, Aarab G, Van Someren EJW. A network analysis of self-reported sleep bruxism in the Netherlands sleep registry: its associations with insomnia and several demographic, psychological, and life-style factors. Sleep Med. 2022;93:63–70. https://doi.org/10.1016/j.sleep.2022.03.018.
54. Manfredini D, Lobbezoo F. Sleep bruxism and temporomandibular disorders: A scoping review of the literature. J Dent. 2021;111: 103711. https://doi.org/10.1016/j.jdent.2021.103711.

Publisher's Note