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Comparative Evaluation Between Pharmacological and Splint Therapy for The Treatment of Bruxism- Systematic Review and Meta-Analysis

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Abstract

Introduction: Sleep bruxism or nocturnal bruxism (SB) is an involuntary act, with repetitive functional activity characterized by clenching or grinding of teeth during sleep.

Objective: To compare the efficiency of pharmacological and splint therapy for treatment of bruxism in children.

Materials & Methodology: Randomized controlled trials evaluating the efficacy of use of various pharmacological and splint therapies were included by searching multiple databases. A comprehensive electronic search was performed till December 2022 for the studies published within the last 22 years on multiple databases from which 180 were screened and 5 were selected for meta-analysis. Five studies containing data on 161 (n=161) participants, of which (n=88) participants were evaluated by treatment group and (n=73) patients were evaluated by control group for the evaluation or the better effectiveness between the two treatment modalities

Result & Observations: The data signifies that the treatment group effectiveness on an average is 0.28 times more than the control group but this difference is not statistically significant. Conclusion: The current meta-analysis was conducted on a very preliminary data setting due to the paucity of published studies. It has shown weak evidence of a possible efficacy on reducing bruxism symptoms and signs.

Conclusion: The current meta-analysis was conducted on a very preliminary data setting due to the paucity of published studies. It has shown weak evidence of a possible efficacy in reducing bruxism signs and symptoms.

Summary: There is minimal evidence that this therapy can completely cure bruxism, although they can minimize the signs and symptoms of bruxism.

Keywords: Occlusal splint, Pharmacological management, Sleep bruxism

Introduction

Bruxism is a repetitive muscle activity involving the clenching or grinding of one's teeth during sleep or waking hours. It is often found in children and adolescents. This habit can have harmful effects on the teeth, periodontium, masticatory muscles, and temporomandibular joint.[1] The prevalence of this condition among children ranges from 13.5 to 33.0%. Treatment should be directed at reducing the habit through awareness of the problem and mechanical prevention to avoid wear of the permanent dentition. There is no consensus in the literature regarding the treatment of bruxism in children.[2]

Sleep bruxism (SB) prevalence is associated with age and its prevalence in younger children is more than older ones.[3] The rate of parent-reported sleep bruxism in children is 59%. Another study reported the prevalence of 23% in children.[4] Sleep bruxism is associated with behavioural problems and potential emotional problems. High stress level is a risk factor of sleep bruxism in children. Moreover, sleep bruxism is associated with higher depression and physical complaints. However, the association of depression and sleep bruxism is not confirmed by another study.[5]

Drugs such as type a botulinum toxin, benzodiazepine, anticonvulsants, beta blockers, dopamine, antidepressants, and muscle relaxers may help control bruxism, but the use of these agents in children is restricted.[6] Herbal products have been used since antiquity by humans as a way to improve or recover health. Since the Declaration of Alma-Ata in 1978, the World Health Organization (WHO) has expressed the need to appreciate the use of medicinal plants in public health systems, as some studies have indicated that almost 80% of the world population uses these plants in primary care.[7]

According to Druss et al[8]., the majority of people use medicinal plants in therapies in conjunction with conventional medical treatment. The search for alternative products continues, and natural phytochemicals isolated from plants used as traditional medicines are considered good alternatives. From the results of these investigations, it would appear that phytotherapy is a matter of great importance to the world's population, and is of interest in different areas of health.[9]

The use of these practices has also been incorporated into dentistry and numerous studies have been conducted to evaluate vegetable species as natural agents that are economically feasible and provide effective alternatives for treating oral, diseases. This systematic review aims to evaluate the effectiveness of pharmacological therapy and splint therapy in the treatment of bruxism.

Methods

Protocol Development

This review was conducted and performed in according to the preferred reporting items for systematic review and meta-analysis (PRISMA) statement[10] and registered in Prospective registration of Systematic Review (PROSPERO)- CRD42023430000.

The focused review question was to evaluate and assess the effectiveness of pharmacological and surgical

modality for treatment of bruxism in paediatric children. The following focused research question in the Participants (P), Intervention (I), Comparison and Outcome (O) format was proposed "Is there any difference in the effectiveness between pharmacological and splint therapy in the treatment of bruxism among children?

The PICO criteria for this review were as follows:

P (Participants) – Patients with habit of bruxism

I (Intervention) – Use of pharmacological intervention in treating bruxism

C (Comparison) – Use of splint therapy in treating bruxism

O (Outcome) – to assess the better effectiveness between the two modalities

S (Study designs) – randomized controlled trials, prospective study, retrospective study, comparative study

Inclusion Criteria

1. Articles published in English language
2. Articles having sufficient data on bruxism being treated by pharmacological modality and surgical modality
3. Studies published between 2000 – 2022 and having relevant data on bruxism being treated by pharmacological modality and surgical modality
4. Clinical studies, cross-sectional studies, cohort studies, longitudinal studies, follow up studies, comparative studies will be included
5. Articles from open access journals
6. Articles reporting the study outcomes in terms of mean and standard deviation

Exclusion Criteria

1. Any studies conducted before 2000
2. Articles in other than English language
3. Reviews, abstracts, letter to the editor, editorials, animal studies and in vitro studies will be excluded
4. Articles not from open access journals
5. Articles not reporting the study outcomes in terms of mean and standard deviation

Search Strategy

A comprehensive electronic search was performed till December 2022 for the studies published within the last 22 years (from January 2000 to December 2022) using the following databases: PubMed, google scholar and EBSCO host to retrieve articles in the English language. The searches in the clinical trials database, cross-referencing and grey literature were conducted using Google Scholar, Greylist, and Open Grey.

A manual search of pedodontic and preventive dentistry, including the Journal of Indian Society of Pedodontics and Preventive Dentistry, International Journal of Paediatric Dentistry, Journal of Clinical Paediatric Dentistry, European journal of Paediatric Dentistry, Journal of South Asian Association of Paediatric Dentistry, Paediatric Dental Journal, Journal of Korean Academy of Paediatric Dentistry, Interventions in Pediatric Dentistry and the journal of American Dental Association was also performed.

Appropriate key words and Medical Subject Heading (MeSH) terms were selected and combined with Boolean operators like AND, OR, NOT. The relevant data was searched using the following keywords and their combinations: "bruxism" (MeSH term) AND "paediatrics" (MeSH term); "teeth grinding disorder" (MeSH term) AND "sleep bruxism" (MeSH term); "nocturnal bruxism" (MeSH term) AND "childhood" (MeSH term) AND bruxism therapy (MeSH term); "bruxism therapeutics" (MeSH term) AND "kid/children" (MeSH term) AND "edentualism/surgery" (MeSH term); "pharmacological

rehabilitation" AND "surgical rehabilitation" (MeSH term).

In addition to the electronic search, a hand search was also made, and reference lists of the selected articles were screened. The reference lists of identified studies and relevant reviews on the subject were also scanned for possible additional studies.

Screening Process

The search and screening, according to previously established protocol were conducted by two authors. A two-phase selection of articles was conducted. In phase one, two reviewers reviewed titles and abstracts of all articles. Articles that did meet inclusion criteria were excluded. In phase-two, selected full articles were independently reviewed and screened by same reviewers. Any disagreement was resolved by discussion. When mutual agreement between two reviewers was not reached, a third reviewer was involved to make final decision. The final selection was based on consensus among all three authors. The corresponding authors of study were contacted via email where further information was required.

Data Extraction

For all included studies, following descriptive study details were extracted by two independent reviewing authors and using pilot-tested customized data extraction forms in Microsoft excel sheet with the following headings included in the final analysis: study ID, author(s), country of study, year of study, mean age of the participants, sample size, study design, duration of follow up, outcome, conclusion.

Quality assessment of included studies

The quality of included studies for observational studies was evaluated based on Newcastle Ottawa Scale[11] and accordingly a numeric score (NOS Score) was assigned.[18] It was designed to evaluate bias based on participant selection, study group comparability in cross-sectional study, attainment of exposure in case-control studies and outcome of interest in cohort study. It is a valid and reliable tool for assessing the quality of non-randomized studies, supported by the Cochrane Collaboration for the quality appraisal of non-randomized trials. The NOS uses a nine-star rating system with a maximum of four points available for selection, two for comparability and three for the assessment of the outcome or exposure. The tool was deemed acceptable for the appraisal of cross-sectional studies as the effectiveness of an intervention was not being measured. Quality appraisal of the included studies was undertaken by the two authors and a third author was consulted in the event of any discrepancy. A study with a score from 7 to 9 will be considered as high quality, 4 to 6 will be considered as moderate quality and 0 to 3 will be considered as low quality or very high risk of bias.

The methodological quality among included studies was executed by using Cochrane collaboration risk of bias (ROB) -2 tool[12]. The tool has various domains like random sequence generation (selection bias), allocation concealment (selection bias), blinding of personnel and equipments (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other biases through their signalling questions in Review Manager (RevMan) 5.3 software. The overall risk for individual studies was assessed as low, moderate or high risk based on domains and criteria. The study was assessed to have a low overall risk only if all domains were found to have low risk. High overall risk was assessed if one or more of the six domains were found to be at high risk. A moderate risk assessment was

provided to studies when one or more domains were found to be uncertain, with none at high risk.

Statistical analysis

The standardized mean difference (SDM) with 95% CI was calculated for continuous outcomes. A fixed effects model (Mantel-Haenszel method) was used if there was no heterogeneity ($p > 0.05$ or I-squared $\leq 24\%$), otherwise a random effects model (Der Simonian- Laird method) was used.[13] All statistical analyses were performed using the RevMan 5.3 (Cochrane Collaboration, Software Update, Oxford, UK). The significance level was kept at $p<0.05$. The significance of any discrepancies in the estimates of the treatment effects of the different trials was assessed by means of Cochran's test for heterogeneity and the I2 statistics, which describes the percentage of the total variation across studies that is due to heterogeneity rather than chance.

Investigation of publication bias

To test for the presence of publication bias, the relative symmetry of the individual study estimates was assessed around the overall estimates using Begg's funnel plot. A funnel plot (plot of the effect size versus standard error) was drawn. Asymmetry of the funnel plot may indicate publication bias and other biases related to sample size, although asymmetry may also represent a true relationship between trial size and effect size.

Results

Study Selection

After duplicates removal, reference list of included studies was screened. Of which 29 studies did not were not available in English language, 65 studies were not available in free full text articles, and 26 studies did not mention the required comparison group. Hence 120 studies were excluded. After this full text articles were assessed for eligibility and articles that did not meet inclusion criteria were excluded. Only seven studies fulfilled eligibility criteria and were included in qualitative synthesis. Of which only five studies were included in meta – analysis. A flowchart of identification, inclusion and exclusion of studies is shown in Figure 1 below.

Assessment of methodological Quality of included studies

All the included studies were largely comparable in methodological quality. All the included studies had moderate to high risk of bias with all the respected domains. The highest risk of bias was seen for allocation concealment (selection bias) followed by blinding of participants and personnel (performance bias) and blinding of outcome assessment (detection bias). Among the included studies, Ghanizadeh et al 2013 followed by Dalewski et al 2017 and Reimao et al 2013 had the high risk of bias compared to all other studies. Coppede et al 2017 followed by Bedrossian et al 2010 reported lowest risk of bias. Domains of selective reporting (reporting bias) followed by other biases and incomplete outcome data (attrition bias) and other bias were given the lowest risk of bias by included studies. Risk of bias of included studies through Cochrane risk of bias (ROB)-2 tool is depicted in Figure 2 and 3 as shown below

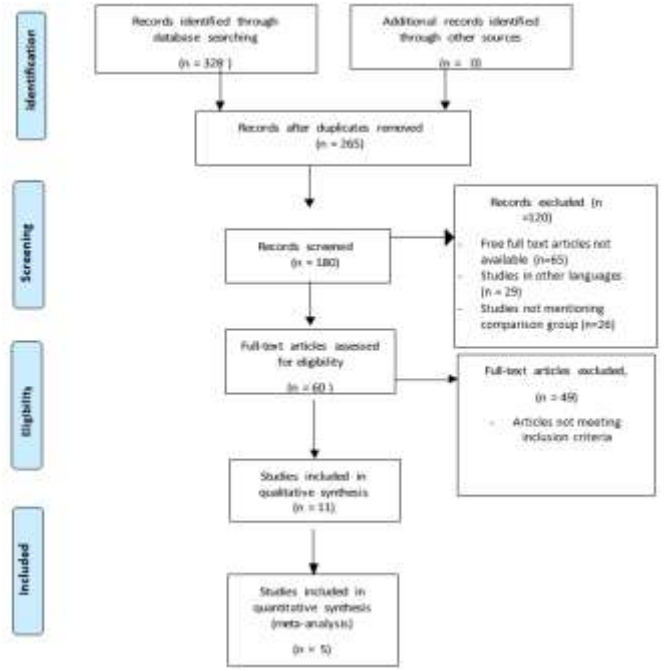

Figure 1:

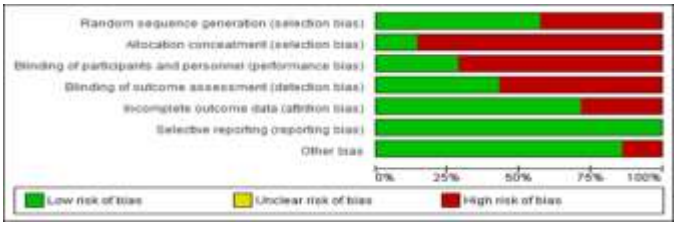

Figure 2: Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

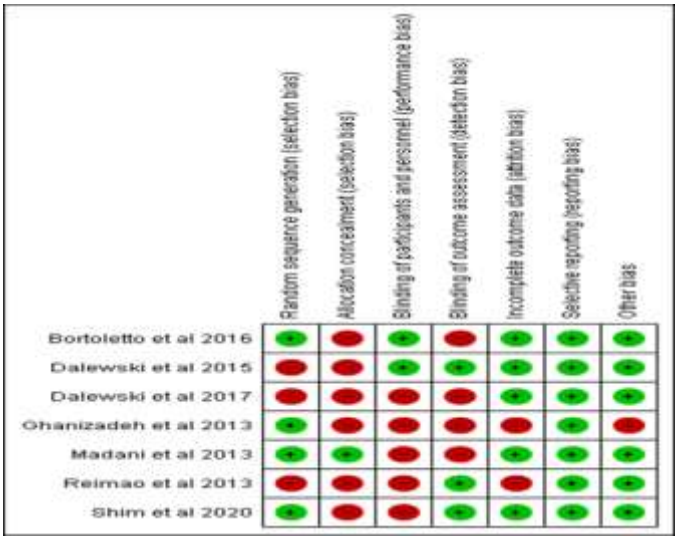

Figure 3: Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Synthesis of Result

The standardized mean difference is used as a summary statistic in meta-analysis when the studies all assess the same outcome but measure it in different way. Therefore, it is necessary to standardized the results of the studies to a common scale before they can be combined to an overall pooled estimate.

Five studies containing data on 161 (n=161) participants, of which (n=88) participants were evaluated by treatment group and (n=73) patients were evaluated by control group for the evaluation or the better effectiveness between the two treatment modalities.

As shown in Figure 4. the SDM 0.28 (8.88 – 9.35) and the pooled estimates favours control group. This signifies that the better effectiveness on an average is 0.28 times more by control groups as compared to treatment groups but this difference is not statistically significant (p>0.05).

Among all the included studies, Dalewski et al 2015 had highest weightage at the overall pooled estimate while the lowest weightage was observed for Shim et al 2020 at the pooled estimate.

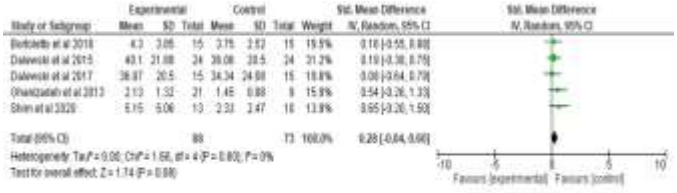

Figure 4: showing Forest plot showing treatment group versus control group with regards to the better effectiveness between the two procedures as an outcome

The funnel plot did not show significant asymmetry, indicating absence of publication bias as shown in Figure 5. Funnel plot showing symmetric distribution with absence of systematic heterogeneity of individual study compared to the standard error, showing an absence of publication bias in the meta-analysis.

Figure 5: showing Begg's Funnel plot with 95% confidence intervals demonstrating symmetric distribution without systematic heterogeneity of individual study compared with the standard error of each study, indicating an absence of publication bias.

Discussion

The present systematic review evaluated effectiveness of pharmacological and splint therapy for treatment of bruxism. Currently, no consensus has been reached regarding the diagnosis of Bruxism in children. In the majority of cases, a diagnosis of bruxism was made following the observation of dental wear or patient anxiety. But as these signs were not specific to bruxism, they led to many false positive and false-negative diagnoses.[14] PSG was thought to be a reliable tool, but only during the active phases of bruxism. Parents can report episodes of teeth grinding during sleep, thus influencing the diagnosis. This indication, however, implies that the parents are close to the child during the night, which is rarely the case. Moreover, clenching is completely silent.

Thus, the diagnosis of SB has been based on several elements: interviewing the parents, medical antecedents, extraoral and intraoral examination, and in certain cases, currently very few, EMG recording or PSG.[15] This absence of clearly established guidelines was reflected in the diversity of diagnostic methods, combined or not, described the eight studies selected interviewing the parents, who were asked (or not asked) to sleep near the child, a clinical examination made by a dentist, and, on only one occasion, an EMG. Yet, a variable diagnostic approach between studies led to the establishment of groups of patients whose characteristics are not always comparable with each other. The results of the treatments evaluated must be considered with caution, as each study presented its own diagnostic method. Thus, this absence of consensus in the diagnosis explains the diversity of approaches that were proposed and investigated.[16]

Initially, most research was focused on the immediate effect of different splint types on masticatory muscles' bioelectric activity; therefore, no compelling evidence of sustainable influence has been found, neither was it considered an eventual perspective. SEMG signals were measured largely with and without a splint, in the same day or evening and the morning after, without normalization protocols and bias assessment.[17] Considering that there are limited numbers of effective medications for treating bruxism and all of the investigated medications are associated with serious adverse effects, our findings strongly add another treating option to current literature for children with bruxism. In fact, our findings may answer to current gap in literature.[18]

When compared to non-appliance therapeutic options, such as TENS, both treatments gave no statistically significant effect on bruxism activity and there was no difference between the treatments.[19] CBT and occlusal splints were both found to significantly reduce sleep bruxism activity by Ommerborn et al. but no statistically significant difference was found between interventions. When Gabapentin therapy was compared to an occlusal splint, no difference was detected between interventions in reduction of sleep bruxism variables. Both interventions showed statistically significant therapeutic reductions but the effects were small.

There are certain limitations to this systematic review. The sample size was small and it is subject to referral bias. The children were a clinical sample. We do not know whether those with severe forms of bruxism refer to clinics. Moreover, the rate of response in the control group was very high. It is possible that treating comorbid disorders leads to treating bruxism.[20] In addition, current results cannot be extended to long-term efficacy and safety of hydroxyzine. The participants of this trial were children. The clinician who administered medications and parents was not blind to the allocation groups. It is not clear whether hydroxyzine decreases bruxism in older individuals as well.[21] Moreover, it is not clear whether bruxism is associated with socio-economic status. Therefore, further studies with larger sample sizes should include socio-economic status as a possible covariate factor. Furthermore, the children were not examined by a dentist to screen for a possible malocclusion problem.[22]

Conclusion

The current meta-analysis was conducted on a very preliminary data setting due to the paucity of published studies. It has shown weak evidence of a possible efficacy on reducing bruxism symptoms and signs. Moreover, available data are scarce and on a limited number of patients. Thus, future studies with a proper design, conducted on a meaningful number of patients, and based on standardized and developed diagnostic criteria are warranted to provide strong evidence based on sound clinical recommendations on bruxism therapy in children aged 2–17 years. To design this type of study, there should be a balance between the costs and efficacy of the treatment, which can be calculated basis of the Number of patients Needed to Treat (NNT) to have a complete response.

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