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RESEARCH ARTICLE

Moving beyond bruxism episode index: Discarding misuse of the number of sleep bruxism episodes as masticatory muscle pain biomarker

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Summary

The objective of the current study was to evaluate the clinical utility of bruxism episode index in predicting the level of masticatory muscle pain intensity. The study involved adults ($n = 220$) recruited from the Outpatient Clinic of Temporomandibular Disorders at the Department of Experimental Dentistry, Wroclaw Medical University, during the period 2017–2022. Participants underwent medical interview and dental examination, focusing on signs and symptoms of sleep bruxism. The intensity of masticatory muscle pain was gauged using the Numeric Rating Scale. Patients identified with probable sleep bruxism underwent further evaluation through video-polysomnography. Statistical analyses included the Shapiro–Wilk test, Spearman's rank correlation test, association rules, receiver operating characteristic curves, linear regression, multivariate regression and prediction accuracy analyses. The analysis of correlation and one-factor linear regression revealed no statistically significant

relationships between bruxism episode index and Numeric Rating Scale ($p > 0.05$ for all analyses). Examination of receiver operating characteristic curves and prediction accuracy indicated a lack of predictive utility for bruxism episode index in relation to masticatory muscle pain intensity. Multivariate regression analysis demonstrated no discernible relationship between bruxism episode index and Numeric Rating Scale across all examined masticatory muscles. In conclusion, bruxism episode index and masticatory muscle pain intensity exhibit no correlation, and bruxism episode index lacks predictive value for masticatory muscle pain. Clinicians are advised to refrain from employing the frequency of masticatory muscle activity as a method for assessing the association between masticatory muscle pain and sleep bruxism.

KEYWORDS
bruxism episode index, masticatory muscle pain, numeric rating scale, polysomnography, sleep bruxism

1 | INTRODUCTION

Bruxism, a prevalent masticatory muscle activity, can manifest during wakefulness and/or sleep (Manfredini et al., 2013). Its occurrence is estimated to range from 4% to 32% within the adult population (Manfredini et al., 2013; Oliveira et al., 2023; Wetselaar et al., 2021). According to the 2018 consensus, sleep bruxism (SB) and awake bruxism (AB) are distinct behaviours with separate definitions. SB is characterized by rhythmic (phasic) or non-rhythmic (tonic) masticatory muscle activity during sleep, and is not considered a movement or sleep disorder in otherwise healthy individuals (Lobbezoo et al., 2018). Due to its specific nature, the assessment and management of SB pose significant challenges. Definite diagnosis of masticatory muscle activity associated with SB requires instrumental methods (Lobbezoo et al., 2018). Polysomnography (PSG) is regarded as the gold-standard for evaluating SB, offering quantitative and qualitative assessments of SB events. However, its value for long-term observations and interpreting motor behaviour is limited, as assessments are typically based on a single-night examination (Lobbezoo et al., 2018; Manfredini, Ahlberg, et al., 2019). Among the various indexes used in PSG to evaluate SB, the bruxism episode index (BEI) is one of the most commonly employed. This index calculates the number of episodes of rhythmic masticatory muscle activity (RMMA), also referred to as SB episodes, per hour of sleep. Despite its frequent use to assess the number of SB episodes, it was originally proposed for quantifying oral behaviour rather than determining its severity. Presently, research criteria are applied to assess the frequency of SB episodes: BEI < 2 indicates no bruxism; BEI 2–4 denotes mild to moderate bruxism; and BEI > 4 signifies severe bruxism (American Academy of Sleep Medicine, 2014). These criteria, introduced by Lavigne et al. in 1996 for research purposes, continue to be recommended by the American Academy of Sleep Medicine for sleep medicine physicians evaluating the level of concern in the presence of co-occurring conditions such as sleep apnea, insomnia and periodic limb movement (American Academy of Sleep Medicine, 2014; Lavigne et al., 1996). It is important to note that these criteria do not yet translate into an instrumental assessment of SB severity to gauge the extent of harm to the masticatory system.

In the literature examining the utility of BEI as a tool to assess its association with pain, numerous studies have reported a positive correlation between SB frequency and the occurrence of masticatory muscle pain. Blanco Aguilera et al. reported a statistically significant association between self-reported SB, pain intensity and pain interference with daily activities (Blanco Aguilera et al., 2014). In Costa et al. study with 1200 participants, it was demonstrated that self-reported generic bruxism was associated with masseter muscles palpation-induced pain (Costa et al., 2016). Similar findings were reported by Huhtela et al., who found that self-reported bruxism (both SB and AB) was linked to temporomandibular pain in a group of 4403 Finnish students. It is crucial to note that the results of these studies were solely based on self-reporting (Huhtela et al., 2016). On the contrary, Kothari et al. reported that experimental bracing and thrusting of the mandible evoked transient, mild-to-moderate levels of muscle pain, fatigue, tension and stiffness, along with increased unpleasantness and stress scores in healthy volunteers (Kothari et al., 2021). Among studies using PSG that confirm a positive correlation between masticatory muscle pain and SB, Palinkas et al. study investigated which clinical symptoms, such as muscle fatigue and pain, jaw locking, temporomandibular joint sounds, temporal headache, and tooth wear, correlated with the occurrence of SB. The most common symptoms turned out to be masticatory muscle fatigue and temporal headache (Palinkas et al., 2015). Barbon et al. also reported that participants with PSG-verified SB presented a higher prevalence of headache (Barbon et al., 2023). However, there are PSG investigations indicating a lack of a significant relationship between SB and masticatory muscle pain (Raphael et al., 2012; Wieckiewicz et al., 2020). One of our previous PSG-based studies reported no difference in the distribution of temporomandibular disorders (TMD), including masticatory muscle pain, between subjects with and without SB when applying BEI-based criteria only (Wieckiewicz et al., 2020). Raphael et al. compared

participants with and without myofascial TMD, and reported no significant differences in the number of SB events between groups (Raphael et al., 2012). Additionally, it has been reported that elevated masticatory muscle motor activity measured by electromyography (EMG) does not necessarily imply an increased risk of pain and dysfunction (Haraki et al., 2019; Lund et al., 1991; Santiago & Raphael, 2019). Lund et al. suggested that the pain observed in musculoskeletal conditions (including TMD) does not seem to be maintained by some form of tonic muscular hyperactivity (Lund et al., 1991). Santiago and Raphael reported that study participants with masticatory muscle pain alone showed only significantly higher background EMG when compared with masticatory muscle and temporomandibular joint pain participants (Santiago & Raphael, 2019). A review of the literature from 1998 to 2008 on this topic suggests that investigations based on self-report or clinical inspection of bruxism signs and symptoms show a positive association with TMD pain, but they are characterized by potential bias and confounders at the diagnostic level (e.g. pain as a criterion for bruxism diagnosis). Studies based on more quantitative and specific methods to diagnose bruxism show a much lower association with TMD symptoms (Manfredini & Lobbezoo, 2010). An updated review from 2021 confirmed the conclusions of a previous review, suggesting that literature findings on the relationship between SB and TMDs are dependent on the assessment strategies adopted for SB (Manfredini & Lobbezoo, 2021). It is worth emphasizing that among the presented studies, those that used instrumental methods to assess bruxism seem to deny the relationship between the bruxism severity and the presence of pain in the masticatory muscles. Given the mixed results from available studies and the fact that the latest consensus on SB still identifies muscle activity as the potential source of clinical consequences (Wetselaar et al., 2021), the aim of the present study was to evaluate the clinical utility of BEI in predicting the level of masticatory muscle pain intensity. The study hypothesis was that BEI is not clinically useful/valid in predicting the masticatory muscle pain intensity.

2 | MATERIALS AND METHODS

Details regarding study inclusion and exclusion criteria, and video-polysomnography (vPSG) procedures, as well as sleep parameters and scoring, have been previously partly used in our prior studies (Smardz et al., 2020; Smardz, Martynowicz, Wojakowska, Wezgowiec, Danel, et al., 2022; Smardz, Martynowicz, Wojakowska, Wezgowiec, Olchowy, et al., 2022; Wieczorek et al., 2020). This is a human observational study, and it has been complied with Strengthening the Reporting of Observational studies in Epidemiology (STROBE) protocol. The study was partially financed by Wroclaw Medical University (SUBZ.B160.24.019).

2.1 | Participants

The study involved patients from the Outpatient Clinic of Temporomandibular Disorders at the Department of Experimental Dentistry, Wroclaw Medical University, between 2017 and 2022. The research adhered to the principles of the Declaration of Helsinki and received approval from the Ethical Committee of Wroclaw Medical University (KB-195/2017, KB-794/2019). All participants provided written informed consent before participating in the study. Information on clinical trial registration can be found at www.ClinicalTrials.gov (identifiers: NCT03083405, NCT04214561).

2.2 | Inclusion criteria

The general inclusion criteria were as follows: age ≥ 18 years and a diagnosis of probable SB in accordance with the International Consensus on the Assessment of Bruxism (Lobbezoo et al., 2018).

2.3 | Exclusion criteria

The general exclusion criteria encompassed the following: severe systemic disorders and diseases (including genetic disorders); neurological disorders and/or neuropathic pain (including primary headaches assessed using Third Edition of International Classification of Headache Disorders); active inflammation; active malignancy; severe mental disorders and significant mental (including genetic) disabilities; pregnancy and confinement; treatment with, or addiction to, any analgesic agents and/or drugs affecting the function of the nervous system, muscles and breathing; and a lack of agreement to participate in the study.

2.4 | Recruitment

Study participants were recruited from patients at the Outpatient Clinic of Temporomandibular Disorders operating at the Department of Experimental Dentistry, Wroclaw Medical University, between 2017 and 2022. Patients underwent a comprehensive medical interview and dental inspection, focusing on self-reporting (including bed partner reporting) and signs and symptoms of SB, such as damage to dental hard tissues and oral mucosa, tooth wear, tongue scalloping and linea alba. Additionally, an examination of temporomandibular joints and masticatory muscles was conducted based on the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) Axis I (Schiffman et al., 2014). All procedures were performed by a dentist experienced in DC/TMD. Patients identified with probable SB in accordance with the Third Edition of the International Classification of Sleep Disorders by the American Academy of Sleep Medicine (American Academy of Sleep Medicine, 2014) were referred to the Sleep Laboratory at the Department and Clinic of Internal Medicine, Occupational Diseases, Hypertension, and Clinical Oncology at Wroclaw Medical University and underwent a single-night vPSG to confirm SB (Lobbezoo et al., 2018).

2.5 | Polysomnography

All the enrolled patients underwent a single-night vPSG utilizing NoxA1 (NOX Medical, Iceland). The recordings were conducted from

22:00 hours to 06:00 hours, taking into account the patients' sleeping habits and individual preferences.

The vPSG included the examination of standard elements, comprising electroencephalographic, electrooculographic and electrocardiographic recordings; EMG recordings from the chin area and bilaterally from the masseter muscles; recording of abdominal and thoracic breathing movements; body position; and audio and video recording. To capture saturation levels, pulse and plethysmographic data, a NONIN WristOx2 3150 pulse oximeter (Nonin Medical, Plymouth, MN, USA) was employed. The Noxturnal software (Nox Medical, Reykjavík, Iceland) was utilized for the complete restoration of the vPSG record. A qualified and experienced physician scored and analysed the vPSG recordings in 30-s epochs in accordance with the 2013 American Academy of Sleep Medicine standard criteria for sleep scoring (Berry et al., 2012).

2.5.1 | SB parameters

Definite SB was evaluated through bilateral masseter EMG and audio-video recordings. The following indices were examined: the BEI, phasic bruxism (characterized by more than three cyclic phasic EMG increases lasting 0.25–2 s), tonic bruxism (episodes lasting > 2 s) and mixed bruxism (a combination of both types of episodes mentioned). Additional SB episodes were scored after a minimum of 3 s of stable EMG, and when the activity was at least twice the amplitude of the background EMG (American Academy of Sleep Medicine, 2014; Lobbezoo et al., 2018). SB was categorized based on the frequency of bruxism episodes per hour of sleep (BEI) as non-SB (BEI < 2); mild to moderate SB (BEI 2–4); or severe SB (BEI > 4; Lobbezoo et al., 2018).

2.5.2 | Masticatory muscles pain intensity assessment

Masticatory muscle pain was individually assessed up to 30 days before PSG for each patient through palpation by an experienced dentist, separately for the right and left temporal muscles and the right and left masseter muscles, following the DC/TMD protocol. Examining the muscles on the right and left side separately results clearly from the use of the DC/TMD protocol, where muscle pain during palpation is assessed separately for individual muscles of the right and left side. A calibrated pressure of 1 kg with the duration of 2 s was applied in nine points of each muscle (Schiffman et al., 2014). During the examination, participants self-reported pain symptoms using the Numeric Rating Scale (NRS), a 0–10 scale commonly employed in pain management, where 0 signifies "no pain", and 10 denotes "unbearable pain" or an equivalent statement. NRS scores ≤ 3 indicated mild pain; scores of 4–6 denoted moderate pain; and scores ≥ 7 signified severe pain (Boonstra et al., 2014; Boonstra et al., 2016; Karcioglu et al., 2018). The global NRS value was determined for each muscle, which was the average of all nine tested points within the muscle. For statistical analysis, criteria of "no pain", "mild pain at most" (combining no pain and mild pain) and "severe pain" were additionally used.

2.6 | Statistical analysis

The collected data were analysed using TIBCO Software (2017), Statistica (data analysis software system), version 13, available at http://statistica.io. Results were considered statistically significant at $p < 0.05$. The data distribution and potential deviations from the normal distribution were assessed using the Shapiro–Wilk test ($p < 0.05$ indicates non-normal distribution). Spearman's rank correlation test was employed for correlation analysis. Sensitivity and specificity of the specified criteria were compared using association rules. Receiver operating characteristic (ROC) curves, linear regression, multivariate regression and prediction accuracy analyses were also conducted. Analyses of test accuracy were performed as usual. In the first stage, ROC analyses were performed. Subsequent dichotomous variables regarding NRS were compared with a potential quantitative predictor variable, i.e. the BEI value. ROC curves were determined to indicate optimal cut-off points for BEI. Dichotomous variables were created based on BEI cut-off points. The 2 × 2 tables were created (dichotomous variables regarding NRS versus dichotomous variables regarding BEI, which in terms of nomenclature were a real variable and a predictor variable, respectively). At the final stage, based on the comparison of true positive, true negative, false positive and false negative effects, test accuracy measures were calculated, including the basic ones such as test sensitivity, specificity and Youden's index.

The regression analysis was conducted in two stages. In the first stage, univariate linear models were estimated regarding the relationship between BEI (potential independent variable) versus NRS of individual muscles (subsequent dependent variables). In the second stage, multivariate linear models were estimated regarding the relationship between BEI, age and gender (potential independent variables, including BEI and age as quantitative variables, and gender as a dichotomous variable) versus NRS of individual muscles (dependent variables).

Group size was determined using a sample size calculator. The selection conditions were as follows: population size 3 million (population size of the macroregion where the research was conducted—the Lower Silesian Voivodeship in Poland); fraction size 0.15 (estimated percentage of people with bruxism in the above population); maximum error 5% (typical, restrictive size of error in this type of research); confidence level 95% (standard level of statistical significance). The required minimum size of the study group was 196.

3 | RESULTS

A total of 220 patients were enrolled in this study, comprising 145 women and 75 men. All participants were Caucasians aged between 18 and 71 years, with a mean age of 35.45 ± 10.67 years.

Among the participants, 174 (79.1%) presented with SB (BEI ≥ 2), while 46 (20.9%) did not. Severe SB (BEI > 4) was observed in 100 patients (45.5%). Table 1 provides descriptive statistics for all the parameters studied.

Considering NRS scores for both masseter and temporalis muscles, 74.96% of the study population experienced pain in the right masseter, 76.63% in the left masseter, 81.83% in the right temporalis, and 84.09% in the left temporalis. Detailed qualitative statistics on the occurrence of masticatory muscle pain are presented in Table 2.

3.1 | Relationship between BEI and NRS

Analysis of correlation (Figure 1a–d) and univariate linear regression revealed no statistically significant relationships between BEI and NRS scores for muscle pain during palpation of the right masseter ($p = 0.769$, $r = 0.0199$), left masseter ($p = 0.922$, $r = 0.0067$), right temporalis ($p = 0.177$, $r = -0.0913$) and left temporalis ($p = 0.223$, $r = -0.0824$).

The analysis of ROC curves and prediction accuracy revealed a lack of predictive usefulness of BEI concerning NRS scores (where 0 represents "no pain", and 10 signifies "unbearable pain" or an equivalent statement; scores ≤ 3 indicated mild pain; scores of 4–6 denoted moderate pain; and scores ≥ 7 signified severe pain).

3.1.1 | Right masseter pain intensity (NRS)

Upon analysing the ROC curves, the optimal cut-off point for predicting "no pain", "mild pain at most" and "severe pain" categories of NRS for the right masseter muscle was determined based on the BEI value. The optimal cut-off point for the "no pain" category of NRS was 2.2. The BEI criterion (associated with the specified cut-off point) for the "no pain" category of NRS pain intensity exhibited a sensitivity and specificity of prediction at 77.7% and 37.0%, respectively, resulting in a prediction accuracy of 67.7%. The optimal cut-off point for the "mild pain at most" category of NRS was 2.9. The BEI criterion for the "mild pain at most" category of NRS pain intensity demonstrated a sensitivity and specificity of prediction at 64.7% and 46.9%, respectively, leading to a prediction accuracy of 59.5%. The optimal cut-off point for the "severe pain" category of NRS was 4.1. The BEI criterion for the "severe pain" category of NRS pain intensity showed a sensitivity and specificity of prediction at 57.1% and 50.8%, respectively, resulting in a prediction accuracy of 55.5% (Table 3).

3.1.2 | Left masseter pain intensity (NRS)

Similarly, based on the analysis of ROC curves, the optimal cut-off point for predicting "no pain", "mild pain at most" and "severe pain" categories of NRS for the left masseter muscle was determined using the BEI value. The optimal cut-off point for the "no pain" category of NRS was 2.1. The BEI criterion for the "no pain" category of NRS pain intensity displayed a sensitivity and specificity of prediction at 78.0% and 37.2%, respectively, with a prediction accuracy of 67.3%. The optimal cut-off point for the "mild pain at most" category of NRS was 3.3. The BEI criterion for the "at most mild pain" category of NRS pain intensity demonstrated a sensitivity and specificity of prediction at 59.4% and 50.8%, respectively, resulting in a prediction accuracy of 56.8%. The optimal cut-off point for the "severe pain" category of NRS was 2.2. The BEI criterion for the "severe pain" category of NRS pain intensity exhibited a sensitivity and specificity of prediction at 27.8% and 79.3%, respectively, leading to a prediction accuracy of 41.4% (Table 3).

3.1.3 | Right temporalis pain intensity (NRS)

Upon analysing the ROC curves, the optimal cut-off point for predicting "no pain", "mild pain at most" and "severe pain" categories of NRS for the right temporalis muscle was determined based on the BEI value. The optimal cut-off point of BEI for the "no pain" category of NRS was 0.9. The BEI criterion for the "no pain" category of NRS pain intensity exhibited a sensitivity and specificity of prediction at 92.8% and 7.5%, respectively, resulting in a prediction accuracy of 77.3%. The optimal cut-off point for the "mild pain at most" category of NRS was 13.5. The BEI criterion for the "mild pain at most" category of NRS pain intensity demonstrated a sensitivity and specificity of prediction at 27.4% and 77.8%, respectively, leading to a prediction accuracy of 41.8%. The optimal cut-off point for the "severe pain" category of NRS was 2.2. The BEI criterion for the "severe pain" category of NRS pain intensity displayed a sensitivity and specificity of prediction at 2.9% and 100%, respectively, resulting in a prediction accuracy of 24.1% (Table 4).

3.1.4 | Left temporalis pain intensity (NRS)

Similarly, based on the analysis of the ROC curves, the optimal cut-off point for predicting "no pain", "mild pain at most" and "severe pain" categories of NRS for the left temporalis muscle was determined using the BEI value. The optimal cut-off point of BEI for the "no pain" category of NRS was 13.5. The BEI criterion for the "no pain" category of NRS pain intensity showed a sensitivity and specificity of prediction at 2.7% and 97.1%, respectively, resulting in a prediction accuracy of 17.7%. The optimal cut-off point for the "mild pain at most" category of NRS was 13.5. The BEI criterion for the "at most mild pain" category of NRS pain intensity demonstrated a sensitivity and specificity of prediction at 2.9% and 100%, respectively, leading to a prediction accuracy of 23.6%. The optimal cut-off point for the "severe pain" category of NRS was 4.7. The BEI criterion for the "severe pain" category of NRS pain intensity exhibited a sensitivity and specificity of prediction at 64.0% and 44.1%, respectively, resulting in a prediction accuracy of 58.6% (Table 4).

Parameter	Average	Median	Minimum	Maximum	SD
Age (years)	35.45	35.00	18.00	71.00	10.67
BEI (per hr)	4.67	3.65	0.20	28.80	3.92
Phasic bruxism (per hr of sleep)	2.64	1.70	0.00	22.40	3.05
Tonic bruxism (per hr of sleep)	1.28	1.00	0.00	7.60	1.21
Mixed bruxism (per hr of sleep)	0.81	0.60	0.00	5.00	0.77
NRS right masseter	4.55	5.00	0.00	10.00	3.06
NRS left masseter	4.47	5.00	0.00	10.00	2.98
NRS right temporalis	4.94	5.00	0.00	10.00	2.84
NRS left temporalis	4.90	5.00	0.00	10.00	2.70

Abbreviations: BEI, bruxism episode index; NRS, Numeric Rating Scale; SD, standard deviation.

TABLE 1 Descriptive statistics of all studied parameters for the entire population.

	Right masseter		Left masseter		Right temporalis		Left temporalis	
Pain	*N*	%	*N*	%	*N*	%	*N*	%
No pain	54	24.55	52	23.64	40	18.18	35	15.91
Mild pain	10	4.55	13	5.91	109	49.55	12	5.45
Moderate pain	97	44.09	97	44.09	63	28.64	114	51.82
Severe pain	59	26.82	58	26.36	8	3.64	59	26.82

N, number of study participants.

TABLE 2 Qualitative statistics of the occurrence of masticatory muscle pain for the entire population.

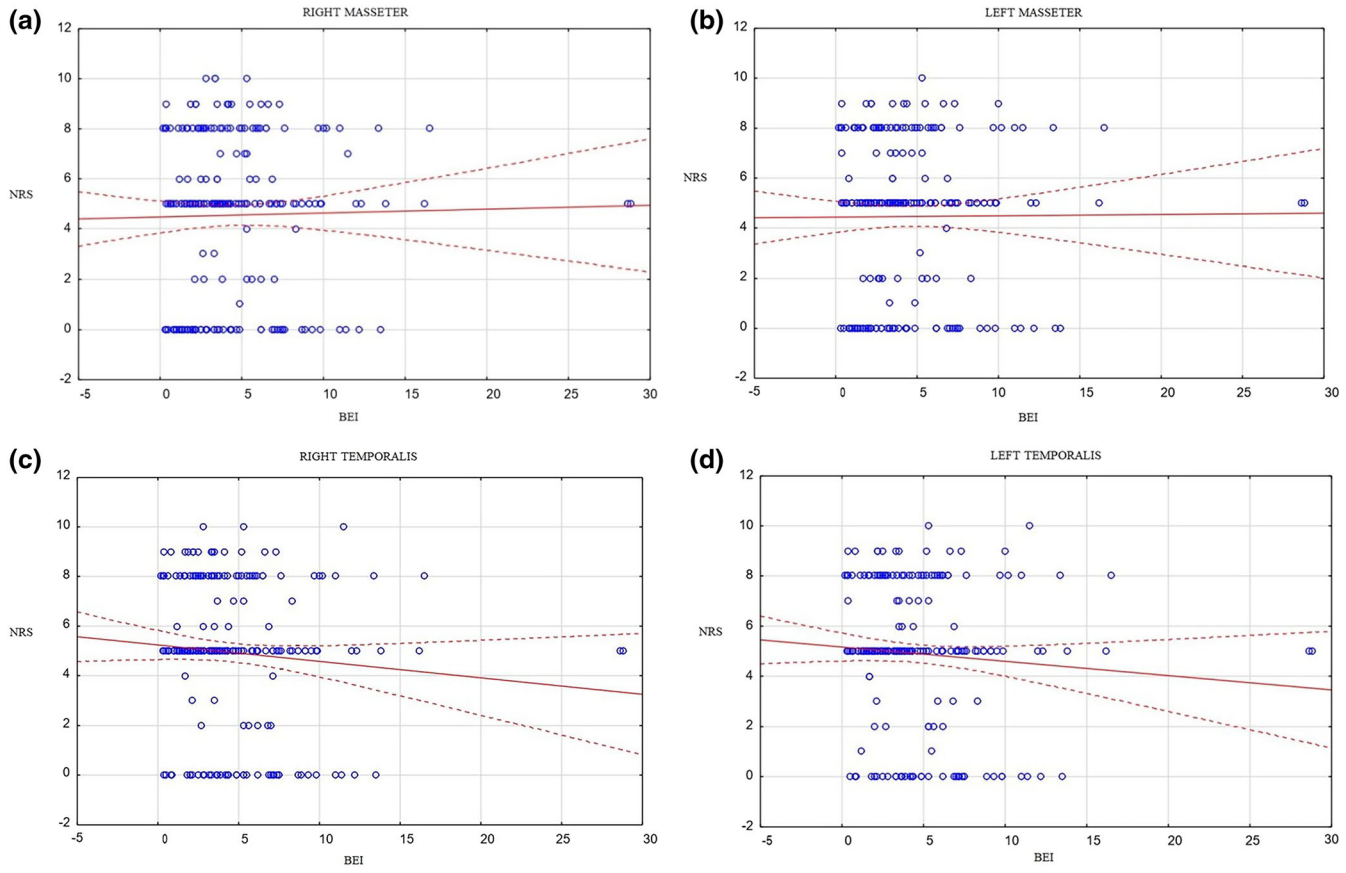

FIGURE 1 BEI versus NRS correlation analysis for the entire study population. (a) BEI versus NRS correlation analysis for the right masseter muscle in the entire study population. (b) BEI versus NRS correlation analysis for the left masseter muscle in the entire study population. (c) BEI versus NRS correlation analysis for the right temporalis muscle in the entire study population. (d) BEI versus NRS correlation analysis for the left temporalis muscle in the entire study population. BEI, bruxism episode index, NRS, Numeric Rating Scale.

TABLE 3 Prediction accuracy of the cut-off points for NRS-based pain criteria for the right and left masseter muscle.

	"No pain" criterion		"Mild pain at most" criterion		"Severe pain" criterion	
Parameter	**Right**	**Left**	**Right**	**Left**	**Right**	**Left**
Optimal cut-off point	BEI < 2.2	BEI < 2.1	BEI ≤ 2.9	BEI ≤ 3.3	BEI ≥ 4.1	BEI ≥ 2.2
Exposed risk	0.791	0.789	0.748	0.742	0.760	0.789
Non-exposed risk	0.351	0.315	0.353	0.344	0.303	0.282
Population risk	0.755	0.764	0.709	0.705	0.732	0.736
Absolute risk reduction	0.142	0.104	0.101	0.086	0.063	0.072
Number needed to treat	7.028	9.618	9.892	11.671	15.783	13.950
Relative risk	1.219	1.152	1.156	1.131	1.091	1.100
−95% CI Relative risk	0.759	0.715	0.755	0.745	0.724	0.696
+95% CI Relative risk	1.958	1.856	1.770	1.715	1.644	1.738
Odds for "Yes"	3.794	3.743	2.971	2.875	3.172	3.750
Odds for "No"	0.541	0.459	0.545	0.524	0.435	0.393
Odds ratio	2.051	1.720	1.620	1.506	1.379	1.474
−95% CI Odds ratio	1.058	0.867	0.898	0.841	0.758	0.716
+95% CI Odds ratio	3.977	3.411	2.925	2.696	2.509	3.036
Accuracy	0.677	0.673	0.595	0.568	0.555	0.414
Sensitivity	0.777	0.780	0.647	0.594	0.571	0.278
Specificity	0.370	0.327	0.469	0.508	0.508	0.793
Positive likelihood ratio	1.234	1.159	1.219	1.206	1.163	1.343
Negative likelihood ratio	0.602	0.674	0.752	0.801	0.843	0.911
J Youden index	0.147	0.107	0.116	0.101	0.080	0.071

BEI, bruxism episode index; CI, confidence interval.

3.2 | Multivariate regression analysis

The multivariate regression analysis revealed no association between BEI and NRS scores for all examined muscles (right and left masseter muscles; right and left temporalis muscles; $p > 0.05$ for all comparisons). This lack of association held true regardless of the confirmed relationship between female gender and NRS scores for all examined muscles ($p < 0.05$ for all comparisons; Table 5).

4 | DISCUSSION

The existing literature on the connection between bruxism and masticatory muscle pain presents conflicting findings. While some scientific reports support such an association (Barbon et al., 2023; Blanco Aguilera et al., 2014; Costa et al., 2016; Huhtela et al., 2016; Kothari et al., 2021; Palinkas et al., 2015), others dismiss it (Lund et al., 1991; Raphael et al., 2012; Wieckiewicz et al., 2020). It is worth emphasizing that among the presented studies, those that used instrumental methods to assess bruxism seem to deny the relationship between the bruxism severity and the presence of pain in the masticatory muscles. Unfortunately, much of the existing research on this subject relies on self-reporting of bruxism. Only a few studies address the described relationship using quantitative methods, such as PSG. Noteworthy among the studies utilizing objective instrumental methods to assess bruxism are some specific findings. Palinkas et al. noted that symptoms most correlated with SB included masticatory muscle fatigue and temporal headaches (Palinkas et al., 2015). Barbon et al. also found that participants with PSG-verified SB exhibited a higher prevalence of headaches (Barbon et al., 2023). Conversely, some scientific reports suggest a lack of a significant relationship between SB and masticatory muscle pain (Lund et al., 1991; Raphael et al., 2012; Wieckiewicz et al., 2020). Lund et al., for instance, proposed that the observed pain in musculoskeletal conditions (including TMD) does not seem to be sustained by some form of tonic muscular hyperactivity (Lund et al., 1991). Raphael et al., in comparing participants with and without myofascial TMD, reported no significant differences in the incidence of SB between the groups (Raphael et al., 2012). Santiago and Raphael found that participants with masticatory muscle pain alone exhibited only significantly higher background EMG when compared with masticatory muscle and temporomandibular joint pain participants (Santiago & Raphael, 2019).

The scientific consensus on bruxism unequivocally points to an elevated risk of adverse outcomes related to fatigue and masticatory pain in individuals with bruxism (Lobbezoo et al., 2018). However, it is crucial to note that a majority of studies confirming the link between bruxism and masticatory muscle pain rely on surveys and lack the use of instrumental diagnostic methods (Blanco Aguilera et al., 2014; Costa et al., 2016; Huhtela et al., 2016). Considering studies that explore this relationship using instrumental methods to assess SB, the

TABLE 4 Prediction accuracy of the cut-off points for NRS-based pain criteria for right and left temporalis muscle.

	"No pain" criterion		"Mild pain at most" criterion		"Severe pain" criterion	
Parameter	**Right**	**Left**	**Right**	**Left**	**Right**	**Left**
Optimal cut-off point	BEI < 0.9	BEI < 13.5	BEI ≤ 13.5	BEI ≤ 13.5	BEI ≥ 2.2	BEI ≥ 4.7
Exposed risk	0.819	0.833	1.000	1.000	0.754	0.757
Non-exposed risk	0.188	0.159	0.223	0.219	0.301	0.310
Population risk	0.818	0.841	0.782	0.786	0.714	0.732
Absolute risk reduction	0.006	−0.008	0.223	0.219	0.055	0.067
Number needed to treat	163.200	−128.400	4.479	4.574	18.182	14.953
Relative risk	1.008	0.991	1.287	1.280	1.079	1.097
−95% CI Relative risk	0.471	0.297	–	–	0.679	0.720
+95% CI Relative risk	2.154	3.300	–	–	1.713	1.672
Odds for "Yes"	4.514	5.000	–	–	3.071	3.121
Odds for "No"	0.231	0.189	0.287	0.280	0.430	0.448
Odds ratio	1.042	0.944	–	–	1.320	1.399
−95% CI Odds ratio	0.282	0.107	–	–	0.662	0.763
+95% CI Odds ratio	3.841	8.339	–	–	2.632	2.566
Accuracy	0.773	0.177	0.241	0.236	0.418	0.586
Sensitivity	0.928	0.027	0.029	0.029	0.274	0.640
Specificity	0.075	0.971	1.000	1.000	0.778	0.441
Positive likelihood ratio	1.003	0.946	–	–	1.232	1.144
Negative likelihood ratio	0.963	1.002	0.971	0.971	0.934	0.817
J Youden index	0.003	−0.002	0.029	0.029	0.052	0.080

BEI: bruxism episode index; CI, confidence interval.

findings appear to be inconclusive (Barbon et al., 2023; Lund et al., 1991; Raphael et al., 2012; Santiago & Raphael, 2019; Wieckiewicz et al., 2020). The BEI has been widely employed, and perhaps excessively so, over many years to gauge the severity of SB (American Academy of Sleep Medicine, 2014; Karcioglu et al., 2018; Lavigne et al., 1996; Lobbezoo et al., 2018; Manfredini, Ahlberg, et al., 2019). To examine the issue comprehensively, aligning with the 2018 bruxism consensus (Lobbezoo et al., 2018), masticatory muscle activity should correlate with negative clinical consequences that may stem from increased muscle activity during sleep (Lobbezoo et al., 2018). The most significant adverse clinical implications associated with SB occurrence (dependent on the phenotype; Manfredini, Ahlberg, et al., 2019; Manfredini et al., 2017) encompass damage to dental hard tissues and oral mucosa, heightened muscle stiffness and pain, and the onset of a muscular-origin headache (Beddis et al., 2018; Lavigne et al., 2008; Lobbezoo et al., 2018; Manfredini et al., 2017; Manfredini, Lombardo, et al., 2019). Symptoms linked to pain appear to exert the most considerable impact on reduced quality of life (Almukhtar & Fabi, 2019). Therefore, a comprehensive and valid index assessing SB should correlate with the intensity of pain to be maximally meaningful for clinical applications. Consequently, the aim of the presented study was to evaluate the clinical validity of BEI in predicting the level of masticatory muscle pain intensity.

The most significant result derived from this study suggests that the BEI is not statistically significantly correlated and lacks predictive validity concerning the intensity of masticatory muscle pain. Furthermore, the multivariate regression analysis revealed no relationship between BEI and NRS scores for all examined muscles (right and left masseter muscles; right and left temporalis muscles), irrespective of the confirmed relationship between female gender and NRS scores for all examined muscles.

The findings of this study prompt us to consider the problem from three distinct perspectives. Firstly, because the frequency of bruxism episodes per hour of sleep appears to have no impact on the intensity of masticatory muscle pain, it raises the question of whether other factors, such as the SB phenotype or the duration and intensity of masticatory muscle contraction, influence it. Researchers should explore additional muscle activities within the bruxism spectrum that may affect masticatory muscle pain (Bracci et al., 2023; Colonna et al., 2022). Secondly, is there a more effective index based on PSG data that could better define the potential risk of negative clinical implications associated with SB? Therefore, researchers might direct their efforts toward identifying a superior index than BEI. Lastly, is there a genuine association between SB and heightened pain and dysfunction in the masticatory system?

Regrettably, the current medical literature lacks extensive publications on the topics mentioned. In a review, Castrillon et al. concluded that the available scientific evidence does not support bruxism as a direct cause of pain (Castrillon & Exposto, 2018). Additionally, Muzalev et al., in their PSG-based study, suggested that

TABLE 5 Multivariate regression analysis considering the influence of age and gender on the BEI versus NRS relationship.

Predictor	Muscle	β	Standard error with β	b	Standard error with b	t (216)	p
Age	Right masseter	−0.022	0.066	−0.006	0.019	−0.333	0.739
	Left masseter	−0.037	0.065	−0.010	0.018	−0.569	0.570
	Right temporalis	−0.016	0.065	−0.004	0.017	−0.241	0.810
	Left temporalis	−0.040	0.070	−0.010	0.020	−0.68	0.500
Female gender	Right masseter	0.278	0.066	1.791	0.428	4.189	0.000
	Left masseter	0.303	0.066	1.904	0.413	4.614	0.000
	Right temporalis	0.290	0.066	1.733	0.393	4.416	0.000
	Left temporalis	0.290	0.070	1.660	0.370	4.450	0.000

β, beta statistic of the estimator; b, regression coefficient.

pain related to TMDs cannot be attributed to an increasing number of SB episodes per hour or a reduction in the time between SB events (Muzalev et al., 2017). Another PSG-based study by Rossetti et al. reported that the presence of SB was not associated with TMD or pain in masticatory muscles upon palpation (Rossetti, Rossetti, et al., 2008). Previous PSG-based studies did not observe differences in the occurrence of both TMD and masticatory muscle pain between individuals with and without bruxism (Blanco Aguilera et al., 2014; Sinclair et al., 2022; Smardz et al., 2019). It is important to note that almost all available studies utilize the BEI as a criterion for the occurrence and harmful consequences of SB. In light of the results presented in this study, this may introduce potential bias. Furthermore, the existing studies confirming the correlation between SB and masticatory muscle pain, in most cases, relied on surveys (Blanco Aguilera et al., 2014; Costa et al., 2016; Huhtela et al., 2016). It is possible that respondents experiencing masticatory muscle l pain were more likely to report bruxism, perceiving it as the cause of their ailments (Raphael et al., 2012; Van Selms et al., 2020). Additionally, the frequent coexistence of bruxism during sleep and wakefulness is noteworthy (Lobbezoo et al., 2018). Rossetti et al. reported a significant association between SB and myofascial pain, with SB representing a low-risk factor for this type of pain. Notably, AB emerged as a strong risk factor for myofascial pain, with the study utilizing PSG as an instrumental method for assessing SB (Rossetti, de Araujo, et al., 2008). Despite the use of instrumental methods, the results regarding the correlation between SB and masticatory muscle pain remain inconclusive, possibly due to the lack of a comprehensive and valid index, composed of multiple variables, that correlates with the risk and severity of masticatory muscle pain in patients with SB. In summary, there is a need to explore other robust tools incorporating various index configurations for assessing the severity and harm of SB. Relying solely on BEI as a quantitative criterion appears inaccurate and insufficient in predicting the consequences of SB. The future may involve searching for qualitative criteria, such as the bruxism phenotype or the duration of muscle contractions. Although van der Zaag et al. introduced the bruxism time index (the percentage of total sleep time spent bruxing) in their study on the efficacy of occlusal stabilization splints in managing SB (van der Zaag et al., 2005), this paradigm should also be considered in future research, emphasizing the potential significance of the duration of SB-related oral behaviours (Colonna et al., 2022; Colonna et al., 2024; van der Zaag et al., 2005). Therefore, it is yet unknown if the classical index (e.g. BEI) alone or in combination with other variables, such as duration or amplitude of EMG activity or inter-burst or episode periodicity, are the most accurate outcomes to assess if SB correlates with pain, if it is meaningful for clinical diagnosis or treatment decision.

While there have been previous studies questioning the BEI index, this study, to the best of our knowledge, is the first to present a comprehensive critique, challenging BEI as a robust biomarker for assessing the severity of SB in the context of masticatory muscle pain intensity. The strength of this study lies in its inclusion of a large participant cohort ($n = 220$), the use of vPSG as the SB diagnostic method, and the application of diverse statistical methods. However, despite these strengths, the study has several limitations: (1) it relies on a single-night vPSG examination, which could potentially underestimate SB frequency due to the first-night effect (Haraki et al., 2020; Hasegawa et al., 2013; Miettinen et al., 2018; Stuginski-Barbosa et al., 2016), mandated by the constraints of the Polish healthcare system; (2) it is a single-centre study; (3) variables related to AB and day-to-day variability of SB were not considered; (4) only palpation and the NRS was utilized to measure the intensity of masticatory muscle pain (Koutris et al., 2013); (5) there were no data including familiar/non-familiar pain obtained in this study (Koutris et al., 2013); (6) there was up to 30 days time lapse between masticatory muscle pain assessment and PSG.

5 | CONCLUSIONS

The utilization of BEI alone appears to lack correlation and predictive usefulness in assessing masticatory muscle pain intensity. Clinicians should exercise caution in misusing BEI to evaluate the correlation between the severity of SB, specifically harm-related aspects, and masticatory muscle pain intensity. The incorporation of phenotyping and endotyping of various variables associated with SB needs to be further emphasized in the assessment of harm-consequences related to this oral behaviour.

INFORMED CONSENT STATEMENT

Informed consent was obtained from all subjects participating in the study.

AUTHOR CONTRIBUTIONS

Mieszko Wieckiewicz: Conceptualization; investigation; funding acquisition; writing – original draft; methodology; validation; project administration; supervision; data curation; resources; formal analysis. **Helena Martynowicz:** Conceptualization; investigation; funding acquisition; methodology; validation; writing – review and editing; formal analysis; project administration; data curation; supervision; resources. **Gilles Lavigne:** Formal analysis; writing – review and editing; data curation. **Takafumi Kato:** Writing – review and editing; formal analysis; data curation. **Frank Lobbezoo:** Formal analysis; data curation; writing – review and editing. **Joanna Smardz:** Conceptualization; investigation; writing – original draft; methodology; formal analysis; data curation; visualization. **Jari Ahlberg:** Writing – review and editing; formal analysis; data curation. **Efraim Winocur:** Writing – review and editing; formal analysis; data curation. **Alona Emodi-Perlman:** Writing – review and editing; formal analysis; data curation. **Claudia Restrepo:** Writing – review and editing; formal analysis; data curation. **Anna Wojakowska:** Investigation; data curation. **Pawel Gac:** Software; formal analysis; data curation; visualization. **Grzegorz Mazur:** Supervision; project administration; resources. **Marta Waliszewska-Prosol:** Writing – review and editing; formal analysis; data curation. **Witold Swienc:** Software; data curation. **Daniele Manfredini:** Writing – review and editing; formal analysis; data curation.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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