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Detection of Sleep Bruxism: Comparison between an Electromyographic and Electrocardiographic
Portable Holter and Polysomnography

Running Title: Detection of sleep bruxism

Original research

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Abstract

Background: Recent polysomnographic studies showed that the sleep bruxism (SB) event is preceded by a sudden shift in autonomic cardiac activity. Therefore, heart rate could be the simplest-to-record parameter for use in addition to portable home-EMG monitoring to improve the accuracy in automatic detection of SB events.

Objectives: The aim of the study was to compare the detection of SB episodes by combined surface electromyography (sEMG) and heart rate (HR) recorded by a compact portable device (Bruxoff®), with the scoring of SB episodes by a polysomnographic (PSG) recording.

Material and Methods: Twenty-five subjects (14 “probable” bruxers and 11 non-bruxers) were selected for the study. Each subject underwent the Bruxoff and the PSG recordings during the same night. Rhythmic masseter muscle activities (RMMA) were scored according to published criteria. Correlation coefficients and the Bland-Altman plots were calculated in order to measure the correlation and agreement between the two methods.

Results: Results showed a high correlation (Pearson’s $r=0.95$, $P<0.0001$) and a high agreement (bias =0.05) between Bruxoff and the PSG. Furthermore, the Receiving Operator Characteristic (ROC) curve analysis showed a high sensitivity and specificity of the portable device (92.3% and 91.6% respectively) when the cut-off was set at 4 SB episodes per hour accordingly to published criteria.

Conclusion: The Bruxoff device showed a good diagnostic accuracy to differentiate RMMA from other oromotor activities. These findings are important in the light of the need for simple and reliable portable devices for the diagnosis of SB both in the clinical and research settings.

Key words: Sleep bruxism, surface electromyography, masseter muscle, heart rate, polysomnography, rhythmic masticatory muscles activity

Introduction

Bruxism is a repetitive jaw-muscle activity characterized by teeth clenching or grinding and/or mandible bracing or thrusting (1). Sleep bruxism (SB) is related with sleep arousals and has a combination of different motor activities, also including tooth grinding (2, 3, 4). A recent review reported a mean prevalence of 12.8% in the adult population, with no gender differences and a tendency to decline with increasing age (5). However a true estimate of SB prevalence is complicated by the low diagnostic specificity of most reviewed papers, thus suggesting that an improvement in SB diagnostic accuracy is a fundamental requisite (5).

The current standard of reference for diagnosing SB is polysomnography (PSG) with audio-video (AV) recordings (1). Such an approach allows identifying SB based on the bruxism generator model, which postulates that a well-defined oromotor activity, called “rhythmic masticatory muscle activity” (RMMA), constitutes the basic pattern of SB (6, 7, 8). Unfortunately, PSG has some disadvantages, such as the high cost, the amount of time needed for manual/visual scoring (9), the laboratory settings, not providing information of oral behaviors occurring in home environment, and the scoring based upon subjective evaluation and the examiner’s skill (10). The use of portable electromyographic (EMG) devices may partly solve these limitations, but it introduces the risk for overestimating the number of true SB episodes because such devices do not record other SB markers related with autonomic activity (11-13).

Recent studies showed that the SB event is preceded in particular by a sudden shift in autonomic cardiac and respiratory activity as well as by a specific brain activation (8). Therefore, heart rate could be the simplest-to-record parameter for use in addition to portable home-EMG monitoring to improve the accuracy in automatic detection of SB events.

Based on these premises, this study compares the analysis of sleep bruxism episodes by combined EMG and electrocardiography (ECG) recorded by a compact portable device (Bruxoff®, Spes Medica, Battipaglia, Italy), with the scoring of sleep episodes by a PSG assessment. The study

was specifically designed to answer the clinical research question “is a portable EMG/ECG recorder accurate to detect PSG-diagnosed sleep bruxism?” The rationale underlying the study was that a positive answer to the above question could lead to the possible introduction of a simplified diagnostic approach to SB in both the clinical and research settings.

Material and Methods

Subjects

The study was performed on 25 subjects (13 men and 12 women, mean age \pm SD 28 ± 10.77 years) selected among patients referring to the Oral Physiology Unit of the Dental School of the University of Torino. To ensure the possibility that subjects with different frequency of sleep bruxism activity took part to the study, as to verify the study hypothesis (i.e., accuracy of the portable device to record SB events) in presence of different SB severity, two groups of subjects were initially recruited on the basis of their probable bruxism or absence of bruxism. The assessment was made by an expert clinician, on the basis of a clinical inspection and questionnaires, concerning awareness of sleep bruxism, sleep habits, anxiety, stress, fatigue, nervousness, current facial pain intensity, painful jaw upon awakening, and fatigue of masticatory muscles at different moments.

With these criteria, 14 probable bruxers (8 men and 6 women, mean age \pm SD 26.4 ± 3.5) and 11 non-bruxers (4 men and 7 women, mean age \pm SD 31.9 ± 13.9) were selected. Both bruxers and non-bruxers subjects were also screened for temporomandibular disorders (TMD) according to the Research Diagnostic Criteria for TMD (RDC/TMD) (14).

Exclusion criteria for both groups were: 1) presence of prosthodontic rehabilitations, 2) missing teeth, with the exception of the third molars 3) periodontal disease, 4) Group II and/or Group III TMDs (discal and/or articular TMDs) (14, 15), 5) medical history of neurological, mental, or sleep disorders (e.g., periodic leg movements, insomnia). The Epworth sleepiness scale

and the Berlin questionnaire were used to exclude possible OSAS. All the subjects were not under medications at the time of recording, and were not under the effect of alcohol, nicotine or caffeine.

The procedures were approved by the Lingotto Dental School ethic committee (#20120098). All individuals gave their informed consent in accordance with the Helsinki Declaration and understood that they were free to withdraw from the experiment at any time.

PSG recordings

Polygraphic studies were performed in the home environment using a commercially available system (Embletta X100®; Flaga, Iceland), allowing a comprehensive portable polysomnography (Type II device) accordingly to the guidelines recommended by the American Academy of Sleep Medicine (16). It measured the following: (i) nasal pressure, (ii) thoraco-abdominal movement, (iii) finger pulse oximetry, (iv) heart rhythm and rate (v), and masseter surface EMG (sEMG). The sleep lab technician assisted the subjects with the application of the PSG device in the participant's home just before the subject went to bed.

Bruxoff recordings

A portable device (Bruxoff®, Spes Medica, Battipaglia, Italy) with three channels acquired sEMG bilaterally from the masseter and the heart frequency. The three signals were sampled at 800 Hz, with 8 bit resolution. Data were stored on a MicroSD card as a binary file. The sEMG channels were filtered between 10 and 400 Hz with gain 4300. The ECG channel was filtered between 15 and 160 Hz with gain 700.

SEMG from the masseter muscle of both sides were detected with disposable bipolar concentric electrodes (Code®, Spes Medica, Battipaglia, Italy) (17), with a 16 mm radius and an AgCl detection site (Fig.1). These electrodes were chosen to permit an easy application, avoiding the electrode orientation problem and reducing EMG crosstalk (17, 18).

ECGs were detected with a disposable bipolar electrode located on the left side of the thorax about 5-10 cm below the sternum. EMG and ECG signals were recorded during two consecutive nights (at least 4 hours of sleep per night). The first night was a familiarization session with the devices, while the recordings during the second night were used for the data analyses.

Masseteric EMG and sleep scoring

To test the accuracy of the Bruxoff device, simultaneous recordings were made with the Bruxoff and the PSG electrodes attached to the same masseter.

Five tapping movements before sleep and after getting up in the morning were performed, and the first burst of the tapping movements was used for synchronization between the PSG recording system and the Bruxoff device. After the five tapping movements at the beginning of the recording session, the subjects were asked to perform three maximum voluntary clenching (MVC) on teeth lasting 3 s each and separated by 10 s of rest. The greatest of the MVC measures was used for normalizing the EMG values as a percent of MVC.

Masseter EMG bursts with duration exceeding 0.25s were selected for oromotor activity scoring (6). Based on literature data (19), the considered SB cut-off values for visual scoring of RMMA episodes on a PSG tracking were: masseter mean EMG amplitude at least 10% of maximum voluntary clenching activity, preceded by an approximately 25% increase of heart rate (beginning 1 second before RMMA onset). Oromotor activity during wakefulness, viz., before falling asleep, was excluded from PSG scoring.

The same cut-off values were used to perform a visual scoring on the Bruxoff records (manual measurement).

Also, the automatic SB scoring performed by the Bruxmeter software (Bruxmeter ®, OT Biolettonica, Torino, Italy) was considered for comparison with the PSG scoring and to the Bruxoff manual scoring. The software is able to classify a SB episode if the sEMG burst is greater than 10%

MVC and if it immediately follows (1-5 seconds interval) a heart rate increase of 20% with respect to the baseline.

An episode scored by Bruxoff was considered a true SB episode when RMMA, preceded by a heart rate increase, was observed with both recording systems.

Only one author (A.B.) scored the Bruxoff signals, with no knowledge of the PSG scoring data. An experienced sleep technician scored the PSG signals blind to the scoring with Bruxoff. Afterwards, the scoring data were matched between Bruxoff, both manual and automatic, and PSG.

Statistical Analysis

Statistical analysis was performed using the software Statistical Package for the Social Sciences (SPSS) 15.0 (SPSS Inc., Chicago, IL, USA). The sample passed the Kolmogorov-Smirnov normality test ($P > 0.10$). The variables used to perform the analysis were the number of SB events per hour and the number of SB events per night. For statistical purposes, the discrimination between bruxers and non bruxers was based on the PSG analysis and not on the initial clinical criteria. According to the PSG analysis 12 non-bruxers (5 men, 7 women, age 29.8 ± 10.4 years) and 13 bruxers (7 men, 6 women, age 28.1 ± 9.8 year) were analyzed.

A Pearson correlation coefficient and the Bland-Altman plot (20) were used to quantify the direction and magnitude of correlation, and to measure the agreement between the between the PSG and the Bruxoff measurements, respectively. The level for statistical significance was set at $P < 0.05$.

A receiver operating characteristics (ROC) curve analysis (21) was performed to detect diagnostic accuracy (area under the curve), true-positive rate (TPR, sensitivity) and false positive rate (FPR, 1-specificity) (20) of each measurement (Bruxoff manual, Bruxoff automatic) to discriminate between bruxers and non-bruxers.

Furthermore a ROC curve analysis was performed to test the diagnostic accuracy of the Bruxoff device (both automatic and manual measurements) in terms of contemporaneity of SB events between PSG and Bruxoff. To do that, considering that the beginning and the end of the two

recordings of each subject were matched and that each device provided the hour and the minute of every SB event, a third operator (T.C.) scored the contemporaneity of SB events recorded with the two devices.

Ten subjects were randomly selected from the entire sample, and all procedures for data acquisition were repeated three times with a 1 week interval between each acquisition. Reproducibility of SB episodes per night and SB episodes per hour was assessed by the intra-class correlation coefficient (ICC). Values higher than 80% indicate excellent reproducibility, whereas values below 60% reflect poor reproducibility. ICC between 60% and 80% is considered good reproducibility (22).

Results

Table I shows descriptive statistics of the sleep bruxism episodes in the analyzed groups.

The Pearson correlation analysis showed a high correlation between PSG and Bruxoff automatic ($r=0.95$, $P<0.0001$) in the whole sample (Fig.2). The correlation was strongly significant in bruxers and control subjects for both comparisons between PSG and Bruxoff automatic ($r=0.94$, $P<0.0001$ and $r=0.58$, $P<0.05$ respectively) and PSG and Bruxoff manual scoring ($r=0.95$, $P<0.0001$ and $r=0.72$, $P<0.001$ respectively).

The Bland-Altman plot for the whole sample showed a high level of agreement between PSG and Bruxoff automatic with a bias value of 0.05 between the two measurements (Fig.3).

ROC curve analysis showed an excellent accuracy for the Bruxoff device with automatic scoring in differentiating between bruxers and controls (area under the curve=0.96, SE=0.03, $P<0.0001$) with a sensitivity of 92.3% and specificity of 91.6% when the cut-off was set at 4 SB episodes per hour of sleep (Fig.4 a). Furthermore the ROC curve analysis showed an excellent accuracy for the Bruxoff device with manual scoring with a sensitivity of 92.3% and specificity of 100% (Fig. 4 b). ROC curve analysis related to the contemporaneity of events between PSG and Bruxoff revealed an excellent accuracy of the Bruxoff automatic (area under the curve=0.91, SE=0.07, $P<0.0001$) with a sensitivity of 91.6% and a specificity of 84.6% when the cut-off was set at 4 SB episodes per hour

of sleep. The same evaluation conducted for the Bruxoff device with manual scoring showed a sensitivity of 83.3% and a specificity of 84.6% (Fig. 5a,b).

The ICC showed a good reproducibility for SB episodes per night (69%) and SB per hour (74%).

Discussion

The study showed a good agreement between a portable device for the combined detection of masseter sEMG and heart frequency (Bruxoff®, Spes Medica, Battipaglia, Italy) and a portable PSG device (Embletta X100®; Flaga, Iceland) in diagnosing SB episodes.

RMMA are observed in the 60% of the general adult population as a physiological activity of the masticatory muscles during sleep (23). Thus, portable devices measuring only the sEMG activity tend to overestimate the SB episodes (13), whilst the combined recordings of sEMG activity from the masseter muscle and heart rate could represent a good solution to improve the reliability of portable devices for the SB diagnosis.

Based on these premises, we compared the Bruxoff device with a comprehensive portable PSG device. Results showed good correlation ($r=0.95$, $P<0.0001$) and agreement of the measurements (bias 0.005). Considering the PSG data as the gold standard, and thus evaluating the contemporaneity of SB events between PSG and Bruxoff, the sensitivity and specificity of Bruxoff automatic measurement (Bruxmeter® software, OT Bioelettronica, Torino, Italia) were 91.6% and 84.6% respectively when the cut-off was set at 4 SB events per hour of sleep, in accordance to previous PSG studies (6, 19). These results indicate an excellent ability of the algorithm in detecting RMMA and true SB episodes and in differentiating SB RMMA from other oromotor activities. When the number of SB events per hour was considered, the sensitivity and specificity of the Bruxoff automatic were 92.3% and 91.6% respectively, while the sensitivity and specificity of the Bruxoff manual, a visual scoring of the SB episodes similar to the PSG scoring, were 92.3% and 100% respectively, when the cut-off was set at 4 SB episodes per hour of sleep.

Findings from this study are hard to compare with literature data, since only a few other sEMG portable devices have been compared to PSG. In Yamaguchi's work (24), a telemetric EMG device was compared with standard sleep laboratory polysomnography with synchronised audio-visual recording (PSG-AV) in eight non-bruxers subjects. Results showed a high number of false-positive detection because the EMG device was not able in differentiating RMMA from other oromotor activities. Another device, the Bitestrip® (Scientific Laboratory Products, Ltd., Tel Aviv, Israel), was compared with PSG in two studies by Mainieri (25) and Shochat (26) performed on bruxers. Results showed a good sensitivity and positive predictive value, but a poor accuracy to discriminate between RMMA and other oromotor activities. Those studies also showed high rates of false negative findings, due to the different thresholds adopted to identify RMMA with the portable device (30% MVC) and the PSG (10% MVC).

The main limitation of this study is that we have not compared the Bruxoff device to a standard sleep laboratory polysomnography with synchronized audio-visual recording (PSG-AV). Thus, PSG-AV recordings should be needed to fully confirm the excellent results achieved with this study. Notwithstanding that, the portable sEMG/ECG device under assessment in this investigation proved to be suitable for measuring what is purported to measure, viz., oromotor activity during sleep, and accurate for diagnosing RMMA associated with SB, if PSG findings are assumed as the reference standard.

Conclusions

In conclusion, Bruxoff was accurate to detect PSG-diagnosed SB in two selected groups of bruxers and non-bruxers. These findings are of special interest on the way to the search for simplified approaches to the diagnosis of sleep bruxism.

Disclosure/Acknowledgements

The procedures were approved by the Lingotto Dental School ethic committee (#20120098). All individuals gave their informed consent in accordance with the Helsinki Declaration. The research funding was provided by University of Torino. The authors do not have any financial relation with Spes Medica or OTBioelettronica. The Authors are sincerely grateful to dr. Lorenzo Sintoni for his precious assistance in the PSG readings.

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TABLES AND FIGURES

Table I. Descriptive statistics of the sleep bruxism episodes in the analyzed groups.

	Bruxers	Controls
Age	26.42±3.5	31.9±13.96
Sex	6 F/ 8 M	7 F/ 4 M
Number of SB episodes per night	24.63±8.42	4.31±4.50
Hours of sleep	6.55±1.46	6.63±1.79
PSG SB per hour	7.89±2.65	2.44±0.79
Bruxoff automatic SB per hour	7.66±2.90	1.78±0.89
Bruxoff manual SB per hour	7.14±2.87	2.57±1.44

FIGURES CAPTIONS

Figure 1: The Bruxoff® and the CoDe® (Spes Medica, Battipaglia, Italy) electrode used in this study for the detection of myoelectric signals from the masseter muscles. This electrode was chosen to avoid any orientation problem. At the top a schematic representation of the electrode location over the masseter muscle is shown. Black line: gonial angle-cantus line used as anatomical landmark.

Figure 2: Correlation between Polygraphic recording and Bruxoff automatic detection of sleep bruxism episodes per hour ($r=0.95$, $P<0.0001$).

Figure 3: The Bland-Altman plot showed a high level of agreement between PSG and Bruxoff automatic with a bias value of 0.05 between the two measurements, a SD of bias of 1.05 and 95% limits of agreement ranging between -2 and 2.11 on the vertical axis. The graph provides an horizontal axis corresponding to 0 (no differences among the measurements) and 95% limits of

agreement ranging between -2 and 2.11. The mean difference is the estimated bias, and the SD of the differences measures the random fluctuations around this mean.

Figure 4: a) Receiver Operating Characteristics curve analysis of the Bruxoff automatic. Area under the curve=0.96, SE=0.03, $P<0.0001$; b) Receiver Operating Characteristics curve analysis of the Bruxoff manual. Area under the curve=0.98, SE=0.02, $P<0.0001$.

Figure 5: a) Contemporaneity of SB events scoring: Receiver Operating Characteristics curve analysis of the Bruxoff automatic. Area under the curve=0.91, SE=0.07, $P<0.0001$; b) Contemporaneity of SB events scoring: Receiver Operating Characteristics curve analysis of the Bruxoff manual. Area under the curve=0.89, SE=0.08, $P<0.0001$