Reduction of sleep bruxism events according to contingent electrical stimulus intensity

Short title: Reduction of sleep bruxism according to electrical stimulus intensity

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Keywords: sleep bruxism, biofeedback, electric stimulation, pain

Reduction of sleep bruxism events according to contingent electrical stimulus intensity

Abstract

Background: The reduction effect of contingent electrical stimulation (CES) on sleep bruxism (SB) has previously been reported. However, although instruction regarding the setting of the intensity of CES is standardized to each bruxer, the difference in the applied CES intensity might affect the effectiveness. Therefore, this study aimed to clarify if the actual applied CES intensity correlates with the reduction of SB events and jaw muscle symptoms in probable sleep bruxers.

Methods: Twenty probable sleep bruxers were first screened based on 2-week recordings of SB events with a portable electromyography recorder (BUTLER®GrindCare®, hereafter GC4) for confirmation of a bruxer. A 3-week recording of SB events without CES with the use of a GC4 was followed by another 3-week recording with CES. At baseline, as well as before and after the CES(+) session, clinical muscle symptoms were assessed using a 0-10 Numerical Rating Scale (NRS). Relationships between the actual applied CES intensity and the number of SB events/hour, as well as NRS of clinical muscle symptoms, were analyzed.

Results: The actual applied CES intensity was positively correlated with the reduction rate of the number of SB events/hour ($R=0.643$, $P=0.002$), and also with the reduction rate of NRS for pain, unpleasantness, fatigue, tension, and stiffness ($R>0.500$, $P<0.011$).

Conclusion: Higher CES elicited a more robust reduction of SB events, as well as muscle symptoms, in probable bruxers. The findings suggest that the tolerance threshold of CES could be a predictor of the effectiveness of CES for reducing SB events and associated muscle symptoms.

Clinical significance: Prior to the selection of CES biofeedback as a management option for SB, it would be beneficial to check the tolerance threshold of CES in each bruxer to predict the effectiveness of CES in probable sleep bruxers.

Keywords: sleep bruxism, biofeedback, electric stimulation, pain

1. Introduction

Bruxism is internationally defined as a repetitive muscle activity characterized by excessive clenching, grinding, or bracing and thrusting of the mandible, and divided into sleep bruxism (SB) and awake bruxism depending on its circadian manifestation[1]. In SB, abnormal repetitive jaw muscle activities called rhythmic masticatory muscle activity (RMMA) can be observed during sleep[2]. It is important for dentists to assess bruxism appropriately, differentiating patho-bruxism that can harm tissue or function in the orofacial region from normo-bruxism, a sort of normal oral behavior, that can contribute to homeostasis of oral function[3]. For the management of patho-bruxism, several management options for SB are available. Among the options, the reduction effect of biofeedback has been reported and studied since the 1970s, accumulating significant clinical evidence of its potential[4–8]. Modalities of biofeedback include auditory, gustatory, vibratory, and electrical stimulation[6,8,9]. Contingent electrical stimulation (CES) has exhibited a significant reduction effect of RMMA in SB in past studies[10–13]. Noteworthy, combining CES with portable electromyography (EMG) recording enabled precise CES in response to abnormal EMG recording during RMMA bruxism events in SB [11]. This has been shown to directly reduce the number of harmful excessive jaw muscle activities in SB[11,14]. The mechanism underlying the inhibitory effect of CES on SB is thought to be related to suppressing activity of the mouth-closing muscle via the trigeminal reflex[15,16]. We previously conducted an RCT to investigate how CES intensity affects the inhibitory effect on EMG activity during sleep in probable bruxers[14]. Only the high CES group, using the device at the maximum level that would not disturb sleep, exhibited a significant inhibitory effect of CES on the number of SB events, which indicated the significance of the setting of CES intensity to obtain an efficient inhibitory effect on RMMA in SB[14]. However, in this previous study, the CES intensity set by the participants during the trial was not recorded, and thus the actual applied stimulation intensity for each participant was unknown. The purpose of this study was to determine the causal relationship between the actual stimulus intensity on the inhibitory effect of excessive masticatory muscle activity in sleep bruxers.

2. Materials and methods

2.1. Participants

Adult individuals (> 18 years old) who had a self-report of SB were recruited from Osaka Dental Hospital and initially participated in the study. After the recruitment, "Probable bruxers" as defined by Lobbezoo et al.[1] were eligible to participate in this study. Each participant was screened with intraoral examination based on the following inclusion criteria; one or more of the following clinical symptoms: the presence of dental wear (grade>1), hypertrophy of the masseter muscle, history of splint use, dental imprints on the buccal mucosa/lip/lingual edge, history of fracture of teeth or crown restorations due to occlusal forces, and history of occlusal trauma. Exclusion criteria were the use of a pacemaker, allergy to nickel or rubber, and participation in other clinical studies. Written informed consent was obtained from all collaborators. This study was approved by the Ethics Committee of Osaka Dental University (Approval No. 111015) and was conducted in accordance with the Declaration of Helsinki. Out of 28 possible bruxers (> 18 years old) recruited initially, 23 probable bruxers participated in the study. Eventually, 20 probable bruxers (4 men and 16 women, mean age ± SD: 26 ± 5) completed the study.

2.2. Baseline measurements

After agreeing to participate, all participants underwent baseline measurements which consisted of an interview and a clinical examination. Age, gender, height, and weight were collected as demographic information. The Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) was performed to identify TMD symptoms. In addition, STOPBANG questionnaire was also conducted for screening of sleep apnea syndrome[17].

2.3. EMG recordings

In this study, a portable electromyography recorder (BUTLER®GrindCare® (GC4), SUNSTAR Suisse SA) was used to record temporal muscle activity during sleep at home[10]. The basic function of the GC4 is to detect RMMA by measuring masticatory muscle activity and to count it as a SB event. In addition, when RMMA occurs during a recording, a CES is applied to the skin, causing a muscle suppression reflex, which has been reported to reduce the frequency of bruxism events[11,18]. The algorithm of the GC4 is called the moving average algorithm which can automatically set and update a threshold value equal to three times higher than the resting muscle activity[19]. This enabled to detect RMMA without a specific calibration done by a user and secured no variation between participants or between measurements[19,20]. A SB event was defined as muscle activity above the threshold persisting for 0.25 seconds or longer, triggering a shot of CES with intensity set prior to the onset of a recording between Level 1-9[19]. When the level of CES intensity is set at Level 1, The output is 0.78 mA and increases proportionally as the level increases up to Level 9 (7.02 mA).

2.4. Study design

The study was designed as a crossover design study in which the number of SB events were recorded in a 3-week session without CES, followed by another 3-week session with CES (Fig. 1). To confirm to be a bruxer objectively, prior to the recording sessions, “probable bruxers” were screened by recording the number of SB events for 2 weeks with use of GC4 without CES. Inclusion criteria to be included in the recording sessions in this study based on the objective assessment of SB were as follows: (1) use for at least 4 hours/night, (2) at least half of all sleep hours with at least 15 muscle activities/hour, and (3) had at least 4 days/week where (1) and (2) were met[14]. Participants who met the conditions continued to participate in the control session without CES for 3 weeks. After the control session, a 3-week CES(+) session followed where the participants were instructed to use GC4 with CES at the maximum level that would not disrupt sleep (Fig.1). Each participant tried GC4 before the first use of GC4 for the CES intervention, in order to confirm the maximum CES appropriate with an examiner. If the CES intensity was too strong to sleep without disturbance at home, the participants were allowed to adjust the intensity.

2.5. Outcome parameters

2.5.1. Number of bruxism events

The GC4 electrodes were attached to the temporalis muscle area on either side and the SB events were recorded[14]. The EMG data were the same as those normally obtained from the muscle activity of the masseter muscle during sleep[21]. The number of SB events and duration of measurement in each session were recorded. The number of SB events/hour was calculated and used for further analysis.

2.5.2. Assessment of jaw muscle symptoms and jaw muscle sensitivity

In addition to the recording of SB events with GC4, clinical jaw muscle symptoms (pain, unpleasantness, fatigue, tension, soreness, stiffness) were evaluated before and after the CES (+) sessions. The participants were asked to score the intensity of clinical symptoms of pain, unpleasantness, fatigue, tension, soreness, and stiffness on a 0-10 NRS (0 indicating 'no sensation at all', and 10 indicating 'the worst sensation imaginable'). Mechanical muscle sensitivity was also evaluated in the masseter and temporalis muscles (masseter left: MAL,and right: MAR, temporalis left: TAL and right: TAR) with the use of a standardized palpation device (BUTLER® Palpeter®, Sunstar Inc) by palpating each muscle with 1.0 kg for 2 sec[22]. Each participant was asked to score mechanical muscle sensitivity on a 0-50-100 NRS (0 indicating 'no sensation at all', 50 indicating 'pain threshold', and 100 indicating 'the worst sensation imaginable')[23].

2.6. Statistics

Statistical analyses were performed using GraphPad Prism 8 for macOS (version 8.4.3, GraphPad Software, USA). Depending on D'Agostino & Pearson test for the data normality, either non-parametric or parametric analysis of variance (ANOVA) was selected. When appropriate, Tukey test for multiple comparisons was also performed. The data are presented as means ± SEM. *p*-values of less than 0.05 were considered statistically significant.

For baseline outcome parameters, one-way ANOVA was performed for NRS in clinical muscle symptoms (pain, unpleasantness, fatigue, tension, soreness, and stiffness) and mechanical muscle sensitivity. For the clinical muscle symptoms, a main factor was each symptom, whereas it was the muscles assessed (MAL, MAR, TAL, and TAR) for mechanical muscle sensitivity.

For the number of SB events/hour and NRS in the clinical muscle symptoms, one-way ANOVA was performed with a main factor of sessions (baseline, the control session [CES(-)], and the intervention session [CES(+)]). For the comparison of the mechanical muscle sensitivity, two-way ANOVA was also analyzed whose main factors were sessions (3 levels: baseline, the control session [CES(-)], and the intervention session [CES(+)]) and muscles (4 levels: MAL, MAR, TAL, and TAR).

Furthermore, Pearson's correlation coefficient for the CES intensity and reduction rate of the number of SB events/hour, as well as the NRS in each muscle symptom and mechanical muscle sensitivity, was conducted. The Reduction rate of the number of SB events/hour was calculated by dividing the difference in a value in the CES(-) and CES(+) sessions by a value in the CES(-) session. Similarly, the reduction rate of NRS in muscle symptoms and mechanical muscle sensitivity was calculated by dividing the difference in values before and after the CES(+) session by a value before the CES(+) session.

3. Results

3.1. Baseline characteristics

The demographic information and baseline characteristics of participants are shown in Table 1. Out of 20 participants, 13 were diagnosed with TMD according to DC/TMD examination. The screening of sleep apnea with STOP-BANG showed that none of the participants were at high risk. The mean number of SB events/hour for all participants confirmed as probable bruxers in this study was 31 ± 4. Regarding clinical muscle symptoms (pain, unpleasantness, fatigue, tension, soreness, and stiffness), the degree of all sensations was not moderate or severe but slight at baseline. In addition, baseline NRS of mechanical muscle sensitivity did not exceed 50, i.e. the pain threshold, in all participants.

3.2. Effect of CES on the number of SB events

The mean±SEM of the number of SB events/hour at baseline and in the CES(-) and CES(+) sessions is shown in Fig. 2. One-way ANOVA showed a significant effect of sessions on the total number of SB events ($P < 0.001$) and the number of SB events/hour ($P < 0.001$). Both parameters significantly decreased in the CES(+) session compared to baseline and the CES(-) session (the total number of SB events and the number of SB events/hour: P < 0.001). Sleep duration did not show any significant differences between the sessions (P = 0.441).

3.3. Effect of CES on jaw muscle symptoms and sensitivity

Fig 3A shows NRS of the jaw muscle symptoms at baseline, before and after the CES (+) sessions. A one-way ANOVA showed that sessions showed a significant effect on NRS of all clinical muscle symptoms (pain, unpleasantness, fatigue, tension, soreness, and stiffness: P < 0.001). In all the symptoms, the NRS decreased significantly after the CES intervention (pain, unpleasantness, fatigue, tension, soreness, and stiffness: P < 0.001). Fig 3B shows NRS of the jaw muscle sensitivity at baseline, before and after the CES (+) sessions. The two-way ANOVA showed that sessions also showed a significant effect on NRS of mechanical muscle symptoms (P < 0.001), whereas the muscles did not show any significant difference (P = 0.081). In all muscles, NRS of the jaw muscle sensitivity decreased significantly after the CES(+) session in all the sites compared to the CES(-) session (MAL: P = 0.001, MAR: P = 0.002, TAL: P = 0.007, and TAR: P = 0.007).

3.4. Correlation between CES intensity and reduction rate of the outcome parameters

A significant moderate correlation between the actual applied CES intensity used by each participant and the resulting reduction rate in SB events/hour between the CES(-) and CES(+) sessions was observed (R = 0.643, P = 0.002) (Fig 4).

Next, the correlation between the actual applied CES intensity and reduction rate in each of the NRS scores for the clinical muscle symptoms was probed (Fig 5). A strong positive correlation with the actual applied CES intensity was observed for the reduction of pain (P < 0.011, R = 0.896). Furthermore, the reduction of unpleasantness, fatigue, tension, and stiffness all exhibited a moderate positive correlation to the actual applied CES intensity (unpleasantness: P = 0.004, R = 0.608; fatigue: P = 0.003, R = 0.636; tension: P = 0.011, R = 0.500; and stiffness: P = 0.003, R = 0.630). Reduction of soreness did not show any significant correlation to CES intensity (R = 0.398, P = 0.082). No correlation between the actual applied CES intensity and reduction rate in NRS of the jaw muscle sensitivity in all muscles (MAL: P = 0.333, R = 0.228; MAR: P = 0.472, R = 0.170; TAL: P = 0.980, R =

0.006; and TAR: P = 0.127, R = 353) (Fig 6).

4. Discussion

To our knowledge, this is the first study to examine the causal relationship between the actual applied CES intensity and its reduction effect on SB events in probable bruxers. In agreement with previous studies, CES had a significant effect on the reduction of SB events in probable bruxers[11,14,18,24]. Furthermore, a significant and moderate correlation between the actual applied CES intensity and the reduction in SB events was demonstrated. Importantly, the reduction in the number of SB events was also associated with a decrease in NRS in clinical muscle symptoms including pain, exhibiting a fairly robust correlation with the actual applied CES intensity. These findings provide important insights into the potential therapeutic benefits of CES for the management of SB and clinical symptoms in the masticatory muscles.

The accurate instruction and execution in terms of the setting of CES influence on the effectiveness on outcomes of SB management. It has been demonstrated that the inhibitory effect of CES on SB could not be triggered by too low CES intensity that is a barely perceivable level of a faint touch[14]. Although the general instruction on the use of the device (GC4) is to set the intensity of CES at the highest level that did not interfere with normal sleep, the specific intensity of the stimulation applied to exhibit the inhibitory effect on SB was unknown[14]. This study where a greater reduction effect was achieved with higher CES intensity directly demonstrated that the reduction effect on SB events by CES significantly correlates to the actual applied CES activity. Thus, this study provides direct clinical advice to dentists and patients for the use of CES as a management option for SB; while it possibly also affects which SB patients can benefit from CES. Some patients might not be able to use CES at a sufficiently high level, without interrupting their sleep. It could therefore be beneficial to screen SB patients with a tolerance threshold of CES to predict the effectiveness prior to the general use of CES in that patient. For those whose threshold is sufficiently high, a beneficial reduction effect of CES can be expected, whereas, for those who are sensitive to CES, it could be preferable to select other management options than CES for SB. Based on our findings, the CES intensity to be applied that can expect more than a 50% reduction effect on SB events was > 5.7, whereas the CES intensity for a 50% reduction in pain was > 4.5.

While the mechanism behind reduction of SB events by CES still remains to be elucidated, exteroceptive suppression (ES) of EMG activity elicited by innocuous electrical stimulation is likely an important factor. ES is represented by a silence period that is considered to be a protective reaction to harmful stimuli[25]. The stimulus intensity is one of the significant factors to be considered for the occurrence of both ES1 with short latency and ES2 with long latency[26,27]. Based on the finding in past studies that ES2 can be induced by mild mechanical stimulation to non-nociceptive fibers, ES2 is not thought to be a nociceptive responses[24,28,29]. The intensity of CES a GC4 device used in this study can deliver ranged between 0.78 mA (Level 1) to 7.02 mA (Level 9). Therefore, the effective range of CES applied in this study that inhibited SB events was below the range of the pain threshold previously reported (11.6±3.2 mA)[30]. This indicates the involvement of ES2 in the possible mechanism explaining the inhibitory effects of CES observed in this study. Also, from the perspective of sleep duration, the reduction of SB events with non-nociceptive stimulation is also supported by no observable change in the participants sleep duration during the CES(+) session. Surprisingly, a robust to moderate correlation between the actual applied CES intensity and NRS in the most clinical muscle symptoms assessed was observed in this study. The effect of CES on both pain and non-painful symptoms has been controversial. In fact, the inhibitory effect of CES on SB events has been presented in the vast majority of past studies, however, its effect on pain relief has not been exhibited. This could be explained by the lack of data on the actual applied CES intensity, which might be too low to exhibit the inhibitory effect. In addition, The variability on the sensitivity to CES between bruxers should be also considered, because the occurrence of ES varies among individuals[26]. In addition, there might be a linguistic background that could affect the results in clinical muscle sensitivity. All participants were Japanese who do not differentiate pain from soreness clearly, which might explain the difference in the result of soreness between previous study held in an European country[14] and this study, even though this interpretation is quite speculative.

As a methodological limitation, the participants' baseline characteristics regarding TMD diagnosis should be discussed. Among the probable sleep bruxers who participated in this study, 13 of them were diagnosed with a TMD condition. In past studies, it was reported that the occurrence of ES can be altered depending on the presence of pain[31]. The participants were divided into 2 groups and further analysis was conducted to clarify if significant differences in any outcome parameters would exist between those with TMD and those without. However, in addition to the resulting small number of participants in each group, there was no significant difference noted between these two groups. Therefore, the results in this study were presented as reported above with a single group of participants. We are planning further studies to test if the presence of TMD conditions affects the effect of CES on SB, as that would be important for clinical advice on the use of CES on SB. Another concern to be considered is the sex difference. Due to the uneven number of men and women (4:16), a statistical analysis to test the effect of sex on the effectiveness of CES on SB was not feasible. However, as a difference in sex has been observed on several pain-related parameters including pain threshold and pain tolerance with electrical stimulation[32]. Therefore, in order to establish a standardized and individualized management plan for SB, further investigation on differences in sex is required for a deeper understanding of possible factors that influence the effectiveness of CES on SB.

5. Conclusion

In conclusion, higher CES resulted in a more significant reduction of SB events in probable sleep bruxers, associated with the reduction of clinical muscle symptoms. The tolerance threshold of CES could be measured as a predictor of the effectiveness of CES for reducing SB events, as well as pain and non-specific jaw muscle symptoms. Clinically, it could be beneficial to screen patients with SB in such manner prior to the selection of management options for SB.

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Table 1: The demographic information and baseline characteristics. BMI: Body Mass Index. DC/TMD: Diagnostic Criteria for Temporomandibular Disorders. TMD: Temporomandibular Disorders. NRS: Numeric Rating Scales. MAL: Left masseter, MAR: Right masseter, TAL: Left temporalis, TAR: Right temporalis. N = 20.

Body measurements	mean	SD
Height (cm)	162.1	6.2
Weight (kg)	54.6	7.2
BMI	20.7	1.6
DC/TMD diagnosis	**N**	**%**
None	7	35
Myalgia only	8	40
Arthralgia only	4	20
Myalgia and Arthralgia	1	5
Headache attributed to TMD	4	20
Disc displacement with reduction without limited opening	1	5
STOPBANG total score	**N**	**%**
0 points	7	35
1 point	9	45
2 points	4	20
1. Do you snore loudly?	1	5

			N	%
2. Do you often feel tired, fatigued, or sleepy during the daytime?			12	60
3. Has anyone observed you stop breathing during sleep?			0	0
4. Do you have (or are you being treated for) high blood pressure?			0	0
5. BMI > 35kg/m^2			0	0
6. Age > 50years			0	0
7. Neck circumference > 40cm			0	0
8. Gender: Male			4	20
Results of oral examination			N	%
Tooth wear score			18	90
Muscular hypertrophy				
		Right	9	45
		Left	9	45
Hyperkeratosis				
	Cheeks	Right	19	95
		Left	20	100
	Tongue	Right	9	45
		Left	7	35
	Lips		2	10
Tooth cusp protection				
		Right	20	100
		Left	20	100

	Protrusion	20	100
History of tooth/prosthesis fracture		3	15
Clinical muscle symptoms (0-10 NRS)		mean±SEM	
	pain	3.1±1.5	
	unpleasantness	3.5±1.4	
	fatigue	3.6±1.6	
	tension	2.5±1.4	
	soreness	1.7±1.2	
	stiffness	2.6±1.2	
Mechanical muscle sensitivity (0-50-100 NRS)			
	MAL	41±4	
	MAR	42±4	
	TAL	34±4	
	TAR	34±4	

Fig. 1. Flow diagram of participants. GC4: GrindCare 4. CES: Contingent Electrical Stimulation.

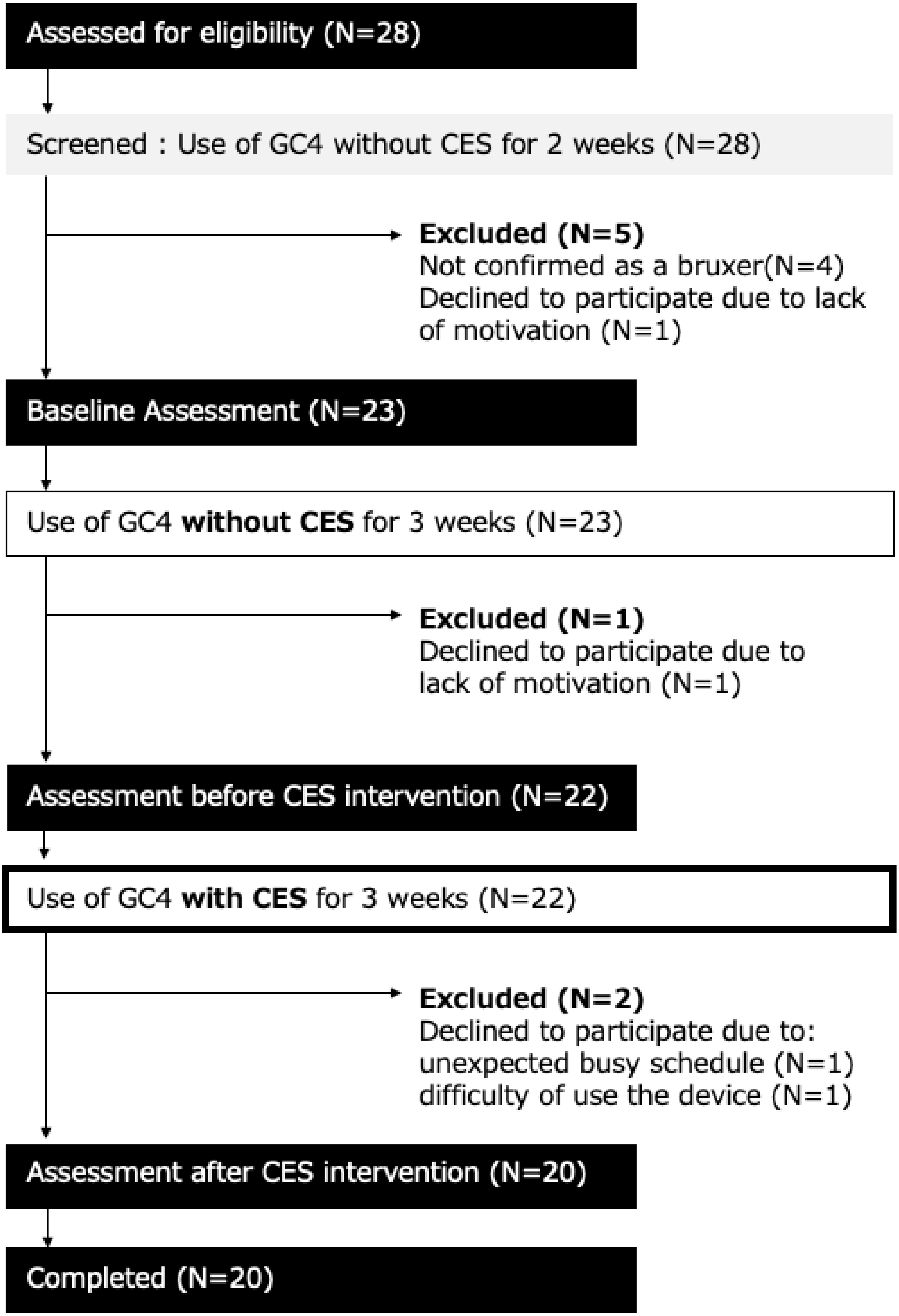
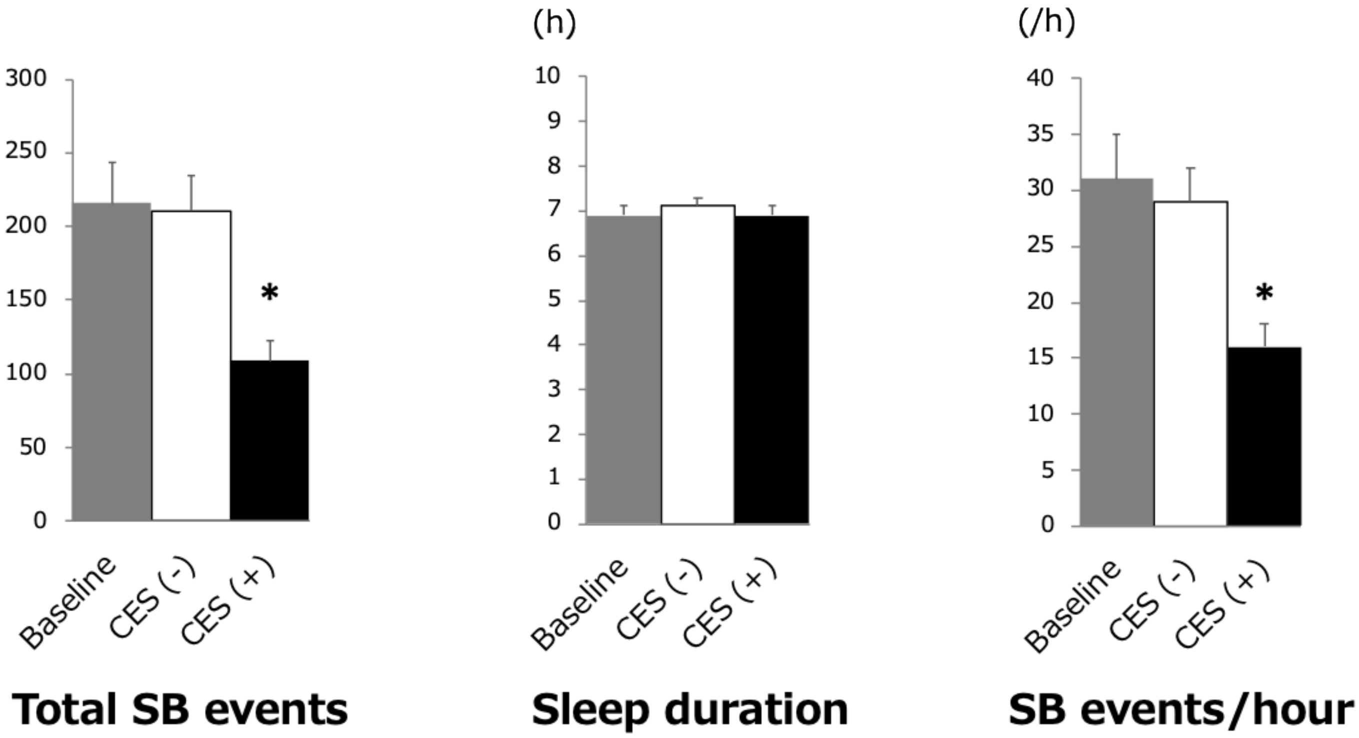


Fig 2. Results of SB recordings. * indicates a significant difference compared to baseline and CES(-) session ($P < 0.05$). CES: Contingent Electrical Stimulation. Mean ± SEM, N = 20.



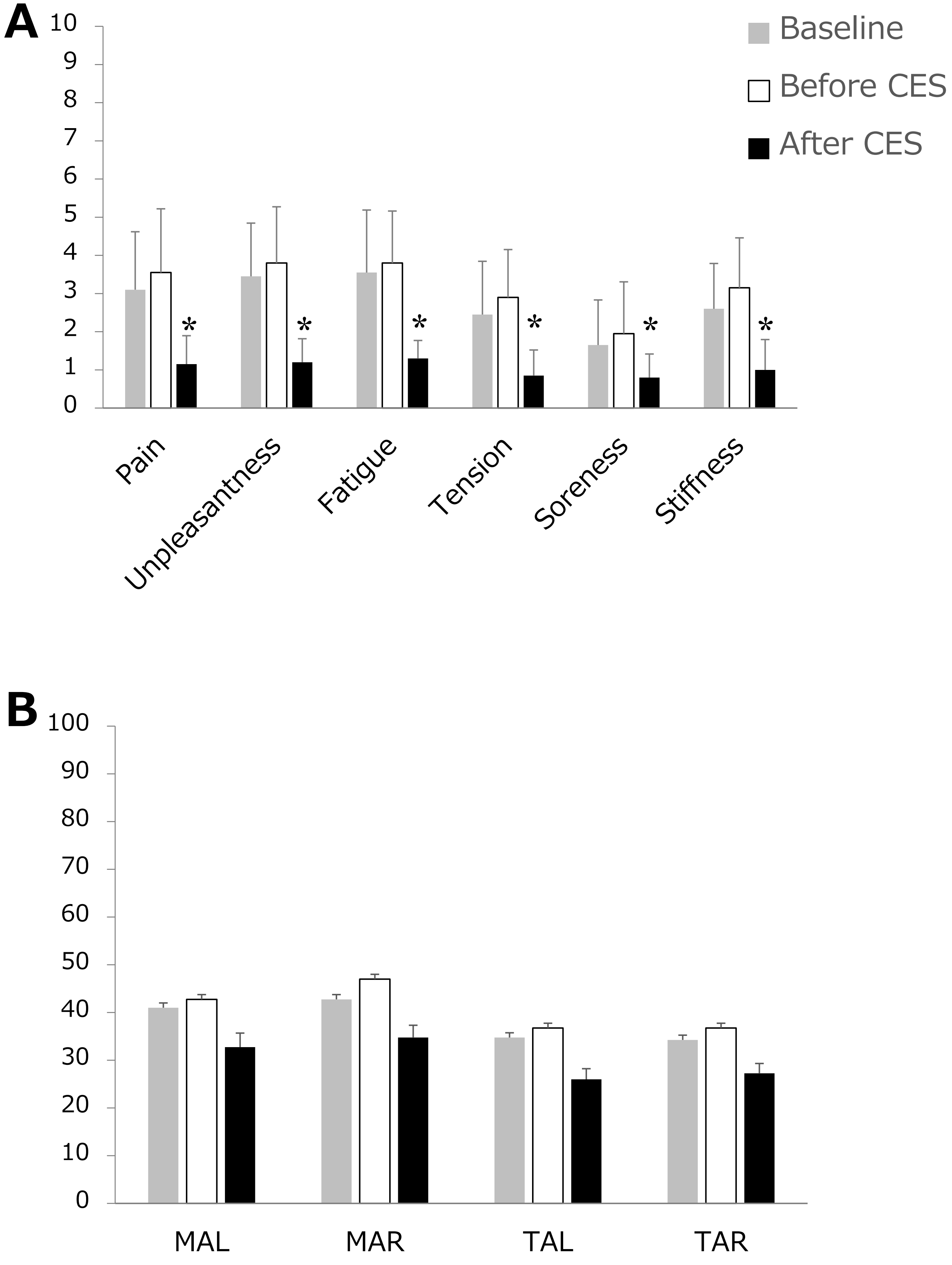


Fig.3. A) Mean (±SEM) Numeric Rating Scale (NRS) of clinical muscle symptoms. B) Mean (±SEM) NRS of mechanical muscle sensitivity. MAL: Left masseter, MAR: Right masseter, TAL: Left temporalis, TAR: Right temporalis. CES: Contingent Electrical Stimulation. * indicates a significant difference compared to baseline and before CES(+) session. $P < 0.05$. N = 20.

Fig. 4. Correlation between the actual applied CES intensity and reduction rate(%) of SB events/hour. CES: Contingent Electrical Stimulation. N = 20.

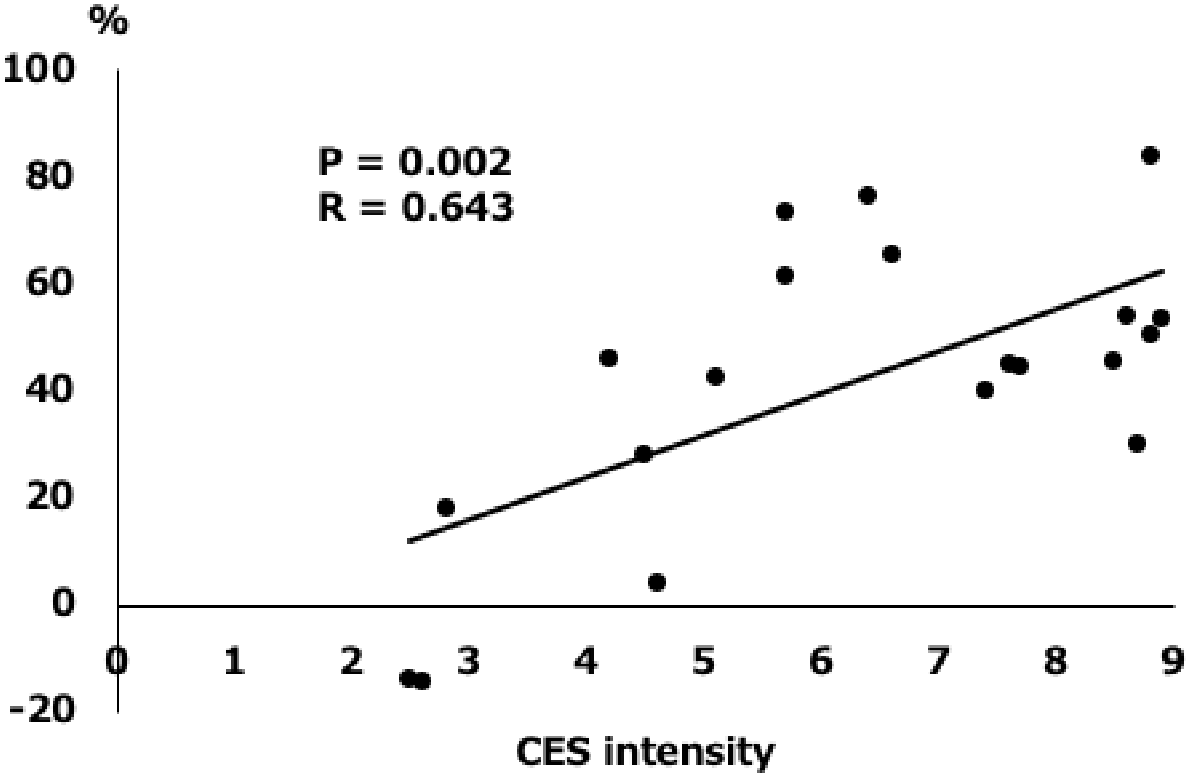


Fig. 5. Correlation between the actual applied CES intensity and reduction rate(%) of NRS on the clinical muscle symptoms. CES: Contingent Electrical Stimulation. NRS: Numeric Rating Scale. N = 20.

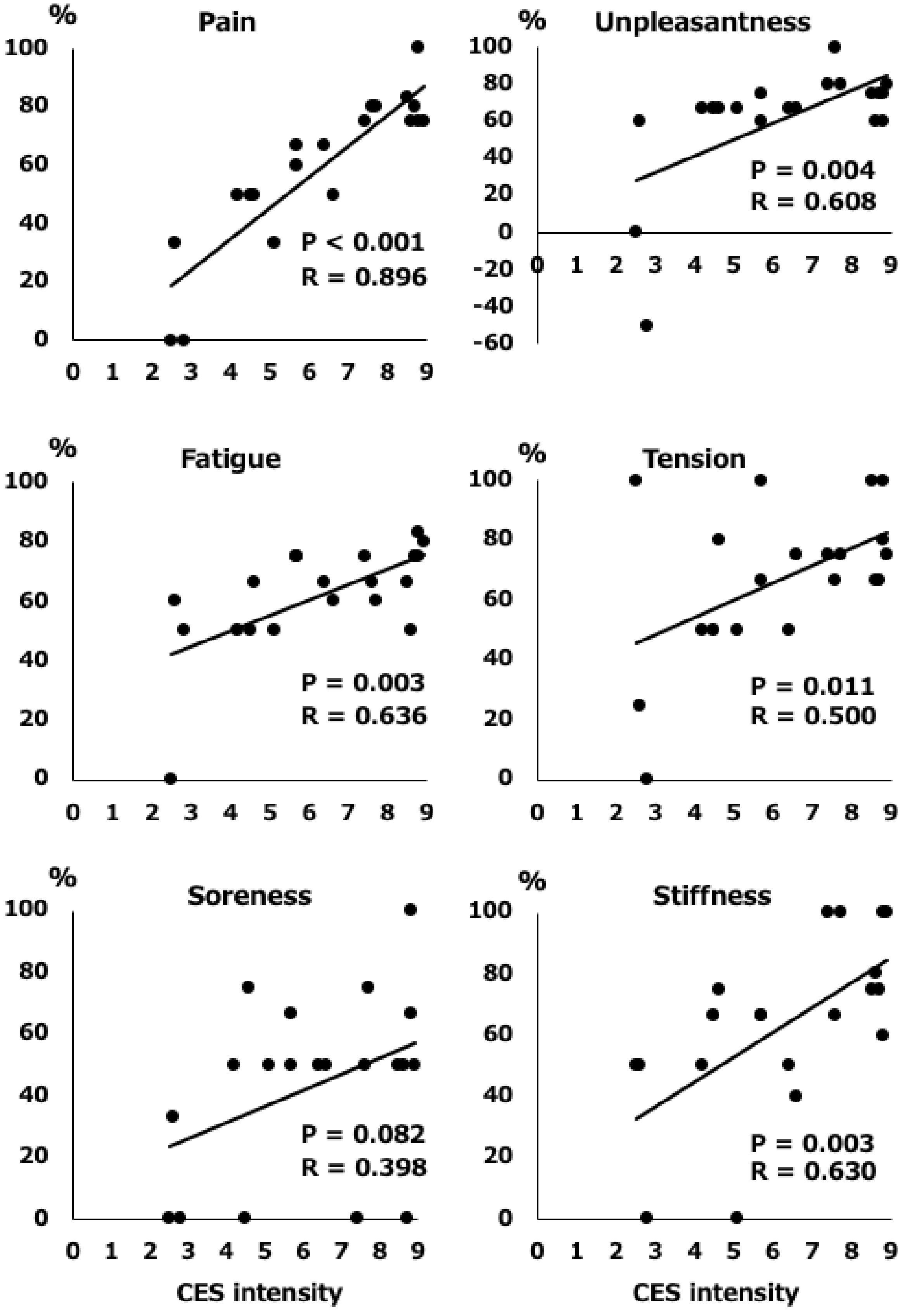


Fig. 6. Correlation between CES intensity and reduction rate(%) of NRS of mechanical muscle sensitivity. CES: Contingent Electrical Stimulation. NRS: Numeric Rating Scale. MAL: Left masseter muscle, MAR = Right masseter muscle, TAL = Left temporalis muscle, TAR = Right temporalis muscle. N = 20.