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Original Article

Kinesiophysiological analysis associated with changes in subjective intensities in belt electrode-skeletal muscle electrical stimulation: a prospective exploratory study

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Abstract. [Purpose] Belt electrode-skeletal muscle electrical stimulation (B-SES) is a novel electrical muscle stimulation treatment that causes less pain and discomfort and induces contraction in a wider skeletal muscle area than conventional electrodes. However, the stimulation intensity depends on patients' subjectivity. In the present study, B-SES and an expiratory gas device were combined to analyze the kinesiophysiological data associated with changes in subjective intensity. [Participants and Methods] Seventeen healthy participants were recruited. The subjective intensities were set to four conditions (weak, normal, strong, and maximum tolerated intensity), and the stimulation was performed in each condition in the "metabolic mode" (frequency, 4 Hz; pulse width, 250 µs). The primary outcome was metabolic equivalents (METs), and this data were compared for each condition. [Results] METs generated by B-SES were 2.0 (1.0) for weak intensity, 2.7 (1.2) for normal intensity, 3.9 (1.3) for strong intensity, and 5.0 (1.3) for the tolerance limit intensity; differences detected between all subjective intensities were statistically significant. [Conclusion] These findings show that objective intensities of >3 METs, as recommended in rehabilitation prescriptions, can be achieved when the subjective intensity is set at strong or maximum tolerated. Treatment with B-SES may provide a viable alternative to therapeutic exercise. Key words: Electrical stimulation, Stimulation intensity, Metabolic equivalent

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INTRODUCTION

Physical activity in the human body necessitates the voluntary contraction of skeletal muscles, which raises the energy demand for metabolism. This is reflected in several kinesiophysiological adaptations such as increased blood flow, accelerated heart rate, and increased oxygen uptake (VO₂), which promote health. However, most adults are not doing the global recommended levels of physical activity^{1, 2)}. People who are insufficiently physically active have a higher risk of death than those who are physically active³). This physical inactivity is pronounced in older adults and/or patients with disabilities. Specifically, it is often difficult for older adults and/or patients with disabilities to perform physical activity at the intensity required to maintain good health during their daily living activities because of their poor exercise capacity. Therefore, clinicians engaged in rehabilitation medicine play an important role in promoting physical activity.

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In the field of rehabilitation medicine, there are various treatments (e.g., therapeutic exercise, electrotherapy) that promote physical activity. In particular, electrical muscle stimulation (EMS) is an electrotherapeutic method of treatment that induces forced muscle contraction by applying electrical stimulation to skeletal muscles. EMS is often used as an alternative for people who have difficulty with therapeutic exercise^{4, 5)}. However, the conventional EMS devices have a limited range of skeletal muscle coverage, and the pain and discomfort caused by the stimulation is so severe that sufficient stimulation intensity is often difficult to achieve.

Recently, belt electrode-skeletal muscle electrical stimulation (B-SES), which evolved from conventional EMS, has received attention (Fig. 1). B-SES consists of belt electrodes set around the waist, thighs, and lower leg. Compared with conventional EMS, the electrode area and the skin contact area are larger, which distributes the current density, enabling significant reduction of pain and discomfort during stimulation, and induces whole muscle contraction in the lower limbs^{6, 7)}. Treatment with B-SES has shown particularly positive results in patients who find it difficult to undertake therapeutic exercise in a clinical setting such as a hospital^{8–13)}. In these studies, the B-SES stimulation intensity was set incrementally dependent on the patient's subjectivity. However, it is unclear whether the stimulation intensity applied is kinesiophysiologically appropriate.

The evolution and widespread availability of expiratory gas analysis systems have facilitated direct measurement of VO_2 during physical activities in clinical settings. VO_2 measurements during physical activity can be used to calculate metabolic equivalents (METs), which indicate the intensity of that activity^{14, 15}). Previous studies have not clarified an objective intensity generated by B-SES. To address this problem, it is necessary to combine expiratory gas analysis and B-SES and perform kinesiophysiological analysis based on subjective intensities. The purpose of this study was to clarify the objective intensity generated by B-SES based on patients' subjectively ranked intensities through kinesiophysiological analysis.

PARTICIPANTS AND METHODS

The study design was a prospective exploratory study. The study was approved by the Ethics Review Board of the Kyoto Prefectural University of Medicine (approval number ERB-C-2788) and was registered in the University Hospital Medical Information Network (trial number UMIN000049748) before study enrollment. This study was conducted in accordance with the Declaration of Helsinki, and participants provided written informed consent for all procedures performed.

This study enrolled healthy individuals without disabilities aged over 20 years who were recruited by advertising on posters and via the internet. The exclusion criteria were cardiac pacemaker, pregnancy or possible pregnancy, uncontrolled hypertension, exercise limitation associated with an action disorder of the heart, hematogenous disorder of the lower extremities, and those deemed ineligible for the study by the co-investigator doctor for other reasons.

The experiment was conducted in the rehabilitation center of our institution. The kinesiophysiological analysis was carried out as follows. The expiratory gas analyzer (AE-100i, Minato Medical Science Co. Ltd., Osaka, Japan) was calibrated prior to the measurements. The equipment was switched on at least 1 hour before the calibration. Flow calibration was performed with a 2,000 mL calibrator, and gas concentration calibration was performed with calibration gas. Participants were fitted with a mask for expiratory gas analysis (FFM-100, Minato Medical Science Co. Ltd., Osaka, Japan), automated sphygmomanometer (EBP-330, Minato Medical Science Co. Ltd., Osaka, Japan), and electrocardiogram (DS-8100 system, Fukuda Denshi Co. Ltd., Tokyo, Japan). Additionally, to protect the accuracy of the expiratory gas analysis, participants were restricted from speaking and were instructed to respond with gestures during the measurement. The participants then rested for 5 minutes in the supine position. This supine rest phase was used to establish the VO₂. B-SES was performed using a G-TES electrical stimulator for general treatment (HOMER ION Laboratory Co., Ltd., Tokyo, Japan). B-SES was applied through five dedicated silicon-rubber electrode bands that were attached around the waist, above the knees, and above the ankles on both sides of the participants and secured with a Velcro strap. This configuration stimulated most of the lower extremity muscles simultaneously between the belt electrodes^{6, 7)}. There are two main modes of use of B-SES. The first is



Fig. 1. B-SES system.

The belt electrodes were attached to five points: around the patient's waist, above the knees, and above the ankles. Electrical stimulation can be applied to both lower extremity muscle groups simultaneously and the current level can be adjusted separately for both thighs and lower legs.

"disuse mode" (stimulation frequency: 20 Hz; pulse width: 250 µs, duty cycle: pattern of 5 seconds of tetanic contraction followed by 2 seconds of rest) for muscle strengthening. The second is "metabolic mode" (stimulation frequency: 4 Hz; pulse width: 250 µs, duty cycle: pattern of repeated twitching) for improving metabolism. Thus, B-SES is considered to improve not only muscle strength but also metabolism. The stimulation in the present study was carried out in metabolic mode and the intensity was increased stepwise every 5 minutes. The participants were asked to rank the intensities to fit four conditions (weak, normal, strong, and maximum tolerated intensity). The stimulation intensity was set for the first 2 minutes of each condition and adjusted to equalize current stimulation in both lower extremities.

Age, gender, height, weight, body mass index, body fat percentage, and skeletal muscle mass index were collected as demographic data. Body fat percentage and skeletal muscle mass index were measured using the bioelectrical impedance analysis method with a body composition device (InBody S10, InBody Japan Inc., Tokyo, Japan). Clinical variables were as follows: vital signs (heart rate, respiratory rate, systolic blood pressure, and diastolic blood pressure) and cardiopulmonary parameters (METs, VO₂, tidal volume [TV]) as kinesiophysiology indices. Kinesiophysiology indices were expressed as mean values in the last 30 seconds of each 5-minute condition. Additionally, the actual current intensity in the thigh and lower leg was recorded at the end of each condition. The primary outcome was expressed in METs, which were calculated by dividing the average value of VO_2 during B-SES of each condition by the body weight and by the value of VO_2 in a resting position.

IBM SPSS Statistics for Windows, version 29.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. P-values <0.05 were considered statistically significant. The data were presented as means (standard deviation) for ratio scale, and as numbers (percentages) for nominal scale. Clinical variables were compared using repeated measures one-way analysis of variance (ANOVA), followed by Bonferroni's post-hoc correction for significant pairs. The effect size for each parameter was classified as none (η^2 <0.01), small (η^2 =0.01–0.06), medium (η^2 =0.06–0.14), or large (η^2 >0.14).

RESULTS

Seventeen healthy individuals were enrolled in the present study. Demographic and representative resting data are shown in Table 1. Participants were mostly healthy adult males. Table 2 shows changes in vital signs with different subjective intensities. As subjective intensity increased, vital signs increased significantly compared with resting data in ascending order of heart rate, respiratory rate, and systolic blood pressure. However, there was no significant difference in diastolic blood pressure. Table 3 shows changes in actual current intensity and cardiopulmonary parameters with different subjective intensities. Repeated ANOVA for the actual current stimulation of the thigh and the lower leg revealed a significant trend between subjective intensities (thigh: F=70.0, p<0.05, η^2 =0.54; lower leg: F=41.7, p<0.05, η^2 =0.72). The actual current stimulation was 1.7 (0.7) mA at the thigh and 0.8 (0.3) mA at the lower leg for weak intensity, 2.4 (0.8) mA at the thigh and 1.1 (0.3) mA at the lower leg for normal intensity, 3.3 (1.2) mA at the thigh and 1.5 (0.5) mA at the lower leg for strong intensity, and 4.0 (1.2) mA at the thigh and 1.9 (0.8) mA at the lower leg for the maximum tolerated intensity (p<0.05 for all

Table 1. Demographic and representative resting data of participants

Demographic data	
Age, years	35.2 ± 9.0
Sex (male/female)	12/5 (70.6/29.4)
Height, cm	169.6 ± 11.3
Weight, kg	71.1 ± 20.1
Body mass index, kg/m ²	24.3 ± 5.0
Body fat, %	25.8 ± 7.5
Skeletal muscle mass index, kg/m ²	7.8 ± 1.3
Resting data	
Vital sign	
Heart rate, beats/minute	69.8 ± 9.7
Respiratory rate, beats/minute	15.6 ± 4.9
Systolic blood pressure, mmHg	119.4 ± 9.7
Diastolic blood pressure, mmHg	78.6 ± 14.6
Cardiopulmonary parameters	
Metabolic equivalents	1.1 ± 0.2
Oxygen uptake, mL/minutes	256.5 ± 41.6
Tidal volume, mL	609.1 ± 238.1

Data are presented as mean \pm standard deviation or number (percentage).

Table 2. Comparison of vital sign parameters associated with different subjective intensities

	Subjective intensity			
	Weak	Normal	Strong	Maximum tolerated
Heart rate, beats/minute	$81.9\pm12.9^{\ast}$	$93.3\pm15.3^{\dagger}$	$106.1\pm14.4^{\ddagger}$	$129.2 \pm 42.9^{\$}$
Respiratory rate, beats/minute	$20.3\pm5.3^{\ast}$	$21.4\pm5.4^{\dagger}$	$22.3\pm5.3^{\ddagger}$	$27.4\pm9.0^{\$}$
Systolic blood pressure, mmHg	$120.3 \pm 13.6^{\ast}$	$130.1\pm19.2^{\dagger}$	$144.4\pm19.1^\ddagger$	$150.8\pm31.5^{\S}$
Diastolic blood pressure, mmHg	78.5 ± 14.1	81.2 ± 13.8	82.5 ± 18.2	81.4 ± 22.6

Data are presented as mean \pm standard deviation. Statistical analysis was performed using repeated measures analysis variance with Bonferroni post-hoc correction. *p<0.05 (vs. Weak), †p<0.05 (vs. Normal), ‡p<0.05 (vs. Strong), [§]p<0.05 (Maximum tolerated), significant difference compared to resting data.

 Table 3. Comparison of actual current intensity and cardiopulmonary parameters associated with different subjective intensities

	Subjective intensity				
	Weak	Normal	Strong	Maximum tolerated	
Current intensity, mA					
Thigh	$1.7\pm 0.7^{*,\ \dagger,\ \ddagger}$	$2.4\pm 0.8^{*,\; \S,\; \ }$	$3.3\pm 1.2^{\dagger,~\$,~\P}$	$4.0 \pm 1.2^{\ddagger, \mid, \mid \P}$	
Lower leg	$0.8\pm0.3^{*,\dagger,\ddagger}$	$1.1\pm 0.3^{*,\; \S, \ }$	$1.5\pm0.5^{\dagger,~\S,~\P}$	$1.9\pm0.8^{\ddagger,\mid,\mid\P}$	
Cardiopulmonary parameters					
Metabolic equivalents	$2.0 \pm 1.0^{*,\dagger,\ddagger}$	$2.7 \pm 1.2^{\text{*, §, }}$	$3.9\pm 1.3^{\dagger,~\$,~\P}$	$5.0 \pm 1.3^{\ddagger, \mid, \mid \P}$	
Oxygen uptake, mL	$448.9 \pm 161.8^{*,\dagger,\ddagger}$	$641.5\pm239.7^{*,\;\$,\parallel}$	$929.8\pm 289.3^{\dagger,\ \$,\ \P}$	$1209.8\pm 369.2^{\ddagger,\parallel,\P}$	
Tidal volume, mL	$682.9 \pm 189.6^{*,\dagger,\ddagger}$	$913.4\pm 307.0^{*,\; \S, \ }$	$1218.5\pm 400.8^{\dagger,\ \$}$	$1358.6\pm 551.7^{\ddagger,\parallel}$	

Data are presented as mean \pm standard deviation. Statistical analysis was performed using repeated measures analysis variance with Bonferroni post-hoc correction. *p<0.05 (Weak vs. Normal), †p<0.05 (Weak vs. Strong), *p<0.05 (Weak vs. Maximum tolerated), *p<0.05 (Normal vs. Strong), "p<0.05 (Normal vs. Maximum tolerated), "p<0.05 (Strong vs. Maximum tolerated).

subjective intensities). Repeated ANOVA for METs, V02, and TV showed a significant trend between subjective intensities (METs: F=112.9, p<0.05, η^2 =0.88; VO₂: F=66.9, p<0.05, η^2 =0.81; TV: F=28.1, p<0.05, η^2 =0.64). The METs value was 2.0 (1.0) for weak intensity, 2.7 (1.2) for normal intensity, 3.9 (1.3) for strong intensity, and 5.0 (1.3) for the maximum tolerated intensity (p<0.05 for all subjective intensities). The VO₂ value was 448.9 (161.8) mL for weak intensity, 641.5 (239.7) mL for normal intensity, 929.8 (289.3) mL for strong intensity, and 1209.8 (369.2) mL for the maximum tolerated intensity (p<0.05 for all subjective intensities). The TV value was 682.9 (189.6) mL for weak intensity, 913.4 (307.0) mL for normal intensity, 1218.5 (400.8) mL for strong intensity, and 1358.6 (551.7) mL for the maximum tolerated intensity (p<0.05 for all subjective intensity and maximum tolerated intensity).

DISCUSSION

B-SES is a device that can concurrently stimulate a wider area of the lower extremity muscles than conventional EMS. Several studies in healthy individuals have reported the effects of B-SES on muscle strength, muscle flexibility, and cardiorespiratory fitness^{7, 16}). In a clinical setting such as a hospital, it is starting to be applied to patients where aggressive therapeutic exercise is difficult^{8–13}). However, the stimulation intensity in B-SES has mostly relied on the patient's subjective intensity choice. Previous studies have shown that patients who can tolerate stronger subjective stimulation in B-SES have greater serum lactate levels¹⁷). This indicates that the stronger the skeletal muscle contraction associated with B-SES, the greater the metabolic response of the muscle. In contrast, if the objective intensity generated by B-SES is too strong, there is a possibility that unexpected adverse events may occur if the participant is an older adult, is frail, and/or has disease such as heart failure, cardiovascular disease, or respiratory disease. The objective intensity generated by B-SES has not yet been quantified. Therefore, we believe that quantifying the objective intensity generated by B-SES based on patients' subjectively ranked intensities through kinesiophysiological analysis will help to ensure treatment safety and efficacy.

METs, measured as the primary outcome in this study, are categorized based on the intensity of physical activity as follows: sedentary behavior (1–1.5 METs), light-intensity (1.6–3 METs), moderate-intensity (3–5.9 METs), and vigorous-intensity (≥ 6 METs)¹⁵). Recent guidelines recommend that not only healthy adults but also adults aged 65 and over and adults with disabilities engage in an appropriate amount of moderate-to-vigorous physical activity to gain health benefits^{2, 18}). Notably, in this study, the subjective intensity generated over 3 METs at strong intensity or maximum tolerated intensity. This

value is sufficient for the recommended intensity of physical activity and is likely to induce sufficient cardiopulmonary stress. These results suggest that treatment with B-SES can be used to promote physical activity for older adults and frail or disabled patients with poor exercise capacity. Additionally, this study showed significant vital sign changes with increasing subjective intensity. Therefore, careful monitoring is essential when using subjective intensity in treatment with B-SES for older adults and frail or disabled patients. However, the following issues should be considered regarding the objective intensity induced by B-SES. Our study did not consider gender differences. Generally, females have less skeletal muscle volume than males, and therefore have a lower basal metabolic rate and lower energy metabolism during physical activity^{19, 20}). Therefore, it is possible that the METs values obtained in this study would be smaller in females. The METs values in this study may be overestimated because of the over-representation of males.

Low levels of intensity are often chosen in a clinical setting such as a hospital because of the patient's fear. These choices are important for improving treatment adherence. In the present study, we found that treatment with weak or normal subjective intensity generated <3 METs and were unlikely to induce sufficient cardiopulmonary stress. However, according to a recent study, light-intensity physical activity has also been shown to have a positive effect on health outcomes in a dose-dependent manner^{21, 22)}. Treatment with B-SES is often reported to last approximately 20 minutes or more per day^{6–13)}, but duration and frequency have not been standardized. Determining FITT (F, frequency; I, intensity; T, time or duration, T; type of exercise) is important in rehabilitation prescriptions²³⁾. If a lower level of subjective intensity is selected, longer time, frequency, and duration of treatment with B-SES may be appropriate. To clarify these issues, further studies are required.

The present study had several limitations. First, the study participants were healthy adults and did not include older adults or frail or disabled patients. Future experiments of the same kind should include participants with a wider variety of age groups. These participants may have different kinesiophysiologic responses. Second, our study did not consider the influence of physique. In general, the thicker the fat tissue, the higher is the required level of current to induce the target level of electric current in the muscle. Third, the stimulation frequency of B-SES was 4 Hz. It is possible that other frequencies could produce different responses. However, high-frequency electrical stimulation is likely to cause muscle fatigue. Fourth, the stimulation time for each condition was 5 minutes. Longer stimulation times may result in habituation to the stimulation and lower subjective intensity levels. Finally, the sample size was small and the subjective intensity was not randomized. Future studies involving larger sample sizes and randomization may yield valuable results.

This study is the first to quantify the objective intensities of B-SES. A notable aspect of this study is that the subjective intensity generated >3 METs at strong intensity or maximum tolerated intensity. This indicates that kinesiophysiologically plausible stimulation intensities can be achieved using patient-dependent subjective intensity, as carried out in previous studies^{8–13}). These results suggest that treatment with B-SES may provide a viable alternative to conventional therapeutic exercise. Further large-scale investigations are needed to determine whether our findings apply not only to healthy adults, but also to older adults and frail or disabled patients.

Funding and Conflict of interest

All authors have no conflict of interest or financial to declare.

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