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Original Article

Respiratory flow and vital signs associated with the intensity of functional electrical stimulation delivered to human abdominal muscles during quiet breathing

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Abstract. [Purpose] The purpose of this study was to examine the effects of increasing the intensity of functional electrical stimulation delivered to abdominal muscles during quiet breathing on respiratory flow, vital signs and pain in healthy subjects. [Subjects and Methods] Electrical stimulation was delivered bilaterally using one pair of high-conductivity gel-skin plate electrodes, placed on both sides of the abdomen, to nine healthy males. Subjects were required to breathe normally through a face mask for 2 minutes while in a supine position. The stimulation intensity was incrementally increased by 10 mA until reaching 100 mA. Respiratory parameters, vital signs and pain based on the visual analog scale were measured for each intensity of electrical stimulation. [Results] Transcutaneous oxygen saturation showed a slight upward trend in association with increasing stimulation intensity, but there were no significant changes in pulse or blood pressure. Respiratory flow, tidal volume, and minute ventilation increased significantly as the stimulation intensity rose. [Conclusion] This study revealed that functional electrical stimulation can be safely delivered to human abdominal muscles without causing vital sign abnormalities. It was also found that the appropriate intensity level of electrical stimulation for achieving effects on respiratory flow while also minimizing pain is 60–80 mA.

Key words: Functional electrical stimulation of abdominal muscles, Vital signs, Respiratory flow

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INTRODUCTION

Electrical stimulation therapy has been widely used to promote glucose metabolism and thereby enhance the lower limb muscle power of patients with diabetes[1, 2)], to serve as an alternative method of exercise therapy for patients with heart failure[3)] and chronic obstructive pulmonary disease[4)], and for functional reconstruction after stroke and spinal cord injury[5, 6)]. In recent years, there have been reports describing a new method, termed functional electrical stimulation of the human abdominal muscles (FES_{abd}), in which paralyzed abdominal muscles are forced to contract by applying functional electrical stimulation in order to facilitate coughing for spinal cord injury patients[7–13)]. This method has proven to be effective for airway clearance in patients with spinal cord injury.

FES_{abd} is also considered to potentially be applicable to not only patients with spinal cord injury but also those with reduced ability to cough for other reasons. However, previous reports have mainly been related to the effects of abdominal electrical stimulation aimed at assisting spinal cord injury patients needing to cough to clear their airways. Thus, it remains

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unclear whether this method would be effective during quiet breathing in normal subjects as well as in patients without abdominal muscle paralysis. Therefore, for clinical application of FES_{abd} as an airway clearance method, whether this method is effective not only for promoting coughing but also for enhancing the respiratory flow rate during quiet breathing needs to be determined. In addition, as electrical stimulation is associated with pain, the level of intensity required to achieve safe and comfortable electrical stimulation should be examined.

This study aimed to examine the effects of FES_{abd} during quiet breathing on respiratory flow, vital signs, and pain, associated with increased stimulation intensity in healthy subjects.

SUBJECTS AND METHODS

Subjects: The subjects were nine healthy males who provided consent to participate in this study. The characteristics of the subjects (average values and standard deviations) were as follows: age, 20.4 ± 1.2 years old; height, 172.6 ± 5.0 cm; weight, 63.7 ± 5.3 kg; body mass index (BMI), 21.5 ± 2.3 kg/m^2; body fat percentage, 14.1 ± 3.5%; and forced vital capacity, 5.2 ± 0.4 l. This study was conducted with the approval of the ethics committee of Ibaraki Prefectural University of Health Sciences.

Recording of vital signs and ventilometry: The subjects breathed through a face mask. Respiratory flow was measured with a pneumotachometer and integrated to yield volume data. All signals were digitized (Chart 5.5.6 ADInstruments, Australia) with a sampling frequency of 1 kHz and stored on a computer.

Electrical stimulation: Electrical stimuli were delivered bilaterally (pulse width, 200 μs; trains, 50 Hz) using one pair of high-conductivity gel-skin plate electrodes (14 × 4 cm, Split1180, 3 M HealthCare, St. Paul, MN, USA). The electrodes were placed bilaterally over the transverse abdominis, rectus abdominis, external and internal oblique muscles (Fig. 1). Functional electrical stimulation was triggered by expiratory flow and automatically applied for 1.5 sec.

Experimental protocol: Subjects were required to breathe normally through a face mask while remaining in supine position. The stimulation intensity was increased from 0 to 100 mA, in increments of 10 mA. The measurement time for each intensity was set as 2 min. The interval between each measurement was set as 3 min to allow for muscle fatigue. Blood pressure and pulse were measured before the start and at the completion of stimulation. After the end of stimulation at each intensity, the level of pain was measured with a visual analog scale (VAS) as a subjective evaluation of pain. Attention was always paid to facial expressions and vital signs of the subjects during the experiment, and the experiment was discontinued whenever pain was severe, regardless of the time point and level of stimulation intensity. Respiratory parameters and transcutaneous oxygen saturation (SpO_2) were measured each time the electrical stimulation intensity was increased. The respiratory parameters measured included peak expiratory flow (PEF), mean expiratory flow (MEF), tidal volume (TV), respiratory rate (RR), minute volume (MV), the time of breathing cycle (Ttot), and the duty cycle of the expiratory phase (Te/Ttot).

Data and statistical analysis: From the respiratory flow rate waveform obtained from the 2-minute measurements, we selected and analyzed the data for 1 minute during which respiration was stable. Data were excluded whenever the respiratory flow waveform was disturbed by such things as conversation and coughing, or when the PEF value deviated from the average ± 2SD. We analyzed PEF, MEF, TV, RR, MV, and Te/Ttot, as respiratory parameters, under each condition. The data for respiratory parameters and vital signs associated with increases in stimulation intensity were analyzed by one-way analysis of variance. Tukey's multiple comparison test was employed when a significant difference was observed. The Friedman test was used for the VAS. Wilcoxon's multiple comparison test was applied when a significant difference was detected. Statistical analyses were performed with statistical processing software (IBM SPSS Statistics 20.0), and difference was considered significant at a probability (p) value of less than 5%.

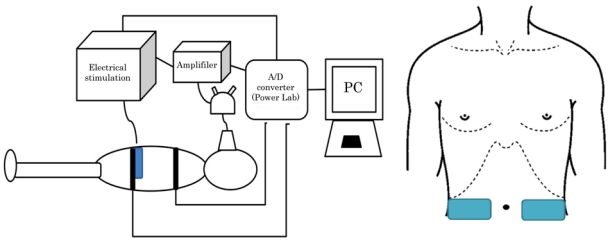

Fig. 1. Experimental equipment
(Left panel) We developed a system in which exhaled gas was collected by employing a mask covering the mouth and nose, and electrical stimulation was triggered by expiratory flow and then automatically applied for 1.5 sec. (Right panel). The electrodes were attached bilaterally in the distribution area of the intercostal nerves at the inferior edge of the 12th rib. Prior to the start of the experiment, the electrode positions were adjusted to allow confirmation of adequate overall abdominal muscle contraction without local discomfort.

RESULTS

The data obtained from seven subjects are presented as average values and standard deviations as two subjects who failed to tolerate the electrical stimulation at less than 100 mA were excluded. Table 1 shows theVAS, blood pressure, pulse, and SpO_2 values measured as the electrical stimulation intensity was increased. VAS showed a significant main effect in association with the Friedman test ($p<0.01$). The VAS values were constant within the range from 0 to 30 mA and began to display a slight upward trend at 40 mA. There were no significant differences among different stimulation intensities when the Wilcoxon test was applied. Two out of nine subjects failed to tolerate the electrical stimulation at less than 100 mA and the experiment was discontinued at 70 mA in both cases. For the seven subjects who tolerated the electrical stimulation up to the maximum intensity, the VAS score was no more than 10 mm for three subjects and was 35–75 mm for the other four subjects. SpO_2 showed no significant main effect in association with the intensity of electrical stimulation according to repeated one-way analysis of variance. It showed a slight upward trend as the electrical stimulation intensity increased but remained constant within the range of 97.0–98.3%. Tukey's multiple comparison test revealed that SpO_2 was significantly higher at 0 mA than at 90 mA. Pulse showed no significant main effect in association with the intensity of electrical stimulation. The values were 59.6–60.9 bpm at 60 mA and 59.6–66 bpm at 70–100 mA. These values began to display a slight upward trend at 60 mA. Blood pressure showed no significant main effect in association with the intensity of the electrical stimulation. Systolic blood pressure was within the range of 119.3 ± 8.9 to 126.4 ± 10.2 mmHg and diastolic blood pressure ranged from 60.6 ± 12.9 to71.3 ± 3.5 mmHg.

Table 2 shows the data for the PEF, MEF, TV, RR, VE, and Te/Ttot respiratory parameters. To analyze the effect of the intensity of electrical stimulation on each respiratory parameter, repeated one-way analysis of variance was performed. The results revealed that PEF and MEF showed a significant main effect in association with the intensity of electrical stimulation. They showed similar trends with the lowest values at 30 mA and the smallest variations. PEF and MEF started to increase at 50 mA as the electrical stimulation intensity rose. Tukey's multiple comparison test revealed that PEF and MEF began to show significant increases at 80 and 60 mA, respectively ($p<0.05$ for each item). TV showed a significant main effect in association with the intensity of electrical stimulation. It showed a significant increase at 100 mA as compared with 20 mA according to Tukey's multiple comparison test ($p<0.05$). RR showed no significant main effect in association with the intensity of electrical stimulation. There was an upward trend in RR as electrical stimulation intensity rose, although the differences did not reach statistical significance. MV showed a significant main effect in association with the intensity of electrical stimulation ($p<0.01$). It began to increase significantly at 70 mA according to Tukey's multiple comparison test ($p<0.05$) and showed an approximately 2-fold increase at the maximum intensity. Te/Ttot showed no significant main effect in association with the intensity of electrical stimulation intensity. Ttot was 5.34 ± 1.89 sec at 10 mA and 4.05 ± 1.11 sec at 90 mA. Te/Ttot tended to decrease in association with the increase in electrical stimulation intensity and was 0.58 ± 0.03 at 40 mA and 0.50 ± 0.03 at 90 mA, though no significant differences were observed.

DISCUSSION

Regarding the association with rising electrical stimulation intensity, mild muscle contraction began to be observed in many of the subjects at around 40 mA, and strong abdominal muscle contraction was apparent in many of the subjects at 60–70 mA. There was an increase in each respiratory function parameter as the stimulation intensity rose. Blood pressure, pulse, and SpO_2 during electrical stimulation were unchanged, even at 100 mA, the maximum intensity. It was previously demonstrated that functional electrical stimulation therapy for all four limbs can be safely performed without affecting vital signs, even in post-cardiovascular surgery patients[14], and similar results were obtained with our FES_{abd} technique.

Regarding pain as determined by the VAS, many subjects began to feel the stimulus at an intensity of 40 mA or greater. In addition, muscle contraction became observable at a similar stimulation intensity. However, in two of our nine subjects, muscle contraction initially manifested at 20 mA, and neither of these subjects could tolerate an increase in the intensity up to the maximum set in this study. This was not because the electrical stimulation caused pain but rather because the subjects experienced discomfort due to the strong muscle contractions evoked. Electrical resistance in the body was considered to be low in these two subjects, with the electrical current flowing even at a low enough stimulation intensity to cause muscle contraction. The causes of reduced electrical resistance are considered to include minimal body fat, high skin moisture, and the short distance between the nerves and electrodes. These two subjects were lean, with BMI values of just 17 kg/m^2 and 20 kg/m^2 and their respective body fat percentages were 15.0% and 9.9%. Since these values were slightly lower than the corresponding values for the other subjects, it is possible that these two study participants had lower levels of electrical resistance than the others and higher sensitivity to the stimulus.

PEF began to increase at a stimulation intensity of approximately 50 mA and continuously increased as the stimulation intensity rose. PEF also began to increase at 40 mA in healthy subjects participating in a previous study using esophageal pressure and intragastric pressure as indicators, which is consistent with the results of our present study[12]. Increases in intrathoracic pressure and intra-abdominal pressure are considered to have increased the expiratory flow rate even during quiet breathing with the electrical stimulation delivery device employed in this study. MEF also began to similarly increase at

Table 1. Changes in vital signs and pain associated with increasing the stimulation intensity during quiet breathing

	Rest	Intensity of electrical stimulation (mA)									
		10	20	30	40	50	60	70	80	90	100
Visual analog scale of pain (mm)	0 ± 0	0 ± 0	0 ± 0	0.4 ± 1.1	2.0 ± 2.9	4.8 ± 6.1	7.0 ± 7.5	10.6 ± 12.4	16.7 ± 18.3	24.6 ± 24.8	32.1 ± 28.3
SpO_2 (%)	97.1 ± 0.7	97.3 ± 1.0	97.0 ± 1.2	97.3 ± 1.1	97.7 ± 1.0	97.9 ± 0.7	97.9 ± 0.7	97.9 ± 0.9	97.9 ± 0.7	98.3 ± 0.8*	98.1 ± 0.9
Pulse (beats/min)	60.7 ± 8.6	59.0 ± 6.6	58.9 ± 7.4	58.9 ± 9.1	59.3 ± 6.9	61.9 ± 4.5	60.7 ± 7.4	63.6 ± 9.5	61.4 ± 6.1	64.1 ± 3.4	66.0 ± 7.2
Systolic blood pressure (mmHg)	125.3 ± 10.1	123.0 ± 8.7	122.3 ± 8.0	123.3 ± 10.8	121.9 ± 8.3	121.7 ± 6.7	119.3 ± 8.9	125.1 ± 10.3	125.1 ± 6.9	127.4 ± 8.3	126.4 ± 10.2
Diastolic blood pressure (mmHg)	69.3 ± 7.1	67.3 ± 4.2	60.6 ± 12.9	66.4 ± 16.8	65.6 ± 4.8	69.1 ± 7.3	65.9 ± 8.0	69.0 ± 8.1	69.9 ± 6.7	71.3 ± 3.5	69.1 ± 9.7

Changes in VAS score were minimal at 40 mA or less but began to gradually rise starting at 50 mA. SpO_2 was nearly constant, though there was a slight upward trend. There were no significant changes in pulse or systolic or diastolic blood pressure as the electrical stimulation intensity rose. The data obtained from seven subjects are presented as average values and standard deviations as two individuals who failed to tolerate the electrical stimulation at less than 100 mA were excluded. Statistical significance was determined by applying the multiple comparison test to the values obtained during quiet breathing (*$p<0.05$).

Table 2. Effects of respiratory parameters associated with increasing the stimulation intensity during quiet breathing

	Rest	Intensity of electrical stimulation (mA)									
		10	20	30	40	50	60	70	80	90	100
Peak expiratory flow (L/s)	0.40 ± 0.16	0.42 ± 0.15	0.36 ± 0.08	0.35 ± 0.07	0.38 ± 0.11	0.48 ± 0.16	0.56 ± 0.14	0.66 ± 0.27	0.70 ± 0.29**	0.75 ± 0.23**	1.00 ± 0.47**
Mean expiratory flow (L/s)	0.23 ± 0.11	0.21 ± 0.11	0.19 ± 0.06	0.19 ± 0.04	0.22 ± 0.07	0.27 ± 0.09	0.32 ± 0.08**	0.37 ± 0.12**	0.35 ± 0.12**	0.44 ± 0.11**	0.43 ± 0.10**
Tidal volume (L)	0.68 ± 0.35	0.68 ± 0.25	0.53 ± 0.12	0.53 ± 0.09	0.57 ± 0.20	0.74 ± 0.43	0.77 ± 0.45	0.85 ± 0.46	0.83 ± 0.53	0.86 ± 0.34	0.98 ± 0.58*
Respiratory rate (breths/min)	12.5 ± 4.1	12.3 ± 3.6	12.9 ± 1.7	14.3 ± 2.8	13.2 ± 1.5	14.1 ± 3.6	14.9 ± 3.3	14.8 ± 4.3	14.6 ± 4.7	15.9 ± 4.8	15.5 ± 5.7
Minute ventilation (L)	7.4 ± 3.1	7.1 ± 2.7	6.7 ± 1.9	6.9 ± 1.3	7.7 ± 2.3	9.5 ± 3.2	10.4 ± 2.8	11.7 ± 4.0*	11.6 ± 5.2*	13.0 ± 2.9*	14.3 ± 5.5*
Ttot (sec)	5.22 ± 1.59	5.34 ± 1.89	4.72 ± 0.61	4.32 ± 0.76	4.59 ± 0.52	4.45 ± 0.91	4.17 ± 0.86	4.31 ± 1.02	4.48 ± 1.41	4.05 ± 1.11	4.40 ± 1.74
Te/Ttot	0.53 ± 0.04	0.53 ± 0.03	0.58 ± 0.05	0.56 ± 0.04	0.58 ± 0.03	0.57 ± 0.04	0.54 ± 0.06	0.53 ± 0.09	0.54 ± 0.06	0.50 ± 0.10	0.53 ± 0.07

Peak expiratory flow (PEF) and mean expiratory flow (MEF) began to show significant increases at 80 and 60 mA, respectively ($p<0.01$ for each item). Tidal volume (TV) showed a significant increase at 100 mA as compared with 20 mA. The respiratory rate (RR) showed an upward trend, although the difference did not reach statistical significance. Minute ventilation (MV) began to increase significantly at 70 mA. The time of breathing cycle (Ttot) and the duty cycle of the expiratory phase (Te/Ttot) showed downward trends, but the differences were not statistically significant. The data obtained from seven subjects are presented as average values and standard deviations as two individuals who failed to tolerate the electrical stimulation at less than 100 mA were excluded. Statistical significance was determined by applying the multiple comparison test to the values obtained during quiet breathing. For TV, the multiple comparison test was applied to the values obtained at 20 mA. *$p<0.05$; **$p<0.01$

50 mA and rose as the stimulation intensity increased. As these results indicated that not only the PEF rate but also the expiratory flow rate in the overall expiratory phase was increased, the expiratory flow rate was suggested to function effectively in airway clearance.

TV also began to increase similarly at 50mA. The maximum increase was 0.47 l, and similar increments and effects (0.35 l, 0.45 l) were obtained in a previous study, though the attachment position of the electrode and the stimulation method were different. These observations suggest that, regardless of where the electrode is attached and the stimulation method, the expiratory flow rate and ventilation volume are both increased by delivery of stimulation at maximum intensity.

Te/Ttot tended to decrease as the respiratory rate rose. We speculated that this might be attributable to the duration of electrical stimulation having been set at only 1.5 sec from the start of exhalation, a brief time period, such that inspiration was forced as the abdominal muscles were rapidly released from contraction at the same time that the electrical stimulation was terminated. Soril and colleagues reported that 1-sec stimulation increased the respiratory rate by 2.6 times[15], which is consistent with our present results. Gollee and colleagues reported that when stimulation was adjusted to the expiratory time, the respiration rate decreased in spinal cord injury patients[10], indicating that the respiration rate could be expected to decrease with adjustment of the duration of stimulation.

The results of our experiment clearly show that FES_{abd} can be safely performed without producing vital sign abnormalities at an electrical stimulation intensity of up to 100 mA when delivered with the electrical stimulation instrument used in this study. However, since pain tends to become more severe as the electrical stimulation intensity rises, it is necessary for the subjects to be fully accustomed to electrical stimulation in advance. In conclusion, the appropriate intensity level of electrical stimulation for achieving effects on respiratory flow while also minimizing pain is 60–80 mA.

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