Polish Annals of Medicine

Journal homepage: https://www.paom.pl

Research paper

Polysomnography in patients with spinal cord injury who underwent robotic assisted gait training

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Article info

Article history
Received: April 11, 2023
Accepted: November 16, 2023
Available online: November 28, 2023

Keywords
Sleep
Apnea-hypopnea index
Tetraparesis
Dynamic parapodium
Paraparesis
Robotic therapy

Doi
https://doi.org/10.29089/paom/175360

Abstract

Introduction: Obstructive sleep apnea in spinal cord injured (SCI) patients is an important but underestimated clinical problem. Spinal cord injury weakens the muscles responsible for breathing, resulting in a reduction in lung capacity. Training of respiratory muscles may present an effective method of increasing respiratory muscle strength and lung volume.

Aim: The aim of study was to evaluate the effectiveness of robot-assisted gait training (RAGT) in 34 patients with SCI in sleep-disordered breathing (SDB) reduction.

Material and methods: We conducted a control trail to compare RAGT (exoskeleton EKSO-GT or Locomat Pro) with conventional gait training using conventional physiotherapy with dynamic parapodium. We included patients with SCI (above T8 level of injury) recruited between 3 months and 2 years post injury. Polysomnographic studies were performed before and after the completion of the 7-week rehabilitation program. Patients were divided into 2 groups above and up 40 years old.

Results and discussion: The comparison of all polysomnographic parameters before and after rehabilitation with RAGT revealed the decline in all polysomnographic parameters (the apnea-hypopnea index – AHI; score reached statistically significant value – $P < 0.02$). In comparison in patients aged up to 40 years with conventional gait rehabilitation the number of apnoea's and shortness of breath during sleep even increased: the AHI index increased after rehabilitation from 1.7 to 3.2 values.

Conclusions: RAGT therapy should be considered as a therapeutic option for SDB reduction in patients after SCI. Additionally, the study identified the need to conduct further studies on larger groups of patients.

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1. INTRODUCTION

The incidence of spinal cord injuries (SCIs) increased gradually with the expansion of human activities.[1] It affects 15 to 40 people per 1 000 000 population, mostly people of young age, and there are 11 000 to 12 000 new cases each year in the United States.[2–4] In addition to impaired musculoskeletal function, these patients also struggle with dysfunctions in other organs. The diaphragm appears to be profoundly sensitive to periods of inactivity. Among the consequences of SCI above the thoracic (Th) 9 level are breathing disorders caused by impaired respiratory muscle function.[2–4] Sleep-disordered breathing (SDB) leads to a decrease in blood saturation and, consequently, to cerebral hypoxia, which causes daytime sleepiness, morning headaches, deterioration of mood and cognitive functions, weight gain and libido disorders, and ultimately may lead to many diseases, e.g.: hypertension, coronary heart disease, stroke, diabetes. As a result of spinal cord damage, the conduction of nerve impulses to the respiratory muscles is interrupted or impaired. This applies particularly to patients with damage from C1 to Th8 level. In epidemiological studies the prevalence of SDB in sub-acute and chronic SCI patients is quite high (ranging between 27% and 82%)[5–6] and it depends on the diagnosis based on the apnea-hypopnea index (AHI). Polysomnography (PSG) is the primary method for diagnosis of SDB.

Training of the muscles used for breathing in patients with SDB after SCI can be a therapeutic option. One of the modern and seemingly effective methods of rehabilitation of patients after SCI is robotic gait therapy. In the literature, there are several studies highlighting that robotic assisted gait training (RAGT) in SCI patients improved the cardiorespiratory, urinary, musculoskeletal, neuronal, and somatosensory systems, due to body compensation and neural plasticity.[7–12]

The rehabilitation process for patients after SCI is usually focused on restoring motor function without paying sufficient attention to exercise respiratory muscles and improve respiratory function. Spinal injury particularly in cervical level weakens the muscles responsible for breathing, resulting in a reduction of lung capacity. Training respiratory muscles may present an effective method of increasing respiratory muscle strength and lung volume, although the literature on this topic is scarce. Little research has been conducted with the consideration of SDB in rehabilitation planning in patients after SCI.[2] No studies concerning the influence of RAGT on the reduction and improvement of SDB changes in PSG examination were done.

2. AIM

The aim of this study was to investigate the efficacy of RAGT influencing SDB abnormalities measured using PSG.

3. MATERIAL AND METHODS

We allocated into the study patients with SCI who were admitted to the research program between 3 months and 2 years after injury at the cervical to thoracic levels (C1–T8) of the spinal cord (complete and incomplete according to the American Spinal Injury Association scale – AIS). The inclusion criteria for the study also included: stability of the postoperative stabilization with completed bone fusion; the patient adapted to upright position; no contraindications to rehabilitation, such as: thrombophlebitis, pulmonary embolism, orthostatic drops of blood pressure, epilepsy, infection; body weight less than 120 kg, height 155–190 cm.

The study was conducted during 2018–2021 in the Research Institute for Innovative Methods of Rehabilitation of Patients with Spinal Cord Injury in Kamień Pomorski, Health Resort Kamień Pomorski, Poland.

Participants were excluded from the study for any of the following: contraindications to RAGT including severe osteoporosis, high muscle tension spasticity (grade 3–4 according to Ashworth), large limitations in the range of mobility in the joints, pregnant females, history of cardiac disease including heart failure, peripheral vascular disease, or stroke; history of head trauma with neurological symptoms – Mini Mental State Examination up to 26 points, extreme obesity (BMI more than 38 kg/m^2), lower extremity and pelvic pressure ulcers.

Primarily we included 121 patients; 16 were excluded because of Covid pandemic and discontinuation of the rehabilitation program. From 105 participants to this single-center, single-blinded, single-arm and prospected study; we enrolled, 34; 25 men (73%) and 9 women (27%); 34 participants of 105 were patients with C1 to Th8 injury level, in whom we expected impaired respiratory muscle function, and thus SDB, caused by the injury (Figure 1). The statistical analysis did not include patients who did not consented to both baseline and follow-up PSG or had only one result because of earlier discharge. Simple randomization was conducted by tossing a coin. A blinded investigator (a physi-

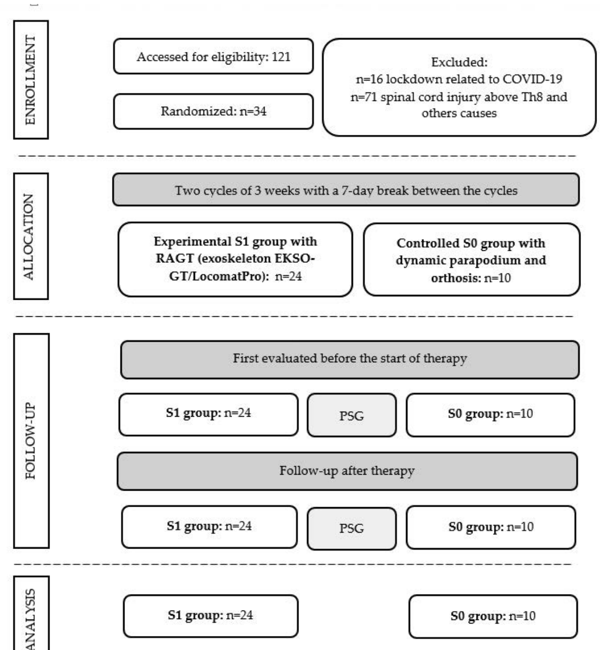

Figure 1. Flowchart of patients' recruitment.

otherapist that was not involved in the treatment process) was responsible for the group allocation process. Physiotherapists blinded to the aim of the study performed the treatments. The PSG examinations on the beginning and after 7 week of training were done.

All subjects were instructed not to use alcohol, caffeine products, or sedatives on the day of the study.

Participants were divided into 2 groups: the control group (S0) which received conventional gait therapy with dynamic parapodium (CGT) and the experimental group (S1) which received RAGT during 6 weeks therapy with 1 week brake after 3 weeks of rehabilitation program. Patients received also physiotherapy sessions consisting of a general exercise program. Patients underwent 30-minute sessions of training or Locomat Pro (model LO218 by Hocoma AG, year of manufacture 2014) or exoskeleton EKSO-GT (model EKSO 1 by Ekso Bionics, year of manufacture 2014). Most patients were allocated to Locomat group because of lack grasping capabilities and trunk stabilization. All participants from the Locomat group with incomplete SCI started with 60% body weight support and an initial treadmill speed of 1.5 km/h, patients with complete SCI started with 100–90% body weight support. In patients with EKSO-GT, minimum 100 steps were required per session.

Due to the greater likelihood of obstructive sleep apnea not related to SCI in people over 40 years of age, the participants were divided into 2 groups: less than and equal to 40 years old and more than 40 years old. Subsequently, the patients were assessed according to the level of SCI and the degree of damage, measured using AIS.[13] The SCI in the cervical (from C1) and thoracic (Th1–Th8) section of the spinal cord, were included. The level of the spinal cord were divided into AIS-A, AIS-B, AIS-C, AIS-D groups (Table 1).

PSG study was performed on the Embletta MPR PG device (polygraph). The study was performed during sleep (on average approximately 7 h of sleep), recording:
(1) respiratory movements of the chest and abdomen using a respiratory effort sensor and body position sensors;
(2) lower limb movements using limb movement sensors;
(3) airflow through the nose using a thermal and pressure sensor;
(4) blood oxygenation using a pulse oximeter;
(5) electrocardiography (ECG).

The PSG results were interpreted by an experienced clinician. The assessments included: the occurrence of respiratory events in the form of apnoea's and shortness of breath; the occurrence of blood desaturation drop events correlating with respiratory distress; the AHI score the number of apneas and shortness of breath per hour of sleep. The determination of apneas was based on airflow detection using a thermal nasal sensor.

Criteria for diagnosis of apnea by American Academy of Sleep Medicine used in the study[7] assume decrease in the amplitude of the thermal sensor signal below 90% of the baseline, duration of the event at least 10 s, at least 90% of the event duration meets the amplitude reduction criterion for apnea.

Table 1. The characteristic of the investigated patients group (*N* = 34).

	Median (IQR)	*N* (%)
Age group		
Less than 40 years old	—	20 (58.82)
More than 40 years old	—	14 (41.18)
Gender		
Female	—	9 (26.47)
Male	—	25 (73.53)
Age, years	33.00 (25.25, 51.75)	—
AIS		
A	—	9 (26.47)
B	—	8 (23.53)
C	—	8 (23.53)
D	—	9 (26.47)
Spinal cord injury		
C	—	17 (50.00)
Th	—	17 (50.00)
PSG before rehabilitation		
Apnea/Hypopnea time, minutes	16.00 (10.00, 79.50)	—
AHI score	2.05 (1.30, 10.50)	—
Number of Apnea/hypopnea	18.50 (9.25, 79.50)	—
Apnea/desaturation 81%–90%	2.50 (0.00, 21.50)	—
PSG after rehabilitation		
Apnea/hypopnea time, minutes	15.50 (6.00, 49.50)	—
AHI score	2.05 (0.80, 7.33)	—
Number of apnea/hypopnea	14.50 (6.00, 45.00)	—
Apnea/desaturation 81%–90%	1.50 (0.00, 10.75)	—

Based on inspiratory effort, apneas were divided into obstructive apneas, associated with continuous or increasing inspiratory effort across the range of no airflow, central apneas, associated with no inspiratory effort over the entire interval of no airflow and mixed apneas, associated with a lack of inspiratory effort in the initial phase of the event followed by a resumption of inspiratory effort in the second phase of the event.

The determination of shallow breathing was based on the detection of a nasal air pressure sensor.

Criteria for the diagnosis of shallow breaths:[7] a drop in nasal air pressure of at least 30% from baseline, duration of the event of at least 10 s, at least 4% desaturation relatively to baseline before the event begins, at least 90% of event time meets amplitude reduction criteria for shallowing.

Results for continuous variables with non-mesocurtic distribution are presented as median and interquartile range (IQR). The normality of the distribution of the variables was checked using the Shapiro–Wilk test and a histogram. Nominal variables were presented as number of observed cases and percentage *N* (%).

Analysis of differences between independent groups was performed using non-parametric tests, Kruskal–Wallis test

Table 2. The comparison of the investigated values of the studied parameters in patients less than or equal to 40 years and more than 40 years with SCI (cervical and thoracic injury level).

	Cervical SCI (N = 17)	Thoracic SCI (N = 17)	P	< 40 years old (N = 20)	> 40 years old (N = 14)	P
Apnea/hypopnea time, minutes	52.00 (13.00, 80.00)	13.00 (7.00, 78.00)	0.24	13.00 (10.00, 37.25)	61.50 (19.00, 108.75)	0.07
AHI score	7.60 (1.60, 10.61)	1.75 (0.90, 10.20)	0.36	1.65 (1.28, 8.35)	8.85 (2.65, 14.15)	0.08
Number of Apnea/hypopnea	52.00 (12.00, 80.00)	11.00 (4.00, 78.00)	0.23	11.50 (8.50, 32.00)	59.50 (28.00, 102.00)	0.04
Apnea/desaturation 81%–90%	9.00 (2.00, 30.00)	2.00 (0.00, 20.00)	0.26	1.00 (0.00, 8.75)	14.50 (2.00, 38.25)	0.04

Comments: values are given as median (IQR)

Table 3. The comparison of all polysomnographic parameters before and after rehabilitation in age group less than or equal to 40 years and more than 40 years (S0, S1 groups and all patients).

Parameter	All patients (N = 20)			Patients assign to S1 rehabilitation (N = 13)			Patients assign to S0 rehabilitation (N = 7)		
	Initial	Final	P	Initial	Final	P	Initial	Final	P
Apnea/hypopnea time, minutes	13.00 (10.00, 37.25)	10.00 (5.75, 18.25)	0.10	13.00 (10.00, 16.00)	7.00 (5.00, 12.00)	0.14	13.00 (10.50, 80.00)	25.00 (15.00, 52.00)	0.53
AHI score	1.65 (1.28, 8.35)	1.35 (0.75, 2.52)	0.08	1.60 (1.20, 2.10)	0.90 (0.60, 1.50)	0.02	1.70 (1.35, 10.60)	3.20 (2.05, 6.60)	1.00
Number of Apnea/hypopnea	11.50 (8.50, 32.00)	9.00 (5.50, 18.25)	0.11	11.00 (7.00, 15.00)	6.00 (4.00, 11.00)	0.17	12.00 (10.50, 80.00)	25.00 (13.00, 51.50)	0.42
Apnea/desaturation 81%–90%	1.00 (0.00, 8.75)	0.00 (0.00, 4.25)	0.04	0.00 (0.00, 4.00)	0.00 (0.00, 1.00)	0.28	2.00 (0.00, 31.00)	2.00 (0.00, 13.00)	0.18

Comments: PSG before and after rehabilitation is given as median (IQR).

or Mann–Whitney U test. Analysis of differences between pre- and post-rehabilitation scores was performed using the Wilcoxon test for dependent groups. Results at a significance level of $P < 0.05$ were considered significant. In assessing the differences in changes in PSG between S1 and S0 rehabilitation, a regression analysis model was used. The rehabilitation group and the initial value of the analyzed parameter were included in the model as explanatory variables. If the assumptions of homoskedasticity were not met, the standard error was calculated using the White-a method for small groups (White-a hc3 homoskedastic correction described in Long and Ervin, 2000)

Statistical analysis, data preparation and visualization were performed using R software (R Core Team, 2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/), supplemented with the following packages: rmarkdown,[14] qwraps2,[15] FSA,[16] ggplot2,[17] ggpubr,[18] lattice,[19] tidyverse.[20] Preparation, and data visualization were performed using the R program (R Core Team, 2021).

4. RESULTS

The characteristics of investigated patients group in the Table 1 is given. Of the whole investigated group 9 patients presented with AIS-A (26%) and AIS-B, AIS-C, and AIS-D – 25 (74%). Out of all 34 patients 10 (29 %) were exercised by conventional rehabilitation method and 24 (71%) by RAGT. The group with conventional therapy (S0) and with RAGT therapy (S1) group did not differ in terms of age or sex. In whole group after rehabilitation the main indicator of improvement was the apnea/desaturation 81%–90% index (Table 1).

In the Table 2 the comparison of investigated values of studied parameters between patients with SCI in cervical and thoracic injury level is given. Patients with cervical level of injury, as we supposed, had significantly worse results in all tested parameters.

As we assumed before the study in the older group polysomnographic parameters would be worse, the number of apnea/hypopnea and apnea/desaturation 81%–90% was significantly higher in those groups of patients ($P < 0.04$).

In the Table 3 the comparison of all polysomnographic parameters before and after rehabilitation in younger age group is given. In all patients the score values declined after rehabilitation and reached the significance in apnea/desaturation 81%–90% parameter reduction ($P < 0.004$). The AHI score dropped statistically significant ($P < 0.02$) in RAGT group.

In the Tables 4 the comparison of the change in the values of the studied parameters after rehabilitation between all groups and with and without RAGT rehabilitation in patients over 40 years of age is given. In this age group with robotic rehabilitation patients had also a visible beneficial effect, reducing the number of respiratory distress – in comparison to the conventional rehabilitation. In those patients as in the previous younger group despite the small number of patients included, the deterioration in PSG results in the S0 group was noticed.

Table 4. Comparison of all parameters before and after rehabilitation in all older age group (after 40 years of age) patients and I S1 and S0 groups.

Parameter	All patients (N = 14)			Patients assign to S1 rehabilitation (N = 11)			Patients assign to S0 rehabilitation (N = 3)	
	Initial	Final	P	Initial	Final	P	Initial	Final
Apnea/Hypopnea time [min]	61.50 (19.00, 108.75)	44.00 (16.00, 141.75)	0.78	62.00 (24.00, 99.50)	37.00 (17.00, 89.50)	0.76	52.00 (28.00, 119.50)	189.00 (97.00, 220.00)
AHI score	8.85 (2.65, 14.15)	6.15 (2.17, 18.10)	0.80	10.60 (3.30, 13.49)	5.20 (2.35, 12.93)	0.62	9.90 (5.35, 17.05)	26.70 (13.70, 33.35)
Number of Apnea/Hypopnea	59.50 (28.00, 102.00)	40.50 (15.00, 129.00)	0.97	60.00 (30.00, 95.00)	36.00 (15.00, 85.50)	0.55	52.00 (28.00, 118.50)	188.00 (96.50, 218.50)
Apnea/desaturation 81-90%	14.50 (2.00, 38.25)	9.00 (0.50, 40.00)	0.61	18.00 (5.50, 35.50)	7.00 (1.00, 39.00)	0.45	2.00 (1.50, 60.50)	110.00 (55.00, 163.50)

Comments: PSG before and after rehabilitation is given as median (IQR).

5. DISCUSSION

Sleep-disordered breathing occurred approximately 4 times more often in the SCI patient population than in the general population.[2,3,6] In a study by Sankari et al., 77% of patients with chronic SCI had AHIs greater than 5, indicating SDB.[2] Evidence in the literature suggests that SDB develops within a few months after injury and the observed disturbances are due to SCI.[2] Unfortunately, SDB is rarely diagnosed because clinicians often focus solely on the movement issues and the remaining disturbances associated with SCIs are missed. Therefore, it should be emphasized that the diagnosis of these disorders is significant as cardiopulmonary complications are the major cause of morbidity and mortality in patients with SCI-D due to reduced lung volume, ineffective cough, mucus retention, and atelectasis.[21–22]

Our present study is the first comparison of RAGT therapy and parapodium gait therapy in the literature; but also concerning the RAGT therapy influencing SDB. The study depicted that rehabilitation with RAGT resulted in better treatment outcomes than CGT especially in AHI score which dropped statistically significant. We think that it is a very important finding because as known from the literature RAGT allows: repetition of specific and stereotyped movements in order to acquire a correct and reproducible gait pattern but also can reduce body mass index and reduce the incidence of SDB after SCI. Furthermore, RAGT used in combination with other new technologies seems to be highly tolerated and supports motivation in SCI patients. In Poland CGT is administered after SCI as a gait and stand therapy at home and RAGT is reimbursed by state. We think that SDB reduction should be also considered as a goal for RAGT implementation for SCI patients. This aspect is relevant in terms of health policies and requires further investigations to establish if RAGT might be economically rewarding.

In the group of patients with CGT (parapodium) the studied PSG parameters were higher; the groups of patients were small, but it is interesting to note that in all age groups, conventional therapy even worsened the studied parameters in PSG. These data were not statistically significant and performed on a small number of patients. Perhaps this was related to the overtraining of these patients and reduced respiratory muscle strength. Our research shows that conventional rehabilitation can adversely affects respiratory parameters perhaps only temporarily, which the physical medicine and rehabilitation doctors or physiotherapists should take into account when ordering this type of treatment. This in our opinion important clinically observed topic requires further study on larger SCI groups.

In our study, in PSG performed in patients during sleep, the occurrence of SDB (apnea and shortness of breath) was analyzed in correlation with a decrease of blood saturation. The results of initial examinations were compared with the results of examinations performed after rehabilitation, evaluating the influence of rehabilitation on respiratory functions. The level and severity of SCI, BMI, and intake of spasmolytic medications were considered in the evaluation. Analysis of the study highlighted that, in the group of patients with SCI in cervical level the respiratory distress was more severe than in the group of patients with SCI in thoracic level. In all cases, respiratory disturbances during sleep followed a decrease in blood saturation below 90%. This conclusion confirms our earlier assumptions and is consistent with the theses described in the world literature.[2–5]

As we suspected earlier, patients older than 40 years had more severe changes in the PSG parameters. Respiratory disturbances during sleep in patients with trauma above Th8, in the age group below 40 years of age, i.e., in the group where the causes of respiratory disorders are found in SCI, were mainly in the form of hypopnea.

Most of the articles available in the literature on respiratory disorders in patients with SCI focus predominantly on the causes and mechanisms of breathing disorders during sleep,[2–5,21,22] indicating the main mechanisms such as: nerve damage (muscle, as a result of which the transmission of nerve impulses to the respiratory muscles is interrupted or impeded, and the traction force is lost due to the reduced volume of the lungs). Lung volume can influence airflow resistance in the upper airway by mechanically influence the geometry and function of the throat. Therefore, reduced lung volume due to weakening of respiratory muscle function or narrowing of the bronchi may contribute to the collapse of the walls of the upper airways. Moreover, the obtained results may be explained by the fact that the patient spends more time lying on their back. Patients with tetraplegia change their body position less frequently during sleep and stay in the supine position for longer periods of time, which contributes to the collapse of the throat walls. Furthermore, altered balance of the sympathetic and parasympathetic systems may contribute to the changes mentioned above. Parasympathetic innervation of the lungs and airways is usually preserved after SCI, but sympathetic dysfunction is common. In the event of an imbalance in the autonomic nervous system, cholinergic (parasympathetic) tension modulation in the airways causes excessive bronchoconstriction. Increased body weight also contributes to apnea. Reduced motor activity in SCI patients is a risk factor for patients who are overweight or obese. Excess fat around the neck and throat can impair the patency of the throat and cause the walls of the throat to collapse during sleep. Additionally, plasticity of the respiratory muscles may also contribute to the apnea. The main muscle of inspiration, the diaphragm, is very sensitive to periodic inactivity.

Muscle training in patients with breathing disorders after SCI improve the strength of the respiratory muscles and increase the efficiency of the respiratory system or is essential. These exercises are based primarily on resistance training which involves breathing through a small diameter hole (resistor), which limits available flow and thus increases ventilatory (training) load. However, the available literature regarding studies related to the evaluation of the effect of rehabilitation on respiratory distress in SCI patients is very scarce and there are no generally accepted standards of therapeutic management in this group of patients.[2,4]

In our study, all patients underwent seven weeks of intensive rehabilitation, which included exercises with a physiotherapist. Exercises were aimed at strengthening limb muscles, postural muscles, and respiratory muscles. In all patients with SCI above Th8 in the less than or equal to 40 age group, who had significant SDB, the usage of 7 weeks of rehabilitation resulted in a decrease in the amount of respiratory distress.

Limitations

The authors declare that the study was in a single-centre performed, and undoubtedly a deeper analysis of the described problem would require multicentre or international studies. However, the fact that patients recruited for the study came from different parts of our country is not without significance.

The same disadvantage of the study is imbalance of in numbers of patients enrolled to control vs experimental group. The explanations is that patients who drew the group without RAGT during the coin toss withdrew from continuation of the research. All patients wanted to join the RAGT group.

Some of patients did not complete the study. It was unfortunately due to the pandemic, and we performed polysomnography examinations not in the centre where the patients were rehabilitated.

6. CONCLUSIONS

In the context of the causes of SDB in patients after SCI described above, it is reasonable to conclude that the most likely mechanism causing improvement in respiratory capacity resulting from rehabilitation is improvement due to strengthening of respiratory muscles in an indirect manner. Our study is the first to compare CGT with RAGT for respiratory impairment in SCI patients. The RAGT should be considered as a therapeutic option when the aim of rehabilitation includes rehabilitation of respiratory muscle dysfunction and can cause SDB reduction in SCI patients. Additionally, the study identified the need to conduct further studies on larger groups of patients.

Conflict of interest

The authors report there are no competing interests to declare.

Funding

The study was supported by a grant from the National Centre for Research and Development, Poland. The grant title was “Advanced programme rehabilitation of patients after spinal cord injury using robotic rehabilitation robots". Implemented under Measure 1.1.1: R&D projects enterprises of the Intelligent Development Operational Programme 2014–2020. Co-financed by the European Regional Development Fund No. agreement: POIR.01.01.01-00-0848/17-00 of 22.06.2018.

Acknowledgments

We thank our colleagues from Research Institute for Innovative Methods of Rehabilitation of Patients with Spinal Cord Injury in Kamień Pomorski, Health Resort Kamień Pomorski, Poland.

Ethics

The study was approved by Ethical Board of the District Medical Chamber in Szczecin (Poland) (No OIL-Sz/MF/KB/452/05/07/2018; No OIL-SZ/MF/KB/450/UKP/10/2018). All participants in this study agreed to participate and signed informed consent forms before the study.

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