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Trening na bieżni z odciążeniem masy ciała poprzez system Parestand w usprawnianiu chodu u pacjentów we wczesnej fazie udaru mózgu: badanie pilotażowe

Body Weight Supported Treadmill Training with Parestand system as walking therapy of patients early after stroke: a pilot study

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Streszczenie:
Wstęp. Trening na bieżni z odciążeniem masy ciała (z ang. Body Weight Supported Treadmill Training - BWSTT) to wysokiej częstotliwości zadaniowa terapia chodu pacjentów po udarze mózgu. Skuteczność BWSTT została wielokrotnie udowodniona, jednak jego wyższość nad treningiem chodu po naturalnym podłożu jest często kwestionowana. W Polsce jest to rzadko stosowana i badana metoda.
Pacjenci i metody. W badaniu brało udział 20 chodzących pacjentów we wczesnej fazie udaru. Wszyscy pacjenci uczestniczyli w standardowej fizjoterapii opartej o koncepcję Bobath i PNF. Do grupy eksperymentalnej włączono 10 osób dodatkowo otrzymujących trening na bieżni z odciążeniem masy ciała (BWSTT), a do grupy kontrolnej włączono 10 osób dodatkowo otrzymujących trening chodu po naturalnym podłożu. Badanych przed i po skończeniu interwencji oceniono Skalą Równowagi Berg, testem Timed Up & Go, Testem 10-metrowym oraz testem 6-minutowego marszu.
Wyniki. Obie grupy uzyskały istotną statystycznie (p<0,05) poprawę we wszystkich testach funkcjonalnych. BWSTT zwiększyła swój dystans o 108,4±75,7 m, a grupa kontrolna o 57±51,3 m. Różnica pomiędzy grupami nie była istotna statystycznie (p=0,28). BWSTT skróciła czas w teście TUG o 9±1,4 s, a grupa kontrolna o 2,7±1,1 s. Różnica pomiędzy grupami nie była istotna statystycznie (p=0,63). BWSTT uzyskała 7,0±3,7 pkt, a grupa kontrolna 6,6±4,4 pkt poprawy w BBS. Różnica pomiędzy grupami nie była istotna statystycznie (p=0,88). BWSTT podniosła prędkość chodu o 0,25±0,13 m/s, a grupa kontrolna o 0,28±0,13 m/s. Różnica pomiędzy grupami nie była istotna statystycznie (p=0,96).
Podsumowanie. Zarówno BWSTT jak i terapia chodu po naturalnym podłożu może poprawić równowagę, wytrzymałość i szybkość chodu oraz zmniejszyć ryzyko upadków u chodzących pacjentów we wczesnej fazie udaru.

Słowa kluczowe:
udar mózgu, niedowład połowiczy, fizjoterapia, rehabilitacja, chód

Abstract
Background. Body Weight Supported Treadmill Training (BWSTT) is high intensive and task-specific gait therapy for stroke patients. Effectiveness of BWSTT is repeatedly proven, however superiority of that training over overground walking is often contested. It is rarely practised and investigated method in Poland.
Patients and Methods. 20 patients in the early post-stroke rehabilitation phase able to walk. All patient participated in traditional physiotherapy based on Bobath and PNF concepts. Experimental group (10 people) additionally received Body Weight Supported Treadmill Training. Control group (10 people) additionally received overground walking. Baseline and postintervention assessments included Berg Balance Scale, Timed Up & Go, 10 m Time Walking Test and 6 Minute Walk Test.
Results. Both groups showed statistically significant improvement in all outcome measures (P<0,05). Group BWSTT increased distance by 108,4±75,7 m and control grouop by 57±51,3 m in 6 Minute Walk Test. Difference between the groups was not statistically significant (p=0,28). Group BWSTT shortened time in Timed Up & Go by 9±1,4 seconds and control group by 2,7±1,1 seconds. Difference between the groups was not statistically significant (p=0,63). Group BWSTT improved by 7,0±3,7 points, and control group by 6,6±4,4 points in Berg Balance Scale. Difference between the groups was not statistically significant (p=0,88). Group BWSTT increased gait velocity by 0,25±0,13 m/s, and control group by 0,28±0,13 m/s. Difference between the groups was not statistically significant (p=0,96).
Conclusions. Either Body Weight Supported Treadmill Training or overground walking could improve balance, reduce risk of falls, increase endurance and velocity of gait in walking subacute stroke patients. BWSTT could have tendency to more effective increasing gait endurance.

Key words:
stroke, hemiparesis, physiotherapy, rehabilitation, gait

Introduction

Around 70% of patients immediately after stroke have problems with walking [1]. During the first week since incident 51% have no walking function, 12% walk with assistance and 37% walk independently. In turn, in 11 week (after early rehabilitation phase) 22% had no walking function, 14% walk with assistance and 37% walk independently [2]. Patient's gait is usually uneconomical, slow, steps are short, phase are asymmetrical and single stance period of the affected limb is short. All the above problems considerably reduces distance that they able to go what affect home and community functioning [3]. There are strong evidences for post-stroke physiotherapy favoring high-intensity task-oriented training [4].

Body Weight Supported Treadmill Training (BWSTT) was one of the first practical application of this concept [5]. Due to eliminate the possibility of fall through assistance of harness and sturdy construction (supporting body weight) BWSTT enable walking therapy early after stroke. This therapy is based on activation of spinal and supraspinal gait pattern [6].

High number of repetitions (supported by BWSTT) is essential in post-stroke rehabilitation and favors brain plasticity [4, 7, 8].

During 30 minute BWSTT training patient could make up to 1000 steps (sliding track enforces locomotion) compared with 100 steps in the conventional therapy session [9]. BWSTT is the most often collated with overground walking [10].

Overground walking can be defined as physiotherapists' active assist or observation of patient's gait. That therapy could be supported with orthopedic aids such as orthosis, tripod or Nordic walking stick etc. [11, 12]. BWSTT is rarely applied and investigated method in Poland (there is a few trial about its application) [13].

The aim of the study was comparison of BWSTT and overground walking influence on:

- balance improvement,
- reduce fall risk,
- increase gait velocity and distance

as an complement of conventional therapy.

Materials and methods

Study was conducted in Ośrodek Rehabilitacji Narządu Ruchu "Krzeszowice" from 01.07.2014 to 31.12.2014. Following patients were included to experiment: first stroke (right or left hemisphere); required a little help and/either control during gait or able to walk independently with/without orthopedic aids but with an abnormal gait pattern; gave informed consent to participate in a research study. Exclusion criteria were: more than one stroke; cerebellar, brainstem or bilateral stroke; normal gait pattern; treadmill training not possible because of comorbidities; inability to understand basic commands because of aphasia, cognitive problems or mental disorders; lack of consent. Baseline characteristics of the subjects who completed the program is placed in Table 1.

Study was conducted with the approval of bioethics committee CM UJ in Krakow. Experiment enrolled 20 patients in the early phase of stroke. 10 persons included in the experimental group (BWSTT) and 10 to the control group. 3 people from the BWSTT group did not complete the intervention because of viral gastroenteritis. The remaining 7 patients in the BWSTT group and 10 in the control group completed the whole program of physiotherapy.

Table 1. Baseline characteristics of BWSTT and control group

	BWSTT group (n=7)	Control group (n=10)	p-value
Age, years	63.9 +/- 10.7	68.6 +/- 11.9	0.64
Women	2 (28.6%)	6 (60%)	0.23
Men	5 (71.4%)	4 (40%)	0.23
Ischemic stroke	4 (57.1%)	8 (80%)	0.35
Hemorrhage	3 (42.9%)	2 (20%)	0.35
Side of lesion, right	5 (71.4%)	3 (30%)	0.11
Side of lesion, left	2 (28.6%)	7 (70%)	0.11
Arterial hypertension	7 (100%)	7 (70%)	0.14
Atrial fibrillation	0 (0%)	3 (30%)	0.14
Coronary artery disease	0 (0%)	2 (20%)	0.26
Diabetes mellitus	2 (28.6%)	4 (40%)	0.68
Hyperlipidemia	1 (14.3%)	3 (30%)	0.51
Overweight	3 (42.9%)	3 (30%)	0.64
Depression	2 (28.6%)	2 (20%)	0.83
Time from stroke to inclusion in the study	9.6 +/- 2.4	4.9+/- 2.9	0.003

Abbreviations: BWSTT- Body Weight Supported Treadmill Training

Intervention

Both experimental and control group practiced individual therapy based on neurophysiological methods (Bobath and PNF concepts).

Physiotherapy was held in the morning and lasted 1.5 hours for each patient [14]. Additionally, each group received gait therapy in the afternoon.

Experimental group (BWSTT)

Gait therapy in BWSTT group lasted 30 minutes, 5 times per week for 3 weeks (each patient received 15 sessions BWSTT). Patients practiced walking on a treadmill BIODEX Gait Trainer 2 with 25% body weight support (BWS) via PARESTAND Inotec company (fig.1).

After placing the patient in a harness and support 25% of body weight, measuring the pulse rate and blood pressure training began. Speed was adjusting to individual patient's capacity and so as not to lead to increased tonicity of the affected side. The last part of the treadmill training was gradually deceleration and remeasuring the pulse and pressure.

In subsequent sessions, with improved gait parameters and heart rate successively increased treadmill velocity. With the patient's adaptation to the velocity BWS was reduced until BWS system was completely deactivating. If subject required manual facilitation during gait therapist initially manually corrected lower limb and then with words as therapy progress. Attention was also paid to the correct trunk movement [14].

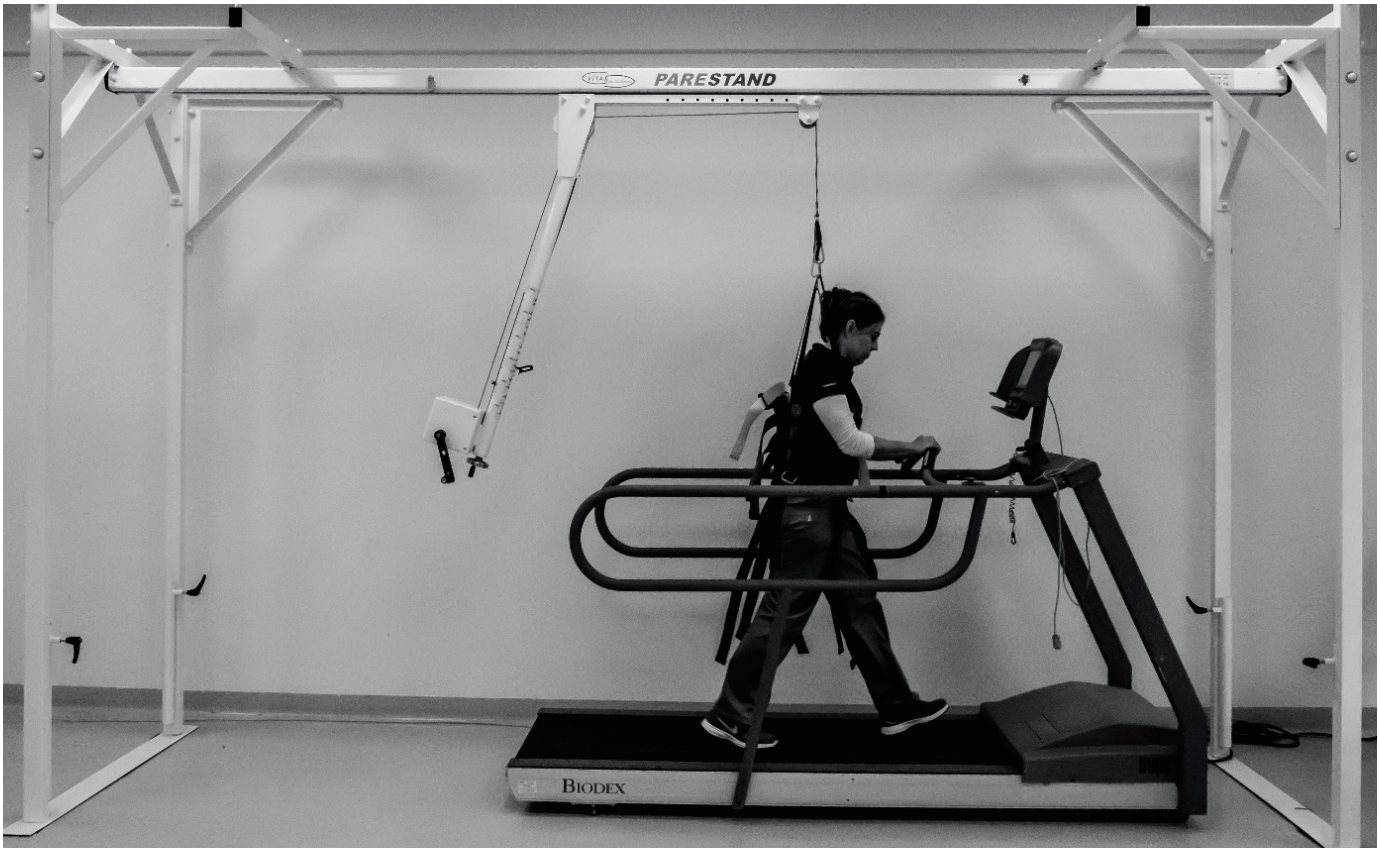

Figure 1. PARESTAND body weight support device in combination with treadmill BIODEX

Control group
The control group practiced overground walking (15 sessions for 30 min during 3 weeks). Additionally, during therapy techniques such as walking facilitation with the therapist's hands using resistance from the front or approximation from above were used.

Outcome measures
Balance and risk of falling were assessed by Berg Balance Scale (BBS) and Timed Up & Go test (TUG). BBS assessed the performance of 14 functional tasks requiring maintaining balance on a scale of 0 to 4. The sum of 56 points indicates excellent balance [15]. The TUG measured the time in which the patient (as soon as possible) stand up from a chair, walk a distance of 3 meters, turn, walk back and sit down. Result ≥ 15 seconds indicates a 63% risk of falling in stroke patient 16]. 10 Meter Walk Test (10MWT) measured walking velocity on a 10-meter path [17]. The result of 0.8 m/s indicates independence at home and outside [18]. Walking capacity measured with 6 Minute Walk Test (6MWT) – patient tried to walk as long as possible distance along a 30 meter section of the corridor (to and from). [19] During TUG, 10MWT and 6MWT patients walked with or without orthopedic aids.

Statistical analysis
Statistical analysis was performed with STATISTICA 10. To check if distribution is normal Shapiro-Wilk test was used. For comparison dependent and independent variables with normal distribution Student's t-test was used. Wilcoxon signed-rank test and Mann-Whitney U test was performed for comparison of, respectively, dependent and independent variables diverged from normal distribution. To determine the relationship between measurable variables the Pearson's correlation coefficient was used. All calculations used standard statistical significance ($p < 0.05$).

Results
There were no statistically significant differences ($p > 0,05$) in baseline between groups as regards the results of functional tests (BBS, TUG, 10MWT, 6MWT), age and BMI (Body Mass Index). The time from stroke to study inclusion was significantly different ($p < 0.05$) between groups (experimental – 9.6 ±2.6, control – 4.5 ±2.9 weeks after stoke). Statistical analysis showed no correlation between improvement in any of the tests (BBS, TUG, 10mWT, 6MWT) and the time from stroke to study inclusion. Both groups received a statistically significant improvement in all functional tests- Berg Balance Scale, Timed Up & Go, 10 Meter Walk Test and 6 Minute Walk Test (Table 2). BWSTT group improved time by an average of 6.3 seconds more in the TUG (difference was not statistically significant p=0.63), reached an average of 51.4 m greater improvement in 6MWT (difference was not statistically significant p=0.28) and acquired an average of 0.4 points more in BBS (difference was not statistically significant p=0.88) compared with the control group. Control group achieved an average of 0.03 m/s more improvement in 10mWT than BWSTT group (difference was not statistically significant p=0.96).

Table 2. Baseline and post training functional tests outcomes

	BWSTT Group				Control Group			
	Baseline M±SD	Post tretment M±SD	Change	Overall significance	Baseline M±SD	Post tretment M±SD	Change	Overall significance
BBS	39.7±9.3	46.7±8.0	7.0±3.7	<0.01	43.5± 9.6	50.1±8	6.6±4.4	<0.01
TUG	25.6±18.7	16.6±11	9±14	<0.05	16.6±16	13.8±16.3	2.7±1.1	<0.01
10MWT	0.58±0.23	0.83±0.33	0.25±0.13	<0.01	0.87±0.33	1.15±0.39	0.28±0.13	<0.01
6MWT	185.2±113.6	293.6±143.6	108.4±75.69	<0.01	227.7±109.1	284.7±114.7	57±51.25	<0.01

Abbreviations: BWSTT - Body Weight Supported Treadmill Training; M - mean; SD - standard deviation; BBS - Berga Balance Skale; TUG - Timed Up &Go; 10MWT - 10 Meter Walk Test; 6MWT - 6 Minute Walk Test

Discussion

In the study both BWSTT and the control group achieved a statistically significant improvement in all functional tests (BBS, TUG, 10mWT, 6MWT). No statistical significant difference between improvement in BWSTT and control groups (p>0,05) could result from a small representation of the groups. It would therefore be useful to undertake a research in this area on a larger group of patients. The results, however, differentiate thresholds for clinically significant changes. Real clinical change in balance is 5.8 points on Berg Balance Scale in stroke rehabilitation [15]. Mean difference in both BWSTT (7 points) and control (6.6 points) exceeded this value. Substantial meaningful change for 6 Minute Walk Test is 49 m and for 10 Meter Walk Test is 0,14 m/s [20]. The threshold of 49 m improvement in 6MWT was exceeded by 5/7 participants in BWSTT group (71%) and 4/10 in the control group (40%). The threshold of 0,14 m/s improvement in 10MWT was exceeded by 5/7 patients in BWSTT group and all 10 patients in control group. In addition, in the subjective feeling of experimental group overground walking became easier after the BWSTT session. Therefore, patients expected the next therapy and Body Weight Supported Treadmill Training was an important motivating factor. What's more, BWSTT participants were more likely to consolidate achieved skills during everyday activities such as using the toilet, moving within and outside the building.

However, considering the randomized controlled trials (RCT) efficiency of BWSTT in comparison with overground walking appears differently. Dean et al. (126 early stroke patients with no walking function) obtained similar effects of BWSTT to those in the our study. People who have achieved independent walking in BWSTT group overcame an average of 57 m more in the 6MWT than the group receiving overground walking. Improvement in walking velocity did not differ between groups [21]. MacKay-Lyons et al. compared the traditional physiotherapy combined with BWSTT or overground walking in 50 early stroke patients walking with or without orthopedic aids/ assist. BWSTT group increased their distance in 6MWT from 189 to 279 m (48% improvement) and control from 196 to 232 m (19% improvement). The distance in both groups increased respectively by 8 and 9 m at 12-month follow-up. VO2 max increased in BWSTT group by 30% versus 8% in the control group. Improvement in gait velocity and balance were similar in both groups [22]. The opposite conclusions drew

Duncan et al., whose study included 408 patients (64 days after stroke) which could move at least 3 m with or without assistance. Two groups received BWSTT and overground walking at different times from stroke (early locomotor training group 2 and late 6 months after stroke) and control group received supervised home-exercise program of active control. All groups had a similar improvement from baseline to one year in the distance walked in 6MWT, walking velocity, number of steps taken in the community, motor recovery, physical mobility, balance, activities of daily living and participation. However, in early locomotor training group were 22% more falls than in home-exercise group. Authors concluded that locomotor-training interventions stressed stepping did not include progressive balance-specific training [23]. However Mehrholz et al. concluded that in patients receiving BWSTT adverse events do not occur more often than in other methods [10], and our own observations confirm this thesis. Also Nilsson et al. (73 walking early stroke patients) obtained similar results in patients additionally receiving BWSTT or overground walking in Functional Independence Measure, 10MWT, Fugl-Meyer Stroke Assessment of locomotor function and control, Functional Ambulation Classification and BBS [24]. In turn, Franceschini et al. compared the effects of conventional physical therapy in combination with either BWSTT or overground walking in 97 early stroke patients with no gait function. Outcomes of Motricity Index, Trunk Control test, Barthel Index, Functional Ambulation Categories, 10MWT, 6MWT and Walking Handicap Scale did not significantly differ both after 20 training sessions, 2 weeks and 6 months follow-up. Also some systematic reviews contest the superiority of treadmill training with or without body weight support in improving gait after stroke compared to other methods [26, 27].

Analyzing the BWSTT studies we should take into account the possibilities of walking at baseline that significantly differentiate obtained results. Analysis Mehrholz et al. review (11 RCTs; 425 walking without assistance stroke patients) showed that BWSTT produced statistically significant higher walking velocity by an average of 0.14 m/s compared with other physiotherapy methods. In turn, BWSTT did not increase walking velocity more than other method in stroke patients requiring assistance during gait at baseline (8 RCTs; 738 subjects). Similarly, there were no significant difference between groups in improving in walking endurance (5 RCTs, 839 patients requiring assistance during gait). In turn, the 5 RCTs (230 walking without assistance patients) indicated clinical significant difference for walking endurance 57 m favored using BWSTT. In own study BWSTT group achieved an average of 51.4 m greater improvements compared with control group. Therefore, independently walking patients (with or without orthopedic aids) will be the main beneficiaries of this method [10]. Also the way of performing BWSTT (achieving cardio-respiratory parameters, training intensity, treadmill velocity, number of training sessions or degree of BWS) can differentiate the results achieved in the individual studies [22, 28]. For example, in Pohl et al. study (60 stroke patients) compared treadmill training, in which STT group practiced intervals reaching a maximum speed, LTT increased initially speed no more than 5% a week, while the control group received gait therapy based on PNF and Bobath concept. After 12 training sessions STT group increased the fastest comfortable overground walking speed from 0.61 up to 1.63 m/s and the step length from 0.42 to 0.72 m, LTT group increased speed from 0.66 to 1.22 m/s and length from 0.45 to 0.60 m, while control group increased speed from 0.66 to 0.97 m/s and length from 0.46 to 0.56 m [28]. In own study, the speed was increased to the extent the patient was able to do. Group BWSTT increased an average walking speed from 0.57 to 0.82 m/s, and the control group from 0.69 to 0.9 m/s. Visintin et al. compared the effects of 24 treadmill training with or without BWS in 79 patients in the first 5 months after stroke. The group using BWS gained an average of 6.2 points more in BBS, 0.08 m/s more in overground walking speed and 47.9 m more in overground walking [29]. According Hesse et al. body weight support less than 30% not only does not impairs gait parameters but prolongs single stance period of the affected limb (through safeguarding by harness) and therefore increases gait symmetry, balance and control directly affected side. However, due to the reduction of activity supported muscle BWS should not be prolonged [30]. Considering the above reports, in our study 25% body weight support was applied at the start of a therapy session, and then when a patient with an increased speed symmetrically loaded both limbs and prolonged the step – BWS was reduced. Another issue raised by BWSTT literature was independence of walking. Ada et al. meta-analysis compared the effects of mechanically assisted walking (i.a. BWSTT) with assisted overground walking in 539 early stroke patients. In 4 of 6 studies overground walking was additionally used in the experimental group. Time of therapy was equal in both groups. Mechanically assisted walking with BWS resulted that more people were able to walk independently after 4 weeks of intervention (53% vs 32%). Six months after completion of therapy 23% difference has remained in favor of the experimental group (follow-up study comprised 312 subjects) [11]. On the one hand meta-analysis of 19 RCT (1210 stroke patients) Mehrholz et al. showed that BWSTT does not increase the chance of obtaining independent walk more than other physiotherapy methods [10]. In own study, all patients walked with or without an orthopedic aid, but with an abnormal gait pattern. After therapy BWSTT group achieved subjectively greater independence, presenting in the independent coming out for a walk or shopping.

BWSTT method is based on the principles of activity-dependent neural plasticity that is: task specificity, high intensity and many repetition [22]. Yang et al. showed greater decrease of motor threshold by an average of 24.4% in the early and 4.3% in the chronic phase of stroke for BWSTT group and 4.4% and 0% in the control group receiving standard physiotherapy, respectively. In BWSTT group map size of the abductor hallucis muscle increased by 134% in early and by 38% in chronic stage and in the control group respectively by only 5% and 19% [31]. Also Yen et al. showed stronger enhancement of neuronal excitability and cortical reorganization in patients additionally receiving BWSTT [32]. Another advantage of using BWSTT could be economic aspect. Stroke patients gait requires 1.5-2 times higher energy effort. Training on a treadmill can improve the economics of walking by 16% and increased by 39%

VO2peak, which, in turn, may simplify performance of everyday life activities [33]. BWSTT can also be used in cardio-respiratory deconditioned patients. According Danielsson and Sunnerhagen subjects during treadmill training with 30% BWS achieved an average of 96.7 beats/min compared to 100.3 beats/min in patients with 0% BWS. Oxygen uptake using 30% BWS was 9.42 mL/(kg•min),compared with 10.82 at 0% BWS [34]. Gordon et al. emphasized that improving strength and timing of muscle activations and cardiorespiratory fitness positively influence self-care, occupational and leisure-time activities, which enhances the increase in exercise tolerance and reduces the risk of cardiovascular events (including recurrent stroke) [35]. It is worthwhile quote that in Poland the risk of recurrence after ischemic stroke within the first 30 days could reach 3%, within a year – 10 to 12% and within five years even 30-40% [36]. Thanks to the long-term outcomes of return patient to active participating in social life and the prevention of further stroke incidents we can positively influence the quality of life [35].
In 2013 Polish National Health Fund (NFZ) allocated approximately 156 million PLN for post-stroke rehabilitation. Total expenditure on services associated with inability to work due to cerebrovascular disease incurred by the Social Insurance Institution (ZUS) in 2010 was 679 million PLN. The rehabilitation services accounted for only 2.2% compared with 89.9% share of pension in respect of incapacity for work. Therefore, one of the recommendations of the experts report Udary mózgu – konsekwencje społeczne i ekonomiczne is the development and appropriate funding of stroke units and neurological rehabilitation centers [36]. The support body weight system can be an investment effectively supportive gait therapy. Faster reaching effects in the BWSTT group associated with a higher possibility of regaining independence and thus the reduction in cost of disability pension [37]. It should be noted that BWSTT will not replace standard physiotherapy covering a variety of motor tasks [10]. According Veerbeek et al. meta-analysis (467 RCT; 25 373 patients) the most effective in stroke physiotherapy seem to be intensive high repetitive task-oriented and task-specific training [4]. BWSTT is an example of that training [35]. What's more, BWSTT supporting patients safe environment provides positive reinforcement so that they could practice walking without fear of falling. The progressive increasing velocity and decreasing BWS contributing the improvement of force paretic limb motor control and power during stance and swing phases of gait [14, 18]. It should be added that the great advantage of BWSTT is ergonomic of therapist work who don't have to carry the patient and could focused on quality of patient's gait. Summary, results of the study present tendency to greater improvement in walking endurance and reduction risk of falling in patients enrolled in Body Weight Supported Treadmill Training compared with overground walking.
A limitation of this study is undoubtedly the lack of assessment of quality of life with standardized tool before and after the intervention. However, according to physiotherapist's observation and subjective evaluation groups were significantly different in terms of improving the quality of life favoring BWSTT group.

Conclusion

Both Body Weight Supported Treadmill Training and overground walking in combination with standard post-stroke physical therapy could produce clinically significant improvements in improving balance, endurance and velocity of gait and reduce fall risk in walking early stroke patients. BWSTT could have tendency to more effective increasing gait endurance than overground walking.

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