World Journal of Medical Sciences 16 (3): 121-127, 2019 ISSN 1817-3055 © IDOSI Publications, 2019 DOI: 10.5829/idosi.wjms.2019.121.127

Robotic Gait Training in Stroke Patients (Systematic Review)

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Abstract: Objective to examine the efficacy of robotic usage in gait training in adult patient with stroke. Data sources a literature search covering the years 2005 till 2019 in Pub med, NCBI, Sage, Cochrane, Medline, PEDRO. Study selection studies of adult stroke patients, in which experimental groups received robotic gait training (Lokomat device) with or without conventional physical therapy and the control group received only conventional physical therapy. Outcomes studies included gait parameter and balance. Study design all studies are randomized controlled trials. Data extraction study quality was assessed by PEDRO scale. All studies were graded equal to or more than 5 out of 10. Results data for meta-analysis could be extracted from the included studies for change in Cadence, 10MWT, Speed and Berg balance scale variables. The 95% confidence intervals of the overall effect estimate overlap null effect value so, the Meta-analysis level revealed a non-significant difference between the experimental groups and control groups. Conclusion gait parameters showed significant improvement in both groups in studies with no superiority of one treatment over another this may be because of the different protocols of Lokomat training or different response of the patients toward machine safety. So, Lokomat device need to be more tested.

Key words: Robot • Hemiparesis • Hemiplegia • Stroke • Lokomat • Gait Training • 10MWT • Berg Balance Scale and Rehabilitation

INTRODUCTION

Stroke is a frequent health problem and one of the most common causes of mortality and acquired adult disability. Many patients survive stroke, but there are usually long-term consequences for the patients and families. Frequently mobility and stability of joints, muscle power, tone and reflexes, muscle endurance, control of movement and gait pattern functions are affected. These impairments lead to problems with transferring, maintaining body position, mobility, balance and walking. In first 6 months post stroke, almost all patients experience at least few predictable degree of functional recovery [1].

Independent walking post stroke is one of the chief goals of rehabilitation to encourage functional activity, social participation and quality of life. In patients with ischemic stroke who have been admitted to rehabilitation hospitals, recovery of some degree of ambulation typically occurs in nearly 55% of patients [2]. Technological innovations are allowing rehabilitation to move forward to more integrated processes, with improved efficiency and less long term impairments. In particular, robot-mediated rehabilitation is a rapidly advancing field, which uses robotic systems to explore new methods for treating neurological injuries, especially stroke. The use of robots in gait training can improve rehabilitation, but it needs to be used according to well-defined scientific principles. The field of robotmediated neuro rehabilitation challenge both bioengineering and clinical practice [3].

A complete review of all machines developed worldwide is very difficult to be achieved because of number of prototypes tested within the scientific community, So we were going to assess efficacy of Lokomat device and its role in gait training in adult stroke patients [4].

New automated locomotion systems have been developed for facilitation of step training and to eliminate manual assistance by the physical therapist. One robotic

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assistive treadmill device, the Lokomat, has been commercially available for several years. No reports of efficacy for walking outcomes have been reported, although several trials are in progress [5].

The Lokomat consists of a treadmill, a driven gait orthosis, a suspension system to provide body weight support and a computer for individual adaptation of gait within preset safety limits. A second computer screen provides the patient with online information about speed, time and distance [6].

In this studied we attempted to examine the role of the Lokomat device in improving gait parameters in adult patients with stroke and to compare its effect with the effect of the conventional gait training.

MATERIALS AND METHODS

The search strategies and selection criteria were described in detail in Figure (1). A computerized search was conducted for randomized control trials in English language published from 2005 till 2019 including databases of Pub med, NCBI, Sage, Cochrane, Medline, PEDRO and by using key words "Robots ", "Hemiparesis", "Hemiplegia", "Stroke", "Lokomat", "Gait training", "10MWT", "Berg balance scale", "Speed", "Cadence", Mesh terms and their combinations were organized in Table (1).

Quality Assessment of Included Studies: The quality of a trial may be defined as "The extent to which its design and conduct are likely to have prevented systematic errors."[7]. Quality assessment was done by PEDro scale. The PEDro scale is a valid measure of the methodological quality of clinical trials. It is valid to sum PEDro scale item scores to obtain a total score that can be treated as interval level measurement and subjected to parametric statistical analysis [8].

Inclusion Criteria

Types of Studies: Randomized control studies.

Types of Participants: The review will include adult stroke patients in acute and chronic stages.

Types of Interventions: Lokomat device gait training with or without conventional physical therapy.

Types of Outcomes Measures: Outcome measures related to gait (Speed, cadence, 10 minute walking test 10MWT and Berg balance scale).

Exclusion Criteria: The studies were excluded if they were:

• Studies that measured outcomes not related to the scope of this study.



Fig. 1: Prisma flow chart

Table 1: Key words and Mesh terms used in search following the PICO method:

Population	Stroke (acute, chronic), hemiplegia, hemiparesis
Intervention	Lokomat device with or without conventional physical therapy
Comparison	Conventional gait training
Outcome	Berg balance scale, 10 minute walking test, cadence, speed

- Studies that combined robotic gait training with any other modalities other than conventional physical therapy.
- Studies published in language other than English.

Limitation of the study:

- Studies published in languages not English.
- Study limited to randomized control studies only.

RESULTS

One hundred and eighty studies were identified as relevant, at the end of searching and applying quality measure and applying inclusion and exclusion criteria only seven studies participated in this study. The result of methodological assessment was summarized in Figure (1).

Seven selected studies were collected and were found typical to the outcome measures and summarized according to PICO in (Table 2).

Measures of Treatment Effect: The outcome variables of interest were continuous outcomes. Data of change scores between pre- and post-intervention measures were evaluated and entered as means and standard deviations (SDs) and the standardized mean difference (SMD) with 95% confidence intervals (CIs) for each trial was calculated. Data were pooled through calculation of the overall SMD and 95% CI.

Data Analysis: A comparison between the experimental group and control group was made and a pooled analysis of outcomes was conducted through calculation of the overall SMD and 95% CI, using a random effects model instead of a fixed-effect model if heterogeneity of the studies was high.

Outcome 10 MWT: Data for meta-analysis could be extracted from the included studies for change in 10 MWT variables. As reflected from Fig. (2) There were total number of subjects included into analysis was 39 in experimental groups and 40 in control groups. The study analysis level revealed that the 95% confidence intervals of the Giovanni Taveggiaa *et al.* [9] study overlap the null effect value so there was non-significant effect of

experimental group on 10 MWT. As well as, the 95% confidence intervals of the Carolyn Kelley et al., 2013 study overlap the null effect value so there was nonsignificant effect of experimental group on 10 MWT. While, the study analysis level revealed that the 95% confidence intervals of the Britta Husemann et al. [10] study overlap the null effect value so there was non-significant effect of experimental group on 10 MWT. AS indicated in Fig. (2). The forest plot of the mean difference across both studies at 95% CI of the mean difference (SMD=-0.26, 95% CI of the mean difference =-0.71, 0.19). Furthermore, the 95% confidence intervals of the overall effect estimate overlap null effect value so, the Meta-analysis level revealed a non-significant difference between the experimental groups and control groups (The overall effect P value is 0.25). The heterogeneity tests aim to determine if there are variations among the three studies, which may not be due to chance. The I² statistic (I² = 0%, P = 0.64, fixed-effects model) is presented as a percentage and represents the total variability in the studies effect measure which is due to heterogeneity. Ideally, the zero heterogeneity among the three studies, thus indicating their suitability to be pooled into a meta-analysis. The test P value >0.05 which would indicate no heterogeneity among the three studies.

Outcome Cadence: Data for meta-analysis could be extracted from the included studies for change in Cadence variable. As reflected from Fig. (3). There were total number of subjects included into analysis was 57 in experimental groups and 54 in control groups. The study analysis level revealed that the 95% confidence intervals of the Joseph Hidler et al. [13] study not overlap the null effect value so there was significant effect of experimental group on Cadence. While, the 95% confidence intervals of the Britta Husemann et al. [10] study overlap the null effect value so there was no significant effect of experimental group on Cadence. However, the study analysis level revealed that the 95% confidence intervals of the Dae-Hyouk Bang and Won Seob Shin [11] study not overlap the null effect value so there was significant effect of control group on Cadence. AS indicated in Fig. (3). The forest plot of the mean difference across both studies at 95% CI of the mean difference (SMD=0.13, 95% CI of the mean difference =-1.58, 1.83). Furthermore, the

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Table 2: Characteristics of Selected Studies according to PICO:

Study	Rating	Population	Experimental group	Control group	Outcome measures	Conclusion
1-Giovanni Taveggiaa <i>al et</i> [9]	7/10	Twenty-eight patients, 39, 3% wornen (72±6 years), with henriparesis (<6 months after stroke)	N=13 -60min of conventional treatment according to the Bobath approach and 30min of robotic gait training on the Lokomat robotic system for 25 sessions.	N=15 60min of conventional treatment according to the Bobath approach, received 30min activities targeted at improvement in walking (i.e. strengthening exercises of the knee extensions, hip lateral rotators and abductors, standing posture, reconditioning exercises) for 25 sessions.	10MWT Experimental Control Pre:0.27(0.25) Pre:0.48(0.25) Post:0.72(0.38) Post:0.53(0.37) Post:0.72(0.38) Post:0.72(0.38)	Both treatments are effective in the improvement of gait performances although only experimental treatment produced functional improvements. Further analyses should be carried out to understand why functional gait improvements are not reflected in the patients.
2-Britta Husemann <i>al et</i> [10]	7/10	 - 30 acute stroke survivors, 21 males and 9 females with mean age 57(16) years. Days after stroke 79(70) days. 	N=15 - received 30 minutes of robotic training daily in addition to 30 minutes of conventional physiotherapy for 40 sessions.	N=15 -60 minutes of conventional physiotherapy daily for 40 sessions.	experimental Control 10MWT Pre:0.14(0.02) Pre:0.12(0.03) Post.0.20(0.03) Post.0.20(0.05) Cadence Cadence Pre:35.9(3.87) Pre:28.9(4.62) Post:43.28(4.21) Post:40.68(6.39)	Lokomat therapy is a promising intervention for gait rehabilitation. There was no significant difference in gain of these parameters between the groups.
3-Dae-Hyouk Ban and Won Seob Shin [11]	7/10	-Eighteen stroke patient including 9 males and 9 females with mean age 53,5(3,94) years and months after stroke 11(65) months.	N=9 - 20 sessions were Ih per day, 5-days a week for four weeks using Lokomat device	N=9 - 20 sessions that were Ih per day, 5-days a week for four weeks doing gait training exercise	experimental Control Speed(m/s) Pre0.48(0.05) Pre0.46(0.04) Post: 0.54(0.04) Post: 0.55(0.04) Operation (1,05) Cadence Pre63.79(1.05) Pre63.78(1.61) Post: 69.3(1.92) Post: 66.24(2.02) BBS Pre43.22(2.54) Pre42.11(2.42) Post: 46.33(1.87) 2.37 Post Post: 46.33(1.87)	Lokomat may be more effective than conventional gait training in improving walking ability, balance in patients with stroke
4- George Hornby al et [12]	5/10	Farty-eight chronic stroke patients > 6 months post stroke 30 males and 18 females with mean age 57(11) years.	N=24 12 sessions (30 minutes/ session) with Lokomat device.	N=24 12 sessions (30 minutes/ session) with therapist assisted locomotor training.	experimental Control Speed(m/s) Pre0.45(0.19) Pre0.43(0.22) Post:0.52(0.21) Post:0.56(0.28) BBS Pre43(10) Pre:42(10) Post:44(11) Post:44(11)	Therapist-assisted training facilitates greater improvements in walking ability in ambulatory stroke survivors as compared to a similar dosage of robotic- assisted training
5-Joseph Hidler al et [13]	5/10	 - 63 stroke patients <6 months post stroke including 39 males and 24 females with mean age 54 (15) years. 	N=33 - Twenty-four 1- hour sessions of Lokomat gait training 3 days per week; for 8 to 10 weeks, for a maximum total of 24 sessions. Each session was 1.5 hours,	N=30 - Twenty-four 1-hour sessions of conventional gait training, 3 days per weeks, for 8 to 10 weeks, for a maximum total of 24 sessions. Each session was 1.5 hours,	experimental Control BBS Pre: 36.7(1.9) Pre: 39.9(2) Post: 6(0.9) Post: 6.6 (1) Cadence Pre: 67.2(5.8) Pre: 65.3(6.4) Post: 5.5(5.3) Post: 13.7(6) Speed(m/s) Speed(m/s) Pre: 0.34(0.03) Pre: 0.35(0.03) Post: 0.46(0.03) Post: 0.60(0.03)	Conventional gait training interventions appears to be more effective than robotic- assisted gait training for facilitating returns in walking ability.
6-Carolyn p. Kelley <i>al et</i> [14]	5/10	-21 stroke patients with 13 males and 8 females with mean age 65.75(9.48) years and mean years 2.87 post stroke.	N=11 - gne hour of Lokomat gait training, 5 days a week for 8 weeks	N=10 - one hour of gait training, 5 days a week for 8 weeks	10MWT Experimental Control Pre:0.20(0.10) Pre: 0.18(0.12) Post: 0.27(0.27) Post: 0.20(0.10) Post: 0.27(0.27) Post: 0.27(0.27)	Walking measures did not show significant changes between groups, motor function and physical functional levels improved over time within both groups.
7-Kelly P Westhk el et. [15]	6/10	- Sixteen volunteers with chronic stroke with 5 females and 11 males with mean age 55.1 (19.6) years.	N=8 -12 sessions (3×kwk over 4 weeks) with> 1 hour per session with Lokomat device.	N=8 -12 sessions (3×/wk over 4 weeks) with> 1 hour per session with gait training.	experimental Control Speed (m/s) Pre : 0.62(0.31) Pre : 0.62(0.28) Post : 0.72(0.38) Post : 0.65(0.29) BBS Pre : 46.9 (7.5) PRE :47(7) Post:48.2(6.8) Post:51(5.4)	Results suggest that Lokomat training may have advantages over manual training following a modest intervention dose in chronic hemi paretic persons and further, that our training speeds produce similar gait improvements. Suggestions for a larger randomized controlled trial with optimal study parameters are provided.

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	Expe	erimen	tal	C	ontrol			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Giovanni Taveggiaa ,et.2016	0.53	0.37	13	0.72	0.38	15	34.7%	-0.49 [-1.25, 0.26]	
Carolyn p. Kelley et, 2013	0.2	0.1	11	0.27	0.27	10	26.6%	-0.34 [-1.20, 0.53]	
Britta Husemann et,2007	0.2	0.03	15	0.2	0.05	15	38.7%	0.00 [-0.72, 0.72]	
Total (95% CI)			39			40	100.0%	-0.26 [-0.71, 0.19]	•
Heterogeneity: Chi# = 0.90, df =	= 2 (P = 0).64); P	= 0%						
Test for overall effect: Z = 1.15	(P = 0.25	5)							Favours [experimental] Favours [control]

Fig. 2: Forest plot: Comparison between experimental group and control group regarding change in 10 MET.

	Expe	erimen	ital	C	ontrol			Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI	
Joseph Hidler et,2009	5.5	5.3	33	13.7	6	30	34.7%	-1.44 [-1.99, -0.88]		
Britta Husemann et,2007	43.28	4.21	15	40.68	6.39	15	33.8%	0.47 [-0.26, 1.19]		
Dae-Hyouk Ban et,2016	69.3	1.92	9	66.24	2.02	9	31.5%	1.48 [0.41, 2.55]		
Total (95% CI)			57			54	100.0%	0.13 [-1.58, 1.83]		
Heterogeneity: Tau ^a = 2.10;	Chi# = 3	0.45, 0	if = 2 (F	P < 0.00	001);1	*= 93%	0			1
Test for overall effect: Z = 0.	15 (P = 1	0.88)							Favours [experimental] Favours [control]	4

Fig. 3: Forest plot: Comparison between experimental group and control group regarding change in cadence.

	Experimental			Control			Std. Mean Difference		Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl
Joseph Hidler et,2009	0.34	0.03	33	0.35	0.03	30	37.3%	-0.33 [-0.83, 0.17]	
T. George Hornby, 2008	0.52	0.21	24	0.56	0.28	24	36.4%	-0.16 [-0.73, 0.41]	
Dae-Hyouk Ban et, 2016	0.64	0.04	9	0.55	0.04	9	26.2%	2.14 [0.93, 3.36]	
Total (95% CI)			66			63	100.0%	0.38 [-0.66, 1.42]	
Heterogeneity: Tau ² = 0.69	; Chi ² =	13.82,	df = 2	(P = 0.0	010); F	^z = 86%			
Test for overall effect: Z = 0	0.72 (P =	0.47)							Favours [experimental] Favours [control]

Fig. 4: Forest plot: Comparison between experimental group and control group regarding change in speed.

95% confidence intervals of the overall effect estimate overlap null effect value so, the Meta-analysis level revealed a non-significant difference between the experimental groups and control groups (The overall effect P value is 0.88). The heterogeneity tests aim to determine if there are variations among the three studies, which may not be due to chance. The I² statistic (I² = 93%, P = 0.0001, random-effects model) is presented as a percentage and represents the total variability in the studies effect measure which is due to heterogeneity. The I² statistic indicates high heterogeneity among three studies.

Outcome Speed: Data for meta-analysis could be extracted from the included studies for change in Speed variable. As reflected from Fig. (4). There were total number of subjects included into analysis was 66 in experimental groups and 63 in control groups. The study analysis level revealed that the 95% confidence intervals of the Joseph Hidler *et al.* [13] study overlap the null effect value so there was no significant effect of experimental group on Speed. As well as, the 95% confidence intervals of the rull effect value so there was no significant effect of experimental group on Speed. While, the study analysis level revealed

that the 95% confidence intervals of the Dae-Hyouk Bang and Won Seob Shin [11] study not overlap the null effect value so there was significant effect of control group on Speed. AS indicated in Fig. (4). The forest plot of the mean difference across both studies at 95% CI of the mean difference (SMD=0.38, 95% CI of the mean difference =-0.66, 1.42). Furthermore, the 95% confidence intervals of the overall effect estimate overlap null effect value so, the Meta-analysis level revealed a nonsignificant difference between the experimental groups and control groups (The overall effect P value is 0.47). The heterogeneity tests aim to determine if there are variations among the three studies, which may not be due to chance. The I² statistic (I² = 86%, P = 0.001, randomeffects model) is presented as a percentage and represents the total variability in the studies effect measure which is due to heterogeneity. The I² statistic indicates high heterogeneity among three studies.

Outcome BBS: Data for meta-analysis could be extracted from the included studies for change in BBS variable. As reflected from Fig. (5). There were total number of subjects included into analysis was 88 in experimental groups and 98 in control groups. The study analysis level revealed that the 95% confidence intervals of the Joseph

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	Expe	erimen	tal	C	ontrol			Std. Mean Difference	Std. Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI		
Joseph Hidler et,2009	6	0.9	33	6.6	1	30	24.9%	-0.62 [-1.13, -0.12]			
Kelly P Westlake et al., 2008	48.3	6.8	8	51	5.4	8	15.1%	-0.42 [-1.41, 0.58]			
T. George Hornby, 2008	44	10	24	44	11	24	23.5%	0.00 [-0.57, 0.57]	-+-		
Bryan Ping et 2017	26	12.4	14	22.3	14.1	27	21.7%	0.27 [-0.38, 0.92]			
Dae-Hyouk Ban et,2016	48.84	2.37	9	46.33	1.87	9	14.8%	1.12 [0.11, 2.13]			
Total (95% CI)			88			98	100.0%	0.01 [-0.52, 0.54]	+		
Heterogeneity: Tau ^a = 0.23; Cl	hi# = 11.4	13, df=	: 4 (P =	0.02); P	r = 659	6			4 .2		
Test for overall effect: Z = 0.02	(P = 0.9	8)							Favours [experimental] Favours [control]		

Fig. 5: Forest plot: Comparison between experimental group and control group regarding change in BBS.

Hidler et al. [13] study not overlap the null effect value so there was significant effect of experimental group on BBS. While, the 95% confidence intervals of the Kelly Westlake et al.[15] study overlap the null effect value so there was no significant effect of control group on BBS. AS well as, the 95% confidence intervals of the George Hornby, 2008 study overlap the null effect value so there was no significant effect of experimental group on BBS. Additionally, the 95% confidence intervals of the Bryan Ping et al. [16] study overlap the null effect value so there was no significant effect of experimental group on BBS. While, the study analysis level revealed that the 95% confidence intervals of the Dae-Hyouk Ban and Won Seob Shin [11] study not overlap the null effect value so there was significant effect of control group on BBS. AS indicated in Fig. (5). The forest plot of the mean difference across both studies at 95% CI of the mean difference (SMD=0.01, 95% CI of the mean difference =-0.52, 0.54). Furthermore, the 95% confidence intervals of the overall effect estimate overlap null effect value so, the Meta-analysis level revealed a non-significant difference between the experimental groups and control groups (The overall effect P value is 0.98). The heterogeneity tests aim to determine if there are variations among the three studies, which may not be due to chance. The I² statistic ($I^2 = 65\%$, P = 0.02, random-effects model) is presented as a percentage and represents the total variability in the studies effect measure which is due to heterogeneity. The I² statistic indicates high heterogeneity among three studies.

DISCUSSION

The purpose of the current review was to systematically review the randomized controlled studies assessing the effectiveness of using Lokomat device in gait training in post stroke adult patients and its effect on gait parameters such as cadence, speed and balance. Systematic reviews differ from traditional narrative reviews in several ways. Narrative reviews tend to be mainly descriptive, do not involve a systematic search of the literature and thereby often focus on a subset of studies in an area chosen based on availability or author selection. Thus narrative reviews while informative can often include an element of selection bias. They can also be confusing at times, particularly if similar studies have diverging results and conclusions. Systematic reviews, as the name implies, typically involve a detailed and comprehensive plan and search strategy derived a priori, with the goal of reducing bias by identifying, appraising and synthesizing all relevant studies on a particular topic. Often, systematic reviews include a meta-analysis component which involves using statistical techniques to synthesize the data from several studies into a single quantitative estimate or summary effect size [17]. Seven RCTs were included, with a total of 224 adult stroke patients all of them used Lokomat in gait training. They were selected out of 194 studies which are convenient to inclusion and exclusion criteria and fulfill the desired outcome measures. The quality and validity of studies were measured by PEDRO scale, in which the seven studies were ranked between 5: 7. All studies fulfill at least one of the outcome measures which were cadence, Berg balance scale, 10MWT and speed. The studies included 113 in the experimental group and 111 in the control group of adult stroke patients in all stages of stroke (Acute, subacute and chronic) ranging from few days to many years post stroke. Speed, cadence and balance were not significantly affected by Lokomat device however there were significant improvement in gait parameters among all the studies in both groups which used therapist assisted gait training or Lokomat gait training but with no statistical significance. At the end, there is conflicting result and we cannot ensure the efficacy or the inefficacy of Lokomat gait training or to consider it as a superior treatment over conventional physical therapy in improving gait parameters in patient with different stages of stroke.

CONCLUSION

Meta-analysis did not support the efficacy of Lokomat device in gait training of post stroke patients in all stages of recovery. However, the improvement noticed in experimental groups in some studies it could not be statistically approved may because of the different techniques of training or frequency and length of training time. From another point of view and considering the cost of Lokomat device, therapist assisted gait training showed better result in some studies.

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