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RESEARCH ARTICLE

EFFECTIVENESS OF ROBOTIC-ASSISTED GAIT TRAINING IN STROKE REHABILITATION: REVOLUTION IN PATIENT OUTCOME

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Abstract

Objective: To evaluate the effectiveness of robotic-assisted gait training (RAGT) in improving the functional outcomes among stroke survivors

Design: Retrospective matched control study.

Setting: Inpatients stroke unit, Qatar Rehabilitation Institute.

Outcome Measures: The Functional Ambulation classification (FAC), The Functional independence measure (FIM), The Berg Balance Scale (BBS), The Dynamic Gait index (DGI), The Ten-meter walk test (10MWT), The timed up and Go test (TUG) and the Five times sit to stand (5XSTS)

Data Analysis: A retrospective comparison of stroke patients who received robotic assisted gait training performed statistically using the 20th version of SPSS statistical package (SPSS Inc. Chicago, IL, USA)

Study Procedures: The investigators reviewed the medical records, the physiotherapy treatment sessions records and data from the Clinical Management System of Qatar rehabilitation institute of the patients during the period from 1stJanuary 2018 to 31 December 2019. RAGT group was created to assign the patients who received more than four RAGT sessions. The other group was created from the patients who completed the stroke rehabilitation program without RAGT to cross match

Conclusion: All the outcome measures were compared between admission and discharge regardless of their group and found that there was a good improvement in the outcome and statistically significant (p value 0.0001) While comparing the lokomat and non lokomat group in functional outcome measurements lokomat group (RAGT) had significant improvement in discharge scores.

Introduction: -

All over the world, Stroke or cerebrovascular accidents are known to be the second leading cause of death and the third leading cause of disability [1]. CVA is the results of the death of some brain cells due to lack of oxygen supply. The disruption of the blood flow to the brain is caused by blockage or rupture of pone of the arteries of the brain, it is also known that stroke is a leading cause of dementia and depression.[2] The recent evidence shows that in 70%

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of strokes and 87% of both deaths related to stroke and disability adjusted life occur in low to middle income countries.[3–5]

The incidence of stroke was more than doubled over the last four decades in low to middle income countries and it declined by 42% in high income countries.[3]Generally, it was noticed that stroke occurs 15 years earlier and causes more deaths in low and middle income countries, when compared to high income countries.[2] CVA remains the second leading cause of mortality and a major cause of disability across the globe, with 6.7 million deaths in 2012 being attributed to stroke alongside 33 million stroke survivors, many of those patients are left with long-term disability [4]

In the middle east it was found that the prevalence rate for stroke was between 508 and 777 per 100,000 population. Where the incidence for strokes had a value between 22.7 and 250 per 100,000 population per year. The gender differences have been identified in some studies where 75% reported a high male to female ratio among stroke patients. Studies also shown that ischemic stroke was the highest followed by intracerebral and subarachnoid hemorrhage. Hypertension was the most reported risk factor followed by diabetes. The overall fatality rate within one month ranged between 12 to 32%.[6]

Bener et al in the Retrospective outcome that was done in Qatar in 1999-2003, reported an incidence of 11.7 per 100,000. Hypertension and diabetes had a strong association with 60% of the stroke patients having had a previous acute myocardial infarction and 46.4% had diabetes mellitus [7.8] [39,40]. Hamad et al. In a prospective hospital-based study from 1997, reported a higher incidence where 47 per100,000 with an overall stroke mortality of 16% [7]. Another retrospective population-based study by Ibrahim in 2015, undertook and reported a stroke incidence of 51.8 per 100,000 and a 30-day stroke mortality of 9.3% [9]

Motor impairment was the predominant recognized impairment caused by stroke, which is known to restrict muscle movement or mobility function [14]. Most of the stroke patients experience walking difficulties, improving walking function and gait pattern is one of the main goals of rehabilitation [15]. It was shown that the process of spontaneous recovery is almost completed within 6 to 10 weeks [16], To maximize the function of the patients after stroke early rehabilitation is essential. High intensity repetitive task-specific practice might be the most effective approach when trying to promote motor recovery after stroke as recent evidence suggests [14].

The Robotic-assisted gait training (RAGT) is one of the emerging physiotherapy technologies that applies the high intensity repetitive task-specific practice principle to improve mobility of patients with neurological conditions. There are some advantages of RAGT and one of them is to reduce the effort and intervention required by therapists compared to bodyweight supported treadmill trainings, Therapists no longer need to set the paretic limbs or assist in trunk movements [17]. The patients who receive additional RAGT in combination with conventional physiotherapy sessions after stroke are more likely to achieve independency in walking more than patients who receive conventional physiotherapy sessions only [18]. More precisely, patients in the first 3 months after stroke and those who lost the ability to walk have higher chance to benefit most from this type of intervention [18]. Evidence have also shown that the use of RAGT in stroke patients has positive effects on their balance [19]. The effectiveness of RAGT have been demonstrated in randomized controlled trials and systemic reviews for stroke patients in terms of functional outcomes such as walking ability [20,22] and balance [19,22] RAGT provides what is known as automated locomotion therapy,patients are attached to the robotic exoskeletal orthosis that assist with basic walking functions while the body weight support system to is used to suspend individuals. It enables the therapist to control the speed while walking, how much body weight he/she can support and how much assistance or guidance force the robotic legs give the patient through the range of motion.

Descriptive Statistics

The investigators reviewed the medical records, the physiotherapy treatment sessions records and data from the Clinical Management System of Qatar rehabilitation institute of the patients during the period from 1stJanuary 2018 to 31 December 2019. RAGT group was created to assign the patients who received more than four RAGT sessions while the other group was created from the patients who completed the stroke rehabilitation program without RAGT to cross matchthe age, length of stay, Total number of physiotherapy sessions and admission functional outcome measures. The patients who all are not matched with the robotic assisted gait training group were excluded and the remaining patients were assigned to the control group. Both groups have similar baseline characteristics such as length of stay and days from stroke

Inclusion criteria were: Ability to follow at least one-step command, Ability to tolerate passive standing for at least 15 minutes, Functional range of motion in lower limbs and the interval between the stroke incidence and the first session of intervention being no longer than 6 weeks.

Exclusion criteria were: Body weight greater than 135 kg; Femur bone length shorter than 35 cm or longer than 47 cm, severe lower-extremity contractures or severe spasticity, Osteoporosis, or dyskinesia that limited normal walking kinematic, Open wound over the trunk or lower limbs, Hemodynamicinstability, Uncontrolled seizures

Baseline characteristics mentioned above and functional outcome measurements including The Functional Ambulation classification (FAC), The Functional independence measure (FIM), The Berg Balance Scale (BBS) were collected for analysis. The conventional physiotherapy treatments were based on the stroke rehabilitation protocol (PAAS Guideline)

Baseline characteristics

Consideration was given to the Baseline characteristics and only male patients was selected for this study, age, Number of days after stroke, Total number of physiotherapy sessions, Duration of training, were collected for further analysis.

Study design

It was a Retrospective matched control study. The investigator reviewed the medical records, the physiotherapy treatment sessions records and data from the Clinical Management System of Qatar rehabilitation institute of the patients during the period from 1stJanuary 2018 to 31 December 2019. Patients was divided into two groups.group was created to assign the patients who received more than four RAGT sessions while The other group was created from the patients who completed the stroke rehabilitation program without RAGT to cross match the age, length of stay, Total number of physiotherapy sessions and admission functional outcome measures

Robotic assisted gait training (RAGT)

The RAGT was provided by a robot system device (Lokomat, Hocoma Inc., Zurich, Switzerland) The machine was operated by only trained and certified physiotherapists with Lokomat certification.

Conventional physiotherapy

The conventional physiotherapy treatments were based on the Physical Therapy After Acute Stroke (PAAS) guideline which is a professional clinical practice guideline for physical therapy following stroke; based on scientific evidence, intended to optimize patient care. These guidelines are intended to serve as an instrument to support physical therapists in making clinical decisions that was developed by the department of physiotherapy in Hamad Medical Corporation, Doha, Qatar in 2016 and first updated in 2018. These guidelines are intended to create the right conditions to ensure that high-quality physical therapy is accessible to the population of Qatar and to promote recognition of the professional expertise of physical therapists.

The PAAS guideline offers recommendations for appropriate physiotherapy care to improve the quality, transparency, and uniformity of the physical therapy provided to stroke patients which is based on scientific research and adjusted where necessary on the basis of consensus among physical therapy experts in primary, secondary and tertiary care, as well as associated professions in the rehabilitation field.

Treatment Duration

Both groups were admitted in same ward (Stroke unit Qatar rehabilitation institute) one group received only conventional physiotherapy treatments given by same therapist 5 days per weeks. The duration of each therapy session will vary from 45 to 60 minutes-based patients' tolerance.

The other group received conventional physiotherapy plus Robotic assisted gait training (Duration of robotic assisted gait training 30-45 minutes based on tolerance level and motivation of the patient)

Statistical analysis

A retrospective matched comparison of stroke patients those have received robotic gait training therapy was performed statistically. The investigators compared the clinical outcomes of the robotic assisted gait training group with those of the control group in order to facilitate the pre and post between- and within-group differences in ADL,

gait, mobility and balance.The within-groupdifferences of admission and discharge outcome of each functional outcome measurement (Functional ambulation classification(FAC), Berg balance scale(BBS), Functional independent measure (FIM), Dynamic Gait index(DGI),Five times sit to stand(5XSTS), Ten meter walk test(TMWT) and between-group differences of FAC, BBS, FIM, DGI, 5XSTS, TMWT gain were compared. The within-group comparisons of both groups were based on paired t test. Results were considered statistically significant when $p < 0.05$. Data were analyzed with the use of the SPSSversion 20 statistical package (SPSS Inc. Chicago, IL, USA).

	Table 1	Frequency	Percent
Nationality	Bangladeshi	26	15.5
	Filipino	16	9.5
	GCC	8	4.8
	Indian	37	22.0
	Nepali	20	11.9
	Other	34	20.2
	Qatari	18	10.7
	Sri lankan	9	5.4
	Total	168	100.0
Comorbidities	Non	34	20.2
	CAD	2	1.2
	DM	14	8.3
	HTN	57	33.9
	HTN, CAD	3	1.8
	HTN, DM	44	26.2
	HTN, DM, CAD, ESRD	3	1.8
	HTN, DM,CAD	10	6.0
	HTN, ESRD	1	0.6
	Total	168	100.0
Comorbidities Group	No	34	20.2
	Yes	134	79.8
	Total	168	100.0
Type of stroke Group	Ischemic	109	64.9
	Hemorrhagic	59	35.1
	Total	168	100.0

Results: -

From 1st January 2018 to 31 December 2019 all stroke patients admitted to the Qatar rehabilitation institute where screened for the study, Total of 168 patients selected for the study in that 84 patients received only conventional physiotherapy and 84 received conventional physiotherapy plus robotic assisted gait training.

Baseline characteristics of the patients are shown in Table 1

Out of 168 patient 109 (65%) were Ischemic stroke and 59 patients (35%) were Hemorrhagic. Hypertension was the comorbidly noticed in 57patients (34%) followed by hypertension and diabetes mellitus in 44(26%) 10 patients had hypertension and diabetes mellitus and coronary heart disease. Out of 168 patient 134 patients (80%) had comorbidities and 34 patients (20%) didn't had any single comorbity. Mean number of physiotherapy session given are 26 and standered deviation was 15.28 and 75 % of the data value were between 15 session to 35 session. Mean Length of stay was 34, SD26, ranging from19 to 46 days. Mean FIM score were 63, SD22 ranging from 47-79) Mean Berg Balance Scale was 10, SD9, ranging from 4-17. Mean FIM discharge was 95, SD 23. BBS was 30, SD13, Mean Functional Ambulation Classification admissions was 1.67, SD 0.85. Mean discharge was 4.

Table 2: -

	Number of PT sessions	LOS	FIM Gain	FAC Gain	5XSTS Gain	TUG Gain	DGI Gain	Ten MWT Gain
Median	26.00	34.00	34.5	3.00	10.00	14.00	10.00	0.4000
Mean	26.76	37.45	32.3988	2.33	7.66	14.89	9.2083	0.4379
Std. Deviation	15.288	26.412	0.94812	0.350	8.037	17.777	7.208	0.37947
Percentiles	15.25	19.00	36	2.00	0.00	0.00	0.00	0.0000
	34.75	46.75	33	3.00	12.00	21.00	16.00	0.7000

Table 3: -

Table 3			Deffernce in mean D-A	P Value
FIM	Admission	63.55 ± 22.086	32.399	0.0001
	Discharge	95.95 ± 23.03		0.0001
BBS	Admission	9.93 ± 9.05	19.655	0.0001
	Discharge	29.59 ± 12.82		0.0001
FAC	Admission	1.67 ± 0.85	2.333	0.0001
	Discharge	4.01 ± 1.2		0.0001
5XSTS	Admission	1.16 ± 4.19	7.661	0.0001
	Discharge	8.82 ± 7.1		0.0001
TUG	Admission	0.54 ± 3.72	14.893	0.0001
	Discharge	15.43 ± 17.35		0.0001
DGI	Admission	0.26 ± 1.48	9.208	0.0001
	Discharge	9.47 ± 7.31		0.0001
Ten MWT	Admission	0.0128 ± 0.0755	0.438	0.0001
	Discharge	0.4507 ± 0.38822		0.0001

All the outcome measures were compared between admission and discharge regardless of their group and found that there was a good improvement in the outcome and statistically significant (p value 0.0001)

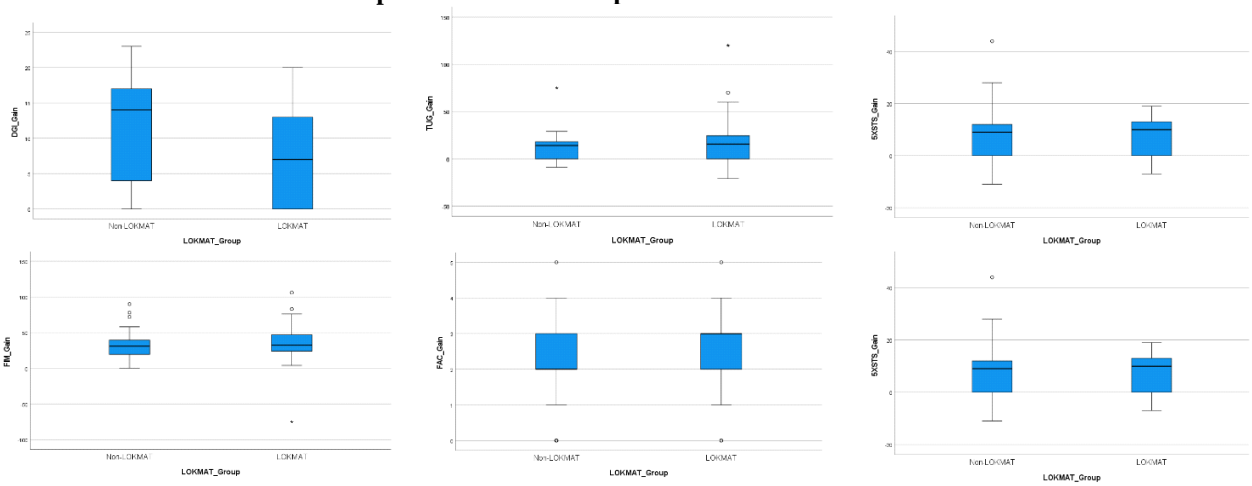
While comparing the lokomat and non lokomat group in functional outcome measurements lokomat group (RAGT) had significant improvement in discharge scores. RAGT Group had significant gain FIM, BBS, FAC, 5XTSTS, DGI, TUG, 10MWT.

Table 4:-

Group Statistics Gain				
			P Value	Mean Difference
FIM	LOKOMAT	35 ± 21.82	0.0869	5.2024
	Non-LOKOMAT	29.8 ± 17.05	0.0870	
BBS	LOKOMAT	21.4 ± 11.35	0.0411	3.5000
	Non-LOKOMAT	17.9 ± 10.67	0.0411	
FAC	LOKOMAT	2.52 ± 1.1	0.0241	0.3810
	Non-LOKOMAT	2.14 ± 1.07	0.0241	
5XSTS	LOKOMAT	8.06 ± 6.77	0.5217	0.7976
	Non-LOKOMAT	7.26 ± 9.16	0.5218	
TUG	LOKOMAT	17.29 ± 22.47	0.0810	4.7857
	Non-LOKOMAT	12.5 ± 10.92	0.0817	
DGI	LOKOMAT	7.2 ± 6.565	0.0001	-4.0119
	Non-LOKOMAT	11.21 ± 7.3	0.0002	
Ten MWT	LOKOMAT	0.3399 ± 0.34436	0.0007	-0.1960
	Non-LOKOMAT	0.5358 ± 0.38951	0.0007	

In table 4 out of seven outcome measures used in this study 4 of them were statistically significant and in 3 scale there was an improvement noted in lokomat group even though not statistically significant while comparing total FIM score with lokomat 35 ± 21.82 and non lokomat group 29.8 ± 17.05 there was a mean deference of 5.202 in lokomat group even though not statistically significant p value 0.0869. Berg balance scale, Functional ambulation classification, Dynamic Gait index, Ten-meter walk test P value 0.0410,0.0240,0.0001,0.0007 respectively

Detailed distribution of values is presented in the box plot



We did an analysis to compare gain score between two groups with comorbidities and didn't found any significance, while comparing Ischemic and hemorrhagic group there was a significant improvement noted in hemorrhagic group and it was statistically significant. Admission and discharge comparison within the lokomat group were statistically significant

Group Statistics Gain			
Type of stroke Group		Mean ± Std. Deviation	P Value
FIM	Hemorrhagic	38.42 ± 21.56	0.003
	Ischemic	29.14 ± 17.88	0.006
BBS	Hemorrhagic	22.05 ± 11.91	0.040
	Ischemic	18.36 ± 10.5	0.048
FAC	Hemorrhagic	2.47 ± 1.16	0.221
	Ischemic	2.26 ± 1.06	0.235
5XSTS	Hemorrhagic	8.51 ± 8.6	0.316
	Ischemic	7.2 ± 7.72	0.332
TUG	Hemorrhagic	14.54 ± 17.5	0.852
	Ischemic	15.08 ± 18	0.850
DGI	Hemorrhagic	9.69 ± 7.19	0.521
	Ischemic	8.94 ± 7.24	0.521
10 MWT	Hemorrhagic	0.4376 ± 0.3395	0.99541
	Ischemic	0.438 ± 0.4009	0.99518

Paired Samples Statistics within LOKOMAT Group			
		Mean ± Std. Deviation	P Value
FIM	Admission	58.17 ± 19.11	0.0001
	Discharge	93.17 ± 20.92	0.0001
BBS	Admission	5.85 ± 6.18	0.0001
	Discharge	27.25 ± 12.57	0.0001
FAC	Admission	1.3 ± 0.64	0.0001
	Discharge	3.82 ± 1.17	0.0001
5XSTS	Admission	0.19 ± 1.75	0.0001
	Discharge	8.25 ± 6.56	0.0001
TUG	Admission	0.42 ± 3.82	0.0001
	Discharge	17.7 ± 22.08	0.0001
DGI	Admission	0.13 ± 1.1	0.0001
	Discharge	7.33 ± 6.58	0.0001
Ten MWT	Admission	0.00392 ± 0.036	0.0001
	Discharge	0.3438 ± 0.3461	0.0001

Correlation between number of PT sessions and outcome measures gain
Table A:-

Correlation Measure	Pearson correlation	P - value
FIM gain	0.291**	0.000
BBS gain	0.246**	0.001
FAC gain	0.251**	0.001
5XSTS gain	0.083	0.286
TUG gain	0.113	0.146
DGI gain	-0.185*	0.016

**. Correlation is significant at the 0.01 level (2-tailed).

Based on the table A. the following correlations existed between number of PT sessions and FIM gain, BBS gain and FAC gain, respectively: 0.291, 0.246 and 0.251, which were all significant at 0.01 level. These results indicate that there is a very low correlation with positive association between number of PT sessions and FIM gain, BBS gain and FAC gain .In the same time there was no correlation between number of PT sessions and DGI gain and a very low correlation between number of PT sessions and 5XSTS gain and TUG gain but not significant , meaning an increase of number of PT sessions given to the patient increases the BBS, FAC and FIM gain but not with DGI , TUG and 5XSTS gain .

Correlation between L.O.S and Number of PT sessions
Table B: -

Correlation Measure	Pearson correlation	P - value
Number of PT sessions	0.889 **	0.000

**. Correlation is significant at the 0.01 level (2-tailed).

Based on Table B, A Very strong correlation was found between the length of stay and number of PT sessions given to the patient with P value being significant (0.000)

Correlation number of PT sessions and discharge value of outcome measures
Table C: -

Correlation Measure	Pearson correlation	P - value
FIM Discharge	- 0.155*	0.044
BBS Discharge	- 0.100	0.196
FAC Discharge	- 0.074	0.343
10 MWT Discharge	-.158*	0.040
TUG discharge	0.090	0.246
DGI discharge	-0.211 *	0.006

Changes in measurements reflecting motor and gait function in the robot group are summarized in Table C. As per above table there was a significant interaction effect between Number of PT sessions and discharge values of some of the outcome measures (FIM discharge value, DGI discharge value and 10 MWT discharge value) No significant interaction in parameters of number of PT sessions and BBS, FAC and TUG discharge values was observed between the robotic group $p > 0.05$ for all parameters.

In stroke rehabilitation most common impairments are problems with balance, muscle weakness, joint instability, abnormal tone can reduce movement efficiency for functional improvement].RAGT will assist stroke patients to counter act with such problems by allowing them to practice typical gait patterns, temporarily reduce their body weight to achieve normal alignment, assist with foot clearance, and promotes an automated intensive walking training program moreover many steps was practiced during each session

On the other hand improvements that happen in RAGT group was based on the selection of treatment parameters such as frequency, duration, guidance force and total number of sessions provided, nonetheless RAGT has got more advantage than the conventional training in terms of guidance force, early gait training and longer training sessions and it also reduces the therapist's burden and secure patient safety by reducing the risk of fall during treatment

session and provides persistently repeatable training. These advantages have important implications in terms of the physiotherapist's work efficiency and the quality of care provided.

Further research should focus on the following strategies to improve the effectiveness of RAGT: Increasing the sample size and designing an optimal patient-specific dosage plan. Therapist should be aware that Robotic gait rehabilitation may not be a stand-alone therapy, there must be an additional Therapy with conventional evidence-based physiotherapy treatment

Conclusions: -

It was a retrospective matched control study and investigators were not biased to secure uniformity of participants in the robotic assisted gait training group and control groups in relation to their age, duration of stroke, premorbid conditions and number of physiotherapy sessions reveling that both groups had similar number of physiotherapy treatments, even though it was a retrospective analysis, there were some limitations. Outcome of control group depends upon patient psychological status; intensity of practice and type of treatment may vary from time to time. Even though therapist were following clinical practice guidelines it's difficult to compare the exact outcome. This result suggesting that robotic assisted training will be an added benefit in terms of ambulation, mobility and balance. Need further randomized control studies to confirm the outcome

Conflicts of interest

No conflicts of interest (All authors declared)

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