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Original Research Paper

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EFFECT OF ROBOTIC ASSISTED GAIT TRAINING ON BALANCE AND FUNCTIONAL OUTCOMES IN STROKE PATIENTS - A CROSS-OVER STUDY

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ABSTRACT

Stroke is a major cause of permanent locomotor disability. Gait disturbances and postural instability are the important challenges to functional independence. While Robotic-assisted gait training (RAGT) has proven role on improving gait function, its impact on balance remains uncertain, especially in the Indian context, where advanced systems incorporating latest technologies like pneumatic actuators, artificial intelligence and virtual reality are emerging. **Objective -** To evaluate the impact of RAGT on balance and functional outcomes in stroke patients. **Materials and Methods:** This was a prospective, controlled, crossover study conducted in a tertiary rehabilitation center. Participants were systematically allocated to two sequences. Group A received RAGT with conventional therapy (CT) in the first phase followed by CT alone. Group B received CT in the first phase followed by RAGT with CT. Each phase had 20 sessions. Outcome assessment carried out initially and after each phase. Berg Balance Scale (BBS) was used as the primary outcome measure. Modified Functional Reach Test (MFRT), Functional Ambulation Category (FAC), Modified Barthel Index (MBI), recoded Modified Ashworth Scale (rMAS) were the secondary outcome measures. Period and carryover effects were ruled out. Within-subject comparisons were analysed using Paired t-tests or Wilcoxon signed-rank tests. Effect sizes were calculated. **Results:** RAGT+CT led to significantly greater improvements compared to CT alone in BBS with a large effect size. Dynamic balance measured by MFRT, Gait function by FAC and functional independence by MBI showed significantly greater improvements. Spasticity showed no significant difference in improvement. **Discussion:** The findings suggest that RAGT promotes neuroplasticity, motor learning, balance strategies, and functional stability responses. Importance of RAGT in stroke rehabilitation is underlined. Effects are not dependent on spasticity reduction. Larger studies with longer follow-up and subgroup analysis are recommended. **Conclusion:** Combining RAGT with CT can provide significant improvements in balance and functional outcomes.

KEYWORDS : Stroke, Rehabilitation, Robotics, Gait, Balance

INTRODUCTION

Stroke is one of the leading causes of disability among adults worldwide, with gait disturbances and postural instability being among the most disabling consequences, reducing independence and quality of life.[1],[2] In India, the burden of stroke is considerable, with a cumulative incidence ranging from 100 to 150 cases per 100,000 people per year and a crude prevalence ranging up to 550 per 100,000, making it a major public health challenge.[3],[4] A Global Burden of Disease (GBD) study published in 2023 emphasized that stroke remains a major contributor to mortality and disability-adjusted life years in low- and middle- income countries, including India.[4]

Restoration of gait function after stroke is a key indicator of functional independence and is essential for social integration.[2] Hence, the restoration of gait capacity and balance are among the primary goals of post stroke rehabilitation.[5]

Conventional rehabilitation programs consist of task- specific trainings and strengthening and balance exercises which are often limited by therapist dependence, intensity variability and patient fatigue.[6],[7] Robot-Assisted Gait Training (RAGT) was developed to address these limitations by providing intensive and task-oriented repetitive musculo-skeletal training, under standardized conditions.[7],[8] Several clinical studies and meta analyses have reported that RAGT improves gait parameters and promote functional independence after stroke, [8],[9],[10],[11] but the evidence regarding its effect on balance has been inconsistent.[12]

However, some recent systematic reviews indicate that RAGT provides measurable improvements in balance. A recent meta-analysis reported a small but statistically significant improvement in balance, particularly when RAGT was given in the early post stroke phase [13]. Additionally, network meta-analyses suggest that combining RAGT with virtual reality may further increase balance and walking capacity [14],[15]. Subgroup analyses suggest that exoskeleton-based RAGT provides better improvements in balance and gait freedom compared to end-effector systems, especially in subacute and chronic stroke populations [16],[17]. Robotic devices using pneumatic actuators have distinctive advantages, including smoother force application, improved compliance, and safer human–robot interaction. However, most of these studies have evaluated exoskeletal robotic systems driven by electrical motors.

The present study is designed to assess the impact of robot assisted gait training (RAGT) on balance in stroke patients. We aim to determine whether the addition of RAGT to conventional therapy will result in further improvements in balance and gait compared to conventional therapy alone.

The primary outcome measures used are Berg Balance Scale (BBS) which is often used as a gold- standard to assess balance in stroke patients,18 and the Modified Functional Reach Test (MFRT) which provides an additional measure of dynamic balance [19].

MATERIALS AND METHODS

This study was conducted in the Department of Physical Medicine and Rehabilitation, Government General Hospital, Thiruvananthapuram, a tertiary care institution under the Department of Health Services, Kerala State. The study was designed as a prospective controlled crossover study.

Patients who attended the department for post stroke rehabilitation with robotic gait trainer were screened and those with dependent ambulation having intact comprehension and sufficient cognition to follow commands and tolerate RAGT were included in the study after getting their informed consent. Patients with acute stroke of less than seven days duration and those with medical, orthopaedic, or neurological comorbidities that limit lower-limb motor function were excluded. The withdrawal criteria were set as inability to tolerate robotic therapy, development of complications requiring cessation of therapy, voluntary withdrawal, or discontinuation of treatment. Participants were assessed initially to collect the baseline scores of outcome variables and allocated alternately in chronological order to Group A and Group B. This systematic allocation ensured equal distribution into two treatment sequences. Group A received robot-assisted gait training plus conventional therapy (RAGT+CT) in the first phase, followed by conventional therapy alone (CT) in the second phase. Group B received the conventional therapy alone in the first phase, followed by RAGT+CT in the second phase.

Each treatment phase consisted of 20 sessions. Each participant went through both treatment phases. During the Conventional therapy alone (CT) phase they received individualized physical therapy, occupational therapy, and electrotherapy interventions for improving mobility, strength, balance, and gait. Each session lasted for three hours. Durin the RAGT+CT phase, they received Robot- aassisted gait training for half an hour in addition to the conventional therapy for two and a half hours Robot-assisted gait training was provided using G-Gaiter, an exoskeletal robotic gait trainer which uses pneumatic actuators to generate and assist lower limb movements. One-week washout period separated the two phases to minimize carryover effects. The conventional therapy continued during was out phase. Second assessment was done by the middle of the wash out period. After the washout phase following the completion of one treatment phase, the participants are allocated to the other treatment phase. After the completion of the second treatment phase, participants were assessed again.

To reduce bias, assessor blinding was implemented. Outcome assessment was carried out by independent assessors who were masked to group allocation and phase. They were directed to fill separate score sheets for each outcome variable. Participants were instructed not to reveal treatment details. The phases were labelled T1 and T2 to deidentify the dataset before taking it up for analysis.

Outcome Measures

Berg Balance Scale (BBS) was used as primary outcome measure. The Berg Balance Scale is a 14- item scale ranging from 0–56 that assesses static and dynamic balance. Higher scores indicate better balance.

The secondary outcomes measures were Modified Functional Reach Test (MFRT) Functional Ambulation Category, mean recorded Modified Ashworth Scale, and Modified Barthel Index.

In Modified Functional Reach Test (MFRT) forward and lateral reach distances were measured in cm while the participant is in sitting position, as most of the participants were non-ambulatory during initial assessment. The test provides a quantitative measure of balance limits in multiple directions. The Functional Ambulation Category (FAC), an ordinal scale from 0–5, was used to measure ambulation ability, with higher scores indicating greater functional independence in gait. Spasticity was assessed using Modified Ashworth Scale (MAS) an ordinal scale which scores from 0 to 4 with an additional 1+. To compute a single mean value for each participant that would represent the level of spasticity on the affected lower limb, we re-coded the score 1+ which represented a score between 1 and 2 as 1.5, and other values were retained as originally defined. The average of the recoded values of all available movements of the affected lower limb was then calculated to obtain a single mean MAS score. Functional independence in activities of daily living was assessed with the Modified Barthel Index (MBI) with values ranging from 0 to 100. Transfer and ambulation sub-scores were also analysed separately. Data collected via semi-structured proformas and variable-specific score sheets were tabulated in Microsoft Excel and analysed using SPSS software.

Analysis: Descriptive statistics summarized continuous variables as mean ± standard deviation (SD) and categorical variables as counts and percentages. Baseline demographic and clinical characteristics were compared between Group A (RAGT→CT) and Group B (CT→RAGT) using Fisher's exact test for categorical variables, while continuous variables were assessed using independent samples t-tests or Mann–Whitney U tests, contingent on Shapiro–Wilk normality testing. For within-subject comparisons, change scores were evaluated using paired t-tests for normally distributed data and Wilcoxon signed-rank tests for non-normally distributed outcomes. Effect sizes were quantified using Cohen's d for parametric tests and effect size r for non-parametric tests, then interpreted according to Cohen's benchmarks. Finally, the crossover design was validated by testing for period effects through a comparison of Phase 1 and Phase 2 change scores across all participants. A linear mixed model with fixed factors for treatment (RAGT+CT vs CT), period, and sequence, previous treatment and a random subject effect, and Phase 2 change scores as the dependent variable was used to assess the presence carryover effect.

Statistical Threshold: A two-tailed p-value < 0.05 was considered statistically significant. All analyses were performed using SPSS

Ethics:

RAGT is a widely used modality for gait rehabilitation in dependent ambulators including stroke patients for more than twenty years. The study protocol was approved by the Institutional Ethics Committee of Government General Hospital, Thiruvananthapuram. All participants provided written informed consent prior to enrolment.

RESULTS

A total of 39 post-stroke participants were recruited for the study. Three subjects discontinued the study. Personal inconveniences and logistical difficulties related to transport and caregiver support were the reasons for drop out. Rest 36 participants completed the study (completion rate: 92.3%), reflecting the high acceptability and feasibility of the study protocol.

Baseline Characteristics

The mean age of participants was 55.6 ± 10.2 years, and the mean duration since stroke was 8.8 ± 5.9 months. There were 28 males (78%) and 8 females (22%). Twenty-six (72%) subjects had ischemic stroke and 10 (28%) had hemorrhagic stroke. Weakness was on right side in 20 subjects (56%), on the left side in 14 (39%) subjects and bilateral in 2 (5%).

Comparison of baseline characteristics using independent t-tests, Mann–Whitney U test, and Fisher's exact test showed no significant differences between Group A and Group B ($p > 0.05$). Hence, both groups were well matched at baseline.

Assessment of Period and Carryover Effects

Due to the crossover study design, period and carryover effects were evaluated to ensure internal validity. Period effects, tested by comparing changes between Phase 1 and Phase 2 irrespective of treatment sequence, showed no significant differences in any outcome measure ($p > 0.05$) confirming the absence of period effects. Carryover effects, analyzed using a linear mixed-effects model (SPSS), demonstrated no significant carryover ($p > 0.05$) for any variable. Thus, the crossover design is validated, permitting within-subject treatment comparison.

Outcome Analysis

Table 1. Primary Outcome Analysis

Outcome	CT-only (Mean ± SD)	RAGT+ CT (Mean ± SD)	P value	Cohen's d
BBS	5.9 ± 4.3	9.7 ± 5.3	< 0.001	0.99

Balance assessed through BBS scale showed a mean improvement of 9.7 ± 5.3 during RAGT+CT phase compared to a mean improvement of 5.9 ± 4.3 during CT only phase (Table 1). The difference in improvement was statistically significant ($p < 0.001$). The effect size was very large (Cohen's d = 0.99), indicating a clinically meaningful gain in balance performance.

Table 2. Analysis of Secondary Outcome Variables

Outcome	CT-only Mean ± SD / Median [IQR]	RAGT + CT Mean ± SD / Median [IQR]	P value	Effect Size
MBI Total	10.3 ± 8.1	17.5 ± 11.1	< 0.001	d = 0.70
MAS (recoded)	−0.07 ± 0.17	−0.05 ± 0.21	0.594	---
MFRT Forward	3 [2–4]	4 [2–7.5]	0.004	0.48
MFRT Lateral (Affected)	2 [1–2.75]	2 [2–4]	0.003	0.50
MFRT Lateral (Unaffected)	2 [0.25–6]	4 [2–6]	0.016	0.40
FAC	0 [0–1]	1 [1–1]	< 0.001	0.72
MBI Transfer	0 [0–4]	4 [0–5]	0.033	0.36
MBI Ambulation	0 [0–3]	3 [3–5]	< 0.001	0.61

Significantly greater improvements were observed in dynamic balance (MFRT forward and lateral), Gait function (FAC), Functional Independence (Modified Barthel Index) and functional mobility (MBI subcomponents) during RAGT+CT phase compared to CT only phase (Table 2). Effect sizes ranged from moderate to large (0.36 –0.72). Spasticity (MAS) did not show significant difference in improvements between the two treatment options.

DISCUSSION

The present study demonstrated that robot-assisted gait training (RAGT), when combined with conventional therapy, produced significant improvements in balance, dynamic stability, functional ambulation, and independence compared with conventional therapy alone in individuals with stroke. These findings confirm that RAGT can enhance recovery outcomes by delivering high-intensity, task-specific, and repetitive gait training under standardized conditions, effectively addressing the limitations of conventional therapist-dependent rehabilitation.[1]

The robotic system used in this study is G-Gaiter, an Indian innovation. This illustrates how indigenous technologies can achieve clinically meaningful outcomes. Unlike conventional motor driven exoskeletons, G-Gaiter employs pneumatic actuators controlled through AI-based algorithms to provide smooth, compliant movement of the hip and knee joints. The system also integrates immersive virtual- reality feedback, promoting engagement and motor learning through enriched sensory input. The successful clinical performance of this device demonstrates that it can match international standards in post-stroke rehabilitation.

Balance, the primary outcome of the study evaluated by BBS, demonstrated a highly significant improvement during the RAGT phase compared to CT phase with a large effect size (Cohen's d = 0.99), indicating a clinically meaningful gain in static and dynamic balance control. This improvement agrees with recent meta-analyses reporting that RAGT can positively influence balance outcomes, especially when administered in the subacute or chronic phases of stroke recovery.[2] The precise, symmetrical gait cycles provided by robotic assistance may help reorganize central postural control networks and recalibrate proprioceptive feedback, leading to enhanced stability and confidence during functional activities, leading to enhanced stability and balance during functional activities[3],[4].

Dynamic balance, as evaluated by the Modified Functional Reach Test (MFRT), also improved significantly in both forward and lateral directions, with medium-to-large effect sizes. These findings indicate that RAGT enhances anticipatory and reactive postural adjustments which is an essential component of functional mobility. Improvement in postural control during activities can reduce the risk of fall substantially and support reintegration into an active social life.

Markedly greater improvement in Functional Ambulation Category (FAC) scores in RAGT+CT phase, with a very large effect size (r = 0.72), suggests that robotic training facilitated more efficient and confident gait initiation and progression. The precise hip and knee movement assistance of the robotic device which synchronized with the natural gait cycle is the most likely contributing factor to this enhancement. Greater Improvement in functional independence was mirrored in the Modified Barthel Index (MBI) total and its mobility subcomponents, reflecting greater functional independence in transfers and walking. These improvements translate directly to real-world functional gains, which are the ultimate goals of stroke rehabilitation.

Interestingly, no significant differences were observed in the reduction of spasticity between the two treatment phases. This suggests that the functional benefits observed were primarily due to enhanced motor control and neuroplastic reorganization and not due to reductions in spasticity. RAGT promotes repetitive, task-specific activation of groups of muscles in lower limbs, providing intensive afferent feedback and facilitating sensorimotor cortical re-engagement. This repetitive practice may strengthen neural pathways involved in coordinated gait and balance, enhancing voluntary control without altering muscle tone per se.

These findings have substantial clinical implications. The integration of robotic-assisted gait training as an adjunct to conventional therapy can optimize rehabilitation outcomes, particularly in patients who have plateaued with traditional methods. The significant improvements in balance, dynamic stability, and ambulation highlight the potential of RAGT to accelerate recovery and enhance independence. Furthermore, the absence of adverse effects and the high completion rate affirm the safety, feasibility, and patient acceptability of this approach. Importantly, the study's robust crossover design strengthens its conclusions by allowing each participant to serve as their own control, thus minimizing interindividual variability. The absence of period and carryover effects further confirms that the improvements were attributable to the intervention itself and not confounded by learning or temporal recovery effects.

Our findings are consistent with international literature demonstrating RAGT-induced improvements in gait performance and independence. However, the magnitude of improvement in balance observed in this study was comparatively greater, possibly due to the synergistic integration of pneumatic actuation, AI-based adaptive control, and virtual-reality feedback. Previous meta-analyses have suggested that virtual-reality-enhanced RAGT may result in greater improvements in dynamic balance and walking capacity than conventional robotic systems. The G-Gaiter's immersive, interactive feedback likely contributed to sustained patient engagement and superior motor learning, thereby amplifying balance recovery.

Future Directions

Although the present study provides strong evidence supporting the efficacy of RAGT in enhancing balance and function, further research is warranted. Larger multicentric cohort studies should be undertaken to validate these findings across diverse stroke populations and rehabilitation settings. Long- term follow-up studies are needed to evaluate the durability of functional gains and to establish optimal maintenance and booster protocols. Patient stratification frameworks should be developed to assess the effect in different subgroups based on stroke chronicity, lesion characteristics, and baseline mobility, to identify the most benefited groups. Finally, integration of real-time data analytics and AI- driven personalization in future iterations of the G- Gaiter system could further optimize therapeutic outcomes.

CONCLUSION

In summary, this study demonstrates that robot- assisted gait training using G-Gaiter system significantly improves balance, dynamic postural control, functional ambulation, and independence in individuals with stroke. These benefits likely arise from enhanced motor learning, neuroplasticity, and postural adaptation and not due to spasticity modulation. The findings support the inclusion of advanced RAGT as an effective and safe adjunct to conventional stroke rehabilitation programs.

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