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Review Article

THE USE OF ROBOT-ASSISTED GAIT TRAINING (RAGT) TO IMPROVE WALKING INDEPENDENCE IN STROKE REHABILITATION: A SYSTEMATIC REVIEW

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ABSTRACT

Introduction: Globally, stroke is the second leading cause of death and third in causing disability, although mortality rates have declined due to treatment advancements. This has led to an increased population of stroke survivors, with over 70% facing long-term motor, sensory, cognitive, or speech impairments, placing a substantial burden on families and society. Gait training plays a crucial role in enhancing daily living activities and independence. Currently, therapist-assisted rehabilitation is the primary approach, though it can be time-intensive and may lead to low adherence. However, technology is developing significantly in stroke rehabilitation with high-intensity, repetitive movements, potentially enhancing recovery
Material and Methods: Therefore, current study aimed to conduct a systematic review of RCTs assessing the effectiveness of RAGT to improve walking independence. The outcome was the assessment of lower limb function using scales, such as the FAC, FMA-LE, and 6MWT. A thorough search was conducted in three databases. The risk for bias was evaluated using the Revised Tool RoB 2.0
Discussion: There are inconsistent findings in the effectiveness of RAGT in improving motor function, walking ability, and walking endurance compared to conventional. But, RAGT showed promising results, particularly in the subacute phase. Peak neurologic recovery of stroke occurs within 1–3 months after the onset of stroke. From this time to 6 months, recovery slows down.
Conclusion: The use of RAGT in stroke rehabilitation yielded a favorable and promising outcome. However, the effectiveness compared to conventional therapy has not yet been consistently significant.

Keywords: stroke, rehabilitation, robot-assisted gait training

INTRODUCTION

Stroke is a common acute condition in older adults, with obvious complaints for weakness of extremity.[1] Stroke remains a significant cause of mortality and disability, despite advances in care. Predicting recovery outcomes in the acute phase is challenging. This has led to an increased population of stroke survivors, with over 70% facing long-term motor, sensory, cognitive, or speech impairments, placing a substantial burden on families and society.

Rehabilitation of stroke, especially

gait training, plays a crucial role in enhancing daily living activities and independence.[2] Rehabilitation for stroke patients varies by recovery phase—acute, subacute, and chronic—each with specific goals. A crucial factor in recovery is the ability to walk independently; however, nearly half of stroke patients do not regain this ability, even after rehabilitation. This underscores the need to more advance rehabilitation strategies specifically targeting walking recovery.[3]

Currently, therapist-assisted stroke rehabilitation is the primary approach worldwide, though it can be time-intensive and may lead to low adherence, often leaving survivors without full functional recovery.[8] However, technology is developing significantly in stroke rehabilitation.[9] Technology-based approaches, like robotic therapy (RT) support rehabilitation by offering high-intensity and repetitive tasks efficiently, thus allowing patients to be more independent in their training.[7] Research on robot-assisted upper extremity rehabilitation for stroke patients began in the late 1990s, and several robotic exoskeletons are now commercially available.[9,10]

Studies comparing robot-assisted rehabilitation with conventional therapy have shown mixed results; some studies report significant improvements in mobility and functional recovery with robotic assistance, while others do not. Systematic reviews and meta-analyses since 2020 have explored various robotic rehabilitation systems, assessing their benefits and limitations. However, no review has comprehensively examined the effectiveness of robotic rehabilitation across the three phases of stroke recovery—acute, subacute, and chronic—highlighting a gap in research. Therefore, current systematic review addresses some research questions as follows: (1) Does the use of RAGT improve independency by assessing the motor function/strength of lower extremity, gait/walking ability, and walking endurance? (2) The effect of stroke rehabilitation phase to improve the motor function/strength of lower extremity, gait/walking ability, and walking endurance.

MATERIAL AND METHODS

Study Design and Search Strategy

This systematic review was conducted based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guidelines. Literature search was conducted in November 2024 on three databases, namely PubMed, ScienceDirect, and Wiley with the following Boolean operator keywords: ("artificial intelligence" OR AI OR robot-assisted) AND ("stroke rehabilitation" OR stroke) AND ("lower limb" OR “lower extremity”) AND (gait OR “gait training”). The restriction given by the publication year of 2020 to the latest. The inclusion criteria of this systematic review refer to the PICO framework in Table 1.

Table 1. Inclusion Criteria Based on PICOS Framework

Population	Patients diagnosed with stroke in the acute, subacute, or chronic phase.
Intervention	Robot-assisted gait training for lower extremity rehabilitation
Comparison	Any conventional therapy
Outcome	- Motor function/strength of lower extremity assessed by Fugl-Meyer Assessment – Lower Extremity (FMA-LE) - Gait /walking ability assessed by functional ambulatory category (FAC) - Walking endurance assessed by 6 minutes walking test (6MWT)

Study Eligibility Criteria

The criteria for inclusion and exclusion were established prior to conducting the literature search, ensuring specificity and homogeneity in the outcomes. The inclusion criteria were 1) Randomized Controlled Trial (RCT), 2) Studies that involve individuals diagnosed with stroke in acute, subacute, or chronic phase, 3) Studies that use any types of robot-assisted gait training as their strategies as their intervention of interest, and 4) Studies that include at least one parameter analyzed in this study, namely: functional ambulatory category (FAC), 6-minute walking test (6MWT), Fugl-Meyer Assessment – Lower Extremity (FMA-LE). The exclusion criteria were 1) Studies without a control group, 2) Studies that involved the combination of robotics with other interventions that could potentially influence the outcomes, such as transcranial Direct Current Stimulation or Virtual Reality. 3) Studies written in a language different from English, and 4) Studies not accessible for free through online databases, 4) Review and protocol studies. Using these inclusion and exclusion criteria, 3 authors (VF, AQN, AMA) independently assessed the eligibility of the papers, and any disagreements were resolved through discussion.

Data Extraction

We used a predetermined outcome sheet in tabular form by utilizing the Google Sheets platform to extract the included studies. It contained the following information: (1) author and year of publication; (2) study location and duration; (3) study population (sample size and sample age mean ± SD); (4) types of intervention and control and (5) study outcomes: motor function/strength, gait/walking ability, and walking endurance. Three reviewers (VF, AQN, AMA) qualitatively assess the studies.

Quality Appraisal

The Revised Tool for Risk of Bias in Randomized Trials (RoB 2.0) was used to assess the potential for bias in the selected final studies. Three authors evaluated bias likelihood using this tool and resolved disagreements through discussion. The results were subsequently recorded in the "bias" domain within the spreadsheet. The Revised Tool RoB 2.0 consisting of five domains for studies is performed to evaluate the risk of bias in the analysed final papers. The results will then be recorded in the domain file bias (.xlsx) then posted to the ROBVIS website for display. All three reviewers separately evaluated the quality of selected studies. Any disagreement was settled by consensus between the reviewers. In Figure 1 and Figure 2, an evaluation of study quality is shown.

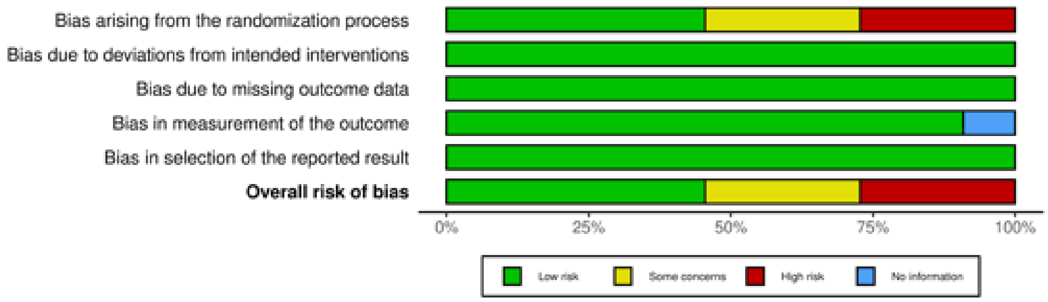

Figure 1. Studies quality assessment based on Cochrane RoB 2.0 (Summary Plot)

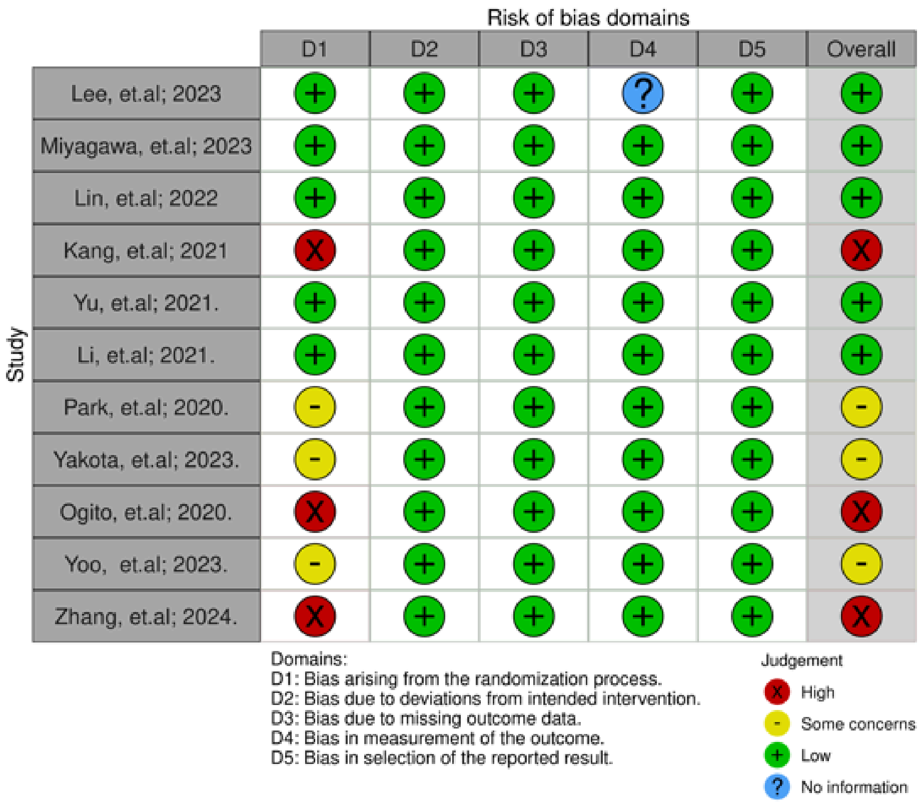

Figure 2. Study Quality Assessment Based on Cochrane RoB 2.0 (Traffic-Light Plot)

Intervention

Our present study involved trials that examined the effects of robot-assisted gait training (RAGT) as compared to conventional therapy. We incorporated various forms of RAGT in our study, including end-effector lower limb, exoskeleton type, one-leg assisted gait robot called Welwalk WW-1000, hybrid form of end-effector and exoskeleton type, Lokomat, cyborg-type robot

Hybrid Assistive Limb (HAL), Gait Exercise Assist Robot (GEAR), and Walkbot-assisted locomotor training (WLT), ground walking exoskeletal robot SUBAR, and wearable rehabilitation robot, “curare”®. Additionally, the term “conventional therapy” primarily refers to physiotherapy in the majority of the studies included in our analysis. Consequently, pertinent details regarding the intervention protocol, such as the robotic device frequency, intensity, duration of the session, and any supplementary interventions, were extracted.

Outcome Measures

The outcome was the assessment of lower limb function using scales, such as the Function Ambulatory Category (FAC), Fugl-Meyer Assessment-Lower Extremity scale (FMA-LE), and 6-minutes walking test (6MWT). The FMA-LE assesses motor function and has been recommended as a part of a core outcome set in stroke rehabilitation studies and is commonly used in stroke research to evaluate motor recovery. The FMA-LE assesses reflex activity, voluntary movement, and coordination and velocity of movement.[11] The FAC was developed by Holden et al. in 1984. The 6-point scale assesses how much human support is needed (regardless of whether a personal assistive device is used) when walking. The FAC can be quickly evaluated in clinical practice and has been used to assess patients suffering from stroke or other neurological conditions. The 6 minutes walking test (6MWT) evaluates submaximal aerobic capacity; the patient walks as far as possible on a flat 30-m-long corridor for 6 minutes at a self-paced speed. The principal outcome is the distance walked in meters. The test is used principally to measure walking and cardiopulmonary endurance and has also been employed to measure gait performance in patients with various neurological diseases including stroke and healthy populations.[12]

RESULTS

Search Results

A literature search from electronic databases yielded 1388 Studies. After removing the duplicates, 734 remaining studies. Screening through the titles and abstracts, the authors excluded studies that does not meet the inclusion criteria. After screening the full text, 11 studies matched the inclusion criteria. Search flowchart and selection method was summarized in Figure 3.

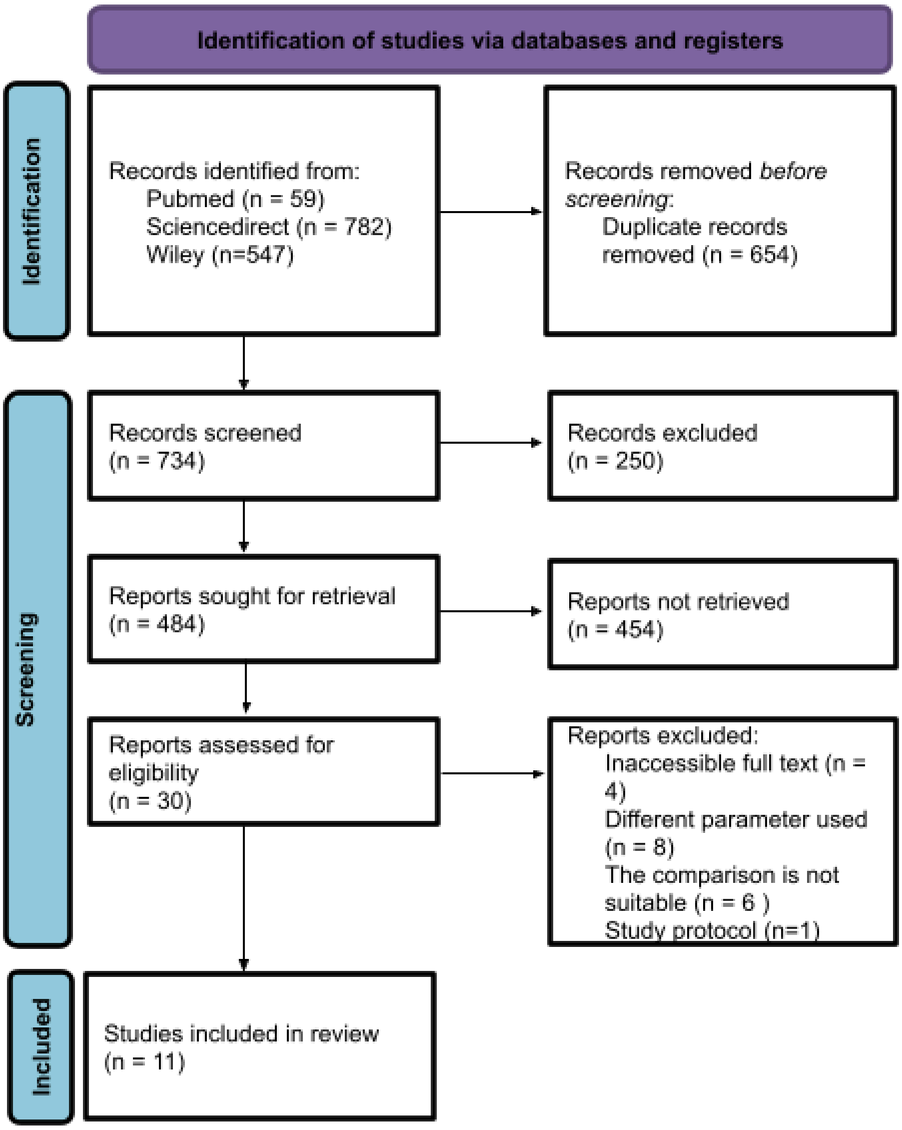

Figure 1. PRISMA 2020 flow diagram

Study Characteristics

All of the included studies were done using the RCT design. Inclusion and exclusion criteria across studies showed similarities. The total population of the present studies are 396 participants. Most of the study were from South Korea, Japan, China, Denmark, and Turkey. The regimen dosage and duration has slight differences amongst studies with similar outcome measures. Detailed characteristics of included studies were summarized in Table 2**.**

Quality assessment

Motor function/strength of lower extremity

A study was conducted on participants diagnosed with stroke during the subacute phase, who underwent a hybrid RAGT intervention. Prior to the intervention, all participants were non-ambulatory, with significant leg impairments and a FAC score of 0-1. After the intervention and at the 3-month follow-up, the number of patients in the RAGT and control groups with improved ambulatory function (independent or assisted walking) was approximately equal. However, the FMA-LE and FMA-total scores were significantly higher in the RAGT group than in the control group.[13]

Same result was also found in a study of exoskeleton RAGT and conventional therapy combination which was being compared to conventional therapy alone for its ability to restore motor function in population with subacute stroke. The robot group showed significant improvements ($P < 0.05$) in the FMA-LE measure.[14] Study of Li,et.al. using exoskeleton RAGT compared to conventional therapy in subacute stroke showed the improvement of FMA-LE score in experimental group was significantly higher than control group (5.76 ± 4.28 vs. 2.67 ± 4.59, $P= 0.044$).[15]

Findings in 4 studies of acute[16] and subacute[17–19] stroke population showed greater changes of RAGT intervention group in the motor function, but no significant difference between intervention and control group. Randomized controlled trial of Yu,et.al. showed the relatively short training time (2 weeks), limiting the conclusions that can be drawn from its findings. It is possible that training differences between the two methods would be revealed after 4 weeks.[16]

Walking ability or walking independency improvement

An end-effector lower limb RAGT intervention in subacute[18], exoskeleton RAGT in subacute[17], and Walkbot-assisted locomotor training (WLT) in acute[20] stroke patients showed greater changes in FAC score compared to its control group. Findings of other 3 studies in subacute and chronic stroke patients with robotic exoskeleton and hybrid RAGT showed greater changes in intervention with no differences between both groups.[21–23]

Walking endurance

Subacute stroke patients with exoskeleton RAGT showed significant differences in 6 minutes walking test compared to conventional therapy.[23] Another study in chronic stroke patients compared an exoskeleton RAGT intervention to conventional therapy showed significantly greater mean changes of 6MWT in the RAGT than control group. This study includes patients with independent gait on treadmill without physical assistance, making it unable to assess its improvements of motor function and walking ability.[24]

DISCUSSION

Principle findings

Based on our findings, it shows that the difference between the use of Robot-assisted gait training (RAGT) compared to conventional therapy had different results related to its superiority on improving motor function, gait ability, and endurance. From the 11 RCTs that met the inclusion criteria for the review, there were 3 studies with statistically significant difference of FAC between both groups and 3 studies with no statistically significant difference. Four studies assessed by FMA showed statistically significant results, while 3 studies showed no significant difference. The 6MWT in 1 study showed statistically significant different results, but the other 3 studies showed no statistically significant difference.

To sum up, there are inconsistent findings in the effectiveness of RAGT compared to conventional therapy in improving motor function, walking ability, and walking endurance.

Table 1. Summary of key findings from the included studies**.**

No	Author, year	Country	Study design	Participants	Intervention	Control	Phase of stroke	Duration of study	Duration of intervention sessions	Findings
1	Lee, et.al; 2023	Korea	RCT	Total:49 Mean age: 63.04 ± 15.69 (intervention) 64.78 ± 12.81 (control)	A 30-minute end-effector lower limb rehabilitation robot training plus 1.5-hour conventional physiotherapy	A 2-hour conventional physiotherapy	Subacute	4 weeks	5 treatments weekly	The robot group improved more in FAC than the control group. No significant difference in FMA-LE.
2	Miyagawa, et.al; 2023	Not mentioned	RCT	Total:35 Mean age: 65.1 ± 12.9 (intervention) 63.0 ± 12.9 (control)	Wearable rehabilitation robot, "curara®	Conventional therapist-assisted gait training.	Subacute	15 days	10 sessions of gait training (5 times per week) each lasting 30±5 min per day.	There was no significant difference in the 6MWD outcome.
3	Lin, et.al; 2022	China	RCT	Total:40 Mean age: - 54.1 ± 8.6 (intervention) -56.5 ± 12.9 (control)	Hybrid form of the end-effector and exo-skeleton type systems	Physiotherapy and occupational therapy.	Subacute	4 weeks	Control: five sessions per week, 100 min/session. Intervention: five sessions per week, 30 min each.	The FMA-LE was significantly higher in the RAGT group than in the control group.
4	Kang, et.al; 2021	South Korea	RCT	Total: 30 Mean age: - 64.3±4.6 (intervention) - 62.9±6.0 (control)	Ground walking exoskeletal robot SUBAR	Conventional physiotherapy	Chronic	3 weeks	10 treatment sessions. Each treatment is 30 minutes.	There were no differences in 10 meter walk test and FAC.

5	Yu, et.al; 2021.	China	RCT	Total: 54 Mean age: - 57.89 (10.08) (intervention) - 52.11 (5.49) (control)	Gait Training and Evaluation System A3 from NX	Conventional overground gait training group	Subacute	2 weeks	A 2-hour course each day for 14 consecutive days. Each training session consisted of two 50-minute training periods, with one 20-minute rest period between them.	There was no significant difference between the two groups in FMA scores (P = 0:26).
6	Li, et.al; 2021.	China	RCT	Total: 32 Mean age: - 50.53(12.26) (intervention) - 50.13(9.49) (control)	BEAR-H1 assisted gait training (BAGT), an exoskeleton robot of lower limb.	Conventional therapy	Subacute	4 weeks	30 minutes/sessions, 5 times/week	The 6MWT and FMA-LE in experimental group was significantly higher than control group. However, there was no difference in the changes of FAC scores.
7	Park, et.al; 2020.	Korea	RCT	Total: 14 Mean age: 72.8 ± 9.9	Walkbot-assisted locomotor training (WLT)	Conventional locomotor training (CLT)	Acute	2 weeks	Both groups received 30 additional minutes of therapy every day, 7 days/week.	The FAC score change was significantly greater for the WLT group.

8	Yakota, et.al; 2023.	Japan	RCT	Total: 22 Mean age: - 65.3 (10.1) (intervention) - 62.5 (10.6) (control)	Cyborg-type robot Hybrid Assistive Limb (HAL) + CPT	Conventional physical therapy (CPT)	Acute	4 weeks	1-3 sessions per day (20 min per session), and 5 or 6 days a week, with a total of 20 sessions.	There were no significant differences in FAC and FMA-LE between groups.
9	Ogino, et.al; 2020.	Japan	RCT	Total: 20 Mean age: - 66.1 (9.6) (intervention) - 65.0 (7.7) (control)	Gait Exercise Assist Robot (GEAR)	Treadmill gait training	Chronic	4 weeks	20 sessions, 1 h/day, 5 days/week	No significant difference was found in gait endurance assessed by 6MWT.
10	Yoo, et.al; 2023.	Korea	RCT	Total: 25 Mean age: - 61 (42–85) (intervention) - 65 (43–87) (control)	A robotic exoskeleton	Conventional training	Subacute	4 weeks	30 minutes/day, 3 days per week	There was significant differences in FAC between groups but no significant differences in FMA-LE
11	Zhang, et.al; 2024.	China	RCT	Total: 24 Mean age: - 63.50 ± 8.97 (intervention) - 63.83 ± 8.28 (control)	Exoskeleton rehabilitation robot training	Upright bed rehabilitation	Subacute	4 weeks	Once a day (60 min each) for 5 days a week	The robot group showed significant improvements ($P < 0.05$) in the FMA-LE measure.

This inconsistent finding might be caused by several factors, such as phase of rehabilitation stroke, duration of the study, the difference of intervention duration between both groups, and the small sample size.

Another objective of this review is to assess the best stroke rehabilitation phase for running the RAGT rehabilitation programme compared to conventional therapy. Studies assessing the chronic phase was limited, but 2 studies of chronic phase that met the inclusion criteria of this review showed no significant results. Five studies with significant results had their patients in the subacute phase of stroke.

According to American Stroke Association, rehabilitation should begin since the hyper-acute phase, with mobilization and supervised active exercises performed in bed. The goal of early mobilization is to minimize immobility-related complications and to promote motor control recovery.[25]

There are two primary mechanisms of neurological recovery. The first is activity-dependent neuroplasticity, which occurs in the injured cortical area and supports task-oriented repetitive training, such as constraint-induced movement therapy and robotic-assisted gait or arm training. Second is vicariation, where unaffected areas of the brain take over the functions of the damaged region, typically observed early after a stroke or in cases of severe cerebral infarction.[26]

During the acute phase, treatment should be focused on addressing the disease according to the critical path specific to the pathophysiology of acute stroke. In the subacute or convalescent phase, rehabilitation programs should be the focus in order to treat several impairments, such as walking, feeding, transferring, etc. In the chronic phase, the priority should shift to compensatory rehabilitation programs, such as house reconstruction, transfer system, caregiver education with the view of quality life, and managing environmental factors to enhance quality of life.[26]

Peak neurologic recovery of stroke occurs within 1–3 months after the onset of stroke. From this time to 6 months, recovery slows down and

5% of the patients, especially those who show severe functional damage at the early stage, continuously recover up to 1 year after the onset. Also, functional recovery mostly occurs 3 months after the onset, suggesting that functional recovery is strongly related to neurologic severity.[26]

In order to manage functional impairment from stroke, subacute stroke rehabilitation is crucial. Since this is the time when neurological and functional recovery is very active, task-oriented, intensive, and repetitive training is needed. To achieve this, it is recommended that stroke patient should be transferred or admitted to a comprehensive stroke rehabilitation unit that offers a multidisciplinary approach.[27] From 6 months to 1 year after the onset of stroke, it reaches the chronic phase in the event of no more functional recovery. Three years after that time, the patient maintains average functions or his/her ability to adapt in everyday life gets better.[27]

Mechanism of robot-assisted gait training for poststroke, advantage, and disadvantage

Robot-assisted gait training (RAGT) provides highly intensive and task-specific gait training for stroke patients and reduces therapist physical burden. It is a widely used rehabilitation strategy for stroke survivors, as ambulation tasks are possible even if the patient cannot walk.[28] RAGT is divided into two based on the system, namely end-effector or end-limb and exoskeleton types. Both are commonly used to provide programmable gait training during rehabilitation. In the end-effector-based approach, the feet are positioned on two-foot plates, which simulate the stance and the swing phase of gait. The exoskeleton-based approach involves the use of an exoskeleton with drives that feel the hips and knees during the swing phase as well as a treadmill to simulate the stance phase. The exoskeleton system was found to be more effective than treadmill gait training and was able to restore symmetrical gait patterns with gait discrepancies in patients with chronic stroke.[28]

In a study with a different RAGT system, patients with subacute stroke using the hybrid assistive limb robot suit outperformed the control group in terms of improvements in maximum walking speed. Moreover, RAGT with alternating stepping movements was reported to induce physiological muscle activation patterns and improve the Motricity Index and Medical Research Council scores in patients with subacute stroke and healthy controls. Studies have examined the clinical, technical, and regulatory aspects involved in the proposed classification. The way RAGT works is based on the assumption that a specific, repetitive approach to a task will support motor learning and facilitate functional recovery. The goal of RAGT is to enable users to perform high-intensity, repetitive tasks and reduce the need for support from a physical therapist; with RAGT, patients can practice 1000 steps in 30 minutes, which is not possible with physical therapist.[29]

Each RAGT device has several different facilities and provisions, although the working principle remains the same. For example, related to the type of security used. Some devices use three-point support (abdomen, hips, and knees) allowing patients to receive weight-bearing training in a more comfortable environment.[30] However, some use a suspension seat belt to the patient's waist. The device can also be adjusted to the patient's leg length and stride length. The pedaling speed limit and maximum weight on each RAGT device also vary according to the manufacturer.[30]

This rehabilitation tool certainly has advantages and disadvantages. One of the advantages of using robot-assisted gait training is reducing the workload of a physiotherapist, as well as increasing safety and reducing the risk of injury during the rehabilitation process. Research shows that the use of RAGT combined with therapist assistance can accelerate recovery and improve the functionality that can be achieved by patients. The rehabilitative effect of the device on stride duration and cadence has been confirmed in this study. This effect is likely to contribute to increased walking speed, and the assistance provided by the device, which shortens the gait cycle and enlarges the joint angle, will result in beneficial changes in stride duration and cadence.[31]

In addition to being a tool for the rehabilitation of post-stroke patients, it was also found that RAGT had positive effects on aerobic capacity, effectively improving walking endurance in the early phase after a stroke. Both studies utilized peak oxygen consumption (VO2) as the outcome measure. The results indicated that after 4 weeks and 20 interventions, respectively, there was an increase in VO2 and lower limb strength, as well as an improvement in arterial stiffness. Conventional therapies did not result in any significant changes in motor function improvement.[32]

However, concerns arise as to whether the assistance provided by the device is best for each patient. We did not set the synchronization gain at the hip and knee joints according to individual gait performance. Synchronization gain may be related to error learning involving trials required for motor learning. Lower synchronization gain means a reduced level of flexibility of voluntary joint movements. Ideally the synchronization gain of the device should be set individually, but this is a complex and time-consuming process to carry out in the limited time available for this clinical trial.[33] Furthermore, not everyone can use the device easily. Elderly people or people with severe disabilities often have more difficulty using the RAGT device and therefore their interest in performing the exercises is also reduced.

Patients' interest in the robot varied from one individual to another. Overall, older individuals tended to have less interest in the device than younger individuals, and individuals with better walking ability had less motivation to practice with the robot.[34] Considering the high purchase and maintenance costs, this is one of the limitations for low-income patients who have to pay a lot for rehabilitation if the costs are not covered by the government.

This study is a collection of RCTs in the last 5 years. The level of trust in this study is also high because it is a collection of several Randomized Controlled Trials which are the most trusted research methods in comparing or testing effectiveness. Current review consists of studies from few countries with several types of RAGT. It includes studies from each type of rehabilitation phase (acute, subacute, and chronic).

This study has some limitations related to some of the studies cited. From this it is expected that there will be better improvements in future studies. Few RCTs included in this review did not have their patients on the same levels of severity before the intervention which may cause bias results. Some studies provide therapy to the intervention group and the control group with different intensities. All RCTs were conducted with small sample sizes and might not enough to show statistically significant different results between both groups.

CONCLUSION

Our findings indicate that the use of RAGT for enhancing motor function, walking ability, and endurance yielded a favorable and promising outcomes, particularly in the subacute phase of stroke. However, the effectiveness compared to conventional therapy has not yet been consistently significant. The notable heterogeneity in the outcomes suggest more extensive studies involving a larger participants pool for incorporating this technology among stroke patients in rehabilitation. In addition, each study is recommended to include data for each independence status and motoric strength in order to do a more comprehensive analysis.

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