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Functional and ambulatory benefits of robotic-assisted gait training during early subacute inpatient rehabilitation following severe stroke

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INTRODUCTION

Stroke is a leading cause of long-term disability in adults, and approximately 40% suffer residual gait impairments requiring physical assistance before hospital discharge.[1] Despite advances in stroke rehabilitation and implementation of gait training in modern rehabilitation protocols, many patients with moderate to severe stroke do not regain independent walking function upon return to the community.[2-4]

In recent years, stroke rehabilitation has increasingly utilized robotic-assisted gait training (RAGT) via electromechanical devices, combined with conventional therapy, to provide high intensity gait training with reduced human effort.[5] However, the effect size of these gains remains modest, with many patients remaining non-ambulant despite receiving RAGT.[6] While the majority of these patients are in the late subacute stroke phase (3-6 months post-stroke), RAGT outcomes in stroke patients, during the acute period of their first month post-stroke, are not well-studied and may not be comparable.[6-8] The ambulatory benefits of RAGT are also mainly limited to moderately disabled stroke survivors who are not totally dependent, and may not apply to severely disabled stroke survivors. In highly disabled survivors of severe stroke, authors of several prospective studies contend that no benefit exists when comparing RAGT over conventional therapy for regaining walking function in early subacute, acute and chronic stroke survivors, despite receiving RAGT sessions for 4-8 weeks.[9,10]

Although a large proportion of these patients may not achieve independent walking as a primary outcome after inpatient rehabilitation with RAGT, some authors have suggested that they may benefit from smaller but clinically relevant functional gains.[11,12] Possible non-ambulatory benefits include improvements in assisted mobility, transfers, activities of daily living and reduced institutionalisation rates. Despite this, there still remains a paucity of studies looking at the clinical and secondary benefits of RAGT on non-ambulatory acute stroke patients undergoing inpatient rehabilitation in their first month after stroke. Hence, this study was conducted to explore functional outcomes of RAGT compared to conventional physiotherapy alone (CPT) during early subacute inpatient stroke rehabilitation.

METHODS

This was a single-centre, retrospectively matched cohort study involving a review of electronic medical records. All data had been entered into a prospectively collected rehabilitation functional database. Ethics approval was obtained from National Healthcare Group Domain Specific Review Board (NHG DSRB 2018/00884) prior to data collection.

The electronic medical records of 50 consecutive patients admitted to a tertiary-level rehabilitation centre from 1 January 2009 to 31 October 2017, all of whom had undergone RAGT with conventional physiotherapy, were retrospectively reviewed. Two control patients were then identified for each patient from a database of all stroke patients admitted to the rehabilitation centre who received CPT only. These control patients did not receive any other form of robotic rehabilitation therapy. The determining factors for matching were in the following order: stroke aetiology, age (within 10 years), gender, admission year (matched within the same year of admission to the rehabilitation centre), admission FAC score and admission FIM-walk score.

RAGT was provided solely by Lokomat [Hocoma Ag, Industriestrasse, Volketswil, Switzerland], a robotic gait orthosis combined with a harness-supported body weight system, used in combination with a treadmill and visual feedback.[(13)] During their acute/early subacute rehabilitation stay at TTSH Rehabilitation Centre, patients were eligible for RAGT if they had dense hemiplegia with poor trunk/neck control, required at least moderate to maximal assistance of 1-2 physiotherapists to ambulate and did not have any medical, orthostatic, skin, spasticity or orthopaedic contraindications to prolonged verticalization in Lokomat and were not terminally ill. In addition, the following inclusion criteria for this study were: a primary diagnosis of first-ever unilateral stroke, either ischemic or intracerebral haemorrhages more than 7 days but less than 3 months prior to RAGT start date, lesions confirmed by computed tomography or magnetic resonance imaging, age between 18 and 80 years old, independent ambulation pre-stroke and significant gait deficits with Functional Ambulation Category (FAC) ≤1 and FIM-walk score ≤2.

Exclusion criteria for this study included presence of traumatic or spontaneous subarachnoid haemorrhages,[(6)] prior cerebrovascular accidents, failure to complete rehabilitation or missing FIM scores.

Both groups had standard inpatient stroke rehabilitation treatment (2h/day for 5 days/week), with daily physiotherapy and occupational therapy session for 1 hour each. Apart from RAGT, all groups did not receive any other form of robotic rehabilitation therapy. Patients who underwent sequential RAGT performed 10-15 consecutive sessions (5 times per week) instead of standard physiotherapy, while daily occupational therapy was continued. Each RAGT session lasted approximately 45 minutes, with a selected walking speed of ~1.5 km/h at the first RAGT session that was increased as soon as possible in accordance with comfortable gait for each patient. Prior to and following each RAGT session on Lokomat, all patients were monitored for any adverse reactions, including harness and orthoses-related skin reactions, abrasions and blisters. If the patient received RAGT, further conventional physiotherapy sessions were not conducted on that day. On days when participants did not receive RAGT sessions, they received daily CPT sessions based on neurodevelopmental techniques, comprising facilitation of movements on the paretic side, upper-limb exercises and improving truncal balance, standing, sitting, transferring, and over-ground walking, until the day of discharge.

Baseline demographic and clinical characteristics of the patients including age, gender, days from stroke, stroke subtype (ischemic/haemorrhagic), side of hemiparetic weakness (left/right), total number of sessions of RAGT and CPT completed were extracted. Data related to walking ability, motor impairment and Activities of Daily Living (ADL) performance were obtained from the institution's inpatient rehabilitation functional database. All outcomes were assessed within 72 hours of rehabilitation admission and discharge.

Walking ability was measured using the Functional Ambulation Category (FAC) and FIM-walk score while lower limb motor impairment was measured using the Fugl Meyer Assessment of Lower Extremity (LeFMA). The FAC assesses ambulation in stroke patients over a distance of 10 feet, regardless of the use of a personal assistive device, and is scored from 0–5.(14) The FIM-walk subscore is scored based on the distance travelled over 150 feet and the level of assistance or device required, and ranges from 1-7.(15) The motor component of the Fugl Meyer Assessment of Lower Extremity (LeFMA) was used to evaluate the degree of muscle recovery of the extremities (comprising motor function and coordination/speed), with a score from 0-34.(16) ADL performance of the patient on admission and discharge was assessed with the total Functional Independence Measure (t-FIM), which ranges from 18-126 and consists of the motor and cognitive subset FIM scores. The motor FIM (m-FIM) score ranges from 13 (totally dependent) to 91 (independent without modification), and the cognitive FIM (c-FIM) score ranges from 5 (totally dependent) to 35 (independent without modification). The t-FIM, m-FIM, c-FIM gain were determined by subtracting discharge t-FIM, m-FIM, c-FIM from admission t-FIM, m-FIM and c-FIM scores respectively. The FIM efficiency (FIMe) was calculated by the FIM gain divided by the days in rehabilitation. As motor recovery of the lower extremity affects locomotion together with transfer function, and motor impairment of the upper limb affects self-care function preferentially, the FIM mobility (FIM-M), FIM self-care (FIM-S) and FIM sphincter subscores (FIM-SP) were calculated separately in addition to the m-FIM score.[17,18] The FIM-M subscore comprises ability to transfer (to and from bed/chair/wheelchair, toilet and tub/shower), walk or propel a wheelchair and climb stairs, and ranges from 5 (totally dependent) to 35 (independent without modifications). The FIM-S subscore comprises eating, grooming, bathing, upper and lower body dressing and toileting, and ranges from 6 (totally dependent) to 42 (independent without modification). The FIM-SP subscore comprises bladder and bowel control, and ranges from 2 (totally dependent) to 14 (independent without modification). Other routine ambulatory measures such as 10m walk test (10mWT), 6 min walk test and Berg Balance Scale (BBS), were not measured as the patients needed more than minimal aid to walk due to severe paresis even after rehabilitation. Discharge disposition related to whether patients returned home to their premorbid living arrangements or were institutionalised was also recorded.

Descriptive statistics were utilised to illustrate patient demographics and clinical characteristics. Paired sample t test was used to test the difference between the RAGT and CPT group for continuous outcomes while conditional logistic regression was used for binary outcomes. A p-value < 0.05 was considered statistically significant for a two-tailed test. Statistical analyses were generated using SPSS Version 22.0 (IBM Corp., Armonk, NY) and STATA Version 16.0 (StataCorp, College Station, TX)

RESULTS

Between 2009 and 2017, we identified 50 patients who received RAGT, who were matched to 100 patients who received conventional therapy only. There were no statistically significant differences in the recorded baseline characteristics between groups in terms of demographic, stroke subtype, side of involvement or days from stroke to inpatient rehabilitation for the RAGT or CPT group (Table I). The mean time from stroke onset to inpatient rehabilitation for the RAGT group (n=50) was 15.0 days (±5.66) while that for CPT was similar, at 15.8 days

(±4.33, $p = 0.425$). The mean time from stroke onset to RAGT was 19.9 days (±6.10). For the RAGT and CPT groups, initial FIM-walk score and FAC ranged from 1-2 and 0-1 respectively, indicating severe locomotor dysfunction in both groups as they were either non-ambulant or needed maximal aid of a least 1 person continuously for ambulation. On average, RAGT patients received either 10, 12, or 15 training sessions on Lokomat (mean of 12.7±2.40 sessions). None of the RAGT patients reported any adverse effects and all planned RAGT sessions were completed.

The FIM and ambulatory outcomes at discharge from inpatient rehabilitation are shown in Table II. At discharge from rehabilitation, RAGT patients had significantly higher t-FIM scores compared to CPT patients (53.5±18.8 vs 45.5±15.6, $p = 0.018$). None of the patients in either group achieved independent ambulation at discharge (FIM-walk ≥6 or FAC score of ≥ 4). There were also no significant differences in the discharge FAC or FIM-walk scores ($p = 0.113$, $p = 0.103$ respectively) (Table II).

At discharge, when compared to CPT, the RAGT group had higher gains in terms of Δt-FIM (25.0±15.7 vs 15.1±10.2, $p < 0.001$), Δm-FIM (19.8±13.3 vs 10.2±8.42, $p < 0.001$), ΔFIM-M (7.66±5.20 vs 3.36 ±4.16, $p < 0.001$), ΔFIM-S (9.80±7.73 vs 5.47±5.33, $p = 0.002$), ΔFIM-SP (2.38±2.88 vs 1.38±1.38, $p = 0.034$) and ΔFIMe (0.46±0.28 vs 0.32±0.24, $p = 0.010$) (Table III). LeFMA gains were significantly higher in RAGT group compared to CPT (5.92±5.32 vs 4.00±2.72, $p = 0.023$). There were no statistical differences in the length of rehabilitation stay or institutionalization rates between both groups.

DISCUSSION

Findings from this study showed that non-ambulatory severely affected stroke patients who underwent early inpatient RAGT at approximately 1 month post-stroke, achieved greater and clinically significant functional improvements, despite minimal improvements in ambulation status when compared with CPT patients. Compared to CPT, RAGT patients achieved superior functional gains in t-FIM (Δ25) and m-FIM (Δ20) (indicating mainly motor gains) which exceeded the minimal clinically important difference threshold of 22 and 17 for t-FIM and m-FIM in stroke patients.(19) As our cohort had highly disabled stroke survivors, it was not surprising that the combinatory RAGT group had a low FIM efficiency of 0.46, which although is marginally higher than the CPT group (0.32), is lesser than a FIM efficiency level of approximately 2 reported by the Uniform Data System for Medical Rehabilitation (UDSMR) in stroke patients.(20)

While a recent systematic review demonstrated that non-ambulatory stroke patients receiving RAGT results have a higher chance of recovery of independent gait ability in a systematic review, we did not find superior ambulatory outcomes for the study sample's RAGT group.(6) However, it should be noted that many of the studies reviewed by Mehrholz et al included patients of a fairly high FAC category of up to 3 (able to ambulate but requiring assistance) but who fell short of being independent ambulators.(6,21-23) In contrast, all 150 patients in our study were non-ambulatory on admission (FAC of 0-1). Severely disabled patients in the early or late subacute phase of stroke are unlikely to achieve independent ambulation by discharge, despite RAGT; and the discharge FAC of 1.3 by Chang et al in a similar cohort, support our findings of FAC of 0.94.(7) Notably though, the shortcoming of FAC lies in its lack of responsiveness to change, especially at the lower end of the scale.(1,24) Furthermore, as all of our patients had severe paresis, other potentially more sensitive clinical ambulatory measures such as walking distance and postural balance could not be recorded. We hypothesise that even though a measurable improvement in walking ability (e.g. FAC) may not be achieved, RAGT likely resulted in an improvement in muscle activation and voluntary motor activity, supported by superior gains in LeFMA for the RAGT group compared to the

CPT group.[25] These reductions in motor impairment then translated into improved lower limb function, transfers, LeFMA scores, potentially leading to reduced dependency.[26]

Several study limitations existed, including firstly, a matched study design where data were collected retrospectively. Although randomised matching was performed to ensure homogeneity of both groups, not all factors could be controlled for e.g. cognition, presence and severity of sensory impairments or medical complications which may influence rehabilitation outcomes. Second, the small number of RAGT patients could limit generalisability. Third, our centre's inpatient RAGT protocol consists of 10-15 sessions per inpatient stay, as time and expertise were needed to address non-motor rehabilitation goals and therapies. RAGT intensity in the literature also varies, possibly reflecting the prescriptive nature of RAGT. In our study, participants received 10-15 RAGT sessions during an average rehabilitation stay of 61.6 days, and it could be argued that the underutilisation of RAGT might have led to nonsignificant ambulatory outcomes. Fourth, data involving improvement in truncal control (e.g. Trunk Impairment Scale), postulated as a possible mechanism for functional improvement, was not available. Fifth, the approximately 9-year survey period meant that inherent variations in our centre's staffing and program content could have affected the comparability of the data. Lastly, no long-term outcomes beyond the first 3 months of stroke were reported.

In summary, this study showed that inpatient RAGT is a feasible, safe and effective rehabilitation tool in early and severely disabling stroke, providing superior functional gains and reducing dependency despite a lack of appreciable changes in walking function. More prospective randomised controlled trials in this population are required to evaluate long-term outcomes for improvement in gait, sitting/standing balance, functional status and cognitive status after RAGT.

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Table I. Baseline clinical and training characteristics by group

Variable	No. (%)		p-value
	Combinatory RAGT (n = 50)	CPT (n = 100)	
Age* (yr)	56.9 (±13.2)	56.6 (±12.4)	0.648
Male gender	32 (64.0)	64 (64.0)	>0.950
Aetiology			>0.950
Haemorrhagic	16 (32.0)	32 (32.0)	
Ischemic	34 (68.0)	68 (68.0)	
Side of hemiparesis (left)	21 (42.0)	51 (51.0)	>0.950
Days from stroke event to inpatient rehabilitation*	15.0 (±5.66)	15.8 (±4.33)	0.425
Conventional physiotherapy sessions*	30.7 (±21.5)	40.8 (±18.6)	0.003
Admission FIM-walk subscore*	1.1 (±0.2)	1.1(±0.2)	>0.950
FIM-walk subscore of 1	47 (94.0)	94 (94.0)	
FIM-walk subscore of 2	3 (6.0)	6 (6.0)	
Admission FAC score*	0.12 (±0.33)	0.12 (±0.33)	>0.950
FAC score of 0	44 (88.0)	88 (88.0)	
FAC score of 1	6 (12.0)	12 (12.0)	
Admission FIM-M subscore*	5.82 (±2.78)	6.04 (±1.44)	0.612
Admission FIM-S subscore*	9.30 (±4.85)	10.77 (±4.60)	0.151
Admission FIM-SP subscore*	2.20 (±0.95)	2.69 (±1.26)	0.006
Admission c-FIM subscore*	11.1 (±7.02)	10.9 (±6.30)	0.798
Admission t-FIM score*	28.5 (±11.52)	30.4 (±9.26)	0.350
Admission LeFMA*	8.14 (±5.21)	8.04 (±3.88)	0.906

Data presented as *mean ± standard deviation. RAGT: Robotic assisted gait training; CPT: Conventional Physiotherapy, FIM: Functional Independence Measure; FIM-M: FIM mobility; FIM-S: FIM selfcare; FIM-SP: FIM sphincter; c-FIM: cognitive FIM, t-FIM: total FIM, LeFMA: Fugl Meyer Assessment of Lower Extremity

Table II. Discharge functional and locomotor outcomes by group

Variable	No. (%)		p-value
	RAGT (n = 50)	CPT (n = 100)	
Discharge t-FIM score*	53.5 (±18.8)	45.5 (±15.6)	0.018**
Discharge FIM-walk subscore*	2.12 (±1.30)	1.77 (±0.99)	0.103
FIM-walk subscore of 1	23 (46.0)	58 (58.0)	
FIM-walk subscore of 2	11 (22.0)	24 (24.0)	
FIM-walk subscore of 3	6 (12.0)	6 (6.0)	
FIM-walk subscore of 4	7 (14.0)	7 (7.0)	
FIM-walk subscore of 5	3 (6.0)	5 (5.0)	
Discharge FAC score*	0.94 (±0.84)	0.73 (±0.61)	0.113
FAC score of 0	16 (32.0)	44 (44.0)	
FAC score of 1	24 (48.0)	44 (44.0)	
FAC score of 2	7 (14.0)	7 (7.0)	
FAC score of 3	3 (6.0)	5 (5.0)	
Discharge LeFMA score*	14.0 (±6.22)	12.0 (±5.08)	0.076
Length of rehabilitation stay (days)*	61.6 (±30.1)	59.6 (±23.1)	0.741
Institutionalization	2 (4.0)	6 (6.0)	0.596

Data presented as *mean ± standard deviation. **p-value < 0.05 is considered statistically significant. RAGT: Robotic assisted gait training; CPT: Conventional Physiotherapy; FIM: Functional Independence Measure; t-FIM: total FIM; FIM-M: FIM mobility; FIM-S: FIM selfcare; FIM-SP: FIM sphincter; LeFMA: Fugl Meyer Assessment of Lower Extremity

Table III. Discharge functional and locomotor gains by group

Variable	Mean (± standard deviation)		p-value
	RAGT (n = 50)	CPT (n = 100)	
t-FIM gain	25.0 (±15.7)	15.1 (±10.2)	<0.001*
m-FIM gain	19.8 (±13.3)	10.2 (±8.42)	<0.001*
c-FIM gain	5.16 (±4.83)	4.88 (±3.52)	0.742
FIM-walk gain	1.06 (±1.22)	0.80 (±1.04)	0.240
FIM-M subscore gain	7.66 (±5.20)	3.36 (±4.16)	<0.001*
FIM-S subscore gain	9.80 (±7.73)	5.47 (±5.33)	0.002*
FIM-SP subscore gain	2.38 (±2.88)	1.38 (±1.38)	0.034*
FIM efficiency (FIM gain/days)	0.46 (±0.28)	0.32 (±0.24)	0.010*
LeFMA gain	5.92 (±5.32)	4.00 (±2.72)	0.023*

*p-value < 0.05 is considered statistically significant. RAGT: Robotic assisted gait training; CPT: Conventional Physiotherapy; FIM: Functional Independence Measure; t-FIM: total FIM, m-FIM: motor FIM, c-FIM: cognitive FIM, FIM-M: FIM mobility; FIM-S: FIM selfcare; FIM-SP: FIM sphincter; LeFMA: Fugl Meyer Assessment of Lower Extremity