Hong Kong Physiotherapy Journal (2017) **36**, 10—16

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journal homepage: www.hkpj-online.com

RESEARCH REPORT

Effectiveness of robotic-assisted gait training in stroke rehabilitation: A retrospective matched control study

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KEYWORDS
gait;
physiotherapy;
rehabilitation;
robotic;
stroke

Abstract *Objective:* This study aimed to evaluate the effectiveness of robotic-assisted gait training (RAGT) in improving functional outcomes among stroke patients.
Design: This was a retrospective matched control study.
Setting: This study was conducted in an extended inpatient rehabilitation centre.
Patients and intervention: There were 14 patients with subacute stroke (4—31 days after stroke) in the RAGT group. Apart from traditional physiotherapy, the RAGT group received RAGT. The number of sessions for RAGT ranged from five to 33, and the frequency was three to five sessions per week, with each session lasting for 15—30 minutes. In the control group, there were 27 subacute stroke patients who were matched with the RAGT group in terms of age, days since stroke, premorbid ambulatory level, functional outcomes at admission, length of training, and number of physiotherapy sessions received. The control group received traditional physiotherapy but not RAGT.
Outcome measures: Modified Functional Ambulation Category (MFAC), Modified Rivermead Mobility Index (MRMI), Berg's Balance Scale (BBS), and Modified Barthel Index (MBI) to measure ambulation, mobility, balance, and activities of daily living, respectively.
Results: Both RAGT and control groups had significant within-group improvement in MFAC, MRMI, BBS, and MBI. However, the RAGT group had higher gain in MFAC, MRMI, BBS, and MBI than the control group. In addition, there were significant between-group differences in MFAC, MRMI, and BBS gains ($p = 0.026$, $p = 0.010$, and $p = 0.042$, respectively). There was no significant between-group difference ($p = 0.597$) in MBI gain ($p = 0.597$).
Conclusion: The results suggested that RAGT can provide stroke patients extra benefits in terms of ambulation, mobility, and balance. However, in the aspect of basic activities of daily living, the effect of RAGT on stroke patients is similar to that of traditional physiotherapy.

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http://dx.doi.org/10.1016/j.hkpj.2016.09.001

Introduction

Stroke, also known as cerebrovascular accident, is an acute disturbance of focal or global cerebral function, with signs and symptoms lasting more than 24 hours or leading to death, presumably of vascular origin [1]. In Hong Kong, around 25,000 stroke patients are admitted to public hospitals under the Hong Kong Hospital Authority annually [2]. Although mortality and morbidity among stroke patients have declined due to medical advances, impacts on stroke survivors and community remain significant. The most widely recognized impairment caused by stroke is motor impairment, which restricts muscle movement or mobility function [3]. Many stroke patients experience difficulties in walking, and improving walking is one of the main goals of rehabilitation [4]. Since it was shown that the process of spontaneous recovery is almost completed within 6—10 weeks [5], early rehabilitation is essential to maximize the function of patients after stroke. Recent evidence suggests that high-intensity repetitive task-specific practice might be the most effective principle when trying to promote motor recovery after stroke [3]. Robotic-assisted gait training (RAGT) is a new global physiotherapy technology that applies the high-intensity repetitive principle to improve mobility of patients with stroke or other neurological disorders. The advantage of RAGT may be the reduction of the effort required by therapists compared with treadmill training with partial bodyweight support, as they no longer need to set the paretic limbs or assist in trunk movements [6]. People who receive electromechanical-assisted gait training in combination with physiotherapy after stroke are more likely to achieve independent walking than people who receive gait training without these devices [7]. More specifically, people in the first 3 months after stroke and those who are not able to walk seem to benefit most from this type of intervention [7]. Evidence also shows that the use of RAGT in stroke patients has positive effects on their balance [8].

Randomized controlled trials and systemic reviews have demonstrated the effectiveness of RAGT for stroke patients in terms of functional outcomes such as walking ability [9—11] and balance [8,11]. However, limited published evidence is available on the effectiveness of RAGT in improving other functioning activities such as basic activities of daily living (ADL) [12,13]. If RAGT can improve walking ability and balance of stroke patient, can RAGT also improve basic ADL of stroke patients? The hierarchical pattern of progression in basic ADL is in the following order: bathing, dressing, transferring, toileting, controlling continence, and feeding, with bathing being the most complex task and feeding the least [14]; however, walking ability and balance contribute to parts of basic ADL. Moreover, factors that make the greatest contribution to ADL after stroke were found to be balance, upper extremity function, and perceptual and cognitive functions [15]. If RAGT can improve ADL of stroke patients, which of the above factors is/are enhanced by RAGT? Can RAGT also enhance perceptual and cognitive functions of stroke patients? Hence, controlled studies are necessary to address these research questions. A retrospective study conducted by Dundar et al [13] investigated the effect of robotic training in functional independence measure and other functional outcomes of patients with subacute and chronic stroke. However, the study concluded that combining robotic training with conventional physiotherapy produced better improvement than conventional physiotherapy in terms of functional independence measure, but not walking status or balance. The result was opposite to the specificity of training principle [16] that gait training should produce more positive effect for walking and balance than ADL. Hence, this study intends to investigate the effectiveness of RAGT in improving functional mobility and basic ADL for stroke patients, and hopefully can lead to further randomized controlled studies to investigate the impact of RAGT on basic ADL.

Methods

Patient selection

All stroke patients admitted to Tai Po Hospital, Tai Po, Hong Kong from 1 January 2014 to 31 December 2015 were screened by physiotherapists for RAGT. Inclusion criteria were independent outdoor walking before the episode of stroke, ability to follow one-step command, ability to tolerate passive standing for at least 15 minutes, and the interval between the stroke and the first session of intervention being no longer than 6 weeks. Exclusion criteria were femur length shorter than 35 cm or longer than 47 cm; body weight greater than 135 kg; severe lower-extremity contractures, spasticity, ataxia, or dyskinesia that limited normal walking kinematics; open wound over trunk or lower limbs; hemodynamic instability; and other active medical illness.

Baseline characteristics

Baseline characteristics of the patients, including age, gender, days from stroke, number of physiotherapy sessions received, and length of training, were collected for further analysis. The length of training of a patient was defined as the total number of days from the start to the end of physiotherapy.

Study design

This was a retrospective case—control study. The investigator of this study reviewed medical records, physiotherapy treatment records, and data, from the Clinical Management System of Hong Kong Hospital Authority, of all patients who had received stroke rehabilitation in Tai Po Hospital during the period from 1 January 2014 to 31 December 2015. The patients who had received more than four RAGT sessions were assigned to the RAGT group. The patients who had completed the stroke rehabilitation programme without RAGT were selected for matching with the RAGT group in terms of age, premorbid ambulatory level, day from stroke, length of training, number of physiotherapy sessions, and admission functional outcome measurements. After excluding the patients who were not matched with the RAGT group, the remaining patients were assigned to the control group. Both groups had similar baseline characteristics such as period of hospitalization, days from stroke, and premorbid walk ability before the episode of stroke. Baseline characteristics mentioned above and functional outcome measurements including modified functional ambulation category (MFAC), Modified Rivermead Mobility Index (MRMI), Berg's Balance Scale (BBS), and Modified Barthel Index (MBI) were collected for analysis. Ethics approval was granted by the Joint Chinese University of Hong Kong—New Territories East Cluster Clinical Research Ethics Committee, Prince of Wales Hospital, Shatin, Hong Kong.

RAGT intervention

The RAGT was provided by a robot system device (Lokomat Pro; Hocoma Inc., Zurich, Switzerland) and operated by trained physiotherapists with Lokomat certification. The system for lower limb training was a motor-driven gait orthosis secured to the patient's lower limbs. The patient's whole body was supported by a bodyweight support system over a synchronized treadmill. The patient's legs were guided on the treadmill according to a preprogrammed physiological gait pattern, which, in combination with the bodyweight support system, transmitted the treadmill movement to levers to induce the stance and swing phases. The system allowed a specific level of guidance compatible to the patient's clinical condition to achieve enhancements in gait speed, endurance, and gait quality while minimizing destructive compensatory gait pattern and avoidable stress to the patient. The physical stress of physiotherapy staff could also be reduced. Consistency and duration of training sessions could be ensured. All patients in the RAGT group received three to five sessions of RAGT per week. Each session lasted for 15—30 minutes depending on patients' tolerance. The amount of bodyweight support was adjusted to maximize lower-extremity weight bearing while ensuring correct stance and swing. The treadmill speed was set at a comfortable level specific to the patient, starting from 1.5 km/h (which is equal to 0.278 m/s) and was increased as tolerated.

Traditional physiotherapy

The traditional physiotherapy treatments were based on the corporate stroke rehabilitation protocol of Hong Kong Hospital Authority [17]. The protocol was designed with reference to the International Classification of Functioning, Disability and Health framework of the World Health Organization [18], which delineated the current practice patterns of physiotherapy intervention including limbs mobilization, muscle tone normalization, muscle strengthening, electrical muscle stimulation, transfer training, gait training, and balance training for patients with stroke. The protocol allowed variations in clinical practice, and the ultimate decision about a particular clinical treatment depended on each individual patient's condition, circumstances, and clinical judgement of physiotherapists.

Treatment duration

Both RAGT and control groups were hospitalized in the same ward and received traditional physiotherapy treatments delivered by the same team of physiotherapists 5 days per week. The duration of each physiotherapy session for both groups was 60—90 minutes, depending on patients' tolerance and motivation. The 15—30-minute RAGT for the RAGT group was also included in the 60—90-minute physiotherapy treatment.

Statistical analysis

A retrospective comparison of stroke patients who have received robotic walking therapy was performed statistically. We compared the clinical outcomes of the RAGT group with those of the control group in order to investigate the pre and post between- and within-group differences in ambulation, mobility, balance, and ADL. The within-group differences of initial and final scores of each functional outcome measurement (MFAC, MRMI, BBS, and MBI) and between-group differences of MFAC gain, MRMI gain, BBS gain, and MBI gain were compared. The within-group comparisons of both groups were based on paired *t* test for MRMI, BBS, and MBI, and Mann—Whitney *U* test for MFAC. The between-group comparison of the RAGT and control groups was based on independent-sampled *t* test for MRMI, BBS, and MBI and Mann—Whitney *U* test for MFAC. Results were considered statistically significant when $p < 0.05$. Data were analysed with the use of the SPSS version 20 statistical package (SPSS Inc., Chicago, IL, USA).

Outcome measures

Outcome measurements were indicated by four functional outcome measurements (i.e., MFAC, MRMI, BBS, and MBI) to measure ambulation, mobility, balance, and ADL of patients, respectively. Each patient had a case physiotherapist who administered all scores—the initial and final scores on admission and in predischarge examination, respectively. All scores were retrieved from the medical records and physiotherapy treatment records for comparison. Gains in MFAC, MRMI, BBS, and MBI were the differences between the respective initial and final scores of each patient. The percentage changes in MFAC, MRMI, BBS, and MBI were the percentage differences between the respective initial and final scores of each group.

Modified Functional Ambulation Category

The MFAC [19] was used to assess patients' ambulation level in this study. The MFACs provided by the two raters were highly reliable [intraclass correlation coefficient (ICC) = 0.960, 95% confidence interval: 0.942—0.972, $p < 0.001$] [19]. The MFAC is a 7-point Likert Scale (I—VII) that is used to classify a patient's walking capacity. Gait is divided into seven categories, ranging from no ability to walk and requiring manual assistance to sit or is unable to sit for 1 minute without back or hand support (MFAC I), to the ability to walk independently on level and nonlevel surfaces, stairs, and inclines (MFAC VII) [19].

Modified Rivermead Mobility Index

The MRMI was used to assess patients' mobility in this study. The MRMI is highly reliable between raters (ICC = 0.98) and has high internal consistency (Cronbach $\alpha = 0.93$) for early-stage stroke patients. The MRMI consists of eight test items, including turning over, changing from lying to sitting, maintaining sitting balance, going from sitting to standing, standing, transferring, walking indoors, and climbing stairs. Scores of the MRMI range from 0 to 40. One main characteristic of the MRMI is that participants are scored by direct observation of their performance on the items [20].

Berg Balance Scale

The BBS was used to assess patients' balance in this study. The BBS has been shown to have excellent inter-rater (ICC = 0.98) and intra-rater (ICC = 0.98) reliability, and is internally consistent (0.96) for patients with acute stroke [21]. The BBS has been shown to have 53% sensitivity to predict falls in elderly persons [22] and be able to detect changes in balance of patients with acute stroke [23]. The BBS is composed of 14 tasks. The scoring of each task is from 0 to 4. A score of 0 is given if the participant is unable to perform the task, while a score of 4 is given if the participant is able to complete the task in accordance with the respective criterion. The total score of the BBS is 56 [21,24–26]. The value of 45 points is used to calculate relative risk estimates, which demonstrated predictive validity [22]. Hence, a score of 45 has been shown to be an appropriate cut-off for safe and independent ambulation, and the need for assistive devices or supervision [26].

Modified Barthel Index

The ADL of participants were assessed by the MBI. The MBI measures a participant's performance in 10 functional items including self-care, continence, and locomotion [27]. The values assigned to each item are based on the amount of physical assistance required to perform the task and added to give a total score ranging from 0 to 100 (0 = fully dependent, 100 = fully independent), with higher scores indicating higher levels of physical function. There are no subtotal scores because there are no subscales [27]. The internal consistency reliability coefficient for the MBI is 0.90 [27].

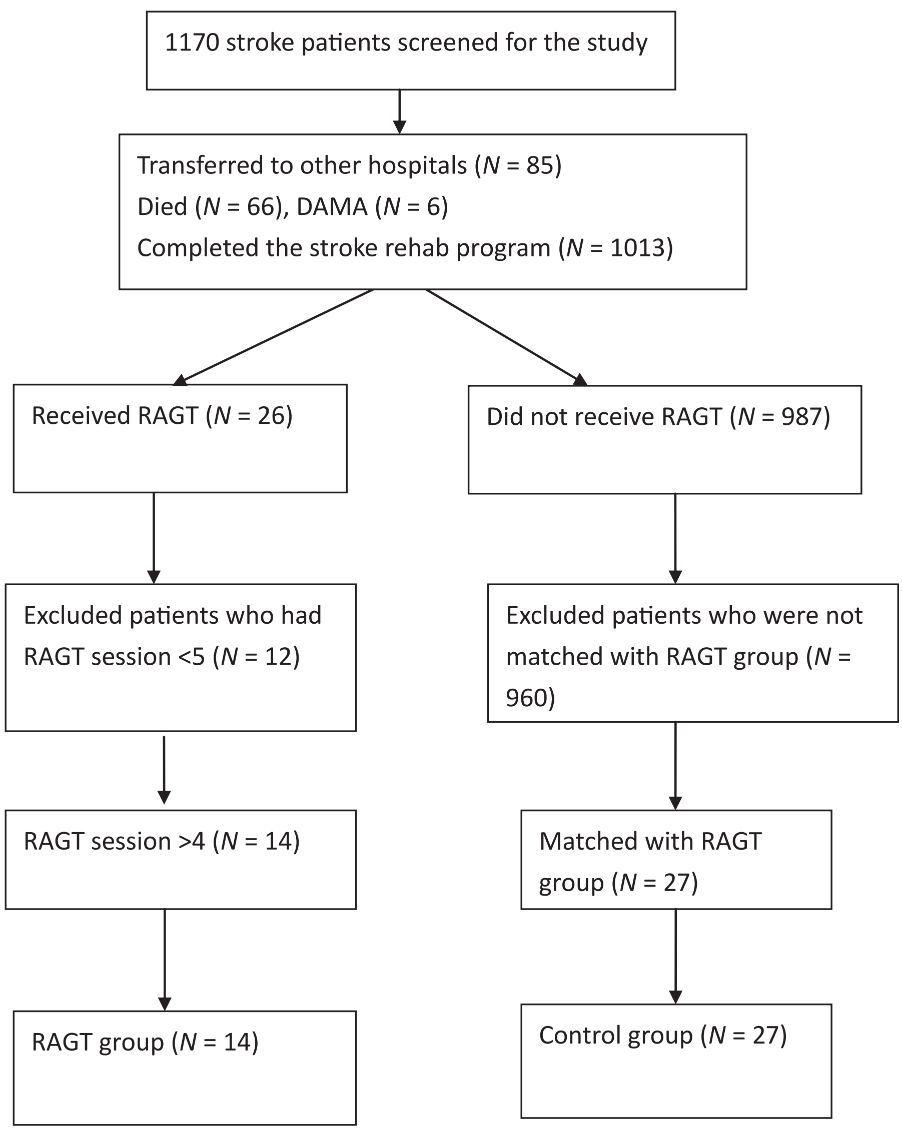

Figure 1. Flowchart of patient assignment. DAMA = discharged against medical advice; RAGT = robotic-assisted gait training.

Results

From January 1, 2014 to December 31, 2015, 1170 stroke patients were admitted to the hospital and screened for the study; of them, 1013 completed the stroke rehabilitation programme, 66 were dead, and six were discharged against medical advice. Among the stroke patients who have completed the stroke rehabilitation programme, 26 received RAGT but 12 of them were excluded from the study because they had less than five sessions of RAGT. The remaining 14 stroke patients were recruited to the RAGT group (Figure 1). Nine hundred and eighty seven patients, who completed the stroke rehabilitation programme but did not receive RAGT, were selected to match with the RAGT group in terms of age, days from stroke, premorbid ambulatory level, admission functional level, length of training, and number of physiotherapy sessions. After excluding 960 patients who were not matched with the RAGT group, the remaining 27 patients were assigned to the control group for comparison (Figure 1).

Table 1 Baseline characteristics of patients.

	RAGT group (n = 14)	Control group (n = 27)	p[a]
Age (y)	59.2 ± 6.1	60.5 ± 6.5	0.529
Males	10 (71.4)	13 (48.2)	0.162
Ischemic stroke	10 (71.4)	24 (88.9)	0.167
Days from stroke (d)	13.9 ± 8.18	11.7 ± 7.4	0.384
Premorbid MFAC	7 ± 0	7 ± 0	NA
Initial MFAC	2.2 ± 0.8	2.7 ± 1.4	0.246
Initial MRMI	12.1 ± 7.4	15.4 ± 9.3	0.266
Initial BBS	6.6 ± 7.1	10.8 ± 13.4	0.279
Initial MBI	36.6 ± 21.4	44.2 ± 20.7	0.276
Length of training (d)	41.1 ± 16.4	34.3 ± 11.7	0.135
No. of physiotherapy sessions	26.0 ± 10.8	21.2 ± 7.8	0.108

Data are presented as mean ± standard deviation or n (%).
BBS = Berg's Balance Scale; MBI = Modified Barthel Index; MFAC = Modified Functional Ambulation Category; MRMI = Modified Rivermead Mobility Index; RAGT = robotic-assisted gait training.
[a] t test.

Baseline characteristics of the patients are shown in Table 1. The RAGT group consisted of 10 males and four females, with a mean age of 59.2 ± 6.1 years; the mean number of days from stroke was 13.9 ± 8.1 (ranging from 4 days to 31 days). The control group consisted of 13 males and 14 females with a mean age of 60.5 ± 6.5 years; the mean number of days from stroke was 11.7 ± 7.4 (ranging from 2 days to 39 days). The premorbid ambulatory level of both groups was independent outdoor walking (MFAC = 7). Upon admission, no significant difference ($p < 0.05$) was observed between both groups in terms if their age, days from stroke, and initial scores of MFAC, MRMI, BBS, and MBI, indicating that both groups were homogeneous. During hospitalization, there was no significant difference ($p < 0.05$) between both groups in terms of length of training and number of physiotherapy sessions. The mean number of RAGT sessions of the RAGT group was 13.0 ± 8.9 (5–33 sessions).

When comparing the baseline and predischarge functional outcome measurements (Table 2), both RAGT and control groups had significant improvements in MFAC, MRMI, BBS, and MBI ($p < 0.05$), but the percentage changes in all functional outcome measurements of the RAGT group were higher than those of the control group. In addition, the RAGT group had higher gains in MFAC, MRMI, BBS, and MBI than those of the control group; there were significant between-group differences in MFAC, MRMI, and BBS gains ($p = 0.026$, $p = 0.010$, and $p = 0.042$, respectively). Although the percentage change in MBI of the RAGT group (51.4%) was higher than that of the control group (36.5%), there was no significant difference ($p = 0.597$) in MBI gain between the RAGT and control groups.

Discussion

Since this was a retrospective matched control study, great efforts were made to ensure homogeneity of participants in the RAGT and control groups. All participants were homogeneous in terms of age, duration of stroke, premorbid mobility level, and admission functional outcome measures because the age, days from stroke, premorbid MFAC, and initial scores of MFAC, MRMI, BBS, and MBI had no significant differences. There were no significant differences

Table 2 Comparison of functional outcomes.

	RAGT group (n = 14)			Within group	Control group (n = 27)			Within group	Between group
Score	Initial	Final	Percentage change	p[a]	Initial	Final	Percentage change	p[a]	p[b]
MFAC	2.2 ± 0.8	4.5 ± 0.7	103.62	<0.001	2.7 ± 1.4	4.1 ± 1.1	55.19	<0.001	0.026*
MRMI	12.1 ± 7.4	28.0 ± 6.4	130.64	<0.001	15.4± 9.3	24.4 ± 9.1	58.60	<0.001	0.010*
BBS	6.6 ± 7.1	26.0 ± 12.4	291.57	<0.001	10.8 ± 13.4	22.3 ± 14.1	105.05	<0.001	0.042*
MBI	36.6 ± 21.4	55.5 ± 17.7	51.47	0.002	44.2 ± 20.7	60.4 ± 21.0	36.56	<0.001	0.597

Data are presented as mean ± standard deviation.
BBS = Berg's Balance Scale; MBI = Modified Barthel Index; MFAC = Modified Functional Ambulation Category; MRMI = Modified Rivermead Mobility Index.
* $p < 0.05$.
[a] Paired t test.
[b] Independent-sampled t test, except independent-sampled Mann–Whitney U test for MFAC.

statistically in the length of training and number of physiotherapy sessions, indicating both groups received similar sessions of physiotherapy treatment. However, since this was a retrospective clinical study, there were some limitations. First, the effectiveness of traditional physiotherapy treatment depended on patients' tolerance and motivation, and the duration, intensity, and type of treatment might vary from day to day. These dynamic changes in treatment parameters made exact recording and comparison of treatment between participants impossible. Second, sizes of the groups were unequal because only a part of the stroke patients was selected for RAGT in the inpatient rehabilitation phase. In fact, an inequality in the group size was expected when the control group was matched with the RAGT group in terms of the participants' baseline characteristics, number of physiotherapy sessions, and length of training. The patient ratio of the treatment group to the control group of the present study and that of the study by Dundar et al [13] were 14:27 and 36:71, respectively. This may reflect that only around one-third of stroke patients suitable for RAGT were selected in real clinical situations. Hence, it was unfair to match the size of both groups using the 1:1 matching method because that would exclude suitable individuals of the control group. Proper statistical techniques have been used in this study according to the study design—paired *t* test for within-group comparison and independent-sampled *t* test for between-group comparison in a nonequivalent group design [28,29].

The mean number of days from stroke in the RAGT group was 13.9, indicating that the patients suffered from subacute stroke. The initial MFAC of patients in the RAGT group was 2.2, which reflected that the patients were nonwalkers on admission. In the present study, the gains in MFAC, MRMI, and BBS of the RAGT group were significantly different from those of the control group; the RAGT group exhibited around two-fold gain in percentage changes in MFAC, MRMI, and BBS. Hence, we suggest that RAGT could provide extra benefits in terms of ambulation, mobility, and balance for subacute stroke patients who were nonwalkers on admission, when compared with the control group. The result echoes with the study conducted by Morone et al [7] who found that people in the first 3 months after stroke and those who could not walk seem to benefit the most from electromechanical-assisted gait training. Statistically, there was no significant difference in MBI gain between both groups, implicating that the effect of RAGT was similar to that of traditional physiotherapy for stroke patients in terms of basic ADL. This result may be explained by the specificity of training principle [16]. Since the major aim of RAGT was to enhance gait speed, endurance, and gait quality of patients, improvement in stroke patients was reflected by gait-related outcome measurements such as MFAC, MRMI, and BBS instead of MBI. It was shown that factors that contributed most in ADL after stroke were balance, upper extremity function, and perceptual and cognitive functions [15]. The present result was opposite to the result of the retrospective study by Dundar et al [13], who found that robotic training, when combined with conventional physiotherapy, produced better improvement than conventional physiotherapy in terms of functional independence measure, but not walking status or balance. A possible explanation of the present result, being reverse of the result of Dundar et al [13], would be that each stroke patient suffered from different patterns of motor, perceptual, and cognitive deficits, and therefore had different degrees of deficits in different components of their basic ADL. For stroke patients who had more deficits in balance, RAGT may improve their basic ADL. By contrast, RAGT may not improve the basic ADL of those who had more deficits in perceptual, cognitive, and even upper extremity functions. In addition, it was reported that a hierarchical pattern of progression in basic ADL was as follows: bathing, dressing, transferring, toileting, control continence, and feeding, with bathing being the most complex task and feeding the least [14]. The complete picture of the relationship between the hierarchical pattern as well as contributing factors of basic ADL and walking status or balance seemed very complicated, and could not be explained by a single clinical study. Further studies with a higher level of evidence, such as randomized controlled trials to investigate the effect of RAGT on basic ADL in terms of hierarchical pattern and contributing factors for stroke patients, are suggested.

Conclusion

The results suggested that RAGT can provide stroke patients extra benefits in terms of ambulation, mobility, and balance. However, in the aspect of basic ADL, the effect of RAGT on stroke patients is similar to that of traditional physiotherapy. Further studies with higher level of evidence, such as randomized controlled trials to investigate the effect of RAGT on basic ADL for stroke patients, are suggested.

Conflicts of interest

All authors declare no conflicts of interest.

Funding/support

No financial or material support of any kind was received for the work described in this article.

Acknowledgements

This study was supported by the Physiotherapy Department of Tai Po Hospital. The author would like to thank his colleagues for their support and contributions.

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