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Effects of Robot Assisted Therapy as an Adjunct to Conventional Therapy in Upper Limb Motor Recovery after Stroke

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ABSTRACT
The recovery of upper extremity (UE) function after stroke is slower and less complete than return of mobility. Neuroplasticity is the key mechanism underlying improvement in functional outcome after stroke. Robotic devices can stimulate neuroplasticity by providing high-intensity, repetitive, task-specific training.
Aim of this prospective randomized controlled study was to evaluate the efficacy of Robot-assisted therapy as an adjunct to conventional rehabilitation program in management of UE weakness in stroke patients in terms of motor recovery & functional outcome.
Sixty four patients, having stroke duration less than two years, included in the study (n=64) and divided in two groups. Thirty two subjects in control group received conventional rehabilitation program & thirty two in study group additionally received Robot-assisted therapy using over four weeks. Assessment was done pre-treatment, at 1 month & at 4 months. The outcome measures were:Fugl-Meyer Assessment(FMA) score for upper extremity & Motor Activity Log scale(MAL) comprising of Amount of Use(AOU) score and Quality of Use (QOU) score.
Chi-Square test and paired t test were used. Results were considered significant at 5% that is P value<0.05.
The study group exhibited greater motor recovery than the control group on the FMA scores at 1month and 4months. The mean AOU and QOS scores of MAL in the study group were also better than that of control group at 1month and 4months.
So it can be concluded thatRobot-assisted therapy can be used as a complement to conventional therapy for improving UE function in stroke.
Keywords: *Stroke, Rehabilitation, Robotics, Upper extremity.*

INTRODUCTION

A vast number of stroke survivors have limited use of their hemiplegic arm. Optimal restoration of upper limb function is necessary for stroke patients to independently perform activities of daily living. Interventions focusing on recovery of upper limb function are important part of stroke rehabilitation. One such intervention is robotic therapy for upper limb, which anchors the principles of neuroplasticity and motor learning. Robotic devices can provide high-intensity, repetitive, task-specific, interactive treatment of the impaired limb, along with performance feedback. This kind of stimulation is associated with increased adaptive plasticity of brain. [(1)]

Many recent studies have shown improvement in motor function of upper limb afterstroke using Robotic therapy. [(2-4)] Most of them havecompared similar duration of robotic and conventional therapy and have found Robotic therapy to be more effective. [(2,3)] Only a limited number of studies have investigated whether robotic assistance improved effectiveness of conventional therapy. Robotic therapy offers consistency, precision, non-fatigability, programmability, feedback and ability to measure and record in parallel with therapy delivery. All these factors have identified robotic training as an additional effective therapy to conventional rehabilitation program of stroke survivors.

In most of the industrial countries, rehabilitation robotics has moved out of the research setting and are being used as a component of routine clinical care, but in developing countries, the scenario is markedly different. Rehabilitation robotics is still in its infancy here. Though there are a large number of studies done worldwide, we are reporting the first experience from India in robot-assisted therapy for stroke.

Our study was conducted to evaluate the efficacy of Robot assisted therapy when added to conventional rehabilitation therapy. Our aim was to see whether addition of robotic therapy to conventional rehabilitation therapy can bring out more improvement than the conventional therapy alone. The results of the study would definitely extend previous research on robotic therapy. It will guide us about the feasibility of use of rehabilitation robotics in India. It is also a reflection of general acceptance of the device-assisted rehabilitation over manual therapy, the former being much less common in India than the latter.

MATERIALS & METHODS

Approvals from the institute ethics committee were taken on the study design prior to commencing the study. Thereafter, all patients of stroke attending the Physical medicine and Rehabilitation out Patient Department (OPD) in a government hospital were examined and screened according to inclusion and exclusion criteria.

The inclusion criteria were:

- Stroke patients with post stroke duration of less than 2 years,
- Patient should be able to understand and follow simple verbal instructions,
- Ability to actively extend at least 10^oat the metacarpophalangeal and interphalangeal joints and 10^oat wrist,
- Spasticity ≤ 3 on modified Ashworth scale, in shoulder flexors, adductors and internal rotators, elbow flexors, forearm pronators, wrist flexors and finger flexors.
- Joint control fair or below (corresponds to antigravity muscle power or less) in shoulder, elbow and wrist.

The exclusion criteria were:

- History of any other neurological disorder,
- History of angina or uncontrolled hypertension,
- Taking medication that could affect neuromuscular performance (e.g. Botulinum toxin type A, Baclofen, Diazepam etc.),
- History of recent trauma to upper limb (e.g. sprained wrist, fractures etc.),
- Visually impairment or hearing impairment,
- Unconsciousness or bed-ridden patients,

- Balance problems compromising safety while performing therapy,
- Unwilling to enrol in the study.

Patients satisfying the criteria and consenting were enrolled in. Baseline work up of each patient was done including history, physical examination and relevant investigations. Subjects were randomly assigned, by closed envelope method, to either study group or control group. In this randomization process, we have generated random numbers using a computer software. The researcher was given randomly generated treatment allocations within sealed opaque envelopes. Once a patient has consented to enter the trial an envelope is opened and the patient is then offered the allocated treatment regimen.The control group received conventional rehabilitation programme for 1 hour daily, 6 days a week, over 4 weeks. In which 30 minutes they were given physiotherapy and 30 minutes of occupational therapy everyday. In the physiotherapy section subjects received range of motion and strengthening exercises for the upper limb; endurance training, gait training and education, as appropriate. In the occupational therapy section they were given activities to improve gross and fine hand function, co-ordination activities and modification and training of activities of daily living (ADL). The study group participated in a Robot Assisted Therapy in addition to the conventional rehabilitation program. The study intervention included 12 hours robot assisted therapy distributed in sessions, 30 min/day, 6 days a week, over 4 weeks. The Robot used in this study is Armeo Spring manufactured by Hocoma.

It can provide arm weight support, exoskeleton for movement guidance, facilitate self-initiated movements, grasp and release exercises and performance feedback. The robot combines an adjustable arm support and a large 3-D workspace that allows functional therapy exercises in a virtual reality environment. The arm exoskeleton with integrated springs embraces the whole upper limb and offers degrees of freedom at wrist (flexion / extension), forearm (pronation / supination), elbow (flexion /extension) and shoulder (flexion / extension, horizontal abduction /adduction, internal /external rotation). The grip sensor allows combined training of hand and arm function and can be used as an input device for exercises. A variety of functional reaching and grasping exercises and games simulating the activities of daily living that stimulate arm movement in meaningful activities was given to the patient. The robot facilitates the patient's own active movements which are directed through specific tasks on a computer screen and allows engaging in self-training with immediate visual and auditory feedback of performance. The performance feedback provided by the software platform encourages and motivates patients to achieve higher number of repetitions.

Assessment was done at 0 month (pre-treatment), 1 month (post-treatment) and 4 months (3 months after completing therapy) using Fugl-Meyer Assessment for Motor recovery of upper extremity, which is an objective scale and Motor Activity Log, which is a subjective scale to measure amount of use and how well the upper limb moves in attempting real life tasks. 30 item MAL was used in English. Therapy and assessment was done by the same person, the researcher, as there was no blinding in this study.

Statistical analysis: After completion of data collection from each subject enrolled in the study the data was entered in Microsoft excel and analysed statistically with SPSS 21 software using Chi-Square test for dichotomous responses and paired t test for comparison of continuous variables. The results were considered significant at 5% that is P value less than 0.05.

RESULTS

A total of sixty four (n=64) subjects were enrolled in the study. Thirty subjects in each group completed the three month follow-up period while others were lost to follow up. One drop out in the control group had medical complications unrelated to the study. Caregivers were unable to bring the subjects to the institution in two drop outs cases, one each in study and control group, before 1st follow up. We were unable to trace another subject in the study group during 2nd follow up, due to change of contact number and address.

Table I shows the baseline values in both the groups.

From table 2 it is seen that at baseline, there was no significant difference in FMA or MAL AOU & QOU Scores between the two groups. All the scores improved both in the study group and the control group after therapy. At 1 month, the mean improvement in scores was higher in the study group as compared to the control group and it was statistically significant. At 4 months also, the mean improvement in the all scores was higher in the study group compared to the control group, which was statistically significant.

.**Table 1:** Baseline Characteristics (original)

Characteristics	**Study group (n=32)**	**Control group (n=32)**	**p value**
Age in years	53.3	57.4	0.185
Sex (M:F)	23:9	20:12	0.424
Literacy (illiterate: primary: secondary: higher secondary:graduate:postgraduate)	5:3:19:2:3:0	6:3:18:3:2:0	0.500
Income (≤5000:≤10000:≤15000: ≤20000:>20000)	10:8:2:4:8	10:11:5:1:5	0.339
Hemiplegic side (left: right)	10:22	17:15	0.076
Cause of Stroke (ischemia: hemorrhage)	20:12	22:10	0.559
Duration of Stroke (days)	180.76	188.81	0.836
Active extension at wrist (degrees)	40.93	42.65	0.464
Active extension at MCP (degrees)	81.56	78.43	0.403
Active extension at PIP (degrees)	87.81	83.75	0.332
Active extension at DIP (degrees)	74.68	71.25	0.330

Table 2: Result score mean values with Standard deviation and significance level inter-group. (Original)

Parameter	**Assessment time**	**Study Mean±SD**	**Control Mean±SD**	**p value**
Fugl Meyer Score	Baseline	38.71±6.07	37.81±8.87	0.635
	1st month	48.10±5.422	41.43±9.06	0.01
	4th month	57±4.03	45.23±8.34	0.01
Motor Activity Log (Amount of Use) Score	Baseline	10.75±3.54	9.65±5.33	0.338
	1st month	15.80±3.28	11.33±5.22	0.01
	4th month	19.96±3.65	13.86±5.06	0.01
Motor Activity Log (Quality of use) Score	Baseline	9.71±2.51	8.93±3.78	0.335
	1st month	14.41±2.57	11.06±4.18	0.01
	4th month	19.23±3.47	3.43±3.64	0.01

Figure 1: Researcher explaining the subject about Robotic therapy

Figure 3: Activities performed in Armeo Spring

Figure 2: Armeo Spring Device

Figure 4: Activities performed in Armeo Spring

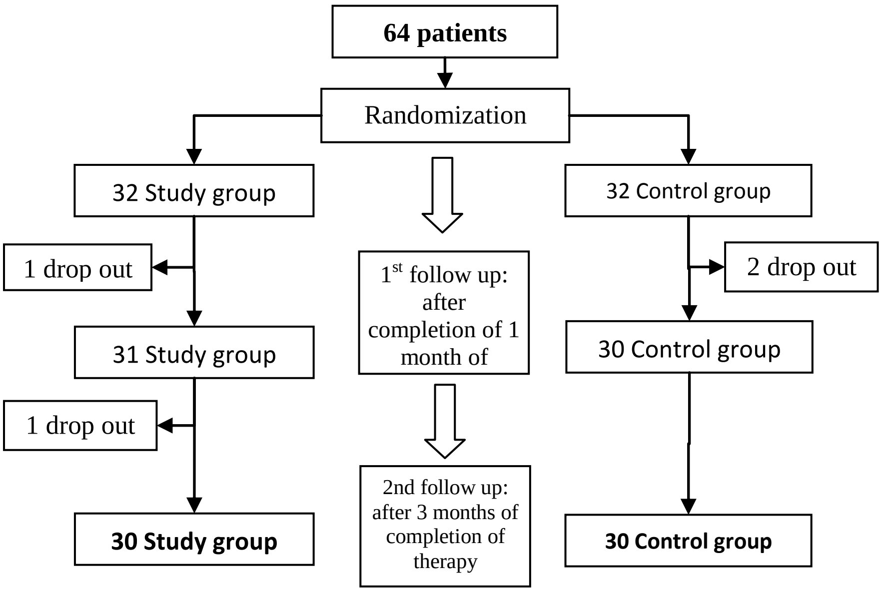

Figure 5: Flow chart

DISCUSSION

Rehabilitation robotics is a novel approach that provides repetitive training in a highly controlled and replicative manner affording careful implementation of neuroplasticity and motor control learning principles.

Our hypothesis was that robotic assistance might improve the effectiveness of conventional therapy in patients with upper limb motor deficits after stroke. The hypothesis was built upon results of several studies showing improvement in motor function of upper limb after Robotic therapy. [2-4]The motivation to investigate robotic therapy is its potential to provide additional effective therapy over and above the conventional therapy given to the patients of stroke. Along with increase in therapy time, robots might enrich the sensori-motor experience of the patient by providing novel patient-environment interaction during active repetitive training. This was one of the rationales to add robotic therapy to conventional therapy.

American Heart Association suggested that robot-assisted therapy for upper extremity has already achieved Class I, level of evidence A for stroke care in outpatient setting and care in chronic care setting. It also suggested that robot-assisted therapy for upper extremity has achieved Class IIa, Level of evidence A for stroke care in inpatient setting.[5] According to this classification in class I is ‘Benefit>>>Risk. Procedure/treatment SHOULD be performed/administered’; class IIa is‘Benefit>>Risk. It is REASONABLE to perform procedure/administer treatment’; Level A is‘multiple populations evaluated: data derived from randomized clinical trials or meta-analysis.’

In our subject base the mean age in study group was 53.3 years and in control group 57.4 years, which was almost similar to earlier studies done on stroke patients. [6-7] The gender ratio was majority of males, which substantiates observation of other studies. [6,8] As of the handedness, right sided hemiplegia was more common in study group as compared to left sided in the control group. Cases of stroke ischemic stroke were more than haemorrhagic stroke, as found in many other studies. [4,6,8-9]

As early commencement of training following stroke tends to yield better rehabilitative outcomes as proven by several studies, [9-10] in our study subjects were enrolled as early as 14 days after stroke. In general, motor improvement plateaus 3-6 months later, [11] but many animal and human studies [12-13] are focusing on treatment efficacy of repetitive exercise of paralysed upper limb to alter motor performance in patients with chronic stroke, [2,8,14] sowe have included patients up to 2 years post-stroke, to see the effects of robotic therapy in chronic motor impairment also.

There was greater improvement in the motor recovery of affected upper limb in the Robot assisted therapy group compared to the control group as measured by FMA for motor recovery of upper extremity. A study done by Masiero et al. in 2007 [15] showed similar improvement in FMA Scores in their study done on 35 stroke patients. Both group received the same dose and duration of standard post-stroke rehabilitation. The experimental group received additional sensorimotor robotic training, 4 hours a week for 5weeks. This group showed significant gains in motor impairments and functional recovery of the upper limb. Another study done in 2000 [16] included 56 patients with stroke who received standard poststroke multidisciplinary rehabilitation or robotic training along with standard rehabilitation. They concluded Robot-delivered quantitative and reproducible sensorimotor training enhanced the motor performance of the treated subjects. The robotic training group also demonstrated improved functional outcome. When added to standard multidisciplinary rehabilitation, robotics provides novel therapeutic strategies that focuses on impairment reduction and improvement in motor performance.

There was greater improvement in functional use of affected hand in the study group compared to the control group as measured by AOU Scores and QOU Scores of MAL scale. The difference in the two outcomes was statistically significant. We believe that the higher scores achieved by the study group on the MAL scale could be due to integration of standard rehabilitation treatment with robot therapy, which promoted higher functional recovery than in the control patients. The larger improvement in motor function in the experimental group facilitated relearning in these ADLs.The study done by Housman et al [3] in 2009 also showed significant improvement in MAL Scores. Improvements were sustained at 6 months.

From table II we can see a lower score in MAL in both study and control group as compared to the high score in FMA. Improvement in motor impairment have not been translated into significant improvement in the performance of basic self-care activities, as was expected by us. In a review of 165 studies, Wagenaar and Meijer (16) concluded that experimental treatments in persons with hemiparesis from CVA often have effects on the parameters specifically trained, but that transfer to ADLs was minimal.

Though it seems that improvement in robotic group may be simply due to increased therapy time, but other researchers has shown that the content of robotic therapy itself can have a greater impact on stroke-related motor impairments than increased duration of therapy alone. (9,16) Patients' attention and interest was kept high throughout the robotic training sessions by immediate visual and acoustic performance feedback in our device. Greater therapeutic gain in Robotic therapy group is likely explained due to intense, repetitive movement, sensorimotor integration and feedback which were the key features in robotic therapy that would induce motor cortex plasticity. (17) Positive patient response also played an important role in achieving higher number of repetitions during the robotic therapy sessions, as evidenced by the researcher. In a systematic review done in 2008 (18) it was written that the number of movements generated by robotic device is far higher than any other form of therapy. This high intensity repetitive movements contributed to the effectiveness of robotic therapy.

The encouraging results of our study could be due to the specialities of the robot used in the study. Many studies were done using only 2D robots (MIT MANUS). (19) Some robotic training focussed specifically on the proximal upper limb (In motion 2.0 Shoulder/Arm Robot, In Motion Linear Robot) (6), while some on distal [Hand Wrist Assistive Rehabilitation Device (HWARD)]. (17) Some has only 2 degrees of freedom (MIT MANUS), some has 3 (NeRoBot), while some has 4 (Arm-Guide). (20) In our device we could use both 2D and 3D activities and we could give robotic training to all major joints of the upper limb, i.e, shoulder, elbow and wrist with 6 degrees of freedom. Along with that we have activities to improve grip function also. The unique features of the robot can justify the very impressive results of the study in comparison to current literature.

Though there are numerous number of trials showing improvement in motor function after robotic therapy, Volpe et al in their study done in 2008, did not find any significant difference in motor performance of chronic stroke patients receiving intensive movement-based training delivered by robotic device or therapist. (19)

An important limitation of this study is absence of blinding. The very impressive result of this study should be interpreted with caution as the subject pool comprises of patients in different stages of stroke, starting from acute to chronic and we were unable to eliminate the confounding effects of natural recovery in subjects who were in the acute phase of stroke.

Despite the continued effort by the researchers, there is still no consistency on dose and carry over effect of robotic therapy. There is lack of consensus statement as to when and how much of robotic therapy and the usefulness of repeating training to sustain the achieved functions. It is therefore important to add to the research subject pool and further research into the use of rehabilitation robots for stroke rehabilitation is justified.

CONCLUSION

The results of the study show that Robot-assisted therapy along with conventional therapy is a more effective way to improve upper extremity function in stroke patients than conventional therapy alone. The benefits are carried over for as much as three months post therapy. Probably by addressing the plasticity of human nervous system it enhances the recovery in stroke. The promise of robotic therapy is to reduce the labour-intensive aspects of human-delivered therapy. However, long term study involving larger sample size and blinding is required for further consolidation of the results.

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