EFFECT OF ROBOTIC TILT TABLE VERSUS CONVENTIONAL EXERCISES ON REHABILITATION OUTCOME IN STROKE PATIENTS: A FOLLOW UP STUDY.

Suraj Kumar¹, Ramakant Yadav² and Aafreen³.

1. Associate Professor and Head, Department of Physiotherapy, UPUMS, Saifai, Etawah, UP, India.
2. Professor and Head, Department of Neurology, UPUMS, Saifai, Etawah, UP, India.
3. Senior Research Fellow, Department of Physiotherapy, UPUMS, Saifai, Etawah, UP, India.

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**Manuscript Info**

**Abstract**

**Background:** Stroke is the main cause of long term disability among adults, living survivors with deficits, and one third remain dependant in activities of daily living thus necessitates early mobilization.

**Purpose:** To determine the efficacy of exercises by Robotic tilt table versus the conventional physiotherapy treatment program in rehabilitation of patients with hemiplegia following stroke.

**Methods:** A total of 80 hemiplegic patients (age 50.36 ±8.36 years, 8.43±4.76 days after stroke) were assigned randomly into two groups for 30 days of Conventional physiotherapy or Robotic tilt-table rehabilitation. The National Institutes of Health Stroke Scale (NIHSS), Mini Mental Scale Examination (MMSE), Modified Ashworth Scale, Quality of Life (QOL) and muscle strength of affected upper and lower limb) outcomes were assessed before (day 0), after (day 30) of the rehabilitative protocols and on 90th day of follow up.

**Results:** The Robotic tilt table group improved with time in 0-90 days QOL=26.6, NIHSS= 9.38, Ashworth= 0.18, MMSE =8.10, muscle strength upper limb =2.08 and lower limb =2.40.Whereas conventional physiotherapy group improved with time within 0-90 days QOL=14.18, NIHSS= 8.30, Ashworth= 0.45, MMSE =8.25, muscle strength upper limb =2.10 and lower limb =2.07.

**Conclusion:** Robotic tilt table group has shown higher improvement than conventional physiotherapy group.

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**Introduction:**

As a consequence of focal brain ischemia or haemorrhage, stroke can have both immediate and ongoing physical effects. Despite the progress made in the acute management of stroke patients, neurorehabilitation remains the main method of treatment in the management of stroke patients with neurological and functional deficits.

However, with a high incidence of residual disability among stroke survivors; neuro-rehabilitation remains one of the cornerstones of post-stroke treatment. It plays a central role in successfully reducing the long-term effects of stroke and achieving optimal functional recovery for community re-integration.

Corresponding Author:- Ramakant Yadav.
Address:- Professor and Head, Department of Neurology, UPUMS, Saifai, Etawah, UP, India.
The automation of lower limb movements during locomotion is ensured by electromechanical/robotic devices, that were developed to help the physiotherapists by increasing the safety, intensity and standardization of non-robotic Body weight supported treadmill training, generate complex multisensory stimulation, provide extensive extrinsic biofeedback to the patient, and reduce working costs (Poli P et al., 2013, Masiero S et al., 2014).

Thus, this study hypothesized that the exercises or early mobilization by robotic tilt table will be beneficial than the conventional physiotherapy in improving the rehabilitation outcomes in acute stroke patients. And the efficacy, safety and feasibility of the robotic tilt table will be seen in acute stroke patients.

**Methodology:**

**Participants and study design**

This study has been designed as a randomized, controlled trial. Total 128 patients were enrolled from in-patient and out-patient department of Neurology, Uttar Pradesh University of Medical Sciences, Saifai, Etawah for rehabilitation of sequelae of their first stroke. Out of those 128, 80 were found suitable and randomized equally to treat either with Conventional Physiotherapy or Robotic Tilt-table treatments. Inclusion criteria were hemiplegia after stroke both is chemic and haemorrhagic, within 7 to 28 days of onset, either male or female aged between 30-60 years, have an independent sitting balance and dependent standing and walking, had score of National Institutes of Health Stroke Scale (NIHSS) between 11-22.

Subjects were excluded from the study if they are with metal implant, recurrent stroke, chronic renal failure, cognitive and speech problem, hemiplegia due to non-vascular causes (malignancy, infections, tumours, brain injury etc.), sensation loss in the lower extremity and poor sitting balance. The study has the approved by the institutional local ethical committee and informed consent were obtained from all the participants.

The subjects were randomized into two groups by lottery method (Kumar S et al., 2009), Group A for Conventional physiotherapy and Group B for Robotic tilt-table rehabilitation. The clinical demographic characteristics were reported (age, height, weight, systolic and diastolic blood pressure). Both treatments were given as individual treatment by same physiotherapist with same intensity and capacity on 30 regular days (except Sunday) and reassessment was done after 30 days and 90 days. The subjects were also informed about the experimental risks, if any. The duration of each individual treatment session was about 50 to 60 minutes per day. All subjects were allowed to take treatment for their comorbid condition like hypertension, dyslipidemia, hypothyroidism, cardiac problem in both the conditions under supervision of Neurologist. No other treatment will be allowed other than mention above.

**Apparatus**

The Erigo is a tilt table with integrated leg drives and can be tilted between 0°-80°. It supports and facilitates the mobilization of bed-bound patients, thus contributing to the prophylaxis of secondary complications caused by a prolonged period of immobility. The Erigo allows patients to be placed in a vertical position, while the patient's legs are moved in a physiological movement pattern and have a load applied to them.

**Training protocols**

**Conventional physiotherapy (Group A)**

All the exercises were done for 10 repetition, 2 sets with 10 seconds hold ones in a day under the supervision of physiotherapist which includes following:

1. Full range of motion (ROM) exercises – passive and active assisted range of motion exercises for upper limb included shoulder (flexion, extension, abduction and adduction), elbow (flexion and extension), forearm (supination and pronation), wrist (flexion, extension, radial and ulnar deviation), and for lower limb included hip (flexion, extension, abduction and adduction), knee (flexion and extension), ankle (dorsiflexion, planterflexion, eversion and inversion).
2. To prevent spasticity - Positioning of the limb, quick icing, brushing, gentle stroking, and gentle tapping.
3. The common mat activities include turning from supine to side-lying to prone and vice versa, prone to prone on elbow, prone on elbow to prone on hand; prone on hand to quadruped; quadruped to kneeling; kneeling to half kneeling; half kneeling to standing with support; standing with support to the standing without support.
4. Bridging exercises.
5. Prolonged and gradually progressive stretching of hamstring, calf and wrist.
6. Strengthening exercises included isometrics of back, quadriceps, gripping exercises.
7. The gentle and controlled weight bearing exercises.
8. Balance and coordination exercises.

Robotic tilt-table therapy (Group B)
Robotic tilt-table therapy was administered according to the following protocol. Patient received treatment session of 40 minutes, 6 times per week (Janice J Eng et al., 2001) for about 4 weeks (Ben M et al., 2005).

Table 1: shows the exercise protocol on Robotic Erigo tilt-table

| Phase I (1st week) | At 30° angle for 40 minutes with 1 minute hold after every 12 minutes at 0° angle |
|-------------------|----------------------------------------------------------------------------------|
| Phase II (2nd and 3rd weeks) | At 50° angle for 40 minutes (approx.) with 1 minute hold after every 12 minutes at 0° angle |
| Phase III (4th week) | At 75° angle for 40 minutes (approx.) with 1 minute hold after every 12 minutes at 0° angle |

The Robotic tilt table exercise session was followed by 15 minutes exercise program for upper extremities which includes range of motion, strengthening and stretching exercises of shoulder, elbow, wrist and fingers.

Outcome variables
The assessment of QOL was done according to SF-36 assessment tool (Turner-Bowker D.M et al., 2000). It is a multipurpose, self-administered, short form (SF) health survey with 36 questions which measures generic health status in the general population and also used earlier in acute stroke patients (Gunaydin R et al., 2011). These questions consist of physical functioning, role functioning, body pain, general health, vitality, social functioning and mental health. Response choices are numbered from left to right, starting with 1. The maximum scores obtained from 36 questions where 149 which represents best QOL whereas minimum score 36 represents the worst.

Muscle strength was measured by MRC classification of Manual Muscle Testing (MMT) (Ciesla N et al., 2011)

The National Institutes of Health Stroke Scale, or NIH Stroke Scale (NIHSS) is a tool used by healthcare providers to objectively quantify the impairment caused by a stroke. The NIHSS is composed of 11 items, each of which scores a specific ability between a 0 and 4. For each item, a score of 0 typically indicates normal function in that specific ability, while a higher score is indicative of some level of impairment. The individual scores from each item are summed in order to calculate a patient's total NIHSS score. The maximum possible score is 42, with the minimum score being a 0 (Williams L S et al., 2000).

The Mini–Mental State Examination (MMSE) or Folstein test is a 30-point questionnaire that is used extensively in clinical and research settings to measure cognitive impairment. Administration of the test takes between 5 and 10 minutes and examines functions including registration (repeating named prompts), attention and calculation, recall, language, ability to follow simple commands and orientation. Any score greater than or equal to 24 points (out of 30) indicates a normal cognition. Below this, scores can indicate severe (≤9 points), moderate (10–18 points) or mild (19–23 points) cognitive impairment (Zwecker M et al., 2002).

The Modified Ashworth Scale is a 6-point rating scale that is used to measure muscle tone with ratings from 0 indicating no increase in tone to 5 indicating limb rigid in flexion or extension (Gregson J M et al., 1999)

Statistical Analysis:-
One way repeated measures ANOVA, with treatments as a between subjects variable (CONV vs. Tilt Table) and time as a repeated measures variable (baseline vs. follow-up) was used to analyse the outcome variables. MS EXCEL (MS Office 97-2013) was used for the analysis. Probability (P) value between 0.05 (P < 0.05) & 0.01 was considered statistically significant; P < 0.01 as highly significant and P >0.05 had no significance (ns).

Results:-
A total of 80 patients were recruited. These 80 patients, 40 were treated with conventional therapy (Group A) and 40 with Robotic Erigo tilt table (Group B). Mean age of the 80 patients was 50.36 ± 8.36 years. Training was started on average 8.43 ± 4.76 days after the stroke.
Table 2: Baseline comparison of the demographic variables of participants.

| Demographic variables | Conventional Physiotherapy group (n=40) | Robotic tilt table group (n=40) | Level of significance (P value) |
|-----------------------|----------------------------------------|--------------------------------|-------------------------------|
| Age (years)           | 51.20 ± 8.36                          | 49.53 ± 7.03                  | 0.3353                        |
| Weight (kg)           | 65.08 ± 11.65                         | 63.83 ± 7.26                  | 0.5664                        |
| Height (m)            | 1.60 ± 0.09                           | 1.61 ± 0.09                   | 0.7372                        |
| Sex (no. of females)  | 22                                     | 18                            | 0.3775                        |
| Side Affected (right side) | 20                                   | 17                            | 0.5073                        |
| Lesion (Ischemic)     | 17                                     | 21                            | 0.3769                        |
| Blood Pressure Systolic | 132.25 ± 16.09                      | 132.50 ± 16.29                | 0.9451                        |
| Blood Pressure diastolic | 86.25 ± 10.55                     | 84.25 ± 9.58                  | 0.3773                        |

Table 2 shows the Independent t-test for between group comparisons of the baseline data, that there was no significant difference between the baseline scores. It shows that both the groups (robotic tilt table and conventional physiotherapy) were homogenous at baseline and there was very little possibility that the any improvement/deterioration in the scores with time could be due to group characteristics.

Table 3: ANOVA comparison among the variable scores with time.

|                      | 0 day       | 30 day      | 90 day      | Level of difference P value |
|----------------------|-------------|-------------|-------------|-----------------------------|
| Quality of Life      |             |             |             |                             |
| Conventional Physiotherapy group | 76.10 ± 7.11 | 83.97 ± 9.97 | 90.27 ± 12.68 | 0.00001*                    |
| Robotic tilt table group | 78.57 ± 9.74 | 90.22 ± 9.71 | 105.17 ± 8.93 | 0.00001*                    |
| Muscle Strength      |             |             |             |                             |
| Upper limb           |             |             |             |                             |
| Conventional Physiotherapy group | 0.86 ± 0.99  | 2.19 ± 0.97  | 2.96 ± 0.93  | 0.00001*                    |
| Robotic tilt table group | 1.37 ± 0.84  | 2.58 ± 0.95  | 3.45 ± 0.94  | 0.00001*                    |
| Muscle Strength      |             |             |             |                             |
| Lower limb           |             |             |             |                             |
| Conventional Physiotherapy group | 1.16 ± 0.99  | 2.32 ± 1.05  | 3.23 ± 0.99  | 0.00001*                    |
| Robotic tilt table group | 1.68 ± 0.95  | 3.07 ± 0.78  | 4.09 ± 0.29  | 0.00001*                    |
| NIHSS                |             |             |             |                             |
| Conventional Physiotherapy group | 12.52 ± 1.73 | 7.07 ± 2.28  | 4.22 ± 2.29  | 0.00001*                    |
| Robotic tilt table group | 11.70 ± 1.43 | 5.82 ± 1.92  | 2.32 ± 1.38  | 0.00001*                    |
| Ashworth             |             |             |             |                             |
| Conventional Physiotherapy group | 0.10 ± 0.30  | 0.55 ± 0.55  | 0.55 ± 0.64  | 0.00001*                    |
| Robotic tilt table group | 0.15 ± 0.36  | 0.27 ± 0.50  | 0.32 ± 0.52  | 0.04781*                    |
| MMSE                 |             |             |             |                             |
| Conventional Physiotherapy group | 15.82 ± 4.71 | 21.47 ± 3.79 | 24.07 ± 3.15 | 0.00001*                    |
| Robotic tilt table group | 16.65 ± 3.82 | 22.47 ± 2.97 | 24.75 ± 2.56 | 0.00001*                    |
Table 3: ANOVA comparison among the variable scores with time show that, the performance of the Conventional Physiotherapy group and Robotic tilt table therapy group shows that for all variables the scores improved significantly with time.

Table 4: shows that the variable scores of the conventional physiotherapy group and Robotic tilt table group.

|                           | Conventional Physiotherapy group mean difference | P value    | Robotic tilt table group mean difference | P value    |
|---------------------------|-----------------------------------------------|------------|----------------------------------------|------------|
| **Quality of Life**       |                                               |            |                                        |            |
| 0 versus 30 days          | 7.88                                          | 0.0001*    | 11.65                                  | 0.0001*    |
| 30 versus 90 day          | 6.30                                          | 0.0001*    | 14.95                                  | 0.0001*    |
| 0 versus 90 days          | 14.18                                         | 0.0001*    | 26.60                                  | 0.0001*    |
| **Muscle Strength**       |                                               |            |                                        |            |
| Upper limb                |                                               |            |                                        |            |
| 0 versus 30 days          | 1.33                                          | 0.0001*    | 1.21                                   | 0.0001*    |
| 30 versus 90 day          | 0.77                                          | 0.0001*    | 0.87                                   | 0.0001*    |
| 0 versus 90 days          | 2.10                                          | 0.0001*    | 2.08                                   | 0.0001*    |
| Lower limb                |                                               |            |                                        |            |
| 0 versus 30 days          | 1.16                                          | 0.0001*    | 1.39                                   | 0.0001*    |
| 30 versus 90 day          | 0.91                                          | 0.0001*    | 1.02                                   | 0.0001*    |
| 0 versus 90 days          | 2.07                                          | 0.0001*    | 2.40                                   | 0.0001*    |
| **NIHSS**                 |                                               |            |                                        |            |
| 0 versus 30 days          | 5.45                                          | 0.0001*    | 5.88                                   | 0.0001*    |
| 30 versus 90 day          | 2.85                                          | 0.0001*    | 3.50                                   | 0.0001*    |
| 0 versus 90 days          | 8.30                                          | 0.0001*    | 9.38                                   | 0.0001*    |
| **Ashworth**              |                                               |            |                                        |            |
| 0 versus 30 days          | 0.45                                          | 0.0001*    | 0.13                                   | 0.0577     |
| 30 versus 90 day          | 0.00                                          | 1          | 0.05                                   | 0.4865     |
| 0 versus 90 days          | 0.45                                          | 0.0003*    | 0.18                                   | 0.0330*    |
| **MMSE**                  |                                               |            |                                        |            |
| 0 versus 30 days          | 5.65                                          | 0.0001*    | 5.83                                   | 0.0001*    |
| 30 versus 90 day          | 2.60                                          | 0.0001*    | 2.28                                   | 0.0001*    |
| 0 versus 90 days          | 8.25                                          | 0.0001*    | 8.10                                   | 0.0001*    |

Table 4 shows that the variable scores of the robotic tilt table group improved significantly higher while compared to the conventional physiotherapy group in Quality of life, NIHSS and Ashworth whereas MMSE, muscle strength of upper and lower limb found to be improved almost equally in both the groups.

While making the month wise comparison it was found that in “0 versus 30 days” comparison all variables improved significantly in both the groups but robotic tilt table group improved higher in all the variables except muscle strength of upper limb.

For “30th day versus 90th day comparison” all variables improved significantly in both the groups except Ashworth scores. Robotic tilt table group shown higher improvement in all the variables except MMSE.
While exploring “0 day versus 90th day” comparison, it was found that all variables improved significantly in both the groups. Robotic tilt table group shown higher improvement in QOL, NIHSS, Ashworth and muscle strength of lower limb while MMSE and muscle strength of upper limb improved equally in both groups.

**Discussion:**

This study hypothesized that the exercise by robotic tilt table will be beneficial than the conventional physiotherapy in improving the rehabilitation outcomes in acute stroke patients was found to be true.

This study emphasizes that the performance of the Conventional Physiotherapy group and Robotic tilt table therapy group shows improved for all variables with time. It was also found in a study ERIGO training could be a valuable tool for the adaptation to the vertical position with a better global function improvement, as also suggested by the sensory-motor and vestibular system plasticity induction in post-stroke patients (Calabro R et al., 2015).

Rehabilitation on a tilt-table has been reported to be a useful way to mobilize severely impaired or non-cooperating patients, since it improves circulation, prevents contractures, and increases pulmonary ventilation (Chang AT et al., 2004, Cumming TB et al., 2011). Our study support the safety and effectiveness of robotic ergo tilt table verticalization in bed ridden post stroke patients even in the acute phase. One of the studies was concerned with the hemodynamic effects of robotic verticalization. It has been shown that robotic tilt-tables are effective in preventing blood pressure drops (Kuznetsov et al., 2013), may prevent orthostatic responses to verticalization by improving the venous return and, hence, potentiate the cardiac output and the cerebral blood flow. Robot-based rehabilitation has been shown to improve motor performance by boosting brain plasticity (Pellegrino et al., 2012; Duret et al., 2014; Basteris et al., 2014).

In our study it was found that in “0 versus 30 days” comparison all variables improved in both the groups but robotic tilt table group shown higher improvement in all the variables except muscle strength of upper limb. Whereas, it has been suggested that verticalization (VT) may play a role in stimulating cortical areas involved in trunk and lower limb control, so that deafferentation and learned non-use can be contrasted (Pittaccio S et al., 2013). VT may actively contribute to enhance cognitive performances through an increase in cerebral blood flow with a consequent induction of cortical plasticity, especially in frontal lobes (Reinstrup P et al., 1994). Robotic verticalization include increased ventilation, increased arousal, improved weight bearing of the lower limbs, and facilitation of antigravity exercise of the limbs (Dean E and Ross J. 1992).

For “30th day versus 90th day comparison” all variables improved in both the groups except Ashworth scores. It could be the reason that exercises prevent developing or reducing spasticity. The study also suggested that the two primary physical treatments applied to patients with involuntary muscle contractions have been described are electrical stimulation and long-term stretch. When applied to the ankle plantar flexor muscles, the benefits of long-term stretch, seem to be augmented by weight loading (Odeen I et al., 1981). This finding, and a personal impression that extensor spasms are sometimes reduced after tilt table standing, prompted a monitored trial of a tilt table standing regimen for a patient with intractable extensor spasms of the lower extremities (Bohannon RW, 1993).

Whereas, on “0 day versus 90th day” comparison, it was found that all variables improved in both the groups. But robotic tilt table group shown higher improvement in QOL, NIHSS, Ashworth and muscle strength of lower limb while MMSE and muscle strength of upper limb improved equally in both groups. The improvement could be related to the fact that robotic rehabilitation may offer standardized, intensive and repetitive exercises, a proper body weight support, with an appropriate sensory feedback amount and a controlled progressive verticalization. As the study also suggested that Robotic verticalization maximizes the potential for longitudinal weight bearing through the lower extremities in a position of hip-extension/knee-extension/ankle-dorsiflexion, which is difficultly obtained in the physiotherapy verticalization setting. Moreover, Robotic verticalization allows strengthen exercises of body weight shifting from one leg to the other, which is not simply carried out in severe post-stroke patients (Calabro R et al., 2015).

Some studies found that greater cerebral blood flow modulation during Robotic VT in comparison to physiotherapy VT could further support plastic changes within sensory-motor areas and vestibular system, with the consequent motor and cognitive functions amelioration (Raethjen J et al., 2008, Duncan J et al., 2000, Wieser M et al., 2010). Another study showed that there was a significantly greater increase in the EMG patterns of the extensors and flexors of the affected leg muscles during flexion and extension movements of both legs and clinical scores in
patients undergoing the progressive task-oriented training on the tilt table compared to the other groups (Kim CY et al., 2015).

Mobilization into a standing position, e.g., with a tilt table, has been shown to improve arousal and awareness in small groups of vegetative state and minimally conscious state patients (Elliot L et al., 2005, Wilson BA et al., 2013, Riberholt CG et al., 2013).

Thus, robotic tilt table can be used by clinicians for effective and safe management of acute stroke patients.

**Conclusion:**
The study concluded that the rehabilitation outcomes were improved both by the conventional physiotherapy and tilt table intervention in post-stroke patients. But the Robotic tilt table exercises proved to be more effective and beneficial for acute hemiplegic patients.

**Acknowledgement:**
The authors acknowledge ICMR for approval and funding of this extramural research project and Vice Chancellor of UPUMS, Saifai, Bawal to conduct the research for the betterment of the patients. The authors wish to acknowledge patients for their supportive nature and cooperation.

**Conflict of Interest:** Nil

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