



Human Journals

**Research Article**

March 2018 Vol.:9, Issue:1

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# Efficacy of Erigo Tilt Table among Male and Female Stroke Patients— A Randomized Control Trial

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HUMAN JOURNALS

[www.ijsr.humanjournals.com](http://www.ijsr.humanjournals.com)**Keywords:** stroke, Erigo tilt-table, rehabilitation, QoL, NIHSS, Ashworth scale**ABSTRACT**

**Background:** Following stroke and during hospitalization, patients who are unable to safely stand and perform independent activities are at an increased risk for multiple medical complications and thus necessitates physical rehabilitation. **Purpose:** To determine the effect of Erigo tilt table in stroke patients among male and female. **Material and method:** Total 63 subjects of acute stroke were included in the study on the basis of inclusion criteria and randomized in two groups by lottery method. Group A (32 subjects) underwent Conventional physiotherapy and Group B (31 subjects) for Robotic Erigo tilt table therapy and both the groups were further divided into sub-groups of male and female. Patients were reassessed after 24 sittings in a month. Outcome measures were National Institutes of Health Stroke Scale (NIHSS), Mini Mental Scale Examination (MMSE), Modified Ashworth Scale (MAS) and Quality of life (QoL) scores. **Result:** In this study both the conventional and Erigo group showed improvement in outcome variables with time but Erigo group showed a little higher improvement than conventional group. Moreover, it was found that there was no significant difference in improvement of male and female for both the groups. **Conclusion:** Results suggest that Erigo training have similar advantage with manual physiotherapy in hemiplegic patients and no differences in functional recovery related to gender were found.

## INTRODUCTION

Stroke survivors remain with neurological and functional impairments that significantly limit personal activities in the family and social environments. Although its efficacy is debated (Lind K, 1982, Reding M J et al., 1989, Dobkin B H, 1989), rehabilitation represents the only therapy that may minimise disability, enhance likelihood of returning home, and reduce social costs (Gibson C J, 1990).

It has been shown that robot-based rehabilitation improves motor performances by boosting brain plasticity, which plays a crucial role for motor control recovery, especially in stroke patients (Pellegrino et al., 2012, Duret et al., 2014, Basteris et al., 2014). Robotic tilt table may bring the patient in a vertical position while moving their legs to prevent blood pressure drop. Robotics has been used successfully in the past in acute stroke patients (Maseiro et al, 2007).

Benefits of standing may result in the reduction in tone and an increase in range of movement or muscle length (Bohannon and Larkin 1985; Bohannon 1993; Deshpande et al. 2004; Dunn et al. 1998; Shields and Dudley-Javorski 2005). There is an associated improved efficiency and regularity of the bowel function noted. Subjectively people report benefits for their bladder (Dunn et al. 1998; Enget al. 2001). There is a reported increase in a sense of well-being and quality of life related to standing and a general sense of improved fitness (Dunn et al. 1998; Enget al. 2001; Walter et al. 1999).

The study provides clear evidence that lack of mobility and weight-bearing early after stroke is an important factor for the greater bone loss in the paretic leg, but that relearning to walk within the first 2 months after stroke (L. Jørgensen, 2000), even with the support of another person, may reduce the bone loss after immobilization.

It has been argued that certain subgroups of the stroke population may benefit more than others from specific rehabilitation services and that, in order to achieve the most efficient use of such services, it is important to identify predictors that discriminate between stroke patients with good and poor prognosis. The objective of the present study is that the effect of Eriko tilt table in improving Quality of life (QoL) score, National Institutes of Health Stroke Scale (NIHSS), Mini Mental Scale Examination (MMSE) and Ashworth Scale in male and female patients of acute hemiplegia.

## METHODOLOGY

Total 63 subjects were enrolled for the study. The subjects were recruited from the indoor patients (IPD) and outpatients departments of Neurology department, Uttar Pradesh University of Medical Sciences, Saifai, Etawah. The study is approved by Institutional Ethical Committee.

Inclusion criteria were hemiplegia after stroke both ischemic and hemorrhagic, within 7 to 28 days of onset, either male or females of age group 30-60 years having independent sitting balance and dependent standing and walking, with NIHSS between 11-22 were included.

Subjects with metal implant, recurrent stroke, chronic renal failure, cognitive and speech problem, hemiplegia due to non-vascular causes (malignancy, infections, tumors, brain injury etc.), sensation loss is there in the lower extremity and poor sitting balance were excluded.

The subjects were randomized in two groups by lottery method (Kumar *et al.*, 2009). Marking on the paper drawn by the subjects allocate their mode of treatment, A for Conventional (control group) or B for Erigo (study group). Both the groups were divided into sub-groups of male and female. 32 patients were recruited in conventional group in which there were 16 males and 16 females. Whereas in Erigo group 31 patients were recruited in which there were 16 males and 15 females. The demographic characteristics Age, BMI, systolic and diastolic blood pressure and pulse of both the groups were assessed at baseline. Outcome variables such as QoL, MMSE, NIHSS and Modified Ashworth Scale were observed by same tester and same physiotherapist supervising the test procedure at baseline as well as on day 30. Test and retest of the two groups were conducted in the same place and environment and at same time of the day. Before experimentation, all subjects were well taught about the measurement variables and their outcomes. After group allocations, respective subjects were treated either with Conventional or Erigo. Both treatments were given as individual treatment by same physiotherapist with same intensity and capacity on 30 regular days (except Sunday). 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 the subject were allowed to take treatment for their comorbid condition like hypertension, dyslipidemia, hypothyroidism, cardiac problem in both the conditions under the supervision of Neurologist.

## Variables

Independent variable was Erigo tilt table exercise and conventional exercises whereas Dependent variables were MMSE, NIHSS, Modified Ashworth Scale and QOL. The cognition was assessed by MMSE, motor and sensory assessment by NIHSS and Spasticity by Modified Ashworth Scale and Quality of life by SF-36 assessment tool.

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. (Scott E. Kasner et al., 1999)

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 ( $\leq 9$  points), moderate (10–18 points) or mild (19–23 points) cognitive impairment. (Ariane Bour et al., 2010)

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 (Marjan Blackburn, 2002)

The **Quality of Life** is a multipurpose, self-administered, short form (SF) health survey with 36 questions which measures generic health status in the general population. 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 were 149 which represents best QOL whereas minimum score 36 represents the worst. (Turner-Bowker et al, 2002).

### **Conventional Exercise**

All the exercises were done under the supervision of physiotherapist which includes following:

- 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, plantarflexion, eversion and inversion).
- To prevent spasticity - Positioning of the limb, quick icing, brushing, gentle stroking, and gentle tapping.
- 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 quadripod; quadripod to kneeling; kneeling to half kneeling; half kneeling to standing with support; standing with support to the standing without support.
- Bridging exercises.
- Prolonged and gradually progressive stretching of hamstring, calf and wrist.
- Strengthening exercises included isometrics of back, quadriceps, griping exercises.
- The gentle and controlled weight bearing exercises.
- Balance and coordination exercises.

### **Erigo Exercise**

Erigo about 40 minutes per session, 6 times per week (Janice et al, 2001) for about 4 weeks (Ben et al, 2005).

**Table 1 shows the exercise protocol on Erigo tilt-table**

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

The Erigo 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.

### Data Analysis

Data were analyse using *priori* alpha level of significance as 0.05. Data were summarized using descriptive statistics of mean and standard deviation. All statistical analysis was performed using excel 2013.

Scores of the dependent variables were National Institutes of Health Stroke Scale (NIHSS), Mini Mental Scale Examination (MMSE), Modified Ashworth Scale and Quality of Life (QOL) was compared for the two instances in each group at baseline and after 30 days using paired t-test and the comparisons between both the groups were evaluated using unpaired t-test. These comparisons were performed to evaluate the differences in the performance of the variable for between group as well as within group comparisons.

### RESULTS

A total of 63 patients were recruited. Out of this 63 patients 32 were treated with conventional therapy (Group A) and 31 with Robotic Erigo tilt table (Group B). Mean age of the 63 patients was  $50.05 \pm 7.35$  years. Training was started on average  $8.65 \pm 6.02$  days after the stroke. Patients demographics, cardiovascular risk parameters shows that there was no significant difference between the baselines scores (Table 2).

In table 3 comparison between conventional and Erigo group for male patients shows that there was significant improvement in all the outcome variables i.e. MMSE, NIHSS, Ashworth and QoL whereas the Erigo shows more improvement, 68% in Ashworth, 5% in

NIHSS, 11% in QoL than conventional group and scores of MMSE was improved more in conventional group by 4% than Erigo group after 30 days of initial assessment.

Table 4 shows comparison between conventional and Erigo group for female patients that there was significant improvement in all the outcome variables i.e. MMSE, NIHSS, Ashworth and QoL whereas the Erigo shows more improvement, 46% in Ashworth, 2% in MMSE, 57% in QoL and 12% in NIHSS than conventional group after 30daysinitial of assessment.

Graph 1 shows the comparison between male and female of Erigo group where there was no significant difference between the scores of variables NIHSS ( $p=0.1114$ ), Ashworth ( $p=0.6660$ ), QoL ( $p=0.2120$ ) whereas MMSE was found to improved 15% more in males than females ( $p=0.0009$ ) at 30<sup>th</sup> day.

Graph 2 shows the comparison between male and female of Conventional group where there was no significant difference between the scores of variables NIHSS ( $p=0.0540$ ), Ashworth ( $p=0.2066$ ), whereas QoL improved 12% and MMSE was found to improved 15% more in males than females ( $p=0.0011$  and  $0.0033$  respectively).

**Table 2 shows the demographic variables of participants of both males and females**

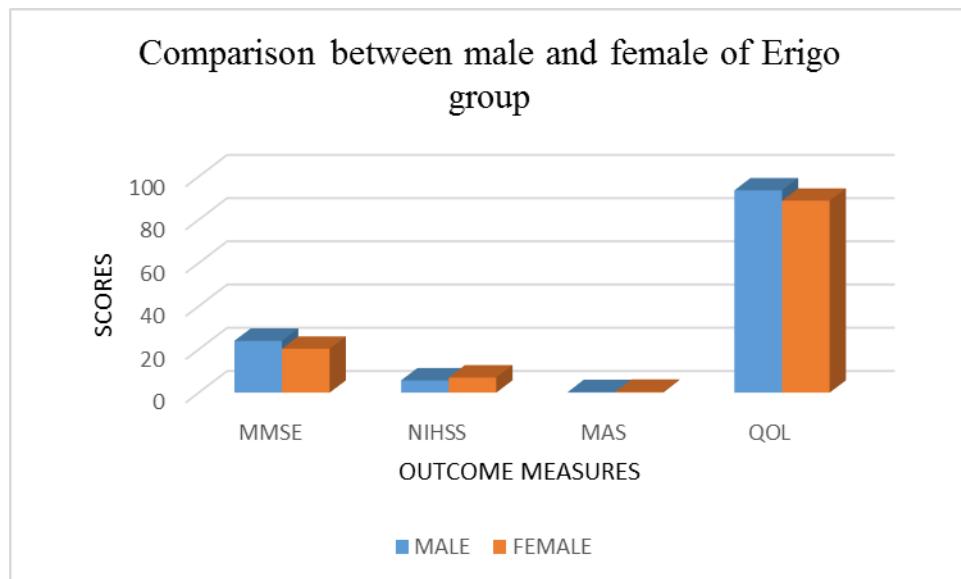
Demographic variables	Male		Level of significance (P value)	Female		Level of significance (P value)
	Conventional (n=16)	Erigo (n=16)		Conventional (n=16)	Erigo(n=15)	
Age (years)	50.19±8.06	49.25±6.51	0.7199	51.00±8.67	49.73±6.52	0.6505
BMI	22.82±2.90	23.01±1.68	0.8190	25.19±3.15	25.87±3.12	0.5558
BP systolic	131.25±14.55	130.38±18.61	0.8831	140.62±14.82	137.33±14.86	0.5419
BP diastolic	83.12±7.93	83.12±9.46	1	90.62±11.24	85.33±8.34	0.1494
Pulse	84.06±9.04	82.88±4.73	0.6448	85.25±8.42	86.13±6.70	0.7498

**Table 3 Comparison (0 versus 30 days) among all the variable scores in males of Conventional and Erigo group**

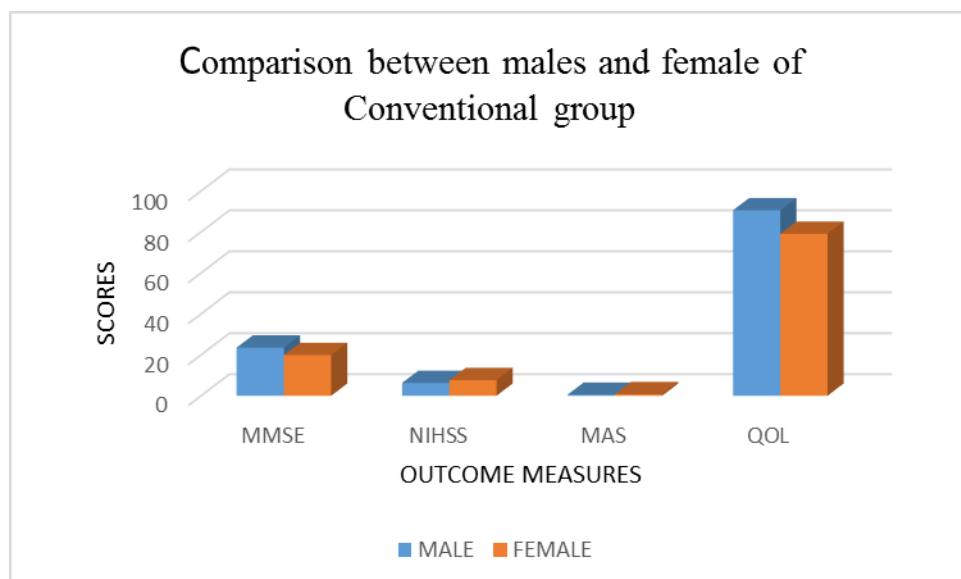
	Male	0 day	30 day	df	Level of difference P value
MMSE	Conventional	17.31±4.48	23.5±3.03	6.19	0.00001*
	Erigo	18.06±4.09	24±2.48	5.94	0.00001*
Modified Ashworth Scale	Conventional	0.12±0.34	0.50±0.63	0.38	0.02852*
	Erigo	0.19±0.40	0.31±0.48	0.12	0.03331*
NIHSS	Conventional	12.50±1.75	6.25±2.24	6.25	0.00001*
	Erigo	12.31±1.82	5.69±2.30	6.62	0.00001*
Quality of Life	Conventional	80.50±6.25	90.56±11.56	10.60	0.00001*
	Erigo	81.81±12.98	93.63±12.99	11.81	0.00001*

**Table 4 Comparison (0 versus 30 days) among all the variable scores in females of Conventional and Erigo group**

	Female	0 day	30 day	df	Level of difference P value
NIHSS	Conventional	14.12±4.27	19.87±3.38	5.57	0.00001*
	Erigo	14.47±3.66	20.33±3.01	5.87	0.00001*
MMSE	Conventional	0.12±0.34	0.75±0.44	0.62	0.00015*
	Erigo	0.07±0.26	0.40±0.63	0.33	0.01921*
Modified Ashworth Scale	Conventional	13.19±1.69	7.62±1.59	5.56	0.00001*
	Erigo	11.86±1.41	7.00±2.14	4.48	0.00001*
Quality of Life	Conventional	71.75±6.17	79.06±5.35	7.31	0.00001*
	Erigo	77.27±7.51	88.80±6.96	11.53	0.00001*



**Graph 1 shows comparison between male and female of Erigo group on 30<sup>th</sup> day**



**Graph 2 shows comparison between male and female of Conventional group on 30<sup>th</sup> day**

## DISCUSSION

The present study shows that the Erigo tilt table found to be effective in improving Quality of life (QoL) score, National Institutes of Health Stroke Scale (NIHSS), Mini Mental Scale Examination (MMSE) and Ashworth Scale in male and female patients of acute hemiplegia.

The result of present study proves that both the conventional and Erigo group for male patients shows improvement in all the outcome variables i.e. MMSE, NIHSS, Ashworth and

QoL whereas the Erigo shows more improvement, 68% in Ashworth, 5% in NIHSS, 11% in QoL than conventional group and scores of MMSE was improved more in conventional group by 4% than Erigo group which could be 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. The other finding of this study suggest that both the conventional and Erigo group for female patients that there was significant improvement in all the outcome variables i.e. MMSE, NIHSS, Ashworth and QoL whereas the Erigo shows more improvement, 46% in Ashworth, 2% in MMSE, 57% in QoL and 12% in NIHSS than conventional group after 30 days initial of assessment.

Previous study also supports the fact 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 strengthening exercises of body weight shifting from one leg to the other, which are not simply carried out in severe post-stroke patients (Rocco Calabro, 2015).

Another study also focus on the similar fact that the 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 function amelioration (Raethjen et al, 2008; Duncan and Owen, 2000; Wieser et al, 2010).

One of the findings of this study also shows that in Erigo group there was no difference between the scores of variables NIHSS, Ashworth, QoL whereas MMSE was found to improved 15% more in males than females. Moreover, in Conventional group also between male and female shows, no difference between the scores of variables NIHSS, Ashworth, whereas QoL improved 12% and MMSE was found to improve 15% more in males than females. The authors speculate that the lower outcome achieved by female patients in MMSE score may result from the fact that there are three major differences in cognitive abilities between men and women have usually been reported: (1) higher verbal abilities, favoring women; (2) higher spatial abilities, favoring men; and, (3) higher arithmetical abilities, also favoring men. However, differences in calculation abilities have at times been interpreted as a result of men's superior spatial abilities (Benbow, 1988; Geary, 1996), hence, these three differences could be reduced to just two.

In summary, the authors of the present study focus on the efficacy of Ergo tilt table rehabilitation difference between male and female and found that there is no any difference in improving the functional ability of stroke patients.

## CONCLUSION

This study concludes that Ergo tilt table is effective in rehabilitation of acute hemiplegic patients for both male and female.

## ACKNOWLEDGMENT

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

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