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Comparative Effectiveness of High-frequency Repetitive Transcranial Magnetic Stimulation at Ipsilateral Site vs Low-frequency Repetitive Transcranial Magnetic Stimulation at Contralateral Site at Cerebral Cortex on Motor Function Improvement in Stroke Patients – An Observational Study

Mohit Kataruka[1,*], Puja Sannyashi[1], Amala Sajeev[1], Souvik Bhattacharjee[1], Boudhayan Das Munshi[2]

[1]All India Institute of Medical Sciences, Kalyani, PMR, West Bengal, India

[2]All India Institute of Medical Sciences, Kalyani, Gen Med, West Bengal, India

[*]Correspondence should be addressed to Mohit Kataruka, mohit25582168@gmail.com

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Abstract

Stroke is a medical emergency where blood supply to the brain is cut off (ischemic) or a blood vessel ruptures (hemorrhagic), leading to potential long-term damage, disability, or death. Transcranial magnetic stimulation (TMS) is used in neurological conditions as a non-invasive form of brain stimulation and can promote motor function recovery after a stroke. There is literature demonstrating improvement with high and low-frequency rTMS in stroke patients; however, the literature on these frequencies is limited. Our humble attempt was to assess the efficacy and persistence of effect of high-frequency and low-frequency repetitive transcranial magnetic stimulation (rTMS) in stroke patients and to compare their efficacy. We included 23 patients, of whom 3 were lost to follow-up. After selecting the patients, they were randomly allocated into two groups: Group A received high-frequency rTMS, and Group B received low-frequency rTMS for 10 days, along with a structured rehabilitation protocol. The patients were assessed before initiating therapy, after completing therapy, and at 2 weeks and 4 weeks post-intervention using the Functional Independence Measure & Functional Assessment Measure (FIM FAM) & Fugl-Meyer Assessment (FMA). It was observed that there was a significant improvement in both the pre- and post-intervention periods, as evidenced by p-values less than 0.05 in both groups. It was also observed that the changes persisted for up to 8 weeks post-therapy in both groups. No significant difference was observed between the groups. We observed no adverse effects during the therapy. To conclude, both high and low-frequency rTMS therapy may be an effective treatment modality for stroke patients, though larger studies are recommended.

Keywords: Development of new rehabilitative technologies, Neurorehabilitation, rTMS, Stroke

Introduction

Stroke is a medical emergency where blood supply to the brain is cut off (ischemic), or a blood vessel ruptures (hemorrhagic), causing brain cells to die from lack of oxygen, leading to potential long-term damage, disability, or death [1]. According to the World Health Organization, approximately 70 % of stroke patients experience motor disorders [2]. It occurs due to damage to the central nervous system and leads to hemiplegia [3], which causes abnormal motor functions of the face and one side of the extremities [4]; muscle tone and deep tendon reflexes are increased. Hemiplegia occurs in the early stages of stroke, and if proper rehabilitation treatment is not provided, permanent limitations in daily life may occur [5].

Transcranial Magnetic Stimulation (TMS) is a safe and non-invasive method for stimulating neurons in the brain. Transcranial magnetic stimulation is a non-invasive brain

stimulation used in the treatment of neurological and psychiatric conditions, especially in Alzheimer's disease, mild cognitive impairment, depression, and mental disease [6,7,8,9].

TMS can be used to promote motor function recovery after stroke [10]. Repetitive Transcranial Magnetic Stimulation (rTMS) can induce neural plasticity in stroke patients. Two strategies have been proposed to support post-stroke motor recovery: (I) enhancing cortical excitability in the ipsilesional hemisphere with high-frequency rTMS, or (II) decreasing cortical excitability in the contralesional hemisphere with low-frequency rTMS [10].

Activation of the motor cortex by TMS causes the generation of descending volleys in the pyramidal system of salient corticospinal tracts. Corticospinal streams, when stimulated, elicit motor-evoked potentials. The recruitment of motor units takes place in an orderly manner from the smallest to the largest [11]. Descending corticospinal activity is triggered by a TMS pulse [12].

The principle of rTMS is based on Faraday's law of electromagnetic induction, which states that when an electric current flows within a circular coil, a magnetic field is generated perpendicular to the plane of the coil and reaches the cerebral cortex after passing through soft tissues and the skull. The magnetic field that reaches the cerebral cortex generates an eddy current that is perpendicular to this magnetic field and thus parallel to the plane of the coil (skull). The direction of the eddy current that is generated is opposite to the direction of the electric current that flows through the coil. This eddy current acts on interneurons in the cerebral cortex and ultimately affects neurons throughout the brainstem and spinal cord that descend from the cerebral cortex. Thus, rTMS evidently results in "transcranial" magnetic stimulation, but what actually affects the neurons is the eddy current generated *in vivo* by the "magnetic stimulation". According to Masahiro Abo in his book Rehabilitation with rTMS, 18 articles were published from 2005, in which rTMS was performed in a total of 392 patients. Three articles focused on the acute phase, three on the subacute phase, seven on the chronic phase, and the remaining articles addressed various phases. With respect to the stimulation method, a low-frequency rTMS to the unaffected hemisphere in eight studies, a high-frequency rTMS to the affected hemisphere in five studies, a low-frequency rTMS to the affected hemisphere in one study, both low-frequency rTMS to the unaffected hemisphere and high-frequency rTMS to the affected hemisphere in two studies, and theta burst stimulation (TBS) in the remaining two studies [13].

Several studies have observed the efficacy of high-frequency and low-frequency rTMS in stroke patients. But there is a paucity of data in the Indian context. This is our humble attempt to assess the effects of rTMS (both high- and low-frequency) in post-stroke patients.

The aims and objectives of this study were to observe the effectiveness of low-frequency and high-frequency repetitive transcranial magnetic stimulation on motor function, pain and ADL in stroke patients and to compare the efficacy of high-frequency rTMS on the ipsilateral lesion vs low-frequency rTMS in the contralateral lesion.

Materials and Methods

The analytical observational pilot study was conducted at the PMR department of a tertiary care hospital, following institutional ethical clearance and informed patient consent. A total of 23 stroke patients, fulfilling the inclusion criteria, were included in this study, of which 3 patients were lost to follow-up. The study period was from January 24 to December 24.

After selecting patients based on inclusion and exclusion criteria (**Table 1**), they were randomly divided into two groups: group A & group B. Group A received high-frequency repetitive transcranial magnetic stimulation (5Hz, 10 pulses over 10 seconds, for a total of 150 pulses) over the ipsilesional primary motor cortex (M1) with a figure of 8 coil with 100% MEP for 5 days a week for 2 weeks. Group B received low-frequency repetitive transcranial magnetic stimulation (1 Hz, 10 pulses over 10 seconds, total of 600 pulses per session) with a figure-of-8 coil with 100% MEP over the contralesional primary motor cortex (M1) for 5 days a week for 2 weeks. Patients in both groups were taught a stroke rehabilitation program that included hand-grip exercises, range-of-motion exercises, and passive stretching. The patients were followed up 2 weeks, 4 weeks, and 8 weeks post-intervention. Fugl-Meyer Assessment (FMA), Passive Joint Motion & Sensation (SMP) & Functional Independence Measure and Functional Assessment Measure (FIM-FAM Scale) were assessed at each visit by the author. Data were recorded at initiation of therapy (V0), at 2 weeks (V1), 4 weeks (V2) & at 8 weeks (V3).

All data entry was completed by the authors, and the data were exported into IBM SPSS (version 27) for statistical analyses. Friedman's two-way analysis of variance by Ranks was used for intra-group comparison. Independent-samples t-tests and Mann-Whitney U tests were used to compare groups at baseline. The level for statistical significance for hypothesis tests was set at 0.05.

Results

A total of 23 patients were included in this study, of whom 3 patients were lost to follow-up. The study comprised 9 male and 11 female patients (**Table 2**). Most of the patients were in the 5th decade, followed by the 4th and 6th decades. It was found that a total of 10 patients had left hemiparesis and 10 patients had right hemiparesis. The demographic data were depicted in **Table 3**.

Table 1. Inclusion and exclusion criteria for patient selection.

Inclusion criteria	Exclusion criteria
Age between 18 to 60 years	Hemorrhagic stroke
Stroke within 3-12months	Intracranial metal implant
Suffering from upper extremity motor dysfunction	Pacemakers
Modified Rankin Scale 2,3,4	Medication pump implant
	Cochlear implant
	History of brain surgery
	History of seizure or epilepsy, family history of epilepsy
	Substance abuser
	History of head trauma

Table 2. Indicates that a total of 9 male and 11 female patients were included in this study.

	High frequency (Group A)	Low frequency (Group B)	Total
Male	1	8	9
Female	9	2	11
Total	10	10	20

Table 3. Indicates the demographic profile of the patients. There is no statistically significant difference between the groups at baseline (data is presented as mean ± SD).

Parameters	Group A (High frequency)	Group B (Low frequency)	p-value
Age	54 (6.4)	54 (7.75)	0.707
M: F	1:9	4:1	
Height (Cm)	162.6 (4.7)	164.4 (8.4)	0.222
Weight (kg)	58.90 (7.529)	61.43 (9.35)	0.136
BMI	22.35 (2.7)	22.73 (2.8)	0.481
Duration (months)	8.6 (2.79)	9.1 (1.79)	0.245
Left hemiparesis: Right Hemiparesis	6:4	6:4	
FMA (Fugl Meyer Assessment) V0	30.7 (±19.7)	28. 4(±13.43)	0.585
SMP (Passive joint motion and sensation) V0	49.5 (±6.34)	50.4 (±5.08)	0.511
FIMV (Functional Independent Measures) V0	163.2 (±39.37)	174.3 (±30.75)	0.639

Results for High-frequency rTMS (group A)- analysis was done by Friedman's Two-way analysis of Variance of Ranks. There were no significant changes observed in the Fugl Meyer Assessment after 2 weeks of therapy (FMAV0-FMAV1), but significant changes were observed at 4 weeks and 8 weeks (FMAV0-FMAV2 & FMAV0-FMAV3), respectively. There were no significant changes observed in Passive Joint Motion & Sensation after 2 weeks of therapy (SMPV0-SMPV1), but there were significant changes observed at 4 weeks and 8 weeks (SMPV0-SMPV2 & SMPV0-SMPV3). Significant changes were observed in Functional Independent Measure after 2 weeks of therapy (FIMV0-FIMV1), as well as at 4 weeks and 8 weeks (FIMV0-FIMV2 & FIMV0-FIMV3), respectively (**Table 4**).

Results of Low frequency rTMS (group B)- Significant changes were observed in Fugl Meyer Assessment, Passive Joint Motion & Sensation and Functional Independent Measure after 2 weeks of therapy (FMAV0-FMAV1), as well as at 4 weeks and 8 weeks (FMAV0-FMAV2 & FMAV0-FMAV3), (SMPV0-SMPV2 & SMPV0-SMPV3) and (FIMV0-FIMV2 & FIMV0-FIMV3) (**Table 5**).

There were no significant differences in Fugl-Meyer Assessment (FMA) scores between the groups at 0, 2, 4, and 8 weeks (**Table 6**). There is an improvement in the Fugl Meyer score at both frequencies, though the difference is not statistically significant. There were no significant differences in Passive Joint Motion & Sensation (SMP) between the groups

Table 4. Showing Changes in Fugl Meyer Assessment (FMA), Passive joint motion and sensation (SMP), Functional Independent Measures (FIM) in Group A. V0-at the starting, V1- after 2 weeks, V2- after 4 weeks and V3- after 8 weeks. A p-value of <0.05 is considered statistically significant. (*) The marked data showed a statistically significant difference.

	Assessment	Data in Mean ± SD	Follow-up visit comparison	P value (Friedman test)
FMA	FMAV0	30.7(±19.7)	FMAV0-FMAV1	0.057*
	FMAV1	38.1(± 17.7)	FMAV1-FMAV2	0.299
	FMAV2	41.7(± 14.4)	FMAV2-FMAV3	0.862
	FMAV3	41.7(±19.5)	FMAV0-FMAV3	0.002*
			FMAV0-FMAV2	0.003*
			FMAV1-FMAV3	0.225
SMP	SMPV0	49.5 (±6.34)	SMPV0-SMPV1	0.083
	SMPV1	53.9(±4.9)	SMPV1-SMPV2	0.488
	SMPV2	54.6(±5.06)	SMPV2-SMPV3	0.729
	SMPV3	54.7(±5.45)	SMPV0-SMPV3	0.038*
			SMPV0-SMPV2	0.015*
			SMPV1-SMPV3	0.759
FIM	FIMV0	163.2(±39.37)	FIMV0-FIMV1	0.146
	FIMV1	166.3(±37.15)	FIMV1-FIMV2	0.299
	FIMV2	171.8(±30.7)	FIMV2-FIMV3	0.862
	FIMV3	171.9(±30.54)	FIMV0-FIMV3	0.001*
			FIMV0-FIMV2	0.001*
			FIMV1-FIMV3	0.225

Table 5. Showing Changes in Fugl Meyer Assessment (FMA), Passive joint motion and sensation (SMP), Functional Independent Measures (FIM) in Group B. V0-at the starting, V1- after 2 weeks, V2- after 4 weeks and V3 – after 8 weeks. A p-value of <0.05 is considered statistically significant. (*) The marked data showed a statistically significant difference.

	Assessment	Data in Mean ± SD	Follow-up visit comparison	P value (Friedman test)
FMA	FMAV0	28.4(±13.43)	FMAV0-FMAV1	0.146
	FMAV1	33.9(±13.81)	FMAV1-FMAV2	0.119
	FMAV2	36.2(±13.05)	FMAV2-FMAV3	0.603
	FMAV3	36.5(±13.27)	FMAV0-FMAV3	0.001*
			FMAV0-FMAV2	0.001*
			FMAV1-FMAV3	0.038*
SMP	SMPV0	50.4(±5.08)	SMPV0-SMPV1	0.024*
	SMPV1	53.8(±3.94)	SMPV1-SMPV2	0.386
	SMPV2	55.3(±3.62)	SMPV2-SMPV3	0.225
	SMPV3	56.7(±2.11)	SMPV0-SMPV3	0.001
			SMPV0-SMPV2	0.002
			SMPV1-SMPV3	0.038*
FIM	FIMV0	174.3(±30.75)	FIMV0-FIMV1	0.038
	FIMV1	177.2(±28.85)	FIMV1-FIMV2	0.194
	FIMV2	177.8(±29.15)	FIMV2-FIMV3	0.386
	FIMV3	178.9(±28.6)	FIMV0-FIMV3	0.001*
			FIMV0-FIMV2	0.001*
			FIMV1-FIMV3	0.030

Table 6. Shows significant changes in Fugl Meyer Assessment (FMA) over time (FMAV0- at baseline, FMAV1- at 2 weeks, FMAV2- at 4 weeks, FMAV3- at 8 weeks) in both groups, but there is no statistically significant difference between the groups. A p-value of <0.05 is considered statistically significant. (*) The marked data showed a statistically significant difference. [FMA: Fugl Meyer Assessment].

Assessment of FMA (Fugl Meyer)	Group-A (High Frequency) (Mean ± SD)	Group-B (Low Frequency) (Mean ± SD)	Intergroup P Value (Mann-Whitney U test)
FMAV0	30.7 (±19.7)	28.4 (±13.43)	0.796
FMAV1	38.1 (± 17.7)	33.9 (±13.81)	0.631
FMAV2	41.7 (± 14.4)	36.2 (±13.05)	0.579
FMAV3	41.7 (±19.5)	36.5 (±13.27)	0.579
P value (Friedman test)	<0.002*	<0.001*	

Table 7. Shows significant changes in the Passive joint motion and sensation (SMP) over time (SMPV0 – at Baseline, SMPV1 - at 2 weeks, SMPV2- at 4 weeks, SMPV3- at 8 weeks) in both groups, but there is no statistically significant difference between the groups. A p-value of <0.05 is considered statistically significant. (*) The marked data showed a statistically significant difference.

Assessment of SMPV (Passive joint motion and sensation)	Group-A (High Frequency) (Mean ± SD)	Group-B (Low Frequency) (Mean ± SD)	Intergroup P Value (Mann-Whitney U test)
SMPV0	49.5 (±6.34)	50.4 (±5.08)	0.579
SMPV1	53.9 (±4.9)	53.8 (±3.94)	1.000
SMPV2	54.6 (±5.06)	55.3 (±3.62)	0.853
SMPV3	54.7 (±5.45)	56.7 (±2.11)	0.853
P value (Friedman test)	0.03*	0.001*	

Table 8. Shows significant changes in the Functional Independent Measures (FIM) over time (FIMV0- at start, FIMV1- at 2 weeks, FIMV2- at 4 weeks, FIMV3- at 8 weeks) in both groups, but there is no statistical difference between the groups. A p-value of <0.05 is considered statistically significant. (*) The marked data showed a statistically significant difference.

Assessment of FIM (FIM-FAM scale)	Group-A (High Frequency) (Mean ± SD)	Group-B (Low Frequency) (Mean ± SD)	Intergroup P Value (Mann-Whitney U test)
FIMV0	163.2 (±39.37)	174.3 (±30.75)	0.353
FIMV1	166.3 (±37.15)	177.2 (±28.85)	0.353
FIMV2	171.8 (±30.7)	177.8 (±29.15)	0.393
FIMV3	171.9 (±30.54)	178.9 (±28.6)	0.393
P value (Friedman test)	0.001*	0.001*	

at 0, 2, 4, and 8 weeks (**Table 7**). There were no significant differences in the FIM-FAM (Functional Independent Measure) scale between the groups at 0, 2, 4, and 8 weeks. There is an improvement in the FIM-FAM score at both frequencies, though the difference is not statistically significant (**Table 8**).

Discussion

The study was conducted at the PMR department of a tertiary care hospital. A total of 23 patients were included in this study, of whom 3 patients were lost to follow-up. Ten patients received high-frequency rTMS, and ten patients received low-frequency rTMS. All the patients were followed up for 8 weeks. A total of 9 male and 11 female patients were included in this study.

We observed significant improvements in the Fugl-Meyer Assessment (FMA), Functional Independence Measure and Functional Assessment Measure (FIM-FAM Scale) & Passive Joint Motion & Sensation at 4 weeks in both groups, namely high frequency (HF rTMS) & low Frequency (LF rTMS), and these improvements persisted even at 8 weeks post-intervention. We did not observe any significant improvement immediately after therapy completion (at 2 weeks).

Xin Chen *et al.* reported significant improvements in the Barthel Index (BI), Modified Barthel Index (MBI), and Functional Independence Measure (FIM) in patients who received HF-TMS in their meta-analysis [14]. In our study, we found significant improvements in the FMA scale at 4 and 8 weeks of therapy, and in the FIM-FAM scale using HF rTMS.

In Hyun Gyu Cha *et al.*'s study, the high-frequency rTMS group (N=12) received 10Hz rTMS to the M1 area on the side of the brain lesion. In contrast, the control group (N=13) received 1Hz rTMS to the cerebral hemisphere contralateral to the lesion. All patients received 10 stimulation sessions, 5 days a week, for 2 weeks, and follow-up was conducted for an additional 2 weeks. They demonstrated that functional recovery occurred after high-frequency and low-frequency rTMS application; however, this difference was not statistically significant. In our study, we applied a 5Hz frequency for high-frequency rTMS and a 1Hz frequency for low-frequency rTMS. We found statistically significant differences in FMA scores in both high-frequency (5Hz) and low-frequency (1Hz) rTMS groups at 4 and 8 weeks post-intervention, although no significant changes were observed at 2 weeks [15].

Toyohiro Hamaguhi *et al.* reported significant improvement in the FMA-upper limb score and the Wolf Motor Function Test (WMFT) following low-frequency rTMS. In addition, when the FMA scores were analyzed separately, the results showed that specific improvements occurred in the shoulder, elbow, wrist, fingers, and coordination, depending on severity [16]. In our study, we also found significant improvements following low-frequency rTMS in the FMA, FIM FAM & Passive Joint Motion & Sensation at 2, 4, and 8 weeks post-intervention.

A study by Hyun Gyu Cha, there were significant differences between before and after intervention in the Wolf Motor Function Test (WMFT includes a wide range of functional tasks from simple to complex tasks, and is used as a functional test of the upper limb, and it evaluates both the execution time and the quality of movement) and FMA in the LF-rTMS group ($p < 0.05$) and in the HF rTMS group, significant differences were observed between pre-intervention and post-intervention FMA scores, as well as between pre-intervention and follow-up test scores ($p <0.01$) 2 weeks after the intervention [17]. We also observed significant improvement with high- and low-frequency rTMS, and follow-up continued for up to 8 weeks. A significant difference was observed in the FIM, FAM, and FMA scales. We also found significant improvement in passive joint motion and sensation in stroke patients with high-frequency and low-frequency rTMS.

Hyun Gyu Cha also demonstrated that LF-rTMS (1 Hz) and HF-rTMS (10 Hz) applied to the primary motor cortex had a positive effect on upper limb function in stroke patients at the acute stage; however, there was no significant difference in the effect between the two groups [17]. In our study, we also did not find significant differences between the groups at 2, 4, and 8 weeks post-intervention; however, we did not include acute stroke patients.

In contrast, Azham Purwandhono *et al.* in their meta-analysis showed that HF-rTMS, using frequencies of 5 Hz and 20Hz, had greater efficacy than LF-rTMS for upper extremity motor rehabilitation therapy after stroke. However, in our study, we did not find any significant differences between high-frequency (HF-rTMS, using a frequency of 5 Hz) and low-frequency rTMS (LF-rTMS, using a frequency of 1 Hz) [18]. This may be related to the frequency differences between Azham Purwandhono's study and ours.

We followed up with the patients 8 weeks post-intervention and found that the improvement was persistent for 8 weeks post-intervention. Very few previous studies followed the participants beyond 2 weeks.

Significant improvement was observed with both high- and low-frequency rTMS on the FIM-FAM and FMA scales. Three patients (2 in group A and 1 from group B) complained of a minor headache on day 0 & 1, which was treated by tablet paracetamol (1 gm) stat dose. No patients experienced convulsions or any other side effects, even after completing therapy. No patients reported worsening of symptoms during or after completion of therapy or during follow-up visits.

The limitations of our study were a small sample size and the absence of a sham-coil control group to see the effectiveness of rTMS. Also, the probability of natural recovery over time may be considered following long-term follow-up. The strength of our study was that we followed patients for 8 weeks, whereas most studies followed patients for only 2 weeks.

More randomized controlled studies with larger samples and a control group may be done. Patients may be followed up for a longer period to assess long-term effects, any side effects, and symptom recurrence.

Conclusions

rTMS (both low- and high-frequency) may be an effective treatment modality for stroke patients, as evidenced by improvements on the FIM-FAM and FMA scales. We followed up with the patients for 8 weeks and observed no recurrence or worsening of symptoms. As this was a pilot study, larger studies are recommended to assess long-term effects, potential side effects, and symptom recurrence.

Conflict of Interest Statement

None.

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