VOLUME - 9, ISSUE - 10, October - 2020 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper | Physiotherapy

EFFECT OF HEAT, COLD AND COMBINED THERMAL STIMULATION ON MOTOR RECOVERY OF PARETIC LOWER LIMB IN ACUTE STROKE PATIENTS - RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Background And Purpose: In acute stroke, flaccidity prevailing on the affected side for first few days or weeks affects the gross functioning of patients like bed mobility, transfers, balance and gait functions. Studies have shown positive effects of combined Thermal Stimulation (TS) on acute hemiplegic patients, however individual thermal agents' effectiveness is yet to be known.

Methods: 36 acute first time stroke patients with paretic lower extremity (Brunnstorm Stage ≥ III) were randomized into 3 groups (A,B,C) where A received heat, B received Cold and C received combined stimulation of heat and cold for 30 minutes followed by conventional physiotherapy for 2 weeks. Motor recovery of affected lower extremity was assessed using FMA – LE, MAS, Balance and postural control was assessed by BBS, PASS and at baseline, 1st week and 2nd week of intervention.

Results: Within group analysis was done using Wilcoxon's Signed Rank Test which showed statistically significant changes in all groups at the end of 2 week session of thermal stimulation. For Paired between group analyses, Mann-Whitney U test was used which did not show much significant difference between the groups.

Conclusion: Thermal agents can be applied either individually or in combination as an adjunct to conventional physical therapy to improve lower extremity paresis in acute stroke population.

KEYWORDS : Thermal Agents, Thermal Stimulation, Acute Stroke, Physiotherapy, Lower extremity paresis, Motor Recovery, Cortical Activation

BACKGROUND

Stroke is defined as a rapidly developing clinical signs of focal, at times global disturbance of cerebral function, with symptoms lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin.[1] According to Global Burden of Diseases, it has become 2nd major cause of mortality and morbidity worldwide. In 2013 stroke resulted in an estimated amount of 6.5 million deaths and 113 Disability Adjusted Life Years (DALYs). In low to middle-income countries by year 2050, more than 80% of predicted global burden of emergent strokes will ensue. In India, stroke is 4th leading cause of mortality and 5th leading cause of DALYs. [2]

Stroke results in various sensorimotor, perceptual and cognitive impairments that affect the functional status and mobility of the subjects.[3] Acute stage can be very challenging as flaccidity in limbs can prevents basic functioning like bed mobility activities, balanced upright sitting, standing and walking.[4-6] Various Neurophysiotherapeutic approaches like Bobath, MRP, PNF etc., used in rehabilitation of stroke emphasize on the importance of improving muscle tone to facilitate motor recovery in terms of active movements.[7,8]

Sensory stimulation in stroke patients results in cortical activation and reorganization, thus facilitating neuroplasticity.[9,10] In typical population, TS has identical cortical activation as seen during motor task performance and more cortical activation when compared with tactile or mechanical stimulation.[11,12] *Chen et.al*, used combined TS (hot and cold) for facilitation of motor recovery in the hemiplegic upper and lower limbs in acute stroke subjects, as an adjunct to conventional Physiotherapy. [13,14]Combined TS is modest yet proven to be effective facilitator in post stroke motor recovery however, effect of individual thermal agent as a facilitator is yet to be found .

METHODS

After getting approval from the Institutional Ethical Committee of Kasturba Medical College Hospitals, Mangaluru , Karnataka, India, 64 acute stroke (within first 4 weeks after onset) patients who got admitted in the hospital for treatment were screened according to selection criteria out of which 36 patients were selected (Figure 1). After getting consent, they were randomly allotted (Block method) into 3 groups where Group A received heat , Group B received Cold and group C received a combination of Heat and Cold Thermal stimulation. Medically stable patients with first ever stroke, Brunnstorm Stage of motor recovery for lower extremity ≤ III, MMSE score ≥ 23, and with a score of 1 or less on Functional Ambulation Classification showing inability to walk independently were included. They were excluded if any cardiac or orthopedic issues hinder thermal application to paretic limb, diabetic neuropathy with gross sensory impairment, PVD, sensory or global aphasias.

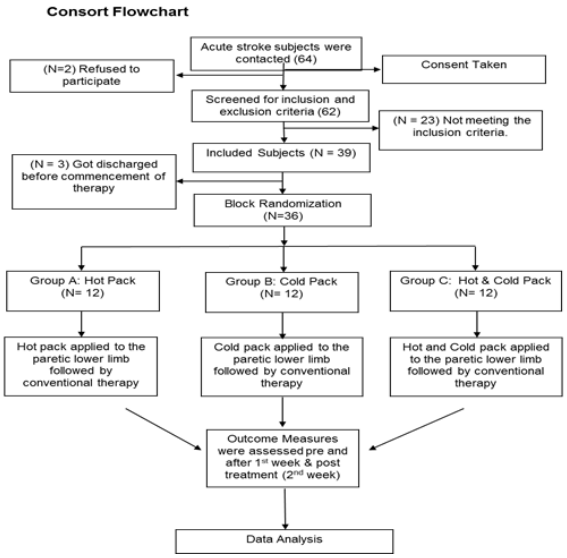

Figure 1: Allotment Flowchart

INTERVENTION

Before commencement of treatment, the procedure was

demonstrated on the non-paretic limb. Patient was instructed to recognize changes in skin temperature and move the limb away from the thermal agent as the discomfort develops. Next, the thermal agent was applied to the paretic extremity and the subject was encouraged to move it away from stimulus as much as possible, either actively or assisted by the therapist in pattern of hip flexion, abduction, external rotation; knee flexion and ankle dorsiflexion Figure 2.

Figure 2: A Thermal Stimulation Applied To Dorsum Of Foot, B: Expected Motor Response.

The thermal agents were wrapped in two layers of towels and applied over the dorsum area of foot of the paretic lower limb with subject positioned in supine or side- lying with affected side up. In Group A and B, hot pack (55° - 75°C, standard size 25cm × 30cm) and cold pack (Cold Pack at -6°C to -12°C, standard size 28cm × 33 cm) were applied respectively. Each application of hot or cold pack was considered as one stimulation, and 8 such stimuli were considered as one set.The stimulus was given till the patient's tolerance or a maximum time limit of 30 seconds. Each session consisted of such three sets which lasted approximately for thirty minutes; 3 × 8 heat/cold stimuli = 24 stimuli per session. Similarly, in Group C; both the thermal agents were applied; first four stimulations were hot then followed by four stimulations of cold; together considered as one set. Rest for 30 seconds in between the stimuli and for 2 minutes in between sets were given totaling intervention session for 30 minutes.[15]

Followed by intervention, all three groups received conventional therapy, commonly followed in the department; which consisted of muscle facilitatory and inhibitory techniques, range of motion exercises, bed mobility and balance training. The intervention was given for five sessions per week, for two weeks.

Outcome Measures

FMA-LE and MAS were used for motor recovery, BBS and PASS were used for balance assessment and postural changes. They were recorded at the beginning of intervention (baseline), at the end of first and second week by a blinded observer.

RESULTS:

Data analysis was performed using SPSS version 20.0 software. General characteristics of the patients between the 3 groups were analysed (Table 1) using Chi Square test (Gender, Dominance and Side of Lesion) and Fisher's Exact test (Type of Lesion and Brunnstorm Stage of Motor Recovery). A p value of 0.05 was set. No significant difference in mean scores of all outcome measures at baseline were observed(Table 2). Wilcoxon's signed rank test was used to perform within group comparison of pre-treatment and post-treatment scores of outcome measures which showed statistically highly significant over the period of time (p= 0.00) (Table 3). A Pair-wise comparison of all groups was done by using Mann-Whitney U Test.

A statistically significant difference was seen when Group A was compared with Group B in MAS scores (p = 0.043) at the end of 2 week intervention. Similarly, when Group A was compared to Group C in PASS scores, statistically significant difference was found at 1st to 2nd week (p = 0.037) and by the end of 2 week intervention (p = 0.042) (Table 4). However, scores of other parameters showed no significant differences between the groups.

Table 1: Demographic And Baseline Characteristics Of Patients Included.

Parameters		Group A (HOT)	Group B (COLD)	Group C (Combined)	p value
Gender	Male	5 (41.7%)	7 (63.6%)	9 (75.0%)	0.235
	Female	7 (58.3%)	5 (36.4%)	3 (25.0%)	
Dominance	Right	12 (100%)	12 (100%)	11 (97.1%)	0.333
	Left	0 (0%)	0 (0%)	1 (8.3%)	
Side of Lesion	Right	7 (58.3%)	5 (36.4%)	6 (50.0%)	0.570
	Left	5 (41.7%)	7 (63.6%)	6 (50.0%)	
Type of Lesion	Hemorrhagic	7 (66.7%)	5 (45.5%)	8 (75%)	0.372
	Ischaemic	5 (33.3%)	7 (54.5%)	4 (25.0%)	
Brunnstorm Stage of Motor Recovery	Stage 1	4 (33.3%)	5 (45.5%)	4 (33.3%)	0.940
	Stage 2	8 (66.7%)	7 (54.5%)	7 (58.3%)	
	Stage 3	0 (0%)	0 (0%)	1(8.3%)	
Age(yrs) (Mean ± SD)		58.25±10.95	64.18±10.87	64.67±13.28	0.348

Table 2: Comparison Of Baseline Assessments Scores Of All The Outcome Measures.

Parameters	Group A Mean (SD)	Group B Mean (SD)	Group C Mean (SD)	p value
FMS- LE	4.33 ± 1.30	4.27 ± 1.10	4 ± 0.853	0.426
BBS	1.83 ± 2.03	1.27 ± 2.102	1.33 ± 2.674	0.486
MAS	4.67 ± 2.77	4.27 ± 2.24	3.38 ± 2.16	0.751
PASS	7.08 ± 3.37	5.73 ± 3.37	6 ± 2.55	0.420

Table 3: Mean Difference Observed In All The Parameters Within The Groups Over The Period Of Time.

		Baseline(0)-1 wk		0-2 wk		1-2 wk	
Parameters	Groups	Mean Difference	p value	Mean Difference	p value	Mean Difference	p value
FMS-LE	A	1.33	0.028	2.75	0.003	1.41	0.007
	B	1.63	0.01	2.72	0.003	1.09	0.006
	C	0.83	0.02	2.41	0.002	1.58	0.003
BBS	A	2.5	0.005	4.75	0.002	2.25	0.003
	B	3.00	0.005	4.45	0.003	1.45	0.016
	C	2.08	0.002	3.66	0.002	1.58	0.018
MAS	A	2.75	0.002	5.56	0.002	2.91	0.003
	B	1.72	0.005	3.36	0.005	1.63	0.007
	C	1.83	0.003	3.41	0.002	1.58	0.007

PASS	A	3.41	0.002	7.83	0.002	4.41	0.003
	B	2.81	0.005	6.27	0.005	3.45	0.007
	C	2.58	0.002	4.83	0.002	2.25	0.003

Table 4: Comparison of the mean difference in all outcome measures between the groups at three intervals: baseline (0) - 1 week, total duration 0-2 weeks and between1 – 2 week.

Parameters		Groups	Mean Difference	A-B (p value)	A-C (p value)	B-C (p value)
FMS-LE	0 - 1 week	A	1.33	0.44	0.60	0.12
		B	1.63			
		C	0.83			
	0 – 2 week	A	2.75	0.61	0.74	0.70
		B	2.72			
		C	2.41			
	1 - 2 week	A	1.41	0.43	0.69	0.12
		B	1.09			
		C	1.58			
BBS	0 - 1 week	A	2.5	0.61	0.45	0.25
		B	3.00			
		C	2.08			
	0 – 2 week	A	4.75	0.57	0.17	0.63
		B	4.45			
		C	3.66			
	1 - 2 week	A	2.25	0.059	0.22	0.89
		B	1.45			
		C	1.58			
MAS	0 - 1 week	A	2.75	0.12	0.17	0.89
		B	1.72			
		C	1.83			
	0 – 2 week	A	5.66	**0.043***	0.09	1.00
		B	3.36			
		C	3.41			
	1 - 2 week	A	2.91	0.06	0.08	0.63
		B	1.63			
		C	1.58			
		B	1.45			
		C	2.58			
PASS	0 - 1 week	A	3.41	0.31	0.13	0.72
		B	2.81			
		C	2.58			
	0 – 2 week	A	7.83	0.24	**0.042***	0.62
		B	6.27			
		C	4.83			
	1 - 2 week	A	4.41	0.36	**0.037***	0.70
		B	3.45			
		C	2.25			

DISCUSSION:

Neurorehabilitation approaches believe in holistic functioning of brain, that is, motor and sensory areas are interdependent. Therefore, stimulation of one system can influence the other. [16] TS results in both cortical activation as well as volitional movement of stimulated limb[17]. As a compensatory mechanism, there is increased recruitment of secondary motor areas such as Dorso-Lateral Pre-Motor Cortex and Supplementary Motor Area.[18] Many studies have shown that by application of noxious thermal stimuli, there is multiple level cortical activation like; Somato-Sensory Area 1 and 2, Insular Cortex, Thalamus, Dorso-Lateral Prefrontal Cortex and Parietal Cortex. Medial temporal lobe including Amygdala also get activated, which is associated with learning and avoidance about the aversive stimulus.[19] Supplementary Motor Cortex is involved in planning and readiness for the withdrawal of the limb during the application of noxious thermal stimulus. According to meta-analysis done by Farrell et. al., Cerebellar, Pre-motor and Supplementary Motor Cortex also get activated along with the above mentioned areas.[20] Some non-specific activation of the cortex was also seen which was explained as due to attention and working memory regarding stimuli. Therefore, TS improves attention towards the paretic limb and hence, avoids hemi-neglect and further issues like learned non-use of the paretic extremity.

Present study demonstrated statistically significant improvement in Motor Function, Balance and Postural Control across all the groups in two weeks. But when compared between the groups, no statistical significant difference was found, except that Heat Group (A) had shown improvement in activity (MAS) scores by the end of two weeks of intervention as compared to Cold Group (B) and also, Heat group (A) had better scores than combined group (C) in PASS measuring postural control by the end of second week. Rest all the parameters showed more or less similar improvements.

Irrespective of the type of thermal stimulation given, there were minimal significant changes seen between the groups implying that all three have similar effects as facilitator. A study done by *Davis et.al*, [12] correlates with our results where, similar cortical activation were viewed in functional MRI when noxious heat and cold stimulus were applied. Modalities like hot and cold packs are easily accessible and are not complicated and expensive as other facilitative modalities like robotic assisted training, FES and EMG Biofeedback. Stimulation application can also be explained to the family members to continue as home program.

The current study shows statistically significant changes, but clinically, very minimal significant changes were seen [21,22] which could be due to population was acute with Brunnstorm stage less than III and the intervention was only for 2 weeks. This duration may not be sufficient for the subject to show much of clinical changes. For future considerations comparison thermal and non-thermal stimulus (tapping, quick stretch, vibration) application can be done. Simultaneous or alternate application of Thermal Stimulation on both upper and lower extremity can also be studied.

CONCLUSION:

Application of thermal agents Heat, Cold or a Combination of both showed statistically significant changes in the acute stroke population. Hence, any single thermal stimulation can be used as a facilitatory technique in adjunct to the conventional physiotherapy during the acute stage of stroke. All three methods had similar effect on motor recovery of the subjects, therefore any method can be used in a clinical setting.

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