



# Evaluating the Effectiveness of classical and clinical Acupuncture on Treating Acute Migraine Attack

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## ABSTRACT

According to WHO migraine is the seventh most disabling and prevalent disorder that affects especially during productive phase of life. Numerous studies were done involving Acupuncture as an effective non-pharmacological approach for migraine. Yet, studies involving TCM diagnosis and providing individualized treatment are few, therefore comparison was done between Classical and Clinical Acupuncture. To evaluate the effectiveness of Classical Acupuncture and Clinical Acupuncture in treating acute migraine attack A prospective, randomized trial performed among 55 migraine subjects, assessed according to ICHD-3 Beta version criteria. Using simple randomization subjects were randomized under Group A (Classical; N = 27) and Group B (Clinical; N= 28) on 1:1 ratio. The Subjects of Group A and Group B received their respective treatment during their acute migraine attacks. Data were collected during every visit before and after treatment using 10 Point- VAS scale, and also pre and post study period (5 months) using MIDAS tool, migraine questionnaire. Primary outcome: Intensity of pain during acute migraine attack showed statistically significant improvement in both Groups (P<0.001). However, on observing variance value Group A showed better improvement than Group B.

**KEY WORDS:** Migraine, Classical Acupuncture, Clinical Acupuncture, VAS, MIDAS

## Introduction

Migraine is a common, incapacitating neurovascular disorder characterized by episodes of severe headache that is often throbbing and frequently unilateral present along with symptoms like nausea, vomiting, sensitivity to light, sounds and movement. When untreated these attacks last for 4 to 72 hours [1]. Migraine usually starts at pubertal age and shows genetic predisposition [2, 3]. Females show higher rate of prevalence and some get headache during their menstrual cycle, which shows influence of hormones in migraine [4]. Migraine can be triggered by many factors like food, environment and mental factors, and may be aggravated by routine physical activity [5].

Migraine has two major subtypes, migraine with aura [MA] and migraine without aura [MO]. Migraine with aura also known as 'classical migraine' starts with non-specific prodrome of malaise and irritability followed by aura. Patients usually suffer from severe, throbbing, hemi cranial headache with photophobia and vomiting. During headache patient prefer to be in quiet, dark room. Migraine without aura also known as 'common migraine' does not have the premonitory symptomatology and are usually present paroxysmal headache with nausea or vomiting [2,4].

Many theories viz vascular theory, neuropeptide theory etc. were hypothesized and experimented to understand the pathophysiology of migraine and being widely debated across the world. It has been considered that the headache phase of migraine is due to the activation and sensitization of trigeminovascular meningeal nociceptors that in turn activate the second-order and third-order central trigeminovascular neurons, which further activates different areas of the brain stem and forebrain. This causes pain and other accompanying migrainous symptoms [6].

Migraine patients often require medical management to overcome the disability caused due to the pain and associated symptoms. Based on the European Federation of Neurological Societies guideline for drug therapy, oral nonsteroidal anti-inflammatory drugs [NSAIDs], and triptans [specific agents with vasoconstriction properties] were recommended for the acute migraine attacks. However, patients still experience some side effects like gastrointestinal and cardiovascular disorders. Medication overuse headache and increased headache frequency is another problem with the migraine drug [7, 8].

The World Health Organization [WHO] recognized migraine as seventh major cause of disability in 2004. Globally, the percentages of the adult population with an active headache disorder are 46% for headache in general, 11% for migraine, 42% for tension-type headache and 3% for chronic daily headache. Considering this global predominance, a joint initiative was taken by WHO 'Lifting the Burden: The Global Campaign to Reduce the Burden of Headache Worldwide'. An important part of this work is to obtain a 'clear and objective understanding of the scale and scope of headache-related burden'. [9].

Many people do not recover completely from the migraine attacks and have significant impacts on the social and economic life. It produces negative impacts on an individual's performance at home, school or work in terms of impairment of normal daily functioning, absence and loss of productivity [9]. The economic burden of migraine is also too high and the estimated annual costs is 17 billion dollars in the U.S. Most of the direct costs are for OPD services and indirect costs are due to lost productivity in the workplace [10].

## MATERIALS AND METHODS

### Description of the subjects including the selection of samples

The study subjects were conveniently recruited from the Government Yoga and Naturopathy Medical College and Hospital, Arumbakkam, Chennai District of Tamilnadu state in India. The subjects were recruited from the above-mentioned hospital through screening done to assess diagnostic criteria, inclusion and exclusion criteria. All the fifty-five subjects were screened through a routine medical check-up and those satisfying the diagnostic criteria for migraine as mentioned in The International Classification of Headache Disorders, 3<sup>rd</sup> edition (Beta Version), (ICHD- 3 Beta) were recruited.

### Ethical clearance

Ethical clearance was sought from the Institutional Ethical Committee prior to the start of the study and the approval for the same was granted. The baseline and post-intervention assessments consisted of primary and secondary outcome variables. Primary outcome variables Pain intensity during every attack with migraine. Secondary outcome variables Pain intensity, Pain frequency and Duration of pain. All the 3 parameters measured before intervention and after follow up period. Pain intensity during every visit with migraine attack was measured using Visual Analog Scale (VAS) 10-point scale.

### VAS- 10-point scale

Intensity of the pain is measured during every visit with the acute attack. Prescore is obtained before needling and post score is obtained 1 hr. after needling. The VAS is the most commonly used scale to measure pain intensity in pain research. VAS score was less biased by pre-treatment pain. The results also suggested that a 33% decrease in pain indicates reasonable standard for determining that a change in pain is meaningful from the patient's perspective [161]. MIDAS tool has been used to obtain intensity and frequency of migraine over a period of 3 months, which was given during the start of the intervention and 2 months after the follow up period (i.e., at the end of 5<sup>th</sup> month). The Migraine Disability Assessment (MIDAS) questionnaire is a self-administered questionnaire designed to quantify headache-related disability over a 3-month period. The MIDAS score has been shown to have moderately high test-retest reliability in headache sufferers and is correlated with clinical judgment regarding the need for medical care [162].

## **Pain frequency**

Pain frequency is measured using MIDAS tool, which reveals the frequency of attack for last 3 months. Pre and post data were obtained respectively. Meanwhile patients were asked to follow headache diary.

## **Duration of pain**

Duration of pain data was collected from the migraine questionnaire which was given at the start and end of the study.

## **Group A (Classical Acupuncture)**

In this group patient who visited our OPD with acute migraine attack were treated with classical acupuncture also known as Traditional Chinese Acupuncture. Point's selection was done by "five element Shu selection method". Needling was given for a period of 30 mins. VAS was given to the patient for scoring before needling and 1 hr. after from the time of needling.

### **Five element Shu selection method:**

In this method each and every symptom presented by the patients are related with respective elements based on their characteristic features and functions. Cumulatively the major element with its yin or yang polarity, which is affected will be jotted. Further, the selected element will be matched with the 'Shu group (1-5) –which is grouped according to the functions', based on this a point is selected from 60 points of command. Along with the selected point supportive points like source, xi-cleft, back-shu, front-mu points are used according to the necessity to notify the affected element. Single needle for Shu point and an average of 3-5 needles for supportive points were used.

## **Group B (Clinical Acupuncture)**

Western Medical Acupuncture is mentioned as clinical acupuncture in the study. In Clinical acupuncture group patients who visited our OPD with acute migraine attack were given specific set of points for a period of 30 mins. VAS was given to the patient for scoring before needling and 1 hr. after from the time of needling.

## **Needling**

Needling methods for both groups were same. Both groups were treated with 'use and throw' stainless steel needles. Needles with the measurement of 0.25 \* 0.25 were used throughout the study. During every visit patients were treated with new needles. Sterile measures were adopted and used needles were carefully disposed. Needles were inserted till the level of the dermis.

## **General instructions**

Subjects belonging to both groups who participated in the study were asked to follow the following instructions: Diet: Avoid deep fried food stuffs, Maida products, and tinned foods. Easy-to digest diet should be taken. Sleep: Instructed to go to bed by 9-10 pm. 7-8 hrs. of compulsory sleep. Should sleep in a dark room.

## **Data Extraction**

Data were collected as self-reported observations using primary outcomes and secondary outcome variables. Baseline data were obtained on the first visit during first month and end point data were collected at the end of 5<sup>th</sup> month. During every visit with attack pain intensity was measured using VAS before needling and 1 hr. after needling. Data were organized in Microsoft Excel sheets (version 2010)

## **Results**

The present study was conducted to compare and evaluate the effectiveness of classical and clinical Acupuncture during acute migraine attack. The effectiveness of intervention was assessed based on the outcome variables viz 10- point VAS score, MIDAS tool and Migraine intake Questionnaire. The primary outcome variable was pain intensity, measured using 10-point VAS score, taken before and after treatment during every visit with migraine attack. The outcome data of first 3 visits has been taken for statistical analysis.

The secondary outcome variable were frequency, intensity measured using MIDAS tool and pain duration measured using Migraine intake Questionnaire, collected pre and post study period (5 months). The measured outcome variable were statistically analyzed using SPSS software – version 16. T-TEST FOR EQUALITY OF MEANS were applied to assess the outcome of pain intensity and frequency; Grading was done to compare the

outcome of pain duration.

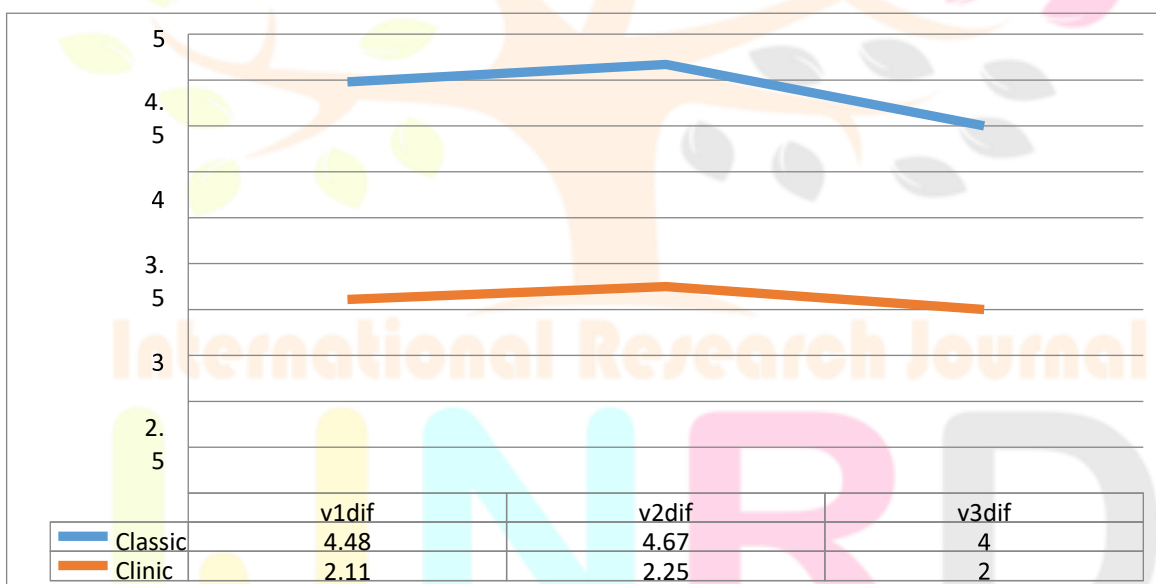
**Primary outcome:** Both the groups are statistically significant in reducing intensity of pain ( $p < 0.001$ ) in all the 3 visits with migraine attack, however on observing variance value Group A showed better improvement than Group B.

**Secondary outcome:** Analysis of frequency showed no significant changes in both groups. However on observing the difference in the mean and SD of pre and post frequency in both groups, Group A showed better improvement in the frequency of migraine. Analysis of intensity showed significant changes in both groups (Group A  $p = 0.007$  and Group B  $p = 0.008$ ).

**Intensity of pain during treatment**

Number of visits	Groups	N	Variance	SD	P value#
Visit 1	Group A	27	4.48	± 1.014	<0.001
	Group B	28	2.11	± 0.737	
Visit 2	Group A	27	4.67	± 1.038	<0.001
	Group B	28	2.25	± 0.585	
Visit 3	Group A	27	4.00	± 0.920	<0.001
	Group B	28	2.00	± 0.471	

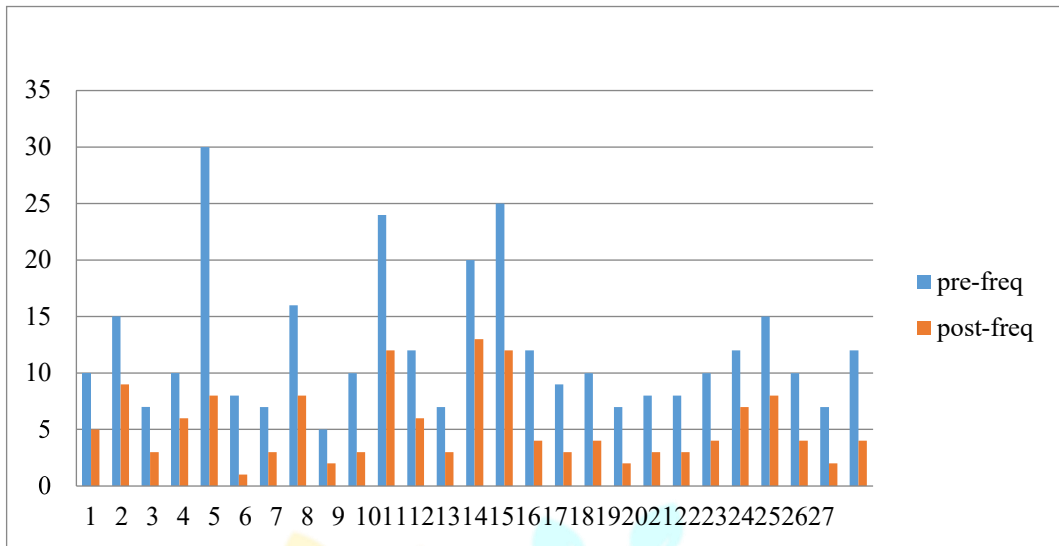
**Intensity of Pain During Treatment**



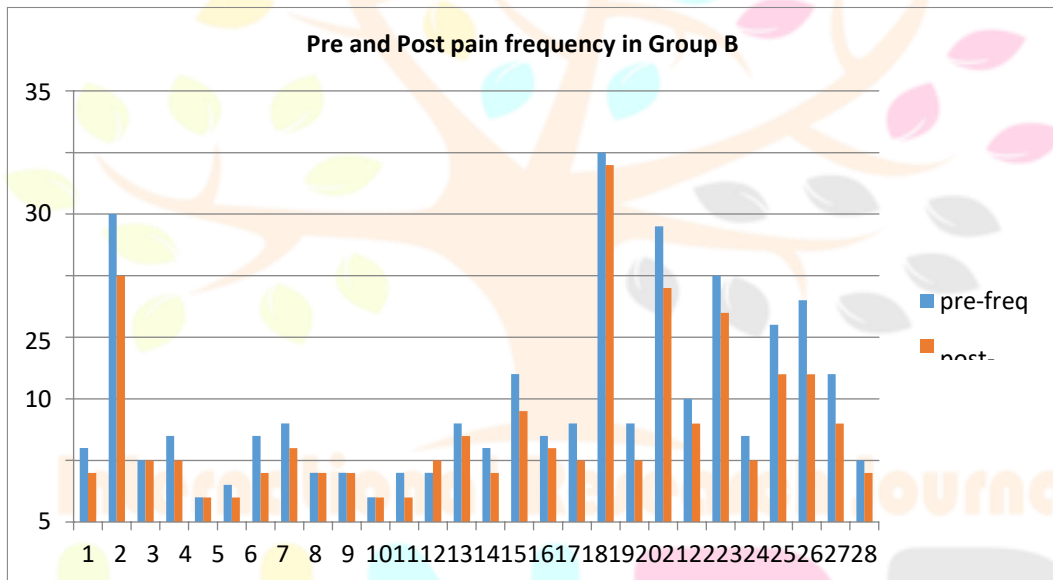
**Frequency of Pain Pre & Post Intervention- In %**

Groups	Total	Improvement in frequency			
		Improved		Not improved	
		N	Count in %	N	Count in %
Group A	27	24	88.8	3	11.11
Group B	28	11	39.28	17	60.71
Total	55	35	63.6	20	36.36

### Frequency of Pain Pre & Post Intervention –Group A



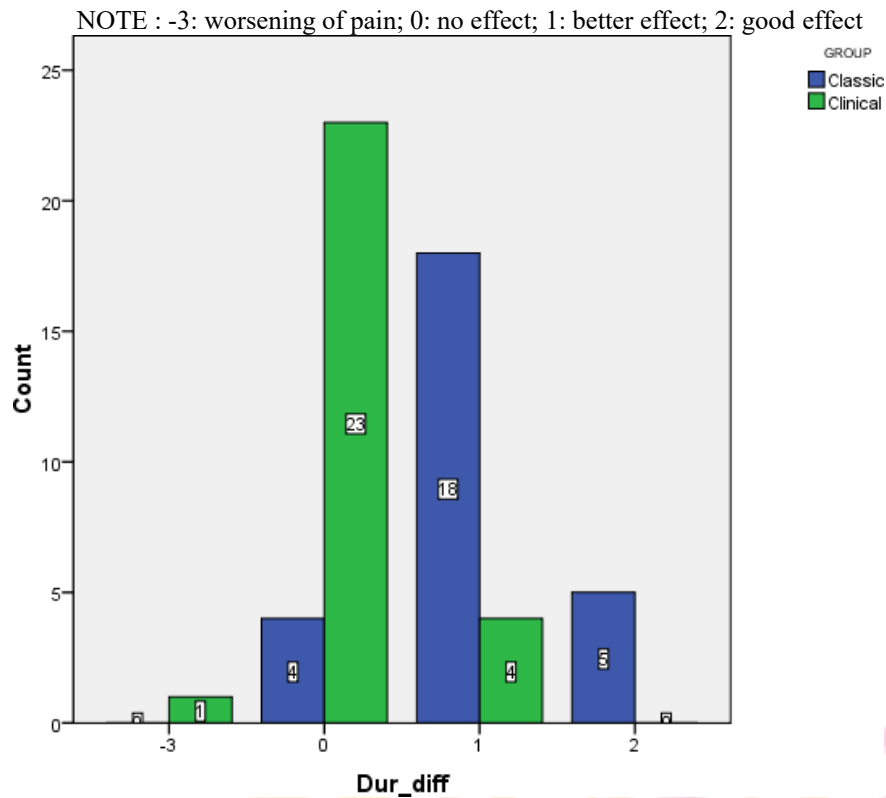
### Frequency of Pain Pre & Post Intervention –Group B



Difference in duration									
Groups	N	Grade 1		Grade 11		Grade 111		Grade 1V	
		N	Count in %	N	Count in %	N	Count in %	N	Count in %
Group A	27	0	0	4	14.8	18	66.7	5	18.5
Group B	28	1	3.6	23	82.1	4	14.3	0	0
Total	55	1	1.8	27	49.1	22	40.0	5	9.1

Grade 1: worsening of pain; Grade 11: no effect; Grade 111: better effect; Grade 1V: good eff

### Comparison of Difference in Pain Duration Among Both Groups



## Discussion

Migraine is the major disabling disease affecting the daily activity. In spite of advancement in pharmacotherapy, as many people did not receive optimal control they seek for non-pharmacological approach. Acupuncture is one such approach. In the current study, the effectiveness of classical and clinical acupuncture during acute migraine attacks was compared. Points used to treat Clinical Acupuncture group were GB 8, GB 20, ST 8, ST 36, P 6, DU 20 and LI 4. Each point has its own character and action which are related to migraine, this has been explained. Similar Clinical points were used by *Lin-Peng* et al in treating pain intensity among migraineurs, in which verum group showed better improvement than sham group [165].

Method adopted to treat Group A was 5 element Shu selection. On reviewing prior studies on migraine, trails were conducted using only verum acupuncture (Chinese acupuncture) with specific set of points. To my knowledge studies involving TCM diagnosis and providing individualized treatment are very few. A study by *Jerusa A.A* et al stated “results of their pilot study used individualized treatment in real acupuncture group, seem to offer best approach. It takes into account all clinical signs and symptoms presented by each patient.”

Another study by *Facco* et al had applied TCM syndrome differentiation (a part of TCM diagnosis) to treat migraine with specific sets of points to that specific syndrome [137]. Therefore, in this study also TCM diagnosis and individualized treatment was given to the subjects in Group A (classical group). Effect of clinical and classical acupuncture among migraineurs on the outcome measures during acute migraine attack: Table 5.3 reveals that both groups help in significant reduction of pain intensity during acute migraine attack ( $P > 0.001$ ). VAS score was obtained from 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> visit during the attack, and the variance of pre and post Group A are 4.48, 4.67, 4.00 and Group B are 2.11, 2.25, 2.00 respectively. From this it is evident that the reduction in the intensity of pain during acute migraine attack is better Group A than in Group B in all the 3 visits respectively.

On clinical observation the changes in pain and associated symptoms started to occur at an average period of 5-15 mins after needling and at times much earlier too. However, it was observed that in some patients the pain symptom got intensified after needling irrespective of the visit. Further this aggravation in the symptom showed significant reduction in pain towards the end of the sitting, as well as pain free by the end of day, which was observed only in Group A. This effect may be synonymous with the healing crisis mentioned in Naturopathy texts [167]. While measuring VAS at the end of one hour during every visit, the difference in the score.

Among the Group A were reduced by an average minimum of 3 points from pre score. Whereas in Group B reduction was not less than 2 points from the pre score. Though the reduction in intensity of pain is obtained in both groups, significant difference in Group A might be due to the correction of root cause of the pain, during

every visit with migraine. With 5 elements Shu selection method (Table 4.1) prevalent symptoms during the visit after the migraine attack and signs observed on the patients were taken into account and the major element disturbed was corrected and tonified. Whereas in Group B correction of imbalance in elements weren't done. However, the change in intensity of pain may be due to specific action of these individual point. This pain-relieving effect of acupuncture can be explained to some extent with the hypothesis from previous studies. During needling A-delta fibers and its collateral terminals are stimulated leading to the inhibition of nociceptive pathway in the dorsal horn of the spinal cord. This releases enkephalin which helps to relieve pain and disturbed autonomic reflexes.

A study by Peroutka et al (2004) also states migraine as chronic sympathetic dysfunction [168]. In both the group this might be the cause of reduction in pain and other associated symptoms of migraine. Another hypothesis relating to pain mechanism is descending pain inhibitory system. When stimulated, descending pain fibers activate periaqueductal grey matter which releases serotonin that in turn release enkephalin and inhibit substantia gelatinosa [150]. Another study reveals low levels of 5HT which is one of the causes for activation of trigemino-vascular system in migraine [155]. From the above paras the difference in the intensity of pain among migraine patients in this study might be due to the release of serotonin while needling.

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