



Research Article

## EFFICACY OF SPINAL MOBILIZATION IN PATIENTS WITH CHRONIC TENSION TYPE HEADACHE- A RANDOMIZED CLINICAL TRIAL

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### ABSTRACT

**Background-** Headache is the most common complaint and experience in adults and in the industrialized population. The prevalence of chronic tension type headache (CTTH) in population of Denmark and the western society lies between 2-5% lasting generally for the lifetime. The female-to-male ratio of Tension Type Headache is 5: 4 that means, females are slightly more affected than men. In both female and male, it begins at any age and the peak level is between 30-39 yrs which slightly decreases with the age.

**Aim-** To determine the efficacy of spinal mobilization in patients with chronic tension type headache.

**Materials and methods-** 40 (both males and females between age group 20-40 yrs) chronic tension type headache patients were recruited. Assessment and treatment was given at baseline, after 2 weeks and after 4 weeks. Towel, theraband, weights, couch were used for the treatment. Stretching, spinal mobilization, deep friction massages, moist heat packs were given.

**Data Analysis and Results-** The data was analyzed using Statistical Package for the Social Sciences (SPSS) version 16. Mann-Whitney U test and Wilcoxon W test was used for between group comparisons and also for the mean change of scores between groups. Friedman test and Chi-square test was used for within group comparison and also for the mean change of scores within group. Results shows there is significant difference between both the groups and both groups have shown improvement.

**Conclusion-** The spinal mobilization along with the conventional treatment group have shown statistically more significant improvement than the conventional treatment group alone in reducing impact, functional disability and pain as headache and in improving the quality of life in patients with CTTH.

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### INTRODUCTION

Headache is the most common complaint and experience in adults and in the industrialized population. This even being a benign disorder has considerable socioeconomic impact on human population due to reduced work efficiency and days.<sup>1,2</sup> The female-to-male ratio of Tension Type Headache is 5: 4 that means, females are slightly more affected than men.<sup>3,5</sup> In both female and male, it begins at any age and the peak level is between 30-39 yrs which slightly decreases with the age.<sup>3</sup>

IHS characterized CTTH as- bilateral location, pressing or tightening quality, mild to moderate intensity not aggravated by normal physical activity like walking or climbing stairs. This differs from the ETTH, which includes all the symptoms of ETTH along with photophobia or phonophobia, mild nausea may be present.<sup>3,8,4,9</sup>

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In CTTH there are 15 or more headache episodes per month or at least 180 days of headache episodes per year.<sup>3,20</sup> The IHS characterized CTTH as- headache occurring on at least 15 days per month for more than 3 months, headache lasting for hours or continuously presents.<sup>8,4,10</sup>

Many studies, shows that pericranial myofascial tissues are more tender and there are more active trigger points in patients with CTTH and the tenderness is associated with the intensity and frequency of CTTH.<sup>3</sup> In peripheral mechanism, peripheral sensitization of myofascial nociceptors plays important role in increased pain sensitivity.<sup>3</sup> In central mechanism, sensitization of the second order neurons, supraspinal neurons, thus increases the myofascial pain sensitivity. The increased excitability of neurons in the CNS, various neuropeptides generated by prolonged nociceptive input from the pericranial myofascial tissues plays an important role in the pathophysiology of chronic tension-type headache and in generation of painful input and in the process of central sensitization.<sup>3,15</sup>

**Study Design-** A Randomized Clinical Trial

**Sampling-** Criteria based purposive sampling

**Inclusion Criteria**

1. Age 20 to 40 yrs.
2. The headache has at least one of the following characteristics:-
  - a. Bilateral location
  - b. Pressing or tightening (nonpulsating) quality
  - c. Mild or moderate intensity, not aggravated by normal physical activity such as walking or climbing stairs.
  - d. Photophobia or phonophobia or mild nausea.
  - e. No mild or severe vomiting.
3. Signed Informed Consent form
4. Both Males and Females
5. Patient should be co-operative

**Exclusion Criteria**

1. Any traumatic injury.
2. Presence of more than one type of headache in addition to tension type headache.
3. Any Physiotherapy treatment for tension type headache during the last six months, especially if they had received manual therapy treatment two months prior to enrolment in the study.
4. Inflammatory, Malignant and Neurological conditions.
5. Pregnancy, seizures.
6. Osteoporosis, metabolic disorders
7. Nocturnal or early morning onset
8. Intake of triptans, ergotamines or opioids on 10 days/month or simple analgesics on 15 days/month on a regular basis for three months

**Outcome Measures**

The primary outcome measures

1. NPRS
2. HIT-6

Secondary outcome measure

- 1) HDI

**Materials Used For Data Collection**

For Evaluation

Assessment forms

Three scales

For Intervention

Couch

Towel

MHP

Thera band (pink colored, Thera Band Company)

Patients were selected by means of purposive sampling based on inclusion and exclusion criteria. Eligible subjects were randomly allocated using small chits of paper containing the treatment allocation for each participant. All the patients received a written explanation of the trial before entry into the study and they were given informed consent to be signed for participation. Then, the patients were randomly allocated into two groups: Group A and Group B. the baseline data for pain, functional disability and impact on daily life activities were recorded using NPRS, HDI and HIT-6 respectively.

**Interventions**

**Conventional Treatment**

Patients of group A and B both received conventional treatment 5 days a week for 4 weeks.

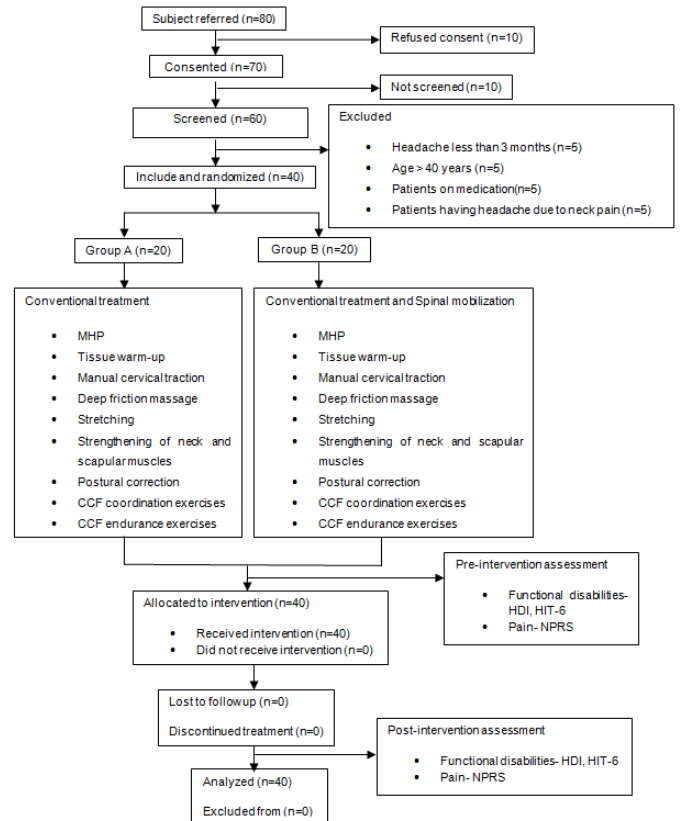


Figure 1 Modified CONSORT flow chart of procedure

**Standard Care**

Tissue warm-up (Figure 2)



Figure 2 TISSUE WARM UP

This is done by bilateral pressure moving from the lower cervical region to the occiput.

This includes application of MHP and bilateral pressure moving from the lower cervical region to the occiput, repeated 3 times bilaterally for 15 minutes.

Manual cervical traction (Figure 3)



**Figure 3** Manual Cervical Traction

The patient was made to lie down in supine lying with hands by the side along the trunk. The therapist stands behind the head of the patient at the edge of the couch. Manual axial cervical traction was given with one hand of the therapist under the head and neck and the other hand on the forehead. Gentle traction was applied with the head first slightly flexed, then with slight lateral flexion (right and left). Traction was held for 15 seconds in each position and was given for 2 minutes.

Deep friction massages (Figure 4)



**Figure 4** Deep Friction Massage

The patient was made to lie down in prone lying by the forehead. A towel roll or pillow was kept under the forehead with arms by the side along the trunk. The therapist stands by the couch facing the patient and locates the trigger points by palpation by pincer or flat palpation method. Firm pressure was given on the trigger points in circular and semicircular manner on the trigger points of the upper trapezius, sternocleidomastoid muscle, suboccipital muscles, and levator scapulae. This procedure was repeated 3 to 5 times each trigger point maintaining pressure for each trigger point for around 2 minutes. It was given for a total of 13 minutes. Stretching (Figure 5)

The patient was made to lie down in supine lying with arms by the side along the trunk. The therapist stands behind the head of the patient at the edge of the couch. The entire procedure was done for 5 minutes. Each stretch was maintained for 30 seconds. Stretching of the upper trapezius, suboccipital muscles, and levator scapulae was done.

Upper trapezius (Figure 5.1)



**Figure 5.1** Stretching of Upper Trapezius

The patient was in supine lying and the therapist behind the head of the patient at the edge of the couch. The patients head was first taken to lateral flexion to the opposite side, rotation to the opposite side and then taken to flexion of the neck.

Levator scapulae (Figure 5.2)



**Figure 5.2** Stretching of Levator Scapulae

The patient was made to lie down in supine lying with the arm of side to be treated stretched out alongside the trunk with the hand supinated. The therapist, standing at the edge of the

couch behind the patient, the therapist's hand passes his contralateral arm under the neck to rest on the patient's shoulder. The therapist lifts the neck into full flexion, the head is fully turned into side flexion and rotation away from the side to be treated.

Suboccipitals (Figure 5.3)



Figure 5.3 Stretching of Suboccipitals

The patient was made to sit down on a stool with the arms by the side along the trunk. The therapist stands behind the patient and takes the patient's neck to full flexion.

Cervical flexor endurance strength training exercises (Figure 6)

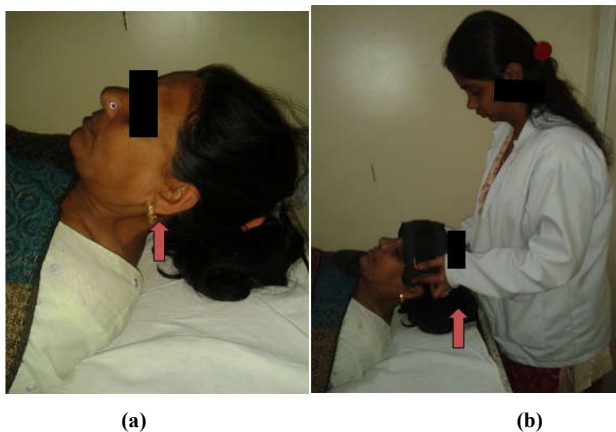


Figure 6 Cervical flexor endurance strength training exercises

The patient was made to lie down in supine lying with the head supported in a comfortable resting position. The endurance-strength training regime consisted of a progressive resistance exercise programme for the neck flexors. Patients were instructed to lift their head so that cervical flexion will be performed maintaining a neutral upper cervical spine. Patients have to slowly move the head and neck through full range of cervical flexion motion as possible without causing discomfort or reproduction of their symptoms. Patients performed 12–15 repetitions with a weight that they could lift 12 times (12 repetitions maximum) and progressed to 15 repetitions and maintained this level during the first treatment session. The subjects were asked to perform three sets of 15 repetitions of the initial 12 repetitions maximum load once per day. Each repetition lasted 3 seconds, with rest intervals of 2 seconds between repetitions. Subjects were asked to rest for 30 seconds between sets (total contraction time 90 seconds). When the repetitions were easily achieved, weighted sandbags were

applied to the patient's forehead in 0.5 kg increments as was required. The entire procedure was carried out for 4 minutes. CCF Coordination exercise (Figure 7)



(a)



(b)

Figure 7 CCF Coordination Exercises

The patient was made to sit on a stool with arms by the side alongside the trunk with a natural lumbar lordosis, under slight scapular retraction and adduction and slightly elongating the cervical spine. This procedure was performed using a latex band or thera band. The latex band was used as a circular band, with one side positioned at the craniocervical region of the patient's neck and the other side fixed somewhat above the horizontal. Participants were instructed to perform slow and controlled craniocervical flexion over various ranges of motion, resulting in various resistances, with various speeds using isometric contractions in various positions. The entire procedure was carried out for 10 minutes.

**Home Programmer**

Patients of both group A and group B were advised for home exercises.

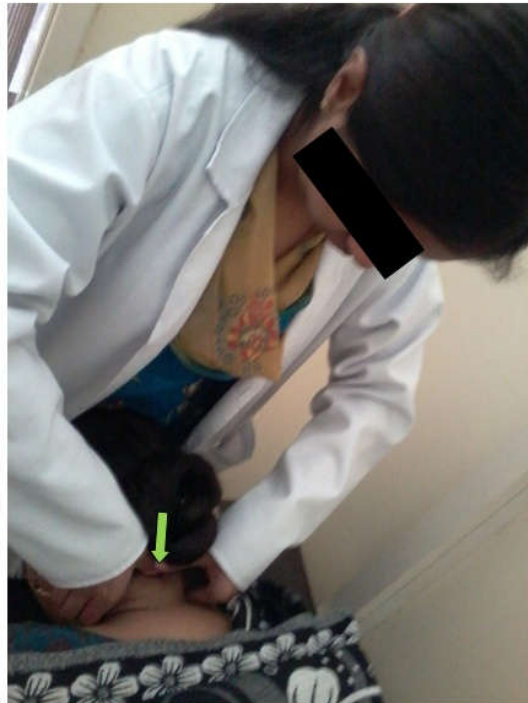
**Postural correction**

Postural correction were advised through craniocervical flexion and cervicothoracic extension, retraction of shoulders, extension of thoracic spine and normalization of the lumbar lordosis

**Strengthening Exercises**

The patient was asked to lie down in supine lying with arms by the side along the trunk. This consisted of exercises as to pull the chin in and to hold this position for 10-20 seconds. In combination with retraction of the cervical spine, this was also instructed in sitting position. This has to be done for 5 minutes and at least 2 times a day.

**Spinal Mobilization (Figure 8)**



**Figure 8** Spinal Mobilization

Patients of group A received spinal mobilization along with the conventional treatment for 5 days a week for 4 weeks.

The patient was made to lie down in prone lying by the forehead. A towel roll or pillow was kept under the forehead with arms by the side along the trunk. The therapist stands by the couch facing the patient and postero-anterior pressures or passive accessory intervertebral movement (PAIVMs) of Maitland grade III and grade IV oscillatory technique are applied with one thumb superimposed on the other. This is performed for 5 minutes.

**Data Collection**

The data was collected by one trial of measurement. The data was collected at three levels- baseline, after 2 weeks and after 4 weeks.

**Data Analysis**

The data was analyzed using Statistical Package for the Social Sciences (SPSS) version 16. Mann-Whitney U test and Wilcoxon signed rank test was used for between group comparisons and also for the mean change of scores between groups. Friedman test and Chi-square test was used for within group comparison and also for the mean change of scores within group. The results were considered statistically significant if the p value was ≤ 0.05.

**RESULTS**

**Sample Size Estimation**

The sample size of 80 patients with CTTH was estimated using the formula (Appendix B) with 80% of power at alpha level= 0.05 assuming 2% drop out during the treatment period and using the MCID value of the primary outcome measure of NPRS.

**Table 1** Overall Demographic Characteristics of Study Participants

Variables	Values
Sample Size (N)	40
Gender	Male 18 (45)
N (%)	Female 22 (55)
Age (yrs.) <sup>a</sup>	32.47±4.20
Duration of headache (weeks) <sup>a</sup>	20.70±7.24

<sup>a</sup>= Mean ± Standard deviation.

The table above shows the mean and standard deviation for the continuous variable (age and duration of weeks) and frequency (%) for categorical variable (gender) for overall demographic details for both groups A and group B. The analysis reveals that there was not statistically significant difference in terms of age, gender and duration of headache in weeks in both the groups.

**Table 2** Between groups comparison of demographic characteristics

Variables	Group A	Group B	P value
<b>Sample Size (N)</b>	<b>20</b>	<b>20</b>	<b>NA</b>
Gender	Male 10 (50)	8 (40)	0.53
N (%)	Female 10 (50)	12 (60)	
Age (yrs.) <sup>a</sup>	32.05±4.27	32.90±4.19	0.52
Duration of pain (weeks) <sup>a</sup>	18.20±5.30	23.20±8.14	0.4

<sup>a</sup>= Mean ± Standard deviation

The table above shows mean and standard deviation of baseline characteristics of variables in group A and group B. The statistical analysis reveals that there was no significant difference exists among the groups.

**Table 3** Within and Between Group Comparison of HDI Scores among the Groups

HDI	Group A	Group B	P value
T0 <sup>a</sup>	76.70±3.57	79.10±3.14	.35
T1 <sup>a</sup>	56.25±3.86	57.35±3.13	.00*
T2 <sup>a</sup>	27.40±1.78	24.95±3.31	.00*
p value	.00	.00	-
T0-T1 <sup>b</sup>	20.45 ± 2.30	21.75 ± 2.17	.04
T1-T2 <sup>b</sup>	28.85 ± 3.55	32.40 ± 2.30	.00*
T0-T2 <sup>b</sup>	49.30 ± 3.62	54.15 ± 2.49	.00*
p value	.00	.00	-

a- Mean ± Standard deviation

b- Mean ± Standard deviation

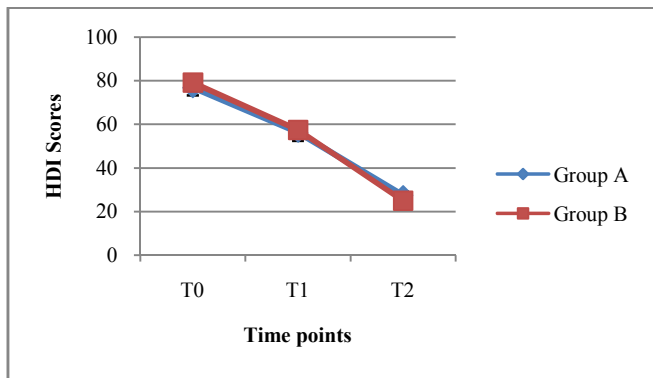
T0- Baseline measurement

T1- After 2 weeks

T2- After 4 weeks

p≤0.05 considered as significant; HDI: Headache Disability Inventory. T0-T1, T1-T2, T0-T2: change scores between and within the group; \* Data are 95% confidence interval; P value <0.0001.

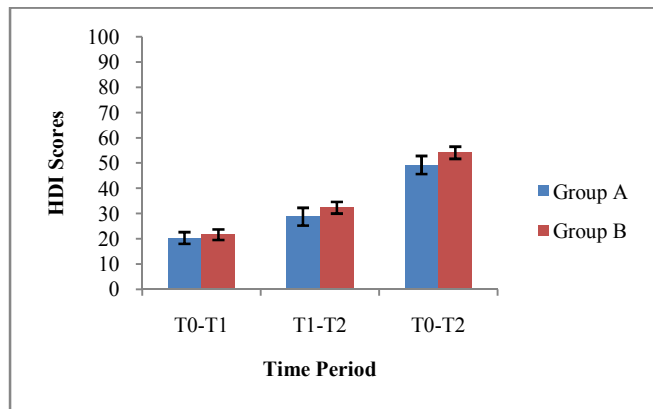
The table above shows HDI scores within as well as between the group A and group B. The analysis reveals that there was statistically significant improvement in both the groups, p value≤0.05.



**Graph 1** Comparison of Actual Scores for HDI among the groups

HDI: Headache Disability Inventory; T0: Baseline-pre treatment; T1: 2<sup>nd</sup> week; T2: 4<sup>th</sup> week.

The graph above shows values of HDI scores at baseline, 2<sup>nd</sup> week and 4<sup>th</sup> week among the group A and group B. The mean and standard deviation for group A was 76.70±3.57 at baseline, 56.25±3.86 after 2 weeks and 27.40±1.78 after 4 weeks. The mean and standard deviation for group B was 79.10±3.14 at baseline, 57.35±3.13 after 2 weeks and 24.95±3.31 after 4 weeks. Statistical significant difference was found in the HDI score after 2 weeks and after 4 weeks in both groups, but decrease in functional disability was more in group B.



**Graph 2** Comparison of Change Scores for HDI among the groups

HDI: Headache Disability Inventory; T0-T1: Baseline- 2<sup>nd</sup> week; T1-T2: 2<sup>nd</sup> week- 4<sup>th</sup> week; T0-T2: Baseline- 4<sup>th</sup> week.

The graph above shows mean change scores of HDI at T0-T1, T1-T2 and T0-T2 among the group A and group B. For group A, HDI score was 20.45 ± 2.30 at T0-T1, 28.85 ± 3.55 at T1-T2 and 49.30 ± 3.62 at T0-T2. For group B, HDI score was 21.75 ± 2.17 at T0-T1, 32.40 ± 2.30 at T1-T2, 54.15 ± 2.49 at T0-T2. The analysis reveals that group B had shown significant improvement than group A.

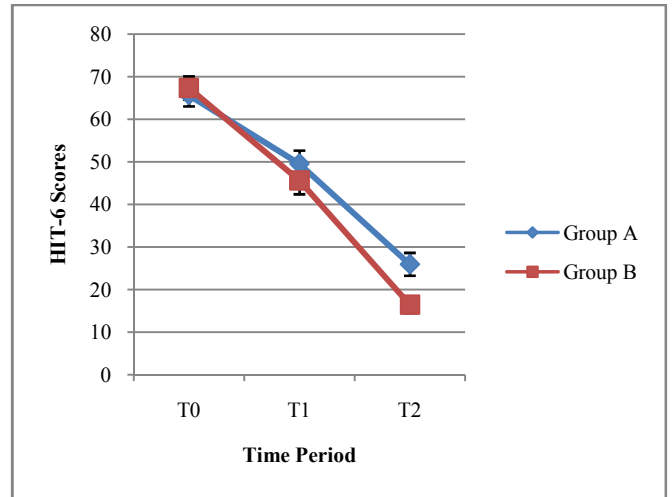
**Table 4** Within and Between Comparison of HIT-6 Score among the Groups

HIT-6	Group A	Group B	P value
T0 <sup>a</sup>	65.65±2.60	67.35±2.73	.48
T1 <sup>a</sup>	49.55±3.13	45.60±3.28	.00
T2 <sup>a</sup>	25.95±2.72	16.45±2.01	.00
p value	.00	.00	-
T0-T1 <sup>b</sup>	16.10 ± 3.24	21.75 ± 1.20	.00
T1-T2 <sup>b</sup>	23.60 ± 4.32	29.15 ± 2.08	.00
T0-T2 <sup>b</sup>	39.70 ± 3.43	50.90 ± 1.77	.00
p value	.00	.00	-

a- Mean ± Standard deviation  
 b- Mean ± Standard deviation  
 T0- Baseline measurement  
 T1- After 2 weeks  
 T2- After 4 weeks

p≤0.05 considered as significant; HIT-6: Headache Impact Test-6. T0-T1, T1-T2, T0-T2: change scores between and within the group; \* Data are 95% confidence interval; P value <0.0001.

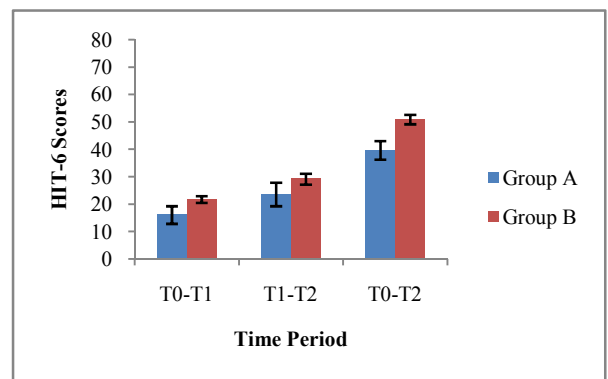
The table above shows HIT-6 scores within as well as between the group A and group B. The analysis reveals that there was statistically significant improvement in both the groups, p value≤0.05.



**Graph 3** Comparison of Actual Scores for HIT-6 among the groups

HIT-6: Headache Impact Test-6; T0: Baseline-pre treatment; T1: 2<sup>nd</sup> week; T2: 4<sup>th</sup> week.

The graph above shows values of HIT-6 scores at baseline, 2<sup>nd</sup> week and 4<sup>th</sup> week among the group A and group B. The mean and standard deviation for group A was 65.65±2.60at baseline, 49.55±3.13after 2 weeks and 25.95±2.72after 4 weeks. The mean and standard deviation for group B was 67.35±2.73 at baseline, 45.60±3.28 after 2 weeks and 16.45±2.01after 4 weeks. Statistical significant difference was found in the HIT-6 score after 2 weeks and after 4 weeks in both groups, but decrease in headache impact was more in group B.



**Graph 4** Comparison of Change Scores for HIT-6 among the groups

HIT-6: Headache Impact Test-6; T0-T1: Baseline- 2<sup>nd</sup> week; T1-T2: 2<sup>nd</sup> week- 4<sup>th</sup> week; T0-T2: Baseline- 4<sup>th</sup> week.

The graph above shows mean change scores of HIT-6 at T0-T1, T1-T2 and T0-T2 among the group A and group B. For group A, HIT-6 score was 16.10 ± 3.24at T0-T1, 23.60 ± 4.32at T1-T2 and 39.70 ± 3.43at T0-T2. For group B, HIT-6 score was 21.75 ± 1.20at T0-T1, 29.15 ± 2.08 at T1-T2, 50.90 ± 1.77at T0-T2. The analysis reveals that group B had shown significant improvement than group A.

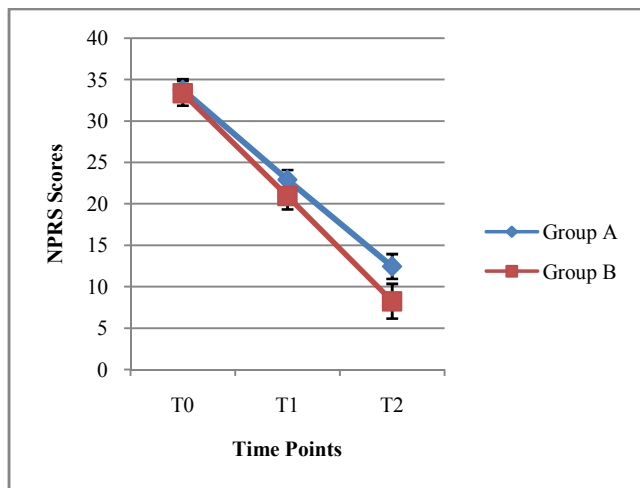
**Table 5** Within and Between Comparison of NPRS Score among the Groups

NPRS	Group A	Group B	P value
T0 <sup>a</sup>	33.75±1.37	33.35±1.59	.41
T1 <sup>a</sup>	22.90±1.29	20.95±1.63	.00
T2 <sup>a</sup>	12.45±1.50	8.25±2.14	.00
p value	.00	.00	-
T0-T1 <sup>b</sup>	10.85 ± 0.93	12.40 ± 0.94	.04
T1-T2 <sup>b</sup>	10.45 ± 0.82	12.70 ± 2.12	.00
T0-T2 <sup>b</sup>	21.30 ± 1.45	25.10 ± 2.29	.00
p value	.00	.00	-

a- Mean ± Standard deviation  
 b- Mean ± Standard deviation  
 T0- Baseline measurement  
 T1- After 2 weeks  
 T2- After 4 weeks

p<0.05 considered as significant; NPRS: Numerical Pain Rating Scale. T0-T1, T1-T2, T0-T2: change scores between and within the group; \* Data are 95% confidence interval; P value <0.0001.

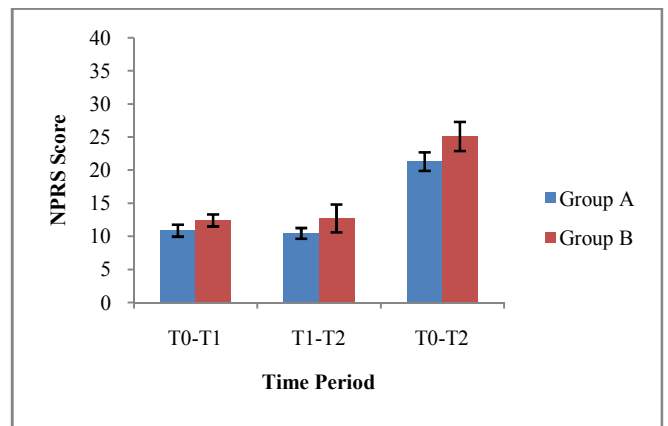
The table above shows NPRS scores within as well as between the group A and group B. The analysis reveals that there was statistically significant improvement in both the groups, p value<0.05.



**Graph 5** Comparison of Actual Scores for NPRS among the groups

NPRS: Numerical Pain Rating Scale; T0: Baseline-pre treatment; T1: 2<sup>nd</sup> week; T2: 4<sup>th</sup> week.

The graph above shows values of NPRS scores at baseline, 2<sup>nd</sup> week and 4<sup>th</sup> week among the group A and group B. The mean and standard deviation for group A was 33.75±1.37 at baseline, 22.90±1.29 after 2 weeks and 12.45±1.50 after 4 weeks. The mean and standard deviation for group B was 33.35±1.59 at baseline, 20.95±1.63 after 2 weeks and 8.25±2.14 after 4 weeks. Statistical significant difference was found in the NPRS score after 2 weeks and after 4 weeks in both groups, but decrease in pain as headache was more in group B.



**Graph 6** Comparison of Change Scores for NPRS among the groups

NPRS: Numerical Pain Rating Scale; T0-T1: Baseline- 2<sup>nd</sup> week; T1-T2: 2<sup>nd</sup> week- 4<sup>th</sup> week; T0-T2: Baseline- 4<sup>th</sup> week.

The graph above shows mean change scores of NPRS at T0-T1, T1-T2 and T0-T2 among the group A and group B. For group A, NPRS score was 10.85 ± 0.93at T0-T1, 10.45 ± 0.82at T1-T2 and 21.30 ± 1.45at T0-T2. For group B, NPRS score was 12.40 ± 0.94at T0-T1, 12.70 ± 2.12at T1-T2, 25.10 ± 2.29at T0-T2. The analysis reveals that group B had shown significant improvement than group A.

**DISCUSSION**

There was more improvement in group B for NPRS score, HIT-6 and HDI score in the 2<sup>nd</sup> week of the treatment and also during the 4<sup>th</sup> week. The results obtained after the data analysis did not support the null hypothesis and was rejected as there was a strong effect of Spinal Mobilization and conventional treatment in patients with CTTH.

In the present study, the average within group change scores of NPRS for participants in both the groups exceeded value of minimal clinically important difference (MCID) which was 2.17, but it was more in group B which was spinal mobilization and conventional treatment group (Table 5). For HDI, the mean within change score for participants was more in group B (Table 3). For HIT-6, the average within group change scores for participants was more in group B (Table 4). For HDI, the mean between group change scores for participants in group B was more than in group A (Table 3). For HIT-6, the mean between group change scores for participants in group B was more as compared to group A (Table 4). For NPRS, the mean between change scores for participants in group B was more as compared to group A (Table 5). Since the MCID values for HDI and HIT-6 scales are not available in the literature, it cannot be compared for the significance levels.

The present study found significant improvement in both the groups but more improvement was found in group B. Therefore, it can be predicted from the following results that patient pain as headache, disability and impact can be improved following spinal mobilization as an adjunct to the conventional treatment.

**Clinical Implication**

Most patients who present with headache have more liability to develop shoulder pain and neck pain. It is more prevalent in the western society and in the industrialized population. It can also be occupation related also prevalent in the lower

socioeconomic status groups. It is more common in emotional disturbances like anxiety, depression and stress. Spinal mobilization can be used for treatment of patients with CTTH as statistically significant improvement was seen.

#### Limitations of the Study

- Control group was not included in the study to interpret the adjunct effect of spinal mobilization to conventional treatment by evaluating any differences between them.
- No follow up was taken to see the long term effect of the treatment due to non availability of the patients.

#### CONCLUSION

Spinal mobilization along with the conventional treatment have additional therapeutic effects over a standard care by reducing impact, functional disability and pain as headache and in improving the quality of life in patients with CTTH. The spinal mobilization along with the conventional treatment group have shown statistically more significant improvement than the conventional treatment group alone in reducing impact, functional disability and pain as headache and in improving the quality of life in patients with CTTH.

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