Original Research Paper

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"EFFICACY OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) ALONG WITH CONVENTIONAL OCCUPATIONAL THERAPY VERSUS COGNITIVE BEHAVIOURAL THERAPY (CBT) ALONG WITH CONVENTIONAL OCCUPATIONAL THERAPY ON PAIN, IN PATIENTS WITH PRIMARY HEADACHE" NAGPUR, MAHARASTRA

Pratiksha Brijesh Ramraje	Masters of Occupational Therapy (Neurosciences) Occupational Therapy School and Cennter, GMCH, Nagpur.
Dr. Mrs. Leena Deshpande	PhD (OT), M.ThO, DROT, B.ThO, Associate Professor, Occupational Therapy School and Centre, GMCH, Nagpur
Dr Bansod Amrit	MBBS, MD, DM, Assistant Professor, Departments of Neurology, Super Speciality Hospital and Govt Medical College, Nagpur, Maharastra
Dr. Chhaya Bohare*	MBBS, MD, Senior Resident, Department of Community Medicine, L.N. Medical College, Bhopal *Corresponding Author

ABSTRACT **Introduction:** evaluating the effectiveness of Transcutaneous Electrical Nerve Stimulation (TENS) combined with Conventional Occupational Therapy versus Cognitive Behavioral Therapy (CBT) combined with Conventional Occupational Therapy in the management of primary headache pain. **Aims and Objectives:** To assess the effect of Transcutaneous electrical nerve stimulation (TENS) along with Conventional Occupational Therapy versus Cognitive Behavioral Therapy (CBT) along with Conventional Occupational Therapy on Pain, in patients having Primary Headache. **Methodology:** Creating a Prospective comparative study to examine Conducted over an 18-month period with 90 participants, the study aimed to determine which combination therapy provides better outcomes in terms of pain relief. Utilizing tools like the McGill Pain Questionnaire, **Result:** the research found significant benefits in both treatment modalities. The TENS group showed marked improvements in physical health metrics, while the CBT group demonstrated significant gains in psychological well-being. **Conclusion:** The study concludes that integrating these therapies into clinical practice can be highly beneficial for patients with primary headache, underscoring the importance of personalized treatment plans. The findings contribute valuable insights into pain management strategies, suggesting that a multimodal approach can enhance patient care and quality of life.

KEYWORDS : Primary Headache, Transcutaneous Electrical Nerve Stimulation (TENS), Cognitive Behavioral Therapy (CBT), Occupational Therapy, Pain Management

INTRODUCTION-

International Classification of Headache Disorder III defines Primary Headache as a headache, or a headache disorder, not caused by or attributed to another disorder. It is distinguished from secondary headache disorder. Headache is one of the most common symptoms, and primary headache disorders are among the most ubiquitous disorders, affecting people in all countries. India appears to be no exception. The Global Burden of Disease Study 2010 (GBD2010) found tension-type headache (TTH) and migraine to be the 2nd and 3rd most prevalent disorders worldwide [1]. Headache arises from a broad range of primary and secondary disorders, defined as a painful sensation in any part of the head, ranging from sharp to dull aches, that may occur with other symptoms. Headache location can suggest the involvement of local structures. Complete neurologic examination is important in the evaluation of headaches. If the examination is abnormal, a neuroimaging study (CT scans, MRI) is indicated as a first step

Types of Primary Headache:

Migraine- Migraine is a common disabling primary headache disorder. Migraine has two major subtypes.

▹ Migraine without aura-

It is a clinical syndrome characterised by headache with specific features and associated symptoms. Recurrent headache disorder manifests in attacks lasting 4-72 hours. Typical headache characteristics are unilateral location, pulsating quality, moderate or severe intensity, aggravation by routine physical activity and association with nausea and/or photophobia.[3]

▹ Migraine with aura-

a type of migraine headache characterised by specific warning signs or symptoms (known as an aura) that precede the headache. These auras typically develop over several minutes and last less than an hour. Common types of aura symptoms include Visual disturbances: Sensory symptoms: Speech or language problems: and Motor weakness. Less commonly, an aura may involve motor weakness, known as hemiplegic migraine., Other brainstem symptoms

OBJECTIVES

1. To compare the effect of Transcutaneous electrical nerve stimulation (TENS) along with Conventional Occupational Therapy versus Cognitive Behavioral Therapy (CBT) along with Conventional Occupational Therapy on Pain in patients with Primary Headache.

MATERIALS AND METHODS

Procedure: - Patients were divided into two groups as mentioned in the method.

Group A-

Received Transcutaneous electrical nerve stimulation (TENS) and Conventional Occupational Therapy. In Group A, 50 patients were enrolled. patients lost follow-up because of travelling and time issues. Lastly, 45 patients were statistically analysed.

Group B-

Received Cognitive Behavioural Therapy (CBT) along with Conventional Occupational Therapy. In GROUP B, 50 patients were enrolled and lost follow-up due to financial and time issues. Finally, 45 patients were analysed for statistical calculations.

In this study, patients came with neurological diagnoses such as headaches. The intervention program lasted for two months. Patients were evaluated on the first day (Baseline evaluation), then after 4weeks, and after 8 weeks. A therapist treated patients for 45- 60 minutes n the follow-up day. Patients were evaluated initially using a case record form.

Types of studies: Prospective comparative study.

Study Population: Patients who were referred from Neurological OPD, Medicine OPD and psychiatry OPD fulfil the inclusion criteria.

Study Settings: Occupational Therapy Centre Tertiary Care hospital. Nagpur City

Study Duration: 18 months

Study Tools: Pre-design questionnaire

Sample size: 90, with 45 participants in each group

Data collection

Patients were selected according to inclusion criteria from Neurology OPD, Psychiatry OPD, Medicine OPD. Demographic data was collected as per the case record form. Patients were enrolled for participation, and their consent forms were taken. They were assigned to Group A or Group B using the Lottery Method. All the selected patients continued taking Medications as prescribed by their physician. Imitrex, Maxalt, and Naratriptan were some of the common medications used by the patients as prescribed by the Neurologist.

Statistical Analysis

The data was initially entered into Microsoft Excel from the customised proforma for analysis. Online software and Excel were used to calculate the p values. Frequency distribution and cross-tabulation were used to prepare the tables. correlation coefficient test was applied to find the association between variables. Categorical variables were compared by chi-square test. Quantitative variables were expressed as the mean and standard deviation. A p-value of <0.05 is considered as significant. The final data was presented in the form of tables and graphs.

RESULTS-:

Table No- 1.- Age Distribution Of Study Population.

Age in years	Total		Group A(TENS+OT)		Group B(TENS+OT)	
	N	%	N	%	N	%
≤20	3	3.06	1	1.89	2	4.44
21 – 30	59	65.5	20	62.2	30	66.67
31 – 40	9	10	9	20	3	6.67
41 – 50	10	11.1	30	6.6	8	17.78
51 – 60	9	10	4	8	2	4.44
Total	90	100	45	100	45	100
Mean SD (Range)	31.23 ± 10.15 (19 – 56)		32.38± 10.36		29.89 ± 9.84	

P=0.2285, NS

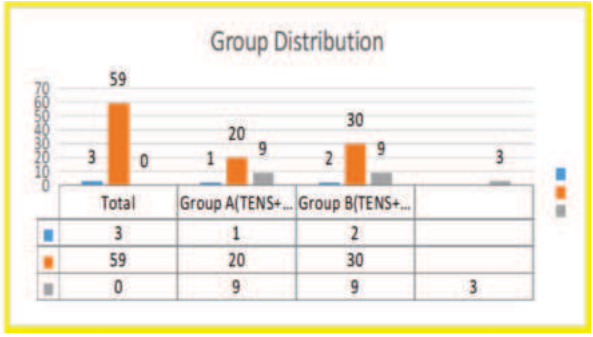

Table No. 2- Comparison Of Pain Within The Group-a & Group-b At Different Follow Ups

	Group A(TENS+OT)		Group B (CBT+OT)	
	Mean	SD	Mean	SD
At Baseline	30.35	5.46	31.28	5.24
At 4 weeks	20.86	3.83	24.68	4.65
At 8 weeks	14.19	1.93	22.88	4.32
F-value	317.71		114.32	
p-value	<0.001, HS**		<0.001, HS**	

Table No. 3- Comparison Of Improvement In Pain At Different Intervals Between The Group A & Group B

	Group A (TENS+OT)		Group B (CBT+OT)		Z-value	p-value
	Mean	SD	Mean	SD		
0-4 WEEKS	9.94	4.15	6.60	3.65	3.6219	0.0005, HS**
0-8 WEEKS	16.43	6.40	9.52	4.09	5.4419	<0.0001, HS**

Table No. 4 Comparison Of Cange In Halt Between The Group A& Group B From Baseline.

	Group A (TENS+OT)		Group B (CBT+OT)		Z-value	p-value
	Mean	SD	Mean	SD		
At 4 WEEKS	19.52	11.71	8.75	7.19	5.497	<0.0001, **HS
At 8 WEEKS	33.82	14.59	13.86	13.73	6.693	<0.0001, **HS

The study was conducted on 90 patients who fulfilled the inclusion criteria and followed up for the period of 8th week of intervention. The study was conducted in Occupational Therapy department of a tertiary care hospital. Outcome measures were: McGill Pain Questionnaire,), HALT Index (Headache-Attributed Lost Time) Patients were evaluated on baseline, 4th week and 8th week of duration. Collected data was entered into Microsoft Excel spreadsheet.

- Continuous variables (objective parameters) are presented as Mean ± SD.
- Categorical variables are expressed in frequency and percentages.
- Demographic variables are compared between 2 groups by performing chi2 test. For small numbers, Fisher exact test was used wherever applicable.
- Mc-Gill Pain Questionnaire, Multiple comparison Bonferroni t-test was used to compared change in mean score at 4 week and 8 weeks from baseline between 2 groups.
- P<0.05 was considered as statistical significance. Statistical software STATA version 14.0 was used for data analysis

Table 1 Represents the overall age distribution of the study population. There are a total 90 cases evaluated out of which there were 3 cases of (3.06%) less than 20 years of age, 59 cases (65.5%) in age group 21-30, 9 (10%) cases of age group 31-40, 10 cases (11.1%) in age group 41-50, 9 cases (10%) of age group 51-60. The mean ± SD is 31.23 ± 10.15 and 19 – 56 years was the mean age range of the group having migraine/tension-type headaches. The P-value obtained is 0.2285, which is non-significant, indicating both groups are comparable in terms of Age.

Table 2 represents a Comparison of Pain within the group at different follow up, mean score of 30.35 (5.46) was obtained at baseline, 20.86 (3.83) at 4th week and 14.19 (1.93) at 8th week in the Group-A, while the mean score of 31.28(5.24) was obtained at baseline, 24.68 (4.65) at 4th week and 22.88 (4.32) at 8th week for Group-B.

The comparison of these scores were statistically significant in both the groups A and B each (p-value of < 0.001) indicating both the treatment are highly significant in reducing pain. Group A (F-317.71) was more effective in decreasing the pain intensity as compared to group B (F-114.32), as a higher the F means more variation in values.

Table 3 represents a comparison of pain at different follow-ups; the mean score of 9.49 (4.15) was obtained for group A, and a mean score of 6.60 (3.65) was obtained for group B at the 4th week, whereas a mean value of 16.43 (6.40) and 9.52 (4.09) was obtained at the 8th week for groups A and B, respectively.

Although the comparison of this score (Z- 3.6219, p-0.0005) is significant in 0-4 th week, it is highly significant in 0-8 th week (Z-5.4419, p-<0.0001) Group A shows a better decrease in pain intensity than Group B.

Table 4 and graph 5A show a comparison of the change in scores of HALT between the group post-intervention from baseline. The difference in mean HALT score between both the groups in the 4th week is 5.497 with a p-value <0.0001, which shows a highly significant improvement in Group A than Group B. The difference in mean HALT score between both the groups in the 8th week is 6.693 with p- a value <0.0001, which shows a highly significant improvement in Group A than Group B.

DISCUSSION:

The purpose of this study was to investigate and compare the effect of Trans-cutaneous electrical nerve stimulation (TENS) along with Conventional Occupational Therapy versus Cognitive Behavioral Therapy (CBT), along with Conventional Occupational Therapy on Pain, in patients having Primary Headache.

100 patients were referred from Neurology OPD, Medicine OPD, and Psychiatry OPD of Tertiary Care Hospital to the O.T department; patients were described the study criteria in detail, and informed consent was obtained. Out of 100 patients, ten were excluded due to transportation, financial problems and health-related issues. Finally, the 90 patients were recruited for the study. They were randomised into Group A and Group B using a lottery method with the allocation of 45

patients in each group. Evaluations were carried out for both groups at Baseline, week 4, and week eight by using the HALT Index (Headache-Attributed Lost Time)

Table 1 and Table 2 show the age and gender distribution of the study population, which was evaluated on the above-mentioned outcome measures. In this study, the prevalence of headaches is higher in the age group 21-30 and less in those below 20. The second most affected age group was 41-50. Early and Middle adulthood population showed major cases of headache in general. The female population showed higher suspensibility to headaches than male population

This is supported by studies conducted by Leslie Kelman in October 2005, who concluded specific age differences in migraine, showing an age decline in the frequency of headaches. The 50+ age group showed trends suggesting a "lesser migraine attack." Also, Hormones as a trigger peaked in women in the 30- to 49-year-old age group resulting more susceptibility to headache. [4] Girish B Kulkarni, Girish N Rao et.al in July 2015 found out the prevalence of any headache is more in female population then the male population.[48]

Table no. 2, shows a comparison of Pain within the group at different follow-ups in Group A (TENS+OT) and Group B(CBT+OT). The population who received Group

A treatment showed a decrease in pain intensity compared to the group B population. Statistically proven by higher F value for Group A (317.71) than Group B (114.32) As the therapeutic effect of TENS is achieved by direct electrical stimulation of skin within the painful region to interact with the sensory nerves by activation of low threshold A-beta fibers which inhibit the nociceptive fibers decreasing the perception of pain, also regular exercising, application of Icepacks, hot bag and blocking the trigger, relaxation therapy which was part of Conventional OT programmer, which may be the reason Group A showed more better results than Group B.

Cognitive Behavioural therapy focuses on changing the automatic thoughts that worsen the emotional state of the patients. CBT changes the brain and body functioning via neoplastic and physiological changes. CBT alters the negative cognitions, emotions (e.g., stress, anxiety, sadness, anger), physical sensations, and maladaptive coping behaviours that perpetuate the Chronic- Pain cycle. Negative thoughts (I will never get better) lead to Emotions like (Pain, Anxiety, and Stress) giving rise to body symptoms like (Muscle tension and aches, Pain and illness, and activation of the Sympathetic nervous system [SnS]) which leads to maladaptive coping behaviour (isolation, inactivity). Thus, in this study by changing the thought process through the techniques best suitable for the patient and changes in sleep, nutrition and exercising lead to breaking of the changes in the negative thought which made changes in the Chronic-Pain cycle thus having a direct impact on brain and body, which lead to results obtained in Group B.[5]This is supported by the studies done on Non-invasive transcutaneous Supraorbital Neurostimulation (tSNS) using Cefaly® device in prevention of primary headaches by Anna Przeklasa-Muszyńska, Kinga Skrzypiec in 2017, They concluded that following the prophylactic program of supraorbital and supratrochlear nerves stimulation, the average monthly number of pain episodes of migraine were reduced by half compared to the pre-treatment period and to the appropriate control groups. [6] Also, a study done by Shpaner, Marina, et al., "Unlearning chronic pain: a randomised controlled trial to investigate changes in intrinsic brain connectivity following cognitive behavioural therapy." *NeuroImage:* In 2014, the differential impact of treatment on intrinsic functional connectivity (iFC) was investigated, and pre–and post-decisions in iFC between groups were compared. In addition, they performed exploratory whole-brain analyses of changes in the fractional amplitude of low-frequency fluctuations (fALFF). The course of CBT led to significant improvements in clinical measures of pain and self-efficacy for coping with chronic pain. Significant group differences in pre–post changes in both iFC and fALFF were correlated with clinical outcomes. Compared to control patients, iFC between the anterior DMN and the amygdala/periaqueductal gray decreased following CBT, whereas iFC between the basal ganglia network and the right secondary somatosensory cortex increased following CBT. CBT patients also had increased post-therapy fALFF in the bilateral posterior cingulate and the cerebellum. By delineating neuroplasticity associated with CBT-related improvements, these results add to mounting evidence that CBT is a valuable treatment option for chronic pain.[7]

Table no. 3, shows a comparison of scores of Pain between the groups, participants receiving TENS+OT (Group A) showed better results than CBT+OT (Group B) with p values 0.0005 at 4th week and <0.0001 at 8th week both highly significant statistically, Group A shows better results than Group B. Application of TENS lead to more direct changes in the pain perceived by the patient, as it is a direct application of the electrical charge on the pain area resulting in more relief over the time, also an inhibitory connection which may exist with Aβ and C fibres, which may form a synapse on the same projection neuron. The same neurons may also form synapses with an inhibitory interneuron that also synapses on the projection neuron, reducing the chance that the latter will fire and transmit pain stimuli to the brain. Over the time the synaptic connection gets stronger which may increase the sustainability of fibre resulting in decreasing the pain perceived by the patient may be this is the reason in this study patients showed better results at 8th week than 4 th week for Group A (TENS+OT).113 Stress has its impact on headache that results in a high sensitivity to environmental stimuli and a highly arousable central nervous system. at least for migraine, the release of corticotrophin-releasing hormone in response to stress contributes to the inflammatory processes that trigger perivascular inflammation and sensitization ofnociceptive afferents. The impact that stress and emotional factors has on individual episodes may be at both the peripheral and central levels. At the peripheral level stress provokes perivascular inflammation and peri cranial muscle tenderness which may have been decreased by the conventional OT programme and at the central level stress influences supraspinal control of neurons of the trigeminal nucleus caudalis, which may lead to increased excitability at the spinal/trigeminal level and undermining the effectiveness of the antinociceptive system, which may have been decreased by the different techniques used in CBT, thus in this study the patients in Group B showed decrease in pain intensity. Similar results were obtained by Antonio Russo, Alessandro Tessitore, in July 2015 in a study done on Transcutaneous supraorbital neurostimulation in "de novo" patients with migraine without aura: the first Italian Experience, concludes that Supraorbital neurostimulation (tSNS) could be considered a first-choice therapy in selected migraine populations due to the high level of efficacy and safety. They demonstrated at least 50 % reduction of monthly migraine attacks and migraine days in respectively 81 and 75 % of patients. All patients showed good compliance levels and no relevant adverse events.[8] In march 2020, Hadas Nahman- Averbuch, Victor J. Schneider, conducted a on study on Alterations in Brain Function After Cognitive Behavioural Therapy for Migraine in Children and Adolescents in which they concluded, the alterations in amygdalar connectivity with areas involved in cognitive control may be the mechanism underlying the preventive effect of CBT in migraine

CONCLUSION:

From the findings and results, it can be concluded that: -

- Highly significant improvements in domains of Pain, Physical health, Environmental
- health was found in Group A who received TENS along with Conventional Occupational Therapy.
- Highly significant improvement in domain of Anxiety was found in Group B who
- received CBT along with Conventional Occupational Therapy.
- Non- Significant improvement in the domain of psychological health, Environmental
- health was found in Group B who received CBT along with Conventional Occupational Therapy.
- Group A shows significant improvements in domain of social health.
- Highly significant improvement in HALT was seen in Group A who received TENS
- along with Conventional Occupational Therapy
- Non-invasive neurostimulation methods are promising for the treatment of patients
- with Primary Headache

Limitations :-

- The study is a single- centric study.
- It was performed on small sample size.
- Study was performed for a limited duration and after effects were not be assessed.
- Patient had a variable duration of Pharmaco-therapy before starting the treatment
- session.

SUMMARY-

The paper investigates the efficacy of Transcutaneous Electrical Nerve Stimulation (TENS) with Conventional Occupational Therapy versus Cognitive Behavioral Therapy (CBT) with Conventional Occupational Therapy in treating primary headache pain. Conducted over 18 months with 90 patients divided into two groups, the study utilized a variety of tools for evaluation, including the McGill Pain Questionnaire . Results showed significant improvements in pain e for the TENS group, compare to the CBT groupt. The study concluded that both interventions are effective, with TENS being particularly beneficial for physical health outcomes and CBT for psychological health. Limitations include the study's single-center nature and small sample size.

7.0. Acknowledgment:

I am grateful to God and my guide for providing me with this wonderful chance to advance in life.

REFERENCES-

1) Chowdhury D, Chandra P S. Headache Disorders: The Painful Truth About the Neglect and Deprivation. Neurol India 2021;69, Suppl S1:1-3 https://core.ac.uk/display/244262805
2) Kasper Fauci, Hauser Longo, Jameson Loscalzo editors Dennis L. Kasper, Anthony S. Fauci, Stephen L. Hauser, Dan L. Longo et.al, Harrison's Manual of Internal Medicine, 19th Edition, New-York, Minion Pro by Cenveo Publisher Services,2016.
3) Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition (beta version) https://ichd-3.org/wp-content/uploads /2016/08/InternationalH eadache-Classification III-ICHD-III-2013-Beta-1.pdf
4) Kelman L. Migraine changes with age: IMPACT on migraine classification. Headache. 2006 Jul-Aug;46(7):1161-71. doi: 10.1111/j.1526-4610.2006.00444.x. PMID: 16866720. https://pubmed.ncbi.nlm.nih.gov/ 16866720/#:~:text= Headache%20triggers%2C%20i n%20general%2C%20showed%20no %20age%20differences%3B,49-yearold%20age%20group%20compared% 20with%20the%20other%20ages.
5) Kulkarni GB, Rao GN, Gururaj G, Stovner LJ, Steiner TJ. Headache disorders and public ill-health in India: prevalence estimates in Karnataka State. J Headache Pain. 2015;16:67. doi: 10.1186/s10194-015-0549-x. Epub 2015 Jul 22. PMID: 26197976; PMCID: PMC4510104. https://pubmed.ncbi.nlm.nih.gov/26197976/
6) Przeklasa-Muszyńska A, Skrzypiec K, Kocot-Kępska M, Dobrogowski J, Wiatr M, Mika J. Non-invasive transcutaneous Supraorbital Neurostimulation (tSNS) using Cefaly® device in prevention of primary headaches. Neurol Neurochir Pol. 2017 Mar Apr;51(2):127-134. doi: https://pubmed.ncbi.nlm.nih.gov/28159327/
7) Shpaner, Marina, et al. "Unlearning chronic pain: a randomized controlled trial to investigate changes in intrinsic brain connectivity following cognitive behavioral therapy." *NeuroImage: Clinical* 5 (2014): 365-376. https://scholar. google.com/scholar_ lookup?journal= NeuroImage+Clin&title=Unlearni ng+chronic+pain:+A+randomized+controlled+ trial+to+investigate+ changes+in+intrinsic+brain+connectivity+following+ Cognitive+Behavioral+ Therapy& author=M+Shpa ner&author=C+Kelly&author=G+Lieberman&author= H+Perelman&author=M+Davi s&volume=5&publication_year=2014&pages=365- 376&pmid=26958466&#d=gs_qabs&t=1678081514836&u=%23p%3DKyKj IE0RWc sJ
8) Russo A, Tessitore A, Conte F, Marcuccio L, Giordano A, Tedeschi G. Transcutaneous supraorbital neurostimulation in "de novo" patients with migraine without aura: the first Italian experience. J Headache Pain. 2015;16:69. doi: 10.1186/s10194-015-0551-3. Epub 2015 Jul 22. PMID: 26197977; PMCID: PMC4510103. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4510103/