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Original Article

Comparison between efficacy of imipramine and transcutaneous electrical nerve stimulation in the prophylaxis of chronic tension-type headache: a randomized controlled clinical trial

Sayed Ali Mousavi [1], Sayed Mohssen Mirbod [2], Fariborz Khorvash [3]

Abstract

BACKGROUND: Chronic tension-type headache (CTTH) is recognized as the most common type of headache and can be further defined as either episodic or chronic. Regarding the chronic nature of CTTH and intolerance or side effects of drugs that are used for treatment, other methods of treatment such as Transcutaneous Electrical Nerve Stimulation (TENS) has been used as a convenient and available method for treatment and prevention of CTTH. In the current study, we evaluated the efficacy of the imipramine versus TENS in the prevention of the CTTH as a prospective clinical trial.

METHODS: In this study, 138 patients with confirmed CTTH were randomized to be treated either with imipramine or TENS method. Sixty nine patients were treated with TENS and 69 cases were regarded as controls and were treated with imipramine. In the Imipramine group, treatment was performed by imipramine tablet, 25mg, twice daily. In the TENS group, patients were treated thrice weekly for ten weeks, each lasting 15 minutes in temporal and occipital regions.

RESULTS: Three months after treatment, both the TENS and imipramine significantly reduced the severity of tension headache ($p < 0.05$). However, imipramine was significantly more effective than TENS in reduction of the headache severity ($p < 0.05$).

CONCLUSIONS: It appears that TENS method may be a good alternative method for patients suffering from CTTH. To better evaluate the efficacy of this method in the prevention and treatment of CTTH, more studies are recommended.

KEYWORDS: Tension Headache, Treatment, Transcutaneous Electrical Nerve Stimulation, Imipramine.

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Tension headache is recognized as the most common type of headache and can be further defined as either episodic or chronic.[1] Episodic tension headache usually is associated with a stressful event. This headache type is of moderate intensity, self-limited and usually responsive to nonprescription drugs.[2] Chronic tension headache often recurs daily and is associated with contracted muscles of the neck and scalp. This type of headache is bilateral and usually occipitofrontal and is very difficult to treat.[2]

At least 40% of the population is affected by tension headache and it has a great impact on quality of life of the affected patients.[3] On the other hand, the 1-year prevalence of Chronic Tension-Type Headache (CTTH) is about 2–5% in the general population and in half of the CTTH cases, headache-related impairment in work performance is reported.[4] In addition to

1- Associated Professor of Neurology, Department of Neurology, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran.
2- Instructor,Department of Physical Therapy, School of Rehabilitation, Isfahan University of Medical Sciences, Isfahan, Iran.
3- Assistant Professor of Neurology, Department of Neurology, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran.
Corresponding Author: Fariborz Khorvash
E-mail: F_Khorvash@med.mui.ac.ir

considerable impact on daily functioning and work participation, CTTH is a risk factor for overuse of analgesic medication.[4]

Pharmacological treatment of the tension headache can be divided into acute treatment and preventive treatment. The tricyclic antidepressants are the most used first-line prophylactic therapeutic agents for CTTH. [5] However, the use of medications is not without side effects and is not always effective. In addition to the different medications, various modalities have been used for treatment and prevention of the tension headache. These include hot or cold packs, ultrasound, electrical stimulation, improvement of posture, trigger point injections, occipital nerve blocks, relaxation techniques as well as regular exercise, stretching, balanced meals, and adequate sleep.[6-8]

One of the suggested methods of treatment for CTTH is the use of Transcutaneous Electrical Nerve Stimulation or TENS. Regarding lack of enough data about the efficacy of TENS in treatment of the CTTH, we designed this study with higher number of cases as compared with the previous study[9] using randomized clinical trial design to better evaluate the efficacy of the imipramine versus TENS in the prevention of the CTTH.

Methods

In a randomized controlled clinical trial that was performed in Al-Zahra hospital, Isfahan, Iran, 138 Iranian patients with confirmed CTTH were randomized to be treated either with imipramine or TENS method. All of the selected patients were over 15 years old. Ethical committee confirmation was obtained before start of the study.

69 patients were randomly allocated to intervention group and treated with TENS and 69 cases were regarded as controls and treated with imipramine. Subjects with previous history of prevention for CTTH and using other prophylactic methods of migraine were not included. Exclusion criteria were unwillingness of the patients to continue the treatment or appearance of the severe side effects. However, there was no drop out throughout the study.

The diagnosis of the tension headache was based on the International Headache Society (IHS) diagnostic criteria. IHS diagnostic criteria for tension-type headaches state that 2 of the following characteristics must be present: pressing or tightening (non-pulsatile quality), frontal-occipital location, bilateral, mild/moderate intensity, not aggravated by physical activity.[7]

TENS was performed using MYODYN 615K, manufactured by Iran Novin Medical Instrument Company, and with the following parameters: pulse shape was rectangular, Pulse width was 200μs, Frequency was 150 Hz, and intensity was 60 milliamperes (Low frequency-High intensity type). In the TENS group, they were treated twice weekly for ten weeks, each lasting 15 minutes in temporal and occipital regions.

In the imipramine group, treatment was performed by imipramine tablet, 25mg, twice daily for three months. Information regarding age, sex and severity of headaches were obtained at the baseline and 3 months after starting the treatment. The overall perception of the patients about severity and frequency of CTTH was assessed by using visual analogue scale (VAS). The collected data were analyzed using SPSS software version 15 (SPSS Inc, USA) and by statistical tests including chi-square and student t-test.

Results

Overall, 138 Iranian patients (69 patients in imipramine group and 69 patients in TENS group) with confirmed diagnosis of the CTTH completed the study. In the imipramine group, 38 (55.1%) patients were male and 31 (44.9%) patients were female. In the TENS group, 36 patients (52.2%) were male and 33 patients (47.8%) were female. There was no significant difference regarding age (28.2 ± 7.6 vs. 28.1 ± 6.3, $p = 0.92$) and sex the two groups ($p > 0.05$) (Table 1, Figure 1 and 2).

The VAS score was 6.71 ± 1.79 at baseline in imipramine group. At the end of study, the

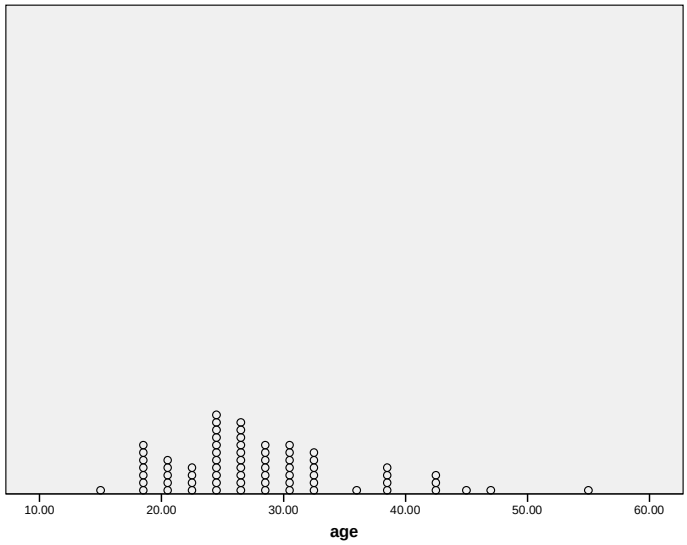

Figure 1. Prevalence distribution of the age (years) in the imipramine group

mean of VAS was reduced to 2.49 ± 2.33 and this difference was statistically significant ($p < 0.001$). In the TENS group, the mean of VAS score significantly increased from 6.12 ± 1.98 at beginning to 5.21 ± 2.59 at the end of study ($p < 0.001$). Figure 3 shows the reduction of VAS score in two groups. The comparison of VAS reduction showed significant difference between the 2 groups in favor of the imipramine group ($p < 0.001$).

Discussion

Tension type headaches occur in high number of the population and the impact on health care utilization and decreased productivity is marked too.[3] Medication remains the mainstay of treatment for all types of headaches and vast amounts of prescription and over-the-counter medications are used. Side effects frequently occur with medication and at times can be life threatening.[4] In addition, a recent meta-analysis of preventive drugs for tension type headache has shown only marginal efficacy for tricyclic antidepressants.[5]

Among non-pharmacological interventions proposed for the treatment of CTTH, physical

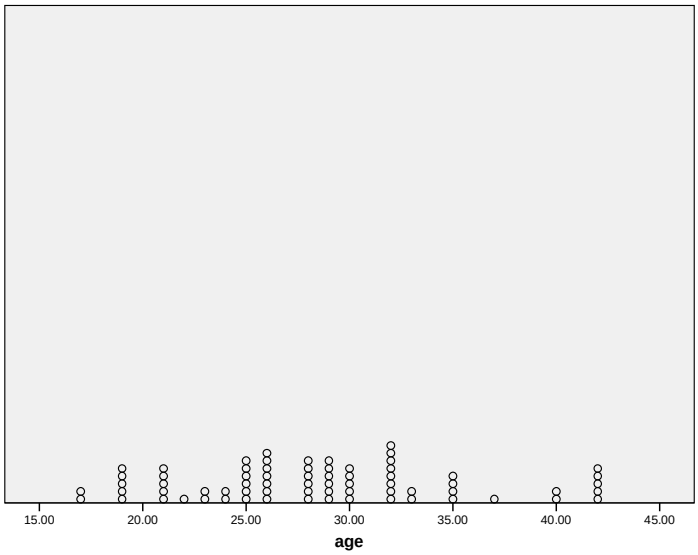

Figure 2. Prevalence distribution of the age (years) in the TENS group

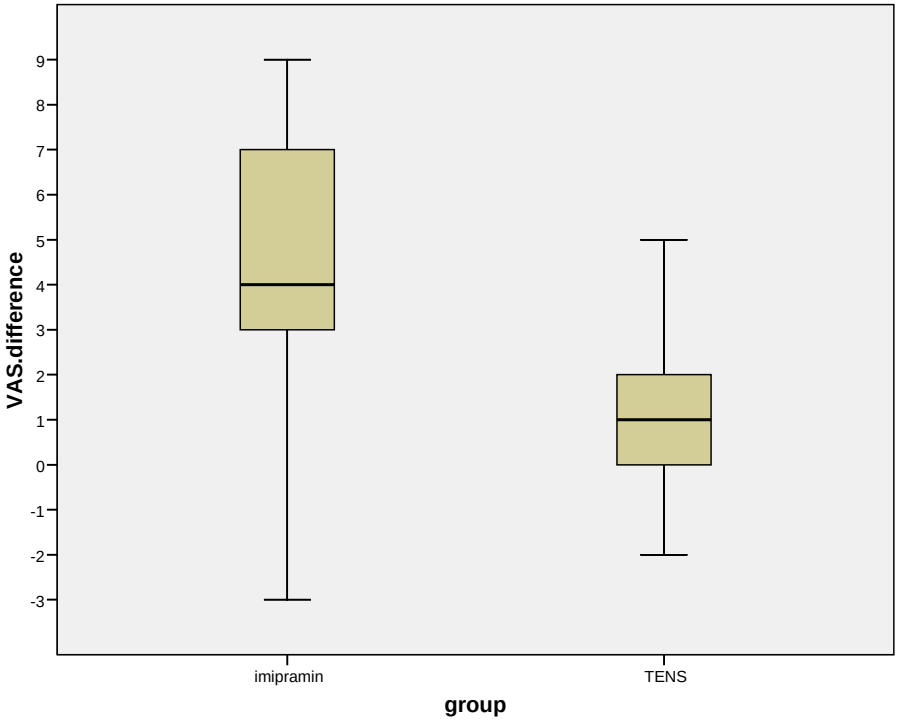

Figure 3. Comparison of the Visual analogue scale (VAS) reduction in the Imipramine and Transcutaneous Electrical Nerve Stimulation (TENS) group

therapy is the most commonly used.[8] However, there is insufficient evidence to support or refute the efficacy of physical therapy for the management of CTTH.[9, 10] Regarding the chronic nature of CTTH and intolerance or side effect of drugs that are used for treatment of it, other methods of treatment such as TENS has been used as a convenient and available method for treatment and prevention of CTTH.

In the current study, we evaluated the efficacy of the imipramine versus TENS in the prevention of the CTTH as a prospective clinical trial. Overall, 2 different types of TENS are usually performed.

1- High frequency-High intensity type that stimulates motor fibers and cause muscles twitching.[11]

2- Low frequency-High intensity type that is more effective for chronic headache. In this method electrical current is delivered with frequency of less than 10 pulse/minute or as a burst that can stimulates endorphin release and decrease pain severity.

TENS is recognized as a method that is effective in treatment of the chronic headache regardless of its etiology.[12] In addition, the efficacy of TENS in treatment of the acute migraine attack has been shown.[12] These effects are possibly due to inhibition of the pain pathways or increase of the secretion of the pain reducing substances in the CNS.

According to our literature review, only one study evaluated efficacy of TENS in the prevention and treatment of the CTTH. In this preliminary study, 8 patients with confirmed diagnosis of the CTTH were recruited to be treated with TENS. They were treated thrice weekly for ten weeks at a pulse rate of 4Hz and pulse width of 200 micros and pain level, functional disability and cervical range of motion were determined. The result showed a significant reduction in pain and functional disability with a significant improvement of cervical range of motion within the studied subjects. The authors concluded that TENS application should be considered in the long-term management of patients with CTTH.[13]

The results of current study confirmed the results of this preliminary study. In addition, in the current study, we used an active control

group that participants were treated with imipramine. Nevertheless, our results were suggestive that although TENS was effective in reduction of CTTH severity and frequency, it was still less effective than imipramine. TENS was tolerated by our patients very well and we did not have any drop-out or side effect in our cases suggesting this method as a safe method.

It appears that TENS method may be a good alternative method for patients suffering from CTTH. To better evaluate the efficacy of this method in the treatment of the CTTH, more prolonged studies with higher number of the patients are recommended.

Conflict of Interests

Authors have no conflict of interests.

Authors' Contributions

FKh, carried out the design, coordinated the sessions and prepared the manuscript, SMM provided care to the patients and analyzed the data statistically, SAM collected data and participated in writing manuscript. All authors have read and approved the content of the manuscript.

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