

Original Article

Comparison of effectiveness of acupuncture therapy and conventional drug therapy on psychological profile of migraine patients

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Abstract

Migraine is a painful condition in which patients suffer from recurrent episodes of disabling pain, which could be very severe and can lead to grave psychological disturbances. There is no curative treatment for migraine, but there are various treatment modalities, though, with conflicting reports on their efficacy. This study was conducted to compare the effectiveness of electro acupuncture therapy and the conventional drug therapy on the psychological profile of migraineurs based on the assessment of quality of life and disability parameters. Migraneurs (n=60) were recruited from the Psychiatry and Neurology OPD, Guru Tegh Bahadur Hospital, Delhi. Following a written consent, migraineurs were randomly allocated into 2 study groups – Group A received 10 sittings of electro acupuncture on selected acupuncture points over a period of 30 days, while for the same duration the Group D received a conventional drug therapy in the form of oral flunarizine 20 mg OD along with paracetamol 500 mg SOS. The patients were assessed twice, before and after completion of the treatment programme (30 days). The quality of life was assessed with WHOQOL BREF (WHO Quality of Life Biomedical Research and Education Foundation) questionnaire and the disability was assessed with MIDAS (Migraine Disability Assessment) questionnaire. Statistical analysis was performed using repeated measure's ANOVA with Tukey's test. Migraneurs were found to have lower quality of life and higher disability scores but following the treatment regimes, the 2 study groups showed a significant improvement in both the parameters studied. It was however observed, that the acupuncture group showed a better response and was thus found to be more effective as compared to the drug group (P=0.005 to 0.000). We thus conclude that acupuncture is a better treatment option than the conventional drug therapy in not only relieving the pain of migraine but in also improving the psychological profile in migraineurs. Hence its use should be encouraged as an alternative/adjunct treatment for migraine.

Introduction

Migraine is the world's most common neurological

condition and is ranked as one of the top 20 causes of disability worldwide (1). It is a chronic neuropsychological condition characterized by episodic attacks of disabling headaches. These attacks often present with any combination of pain, nausea, light and sound sensitivity, or vomiting (2). According to the results of a new survey by the Migraine Association of Ireland, the vast majority of young adults who suffer from migraine believe that

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the condition adversely affects their performance at work or in education, with 39% being severely affected (3). In addition to job issues, a survey revealed that migraine leads to considerable psychological disability that hinders family and social activities and has major impact on an individual's ability to carry out ordinary day to day tasks. Thus, migraine has serious deleterious effect on the patient's quality of life (QOL) even when the patients are not experiencing an attack. This is often termed as interictal burden (4).

Cognitive-affective mechanisms often contribute to the perception of chronic pain and patients with chronic pain frequently become depressed and may illogically interpret and distort experiences of life (5). Thus, chronic pain will produce alterations in daily functioning and perceptions of well-being and satisfaction which determine the quality of a patient's existence. Quality of life is multidimensional, in which each dimension changes over time, and it is a patient-perceived entity (6). Calman defined QOL as the gap between the patient's expectations and achievements and thus, smaller the gap, higher the QOL (7). QOL assessment provides a measurement of functioning and well-being rather than of possible disease and disorder, hence it is more comprehensive and compatible with the WHO's concept of health. It can guide appropriate management strategies and also act as one of the outcome measure for comparing them, including drug trials. It is believed to be a broad concept incorporating, in a complex way, an individual's physical health, psychological state, level of independence, social relationships, personal beliefs and her / his relationships to the salient features of the environment (8).

The Migraine Disability Assessment Score (MIDAS) is another self-administered measure of disability associated with headache. MIDAS scores are derived from three domains of activity related to lost time from work for pay, housework or chores and leisure activities. The total number of headache-related missed days from school, paid work, household work, and from family, social, or leisure activities over the previous three months contribute to the MIDAS score (9). There is no definite curative treatment for migraine, but there are various treatment options like

conventional treatment with drugs and alternative therapies like acupuncture, yoga, dietary modifications and others. The treatment of migraine has advanced dramatically in recent years, with new drugs available for both acute treatment and prophylaxis. Drug treatment with NSAIDs, β -blockers, calcium antagonists, or other agents has been shown to reduce the frequency of migraine attacks; however, the success of treatment is usually modest and tolerability often suboptimal (10). Flunarizine is a difluorinated-piperazine-derivative calcium channel blocker with selectivity for the cerebral vasculature. Flunarizine was first observed to be effective in controlled trials for migraine prevention around 28 years ago (11). Efficacy and safety profile of flunarizine has been further established through several other randomized controlled trials.

Acupuncture is gradually being accepted as a complementary or alternative medicine for preventing migraine attacks and also preventing pain (12). Its use has now been extended to other countries beyond China, its country of origin, especially to the West. Acupuncture is widely used to treat headache, and can be applied as a sole therapy or as a part of a more complex treatment programme although its effectiveness has not yet been fully established.

Thus, there is considerable disparity in results, obtained from various studies, regarding the best treatment option in migraine patients. Most of these studies relating to therapies are also primarily aimed at the alleviation of pain in these patients. In view of this, we designed this randomized controlled study aimed at comparing effectiveness of conventional drug therapy and alternative acupuncture therapy on the psychological profile of migraineurs using the WHO Quality of Life BREF questionnaire and the MIDAS questionnaire.

Materials and methods

A randomized interventional study was conducted to assess the effectiveness of acupuncture and drug therapy on the psychological parameters of migraine patients.

Subjects

Sixty subjects presenting with headache characteristic of migraine, according to the International Classification of Headache Disorder-2 (ICHD-2) criteria (13), were recruited for this trial from the Psychiatry and Neurology outpatient department of Guru Tegh Bahadur Hospital, Delhi. Patients of age 20 to 40 years, of both sexes, having recurrent attacks (> 5 episodes/year) in the past one year, were included in the study. Subjects with secondary headache or co-morbid psychiatric and neurological disorder and those under drug therapy like β -blockers, triptans and ergots were excluded from the study. Randomization was generated to remove bias. According to a computer-generated randomization list, all 60 patients were randomly assigned to 2 study groups of 30 patients each as follows :-

- Acupuncture group (Group A): underwent electro acupuncture therapy for 10 sittings, over a period of 30 days. During the therapy, if the patient experienced any migraine episodes, tab. paracetamol 500 mg was administered SOS.
- Drug group (Group D): received drug therapy (tab flunarizine 20 mg OD and tab. paracetamol 500 mg SOS) for 30 days.

Informed written consent was obtained, after explaining the procedure to be performed, from all subjects, who were then tested under similar laboratory conditions. They were allowed to get familiarized with the experimental and environmental condition of the laboratories. All 60 migraine patients were pre tested and post tested 30 days apart in a pain free state. To ensure the compliance of participants in both the groups, the subjects were counselled regarding the benefits of the therapy and hence the dropout rate was nil.

Assessment of psychological profile

Psychological parameters were assessed by using WHO Quality of Life BREF (Biomedical Research and Education Foundation) questionnaire and MIDAS (Migraine Disability Assessment) questionnaire. Both

the questionnaire were administered in the local language i.e. Hindi.

- 1) In WHO QOL BREF questionnaire the subjects were asked to score the 26 questions regarding their QOL in the following 4 domains: physical health, psychological status, social relationships and environment. The questionnaire was self-administered. The subjects were required to evaluate their QOL in the last 2 weeks. The item score ranged from 1 to 5, with a higher score indicating better QOL on the corresponding item. Since the number of items is different for each domain, the domain scores were calculated by multiplying the average of the scores of all items in the domain by the same factor of 4. Thus, all the domain scores would have the same range (8).
- 2) The MIDAS questionnaire was administered to assess the disability due to migraine headache as it is specific for this disease. This questionnaire is brief, simple to use, consistent, highly reliable, and correlates with the clinical judgment of the physicians (14). The MIDAS scores are derived from three domains of activity where time is lost from work for pay, housework or chores, and leisure activities. The total number of headache-related missed days from school, paid work, or household work, and from family, social, or leisure activities over the previous three months contribute to the MIDAS score. The number of days, where at least 50 percent reduced productivity was incurred, is taken into consideration. Some questions do not contribute to the MIDAS score, but are used to assess the frequency and intensity of the headaches. MIDAS scores have been divided into 4 grades that correspond to levels of headache disability, ranging from minimal or infrequent to severe (15).

Treatment modalities of test subjects

Group A : Acupuncture therapy

This group was subjected to electro acupuncture in the Pain Clinic of the Department of Anesthesiology and Critical Care, Guru Tegh Bahadur Hospital, Delhi.

Pre-sterilized disposable filiform needles of 30 gauge and 2 inch size were used. The patient was asked to lie supine. The exposed skin was cleaned and then the needles were inserted through the skin to various acupuncture points chosen according to the traditional Chinese channels and collaterals for migraine. The eleven points selected with their anatomical locations were Du. 20 (Baihui), P.6 (Neiguan), St.36 (Zusanli), GB.41 (Zulinqi), GB.14 (Yang Bai), Yin tang (EM), LI.4 (Hoku), LI.10 (Shou) St.44 (Neiting), Ear points: Ear shenmen and Ear stomach (16). The needles were stimulated electrically from a battery powered electro stimulator providing a rectangular wave pulse and a current of 0.5 mA; an output of 6-9 volts would be delivered at 10-20 Hz for 20 min (17). All subjects received a total of 10 sittings, delivered on different days, over a period of 30 days.

Group D : Drug therapy

The other group received drug therapy. They were given tab flunarizine 20 mg OD along with tab paracetamol 500 mg SOS for 30 days. No adverse reactions were encountered in both the groups as far as our knowledge is concerned. This included the absence of any vaso-vagal attack during the acupuncture therapy.

Statistical analysis

After 30 days, both the groups were assessed again by WHO QOL BREF and MIDAS questionnaires. The data thus generated by both the questionnaires was administered onto the MS excel spreadsheet. Repeated measure ANOVA with Mann-Whitney U test at 5% level of significance was used to compare the effect of drug therapy with acupuncture therapy for the psychological parameters of migraine patients. All analysis was done using SPSS 17.0.

Results

Basic parameters

Of the 60 migraineurs, when age, height and weight

of both the groups (Group A and D) were compared, it showed that there was no statistically significant difference between the study groups; therefore influence of these parameters over the outcome of the study was almost negligible.

Observations in the study groups

The observations were recorded twice in the study groups: first recording was taken before starting the treatment or pre treatment readings (Groups A1 and D1) while the second recording was carried out one day after the completion of the therapy or post treatment readings (Groups A2 and D2). Psychological parameters were assessed by using WHO QOL BREF questionnaire and disability due to migraine was assessed by MIDAS questionnaire in the test subjects.

Acupuncture group

It was seen that one month of treatment with acupuncture significantly improved the physical and psychological domains of QOL though there was no statistically significant difference found in the social and environmental domains. Thus, acupuncture therapy improved the QOL and hence the psychological status of the migraineurs. Also, there was a significant reduction in the MIDAS scores of the post treatment acupuncture group indicating lesser disability due to the disease (Table I).

Drug group

It was seen that the physical and psychological domain scores of the WHO QOL BREF questionnaire of the post drug therapy group were significantly higher ($p=0.000$) than the pre treatment group. However, there was almost no difference seen in the social and environmental domain scores of both the groups. Hence, the drug therapy in migraineurs had significantly improved the physical and psychological domains and thus the QOL. Also there was a significant reduction in the MIDAS scores of the post drug therapy group which infers that drug therapy in migraineurs had also reduced the disability due to the disease (Table I).

TABLE I: Effect of acupuncture therapy and drug therapy on quality of life (WHO QOL BREF scores) and disability parameter (MIDAS scores) in migraineurs.

WHO QOL BREF scores	Group A1	Group A2	P value	Group D1	Group D2	P value
Physical domain	16.77	44.23	0.000	24.23	36.77	0.05
Psychological domain	20.35	40.65	<0.001	25.2	35.8	0.018
Social domain	30.43	30.57	0.976	30.92	30.08	0.839
Environment domain	30.02	30.98	0.829	30.5	30.5	1.00
MIDAS scores	44.6	16.4	0.001	35.35	25.65	0.014

Values expressed are mean ranks, n = 30 in each group, Group A1 & A2: before and after acupuncture, Group D1 & D2: before and after drug therapy, U - Mann-Whitney U test. P value < 0.05 significant.

Comparison of psychological parameters following acupuncture therapy and drug therapy:

On comparing the outcome of drug therapy with acupuncture therapy, in relation to the psychological parameters studied, it was seen that all the domains of WHO QOL BREF showed a significant greater improvement in their scores in the acupuncture group than the drug therapy group. Hence, the QOL had significantly improved more in the acupuncture therapy group as compared to the drug therapy group. The MIDAS scores remained significantly higher in migraineurs on drug therapy than in migraineurs on acupuncture therapy. These values signify lesser disability in acupuncture therapy group as compared to the drug therapy group. Thus one month of electro acupuncture therapy significantly improved the psychological parameter of QOL and reduced the disability due to migraine as compared to the drug therapy (Table II).

TABLE II: Comparison of acupuncture therapy (Group A2) with drug therapy (Group D2) on quality of life (WHO QOL BREF scores) and disability parameter (MIDAS scores) in migraineurs, after 30 days of therapy.

WHO QOL BREF scores	Group A2	Group D2	P value
Physical domain	14.00±1.5	9.44±1.3	0.000
Psychological domain	13.74±2.12	10.37±1.3	0.000
Social domain	13.51±3.34	11.53±0.8	0.002
Environment domain	10.90±3.6	12.83±1.44	0.009
MIDAS scores	1.87±0.6	2.70±0.60	0.000

Values expressed are mean±SD, n=30 in each group. t is t-test, df is degree of freedom, P is P value <0.05 significant.

Discussion

Migraine is a painful condition in which patients suffer from recurrent episodes of pain leading to considerable disability and altered psychological profile (3). The chronic pain patient may experience dramatic changes in lifestyle as a result of the persistent pain he suffers; this will result in deterioration in what the patient perceives as QOL (18). In the present study also, the QOL in migraineurs, before treatment was instituted, was significantly affected. All the scores of physical, psychological, social and environment domains were significantly lower which is suggestive of a poor QOL in these migraine patients. Several studies support our findings. On the basis of 3 population based studies of QOL in migraine cases versus controls by Skevington, it was concluded that migraine sufferers selected from the general population have substantially lower HRQOL (Health Related QOL) relative to population controls (8). Migraine and depression are highly co-morbid and each exerts a significant and independent influence on HRQOL. In addition, QOL and frequency of attacks were inversely correlated, because, as the frequency of attacks increased, QOL decreased. Guitera et al studied QOL in chronic daily headache and found that QOL was affected more by chronicity rather than by the intensity of pain in patients (19). In another study Ruiz de et al concluded that migraine had a negative effect on QOL, including physical, emotional and social aspects of daily life (20).

Disability caused due to migraine was specifically

assessed using MIDAS scores and was found to be significantly higher in both test groups as a high score of MIDAS signifies more disability in the patients. Bigal et al concluded that patients with chronic migraine demonstrate remarkable impairment of their daily activities and are severely burdened by their headache syndrome as reflected by their high MIDAS scores (13).

The treatment of migraine has advanced dramatically in recent years, with new drugs available for both acute treatment and prophylaxis. Drugs like aspirin and paracetamol block transmission at sites in peripheral tissues and/or at non-opioid receptors in CNS (10). Flunarizine is a calcium channel blocker with selectivity for the cerebral vasculature. It is believed to function as an inhibitor of intra cellular calcium overload. Amery and colleagues compiled the data from several studies performed in Europe in which flunarizine was given in a daily dosage of 10 mg for at least three months and reported that flunarizine therapy was marked by progressive improvement over the test duration. After one month of treatment, 61.9% of the patients had a reduction in attack frequency, and this percentage increased to 83.2% over a period of three months (11). Centonze et al studied 20 patients in a single blind, cross-over study comparing flunarizine 10 mg at bedtime with taking a placebo. Of the 20 patients studied, 14 noted an average reduction of 50.5% in headache unit index over the 3 to 7 month trial. If combination prophylactic therapy is required, it would be sensible to combine agents that act at different sites with the hope of achieving synergistic therapeutic benefits (21).

Acupuncture was first described in the western world by Willen Ten Rhyne in 1683 and since then various animal and human studies have been performed to evaluate the mechanism and effectiveness of acupuncture (22). Currently, various modern theories are available to define the neurophysiological basis of the mechanism of acupuncture. Some have suggested that acupuncture acts according to principles enunciated by the gate control theory of pain while some are of the view that there is release of endorphins that bind to opiate receptors in the brain and mediate analgesia through the descending

pain inhibitory system (23). When a needle is inserted on the acupuncture points of the body, it leads to various types of subjective and objective effects. There will be a sensation of pain, numbness, soreness and heaviness experienced by the patient, whereas objective effects will result in analgesia, sedation, motor recovery, homeostasis and immunity-improvement as explained by various theories (24). It is known that stimulation of a few specific areas on the human body is capable of maintaining the equilibrium of the energy flow in the body. Electro stimulation is being used commonly for treatment of various diseases. It works on the principle of twirling and pecking technique, that is, the nerves around the insertion point of the needle are stimulated by electricity, get excited and create an impulse. The advantage of using electro stimulator is that it has stimulating capacity around the acupuncture point within a field of 5 mm around the point in all directions. Acupuncture points transmit vital energy of the viscera and channel it to the superficial parts of the body (25). Alecrim et al (22) and Facco et al (26) in individual studies assessed the efficacy of acupuncture in migraine prophylaxis and found that the real acupuncture group showed significant improvement as compared to the sham acupuncture group. Melchart et al assessed the efficacy of acupuncture in migraine prophylaxis. They allocated 37 patients to real and sham acupuncture group. Each group received 16 acupuncture sessions over 3 months. They observed that the real acupuncture group showed significant improvement in their condition as compared to the sham acupuncture group (27).

It was observed that following acupuncture and drug therapy, pain patients showed a significant change in their overall QOL. A significant improvement in QOL associated with pain and discomfort was seen, mainly in the facets of physical and psychological domains which relate to sleep and rest, self-esteem, positive and negative feelings, activities of daily living, sexual activity, recreation & leisure, dependence on medication and availability of health & social care. The social relationships domain did not show a significant improvement suggesting that personal relationships and social support together with physical and home environment are stable aspects

of QOL in patients with chronic pain and do not appear to be affected by any of the interventions applied. Skevington et al concluded that after one month of pain management program for chronic pain, QOL significantly improved. They found that not every facet on the QOL profile showed a significant improvement after treatment. Improvement was found to be broader on physical, psychological and in the independent dimensions of QOL (28). When both the treatment groups were compared, acupuncture group showed more significant improvement in their scores than the drug therapy group. These results suggests that acupuncture is a more effective and useful treatment for migraneurs than the drug treatment.

On MIDAS scores, a significantly greater disability relief was reported in response to acupuncture therapy in migraneurs as compared to a mild disability

relief observed in the drug group suggesting that acupuncture was more effective than drug therapy in migraine patients. Similar findings were reported by Liguori et al who found that acupuncture improved the symptoms of migraine without aura “more significantly” than any type of pharmacological therapy (29). Wonderling D et al in their study concluded that acupuncture is a useful, cost effective treatment for chronic headaches, particularly migraines (30).

Although drug therapy improves the QOL but the effect of acupuncture therapy was better as compared to the improvement gained by drug therapy alone. Moreover, acupuncture therapy is more cost effective and with no side effects. Therefore, we conclude that acupuncture therapy can be used alone or as an adjunct treatment for migraneurs.

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