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Original Research Article

Efficacy of biofeedback in treatment of migraine

David Rosario[1], Ashwith B.[2]*, Anitha Sequeira[2]

[1]Department of ENT, [2]Department of General Medicine, Srinivas Institute of Medical Science and Research Centre, Mukka, Surathkal, Karnataka, India

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***Correspondence:**
Dr. Ashwith B.,
E-mail: ashwitht60@gmail.com

ABSTRACT

Background: Migraine is characterized by increased excitability of CNS. Biofeedback is a non-invasive, non-pharmacologic therapeutic technique, which helps patients control stress response by deep breathing,visualization and medication. The aim of the study was to compare efficacy of conventional therapy, biofeedback and combination of pharmacotherapy with biofeedback.
Methods: This is a randomized study conducted for period of 2 years from April 2020 to May 2022 in Srinivas Institute of Medical Science and Research Centre, Mukka, Surathkal. 100 patients who were diagnosed with migraine between 18 and 60 years of age were included in the study after ruling out other primary causes of headache. Patients<18 years of age >60 years of age, with known comorbidities that can precipitate headache and on treatment for any other condition were excluded from the study. They were randomly assigned to groups for receiving conventional therapy, biofeedback therapy and combination of pharmacotherapy and biofeedback. 35 patients were allotted to group which received conventional therapy, 35 were assigned to the group that received combination of biofeedback and pharmacotherapy and 30 patients were allotted to the group that received biofeedback alone.
Results: Among 100 migraine patients 58 were females and 42 were males. 62 of them were in the age group of 30 to 40 years of age. 66 patients belonged to moderate to severe category of migraine. Out of 35 patients who received conventional therapy 21 (57.4%) reported improvement in quality of life, whereas 26 out of 35 (74.28%) who received combination of biofeedback and pharmacotherapy reported reduction in severity and frequency of headaches with better quality of life compared to 13 patients out of 30 who received biofeedback alone (43.3%).
Conclusions: Patients who received combination of biofeedback and pharmacotherapy had best outcome (74.28%) compared to the ones who received biofeedback (43.3%) or conventional therapy (57.4%) alone.

Keywords: Conventional, Frequency, Headache, Pharmacotherapy, Severity

INTRODUCTION

Migraine is characterized by increased excitability of CNS and is often progressive and disabling. It is characterized by episodic attacks of unilateral headaches with photo and phonophobia with associated nausea and vomiting.[1]

Migraine can be episodic in which headache occurs less than 15 days per month and chronic migraine where 15 or more days of headache per month for atleast 3 months.[1] Episodic migraine can progress to chronic migraine. The most common form of migraine is without aura seen in about 80% of patients and migraine with aura is seen in about 20% of patients. Biofeedback is a noninvasive, non-pharmacologic therapeutic technique for treatment of migraine, which helps patients control stress response by deep breathing, visualization and meditation. Budzinski, Stoyva and Adler in 1970 introduced use of electromyographic (EMG) biofeedback in treatment of tension type headaches.[1] The development of chronic migraine has been associated with female gender, obesity,

stressful events and low socioeconomic status. Migraine is also a cause of significant socioeconomic burden as it reduces quality of life and limits daily activities of the patient.[2]

Moderate to severe migraine significantly affects quality of life of patients by impairing their professional and personal lives hence interventions that reduce severity and frequency of headaches thereby improving patients' lives are very much necessary. Biofeedback along with conventional therapy adds new dimension in management of migraine thereby reducing requirement of various abortive and preventive medications.

Most frequently used biofeedback methods have been peripheral skin temperature biofeedback, blood-volume-pulse and electromyography feedback.[6]

Aim

The aim of the study was to compare efficacy of conventional therapy, biofeedback and combination of pharmacotherapy with biofeedback in treatment of migraine.

METHODS

This is a randomized study conducted for period of 2 years from April 2020 to May 2022 in Srinivas Institute of Medical Science and Research Centre, Mukka, Surathkal. The study was conducted after obtaining approval of institutional ethical committee. Total of 100 patients who were diagnosed with migraine between 18 and 60 years of age were included in the study after ruling out other primary causes of headache. Patients <18 years of age, >60 years of age, with known comorbidities that can precipitate headache and on treatment for any other condition were excluded from the study. Severity of headache was calculated using MIDAS questionnaire. They were assigned to groups by block randomization for receiving conventional thera, biofeedback therapy and combination of pharmacotherapy and biofeedback. 35 patients were allotted to group which received conventional therapy, 35 were assigned to the group that received combination of biofeedback and pharmacotherapy and 30 patients were allotted to the group that received biofeedback alone. The other two groups were aware of the interventions being done. Biofeedback sessions were given 2-3 times per week and duration of each session was 30 min to 1 hour and was given to the group that received biofeedback alone with the one that received combination of pharmacotherapy with biofeedback. Breathing technique is the modality of biofeedback that was used.

Descriptive tables are presented showing changing means for 3 outcome variables over time. The hypothesis in this study was that patients receiving biofeedback with pharmacotherapy will have best outcomes among the groups. The structure of the data is that each person was represented by a row of data at every occasion of assessment. Cluster adjusted standard errors were used to correct for lack of independence as same patients were represented in more than one row when they were assessed more than once. Anova with Bonferroni't' test were used to calculate significance of the results across each time period. Anova with Tukey's test was used to calculate significance of values across each study group. All data were entered in Microsoft excel for statistical analysis. All statistical analysis were performed using SPSS software (Version 23.0).

The primary outcome of the study was reduction in severity and frequency of headache in each groups during course of the study. Secondary outcome was decrease in number of hospital visits during course of study.

RESULTS

Among 100 migraine patients 58 were females and 42 were males. 62 of them were in the age group of 30 to 40 years of age. 66 patients belonged to moderate to severe category of migraine. Two of the main outcomes, number and severity of headaches were measured via periodic survey. Severity of the headache was assessed using MIDAS questionnaire. Number of hospital visits were based on data collected from electronic medical records. Each row in the table shows the time since start of subject in the study; columns represent study group. The mean number of headaches and standard deviation was shown in the below table with significance. Table 1 shows similar mean values at the start of the study and in the end as well as other points of time reduction in mean number of headaches in all the three groups, more so in third group representing patients receiving pharmacotherapy and biofeedback can be seen. This suggests significant role of biofeedback in combination with pharmacotherapy in reducing frequency of headaches ($p<0.001$). Group wise comparison was significant at the time of 12 and 24 months.

Table 2 shows mean number of severe headaches/month. The means start at similar level but reduction in frequency of severe headaches is seen significantly in group receiving pharmacotherapy with biofeedback ($p<0.001$). Group wise comparison at each time interval is not found to be significant except at 24 months. At 24 months the mean number of severe headaches/ month was 2.03 at conventional therapy and 2.2 at biofeed back and 1.2 with the combination of biofeedback and pharmacotherapy. Out of 35 patients who received conventional therapy 21 (57.4%) reported improvement in quality of life, whereas 26 out of 35 (74.28%) who received combination of biofeedback and pharmacotherapy reported reduction in severity and frequency of headaches with better quality of life compared to 13 patients out of 30 who received biofeedback alone (43.3%). Table 3 shows number of visits in preceding 6 months. Even though there is general trend in decline in number of visits in all 3 groups, more significant difference was observed in 3rd group receiving conventional therapy with biofeedback.

Table 1: Comparison of mean number of headaches/month among the three groups at different time intervals.

Time in months	Conventional therapy	Biofeedback	Biofeedback+pharmacotherapy	F*	P
0	5.1±0.96	4.9±0.6	5.1±0.9	0.633	0.533
3	4.9±1.1	4.8±1.0	4.6±1.3	0.601	0.55
6	4.6±1.3	4.7±1.2	4.4±1.0	0.571	0.567
9	3.9±1.0	4.3±1.3	3.9±1.2	1.284	0.282
12	3.8±1.3	4.1±1.1	3.4±0.92	3.323	0.04*
24	2.8±1.4	3.9±0.94	2.3±0.98	17.672	<0.001***
F	51.962, p<0.001***	15.2, p<0.001***	88.486, p<0.001***		

Note: *-Anova;*-significant; ***-very highly significant.

Table 2: Comparison of mean number of severe headaches/month among the three groups at different time intervals.

Time in months	Conventional therapy	Biofeedback	Biofeedback+pharmacotherapy	F*	P
0	4.0±0.99	3.49±1.1	3.81±1.2	2.442	0.091
3	3.8±0.97	3.2±1.21	3.62±1.13	2.551	0.083
6	3.5±1.14	3.1±1.12	3.03±0.91	1.902	0.155
9	3.2±1.12	2.9±1.09	2.82±0.98	1.18	0.312
12	2.9±1.23	2.7±1.34	2.32±1.15	1.891	0.156
24	2.03±1.2	2.2±0.99	1.2±0.98	8.561	<0.001***
F	46.496, p<0.001***	15.236, p<0.001***	79.883, p<0.001***		

Note: *-Anova;*-significant; ***-very highly significant.

Table 3: Comparison of mean number of severe headaches/month among the three groups at different time intervals.

Time in months	Conventional therapy	Biofeedback	Biofeedback+pharmacotherapy	F*	P
0	4.52±4.10	4.82±4.21	5.34±4.92	0.294	0.746
6	3.12±3.01	4.06±4.10	3.13±2.21	0.948	0.391
12	2.33±2.42	3.52±3.23	2.12±2.74	2.391	0.097
24	2.14±1.23	3.14±1.45	1.76±1.32	9.487	<0.001***
F	14.081, p<0.001 ***	4.513, p=0.004 **	27.035, p<0.001 ***		

Note: *-Anova;*-significant; ***-very highly significant.

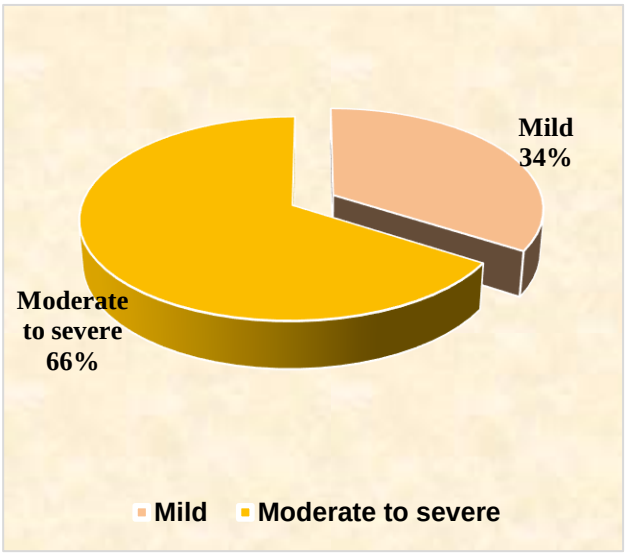

Figure 1: Distribution among participants based on severity.

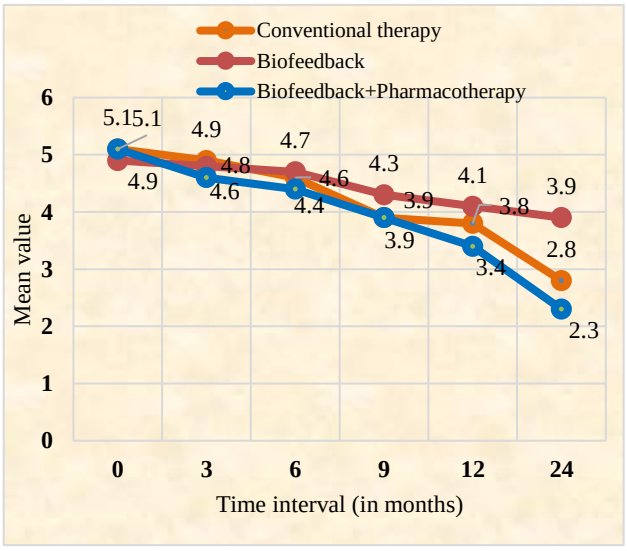

Figure 2: Efficacy of various interventions on frequency of migraine headaches.

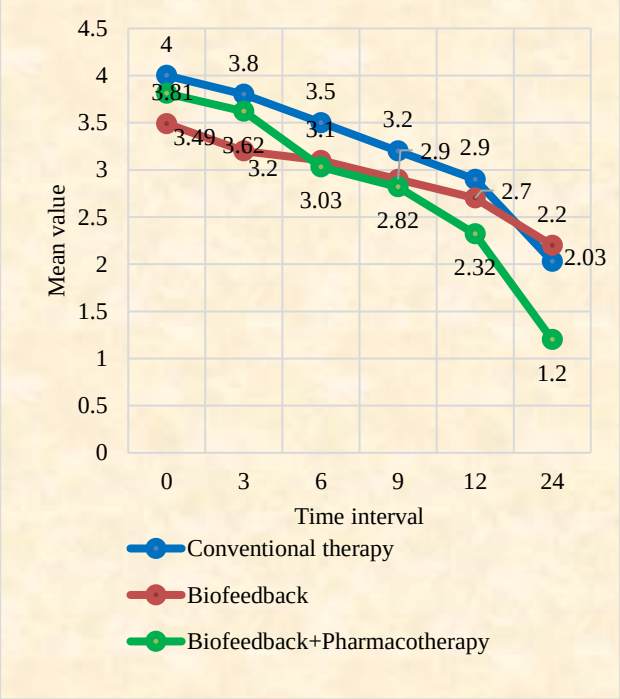

Figure 3: Efficacy of various interventions on frequency of severe headaches.

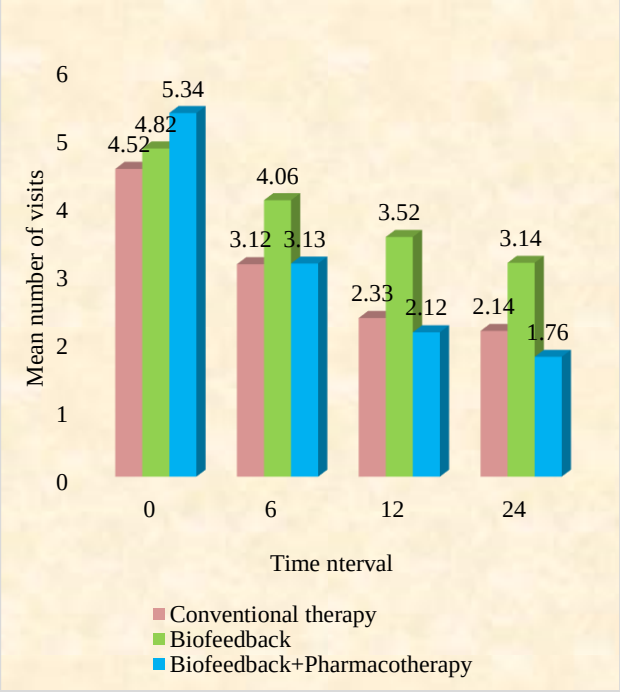

Figure 4: Among the three groups at different time intervals.

DISCUSSION

This study was done to compare outcomes between various interventions for migraine. Biofeedback sessions were given 2-3 times per week and duration of each session was 30 min to 1 hour to group that received biofeed back alone and the group that received combination of pharmacotherapy with biofeedback. Breathing technique is the modality of biofeedback that was used. Biofeedback is free from any adverse effects and is effective for preventive or abortive treatment of migraine and preferable over conventional pharmacotherapy.[1] This study showed reduction in severity of migraine and frequency over the course of time in all three groups, suggesting significant efficacy with both pharmacotherapy and biofeedback.

The data obtained showed reduction in severity and frequency of headaches in the first 12 months of therapy and continued to 24 months. Out of 35 patients who received conventional therapy 21 (57.4%) reported improvement in quality of life, whereas 26 out of 35 (74.28%) who received combination of biofeedback and pharmacotherapy reported reduction in severity and frequency of headaches with better quality of life compared to 13 patients out of 30 who received biofeedback alone (43.3%).Group wise comparison at each time interval is not found to be significant except at 24 months. At 24 months the mean number of severe headaches/month was 2.03 at conventional therapy and 2.2 at biofeedback and 1.2 with the combination of biofeedback and pharmacotherapy. The significance of the results among different time periods was confirmed by Anova with Bonferroni't' test and across each study groups was confirmed by Anova with Tukey's test. The result of the study suggested that the group which received pharmacotherapy in combination with biofeedback had best outcome compared to other 2 groups. But there was significant reduction in severity and frequency of headaches in all 3 groups.

There was general trend in decline in number of visits in all 3 groups, most significant difference was observed in 3rd group receiving conventional therapy with biofeedback with mean number of visits being 1.76±1.32 compared to 3.14±1.45 in biofeedback group and 2.14±1.23 in conventional therapy group at 24 months.

A study done by Mullaly et al concluded that simple relaxation techniques and education in pain theory, should remain an integral part of the treatment program for migraine and tension type headaches. As per this study after 6 months of therapy 52% of patients in the biofeedback group had reduced frequency of severe headaches. According to preventive treatment, it is recommended in patients with high frequency of migraine attacks (usually 4-5 days per month), but also when attacks are rare but severe and disabling, or when patients have contraindications or no response to triptans.[2] In study done by Mullaly et al there was reduction in number of hospital visits among patients receiving biofeedback similar to our study over course of time. As per study conducted by Sullivan et al psychological interventions (like cognitive behavioral therapy, relaxation techniques and neurofeedback) showed broad range of efficacy from 20-67%.[3] But there was no evidence to suggest one form of psychological intervention was superior to the other.[3] Case

study done by Zivoder et al. Showed 50% reduction in frequency of headaches in patients attending biofeedback sessions.[4] It was concluded that combination of pharmacologic and behavioral treatments such as relaxation training and cognitive behavioral therapy can lead to faster and better results with people who suffer from migraine.[4]

Study done by Stokes et al showed 50% or more reduction of headache frequency and severity in 70% of participants. Suggesting significant role of biofeedback in treatment of migraine.[5] Compared to these studies, 43.3% of patients who received biofeedback alone in our trial had reduction in severity and frequency of migraine headaches.

As per Kropp et al besides pharmacological and interventional possibilities non pharmacological options, deriving from behavioural approaches may be helpful in the treatment of migraine. Biofeedback as well as cognitive behavioural therapy are effective in treatment of migraine. The combination of these with pharmacological interventions has additional benefits in improving quality of life in migraine patients.[11] As per study done by Powers et al at 12-month follow-up, 86% of the cognitive behaviour therapy group had a 50% or greater reduction in headache days verses 69% of the headache education group. Here both the groups were receiving pharmacological interventions.[15] In our study, the group that received biofeedback with pharmacological intervention showed improvement in severity and frequency of headaches in about 74.28% of patients.

According to study conducted by Kroner et al at 20 weeks (post treatment), 47% of the cognitive behavioral therapy plus amitriptyline group had ≤4 headache days per month compared to 20% of the headache education plus amitriptyline group and 32% of the cognitive behavioral therapy plus amitriptyline group had ≤3 headache days per month at 20 weeks. At the month 12 follow-up, 72% of the cognitive behavioral therapy plus amitriptyline group had ≤4 headache days per month and 61% of the cognitive behavioral therapy plus amitriptyline group had ≤3 headache days per month at their month 12 follow-up.[16]

Limitations

Limitation of the study was the small sample size for each intervention group.

CONCLUSION

Based on the data obtained from various interventions used in the study it was found that pharmacotherapy when used with biofeedback was highly efficient in improving quality of life in patients with migraine,making them perform better in their respective professional and personal lives.HenceIt is important to conduct larger scale controlled studies to treat migraine and other chronic disorders.Other behavioral treatments include combination of relaxation technique with biofeedback,stress management training cognitive behavioral therapy.Multifaceted approach is the need of the day in treatment of migraine to achieve reduction in severity and frequency of headache at the earliest and better therapeutic outcomes.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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