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RESEARCH ARTICLE

A COMPARATIVE STUDY OF EFFECTIVENESS OF BIOFEEDBACK AND PHARMACOTHERAPY IN PROPHYLAXISOF MIGRAINE

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Abstract

Context: Migraine is a common disabling episodic primary headache disorder presenting with variety of clinical features. Most of the manifestations occur due to dysfunction of the sympathetic nervous system. Biofeedback treatments provide patients with feedback of physiological processes, human autonomic nervous system, particularly the sympathetic nervous system and thus may be helpful in treatment of Migraine.

Aims: To determine and compare effectiveness of biofeedback therapy with Pharmacotherapy in reducing frequency and severity of migraine episodes.

Settings and Design: it was a longitudinal interventional analytic study, conducted at Department of Psychiatry, JLN medical college, Ajmer.

Methods and Material: A total of 60 patients aged 18 to 55 years suffering from migraine for more than six months, diagnosed by ICHD-3 criteria were randomly assigned to receive either biofeedback therapy or prophylactic pharmacotherapy. The primary outcome compared after 5 months of follow-up were Pain index, frequency of attack and global evaluation.

Statistical analysis used: All statistical analysis was done using Epi info version 7.

Results: Response rate in Biofeedback and Pharmacotherapy group was 65% and 72% respectively. Significant reduction was seen in migraine index and migraine attack frequency in both groups ($P<0.05$). No significant difference was seen between the two groups at 5 month follow up in relation to migraine index, frequency or global evaluation of improvement

Conclusions: Biofeedback therapy is as effective as pharmacotherapy in prophylactic management of migraine, without the risk of side effect associated with the drugs.

Introduction:-

Headache disorders are a major public health issue due to their high prevalence and the significant associated disability and financial burden to individual, their family and society [1-4]. Patients suffering from headache have significant deteriorations of functional level at work, home, and school. [5]

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Migraine is a common disabling primary headache disorder. It can occur at all ages and mostly begins before the age of 20 years in nearly half cases [6,7]. In the Global Burden of Disease Survey 2010, migraine was found to be the third most common disorder and seventh specific cause of disability worldwide. It is presumed that diagnosis of migraine is relatively easy and treatment straightforward, still in many patients it can be complex and debilitating. In many patients, migraine can progress from an episodic disorder to a chronic disease, and can be difficult to treat.

Migraine is an episodic syndrome manifesting as a variety of clinical features that are a result of sympathetic nervous system dysfunction. Autonomic symptoms are common during acute migraine headaches and include nausea, vomiting, diarrhoea, cutaneous vasoconstriction (pallor), vasodilation (flushing), pilo-erection, and diaphoresis.[8,9]. Migraine attack is thought to occur due to relative depletion of sympathetic norepinephrine stores in and an increase in the release of other sympathetic co-transmitters like dopamine, prostaglandins, adenosine and ATP.[10]

Biofeedback is a behavioural treatment that involves patient's active role in the management of chronic pain, hence allowing better psychological and psycho-social coping. The autonomic nervous system, particularly the sympathetic nervous system is a primary target of peripheral biofeedback. It helps to gain control over autonomic nervous system dysfunction occurring in migraine and also by operant conditioning it reduces the psychological attributes like stress and improves self-efficacy in dealing with acute episodes.

Subjects and Methods:-

Ethical consideration:

A prospective, randomized interventional study was conducted in the department of psychiatry from November 2016 to march 2017. The study was approved by the institutional ethical committee of the medical college and written informed consent was obtained by each subject willing to participate in the study.

Study design:

A total of 60 patients, aged 18 to 55 years, who had been suffering from migraine for more than six months, diagnosed by ICHD-3 criteria and who gave written informed consent were included in the study. Patients with a history of psychosis, headache other than migraine and those with neurological examination or lab tests indicative of other brain disorder were excluded from study. Patients fulfilling the inclusion were randomly assigned to two study groups using block randomization technique. Block size of four was used for randomization. Patients assigned to Group A (N=30) received biofeedback therapy while those assigned to Group B (N=30) received Preventive/Prophylactic Pharmacotherapy in the form of Propranolol 40 mg and Flunarizine 10 mg once a day, preferably in the evening. Both groups received a standard combination of Naproxen 500mg and Sumatriptan 85 mg during acute episodes. Preventive treatment was not given for initial 10 days of the study in order to calculate baseline "migraine index" i.e. sum of daily pain scores during a period of 10 days and attack frequency. Biofeedback therapy consisted of thrice per week 20-30-minute sessions utilizing standard EMG feedback from the frontalis and trapezius muscles, skin conductance feedback from palmer aspect of fingers and pulse rate feedback using pulse-oxymeter. Visual and auditory feedback was given using animations and music. All patients were periodically evaluated every 11^{th} day for response to treatment for 5 months. All participants were asked to maintain a headache diary and note the intensity of pain on a 5-point scale: 0= no pain, 1= mild, not interfering with usual activities; 2= moderate, disturbing usual activities; 3= intense, prohibits activities,' 4= extremely intense, must go to bed. Effectiveness of treatment was assessed using migraine index (the sum of daily scores of headache), frequency of attacks and global evaluation. Global evaluation was determined by asking the patients to classify their response to the treatment as poor, good, very good or excellent. The headache diaries were checked and BP and HR were recorded periodically on each follow up visit. Two patients in Group A and one patient in Group B were lost to follow up and were excluded from study.

Statistical analysis:

Categorical data was expressed as percentage and analysed using Chi square test. Continuous data was expressed as mean and standard deviation and compared using unpaired t-test and paired t-test for inter group and within group comparison respectively. Ordinal data was analysed using Mann Whitney test and Wilcoxon rank sum test for inter group and within group comparison respectively. Confidence level of 95% and significance level of P value ≤ 0.05 was used in the data analysis. All statistical analysis was done using Epi info version 7.

Results:-

A total of 60 subjects were randomized into two treatment groups – Biofeedback group and Pharmacotherapy group. 28 subjects in Biofeedback group and 29 subjects in Pharmacotherapy group completed the study. Both groups were similar in their age and sex composition (Table 1).

64.3 %(n=18) subjects who were given biofeedback therapy responded. No gender difference was found with respect to response to Biofeedback therapy (P=0.953), (Table 2). 72.4%(n=21) subjects responded to pharmacotherapy and both female and male subjects responded similarly (p=0.361), (Table 3). Intergroup comparison did not show superiority of one mode of treatment over other (X^2=0.141, p=0.708), (Table 4).

The mean Migraine index in Biofeedback treatment group changed from 28.6 to 12.7 (P<0.001) and 26.5 to 10.9 (p<0.001) in pharmacotherapy group after completion of therapy. No significant difference in change in migraine index was found between the two groups (p=0.1), (Table 5). Significant reduction in mean frequency of migraine attack was observed in both groups (P<0.001), no difference was observed between Biofeedback and Pharmacotherapy groups (P=0.712), (Table 6). The global evaluation of improvement score was good, very good or excellent in 82.1% (n=23) subjects in Biofeedback treatment group and in 89.7% (n=26) subjects in Pharmacotherapy group while no significant difference was between the groups (P=0.664), (Table 7).

Discussion:-

Biofeedback therapy in Migraine helps patients to gain control over physiological processes, particularly autonomic nervous system, allowing them voluntary control over various bodily functions like pulse rate, breathing, peripheral blood flow, peripheral temperature and muscle tension. One of the principles of biofeedback is that there is reciprocal relationship between the brain and body, Not only does the brain control the body, but the body also controls the brain.

Past research has shown that positive reinforcement (operant conditioning) increases the likelihood of behaviour and when behaviour is reinforced repeatedly and consistently over time, it can be learned and retained. This is why the biofeedback treatment gains endure even after treatment ends.

EMG biofeedback provides relaxation of the entire body using an informational feedback system where the patient is given audio and/or visual cues about the EMG activity in the muscle (most often the frontalis muscle in headache) being monitored. Temperature biofeedback trains the patient to increase skin temperature, stabilizing the vasomotor responses of migraine. The biofeedback monitor is only a temporary facilitating device and patients need to practice the techniques to be able to effect the same changes after they are weaned from the sessions. This will ultimately decrease the frequency and severity of their headaches [11].

Results of the present study prove that biofeedback therapy is as effective as pharmacotherapy for prevention and prophylaxis of migraine attacks. About two thirds (64.3%) of the patients in biofeedback group responded well. Apparently more patients responded positively to pharmacotherapy (72.4%) but the difference was not significant (p=0.708). It was also depicted that there was no gender wise difference in the pattern of response to both biofeedback treatment (m= 60%, f= 66.7%, p=0.953) and pharmacotherapy (m= 55.6%, f= 80%, p=0.361). So we may assume that the etiology and mechanism of response to treatment is same in both male and female patients.

Comparison of migraine index (sum of daily score of headache calculated in 10 days) at baseline and after end of therapy clearly shows significant reduction in migraine index (p<0.001) and mean frequency of migraine attack (the mean of attack of migraine calculated per 10 days). Similar results were found in the pharmacotherapy group. The findings are very significant as they robustly proved the effectiveness of biofeedback therapy in reducing frequency of migraine attacks as well as in reducing daily pain scores. It further consolidated the evidence of effectiveness of Propranolol and flunarizine in prevention of migraine attacks. More than 80% of patients reported that overall response to biofeedback therapy was satisfactory (good, very good or excellent). Global evaluation of the patients in terms of overall improvement in health status in context of migraine also suggests that biofeedback is an effective modality of treatment. Not only it is as effective as pharmacotherapy but in addition, it also saves the patients from potential side effects of pharmacotherapy like hypotension, bradycardia, weight gain, glucose intolerance etc.

The comparative efficacy of pharmacological versus behavioral therapies for migraine has only rarely been directly assessed [12,13,14,15], however, available meta-analyses show virtually identical improvement in migraine with propranolol (32 trials), flunarizine (31 trials), and combined relaxation and biofeedback training [16]. Marialuisa Rausa et al 2016[17] in a pilot study found that treatment with Biofeedback group reduced the headache frequency and the quantity of drug intake and showed more active coping with pain, compared with the Control group. Grazzi L et al 2002[18] found that a combination of pharmacotherapy and behavioral treatment is more effective than medicine alone in the long-term management of migraine with analgesic overuse. At year 3, participants receiving combined treatment showed greater sustained improvement on two of three outcome measures assessed (fewer days of headache and reduced consumption of analgesic medication). In addition, a greater number of patients assigned to pharmacologic treatment alone relapsed (resumed overuse of analgesics) compared to patients receiving combined treatment.

Propranolol acts by decreasing central catecholaminergic activity by inhibition of norepinephrine release, reducing neuronal activity and excitability, has membrane-stabilizing properties, and inhibits production of nitric oxide[19]. Flunarizine, calcium-channel blocker, is also very effective in migraine prohylaxis. It decreases nitric oxide synthase by decreasing calcium influx.[20].The effect of both these drugs is not maintained for long if the treatment is abruptly stopped. The effect of biofeedback is long lasting as it helps in treating the disorder using one's own body and mind as the treating agent as well as treatment recipient. Nestoriuc & Martin in their meta-analytical study found that the effect of biofeedback treatment remained stable over an average follow-up duration of 14 months [21, 22]. Further significant improvements were shown for perceived self-efficacy, symptoms of anxiety and depression, and medicine consumption. The improvement in headache frequency and duration were significantly stronger than the improvement with medicine intake alone.

Kaushik R in an study titled 'Biofeedback assisted diaphragmatic breathing and systematic relaxation versus propranolol in long term prophylaxis of migraine', found significant response with biofeedback therapy in 66.66% and with propranolol in 64.58% of patients [23]. Frequency, intensity, duration of attacks and number of vomiting episodes were significantly reduced in both the groups at the end of six months but inter-group differences were statistically insignificant. During one year post-treatment follow-up period, significantly lesser recurrence of migraine was seen in biofeedback group (9.37%) in comparison to recurrence of migraine in propranolol group as whole (38.54%).

Biofeedback is free from any adverse effect and is therefore a safer and effective mode of treatment for prevention of migraine. Biofeedback has been a mainstay of headache treatment for decades and is offered at many of the major pain and headache clinics.

Conclusion:-

Present study provides substantial proof of the effectiveness of both biofeedback training and pharmacotherapy, and that both form of therapy are equally effective in management of migraine. Biofeedback therapy has potential for long lasting therapeutic effects without risk of side effects of drugs which may occur after prolonged use. Moreover, biofeedback therapy teaches patients to effectively deal with stress and psychological attributes of chronic pain.

Limitations:

The sample size of the study was relatively small to study such wide spread health problem. The patients agreed to biofeedback sessions were those living in vicinity of the hospital who could afford to visit the hospital for frequent biofeedback sessions. They might not truly represent the population. Moreover due to technical difficulties, biofeedback therapy could be given only to educated patients.

Table 1:- General characteristics of study subjects.

	Biofeedback (N=28)	**Pharmacotherapy (N=29)**	**P value**
Sex Male **Female**	**10 (35.7%)** **18 (64.3%)**	**09 (31%)** **20 (69%)**	**0.925**
Age (years) **Mean ± SD**	**39 ± 14.2**	**38 ± 13.7**	**0.788**

Table 2:- Response to biofeedback therapy after 5 months.

	Responded	Not- responded	X^2	P value
Female (N=18)	12 (66.7%)	6 (33.3%)	0.003	0.953
Male (N=10)	6 (60%)	4 (40%)		
total (N=28)	18 (64.3%)	10 (35.7%)		

Table 3:- Respond to pharmacotherapy after 5 months.

	Responded	Not – responded	X^2	P value
Female (N=20)	16 (80%)	4 (20%)	0.835	0.361
Male (N=9)	5 (55.6%)	4 (44.4%)		
Total (N=29)	21 (72.4%)	8 (27.6%)		

Table 4:- Distribution of subjects in relation to Response to therapy.

Group	Respond	Not respond	X^2	P value
Biofeedback (N=28)	18 (64.3%)	10 (35.7%)	0.141	0.708
Pharmacotherapy(N=29)	21 (72.4%)	8 (27.6%)		
Total (N=57)	39 (68.4%)	18 (31.6%)		

Table 5:- Comparison of Migraine index in study groups.

Group	Baseline	After 5 months	P value
Biofeedback(N=28)	28.6 ± 7.5	12.7 ± 4.2	<0.001
Pharmacotherapy(n=29)	26.5 ± 6.9	10.9 ±3.9	<0.001
P value	0.283	0.196	

Table 6:- Change in Mean frequency of migraine attack in both groups.

Group	Baseline	Last 10 day	P value[1]
Biofeedback(N=28)	**3.7**	**1.21**	**<0.001**
Pharmacotherapy(n=29)	**3.5**	**1.17**	**<0.001**
P value[2]	**0.683**	**0.712**	

Calculated using Mann Whitney test
Calculated using Wilcoxon Rank sum test

Table 7:- Global evaluation of improvement at the end of the treatment.

Group	Poor	Good / Excellent	X^2	P value
Biofeedback(N=28)	5 (17.9%)	23 (82.1%)	0.189	0.664
Pharmacotherapy(n=29)	3 (10.3%)	26 (89.7%)		
Total (N=57)	8 (14%)	49 (86%)		

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