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RESEARCH ARTICLE

STUDY OF PROPRANOLOL AND FLUNARIZINE IN THE PROPHYLACTIC THERAPY OF MIGRAINE: A PROSPECTIVE STUDY

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ABSTRACT

Migraine is a common type of headache. Its symptoms can lasts for days and disrupt ability to perform basic, daily tasks and in turn affects the physical, emotional and social aspects of life. It is a recurrent, severe headache that interferes with normal functioning and quality of life . This prospective observational study was conducted to evaluate and compare the effectiveness and safety flunarizine(10mg), calcium channel antagonist, and propranolol(40mg) in the prophylaxis of migraine with or without aura. This Study included 70 patients of migraine and was divided into 2 treatment groups.

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INTRODUCTION

Migraines which are primary recurrent headaches last for 4 to 72 hours with at least two of the following pain characteristics—unilateral, pulsating, moderate or severe intensity—define migraine, a common and frequently disabling neurological condition[1]. Physical activity generally makes the ache worse. Migraines commonly start out as a severe, persistent headache that is self-limited and accompanied by autonomic symptoms. The terms migraine with aura and migraine without aura have taken the role of classical migraine and nonclassical migraine. Aura-related migraines occur in 15–30% of migraineurs, and those who have them frequently also get migraines without an aura. Variables can affect the level of discomfort, length of the headache, and frequency of attacks. Status migrainosus refers to a migraine that persists for more than 72 hours.

The World Health Organisation ranks migraine as the 19th most disabling disease and the 12th most common cause of years spent disabled among women worldwide, regardless of age[2] . It is thought that a combination of environmental and hereditary factors contributes to migraines. A little over two thirds of cases involve families. Since boys are affected by migraines slightly more frequently than girls before puberty, changing hormone levels may potentially be a factor.

According to International Headache Society (IHS) recommendations, migraine is categorised as either episodic (EM) or chronic (CM), with CM being defined as having 15 or more headache days, of which at least three months must pass [1] . Additionally, patients with CM had higher health care costs and productivity losses at work than those without CM. The aim of the study is to evaluate comparative effectiveness and safety of Propranolol *vs* Flunarizine in the prophylactic treatment of migraine

MATERIALS AND METHODS

STUDY DESIGN: Prospective observational study.

STUDY POPULATION: Patients diagnosed with migraine.

INCLUSION CRITERIA

- Patients with migraine.
- Prescription with either flunarizine (10 mg) or propranolol (40 mg).
- OP patients.
- Both male and female patients.

- Age group >16 years
- Those who give consent voluntarily to participate in the study.

EXCLUSION CRITERIA

- Patients not willing to participate.
- Patient who take more than one medication for migraine prophylaxis.
- Patient who overuse pain medication

STUDY SITE: Neurology department and ENT department of SH Medical Centre, Kottayam, Kerala.

SAMPLE SIZE: 70 patients diagnosed with migraine, 35 treated with propranolol and remaining 35 with flunarizine.

EQUATION

$$N = \frac{(Z_\alpha + Z_\beta)^2 [\, P_1 (1-P_1) + P (1-P_2)]}{(P_1 - P_2)^2}$$

α = Type I error (fixed at 5 % level)
β = Power (fixed at 80 % level)
P_1 = Proportion having clinical response in propranolol arm
P_2 = Proportion having clinical response in flunarizine arm.

STUDY PERIOD: 3 months, From March 2023- June 2023

ETHICAL CONSIDERATION: The institutional ethics committee clearance was obtained(KVMCPIEC/EA/01/2023), after that started the study. Informed consent was obtained from all patients who met the inclusion criteria were enrolled for the study.

RESULTS AND DISCUSSION

Effectiveness

Effectiveness of medication based on severity of migraine patients In the study population, the average severity score of the patients with propranolol were decreased from 8.0 to 2.0, indicating the effectiveness of propranolol on severity of migraine patients. Here the P value was found to be < 0.0001 indicating that the effectiveness of medication on severity was significant.

Effectiveness of medication based on frequency of migraine patients: In the study population, average frequency score of the patients with propranolol were decreased from 10.65 to 1.54, indicating the effectiveness of propranolol on frequency of migraine patients. Here the P value was found to be <0.0001 indicating that the effectiveness of medication on frequency was significant.

Effectiveness of medication based on duration of migraine patients: In the study population, average duration score of the patients with propranolol were decreased from 9.0 to 2.31 and patients with flunarizine decreased from 8.1 to 1.45 and the mean difference were almost equal indicating that both propranolol and flunarizine were equally effective on duration of migraine patients. Here the P value was found to be <0.0001 indicating that the effectiveness of medication on duration was significant.

Safety

Distribution of patients based on the occurrence of ADR: Out of 70 patients, commonly observed ADR was sedation (15.1%) and weight gain (4.7%) associated by the use of flunarizine and for Propranolol was sedation (3.9%) and hypotension (6.7%). By Naranjo algorithm, 84.3% were doubtful ADR and 15.7% was possible chance of ADR.

RISK FACTORS OF MIGRAINE:

Table 1. Distribution of migraine in patients based on triggering factors

Triggering factors	frequency	percentage (%)
STRESS	19	27.1
MISSED MEALS	13	18.6
CHANGE IN CLIMATE	17	24.3
TRAVEL	9	12.9
CHANGE IN SLEEP PATTERN.	12	17.1

From table 1, it was clear that stress and climatic changes can trigger migraine in most of the study population.

RECURRENCE RATE OF MIGRAINE DURING STUDY PERIOD:

Table 2. Distribution of patients based on recurrence rate

Recurrence rate	propranolol	flunarizine
RECURRENCE	17.1	11.4
NO RECURRENCE	82.9	88.6

From table 2 shows that majority of the study population reported no recurrence of migraine. Recurrence rate was only 14.2% in the study population. Recurrence rate was higher with propranolol use than with flunarizine by 5% only.

CONCLUSION

In this trial, propranolol was found to be noticeably more effective. Patients receiving propranolol medication had a slightly greater rate of migraine recurrence at the same time. With the exception of energy, mental health, and social functioning, both therapies' quality of life was comparable. Propranolol therapy produced a more significant difference. As a result, it can be said that propranolol can be used as an effective substitute for flunarizine in the treatment of migraines.

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