Original Research Paper

Volume-9 | Issue-1 | January-2019 | PRINT ISSN - 2249-555X

Neurology

A PROSPECTIVE OBSERVATIONAL STUDY ON ASSESSMENT OF CLINICAL OUTCOMES OF PROPHYLACTIC THERAPY IN MIGRAINE

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ABSTRACT

Introduction: The goal of migraine treatment is to reduce the frequency, severity of migraine and to improve the quality of life in migraine patients. Hence, the study was aimed to assess the Clinical Outcomes in patients with Migraine taking different Prophylactic Anti Migraine drugs for a fixed duration of time along with adverse drug reactions associated with the therapy.

Methodology: The study was aProspective Observational Study conducted in patients seeking treatment for migraine in a tertiary hospital in Guntur with from September 2017 to March 2018. The patients were divided into 2 groups (Group I: Amitriptyline and Propranolol and group II: Flunarizine and Propranolol) depending on the combinational drugs used for the prophylaxis. Migraine disability Assessment Scale (MIDAS) and Headache Impact Test (HIT-6) scores were used at the baseline and at 10-12 weeks after treatment and the clinical outcomes was assessed.

Results: Of these 132 patients, 51 (38.63%) patients belongs to Group I and 81 (61.36%) belongs to Group II. The mean age of population of Group I was found to be 38.31±11.61 and Group II was 35.91±11.02. The baseline MIDAS score was 126.17±99.42 for group I and 100.72±85.42 in group II. The baseline HIT-6 score was 70.39±8.21 for group I and 69.08±11.46 in group II. Both MIDAS and HIT-6 scores significantly reduced after receiving treatment (p value <0.05). Group-II was more effective prophylactic therapy in migraine when compared to Group-I. In both the Groups some commonly observed Adverse Drug reactions were weight gain, sedation and dizziness.

Conclusion: The baseline mean scores obtained improved after 10-12 weeks of interventional drug therapy concluding that the both Groups were effective in reducing the frequency and severity of migraine.

KEYWORDS

INTRODUCTION

Migraine is a paroxysmal disorder with attacks of headache, nausea, vomiting, photo- and phonophobia and malaise.1It involves both sides of the head, from its onset in about 40% of patients. Another 40% experience strictly unilateral headaches, and approximately 20% have headaches that start on one side and later become generalized. Migraine is of two types, common migraine (without aura) and classical migraine (with aura).[1, 2]Migraine is highly prevalent and is often accompanied with severe pain, discomfort, and disability and subsequently associated with lesser quality of life. Thus, migraine management is an important health care issue.[3]

Management of migraine mainly consisted of avoidance of trigger factors, lifestyle modifications and medications.[3] The pharmacologic treatment of migraine may be acute (abortive) or preventive (prophylactic)[4]. While Preventive therapy is used to reduce the frequency, duration, or severity of attacks, the prophylaxis requires daily administration of anti-migraine compounds, whether or not a migraine attack is occurring.[3,4] The primary aim in prophylactic treatment of migraine is to decrease the frequency, severity and time of attacks. In addition, it is also aimed to increase the benefit of acute attack treatment, improve the functional status and decrease the disability caused by headache with prophylactic treatment.[5] Hence, the study was conducted to assess the Clinical Outcomes in patients with Migraine taking different Prophylactic Anti Migraine drugs for a fixed duration of time along with adverse drug reactions associated with the therapy.

MATERIALS AND METHODS:

The study was a prospective observational study conducted in a tertiary hospital, Guntur from September 2017 to March 2018 over a period of 7 months. The study population included those who visited the Department of Neurology who were prescribed with prophylactic anti migraine drugs to the patients.

Inclusion criteria:

- All the out patients who visited Neurology department, diagnosed as Migraine and receiving any one of the following prophylactic therapy
  - o Group I: Amitriptyline and Propranolol
  - o Group II: Flunarizine and Propranolol
- Patients with minimum 3months of Migraine history

Exclusion criteria:

- Migraine patients on any other prophylactic therapy
- Patients who are below 18 years
- Patients who are mentally retarded

The study was initiated after obtaining approval from the Institutional Ethical Committee, CHIPS, Guntur.The prescription of the outpatients who were diagnosed with migraine in Neurology department at NRI General Hospital was studied. Purposive sampling technique was employed in the study. Those patients who met the inclusion criteria were enrolled in to the study. Those patients who were treated for

prophylaxis of migraine with drugs like Propranolol and Amitriptyline, Propranolol and Flunarizine were divided into two groups respectively. An appropriate Informed Consent Form was designed and administered to all the patients in the inclusion criteria. A suitable data collection form was designed to collect all the necessary and relevant information related to the study. Initially, an interview was conducted in all the participants to collect relevant information using Migraine disability Assessment Scale (MIDAS-5 item questionnaire) and Headache Impact Test (HIT-6 item questionnaire). The relevant information was collected in the form of score which showed the disability of patients with migraine. After a follow up period of 10-12 weeks these patients were re-interviewed by using the same scales to assess the change in score which reflected the efficacy of the treatment.

An excel sheet was prepared for data entry. The scores obtained by the patients (MIDAS, HIT-6) were recorded and calculated for total scores and their respective mean values.Data was analyzed by using paired and unpaired t test at a significance of 5% (P<0.05) in which significance of the interventional treatment was determined.

RESULTS

A total of 132 patients were included in the study. Group I (Amitriptyline + Propranolol) had 51(38.63 %) participants and Group II (Flunarizine + Propranolol) had 81(61.36%) participants. The baseline and demographic characteristics were noted down. (Table 1)
Comparison was done between Baseline and Post treatment MIDAS Scoreand HIT-6 Score was done using paired sample t test and it was found that the scores in both the groups decreased significantly post treatment.(p<0.05)(Table 2 and Table 3)

ThePost treatment effect between group-I and group-II was compared using unpaired sample t test. Group II (Flunarizine + Propranolol) had lesser MIDAS Score and HIT-6 Score compared to group I. the difference was found to be statistically significant. (p<0.05)(Table 4)
A total of 21(41.2%) participants in Group I and 36(44.4%) participants in Group II experienced adverse drug reactions. Some of the common ADRs observed in both the groups were weight gain,sedation and dizziness (Table 5).

Table 1: descriptive analysis of the baseline characteristic

Parameter	Group I :(Amitriptyline + Propranolol) (n=51)	Group II (Flunarizine + Propranolol) (n=81)
Number of participants, n (%)	51(38.63 %)	81(61.36%)
Age in years (Mean ±SD)	38.31±11.61	35.91±11.02.
Gender		
Males	12 (23.5%)	14 (17.3%)
Females	39 (76.5%)	67(82.7%)
Presence of aura		
Migraine without aura	45(88.3%)	75(%)
Migraine with Aura	4(7.8%)	2(%)
Others	2(3.9%)	4(%)
Age at onset	34.16±11.82	31.74±11.36
Years since onset	4.12±4.03	4.21±5.26

Table 2: Comparisons of Baseline and Post treatmentMIDAS Score

MIDAS SCORE				
Groups	**Baseline score (Mean±SD)**	**Post treatment score (Mean±SD)**	**t-value**	**p- value**
Group I (Amitriptyline + Propranolol)	126.17±99.42	64.94±85.63	4.22	<0.0005
Group II (Flunarizine + Propranolol)	100.72±85.42	35.18±49.14	7.44	<0.0005

Table 3: Comparison of Baseline and Post treatmentHIT-6 Scores

HIT-6 SCORE				
Groups	**Baseline score (Mean±SD)**	**Post treatment score (Mean±SD)**	**t-value**	**p- value**
Group I (Amitriptyline + Propranolol)	70.39±8.21	50.65±16.73	8.70	<0.0007
Group II (Flunarizine + Propranolol)	69.08±11.46	45.21±11.20	14.27	<0.0005

Table 4: Comparison of Post-treatment Scores between the study groups

Scales	Post treatment score of Group-I (Mean±SD)	Post treatment score of Group-II (Mean±SD)	t-value	p-value
MIDAS	64.94±85.63	35.18±49.14	2.25	0.014
HIT-6	50.65±16.72	45.21±11.20	2.049	0.021

Table 5: Adverse reactions associated with therapy

ADR	Group I :(Amitriptyline + Propranolol) (n=51) n (%)	Group II (Flunarizine + Propranolol) (n=81) n(%)
Weight gain	**6 (28.5 %)**	**13 (36.1 %)**
Sedation	**9 (42.8 %)**	**16 (44.4 %)**
Dizziness	**4 (19 %)**	**5 (13.88 %)**
Others	**2 (9.9 %)**	**2 (5.55 %)**

Discussion

Migraine prophylaxis is normally implemented when more than 3 migraine attacks occur per month and if attacks do not respond to acute treatment or if the adverse effects of acute treatment are severe.

In the current study in Group I and Group II, 90.2% of the sample population responded to the therapy which was similar to that of *DienerHCet al*[1]., among these 90.2% of the sample population in Group I, 21.72% of sample population were recovered completely with no single episode of migraine. In Group II among 90.2%, 30.6% of sample population was recovered completely with no single episode of migraine.

In our study, the patients with no change in episodes and patients with decreased episodes of migraine were equal in both the groups. But the total number of complete recovered patients wasmore in Group-II than in Group-I and the patients with increased number of episodes were more in Group-I than compared Group-II.

In order to assess the reduction in frequency of migraine attacks, MIDAS scale andHIT-6 was used. The mean scores wasobtained from the sample population at the baseline and post-intervention were compared. In both the groups, we observed reduction in frequency of migraine attacks which was evident by reduction in Mean MIDAS scores and HIT-6 scores . Further, the reduction in the mean MIDAS scores and HIT-6 scoresafter intervention indicated that both the groups were effective in reducing the frequency of migraine attacks.

Propranolol was more effective prophylactic therapy in migraine according to *Diamond S et al.*[6] study. In our study, Propranolol was commonly prescribed drug in both the groups. Our study results were compared to the above study results which shows efficacy of Propranolol in prophylactic treatment of migraine. The above findings were similar to that of a study conducted by *KuldeepM et al*[7] which showed that Amitriptyline was effective in reducing MIDAS scores thereby reduction in frequency, severity of migraine attacks. Our study results were similar to that of *Sørensen, P. S., et al*[8]*. and Sorge, F., et al.*[9] which showedFlunarizine was effective in reducing the frequency and duration of migraine.

The Post-interventional scores of Group-I and Group-II obtained by using MIDAS and HIT-6 were compared and the reduction in post interventional scores of Group II were more significant (p < 0.05) than Group I for both MIDAS and HIT-6. Therefore, Flunarizine and Propranolol was found to be more effective in reducing the frequency and severity of migraine and is a better prophylactic choice compared to Amitriptyline and Propranolol. According to *Mathew NT et al*[10] study, combination of Amitriptyline and Propranolol was effective prophylactic Migraine therapy. Our study results showed Amitriptyline and Propranolol was effective Prophylactic Migraine

therapy but not as effective as Flunarizine and Propranolol.

Our study results were similar to that of *HC Diener et al.,*[1] that Propranolol was effective prophylactic therapy in migraine. A study by *Lucking CH et al.,*[11] proved that Flunarizine is effective prophylactic therapy in reducing frequency and severity of migraine.

Conclusion:

Though both groups were useful in Prophylactic therapy of Migraine, Group-II therapeutics were more effective than Group-I therapeutics in reducing the intensity, frequency, duration and severity as demonstrated with respective scales used in the study. Similar studies has to be carried out in large cohort of patients with biomarkers for further stratification of the studied population so as to increase the health related quality of life and to reduce the morbidity and disability related to migraine.

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