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Comparison Of Efficacy Among the Migraine Patients Prescribed With Flunarizine, Propranolol And Petasites In The Management Of Severity Of Pain And Disability

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ABSTRACT

Aim: To compare the efficacy among the migraine patients prescribed with flunarizine, propranolol and petasites in the management of severity of pain and disability.

Methods: A total of 90 patients who were recruited in this study were categorized into three groups i.e., group A, B & C where flunarizine, propranolol and petasites were prescribed respectively. The severity of pain and disability among the three groups were assessed by using the visual analogue scale (VAS) and migraine disability assessment test (MIDAS questionnaire) before and after the treatment with respective drugs.

Results: Among the group-A subjects, the mean VAS score was observed to be 8.46 (±2.01) before the treatment and was reduced to 4.43 (±1.67) with a mean score difference of 4.03 ($p<0.0001$*) where as in case of group-B subjects, the mean VAS score was observed to be 8.33(±1.93) before the initiation of the treatment and was reduced to 5.40 (±1.65) with a mean score difference of 2.93 ($p<0.0001$*) and in case of group-C subjects, the mean VAS score was observed to be 7.83 (±1.87) before the initiation of treatment and was reduced to 5.26 (±2.01) with a mean score difference of 2.57 ($p<0.0001$*). Among the group-A subjects, the mean MIDAS score was observed to be 15.67 (±5.38) before the initiation of the treatment and was reduced to 11.0 (±4.16) with a mean score difference of 4.67 ($p=0.0004$*) whereas in case of group-B subjects, the mean MIDAS score was observed to be 12.07 (±3.99) before starting the treatment and was reduced to 7.9 (±2.64) with a mean score difference of 4.17 ($p<0.0001$*) and in case of group-C subjects, the mean MIDAS score was observed to be 13.77 (±5.40) before the initiation of the treatment and was reduced to 9.83 (±5.20) with a mean score difference of 3.94 ($p=0.0056$*).

Conclusion: In this study, a highest reduction of the mean VAS score and mean MIDAS score was observed in the group-A subjects who were prescribed with flunarizine when compared to the group-B and group-C subjects who were prescribed with propranolol and petasites respectively. It is the responsibility of the clinical pharmacists to get involved in the pharmaceutical care of the migraine

patients along with the other health care professionals in order to increase the quality of life among them by managing the severity of pain and disability due to migraine.

Keywords: *Flunarizine, Headache, Migraine, Pain, Petasites, Propranolol*

INTRODUCTION

Migraine is a common, recurrent, primary headache of moderate to severe intensity which interferes with the normal functioning and is associated with neurologic, gastrointestinal and autonomic symptoms [1]. It is the third most prevalent and sixth most disabling illness in the world [2,3]. A family history of migraine is most common among 90% of the migraine sufferers [4]. Most of the migraine patients can be observed with sensitivity to light, sound, smell and as well as nausea & vomiting [5]. Migraine must be managed by proper medication with self help remedies and life style modifications. Beta blockers, NSAIDs, triptans, opiods, calcium channel blockers and petasites play a significant role in the management of migraine [6-13]. Migraine may impact patient's daily activities and the job which may result in decreased productivity at work due to the pain and disability caused by it. This may often impact the family and social life of the patients. Hence, in this study we made an attempt to compare the efficacy among the migraine patients prescribed with flunarizine, propranolol and petasites in the management of severity of pain and disability.

MATERIALS AND METHODS

Data was collected prospectively after getting the ethical clearance from the institutional ethics committee (GSPRJY-IEC/Pharm.D/2019/06) by strictly adhering to the inclusion and exclusion criteria. Patients who met the ICHD criteria for migraine of either gender with age above 18 years and who were willing to give their consent to participate in the study were included. Patients with other neurological problems and who were not willing to give their consent to participate in the study were excluded. A total of 90 patients were recruited in this study and were categorized into three groups (A, B & C) where group-A subjects were prescribed with flunarizine, group-B subjects were prescribed with propranolol and group-C subjects were prescribed with petasites. The severity of pain and disability among the three groups were assessed by using Visual Analogue Scale (VAS) and Migraine Disability Assessment Test (MIDAS questionnaire) before and after two weeks of the treatment with the respective drugs. Visual analogue scale was used in order to assess the pain severity. The severity of pain was classified into mild (1-3), moderate (4-6), severe (6-8) and very severe (9-10). The migraine disability test assessment was done by using migraine disability assessment questionnaire (MIDAS) in order to measure the impact of headaches and also to determine the level of pain and disability caused by the headache to the patients. If the MIDAS score is in between 0-5, the patient was considered with no/little disability and can be categorized with Grade-I. If the MIDAS score is in between 6-10, the patient was considered with mild disability and can be categorized as Grade-II. If the MIDAS score is in between 11-20, the patient was considered with moderate disability and can be categorized as Grade-III. If the MIDAS score is > 21, the patient was considered with severe disability and can be categorized as Grade-IV [14-16]. The mean scores were taken into consideration for comparing the severity of pain and disability among the three study groups for comparing the efficacy of treatment.

Statistical Analysis

The data was analyzed by using the statistical software - Statistical Package for the Social Sciences (SPSS version 21.0). Mean and standard deviations were calculated and t-test was performed in order to obtain the p-values at 95% confidence interval ($p \leq 0.05$). The statistically significant values were denoted with asterisk (*).

RESULTS AND DISCUSSION

A total of 90 patients who were diagnosed with migraine were recruited in this study. Out of them

8(8.9%) were found to be males and 82(91.1%) were found to be females. Usually, females are more prone to migraine when compared to males. Table 1 represents the age wise categorization of the study participants. Most of the study participants were observed in the age group 21-30 years (47.8%) followed by 31-40 years (40%). According to the recent studies, about 90% of the patients with migraine may experience their first attack before the age of 40 years and it usually improves as the age of the patient increases. Therefore, about 40% migraine patients do not have attacks by the age of 65 years as per the literature available [17].

TABLE 1: Age wise categorization of the study participants

Age	Male (%)	Female (%)	Total (%)
21-30	5 (62.5)	38 (46.3)	43 (47.8)
31-40	1 (12.5)	35 (42.7)	36 (40)
41-50	1 (12.5)	7 (8.6)	8 (8.9)
51-60	1 (12.5)	2 (2.4)	3 (3.3)
Total	8 (100)	82 (100)	90(100)

In the present study, the study participants were categorized based on the type of headache. About 30(33.3%) patients were found to be with throbbing type of headache, 27(30%) were found to be with pin and needle type of headache, 31(34.5%) were found to be with heaviness and only 2(2.2%) patients were observed with paresthesia. The study participants were also categorized based on the specific region of sensory pain stimuli located in the brain. About 34(37.8%) patients were observed with hemi cranial region, 31(34.5%) were observed with holocranial region, 12(13.3%) were observed with occipital region and about 13(14.4%) were observed with frontal region. Migraine patients are often associated with various phobias like photophobia and phonophobia. About 11(12.2%) patients were observed with photophobia, 9(10%) patients were observed with phonophobia and about 53(58.9%) patients were observed with both the phonophobia and photophobia. No phobia was observed among 17 (18.9%) patients and all the patients who were observed with the above phobias were recovered irrespective of the drug prescribed for them.

Assessment of the Severity of Pain by Using Visual Analogue Scale

Table 2 represents the severity of the pain of migraine patients based on visual analogue scale. Most of the study participants were observed with very severe pain (56.7%) followed by severe pain (27.8%).

TABLE 2: Severity of the Pain of Migraine Patients based on Visual Analogue Scale

VAS Severity	Frequency	Percentage
Mild (1-3)	4	4.4%
Moderate (4-6)	10	11.1%
Severe (7-8)	25	27.8%
Very Severe (9-10)	51	56.7%
Total	90	100%

Table 3 represents the comparison of the severity of the mean scores of visual analogue scale before and after the treatment among the three study groups. Among the group-A subjects, the mean VAS score was observed to be 8.46 (±2.01) before the treatment and was reduced to 4.43 (±1.67) with a mean score difference of 4.03 after two weeks of treatment with flunarizine ($p<0.0001$*). Among the group-B subjects, the mean VAS score was observed to be 8.33(±1.93)

before the initiation of the treatment and was reduced to 5.40 (±1.65) with a mean score difference of 2.93 after two weeks of treatment with propranolol (p<0.0001*). Among the group-C subjects, the mean VAS score was observed to be 7.83 (±1.87) before the initiation of treatment and was reduced to 5.26 (±2.01) with a mean score difference of 2.57 after two weeks of treatment with petasites (p<0.0001*). The differences were considered to be statistically significant among all the three groups.

TABLE 3: Comparison of the severity of the mean scores of visual analogue scale before and after the treatment

Group/Drug Prescribed	Before treatment (Mean ±SD)	After treatment (Mean ±SD)	p-value
Group-A (Flunarizine)	8.46 (±2.01)	4.43 (±1.67)	p<0.0001*
Group-B (Propranolol)	8.33 (±1.93)	5.40 (±1.65)	p<0.0001*
Group-C (Petasites)	7.83 (±1.87)	5.26 (±2.01)	p<0.0001*

Assessment of the Severity of Disability by Using Migraine Disability Assessment Test Questionnaire

Table 4 represents the severity of the disability of the migraine patients assessed by using the Migraine Disability Assessment Test (MIDAS Test). In this study, most of the study participants were observed to be with moderate disability (48.9%) followed by severe disability (22.2%).

TABLE 4: Severity of the disability of migraine patients based Migraine Disability Assessment Test questionnaire

MIDAS Grade	**Frequency**	**Percentage**
Grade-I (No disability)	9	10%
Grade-II (Mild disability)	17	18.9%
Grade-III (Moderate disability)	44	48.9%
Grade-IV (Severe disability)	20	22.2%
Total	90	100%

Table 5 represents the comparison of the severity of the mean scores of migraine disability assessment test questionnaire before and after the treatment among the three study groups. Among the group-A subjects, the mean MIDAS score was observed to be 15.67 (±5.38) before the initiation of the treatment and was reduced to 11.0 (±4.16) with a mean score difference of 4.67 after two weeks of treatment with flunarizine (p=0.0004*). Among the group-B subjects, the mean MIDAS score was observed to be 12.07 (±3.99) before starting the treatment and was reduced to 7.9 (±2.64) with a mean score difference of 4.17 after two weeks of treatment with propranolol (p<0.0001*). Among the group-C subjects, the mean MIDAS score was observed to be 13.77 (±5.40) before the initiation of the treatment and was reduced to 9.83 (±5.20) with a mean score difference of 3.94 after two weeks of treatment with petasites (p=0.0056*). The differences were considered to be statistically significant among all the three groups.

TABLE 5: Comparison of the severity of the mean scores of Migraine Disability Assessment Test questionnaire before and after the treatment

Group/Drug Prescribed	Before treatment (Mean ±SD)	After treatment (Mean ±SD)	p-value
Group-A (Flunarizine)	15.67 (±5.38)	11.0 (±4.16)	0.0004*
Group-B (Propranolol)	12.07 (±3.99)	7.9 (±2.64)	<0.0001*
Group-C (Petasites)	13.77 (±5.40)	9.83 (±5.20)	0.0056*

CONCLUSION

In this study, a highest reduction of the mean VAS score and mean MIDAS score was observed in the group-A subjects who were prescribed with flunarizine when compare to the group-B and group-C subjects who were prescribed with propranolol and petasites respectively. It is the responsibility of the clinical pharmacists to get involved in the pharmaceutical care of the migraine patients along with the other health care professionals in order to increase the quality of life among them by managing the severity of pain and disability due to migraine.

Abbreviations

ICHD: International Classification of Headache Disorders; MIDAS: Migraine Disability Assessment Test; NSAIDs: Non-Steroidal Anti-Inflammatory Drugs; SPSS: Statistical Package for the Social Sciences; VAS: Visual Analogue Scale.

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CONFLICT OF INTEREST

None

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