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Original Research Article

Comparative Study of Safety and Efficacy of Flunarizine Versus Sodium Valproate In Prophylaxis of Patients of Migraine in A Tertiary Care Hospital

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Conflict of interest: Nil

Abstract

Introduction: Migraine is a headache disorder caused by release of pain-producing inflammatory substances around cranial nerves and blood vessels. Moderate-severe headache occurs, associated with nausea and vomiting (WHO), which leads to impaired quality of life. In this study, Flunarizine and Sodium Valproate were prescribed to assess the effect of migraine on disability and quality of life of participants.

Methods: Patients aged 18 years and above suffering from headache were selected after taking proper consent. Physiological parameters like Height, Body weight, Blood Pressure, Pulse rate and baseline investigations like Complete Blood Count, Kidney Function Test, Liver Function Test were safety parameters performed as screening procedures. Patients were also assessed by efficacy parameters like Migraine frequency, Migraine duration, Migraine Disability Assessment Scale (MIDAS) and Migraine Specific Quality of Life (MSQ) Questionnaire, version 2.1. Patients were divided into two groups, each with 60 patients, and administered tablet Flunarizine and tablet Sodium valproate once daily. Patients were followed up at 3- and 6-months interval with all efficacy and safety parameters.

Results: Regarding demographic profile we noted that most patients were females and were within age range of 20-40 years. Both drugs decreased migraine frequency, migraine duration and MIDAS score and increased MSQL score significantly after 6 months as compared to baseline. Flunarizine was slightly safer than valproate.

Conclusion: Both study drugs were very much effective in migraine prophylaxis in terms of efficacy and safety. While considering adverse events, prescribing flunarizine may be safer than valproate, though this finding has to be confirmed by more research.

Keywords: Migraine, MIDAS score, MSQL score, Flunarizine, Sodium valproate.

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Introduction

One of the most prevalent recurrent headache disorders is migraine, which is brought about by the CNS's heightened excitability.[1] The hallmark of migraine is the presence of a one-sided, pulsating headache that ranges in intensity from mild to severe. Normal physical activity frequently exacerbates the headache, which can occasionally be accompanied by nausea, vomiting, and increased sensitivity to light and sound.[2] According to American Migraine Prevalence and Prevention study report, incidence of migraine peaked in women between the ages of 20 to 24 years. (18.2/1000 person-years). Additionally, it was noted that women (43%) had a higher prevalence of occurrence than men (18%) in the population.[3]

Significant functional and quality-of life impairments are experienced by migraine sufferers as a result of the illness. These impairments include decreased occupational functioning, a diminished capacity for household chores, and restrictions on social and recreational activities as well as familial obligations.[4]

Management of migraine is a very challenging task. There are various pharmacological and non-pharmacological modalities of treatment of migraine. Non-pharmacological mode of management includes lifestyle and behavioural changes like avoidance of trigger factors, providing assurance and patient follow-up.[5]. Anti-migraine drugs used for prophylactic therapy are Beta-blockers (Propranolol), Calcium channel blockers (Flunarizine), Tricyclic antidepressants (Amitriptyline), and Anti-epileptics like Sodium valproate and Topiramate. Regardless of whether migraine attacks are recurrent or not, daily administration of anti-migraine drugs for prophylaxis should be continued.[6]

While there is a large range of medications available, flunarizine and sodium valproate are the two most often utilised alternatives in preventive therapy of migraine. Flunarizine has been proposed to act on the theories of channelopathy, cortical spreading depression and neurogenic inflammation by blocking the neuronal Ca2+ channels. Long-term flunarizine prophylaxis results in a significant reduction in disease frequency and severity, with manageable side effects.[7] Recommended dose is 10-20 mg/day for migraine prophylaxis.[8] Valproic acid is used for treating epilepsy of different seizure subtypes, management of bipolar disorder and prevention of migraine headaches.[9] Increases in inhibitory GABAergic neurotransmission mediated by valproate may reduce the aberrant cortical processes that cause migraine auras.[10] 400–1200 mg of valproic acid per day has some preventative effects on migraine.[8]

Few studies were carried out previously comparing the efficacy and safety profile of Flunarizine and Sodium valproate for migraine prophylaxis. These two drugs are available in the hospital medicine store, free of cost. Moreover, we didn't find any study where flunarizine and sodium valproate were compared using Migraine Specific Quality of Life (MSQ) Questionnaire, version 2.1 to assess the improvement in migraine prophylaxis of the patients. So, this study was conducted to find out which drug is safer and more effective in migraine prophylaxis and evaluate the best treatment option that can be helpful in treating patients suffering from migraine in future.

Objectives

Primary Objective: To compare the efficacy of flunarizine versus sodium valproate in prophylaxis of patients of migraine.

Secondary Objective:

i) To compare the safety of flunarizine versus sodium valproate in prophylaxis of patients of migraine.

ii) To assess the adverse events during the tenure of the study.

Methodology

Study Design: It was a prospective and observational study conducted in Medicine OPD and Department of Pharmacology at R. G. Kar Medical College and Hospital, Kolkata. The study was done for 18 months from July 2023 to January 2025.

Inclusion Criteria:

1. Patients of age 18 years and above.
2. Any gender.
3. Patients diagnosed with migraine based on International Headache Society criteria having more than 4 migraine attack per month who were not on flunarizine or sodium valproate prophylactic therapy were included in the study.

Exclusion Criteria:

1. Pregnant and lactating women.
2. Patients aged below 18 years.
3. Any other cause of headache.
4. Presence of any liver or kidney dysfunction, malignant tumour or on corticosteroids and immunosuppressants.
5. Hypersensitivity to flunarizine and sodium valproate.

Sample size: Sample size was calculated by formula $2\times (Z_\alpha+Z_\beta)^2 \times SD^2/d^2$ where Z_α is α error = 1.96, Z_β is β error = 0.84 at 95% confidence level, SD = Standard deviation, d=Mean difference. Sample size was found as 46 where 23 patients could be included in each group. Thus, a minimum of 52 patients (26 patients in each group) could be included in the study considering 10% dropouts. The sample size was calculated based on a similar previous study.[11]

Data Collection Procedure: For comparing efficacy patients were assessed by parameters like Migraine frequency which estimates the number of headache days per month, Migraine Duration which estimates that for how many hours the headache persists, MIDAS score – Migraine Disability Assessment test was used to estimate the intensity of headache. It contains 5 questions where each is answerable with number of days. Ultimately the sum of days is used for final score assessment. Greater score indicates more severe pain and associated disability.[12] The improvement in quality of life was assessed using Migraine Specific Quality of Life (MSQ) Questionnaire, version 2.1. It contains 3 parts where the first part represents Role Function Restrictive (RFR), second part represents Role Function Preventive (RFP), and third part represents Role Function Emotional (RFE). First part contains 7 questions, second part contains 4 questions and third part contains 3 questions. Final score ranges

from 0 to 100 in each part. Greater score denotes good quality of life.[13]

The study was carried out after obtaining approval from the Institutional Ethics Committee of R. G. Kar Medical College and Hospital (RKC/850) on 13/06/2023. Proper written informed consent was taken from every study patient before conducting the study, explained in detail about the study protocol and related hazards.

Non-contrast CT scan of brain was carried out in all study participants to rule out other causes of headache. Height, body weight, Blood Pressure (BP), Pulse rate of patients was recorded. All baseline investigations like Complete Blood Count (CBC), Kidney Function Test (KFT), Liver Function Test (LFT) were carried out as screening procedures for those who were enrolled in the study. Patients were also assessed on basis of Migraine frequency, Migraine duration, Migraine Disability Assessment Scale (MIDAS) and Migraine Specific Quality of Life (MSQ) Questionnaire, version 2.1. In one group tablet Flunarizine 10mg in Once Daily dose [8] was administered and in other group tablet Sodium Valproate 500mg in Once Daily dose [8] was administered. Patients were followed up at 3 month and 6-month interval with physical examination, laboratory investigations, MIDAS scale and MSQ Questionnaire. Also, any treatment emergent adverse events were noted for each follow up visit. Any withdrawals or dropouts were noted, along with the reason behind it.

Statistical Analysis: Data were entered in Microsoft Excel sheet and analysed by using SPSS 26 version software. Independent t-test and Mann-Whitney U test were performed to estimate the changes in the study parameters in between flunarizine and sodium valproate groups at different follow-up visits. Repeated measures ANOVA test and Friedman's ANOVA test were done to find out the improvement within a particular group. P value < 0.05 was taken as statistically significant.

Results

During the entire study period, a total of 120 patients satisfying the inclusion and exclusion criteria were enrolled for the study. But 5 patients were lost to follow up (2 patients from flunarizine group and 3 patients from sodium valproate group). So, the final analysis regarding efficacy and safety of flunarizine and sodium valproate drugs were done on 115 migraine patients.

Majority of the patients were females (65.20%) as compared to males (34.80%) to a great extent (Figure 1). Maximum number of patients belonged to age group of 20-40 years (66.08%) (Figure 2).

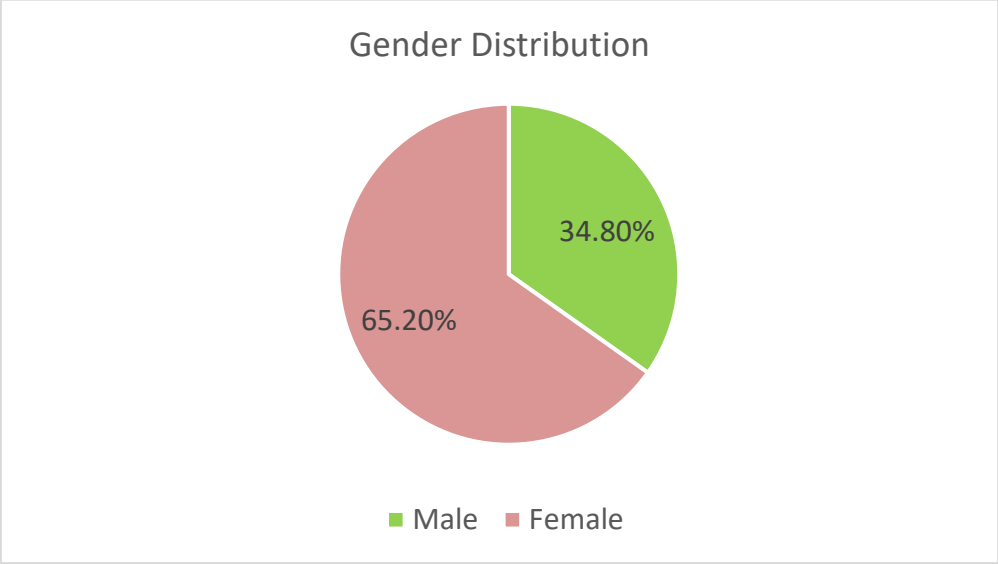

Figure 1: Gender Distribution

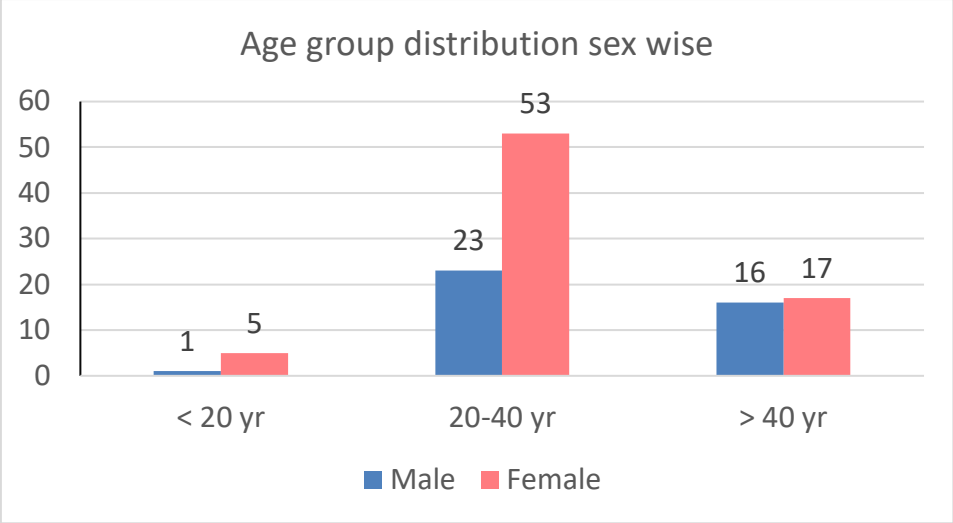

Figure 2: Age group distribution sex wise

The safety (Weight, SBP, DBP, Pulse rate, Platelet count, Creatinine, SGOT, SGPT) and efficacy parameters (Migraine Frequency, Migraine Duration, MIDAS score and MSQL score) of both flunarizine and sodium valproate groups showed no statistically significant difference and were comparable at baseline.

At first follow-up and second follow-up visits, Independent t-test was done to find out any statistically significant difference in terms of Migraine frequency, MSQL score (Role Function Restrictive, Role Function Preventive, Role Function Emotional). In case of Migraine duration and MIDAS score, Mann-Whitney U test was done.

While performing inter-group variation in case of migraine frequency, we found P value was statistically significant in first follow-up (0.031) visit (Table 1), but statistically non-significant in second follow-up (0.407) visit (Table 2). So, we can conclude that though migraine frequency decreased more in flunarizine group as compared to sodium valproate group in first follow-up visit but in second follow-up, both the drugs were equally effective in reducing migraine frequency.

There was no inter-group variation regarding migraine duration as we found that P value was statistically non-significant in first follow-up (0.797) visit (Table 1) and second follow-up (0.171) visit (Table 2). So, we can say that both the drugs were equally effective in decreasing duration of migraine headache.

There was no inter-group variation regarding MIDAS score as we found that P value was statistically non-significant in first follow-up (0.080) visit (Table 1) and second follow-up (0.167) visits (Table 2). So, we can say that both the drugs were equally effective in decreasing MIDAS score.

In case of Role Function Restrictive part of MSQL score, while doing inter-group analysis we found that P value was statistically non-significant (0.691) at 1st follow-up visit (Table 1) but statistically significant (0.021) at 2nd follow-up visit (Table 2). This concluded that the efficacy was more in flunarizine group than sodium valproate group in Role Function Restrictive part of MSQL score at 2nd follow-up visit.

For Role Function Preventive part of MSQL score, on inter-group analysis we observed that P value was statistically non-significant at 1st follow-up (0.521) visit (Table 1) and 2nd follow-up (0.555) visit (Table 2). So, we can say that both the drugs were equally effective in increasing the Role Function Preventive part of MSQL score.

For Role Function Emotional part of MSQL score, while performing inter-group variation we found that P value was statistically non-significant at 1st follow-up (0.782) visit (Table 1) and 2nd follow-up (0.088) visit (Table 2). So, we can say that both the drugs were equally effective in increasing the Role Function Emotional part of MSQL score.

The descriptive statistics of the safety parameters among the study groups (Weight, SBP, DBP, Pulse rate, Platelet count, Creatinine, SGOT, SGPT) of first follow-up visit is shown (Table 1). Independent t-test was done to find out any statistically significant difference between these parameters. It showed that the changes in the physiological parameters and laboratory investigations from baseline were more or less equivalent in the two groups.

The descriptive statistics of the safety parameters among the two study groups (Weight, SBP, DBP, Pulse rate, Platelet count, Creatinine, SGOT, SGPT) at 2nd follow-up visit is shown (Table 2). Independent t-test was done to find out any statistically significant difference between the parameters. No statistically significant difference

was found in the safety parameters in between the two groups.

Table 1: Efficacy and Safety Parameters at 1st Follow-Up Visit

Parameter	Group – 1 (Flunarizine)	Group – 2 (Sodium valproate)	P value
Migraine Frequency	3.34 ± 2.95	4.80 ± 4.13	*0.031
Migraine Duration	1 (0.5,1)	1 (0.5,1.25)	0.797
MIDAS	4 (2,5)	4 (2,7.5)	0.080
MSQL RFR	68.72 ± 8.39	68.07 ± 8.98	0.691
MSQL RFP	69.82 ± 7.25	68.86 ± 8.81	0.521
MSQL RFE	66.08 ± 9.77	65.61 ± 8.61	0.782
Weight	63.89 ± 10.67	64.29 ± 9.14	0.829
SBP	122.07 ± 10.02	120.12 ± 9.24	0.282
DBP	80.03 ± 4.80	78.52 ± 5.27	0.112
Pulse rate	78.70 ± 5.35	76.85 ± 4.79	0.054
Platelet count	224681.03 ± 43828.28	220649.12 ± 38416.18	0.601
Creatinine	0.91 ± 0.13	0.90 ± 0.09	0.944
SGOT	28.48 ± 5.69	28.29 ± 5.24	0.854
SGPT	28.37 ± 5.74	28.35 ± 4.78	0.987

Values are expressed in terms of Mean ± SD for Migraine frequency, MSQL RFR, MSQL RFP, MSQL RFE, Weight, SBP, DBP, Pulse rate, Platelet count, Creatinine, SGOT, SGPT. Values are expressed as Median (Q1, Q3) for Migraine duration and MIDAS Score. MIDAS: Migraine Disability Assessment Score, MSQL RFR: Migraine Specific Quality of Life (Role Function Restrictive) score, MSQL RFP: Migraine Specific Quality of Life (Role Function Preventive) score, MSQL RFE: Migraine Specific Quality of Life (Role Function Emotional) score, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, SGOT: Serum Glutamic Oxaloacetic Transaminase, SGPT: Serum Glutamic Pyruvic Transaminase.

2: Efficacy and Safety Parameters at 2nd Follow-Up Visit

Parameter	Group – 1 (Flunarizine)	Group – 2 (Sodium valproate)	P value
Migraine Frequency	1 (1,2)	1 (1,2)	0.407
Migraine Duration	0.5 (0.5,1)	1 (0.5,1)	0.171
MIDAS	1 (1,2)	2 (1,3)	0.167
MSQL RFR	75.76 ± 5.14	72.93 ± 7.63	*0.021
MSQL RFP	74.91 ± 4.44	74.38 ± 5.09	0.555
MSQL RFE	74.68 ± 7.10	72.63 ± 5.58	0.088
Weight	64.36 ± 10.65	64.87 ± 9.02	0.780
SBP	123.51 ± 10.16	122.70 ± 8.63	0.644
DBP	80.10 ± 4.45	79.68 ± 4.61	0.621
Pulse rate	79.10 ± 4.54	77.94 ± 4.53	0.175
Platelet count	229248.27 ± 59108.94	238842.10 ± 37110.25	0.300
Creatinine	0.92 ± 0.12	0.93 ± 0.11	0.715
SGOT	30.72 ± 4.63	31.87 ± 9.36	0.406
SGPT	30.70 ± 4.41	31.23 ± 7.41	0.644

Values are expressed in terms of Mean ± SD for MSQL RFR, MSQL RFP, MSQL RFE, Weight, SBP, DBP, Pulse rate, Platelet count, Creatinine, SGOT, SGPT. Values are expressed as Median (Q1, Q3) for Migraine frequency, Migraine duration and MIDAS Score. MIDAS: Migraine Disability Assessment Score, MSQL RFR: Migraine Specific Quality of Life (Role Function Restrictive) score, MSQL RFP: Migraine Specific Quality of Life (Role Function Preventive) score, MSQL RFE: Migraine Specific Quality of Life (Role Function Emotional) score, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, SGOT: Serum Glutamic Oxaloacetic Transaminase, SGPT: Serum Glutamic Pyruvic Transaminase.

In the study, we have encountered a total of 105 adverse events in 115 patients with 0.929 adverse events per patient (Figure 3). Patients in sodium valproate group suffered more adverse events (69.52%) as compared to flunarizine group (30.48%). Sedation and weight gain were the common adverse events in both the groups. Liver enzymes were found raised in 3 patients in sodium valproate group. 3 patients also suffered from menstrual irregularity in sodium valproate group.

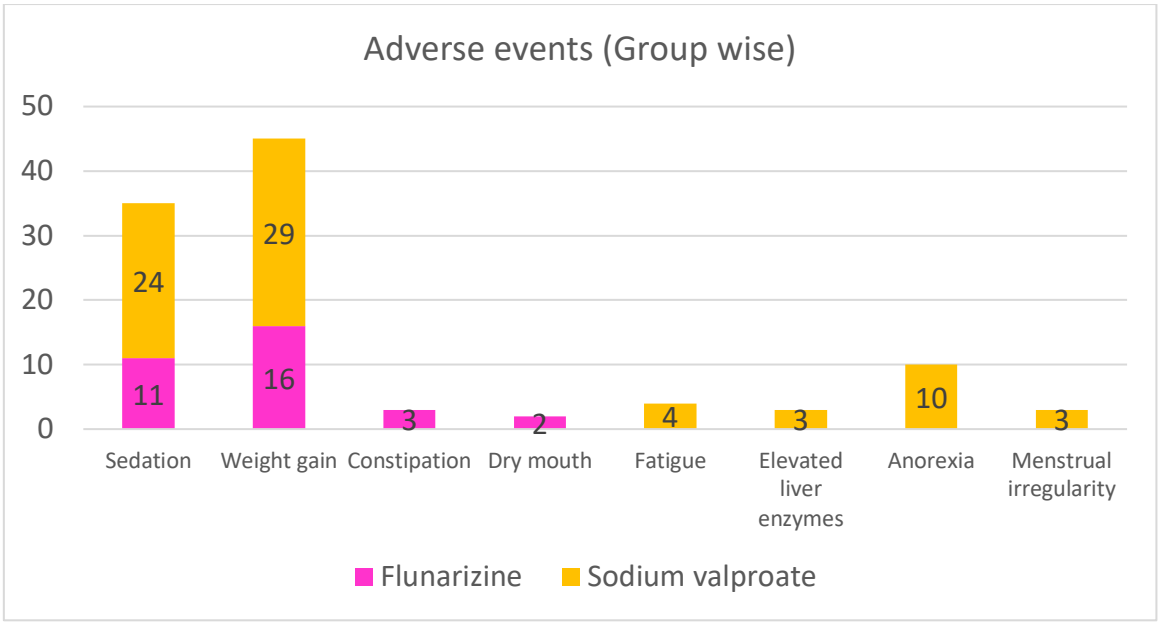

Figure 3: Treatment emergent adverse events – group wise

Discussion

Despite the availability of numerous treatment alternatives, migraine management has not achieved the expected level. Also, migraine patients suffer from significant disability and quality of life impairments. Low quality of life frequently interferes with patient compliance and medication adherence. Long term use of these migraine medications often leads to various adverse events. As a result, it is critical to determine the best pharmacological treatment in terms of efficacy and safety. After thorough search of published literature, we have found only two studies in which flunarizine and sodium valproate were used for comparing efficacy and safety for prophylactic treatment of migraine in OPD settings. We have also found some studies that included any one of the investigational drugs in comparison with some other drugs.

Samira Khani et al. conducted a comparative study which was a single-centre placebo-controlled double-blind randomized trial on migraine patients within the age range of 18-65 years.[14] Majid F. Bhat et al. conducted a 12-week prospective, randomized, comparative, open-label study on migraine patients aged 18 to 65 years.[15] In our study, we enrolled patients diagnosed case of migraine whose age was 18 years and above.

In our study regarding demographic profile, we noted that out of these 115 patients, most of the patients were within the age range of 20-40 years. (66.08%, 23 male and 53 female patients). It was also found that majority of the patients suffering from migraine were females (65.20%). Majid F. Bhat et al. [15], Shibata M et al. [4] also found female preponderance in their study.

Majid F. Bhat et al. conducted a randomized, open, comparative study on evaluation of propranolol, flunarizine and divalproex sodium in migraine prophylaxis. All the drugs led to significant decrease in migraine frequency, migraine duration and MIDAS score. Thus, all the three drugs were equally effective and had acceptable tolerability profile. Divalproex sodium group showed more side effects but none of them were serious.[15]

Bajaj V A et al. conducted a randomized, prospective observational comparative study on the effect of sodium valproate and flunarizine on psychomotor performance in patients of common migraine. No statistical significance was found in frequency, duration, severity of headache, critical flicker fusion test, arithmetic ability test, hand steadiness test, reaction time monitoring when flunarizine was compared to valproate. Both flunarizine and sodium valproate were observed to be efficacious equally for improving psychomotor performance.[11]

J Kalita et al. conducted a randomized controlled open-labelled study to evaluate the efficacy and safety of amitriptyline versus divalproate in migraine prophylaxis. The divalproate group showed a substantial improvement in headache frequency compared to amitriptyline group after 3 months. However, at 6 months, there was no significant difference in response between the two groups. The severity of headache reduced in both the groups at 3 months and 6 months compared to baseline, although there was no statistically significant difference between the divalproate and amitriptyline groups at 3 months and 6 months. Drowsiness and dry mouth were the common adverse effects in amitriptyline group, while hair

loss, menstrual irregularity, gastro intestinal symptoms, weight gain, and polycystic ovary syndrome were more common adverse effects in the divalproate group.[16]

After thorough literature search, we did not find any study where efficacy was compared between flunarizine and sodium valproate using Migraine-Specific Quality-of-Life Questionnaire (MSQ) Version 2.1 on migraine patients. But we found a similar type study conducted by Shibata M et al. where they used Migraine-Specific Quality-of-Life Questionnaire (MSQ) Version 2.1 to find out the efficacy of Galcanezumab on patients suffering from migraine. They divided the migraine patients into groups receiving placebo, Galcanezumab 120 mg, Galcanezumab 240 mg respectively and found that preventive treatment with Galcanezumab 120 mg and 240 mg improved MSQL score in patients of episodic migraine.[4]

In our study we have done the treatment by administering Tablet Flunarizine 10 mg and Tablet Sodium valproate 500 mg both once daily orally. We found that both the drugs were very much effective in reducing migraine frequency, migraine duration, MIDAS score and in improving quality of life in two follow-up visits, but no significant changes were noted between the two treatment groups. Headache reduced earlier in flunarizine group than in valproate group. Previous studies also reported similar results.

Conclusion

In this prospective, observational study, we found that both flunarizine and sodium valproate were highly efficacious in prophylaxis of migraine patients in terms of efficacy and safety. Both drugs significantly decreased the migraine frequency, migraine duration and MIDAS score and significantly increased the MSQL score at 1st follow-up and 2nd follow-up visits as compared to baseline. Prescribing flunarizine may be safer than sodium valproate as more adverse events were found to occur with sodium valproate. Further studies with a greater number of people and for longer duration is required to confirm this finding.

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Data collection- Tamasi Choudhury
Data analysis and interpretation- Ratul Banerjee, Tamasi Choudhury
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Critical review- Lopamudra (Dhar) Chowdhury, Ramtanu Bandyopadhyay
Article editing- Ratul Banerjee, Tamasi Choudhury
Final approval- Lopamudra (Dhar) Chowdhury, Ramtanu Bandyopadhyay

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