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Comparative Study of Safety and Efficacy of Amitriptyline versus Sodium Valproate in Prophylaxis of Patients of Migraine in a Tertiary Care Hospital

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ABSTRACT

Background: Migraine is the second most common cause of headache which affects 15% of women and 6% of men over a period of one year. Amitriptyline and sodium valproate are the two most commonly used drugs for migraine prevention and there are few studies comparing their efficacy and safety. So, this study was carried out to compare safety and efficacy of amitriptyline and sodium valproate in migraine prophylaxis.

Methods: Patients with headache, aged 18 years and above were selected after obtaining proper consent. Physiological parameters like Height, Body weight, Body Mass Index, and Blood Pressure and baseline investigations like Complete Blood Count, Kidney Function Test, Liver Function Test were safety parameters recorded during screening. Efficacy parameters like Migraine frequency, Migraine duration, Migraine Disability Assessment Scale (MIDAS) and Migraine Specific Quality of Life (MSQL) Questionnaire, version 2.1 were taken into account. Patients were divided up into two groups, each with 60 patients, and given tablet amitriptyline and sodium valproate once daily. At 3- and 6-month intervals, patients were assessed with above safety and efficacy parameters.

Results: In demographic profile, we noted that majority of patients were female and between ages of 20 and 40 years. Both medications considerably reduced migraine frequency, migraine duration and MIDAS score and increased MSQL score after 6 months compared to baseline. Amitriptyline was found safer than valproate.

Conclusion: Both the study drugs used for migraine prophylaxis were effective and improving quality of life. Amitriptyline is slightly safer according to statistics. Additional research is required to corroborate the findings.

Key-words: Amitriptyline, Migraine, MIDAS score, MSQL score, Sodium valproate

INTRODUCTION

A complicated neurological illness with a genetic component, migraine is typified by episodes of moderate-to-severe headaches, usually unilateral, often accompanied by nausea and increased sensitivity to light and sound.[1]

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Originating from the ancient Greek word *hemikranios*, which means "half head," the term *migraine* emphasises the unilateral distribution of head pain that affects roughly 60–75% of migraineurs. In the general population, 12% of people suffer from migraines within a year, with 18% of women and 6% of men affected.[2] According to the 2010 Global Burden of Disease Survey, migraine was the third most common disorder globally and the seventh-highest specific cause of disability.[3]

It was found that migraine sufferers' quality of life is severely impaired, leading to substantial disability. Patients who experienced frequent episodes were shown to have psychological, social, intellectual, and occupational effects. Migraine headaches lower

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productivity, cause lost work or school days, and put a financial strain on people due to the expense of the treatments.[4]

Tricyclic antidepressants (Amitriptyline), beta-blockers (Propranolol), calcium channel blockers (Flunarizine), and anti-epileptic medications (Sodium Valproate and Topiramate) are examples of anti-migraine medications used as preventive therapy. Prophylactic anti-migraine medications should be taken daily, regardless of whether migraine attacks occur frequently or not. Preventive treatment aims to reduce migraine attacks' frequency, intensity, and duration.[5]

Although there are many different drugs available, the two most typically used alternatives in migraine prevention therapy are amitriptyline and sodium valproate. Amitriptyline's antimigraine actions most likely come from its effects on serotonergic transmission since tricyclic antidepressants prevent 5-HT from being taken up in the synaptic cleft. In addition, inhibition of reuptake of noradrenaline increases noradrenaline concentrations in the synaptic cleft, which could have antinociceptive effects via activating α_2-adrenoreceptors.[6] Recommended dose of amitriptyline is 25-100 mg/day for migraine prophylaxis.[7] Valproic acid is used to treat bipolar disorder, reduce migraine headaches, and treat epilepsy of various seizure subtypes.[8] Valproate-mediated increases in inhibitory GABAergic neurotransmission may lessen the abnormal cortical processes that result in migraine auras.[9] For migraine prophylaxis, the recommended dose of sodium valproate is 400-1200 mg/day.[7]

No previous research was found that used Migraine Specific Quality of Life (MSQ) Questionnaire, version 2.1 to compare and assess the preventive effects of amitriptyline and valproate in migraine patients. Moreover, these two medications are offered free of cost in the hospital pharmacy. Also, very few studies were conducted previously on efficacy of amitriptyline and sodium valproate on migraine prophylaxis, where there weren't many differences found in terms of efficacy and safety. Therefore, the purpose of this study was to determine which medication is safer and more successful for preventing migraines and to assess the best course of action for treating migraine sufferers in the future.

MATERIALS AND METHODS

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 12 months from December 2023 to November 2024.

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 52 where 26 patients could be included in each group. Thus considering 10% dropouts, a minimum of 58 patients (29 patients in each group) could be included in the study. The sample size was calculated from a similar previous study.[10]

Inclusion criteria

1. Age of patients 18 years and above of any gender.
2. Patients diagnosed with migraine based on International Headache Society criteria having more than 4 migraine attack per month who were not on any prophylactic anti-migraine therapy were included in the study.

Exclusion criteria

1. Pregnant and lactating women.
2. Patients below 18 years of age.
3. Any other cause of headache.
4. Patients taking amitriptyline or sodium valproate for any other therapeutic indication.
5. Presence of any liver or kidney dysfunction, malignant tumour or on corticosteroids and immunosuppressants.
6. Hypersensitivity to amitriptyline and sodium valproate.

Procedure- While comparing efficacy, patients were assessed with parameters like Migraine Frequency which measures 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. The sum of days is used for assessment of final score. Greater score denotes more severe pain and associated disability.[11] The improvement in quality of life was assessed using MSQ Questionnaire, version 2.1. It consists of 3 parts

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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. In each part, final score ranges from 0 to 100. Greater score indicates good quality of life [12]. The study was conducted after getting approval from the Institutional Ethics Committee of R. G. Kar Medical College and Hospital (RKC/1019) on 23/11/2023. Proper written informed consent was obtained from every study participant before conducting the study.

Non-contrast CT scan of brain was done in every patient to rule out other causes of headache. Height, body weight, Body Mass Index (BMI), and Blood Pressure (BP), of patients were noted. All baseline investigations like Complete Blood Count (CBC), Kidney Function Test (KFT), Liver Function Test (LFT), were done as screening procedures for those who were selected for the study. Patients were also assessed in terms of Migraine frequency, MIDAS and MSQ Questionnaire, version 2.1. The following drugs were administered in the two groups by consultant physician.

Group 1: Tablet Amitriptyline 25mg Once Daily dose [7]

Group 2: Tablet Sodium Valproate 500mg in Once Daily dose [7]

Patients were followed up at 3-month and 6-month intervals by physical examination, laboratory investigations, MIDAS scale and MSQ Questionnaire. Also, any treatment-emergent adverse events were recorded for each follow-up visit. Any withdrawals or dropouts were recorded, along with the reasons behind them.

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 done to estimate the changes in the study parameters in between amitriptyline 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

A total of 120 patients who met the inclusion criteria were enrolled in the study during the entire study duration. However, seven patients were lost to follow-up: three from the sodium valproate group and four from the amitriptyline group. Thus, the final evaluation of the safety and efficacy of amitriptyline and sodium valproate medications was conducted on 113 migraineurs. Majority of the patients were females (67.30%) as compared to males (32.70%) (Fig. 1) Maximum number of patients belonged to age group of 20-40 years (64.60%) (Fig. 2).

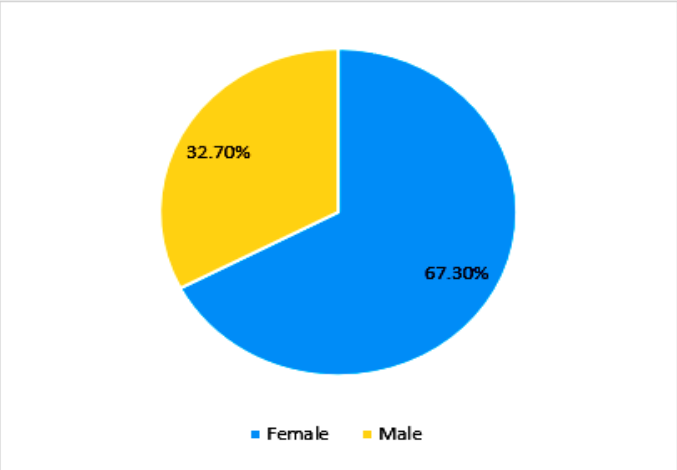

Fig. 1: Gender distribution

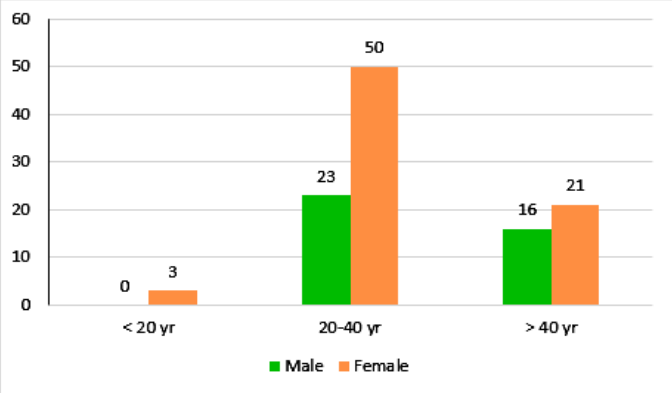

Fig. 2: Age group distribution sex wise

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

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

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frequency and MIDAS score, Mann-Whitney U test was performed.

There was no inter-group variation regarding migraine frequency as we found that p-value was statistically non-significant in both first follow-up (0.076) visit (Table 1) and second follow-up (0.495) visit (Table 2). So, we can say that both the drugs were equally effective in reducing migraine frequency.

No inter-group variation was found regarding migraine duration as the p-value was statistically non-significant in first follow-up (0.521) visit (Table 1) and second follow-up (0.561) 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 observed that p-value was statistically non-significant in first follow-up (0.055) visit (Table 1) and second follow-up (0.179) visits (Table 2). So, we can say that both the drugs were equally effective in decreasing MIDAS score.

For Role Function Restrictive part of MSQL score, on inter-group analysis we noted that p-value was statistically non-significant at 1st follow-up (0.223) visit (Table 1) and 2nd follow-up (0.201) visit (Table 2). So, we can say that both the drugs were equally effective in increasing the Role Function Restrictive part of MSQL score.

In case of Role Function Preventive part of MSQL score, while doing inter-group analysis we found that p-value was statistically non-significant (0.237) at 1st follow-up visit (Table 1) but statistically significant (0.019) at 2nd follow-up visit (Table 2). This concluded that the efficacy was more in amitriptyline group than sodium valproate group in Role Function Preventive part of MSQL score at 2nd follow-up visit.

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 (0.446) visit (Table 1) and 2nd follow-up (0.910) 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 (BMI, SBP, DBP, 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 in 1st follow-up visit were more or less equivalent in the two groups.

The descriptive statistics of the safety parameters among the two study groups (BMI, SBP, DBP, 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 any of the safety parameters in the 2nd follow-up visit as p-value was more than 0.05.

Table 1: Efficacy and safety parameters at 1st follow-up visit

Parameter	Group – 1 Amitriptyline	Group – 2 Sodium Valproate	p-value
Migraine Frequency	3 (2,4.75)	4 (2,6)	0.076
Migraine Duration	1.02 ± 0.51	1.10 ± 0.76	0.521
MIDAS	3 (2,5)	4 (2,7.5)	0.055
MSQL RFR	65.89 ± 9.92	68.07 ± 8.98	0.223
MSQL RFP	66.96 ± 8.13	68.86 ± 8.81	0.237
MSQL RFE	66.96 ± 10.09	65.61 ± 8.61	0.446
BMI	25.06 ± 3.13	25.72 ± 3.23	0.267
SBP	125.11 ± 10.73	120.12 ± 9.25	0.107
DBP	80.71 ± 4.68	78.53 ± 5.27	0.256

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Platelet	243660.71 ± 30763.78	220649.12 ± 38416.18	0.211
Creatinine	0.84 ± 0.12	0.90 ± 0.09	0.436
SGOT	26.75 ± 5.56	28.29 ± 5.24	0.131
SGPT	27.06 ± 5.32	28.36 ± 4.78	0.177

Values are expressed in terms of Mean ± SD for Migraine duration, MSQL RFR, MSQL RFP, MSQL RFE, BMI, SBP, DBP, Platelet, Creatinine, SGOT, SGPT. Values are expressed as Median (Q1, Q3) for Migraine frequency 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

Table 2: Efficacy and safety parameters at 2nd follow-up visit

Parameter	**Group – 1 Amitriptyline**	**Group – 2 Sodium Valproate**	**p-value**
Migraine Frequency	1 (1,2)	1 (1,2)	0.495
Migraine Duration	0.83 ± 0.41	0.88 ± 0.44	0.561
MIDAS	1 (1,2)	2 (1,3)	0.179
MSQL RFR	71.07 ± 7.72	72.93 ± 7.63	0.201
MSQL RFP	74.67 ± 6.97	71.39 ± 5.09	*0.019
MSQL RFE	72.76 ± 7.00	72.63 ± 5.58	0.910
BMI	25.16 ± 3.18	25.96 ± 3.22	0.185
SBP	125.50 ± 10.38	122.70 ± 8.64	0.122
DBP	81.11 ± 4.74	79.68 ± 4.61	0.109
PLATELET	248875.00 ± 30103.49	238842.11 ± 37110.25	0.118
CREATININE	0.85 ± 0.12	0.93 ± 0.11	0.244
SGOT	27.19 ± 5.33	37.38 ± 16.47	0.643
SGPT	33.14 ± 12.95	37.61 ± 16.83	0.448

Values are expressed in terms of Mean ± SD for Migraine duration, MSQL RFR, MSQL RFP, MSQL RFE, BMI, SBP, DBP, Platelet, Creatinine, SGOT, SGPT. Values are expressed as Median (Q1, Q3) for Migraine frequency, 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

A total of 113 patients experienced 66 adverse events during the course of the study (Fig. 3). Compared with the amitriptyline group (34.85%), patients in the sodium valproate group experienced more adverse events (65.15%). The most frequent adverse events in both groups were sedation and weight gain. Twelve of the participants in the sodium valproate group had elevated liver enzymes. In addition, three patients in the sodium valproate group experienced irregular menstruation.

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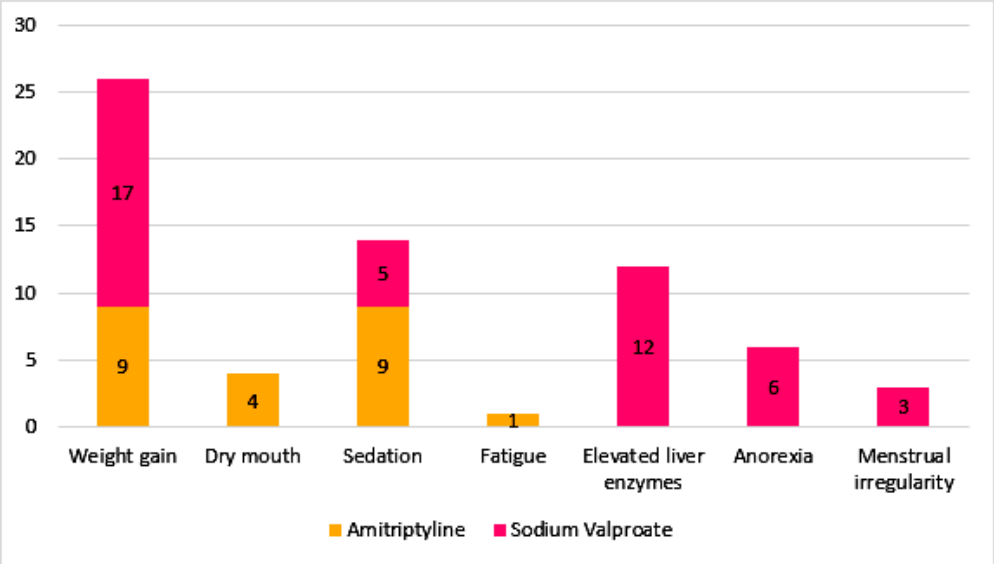

Fig. 3: Treatment emergent adverse events – group-wise

DISCUSSION

A randomised controlled open-label trial was carried out by Kalita *et al.* to compare the safety and efficacy of amitriptyline and divalproate in the prophylaxis of migraines. After three months, the divalproate group significantly reduced the frequency of headaches when compared to the amitriptyline group. Nevertheless, there was no discernible difference in the two groups' responses at six months. There was no statistically significant difference in headache severity between the divalproate and amitriptyline groups at 3 and 6 months, both groups experienced a decrease in headache severity as compared to baseline. The common adverse effects in amitriptyline group were drowsiness and dry mouth, while hair loss, gastrointestinal symptoms, menstrual irregularity, weight gain, and polycystic ovary syndrome were more common adverse effects in the divalproate group.[13]

A randomised, open, comparative study evaluating the efficacy of propranolol, flunarizine, and divalproex sodium in migraine prevention was carried out by Bhat *et al*. The migraine frequency, migraine duration, and MIDAS score were all significantly reduced by all of the medications. All three medications had acceptable tolerability profile and were equally effective. There were more adverse effects in the divalproex sodium group, but none of them was serious.[3]

Jyothi *et al.* conducted a prospective, comparative open-label study to evaluate the efficacy, safety and tolerability of oral propranolol with oral amitriptyline for prophylaxis in migraine patients.

As the length of treatment increased the mean number of migraine attacks in the Amitriptyline and Propranolol groups reduced. We observed that amitriptyline was superior to propranolol in terms of reducing the frequency, length, and intensity of attacks with significant p-values.[14]

In a randomised, prospective, parallel, open-label study, Dakhale *et al.* compared low-dose sodium valproate versus low-dose propranolol for the prevention of common migraine headaches. They discovered that while both medications decreased migraine headache severity, frequency, and duration, propranolol significantly reduced headache severity more than sodium valproate. Both drugs were well tolerated.[15]

Following a comprehensive review of the literature, we were unable to locate any studies that compared the efficacy of sodium valproate and amitriptyline in treating migraine patients using the Migraine-Specific Quality-of-Life Questionnaire (MSQ) Version 2.1. However, we discovered a similar study by Shibata *et al.* in which they assessed the efficacy of galcanezumab on migraine patients using the MSQ Version 2.1. They separated the migraine patients into groups that received a placebo, 120 mg of galcanezumab, and 240 mg of galcanezumab, respectively. Patients with episodic migraine showed improved MSQL scores after receiving preventive medication with Galcanezumab 120 mg and 240 mg. [16]

Amitriptyline 25 mg and sodium valproate 500 mg tablets were given orally once a day as part of the treatment in our study. In two follow-up visits, we noticed that both the drugs were highly effective in

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reducing migraine frequency, migraine duration, MIDAS score and in improving the quality of life. But no significant differences were noted between the two treatment groups. Previous research has also revealed similar results.

CONCLUSIONS

The result of this prospective, observational study shows that prophylactic treatment either with amitriptyline or sodium valproate were equally effective in reducing the migraine frequency, migraine duration and MIDAS score at 1st follow-up and 2nd follow-up visits. Improvement of quality of life was also noticed with both amitriptyline and sodium valproate as there was a significant increase in MSQL score in both follow-up visits. Thus, both the drugs were observed to be highly efficacious in terms of safety and efficacy for migraine prophylaxis. Considering that sodium valproate was proven to cause greater adverse events, prescribing amitriptyline may be safer. To validate this result, more research involving a larger sample size and a longer time frame is needed.

CONTRIBUTION OF AUTHORS

Research concept- Tamasi Choudhury
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Supervision- Lopamudra (Dhar) Chowdhury
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Critical review- Lopamudra (Dhar) Chowdhury
Article editing- Ratul Banerjee, Tamasi Choudhury
Final approval- Lopamudra (Dhar) Chowdhury

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