

A study of drug prescription patterns, disease-therapy awareness and of quality of life among patients with migraine visiting a tertiary care hospital in Mumbai, India

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Received: 11 September 2023

Revised: 05 October 2023

Accepted: 06 October 2023

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ABSTRACT

Background: Migraine is one of the leading causes of disability globally. There is scarcity of data on disease -therapy awareness and its correlation with demographic factors. Hence its was of interest to assess those along with quality of life in these patients.

Methods: A Cross-sectional observational study was conducted in 108 patients attending the Neurology and headache OPD at a tertiary care hospital between March 2017 and August 2018. Disease and therapy awareness among patients were evaluated using validated questionnaires and correlation was done with demographic factors. The severity of the disease and its impact on the patients' quality of life were assessed using the migraine disability assessment scale.

Results: The mean disease and therapy awareness scores were 9 and 7 respectively. Both had a positive correlation with education and socioeconomic factors. The quality of life was affected moderately in 48.1% of the patients followed by severely 32.4% of the patients. The average number of drugs prescribed per encounter was 3.05. NSAIDS were used more commonly as compared to Triptans for acute attacks.

Conclusions: The disease and therapy awareness were fair and positively correlated with education/ socioeconomic status. However, a significant disability was found among patients even with treatment. This highlights the need for educating these patients for effectively controlling the disability.

Keywords: Drug prescription patterns, Disease therapy awareness, Migraine

INTRODUCTION

Migraine is a common, chronic, incapacitating complex neurovascular disorder that manifests as recurrent attacks of moderate to severe headache lasting 4-72 hours, and autonomic nervous system dysfunction. The headache is typically unilateral, has a pulsating quality, is aggravated by routine physical activity and is associated with nausea and/or sensitivity to light and sound.¹ It is ranked as the third most common disease worldwide, with a lifetime

prevalence of 15-19% affecting up to one billion people across the globe and affects more females than males, during the ages of 15-49 years, with a peak in prevalence between ages 35 and 39 years.^{2,3} In a recent study, migraine was reported as highly prevalent ailment with age-standardized prevalence of one-year being 25.2% in the state of Karnataka in India.⁴ Presently, though a few therapeutic guidelines for management of migraine exist.⁵⁻⁸ There is scarcity of data about the awareness about the disease & therapy, drug prescription patterns for migraine

as well as the quality of life (QOL) in these patients. This study was conducted to assess the awareness and correlation with demographic factors, prescription pattern of drugs and to assess the quality of life in migraine patients.

Objectives

Primary objective was to study current prescription pattern for acute attack & prophylaxis of Migraine in Neurology OPD and Headache OPD of a tertiary care hospital. Secondary objectives were to assess the awareness of migraine patients regarding the disease & the therapy being received and correlation of awareness with demographic factors and to assess severity of disease and quality of life (QOL) in migraine patients.

METHODS

This was a prospective, cross sectional observational study conducted among migraine patients attending Headache OPD and/or Neurology OPD at a tertiary care hospital. Convenience sampling was used and 108 patients were recruited between March 2017 to August 2018.

Inclusion criteria

Patients of either sex, aged ≥ 18 and ≤ 60 years, Diagnosed of Migraine as per International Classification of Headache Disorders (ICHD) Criteria (2013)¹, attending Headache OPD and/or Neurology OPD at a tertiary care hospital since at least last 6 weeks and those willing to give informed voluntary consent were included.

Exclusion criteria

Patients with history of epilepsy, heart disease kidney disease, stroke, insulin dependent diabetes, tuberculosis, clinically significant ECG abnormality, substance addiction, hypersensitivity, intolerance or contraindication to use of migraine medication or those having medication overuse headaches or those with other pain diagnosis as primary presenting condition or those unable to comprehend, record information in questionnaires or unwilling to give written informed consent were excluded from the study.

Study tools and procedure

Following the ethics committee approval all eligible patients were screened and enrolled after fulfilling the inclusion/exclusion criteria. A written informed consent was obtained and following data was captured from the case papers of participants. Demographic details and disease information, Details of the prescription included name of prescribed drug, whether branded or prescribed by generic name, class of drug, Completeness of prescription along with prescribed daily dose (PDD) and defined daily dose (DDD), Awareness about migraine and its treatment was assessed by using two prevalidated questionnaires

namely, patient disease awareness questionnaire, therapy awareness questionnaire and for disease severity and its impact on quality of life was assessed by migraine disability assessment scale (MIDAS).^{9,10}

Data analysis

Data was analyzed using SPSS (V. 26) software in which descriptive statistics, Pearson’s correlation test and Spearman's correlation test was applied at a significance level of $p < 0.05$.

RESULTS

Demographic profile

A total of 108 patients were enrolled and demographics and disease profile has been summarized in (Table 1). 89 (82.4%) patients had migraine without aura as compared to 19 (17.6%) who had it with aura. 87 (80%) had episodic migraine as compared to 21 (19.4%) who had chronic migraine. 45 (41.7%) patients had a disease duration ranging from 1-5 years followed by 28 (25.9%) having duration of 6-10 years and very few patients 3 (2.8%) had disease duration less than a year.

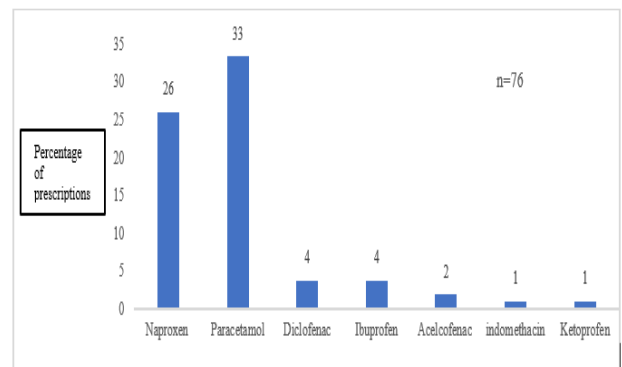


Figure 1: Percentage of prescriptions in which analgesics were prescribed for acute attacks of migraine.

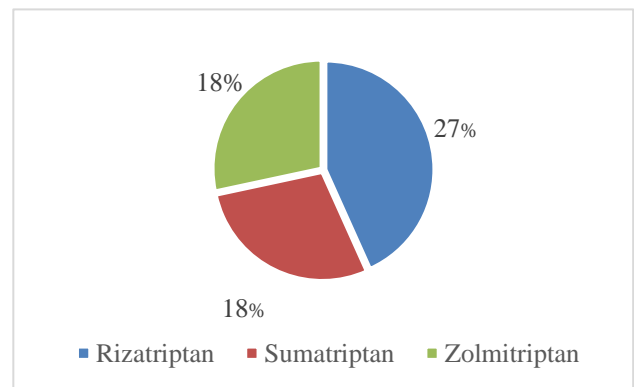


Figure 2: Percentage of prescriptions in which Triptans were prescribed for acute attacks of migraine (n=57).

Table 1: Demographic and disease profile (n=108).

Demographic details	N	%	
Gender	Male	32	29.6
	Female	76	70.4
Age (years)	18-20	8	7.4
	21-29	24	22.22
	30-39	33	30.55
	40-49	26	24.07
	50-59	17	15.74
Socioeconomic class (as per modified Kuppuswamy scale)	Upper class (26-29)	11	10.2
	Upper middle (16-25)	28	25.9
	Lower middle (11-15)	44	40.7
	Upper lower (5-10)	17	15.7
	Lower (Less than 5)	8	7.4
Literacy	Post graduate or professional degree	25	23.15
	Graduate degree	16	14.81
	Higher secondary certificate	13	12.03
	High school certificate	14	12.96
	Middle school certificate	15	13.88
	Literate (less than middle school certificate)	18	16.67
	Illiterate	7	6.48

Drug prescription patterns

The (Table 2) shows prescription patterns as per WHO indicators. Most drugs (86.36%) were prescribed by brand names and average number of drugs prescribed per encounter was 3.05. Regarding completeness of prescription 71% were complete and 37% were incomplete. Out of all the incomplete prescriptions, 49% had missing instructions and 23.15% failed to mention non-pharmacological methods. The (Table 3) depicts PDD, DDD and the of PDD/DDD ratio. The ratio of PDD/DDD was found to be less than 1.1 with all drugs.

Table 2: Prescription pattern indicators.

WHO Drug use indicators	Value
Average number of drugs per encounter	3.05
Percentage of drugs prescribed by brand names	86.36%
Percentage of drugs prescribed by generic names	13.63%
Percentage of drugs prescribed from the formulary	14.24%

The (Figure 1) depicts the Percentage of prescriptions in which of Analgesics were used for acute attack. Paracetamol (30 %) and naproxen were used most commonly alone as well as in FDC. The (Figure 2) depicts triptan use. Rizatriptan was used most commonly alone followed by Sumatriptan which also used as FDC.

Prokinetics and antiemetics were used in 54/108 patients of whom 42 were prescribed and Domperidone 12 were prescribed metoclopramide. Antacids were used in 41/108 patients, of whom was 29 were ranitidine and 12 were prescribed pantoprazole Caffeine was used in combination with other drugs in only 7/108 (2%) patients. Prophylactic drugs used are shown in the (Figure 3). Propranolol (28 %) was most prescribed followed by nortriptyline.

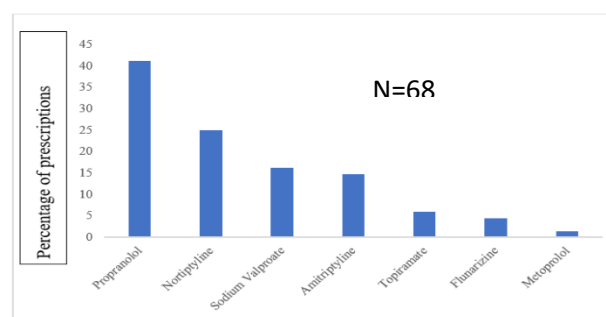


Figure 3: Percentage of prescriptions in with Prophylactic drugs for migraine were prescribed (n=68).

Disease and therapy awareness

The median disease awareness score patients were 9 in the scoring range from -17 to +10. All 108 patients were aware of disease and duration. 84.3% knew about the triggers and 82.4% knew how to avoid triggers, 62 % sought advice from health care workers to improve migraine.

Table 3: Prescribed daily dose and defined daily dose and Ratio PDD/DDD.

Drugs with PDD/DDD <1	Drugs with PDD/DDD=1	Drugs with PDD/DDD >1
Triptans		
Sumatriptan 25 mg oral, Rizatriptan 5 mg oral.	Sumatriptan 20mg (nasal), 50 mg (oral); Rizatriptan 10 mg oral, Zolmitriptan 2.5 mg oral	Sumatriptan 100mg oral, Zolmitriptan 5 mg nasal
NSAIDs & Paracetamol		
Paracetamol 1 gm oral, Diclofenac 50 mg oral, Aspirin 350 mg oral, Ibuprofen 400 mg oral, Indomethacin 25 mg oral.	Naproxen 500 mg oral, Diclofenac 100 mg oral, Aceclofenac 200 mg oral, Ketoprofen 150 mg oral.	
Other drugs		
Domperidone 10 mg oral, Metoclopramide 5, 10 mg oral, Ranitidine 150 mg oral, Pantoprazole 20 mg oral	Pantoprazole 40 mg oral	
Drugs used for prophylaxis of migraine		
Propranolol 20,40,80 mg oral, Metoprolol 50 mg oral, Flunarizine 5 mg oral, Topiramate 25,50,100 mg oral, Sodium valproate 400 mg oral, Amitriptyline 10,25 mg oral, Nortriptyline 15 mg oral/	Flunarizine 10 mg oral.	

Table 4: Correlation of demographic factors with disease awareness.

Demographic factor	Correlation coefficient (ρ) for disease awareness	P value	Correlation coefficient (ρ) for therapy awareness	P value
Age	-0.032	0.744	0.018	0.855
Education	0.747**	0.000	0.837**	0.000
Duration of disease	0.137	0.159	0.098	0.315
Socio-economic status	0.711**	0.000	0.796 **	0.000

**Correlation is significant at the 0.01 level (2-tailed)

However, 52.8% of the patients also had collected information on migraine from a source other than health care providers. Median therapy awareness score was 7 in the scoring range from -13 to +12. 81% of patients knew about drugs for acute attack and for prophylaxis. 49% named all the drugs correctly. However, 62.2% of patients were unaware about the maximum safety dose of the drugs, 84.3% were unaware that Ergotamine and Triptans cannot be taken together, 62% per unaware about the side effects of the drugs being prescribed to them 82.4% of the patients were unaware of the conditions when the medicines are to be avoided. Correlation analysis of demographic factors with disease and therapy awareness has been shown in (Table 4). A strong positive correlation was found between education and socioeconomic status for disease as well as therapy awareness.

As shown in (Table 5) the quality of life was affected moderately in 48.1% of the patients followed by severely 32.4% of the patients with migraine. When analyzed gender-wise, a greater number of males (62.5%) had moderate disability, while a greater number of females (35.5%) suffered from severe degree of disability. Out of 108 participants, 71 (65.74%) were on prophylactic drugs

to prevent recurrence of migraine and to reduce the severity and duration of headaches.

Table 5: Quality of life assessment of patients with Migraine by MIDAS Questionnaire (n=108).

Grade	Degree of disability	N	%
I	Minimal	9	8.3
II	Mild	12	11.1
III	Moderate	52	48.1
IV	Severe	35	32.4

Among these patients who were on prophylaxis, 48 % had moderate degree of disability and 47% had severe degree of disability.

DISCUSSION

We observed that the most prescribed drugs class-wise were acetaminophen and NSAIDs (44.8%), followed by triptans (25.7%), indicating that triptans still remain an underutilized as abortive medications for migraine attacks. A female predominance was observed. For acute attack, most prescribed drug was paracetamol (19.07%), followed by naproxen and sumatriptan & rizatriptan. Similar pattern

of drug use was seen in a pan India study conducted by Singh et al.¹¹ The plausible explanation for this could be estrogen withdrawal.¹² Maximum burden was found among patients aged between 30 to 39 years similar to report by Bhatia and Gupta.¹³ This peak of Migraine during the most productive years causes loss in work days and increases societal cost.¹⁴ Chronic migraine patients constituted 19.4% of the study population, in contrast to a previous study by Ramasamy et al as most probable reason could be that our study was conducted at tertiary care facility.¹⁵ Simple analgesics (NSAIDs, acetaminophen) or combination analgesics are effective first line agents for mild to moderate severity migraine attacks not coupled with severe nausea or vomiting are not only efficacious but also less expensive, easily available and cause less adverse effects than migraine-specific treatment agents (triptans).¹⁶ Most common FDCs prescribed for acute attack in this study was diclofenac plus paracetamol, followed by sumatriptan plus naproxen & naproxen plus domperidone. These results differ from Singh et al, in which the most prescribed FDC was domperidone plus naproxen.¹¹ Sumatriptan plus naproxen combination works well in acute attack and was found to be much better than using naproxen alone in a Cochrane review.¹⁷

Average number of drugs per encounter was 3.05, which is similar to the study by Rawat *et al.*¹⁸ This can be improved by urging the physicians to prescribe by generic names. Most drugs in our study had a PDD/DDD ratio of either 1 or less than 1. Only zolmitriptan nasal formulation (5 mg) and 100 mg dose of oral sumatriptan were found to be over-prescribed, having PDD/DDD ratio >1. According to WHO Collaborating Centre for Drug Statistics Methodology, DDDs for the triptans given for migraine are based on the approved initial dose. The initial dose may differ from the maintenance dose, but this is not reflected in the DDD.¹⁹ Prophylactic drugs, on an average, reduce migraine frequency by half in 40-45% of patients. Evidence suggests that propranolol, divalproex sodium/sodium valproate, topiramate and metoprolol are effective for migraine prevention and reduce migraine attack frequency and severity.²⁰ The most commonly prescribed drug for prophylaxis was propranolol (39.4 %), followed by flunarizine (23.9%), amitriptyline (14.1%). In the pan India study by Singh et al for prophylaxis, similar pattern of prescription was found with propranolol prescribed in approximately half of patients.¹¹ Disease awareness for migraine was satisfactory, however therapy awareness was low, which was consistent with the previous study by Goodhew.¹⁸⁻²¹ Lack of awareness is harmful not only in terms of worsening health outcomes, and adversely affects quality of life. Awareness of migraine patients towards therapy being received was found to be low, which emphasizes the need for patient education to improve patient safety, drug adherence and better control of migraine. It has been confirmed from previous studies that patients' knowledge and awareness have a dramatic effect on medication adherence behavior.²² The patient's disease awareness score showed a strong positive correlation with patient's education and socioeconomic status, inferring

that with patients' higher education and better socioeconomic status have better disease and therapy awareness. Our results are consistent with report from Florianopolis at Brazil, wherein knowledge of migraine was significantly associated with socio economic status and education.²³ Quality of life among migraine patients in this study was found to be compromised, in consistent with other studies.²⁴⁻²⁶ Even among patients who were on prophylaxis there was moderate to severe degree of disability. Despite taking acute and/or preventive treatment, 29.2% of episodic migraineurs and 73.2% of chronic migraineurs had moderate-to-severe headache-related disability.²⁶ Overall, these results indicate that current prophylactic medications may not be adequate in preventing migraine attacks or reducing severity/duration, and there is a need for better drugs and therapeutic measures in addition to patient education to help improve quality of life of migraine patients.

Limitations

The study was conducted at the neurology and headache OPDs of a tertiary referral center, which restrains the generalization of these findings to the general population.

CONCLUSION

In conclusion, the findings of the study highlight the need to educate patients on therapy awareness to enhance their quality of life and reduce the current substantial disability.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Bhide S, Verma P, Ravat S, Phirke C, Rao S. A study of drug prescription patterns, disease-therapy awareness and of quality of life among patients with migraine visiting a tertiary care hospital in Mumbai, India. *Int J Basic Clin Pharmacol* 2023;12:855-60.