

CURRENT TRENDS IN PRESCRIBING PATTERN OF ANTI-MIGRAINE DRUGS IN PATIENTS OF MIGRAINE AT A TERTIARY CARE TEACHING HOSPITAL

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Background. An inappropriate prescribing pattern of antimigraine drugs by doctors may often encourage inappropriate self-medication by patients because of the asymmetry of medical information.

Objective. The study is aimed to assess the current trends in prescribing patterns of anti-migraine drugs, rationality of prescription, and pattern of migraine severity in patients of migraine.

Methods. A cross sectional study was conducted at a tertiary care teaching hospital. All the prescribing details including patient's demographic details, diagnosis, details of drug therapy (drug name, dose, duration, and frequency) were recorded. Rationality of prescription was assessed using the WHO core drug prescribing indicators and the pattern of severity of migraine was assessed using MIDAS scoring system.

Results. Out of 85 patients, 71 were female (83.5%), mostly around 21-30 years of age, and 27 (31.7%) patients had other comorbidities. Naproxen was the most commonly used NSAID for termination of acute migraine attack (15.3%). The most common drugs prescribed for prophylaxis included beta adrenergic blockers (Propranolol, 14.66%), antidepressants (Amitriptyline, 9.33% and Fluoxetine 3.33%), and antipsychotics (Prochlorperazine, 4.66%). Domperidone (17.30%) was the most commonly prescribed antiemetic. Prescription of triptans was low (2.66%) with Rizatriptan as the most commonly prescribed triptan.

Conclusions. The current study revealed that further improvements are required in prescribing practices especially in average number of drugs per prescription, prescription of drugs with generic names, and prescription of drugs of the essential drugs list.

KEYWORDS: DALY; MIDAS Score System; migraine; WHO Prescribing Indicators.

Introduction

Migraine is a primary, heterogeneous headache disorder characterized by recurrent, very painful and long duration headache that is moderate to severe as compared to other types of headache [1]. Typically, migraine is unilateral, pulsatile, and lasts for a few hours to 3 days. Associated symptoms may include nausea, vomiting, and increased sensitivity to light, sound or smell. The pain is generally worsened by physical activity. Up to one-third of the affected people experience the aura, which is a short period of visual disturbance, signals that headache will occur soon. Occasionally, it occurs with little or no headache following it [2].

Though tension headache is the most common type of headache, migraine is the commonest headache complaint that is presented in clinical practice and is the leading cause of headache related disability in the

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world. It affects approximately 13% of adults in the US and its prevalence ranges between 12% and 20% in various countries around the world [3]. Being more common in females than males, 19% and 7% prevalence, respectively [4], it's Disability Adjusted Life Year (DALY) showed the maximum burden among women in the age of 30-34 years [5]. Over 70% of migraine sufferers have a positive family history, and approximately 75% of the precipitating factors include environmental exposure, travel, education, or use of contraceptives [6].

While managing any case of headache, specific type must be ascertained using the International Classification of Headache Disorders (ICHD) criteria before assessing the response or refractoriness to any specific treatment [7]. For termination of acute attack of migraine, the commonly used pharmacotherapeutic options are nonsteroidal anti-inflammatory drugs (NSAIDs), 5HT_{1B/1D} receptor agonists, and dopamine receptor antagonists. For prophylaxis, beta blockers, antidepressants, anticonvulsant, and flunarizine are used. In addition to these

there are the new drugs approved by the FDA in 2018 including monoclonal antibodies that target the CGRP pathway like Erenumab, Fremanezumab, and Galcanezumab; and Ubrogapant which is a calcitonin gene-related peptide receptor antagonist. Ubrogapant is used for immediate treatment of migraine with or without aura.

Because of a boost in marketing of new drugs and variations in pattern of prescribing and consumption of drugs there is an increasing concern about delayed adverse effects, cost-effectiveness of drugs, and volume of prescription [8]. Therefore, prescription patterns for treatment of migraine needs to be monitored. Further, inappropriate drug use has occurred for as long as medicines have been available. Several choices of therapy are available in treating patients with modern medicines which might be one reason to increase the number of irrational medicine treatment encounters and ultimately, poor patient outcomes. Common drug use problems include: choosing incorrect medicines, polypharmacy, prescribing the incorrect dose, prescribing medicines that cause adverse drug reactions (ADRs) or drug interactions, and prescribing drugs by brand names which increases the cost of treatment [9]. An inappropriate prescribing pattern by doctors often encourages inappropriate self-medication by patients because of the asymmetry of medical information [10]. The attitude today is the root on which the future grows. Hence, it is generally agreed that the teaching hospitals have a special responsibility to society to promote rational prescribing by their staff and, through them – the future generations of doctors [11]. Further, to increase prescription quality and improve the rationality of drug use, we need to investigate the subjective and objective factors that affect doctors' prescription patterns [12]

Therefore, the present study was planned to assess the current trends in the prescribing pattern of anti-migraine drugs and to evaluate the distribution of severity of migraine among patients of migraine attending the outpatient Neurology Department at a tertiary care private hospital in Jaipur, Rajasthan.

Methods

A cross sectional study was conducted in the Department of Pharmacology in collaboration with the Department of Neurology in Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan in June 2020 – March 2021. The study was undertaken after approval from the

Institutional Ethics Committee and an informed consent was obtained from the participants before enrolling them into the study. All patients of any gender and age >18 years attending the Neurology OPD and diagnosed with migraine according to the International Headache Society Classification characterized by presence of any two of the following criteria: at least unilateral pain, throbbing pain aggravated by movement, moderate or severe intensity, or accompanied by either nausea/vomiting or photophobia/phonophobia, were included in the study. Patients with recent history of CNS infection or any major medical illness such as malignancy, autoimmune disorder or co-existent neurological disorder, or a case where an attending physician believes any other non-migraine diagnosis to be more likely, or a patient not willing to give an informed written consent were excluded.

Data collection

All the prescribing details from each prescription were recorded in the case history form. The information included patient's demographic details (name, age, sex), diagnosis, details of drug therapy (drug name, dose, duration, and frequency).

Study tools

1) Rationality of prescription was done by using the WHO prescribing indicators. The prescribing indicators include average number of drugs per encounter, percentage of drugs prescribed by generic name, percentage of encounters with antibiotics prescribed, percentage of encounters with an injection prescribed, percentage of drugs prescribed from essential drug list or formulary.

2) The Migraine Disability Assessment test (MIDAS): The MIDAS questionnaire was put together to assess the impact headaches have on one's life. Table 1 details the MIDAS scoring.

Data was collected and tabulated using MS Excel 2007 and was checked for normalcy before analyzing. Qualitative data was presented as percentages and proportions.

Table 1. MIDAS grade, definition, and MIDAS score

MIDAS Grade	Definition	MIDAS Score
I	Little or no disability	0-5
II	Mild disability	6-10
III	Moderate disability	11-20
IV	Severe disability	21+

Results

In the present study, 85 patients with a diagnosis of migraine were recruited. Most of the patients were female (83.5%), around 21-30 years of age (31.7%), and 29.4% had a co-morbidity. The description of the study participants is presented in Table 2.

The severity of migraine was assessed using MIDAS scoring system (Migraine Disability

Assessment) in which 45 (52.94%) were found to have moderate degree of migraine and 18 (21.17%) had aura. Description of severity of migraine among the study population is presented in Fig. 1a and 1b regarding the presence or absence of aura among the study population. Out of 85 patients, little disability was observed in 8.23% patients, mild in 21.12%, moderate in 52.94%, and severe in 17.71% patients.

Table 2. Description of the study participants (n=85)

Variables	Frequency (n)	Percent (%)
Gender		
Male	14	16.4%
Female	71	83.5%
Age (in years)		
10-20	7	8.2%
21-30	27	31.7%
31-40	24	28.2%
41-50	20	23.5%
51-60	5	5.8%
61-70	2	2.35%
>70	0	0%
Comorbidity		
Yes	25	29.4%
No	60	70.5%
Pattern of co-morbidities		
Benign Paroxysmal Positional Vertigo [BPPV]	1	4%
Agitated Depression	4	16%
Allodynia	3	12%
Depression	6	24%
Diabetes Mellitus	2	8%
Head Injury	4	16%
Hypertension	3	12%
Hyperprolectenimia	1	4%
Lumbar Prolapsed Intervertebral Disc [PIVD]	1	4%

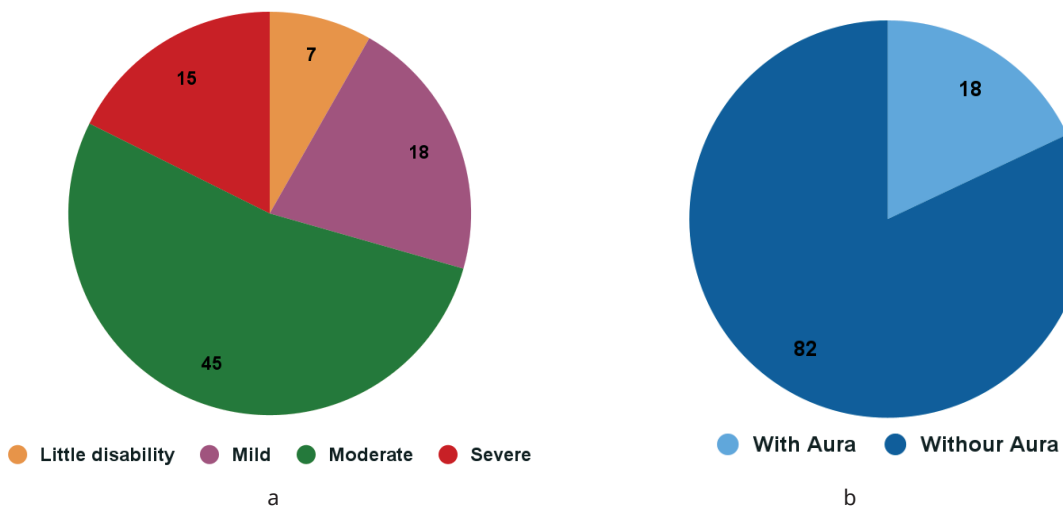


Fig. 1. a) Severity of migraine and b) Presence of aura among the study participants (n=85).

Out of 85 patients, 29.4% patients had comorbidities which included depression in 24%, head injury in 16%, agitated depression in 16%, alodynia (12%), hypertension (12%), diabetes mellitus, benign paroxysmal positional vertigo [BPPV], hyperprolactinemia, and lumbar prolapsed intervertebral disc [PIVD]. The distribution of co-morbidities among the study participants is presented in Fig. 2.

Table 3 and Fig. 3 describes the pattern of prescription of drugs for managing migraine among the study participants. The main drug class prescribed for controlling acute attack was NSAIDs (17%), while Propranolol (14.66%) was the mainstay of migraine prophylaxis. The most common NSAID used was Naproxem followed by Etoricoxib. Antiemetics were prescribed to 17.3% patients and included D2 receptor antagonist, Domepridone in all cases. In 8% patients, antipsychotics were prescribed; Prochlorperazin in 4.66% and Olanzapine in 3.33% patients. Antidepressants were pre-

scribed in 12.66% patients (Amitriptyline in 9.33%, and Fluoxetine in 3.33%), antiepileptics in 5.33% (Pregabalin in 4%, Topiramate in 0.60%), proton pump inhibitors (Omeprazole) in 2% patients, calcium channel blockers (Flunarazine) in 7.33%, and anxiolytics (Clonazepam) in 2% of patients. Other miscellaneous drugs prescribed to the study patients included Calcium citrate+vitamin D3 (8%), Cyproheptadine+sorbitol+tricholine citrate (0.60%), Thiocolchicoside (2%), and Magnesium+Riboflavin (0.60%).

The observed values of the core drug prescribing indicators as compared with the WHO standard values are presented in Fig. 4. The observed average number of drugs per encounter were 3.67; the percentage of drugs prescribed by generic name and percentage of encounters with antibiotics prescribed were 0% each; 50.6% of the prescribed drugs were from the essential list, and 0.003% of the encounters were with an injection prescribed.

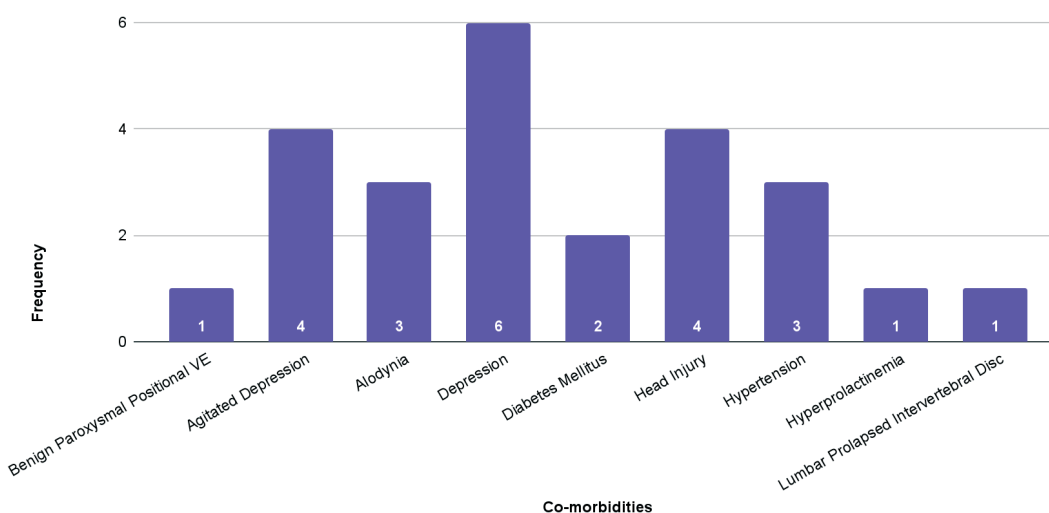


Fig. 2. Description of co-morbidities among the study participants (n=25).

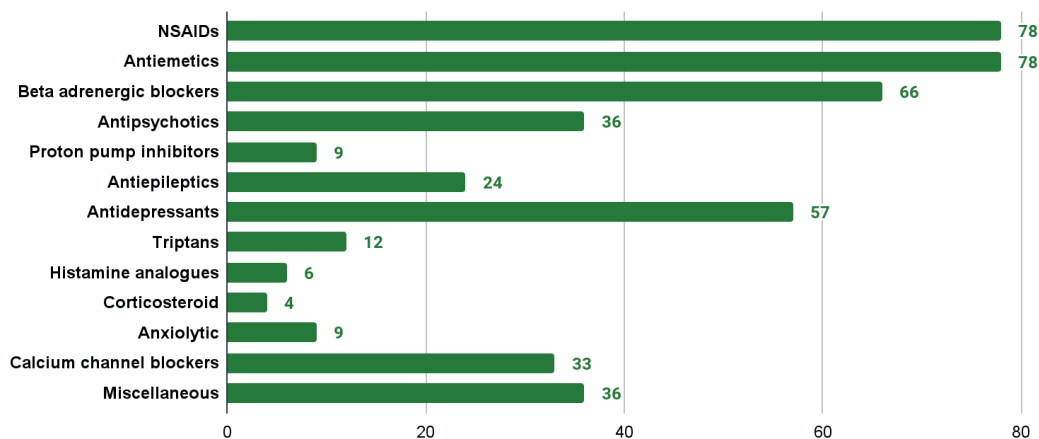


Fig. 3. Prescription pattern of drugs for migraine among the study participants.

Table 3. Prescription pattern of drugs for migraine among the study participants

S. No.	Drug class	Drugs	Number	Individual %	Total	Total %
1	NSAIDs	Naproxen	69	15.30%	78	17.30
		Etoricoxib	9	2%		
2	Antiemetics: D2 receptor antagonist	Domperidone	78	17.30%	78	17.30
3	β-adrenergic blocker	Propranolol	66	14.66%	66	14.66
4	Antipsychotics	Prochlorperazine	21	4.66%	36	8
		Olanzapine	15	3.33%		
5	Proton pump inhibitors	Omeprazole	9	2%	9	2
6	Antiepileptics	Pregabalin	18	4%	24	5.33
		Topiramate	3	0.60%		
		Divalproex sodium	3	0.60%		
7	Antidepressant	Amitriptyline	42	9.33%	57	12.66
		Fluoxetine	15	3.33%		
8	Triptans	Rizatriptan	12	2.66%	12	2.66
9	Histamine analogue	Betahistine	6	1.33%	6	1.33
10	Corticosteroid	Methylprednisolone	1	0.22%	4	0.82
		Prednisolone	3	0.60%		
11	Anxiolytic	Clonazepam	9	2%	9	2
12	Calcium channel blocker	Flunarizine	33	7.33%	33	7.33
13	Miscellaneous	Calcium citrate + vitamin D3	21	4.66%	36	8
		Cyproheptadine + sorbitol + tricholine citrate	3	0.60%		
		Thiocolchicoside	9	2%		
		Magnesium + Riboflavin	3	0.60%		

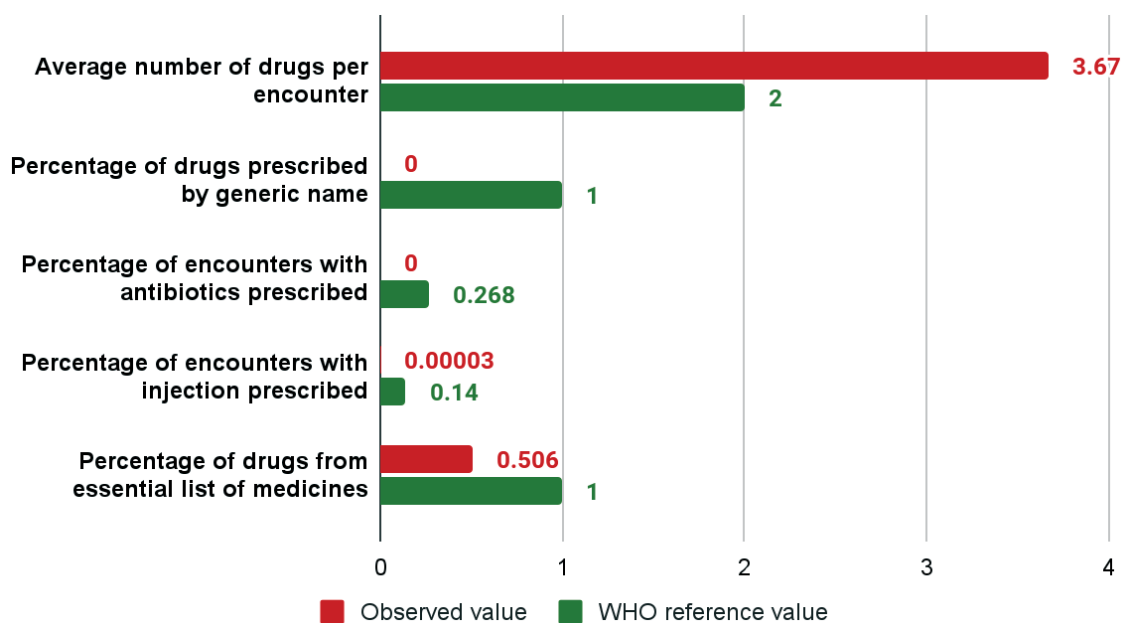


Fig. 4. WHO Prescribing Indicators.

Discussion

Migraine is a headache disorder characterized by throbbing pain or a pulsating sensation, usually on one side of the head. It is often accompanied by nausea, vomiting, and extreme sensitivity to light and sound. Migraine attacks can last for hours to days, and the pain can be so severe that it interferes with daily activities. The prevalence of migraine is commonly high in females of age group 21-30 years. The study was aimed to assess the current trends in the prescribing pattern of anti-migraine drugs and distribution of severity of migraine among the patients of migraine attending the outpatient Neurology Department at a tertiary care private hospital in Jaipur, Rajasthan.

It was established that the majority of the patients were females. Women reported episodic pain for a longer time and more frequent chronic pain than men. This may often result due to changes in estrogen levels. Since estrogen controls chemicals in the brain that affect the pain sensation, therefore a drop in its level can trigger a headache. Hormone levels change for a variety of reasons including menstrual cycle, pregnancy, menopause, use of oral contraceptive pills, and hormone replacement therapies.

In the study, the most common comorbidity among the study patients was depression or agitated depression. Migraine without an aura was present in two-third patients of this study. Migraine without aura is the commonest presentation in both Indian and western studies. However, in a study conducted by Mukhopadhyay et al [2] the prevalence of migraine with and without aura was reported to be 68% and 30%, respectively.

The mean MIDAS score in the study suggested that the majority of the study participants were suffering from mild to moderate migraine (grade 2 and grade 3). This is contrary to a study by Jawed et al [13], which reported that the majority of migraine patients had severe disability. Many studies have proved that the MIDAS score often correlates with a physician's assessment of migraine and is a useful tool for establishing the level of care and treatment required. Its use may improve physician-patient communication about headache-related disability and may favorably influence healthcare delivery for migraine patients. The MIDAS score indicated that in the present study, moderate disability was present in the majority of the study patients. Genetic, hormonal,

psychological and other lifestyle factors might underlie these differences in MIDAS score between different families and individuals in the same family [14]. Epidemiological factors are also known to play a significant role and MIDAS scores variations have been observed across different educational levels and socioeconomic status. An increased awareness may result in avoiding the precipitating triggers and seeking appropriate and timely treatment in the educated people. Also, low socioeconomic status is likely to cause more stress and a difficult living and working environment, thus triggering an acute episode of migraine. Psychological factors were also significant in migraine disability as observed in a study showing MIDAS scores to be worse in depressed patients [2].

NSAIDs were the most common class of drugs to terminate acute attack in the study and Naproxen was the most commonly prescribed analgesic among NSAIDs. These findings are similar to Khan et al [15]. Similarly, a study by Sumelathi et al [1] also states that NSAIDs are predominantly effective in both acute and chronic attack of migraine. NSAIDs are the most commonly used due to their wide availability as over the counter drugs and their pharmaco-economic advantages. Kefee et al [16] reported in their study that Paracetamol was primarily used in Karachi because they provide an early symptomatic effect, thus improving the treatment acceptability by patients. However, NSAIDs may cause some serious adverse effects, most common gastrointestinal like gas, feeling bloated, heartburn, stomach pain, nausea, vomiting, diarrhea and/or constipation. These gastrointestinal symptoms can generally be prevented by taking the drug with food, milk, or antacids. NSAIDs also can induce different forms of renal injury and hepatic side effects. Long term use and an inappropriate high dose may cause high risk to all these adverse drug reactions.

However, triptans are most commonly used in developed countries for termination of acute and chronic attack of migraine (Germany, USA, Australia) [1].

Triptans are considered as first-line therapy for moderate to severe migraine and also mild to moderate migraine in selective cases [4]. It was established that the most commonly prescribed triptan was Rizatriptan. However, only 2.66% triptans were prescribed in this study. According to US National Surveillance Studies (2009), triptans are the primary pre-

scribed drugs and Rizatriptan showed the major share among all triptans. The findings of the present study are also similar to these observations except for low rates of triptan use. Shao et al [8], suggested that reduced effectiveness in patients with late attacks may have played a role in lower frequency of triptans use. Additionally, given that Sumatriptan is contraindicated in common conditions including cardiovascular disease and pregnancy, the appropriateness of its use may be narrower than was expected previously. Shao et al [8] also believed that frequent occurrences of adverse effects in more than half of the patients after triptan administration may have led the physicians to avoid their use. Individual factors such as previously reported poor response to triptans by patients, physician's unfamiliarity with medication and their high cost may also contribute to low use. The characterization of such details in future studies will further elucidate the extent to which triptan prescription practices are deviated from guidelines, potentially allowing a more targeted solution to this problem. Further observations on whether opiates are being prescribed as first line treatment or rescue therapy and noting the eligibility of patient populations when commenting on levels of triptan therapy may also be helpful.

Beta adrenergic blockers, antipsychotics, and tricyclic antidepressants were the frequently prescribed medicines after NSAIDs. Depression is commonly present as one of the commonly associated factors of migraine. Hence, these medications are considered as better choices after NSAIDs. These findings are consistent with the guidelines that recommend beta-blockers to be prescribed to patients with both migraine and hypertension, and antidepressants - to patients with both migraine and depression [7].

In this study, antiemetics have also been prescribed along with NSAIDs. The literature indicates that patients of migraine are hypersensitive to dopamine that is important in causing some of the premonitory symptoms of migraine such as nausea and vomiting. It is established that dopamine receptor over sensitivity also is significant in pathogenesis of migraine. This may explain the use of dopamine receptor blockers like domperidone in the present study. Domperidone is a peripherally acting dopamine antagonist used for gastric motility disorder and nausea. It is less expensive, easily tolerated and is safe and efficacious in migraine treatment. Other drugs like Metoclopramide and Prochlorperazine can also be

used as monotherapy for acute migraine headaches as these are also dopamine receptor antagonists and have antiemetics action.

In this study, an average of 3.6 medicines were prescribed per prescription. This finding is greater than the standard value recommended by the WHO, which is less than 2 medicines per prescription. Similar findings were reported in a study by Aravamuthan et. al [17]. This observation may be due to the fact that most of the developing countries, including India are experiencing an epidemiological shift in the disease burden of both communicable and chronic diseases. Consequently, poly-pharmacy has become more prevalent since healthcare professionals have to treat several diseases concurrently in a patient. However, this shift towards polypharmacy may result in an increased risk of drug interaction, low adherence to treatment, dispensing errors, and increase therapy cost. A relationship has been established between polypharmacy and chronic polypharmacy that is prescription of multiple medicines is a predisposing factor to adding further drugs.

The prescription of drugs in generic names ensures rational use of drugs and reduces the cost of treatment. In this study, no drug was prescribed with generic names. This is very low as compared to other studies and is even lower than Ghana, Lebanon, Nepal and Pakistan (2.9% to 65.0%) and much higher indicators (75-99.8%) of generic prescription have been reported from Bangladesh, Cambodia, Ethiopia, and Tanzania [18]. Prescription of drugs in generic name may help in controlling drug costs in the healthcare service and decrease the influence of medical marketing on prescription.

The findings from this study show that no antibiotics were prescribed as compared to the WHO standard that ranged 20-26.8%. There is huge variation in this finding among other studies in India by Hazra et al. (72.8%) [18].

Percentage of encounters prescribed with injection were 0.003%. This is less than the standard WHO range (13.4-24.1%). Since the present study was done for out patients who were otherwise in optimal state health and most of the patients had mild-moderate migraine, this may be the reason for low rate of injection usage. These findings are comparable to that of Hazra et al. (8%) [18] but are very low as compared to other regions, South Ethiopia (38.1%) and Uganda (48%) [19]. The lower rate of injections use would reduce the incidence of blood borne pathogenic infection,

reduce the transmission of HIV infection, and reduce the cost of treatment, which in turn decreases the economic burden on the patient and eventually improves compliance of the patient to the treatment.

Thus, the study reported that the median value of the percentage of medicines prescribed from the essential medicine list was 50.6% that was half of the standard value suggested by the WHO. These values are also lower as compared to the other countries such as Ethiopia (99%), South Ethiopia (99.6%), and Nepal. This indicator helps in measuring the degree to which practices conform to the current National List of Essential Medicine (NLEM) of 2019. Following the essential drug list guarantees treatment of the principal diseases of the population besides controlling overall cost of medications.

Conclusions

The current trends in prescription pattern of anti-migraine drugs observed were: Naproxen was the most commonly used NSAID for termination of an acute migraine attack and for prophylaxis; beta adrenergic blockers (Propranolol), antidepressants (Amitriptyline), and antipsychotics (Prochlorperazine) were prescribed the most. Domperidone was the most commonly prescribed antiemetic. Prescription of triptans was low (2.66%) with Rizatriptan as the most commonly prescribed triptan. This study revealed that further improvements are required in prescribing

practices especially in average number of drugs per prescription, prescription of drugs with generic names, and prescription of drugs of the essential drugs list.

Recommendations: Continuous education and training of physicians regarding rational use of drugs should be implemented and monitored so that the required changes in prescribing become sustainable. Further prospective analytical studies should be conducted on a large population with strict observation and follow up focusing largely on quality of life, adverse effect profiles of the drugs, compliance, and cost of treatment.

Limitations

Since the study was conducted during COVID pandemic, the number of cases attending the OPD was less than expected and only a cross-sectional study was carried out. Therefore, follow-up data, comparative analysis and tests of significance could not have been applied. We enrolled only adult patients from Neurology OPD; further research may include patients of all ages and from other departments as well.

Author's Contributions

Gopesh Soni, Anusha Vohra, Priyanka Rathi – conceptualization; *Gopesh Soni, Anusha Vohra, Prerana Shiv Goswami, Priyanka Rathi* – methodology; *Gopesh Soni, Anusha Vohra, Prerana Shiv Goswami, Shipra Jain, Priyanka Rathi* investigation, formal analysis, data curation, writing – original draft, writing – reviewing and editing.

СУЧАСНІ ТЕНДЕНЦІЇ ПРИЗНАЧЕННЯ ПРОТИМІГРЕНОЗНИХ ПРЕПАРАТІВ ПАЦІЄНТАМ З МІГРЕННЮ В УНІВЕРСИТЕТСЬКІЙ ЛІКАРНІ ТРЕТИННОГО РІВНЯ

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Вступ. Невідповідна схема призначення протимігренозних препаратів лікарем часто може спонукати пацієнтів до самолікування через асиметричність доступної медичної інформації.

Мета дослідження – оцінити сучасні тенденції в призначенні протимігренозних препаратів, раціональність їх призначення та тяжкість перебігу мігрени у пацієнтів.

Методи. Перехресне дослідження було проведено в університетській лікарні третинного рівня. Вивчалися всі відомості про призначення, включаючи демографічні дані пацієнта, діагноз, деталі медикаментозної терапії (назва препарату, доза, тривалість та частота прийому). Раціональність призначення ліків оцінювалася з використанням основних індикаторів призначення ліків BOO3, а характер тяжкості мігрени – за допомогою системи оцінки MIDAS.

Результати. З 85 пацієнтів 71 були жінки (83,5%), переважно у віці 21-30 років, а 27 (31,7%) пацієнтів мали інші супутні захворювання. Напроксен був найбільш часто використовуваним НПЗП для припинення гострого нападу мігрені (15,3 %). Найпоширенішими препаратами, які призначали для профілактики, були бета-адреноблокатори (пропранолол, 14,66%), антидепресанти (амітриптилін, 9,33% і флуоксетин 3,33%) та нейролептики (прохлорперазин, 4,66%). Домперидон (17,30%) був найбільш поширеним протиблювотним засобом. Призначення триптанів було низьким (2,66%), при цьому найчастіше призначали ризатриптан.

Висновки. Дане дослідження показало, що необхідні подальші вдосконалення практики виписування рецептів, особливо щодо середньої кількості ліків за рецептом, призначення ліків із загальними назвами та призначення ліків із переліку основних лікарських засобів.

КЛЮЧОВІ СЛОВА: DALY; система оцінювання MIDAS; мігрень; індикатори призначення ВООЗ.

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