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ORIGINAL RESEARCH

A Study of the Effect of Treatment On the Clinical Profile, Pain, and Disability in Migraine Patients Seen in a Tertiary Hospital

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Background: Migraine is a disabling disease that poses a significant societal burden. Migraine is a major cause of disability. Migraine is the eighth leading disease-causing disability in the population.

Objective: To study the clinical profile and measure the pain and migraine-related disability of patients with all types of migraine using the McGill pain assessment scale and Migraine Disability Assessment (MIDAS) before and after 3 months of effect on the medication.

Methods: A Prospective-Cross sectional study was carried out in a multispecialty hospital with male and female patients between 18 and 65 years. The data were collected from the patients directly through the questionnaire of McGill pain assessment scale-short form (SF) and MIDAS, which was provided before and after the medication.

Results: There were 165 subjects of which 52 were men and 113 were women. The mean age of all the subjects was 43 years. About 26.06% of the subjects had a family history of headaches. The scores of McGill pain and MIDAS assessment before and after medication were as follows: 0–15 were 30.90% and 73.33%, Score 16–30 were 54.54% and 18.18%, the score of 31–45 were 14.54% and 7.87% of the subjects. MIDAS grade I was 17.57% and 50.90%, Grade II 33.93% and 21.81%, Grade III 30.30% and 15.75% Grade IV 18.18% and 11.51% of the subjects.

Discussion: The calculated "t" value between the before and after medication values of McGill and MIDAS by paired '*t*-test was 13.85 and 17.49 respectively. As the calculated "t" value is more than the table value, the alternate hypothesis is accepted.

Conclusion: This study confirms that there is a significant difference in disability levels before and after acute and preventative treatments when measured over 3 months. In addition, the preponderance of females was high, and the functional disability that affects work and social activity associated with migraine is moderate to severe.

Keywords: migraine, pain, disability, loss of productivity, MIDAS

Introduction

Migraine is a disabling disease that poses a significant societal burden.[1] Migraine headache is characterized by episodic, generally unilateral severe pain. There may be phonophobia or scotoma nausea, vomiting, or dizziness. Ocular migraine may have ophthalmoplegia resulting in diplopia. Classic migraine may have visual, sensory, or motor symptoms that precede the actual headache. Eight to twelve percent of patients suffer from migraines; this demographic is

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overwhelmingly female, and eight percent of migraineurs have disability.[2] Migraine can be episodic or chronic and chronic migraine is more disabling than episodic. Migraine is characterized by attacks of a severe, pulsatile, and throbbing headache, classically unilateral. A smaller number of migraine patients experience a more definite sensory disturbance before the headache, called "aura" which generally has visual disturbances. Classic migraine (migraines with aura) and non-classic migraines (migraines without aura) are the two main types of migraine. Migraine affects a substantial fraction of the world population (more women than men). Migraine exerts an incredible toll on the well-being of affected individuals, family members, and social life. Reduced productivity of individuals with migraine was observed as a result of chronic manifestations with prominent episodic manifestations, migraine is associated with an extensive disability that undermines normal function. Pain and related symptoms and limited activity not only impose personal problems but also have wide-cost consequences.[3] Migraine accounts for about 89% of the total workdays missed/efficiency by the individual. Migraine-related productivity loss may undesirably affect individuals' profession, job rank and/or security, economic position, work relationships, attitude, and self-confidence.[4] In the International Headache Society's third edition of the International Classification of Headache Disorders (ICHD-3), headaches can be categorized into primary headaches and secondary headaches. Primary headaches consist of migraine, tension-type headaches, trigeminal autonomic cephalgia, and other primary headache disorders that do not fall under the above three categories, not the secondary cause. Secondary headaches can be caused due to various medical conditions. ICHD-3 classifies chronic migraine as a headache that persists for 15 or more days in a month for more than 3 months, while episodic migraine is categorized as having less than 15 days of headaches per month for more than 3 months.[5]

Migraine is one of the main causes of disability, and the quality of life was also affected in migraine patients.[6,7] With recurrent migraine attacks, patients were found to be affected emotionally, socially, mentally, and occupation wise. Recurrent attacks cause functional impairments, including both physical and emotional effects; this may occur either during or subsequently after a migraine attack. Migraine sufferers have worse subjective well-being and a reduced quality of life compared with non-migraine individuals.[8] While migraine has an insignificant correlation with mortality, headache disorders severely affect disability-adjusted life years (DALYs) over collective neurological disorders.[9] Despite the high incidence rates, it remains underdiagnosed and undertreated. Physicians regularly have a tendency to concentrate on therapeutic aspects and fail to identify the functional disabilities and emotional aspects of the disease, leading to the insufficiency of a complex approach to the disease. Data are scarce on the Indian population related to disability and level of well-being in migraine patients.[10] This study aims to discover the clinical profile, pain, and disability associated with migraine patients before and after 3 months effect on treatment in tertiary care teaching hospitals.

Methods

Study Design

A Prospective-Cross sectional study was carried out in a multispecialty hospital to assess the clinical profile, pain, and disability in migraine patients.

Inclusion Criteria

Male and female outpatients aged 18 to 65 years were included in the study. Individuals with newly diagnosed with migraine were included. All types of migraine, including classic migraine, migraine with typical aura (aura lasting than 1 hour), migraine with prolonged aura (aura lasting more than 1 hour and less than 1 week) diagnosed by a neurologist based on the ICHD-3 criteria.[11] Informed consent was obtained from participants who have agreed to participate in the study.

Exclusion Criteria

Additionally, patients with severe psychiatric and terminal illnesses have been excluded. Because migraine patients' pain and disabilities are assessed as part of the study. Severe mental and terminal illness patients have been eliminated in order

to prevent inaccurate responses on the aforementioned scales. The Institutional Review Board of the Multispecialty Hospital, India, gave its approval to the methodology of the study.

Data Collection and Sampling Procedure

We enrolled the study participants by using a consecutive sampling strategy. A specially designed data entry form was used to collect information which included patient details, patient name, occupation, age, sex, and family history of migraine. Details about present complaints, current medications, medical diagnosis site of pain and symptoms experienced with headaches were also recorded. The conduct of the study was approved by the Ethics Committee of Kovai Medical Centre and Hospital. The MIDAS (Migraine Disability Assessment Scale) questionnaire is based on five disability questions that focus on lost time in three domains: school work or work for pay; household work and improve physician–patient communication, headache related disability and the functional consequences of migraine. The McGill Pain Questionnaire can be used to evaluate a person experiencing a multidimensional assessment of pain. It can be used to monitor pain over time and to determine the effectiveness of any intervention. Our aim was to measure the pain and migraine-related disability of patients with all types of migraine, the duration between the before and after the treatment is 3 months. These two questionnaires exactly has the same description. Therefore, we used this as the basis for our study. Hence, we have chosen the short form of the MIDAS and McGill pain Questionnaire for our study. McGill pain assessment scale-short form questionnaire and MIDAS, which was provided before and after treatment.

McGill Pain Questionnaire

Includes the short form of McGill pain questionnaires[12] consisting of 15 different types of pain lists, patient name, age, sex, and numerical pain assessment scale. A short form of the McGill Pain Questionnaire (SF-MPQ) has been used in this study. The questionnaire SF-MPQ comprises 15 items (11 belong to sensories; 4 belong to affective) which are scored on an intensity scale as "0" is none, "1" is mild, "2" is moderate and 3 is severe. Pain scores for individual participants are calculated based on the words chosen by adding all 15 items, including sensory and affective.

MIDAS Questionnaire

The use of the migraine disability assessment scale[13] (MIDAS) questionnaire is to measure the disability associated with migraine over the last 3 months. This questionnaire involves five questions on three different dimensions of action. MIDAS consists of five questions, based on the disabilities which have gradings of I, II, III, and IV. Each grade has values of 0–5 scores indicate little or no disability, 6–10 scores indicate mild disability, 11–20 indicate moderate disability, and 21+: which indicates severe disability, respectively. The first two questions are associated with school and work activities. The third and fourth questions are associated with the housework activity. The last question is associated with social activity.

Statistics

We presented our data as frequencies and percentages and standard deviation for descriptive statistics and studied the outcomes using GraphPad Prism. One way ANOVA have been done for demographic variables. Due to the nature of the study design, that is where pre and post tests are conducted, paired sample *t*-test is more appropriate. The result of the study for the MIDAS and McGill pain assessment before and after the medication were analyzed using paired sample "t" test. Paired "t" $P < 0.01$ level of significance was used. The effect size is 0.3 when the df (degrees of freedom) is as high as 5 (between two variables of interest) and for the power of the study is 0.80.

Results

The study on drug use patterns and assessment of pain and disability in migraine patients was carried out in a tertiary care teaching hospital in India. A total of 165 migraine patients participated in this prospective study. Among the 210 migraine subjects studied for the assessment of pain and disability, 45 were nonrespondents, while 165 wrote the questionnaire correctly. Nonrespondents were not included in the study. Among these 165 subjects, 52 were men and 113

were women. Refer to Table 1. For sociodemographic details, family history, site of pain, symptoms etc. From the past medical history, 33.33% were migraineurs: 9.09% were hypertensives: 5.45% were non-insulin-dependent diabetes mellitus (DM) and 52.12% of the patients had no other complications. From the data obtained it was discovered that the symptoms refer to Table 1.

From diagnosis 70.90% (n = 117) had non-classic migraine: 9.09% (n = 15) of the patients were basilar migraine, 9.09% (n = 15) had classic migraine 4.84% (n = 8) had migraine with hypertension, 1.21% (n = 2) were migraine with anxiety, 1.21% (n = 2) were transformed into migraine, 1.21% (n = 2) had migraine with hypothyroidism, 1.21% (n = 2) migraine with DM, 0.6 (n = 1) had migraine with seizure, 0.6% (n = 1) had ophthalmoplegic migraine. Furthermore, history showed that acute and preventive pharmacotherapy among the study population. Details are given in Table 2.

As seen in Tables 3 and 4 the SF McGill Pain questionnaire scores fell in all categories, ie scores of 0–15, 16–30, 31–45. The values of the McGill pain scale show that after the medication the pain level has been reduced. The calculated

Table 1 Demographic Variables Among the Study Population

Variables	Number (%)	P value
Male	52 (31.51)	0.0037*
Female	113 (68.48)	
Age		
<20	19 (11.51)	0.1245
21–30	49 (26.69)	
31–40	47 (28.48)	
41–50	36 (21.81)	
51–60	13 (7.87)	
>60	1 (0.6)	
Family history		
Yes	43 (26.06)	0.0009*
No	122 (73.93)	
Occupation		
Working	28 (16.96)	0.0987
Student	21 (12.72)	
Agriculture	15 (9.09)	
Housewife	69 (41.8)	
Business	14 (8.48)	
Unemployed	18 (10.9)	
Site of Pain		
Unilateral	109 (66.06)	0.0416*
Bilateral	40 (24.24)	
Both	16 (9.69)	

(*Continued*)

Table 1 (Continued).

Variables	Number (%)	P value
Symptoms		
Vomiting	61(36.17)	0.2145
Nausea	44 (26.67)	
Phonophobia	30 (18.18)	
Photophobia	30 (18.18)	
Visual aura	18 (10.9)	
Vertigo	22 (13.33)	
Pulsatile	15 (7.88)	
Decrease sleep	13 (6.06)	
Giddiness	11 (4.24)	
Tiredness	12 (2.42)	
Decrease appetite	10 (2.42)	
Others	28 (16.76)	

Note: *Significance P<0.05.

Table 2 Shows Acute and Preventive Pharmacotherapy Among Study Population

Acute Pharmacotherapy	Number (%)	Preventive pharmacotherapy	Number (%)
Ergot alkaloids	59 (35.75)	**Beta-Blocker**	
Ergotamines		Propranolol	40 (24.24)
Selective serotonin Agonists		Atenolol	5 (3.30)
Sumatriptan	15 (9.09)	**Calcium Channel Blockers**	
Non opioid analgesics		Flunarizine	100 (60.06)
Naproxen	24 (14.54)	**Antidepressants**	
Acetaminophen	16 (9.69)	Amitriptyline	55 (33.33)
Ketorolac	8 (4.84)	**Anticonvulsants**	
Antiemetics		Divalproex	56 (33.93)
Prochlorperazine	13 (7.87)		
Anti-vertigo			
Cinnarizine	5 (3.03)		

value between before and after the medication values by paired "*t* test" was 13.85. The table "t" value for 164 degrees of freedom at a 1% level of significance was 2.57. As the calculated "t" value is higher than the table value, the alternate hypothesis is accepted.

As seen in Tables 3 and 4 the MIDAS scores fell in all categories ie grade I distribution (none), grade II (grade II (mild disability), grade III (moderate disability), grade IV (severe disability). The scores of MIDAS indicate that after the

Table 3 Shows Mc Gill Pain Assessment Scores - Short Form & Migraine Disability Assessment Scale Scores Before and After the Medication Among the Study Population

Mc Gill Pain scale - short form	Before Medication	After Medication
	Number (%)	Number (%)
0–15	51 (30.90)	122 (73.33)
16–30	90 (54.54)	30 (18.18)
31–45	24 (14.54)	13 (7.87)
MIDAS Scale		
Grade I	29 (17.57)	84 (50.90)
Grade II	56 (33.93)	36 (21.81)
Grade III	50 (30.30)	26 (15.75)
Grade IV	30 (18.18)	19 (11.51)

Table 4 Shows the Student's "T" Test of the Mc Gill Pain Assessment Scores – Short Form & MIDAS Among the Study Groups Before and After the Medication

Scale	Before Medication	After medication	"t" value	P value
Mean Value				
Mc Gill Pain scores – short form	17.89± 3.52	7.99± 1.46	13.85	P<0.01*
MIDAS scores	13.07± 2.31	5.8± 1.02	17.49	P<0.01*

Note: *Significance.

treatment, the migraine disability level has been reduced. When the before medication and after medication values of the subjects were analyzed by paired *t*-test, the calculated value was 17.49. The value of table "t" at 164 degrees of freedom is 2.57; therefore, the null hypothesis is rejected.

Discussion

There were 165 subjects of which 52 were men and 113 were women. The mean age of all the subjects was 43 years. The most common age associated with migraine was 25 to 55 years of age during their working period, and it may decrease the frequency in later life for some patients, but not for all.[14] Another study also revealed that the majority of the population 70% were female with migraine.[15] The current study confirms the findings of previous studies,[16,17] and greater incidences of migraine were reported in females. In the present study, 58% fall under the age of 20 to 40 years. Similar to our study, another study reported that ages between 18 and 40 constitute 65% of migraine. In addition, in this study, housewives were prevalent nearly 42%. The findings of the present study are consistent with earlier studies that is, about 68% of the patients who were housewives.[18]

The study also revealed that 26.06% of the subjects had a family history of headaches. Similar to our study results, a positive family history of migraine was shown in 28.3% of the study participants.[15] In contrast to our findings, a study done by Frederick et al, on the lifetime prevalence of migraine among women is strongly correlated with a family history of migraine.[19] Similar results in terms of symptoms were found in another study by Mudassir et al and Lipton et al[20,21] discovered symptoms experienced during migraine were vomiting at 56.9%, nausea at 87%, phonophobia at 88.2%, photophobia at 76.8% and vertigo 2.8%. A study in Saudi Arabia among the general population states that phonophobia is 22.6% followed by photophobia at 13.6%.[22] Pain occurred unilaterally in 62 patients: bilaterally in 40 patients;

transformed migraine in 16 patients (When migraine attacks start to occur on a regular basis, they are known as transformed migraines. These results are consistent with the study by Mudassir et al,[20] reported that unilateral pain was found in 59.1% of the patients. From past medical history, it was noted that 33.33% were migraineurs: 9.09% were hypertensives: 5.45% were non-insulin dependent diabetes mellitus and 52.12% of the patients had no other complications. A study done by Haghighi et al reported that there was no significant difference observed in migraine prevalence and Type 2 DM but hypoglycemic attacks and duration of DM and family history of migraine were also associated with migraine prevalence.[23] The population-based study revealed that migraine patients with DM have associated with a major risk of cardiovascular events.[24] In contrast to previous study results in Lopez-de-Andres A et al concluded in their study that no potential differences were found between migraine and DM and non-diabetic age and sex-matched controls.[25] From the diagnosis 70.90% had non-classic migraine: 9.09% of the patients were basilar migraine; 9.09% were classic migraine, 4.8% were migraine with hypertension, 1.21% were migraine with anxiety, 1.21% were transformed into migraine, 2.21% had migraine with hypothyroidism, migraine with DM, 0.6 had migraine with seizures, 0.6% had ophthalmoplegic migraine. A cross-sectional study conducted by Ilse F. de Coo et al, found that 7% of the respondents with cluster headaches had a typical aura, with symptoms mainly visual symptoms.[26] The research study stated that anxiety was strongly related to migraine.[27] Another study conducted a relationship between migraine and thyroidism established that migraine increases the risk of developing hypothyroidism.[28] In large-scale population-based cohort study established a reverse association between blood pressure and the consequent development of headaches.[29] Another cross-sectional study confirms that positive correlation between migraine, severe headaches, and hypertension.[30]

It came to light that the most commonly used OTC medicines were acetaminophen combinations (27.24%); diclofenac sodium (5.45%). A study conducted among the working-age population derives that the most frequently used OTC medications are NSAIDs 34%.[31]

In this study, ergotamine combinations were the highest percentage among acute pharmacotherapy medications 35.75% followed by non-opioid analgesics- naproxen 14.54% and selective serotonin agonists- sumatriptan nasal spray, acetaminophen, ketorolac, Antiemetics- prochlorperazine, anti-vertigo- cinnarizine 9.09%, 9.69%, 4.84%, 7.87%, and 3.03% respectively. Preventive pharmacotherapy calcium channel blocker; flunarizine 60.06%, anticonvulsant-divalproex 33.93%, antidepressants-amitriptyline 33.33%, β blocker- propranolol 24.24%, atenolol 3.30%. A study by Jawed et al showed that acetaminophen was the most commonly used medication by migraine patients at 48%, followed by non-steroidal anti-inflammatory drugs at 40%. Preventive medications β-blockers were the most prescribed at 20%, followed by tricyclic antidepressants in 18%.[18] More than two-thirds of the patients were prescribed an acute treatment, most of the prescriptions were triptans, and in preventive pharmacotherapy antidepressants more than 60% of the patients.[32]

The McGill pain measurement scale scores of 0–15 were 30.90% of the subjects before the medication and 73.33% of the subjects after the medication. Similarly, the score of 16–30 was 54.54% of the subjects before medication, while 18.18% of the subjects were after the medication. The score of the 31–45 was 14.54% of the subjects before medication and 7.87% of the subjects were after the medication. The values of the McGill pain scale show that after the medication the pain level has been reduced. The MIDAS distribution Grade I (none) 17.57% of the subjects were before medication, while 50.90% of the subjects were after medication. Grade II (mild disability) includes 33.93% of the subjects who were before the medication, while 21.81% were after the medication. In grade III (moderate disability), 30.30% of the subjects were before medication, while 15.75% of the subjects were after medication. In grade IV (severe disability) 18.18% of subjects were under the category before medication, while 11.51% of the subjects were after the medication. The scores of MIDAS indicate that after the medication, the migraine disability level has been reduced. The details were given in Table 3. The results of our study are on par with another study, which was shown that a major proportion of participants fell under the category of moderate-to-severe disability.

The majority of our study findings are consistent with migraine research conducted in other countries. Despite, a growth in the rates of disability caused by migraines.[25] Consistent with our findings, another study discovered that migraine sufferers had significant disability.[33] Clinicians should regularly assess disability linked to migraine and quality of life (QOL) and make sure that patients are receiving the right treatment and that extra techniques are not required.[34] According to previous study findings, there was a strong correlation between migraine headaches and severe functional

impairment. When comparing students with and without migraine symptoms, the former group showed a considerably higher functional impact.[35,36] The details are given in Table 4. According to prior investigation, managing comorbidities, changing one's lifestyle, receiving physical therapy, and using medication are all preventive measures for reducing migraine episodes.[37] Prior research has shown that behavioral therapy, such as cognitive behavioral therapy (CBT) and relaxation, can effectively reduce the incidence of migraine attacks and migraine-related illnesses.[38] It has been shown that the most effective strategy to avoid severe episodes that necessitate acute care is to implement complete migraine treatment programs that involve frequent follow-ups and therapeutic patient education, medication therapy.[39]

Limitations

This is a single-institution study. So, the results of the study are not considered generalizable. This was one of the major limitations of our study. Future national studies should also involve a multicenter studies or population-based surveys with large representative sample of the Indian population to have a better understanding of the scope of the problem.

Recommendations

Furthermore, this study recommends the need for comprehensive management strategies for patients with migraine headaches, such as workplace migraine education and management programmes, a migraine-friendly work atmosphere, along with migraine treatment. In order to ascertain if patients are receiving an appropriate course of therapy and whether further treatment options are necessary, healthcare practitioners should routinely assess pain and disability associated with migraines.

Conclusions

This study confirms that there is a significant difference in disability levels before and after acute and preventative treatments when measured over 3 months. In addition, the preponderance of females was high, and the functional disability that affects work and social activity associated with migraine is moderate to severe. Integrated migraine management can be accomplished by recommending that a thorough evaluation of migraine headaches include an examination of the patient's mental health, pain, disability, well-being, and impact in real life.

Data Sharing Statement

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

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Disclosure

The authors declare no conflict of interest.

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