Estimating quality of life in a headache referral population based on Migraine disability assessment scale and headache impact test

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Abstract
Background: Headache is among the most common disabling neurologic disorders. We measured quality of life in chronic migraine (CM) and episodic migraine (EM), stratified by medication overuse headache (MOH) and presence of aura.
Methods: In this observational study, conducted from January 2016 to December 2018, adult patients referred to the tertiary headache clinic of Sina Hospital in Tehran, Iran, who met International Classification of Headache Disorders, 3rd Edition-beta (ICHD-3 β) criteria for migraine were classified to EM and CM subtyped based on presence of aura and MOH. Validated Farsi versions of Migraine Disability Assessment Scale (MIDAS) and 6-item Headache Impact Test (HIT-6) questionnaires were used.

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Results: A total of 2454 patients (1907 women) were enrolled from which 1261 (51.4%) patients had EM and 1193 (48.6%) had CM, while 908 subjects (37.0%) had MOH, of whom 890 (98.0%) had CM. Median scores of MIDAS and HIT-6 were significantly higher in patients with CM compared to EM sufferers. Chronic migraineurs with MOH had a significantly higher median score of MIDAS and HIT-6 compared to patients with non-MOH CM. Also, there was a moderate positive correlation between MIDAS (disability) and HIT-6 scores (impact on patients' life) and a moderate correlation between HIT-6 and pain severity.

Conclusion: The results of this study confirm that CM and MOH are associated with a higher headache-related disability and impact on life compared to EM. Therefore, treatment goals in prevention of MOH and migraine transformation warrant higher quality of life in patients with migraine.

Introduction

Headaches can be categorized based on the International Classification of Headache Disorders (ICHD), first introduced in 1988 and updated and applied worldwide for clinic and research.[1] Migraine headaches can be classified to migraine with aura (MA) and migraine without aura (MO), previously called classic and common migraine, respectively. MO comprises about 70.0% of total migraine attacks, with the remaining attacks being MA.[2-4] Migraine can further be categorized based on headache frequency to episodic migraine (EM) (< 15 days per month) and chronic migraine (CM) (≥ 15 days per month for at least 3 months, with 8 days fulfilling migraine characteristics)[1] with chronic headache associated with a higher disability.[5] However, there may be some overlap on the diagnosis of CM, defined by ICHD-3rd Edition (ICHD-3) and medication overuse headache (MOH) throughout the studies, with the two conditions present simultaneously in 31%-51% of cases.[6] However, even with scarce data on prevalence of MOH in many regions, it has been ranked 20th cause of global years lost due to disability (YLD) in Global Burden of Disease Study 2015 (GBD 2015).[7]

There are not many studies on prevalence of headaches in Iran; however, based on the GBD 2017 data, it is estimated to be 52.3%, 33.1%, and 35.2% for all headaches, migraine, and tension-type headache (TTH), respectively, which places Iran among the countries with high prevalence of migraine headaches.[8] Various tools, in the form of questionnaires, have been designed to measure the impact of headaches on quality of life. The Migraine Disability Assessment Scale (MIDAS) and 6-item

Headache Impact Test (HIT-6)[9,10] are of the widely used questionnaires[5,11] which have been translated and validated in different languages.[12-19] Sauro et al. have compared HIT-6 and MIDAS scores of 798 patients and have found a positive correlation between the scores; they showed that headache intensity might widely influence HIT-6 scores whereas headache frequency seemed to be better reflected by the MIDAS score.[11] In another study, Shin et al. compared migraine-related disability based on headache diaries and HIT-6 and demonstrated that HIT-6 could be a reliable measure of headache disability.[10] In a population-based survey from Korea, clinical characteristics and disability of migraine were measured based on HIT-6, where 29.0% had substantial to severe headache and the median HIT-6 score was reported to be 51.[20]

Due to the high prevalence of migraine in Iran and its impact on daily life, we aimed to measure the quality of life in patients with CM and EM, stratified by MOH and presence of aura, by the scales of MIDAS and HIT-6.

Materials and Methods

Patients and data collection: This study was an observational analytic study with a cross-sectional approach conducted from January 2016 to December 2018. Adult patients referred to a well-known referral tertiary headache clinic in Sina University Hospital in Tehran, Iran, were evaluated by specialists in headache based on ICHD-3 β criteria for migraine and were included in the study if the criteria were fulfilled. Patients were assured of the anonymous data collection, and they were excluded if they did not have consent. This study was approved by the Ethics Committee of Tehran University of Medical Sciences, Tehran (reference number: IR.TUMS.NI.REC.1398.001). They were asked to fill a questionnaire consisting of their age, gender, education, and employment status. Migraine was further classified to EM and CM and each group was subtyped based on presence of aura and MOH. The inclusion criteria and migraine diagnosis were re-evaluated by the corresponding author to avoid selection bias.

We used validated Farsi versions of MIDAS and HIT-6 questionnaires.[17,18] MIDAS is a self-report tool consisting of 7 items (with 5 scored items) designed to evaluate migraine-related disability in the previous three months. The questions address missed days or reduced productivity at paid work, schoolwork, or household work, and missed family, social, and leisure activity due to headache.

The MIDAS score is calculated based on the sum of each domain, ranging from 0-270, where four severity grades are calculated; little or no disability (0-5), mild disability (6-10), moderate disability (11-20), and severe disability (> 21). Furthermore, based on the study of Blumenfeld et al.,[21] MIDAS grade IV was subdivided into grade IV-A, severe disability (scores of 21-40) and grade IV-B, very severe disability (scores of 41-270) to allow for a finer examination of variation within the most severely-disabled group.

The HIT-6 is another 6-item tool for measurement of migraine-related disability which takes the preceding four weeks into account, reducing the amount of recall bias. The questions are designed to cover social and role functioning, vitality, cognitive functioning, and psychological distress, ranging from 36 to 78. Afterwards, an impact grade is calculated based on the obtained scores as follows: little or no impact (grade 1, scores ≤ 49), moderate impact (grade 2, scores: 50-55), substantial impact (grade 3, scores: 56-59), and severe impact (grade 4, scores ≥ 60).[22]

For each headache type, headache intensity was measured using the 11-point Numerical Rating Scale (NRS-11) score with 0 and 10 representing "no pain" and "worst possible pain", respectively.[23]

Statistical analysis: The categorical variables (EM, CM, MOH, gender, aura) were summarized using percentages and the continuous one (age) was reported by descriptive statistics, using mean and standard deviation (SD) values. The chi-square test was used for categorical data evaluation.

One-sample Kolmogorov-Smirnov test (K-S test) was used to evaluate the normality of MIDAS and HIT-6 scores, which did not have a normal distribution; thus, the results were reported using median and interquartile range (IQR). Mann-Whitney U test was used to compare the non-parametric variables. The Spearman's correlation coefficient (ρ) was calculated to measure the correlation between MIDAS and HIT-6 total scores. SPSS statistical software (version 19, SPSS Inc., Chicago, IL, USA) was used for all the analyses and a P-value of < 0.05 was considered significant.

Results

Sociodemographic and migraine-associated symptoms: A total of 2454 patients with confirmed migraine, 1907 women (77.7%) and 547 men (22.3%), were enrolled in the study. The mean age of patients was 37 years (SD = 15) with episodic migraineurs being younger than patients with CM (median age = 35 vs. 37 years, respectively, P < 0.001). Different job titles, female gender, and those with MA did not differ between EM and CM sufferers. Tables 1 and 2 provide an overview of gender, age, and migraine-associated symptoms in the studied population according to migraine types. All of the 2454 patients completed the MIDAS questionnaire; however, only 1540 patients agreed to fill the HIT-6 questionnaire as well.

Based on ICHD-3 β criteria, 1261 (51.4%) patients had EM and 1193 (48.6%) had CM. 66 subjects (2.7%) had MA which was reported to be 3.3% (41 patients) in the EM group and 2.1% (25 patients) in the CM group. 908 patients (37.0%) had MOH, which 890 (98.0%) of them had CM. MOH frequency was 77.2% and 22.8% in women and men, respectively. About 74.6% of patients with CM had MOH, whereas only 1.4% of the patients in EM group suffered from MOH (P = 0.005).

Median pain intensity (based on question 7 of MIDAS) was 8.0 (IQR = 5-10) in CM and 6.0 (IQR = 4-8) in EM, which was significantly greater in CM (P < 0.001). There was also a higher median pain intensity in patients with MOH compared with patients without MOH [9 (IQR = 6-10) vs. 7 (IQR = 5-8), P < 0.001].

Regarding migraine symptoms, patients with MOH and patients with CM reported higher incidence of pulsatile headache, nausea, and photophobia/phonophobia than patients without MOH and patients with EM (P < 0.05).

MIDAS findings: MIDAS score was calculated in patients with EM and CM. As the MIDAS score was a non-parametric variable, median values were reported. Median MIDAS scores in EM and CM were 10 (IQR = 2-26) and 30 (IQR = 8-79), respectively, which was significantly higher in patients with CM (P < 0.001). Median MIDAS score was also significantly higher in patients with MOH than the others [34 (IQR = 9-83) vs. 12 (IQR = 2-30), P < 0.001]. There was no statistically significant difference between median MIDAS in subjects with MA and MO (P = 0.616).

Furthermore, we stratified patients based on their migraine type, and in each group, we compared the MIDAS scores in patients with and without MOH. Among patients with CM, median MIDAS was significantly higher in patients with MOH [34 (IQR = 9-84) vs. 22 (IQR = 4-60), respectively, P = 0.005]. Among patients with EM, the median MIDAS scores in patients with and without MOH were 32 (IQR = 3-65) and 10 (IQR = 2-26), respectively (P = 0.041).

Table 1. An overview of age, gender, and migraine-associated symptoms in studied population according to migraine types

Variable		Migraine type		P*	Having aura		P*	MOH		P*
		EM (n = 1261)	CM (n = 1193)		Yes (n = 66)	No (n = 2388)		Yes (n = 908)	No (n = 1546)	
		n (%)	n (%)		n (%)	n (%)		n (%)	n (%)	
Gender	Female	974 (77.2)	933 (78.2)	0.560	54 (81.8)	1853 (77.6)	0.410	701 (77.2)	1206 (78.0)	0.640
	Male	287 (22.8)	260 (21.8)		12 (18.2)	535 (22.4)		207 (22.8)	340 (22.0)	
Job	Employee	331 (41.5)	259 (37.7)	0.290	25 (38.5)	565 (39.8)	0.350	157 (38.0)	433 (40.4)	0.300
	Self-employed	71 (8.9)	65 (9.5)		10 (15.4)	126 (8.9)		37 (9.0)	99 (9.2)	
	Student	110 (13.8)	87 (12.7)		8 (12.3)	189 (13.3)		48 (11.6)	149 (13.9)	
	Housewife	285 (35.8)	276 (40.2)		22 (33.8)	539 (38.0)		171 (41.4)	390 (36.4)	
Unilateral headache	Yes	631 (55.4)	589 (54.3)	0.610	17 (40.5)	1203 (55.2)	0.050	473 (57.1)	747 (53.5)	0.100
	No	508 (44.6)	495 (45.7)		25 (59.5)	978 (44.8)		355 (42.9)	648 (46.5)	
Having pulsatile headache	Yes	771 (67.7)	845 (77.9)	< 0.001	34 (81.0)	1582 (72.5)	0.220	654 (78.9)	962 (69.0)	< 0.001
	No	368 (32.3)	240 (22.1)		8 (19.0)	600 (27.5)		175 (21.1)	433 (31.0)	
Having nausea during headache	Yes	645 (56.6)	662 (61.0)	0.036	32 (76.2)	1275 (58.4)	0.021	512 (61.8)	795 (57.0)	0.027
	No	494 (43.4)	423 (39.0)		10 (23.8)	907 (41.6)		317 (38.2)	600 (43.0)	
Having photo/phonophobia during headache	Yes	844 (74.1)	849 (78.2)	0.022	37 (88.1)	1656 (75.9)	0.060	654 (78.9)	1039 (74.5)	0.018
	No	295 (25.9)	236 (21.8)		5 (11.9)	526 (24.1)		175 (21.1)	356 (25.5)	

*From chi-square test

EM: Episodic migraine; CM: Chronic migraine; MOH: Medication overuse headache

Table 2. An overview of age and migraine severity in studied population according to migraine types

		Age	Intensity
Migraine type			
EM	Median	35.00	6.00
	25th percentile	29.00	4.00
	75th percentile	45.00	8.00
CM	Median	37.00	8.00
	25th percentile	30.00	5.00
	75th percentile	46.00	10.00
P*		< 0.001	0.005
Having aura			
Yes	Median	36.00	7.00
	25th percentile	29.00	5.00
	75th percentile	48.00	9.00
No	Median	36.00	7.00
	25th percentile	29.00	5.00
	75th percentile	45.00	9.00
P*		0.798	0.700
MOH			
Yes	Median	37.00	9.00
	25th percentile	30.00	6.00
	75th percentile	46.00	10.00
No	Median	35.00	7.00
	25th percentile	29.00	5.00
	75th percentile	45.00	8.00
P*		0.002	< 0.001

EM: Episodic migraine; CM: Chronic migraine; MOH: Medication overuse headache
*From Mann-Whitney U test

Table 3 shows the distribution of MIDAS score category based on migraine type, presence of aura, and MOH. According to the defined degrees of severity for the 3-month MIDAS, patients with CM had the highest level of disability, followed by patients with MOH, with 44.5% of the chronic migraineurs and 42.5% of patients with MOH in grade IV-B of MIDAS, respectively (Table 3 and Figure 1).

Figure 4 depicts EM and CM distribution across MIDAS total score categories. The greatest disability (grade IV-B) consisted of 72.25% CM and 27.75% EM. Furthermore, the least disability (grade I) mostly consisted of EM compared to CM (62.61% vs. 37.39%, respectively).

HIT-6 findings: HIT-6 score was also calculated in 1540 patients with migraine (Figure 2), which was also a non-parametric variable. Median HIT-6 scores in EM and CM were 63 (IQR = 58-67) and 67 (IQR = 62-72), respectively, which were significantly higher in patients with CM (P < 0.001). Median HIT-6 score was also significantly higher in patients with MOH compared to the patients without MOH [68 (IQR = 63-72) vs. 63 (IQR = 59-68), respectively, P < 0.001]. There was no statistically significant difference of HIT-6 scores between MA and MO (P = 0.668).
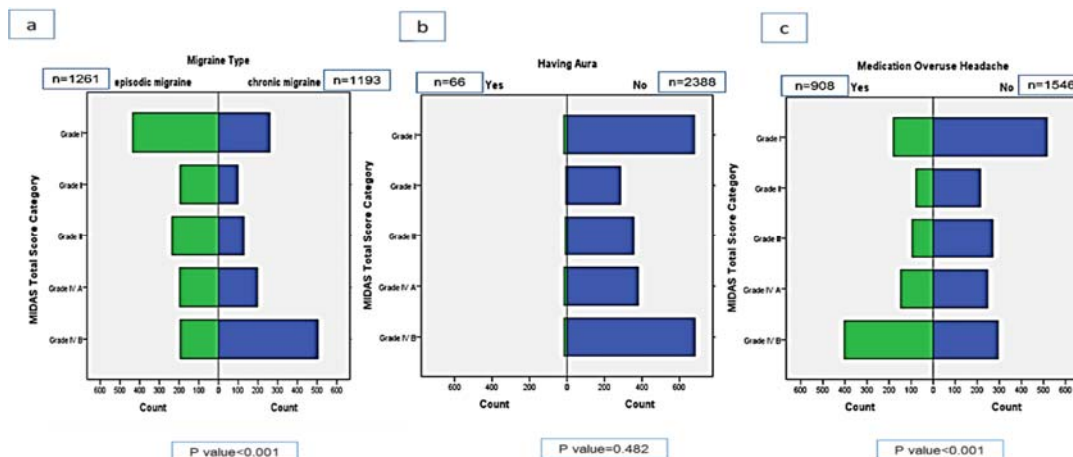
We also stratified the chronic migraineurs based on the presence of MOH and found a significantly higher median HIT-6 score in patients with CM with MOH compared to non-MOH chronic migraineurs [68 (IQR = 63-72) vs. 66 (IQR = 61-71), respectively, P < 0.001]. The same stratification applied to the EM group was not statistically significant (P = 0.356).

MIDAS and HIT-6 scores correlation: Spearman's correlation was run to determine the correlation between MIDAS and HIT-6 scores. There was a moderate (0.40 ≤ ρ ≤ 0.59) positive correlation between MIDAS (as an indicator of headache-related disability) and HIT-6 scores (as an indicator of headache impact on patient's life), which was statistically significant (ρ = 0.441, P < 0.001) (Figure 3). We also evaluated the correlation between HIT-6 and pain intensity and found a moderate (ρ = 0.441, P < 0.001) correlation. Furthermore, we found a weak (ρ = 0.203, P < 0.001) correlation between MIDAS and pain intensity.

Discussion

In this study, we assessed the quality of life in 2454 patients with EM and CM, estimated on basis of MIDAS and stratified based on the presence of MOH and aura, and found that the patients with MOH and the CM group had a reported overall severe disability due to migraine headache (MIDAS grade IV-A).

Table 3. Distribution of Migraine Disability Assessment Scale (MIDAS) score category based on migraine type, presence of aura, and medication overuse headache (MOH)

Variable		Migraine type		Having aura		MOH	
		EM	CM	Yes	No	Yes	No
MIDAS total score category	Grade I	437	261	17	681	181	517
	Grade II	195	99	7	287	79	215
	Grade III	237	130	10	357	96	271
	Grade IV A	198	198	16	380	148	248
	Grade IV B	194	505	16	683	404	295
Median MIDAS (IQR)		10 (2-26)	30 (8-79)	18 (5-40)	16 (3-48)	34 (9-83)	12 (2-30)
		P < 0.010		P = 0.616		P < 0.001	

MIDAS: Migraine Disability Assessment Scale; EM: Episodic migraine; CM: Chronic migraine; MOH: Medication overuse headache; IQR: Interquartile range
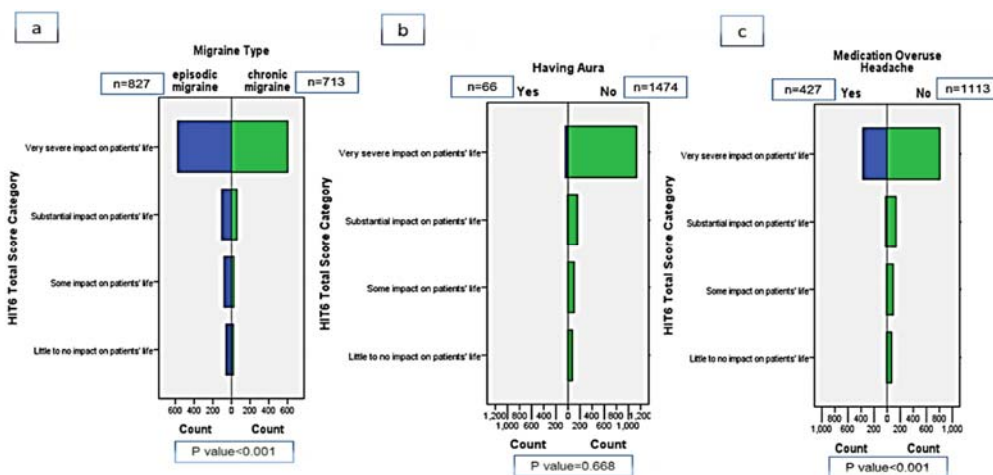
Figure 1. Distribution of migraineurs according to Migraine Disability Assessment Scale (MIDAS) scores categories

The overall HIT-6 score in 1540 evaluated migraineurs was more than 60, representing severe impact on life. It was shown that patients with CM and MOH were more severely affected by migraine than those with EM and non-MOH subjects, which is in line with the results of previous studies.[21,24-27] Moreover, as shown in our study and previous ones, HIT-6 score is a better indicator of pain intensity,[11] evident by the higher correlation observed between HIT-6 and pain intensity, compared to MIDAS which correlates better with headache frequency.

There are several large studies conducted in the western population which estimated the migraine impact and severity using various measuring tools. The American Migraine Prevalence and Prevention (AMPP) Study,[24] carried out as a population-based survey, showed that individuals with CM had greater

headache-related disability with a higher MIDAS score compared to those with EM. The distribution of MIDAS grade showed that 13.1% and 24.8% of the patients with CM were categorized as grade IV-B and IV-A, respectively. In our study, higher grade of IV-B and IV-A scores was observed in the CM group (42.3% and 16.6%, respectively). The higher disability in our sample could be related to the fact that the data are collected from a tertiary clinic, where patients with failed treatments were referred to, in comparison to the lower observed CM prevalence in the aforementioned study (7.86% vs. 48.60%). The International Burden of Migraine Study (IBMS),[21] conducted as a web-based survey from nine countries, compared migraine characteristics and showed that mean headache intensity was significantly higher in CM group compared to EM (headache intensity based on a 0-10 scale).


Figure 2. Distribution of migraineurs according to Headache Impact Test (HIT-6) scores categories
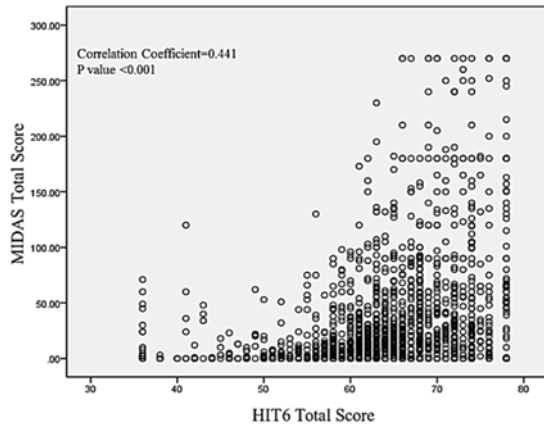
Figure 3. Scatter plot of Headache Impact Test (HIT-6) total scores versus Migraine Disability Assessment Scale (MIDAS) total scores

They also reported a significantly higher least square mean of MIDAS score in the CM group compared to EM and when stratified based on MIDAS grading, 62.62% were categorized as very severe disability compared to 6.28% in patients with EM; while 42.3% of chronic migraineurs in our study were categorized as grade IV-B, we had a higher percentage (15.4%) of patients with EM with very severe disability which could also be the result of our data collection center.
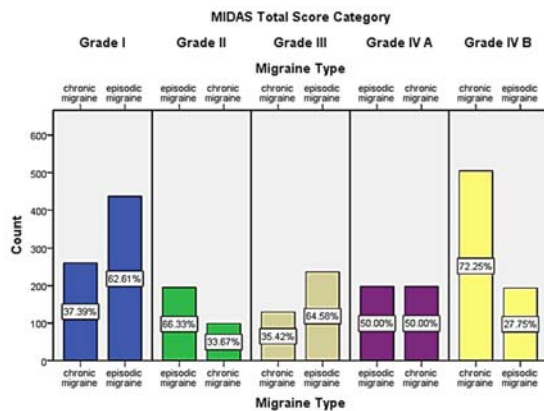
Figure 4. Distribution of episodic migraine (EM) and chronic migraine (CM) in each Migraine Disability Assessment Scale (MIDAS) category

In the Chronic Migraine Epidemiology and Outcomes (CaMEO) Study,[28] a cross-sectional internet-based study conducted in 2012, 16789 migraineurs were identified and a mean MIDAS score of 13.1 and 60.5 was estimated for EM and CM, respectively. Additionally, Kim et al. in a

population-based study in Korea calculated the median HIT-6 score of 51 (IQR = 44.0-57.2) with 18.7% being in the severe impact group.[20] The Canadian Headache Outpatient Registry and Database (CHORD) Study,[11] another clinic-based study in Canada, has reported a median HIT-6 and MIDAS score of 64 (IQR = 61-67) and 24 (IQR = 10-54), respectively. However, neither of the aforementioned studies stratified their results based on migraine subgroups. Nonetheless, our results are compatible with the CHORD study.[11] Both studies are conducted as a tertiary clinic-based study, with an overall HIT-6 score of above 60, indicating that the patients referred to tertiary headache clinics had headaches with severe impact on life. Therefore, proper medical and behavioral modalities should be taken into account, even in patients with EM.

When evaluating headache features, we encountered participants with CM and patients with MOH reporting higher incidence of pulsatile headache, nausea, photophobia/phonophobia, and a significantly higher mean headache intensity compared to patients without MOH and patients with EM, which was congruent with other studies.[21,25,29] This is an indicator that in CM not only the higher headache frequency is a source of disability in patients, but also the intensity and the accompanying characteristics of migraine are troublesome as well.

One of the distinct features of this study was assessment of MOH role in migraine impact and disability in CM and EM, based on HIT-6 and MIDAS, respectively which was significant in CM. Rojo et al. found no significant difference in HIT-6 score in patients with CM with and without MOH.[30] However, our results implicate that the presence of MOH in CM is a troublesome factor adding to the disability and impact which is high by itself in CM.

There were several limitations in the way of this study. As this study is a clinical-based study of the migraineurs referred to a tertiary clinic, its results may be representative of the upper end of headache spectrum; therefore, they should not be implicated to the general migraineur population. However, as the patients are fairly distributed over the MIDAS grades, it could be concluded that our sample is well composed. The other limitation is the recall bias which is due to the nature of retrospective questionnaire-based studies. Each of the two questionnaires has its advantages and disadvantages; HIT-6 refers to a

time frame of 4 weeks, which is more readily recalled by the patient, in contrast to the 3-month recall time related to MIDAS. Therefore, each could be valuable when evaluating treatment efficacy, in its own time frame.

The strength of this study is its relatively large clinical-based sample size, which, up to our knowledge, is the largest data base of its kind in the region. Moreover, the fact that the diagnosis of migraine has been clinically approved according to ICHD-3 β is unique, since many of the large-sample studies are diagnosed based on self-report mail/web surveys or applications.[21,24,28,31] Detailed stratification of results based on migraine chronicity, MOH, and aura is also unique, which is not estimated in many studies of this kind.

Conclusion

The results of this study confirm the previous findings that CM and MOH are associated with a higher headache-related disability and impact on life than EM. Thus, migraine headache warrants more investigation and attention from researchers, healthcare providers, health policymakers, and legislators in order to attenuate the impact of headache on patients and increase their quality of life. Also, as headache is the first cause of YLD in 15-49-year-old patients[8] and is a potentially treatable condition, treatments should be targeted in easing the patient sufferings and progression of EM and its transformation to CM.

Conflict of Interests

The authors declare no conflict of interest in this study.

Acknowledgments

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