Study of Clinical Profile of Patients with Medication Overuse Headache in India

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Abstract
Background: Indian data on Medication overuse headache (MOH) is sparse and inadequate. Hence this prospective observational study was conducted.
Aim: To study the socio-demographic and clinical profile of patients with MOH.
Material and Methods: 42 consecutive patients; age ≥ 18 years, fulfilling the diagnostic criteria of MOH according to ICDH-3 Beta were enrolled in the study from Neurology OPD between March 2017 to April 2019 after excluding patients with secondary causes of headache and those who denied consent. Socio-demographic and clinical data of those were recorded using a pre-designed proforma and analyzed using descriptive statistics.
Results: The study revealed female predominance (85.7%) among the study subjects with a mean age of 34.7 years; most (40.5%) were between 31-40 years of age. Most of the patients received education up to primary (30.9%) or secondary level (40.5%) and were from the lower (26.2), upper lower (45.2%) or the lower middle (21.4%) socio-economic class. Migraine (54.7%) was the most common primary underlying headache type, followed by Tension type headache (40.5%); mean duration of headache being 4.5 years. Most common overused medication was non-opioid containing combination analgesics (50%). 11.9% patients were obese and 33.3% were overweight; 19% fulfilled the WHO criteria for inactivity. Prior stressful life event was found in 11.9% patients, chronic musculoskeletal pain in 23.8% and sleep disturbances in 80.9% patients. 73.8% patients suffered from depression while 57.1% suffered from anxiety. 64.3% had a prior visit to a qualified physician for headache. None of the patients maintained a headache diary and none were cautioned previously against medication overuse.
Conclusion: Along with low educational and socio-economic status, easy availability of over-the-counter pain medications, lack of awareness regarding their overuse contribute to MOH in Indian scenario.
Keywords: Medication overuse headache, MOH.

Introduction
Medication overuse headache (MOH) is a frequently encountered headache disorder with an approximate incidence of 3.08% in Indian clinic. MOH is described as headache occurring on ≥ 15 days per month in a patient with a pre-existing primary headache developing due to regular overuse of acute or symptomatic headache...
medication (on ≥10, or ≥ 15 per month, depending on the medication) for more than 3 months. Indian data on MOH is sparse and inadequate. Hence this hospital-based prospective observational study was conducted with an aim to study the socio-demographic and clinical profile of patients with MOH to supplement our existing knowledge on MOH in Indian context.

Materials and Methods
42 consecutive patients; age ≥ 18 years, fulfilling the diagnostic criteria of MOH according to ICHD-3 Beta were enrolled in the study from Neurology OPD between March 2017 to April 2019 after excluding patients with secondary causes of headache and those who denied consent. Socio-demographic and clinical data of those patients including age, gender, level of education, socio-economic status (modified Kuppuswamy scale), type and duration of the pre-existing primary headache, type of medication overused, body mass index (BMI), history of prior stressful event, presence of chronic musculoskeletal pain, sleep disturbance, inactivity, co-existing anxiety or depression were recorded using a pre-designed proforma. It was also noted whether the patient had any prior visit to a qualified physician for their headache and whether he/she was cautioned previously regarding medication overuse. The pre-existing primary headache was classified on the basis of the criteria in ICHD-3 Beta. All the enrolled patients were screened for anxiety and depression using the Hospital Anxiety and Depression Scale (HADS). Descriptive statistics were used to analyze the data.

Results
Among the 42 MOH patients in the study, 6 patients (14.3%) were males whereas 36 patients (85.7%) were females. Mean age of the study subjects was 34.7 years with age range between 21-54 years. MOH was found to be more common among younger age groups; the most common age group affected was 31 to 40 years (17 patients or 40.5 %) followed by 18–30 years (14patients or 33.3%) (Table 1). MOH was most common among those who received education up to secondary level (17 patients or 40.5%) followed by education up to primary level (13 patients or 30.9%) (Table 2).Most of the MOH patients in our study belonged to upper lower socio-economic class (19 patients or 45.2%) followed by lower (11 patients or 26.2%) and lower middle (9 patients or 21.4%) class (Table 3). The most common primary underlying headache type noted among the study subjects was Migraine (23 patients or 54.7%), followed by Tension type headache (17 patients or 40.5%) (Table 4). The mean duration of the underlying primary headache was 4.5 years (Range: 1-10 years). Most common overused medication was non-opioid containing combination analgesics (21 patients or 50%); followed by opioid containing combination analgesic (09 patients or 21.4%). Only 3 patients (07.2%) overused ergot derivative and none have overused triptan (Table 5). Among the MOH patients studied, 14 patients (33.3%) were overweight and 5 patients (11.9%) were obese according to WHO criteria (Table 6). Prior stressful life event was found in 5 patients (11.9%), chronic musculoskeletal pain in 10 patients (23.8%) and sleep disturbances in 34 patients (80.9%). 8 patients (19%) fulfilled the WHO criteria for inactivity.31 patients (73.8%) suffered from depression (HAD-D score ≥ 11) while 24 patients (57.1%) suffered from anxiety (HAD-A score ≥ 11) (Table 7). 27 patients (64.3%) had prior visit to a qualified physician for their headache. None of the patients maintained a headache diary and none of them were apparently cautioned previously against medication overuse.

Table 1 Distribution of subjects based on Age groups

| Age group (years) | N  | %    |
|------------------|----|------|
| 18–30            | 14 | 33.3 %|
| 31-40            | 17 | 40.5% |
| 41-50            | 09 | 21.4% |
| >50              | 02 | 04.8% |
| Total            | 42 | 100.0 %|

Mean Age – 34.66666667; Range 21-54 years
Table 2: Distribution of subjects based on Education

| Education       | N  | %   |
|-----------------|----|-----|
| Illiterate      | 04 | 09.5%|
| Primary         | 13 | 30.9%|
| Secondary       | 17 | 40.5%|
| Higher Secondary| 05 | 11.9%|
| Graduation & Above | 03 | 07.2%|
| Total           | 42 | 100.0%|

Table 3: Distribution of subjects based on Socio-economic Status (modified Kuppuswamy Classification)

| Socio-economic Class (modified Kuppuswamy Classification) | N  | %   |
|-----------------------------------------------------------|----|-----|
| Class I (Upper)                                           | 01 | 02.4%|
| Class II (Upper middle)                                   | 02 | 04.8%|
| Class III (Lower middle)                                  | 09 | 21.4%|
| Class IV (Upper lower)                                    | 19 | 45.2%|
| Class V (Lower)                                            | 11 | 26.2%|
| Total                                                      | 42 | 100.0%|

Table 4: Distribution of subjects based on type of primary underlying headache

| Broad Headache types | N   | %   | ICHD-3 Beta classification | N   | %   |
|----------------------|-----|-----|----------------------------|-----|-----|
| Migraine             | 23  | 54.7%| Chronic Migraine           | 14  | 33.3%|
|                      |     |     | Probable Chronic Migraine  | 09  | 21.4%|
| Tension type headache| 17  | 40.5%| Chronic Tension type headache | 12  | 28.6%|
|                      |     |     | Probable Chronic Tension type headache | 03  | 07.1%|
|                      |     |     | Frequent episodic Tension type headache | 02  | 04.8%|
| Paroxysmal hemicrania continua | 02  | 04.8%| Paroxysmal hemicrania continua | 02  | 04.8%|
| Total                | 42  | 100.0%| Total                      | 42  | 100.0%|

Table 5: Distribution of subjects based on overused medication

| Overused medication                  | N   | %   |
|--------------------------------------|-----|-----|
| Simple analgesic/ NSAID              | 05  | 11.9%|
| Ergotamine                           | 03  | 07.2%|
| Combination-analgesic (opiod containing) | 09  | 21.4%|
| Combination-analgesic (not containing opioid) | 21  | 50.0%|
| Unverified overuse of multiple drug classes | 04  | 09.5%|
| Total                                | 42  | 100.0%|

Table 6: MOH and Obesity

| Weight based group (according to WHO classification) | N   | %   |
|------------------------------------------------------|-----|-----|
| Normal                                               | 23  | 54.8%|
| Overweight                                           | 14  | 33.3%|
| Obese                                                | 05  | 11.9%|
| Total                                                | 42  | 100.0%|

Table 7: Risk factors and associations of MOH

| Associations                                      | N   | %   |
|---------------------------------------------------|-----|-----|
| Prior stressful events                            | 05  | 11.9%|
| Sleep disturbances                                | 34  | 80.9%|
| Physical Inactivity                               | 08  | 19.0%|
| Chronic musculoskeletal pain                      | 10  | 23.8%|
| Anxiety                                           | 24  | 57.1%|
| Depression                                        | 31  | 73.8%|

Discussion

In India, majority of the headache patients are managed by either non-neurologists or quacks or practitioners of complementary and alternative medicine; many patients resort to self-medication. Inappropriate use of symptomatic pain medication for relief of a chronic headache often may lead to MOH. MOH is associated with significant morbidity leading to reduced quality of life. In our study of 42 MOH patients, chronic migraine was the most common type of underlying primary headache followed by chronic tension type headache which is in concordance with previous Indian studies by Ravishankar K and Agarwal N. Similar finding was also noted by Imai N et al in his Japanese study and Radat F et in his French study on MOH. The demographic analysis of the study subjects reveals a strong female preponderance (85.7%) as seen in other studies on MOH from India as well as abroad. The age group most commonly affected is between 31-40 years (40.5%), followed by 18-30 years (33.3%) which is similar to an Indian study by Agarwal N, in which 50% and 25% of the study population belonged to above age groups respectively. Most of the patients received education up to primary (30.9%) or secondary level (40.5%) and were from the lower (26.2), upper lower (45.2%) or the lower middle (21.4%) socio-economic class. This study reveals that MOH in India is more prevalent among the people from the low socio-economic class. 

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strata and those with low education level. Headache is often considered a trivial ailment in such household. Due to lack of awareness and financial constraints they often resort to self-medication, visit quacks for intermittent pain relief which is evident by the fact that only 64.3% of the MOH patients in our study had a prior visit to a qualified physician for their headache. Even if they visit a qualified doctor, they often tend to discontinue medications for chronic prophylaxis on their own and are reluctant or irregular for follow-ups. Regardless of previous visit to a qualified doctor, all the MOH patients denied being cautioned previously against medication overuse. Similar observation was made by Ravishankar K. in his study on MOH in India.\textsuperscript{1} Hence, a lack of communication by the treating physician to the patients in this regard may also possibly contribute to the burden of MOH in India. Most common overused medication was non opioid containing combination analgesics (50%) followed by opioid containing combination analgesics (21.4%). This do not correspond to the results of the study by Ravishankar K, according to which ergotamine overuse headache (56.52%) was higher than that due to combination analgesics (38.04%).\textsuperscript{1} However, a more recent study by Agarwal N. found analgesics or combination analgesics alone as the most commonly overused medications in MOH patients (70%). This discrepancy can probably be explained by the reduced availability of ergot derivatives now a days in India with combination analgesics being freely available as OTC headache remedies. Combination analgesics were also found to be the most commonly overused drug class in a Japanese study on MOH by Imai N et al.\textsuperscript{7} None of the patients in our study overused Triptans. Previous Indian study on MOH by Ravishankar K have also found Triptans to be the least overused (5.43%) among all drug classes.\textsuperscript{1} The most likely responsible factor seems to be the cost. Also Triptans are rarely prescribed by quacks, neither it is commonly used as OTC headache remedy; thereby reducing further the chances of its overuse. Among the MOH patients studied, 5 patients (11.9%) were found to be obese and 14 patients (33.3%) were found overweight; 8 patients (19%) fulfilled the WHO criteria for inactivity. Obesity and physical inactivity has been found to be a risk factor for MOH in European studies by Westergaard et al\textsuperscript{8} and Hagen et al.\textsuperscript{10} Also in an Indian study by Agarwal N, 30% of MOH patients were obese.\textsuperscript{6} In our study, sleep disturbances were found 80.9% of MOH patients, 73.8% patients suffered from depression while 57.1% suffered from anxiety. Previous Indian studies by Ravishankar K and Agarwal N also found significant depression and anxiety among MOH patients.\textsuperscript{1,6}

**Conclusion**

Along with low educational and socio-economic status, easy availability of OTC headache remedies, lack of awareness regarding their overuse and often lack of communication by the treating doctor contribute to MOH in Indian scenario, which often causes significant morbidity. With the identification of multiple risk factors, a multidisciplinary approach for prevention as well as holistic management of MOH seems to be the future.

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