

# A PROSPECTIVE CLINICAL OBSERVATIONAL STUDY ON THE ASSESSMENT OF RISK FACTORS DIAGNOSIS AND TREATMENT PATTERNS OF MIGRAINE

Preethi Mandati<sup>1</sup>, Prashanth Parupathi<sup>2</sup>, S.K.Sirajuddin<sup>3</sup>, Mahender Vatipelli\*.

1,2,3 Doctor of Pharmacy, St. Peter's Institute of Pharmaceutical Sciences, Vidyanagar, Hanamkonda, Warangal, Telangana, India.

4 Associate Professor, Department of Pharmacy Practice, St. Peter's Institute of Pharmaceutical Sciences, Vidyanagar, Hanamkonda, Warangal, Telangana, India.

## Abstract:

**Aims and objectives:** To evaluate and provide a useful study on clinical assessment of triggering factors, diagnostic criteria and treatment patterns in migraine patients. **Methodology::** A hospital based prospective clinical observational study was carried out for 6 months to evaluate the triggering factors, diagnosis of migraine. **Results:** A total number of 300 patients were enrolled in this study. According to gender wise distribution 53 (17.66%) were males and 247 (82.33%) were females and patients under the age group 24-30 (20.33%) were at higher risk and the migraine headache mostly starts at the age group of 24-30(25%) The time period for each episode was 0-24hours 87.66% patients. The nature of pain was pulsatile in 76% patients & non pulsatile in 24.33% patients and feeling sense of pressure and heaviness in 50%, stabbing sensation in 40.3% ,pricking sensation in 67.6% patients. Nausea & vomiting is seen in 84.66% patients, giddiness in 40.66% patients, photophobia in 84.33% patients, phonophobia in 71% patients, aggravation by daily activities in 59.33% patients. Among 300 patients enrolled in the study food is a trigger in 36% patients, sleep in 48.66%, stress in 72%, journey in 72%, strong smell in 33.66% patients, change in weather in 44.66% patients, head bath in 29.33% patients. **Conclusion:** Migraine is common treatable cause of neurological disability. It is vital to make effective diagnosis of migraine and knowledge of triggers may help in the management of migraine by avoiding them.

**Key Words:** Migraine, Triggers, Diagnosis, therapeutic response.

## INTRODUCTION:

Migraine is a common chronic, incapacitating neurovascular disorder, characterized by attacks of severe headache, autonomic nervous system dysfunction, and in some patients, an aura involving neurologic symptoms.<sup>1,2</sup> The World Health Organization rates a day with severe migraine to be as disabling as a day spent quadriplegic.<sup>3</sup>

Migraines typically present with self-limited, recurrent severe headache associated with autonomic symptoms.<sup>6</sup> There are four possible phases to a migraine, although not all the phases are necessarily experienced.<sup>7,8</sup>

- 1. Prodrome phase:** This phase usually occurs hours or days before headache. In this phase symptoms include wide variety of phenomena including altered mood, irritability, depression or euphoria, fatigue, craving for certain food(s), stiff muscles (especially in the neck), constipation or diarrhea, and sensitivity to smells or noise.
- 2. Aura phase:** An aura is a transient focal neurological phenomenon that occurs before or during the headache. Auras appear gradually over a number of minutes and generally last less than 60 minutes. Symptoms can be visual, sensory or motor in nature and many people experience more than one. Visual effects occur most frequently.<sup>10</sup>

**Visual symptoms**

- Homonymous hemianopic or quadrantic field defects
- Central scotomas
- Tunnel vision
- Altitudinal visual defects
- Complete blindness

**Sensory symptoms:**

They are often cheiro-oral, with numbness starting in the hand, migrating to the arm, and then jumping to involve the face, lips, and tongue. As with visual auras, positive symptoms typically are followed by negative symptoms; paresthesia may be followed by numbness<sup>11</sup>.

**Motor symptoms**

Motor symptoms may occur in 18% of patients and usually are associated with sensory symptoms.. Speech and language disturbances have been reported in 17-20% of patients. These disturbances are commonly associated with upper extremity heaviness or weakness.<sup>12</sup>

3. **Pain phase:** Classically the headache is unilateral, throbbing, and moderate to severe in intensity.<sup>12</sup> It usually comes on gradually and is aggravated by physical activity.<sup>13</sup> Bilateral pain is particularly common in those who have migraines without an aura. Less commonly pain may occur primarily in the back or top of the head. The pain usually lasts 4 to 72 hours in adults.<sup>14</sup> The pain is frequently accompanied by nausea, vomiting, sensitivity to light, sensitivity to sound, sensitivity to smells, fatigue and irritability.
4. **Postdrome phase:** The migraine postdrome could be defined as that constellation of symptoms occurring once the acute headache has settled.<sup>15</sup> Postdromal symptoms may persist for 24 hours after the headache and can include the following:<sup>16</sup>
  - Tired, “washed out,” or irritable feeling
  - Unusually refreshed or euphoric feeling
  - Muscle weakness or myalgias
  - Anorexia or food craving

**Triggers for migraine headache:**

Some common triggers of migraine includes:



Figure 1: Triggers for Migraine Headache.

**Food:** Food related triggers occur in about 10% of people with migraine. Food such as chocolate aged cheeses, salty foods and processed foods may trigger migraines. Skipping meals or fasting also can trigger attacks.

**Changes in wake-sleep pattern:** The complex nature of trigger factors is illustrated by sleep. Missing sleep or getting too much sleep may trigger migraines in some people, as can jet lag can be implicated in a migraine starting.

**Stress:** A dramatic increase or decrease in physical or psychological stress can trigger migraine. Migraine and stress are strongly linked. Indeed, anxiety, excitement and any form of tension and shock may all lead to a migraine attack.<sup>34,35</sup>

**Journey:** It is associated with a host of potential migraine triggers: lack of sleep from preparation for the trip and from the trip itself, stress, missed or delayed meals, noise, and dehydration.

**Strong Smell:** Migraine patients frequently report that strong or unusual smells trigger their headaches. It includes perfume, paint thinner, secondhand smoke and others can trigger migraines.<sup>36</sup>

**Change in weather:** A change of weather or barometric pressure can prompt a migraine.<sup>36</sup> There are certain trigger factors which can be related to environmental issues such as high altitude, weather changes, high humidity, loud noises, exposure to glare or flickering lights.<sup>34,35</sup>

**Head Bath:** some people observe that their headache increases after doing head bath.

**Change in Routine:** Some people find that changes in their routine can contribute to a migraine. For example changing sleep patterns or changes caused by long journeys can precede an attack. Even pleasant changes such as a holiday can be implicated.<sup>34,35</sup>

**Hormonal Changes in Women:** Women are three times more likely to suffer from migraine headache than men. Evidence suggests that female sex hormone fluctuations may play a role in headache onset and severity.<sup>34,35</sup> Migraine is closely associated with female hormones. Some women find their migraines start at puberty, and are linked to their menstrual cycle<sup>37,38</sup>

### **Treatment:**

Approaches to treating migraine can be divided into nonpharmacologic therapies and pharmacologic therapies.

#### **Non pharmacological therapy:**

Non pharmacologic therapies include education of the patient about the disorder, its mechanisms, approaches to treatment, and changes in lifestyle involved in the avoidance of triggers of migraine. Thus, regular sleep, regular meals, exercise, avoidance of peaks of stress and troughs of relaxation, and avoidance of dietary triggers can be helpful.<sup>40,41,42</sup>

#### **Pharmacological therapy:**

The pharmacological treatment of migraine include treatment of acute attacks and preventive treatment.

#### **Treatment of acute attacks for migraine:**

Acute attack treatments for migraine can be usefully divided into

- (i) Disease non-specific treatments, such as analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) and
- (ii) Relatively disease-specific treatments, such as ergot-related compounds and triptans.

**Objectives:**

- The primary objective of this study was to evaluate and provide a useful study on clinical assessment of triggering factors, diagnostic criteria and treatment patterns in migraine patients.
- The major objective of the study was to collect the information regarding the risk factors of migraine headache, know how the migraine headache is diagnosed and compare the efficacy of the drugs to treat migraine headache.
- To collect the information regarding the usage of drugs and discuss about the outcomes with physicians and also provide the recorded data to the physicians and other healthcare professionals

**Methods and materials:****Study site:**

The present study was conducted at two neurology centres, Sri Sri Neuro Centre and Telangana Neuro Multi Clinic Hanamkonda, Warangal, Telangana, India. These neuro care Centre's are situated in the heart of the city with basic objective of providing Pharmacological and Non-pharmacological management of migraine patients.

**Study design:**

A hospital based Prospective Observational Study.

**Study period:**

The study was carried out for a period of 6months (February-July) 2017.

**Study sample size:** The study was conducted on 300 patients at multi centers.

**Study criteria:****Inclusion criteria:**

- Patients who are complaining with a symptoms of headache
- Patient whose prescription contains antimigraine drugs
- Only outpatients
- Patients whose age group is above 10years

**Exclusion criteria:**

- Patients with below 10 years age.
- Pregnancy women
- Patients who were not willing to participate in the study.

**Study Procedure:**

The study was initiated at two Neuro Centre by selecting the patients based on inclusion criteria of the study. Patients with Migraine enrolled in our study, were regular attenders of the clinic for each month.

Patients were enrolled in this study based upon risk factors, diagnosis and their treatment. Our study reviews the information regarding the triggering factors, diagnosis of migraine headache and discusses the efficacy and safety of abortive and chronic pharmacological therapy for migraine.

**Sources of Data:**

All the relevant and necessary data was collected from Patient's case notes.

Risk factors.

Treatment charts.

Interviewing patient.

**Statistical methods:**

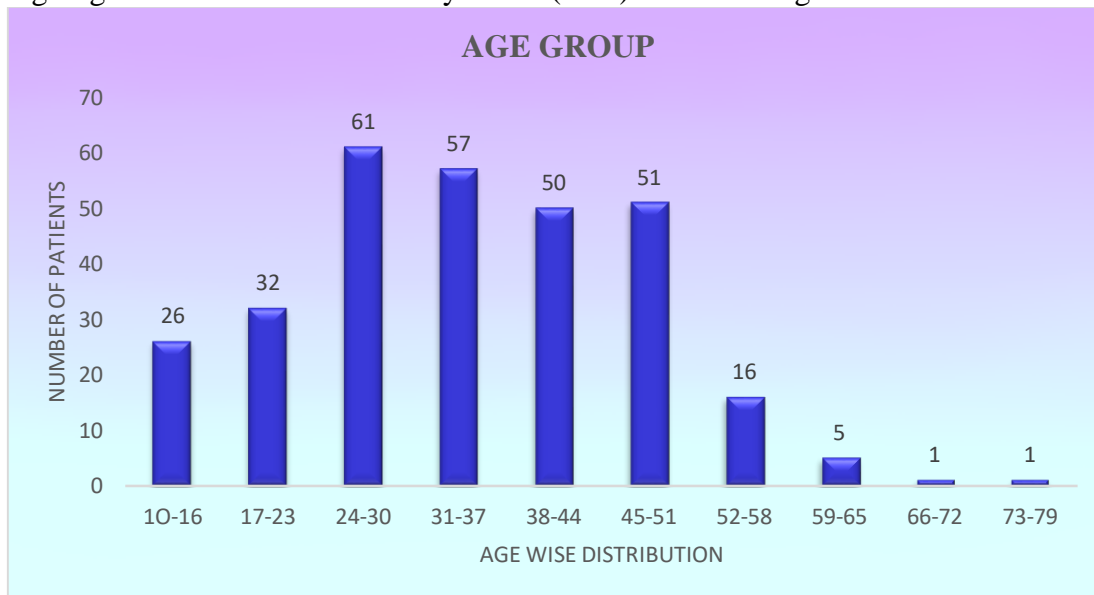
Descriptive statistics was applied, collected data's are entered and documented in Microsoft excel spread sheet for further interpretations.

**Data collection Form:**

A suitably designed data collection form was prepared for patients (Annexure-I) which includes demographic details of the patients such as age, gender, weight, address, past medical history, social history, medication history, nature of the patient, Intensity of the patient, Triggering factors of headache, Diagnostic criteria, current medication chart.

**RESULTS:**

According to the gender wise 300 patients were divided 247 (82.33%) females and 53 (17.66%) males. According to age-wise categorization of the study population, patients from age of 10 years to 79 years were included. According to observation males and females under the age group 24-30 (20.33%) were at higher risk of getting migraine headache followed by 31-37 (19%). The mean age was found to be  $35.08 \pm 11.57$ .

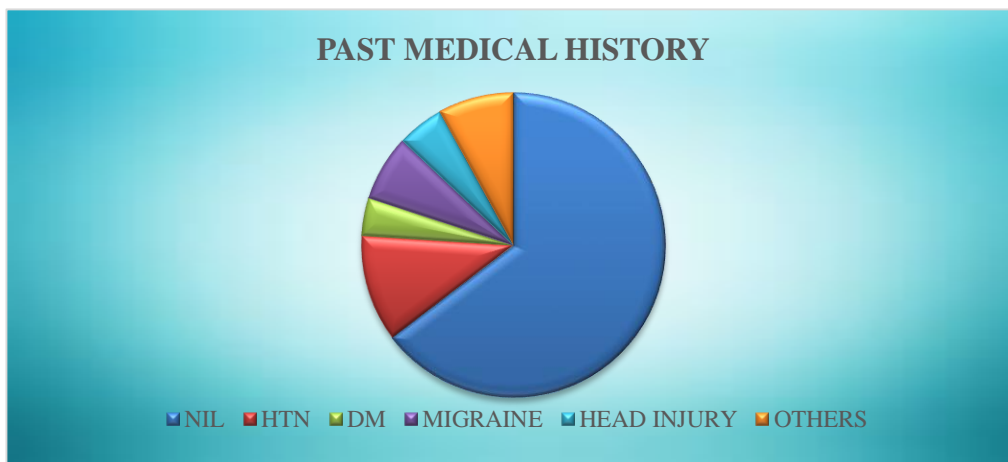


**Figure 2: Age wise distribution**

**Table 1: Gender wise distribution**

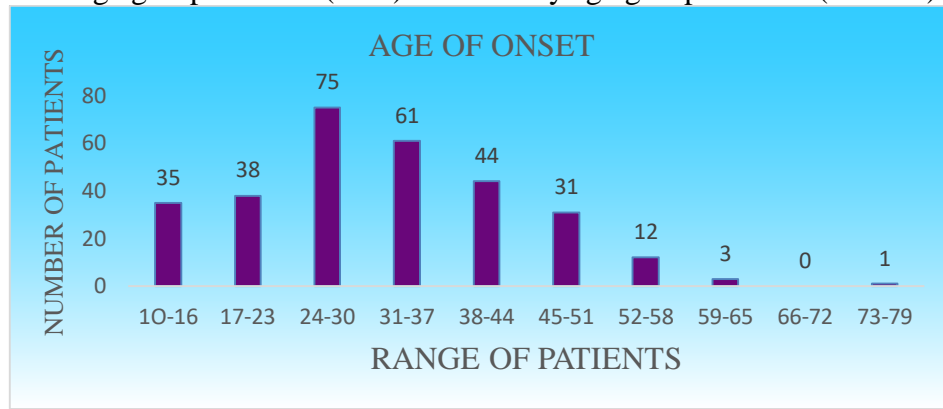
Gender	Frequency (%)
Male	53 (17.66)
female	247 (82.33)

- Past Medical History:** Among 300 patients, past medical history of HTN was observed in 11.33% (n=34), DM was observed in 4% (n=12), Migraine was observed in 7% (21), Head injury was observed in 5% (n=15), others 8% (24), Nil 64.66% (n=194). Incidence of past medical history in the migraine patients was at low risk



**Figure 3: Past Medical History**

- **Age of onset:** According to the age of onset distribution we observed that the migraine headache mostly starts at the age group of 24-30(25%) followed by age group of 31-37(20.33%).



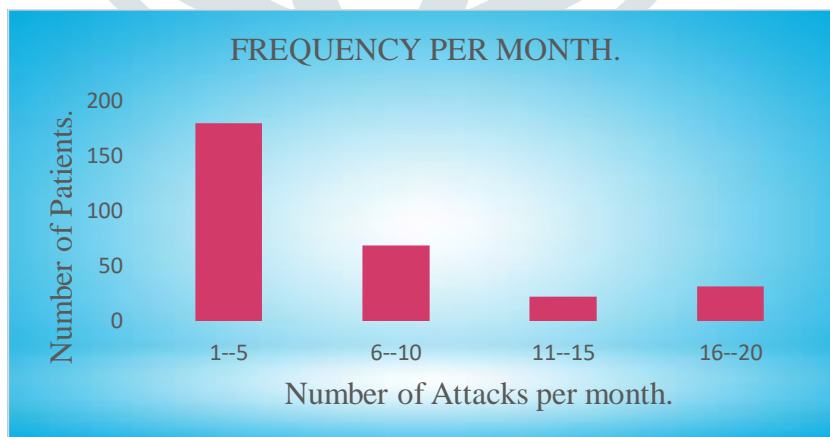
**Figure 4: Age of onset wise distribution**

- **Duration of migraine headache:** Based on duration of headache we have enrolled patients with less than one month of duration to greater than 10 years. The data was evaluated and we observed that most of the people are having duration of 1-5 year

**Table 2: Duration of migraine**

Duration of headache	Frequency (%)
<1 month	15 (5)
1 month - 1 year	67 (20.33)
1 year-5 years	162 (54)
6 years- 10 years	31 (10.33)
>10 years	25 (8.33)

- **Frequency per Month:** For most of the people who enrolled in the study the frequency of migraine was 1-5 (59.66%) times per month. On an average, each patient has migraine attacks of 6.4 times per month.



**Figure 5: Frequency of Migraine per Month**

- **Time Period for Each Episode**  
Among 300 migraine patients most of the time period for each episode was 0-24hours n=263 (87.66). On an average time period for each episode lasting for 16.4 hours.

**Table 3: Time Period for Each Episode**

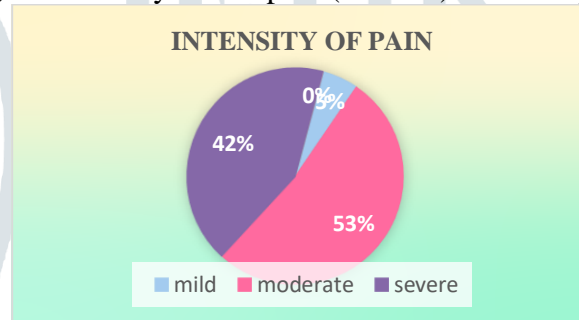
Episodes	Frequency (%)
0-24	263 (87.66)
24-48	19 (6.33)
48-72	18 (6)

- **Location of headache:** Most of the patients enrolled in the study are having headache bilaterally (n=237) than unilateral same side (n=55) and unilateral side shift (n=8).

**Table 4: Location of migraine headache**

Location	Frequency (%)
Bilateral	237 (79)
Unilateral same side	55 (18.33)
Unilateral side shift	8 (2.66)

- **Intensity of pain:** Among the patients enrolled in the study the intensity of pain was calculated by using MIDAS questionnaire. The data was evaluated and observed that most of the patients are having moderate pain (52.33%) followed by severe pain (42.33%) and mild pain (5.33%).



**Figure 6: Intensity of pain of Migraine Headache**

- **Nature:** Among the patients enrolled in the study the nature of pain was pulsatile in 76% patients & non pulsatile in 24.33% patients. 50 % patients are feeling sense of pressure and heaviness, 40.3 % patients feel stabbing sensation, 67.6% patients feel pricking sensation.



**Figure 7: Nature of pain**

- **Associated features:** Among 300 patients enrolled in the study nausea & vomiting is seen in 84.66% patients, giddiness in 40.66% patients, photophobia in 84.33% patients, phonophobia in 71% patients, aggravation by daily activities in 59.33% patients.

Table 5: Associated features with migraine

Associated feature	Frequency (%)
Nausea & vomiting	254 (84.66)
Giddiness	122 (40.66)
Photophobia	253 (84.33)
Phonophobia	213 (71)
Aggravates by daily activities	178 (59.33)

**Triggering factors:** Among 300 patients enrolled in the study food is a trigger for 36% patients, sleep is a trigger for 48.66%, stress is a trigger in 72%, journey is a trigger in 72%, strong smell is a trigger in 33.66% patients, change in weather is a trigger in 44.66% patients, head bath is a trigger in 29.33% patients.

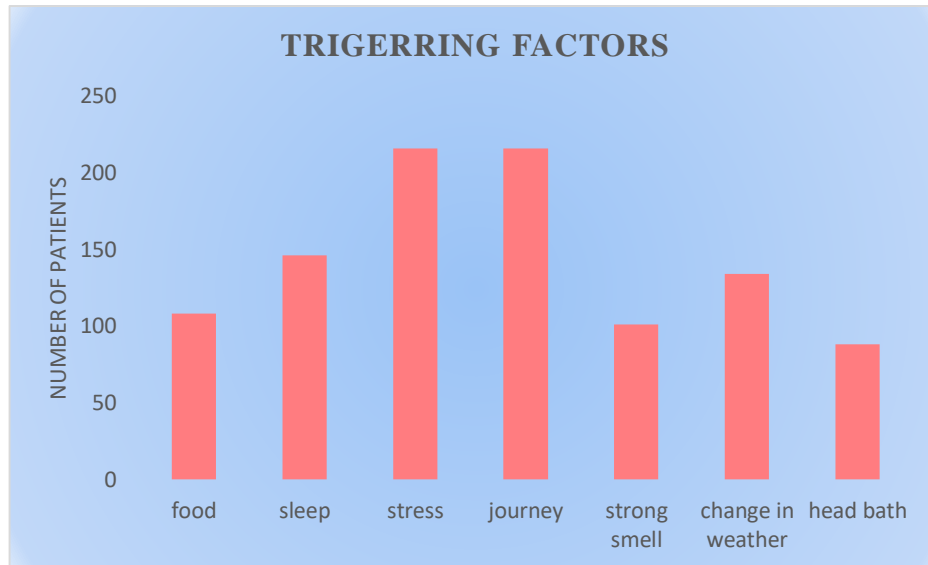


Figure 8: Triggering factors in migraine

Table 6: Distribution of number of triggers between male &amp; female in migraine patients

Number of trigger	Males (53)	Females (247)
1 Trigger	4 (7.54%)	21 (8.50%)
2 Triggers	8 (15.09%)	38 (15.38%)
3 Triggers	21 (39.62%)	59 (23.88%)
4 Triggers	15 (28.30%)	82 (33.19%)
5 Triggers	5 (9.43%)	35 (14.17%)
6 Triggers	nil	12 (4.85%)

**Treatment Patterns of Migraine Patients:** Among 300 enrolled in the study, most of the patients are received with acute migraine specific treatment with NSAID'S & triptans along with the preventive therapy with Anti-depressants &  $\beta$ -blockers.



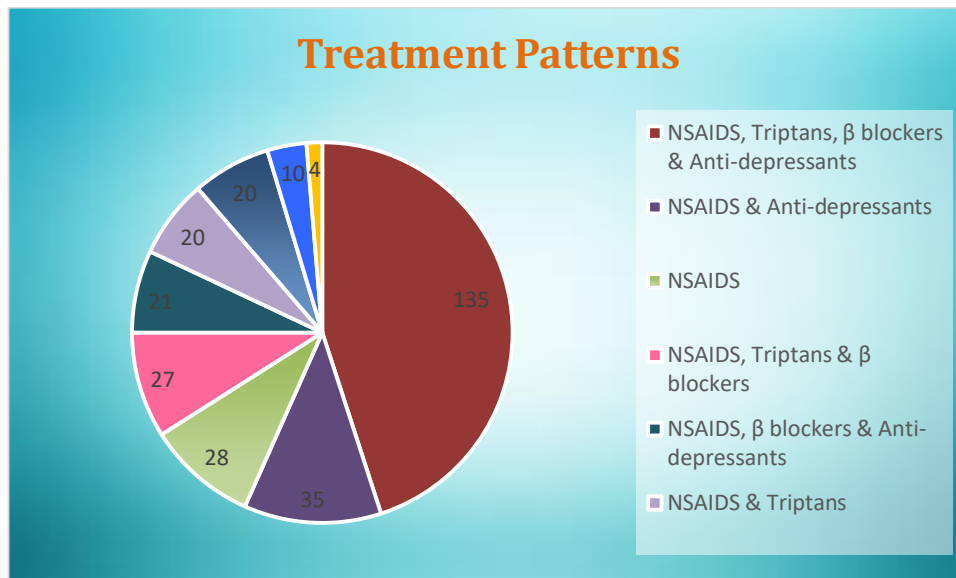


Figure 9: Treatment Patterns

Table 7: Distribution of various triggers between male & female in migraine patients.

Triggers	Males	Females
Food	21	87
Sleep	27	119
Stress	37	178
Journey	32	185
Smell	13	86
Weather	220	112
Head Bath	14	74

**Conclusion:**

Migraine is common and important treatable cause of neurological disability. It is vital to make a diagnosis and ensure that any concomitant medical or psychological conditions are treated in parallel with interventions aimed at reducing the biological tendency to headaches. It can be concluded that knowledge of triggers may help in the management of migraine by avoiding them. Migraine is diagnosed by patient history only and no neuro-imaging studies are done so there is a need to improve migraine diagnosis and doctor patient communication about migraine.

**Acknowledgements:**

We would like to express our sincere thanks to **Dr. Om Prakash. P** MD,DM(NEURO) and **Dr.RajeevRanjan**MD,DM(NEURO) and those who helped us in making the project a success by providing adequate facilities to carry out the project work.

We should be failing in our duties if we don't mention the help of **Authors of journals and books**, the sentinels of our project work.

Finally, we thank all the patients who **participated** and who are **not willing to participate** in the study without whom the study would not have been possible.

**FUNDING:** This research did not receive any specific grant from funding agencies in public, commercial, or not-for-profit sectors.

**CONFLICTS OF INTEREST:** No

**REFERENCES:**

1. Lance JW, Goadsby PJ. Mechanism and management of headache. 6th ed. Boston: Butterworth-Heinemann, 1998.
2. Silberstein SD, Lipton RB, Goadsby PJ. Headache in clinical practice. Oxford, England: Isis Medical Media, 1998.
3. Menken M, Munsat TL, Toole JF. The global burden of disease study – implications for neurology. *Arch Neurol* 2000; 57:418–20.
4. Goadsby PJ, Lipton RB, Ferrari MD. Migraine – current understanding and treatment. *N Engl J Med* 2002; 346: 257–70.
5. Headache Classification Committee of the International Headache Society. Classification and diagnostic criteria for headache disorders, cranial neuralgias and facial pain. *Cephalalgia* 1988; 8: 1–96.
6. Bigal, ME; Lipton, RB (June 2008). "The prognosis of migraine". *Current Opinion in Neurology*. **21** (3): 301–8.
7. Gilmore, B; Michael, M (2011-02-01). "Treatment of acute migraine headache". *American family physician*. 83 (3): 271–80.
8. al.], ed. Jes Olesen, ... [et (2006). *The headaches*. (3 ed.). Philadelphia: Lippincott Williams & Wilkins. p. 512. ISBN 9780781754002. Archived from the original on 2016-12-22.
9. Rae-Grant, [edited by] D. Joanne Lynn, Herbert B. Newton, Alexander D. (2004). *The 5-minute neurology consult*. Philadelphia: Lippincott Williams & Wilkins. p. 26. ISBN 9780683307238. Archived from the original on 2017-03-13.
10. *The Headaches*, pp.407–19
11. Aminoff, Roger P. Simon, David A. Greenberg, Michael J. (2009). *Clinical neurology* (7 ed.). New York, N.Y: Lange Medical Books/McGraw-Hill. pp. 85–88.