A correlational study between time taken for pain relief and quality of life in acute episode of migraine using homoeopathy

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Abstract
Migraine, a common primary headache disorder impairs functioning and exerts an enormous burden on the quality of life of the affected migraine patients, their families, and the whole community [1]. Migraine consistently remains the second cardinal contributor of years lived with disability (YLDs) accounting for 47.24 million YLDs globally [2]. Migraine is chronic headache disorder characterized by recurrent acute episodes with a potential to progress into more frequent and intense patterns [3]. Migraine is an extremely painful condition with severe headache, nausea, vomiting, photophobia and phonophobia lasting 4 hours to 72 hours when untreated. It is extremely difficult to maintain normal functioning during an attack, wherein some patients may remain bedridden for days till symptoms resolve [4]. Fear of getting another attack and expectation due to it reduces quality of life even between migraine attacks [5]. Hence there is impairment in quality of life not only during but also in between migraine attacks [6]. This leads to substantial functional impairment causing enormous physical, mental, social and economic burden to patients [7].

Migraine being a cause of severe disability and impairment in quality of life necessitates treatment in such a manner that rapid relief is obtained so the patient can resume their normal function [8]. With an appropriate treatment paradigm using acute medication during acute episodes [9], and prophylactic treatment to reduce the recurrence [10], there should be reduction of overall functional impairment. Homoeopathy, a holistic system of alternative medicine shows promising scope in treatment of several acute conditions, including migraine [11]. The aim of this study was to assess impairment in Quality of Life due to acute episode of Migraine and to find correlation between time taken for pain relief using homeopathic medicines and Quality of Life of the patients.

Materials and Methods
Study setting: Outpatient and inpatient departments as well as Peripheral Health Centers of Sarada Krishna Homoeopathic Medical College Hospital.

Sampling: 20 cases, purposive sampling
Study duration: 3 acute episodes of migraine in each case (total 60 acute episodes of migraine)
**Inclusion criteria:** Cases satisfying ICHD-3 diagnostic criteria of IHS for migraine \(^{[12]}\), Frequency of 2 to 8 attacks of migraine monthly for a period of greater than or equal to 1 year, Adults with 18 to 65 years age, both males and females, Informed consent given.

**Exclusion criteria:** Patients with other varieties of primary headaches (tension type headache, trigeminal autonomic cephalalgias, etc.), secondary headaches (headache due to identifiable cause like trauma, vascular disorder, substance abuse or withdrawal, infections, disorder of homeostasis, psychiatric disorders, etc.), Pregnant women were excluded from the study.

**Procedure:** A sample of 20 cases of migraine fulfilling diagnostic and inclusion criteria were enrolled from Outpatient and inpatient departments as well as Peripheral Health Centers of Sarada Krishna Homoeopathic Medical College Hospital. History taking and physical examination were done for each patient. Homeopathic medicine selected based on acute totality was administered in water dose with frequent repetition as necessary. Three attacks of migraine were assessed in each patient.

**Assessment:** The time taken for the beginning of pain relief and the time taken for total pain relief was measured in each migraine attack. Impact on the Quality of life of the cases due to acute episode of migraine was assessed using 24 hour Migraine specific Quality of life Questionnaire (24h MQoLQ). 24-hr MQoLQ is a validated questionnaire to appraise the effect of the attack of migraine and its management on the life of patient for a clinically significant, focused time interval, that is for 24 hours following onset of headache. It consists of fifteen items comprising five domains with three items within each domain: Work functioning, Social functioning, Energy/Vitality, Migraine symptoms, Feelings/concerns. The responses of the patient are assessed on a 7-point scale where 7 signifies no impairment and 1 signifies maximum impairment of QoL. Every domain has a least score as 3 and a highest score as 21 \(^{[13]}\). The 24h MQoLQ has fine construct validity, discriminant validity, excellent internal consistency, and responsiveness to acute migraine attacks. \(^{[14]}\). Intra-individual consistency of response was evaluated by assessing 3 attacks of migraine in each patient.

**Results**

**Baseline data:** Nine variables were studied in all the participants- age, sex, occupation, marital status, diagnosis, duration of migraine, triggers, site of headache, family history. The baseline data of all the patients are summarized in the table.

| Table 1: Baseline characteristics of patients: N(%) |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Age             | 21 to 25 years: 6 (30%), 26 to 30 years: 1(5%), 31 to 35 years: 1(5%), 36 to 40 years: 4 (20%), 41 to 45 years: 2 (10%), 46 to 50 years: 2 (10%), 51 to 55 years: 1(5%), 56 to 60 years: 2 (10%), 61 to 65 years: 1(5%). |
| Sex             | Female: 18(90%), Male: 2(10%) |
| Occupation      | Housewives: 8 (40%), Students: 5 (25%), Retired teacher: 1(5%), Staff nurse: 1(5%), Accountant: 1(5%), NGO worker: 1(5%), Daily wages: 1(5%), Business: 1(5%), Unemployed: 1(5%) |
| Marital Status  | Unmarried: 14(70%), Married: 6(30%) |
| Diagnosis       | Migraine without aura: 15 (75%), Migraine with aura: 5 (25%) |
| Duration of Migraine | 1 to 5 years: 8(40%), 6 to 10 years: 5(25%), 11 to 15 years: 3(15%), 16 to 20 years: 1(5%), 21 to 25 years: 1(5%), 26 to 30 years: 1(5%), 31 to 35 years: 1(5%) |
| Triggers        | Sun exposure: 14 (70%), Mental stress: 9 (45%), Travel: 9 (45%), Loud sounds: 7 (35%) |
| Site of Headache| Left side: 6 (30%), Right side: 4(20%), Both sides: 6 (30%), Right to left side: 3(15%), Left to right side: 1(5%) |
| Family History  | Positive family history: 5(25%) |

**Outcome estimation:** 24h MQoLQ Scores was assessed during 3 acute episodes of migraine for all the patients. The mean 24h MQoLQ score was 70.68 ± 14.33.

![Fig 1: 24hMQoLQ scores](image)

The mean time taken for beginning of relief from pain was 1.34 hours with a standard deviation of 0.72 hours. The mean time taken for total relief from pain was 5.22 hours with a standard deviation of 2.94 hours. A correlation graph was plotted to understand the relationship between rapidity of action of homeopathic...
medicines and quality of life measured using 24h MQolQ Scores. First a correlation graph, i.e. scatter diagram was plotted between time taken for beginning of pain relief and 24h MQolQ scores. Secondly, a correlation graph, i.e.

Further confirmation of correlation was done statistically by calculation of the Correlation coefficient. The correlation between time taken for total pain relief by homoeopathic medicine and Quality of life was found to have strong negative correlation as per Pearson’s correlation coefficient (r= -0.58, p<0.001). When a similar correlation test was done between time taken for beginning of pain relief and quality of life calculated by 24h MQolQ score, the Pearson’s correlation coefficient value ‘r’ was -0.41 which indicates a weak negative correlation significant at 0.1% significance level. There is a marked difference in correlation coefficients calculated with time taken for beginning of relief from pain and time taken for total relief from pain with quality of life respectively. This shows that the quality of life is better correlated with total relief from pain rather than just the beginning of relief.

Medicines used: The homeopathic medicines used in the 60 migraine episodes treated were Natrium muriaticum (n=15, 25%), Bryonia alba (n=6, 10%), Silicea (n=5, 5.33%); Spigelia, Nux vomica, Antimonium crudum (n=4, 6.67% each); Veratrum album, Sepia, Glonoine (n=3, 5% each), Sanguinaria and Picric acid (n=2, 3.33% each); and Pulsatilla, Lachesis, Ignatia, Hepar sulph, Gelsemium, Dulcamara, China officinalis, Belladonna, Arsenicum album (n=1, 1.67% each). The potency of medicine used was 30C potency in 4 cases (6.67%), 200C potency in 50 cases (83.33%), 1M potency in 3 cases (5%) and LM potency in 3 cases (5%).

Adverse effects: There were no relapses in any of the cases. Mild homeopathic aggravation was seen in few cases. No harms, unintended effects, serious adverse events were noted.

Discussion
This clinical correlational study was conducted to assess impairment in Quality of Life due to acute episode of Migraine and to find correlation between time taken for pain relief using homeopathic medicines and Quality of Life of the patients. Several research studies have been conducted earlier on Quality of life due to migraine. A prospective observational study on homeopathic treatment of Migraine with a 2 year follow up period conducted on 212 migraine patients treated by 67 physicians showed obvious improvement in migraine severity and quality of life.(15) A study conducted at Dr. ML Dhawale Memorial Homeopathic institute, Palghar on 30 cases to assess the action of homeopathic remedies in the management of common migraine using Headache Impact Test-6(HIT-6)
tool showed reduction in disability index and improved functioning in migraine after a 3 month period. (16) The findings of this study are also in support of the previous studies.

The major strength of this study is the usage of an acute tool to measure the quality of life in a well-defined time period, that is 24 hours following onset a migraine attack using the 24 hour Migraine specific Quality of life Questionnaire (24hMQolQ). It indicates impact on the functioning and Quality of life during an attack of migraine. Further, this study also attempted to find out the correlation between the time taken for pain relief with homeopathic medicines during an acute episode of migraine with the quality of life during that period. Such a study is first of its kind in homeopathy. Relief of severity of migraine is measures in many studies, but the actual time taken to relief is measured only in this study. Since relief is a subjective parameter, marked reliance had to be placed on the patient’s responses. Also, three attacks of migraine were studied on each patient to evaluate the consistency of responses. There was an intra-individual and inter-individual variation in the Quality of life during each migraine attack. This shows that each migraine attack varies and not all individuals have a consistent presentation of severity of migraine and relief obtained with homeopathic medicines.

The limitation of this study was that it considered only time taken to relief and not assessment of the severity of other symptoms. The Quality of life impairment in between migraine attacks was not taken into account. The study was conducted on a small sample of 20 patients, but to overcome this limitation, 3 migraine episodes were assessed in each patient thus summing up to 60 migraine episodes.

Conclusion
The study demonstrates a strong negative correlation between time taken for pain relief with homeopathic medicines and quality of life of the patients during acute episode of migraine. The more the time taken for relief of pain, the lesser will be the quality of life. The lesser the time taken for relief of pain which means rapid action of medicine, it indicates greater quality of life. Since the homeopathic medicines in water doses have statistically significant rapid action, the faster they relieve the pain, the better will be the quality of life of the person. Accurate selection of individualistic homeopathic medicine allows for rapid relief from pain causing reduction in burden and disability and better quality of life of patients. Further studies can be conducted with larger sample size and control group for stronger scientific validation. Comparison of quality of life in acute attack before and after treatment with homeopathic medicines can be studied.

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