

Assessment of Quality of Life in patients with Migraine Receiving Topiramate

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Abstract

Introduction: Migraine is one of the most common disabling conditions among neurological disorders and the World Health Organization [WHO] has identified migraine among the world's top 20 leading causes of disability. Quality of life in migraine sufferers is usually associated with severe, noticeable disability, which in turn affects daily activity.

Objective: To assess the impact of migraine on Quality of Life (QOL) of migraineurs receiving topiramate (TPM) using Migraine Disability Assessment Test [MIDAS].

Method: A cross sectional, observational study was carried out among outpatients with migraine who were receiving topiramate. Baseline demographic information, treatment history, adverse drug reactions, and QOL data were collected. Statistical analysis was done and descriptive statistics were reported to summarize the data.

Results: There were 123 patients with migraine in the mean age range of 26.49 ± 6.29 years, with 67.47% being females. A majority of patients received TPM monotherapy [61.78%]. At the time of enrolment, 45.52% of patients were severely disabled and at 3 months of treatment with TPM, 57.72% of patients showed improvement. The mean MIDAS score was 22.70 ± 13.68 at the time of enrolment which was reduced to 10.44 ± 4.25 at 3 month treatment duration with TPM.

Conclusion: Improvement in the total mean MIDAS score was observed in these patients receiving TPM. The frequency, intensity and duration of migraine attack were reduced thereby improving the quality of life in migraineurs. Use of topiramate can improve the QOL and wellbeing of these patients.

Keywords: Migraine, topiramate, Quality of Life, MIDAS.

Introduction

Migraine is a complex brain event that produces a wide range of neurologic, autonomic and systemic symptoms of which headache is the most prominent¹. Migraine has been described as one of the most common disabling conditions among neurological disorders. The World Health Organization [WHO] has identified migraine among the world's top 20 leading causes of disability. Migraine is estimated to account for 2% years of life lost (YLL) due to a disability. In both genders of all ages, migraine is responsible for 1.4% of total life lost².

The Quality of Life (QOL) in migraine sufferers is usually associated with severe, noticeable disability, which in turn affects daily activity. The various guidelines developed for migraine management emphasize the need for assessment of disability in migraine sufferers such that effective treatment regimens can be employed. There are three main questionnaires or tools which are employed in assessing migraineurs disability. These include the Headache Impact Test [HIT], Headache Disability Inventory [HDI] and Migraine Disability Assessment Test [MIDAS]³.

The aim of this study was to assess the impact of migraine on Quality of life [QOL] of migraineurs receiving topiramate [TPM] using the Migraine Disability Assessment Test [MIDAS].

Materials and Methods

A cross sectional, observational study was conducted in accordance with ICH-GCP Guidelines following approval from the Institutional Ethics Review Board [IERB]. Informed and written consent was obtained from all the study participants prior to enrolment. Patients reporting at the outpatient department with a confirmed diagnosis of migraine and receiving TPM for more than one month, either as monotherapy or polytherapy were included in the study. Patients with migraine \geq 18 years of age, of both genders were included. Pregnant, lactating women and those patients with co-morbidities were excluded from the study. Data was collected in a specially designed Case Record Form [CRF]. The QOL was assessed once at the time of enrolment and followed up at 3 month treatment duration.

Baseline demographic information of all 123 patients was collected along with duration of disease, treatment history and were subjected to the QOL questionnaire. Data was computed and descriptive statistics such as mean and frequencies were used to describe. Assessment of QOL was done using the MIDAS score.

Results

A total of 123 patients with migraine were enrolled between the age range of 18-65 years [mean \pm SD; 26.49 \pm 6.29] with 40 [32.52%] males and 83 [67.47%] females during the study period of 1.5 years. Of the 123 patients, 5 patients provided a history of smoking while 29 of them had a family history of migraine.

The pattern of TPM use showed 76 [61.78%] on monotherapy and, 47 [38.21%] on polytherapy. The total daily dose of TPM varied between 25 mg to 100 mg, which were well within the therapeutic range. With regards to adverse drug reaction [ADR] profile, a total of 09/123 patients complained of weakness, loss of appetite and gastritis. However, no serious adverse drug reactions were reported by any of the patients.

With respect to QOL, disability was assessed employing the MIDAS questionnaire by comparing the total scores at the time of enrolment and scores at 3 month treatment follow up. The MIDAS score was graded from I- IV with the grades defined at I - little or no disability, II- mild disability, III- moderate disability, and IV- severe disability.

At the time of enrolment, majority [56/123] of patients were severely disabled, among which 22/56 received treatment TPM alone and 34/56 received other drugs along with TPM [Table1]. After 3 months of treatment with TPM, 71/123 [57.72%] reported to have mild disability and showed improvement in their quality of life [Table 1]. Among 71 patients, 47 received monotherapy with TPM and 24 received polytherapy. The mean MIDAS score was 22.70 \pm 13.68 at the time of enrolment which was reduced to 10.44 \pm 4.25 at 3 month treatment with TPM.

Table 1: MIDAS grade in patients with migraine N=123

MIDAS Grade	At the time of enrolment n[%]	At 3 month follow up n [%]
I – Little or no disability	05 [4.06]	35 [28.45]
II – Mild disability	24 [19.52]	71 [57.72]
III – Moderate disability	38 [30.89]	16 [13.01]
IV – Severe disability	56 [45.53]	01 [0.82]

Discussion

Quality of Life is a multidimensional concept and cannot be quantified easily. It comprises the overall well-being of the patient, which is closely related to happiness, morale and satisfaction. Health is considered as one of the most important determinants of QOL⁴. Historically, QOL has been employed extensively in chronic disease studies on conditions such as cancers, trauma-induced disabilities and myocardial infarction, all of which could negatively influence life expectancy⁵. In the recent past, attention has been focused on the role of QOL in functional pathologies such as migraine and epilepsy which have a profound impact on the subject's general health and one's ability to actively function in society^{6, 7}.

Migraine has been shown to have a negative impact on QOL, which includes physical, emotional and social aspects of daily life such as work, family and social relationships. Although the impact of migraine on QOL has been traditionally evaluated by qualitative methodologies, many diverse aspects remain insufficiently assessed⁸.

A wide range of drugs are being used for migraine prophylaxis. These drugs are mainly used to reduce migraine frequency, intensity, duration and most importantly to improve QOL such that the patient's daily routine and activity is unaffected largely. The newer antiepileptic drug, TPM, acts by various mechanisms - by blocking voltage-sensitive sodium channels, increasing the activity of GABA, by decreasing calcium channel opening and by decreasing excitatory neurotransmitter glutamate. Recently, TPM has been approved by FDA in the prophylactic treatment of migraine³.

As seen in this study, treatment with TPM decreased the number of headaches and correspondingly the MIDAS score showed great improvement in the QOL and normal functioning of migraine sufferers at 3 month treatment duration. Hence, therapeutically topiramate seems to alleviate symptoms in migraine sufferers and hence improve the QOL of these patients. A similar study by D'Amico⁹ et al had also reported that the number of headaches per day or per month reduced significantly which in turn improved the QOL and MIDAS total score. In another study, M Jamil³ and his colleagues concluded that topiramate in moderate doses can reduce migraine related disability and can improve quality of life in patients.

Conclusion

The results of this study showed improvement in the total mean MIDAS score. The frequency, intensity and duration of migraine attack were reduced thereby improving the quality of life in migraineurs. Thus, the use of topiramate can improve QOL and wellbeing of these patients. Further research employing concepts of Quality Adjusted Life Years (QUALY) and Disability Adjusted Life Years (DALY) will offer better insights into the effects of therapeutic agents on pathological conditions such as migraine. Mixed methodology research which would involve both quantitative and qualitative studies on the subjects could also provide rich information on the perceptions and feelings of patients suffering from such conditions and the beneficial effects of therapeutic agents on the quality of life and satisfaction.

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