

# A Study on Efficacy of Topiramate in Reducing Migraine Related Disability and Pain

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## ABSTRACT

Submitted: 26/11/2012

Accepted: 15/05/2013

Migraine, a chronic neurological disorder accounts for about 90% of the total workdays lost by an individual. Migraine with a peak onset of action at second and third decades of life exerts a tremendous burden on patients' personal and social functioning and undermines the normal function and productivity. Migraine related disability assessment is crucial to provide a rational basis for treatment. The disruption caused by migraine is assessed by using Migraine Disability Assessment Scale (MIDAS) and Mc-Gill pain scale questionnaires. The patients who were newly diagnosed with migraine with no abnormalities on neurological examination aged 18 – 65 years were included in the study. Patients were asked to fill the questionnaire at baseline (before starting the drug therapy) and at final visit (3 months after drug therapy). There was a significant ( $p \leq 0.01$ ) improvement in the Migraine Disability Assessment Scale (MIDAS) and Mc-Gill pain scales in the final visit from the baseline. This prospective study thus revealed Topiramate is efficacious in reducing migraine related disability, pain and also improve the ability to function in their daily lives. Individual patient care and patient counseling may improve patient compliance in migraine which leads to better therapeutic efficacy.

**Keywords:** Disability, Midas, Migraine, MC-gill Pain Scale, Topiramate

## INTRODUCTION

Migraine, a chronic neurological disorder affects 10% of the world population and accounts for about 90% of the total workdays lost by an individual. It is ranked 19 amongst the diseases causing disability by the World Health Organization. Migraine with a peak onset of action at second and third decades of life exerts a tremendous burden on patients' personal and social functioning and undermines the normal function and productivity.<sup>1,2,3,4</sup>

Migraine related disability assessment is crucial to provide a rational basis for treatment. The disruption caused by migraine in the areas of work and school as well as social, family and leisure activities is assessed by using Migraine Disability Assessment Questionnaire (MIDAS).<sup>5,6</sup> Mc-Gill Pain scale (short form) questionnaire (Mc-Gill) consists of 15 descriptors (11 sensory; 4 affective) which are rated on an intensity scale as 0= none, 1=mild, 2=moderate or 3=severe is used to assess the intensity of pain.<sup>7</sup>

Topiramate, a fructopyranose sulfamate derivative was originally synthesized as a hypoglycemic agent but was found to be devoid of hypoglycemic activity, later in 1995 in the UK it was initially approved as an antiepileptic drug.<sup>8</sup> Owing to

non negligible incidence of adverse effects and with its varied mechanism of action it is found to be efficacious in preventing migraine headaches thereby reducing migraine related disability.<sup>9</sup> The main aim of this study is to assess the efficacy of topiramate in reducing the headache related disability and the intensity of pain.

## MATERIALS and METHODS

A prospective observational study was conducted in a multi specialty hospital to assess the migraine related disability and intensity of pain using MIDAS and Mc-Gill pain scale questionnaire respectively. The study was carried out for a period of eight months from June 2011 to March 2012 and all the patients who were newly diagnosed with migraine with no abnormalities on neurological examination aged 18 – 65 years were included in the study. The study was approved by Institutional review Board of Kovai Medical Center and Hospital, Coimbatore (Ref: EC/AP/136/06-2010). The study was explained and oral consent is obtained from them, the patients were then asked to fill both (MIDAS and Mc-Gill) questionnaires before initiation of topiramate therapy (baseline) and during first review (after 3 months of drug therapy). The values are expressed as percentages or Mean  $\pm$  SD as applicable and evaluated for significance using Paired 't' test. All statistical data was assessed using SPSS (V 11.0). Values of  $p \leq 0.05$  were taken to be significant.

## RESULTS

In this prospective observational study, a total of 115 patients

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who were newly diagnosed with migraine were recruited to analyze the efficacy of topiramate in reducing the migraine related disability and intensity of pain. Among the 115 patients recruited 15 did not turn up for the first review after 3 months. Amongst the 100 patients included in the study 85 were females and 15 were males. The mean age of the study population was found to be 28.6(4.49) years.

The Disability assessment by MIDAS shows that 06 subjects scored moderate headache (11-20) at first visit when compare to 10 subjects at baseline. Similarly, 84 patients showed mild headache (6-10) in final visit; while only 2 subjects had the same score in the baseline visit. Ninety (90) patients reported to have severe headache (21+) before drug therapy; whereas after 3 months of drug therapy only one patient reported the same score. Complete reduction of headache (0-5) was reported by 9 patients (Fig 1). The mean MIDAS score of the final visit 7.25(1.87) from the baseline score 32.87(11.70) was found to be significant ( $p \leq 0.01$ ) (Fig 2).

The intensity of pain in the study population assessed using Mc-Gill pain scale (short form) showed a significant ( $p \leq 0.01$ ) reduction in the pain intensity in the final visit 8.56 (1.82) from the baseline 27.28 (6.88) (Fig 3).

## DISCUSSION

Migraine a neurological disorder is conceptualized as a chronic disease with episodic manifestations of headaches that increase in frequency and significantly impairs the quality of life and daily activities.<sup>10,11</sup> Migraine a neurological syndrome affects a significant fraction of the world population is found to be more prevalent in women (15%) as compared to (6%) in men, with a peak onset of action during the second and third decades of life.<sup>2,3</sup> In our study population also migraine is found to be more prevalent in females (85%) as compared to males (15%) and the peak onset of action is found to be in the third decade of life.

A randomized, double – blind, placebo controlled study of topiramate for the prevention of headache in chronic migraine reported that there is a reduction in MIDAS score from the baseline score of 67 to 41 in the treated group while for placebo similar scores increased from 61 to 41.<sup>12</sup> In another multi-center trial by Silberstein et.al., also showed that the mean MIDAS score reduced from 64.4 (46.6) to 31.4 (53.8) in the test group while in placebo group mean MIDAS score reduced from 62.2(43.4) to 21.0 (52.2), indicating that the topiramate treated group showed a greater improvement.<sup>13</sup> In this study also there was a significant ( $p \leq 0.01$ ) reduction in the mean MIDAS score in the final visit 7.25(1.87) from the baseline score of 32.87(11.70). A significant reduction in the intensity of pain (assessed using Mc-Gill pain scale questionnaire – short form) from baseline 27.28 (6.88) to final 8.56 (1.82) was also observed in our study population.

Fig 1: Number of patients showing various categories of MIDAS scores

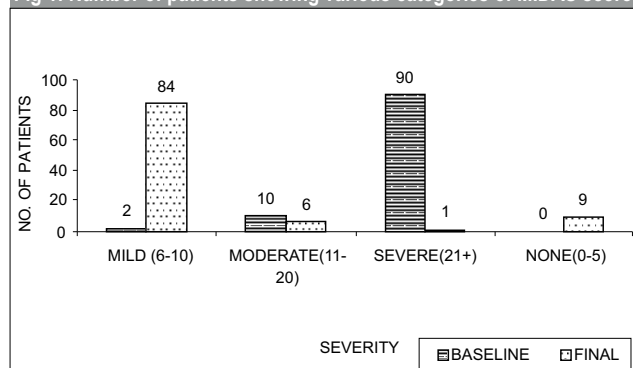


Fig. 1 shows the number of patients showing various categories of MIDAS scores. Mild (6-10), Moderate (11-20), Severe (21 +), No headache (0-5)

Fig. 2: Midas score of the study population. Mean (SD)

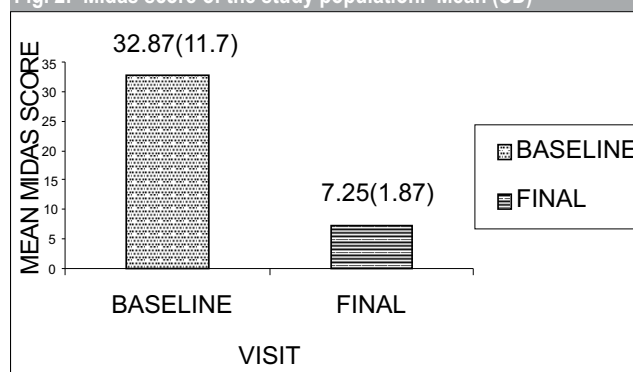


Fig. 2 shows the Mean (SD) scores of the MIDAS questionnaire of the study population at baseline and at the final visit.

Fig. 3: Mc- gill pain scale score before and after medication. Mean(SD)

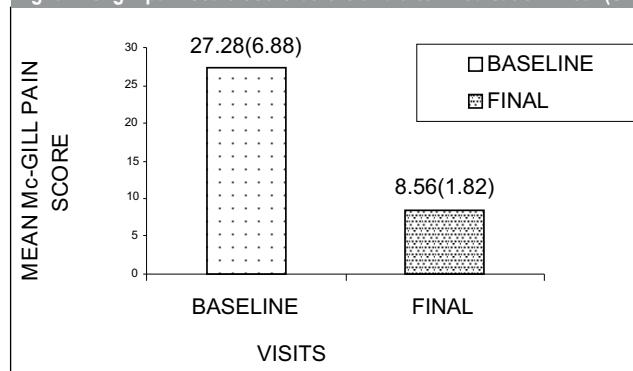


Fig. 3 shows the Mean (SD) scores of the Mc-Gill Pain scale questionnaire of the study population at baseline and at the final visit

## CONCLUSION

Migraine is a common neurological disorder affecting 85% of women and 15% of men. Owing to the negative impact on the quality of life, daily activity and work -related productivity, timely diagnosis and effective management of the patient is important. The migraine related pain and disability has reduced significantly with topiramate therapy and it has also been found to improve the ability to function in their daily

lives. Individual patient care and patient counseling may improve patient compliance in migraine which leads to better therapeutic efficacy.

## ACKNOWLEDGEMENTS

The authors acknowledge Dr. Nalla. G. Palanisamy, Chairman, Managing Director, Dr.Thavamani D. Palanisamy Trustee, and Dr. Vijayan. K MBBS., MD., DNB Consultant Neurologist, of the Kovai Medical Center and Hospital, Coimbatore for providing necessary facilities and constant encouragement.

The authors also acknowledge Mr. Vijayakumar M.Pharm (Ph.D)., Mrs. Geetha .K M.Pharm (Ph.D)., Mr. Dhandapani M.Pharm., Mr. Shivakumar M.Pharm (Ph.D)., Asst.Professors, Drug and Poison information Center, KMCH college of Pharmacy, Coimbatore, for providing constant encouragement to complete this project into a successfully.

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