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IMPACT OF PATIENT EDUCATION ON HEALTH RELATED QUALITY OF LIFE IN MIGRAINE PATIENTS

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ABSTRACT

Background: Migraine is rated as one of the leading causes of the global burden of diseases (GBD) and accounting for 1.4% of total global years lived with disability (YLD). Although migraine is not a life threatening disease however it impairs an individual's quality of life. **Objective:** To assess the influence of pharmacist provided medication counselling on knowledge, attitude and practice, medication adherence behaviour and overall health related quality of life in migraine patients. **Setting:** The study was conducted at outpatient Neurology clinic in a South Indian Tertiary Care Teaching Hospital. **Methods:** The enrolled patients were randomized into control and test groups. Validated KAP questionnaire, Morisky's medication adherence behaviour questionnaire and Migraine specific HRQoL questionnaire were administered to each patient at every follow up. The test group patients received education regarding the disease, medication and life style modifications. The control group patients received education at the final follow up. **Results:** Anxiety and stress were the major triggering factors for migraine in study patients. A statistically significant improvement ($P<0.05$) was observed in scores of KAP, medication adherence and migraine specific quality of life in test group patients when compared to the control group patients. **Conclusion:** Pharmacist provided medication and disease counselling has improved the knowledge, attitude and practice towards the disease, medication adherence behaviour, and over health related quality of life in patients with migraine.

KEY WORDS: Migraine, Health Related Quality of life, Patient Education, Medication adherence, Therapeutic outcomes

INTRODUCTION

Migraine is defined as an idiopathic, recurring headache disorder manifesting in attacks lasting for 4 to 72 hours[1]. It is characterized by unilateral location, pulsating quality with moderate to severe intensity and aggravation by triggering factors such as high temperature, noise pollution and frequent fasting. It is one of the top ten presenting complaints in ambulatory medical care and associated with nausea, vomiting, photophobia and phonophobia [2].

Migraine starts at puberty and also may affect younger individuals and is common in the age group of 25-55 years [3]. The prevalence of migraine increases until the fourth decade and then decreases with increasing age. The overall prevalence of migraine is estimated to be 12 to 16 percent. The genetic predisposition with a positive family history of migraine was established in 70-80% of cases[4,5,6]. Studies also suggested that migraine is more common among females than males [6,7]. This is mainly due to the hormonal changes in women especially during menstrual cycle. [8,9]

As per the Global Burden of Disease (GBD) 2000 study, migraine was identified as 20th leading cause of Years Lived with Disability (YLD) and accounted for 1.4% of total global YLDs[3]. Although migraine is not a life threatening disease, it affects various domains of an individual's QoL and financial costs.[10] Recurrent attacks often trigger fear in the mind of the sufferer and damage the family life, the social life and the professional life. [11,12]. Various studies reported that the overall economic burden of migraineur per annum is comparatively greater than that of non-migraineur. A US based study, the combined total expenditure of a migraineur was estimated as 1656 US $ per annum and 685 US $ per annum for a non migraineur [11]

Management of migraine include both nonpharmacological and pharmacological interventions [13]. Many research studies have shown the importance of self management interventions such as behavioural therapy and stress management in the treatment of migraine. Non pharmacological intervention includes identifying and avoiding the triggers, eating nutritious food regularly, having sound sleep and stress management. Pharmacological treatment includes acute treatment taken at the time of attack to relieve pain and restore

function, and preventive treatment taken daily to reduce headache frequency.[14, 15] Imparting adequate knowledge regarding the signs and symptoms of the disease, necessary information about the diet and other lifestyle modification empowers the patients to gain the confidence in the therapy and helps in achieving the desired therapeutic outcomes. Findings of various Knowledge, Attitudes and Practice studies have corroborated the improved therapeutic outcomes in patients received the structured education [16]. Adequate medication related information to patients helps them to understand the importance of medication and improves their adherence behaviour helps in achieving the desired therapeutic goals.[17,18] It was also found that educated patients have a better social functioning and have better overall quality of life.[19,20,21]The present study was conducted to assess the influence of pharmacist provided disease and medication counselling on HRQoL in patients with migraine.

METHOD

Study Population

Migraine patients of either gender, aged more than 18 years, visiting Neurology Outpatient Department (OPD) of a South Indian tertiary care teaching hospital. Patients under the age of 18 years, and patients with a diagnosis of tension headache, secondary headache (due to tumour or infection), refractory or status migranicus, non co-operative patients, and patients with other co morbidities were excluded from the study.

Data collection

Patient's demographics, social history, educational level, past medical history and known allergies were collected from patients' prescriptions, interviews with patient and/or their care takers in a suitably designed data collection form . Validated Migraine Specific Quality (MSQ) of life questionnaire was applied to assess the influence of patient education on quality of life in enrolled patients.

Preparation of educational material

A patient information leaflet was prepared explaining about signs, symptoms, triggering factors, pharmacological and non-pharmacological management plans and life style modifications. Content validation was done by the neurologist and clinical pharmacist of the Hospital. The leaflet was translated in to the vernacular language by Central Institute of Indian Language (CIIL), Mysore, India and translation validation was also done by them. A Patient diary was prepared to record headache frequency, duration and triggers and provided to the enrolled patients.

Study procedure

Patients meeting the study criteria, intended to participate and give written informed consent were recruited and randomized in to control and test through simple randomization technique (Patients with odd serial number goes in to control and patient s with even serial number goes in to Test group). At the time of enrolment, data pertaining to demographics, educational level, socio economic status, past medical history, alcohol and smoking history were collected. Patient diary was provided to all patients at baseline visit to record their headache frequency, duration and triggers of their headache. Structured patient education including patient information leaflet (PIL) was provided to all test group patients at the baseline visit. The control group patients received patient education and PIL only at the final visit.

Measures

Knowledge, attitude and practice (KAP) of study population

A validated KAP questionnaire was used in the study to assess the knowledge attitude and practice of the enrolled patients towards the disease management. The questionnaire was administered on all enrolled patients at baseline visit and re-administered in the final follow up visit in order to compare the change in the scores.

Medication adherence

Morisky's Medication Adherence Scale was applied to assess medication adherence behaviour in the enrolled patients. Morisky Medication Adherence scale consists of four questions. Patients answered 4 questions and each 'Yes' answer scored zero points and each 'No' answer scored one point. The patients who scored a total of 3 and 4 were categorized as having high adherence, those scored 1 and 2 were categorized as having medium adherence and those scored zero point was categorized as having low adherence. The medication adherence scoring was done at the time of follow up visits and patients were categorized as patients with high non adherence, medium non adherence and high adherence. Difference in scoring at the time of first, second and third follow up visits was compared and the difference in percentage was calculated.

Health related quality of life in the enrolled patients

In migraine patients, health related quality of life was assessed by using 16 item Migraine Specific Quality of Life Questionnaire (MSQ) which was developed by Glaxo Wellcome

Inc.[22,23] The study used Kannada (local language) version of the original MSQ which was translated and approved by Central Institute of Indian Languages (CIL), Mysore.

MSQ measures three dimensions namely

1. Role function-restrictive comprises of seven questions (items) that measure the degree to which performance of normal activities is limited due to migraine.
2. Role Function-Preventive comprises of four items (questions) that measure the degree to which performance of normal activities is prevented or completely interrupted by migraine.
3. Emotional Function comprises of three items that measure the emotional effects of migraine. [22, 23]

The questionnaire was administered at the baseline visit and re administered in each follow up visits to compare the difference in their QoL.

Symptoms and triggering factors of migraine

Patients or caregivers were asked "Over the past 30 days, on how many days did you or *your child* have migraine Symptoms during the day?" Migraine Symptoms include: nausea, vomiting, photophobia, phonophobia, numbness or tingling sensation. The various triggering factors identified in the study population were also recorded for better education and for educating the importance of avoiding of triggering factors.

Statistical analysis

Results were analyzed using Statistical Package for the Social Science (SPSS) for windows version 16.0.Initially the age and sex distribution was compared between the test and control, to study the homogeneity between the two groups. The age and gender distribution was compared by using Contingency Coefficient test.

The average levels of HRQoL scores in the test group were compared with the control group during baseline, first, second and third month by adopting Repeated Measure Anova. The average levels of overall HRQoL scores between three follow up periods in test and control group were also compared. Significance of change in KAP and MAS scores from baseline to final follow up were also assessed using Repeated Measure Anova. P value of <0.05 is considered as significant.

RESULTS

A total of 190 patients were enrolled into the study. Out of them 168 patients completed all the study follow-ups and 22 patients were considered as drop out because of the missed follow-ups. Out of the 22 patients lost to follow up, 15 patients were test and 7 were control. The mean age of the enrolled patients was 30.95 years. There was no significant difference found between the age and gender of the enrolled patients (P>0.05). The demographic details of the study patients are given in Table 01.

Symptoms of migraine

In our study the majority of patients had photophobia [133(78.7%)] and phonophobia [125 (74%)] as their migraine symptoms. Patients also experienced symptoms like nausea [88 (52.1%)], vomiting [69 (40.8%)], blurring of vision [16 (9.5%)], visual auras [3 (1.8%)] and neurological aura like numbness of hand [3(1.8%)]. The details of the symptoms experienced by the study population are presented in the Table 02

Triggering factors of migraine in study population

It was found that anxiety and stress, as major triggers of migraine in study patients followed by bright light and loud noise. The details of triggering factors shown in figure 01

.Influence of education on KAP score of the study patients

Control vs. test

The mean value of KAP scores between control and test was almost matching in the baseline visits. However the mean score of the test was significantly increased at final follow up than the control group. The influence of education on KAP score are shown in (Table 03) .

Between the follow ups

The mean value of the test group was increased at the final follow up from the baseline visit which was statistically significant (P < 0.05). Whereas the mean value of control increased from baseline to final only to a lesser extent which was not statistically significant (p>0.05)

Influence of patient education on medication adherence behaviour of migraine patients

There was a significant increase in the MAQ score of the test patients (educated patients) from first follow up to third follow up. The mean scores of medication adherence among control patients were not consistent in the follow ups and the details of which is represented in the Table 04.

Relationship between the patient education and quality of life of migraine patients

The quality of life in migraine patients was assessed by using a questionnaire called Migraine Specific Quality of Life Questionnaire (MSQ). MSQ is a 14 item questionnaire that assesses the overall QOL by determining functioning of 3 main domains such as restrictive function, preventive function and emotional function.[22,23,24]

i) Restrictive function assessment

It determines the extent to which performance of normal activities are limited by migraine. It includes seven questions. The scores of these questions for both control and test in baseline and at each follow up were calculated and compared. The mean score of the test group was increased from the baseline visit to the final follow up. Whereas in control group the mean score was slightly increased in first follow up from baseline and then decreased in the next two follow ups. The details are represented in the (table 05)

ii) Preventive function assessment

Preventive function is determined by four questions that measure the degree to which normal daily activities are prevented or completely interrupted by migraine. These questions were asked at baseline and at each follow ups and scores were noted. The comparison was done statistically by Repeated Measure ANOVA.

The mean score of the test group was increased from baseline to final follow up and the change was found to be statistically significant. Whereas the mean score in control group was decreased from baseline to final follow up. And the data is shown in Table 06.

iii) Emotional function assessment

Emotional function is determined by using three questions in the MSQ. These three items specifically measure the emotional effects of migraine. The score between the test and control was compared by using Repeated Measure ANOVA. The mean score of the test group was significantly increased from baseline to final follow up whereas the mean score of control group was reduced from baseline to final follow up is presented in Table 07.

iv) Overall quality of life

The overall quality of life score in the test group patients was increased significantly from baseline (128.42) to final follow up (291.02) whereas in the control group patients the score was decreased from baseline (122.98) to final follow up (115.82) [figure 02].

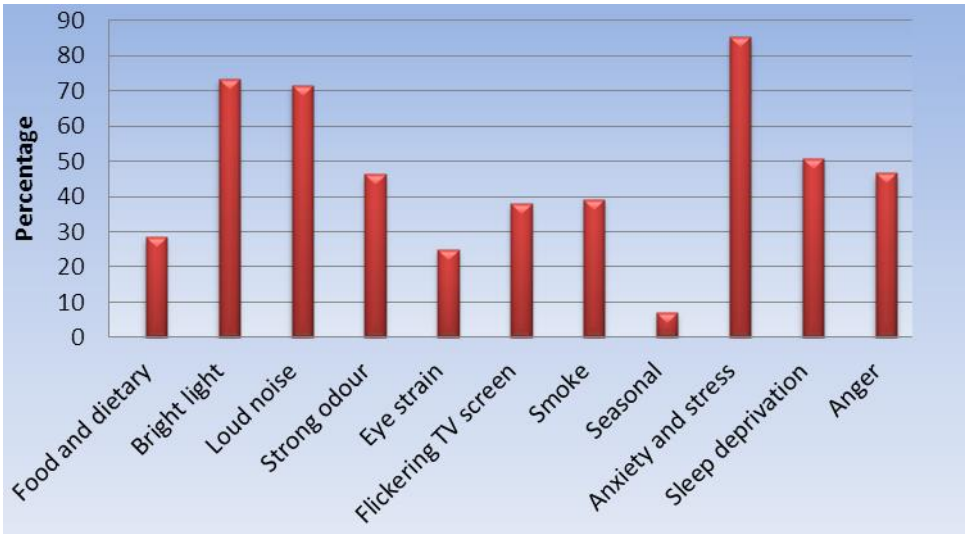

Figure 01 : Triggering factors of migraine in study population

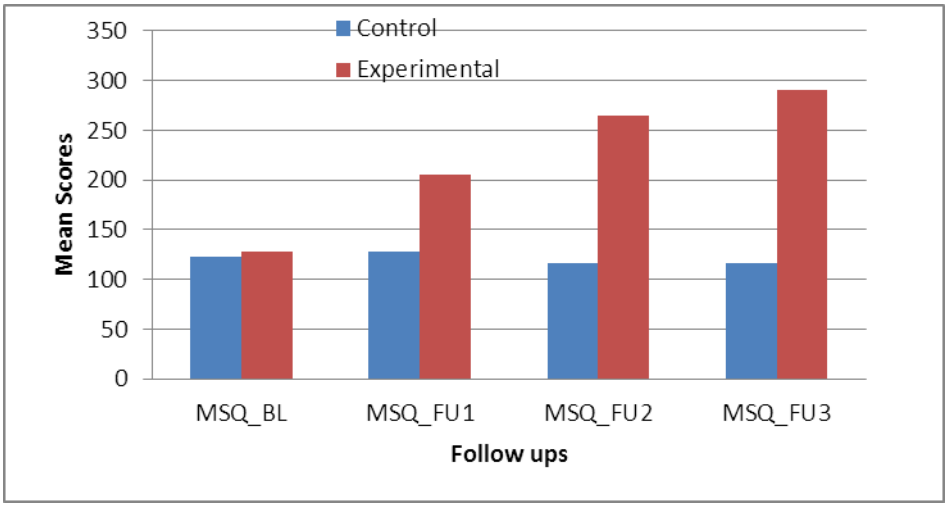

Figure 02 : Overall QoL Scores

MSQ_BL: Migraine Specific Quality of Life Questionnaire _ Baseline visit

MSQ_FUI: Migraine Specific Quality of Life Questionnaire _ Follow UP 1

MSQ_FU2 Migraine Specific Quality of Life Questionnaire _ Follow Up 2

MSQ_FU3 Migraine Specific Quality of Life Questionnaire _ Follow Up 3

Table 1. Demographics:

Age	Group		Total (Control +Test) [%]	Significance(P)
	Control [%]	Test [%]		
11--20	10 [11.4]	**9** [11.3]	19 [11.3]	0.112
21-30	44 [50]	31 [38.8]	75 [44.6]	
31-40	22 [25]	30 [37.5]	52 [31]	
41-50	12 [13.6]	7 [8.8]	19 [11.3]	
51 and above	0	3 [3.8]	3 [1.8]	

Gender				
Male	31 [35.2]	21 [26.3]	52 [31]	0.209
Female	57 [64.8]	59 [73.8]	116 [69]	
Total (N)	88 [100]	80 [100]	168 [100]	

Education				
Illiterate	19 [21.6]	12 [15]	31 [18.4]	
Primary school	27 [30.6]	27[33.7]	54 [32.1]	---
Secondary school	20 [22.7]	13 [16.2]	33 [19.6]	
Pre University	11 [12.5]	16 [20]	27 [16]	
University	11 [12.5]	12 [15]	23 [13.7]	
Employment status				
Employed	21 [23.9]	14 [17.5]	35 [20.8]	---
Unemployed	50 [56.8]	44 [55]	94 [55.9]	
Students	8 [9.09]	7 [8.8]	15 [8.9]	
Agriculture	9 [10.2]	15[18.8]	23 [14.2]	
Marrital status				
Married	54 [61.4]	60 [75]	114 [67.9]	---
Unmarried	34 [38.6]	20 [25]	54 [32.14]	

Table 02: Associated symptoms of migraine in study population:

Symptoms	**Group**		**Total [%]**
	Control [%]	**Test [%]**	
Nausea	41 [46.6]	47 [58]	88 [52.1]
Vomiting	37 [42]	32 [39.5]	69 [40.8]
Photophobia	65 [73.9]	68 [84]	133 [78.7]
Phonophobia	60 [68.2]	65 [80.2]	125 [74]
Blurring of vision	9 [10.2]	7 [8.6]	16 [9.5]
Numbness of hand	1 [1.1]	1 [1.2]	2 [1.2]
Spots in visual field	1 [1.1]	2 [2.5]	3 [1.8]

Table :03: Influence of education on KAP scores

Groups	**Visits**				**Change/gain**	**Significance(P)**
	Baseline		Final			
	Mean	**S.D**	**Mean**	**S.D**		
Control	13.22	2.84	14.30	3.85	1.1	0.000
Test	13.36	3.96	20.8	3.20	7.5	
Overall	13.29	3.41	17.39	4.81	4.1	

Table 04: Influence of education on MAS score

Groups	**Visits**						**Significance**
	Follow up -1		**Follow up 2**		**Follow up 3**		
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	
Control	3.24	.844	3.02	1.01	3.04	1.03	0.000
Test	3.45	0.73	3.57	0.65	3.91	0.34	
Overall	3.35	0.8	3.28	0.90	3.45	0.89	

Table 05 : Restrictive function QoL scores

Group	Visits							
	Baseline		Follow up 1		Follow up 2		Follow up 3	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Control	32.4	20.56	36.84	19.9	33.94	23.76	33.5	29.17
Test	36.21	20.13	59.41	19.15	82.86	13.01	96.4	3.09
Overall	34.22	20.39	47.58	22.53	57.24	31.22	63.46	37.94
Significance	< 0.05							

Table 06 : Preventive function QoL scores

Group	Visits							
	Baseline		Follow up 1		Follow up 2		Follow up 3	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Control	40.47	24.4	40.25	24.05	35.9	26.54	34.5	30.31
Test	40.73	24.1	68.13	18.9	88.43	11.4	98.6	2.74
Overall	40.60	24.2	53.52	25.8	60.91	33.5	65.05	38.94
Significance	< 0.05							

Table 07: Emotional function QoL score

Group	Visits							
	Baseline		Follow up 1		Follow up 2		Follow up 3	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Control	50.10	21.5	51.54	27.08	46.13	29.01	47.82	30.25
Test	51.47	26.8	78.4	17.14	93.05	7.1	98.68	2.74
Overall	50.75	24.1	64.3	26.5	68.5	31.85	72.04	33.6
Significance	< 0.05							

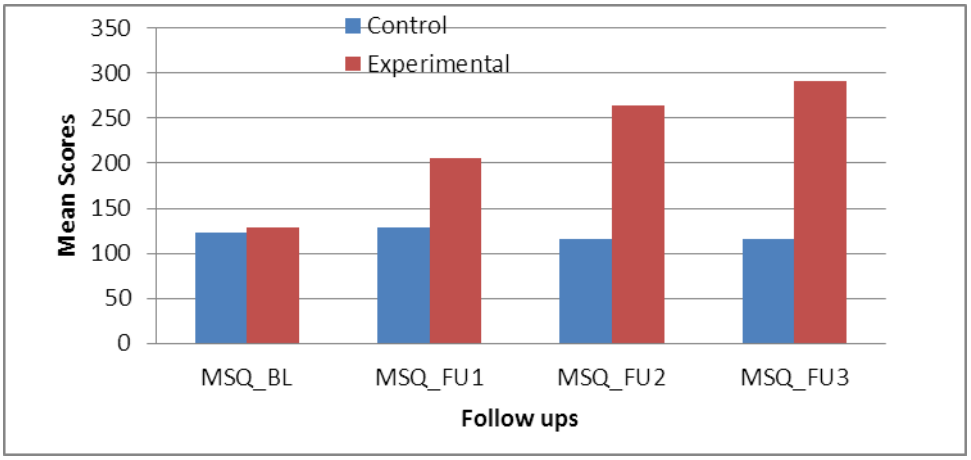

Figure 02 : Overall QoL Scores

MSQ_BL : Migraine Specific Quality of Life Questionnaire _Baseline visit

MSQ_FU1: Migraine Specific Quality of Life Questionnaire _ Follow up 1

MSQ-FU2: Migraine Specific Quality of Life Questionnaire _ Follow up 2

MSQ_FU3 : Migriane Specific Quality of Life Questionnaire _Follow up 3

4. DISCUSSION

Many studies suggested that, pharmacists can play an important role by providing the counselling, which has shown a positive impact on health care and decrease the mortality and morbidity [20,21] . Migraine is one of the common disorders where patient reports lower quality of life [11,12]. In the present study, female patients were 69% of the total study population. In many studies conducted overseas found that a predominance of female gender over the male gender [6,9] . In a study conducted by Richard B Lipton et al, the prevalence of migraine among females was found to be 18.2% and that in males was 6.5% [25]. In a study conducted by Roncolato. M et al, the prevalence of migraine was found to be higher in women than men irrespective of the age range. In another study conducted by Ulku T B et al also found that the prevalence of migraine was high in women in reproductive age group. This predominance can be attributed to the hormonally driven changes in females.[9] In the present study majority of patients were in the age range of 21-30 (44.6%) followed by 31-40 (31%). The reasons may be attributed to high stress and tension during that age. This finding was found to be comparable with previous studies findings and also reported in the Global burden of Disease (GBD) 2000 study that the prevalence of migraine is highest during the peak productive years (between the ages of 25-55 years) .[3,6] These results supports our study findings where we found that the majority of patients were in the age range of 21 -40 years.

In general migraine is unilateral in location pulsating quality, moderate to severe intensity and aggravated by physical activities. It is associated with symptoms such as nausea, vomiting, photophobia, phonophobia, blurring of vision, numbness (rare) and sometimes spots in visual field (in cases of migraine with aura) [1,2]. In the present study, photophobia (78.7%) and phonophobia (74%) among migraine associated symptoms were seen more frequently than other symptoms. The other symptoms reported included nausea (52.1%), vomiting (40.8%), blurring of vision (9.5%), spots in visual field (1.8%) and numbness of hands (1.2%). In a study conducted by Boru U T et al, phonophobia (91.3%) and nausea (74.8%) were more frequently seen symptoms than the other symptoms. In another study by Richard B L, the most frequently reported symptoms were in the order, pulsatile pain (85%), light sensitivity or photophobia (80%) sound sensitivity or phonophobia (76%), nausea (73%), unilateral pain (59%), blurred vision (44%), aura (36%) and vomiting (29%). This report was comparable with the present study findings. The association of photophobia and migraine in our study mainly attributed to the hot day time weather of the city which may trigger headache in majority of patients. In our study it was found that 18.9% of patients

experienced pulsating type of pain and 37.9% reported that their pain is aggravated by physical activity. It was also found that 43.2% of patients experienced both at a time. The location of migraine was reported to be unilateral by 42.6% of our study population. It was similar to the findings of the study conducted by U T Boru Et al where they reported (67.2%) patients experienced unilateral pain and 86.2% patients felt their pain is pulsatile.

Patient's knowledge, attitude and practices have an effect on medication adherence behaviour. An understanding about cause of the disease, its signs and symptoms, importance of regular intake of medicines and necessary life style modifications to be taken in controlling the headache will help to improve the therapeutic outcomes. At baseline visit only few patients were aware of the causes, signs and symptoms, triggers and proper management about migraine in both control and test group. Their attitude towards practicing self management of the disease was also poor. Some of the patients were aware of the various triggers of their migraine and the relaxation training and stress management for preventing their headache. But their attitude towards the practice was found to be very poor. In the present study, patients were educated about the importance of practicing the self management strategies to control the disease. At the final follow up, the test group patients, who received an extensive education about their disease (migraine), medications and life style modification showed a statistically significant improvement in the attitude and also in the overall KAP score than the control group. This improvement in the scores was mainly due to pharmacist's educational intervention. A study conducted by Gobel et al with an objective to analyse patient's knowledge regarding their disease and to understand the impact of headache in their day-to-day life, found that people suffering from headache do not have an up to date knowledge regarding the proper management of the disease. The participants of the study received the information regarding the characteristics of their headache, behavioural rules and preventive measures. The results of this study have shown that imparting a comprehensive education programme improved the patients' health consciousness and also influenced the KAP scores and HRQoL scores.

Although no statistically significant difference in the KAP score and educational status of patients, however Pre University and University grade patients scored comparatively higher in final follow up than the other patients. This can be attributed to the education level of the patients which provided them better ability to answer the questions appropriately. In our

study, it was found that unmarried patients had a higher KAP score than the married patients. But this difference was not statistically significant.

Patient education has an important role in patient's medication adherence behaviour. The information regarding the importance of taking medicines at proper timings along with other life style changes for the effective management will improve patient's awareness and reduce the frequency of attacks. The mean Medication Adherence Scale (MAS) value of test group patients were increased from first follow up to third follow up significantly at a $p<0.05$ whereas the mean score of the MAS of the control were decreased from the first to second follow up which then increased slightly in the third follow up. There was no significant difference found in the scores with the educational status or employment status of the patients.

The effect of migraine and its treatment on patient's health related quality of life was assessed by using Migraine Specific Quality of Life Questionnaire (MSQ) version 2 which was developed by Glaxo Wellcome Inc. [22,23,] T his questionnaire contain 14 questions and has 3 subscales: Restrictive function subscale (7 questions), preventive subscale (4 questions), and emotional subscale (3 questions). An increase in the quality of life scores indicates an improvement in the quality of life. The score was increased from baseline to final visit in each of this subscale and showed an improvement in the quality of life.

It was found that the patients who are in a grade of secondary education showed a higher improvement in their quality of life scores than other patients even though this difference was not statistically significant. The overall improvement was seen in the quality of life score which is a sub total of the three subscales of the QoL questionnaire. Continuous education regarding the proper use of medication, life style changes and self management techniques has improved the patient's health, functioning capacity, family life, social life and ultimately their overall quality of life. A study conducted by John F Rothrock found that the intensive education of migraine patients along with the routine medical management improved the clinical status of migraineurs and reduced the headache frequency and disability when compared to the control group patients [19,20] . In another study it was found that quality of care for migraine patients can be improved with better patient understanding or physician patient communication regarding the self management of disease[21]

A study conducted by Lemstra et al reported that the intervention group which received multidisciplinary management (exercise therapy, massage therapy, and lectures regarding stress management, relaxation therapy and diet) showed significantly greater reduction in the pain frequency, intensity and improved functional status and quality of life .[26] This finding was also observed in our study too.

Hence in order to improve the therapeutic outcomes and the overall HRQoL of patients suffering from migraine, the proper education about their disease, medication and life style changes are very much essential. The present study shows that the pharmacist provided education can improve the patient's therapeutic outcome and the overall HRQoL.

CONCLUSION

At the end of the study, test group patients had shown a greater improvement in the KAP score, medication adherence, and reduction in migraine frequency, severity of migraine and therapeutic outcomes due to education and support by the pharmacist. Hence our study concludes that improving patient's knowledge, attitude and practice about their disease can improve the medication adherence behaviour, which in turn improves the overall quality of life. Thus the study emphasized the pharmacist role in patient education and in the effective management of migraine along with appropriate pharmacotherapy.

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