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Research Article

EDUCATIONAL INTERVENTION WITH MEDICATIONS IMPACT ON HEALTH-RELATED QUALITY OF LIFE IN MIGRAINEURS

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ABSTRACT

Migraine has greater impact on person's quality of life and also contributes a financial burden on health care system. Assessing quality of life of the patient has become an important tool that helps in the management of migraine. Educational programs are used to provide information and teaching the skills that are difficult to understand by patients. Migraine education programs by the Clinical Pharmacist will have a positive impact on person living with migraine understanding of the disease that results in satisfaction of the patient and can also improve migraineur physician consultation rates and overall care. The study revealed that mostly prescribed monotherapy agent is NSAID and single pill combination therapy is Antiemetic and NSAID. Monotherapy is mostly preferred than combination therapy. There was a significant improvement in the Health-related Quality of Life in the both scales, MSQ and SF 36. The patient education along with appropriate treatment helped the Migraine patients in the improvement of their Health-related Quality of life and thus decreased the Migraine related burden on the individual.

Keywords: Quality of Life, Person living with migraine, Patient Education.

INTRODUCTION

Migraine is a common neurological disorder that is characterized by idiopathic and recurrent attacks of headache.[1] Migraine is generally associated with personal burden which is a result of headache related disability, higher rates of co-morbidities, reduced health related quality of life and direct and indirect costs.[2,3] Person living with migraine who are chronically affected have recurrent episodic attacks that may progress to severe and frequent attack patterns.[4]

Assessing quality of life of the patient has become an important tool that helps in the management of migraine.[4,5] According to World Health Organization (WHO), quality of life (QOL) is defined as an individual perception of his/her position in life in the context of culture and value systems and in relation to his/her goals, expectations, standards and concerns.[6,7]

Researches based on clinical population have reported that migraine patients have reduced quality of life[8] when compared with age and sex matched people without migraine.[9] Also the impact of migraine on quality of life have been established in many studies.[6] Migraine has greater impact on person's quality of life and also contributes a financial burden on health care system.[10] Assessment of patient quality of life is an important way to measure the disease burden as it has more focus on activity limitation and disabilities that occur temporarily.[4] It is also an important approach for therapeutic endpoints that are usually used in determining the effectiveness of drugs used in migraine treatment either acute or preventive.[11]

Patients who are having migraine disorder also tend to show lower Health related quality of life (HRQOL).[12] Studies reported that patients who are having higher frequency of migraine attacks are said to have lower levels of HRQOL.[3] According to the reviews it was reported that migraine substantially affects the functional activities of the person in different ways during attacks and also decreases the HRQOL during and between the attacks resulting difficulties in case of vitality, social functioning, mental and physical health.[13] There is evidence that person living with migraine when compared with other patients with chronic diseases such as Diabetes and Hypertension have far worse health related quality of life and they also have low quality of life in between the migraine attacks.[14,15]

The quality of life assessment primarily depends upon the answers to questionnaires that are given by patients and are of two types generic and disease specific.[11,15] Generic measures are those measures that are applicable for types and disease severities for different therapies or interventions among different subgroups and demographics. Disease specific measures are the measures that are applicable for specific disease or patient groups with a goal of response and/or any important clinical changes.[15]

Generic questionnaires like Short Form Health Survey (SF-36) are used in migraine but this is not designed for measuring the limitations and restrictions particularly associated with migraine.[11] In this aspect disease specific questionnaire like migraine specific quality of life (MSQ) questionnaire is more sensitive for assessing quality of life in migraine patients.[11,16] It is a 14 item PRO instrument that assess the quality of life in migraine patients in three essential aspects over past 4 weeks: role function restrictive (RR), role function preventive (RP) and emotional function (EF).[3,17] The QOL studies are of two types in headache, they are either population based or hospital based.[18] Drugs used in acute treatment of migraine includes the simple analgesics like NSAIDs, paracetamol, aspirin etc., triptans like sumatriptan, zolmitriptan and combinations of an NSAID and

triptan. In order to avoid medication overuse headache, the use of NSAIDs is limited to less than 15 days and use of triptans to less than 10 days. Acute treatment is started early, and the drug of choice depends on intensity of attacks.[19] Preventive therapy is optional for patients who are having long term migraines and frequent attacks.[20] It should decrease the frequency of attacks as well as increase the QOL of patient. General drugs used for preventive therapy are beta-blockers, tricyclic antidepressants, antiepileptic, antihistamines, barbiturates, botulinum toxins, and ergot derivatives.[19, 21] The main goal of migraine therapy is evolved from reducing pain towards preventing migraine symptoms and disability as well as increased HRQOL and reduction in activity limitations.[14,15]

Person living with migraine often refuse or avoid taking treatment because of low healthcare focus and belief that they are not suffering from migraine but a normal headache.[22] Many associations of doctors, regulatory agencies, educators, researchers and patients aware that there is a need for communication between patients and health care providers in order to provide good medical care.[23]

Due to their busy schedule and a large number of patients the prescribers do not have time to explain the proper information regarding usage of medication. Also, the pharmacists in hospitals and pharmacies do not have adequate training and education to provide information to patients. Therefore, the patients do not have proper knowledge about the drugs regarding how and when to take the drug, duration of treatment, what measures to be taken if any adverse event occurs or if a dose is missed. Due to this the patient medication adherence is decreased leading to therapeutic failure.[24]

Educational programs are used to provide information and teaching the skills that are difficult to understand by patients and they can impact positively on headache and quality of life.[22,23] Implementation of migraine education programs have a greater impact on patient's understanding of the disease that results in satisfaction of the patient.[23] Counseling by the pharmacist have a positive impact on person living with migraine and can also improve migraineur physician consultation rates and overall care.[25]

Patient Counseling is defined as an activity of providing detailed information of prescribed education in a written or oral form to the patient or patient representative regarding the use of drug, dose to be taken, side effects, precautions, drug interactions, storage and life style modifications.[24,26] Counseling should be done by using Counseling aids as it is difficult for patients to remember entire information. Medication charts, patient information leaflets and medication handouts are useful Counseling aids for patients.[24]

Objectives

Primary objective

- To evaluate the anti-migraine treatment prescribing patterns and assesses the impact of patient Counseling along with medical management on the Health-related quality of life in person living with migraine.

Secondary objectives

- To evaluate different classes of anti-migraine medications used in treatment.
- To evaluate the single and combination therapies.
- To evaluate the health-related quality of life in patients with migraine by using MSQ (Migraine Specific Quality of life) and SF-36 (Short Form-36).

MATERIALS AND METHODS

This Prospective and Observational study was conducted at Sivaranjani Hospital, Bhimavaram, West Godavari, Andhra Pradesh, India. The hospital is specialized in neurology department treating various disorders. Every day 100 to 150 patients were treated either in inpatient or outpatient department. A Total of 100 patients were participated in the study which was carried out over a period of seven months.

Source of data and materials

Method of collection of data

- Patient interview
- Patient case report and prescription

Method of collection of material

- Patient health related quality of life documentation form.(MSQ and SF-36)
- Patient consent form.
- Patient data collection form.

Study criteria

Inclusion criteria

- Patients with diagnosis of all types of migraine and already under the treatment in this hospital.
- Patients of age 13 years and above.

Exclusion criteria

- Patients with any other neurological disorder.
- Patients other than allopathy medications.
- Patients who are not willing to give the consent form.
- Pregnant/lactating women

Study procedure

Method of data collection

An approval of ethical clearance has been obtained from Institutional Ethical Committee prior to the initiation of study. Patients who were coming to the hospital regarding the disease in outpatient department were screened based on the inclusion and exclusion criteria, subjects who met the inclusion criteria were enrolled for the study. Informed consent was obtained from the patient or attenders of patient. Patient Counseling was done, and the patients are provided with leaflets, follow up was done after 2 months during their next hospital visit. Details regarding the current therapy, their quality of life by using questionnaires were obtained by patient interview and by observing case notes. Patient therapy was monitored by using patient data collection form for present medication to obtain single and combination drug therapy to find out prescribing patterns and it was documented.

Assessment of health-related quality of life

According to study design patient's health related quality of life was measured by using two scales namely, a migraine disease specific scale such as MSQ and a generic scale such as SF-36.

Collection of patient health related issues according to their quality of life was done by using appropriate questionnaires and assessed by using scores which have been included according to scales.

Research and ethical committee approval

Institutional research and ethical committee approved the study and issued a letter of permission to conduct the study.

Ethical clearance number: SVCP/IEC/16/7

Statistical methods

The Prescribing pattern of Anti-migraine treatment was evaluated. The psychometric evaluation of the quality of life (QOL) of patients was employed a disease specific questionnaire, the MSQ and a generic questionnaire, the SF-36.Descriptive statistics of demographic and clinical variables included frequencies, percentages and mean, Standard Deviation (SD). Mean scores at the before and after Counseling and mean changes were calculated for the domains (sub scales) of MSQ and SF-36. Internal consistency reliability was evaluated by examining the equivalence of responses within the MSQ and SF-36 by Cronbach's alpha. A paired t-test was used to determine if the change detected from the before and after Counseling was significant. In all analysis, $P < 0.05$ was considered to be significant. All statistical analyses were performed using SPSS statistical software, version 22.

RESULTS

A total of 100 patients were enrolled, counseled and followed up after 2 months from counseling date, during the period of 7 months from outpatient department of the hospital.

Females (84%) are more prone to Migraine headaches than Males (16%) (Figure 1)

Age group of 26-40 is more prone to Migraine Headaches. Out of 100 patients age group of 26-40 is about 62% (Figure 2).

NSAIDS (21.49%) were prescribed more as a single drug when compared to other classes of drugs (Figure 3).

Antiemetic and NSAID single pill combination (61%) prescribed more when compared to other single pill combination drugs (Figure 4).

Single drug (77%) is prescribed more than combination drug in the overall Treatment (Figure 5).

Response score in each function and total score declined significantly in MSQ Scale, which is indicative of improvement in migraine specific Quality of life (Figure 6).

The before and after counseling mean scores on the multi items sub scales domain evaluated by MSQ for migraine patients (Role function-Restrictive, Role function-Preventive and Emotional function)*-showed statistically significant decrease ($p < 0.05$), it seems improvement in Quality of Life of patients after counseling (Figure 6). Internal consistency reliability (> 0.70) Cronbach's alpha varying between 0.91 and 0.98, across the three sub-scales. Cronbach's alpha supported the notion of nearly uniform contributions of each item to its scale (Table 1).

The response score of all SF-36 sub scales increased significantly, which indicates the improvement in Health-Related Quality of life (Figure 7).

The before and after counseling mean scores on the multi items sub scales domain evaluated by SF-36 for migraine patients (Physical functioning, Role limitation due to physical health, Role limitation due to emotional problems, Energy / fatigue, Emotional well-being, Social functioning, Pain, General health and Health change) *-showed statistically significant increase ($p < 0.05$), it seems improvement in Quality of Life of patients after counseling (Figure 7). Internal consistency reliability (> 0.70) Cronbach's alpha varying between 0.69 and 0.90, across the 8 sub-scales. Cronbach's alpha supported the notion of nearly uniform contributions of each item to its scale (Table 2).

DISCUSSION

Prescription patterns

The drugs prescribed for the treatment of migraine in our study are Anti emetics, Analgesics, β-Adrenergic antagonists, NSAIDs, Benzodiazepines, Antidepressants, Antihistamines, Proton pump inhibitors and Anticonvulsants.

Our study shows that Non-steroidal Anti-inflammatory drugs (21.49%) are the most prescribed mono therapy for migraine treatment followed by Anti emetics (20.21%), Antihistamines (19.95%), β-Adrenergic antagonists (13.55%), Proton pump inhibitors (13.55%), Antidepressants (4.09%), Anticonvulsants (2.81%), Benzodiazepines (2.56%) and Analgesics (1.79%).

A study conducted by Becker WJ in 2015 shows that NSAIDs are the most commonly used mono therapy in migraine.[27]
Patients on single pill combination therapy, Antiemetic and NSAID (61.21%) followed by β-Adrenergic antagonist and Antihistamine (26.73%), Antiemetic and Analgesic (5.17%), Benzodiazepine and Antidepressant (4.31%), Antiemetic and Proton pump inhibitor (1.72%), and β-Adrenergic antagonist and Benzodiazepine (0.86%).

Manzoni GC *et al* (2014) found that combination with Anti emetics were most preferred and important in case of migraine patients.[28]
Rebecca E. Wells *et al*. identified that Triptans are Migraine specific medications which have revolutionized the acute treatment of Migraine. There are many reasons involved in the discontinuation of triptans such as failure to relieve pain, reoccurrence of pain after initial relief, concern over medication side effects, loss of initial efficacy but other important factors associated with discontinuation of triptans are such as greater migraine related disability, depression and the use of opioids for migraine attacks.[29]

In the review by Cho SJ, Song TJ, Chu MK on Treatment Update of Chronic Migraine (2017) shows that the treatment strategy pharmacologically involves both acute and preventive measures. The acute treatment for both chronic migraine and episodic migraine are similar. In more than two randomized controlled trials the preventive treatment with topiramate and botulinum toxin A exhibited more efficacy.[30]

Overall prescribing patterns showed that mono therapy (77.12%) was used more than combination therapy (22.88%).

Table 1: Cronbach's Alpha, T-Value and P-Value of MSQ Domains and Total MSQ Score

Scale (Q. Nos)	Items	Cronbach's Alpha	Counseling		(t-value and P-value)
			Before	After	
Role function-Restrictive (1-7)	**7**	**0.96**	66.14 (15.15)	29.34 (6.76)	(22.19,0.000*)
Role function-Preventive (8-11)	**4**	**0.92**	62.78 (17.69)	27.10 (8.05)	(18.36,0.000*)
Emotional Function (12-14)	**3**	**0.91**	62.00 (18.84)	27.33 (10.53)	(16.06,0.000*)
Total Score (1-14)	**14**	**0.98**	64.29 (15.63)	28.27 (7.00)	(21.03,0.000*)

Values are expressed as Mean (S.D.).
*_Values are statistically different from before counseling by Paired t-test; P < 0.05

Table 2: Cronbach's Alpha, T-Value and P-Value of SF 36 Scales

SF36 Scale (Q. Nos.)	Items	Cronbach's Alpha	Counseling		(t-value and P-value)
			Before	After	
Physical functioning (3-12)	10	**0.90**	68.50 (17.27)	92.75 (7.53)	(-12.87,0.000*)
Role limitation due to physical health (13-16)	4	**0.82**	26.75 (26.65)	92 (15.03)	(-21.33,0.000*)
Role limitation due to emotional problems (17-19)	3	**0.78**	22.67 (27.58)	90.00 (16.07)	(-21.09,0.000*)
Energy / fatigue (23, 27, 29, 31)	4	**0.81**	44.95 (12.15)	78.05 (8.76)	(-22.09,0.000*)
Emotional well being (24, 25, 26, 28, 30)	5	**0.86**	41.32 (12.78)	75.82 (11.42)	(-20.13,0.000*)
Social functioning (20, 32)	2	**0.73**	39.45 (14.99)	72.17 (11.57)	(-17.28,0.000*)
Pain (21, 22)	2	**0.83**	31.525 (14.54)	67.82 (11.40)	(-19.65,0.000*)
General health (1, 33-36)	5	**0.69**	51.45 (11.42)	61.02 (6.69)	(-7.23,0.000*)
Health change (2)	1	-	37.75 (16.47)	64.75 (13.81)	(-12.56,0.000*)

Values are expressed as Mean (S.D).
*_Values are statistically different from before counseling by Paired t-test; P < 0.05

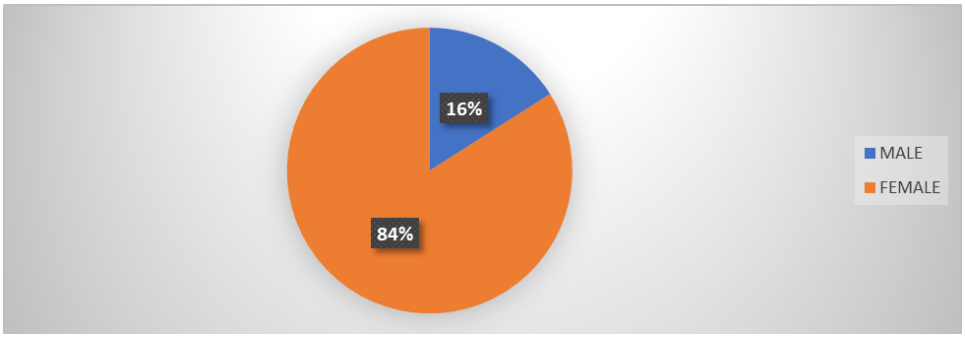

Figure 1: Distribution of Study Population Based On Gender

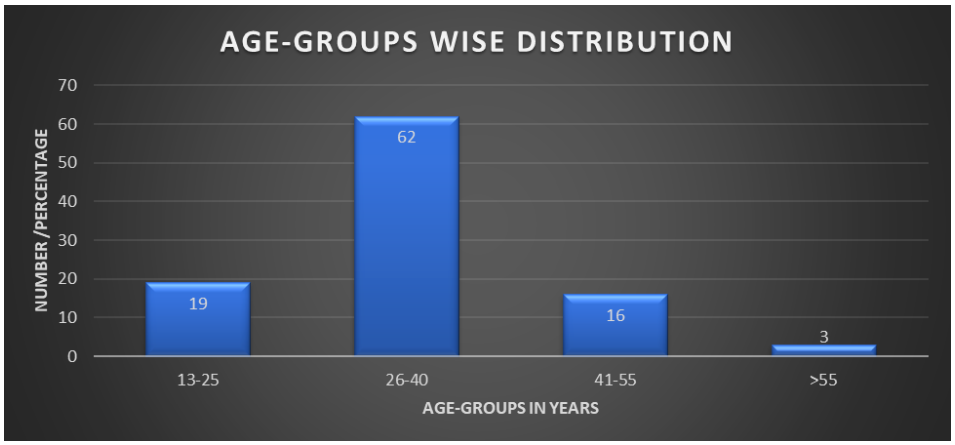

Figure 2: Distribution of Study Population Based On Age Groups

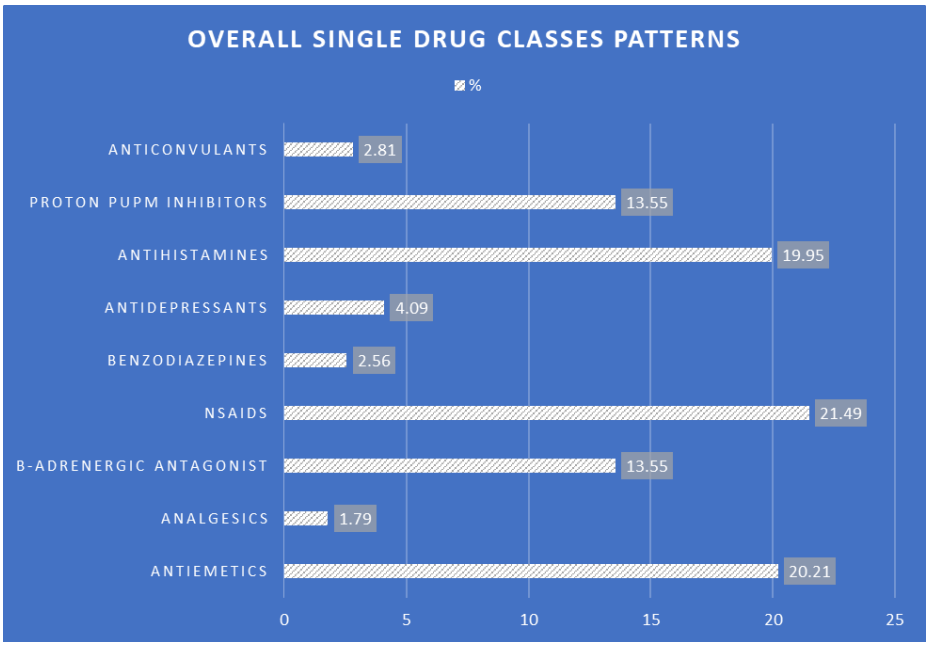

Figure 3: Distribution of Various Drug Classes Which Are Prescribed As Single Drug in Overall Migraine Treatment

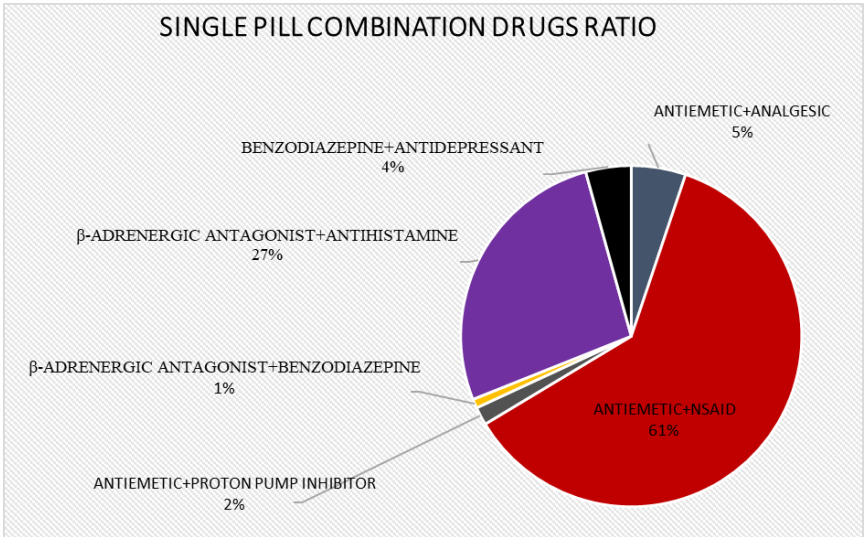

Figure 4: Distribution of Various Single Pill Combination Drugs Which are Prescribed in Overall Migraine Treatment

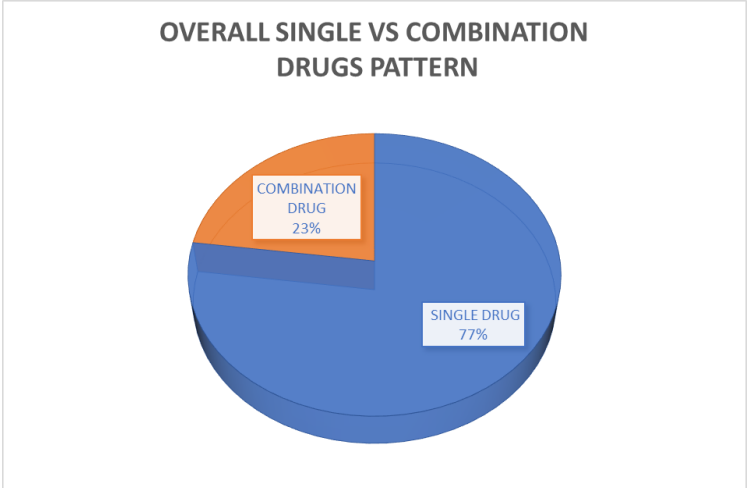

Figure 5: Distribution of Overall Single Vs Combination Drugs in Migraine Treatment

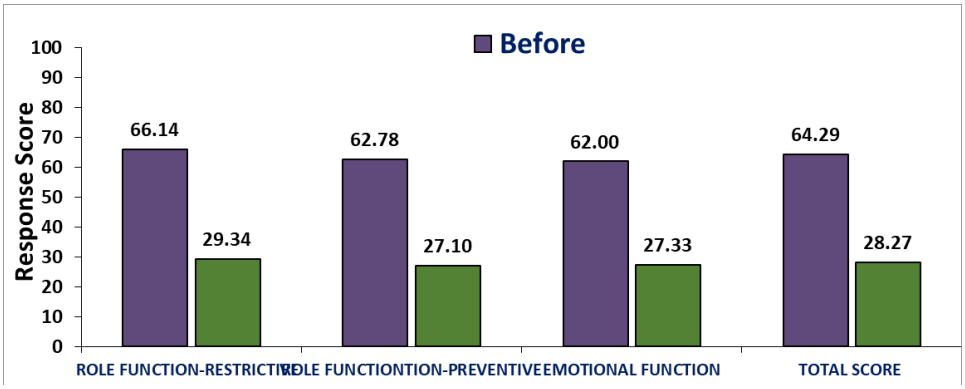

Figure 6: Comparison of Mean Scores of MSQ Scales and Total MSQ Score Before and After Counseling

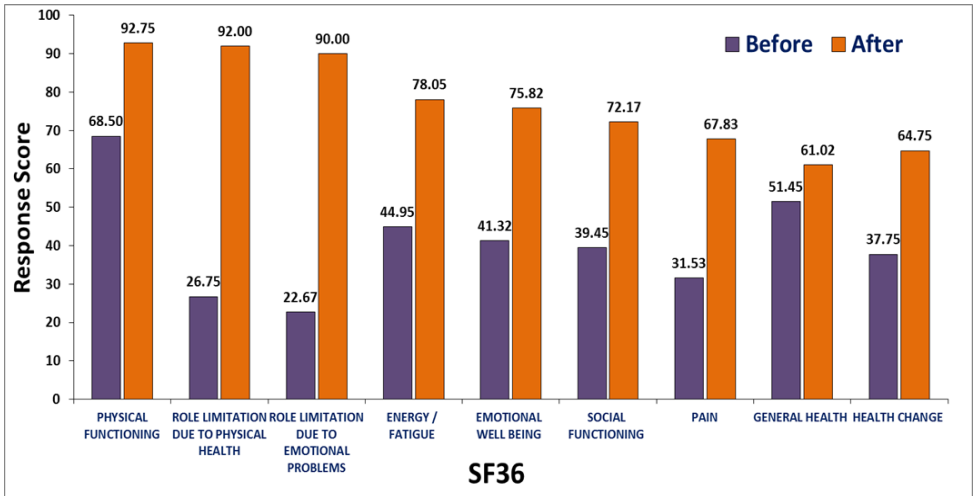

Figure 7: Comparison of Mean Scores of SF 36 Scales before and After Counseling

Patient Counseling

Patient Counseling for the subjects was done at the Outpatient department in the hospital. The Counseling was done with the aid of leaflets. The leaflets contain information about the disease, symptoms, when to seek medical advice, managing migraine by self-care and some home remedies for reducing frequent migraine attacks. The leaflet was printed in both English and Telugu (local language) for easy understanding by patients.

The patient counseling was done at the time of hospital visit. Patients were advised to follow the guidance given during counseling to reduce the burden of headache and frequency of attacks. A review of the Counseling was taken from all the patients with a gap of about 2 months and above during their follow-up hospital visit after initial counseling to know the impact of Counseling on the Health-Related Quality of Life.

Health Related Quality of life in migraine patients using MSQ Questionnaire

The questionnaire is disease specific which consists of 14 questions of three domains: Role Function-Restrictive (RR) 1-7, Role Function-Preventive (RP) 8-11 and Emotional function (EF) 12-14.[31]

The scores of these 3 domains were compared before and after the Counseling, higher the score of the domains higher the impact of disease on patient[3] and impaired quality of life.
The scores of these 3 domains and total score in all the patients were higher before the Counseling: RR (Mean = 66.14), RP (Mean = 62.78), EF (Mean = 62.00) and Total Score (Mean = 64.29) during their hospital visit, while the scores were decreased such that RR (Mean = 29.34), RP (Mean = 27.10), EF (Mean = 27.33) and Total Score (Mean = 28.27) after the Counseling in follow-up review. Almost all the patients were improved in the review after patient counseling in all the 3 domains and Total Score.

There was a significant decrease in the scores of MSQ in all the 3 domains and Total Score after review indicating that patient counseling had improved the Migraine health related quality of life in these patients.

K. S. Anand and Sangeetha Sharma had conducted a study on Quality of life using MSQOL as one of the scales which showed improvement in patients after specific treatment and education on migraine.[7]

Moshen Tavakol and Reg Dennick mentioned that Cronbach's alpha is an important concept in the evaluation of assessments and questionnaires. For the addition of validity and accuracy to the data interpretation the estimation of this quantity is mandatory for assessors and researchers.[32]

Health related Quality of life in migraine patients using generic questionnaire SF-36

It is the most widely used generic questionnaire to assess the QOL. It contains 36 questions in eight health related categories: Physical Functioning (3-12), Role Limitations due to Physical Health (13-16), Role Limitation due to emotional problems (17-

19), Energy/Fatigue (23, 27, 29, and 31), Emotional well-being (24, 25, 26, 28, and 30), Social Functioning (20, 32), Pain (21, 22) and General health (1, 33-36). It also includes which is about health change (2) compared to a year ago.[33]

The lower the score of the health-related category the higher the impact of disease on quality of life.[15]

The mean score of the all health related categories was low before the Counseling during the hospital visit were such that Physical Functioning (Mean = 68.50), Role Limitations due to Physical Health (Mean = 26.75), Role Limitation due to emotional problems (Mean = 22.67), Energy/Fatigue (Mean = 44.95), Emotional well-being (Mean = 41.32), Social Functioning (Mean = 39.45), Pain (Mean = 31.53) and General health (Mean = 51.45) while there is significant improvement in the mean scores were found after the 2 months during follow-up were such that Physical Functioning (Mean = 92.75), Role Limitations due to Physical Health (Mean = 92.00), Role Limitation due to emotional problems (Mean = 90.00), Energy/Fatigue (Mean = 78.05), Emotional well-being (Mean = 75.82), Social Functioning (72.17), Pain (Mean = 67.83) and General health (Mean = 61.02).

Health change compared to one year ago was also assessed such that during initial assessment the health condition one year ago was mentioned and it was compared with present health condition in the review assessment. Health change in initial assessment (Mean = 37.75) is compared with the health change in review assessment (Mean = 64.75).

There was significant improvement in all the health-related categories of the scale, indicating that education about migraine disease had shown the impact on the improvement of HRQOL in the patients.

A study was done by Carlos. A. Bordini *et al* on the effect of preventive treatment on QOL in migraine by using SF-36 general questionnaire that shows improvement in HRQOL after preventive treatment.[15]

There was a significant improvement in the Health-related Quality of Life in the both scales of MSQ, disease specific scale and SF 36, generic scale. The patient counseling along with the medication management shows the improvement in the clinical outcomes and the Health-related Quality of Life of the Migraine patients.

Rothrock JF *et al*. in the study concluded that intensive education of migraine patients in addition to medical management is improves the clinical status and is much beneficial to the Migraine patients.[34]

CONCLUSION

Migraine Headache leads with highest ratio among the nonfatal disease-related burden worldwide. It mainly affects the Health-related Quality of Life of the patient having much negative effect on the normal functioning which involves physical, emotional and social aspects of daily life influencing very badly on family, work and social relationships.

This prospective observational study assessed the prescribing patterns of Anti-Migraine Treatment and significant improvement in the Health-related Quality of life for the migraine patients was observed by educational intervention of clinical pharmacist providing information regarding proper understanding about the disease, course of treatment and self-care to be taken which includes certain precautions, food habits and as such non pharmacological measures for well management of the Migraine Headache.

The patient education along with appropriate treatment helped the Migraine patients in the improvement of their Health-related Quality of life and thus decreased the Migraine related burden on the individual.

Clinical implications

- The Educational programmes by the Clinical Pharmacists providing the necessary information for the Migraine patients in proper management of the Migraine Headache helps in the improvement of their Health-related Quality of life.
- As the disease cannot be cured totally and the patient cannot be out from the Migraine Headache attacks there is much demand in the development of various Non-Pharmacological measures.
- The advanced treatment strategies should be considered by the researchers for decreasing disease related burden and for the improving the Health-related Quality of Life of Person living with migraine.

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