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Study of Health Related Quality Of Life in Patients with Gastro esophageal Reflux Disease

Dr. Krishna Pavan Kumar J*,K Bindu Madhuri[2], B Prasanthi[3], Dr Shaik Faizan Ali[4], Mr G Sada Sivarao[5], Mr V D C Sravan Kumar[6], Dr Konda Ravi Kumar[7].

**: - Asst Professor, Dept. of Pharmacy Practice, Hindu College of Pharmacy, Amaravathi Road, Guntur-522002*

[2]Pharm.D (internee), Dept. of Pharmacy Practice, Hindu College of Pharmacy, Amaravathi Road, Guntur 522002

[3]Pharm.D (internee), Dept. of Pharmacy Practice, Hindu College of Pharmacy, Amaravathi Road, Guntur-522002

[4] Asst Professor, Dept. of Pharmacy Practice, Hindu College of Pharmacy, Amaravathi Road, Guntur-522002

[5] Asst Professor, Dept. of Pharmacy Practice, Hindu College of Pharmacy, Amaravathi Road, Guntur-522002

[6]Asst Professor, Dept. of Pharmacy Practice, Hindu College of Pharmacy, Amaravathi Road, Guntur-522002

Corresponding Author: Dr. Krishna Pavan Kumar J

Abstract:

Background*: Gastro esophageal reflux disease (GERD) is a common problem worldwide with a wide range of clinical manifestations and potential complications like esophagitis, ulceration and stricture formation. It is a common disorder associated with substantial reduction in health related quality of life.*

Objective*: To assess the health related quality of life in GERD patients.*

Methodology: *The study was conducted at Gastroenterology department (outpatient and inpatient) of St Joseph General Hospital, Guntur. The study was a prospective interventional observational study conducted over a period of six months from December 2017 till April 2018. Patients satisfying the study criteria were enrolled into the study after obtaining an informed consent. The enrolled patients were interviewed and their medical records were reviewed to record information about their demographic variables, level of education, social habits, diagnosis, current and past medical and medication history. Patients Health Related Quality of life was assessed using SF12 questionnaire at the baseline. The patients were then counseled in a private area to ensure privacy and provided with education about GERD. The patients were followed up for 30 days and their HRQOL was re-assessed using SF12 Questionnaire and their scores were calculated and outcome was measured to assess improvement in HRQOL.*

Results: *A total of 80 patients were included in the study. 15 patients (13.07%) were considered as drop outs due to irregularity in follow up. Of the 80 patients who completed the follow up and considered for study, preference existed for the gender and GERD was found to be more prevalent among the males [n=54(67.5%)] then in females [n=26(32.5%)]. In the study it was found that GERD occurred in all age groups with an average age of 44 years. Physical Composite Score (PCS) of the patients were found to be 34.96 and most of the patients distributed in the mean range of 30 to 35 years. In the follow up after providing education for the patient about disease and lifestyle modifications the mean score of the patient increased (46.9). The Mental composite score (MCS) score was also found to be higher compared to baseline among the patients after counseling (from 40.5 to 53) .*

Conclusion: *This study has helped to identify and track unmet health needs and disparities. The complete resolution of symptoms were not observed since the patients were followed up for only 4 weeks but improvement in their quality of life were seen. This study concludes that improving patient knowledge about GERD by providing patient education can improve their overall health related quality of life.*

Key Words: *Gastro esophageal Reflux Disease (GERD), Health Related Quality of Life (HRQOL), Short Form Health Survey Questionnaire(SF-12), Patient Education.*

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I. Introduction

According to WHO Health may be defined as a complete physical, mental and social well being-not merely the absence of a disease or infirmity.QOL is termed as an overall sense of well being, including aspects of happiness and satisfaction with life as a whole.[1]Gastroesophageal reflux disease (GERD) is a common problem worldwide with a wide range of clinical manifestations and potential complications like esophagitis,

ulceration and stricture formation. It is a common disorder associated with substantial reduction in health related quality of life. The prevalence of GERD in developed nations is linked with age, 50 years and above are mainly affected.[2] .GERD is caused by a failure of the Lower Esophageal Sphincter. The symptoms of GERD can have a profound impact on patients quality of life such as sleep disturbances, problems with eating and drinking impaired social activity or even decreased productivity can occur. International guidelines recommend that the diagnosis and initial management of GERD should be based on symptoms, but the frequency of symptoms that constitutes disease is not well defined. Heartburn and regurgitation are generally accepted as the most useful indicators of the presence of GERD in clinical practice. However, GERD is also associated with a range of other symptoms originating in the esophagus, chest and respiratory tract; up to one-third of GERD patients are affected by atypical symptoms, such as chronic cough, hoarseness, wheezing and chest pain

OBJECTIVE:
To assess the health related quality of life in GERD patients.

II. Methodology

Study Criteria:
Inclusion Criteria:

- Patients of either sex aged ≥ 18 years.
- Patients who are newly diagnosed with GERD or those who are already on treatment of GERD.
- Patients, who are able to read, write and understand working Kannada or English language or those able to get support from the attendants.

Exclusion Criteria:

- Patient with other Gastro intestinal diseases other than GERD (gastrointestinal cancer, liver disease, pancreatic disease, peptic ulcer, inflammatory digestive tract diseases).
- Patients with major psychiatric illness.
- Pregnant or lactating women.

Study procedure
Development of patient data collection form:

A specially designed data collection form was developed and implemented for this study. The data collection form had provision for collecting key information like demographics (name, age, sex, and marital status), education, diagnosis, current and relevant past medical conditions, past and current medication history (medication details, dose and indication), as well as social habits (alcohol and smoking). It also included recording of the SF-12 scores for the visits as well as the score outcomes. The data collection and assessment form designed for use in this study was computerized using Microsoft® Access 2007 and Microsoft® Excel 2007 for easy accessibility, retrieval and analysis of data.

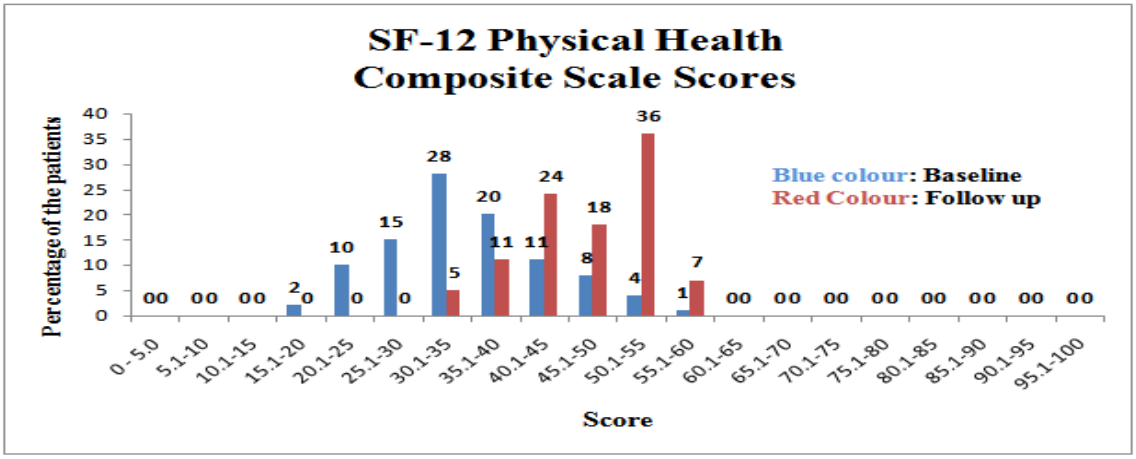
III. Results and Discussion

During the study period from December 2017-April 2018, 80 patients were selected in our study. At baseline 95 patients answered SF 12HRQOL questionnaire and 15 patient were dropped out from the study as they could not come for visit. Total 80 patients answered SF 12 at baseline (before education) and at first follow up (after education).

In this study, 54(67.5%) patients were male and 26(32.5%) were female.

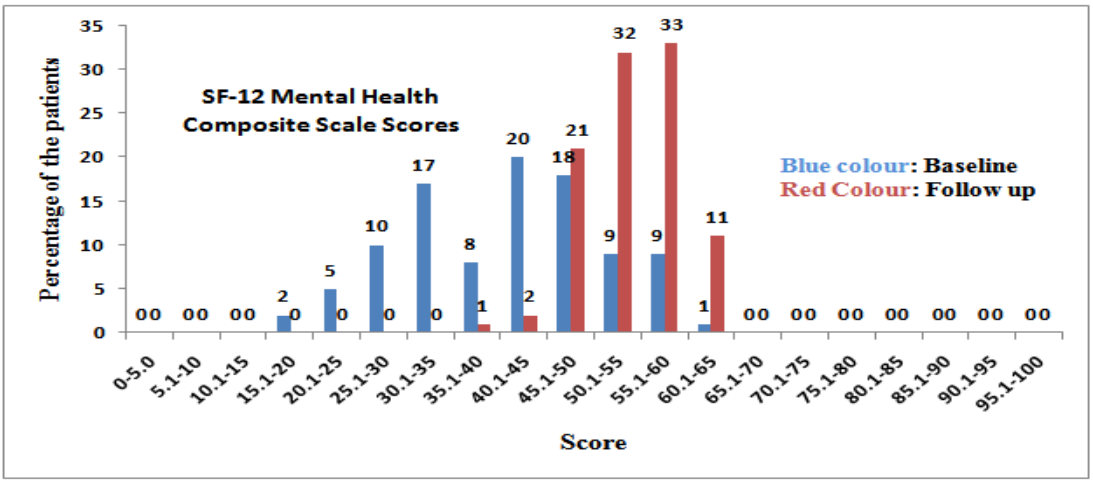
Among the study population, in more number of patients physical health or emotional problems were interfering with their social activities some of the time 35(43.75%) at baseline. After education and life style modifications the physical health or emotional problems were interfering with their social activities but a little of the time 36(45%). There is significant ($p<0.05$) improvement in all categories of patients from baseline to first follow up.

Figure No 1: Distribution of patients based on Physical Health Composite Score



In general PCS will range from 0 to 100 in that 0 indicating that least quality of life and 100 indicating highest quality of life. Among the 80 patients at the base line before providing education regarding GERD and life style modification for the disease mean PCS of the patients was found to be 34.96 and most of the patients distributed in the mean range found to be 30 to 35 years only. In the first follow up after providing of education for the patient about disease and lifestyle modifications the mean score of the patient was found to be 46.9.There is a significant ($p<0.05$) improvement in the mean PCS at the first follow up from baseline.

Figure No:2 Distribution of patients based on Mental Health Composite Score



Generally MCS will be distributing between 0to 100 and 0 indicating that poor quality of life and 100 indicates highest quality of life In the study patients before providing education and lifestyle modification to the patients mean mental composite score was found to be 40.5 that is less compared to highest quality of life. In the first follow up after providing education about disease to the patient average MCS was be 53.There was significant ($p<0.05$) improvement in the mean PCS in first follow up when compared to baseline.

IV. Discussion

Patient demographics

A total of 80 patients were enrolled at base line into the study. 15 patients (13.07%) were considered as drop outs due to irregularity in follow up may be because of personal reasons, lack of time or lack of transport. Among the drop outs there were a significant number of male patients [n=10(66.66%)] compared to females [n=5(33.33%)] and [n=8(53.3%)] patients were aged between 50 to 72 years and indicating that the females are more regular in their follow up for their disease and that elderly people skip the follow up or appointments compared to younger individuals, a casual approach that could be the reason behind more prevalence of GERD among the elderly and the development of complications.

Of the 80 patients who completed the follow up and considered for study, preference existed for the gender and GERD was found to be more prevalent among the males [n=54(67.5%)] than in females [n=26(32.5%)]. In the

study it was found that GERD occurred in all age groups with an average age of 44 years. This was in accordance with the study conducted by Gibbs, S. Waters WE. George CF. Prescription Information leaflets, a national survey.[8]

Education, Social history and Diagnosis:

There was no significant difference found in the education levels and social history of the enrolled patients. Among the study population, most of the patients had completed secondary school education[n=22(27.5%)] followed by primary school education[n=18(22.5%)],pre university college level of education [n=13(16.25%)]and the least number of patients had completed university education[n=12(15%)] and 15 patients (18.75%) were illiterate . Among the study subjects 45 (56.25%) patients were non smokers and [n=08(10%)] were non alcoholics, while the others were either current or past smokers or alcoholics. (Past smokers and alcoholics were defined as patients who had quit smoking and consuming alcohol 1 year prior to data collection). The social history findings thus suggest that cigarette smoking and alcohol consumption may be associated with GERD. However in our study there was no significant difference between current smokers [22(27.5%)] and non smokers [45(56.25%)] for the development of GERD. Similarly there was no significant difference between alcoholics [27(33.75%)]and non alcoholics [08(10%)] for the development of GERD(Table 1). This indicates that either current or past smokers and alcoholics are at increased risk for the development of GERD. This was similar to the study conducted by Kaltenbach et. Al. Are lifestyle measures effective in patients with gastroesophageal reflux disease [29] which identified smoking and alcohol consumption as the risk factors for developing GERD symptoms along with obesity and consumption of certain food items like citrus fruits, mint, coffee spicy items and chocolates.

In the enrolled patients, [57(67%)] were suffering only from GERD with no other co morbidities. 64(80.54%)patients were newly diagnosed with GERD while 16 (19.46%) patients were known cases of GERD. The diagnosis of GERD was confirmed by endoscopic procedure in majority of the patients [n=52(65.26%)] and rest based on the signs and symptoms.

Education on Health Related Quality of Life in Patients

Enabling the patients to understand the cause of the disease, importance of regular intake of medicines and necessary lifestyle modifications in controlling the disease through counselling will help to improve the therapeutic outcomes.

The present study assessed and provided data on influence of pharmacist mediated patient education on Health Related Quality of life suffering from GERD visiting JSS Hospital. In the present study patients were educated about the disease, changing their life style modifications and the self management strategies to control the disease. During the follow up, there was a statistically significant improvement in the overall SF-12 score in both PCS and MCS for the patients.

Physical score assessment:

PCS was assessed based on the physical quality of life and SF-12 questionnaire by taking the health and working status throughout the day. The responses given by the patients were entered in the SF-12 software to get the PCS.PCS ranges from 0 to 100, where 0 indicates poor quality of life and 100 indicates very good quality of life.

In the over all age groups (18-87 years) there was a significant improvement in the mean PCS(40.52) at first follow up compared to baseline PCS (34.96) .Secondly comparing PCS of different age groups by getting mean value from each group, mean PCS score decreasing with increase in age from 18 to 87 years (52 to 36.16). This indicating that younger people having higher physical health and energy in compared with older one and for younger people it is easy to improve their physical health in compared with older one because of higher metabolic rate and lesser medical problems.[13]

Mental Composite score assessment

MCS was assessed based on the mental quality of life and emotional status of the patient based on SF-12 questionnaire by taking the energy status throughout the day. The responses given by the patients were entered in the SF-12 software to get the MCS.MCS ranges from 0 to 100, where 0 indicates poor quality of life and 100 indicates very good quality of life. The mean MCS for over all age groups (18-87) was found to be 46.9.Then patient education was provided about the life style modifications.

In the follow up same questionnaire was used for assessing the patient's mental quality of life and collected the answers provided by the patient and entered in the SF-12 software and compared with patients base line score most of the patients were found to be improved in their MCS (mean baseline value 46.9 to mean first follow value 53.70) score. The MCS score was also found to be higher compared to baseline among the patients after counselling. MCS score in different age groups was assessed. It was found that there is no much

difference in MCS from 18 to 57 years age group but increasing in the age from 58 to 87 years the MCS has decreased because of comorbid conditions.

Influence of education on HRQOL

The current approach to treatment of GERD includes lifestyle recommendations in conjugation with pharmacologic therapy primarily with proton pump inhibitors (PPI) and Histamine-2 receptor antagonists (H2RA) along with antiemetic drugs. After education number of people in good health has increased from [n= 27(33.75%)] to [n=45(56.25%)], very good health quality patients has increased from [n=07(8.75%)] to [n=23(28.75%)] and excellent health group has been increased from [n=0(0%)] to [n=2(2.5%)] in the overall in general patients health has been increased.

Limitation in their daily activities because of health also decreased significantly in yes, limited a lot group from [n=20(29%)] patients to [n=10(12.5%)] during follow up, yes, limited a little group patients also decreased significantly from [n=51(63.8%)] to [n=43(53.75%)]and not limited a lot group has increased tremendously from 09(11.3%) to 27(33.8%) patients.

Javier P Gisbert et al conducted a European observational study in primary care centres to assess impact of GERD on patient's daily lives. The study showed that GERD was associated with a substantial impact on the daily lives of affected individuals managed in the primary care setting.[19]

Patients were not able to do their work or other regular activities because of emotional problems and some patients were able to do their regular work but not to that extent what they were thinking to do, these findings are during baseline but during the follow up patients were improved significantly from [n=68(85%)] to [n= 27(33.8%)] about [n=12(15%)] of the people able to do their work properly up to that extent what they feel like.

In the study by Degl' Innocenti et al, found that there was a significant correlation between emotional distress, sleep disturbance, problem with food ,drink and GERD and patients having mild(32%), moderate (50%) and severe(18%); 83% were on proton pump inhibitors and education have shown greater the improvement in vitality with treatment, the more likely it was that patients would be satisfied with their treatment ($P \leq 0.001$).[15]

Patients pain at baseline was interfering in their normal work moderately[n=32(40%)] and 'little bit' [n=23(28.75%)] but after providing of education about GERD and life style modifications their pain was reduced from 'moderately' to' little bit'[n=40(50%)] and not at all [n=18(22.5%)] at first follow up.

Patients mental status includes calmness, peacefulness ,energy, downheartedness and emotions which were interfering in their daily activities because of GERD. After pharmacists education to the patient about the disease and life style modifications the mental status was improved but not up to that extent the patient needs.

Study conducted by Tiing-Leong Ang, Kwong-Ming Fock et al conducted a comparative study on the clinical, demographic and psychiatric profiles among patients with erosive and non-erosive reflux disease (NERD). The psycho-emotional profile of patients with reflux disease was assessed using the General Health Questionnaire. Compared to patients with erosive reflux disease, patients with NERD were younger and had a higher prevalence for minor psychiatric morbidity was found out.[21]

V. Conclusion

In our study more male[54(67.5%)]patients were suffering from GERD than in female [26(32.5%)]patients.Another finding was that GERD was more prevalent in (40-49years) age group. In our study there was an improvement in both PCS and MCS scores from baseline to follow up. It was found that the physical composite score (34.96 to46.9) and mental composite score(40.5 to 53) of the patients were decreased with increase in age because of the presence of comorbidities in older patients. Enabling the patients to understand the cause of the disease, importance of regular intake of medicines and necessary lifestyle modifications in controlling the disease through counselling helped to improve the therapeutic outcomes and there by improvement in the Health related quality of life in patients with GERD.

The study result found that after providing patient education regarding disease, importance of medication adherence and life style modification improved the HRQOL in GERD patients.

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