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"ASSESSMENT OF HRQoL IN HEPATIC IMPAIRED PATIENTS: A QUESTIONNAIRE BASED STUDY"

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ABSTRACT

The term health-related quality of life (HRQoL) reflects the impact of the disease upon a person's quality of life.³ Chronic liver disease patients experience symptoms of fatigue, anxiety, depression, loss of self-esteem, etc. as a result of disease progression including side-effects of treatment specific therapy, which have a huge impact on their HRQoL. Moreover rising medical costs and declining socio-economic conditions further contribute to the deterioration of the patient's mental health and subsequently, HRQoL.^[2] CLDQ gave a better understanding of HRQoL in patients with different forms of chronic liver disease and also disease progression. Age and sex did not affect CLDQ scores. Medication nonadherence is a highly prevalent obstacle to achieve and maintain wellness in liver diseased patients. The objective of this study is to assess the impact of chronic liver disease on quality of life and to determine whether non adherence is a factor for impaired QoL in patients with liver disease. A prospective observational questionnaire based study was conducted in hepatic impaired patients on drug dosing for a period of 6 months in a tertiary care teaching hospital. The degree of hepatic impairment was calculated using Child-Pugh classification. Self-reported medication adherence was examined using the 8-Question Morisky Medication Adherence Scale (MMAS-8). From the 52 CLDQ responses obtained, higher mean scores were found for emotional function [37.01(7.19)] while lower mean scores for activity [11.21(3.72)] and abdominal [11.40(3.56)]. The overall CLDQ scores for patients belonging to Child C [4.82(0.73)] and Child B [4.15(0.80)] were higher compared to patients belonging to Child A [3.61(0.80)]. Out of 52 patients, 43 (83%) were observed with an overall CLDQ scores less than five and 9 (17%) patients with an overall CLDQ scores more than or equal to five. Out of 52 patients, 33 had a score less than two and 19 patients with score between 1 or 2 for MMAS-8. Of the 43 patients with an overall CLDQ scores less than five, 27 of them had an MMAS-8 score more than 2 and 16 of them had an MMAS-8 score of 1 or 2. Among the 9 patients with an overall CLDQ score greater than five, 6 patients scored more than 2 and 3 patients scored 1 or 2. The most affected domains were activity and abdominal symptoms whilst the least affected was Emotional function. In conclusion to our study, the domains like Activity, Abdominal and Fatigue were equally affected in Child A, Child B and Child C categories. These findings had statistical significance with P-value <0.05. Our objective on determining the impact of adherence on QoL was successful in highlighting a positive correlation between low medication adherence and poor QoL. This finding was statistically significant with P-value of 0.048. Our conclusion from the CLDQ responses collected is that a major population had poor HRQoL.

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INTRODUCTION

Health related quality of life

Health has been defined as being not only the absence of disease and debility but also the presence of physical, mental and social well-being. Quality of life (QoL) is a concept that incorporates many aspects of an individual's experience, general well-being, satisfaction, social and physical function. Measuring QoL provides a better measurement of the impact of such events on the general well being of the patient. Also it helps to assess the impact of treatment on day-to-day life of a patient.^[3]

Health related quality of life (HRQoL) as a multidimensional concept includes subjective evaluations of domains related to physical, emotional, mental and social functioning in a context of a disease and its treatment.^[4]

Chronic liver disease (CLD) results from a variety of disorders and is a major cause of morbidity and mortality worldwide. Death from liver disease or its complications is the ninth leading cause of mortality in the United States.^[5]

Over the last few decades, assessing quality of life (QoL) of individuals with diseases has become common clinical practice, as a consequence of increased survival of patients with chronic diseases. The term health-related quality of life (HRQoL) reflects the impact of the disease upon a person's quality of life.^[1] Chronic liver disease patients experience symptoms of fatigue, anxiety, depression, loss of self-esteem, etc. as a result of disease progression including side-effects of treatment specific therapy, which have a huge impact on their HRQoL. Moreover rising medical costs and declining socio-economic conditions further contribute to the deterioration of the patient's mental health and subsequently, HRQoL.^[2]

CLDQ

Well-developed and validated questionnaires have been used as instruments for QoL measurement. The CLDQ has been translated, validated and used across the world in estimating the QoL in patients with CLD.^[3]

The CLDQ is the only validated instrument for the different etiologies and degrees of severity of liver disease. It yields both domains and total scores, demonstrating both multidimensional and overall perception of QoL, emphasizing the effects of liver disease symptoms. The CLDQ comprises 29 questions encompassing six domains: Abdominal Symptoms (AS), Fatigue (FA), Systemic Symptoms (SS), Activity (AT), Emotional Function (EM), and Worry (WR). AS and AT domains have 3 items each; FA, SS, and WR have 5 items each; whereas EM comprises 8 items.^[1] The response of CLDQ results in 1–7 scales: ranging from “all of the time” to “none of the time.”^[3] Higher score on the questionnaire is indicative of minimum symptoms and lower score indicates more pronounced symptoms. A CLDQ cut-off score was determined to evaluate HRQoL; mean CLDQ scores ≥ 5 was considered to represent high HRQoL and mean CLDQ scores < 5 implied low HRQoL.^[1]

CLDQ gave a better understanding of HRQoL in patients with different forms of chronic liver disease and also disease progression. Age and sex did not affect CLDQ scores. CLDQ appears to be a more convenient tool to study the HRQoL in chronic liver disease patients. The CLDQ responds to specific changes in HRQoL, caused by Chronic liver disease. The use of the original CLDQ in western countries and translated versions in other countries have all demonstrated that HRQoL is reduced in patients with chronic liver disease.^[2]

Medication adherence

Medication adherence is defined by the World Health Organisation (WHO) as “the extent to which a person's behaviour - taking medication, following a diet, and/or executing lifestyle changes – corresponds with agreed recommendations from a health care provider”.^[6] Medication nonadherence is a highly prevalent obstacle to achieve and maintain wellness in liver diseased patients. Patients are nonadherent for various reasons, with some factors beyond their control. There is a clear need for well designed studies that examine various medication adherence tools and interventions in the liver disease population, as well as take into consideration the many challenges that patient face when taking their medication.^[7]

Medication non-adherence is widely seen in people with decompensated cirrhosis but the impact that patients' medication reliance and illness perceptions have on adherence is under-recognised. Clinician engagement with non-adherent patients should include open discussion of medications and liver disease.

Acknowledgement of patient concerns surrounding their medicines, with positive reinforcement of medication necessity in terms of disease management may improve adherence behaviour and patients standard of living. A complex regimen of medications is usually prescribed to manage complications of portal hypertension and liver insufficiency, however medication mismanagement and non-adherence is relatively seen among patients with decompensated cirrhosis. Non-adherence with medications has been associated with increased mortality.^[6] Poor adherence to medication regimens adversely impacts health outcomes in many chronic conditions.^[8] Non-adherence and mismanagement of diuretic therapy, which is prescribed in the management of abdominal ascites, peripheral oedema or pleural complications, contributes to 55% of potentially preventable 30-day readmissions among people with decompensated cirrhosis. The WHO has identified non-adherence as an international concern in the prevention of patient harm and optimisation of limited health resources. However, medication adherence is a complex health behaviour that is the result of numerous interacting dynamic variables including health literacy, self-efficacy, psychological views of medicines and disease, quality of life, and other internal and external hurdles.^[6]

Morisky medication adherence scale 8

Self-reported medication adherence was analysed using the 8-Question Morisky Medication Adherence Scale (MMAS-8) which consists of seven questions with yes/no alternatives, and one question which features a 5-point Likert scale. The scores from answered questionnaires are grouped into “High” (score =8), “Medium” (score 6 to < 8) and “Low” (score < 6) adherence groups. A huge proportion of ambulant patients with decompensated cirrhosis are nonadherent with prescribed regimens. The relation between “Low” medication adherence and patients having firm concerns or doubting the necessity of their medications should be probed further given the potential clinical relevance.^[6]

Interventions that promote positive reinforcement of the value and necessity of medications in addition to education about disease and medication management tailored to individual patient needs may improve adherence.^[6] Techniques to improve and maintain adherence levels are mandatory including enhanced adherence counseling offered to patients who are deteriorating or undergoing periodic exacerbation of symptoms.^[9]

Chronic liver diseases require long-term management. Patient understanding of these diseases may contribute to controlling the course and the manifestations of liver diseases. However, chronic liver disease can be extensive and encompasses a wide variety of conditions including chronic hepatitis, cirrhosis, and hepatic cancer. Therefore, patients are required to master a broad range of knowledge to manage these diseases. Often, patients must make difficult decisions about their own treatment. However, it is not easy for physicians to provide sufficient information for patients during routine appointments of out-patients department because the amount of time that can be spent with one patient is quite limited. Providing the latest and most accurate information is important for the treatment decision-making course in patients with chronic hepatitis. Studies have shown treatment coupled with a patient counselling program to be more effective than conventional treatment for improving both quality of life (QoL) and disease management in patients with chronic disease.

Therefore our research was focussed to assess the impact of chronic liver disease on quality of life and to determine whether non adherence is an aspect for impaired QoL in patients with liver disease.^[9]

METHODOLOGY

A prospective observational questionnaire based study was conducted to assess the impact of chronic liver disease on quality of life and to identify whether non adherence is a factor affecting QoL in patients with liver disease in a tertiary care teaching hospital for a period of six months at Davangere. All patients admitted to the hospital who was more than 18 years of age and who were confirmed with liver disease, and receiving at least one drug were included in the study. Comatose patients, pregnant and nursing women, patients receiving herbal medicines and placebos and subjects with insufficient data in their records were excluded from the study. The research protocol was approved by Institutional Review Board. Informed consent was collected from the patients prior to the study. CLDQ, which is a well-developed and validated questionnaire was used as an instrument for QoL measurement. Self-reported medication adherence was examined using the 8-Question Morisky Medication Adherence Scale (MMAS-8).

RESULT

A total of 52 patients with hepatic impairment were included in the study. The mean age of study population was 44.69 ± 13.97 . Among them, 49 (94.23%) were males and 3 (5.76%) were females. The mean total bilirubin was found to be 4.53 ± 5.0 , serum albumin was 2.95 ± 1.19 , prothrombin time was 2.59 ± 1.19 sec. SGOT of the candidates were 92.45 ± 85.89 and SGPT of the patients were 94.98 ± 99.97 . [Table 1]

Table 1: Demographic and Laboratory Data(n=52).

SL.NO	PARAMETERS	VALUES
1	Mean Age	44.69 ± 13.97
2	Male	49 (94.23%)
3	Female	3 (5.76%)
4	Total bilirubin	4.53 ± 5.01
5	Serum albumin	2.95 ± 1.19
6	Prothrombin time	2.59 ± 1.98
7	SGOT	92.45 ± 85.89
8	SGPT	99.97

Out of 52 patients, 27 (51.92%) belong to Child C, followed by 16 (30.76%) patients in Child B and 9 (17.3%) patients in Child A. [Table 2]

Table 2: Categorization of patients with hepatic impairment based on severity (n=52).

SEVERITY	CHILD-PUGH SCORE	NO. OF PATIENTS	PERCENTAGE(%)
Child A	5-6	9	17.30
Child B	7-9	16	30.76
Child C	10-15	27	51.92

From the 52 CLDQ responses collected, higher mean scores were seen for emotional function [37.01(7.19)] while low mean scores for activity [11.21(3.72)] and abdominal [11.40(3.56)]. [Table 3].

Table 3 : CLDQ score in domains.

SL. NO	VARIABLES	MEAN (SD)
1	Abdominal symptoms (AS)	11.40 (3.56)
2	Fatigue (FA)	22.23 (5.49)
3	Systemic symptoms (SS)	22.17 (5.42)
4	Activity (AT)	11.21 (3.72)
5	Emotional function (EM)	37.01 (7.19)
6	Worry (WR)	26.92 (6.28)

The overall CLDQ scores for patients belonging to Child C [4.82(0.73)] and Child B [4.15(0.80)] were higher compared to patients belonging to Child A [3.61(0.80)]. [Table 4].

Table 4: CLDQ scores based on the gravity of liver disease (n=52).

DOMAINS	CHILD A MEAN (SD)	CHILD B MEAN (SD)	CHILD C MEAN (SD)	P VALUE
AS	4.18 (0.70)	4.35 (1.02)	3.31 (1.24)	<0.05
FA	3.09 (0.43)	3.61 (0.39)	5.43 (0.50)	<0.05
SS	3.02 (0.46)	3.69 (0.28)	5.39 (0.57)	<0.05
AT	3.91 (1.11)	4.48 (0.97)	3.20 (1.22)	<0.05
EM	3.67 (0.34)	4.00 (0.61)	5.24 (0.65)	<0.05
WR	3.80 (1.06)	4.80 (0.61)	6.35 (0.64)	<0.05
TOTAL	3.61(0.80)	4.15(0.80)	4.82 (0.73)	<0.05

Out of 52 patients, 43 (83%) were found with an overall CLDQ scores below five and 9 patients (17%) with a total CLDQ scores more than or equal to five. [Table 5].

Table 5: Grouping of patients based on overall CLDQ scores (n=52).

CLDQ	FREQUENCY	PERCENTAGE (%)
<5 (low HRQoL)	43	82.7
≥5 (high HRQoL)	9	17.3
Total	52	100.0

Out of 52 patients, 33 had a score below two and 19 patients with score 1 or 2 for MMAS-8. [Table 6]

Table 6: Categorization of patients according to MMAS-8 score (n=52).

MMAS-8	FREQUENCY	PERCENTAGE (%)
0 (high adherence)	-	-
1 or 2 (medium adherence)	19	36.5
>2 (low adherence)	33	63.5
Total	52	100.0

Of the 43 patients with an overall CLDQ scores < five, 27 of them had an MMAS-8 score above 2 and 16 had an MMAS-8 score of 1 or 2. Among the 9 patients with an overall CLDQ score ≥ five, 6 patients scored more than 2 and 3 patients scored 1 or 2. [Table 7]

Table 7: Correlation of QOL and adherence.

MMAS-8	CLDQ SCORE		TOTAL	P VALUE
	<5	≥5		
1-2	16	3	19	0.048
>2	27	6	33	
Total	43	9	52	

DISCUSSION

Our study was conducted for a period of 6 months and data of 52 patients, who satisfied the inclusion criteria, were analyzed in a prospective manner. The severity of hepatic impairment was assessed by applying Child-Pugh classification as that of a study conducted by Sobhonslidsuk A et al.¹³ The study explores the dominancy of males over females in the development of hepatic impairment as similar to that of study performed by N.P Souza et al with a male population of 84%.¹ Among the 52 patients, 49 (94.2%) were males and 3 (5.8%) were females in our study.

From the 52 CLDQ responses received, higher mean CLDQ scores were observed for emotional function (37.01 ± 7.19) while lower mean CLDQ scores were seen for activity (11.21 ± 3.72) and abdominal symptoms (11.40 ± 3.56). The most affected domain of Child A category was Systemic symptoms (3.02 ± 0.46) while least affected was Abdominal (4.18 ± 0.70) domain. For Child B category Fatigue (3.61 ± 0.39) was the greatly affected domain whereas Worry (4.80 ± 0.61) was leastly affected. In case of Child C category, the most impaired was Abdominal (3.31 ± 1.24) and least affected was Worry (6.35 ± 0.64) domain. In contrast to the study conducted by Z.M Younossi et al which states that as the degree of liver disease increases patient's HRQoL as measured by CLDQ impairs,⁵ our study came to a conclusion that irrespective of the severity of liver disease, HRQoL can be impaired. These observations were statistically relevant with a p-value of (<0.05). The overall CLDQ scores were low (<5) for 43 patients and high (≥ 5) for 9 patients. These findings were similar to the studies conducted by Z.M. Younossi et al, Irene Ray et al and N.P. Souza et al. Of the 52 patient responses obtained for MMAS-8, 19 patients had a medium adherence with score 1 or 2 and 33 candidates were found to have less adherence with scores >2 . Of the 43 patients with poor QoL, 27 were found to be less adherent to medications. Our study was extended to find out a relation between adherence and QoL and there was a positive correlation between low medication adherence and poor QoL with a significant p-value of 0.048.

The study was concerned with prescription pattern evaluation in patients with hepatic impairment and assessing the QoL of patients with hepatic impairment. Our study also focused in determining the effect of medication adherence on the QoL of patients. The resources mainly encompassed were Lexicomp software, CLDQ and MMAS-8 item. The study was successful in providing patient education in the form of pamphlet and formulating dosage recommendation. The study emphasizes the need for adequate evaluation of drugs given to hepatic impaired patients by physicians and the role of clinical pharmacists in providing patient education.

CONCLUSION

From the CLDQ responses collected, a major population had poor HRQoL. The most affected domains were activity and abdominal symptoms whilst the least affected was Emotional function. In conclusion to our study we had found that the domains like Activity, Abdominal and Fatigue were equally affected in Child A, Child B and Child C categories. These findings had statistical significance with a P-value <0.05 . Subjects of Child A category who were newly diagnosed with the disease had prominent effects on Emotional and Worry functions due to the sudden and unexpected changes in their lives. Unfamiliarity towards the hospital setup and therapies could be the factors which make them more stressed compared to subjects of Child C category who are accustomed to these circumstances.

The MMAS-8 item responses collected from 52 patients showed a majority (63.5%) with low medication adherence. Our objective on determining the impact of adherence on QoL was successful in highlighting a positive correlation between low medication adherence and poor QoL. This finding was statistically significant with a P-value of 0.048.

We recommend future researches on our topic.

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CONFLICT OF INTREST

No conflict of interest amidst the authors.

ABBREVIATIONS

HRQoL - Health Related Quality of Life
 CLDQ - Chronic Liver Disease Questionnaire
 QoL - Quality of Life
 MMAS-8- Morisky Medication Adherence Scale 8
 CLD - Chronic Liver Disease

WHO - World Health Organisation

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