Assessment of Health-Related Quality of Life in Alcoholic Liver Disease Patients

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ABSTRACT

Alcohol induced cirrhosis prevalence has increased worldwide of late and has added markedly to the global burden of diseases. However, research involving quality of life as treatment outcome for alcoholic liver disease is limited. The primary objective of the study was to evaluate the health related quality of life and factors affecting it in alcoholic liver disease patients. Secondary objective was to analyze mental health status and prescription pattern in alcoholic liver disease patients. Patients, eligible to participate, were briefed regarding the purpose of the study and informed consent was obtained. Self-designed case report form and validated questionnaires were used to record information on physical, mental and emotional functioning of the patient. The study included 51 patients. It was found that majority had low quality of life scores with role limitation due to physical health (5.39 ± 16.9) domain being the most affected. It was also found that the symptom fatigue caused the most hindrance to patient’s daily activities (1.31 ± 1.20). Most of the patients reported having mild depression (50.98%). Prescription analysis showed that diuretics (74.50%) and drugs for hepatic encephalopathy were the most commonly used drugs. The present study found that alcoholic liver disease considerably impaired health related quality of life and identified the contributing factors as presence of complication, age, severity of disease and symptoms like fatigue and abdominal pain. Hence, evaluating factors affecting quality of life and prescription patterns help identify targets for novel treatment strategies.

INTRODUCTION

Chronic heavy alcohol ingestion is the most common cause of liver related mortality in the west and contributes markedly to the global burden of disease.

Despite significant advances in understanding of pathogenesis of alcoholic liver disease, there is no Food and Drug Administration (FDA) approved treatments. Abstinence is the hallmark of therapy for patients with ALD and nutritional therapy is the first line of therapeutic intervention (Mailliard and Sorrell, 2018).

The World Health Organization (WHO) estimates...
that 3.9% of the global mortality and 4.7% of Disability Adjusted Life Years (DALYs) is a consequence of alcohol consumption. In India as well as other Asian countries, alcohol ingestion is emerging as the commonest cause of liver diseases. In India, 4.9% of the population of ages 15 years and older suffer from alcohol use disorders and 3.8% of individuals suffer from alcohol dependence. Hence, there is a casual relationship between the chronic use of alcohol and a range of mental and behavioral disorders as well as injuries (Rehm et al., 2013).

In recent times, quality of life assessment has gotten much popularity as a treatment outcome measure, especially in chronic diseases. Health related quality of life (HRQOL) evaluates the extent of disability caused by a disease in a person's life and provides perspective regarding their disease and their treatment options. Alcoholic Liver Disease (ALD) affects not only the patient's life but also of their families and imposes marked burden on the society (Srivastava and Bhatia, 2013). Thus, assessing health-related quality of life is particularly important given a lack of inclusion of the patient's perspective as treatment outcome in clinical settings.

ALD has an undesirable influence on HRQOL due to the manifestation of symptoms like pain in abdomen, nausea and vomiting, decreased appetite and jaundice as well as complications including ascites, esophageal varices, portal hypertension, hepatic encephalopathy, which can be debilitating for the patients (Janani et al., 2018). Moreover, ALD is associated with various emotional problems like anxiety, depression and mood swings that severely affect mental functioning of patients, majority of which is under-diagnosed (Strat et al., 2015).

Even though there is substantial understanding of pathogenesis of alcoholic liver disease, abstinence remains the main therapy along with pharmacotherapy and psychosocial counseling that helps in maintenance of abstinence from alcohol (O’shea et al., 2010). The results from studies that evaluate health related quality of life in ALD patients can help devise policies aimed at improving patient’s quality of life and their clinical outcome. Hence, this current study aims to evaluate health related quality of life and factors affecting it in alcoholic liver disease patients. Secondary objectives are to study the effect of ALD on mental health of the patients and to analyze prescription pattern in alcoholic liver disease patients. A very few studies have been conducted on alcoholic liver disease till-date, the majority being only on chronic liver disease. Therefore, with the increasing prevalence of ALD, we need more studies to help make better interventions.

**MATERIALS AND METHODS**

**Study site**
The study was carried out, at ESIC MC-PGIMSR & Model Hospital, Rajajinagar, Bengaluru.

**Study design and duration**
This was an observational study over six months.

**Sample Size**
A total of 51 patients were taken up for the study.

**Inclusion criteria**
Patients above 18 years of age admitted to the inpatient wards of General Medicine with confirmed diagnosis of alcoholic liver disease and patients who are willing to participate and sign the written informed consent, were included in the study.

**Exclusion criteria**
Subjects with advanced hepatic encephalopathy (≥ grade 2), post liver transplantation subjects and subjects with hepatic carcinoma are excluded from this study.

**Source of data**
1. case report form.
2. prescriptions of patients.
3. Patients case sheet/medication chart.
4. Lab reports.

**Study tools**
The following tools were used to obtain information pertaining to the study:

**Case Report Form**
Data was collected by using a self-designed data collection form which consists of details like age, sex, lab data, diagnosis, history of the illness, drug therapy and other relevant information.

**SF 36**
This questionnaire consists of 36 questions grouped into eight domains and evaluates the health-related quality of life. The lower the score the more the disability.

The eight domains are, vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning and mental health.

**Patient Health Questionnaire (PHQ9)**
It is a questionnaire for monitoring and determining severity of depression. Each question is based
on 9 DSM IV criteria and is scored from 0 (not at all) to 3 (nearly every day). Based on the score depression severity is classified as none (0-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe (20-27).

Liver disease symptom index 2.0 (LDSI)
This questionnaire consists of 24 items and measures the severity of symptoms experienced by the patient. It also evaluates to what extent the symptom causes problem in patient’s daily life. It scores the symptoms experienced by the patient in past week as 0 (not at all) to 4 (to a high extent).

Stages of Change Readiness and Treatment Eagerness Scale for Alcohol (SOCRATES 8A)
It is an instrument which assesses the eagerness and motivation level of patient to change their alcohol abuse behaviour. It scores three categories namely: recognition, ambivalence and taking steps.

Recognition
This scale provides patient’s level of awareness of the link between the alcohol use and current problem. High scorers directly acknowledge that they are having problems related to their alcohol use. Low scores deny that alcohol is causing any serious problem and reject any labels such as alcoholic or addict.

Ambivalence
Provides information whether the patient is certain or uncertain that he or she has or does not have a problem. High scores reflect uncertainty, whether they are in control of their drinking or not, or are they an addict or not.

Taking Steps
High scores report patients are already doing things to make a positive change in their drinking while, low scores indicate that patients have not made any change in their drinking habits. Each question on the questionnaire represents one of the three categories, and the patient obtains a total score in each category.

Ethical clearance
This study was approved by the Institutional Ethics Committee of ESIC-MC PGIMSR & Model Hospital with approval number 532/L/11/12/Ethics/ESICMC&PGIMSR/Estt. Vol. III, dated 04/12/2018.

Study Procedure
This observational study was conducted on patients with alcoholic liver disease who met the inclusion and exclusion criteria in inpatient department of general medicine. Patients eligible for the study were apprised about the study and the consent was obtained from the patients. Data regarding demographic information, disease information, and other relevant information was obtained from self-designed case report form and the questionnaires were used to obtain information about quality of life and medication adherence. The study included five questionnaires- Short Form-36 (SF-36), Morisky Green Levine Scale, Patient Health Questionnaire-9 (PHQ-9), Stages of Change Readiness and Treatment Eagerness Scale for Alcohol (SOCRATES 8A) and Liver Disease Symptom Index (LDSI 2.0) questionnaire which were filled by the patient to provide information on emotional physical, mental functioning of the patient.

Statistical analysis
Microsoft excel was used to enter the collected data. The qualitative data was presented as proportion while, quantitative data was presented as mean and standard deviation. The relationship between quality of life and other variables such as, age, severity of disease, complications and depression was determined in SPSS software using appropriate statistics (chi square, correlation and Mann Whitney tests). When p value was below 0.05, the results were regarded as statistically significant.

RESULTS AND DISCUSSION
Fifty-one patients, included in the study, were classified based on their age and most of the patients belonged to the age group of 45-54 years (33.33%) which was analogous to the study conducted by (Kolasani et al., 2017). The mean age of the patients were 52 ±10.4 years, with 82.35% being males. In the current study it was seen that all the patients consumed hard liquors out of which whisky (76.47%) was largely consumed as compared to brandy (19.6%) and rum (3.93%). This was in contrast to the findings of the study conducted by (Bellentani et al., 1997) which showed wine as the preferred alcoholic beverage and About half (56.96%) of the patients were found to be smokers.

Finding of this study revealed that ascites (47.77%) was the most common complication occurring in ALD patients followed by portal hypertension (30%) which is consistent with the study performed by (James et al., 2017). According to the child Pugh score, the patients of the present study were classified into class A, B and C with maximum patients falling under class C (45.09%), parallel to the findings of study conducted by (Janani et al., 2018). Whereas the study con-
Table 1: Distribution of patients based on readiness to change their alcohol abuse behavior.

| Score      | Recognition | Ambivalence | Taking Steps |
|------------|-------------|-------------|--------------|
|            | N   | %  | N   | %  | N   | %  |
| Very Low   | 35  | 68.62 | 0   | 0   | 24  | 47.05 |
| Low        | 16  | 31.37 | 19  | 37.25 | 10  | 19.60 |
| Medium     | 0   | 0   | 19  | 37.25 | 9   | 17.64 |
| High       | 0   | 0   | 12  | 23.52 | 4   | 7.84  |
| Very High  | 0   | 0   | 1   | 1.96  | 4   | 7.84  |

Figure 1: Average scores obtained in SF-36 questionnaire (for health related quality of life).

Figure 2: Prescription pattern of drugs given for alcoholic liver disease patients.

Most of the patients presented with only a single complication (45.09%), among which ascites (84.31%) was the most common complication, followed by portal hypertension (52.94%). Presence of complications (ascites, portal hypertension, hepatic encephalopathy and esophageal varices) and reduced HRQOL also showed a significant association with Fischer’s exact test of independence (p<0.05). Child Pugh Classification was used to evaluate severity of disease and maximum patients fell under class C (45.09%) indicating severe form of liver disease. Child pugh scores and SF-36 scores exhibited a negative correlation (r = -0.30, p =0.02), showing that severe form of liver disease significantly impaired patient’s quality of life. However, the child pugh scores did not show any significant correlation with quantity of alcohol consumed by the patients (r = 0.19, p>0.05).

Evaluation of mental health status of the study subjects using PHQ9 questionnaire revealed that about half of the patients had mild depression (50.98%). Correlation test showed that increased age significantly affected depression severity (r =-0.30, p= 0.03). SOCRATES questionnaire was used to assess the readiness to change and treatment eagerness in...
the study subjects and most of the patients were found to have low motivation and low recognition of their alcohol use problem as shown in Table 1.

Liver disease symptom index (LDSI 2.0), used to assess the symptom severity observed that the symptom causing the most hindrance to patient’s daily activities was fatigue (1.31 ± 1.20), whereas itch (0.22 ± 0.61) caused the least hindrance. The effect of different symptoms (LDSI domains) on patient’s quality of life was evaluated using Mann Whitney U test, which revealed decrease in HRQOL was greater for ‘Fear of developing complication’ domain (U = 59, p = 0.003, r = 0.40). Prescription analysis showed that 519 drugs were prescribed to 51 patients included in the study, out of which diuretics (13.48%) and drugs for encephalopathy (13.10%) were the commonly prescribed, followed by vitamins 59 (11.36%) as shown in Figure 2.

Among the drugs given for treating hepatic encephalopathy, lactulose 34(50%) was majorly prescribed followed by rifaximin 26 (38.23%) as depicted in Figure 3. Combination therapy of furosemide and spironolactone (86.48%) was largely used as compared to mono-therapy (13.51%).

Ceftriaxone was the most frequently given antibiotic (63.15%), while ursodeoxycholic acid (69.09%) was the preferred hepatoprotective agent. For portal hypertension, propranolol was the drug of choice whereas, lorazepam 9(90%) was the preferred drug for withdrawal symptoms. Non-opioids (58.33%) were mainly used for pain management in the patients compared to opioids (41.66%) and among non-opioids paracetamol was the preferred drug. This was coherent with the results obtained in the study conducted by (Jamdađe et al., 2015). The current study showed that alcoholic liver disease patients had low health-related quality of life. It was observed that the most affected aspect of patient’s quality of life was their role limitation due to physical health. The present study also found that symptoms like fatigue, abdominal pain and the fear of developing complications profoundly affected quality of life (Sobhonslidsuk, 2006). Though these symptoms are not life threatening and are not of immediate clinical concern for a physician, they are important enough to cause significant distress to the patients. This shows the need to take into account patient’s perspective as well, while treating a long-term illness like cirrhosis.

Quality of life is emerging as an essential treatment outcome during recent years. It helps to understand the nature and extent of the influence of chronic illnesses on patient’s life. Previous researches have pointed that chronic diseases adversely influence the quality of life of patients, but researches involving alcoholic liver disease are limited. The present study identified factors such as, age, high child pugh scores and presence of complications to affect quality of life. It was observed that in comparison to younger patients, older patients had lower quality of life. In contrast, study carried out by (Marchesi et al., 2001) showed low quality of life in younger patients. Moreover, presence of complications (ascites, portal hypertension, esophageal varices) and high child pugh scores were related with low quality of life and a poor prognosis. This was coherent with results of study by (Gutteling et al., 2006).

Mental health status of the patients was assessed, which showed majority of them had mild depression. The severity of depression was seen to be more in older patients. This result is parallel to the results obtained in the study by (Đ Popović et al., 2015). However, the current study does not study the causal association between depression and alcoholic liver disease showing the need for further studies (Ewusi-Mensah et al., 1983).

The present study identifies factors affecting health related quality of life, which helps to identify targets for novel treatment strategies focusing on patient oriented outcomes. In addition, it also shows that patient’s with more duration of alcohol use and taking high amounts of alcohol are more open to contemplation and reflection of their alcohol abuse problem (Júnior and Malbergier, 2003). Thus, identifying target population that needs more counseling.

Small sample size was the major limitation of this study and its single-centric nature. Another limitation of the study is that it included only inpatients admitted in the general medicine wards and not the outpatients. Hence, the results may not be characteristic of the whole population. Finally, no follow-ups were done to see the result of treatment on patient’s quality of life.

CONCLUSIONS

The study found alcoholic liver disease adversely affects quality of life and identified the factors influencing it, such as age, severity of disease, presence of complication and symptoms life fatigue and abdominal pain. Hence, evaluating factors affecting quality of life can help devise novel treatment guidelines for the better management of ALD patients. It also highlights the need to assess willingness to change in alcohol abusers and plan counseling therapy accordingly. The study also found that most patients had
mild depression and some had moderate depression. Majority of the cases of depression in ALD patients remain under-diagnosed, which indicates the need for further studies to be conducted to find the prevalence of depression in a larger population and to assess the link between depression and alcohol consumption.

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Conflict of interest

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