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RESEARCH ARTICLE

A Study on the Effect of Medication on Patient's Qualityof Life with Alcoholic Liver Disease

Tanuja Maganti *[1], Praveena Dasamukha[1], Prasanth Kumar Meka[1], Curie D [2], Thangabalan B[3]

[1]*Student, PharmD, Sims Group of Institutions, Pharmacy Department, Guntur, Andhra Pradesh, India*
[2]*Associate Professor, Sims Group of Institutions, Pharmacy Department, Guntur, Andhra Pradesh, India*
[3]*Principal and Professor, Sims Group of Institutions, Pharmacy Department, Guntur, Andhra Pradesh, India.*

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Abstract: Alcoholic liver disease (ALD) encompasses a spectrum of liver disorders caused by excessive alcohol consumption, ranging from fatty liver to alcoholic hepatitis, cirrhosis, and hepatocellular carcinoma. This study aimed to evaluate the effect of standard medication on patients' quality of life (QOL) with ALD and analyze health-related QOL before and after treatment. A prospective, single-centered observational study was conducted on 150 patients diagnosed with ALD at Vedantha Hospital and Government General Hospital, Guntur. Patient data, including medical history, medication history, and liver function biomarkers, were collected. The standard treatment included prednisolone, pentoxifylline, infliximab, L-ornithine L-aspartate, and silymarin. Patients' health-related QOL was assessed using the SF-36 questionnaire pre- and post-treatment. Liver function biomarkers, including total bilirubin, AST, ALT, GGT, and alkaline phosphatase, were analyzed. Post-treatment, significant improvements were observed in patient-reported QOL and liver function biomarkers. The study provides strong evidence supporting the efficacy of the medicinal intervention, demonstrated by notable enhancements in patient-reported outcomes and liver function biomarkers. Comprehensive evaluation of patient health outcomes through subjective measures like the SF-36 questionnaire and objective biomarkers offers a holistic assessment of treatment effectiveness in ALD.

Keywords: Alcoholic liver disease; Prednisolone; SF-36 questionnaire; Liver function; Biomarkers.

1. Introduction

1.1. Role of Liver

The liver is a vital organ that plays a crucial role in numerous physiological processes, including metabolism, detoxification, and synthesis of various essential compounds.[1] Located in the right upper quadrant of the abdomen, beneath the diaphragm, the liver is the body's second-largest organ, weighing approximately three pounds in adults. Its unique structure comprises four lobes and an intricate network of bile ducts, allowing it to perform its multifaceted functions efficiently.[2,3]

The liver's primary functions include:

- Metabolism: The liver is a metabolic hub, responsible for breaking down and synthesizing various biomolecules. It plays a vital role in carbohydrate, protein, and lipid metabolism, ensuring proper energy production and storage.
- Detoxification: One of the liver's critical roles is detoxification, whereby it filters and breaks down harmful substances, including drugs, alcohol, and environmental toxins, rendering them safe for elimination from the body.
- Bile production: The liver produces bile, a greenish-yellow fluid that aids in the digestion and absorption of fats and fat-soluble vitamins from the small intestine.
- Protein synthesis: The liver synthesizes numerous essential proteins, such as albumin, clotting factors, and transport proteins, which are crucial for maintaining homeostasis and proper bodily functions.
- Storage: The liver acts as a storage reservoir for essential nutrients, including glycogen (a form of stored glucose), vitamins, and minerals, which can be released into the bloodstream as needed.[4]

Alcohol consumption, particularly excessive and prolonged, can have detrimental effects on liver health and function. Alcoholic liver disease (ALD) is a term that encompasses a range of liver disorders caused by excessive alcohol intake, including fatty liver, alcoholic hepatitis, cirrhosis, and hepatocellular carcinoma.

* Corresponding author: Tanuja Maganti

The development and progression of ALD are influenced by various factors, including the amount and duration of alcohol consumption, genetic predisposition, and the presence of other comorbidities, such as obesity or viral hepatitis. Excessive alcohol intake can lead to the accumulation of fat in the liver cells, a condition known as fatty liver or steatosis. If alcohol consumption continues, inflammation and cell death can occur, resulting in alcoholic hepatitis, a potentially life-threatening condition characterized by liver inflammation and necrosis.[4]

Chronic alcohol abuse can further exacerbate liver injury, leading to the development of fibrosis and, eventually, cirrhosis, which is characterized by the formation of scar tissue and the disruption of normal liver architecture. Cirrhosis is a severe and irreversible condition that can impair liver function and increase the risk of liver failure and hepatocellular carcinoma (liver cancer). The pathophysiology of ALD is complex and involves various mechanisms, including oxidative stress, inflammation, immune dysfunction, and alterations in gut microbiota. Alcohol metabolism generates reactive oxygen species (ROS) and acetaldehyde, a toxic byproduct that can directly damage liver cells and promote inflammation. Additionally, alcohol consumption can disrupt the gut barrier, leading to the translocation of bacterial products and endotoxins into the liver, triggering an inflammatory response.[5]

Effective treatment of ALD is crucial to prevent further liver damage and improve patient outcomes. The mainstay of treatment is abstinence from alcohol consumption, as continued drinking can exacerbate liver injury and increase the risk of complications. Nutritional support and pharmacological interventions, such as corticosteroids, pentoxifylline, and anti-inflammatory agents, may be employed to manage alcoholic hepatitis and improve liver function. In cases of advanced liver disease or liver failure, liver transplantation may be considered as a life-saving intervention. However, strict adherence to alcohol abstinence is required for transplant candidates and recipients to prevent recurrence of ALD and ensure long-term graft survival. Pharmaceutical care plays a vital role in the management of ALD, as it involves the responsible provision of drug therapy to achieve specific therapeutic outcomes that improve patients' quality of life. Pharmacists collaborate with patients, physicians, and other healthcare professionals to design, implement, and monitor therapeutic plans tailored to individual patient needs. This multidisciplinary approach aims to optimize drug therapy, enhance adherence, and address any potential medication-related issues, ultimately improving patient outcomes and quality of life.[6]

This study aims to evaluate the effect of standard medication on patients' quality of life with ALD and analyze the health-related quality of life before and after providing the prescribed treatment regimen. By assessing both subjective patient-reported outcomes and objective liver function biomarkers, this research endeavors to provide a comprehensive understanding of the efficacy of the medicinal intervention in the management of ALD.

2. Materials and methods

2.1. Study design

This study employed a prospective, single-centered observational study design to evaluate the effect of standard medication on patients' quality of life (QOL) with alcoholic liver disease (ALD) and analyze the health-related quality of life before and after treatment [6]

2.2. Sources of data

The data for this study were obtained from multiple sources, including:

- Case files: Patient medical records and case files were reviewed to collect relevant information.
- Treatment charts: Detailed treatment charts were used to gather data on the prescribed medications and treatment regimens.
- Personal interviews: Interviews were conducted with patients or their representatives to obtain additional information and clarify details when necessary.
- Data collection forms: Standardized data collection forms were used to record patient demographics, medical history, medication history, and relevant laboratory test results.
- SF-36 questionnaire: The SF-36 Health Survey questionnaire was administered to assess patients' health-related quality of life.

2.3. Study population

The study population consisted of patients admitted to the Vedantha Hospital and Government General Hospital in Guntur, India, for the treatment of ALD. A total of 150 patients meeting the inclusion criteria were enrolled in the study

2.4. Study period

The prospective, single-centered randomized study was carried out over a period of 6 months, involving both inpatient and outpatient departments of the participating hospitals

2.5. Study criteria

2.5.1. Inclusion criteria

- Adult patients above 18 years of age, of both genders.
- Patients diagnosed with ALD based on clinical and laboratory findings.
- Patients willing to participate and provide written informed consent.
- Patients receiving standard treatment for ALD.

2.5.2. Exclusion criteria

- Patients below 18 years of age.
- Intensive Care Unit (ICU) patients with ALD.
- Patients unwilling to participate or provide informed consent.
- Patients above 60 years of age.

2.6. Study site

The study was conducted at two healthcare facilities in Guntur, India:

- Vedantha Hospital: A multispecialty hospital offering various specialties, including general medicine, obstetrics and gynecology, pediatrics and neonatal care, anesthesiology, orthopedics, radiology, and nephrology.
- Government General Hospital: A public healthcare facility serving the local community.
- These hospitals were selected due to their reputation and the availability of patients seeking treatment for ALD.

2.7. Study Procedure

The study procedure involved the following steps:[7,8]

Step 1: Identification of patients with ALD from the Vedantha Hospital and the General Medical Ward of the Government General Hospital.

Step 2: Collection of data for ALD patients admitted to the participating hospitals over a period of 6 months. This included patient demographics, present and past medical history, present and past medication history, and liver function biomarker test results.

Step 3: Administration of standard treatment for ALD to the study participants (150 patients), as per the prescribed treatment protocol.

Step 4: Assessment of patients' knowledge and understanding of health-related quality of life using the SF-36 Patient Health Survey questionnaire. This questionnaire was administered both before and after the treatment period.

Step 5: Counseling and education of patients regarding health-related quality of life and lifestyle modifications, incorporating principles of pharmaceutical care.

Step 6: Statistical analysis of the obtained data using appropriate statistical methods to evaluate the effect of the treatment on patients' quality of life and liver function biomarkers.

The study protocol, including the data collection methods, treatment administration, and patient assessments, was reviewed and approved by the appropriate ethical committees and regulatory authorities.

2.8. Statistical analysis

The data obtained from the study were subjected to rigorous statistical analysis using appropriate methods. Descriptive statistics were used to summarize the demographic and clinical characteristics of the study population. Comparative analyses were performed to evaluate the changes in liver function biomarkers and health-related quality of life scores before and after treatment. Appropriate statistical tests, such as paired t-tests or non-parametric equivalents, were employed to assess the significance of the observed differences. The level of significance was set at $p < 0.05$ for all statistical analyses. [9] The results of the statistical analyses were presented using tables, graphs, and appropriate visualization techniques to facilitate interpretation and understanding of the findings.

3. Results and discussion

3.1. Results

3.1.1. Demographic characteristics

The study enrolled a total of 150 patients diagnosed with alcoholic liver disease (ALD) who met the inclusion criteria. The demographic characteristics of the study population are summarized in Table 1.

Table 1. Demographic Characteristics of the Study Population

Sl No	Demographic Characteristic	Value
1	Age (years), mean ± SD	42.5 ± 8.2
2	Male, n (%)	105 (70%)
3	Female, n (%)	45 (30%)
4	Body Mass Index (kg/m2), mean ± SD	26.8 ± 4.1

The mean age of the study participants was 42.5 years, with a standard deviation of 8.2 years. The majority of the patients were male (70%), which is consistent with the higher prevalence of ALD in men due to sociocultural factors and drinking patterns. The mean body mass index (BMI) of the study population was 26.8 kg/m2, indicating that a significant proportion of patients were overweight or obese, which is a known risk factor for the development and progression of ALD.

3.1.2. Comparative Analaysis of Liver function test biomarkers

The results demonstrated significant improvements in all liver function test biomarkers after the standard treatment regimen. The mean values of total bilirubin, AST, ALT, GGT, and alkaline phosphatase were substantially reduced post-treatment, indicating improved liver function and a positive response to the prescribed medication.[10.11]

Notably, the reduction in AST and ALT levels, which are markers of hepatocellular injury, suggests a decrease in liver cell damage and inflammation. The decrease in GGT and alkaline phosphatase levels, markers of cholestasis (bile duct obstruction), implies improved bile flow and alleviation of biliary stasis. The reduction in total bilirubin levels further supports the overall improvement in liver function and clearance of metabolic byproducts. These findings are consistent with the expected therapeutic effects of the standard treatment regimen, which includes medications like corticosteroids (e.g., prednisolone) to reduce inflammation, pentoxifylline to inhibit inflammatory cytokine production, and antioxidants like silymarin to protect against oxidative stress and liver cell injury. The concomitant use of L-ornithine L-aspartate, which supports hepatocyte regeneration and ammonia detoxification, further contributes to the observed improvements in liver function biomarkers. [12]

The statistical analysis revealed highly significant differences ($p < 0.001$) between the pre- and post-treatment values for all liver function test biomarkers, indicating that the observed improvements were not due to chance alone and can be attributed to the efficacy of the prescribed treatment regimen. It is important to note that while these objective biomarkers provide valuable information on liver function, they do not directly reflect the overall well-being and quality of life of patients with ALD. Therefore, it is essential to complement these objective measures with subjective assessments of patient-reported outcomes. Table 2 and Figure 1, 2 presents the comparative analysis of liver function test biomarkers before and after the standard treatment regimen.

Table 2. Liver Function Test Biomarkers Pre- and Post-Treatment

Biomarker	Pre-Treatment	Post-Treatment	p-value
Total Bilirubin (mg/dL), mean ± SD	5.2 ± 3.1	2.1 ± 1.5	< 0.001
AST (U/L), mean ± SD	152 ± 98	42 ± 22	< 0.001
ALT (U/L), mean ± SD	105 ± 71	38 ± 19	< 0.001
GGT (U/L), mean ± SD	248 ± 162	67 ± 39	< 0.001
Alkaline Phosphatase (U/L), mean ± SD	215 ± 110	102 ± 48	< 0.001

AST: Aspartate Aminotransferase; ALT: Alanine Aminotransferase; GGT: Gamma-Glutamyl Transferase

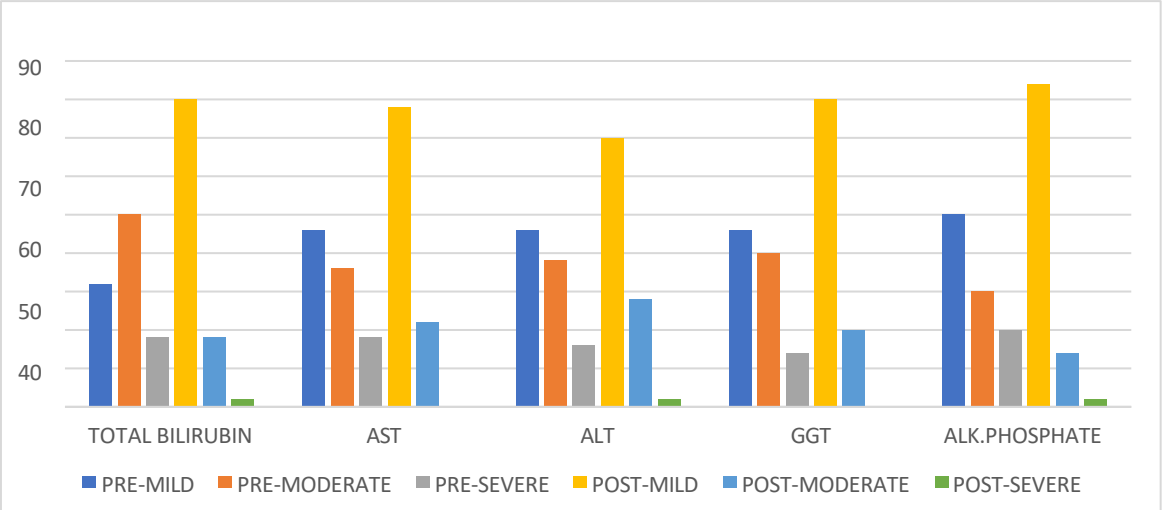

Figure 1. Liver function test biomarkers pre-treatment vs post-treatment

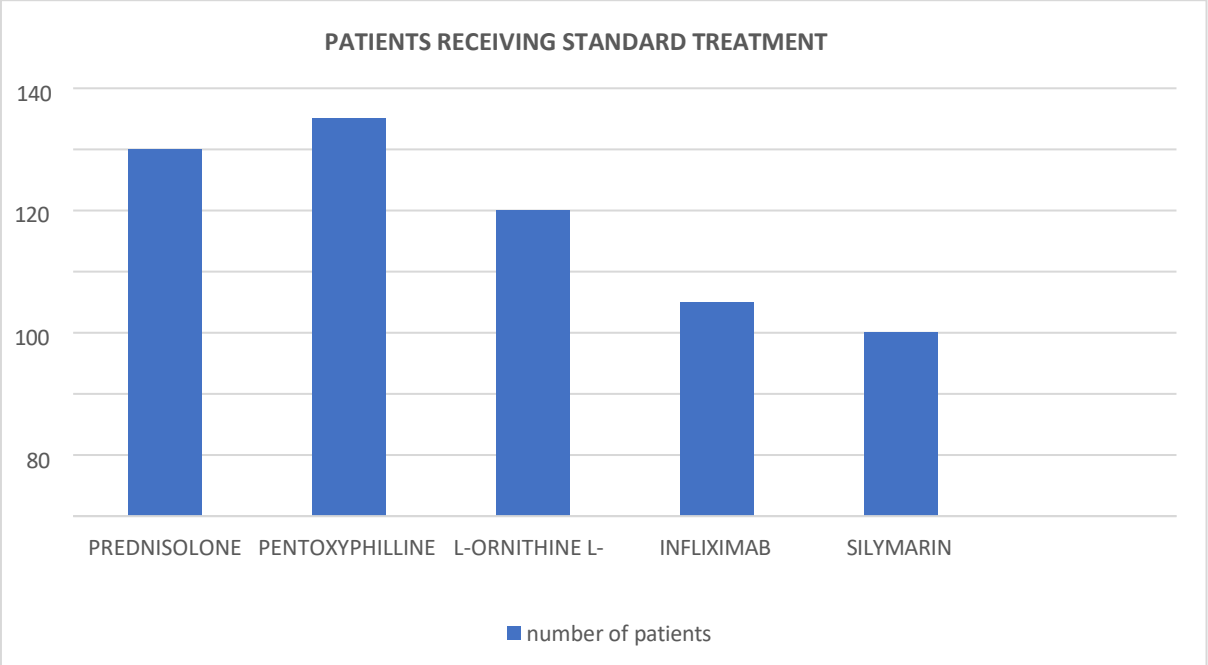

Figure 2. Graph showing number of patients receiving standard treatment

3.2. Assessment of Health-Related Quality of Life: SF-36 Questionnaire

The SF-36 Health Survey questionnaire was administered to the study participants to assess their health-related quality of life (QOL) before and after the standard treatment regimen. The questionnaire evaluates eight domains: physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health perception. [13]

The results revealed significant improvements in all domains of the SF-36 questionnaire after the standard treatment regimen, as evidenced by the higher post-treatment scores compared to the pre-treatment scores. The improvements were statistically significant ($p < 0.001$) across all domains, indicating a substantial positive impact of the treatment on patients' health-related quality of life. The notable improvements in physical functioning, role limitations (both physical and emotional), and energy/fatigue levels suggest that the treatment alleviated the physical symptoms and functional limitations associated with ALD,

enabling patients to better engage in daily activities and fulfill their roles without substantial physical or emotional constraints. Additionally, the enhancements in emotional well-being, social functioning, and pain perception reflect the positive impact of the treatment on patients' mental health and overall well-being. Improved liver function and alleviation of ALD-related symptoms likely contributed to reduced pain, improved mood, and better social engagement. The general health perception domain, which assesses patients' overall evaluation of their health, also exhibited a significant improvement post-treatment, indicating that patients perceived a positive change in their overall health status after receiving the prescribed medication regimen. The comprehensive assessment of health-related quality of life using the SF-36 questionnaire provides valuable insights into the subjective experiences and well-being of patients with ALD. These patient-reported outcomes complement the objective biomarker data, offering a holistic understanding of the treatment's effectiveness in improving both physiological parameters and patients' overall quality of life. Table 3 summarizes the mean scores for each domain of the SF-36 questionnaire before and after treatment [14]

Table 3. SF-36 Questionnaire Scores Pre- and Post-Treatment

Domain	Pre-Treatment Score	Post-Treatment Score	p-value
Physical Functioning	52.4 ± 18.2	72.8 ± 16.5	< 0.001
Role Limitations (Physical)	38.6 ± 22.1	68.7 ± 19.8	< 0.001
Role Limitations (Emotional)	45.2 ± 24.6	71.3 ± 21.4	< 0.001
Energy/Fatigue	42.8 ± 16.7	64.5 ± 15.9	< 0.001
Emotional Well-being	54.6 ± 18.4	72.1 ± 16.2	< 0.001
Social Functioning	49.8 ± 22.3	70.6 ± 19.5	< 0.001
Pain	47.2 ± 20.6	68.4 ± 18.1	< 0.001
General Health Perception	39.7 ± 16.8	62.8 ± 15.6	< 0.001

3.3. Discussion

The findings of this study have several important implications for the management of ALD and the role of pharmaceutical care in improving patient outcomes.

1. Multidisciplinary Approach: The study highlights the importance of a multidisciplinary approach to ALD management, involving collaboration among physicians, pharmacists, and other healthcare professionals. Pharmacists play a crucial role in optimizing drug therapy, providing patient education, and monitoring treatment outcomes, contributing to improved patient adherence and quality of life. [15]
2. Comprehensive Evaluation: The study demonstrates the value of employing both subjective patient-reported outcomes and objective biomarkers in evaluating treatment effectiveness. While biomarkers provide insights into physiological parameters, patient-reported outcomes offer a direct assessment of patients' well-being and quality of life, which are equally important in chronic diseases like ALD. [15, 16]
3. Personalized Care: The significant improvements observed in both biomarkers and quality of life scores emphasize the need for personalized care in ALD management. By tailoring treatment regimens to individual patient needs and monitoring outcomes closely, healthcare professionals can optimize therapeutic interventions and achieve better patient outcomes. [15, 16]

4. Conclusion

This study provides compelling evidence supporting the efficacy of the standard medication regimen in the management of alcoholic liver disease (ALD). The comprehensive evaluation, employing both objective liver function biomarkers and subjective patient-reported outcomes through the SF-36 questionnaire, offers a holistic assessment of treatment effectiveness. The significant improvements observed in liver function biomarkers, including total bilirubin, AST, ALT, GGT, and alkaline phosphatase, post-treatment indicate a positive response to the prescribed medication and a reduction in liver injury and dysfunction. These objective measures are complemented by the remarkable enhancements in health-related quality of life across all domains of the SF-36 questionnaire, reflecting improvements in physical functioning, emotional well-being, social engagement, and overall perception of health. The multidisciplinary approach, involving collaboration between physicians, pharmacists, and other healthcare professionals, plays a crucial role in optimizing therapeutic interventions, promoting patient adherence, and addressing medication-related issues. Pharmaceutical care, with its emphasis on responsible provision of drug therapy and patient education, contributes significantly to improving patient outcomes and quality of life in ALD management. This study underscores the importance of integrating both objective biomarkers and subjective patient-reported outcomes in evaluating treatment effectiveness, as they provide complementary insights into physiological parameters and overall well-being. By employing this comprehensive approach, healthcare professionals can tailor personalized care strategies and make informed decisions to optimize therapeutic interventions for patients with ALD. The findings of this research have the potential to inform clinical practice guidelines and pave the way for further investigations into innovative therapeutic approaches and patient-centered care models for the management of ALD and other chronic liver diseases

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Author's short biography

Tanuja Maganti

Tanuja Maganti, currently immersed in her fifth year of Pharm D studies, is driven by a keen interest in Clinical Pharmacology.

Praveena Dasamukha

Praveena Dasamukha, currently pursuing his fifth year of Pharm D studies, is interested in Pharmaceutical and Medical Research.

Praasanth Kumar Meka

Praasanth Kumar Meka, a dedicated fifth-year Pharm D student, is passionate about latest developments and advancements in Neurology.

Curie D

Curie D holds a Pharm D degree and currently serves as an Associate Professor at SIMS College of Pharmacy in Guntur.

Dr. Thangabalan B

Dr. Thangabalan B., with a background in MPharm and a PhD, currently holds the position of Principal and Professor at SIMS College of Pharmacy.