Original Research

SAFETY AND EFFICACY OF URSODEOXYCHOLIC ACID IN ALCOHOLIC LIVER DISEASE

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ABSTRACT

Background & Aim: An important worldwide public health concern is Alcoholic Liver Disease (ALD), a hazardous and debilitating consequence of chronic alcohol consumption and alcohol dependence. Alcohol dependence not only has significant morbidity and mortality implications, but also imposes substantial socioeconomic burdens. Our goal is to assess Ursodeoxycholic acid's safety and effectiveness in treating ALD.
Methodology: 203 patients made up the sample for this six-month prospective observational research, which was conducted at the Mahatma Gandhi Memorial Hospital in Warangal. Information was gathered via laboratory tests and the patient profile.
Results: Among 203 1 males (96.5%) are more predominantly affected than females (3.4%) at an age group of 39-48. Ursodeoxycholic acid caused diarrhoea in 9 patients and pruritis in 5 patients and indigestion in 3 patients. Serum Total Bilirubin, Conjugated Bilirubin, Unconjugated Bilirubin, Alkaline Phosphatase, Alanine transaminase, and Aspartate transaminase were among the elevated liver enzymes that Ursodeoxycholic acid reduced over the course of a week.
Conclusion: Ursodeoxycholic acid was safe, well tolerated, and effective drug in this study population.

Keywords: Alcoholic Liver Disease, Ursodeoxycholic Acid, Safety, Efficacy.

INTRODUCTION

Cirrhosis, fibrosis, and alcoholic fatty liver (AFL) are all part of the spectrum of liver disease known as Alcoholic Liver Disease (ALD) or steatosis, alcoholic steatohepatitis (ASH), and the development of hepatocellular carcinoma, is mostly caused by chronic excessive alcohol intake [1]. Over 90–100% of heavy drinkers develop steatosis, or alcoholic fatty liver, which is caused by the metabolism of ethanol and results in the build up of fat in liver cells [2]. Alcoholic Hepatitis (AH) affects 10–35% of heavy drinkers due to an inflammatory response caused by ethanol metabolism, which can generate neo-antigens and Reactive Oxygen Species (ROS)[3]. Prolonged hepatocellular damage triggers hepatic stellate cell activation, leading to myofibroblast transformation and collagen production thus causes hepatic fibrosis.

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Heavy drinking leads to cirrhosis in 8-20% of individuals, often present as asymptomatic [4].
Cirrhosis is a major contributor to global mortality, with an estimated 150,000 annual deaths worldwide, and alcoholic cirrhosis is responsible for approximately 38-50% of all cirrhosis-related mortality [5]. Genetics, gender (women show greater susceptibility than men), viral infections (Hepatitis B, Hepatitis C), obesity, malnutrition, genetics, age, chronic alcoholism are the risk factors associated with alcoholic liver disease [6]. Decompensated cirrhosis, the last stage of alcoholic liver disease, is more likely to cause weakness, fatigue, weight loss, ascites, cachexia, palmar erythema, Dupuytren's contractures, and clubbing of the digits if hepatopulmonary syndrome is present. Additionally, the Lacrimal and parotid glands are enlarged [7], history of alcohol use, a physical examination, and test results for gamma-glutamyl transpeptidase (GGTP), aspartate aminotransferase (AST), and alanine transferase (ALT) are currently used to diagnose ALD [8]. Abstinence from alcohol

is the cornerstone of management for Alcoholic Liver Disease (ALD), and the treatment approach based on disease stage. A multidisciplinary treatment plan may encompass abstinence, nutritional support, pharmacological interventions (including corticosteroids and pentoxifylline for severe alcoholic hepatitis, as per established guidelines), psychotherapeutic interventions, and surgical options, aiming to improve patient outcomes [9].

Thus, our study's goal was to assess a UDCA therapy's efficacy and possible side effects in individuals with alcoholic liver disease.

METHODOLOGY

Study design

The Mahatma Gandhi Memorial Hospital in Warangal was the site of the prospective observational study over a period of 6 months in 203 patients diagnosed with Alcoholic Liver Disease. The Kakatiya Institutional Human Ethics Committee (KIEC) granted permission for the study to be carried out. The given approval number was KIEC-2024/Pharm.D-2019/Project-09.

Study criteria

Inclusion criteria Patients who are at least eighteen years old and who have been diagnosed with Alcoholic Liver Disease, Patients who are receiving Ursodeoxycholic acid, Patients who are willing to participate and submit the informed consent.

Exclusion criteria: Patients under the age of 18, women who are pregnant or nursing, and patients who refuse to participate in the study are all excluded.

In order to facilitate data collection and analysis, patients who satisfied the predetermined inclusion criteria as specified in the study protocol were included in the study, and the required information was taken from their medical records, particularly from the patient case sheets. Vital signs and laboratory findings were routinely documented on a data collection form, including blood levels of total bilirubin (STB), conjugated bilirubin (SCB), unconjugated bilirubin (SUB), aspartate transaminase (AST), and alanine transaminase (ALT) and alkaline phosphatase (ALP). In order to evaluate the hepatic response to treatment, patients receiving Ursodeoxycholic acid had their ALP, AST, ALT, and bilirubin levels evaluated. ALP, AST, ALT, STB, SCB, and SUB were plotted on a graph both at the time of admission and following Ursodeoxycholic acid treatment. Patients taking Ursodeoxycholic acid experienced any negative medication responses during the research.

Statistical analysis: The obtained data will be subjected to suitable statistical methods like Paired *t* test by Graph pad prism version 10.0 to draw the Safety and Efficacy of Ursodeoxycholic acid in Alcoholic Liver Disease.

RESULTS

Every patient in the study ranged in age from 19 to 78. Among 203 patients 96.5% (196) were male patients and 3.4% (7) were female patients. Males are more affected than females

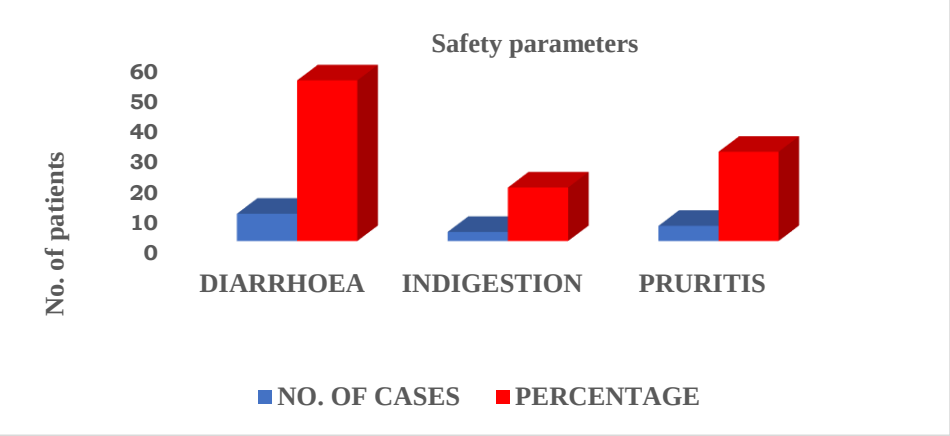

Fig 1: Safety Parameters of Ursodeoxycholic Acid

The most common adverse effect found with Ursodeoxycholic acid was Diarrhoea (52.9%) followed by Pruritis (29.4%). The least found adverse effect was Indigestion (17.6%).

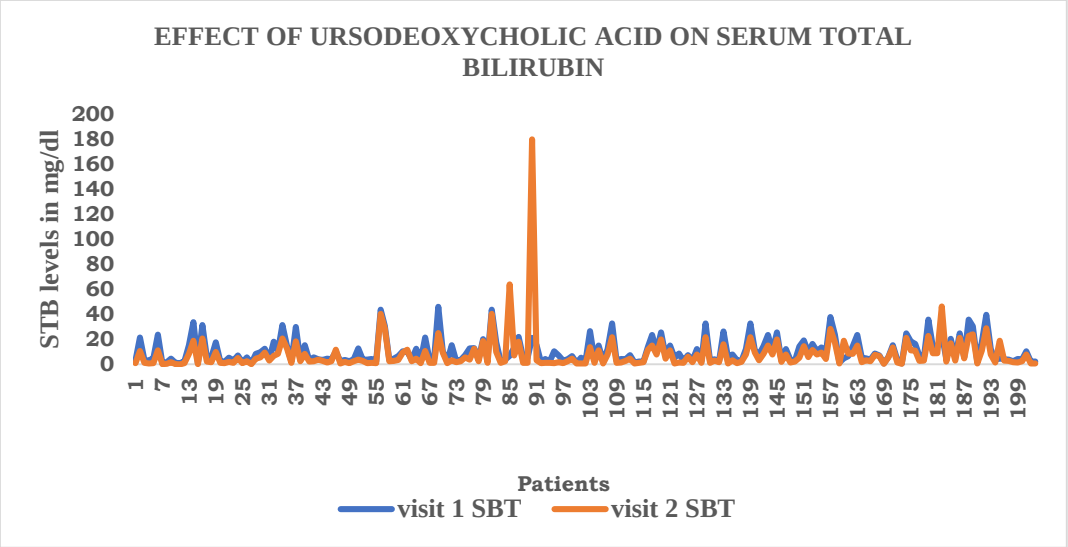

Fig 2: Effect of Ursodeoxycholic Acid on STB

Changes from baseline to 1 week. STB, Serum Total Bilirubin. The Baseline percentage of STB is 10.3% before administration of UDCA and 8.8% after the administration of drug and P value <0.0001 and the pairing was significantly effective.

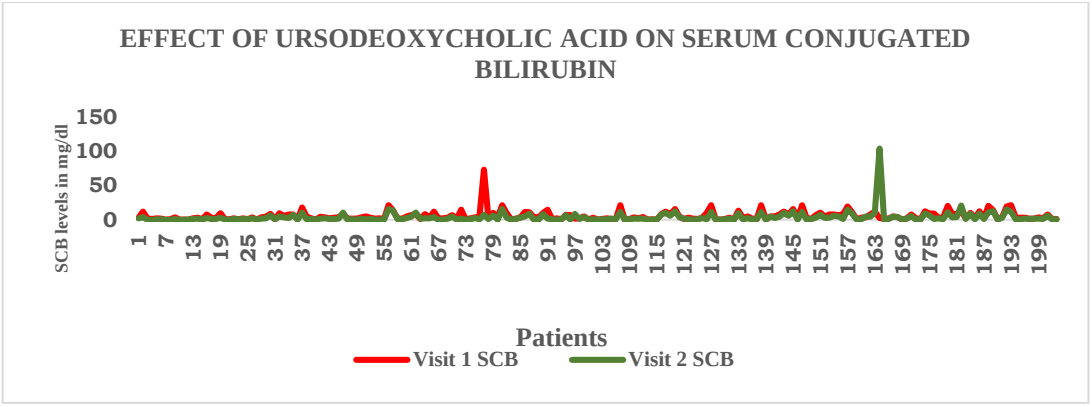

Fig3: Effect of Ursodeoxycholic Acid on SCB

Changes from baseline to 1 week. SCB, Serum Conjugated Bilirubin.The Baseline percentage of SCB is 6% before administration of UDCA and1.8% after the administration of drug.

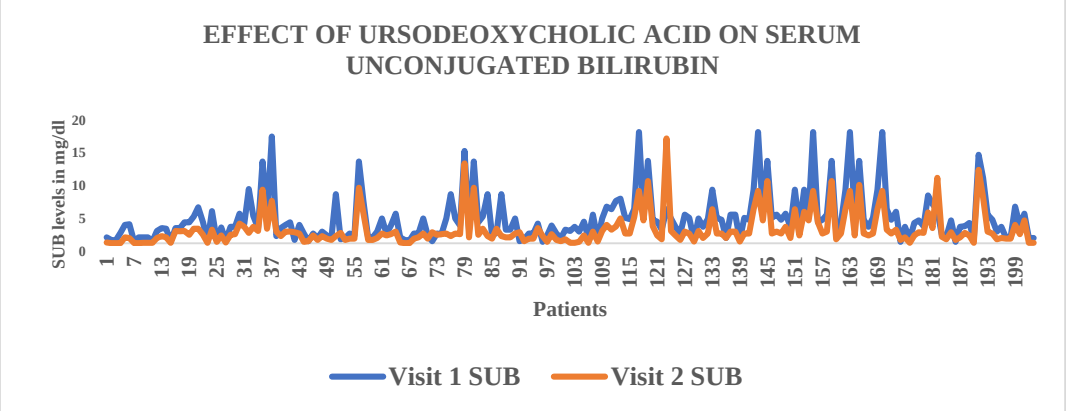

Fig 4: Effect of Ursodeoxycholic Acid on SUB

Changes from baseline to 1 week. SUB, Serum Unconjugated Bilirubin.The Baseline percentage of SUB is 3.7% before administration of UDCA and 2% after the administration of drug.

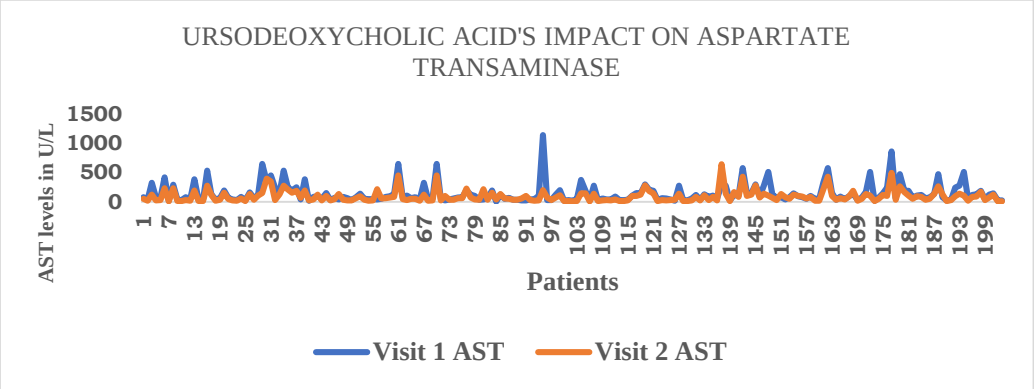

Fig5: Effect of Ursodeoxycholic Acid on AST.

Changes from baseline to 1 week. AST, Asparate Transaminase.The Baseline percentage of AST is 140.6% before administration of UDCA and 93.1% after the administration of drug.

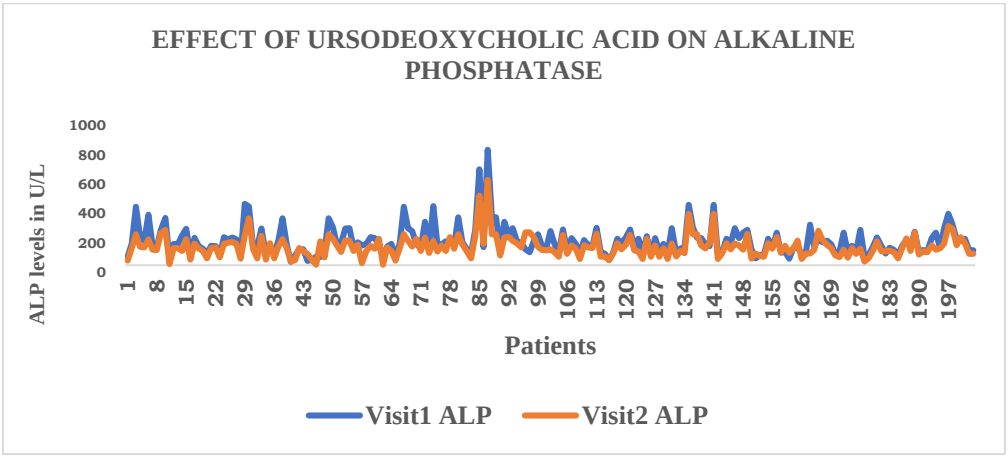

Fig 6: Effect of Ursodeoxycholic Acid on Alkaline Phosphate

Baseline to one-week changes ALP, Alkaline Phosphatase.The Baseline percentage of ALP is 164.7% before administration of UDCA and 126.8% after the administration of drug.

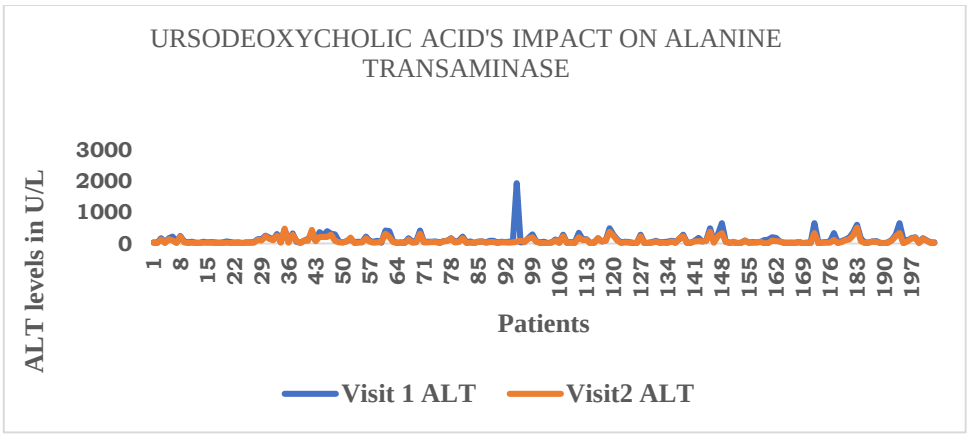

Fig 7: Effect of Ursodeoxycholic Acid on ALT

Baseline to one-week changes ALT, Alanine Transaminase.The baseline percentage of ALT is 122.9% before administration of UDCA and 81.6% after the administration of drug.

DISCUSSION

A serious and crippling result of long-term alcohol use and alcoholism, alcoholic liver disease is a significant worldwide public health issue. UDCA likely exerts hepatoprotection via choleretic effects, reducing toxic bile acids in ALD, explaining rapid enzyme normalization observed. In this study conjugated bilirubin fell most sharply (70% reduction), supporting UDCA's role in cholestasis relief. The Baseline percentage of STB is 10.3% before administration of UDCA and 8.8% after the administration of drug. The Baseline percentage of SCB is 6% before administration of UDCA and1.8% after the administration of drug. The Baseline percentage of SUB is 3.7% before administration of UDCA and 2% after the administration of drug. The Baseline percentage of AST is 140.6% before administration of UDCA and 93.1% after the administration of drug. The Baseline percentage of ALP is 164.7% before administration of UDCA and 126.8% after the administration of drug. The baseline percentage of ALT is 122.9% before administration of UDCA and 81.6% after the administration of drug. Diarrhoea (52.9% of AEs, n=9), pruritus (29.4%, n=5), and indigestion (17.6%, n=3) were mild and infrequent (8.4% overall incidence), affirming good tolerability in ALD. This aligns with low adverse event rates in UDCA trials for liver dysfunction, where fatigue relief exceeded placebo without excess risks which was parallel to the study conducted by Ahmed H, Naseem S *et al* (2018) [10].

Alcohol dependence not only has significant morbidity and mortality implications, but also imposes substantial socioeconomic burdens. Among 203 patient's males (96.5%) are more predominantly affected than females (3.4%) which was similar to the previous study conducted by Kumar S, Priyanka N. (2020) [11].

CONCLUSION

The present study concluded that Ursodeoxycholic acid was safe, well tolerated and effective drug in this study population.

The Acronyms

ALD: Alcoholic Liver Disease; **AFL:** Alcoholic Fatty Liver; **ASH:** Alcoholic Steatohepatitis; **AH:** Alcoholic Hepatitis; **ALT:** Alanine Transaminase; **AST:** Aspartate Transaminase; **ALP:** Alkaline Phosphatase; **FDA:** Food and Drug Administration; **GGTP:** Gamma Glutamyl Transpeptidase; **MODS:** Multi-Organ Dysfunction Syndrome; **LFT:** Liver Function Test; **MOF:** Multi Organ Failure; **ROS:** Reactive Oxygen Species; **SIRS:** Systemic Inflammatory Response Syndrome; **SUB:** Serum Unconjugated Bilirubin; **SCB:** Serum Conjugated Bilirubin; **UDCA:** Ursodeoxycholic Acid.

Conflict Of Interest

There is no conflict of interest, according to the authors.

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