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A COMPARATIVE EVALUATION OF EFFICACY OF OBETICHOLIC ACID *VS.* URSODEOXYCHOLIC ACID IN PATIENTS WITH ACUTE VIRAL HEPATITIS

Asif Rasheed [*1], Syed Ibrahim Hassan [2], Faiza Habeeb [1], Hafsa Alavi [1] Jameela Maqsood [1] and Sheema Jabeen [1]

Department of Pharmacology [1], Deccan School of Pharmacy, Goshamahal, Aghapura, Hyderabad - 500001, Telangana, India.
Department of Gastroenterology [2], Princess Esra Hospital, Moghalpura, Hyderabad - 500002, Telangana, India.

Keywords:

Hepatitis, Obeticholic acid, Ursodeoxycholic acid, Symptoms, Liver parameters

Correspondence to Author:
Dr. Asif Rasheed

Professor & Head,
Department of Pharmacology,
Deccan School of Pharmacy,
Goshamahal, Aghapura, Hyderabad - 500001, Telangana, India.

E-mail: asifrasheed707@gmail.com

ABSTRACT: Background: Acute viral hepatitis (AVH) is a major public health problem. There is no specific treatment to attenuate AVH. The potential for adding bile acid in the treatment of AVH is consistently increasing. The objective of this study was to assess the effect of obeticholic acid (OCA) in treating AVH patients and also to compare its efficacy with ursodeoxycholic acid (UDCA). **Methods:** A prospective comparative observational study carried out at the Department of Gastroenterology of tertiary care hospital. A total of 38 patients were allowed to participate in the study and randomized into two study groups, Group I and II. Each group consists of 19 patients. Patients in group I treated with UDCA. Group II patients treated with OCA. **Results:** The most common symptoms observed in the two study groups were nausea /vomiting followed by loss of appetite and abdominal pain. Both Group I and II patients showed significant improvement in their symptoms after treatment. The mean of liver function test (LFT) parameters was compared before and after treatment. Group II patients showed more SGOT, SGPT, and prothrombin time reduction. The common ADR noted in both groups was fatigue followed by constipation. **Conclusion:** This study concludes that OCA-treated patients showed better efficacy when compared with UDCA-treated patients in the reduction of LFT parameters that prevent further progression and complications associated with AVH.

INTRODUCTION: Acute viral hepatitis (AVH) is the liver inflammation caused by infection of hepatotropic viruses A, B, C, D and E. Among 5 types of hepatitis viruses, hepatitis A virus (HAV) is the familiar cause of AVH in many countries. Chronic infection is common with hepatitis B virus (HBV) [1].

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Hepatitis is classified as acute or chronic based upon the duration of the inflammation and level of damage to the hepatic parenchyma. Hepatitis is acute if it is resolved within six months and chronic if it lasts longer than six months [2]. Structural differences and epidemiology define the major differences in the course of each of these viral infections.

Hepatitis has become a major problem worldwide due to its complications. Acute liver failure is the most severe complication of AVH [3]. There is no precise data on the epidemiology of the prevalence of viral hepatitis throughout the world. It varies from country to country. According to the World

Health Organization (WHO) report, 1 in 3 people had been infected with either HBV or hepatitis C virus (HCV). HAV has affected more than 90% of children by age 10 in endemic areas. The majority of AVH cases are from the region of low income. Various laboratory tests, especially liver function test (LFT) parameters aid in forecasting liver functions. Any abnormalities in the LFT indicate an injury to the liver cells [4, 5]. Treatment for AVH is mainly supportive. The initial treatment comprises relieving symptoms such as nausea, vomiting, and abdominal pain. In addition, complete rest and maintenance of adequate fluid intake are also required. A few cases need administration of the anti-viral agents [6]. Several studies suggest adding bile acid to the treatment of AVH significantly improves the clinical condition of the patients by altering the liver enzyme levels. Some studies have proved the positive effect of ursodeoxycholic acid (UDCA) in AVH, but its role remains unclear. UDCA exhibits the properties of membrane stabilizing, antioxidant, cytoprotective and anti-apoptosis [7, 8]. A semi-synthetic bile acid analog obeticholic acid (OCA) is an agonist of farnesoid X receptor (FXR) that is found in the nucleus of liver and intestinal cells. OCA acts by binding to FXR, which regulates the hepatic metabolism of bile and cholesterol. OBA has shown promising results in treating alcoholic hepatitis and primary biliary cholangitis [9]. Although, the effect of OCA in treating AVH patients is not yet proven. Due to the limitation of studies on the effect of OCA in treating AVH, we took up this research to explore its effect. This study aimed to assess the effect of obeticholic acid in treating AVH patients and compare its efficacy with ursodeoxycholic acid by monitoring the various LFT parameters and clinical symptoms of the AVH patients.

METHODOLOGY:

Study Design: This prospective comparative observational study carried out at the inpatient unit of the Department of Gastroenterology of tertiary care hospital Hyderabad over six months. This study was conducted between the period November 2020 and April 2021. People with the following criteria were allowed to participate in this study: a) Above 18 years; b) Slight and abnormal increase in alkaline phosphatase (ALP) level; c) Marked increase in Serum glutamic oxaloacetic transaminase (SGOT) and Serum glutamic pyruvic transaminase(SGPT) levels and low SGOT/SGPT ratio; d) Patients positive for acute viral hepatitis. Patients with the following criteria were excluded from the study: a) Patients that are anti-nuclear antibody (ANA) and antimitochondrial antibody (AMA) positive; b) Patients diagnosed with non-viral hepatitis; c) Patients ≤ 18 years of age; d) Patients who were diagnosed with primary biliary cholangitis and primary sclerosing cholangitis; e) Patients suffering from stone diseases like cholelithiasis; f) Pregnant females.

Sample size and Data Collection: A total of 62 patients diagnosed with acute viral hepatitis were enrolled in this study. But 24 patients were excluded from the study because they did not meet the inclusion criteria and were lost to follow-up. Hence, only 38 patients were allowed to participate in the study. They were randomized into two study groups namely Group I and II. Each group consists of 19 patients. Patients in group I were treated with UDCA at a dose of 300 milligrams twice daily for 15 days. Group II patients were treated with OCA at a dose of 5 milligrams once daily for 15 days. Data relevant to the study was obtained from the patient's case sheet, laboratory report, and history interview. The collected data were documented in a designed case report form.

Study Outcomes: The primary endpoint was to prove the better efficacy of OCA by a marked and significant reduction in the levels of laboratory parameters. The secondary endpoint was to reduce the occurrence of adverse drug reactions (ADR) & drug toxicity and to prevent further liver damage &the development of complications.

Statistical Analysis: The data was analyzed using Microsoft Excel and Statistical Package for Social Service (SPSS) Version 20. All continuous data was presented as the mean ±standard error of the mean (SEM). Categorical data were presented as frequencies and percentages.

Independent t-test and one-way analysis of variance (ANOVA) were used to compare the mean of two study groups and treatment review. A chi-square test was carried out for analyzing categorical variables. *P-values* less than 0.05 were considered statistically significant at a 5% level of significance with a confidence interval of 95%.

Ethical Approval: The present study was conducted consistent with the protocol and principles of the Declaration of Helsinki. This study was approved by the Ethical Committee of Deccan College of Medical Sciences with IRB project No.

RESULTS:

Baseline Characteristics: Thirty-eight patients with AVH were included in this study, and each group consisted of 19 patients. The mean age of the two study groups was 45.79±2.83 and 45.11±3.62 years. Each group comprises 68% of males and 32% females showing male preponderance. Acute viral hepatitis B was found to be the most common type in most patients of both groups, accounting for 76.3% of all patients. The most common comorbidity noticed in these patients was hypertension (47%) followed by diabetes mellitus (42%) and other conditions. The two treatment groups were similar in their baseline characteristics except for the length of stay. The length of stay was significantly more in Group I patients (8.84±0.62 days) when compared with Group II patients (7.26±0.39 days) as shown in **Table 1.**

TABLE 1: BASELINE CHARACTERISTICS OF THE STUDY POPULATION

Characteristics	Group I (UDCA)	Group II (OCA)	P value
Age (years)	45.79±2.83	45.11±3.62	0.8826
Gender			
Male	13 (68)	13 (68)	0.9999
Female	6 (32)	6 (32)	
Type of AVH			
A	5(26)	4(21)	0.7028
B	14(74)	15(79)	
Comorbidity			
Hypertension	8(42)	10(53)	0.5158
Diabetes mellitus	9(47)	7(37)	0.5111
Coronary artery disease	2(11)	4(21)	0.3736
Anemia	5(26)	7(37)	0.4852
Asthma	2(11)	2(11)	0.9999
Hypothyroidism	2(11)	3(16)	0.6313
Length of hospital stay(days)	8.84±0.62	7.26±0.39	0.0392*

Comparison of Symptoms and LFT Parameters at Baseline: The most common symptoms observed in the two study groups were nausea/vomiting, followed by loss of appetite and abdominal pain. There was no significant difference between the study group at baseline symptoms, is shown in **Table 2**. While comparing the liver function test (LFT) parameters at baseline, a significant difference was seen only in the SGOT level, shown in **Table 3.**

TABLE 2: SYMPTOMS AT BASELINE

Symptom	Group				*P-value*
	I		II		
	N	%	N	%	
Abdominal pain	14	74	14	74	0.9999
Nausea/vomiting	16	84	17	89	0.6313
Fever	9	47	11	58	0.5158
Loss of appetite	15	79	16	84	0.6756
Malaise	10	53	8	42	0.5158
Dark urine	8	42	6	32	0.5012

TABLE 3: BASELINE LFT PARAMETERS

Parameter	Group I	Group II	P value
SGOT (U/L)	124.4±40.11	379.9±87.03	0.0114*
SGPT (U/L)	237.8±77.61	480.7±114.6	0.0878
ALP (U/L)	154.9±26.75	138.1±17.19	0.5996
Total bilirubin (mg/ dL)	2.74±0.65	2.35±0.49	0.6379
Albumin (g/dL)	5.32±0.32	5.06±0.34	0.5940
Prothrombin time (sec)	14.12±0.30	16.67±1.83	0.1783

Comparison of Treatment Efficacy: The significance in the improvement of symptoms was measured between baseline and day 20 of post-treatment. Both Group 1 and II patients showed significant improvement in their symptoms after treatment, presented in **Table 4.**

TABLE 4: COMPARISON OF SYMPTOMS BEFORE AND AFTER TREATMENT

Symptoms	Group	Review								*P-value*
		Baseline		Day 4		Day 8		Day 20		
		N	%	N	%	N	%	N	%	
Abdominal pain	I	14	74	8	42	4	21	4	21	0.0012*
	II	14	74	7	37	2	11	2	11	<0.0001*
Nausea/vomiting	I	16	84	6	32	4	21	2	11	<0.0001*
	II	17	89	5	26	4	21	2	11	<0.0001*
Fever	I	9	47	3	16	1	5	0	0	0.0006*
	II	11	58	2	11	1	5	0	0	<0.0001*
Loss of appetite	I	15	79	10	53	6	32	3	16	<0.0001*
	II	16	84	7	37	5	26	4	21	<0.0001*
Malaise	I	10	53	6	32	3	16	4	21	0.0436*
	II	8	42	5	26	4	21	2	11	0.0271*
Dark urine	I	8	42	4	21	2	11	0	0	0.0015*
	II	6	32	5	26	0	0	0	0	0.0076*

The mean of LFT parameters was compared before (baseline) and after treatment (day 4, day 8 and day 20). Both the group participants have shown a significant reduction in their LFT parameters post-treatment, which is indicated in **Table 5.**

TABLE 5: COMPARISON OF PARAMETERS BEFORE AND AFTER TREATMENT

Parameter	Group	Review				*P-value*
		Baseline	Day 4	Day 8	Day 20	
SGOT (U/L)	I	124.4±40.11	178.7±56.92	145.2±46.82	56.32±7.49	0.0936
	II	379.9±87.03	318.5±89.17	118.7±25.05	40.84±3.08	0.0007*
SGPT (U/L)	I	237.8±77.61	377.5±111.7	199.5±47.28	85±13.96	0.0515
	II	480.7±114.6	370.6±96.52	147.2±29.28	47.74±5.53	0.0004*
ALP(U/L)	I	154.9±26.75	136.7±25.08	99.42±14.65	81.79±7.88	0.0033*
	II	138.1±17.19	123.9±10.69	111.6±6.49	95±6.05	0.0090*
Total bilirubin (mg/ dL)	I	2.74±0.65	2.11±0.53	1.71±0.36	1.17±0.17	0.0056*
	II	2.35±0.49	2.13±0.42	1.67±0.29	1.24±0.21	0.0028*
Albumin (g/ dL)	I	5.32±0.32	5.02±0.27	4.81±0.21	4.55±0.18	0.0012*
	II	5.06±0.34	4.80±0.29	4.67±0.22	4.47±0.18	0.0183*
Prothrombin time (sec)	I	14.12±0.30	13.86±0.26	13.43±0.23	13.06±0.17	<0.0001*
	II	16.29±1.89	16.02±1.92	13.26±0.58	12.57±0.43	0.0612

When the percentage of improvement in symptoms from baseline to day 20 was evaluated, we found that patients receiving OCA (Group II) showed more improvement in abdominal pain, nausea/vomiting, and fever, whereas UDCA (Group I) patients showed increased improvement in dark urine alone. Improvement in loss of appetite and malaise were equal in both groups. A significant difference was not found in the percentage of improvement of symptoms between the study groups as shown in **Table 6** and **Fig. 1.**

TABLE 6: EFFECTIVENESS OF TREATMENT ON SYMPTOM REDUCTION

Symptom	Group		*P-value*
	I	II	
Abdominal pain	53	63	0.1520
Nausea/vomiting	74	79	0.4044
Fever	47	58	0.1193
Loss of appetite	63	63	0.9999
Malaise	32	32	0.9999
Dark urine	42	32	0.1430

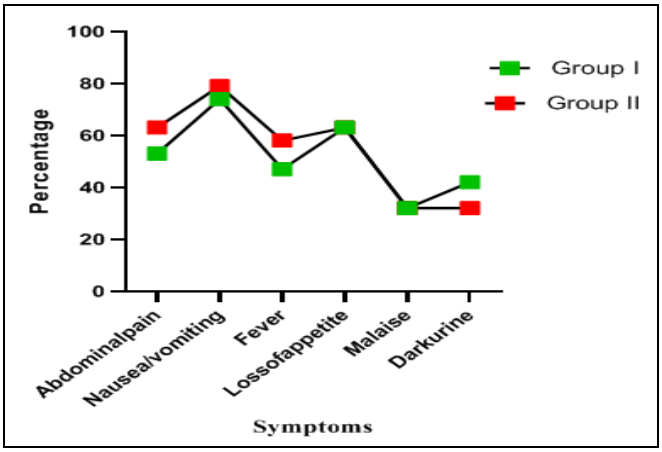

FIG. 1: EFFECTIVENESS OF TREATMENT ON SYMPTOM REDUCTION

When the percentage of reduction in LFT parameters from baseline to day 20 was evaluated, it is noticed that Group II patients showed more reduction in SGOT, SGPT and prothrombin time whereas Group I patients showed a marked reduction in ALP. A significant difference was seen in the parameters of SGOT, SGPT, ALP and prothrombin time between the study groups as displayed in **Table 7** and **Fig. 2.**

TABLE 7: COMPARISON OF EFFECTIVENESS OF TREATMENT ON LABORATORY PARAMETERS

Parameter	Group		P value
	I	II	
SGOT	55	89	<0.0001*
SGPT	64	90	<0.0001*
ALP	47	31	0.0204*
Total bilirubin	57	47	0.1570
Albumin	14	12	0.6741
Prothrombin time	8	23	0.0034*

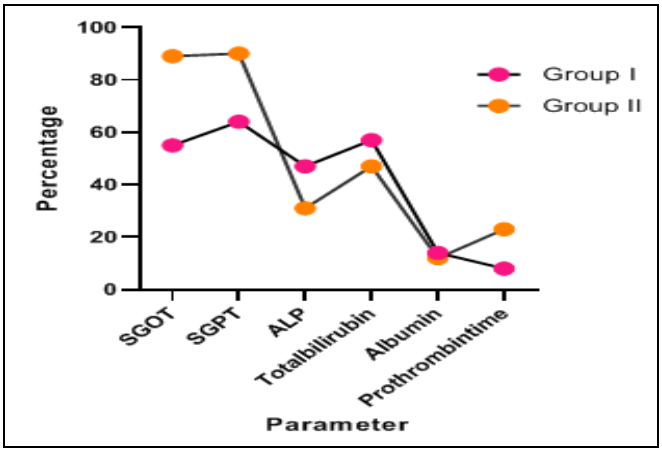

FIG. 2: COMPARISON OF EFFECTIVENESS OF TREATMENT ON LABORATORY PARAMETERS

The common ADR noted in both groups was fatigue followed by constipation. Pruritus and abdominal pain were observed only in Group II patients. No serious adverse events were reported. Patients were observed with minor ADR which was either reduced with time or managed by symptomatic treatment. There was no significant difference in the occurrence of ADR between the groups as illustrated in **Table 8.**

TABLE 8: ADR

ADR	Group				P value
	I		II		
	N	%	N	%	
Pruritus	0	0	3	16	0.0711
Fatigue	5	26	3	16	0.4261
Abdominal pain	0	0	3	16	0.0711
Constipation	4	21	2	11	0.3736

Discharge medications of patients of both groups were recorded. Tablet Rixmin and Tablet Viboliv was prescribed to all patients of group I and II. This is shown in **Table 9.**

TABLE 9: DRUGS PRESCRIBED IN DISCHARGE CHART

Drug	Group I		Group II	
	N	%	N	%
Tab. Ulyses	19	100	0	0
Tab. Obetohep	0	0	19	100
Tab. Rixmin	19	100	19	100
Tab. Viboliv	19	100	19	100
Syp.Sorbiline	14	74	10	53
Tab Zofer	9	47	10	53
Tab. Meaxon Plus	11	58	8	42
Tab. Domstal	10	53	9	47
Tab. Heptivite	4	21	3	16
Tab. Pantium	12	63	9	47
Tab. Glucosed forte	7	37	5	26
Susp. Sucral-O	4	21	2	11

DISCUSSION: Viral hepatitis is a major public health problem and health care burden. There is no specific treatment to attenuate AVH. The treatment of AVH depends on the causes or etiology by which hepatocyte injury had developed. Acute hepatitis usually resolves in 2 to 4 weeks with supportive treatment. Diet and activity restriction along with bed rest is also essential in managing AVH patients [10].

The potential for adding bile acid in the treatment of AVH is consistently increasing particularly when liver diseases are characterized by cholestasis. Because cholestasis is a constant feature of acute hepatitis. Certain evidence reveals bile acids exhibited significant improvement in serum transaminases activities but adequate effects were not seen on the virus clearance [11, 12].

Our study compared the effect of two bile acids (UDCA and OCA) in 38 patients. UDCA is a secondary bile acid used to prevent several liver problems, including hepatitis, usually at 300mg/day. OCA is an FXR agonist found to be effective in the treatment of PBC and other liver disorders, but its effectiveness in the treatment of AVH is not yet proven. HAV is generally common in children before the age of 10 years because older children and adults have good immunity. HBV is common among people aged 30-49 years because they have not been vaccinated as recommended [13]. This is compatible with our results. The mean age of both the study groups was 45 years. Both gender gets affected at the same rate. Although male sex is a risk factor for HBV prevalence. Several studies carried out in AVH patients have shown male predominance [14] which is consistent with the present study findings. 68% of the study population were males in this study.

Despite the availability of a prophylactic vaccine for more than 20 years, HBV infection remains a disease of significant global health burden and is the most common type of all [15]. In this study, acute Viral Hepatitis B was found to be the most common type in the majority of patients of both groups, accounting for 76.3% of all patients. Patients with AVH usually present with symptoms like fever, malaise, fatigue, loss of appetite, vomiting, diarrhea, and abdominal pain [16]. The most common symptoms observed in this study population were nausea/vomiting and loss of appetite, followed closely by abdominal pain, fever, malaise and dark urine. The results showed that both the groups shared equal effectiveness in terms of reducing the symptoms from baseline to day 20 showed no significant difference.

Diagnosis of AVH includes LFT, viral serology testing, and prothrombin / international normalized ratio (PT/INR) measurement. We have used LFT and prothrombin as monitoring parameters to examine the effect of OCA. LFT parameters that were recorded at the time of admission for every patient in both groups showed a significant difference in SGOT levels at baseline ($p = 0.0114$). In contrast, the significant difference was not seen in SGPT ($p=0.0878$), ALP ($p=0.5996$), total Bilirubin ($p=0.6379$), albumin ($p=0.5940$) levels and prothrombin time ($p=0.1783$). While comparing the post-treatment LFT parameters, patients treated with OCA showed a higher reduction in the level of SGOT ($p<0.0001$), SGPT ($p<0.0001$) and prothrombin time ($p=0.0034$) levels. These results were consistent with the previous studies, which predicted that OCA monotherapy would significantly improve biochemical markers predictive of improved long-term clinical outcomes [17]. Patients treated with UDCA showed a more significant reduction in ALP level ($p=0.0204$).

Furthermore, adverse events were also recorded during the study and it was found that no serious adverse effects were noted. Pruritus (16%) and abdominal pain (16%) were observed only in Group II patients, similar to the previous research studies [18]. Fatigue (26%) was observed more in Group I, similar to the adverse events reported in UDCA treated patients with primary biliary cirrhosis who participated in a Canadian trial [19]. Most adverse events observed were mild, either reduced with time or managed by symptomatic treatment. Comparison between the groups shows no significant difference in ADR occurrence, which proves that OCA is also a safer medication for the effective treatment of AVH. UDCA has low detergent properties requiring administration of large doses (13–15 mg/kg/d) to be effective in the treatment of disease.

Consequently, UDCA becomes the predominant bile acid comprising >60% of the bile acid pool. In contrast, OCA, which comprised <2% of the serum bile acids, appears to exert its effects at approximately 100-fold lower doses than UDCA [20]. Our study has some limitations, including the limited duration of the study and smaller sample size. A multicenter study would have produced more significant results. Hence, further studies and research are substantial for absolute results.

CONCLUSION: This study concludes that OCA monotherapy was efficacious in patients with acute viral hepatitis A and B. It was also proven that OCA treated patients showed better efficacy when compared with UDCA treated patients in reduction of LFT parameters that prevent progression and complications associated with acute viral Hepatitis. Most adverse events observed were mild and were resolved eventually. Based on the present study

findings, OCA can be considered safe and effective in the treatment of acute viral hepatitis.

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