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AN OBSERVATIONAL, DESCRIPTIVE, AND CROSS-SECTIONAL STUDY ON THE IMPACT OF TERLIPRESSIN ON HEPATORENAL DISEASE

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ABSTRACT:

The purpose of this research is to evaluate the effectiveness of Terlipressin in conjunction with albumin against albumin alone in treating hepatorenal syndrome in individuals of varying ages and sexes. Twenty-four older patients and sixty-four younger ones were split evenly between the two groups. Everybody got the same amount of respect. Albumin was used alone in Group 1, while albumin and Terlipressin were used in Group 2. IBM SPSS version 20 was used for all statistical analyses in this study. We used frequency analysis and cross-tabulation to create the tables. In this table, we present the means, standard deviations, and medians in that order (minimum–maximum). “Student's t and Mann-Whitney U tests were used to compare continuous variables. Pearson Chi-square and Fisher's exact tests for significance at p 0.05 are necessary for analysis of categorical data. In terms of mean age and distribution of ages, there was no statistically significant difference between the two groups (p = 0.71). This demonstrates that the effect of the current investigation was not modified by the ages of the patients. Researchers also did not find any statistically significant differences in sex distribution between the two treatment groups (p = 0.44). According to the results of this study, both methods of therapy were equally effective for male and female patients. Group 2, which included Terlipressin in addition to albumin, showed a stronger response to treatment than the albumin group alone, despite their being no statistically significant differences between the groups”. Overall, the safety profile was improved when Terlipressin was coupled with albumin.

KEYWORDS: Terlipressin, Albumin, Hepatorenal disease.

INTRODUCTION

Advanced cirrhosis patients frequently display the symptoms of hepatorenal syndrome (HRS), which is characterised by a marked reduction in renal blood flow and glomerular filtration rate (GFR) in the absence of severe histological abnormalities in the kidney and of other recognised

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causes of renal failure. People with more severe cirrhosis have higher rates of this condition. 1 Local, systemic, and neurohumoral hemodynamics are all significantly impacted by renal vasoconstriction, which is crucial to HRS. Some of these include a lack of osmotic hypersecretion of antidiuretic hormone, sinusoidal portal hypertension, peripheral arteriolar vasodilation, an elevated cardiac index and plasma volume, decreased arterial blood pressure, increased sympathetic nervous system activity, and elevated cardiac index and plasma volume. There is no proof that increasing renal blood flow (renal vasodilation) with any of the drugs currently on the market is advantageous (2, 6). 7 This potentially causal view has led to a change in the treatment approach for HRS, which now includes assessing the capacity of vasoconstrictors, most notably vasopressin analogues, to raise effective arterial blood volume. 8 Vasopressin analogues, as demonstrated in this study, can help persons with HRS regain their renal function. Data are unfortunately scarce because the majority of trials either had few patients, were retrospective in nature, or were not randomised. As a result, the current study sought to find out how Terlipressin affected renal function and overall survival in patients with cirrhosis and HRS.

AIM: The goal of this study is to compare how well Terlipressin combined with albumin versus albumin alone treats hepatorenal syndrome in people of various ages and sexes.

SOURCE OF SAMPLE: Patients admitted to the Intensive Care Unit were the subjects of this hospital-based study (ICU).

INCLUSION CRITERIA

MAJOR CRITERIA

i. “Chronic or acute liver disease with advanced hepatic failure and portal hypertension.

ii. Low GFR as indicated by serum creatinine > 1.5 mg/dL or 24 hr. creatinine clearance < 40 mL/min.

iii. Absence of shock, on-going bacterial infection, and current or recent treatment with nephrotoxic drugs and absence of gastrointestinal fluid losses (repeated vomiting or intense diarrhea).

iv. No sustained improvement in renal function (decrease in serum creatinine ≤ 1.5 mg/dL or increase in creatinine clearance to ≥ 40 mL/min) following diuretic withdrawal for 48 hrs. and expansion of plasma volume with 1.5 L of isotonic saline.

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v. No sonographic evidence of obstructive uropathy or parenchymal renal disease".

ADDITIONAL CRITERIA

1. Serum sodium < 130 mEq/L
2. Cirrhosis with ascites.
3. Serum creatinine > 133 μmol/L (1.5 mg/dL)
4. No current or recent treatment with nephrotoxic drugs

EXCLUSION CRITERIA

The exclusion criteria were as follows:

"Septic shock, hepatocellular cancer, and other life-threatening conditions beyond the liver. Severe cardiovascular (coronary and/or peripheral artery disease), neurological, or other extrahepatic illness".

STUDY DESIGN: This was a cross-sectional, observational study that also included descriptive aspects.

STUDY PERIOD: From October 2019 to March 2021, which is 18 months, the current research was done.

MATERIAL& METHOD

There were two groups of 40 patients each, each with the identical distribution of ages and genders. There was no difference in care between the two groups. In Group 1, patients were simply given albumin, while in Group 2 patients were given both albumin and Terlipressin.

SAMPLE SIZE: A total of 80 patients with Hepatorenal Syndrome took part in the study.

STASTICAL ANALYSIS

Throughout the entirety of the data analysis process, IBM SPSS version 20, a statistical software package tailored exclusively for the social sciences, was used. Before finalising the tables, we performed a frequency distribution and then a cross tabulation. There are three measures of central tendency used to summarise the data: the mean, "the standard deviation (SD), and the median (minimum–maximum). Two statistical tests, the student's t test and the

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Mann-Whitney U test, were used to examine the data and make comparisons between the continuous variables. We used both the Pearson Chi-square and the Fisher's exact test to analyse the data that comprised categorical variables. Statistical significance was defined as a p-value of 0.05 or less".

RESULT

DEMOGRAPHIC PROFILE AND FREQUENCY DISTRIBUTION OF AGE IN BOTH THE GROUPS

Eighty people took part in this study, with forty people in each of two groups. Patients in one group have received albumin plus the drug Terlipressin, whereas those in the other group have received albumin alone. The current research examines the differences in age distribution between two treatment groups. We found that the p value was 0.71, which means that there was no statistically significant difference in mean age or distribution of ages between the two groups. This proves that age had no affect on the effect found in the present study.

Age groups (years)	Treatment		Total	P value
	Albumin	Terlipressin +Albumin		
≤30	2	3	5	0.71
31-40	10	5	18	
41-50	13	15	23	
51-60	10	9	21	
>60	5	8	13	
Grand Total	40	40	80	
Mean age	51.04	46.94	49.25	0.742
SD	11.40	12.56	12.02	

Table 1: Demographic profile and frequency distribution of age in both the groups

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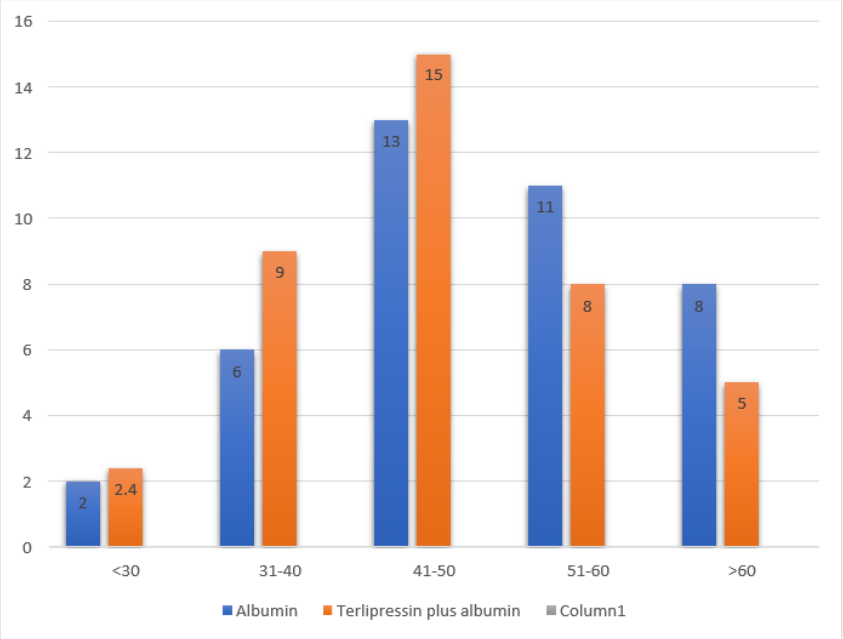

Figure1: Demographic profile and frequency distribution of age in both the groups

DEMOGRAPHIC PROFILE AND FREQUENCY DISTRIBUTION OF SEX IN BOTH THE GROUPS

The non-significant p value of 0.44 reveals that the researchers did not find any statistically significant differences in the sex distribution of the participants who were given either of the two medication regimens in this study. This shows that both of the treatment plans tested in this study have the same effect, no matter what gender the patient is in the clinical trial.

Sex	Treatment		Total	P value
	Albumin	Terlipressin +Albumin		
Female	3	3	5	0.44
Male	37	38	75	
Grand Total	40	40	80	

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Table 2: Demographic profile and frequency distribution of sex in both the groups

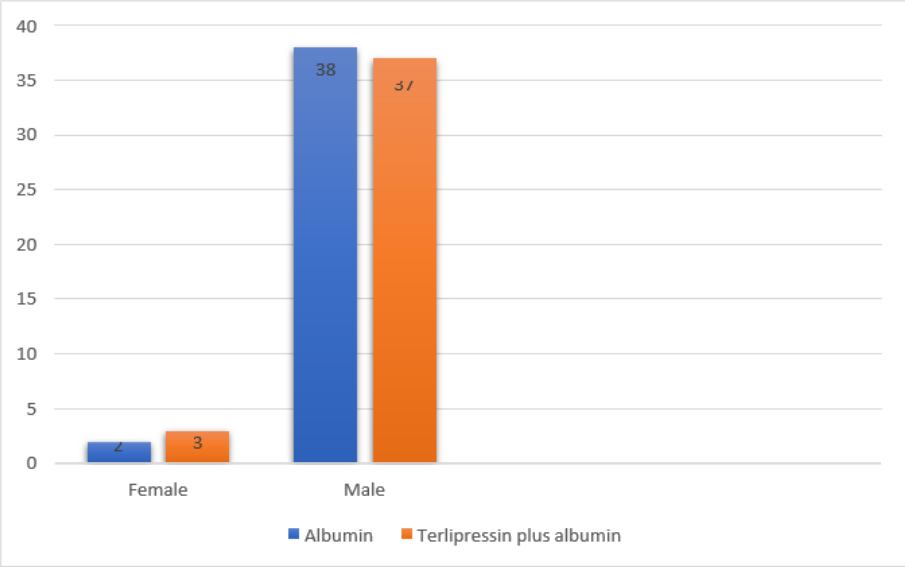

Figure 2: Demographic profile and frequency distribution of sex in both thegroups.

DISCUSSION

Eighty people took part in this study, "with forty people in each of two groups. Albumin was administered in combination with Terlipressin to one set of patients, while albumin alone was used to treat another set. In this study, we found no statistically significant differences in mean age or distribution of ages between the two groups ($p = 0.71$ indicates this is not the case). This proves that the age of the patients had no affect on the effect found in the present study. The results of an investigation conducted by Sanyal AJ were similar". 9

The sex distributions of the two groups were also compared in this analysis. The p value of 0.44 indicates that no significant variation in the proportion of male to female participants was observed across treatment groups. This shows that patients' gender played no effect in determining the outcome of the intervention under review. Several groups of researchers came to the same conclusions about their findings: Pere Ginès et al.10, Mads Egerod Israelsen et al.11, and Francesco Salerno et al.12.

CONCLUSION

In spite of the fact that there were no discernible differences between the groups' respective outcomes, group 2 (which received both Terlipressin and albumin) responded better to treatment than group 1 (which received albumin alone). Overall, the safety profile was best

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for the treatment group that received both Terlipressin and albumin.

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