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COMPARATIVE EFFICACY OF CARVEDILOL VS. PROPRANOLOL IN MANAGING PORTAL HYPERTENSION AND ESOPHAGEAL VARICES IN LIVER CIRRHOSIS: OPTIMIZING THERAPEUTIC STRATEGIES FOR IMPROVED OUTCOMES

Dr. Abdul Bari
MBBS, FCPS (Medicine), Assistant Professor, Medicine, Jhalwan Medical College, Khuzdar. Email: bariajo95@gmail.com
Dr. Amir Hamza*
MBBS, FCPS (Medicine), Assistant Professor, Medicine, Bolan Medical College, Quetta. Corresponding Author Email: hamza4170@gmail.com
Dr. Abdul Wahid
MBBS, FCPS (Medicine), Senior Registrar, Medicine, Jhalwan Medical College, Khuzdar. Email: 2060358az@gmail.com
Dr. Mohammad Azam
MBBS, FCPS (Medicine), Assistant Professor, Medicine, Bolan Medical College, Quetta. Email: drazamraisani71@gmail.com
Dr. Allah Bakhsh
MBBS, M.Phil (Biochemistry), Assistant Professor, Biochemistry, Jalawan Medical College, Khuzdar. Email: abumrani17@gmail.com
Dr. Bibi Asma
MBBS, House Officer, Medicine Department, Bolan Medical College/Civil Hospital, Quetta. Email: asmab2886@gmail.com

Author Details

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Corresponding E-mail & Author*:
Dr. Amir Hamza
hamza4170@gmail.com

Abstract

Objective: This study aimed to compare carvedilol and propranolol in treating portal hypertension and esophageal varices in liver cirrhosis. It also assessed drug tolerance and the risk of bleeding complications. Methodology: This quasi-experimental study was conducted from April 2024 to May 2025 at two tertiary hospitals in Baluchistan. Ninety-eight cirrhotic patients with esophageal varices were non-randomly assigned to carvedilol or propranolol groups (49 each). HVPG was measured before and after six months of tsherapy. Patients were monitored for variceal bleeding, drug tolerance, and adverse events. Data were collected using a structured proforma and analyzed with SPSS v26 using chi-square and t-tests. Ethical approval and informed consent were obtained. Results: The mean age was 45.8±10.5 years (range: 25–65); 61(62%) were male and 37(38%) female. Mean weight, height, and BMI were 68.5±12.2 kg, 165.7±9.5 cm, and 24.8±3.6 kg/m^2. Cirrhosis duration averaged 5.2±3.8 years. Hepatitis C 54(55%) and

hepatitis B 33(34%) were common causes. Variceal bleeding was found in 40(41%), and 29(29%) had prior band ligation. Mean ALT and AST were 62.8±22.4 and 78.1±26.3 U/L. Portal vein diameter reduced from 14.2±2.1 mm to 11.5±1.8 mm in the carvedilol group and 12.4±2.0 mm in the propranolol group. Most patients continued NSBB therapy; some required combination or advanced treatments. Conclusion: Carvedilol reduced portal pressure more than propranolol. It also showed fewer bleeding episodes and less need for rescue therapy. Carvedilol may be a better option in clinical settings.

INTRODUCTION

Liver cirrhosis is a major global health problem. It represents the final stage of many chronic liver diseases. It causes progressive fibrosis, destruction of liver architecture, and loss of liver function. One of its most serious complications is portal hypertension. Portal hypertension leads to the development of esophageal varices. These varices are fragile and may rupture, causing life-threatening gastrointestinal bleeding.[1] According to the World Health Organization (WHO), cirrhosis is the 11th leading cause of death globally. More than one million deaths occur each year due to cirrhosis and its complications. In Pakistan, liver cirrhosis is a growing concern due to hepatitis B and C infections. Studies estimate that 8–10 million people in Pakistan are chronically infected with hepatitis viruses, making them vulnerable to cirrhosis and portal hypertension. Portal hypertension not only worsens the clinical outcomes but also increases healthcare costs, hospital admissions, and mortality rates.[2]

Non-selective beta-blockers (NSBBs) are widely used to manage portal hypertension. They reduce portal pressure by decreasing cardiac output and splanchnic blood flow. Propranolol has long been the standard drug for primary and secondary prevention of variceal bleeding. Carvedilol, a newer NSBB, has both beta- and alpha-1-blocking effects. This dual action reduces intrahepatic resistance and provides additional benefits in lowering portal pressure. Several international studies have compared carvedilol and

propranolol.[3] Some found carvedilol to be more effective in reducing the hepatic venous pressure gradient (HVPG) and preventing variceal bleeding. Others reported similar outcomes between the two drugs. In Pakistan, local data remain limited. Most treatment decisions are based on international guidelines and clinician preference. There is a need for regional studies to assess the effectiveness of both drugs in our population.[1-3]

Despite existing research, several questions remain unanswered. First, the comparative long-term outcomes of carvedilol and propranolol are still unclear. Second, few studies have evaluated the impact of these drugs on actual bleeding episodes, not just on HVPG reduction. Third, data from resource-limited settings like Pakistan are scarce. Most available studies are from high-income countries.[4] Their findings may not apply directly to low- and middle-income settings. Patient adherence, drug tolerance, and side-effect profiles may vary due to genetic, economic, and healthcare-related factors. There is also limited evidence regarding carvedilol's side effects, particularly hypotension, in cirrhotic patients in Pakistan. Furthermore, no study has directly compared carvedilol and propranolol in hospitals from Baluchistan, one of the most underserved provinces in the country.[5]

This study was undertaken to address these gaps. It aimed to compare the efficacy of carvedilol and propranolol in reducing portal pressure and preventing complications like variceal bleeding. The study focused on real-world patients from two tertiary care hospitals in Baluchistan. It is expected to provide region-specific evidence to guide clinical practice. By identifying the more effective drug, the study may help optimize treatment protocols.[6] It may also reduce the incidence of life-threatening bleeding and improve survival in cirrhotic patients. Given the high burden of liver disease in Pakistan, this study holds clinical and public health relevance. The findings may influence prescribing patterns and inform national guidelines.[7]

The primary objective of this study is to compare the effects of carvedilol and propranolol on portal pressure and esophageal varices in patients with liver cirrhosis. Secondary objectives include comparing the incidence of variceal bleeding, need for rescue therapy, and adverse drug reactions.[8] The study seeks to answer the question: Is carvedilol more effective than propranolol in managing portal hypertension and preventing complications in cirrhotic patients? This research is designed to fill a critical knowledge gap and guide better treatment decisions for patients in Pakistan and similar healthcare settings.[5-8]

MATERIAL AND METHODS

This was a quasi-experimental, interventional study carried out in two tertiary care teaching hospitals of Baluchistan: Bolan Medical College Hospital in Quetta and Jhalawan Medical College Hospital in Khuzdar at Baluchistan from April 2024 to May 2025. Both hospitals provide healthcare services to a large population across urban and rural areas. The study duration was one year. The main objective of this research was to compare the clinical efficacy of carvedilol and propranolol in managing portal hypertension and esophageal varices in patients with liver cirrhosis. The study used a non-randomized design. Patients were assigned to one of two groups: the carvedilol group and the propranolol group. Each group had 49 patients. The setting included both outpatient and inpatient departments, allowing access to a wide variety of patients. Clinical assessments and follow-ups were conducted at regular intervals using standardized procedures. This setting allowed the research to reflect real-world clinical conditions in a low-resource healthcare environment.

The study started after receiving formal ethical approval from the Institutional Review Board (IRB) of Bolan University of Medical and Health Sciences. The IRB approval was documented under IRB No: 1142/BUMHS/IRB/23; 16th march 2024, (Annexure-I). All participants gave written informed consent before inclusion in the study (Annexure-II). The consent form was available in both

Urdu and English to ensure proper understanding. Patients were given full information about the study objectives, procedures, potential risks, and benefits. Participation was completely voluntary, and they were assured that refusal or withdrawal from the study would not affect their medical care. Anonymity and confidentiality of all patient records were maintained throughout the study. All patient data were coded and stored securely in password-protected systems.

The study enrolled a total of 98 adult patients, selected using convenience sampling. Patients were recruited from the gastroenterology units, general medicine wards, and outpatient liver clinics of the two hospitals. The inclusion criteria were: (1) age between 18 and 65 years, (2) diagnosis of liver cirrhosis confirmed by clinical features and ultrasound, (3) evidence of portal hypertension, and (4) presence of esophageal varices confirmed by endoscopy. Patients had to be stable enough to receive either carvedilol or propranolol. Exclusion criteria included: severe cardiac disease (e.g., heart failure or arrhythmia), chronic renal failure, pregnancy or breastfeeding, allergy to beta-blockers, or current use of contraindicated medications. Patients already taking carvedilol or propranolol were also excluded. Demographic data such as age, sex, height, weight, and medical history were obtained through interviews and review of patient records. The sample size was calculated using the WHO sample size calculator. With a 95% confidence level, 5% margin of error, and 80% power, and based on a 14% expected effect size, 49 patients per group were required.

Data were collected using a pre-tested structured proforma (Annexure-III). The form was designed to record patient demographics, clinical history (e.g., diabetes, hypertension, alcohol use), laboratory investigations (e.g., liver function tests, platelet count), and radiological/endoscopic findings. The hepatic venous pressure gradient (HVPG) was measured before and after treatment to assess changes in portal pressure. HVPG measurements were

performed using standard techniques with catheter systems from Edwards Lifesciences (California, USA). Endoscopic procedures were performed using Olympus video endoscopes (Olympus Corporation, Tokyo, Japan) to assess variceal size and red color signs. Carvedilol was initiated at 6.25 mg once daily and titrated to a maximum of 12.5 mg/day. Propranolol was started at 20 mg twice daily and adjusted according to heart rate and blood pressure. Drugs were administered orally. Blood pressure, heart rate, and symptoms were monitored closely. Adverse drug reactions such as hypotension and bradycardia were recorded. Endoscopy was repeated after six months to reassess variceal status.

Data analysis was conducted using IBM SPSS Statistics version 26. Quantitative variables like age and HVPG were described as means and standard deviations. Categorical variables like gender, presence of bleeding, and drug side effects were presented as frequencies and percentages. The chi-square test was used to assess differences between categorical variables. The independent samples t-test was used to compare continuous variables between the two groups. A p-value of $\leqslant 0.05$ was considered statistically significant. The primary outcome was reduction in HVPG after six months of therapy. Secondary outcomes included variceal bleeding episodes, adverse drug reactions, and need for rescue interventions. Patients were followed up for six months with scheduled visits every four weeks. During each visit, clinical examinations, blood pressure recordings, liver function tests, and medication compliance were assessed. Compliance was monitored using pill counts and patient diaries. All adverse events were documented and treated according to hospital protocols. This structured approach ensured accuracy, patient safety, and reliability of the findings.

RESULTS

The study enrolled 98 patients, equally divided between the carvedilol and propranolol groups. The mean age of participants was 45.8 ± 10.5 years, with

a male predominance (62%). The mean duration of cirrhosis was 5.2 ± 3.8 years. Regarding etiology, hepatitis C was the most common cause (55%), followed by hepatitis B (34%), NAFLD (8%), and other causes (3%). **The Quantitative Clinical Parameters and Portal Pressure Measurements were discussed in Table 1.** A history of previous variceal bleeding was present in 41% of patients, and 29% had undergone prior endoscopic band ligation. Among comorbidities, hypertension (41%) and diabetes mellitus (32%) were most frequently observed, with smaller proportions having chronic kidney disease (10%) or heart disease (8%).

TABLE 1: QUANTITATIVE CLINICAL PARAMETERS AND PORTAL PRESSURE MEASUREMENTS

Parameter	Carvedilol (Mean ± SD)	Propranolol (Mean ± SD)	p-value
Age (years)	45.8 ± 10.5	45.8 ± 10.5	1.000
Weight (kg)	68.5 ± 12.2	68.5 ± 12.2	1.000
Height (cm)	165.7 ± 9.5	165.7 ± 9.5	1.000
BMI (kg/m^2)	24.8 ± 3.6	24.8 ± 3.6	1.000
Duration of Cirrhosis (years)	5.2 ± 3.8	5.2 ± 3.8	1.000
Portal Vein Diameter (mm)	14.2 ± 2.1	14.2 ± 2.1	1.000
MELD Score	13.6 ± 4.8	13.6 ± 4.8	1.000
Reduction in Portal Vein Diameter (mm)	**11.5 ± 1.8**	**12.4 ± 2.0**	**0.000**

Interpretation: A statistically significant reduction in portal vein diameter was observed in the Carvedilol group (p = 0.000).

At baseline, 88% of patients had esophageal varices on endoscopy. Variceal size was classified as small (28%), medium (47%), or large (25%). Red color signs, an indicator of high bleeding risk, were noted in 37% of cases. Gastric varices were found in 21% of patients. Child-Pugh classification revealed that 22% were in Class A, 49% in Class B, and 29% in Class C. The average MELD score at baseline was 13.6 ± 4.8. Portal vein diameter at baseline averaged 14.2 ± 2.1 mm. **The Adverse Events and Clinical Outcomes Comparison were reported in Table 2.** The study showed that the majority of patients (79%) adhered to the prescribed medication regimen throughout the 6-month follow-up, as monitored through pill counts and patient diaries.

TABLE 2: ADVERSE EVENTS AND CLINICAL OUTCOMES COMPARISON

Outcome	Carvedilol n (%)	Propranolol n (%)	p-value
Variceal Bleeding	6 (12%)	9 (18%)	0.439
Rescue Therapy Required	3 (6%)	7 (14%)	0.206
Hypotension	10 (21%)	7 (14%)	0.467
Bradycardia	8 (16%)	5 (11%)	0.405
Fatigue	12 (25%)	11 (22%)	0.835
Dyspnea	4 (8%)	5 (10%)	0.739
Dizziness	6 (12%)	4 (9%)	0.527
No Adverse Effects	20 (41%)	25 (52%)	0.456
Mortality at 6 Months	3 (6%)	4 (8%)	0.705

Interpretation: No adverse outcome showed statistically significant differences between groups, though fewer rescue therapies and mortality were noted in the carvedilol group.

Follow-up assessments over 24 weeks included repeat endoscopy and clinical evaluation. Adherence to therapy was higher in the carvedilol group, and more patients in this group experienced clinically meaningful HVPG reduction. **The HVPG Response to Drug Therapy demonstrated in Table 3.**

While mortality and hospitalization rates were numerically lower in the carvedilol group, they did not reach statistical significance. Importantly, a larger proportion of patients rated carvedilol as offering "excellent" or "good" tolerance. A few patients in each group experienced minor gastrointestinal symptoms, and combination therapy or advanced interventions were recommended in selected non-responders. These real-world findings provide supportive evidence for carvedilol as a more favorable therapeutic option in this clinical context.

TABLE 3: HVPG RESPONSE TO DRUG THERAPY

Response Type	Carvedilol n (%)	Propranolol n (%)	p-value
Significant	19 (38%)	13 (26%)	0.289
Moderate	20 (41%)	21 (42%)	0.876
Minimal	8 (16%)	12 (24%)	0.371
No Change	2 (5%)	4 (8%)	0.414

DISCUSSION

Our study compared carvedilol and propranolol in cirrhotic patients with portal hypertension and esophageal varices. Carvedilol showed better outcomes in reducing portal vein diameter and variceal size. The incidence of variceal bleeding and need for rescue therapy were lower in the carvedilol group. Though the differences were not statistically significant in all areas, trends consistently favored carvedilol. Tolerance was good for both drugs, but mild adverse effects like hypotension were slightly more frequent in the carvedilol group. The majority of patients maintained medication adherence throughout the six-month follow-up. HVPG responses were also better in the carvedilol group. These findings provide useful insights for clinical decision-making in the management of portal hypertension in liver cirrhosis.

The reduction in portal pressure is crucial to prevent complications in cirrhotic patients. Carvedilol achieved a greater decrease in portal vein

diameter and showed a better overall HVPG response than propranolol. This effect can be attributed to carvedilol's dual action on both beta and alpha receptors, which lowers intrahepatic resistance and improves blood flow. Though carvedilol was associated with more cases of hypotension, most were manageable with dose adjustments. A lower frequency of rescue therapy and reduced bleeding episodes, even if not statistically significant, supports carvedilol's clinical usefulness. These effects suggest carvedilol may be superior in real-world use, where achieving target HVPG reductions can be difficult.

Several published studies support our findings. A meta-analysis by Banares et al. (2012) concluded that carvedilol produced greater reductions in HVPG than propranolol. Similar results were reported by Tripathi et al. (2009), who found carvedilol reduced HVPG by approximately 20%, compared to 12% with propranolol. Our study supports these findings with slightly better response rates in the carvedilol group. However, unlike in some previous trials, the difference in bleeding rates in our study was not statistically significant. This may be due to our smaller sample size and shorter follow-up. A study by De et al. (2016) in India showed significantly reduced variceal bleeding in patients on carvedilol. In contrast, a Pakistani study by Khokhar et al. (2015) showed no major difference in bleeding rates between the two drugs, although portal pressure reduction was greater with carvedilol. Our results are in between these extremes, showing a favorable trend toward carvedilol with outcomes just shy of significance.

Our study has several strengths. It was conducted in two tertiary care centers in Baluchistan, providing data from a resource-limited and under-represented region. Few studies have focused on this area of Pakistan, making our findings locally relevant. The sample included patients from both urban and rural populations, improving generalizability. Additionally, the six-month follow-up period allowed assessment of both short- and mid-term outcomes.

We used standardized techniques for HVPG measurement and endoscopy, ensuring accuracy. Drug dosing was titrated carefully, and adherence was actively monitored through pill counts and patient diaries. This enhanced the reliability of our results and minimized bias related to non-compliance.

Despite these strengths, some limitations must be acknowledged. The study was non-randomized and used convenience sampling. This could introduce selection bias. The sample size was modest, with only 49 patients in each group, reducing the power to detect small but meaningful differences. Our follow-up duration was limited to one year, which may not reflect long-term outcomes like mortality or re-bleeding over one year. HVPG was measured using standard methods, but availability of equipment was sometimes delayed, affecting timing. Patient adherence was based on pill counts and diaries, which may be subject to reporting bias. Also, adverse effects like fatigue or dizziness were self-reported, and not measured using formal scales.

The findings have clear clinical implications. Carvedilol appears to offer better portal pressure control than propranolol, with fewer bleeding events and a reduced need for rescue therapy. These benefits were observed despite similar baseline MELD scores and variceal sizes in both groups. In clinical settings, especially in resource-constrained environments, a drug with better efficacy and similar tolerability is advantageous. Although carvedilol requires careful monitoring of blood pressure, especially in elderly or frail patients, it can be safely used with proper titration. Its superior hemodynamic profile may help prevent first or recurrent variceal bleeding, which is a leading cause of mortality in cirrhotic patients. Therefore, carvedilol may be preferred over propranolol in suitable patients with stable hemodynamics.

Further research is needed to expand upon our findings. A larger, multicenter randomized controlled trial is recommended to confirm the superiority of carvedilol and establish statistical significance. Such studies

should include longer follow-up, possibly 12 to 24 months, to assess the impact on mortality, re-bleeding, and quality of life. Future research should also evaluate combination strategies, such as carvedilol plus endoscopic band ligation, to determine whether dual therapy offers additional benefits. Pharmacogenetic studies may help explain individual differences in drug response, which could improve personalized treatment. Additionally, economic evaluations comparing the cost-effectiveness of carvedilol and propranolol in Pakistan could guide national policy, especially in public hospitals.

Our experience highlights the need for more region-specific evidence in Pakistan. Many treatment guidelines are based on Western studies, which may not reflect the real-world challenges faced in low-income settings. Patients in Baluchistan often have delayed access to healthcare, making preventive therapy even more important. Carvedilol, when used appropriately, may help reduce emergency admissions for variceal bleeding. This is particularly valuable in hospitals with limited endoscopy services or ICU beds. The side effect profile of carvedilol was manageable in our study, and most patients tolerated the drug well. Education and regular follow-up improved adherence and minimized complications.

our study shows that carvedilol has several advantages over propranolol in the treatment of portal hypertension and varices in cirrhotic patients. While the differences were not statistically significant in all measures, the consistent trend in favor of carvedilol suggests a potential clinical benefit. Its superior effect on portal pressure and variceal features, coupled with good tolerance, make it a viable first-line option. Larger, longer, and randomized studies are needed to validate our findings and develop clear clinical pathways for managing these high-risk patients in Pakistan and similar settings.

CONCLUSION

This study found that carvedilol reduced portal pressure and variceal size more effectively than propranolol in cirrhotic patients. It also showed fewer bleeding episodes and less need for rescue therapy. Carvedilol was generally well tolerated, though hypotension was more common. These results suggest carvedilol may be a better option, especially in settings like Pakistan where early control of complications is crucial.

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DISCLAIMER

This research is conducted solely for academic and scientific purposes. The findings, interpretations, and conclusions expressed herein are those of the authors and do not constitute medical advice. Clinicians and readers are advised to interpret the results within their clinical context and verify data independently. The authors assume no responsibility for any consequences resulting from the use of this information.

CONFLICT OF INTEREST

The authors declare no conflict of interest in relation to this study. There were no personal, financial, or institutional influences that could have affected the design, conduct, analysis, or reporting of the research.

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