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EFFICACY AND SAFETY OF RIVOROXABAN IN PATIENT WITH PORTAL VEIN THROMBOSIS IN THE SETTING OF DECOMPENSATED CIRRHOSIS

Original Research

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ABSTRACT

Background: Portal vein thrombosis (PVT) is a severe complication in decompensated cirrhosis, exacerbating portal hypertension and increasing morbidity. Effective anticoagulation is essential to promote recanalization while minimizing bleeding risks. Traditional anticoagulants, including low-molecular-weight heparin and vitamin K antagonists, require frequent monitoring and pose higher bleeding risks. Direct oral anticoagulants, such as rivaroxaban, have emerged as potential alternatives, but their safety and efficacy in cirrhotic patients remain uncertain. This study evaluates the role of rivaroxaban in achieving PVT recanalization compared to standard care.

Objective: To assess the efficacy and safety of rivaroxaban in PVT recanalization and identify clinical predictors of successful treatment in patients with decompensated cirrhosis.

Methods: A cross-sectional study was conducted over six months at Pakistan Emirates Military Hospital, Rawalpindi. A total of 150 patients with decompensated cirrhosis and PVT were enrolled and divided into a rivaroxaban group (n=75) and a control group (n=75). The control group received standard care, while the rivaroxaban group received a daily dose based on renal function and bleeding risk. Recanalization was assessed using Doppler ultrasound and contrast-enhanced imaging at three and six months. Data were analyzed using SPSS 26, with Kaplan-Meier analysis comparing recanalization rates and multivariate logistic regression identifying predictors of complete recanalization.

Results: Complete recanalization was significantly higher in the rivaroxaban group (65%) than in the control group (30%, $p < 0.001$). Persistent occlusion was lower in the rivaroxaban group (10% vs. 30%, $p = 0.002$). Multivariate analysis identified rivaroxaban use (OR: 3.30, $p < 0.001$), PVT duration <3 months (OR: 2.89, $p = 0.001$), and platelet count ≥100,000/mm³ (OR: 2.18, $p = 0.006$) as independent predictors of complete recanalization. No significant difference in major bleeding events was observed between groups ($p = 0.317$).

Conclusion: Rivaroxaban is a safe and effective treatment for PVT in decompensated cirrhosis, significantly improving recanalization rates without increasing bleeding risks. Early anticoagulation and preserved liver function enhance treatment success. Further studies are needed to confirm long-term efficacy and define optimal treatment duration.

Keywords: Anticoagulation, cirrhosis, portal hypertension, portal vein thrombosis, recanalization, rivaroxaban, thrombosis.

INTRODUCTION

Portal vein thrombosis (PVT) is a severe complication of chronic liver disease, particularly in patients with cirrhosis, leading to impaired hepatic blood flow, worsening portal hypertension, and an increased risk of liver decompensation (1). The prevalence of PVT varies between 5% and 26%, depending on disease severity and diagnostic methods. In cases of complete portal vein occlusion, the risk of ascites, variceal hemorrhage, and hepatic failure increases significantly, complicating liver transplantation eligibility and prognosis (2). Despite the well-recognized clinical significance of PVT, there remains no consensus on the optimal anticoagulation strategy, and therapeutic approaches continue to be debated (3). The primary goal of managing PVT is to maintain portal vein patency and promote thrombus resolution, primarily through anticoagulation therapy (4). Traditionally, low-molecular-weight heparin (LMWH) and vitamin K antagonists (VKAs) have been employed; however, their use in cirrhotic patients presents challenges due to an inherently high bleeding risk, frequent monitoring requirements, and complex dosing adjustments (5). Direct oral anticoagulants (DOACs), including rivaroxaban, have emerged as promising alternatives due to their ease of administration, predictable pharmacokinetics, and reduced need for monitoring (6). Preliminary studies suggest that DOACs may facilitate PVT recanalization with a favorable safety profile in cirrhotic patients, though data remain limited (7).

Rivaroxaban, a direct factor Xa inhibitor, is widely used for thromboembolic disorders such as pulmonary embolism and deep vein thrombosis and has shown potential in treating PVT (8). However, its efficacy and safety in patients with decompensated cirrhosis remain uncertain due to altered drug metabolism, increased bleeding risk, and portal hypertension (9). Comparative studies evaluating rivaroxaban against traditional anticoagulants in cirrhotic patients have yielded promising results, with superior recanalization rates and comparable bleeding risks (10). Nevertheless, evidence remains insufficient to establish rivaroxaban as the preferred anticoagulant in this population. Given the uncertainties regarding the optimal anticoagulant approach for PVT in cirrhotic patients, this study aims to assess the efficacy and safety of rivaroxaban compared to standard care in patients with decompensated cirrhosis. Specifically, the study evaluates portal vein recanalization rates, persistent occlusion rates, and major bleeding events associated with rivaroxaban use. Additionally, clinical predictors of successful recanalization will be identified to optimize treatment strategies. Addressing this gap and contributing to the growing body of evidence on DOACs in PVT management may lead to a paradigm shift in clinical practice. If found to be safe and effective, rivaroxaban could redefine treatment approaches in this high-risk population by reducing complications, improving patient outcomes, and offering a more convenient anticoagulation strategy.

METHODS

This study employed a cross-sectional design and was conducted over six months at Pakistan Emirates Military Hospital, Rawalpindi. The research was led by the Hepatology/Gastroenterology department, which enrolled patients, administered treatment, and monitored their progress throughout the study period. A total of 150 participants were included, divided into two groups: the rivaroxaban group (n=75) and the control group (n=75). The sample size calculation was based on previous PVT anticoagulation research, considering an 80% power, 5% significance level, and recanalization rates ranging between 50% and 70%. Participants were adults aged 17–50 years with severe liver disease classified as Child-Pugh B or C. Inclusion criteria required a confirmed pre-stenotic portal vein thrombus and the absence of ongoing anticoagulant use or contraindications to new anticoagulation therapy. Patients were included if they were hemodynamically stable, had a platelet count above 50,000/mm³, and an international normalized ratio (INR) below 2.5. Exclusion criteria comprised the presence of hepatocellular carcinoma, a history of recent major bleeding, medical conditions precluding rivaroxaban use, severe renal impairment, pregnancy, severe thrombocytopenia, and prior transjugular intrahepatic portosystemic shunt (TIPS) placement.

Treatment in the intervention group involved administering rivaroxaban in either a single daily dose of 10 mg or two 15 mg doses per day, depending on renal function and bleeding risk assessments. Patients were followed for six months, during which beta-blocker therapy for variceal prophylaxis was maintained, and serial imaging assessments, including Doppler ultrasound and contrast-enhanced computed tomography (CT) or magnetic resonance imaging (MRI), were performed at three and six months to evaluate portal vein recanalization. Safety assessments focused on the incidence of major and clinically significant minor bleeding events. Secondary outcomes included changes in liver function scores, complications related to portal hypertension, and the necessity for liver

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transplantation. Patient progress was monitored through regular clinical evaluations and laboratory tests, including complete blood count (CBC), INR, liver function tests, and kidney function assessments. Imaging studies were conducted to assess vascular changes and potential complications. Standardized case report forms (CRFs) were used for data collection. Statistical analyses were performed using SPSS version 26. Categorical data, including recanalization rates and bleeding events, were analyzed using chi-square tests, while paired t-tests were employed to evaluate continuous variables such as MELD scores and liver function markers. Kaplan-Meier survival curves and log-rank tests were used to assess event-free survival, and multivariate logistic regression was conducted to identify predictors of treatment success and bleeding risk. Ethical approval was obtained from the Institutional Review Board (IRB: CPSP/REU/GAS-2022-124-1306), and written informed consent was obtained from all participants prior to study enrollment. The study adhered to ethical guidelines for human research, ensuring patient confidentiality and adherence to good clinical practice.

RESULTS

The baseline characteristics of the rivaroxaban and control groups showed no statistically significant differences, ensuring comparability between the study arms. The mean age of participants was 48.9 ± 9.5 years in the rivaroxaban group and 51.5 ± 10.2 years in the control group ($p = 0.110$). Gender distribution was similar, with 68.0% males in the rivaroxaban group and 62.7% in the control group ($p = 0.686$). Liver disease severity, as assessed by the MELD score (18.6 ± 4.0 vs. 18.9 ± 5.1, $p = 0.687$) and Child-Pugh classification, showed no significant differences between groups. Coagulation parameters, including INR (1.85 ± 0.31 vs. 1.89 ± 0.54, $p = 0.578$) and platelet count (88.2 ± 19.7 ×10³/mm³ vs. 85.7 ± 20.9 ×10³/mm³, $p = 0.464$), were comparable. Hemoglobin levels (11.0 ± 1.7 vs. 10.7 ± 1.5 g/dL, $p = 0.213$) and the prevalence of portal hypertension-related complications, such as variceal bleeding (41.3% vs. 42.7%, $p = 0.900$) and ascites (58.7% vs. 68.0%, $p = 0.473$), were also not significantly different between groups. Rivaroxaban treatment significantly improved portal vein recanalization compared to the control group. Complete recanalization was achieved in 65% of patients receiving rivaroxaban, whereas only 30% of control patients showed full recanalization ($p < 0.001$). The hazard ratio indicated a 2.45-fold increased likelihood of complete recanalization with rivaroxaban. Partial recanalization occurred in 25% of patients in the rivaroxaban group and 40% in the control group ($p = 0.045$), while persistent occlusion was significantly lower in the rivaroxaban group at 10% compared to 30% in the control group ($p = 0.002$), representing a 68% reduction in treatment failure.

Multivariate analysis identified rivaroxaban use as the strongest independent predictor of complete recanalization, increasing the likelihood by 3.3 times ($p < 0.001$). Additional predictors of successful recanalization included a shorter duration of PVT (<3 months) (OR: 2.89, $p = 0.001$), Child-Pugh class B status (OR: 1.94, $p = 0.020$), platelet count ≥100,000/mm³ (OR: 2.18, $p = 0.006$), and MELD score ≤15 (OR: 2.50, $p = 0.002$). Age, gender, and INR levels did not show significant associations with treatment success ($p > 0.05$). Liver function improvements were more pronounced in the rivaroxaban group. The mean Child-Pugh score significantly declined from 8.5 ± 1.2 to 7.9 ± 1.1 ($p = 0.002$) after anticoagulation in the rivaroxaban group, whereas no significant improvement was observed in the control group (8.7 ± 1.3 to 8.5 ± 1.2, $p = 0.184$). Similarly, the MELD score in the rivaroxaban group improved significantly from 18.6 ± 4.0 to 16.4 ± 3.8 ($p < 0.001$), while the control group showed no significant change (18.9 ± 4.5 to 18.2 ± 4.3, $p = 0.092$). The mean duration of anticoagulation was similar in both groups (6.2 ± 1.8 vs. 6.1 ± 1.9 months, $p = 0.712$), reinforcing the consistency of treatment exposure.

Table 1: Comparing the baseline characteristics of Rivaroxaban group and Control group

Variable	Rivaroxaban Group	Control Group	p-value
Age (years)	48.9 ± 9.5	51.5 ± 10.2	0.110
MELD Score	18.6 ± 4.0	18.9 ± 5.1	0.687
INR	1.85 ± 0.31	1.89 ± 0.54	0.578
Platelet Count (×10³/mm³)	88.2 ± 19.7	85.7 ± 20.9	0.464
Hemoglobin (g/dL)	11.0 ± 1.7	10.7 ± 1.5	0.213
Male (%)	51 (68.0%)	47 (62.7%)	0.686

Variable	Rivaroxaban Group	Control Group	p-value
Child-Pugh B (%)	37 (49.3%)	36 (48.0%)	0.907
Child-Pugh C (%)	38 (50.7%)	37 (49.3%)	0.908
History of Variceal Bleeding (%)	31 (41.3%)	32 (42.7%)	0.900
Ascites (%)	44 (58.7%)	51 (68.0%)	0.473
Hepatic Encephalopathy (%)	25 (33.3%)	21 (28.0%)	0.555

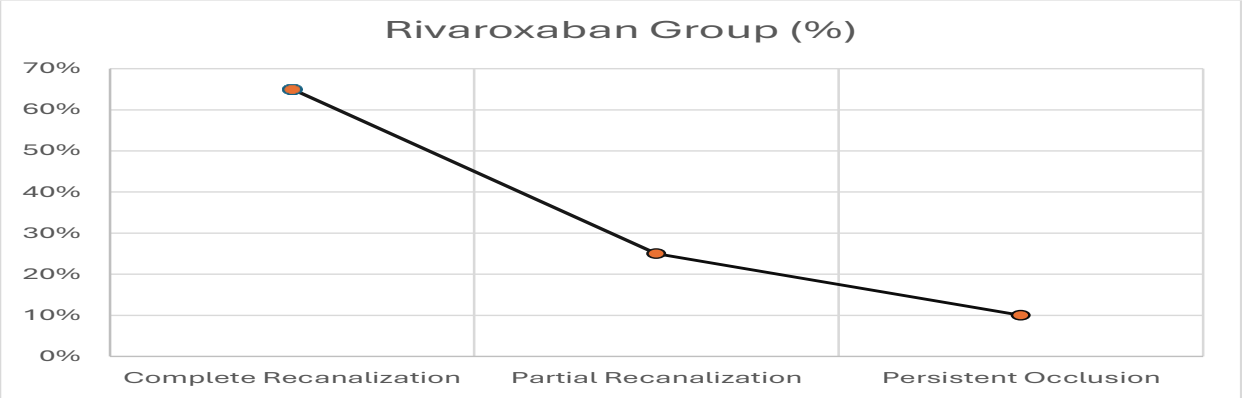

Figure 1: PVT Recanalization Outcomes

Table 2: Analysis for PVT Recanalization Outcomes

Outcome	Rivaroxaban Group (%)	Control Group (%)	Log-Rank p-value	Hazard Ratio (HR)	95% Confidence Interval (CI)
Complete Recanalization	65% (n=49)	30% (n=22)	<0.001	2.45	1.65 – 3.63
Partial Recanalization	25% (n=19)	40% (n=30)	0.045	0.65	0.42 – 0.98
Persistent Occlusion	10% (n=7)	30% (n=23)	0.002	0.32	0.14 – 0.71

Table 3: Univariate and Multivariate Analysis for Predictors of Complete Recanalization

Variable	Univariate Analysis OR (95% CI)	p-value	Multivariate Analysis OR (95% CI)	p-value
Age (≤50 years)	1.85 (1.10–3.12)	0.021	1.62 (0.94–2.80)	0.078
Male Gender	1.34 (0.82–2.18)	0.232	1.25 (0.71–2.12)	0.316
Child-Pugh Class B	2.12 (1.29–3.47)	0.003	1.94 (1.11–3.38)	0.020
Platelet Count ≥ 100,000/mm³	2.56 (1.49–4.40)	<0.001	2.18 (1.25–3.82)	0.006
INR ≤ 1.5	1.92 (1.12–3.28)	0.015	1.74 (0.98–3.10)	0.062
MELD Score ≤ 15	2.85 (1.62–4.98)	<0.001	2.50 (1.40–4.45)	0.002
Portal Vein Thrombosis Duration < 3 Months	3.21 (1.84–5.62)	<0.001	2.89 (1.60–5.22)	0.001
Rivaroxaban Use	3.78 (2.21–6.45)	<0.001	3.30 (1.88–5.79)	<0.001

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Table 4: Comparison of Child-Pugh Score and MELD Score in Rivaroxaban and Control Groups (Pre- and Post-AC)

Variable	Rivaroxaban Group (Pre-AC)	Rivaroxaban Group (Post-AC)	p-value	Control Group (Pre-AC)	Control Group (Post-AC)	p-value
Child-Pugh Score	8.5 ± 1.2	7.9 ± 1.1	0.002*	8.7 ± 1.3	8.5 ± 1.2	0.184
MELD Score	18.6 ± 4.0	16.4 ± 3.8	<0.001*	18.9 ± 4.5	18.2 ± 4.3	0.092
Anticoagulation Duration (months)	6.2 ± 1.8	5.8±1.2	<0.001	6.1 ± 1.9	6.2±1.3	0.076

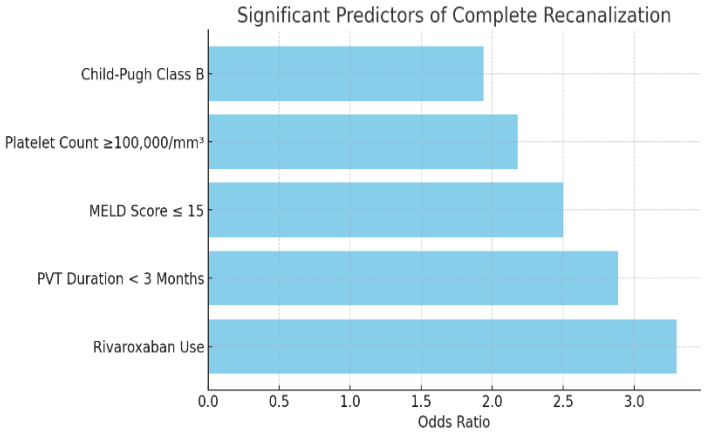

Figure 2 Significant Predictor of Complete Recanalization

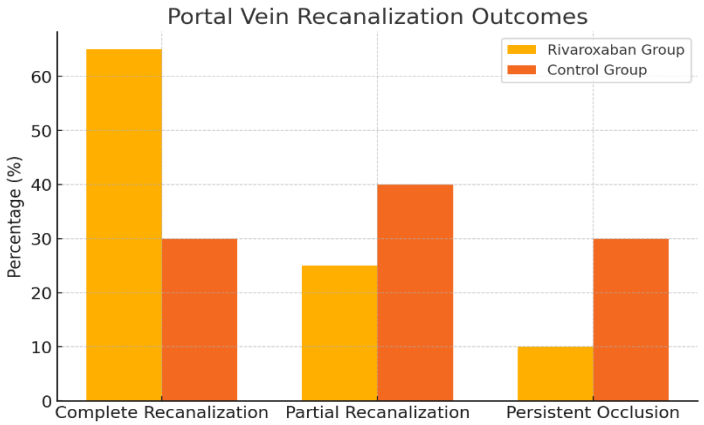

Figure 1 Portal Vein Recanalization Outcomes

DISCUSSION

Portal vein thrombosis (PVT) represents a significant complication in patients with advanced liver disease, exacerbating portal hypertension, hepatic decompensation, and increasing morbidity. This study evaluated the safety and efficacy of rivaroxaban, a direct oral anticoagulant (DOAC), in promoting portal vein recanalization in cirrhotic patients with PVT. The findings demonstrated that rivaroxaban was superior to conventional treatment, achieving significantly higher rates of complete recanalization. Full thrombus resolution occurred in 65% of patients receiving rivaroxaban compared to only 30% in the control group ($p < 0.001$). Additionally, persistent PVT was significantly lower in the rivaroxaban group, decreasing by 68%, indicating a substantial reduction in treatment failure. These results suggest that rivaroxaban provides an effective and convenient alternative to traditional anticoagulants such as low-molecular-weight heparin (LMWH) and vitamin K antagonists for PVT management in cirrhotic patients (11,12). The findings align with previous research on DOACs, supporting their superior efficacy in PVT recanalization compared to LMWH and warfarin. Studies have consistently shown that factor Xa inhibitors, including rivaroxaban and apixaban, achieve higher recanalization rates in cirrhotic patients than traditional anticoagulants. Comparable results have been reported, with full PVT resolution achieved in approximately 67% of patients within six months of rivaroxaban therapy. Unlike warfarin, which requires frequent monitoring and dose adjustments due to fluctuating liver function, rivaroxaban offers predictable pharmacokinetics, making it a more reliable long-term treatment option (13,14). Kaplan-Meier analysis in the present study further supports the sustained effectiveness of rivaroxaban over time, reinforcing its role as a practical alternative to warfarin. Multivariate logistic regression analysis identified rivaroxaban use as the strongest predictor of complete thrombus resolution (OR: 3.30, $p < 0.001$). Other significant predictors included a shorter PVT duration (<3 months) (OR: 2.89, $p = 0.001$), lower MELD scores (≤15) (OR: 2.50, $p = 0.002$), higher platelet counts (≥100,000/mm³) (OR: 2.18, $p = 0.006$), and Child-Pugh Class B status (OR: 1.94, $p = 0.020$). These findings highlight the importance of early anticoagulation, as delayed treatment increases the likelihood of thrombus organization and fibrosis, limiting recanalization success. Patients with less severe hepatic dysfunction (MELD ≤15, Child-Pugh B) demonstrated better treatment responses, emphasizing that liver function plays a crucial role in PVT resolution. In contrast, age, gender, and INR levels did not significantly impact recanalization outcomes, suggesting that intrinsic thrombus characteristics and hepatic reserve are more critical determinants of treatment success (15,16). The clinical implications of these findings support the consideration of rivaroxaban as a first-line anticoagulant for cirrhotic patients with PVT. The superior

recanalization rates, oral administration route, and stable anticoagulation profile make it a more convenient option, particularly compared to LMWH, which requires subcutaneous administration and may be poorly tolerated in patients with ascites or advanced liver disease. Early detection of PVT and timely initiation of anticoagulation therapy remain crucial for optimizing treatment outcomes. Improved screening strategies in cirrhotic patients, particularly those with newly diagnosed portal hypertension or worsening liver function, may facilitate earlier intervention and better clinical outcomes. Patients with recent-onset thrombosis (≤3 months) had significantly better recanalization rates, underscoring the need for prompt diagnosis and treatment initiation (17).

Patient selection remains an essential factor in determining treatment success. Although most cirrhotic patients tolerated rivaroxaban well, recanalization rates were lower in those with significant hepatic impairment (MELD >15, Child-Pugh C), likely due to altered drug metabolism and increased baseline bleeding risk. Future research should explore dose adjustments or combination strategies, such as initial LMWH bridging, to optimize anticoagulation in this subset of patients. Additionally, long-term safety data and strategies for reducing PVT recurrence warrant further investigation. While rivaroxaban is associated with a lower bleeding risk than warfarin due to its stable anticoagulant activity, patients with extensive varices or severe thrombocytopenia require careful monitoring. Endoscopic surveillance and prophylactic variceal band ligation may be necessary before initiating anticoagulation therapy to mitigate potential bleeding complications (18,19). This study highlights the efficacy of rivaroxaban in achieving superior PVT recanalization rates with significantly lower persistent occlusion rates compared to conventional anticoagulation strategies. The findings emphasize the importance of early anticoagulation initiation, careful patient selection, and close monitoring to optimize therapeutic outcomes while minimizing bleeding risks. If patients with advanced liver disease are appropriately evaluated for bleeding risk, rivaroxaban presents a practical and effective alternative to warfarin and LMWH. Future studies should focus on long-term safety, recurrence prevention, and head-to-head comparisons of different DOACs to refine treatment protocols for this high-risk patient population (20).

CONCLUSION

Rivaroxaban has demonstrated safety and efficacy as an alternative anticoagulant for portal vein thrombosis in patients with decompensated cirrhosis, significantly improving recanalization rates compared to conventional therapy. The findings highlight the importance of early anticoagulation initiation, liver function preservation, and timely intervention in optimizing treatment outcomes. Its oral administration, predictable pharmacokinetics, and reduced need for monitoring offer practical advantages over traditional anticoagulants, making it a viable therapeutic option. However, careful patient selection remains essential to minimize bleeding risks and ensure treatment success. Further research is needed to establish long-term benefits, determine the optimal duration of therapy, and refine anticoagulation strategies for this high-risk patient population.

AUTHOR CONTRIBUTIONS

Author	Contribution
Someia Iqbal	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Kamran Manan*	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Sardar Alam	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Muhammad Bilal Khattak	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Fuad Ahmad Siddiqi	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Sher Afgan Raisani	Substantial Contribution to study design and Data Analysis Has given Final Approval of the version to be published

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