RECANALIZATION RATE IN PATIENTS WITH DEEP VENOUS THROMBOSIS ON RIVAROXABAN THERAPY: A PROSPECTIVE OBSERVATIONAL STUDY AT UCMS-TH

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ABSTRACT

INTRODUCTION

Deep venous thrombosis (DVT) is a critical condition with significant morbidity and mortality risks. Direct oral anticoagulants, such as rivaroxaban, have emerged as effective alternatives for DVT management, yet their impact on recanalization rates remains underexplored.

MATERIAL AND METHODS

A prospective observational study conducted at UCMS Teaching Hospital enrolled 104 patients diagnosed with DVT of both upper and lower limbs from February to September 2024. Duplex ultrasonography assessed thrombus resolution at baseline and after six months of rivaroxaban therapy. This study evaluates the recanalization rates in patients with DVT treated with rivaroxaban using duplex ultrasonography.

RESULTS

Among 104 patients (41% male, 59% female), 23.8% achieved complete recanalization, 66.7% had partial recanalization, and 9.5% showed residual thrombi. Complete recanalization rates were highest in femoral veins (25.8%) and lowest in popliteal veins (24%).

CONCLUSION

Rivaroxaban demonstrates favorable recanalization outcomes in DVT patients, supporting its use as first-line therapy. Further studies are needed to optimize treatment and prevent complications like post-thrombotic syndrome.

KEYWORDS

Deep venous thrombosis, direct oral anticoagulants, duplex ultrasonography, recanalization, rivaroxaban, thrombus resolution.

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INTRODUCTION

Deep venous thrombosis (DVT) is a common and life-threatening condition characterized by the formation of thrombi in deep veins, leading to partial or complete venous obstruction. Its annual incidence in the United States is approximately 900,000 cases, with a significant risk of progression to pulmonary embolism (PE) in 21%–39% of cases.[1–3]

Venous thromboembolism (VTE), comprising DVT and PE, is a major global health concern, affecting two per 1,000 individuals annually, with increased incidence in older populations.[4,5]

DVT treatment aims to prevent thrombus progression and PE. Traditionally, anticoagulation with unfractionated heparin (UFH), low molecular weight heparin (LMWH), or vitamin K antagonists has been the mainstay of therapy. Recent advances, including direct oral anticoagulants (DOACs) like rivaroxaban, have shown promise due to their ease of administration, wider therapeutic window, and minimal need for monitoring.[6]

The natural process of thrombus recanalization involves fibrocellular organization, local fibrinolysis, and neovascularization.[7] This process, influenced by various factors, including anticoagulation therapy, is critical in reducing long-term complications such as post-thrombotic syndrome (PTS).[8]

Although studies have demonstrated favorable outcomes with rivaroxaban, limited research has explored its effect on recanalization rates as assessed by duplex ultrasonography.[9,10] This study aims to evaluate the recanalization rate in patients with lower-limb DVT treated with rivaroxaban using duplex ultrasonography.

MATERIAL AND METHODS

The study was conducted as a prospective observational study at Universal College of Medical Sciences Teaching Hospital (UCMS-TH), Bhairahawa, from February 2024 to September 2024. This study was carried out with ethical clearance from Institutional review committee of UCMS-Th with reference number UCMS/IRC/022/24.

A total of 104 patients diagnosed with DVT cases of extremities were enrolled for this study. Patients aged 18–70 years with a confirmed diagnosis of DVT were included and patients with creatinine clearance <30 mL/min were excluded. Informed consent was obtained from all participants.

Privacy and confidentiality of patient data were strictly maintained. Using the Cochran formula, assuming a DVT prevalence of 11% and a margin of error of 6%, the required sample size was calculated to be 104.[11]

Demographic and clinical data, including age, sex, history of trauma, and comorbidities, were collected. Ultrasonography evaluation at baseline and after six months of rivaroxaban therapy assessed thrombus site, venous reflux, and residual thrombi. Data analysis was performed using SPSS 19.0. using chi square test.

RESULTS

The study enrolled 104 patients, with a male-to-female ratio of 41:59. Most patients were housewives (31.4%) or farmers (26.7%). The most common thrombus sites were the left lower limb (51.4%) and right lower limb (45.7%) as shown in Table 1.

Table 1. Demographic Variables of DVT patients (N=104)

Variables	Group	Frequency (n)	Percentage (%)
Gender	Male	43	41.0
	Female	62	59.0
Occupation	Army	11	10.5
	Cook	7	6.7
	Farmer	28	26.7
	Housewife	33	31.4
	Office staff	17	16.2
	Student	4	3.8
	Teacher	5	4.8
Diagnosis	Bilateral lower limb	1	1.0
	Bilateral upper limb	1	1.0
	Left lower limb	54	51.4
	Left upper limb	1	1.0
	Right lower limb	48	45.7

Complete recanalization occurred in 23.8% of patients. Partial recanalization was observed in 66.7%. Residual thrombi persisted in 9.5%. Venous segment-specific recanalization rates varied, with the highest complete recanalization seen in the femoral vein (25.8%) and lowest in the popliteal vein (24%) (p=0.353) as shown in Table 2.

Table 2. Recanalization outcome of DVT patients (N=104)

Doppler Findings on the day of initiation of treatment	Doppler findings after 6 months of initiation of n%			Total	p value
	Complete recanalization	Partial recanalization	Residual recanalization		
B/l popliteal vein DVT	0 (0)	0 (0)	1 (100)	1	
Left femoral vein DVT	8 25.8)	21 (67.7)	2 (6.5)	31	
Left popliteal vein DVT	6 (24)	18 (72)	1 (4)	25	
Right axillary and left basilic vein DVT	0 (0)	0 (0)	1 (100)	1	0.353
Right femoral vein DVT	6 (23.1)	17 (65.4)	3 (11.5)	26	
Right popliteal vein DVT	5 (23.8)	14 (66.7)	2 (9.5)	21	
Total	25 (23.8)	70 (66.7)	10 (9.5)	105	

Complete recanalization occurred in 23.8% of patients. Partial recanalization was observed in 66.7%. Residual thrombi persisted in 9.5%. Venous segment-specific recanalization rates varied, with the highest complete recanalization seen in the femoral vein (25.8%) and lowest in the popliteal vein (24%) (p=0.353) as shown in Table 2.

DISCUSSION

Our study's findings align with prior research, such as Soares et al, who compared 51 patients with DVT treated with rivaroxaban for 6 months. In that study, they found that total venous recanalization at 12 months was 76.4% and partial venous recanalization was 23.5%.[9]

In another study done by Rafael et al, who divided 88 patients with DVT in two groups on basis of treatment given with rivaroxaban (group 1) and warfarin (group 2) for 6 months. In their study during period of 12 months they found total venous recanalization of 76.1% in group 1 and 13.2% in group 2 which was statistically significant. Partial venous

recanalization was 73.7% in group 2 and 23.9% in group 1 which was not statistically significant.[12]

In a study done by Polyana et al, comparing 77 patients treated for DVT in two groups, group 1(Heparin and Warfarin) and group 2(Rivaroxaban). They found that recanalization rates at 30, 90, and 180 days were 10%, 52.5%, and 78.9%, respectively, in Group I, and 55.3%, 83.5%, and 92.4%, respectively, in Group II, with statistically significant.[13]

The observed partial recanalization rate (66.7%) in our study raises concerns about long-term complications, including post-thrombotic syndrome (PTS). This underscores the need for adjunct therapies, such as compression stockings or structured exercise programs, to optimize patient outcomes. Further multicenter studies with larger cohorts are warranted to validate these findings and explore factors influencing recanalization, such as thrombus chronicity, anticoagulation duration, and adjunctive therapies. Comparative studies assessing rivaroxaban against other direct oral anticoagulants (DOACs) could also provide valuable insights.

CONCLUSION

Rivaroxaban demonstrated effective recanalization rates in patients with lower-limb DVT, as evidenced by duplex ultrasonography findings. These results support its use as a first-line therapy in DVT management. Further studies with larger sample sizes are recommended to validate these findings.

CONFLICT OF INTEREST

None

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