Original Article

Efficacy Of Rivaroxaban Versus Warfarin For The Treatment Of Deep Vein Thrombosis At Tertiary Care Hospital, Islamabad

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Abstract

Objective: The occurrence of venous thromboembolism outside the pulmonary arteries or lower extremity conventional deep vein is referred to as deep vein thrombosis (DVT). The optimal anticoagulation treatment for deep vein thrombosis remained debatable. Therefore, the purpose of the current study was to compare Rivaroxaban versus Warfarin in treating deep vein thromboembolism at the Tertiary Care Hospital, Islamabad.

Methods: A randomised controlled trial investigated 170 deep vein thrombosis (DVT) patients in the Department of Medicine, Pakistan Institute of Medical Sciences, Islamabad, from July 2023 to January 2024. Patients were categorised into two groups: Group R (Rivaroxaban) (N=85) and Group W (Warfarin) (N=85). Demographic data, such as age, gender, comorbidities, clinical outcomes, and efficacy recorded for both groups. Major bleeding included any fatal bleeding, bleeding in critical organs, or bleeding causing a haemoglobin drop ≥2 g/dL or requiring ≥2 units of blood transfusion. Minor bleeding is defined as overt bleeding, including events like mild epistaxis or bruising not requiring medical intervention. SPSS version 16 was used for statistical analysis.

Results: The overall mean age of group R and W was 47.78±17.91 years and 46.45±18.01 years, respectively. Out of 170 patients, there were 83 (48.8%) males and 87 (51.2%) females. Gender based distribution of patients in both groups was as follows: Group R, N=85 (Male 42 (49.4%) and female 43 (50.6%) and Group W (Male 41 (48.2%) and female 44 (51.8%). Rivaroxaban (Group-R) showed higher efficacy, 72 (84.7%), than Warfarin (Group-W), 62 (72.9%).

Conclusion: The present study observed that treatment with Rivaroxaban is preferred over Warfarin due to reduced risk of DVT, major bleeding, and minor bleeding.

Keywords: Rivaroxaban, Warfarin, Venous Thrombosis, Venous Thromboembolism, Treatment Outcome.

Contributions:
MY - Conception, Design
MY, AJ, MZ, ZS - Acquisition, Analysis, Interpretation
MY, ZS - Drafting
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Introduction

Deep vein thrombosis (DVT) and pulmonary embolism (PE) are known by the collective name venous thromboembolism.[1] In the Western World, the cases of venous thromboembolism vary from 1/1000 to 2/1000 population, among which 0.5 cases develop pulmonary embolism.[2] DVT, a life-threatening disorder that might lead to major problems in case left untreated, and deep veins develop a clot that reaches the lung artery. Bleeding and pulmonary embolism are the main complications of DVT. An earlier study reported that the prevalence of major risk factors such as surgery, immobility, cancer, prior history of DVT/PE, and trauma was 20%, 8%, 25%, 4-6%, and 12% respectively.[3] The prevalence of venous thrombosis, 10% cases collectively come from splanchnic vein thrombosis (SVT), cerebral venous thrombosis (CVT), and upper extremity deep vein thrombosis (UEDVT), yet unveiling a higher mortality rate.[4]

The primary approach to treating acute venous thromboembolism requires starting with parenteral heparin usage and overlapping with a vitamin K antagonist administration; therefore, it is limited.[5] This poses a challenge for outpatient care since administering a vitamin K antagonist requires lab tests to monitor the treatment and can be complicated with interactions from other drugs and food. Interactions with other drugs and food can complicate the treatment. After one year, vitamin K antagonists are associated with a risk of major bleeding that varies from 1% to 2%.[6,7] Subsequently, the benefits and risks of continued treatment remain debatable despite the higher risk for recurrent venous thromboembolism. Oral anticoagulation administration could resolve issues that require no laboratory monitoring, and provides effective results in continuous and acute venous thromboembolism treatment.[8] The prevention of venous thromboembolism developed after orthopaedic surgery by taking a treatment with a direct factor Xa inhibitor taken orally, with Rivaroxaban.[9,10] Earlier studies investigated 151 acute symptomatic deep vein thrombosis cases and reported that the vessel patency in the rivaroxaban group was 84.2% as compared to the warfarin group (68%).[11]

Warfarin, an oral anticoagulant, prevents blood clotting and is used to treat venous thrombosis, PE, and prophylaxis, reducing the risk of mortality, stroke and systemic embolisation, like thromboembolic events, and recurrent myocardial infarction.[12-15] The primary purpose of treating DVT patients is to prevent complications, alleviate clotting, and promote cure. In Pakistan, the standard treatment for DVT is still warfarin with unfractionated heparin (UFH). Treatment with warfarin is economical, less efficient, and has a slower effect with drug and food interaction, needs continuous monitoring, severe bleeding. Moreover, there is are paucity of studies in the Pakistan setting comparing the two strategies. Therefore, the purpose of the current study was to compare Rivaroxaban versus Warfarin in treating deep vein thromboembolism at the Tertiary Care Hospital, Islamabad.

Materials And Methods

A randomised controlled trial investigated 170 deep vein thrombosis (DVT) patients in the Department of Medicine, Pakistan Institute of Medical Sciences, Islamabad, from July 2023 to January 2024. Patients of either gender (aged 20-80 years) and recently diagnosed with deep vein thrombosis were enrolled. Exclusion criteria include patients with a history of previous total hip or knee arthroplasty, hypo or hyperthyroidism, pulmonary embolism, malignancy, varicose veins, blood transfusion within one week, and acute coronary syndrome, asthma, congestive heart failure and chronic liver disease. The sample size of 170 patients (85 patients in each group) was calculated by taking Alpha=5%, Power of the test 1-beta=80%, taking efficacy in the rivaroxaban group (84.2%) as compared to the warfarin group (68%) [11]. Patients were grouped into Group R (Rivaroxaban) (N=85) and Group W (Warfarin) (N=85). For three weeks, Group R patients were administered with 15 mg dosage of rivaroxaban taken twice daily orally, followed by 20 mg once daily, whereas Group W patients were administered 10 mg Warfarin once daily for two days and 5 mg once daily for six months. Efficacy, defined as the absence of objectively confirmed recurrent venous thromboembolism (either deep vein thrombosis or pulmonary embolism) confirmed by appropriate imaging techniques such as Doppler ultrasound or CT pulmonary angiography during the 3-month treatment and follow-up period. Bleeding events are categorised based on the International Society on Thrombosis and Hemostasis (ISTH) criteria. Major bleeding included any fatal bleeding, bleeding in critical organs, or bleeding causing a haemoglobin drop ≥2 g/dL or requiring ≥2 units of blood transfusion. Minor bleeding is defined as overt bleeding, including events like mild epistaxis or bruising not requiring medical intervention. A duplex ultrasound study of the affected lower limbs was performed after three months of treatment in both groups to evaluate for efficacy. The findings of quantitative variables (age) and qualitative variables (gender, residence status, diabetes mellitus type II, hypertension, dyslipidemia, smoking status, occupational status, major bleeding, minor bleeding and efficacy) were recorded.

SPSS version 16 was used for statistical analysis. Frequencies and percentages for the qualitative variables like gender, residence status, diabetes mellitus type II, hypertension, dyslipidemia, smoking status, occupational status, major bleeding, minor bleeding and efficacy (yes/no). Efficacy of both groups compared using the Chi-square test. Outcome variables stratified by age, gender, residence status, diabetes mellitus type II, hypertension, dyslipidemia, smoking status and occupational status to see the effect modifier. Post-stratification chi-square test/Fisher's exact test applied by considering p-value of ≤ 0.05 as significant.

Results

The overall mean age of group R and W was 47.78±17.91 years and 46.45±18.01 years, respectively. Out of 170 patients, there were 83 (48.8%) males and 87 (51.2%) females. Gender based distribution of patients in both groups was as follows: Group R, N=85 (Male 42 (49.4%) and female 43 (50.6%) and Group W (Male 41 (48.2%) and female 44 (51.8%). Patient's distribution based on their age group was as follows: 56 (32.9%), 20-50 years and 114 (67.1%), 51-80 years. Out of 85 patients in group R, 28 (32.9%) and 57 (67.1%) patients were in age groups 20-50 years and 51-80 years, respectively. Whereas, out of 85 patients in group W, 28 (32.9%) and 57 (67.1%) patients were in age groups 20-50 years and 51-80 years, respectively. Rivaroxaban (Group-R) showed higher efficacy, 72 (84.7%), than Warfarin (Group-W), 62 (72.9%). Patient Characteristics: Demographic and Clinical Parameters are shown in Table I. Outcome Measures Stratified by Patient Demographics and Clinical Conditions as shown in Table 2. Efficacy Outcomes in Rivaroxaban and Warfarin Groups are illustrated in Figure 1.

The present study mainly focused on the comparison of the efficacy of anticoagulation treatment with Rivaroxaban and Warfarin for deep vein thrombosis and reported that DVT patients treated with Rivaroxaban had higher efficacy in terms of lower risk of major and minor bleeding complications as compared to warfarin. VTE is a life-threatening issues that adversely affect the patient's normal life. The increasing bleeding risk and reduced INR levels are caused by warfarin when used as an anticoagulant. Coagulation requires consistent and recurrent testing in cases where DVT patients are treated with warfarin. Traditional anticoagulants are overcome by Rivaroxaban used in the treatment of arteriovenous thromboembolism.

Table 1: Patient Characteristics: Demographic and Clinical Parameters (N=170)

Variables	Group-R (N=85)	Group-W (N=85)
Mean age (years)	47.78±17.91	46.45±18.01
Age Groups		
20-50	28 (32.9%)	28 (32.9%)
51-80	57 (67.1%)	57 (67.1%)
Gender N (%)		
Male	42 (49.4%)	41 (48.2%)
Female	43 (50.6%)	44 (51.8%).
Residential status N (%)		
Urban	66 (77.6%)	69 (81.2%)
Rural	19 (22.4%)	16 (18.8%)
Employment status N (%)		
Yes	39 (45.9%)	31 (36.5%)
No	46 (54.1%)	54 (63.5%)
Smoking status N (%)		
Yes	22 (25.9%)	37 (43.5%)
No	63 (74.1%)	48 (56.5%)
Comorbidities N (%)		
Hypertension		
Yes	70 (82.4%)	26 (30.6%)
No	15 (17.6%)	59 (69.4%)
Diabetes		
Yes	38 (44.7%)	31 (36.5%)
No	47 (53.3%)	54 (63.5%)
Dyslipidemia		
Yes	27 (31.8%)	41 (48.2%)
No	58 (68.2%)	44 (51.8%)
Complications N (%)		
Major Bleeding		
Yes	07 (8.2%)	16 (18.8%)
No	78 (91.8%)	69 (81.2%)
Minor Bleeding		
Yes	27 (31.8%)	41 (48.2%)
No	58 (68.2%)	44 (51.8%)

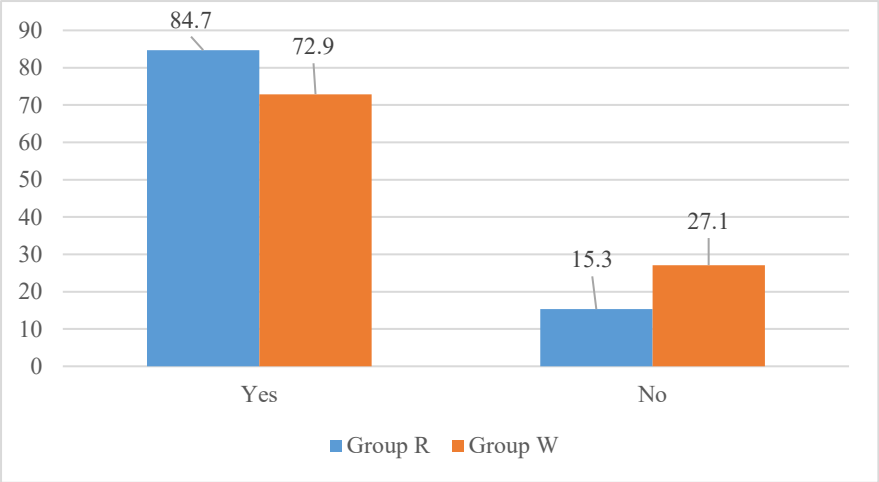

Figure 1: Efficacy Outcomes in Rivaroxaban and Warfarin Groups

Table 2: Outcome Measures Stratified by Patient Demographics and Clinical Conditions

Parameters	Group R		Group W		P-value
	YES	NO	YES	NO	
Age (years)					
40-60	23 (82.1%)	05 (17.9%)	22 (78.6%)	06 (21.4%)	0.73
61-80	49 (86%)	08 (14%)	40 (70.2%)	17 (29.8%)	0.04
Gender					
Male	36 (85.7%)	06 (14.3%)	31 (75.6%)	10 (24.4%)	0.24
Female	36 (83.7%)	07 (16.3%)	31 (70.5%)	13 (29.5%)	0.14
Resident status					
Urban	57 (86.4%)	9 (13.6%)	50 (72.5%)	19 (27.5%)	0.04
Rural	15 (78.9%)	4 (21.1%)	12 (75%)	04 (25%)	0.78
Employment Status					
Yes	35 (89.7%)	4 (10.3%)	26 (83.9%)	05 (16.1%)	0.46
No	37 (80.4%)	9 (19.6%)	36 (66.7%)	18 (33.3%)	0.12
Smoking status					
Yes	20 (90.9%)	2 (9.1%)	22 (59.5%)	15 (40.5%)	0.01
No	52 (82.5%)	11(17.5%)	40 (83.3%)	08 (16.7%)	0.91
Hypertension					
Yes	60 (85.7%)	10 (14.3%)	20 (76.9%)	06 (23.1%)	0.30
No	12 (80%)	03 (20%)	42 (71.2%)	17 (28.8%)	0.49
Diabetes					
Yes	32 (84.2%)	06 (15.8%)	23 (74.2%)	08 (25.8%)	0.30
No	40 (85.1%)	07 (14.9%)	39 (72.2%)	15 (27.8%)	0.11
Dyslipidemia					
Yes	25 (92.6%)	02 (7.4%)	34 (82.9%)	07 (17.1%)	0.24
No	47 (81%)	11 (19%)	28 (63.6%)	16 (36.4%)	0.04
Major Bleeding					
Yes	07 (100%)	07 (100%)	00 (00%)	15 (93.8%)	0.01
No	65 (83.3%)	65 (83.3%)	13 (16.7%)	47 (68.1%)	0.03
Minor Bleeding					
Yes	25 (92.6%)	02 (7.4%)	34 (82.9%)	07 (17.1%)	0.24
No	47 (81%)	11 (19%)	28 (63.6%)	16 (36.4%)	0.04

Discussion

The present study reported that the mean age in group R and W was 47.78±17.91 years and 46.45±18.01 years, respectively. Stratification for group R and W concerning efficacy showed that 72 (84.7%) and 62 (72.9%) had efficacy, respectively, with taking p-value of 0.06. An earlier meta-analysis conducted on 27,945 patients of 11 randomised controlled trials investigated and compared the VTE and PE treatment with standard anticoagulants, vitamin K antagonists, and direct thrombin inhibitors. Warfarin and Xa inhibitors showed similar results in terms of non-fatal and fatal PE rates. Trails that include Rivaroxaban comparison with warfarin for PE prevention, as the primary outcome, have not lasted for more than three months.[16-20]

Earlier investigations focused on the VTE prevention in adult patients on prior treatment and compared the efficacy by administration of warfarin, factor Xa inhibitors, aspirin, direct thrombin inhibitors, and aspirin.[21] A combination of Xa inhibitors with direct thrombin inhibitors vs. warfarin compared in four trials out of a previously done review showed that mortality, non-major bleeding, VTE, and VTE-related mortality were different primary outcomes. DVT and PE were additional outcomes.[22-24] Another study compared the VTE rates and VTE-related mortality by comparing warfarin with rivaroxaban, showing no significant variance.[25]

RCT investigated 202 adults administered with warfarin as placebo and 200 with rivaroxaban reported that 43% (N=86) and 40% (N=81) patients had unprovoked Isolated distal DVT, respectively. Rivaroxaban group patients had 11% (N=23) primary efficacy outcome as compared to warfarin 19% (N=39). Recurrent DVTs were seen among 8% (N=16) in Rivaroxaban and 15% (N=31) in warfarin, respectively. The prevalence of PE in rivaroxaban and warfarin was 3% (N=7) and 4% (N=8), respectively. There were null major bleeding cases in both groups [26]

An earlier meta-analysis observed that male patients treated with anticoagulation therapy had a significantly higher risk of major bleeding than females. The major bleeding risk varies with gender. Although rivaroxaban reduces the major bleeding risk, certain studies suggest that intense menstrual bleeding is reported in young female patients.[27,28]

Conclusions

Treatment with Rivaroxaban is preferred over Warfarin due to reduced risk of DVT, major bleeding, and minor bleeding. Further large group studies with long-term follow-up to consider rivaroxaban as the drug of choice for VTE anticoagulation.

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