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# Comparative Study of Efficacy of Rivaroxaban with Warfarin for The Treatment of Deep Vein Thrombosis

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## Abstract

**Introduction:** Deep vein thrombosis (DVT) is a condition characterized by the formation of a blood clot (thrombus) in a deep vein, predominantly in the legs. It is a significant public health issue due to its potential to cause serious complications such as pulmonary embolism, where the clot dislodges and travels to the lungs, potentially leading to fatal outcomes. In India, the incidence of DVT ranges from 8% to 20% in major lower limb surgeries, particularly affecting individuals over 40 years of age[2]. Without timely and effective treatment, DVT can lead to long-term complications, including post-thrombotic syndrome.

**Methodology:** Study was conducted at tertiary Centre of GIMS, Gadag with confirm diagnosis of DVT. After taking written informed consent and ethical committee clearance. After confirmation of DVT by clinical examination, laboratory investigation and Doppler ultrasonography, 100 participants selected via simple random sampling and divided into two groups of 50 each, group A treated with Rivaroxaban, and group B treated with Warfarin, and efficacy of Rivaroxaban with warfarin in therapeutic outcome, side effect of Rivaroxaban with warfarin were compared. All cases followed up to discharge and subsequently for a follow-up period of 3 months on every 3rd week. Statistical analyses were performed using SPSS software.

**Results:** The study demonstrates that Rivaroxaban is associated with a significantly lower recurrence rate(10%) of venous thromboembolism compared to Warfarin(24%) in patients with DVT (p=0.034). The incidence of major bleeding events was lower in the Rivaroxaban group (6%) compared to the Warfarin group (14%), although this difference was not statistically significant (p=0.182). The cost was higher for Rivaroxaban, this difference was statistically significant (p=0.045).

**Conclusion:** Rivaroxaban is a more effective and patient- friendly alternative to Warfarin for the treatment of DVT. The lower chances of bleeding in patients treated with Rivaroxaban highlight its superior therapeutic benefits. Although the initial treatment costs for Rivaroxaban are higher, the overall cost-effectiveness, considering the reduced need for monitoring and fewer complications, makes it a viable option for long-term anticoagulation therapy.

**Keywords:** DVT, Rivaroxaban, Warfarin, Efficacy, Safety

## Introduction

Deep vein thrombosis (DVT) is a condition characterized by the formation of a blood clot (thrombus) in a deep vein, predominantly in the legs. It is a

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significant public health issue due to its potential to cause serious complications such as pulmonary embolism (PE), where the clot dislodges and travels to the lungs, potentially leading to fatal outcomes. It is the third most common cardiovascular disorder worldwide, and its incidence varies based on factors such as age, surgery, trauma, and underlying medical conditions like hormone replacement therapy or contraceptives [1]. In India, the incidence of DVT ranges from 8% to 20% in major lower limb surgeries, particularly affecting individuals over 40 years of age[2]. Without timely and effective treatment, DVT can lead to long-term complications, including post-thrombotic syndrome (PTS). The development of DVT occur due to a combination of factors including venous stasis, endothelial injury, and hypercoagulability, collectively known as Virchow's triad. Its Common symptoms include swelling, pain, and tenderness in the affected limb, often accompanied by redness and warmth and sometime asymptomatic. Diagnosis made by a combination of clinical assessment and imaging studies such as duplex ultrasonography.

Aim of the management of DVT is to prevent thrombus extension, embolization, and recurrence while minimizing the risk of bleeding complications. Anticoagulation has been achieved using low-molecular-weight heparin (LMWH) for initial treatment, followed by oral vitamin K antagonists (VKAs) like warfarin for long-term management. As warfarin requires regular monitoring of the International Normalized Ratio (INR) to ensure therapeutic levels, which can be challenging for patients and healthcare providers due to its narrow therapeutic window and numerous drug and dietary interactions[3].In recent years, direct oral anticoagulants (DOACs) including rivaroxaban, apixaban, edoxaban, and dabigatran, offer fixed dosing regimens without the need for routine INR monitoring, making them more user-friendly. This study findings will help in filling the gap results of other studies and support that which one is preferred treatment in clinical guidelines for DVT management, potentially leading to improved patient outcomes, quality of life and healthcare efficiency.

### Aims and Objectives

Aims of this study are to compare the efficacy of Rivaroxaban with Warfarin in achieving therapeutic outcomes in patients with DVT and to evaluate the side effect profile of Rivaroxaban compared to Warfarin.

### Methodology

This study is a longitudinal study. Participants were recruited from a general surgery department. Simple random sampling with single blinding was done. Ethical approval was obtained from the institutional ethical committee, and informed consent was provided by all participants. Patients aged 18 years or older with confirmed lower limb Deep Vein Thrombosis included and patients with symptomatic peripheral arterial disease, Chronic inflammatory disease, metastatic cancer, Previous history of DVT, or Iliac vein and inferior vena cava involvement were excluded. The study included a total of 100 participants, with 50 participants in group A and 50 participants in group B. Patients in the group A received Rivaroxaban 15 mg twice daily for the first 5 days, followed by 20 mg once daily. Patients in the group B received Warfarin, starting with a dose of 5 mg once daily and injection Enoxaparin 40 microgram subcutaneous twice daily for first 5 days, adjusted based on INR values to maintain a therapeutic range of 2.0 to 3.0. Data was collected through clinical history and physical examination supported by laboratory investigations including complete blood count, blood sugar levels, renal function tests, liver function tests, prothrombin time, international normalized ratio while confirmation of DVT done by Doppler ultrasonography. Patients were followed up at regular intervals to assess treatment outcomes, including the recurrence of VTE, bleeding events, and other adverse effects. Follow-up visits was scheduled at 3 weeks, 6 weeks ,9 weeks and 12 weeks post-treatment initiation. Outcome measurements included clinical assessment, repeat laboratory tests, and imaging studies as necessary to get efficacy of Rivaroxaban with Warfarin in achieving therapeutic outcomes and to evaluate the side effect profile of Rivaroxaban compared to Warfarin.

### Statistical Analysis and Significance

Statistical analyses were performed using SPSS software. Continuous variables were expressed as mean ± standard deviation and compared using the Student's t-test. Categorical variables were expressed as frequencies and percentages and compared using the Chi-squared test. A p-value of less than 0.05 was considered statistically significant.

## Results

The mean age of patients in the group A was 48.1 years, while in the group B it was 47.3 years. The gender distribution was similar in both groups, with a higher number of males.

**Table 1:** Demographic and Baseline Characteristics.

| Characteristic | Group A (n=50) | Group B (n=50) | Total (n=100) |
|---|---|---|---|
| Age (mean ± SD) | 48.1 ± 16.5 | 47.3 ± 15.3 | 47.7 ± 15.9 |
| Gender (Male/female) | 30/20 | 35/15 | 65/35 |

The primary outcome measured was the recurrence of venous thromboembolism (VTE). The results are summarized in Table 2. The recurrence rate of VTE was significantly lower in the group A (10%) compared to the group B (24%) (p=0.034). The side effects and complications associated with each treatment are summarized in Table 2. The incidence of major bleeding events was lower in the group A (6%)

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compared to the group B (14%), although this difference was not statistically significant (p=0.182). While the group A experienced fewer minor bleeding events compared to the group B, these differences were not statistically significant. Gastrointestinal issues were also slightly lower in the group A. The total treatment costs were analyzed to determine the cost-effectiveness of Rivaroxaban compared to Warfarin. The results are summarized in **Table 2**. Average cost of Tab Rivaroxaban 15mg is 19.10 Rs. As patients have taken Tab Rivaroxaban 15mg BD for 1st 5 days. Average cost of Tab Rivaroxaban 20mg is 29 Rs. From day 6 to 3 months patients have taken Tab Rivaroxaban 20mg OD. The mean total treatment cost for patients in the group A was Rs.132800. Average cost of Injection Enoxaparin 40mcg is 40 Rs. As, patients have taken Inj. enoxaparin 40mcg. Average cost of Tab. Warfarin 5mg is 3 Rs, As patients have taken Tab. Warfarin 5mg OD for 90 days. Average Cost of single PT INR is 330 Rs Minimum 5 PT INR test is required for a patient for monitoring. The mean total treatment cost for patients for the Warfarin group it was Rs.116200. The cost was higher for Rivaroxaban, this difference was statistically significant (p=0.045).

**Table 2:** Comparison of Therapeutic Outcomes Between Rivaroxaban and Warfarin, Side Effects and Complications and Cost-Effectiveness Analysis

| | Group A (n=50) | Group B (n=50) | p-value |
|---|---|---|---|
| **Outcome** | | | |
| VTE | 5 | 12 | 0.034 |
| **Side Effect/Complication** | | | |
| Major Bleeding Event | 3 | 7 | 0.182 |
| Minor Bleeding Event | 8 | 15 | 0.105 |
| Gastrointestinal Issues | 5 | 9 | 0.248 |
| **Cost Parameter** | | | |
| Total Treatment Cost (Rs.) | 132800 ± 2850 | 116200 ± 3950 | 0.045* |

## Discussion

This study is a longitudinal study, included a total of 100 participants, with 50 participants in group A and 50 participants in group B. The study demonstrates that the recurrence rate of VTE was significantly lower in the group A (10%) compared to the group B (24%) (p=0.034). The findings of this study are consistent with existing literature. Bauersachs et al. (2010) reported that Rivaroxaban was as effective as Warfarin in preventing recurrent VTE with a comparable safety profile. The incidence of major bleeding events, although lower in the group A, was not statistically significant (p=0.182). The lower incidence of major bleeding events observed in this study aligns with the findings of previous research of Schulman et al ,which indicates that Rivaroxaban has a favorable safety profile compared to Warfarin [5]. The total treatment costs were higher for Rivaroxaban, but this was offset by its superior efficacy and patient satisfaction, suggesting long-term cost-effectiveness. Furthermore, studies by Deitelzweig et al. (2017) and Laliberte et al. (2014) have highlighted the economic benefits of Rivaroxaban, noting lower healthcare resource utilization and overall treatment costs, despite its higher per-dose cost. These findings support the growing preference for DOACs in the management of DVT and highlight the need for a holistic approach to anticoagulant therapy that considers both clinical efficacy and patient-centered outcomes. As the evidence base for DOACs continues to grow, Rivaroxaban is likely to become an increasingly important tool in the prevention and treatment of thrombotic disorders, offering a more effective and patient-friendly alternative to traditional anticoagulant therapies.

The findings of this study are consistent with existing literature, reaffirming the efficacy, safety, and economic benefits of Rivaroxaban compared to Warfarin in the treatment of DVT and prevention of VTE. The lower recurrence rate of VTE and favorable safety profile of Rivaroxaban make it a superior choice for many patients. These advantages, coupled with the economic benefits of reduced healthcare resource utilization, support the growing preference for Rivaroxaban in clinical practice. As the evidence base for DOACs continues to expand, Rivaroxaban is likely to play an increasingly important role in the management of thrombotic disorders, offering a more effective and patient- friendly alternative to traditional anticoagulant therapies.

## Conclusion

This study is a longitudinal study, included a total of 100 participants, with 50 participants in group A and 50 participants in group B .This study demonstrates that Rivaroxaban is a superior alternative to Warfarin for the treatment of DVT, offering significant benefits in terms of lower recurrence rates of VTE, higher patient satisfaction, and improved quality of life. The reduced need for monitoring and fixed dosing regimen make Rivaroxaban a more convenient and patient-friendly option. These findings support the inclusion of Rivaroxaban as a preferred treatment in clinical guidelines for DVT management, potentially leading to improved patient outcomes and healthcare efficiency. The comprehensive benefits of Rivaroxaban, including its efficacy, safety, convenience, and cost-effectiveness, position it as a valuable option in the management of DVT, aligning with the goals of providing high-quality, patient-centered care in clinical practice. As more evidence emerges, Rivaroxaban's role in anticoagulation therapy is likely to continue expanding, offering a robust alternative to traditional therapies like Warfarin and enhancing the standard of care for patients with DVT.

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