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Research Article

A COMPARATIVE STUDY OF ASPIRIN AND RIVAROXABAN FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS AFTER TOTAL JOINT ARTHROPLASTY

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Abstract

Introduction: Patients undergoing major orthopedic surgery, such as total knee arthroplasty (TKA), total hip arthroplasty (TKA), and hip fracture surgery (HFS), are at an elevated risk of developing venous thromboembolism (VTE). VTE is a serious condition that can result in deep vein thrombosis (DVT), where blood clots form in the deep veins of the body particularly in the legs, or pulmonary embolism (PE), where a blood clot travels to the lungs and blocks the blood flow.

Materials and methods: This study was conducted among the inpatients at the Department of Orthopaedics at MIMS hospital, Nellimarla, Vizianagaram for 18 months (June 2023 – December 2024). 50 Patients who have undergone either THA or TKA and were given Aspirin or Riviroxaban during the period from June 2023 to December 2024 were included in the study. Between the two groups, randomization was performed. In the study, block randomization was used by generating random sequential blocks. These blocks consisted of a sequence like BABABA. Alternatively, participants enrolled in the study were allocated to either the B (Rivaroxaban) group or the A (Aspirin) group to achieve allocation concealment.

Results: The age of patients in our study ranges from 45 to 69 years. In our study number of females were more than males. Males are 21, Females are 29. Among 50 patients, 32 underwent Total Knee Replacement and 18 underwent Total Hip Replacement. The mean age in our study was 56.22 years. Females out number males in the ratio 29:21. Majority of the surgeries were Total Knee Replacement.

BMI of the patients range from 21.0 to 33.7 and the average was 25. Bleeding time ranges from 1 minute 46 seconds to 5minutes 58 seconds. The average bleeding time was 3 minutes 53 seconds. Clotting time ranges from 3 minutes 13 seconds to 7 minutes 59 seconds. The average clotting time was 5 minutes 52 seconds. Platelet count of the patients ranges from 1.4 lakh to 3.9 lakh. The average platelet count was 2.8 lakhs. All the Total Hip Arthroplasties were Uncemented and all the Total Knee Arthroplasties were Cemented.

Conclusion: It was observed that aspirin was not significantly different from the direct oral anticoagulant rivaroxaban in preventing symptomatic and clinically important events such as proximal deep-vein thrombosis or pulmonary embolism after total hip or knee replacement surgery. Both drugs are effective in preventing deep vein thrombosis (DVT), pulmonary embolism (PE), major bleeding, and clinically significant minor bleeding. However, aspirin, an inexpensive and prominently available generic drug, was as effective as rivaroxaban, a more expensive direct oral anticoagulant, in preventing venous thromboembolism following these surgeries.

Key Words: total knee arthroplasty, hip fracture surgery, deep vein thrombosis, Rivaroxaban, aspirin.

INTRODUCTION

Patients undergoing major orthopedic surgery, such as total knee arthroplasty (TKA), total hip arthroplasty (TKA), and hip fracture surgery (HFS), are at an elevated risk of developing venous thromboembolism (VTE). VTE is a serious condition that can result in deep vein thrombosis (DVT), where blood clots form in the deep veins of the body particularly in the legs, or pulmonary embolism (PE), where a blood clot travels to the lungs and blocks the blood flow.[1]

Without an effective thrombosis prevention, post-operative thrombosis rates for the Total-Hip Arthroplasty and Total-Knee Arthroplasty can be 42%–57% and 40%–80%, respectively. Additionally, risk of life-threatening pulmonary embolism (PE) can be up to 2%. In recent times, there has been a significant increase in the number of elective hip and knee arthroplasty procedures performed worldwide. There's been a growing trend of surgeries, especially joint-replacement in India, particularly for knee arthroplasty, with figures nearing 2,00,000 in 2020 and the hip arthroplasties are projected to experience the most rapid growth globally between 2020–2026.[2]

With the increasing trend of arthroplasty surgeries, it is vital to implement effective perioperative prophylaxis to prevent thromboembolism, a serious complication that can occur after these procedures. Evidence-based summaries are essential for informing the choice of appropriate preventive measures, ensuring patient safety and optimizing outcomes.[3]

As per the current guidelines, Patients who are undergoing major Orthopedic surgeries should be administered a Prophylaxis against thromboembolism for at least 10 to 14 days. This duration is based on the increased risk of blood clots forming during the post-operative period, particularly in the first two

weeks after surgery. But it is the factors like type of surgery, the patient's overall health and the specific risk factors for thromboembolism which dictates the exact duration of prophylaxis.[4]

Most used drugs for VTE prevention include rivaroxaban and other direct oral anticoagulants (DOACs), heparin-based agents, Coumarin derivatives like wafarin, and aspirin. While these drugs have demonstrated efficacy in preventing VTE, there are notable differences in their bleeding risk profiles.[5]

AIMS AND OBJECTIVES

To observe and compare the effectiveness of aspirin versus rivaroxaban in preventing venous thromboembolism following total knee or hip replacement surgery

MATERIALS AND METHODS

STUDY SITE: This study was conducted among the inpatients at the Department of Orthopaedics at MIMS hospital, Nellimarla, Vizianagaram.

STUDY DESIGN: Randomized prospective observational study.

STUDY POPULATION: This study involves both male and female patients who underwent TKA or THA in MIMS General Hospital Nellimarla.

DURATION OF STUDY: 18 months (June 2023 – December 2024)

SAMPLE SIZE: 50 Patients who have undergone either THA or TKA and were given Aspirin or Riviroxaban during the period from June 2023 to December 2024 were included in the study.

INCLUSION CRITERIA

1. Patients who have undergone Unilateral or staged bilateral total knee or hip arthroplasty.

2. Aged 20-80 years, male and female.

3. If the patient is an aspirin user should stop using for at least more than one week.

4. Patients with previous informed consent.

EXCLUSION CRITERIA

1. Patients who use aspirin for tertiary prevention or double antiplatelet therapy, including acute coronary syndrome in past 3 months, post –operation of PCI or cardiac valve replacement.

2. Patient with high risk of VTE, including previous VTE history, malignant tumor, hypercoagulable state, other known states that easily lead to thrombosis and undergoing anticoagulation.

3. Patient with other severe disease in heart, brain, lung, kidney or blood.

4. Patient with coagulation dysfunction, trend of hemorrhage or has active hemorrhage before operation.

OPERATIONAL DEFINITION: Venous thromboembolism (VTE) is a clinical condition characterized by the formation of a blood clot (thrombus) in a deep vein, typically in the legs or pelvis. This clot can dislodge and travel to the lungs, causing a pulmonary embolism (PE).

SAMPLE SIZE: For the study, a total of 50 participants are taken. 25 participants are included in control group and 25 participants are included in interventional group.

SAMPLING TECHNIQUE: Between the two groups, randomization was performed. In the study, block randomization was used by generating random sequential blocks. These blocks consisted of a sequence like BABABA. Alternatively, participants enrolled in the study were allocated to either the B (Rivaroxaban) group or the A (Aspirin) group to achieve allocation concealment.

RESULTS

Age Distribution

The age of patients in our study ranges from 45 to 69 years.

Age group	No. of patients	Percentage %
45-50	6	12
51-55	18	36
56-60	13	26
61-65	10	20

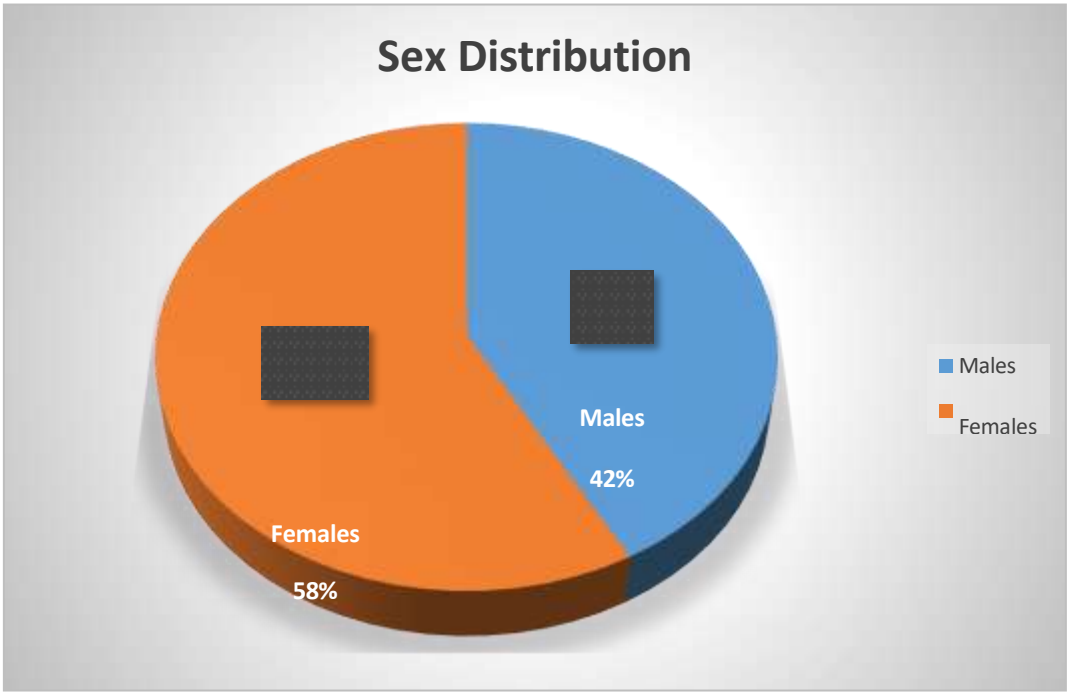
66-70	3	6

Sex Distribution

In our study number of females were more than males.

Males: 21

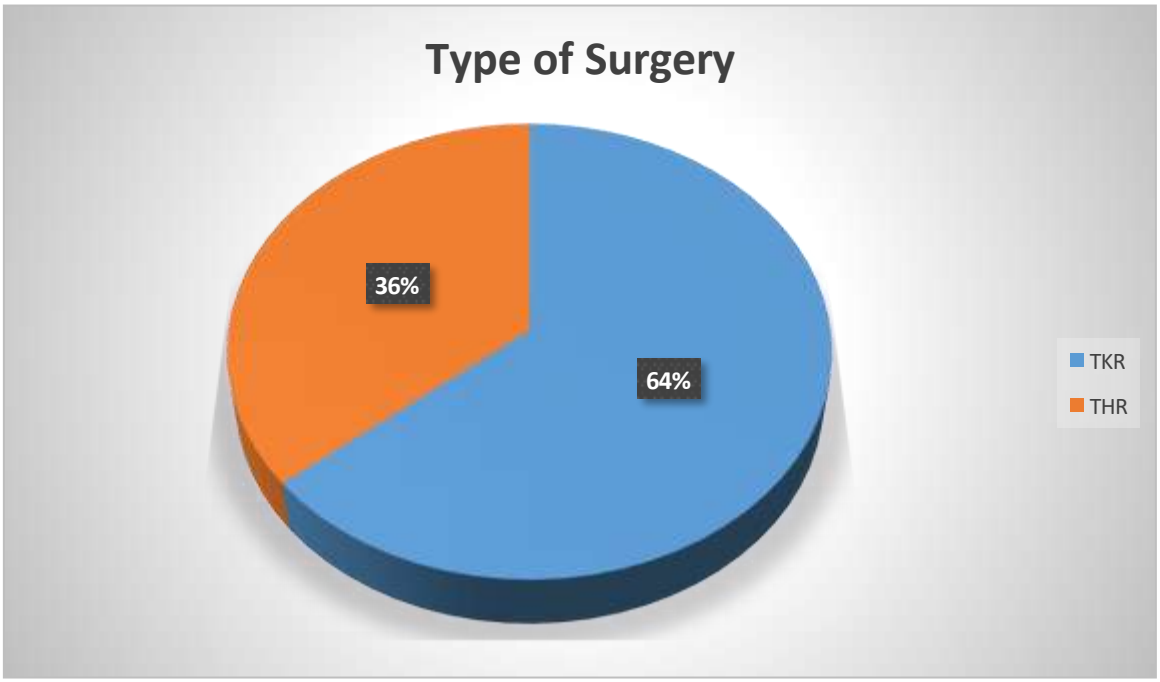
Females: 29



Type of Surgery

Among 50 patients, 32 underwent Total Knee Replacement and 18 underwent Total Hip Replacement.

Type of Surgery	No. of patients	Percentage
Total Knee Replacement	32	64
Total Hip Replacement	18	36

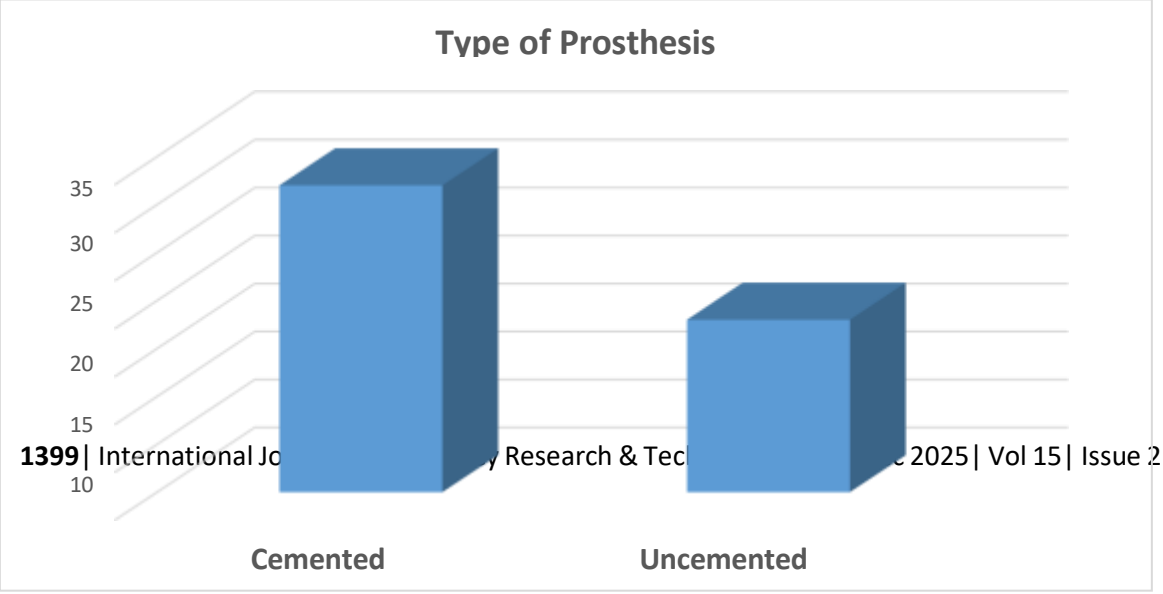


- The mean age in our study was 56.22 years.
- Females out number males in the ratio 29:21.
- Majority of the surgeries were Total Knee Replacement.
- BMI of the patients range from 21.0 to 33.7 and the average was 25.
- Bleeding time ranges from 1 minute 46 seconds to 5minutes 58 seconds. The average bleeding time was 3 minutes 53 seconds.
- Clotting time ranges from 3 minutes 13 seconds to 7 minutes 59 seconds. The average clotting time was 5 minutes 52 seconds.
- Platelet count of the patients ranges from 1.4 lakh to 3.9 lakh. The average platelet count was 2.8 lakhs.
- All the Total Hip Arthroplasties were Uncemented and all the Total Knee Arthroplasties were Cemented.

Types of Prosthesis

Both cemented and uncemented prosthesis were included in the study.

Type of Prosthesis	No. of Patients	Percentage
Cemented	32	64
Uncemented	18	36



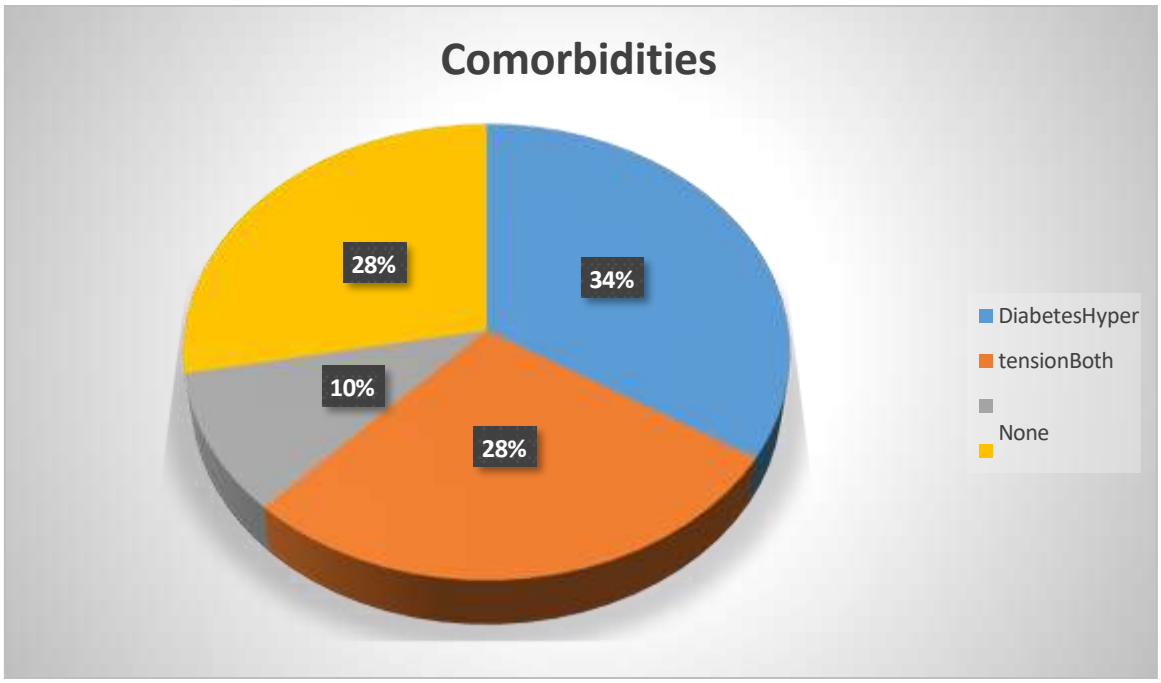
COMORBIDITIES

Among the 50 patients, 36 patients had comorbidities

a. 17 Patients had Diabetes

b. 14 patients had Hypertension

c. 5 patients had both Diabetes and Hypertension



Age in years Vs Drug Used

Age in years	Drug Used		Total
	Aspirin	Rivaroxaban	
45-50	3	3	6
51-55	10	9	19
56-60	8	4	12
61-65	3	7	10
65-70	1	2	3
Total	25	25	50

The highest number of patients (19) falls within the 51-55 age range. The 45-50 and 61-65 age groups account for 6 patients and 10 patients each. In the age group of 56-60 there are12 patients. In65-70 age group there are 3 patients.

Sex Vs Drug used

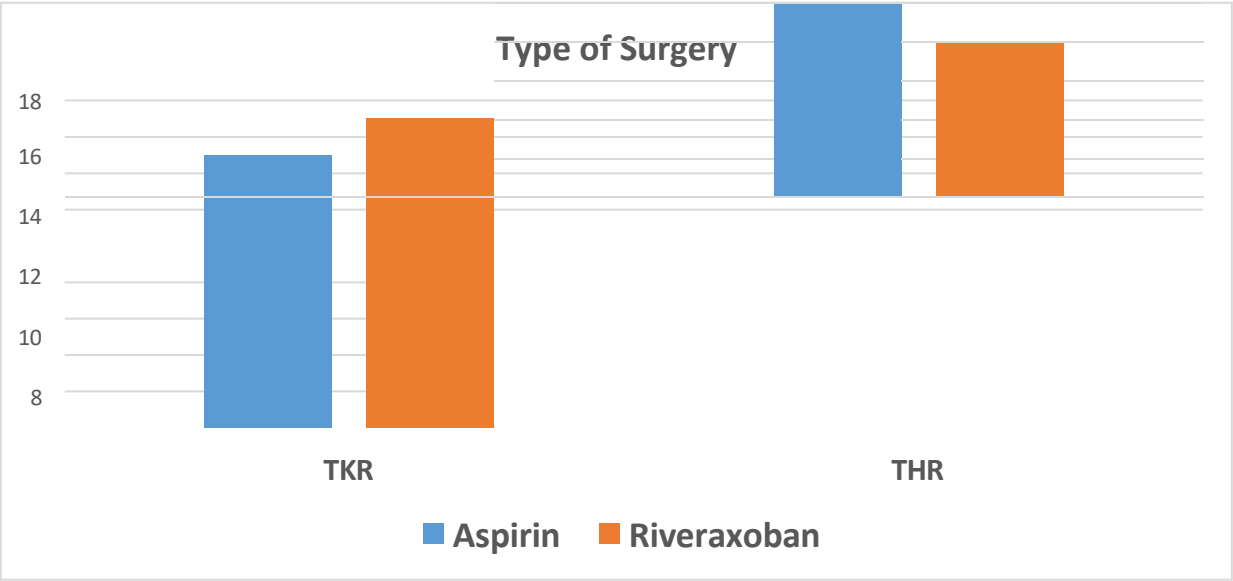
Sex			Drug Used		Total
			Aspirin	Rivaroxaban	
1	Male	Count	10	11	21
2	Female	Count	15	14	29
Total		Count	25	25	50

In this study Females out number the Males in the ratio 29:21.

Type of Surgery Vs Drug Used

Type of Surgery	**Drug Used**		**Total**
	Aspirin	**Rivaroxaban**	

TKR	15	17	32
THR	10	8	18
Total	25	25	50



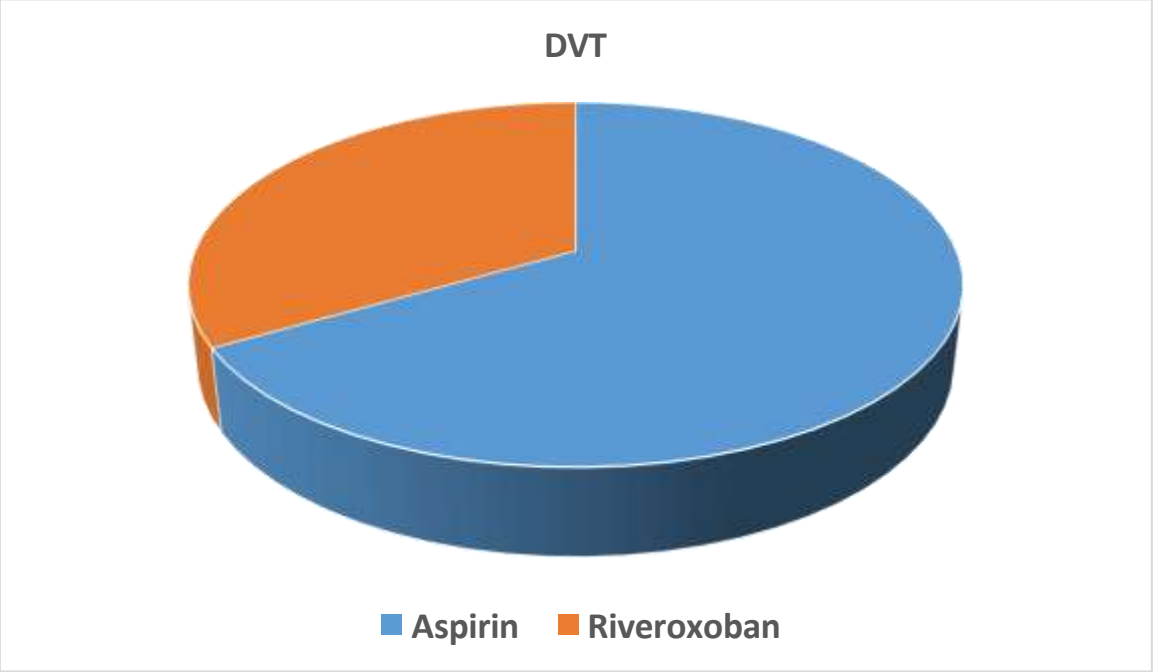
Total Knee Replacement (TKR) surgeries account for the majority, with 32 cases. Total Hip Replacement (THR) surgeries represent 18 cases. This distribution highlights that TKR surgeries are more frequent than THR surgeries

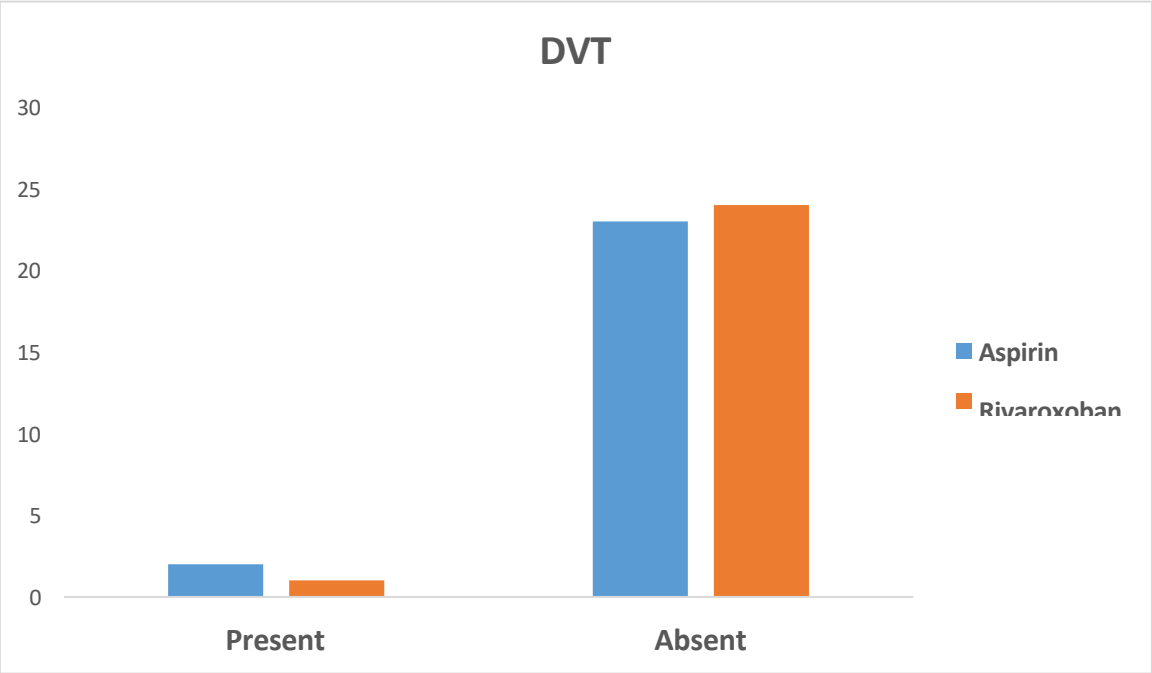
Primary Outcomes Observed

DVT Vs Drug Used

DVT	Drug Used		Total	P value
	Aspirin	Rivaroxaban		
Present	2	1	3	0.551
Absent	23	24	47	
Total	25	25	50	

The P value using Chi-square test of Independence is >0.05. It is statistically insignificant.


DVT
Aspirin
Riveroxoban



In this study DVT was seen in three patients, two from Aspirin Group and one from Rivaroxaban group. In contrast, within the set of 47 patients who did not develop DVT, the distribution of anticoagulants was nearly equal, with 23 receiving Aspirin and 24 receiving Rivaroxaban. Statistical analysis, however, did not demonstrate a significant association between the occurrence of DVT and the specific anticoagulant chosen ($p = 0.551$).

Pulmonary Embolism VS Drug Used

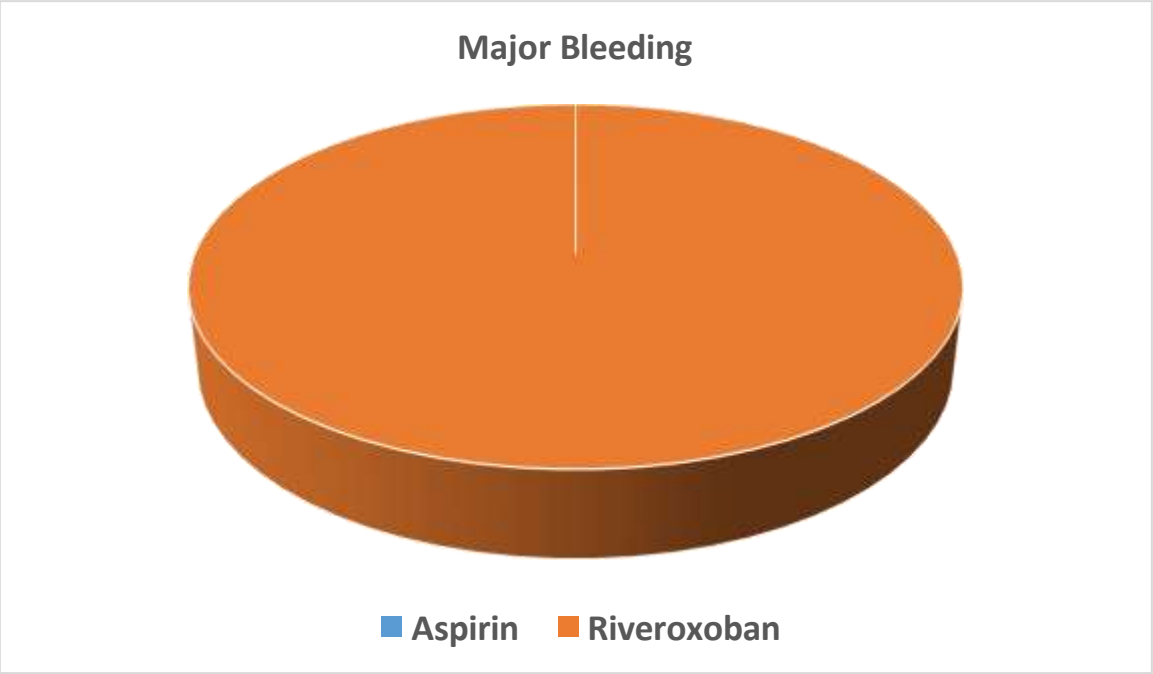
No patients in either the Aspirin or Rivaroxaban groups developed pulmonaryembolism (PE). Among the 50 patients who have not develop PE, the anticoagulant distribution was perfectly balanced: 25 received Aspirin, and 25 received Rivaroxaban. This indicates no observed association between either Aspirin or Rivaroxaban and the occurrence of PE within this study population. A Chi-squared test would be inappropriate here because there are zero counts in one of the categories. Fisher's exact test could be used, but is also uninformative, because there is no observed PE in either group. Therefore, this data shows no variation in PE incidence among the two anticoagulants, within this study.

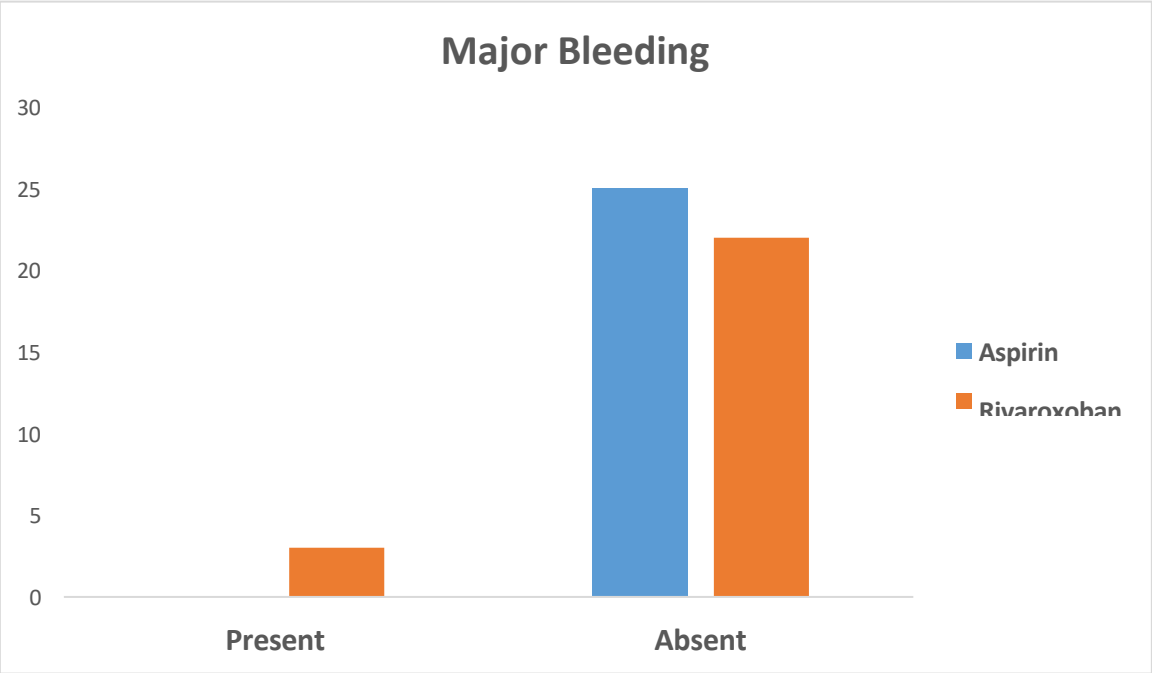
Major Bleeding Vs Drug Used

Major Bleeding	Drug Used		Total	P value
	Aspirin	Rivaroxaban		
Present	0	3	3	

Absent	25	22	47	0.074
Total	25	25	50	

The P value using Chi-square test of Independence is >0.05. It is statistically insignificant.



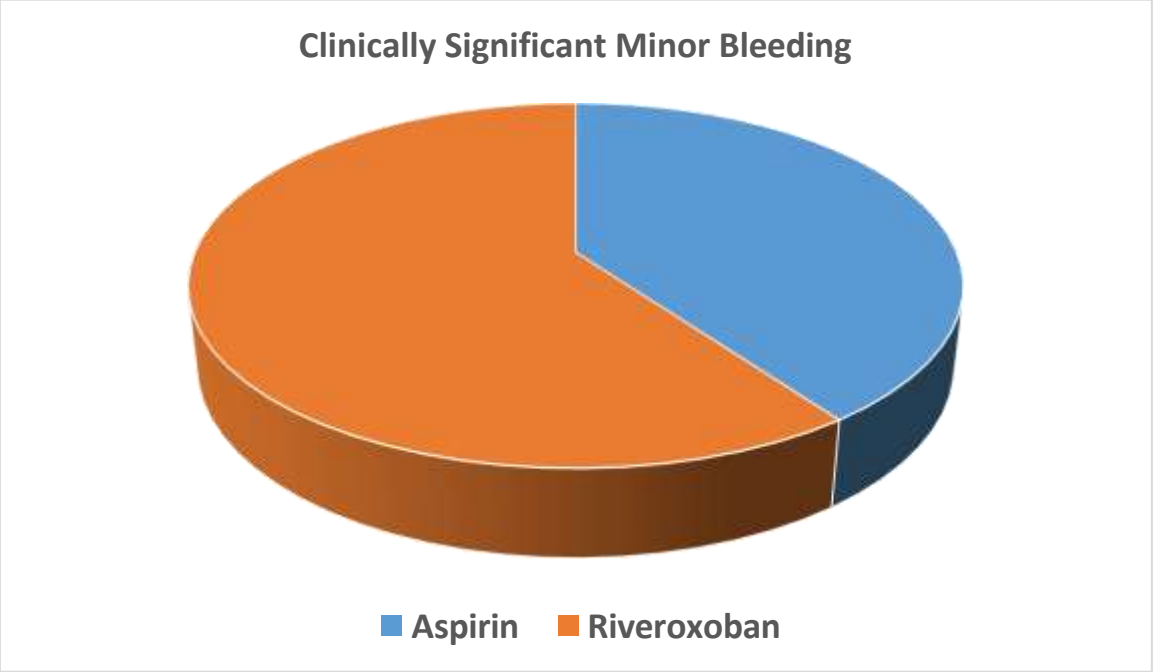


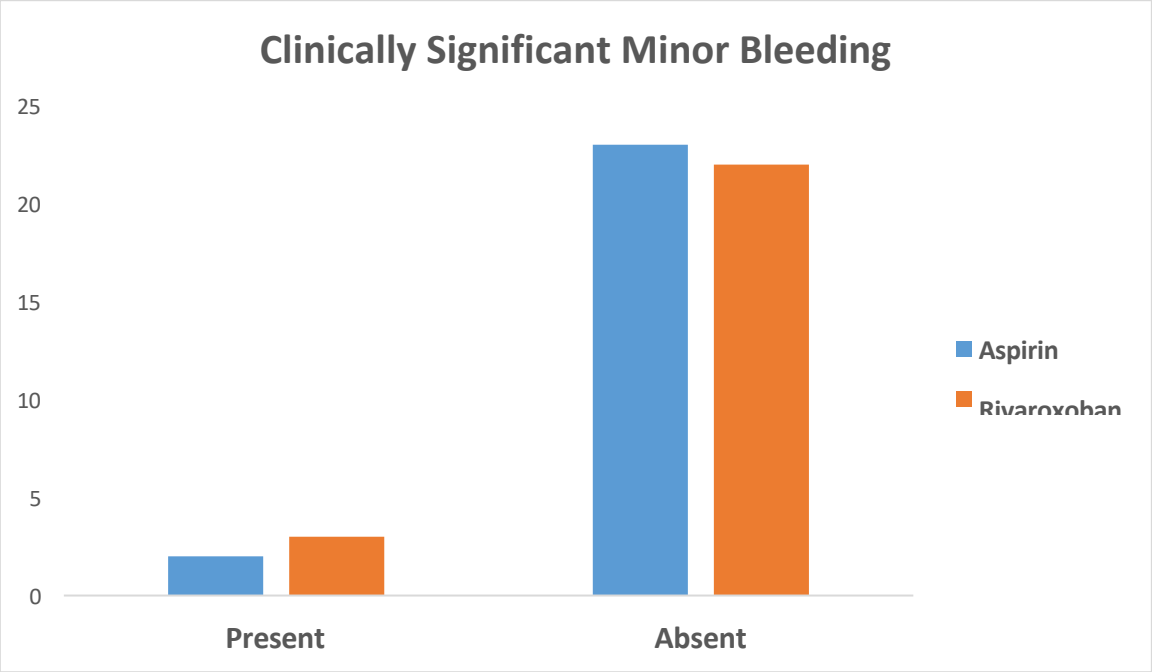
Major Bleeding was reported in 3 cases, all of which involved Rivaroxaban, while no such complications were observed in the Aspirin group. Among the 47 cases without Major Bleeding, Aspirin was used in 25 instances, and Rivaroxaban in 22. The p-value of 0.074 indicates a statistical insignificance, indicating no major association between Major Bleeding and the choice of drug.

Clinically Significant Minor Bleeding Vs Drug Used

Clinically Significant Minor Bleeding	Drug Used		Total	P value
	Aspirin	Rivaroxaban		
Present	2	3	5	0.637
Absent	23	22	45	
Total	25	25	50	

The P value using Chi-square test of Independence is>0.05. It is statistically insignificant.


Clinically Significant Minor Bleeding
Aspirin
Riveroxoban

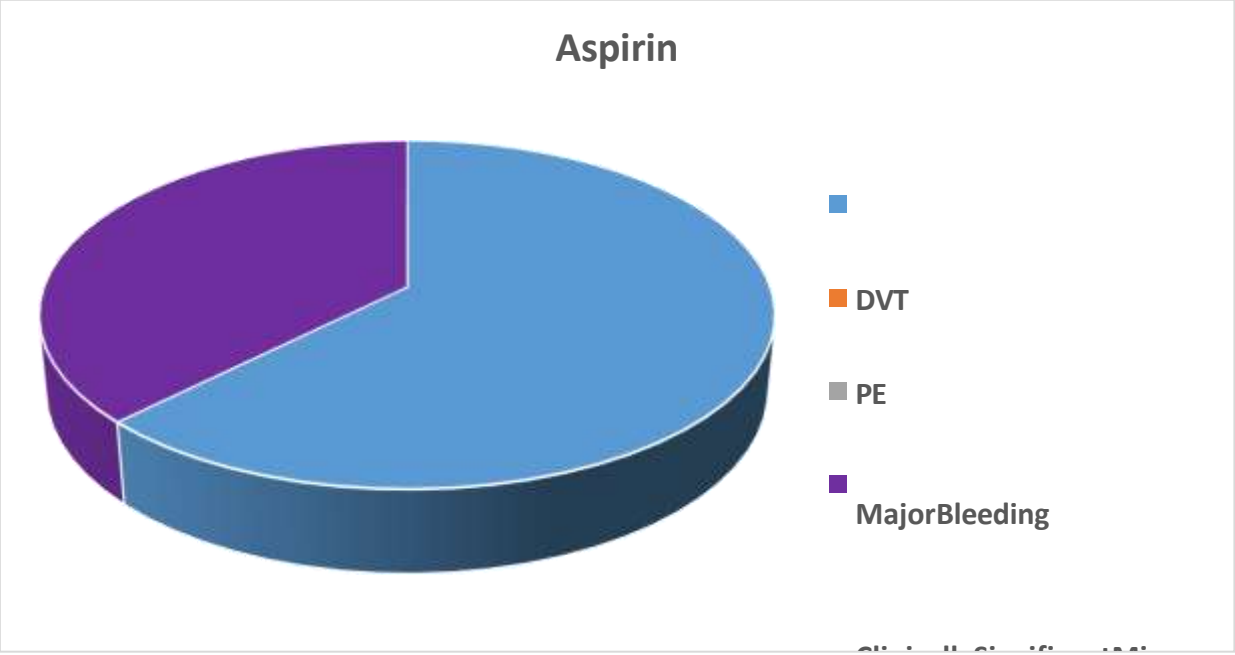


Clinically significant minor bleeding was reported in 5 cases, with 2 instances occurring in the Aspirin group and 3 in the Rivaroxaban group. Among the 45 cases without Clinically Significant Minor Bleeding, 23 involved Aspirin, and 22 involved Rivaroxaban. The p-value of 0.637 suggests that between the two drugs there is no statistically significant difference in terms of the occurrence of Clinically Significant Minor Bleeding.

AGE WISE COMPLICATIONS

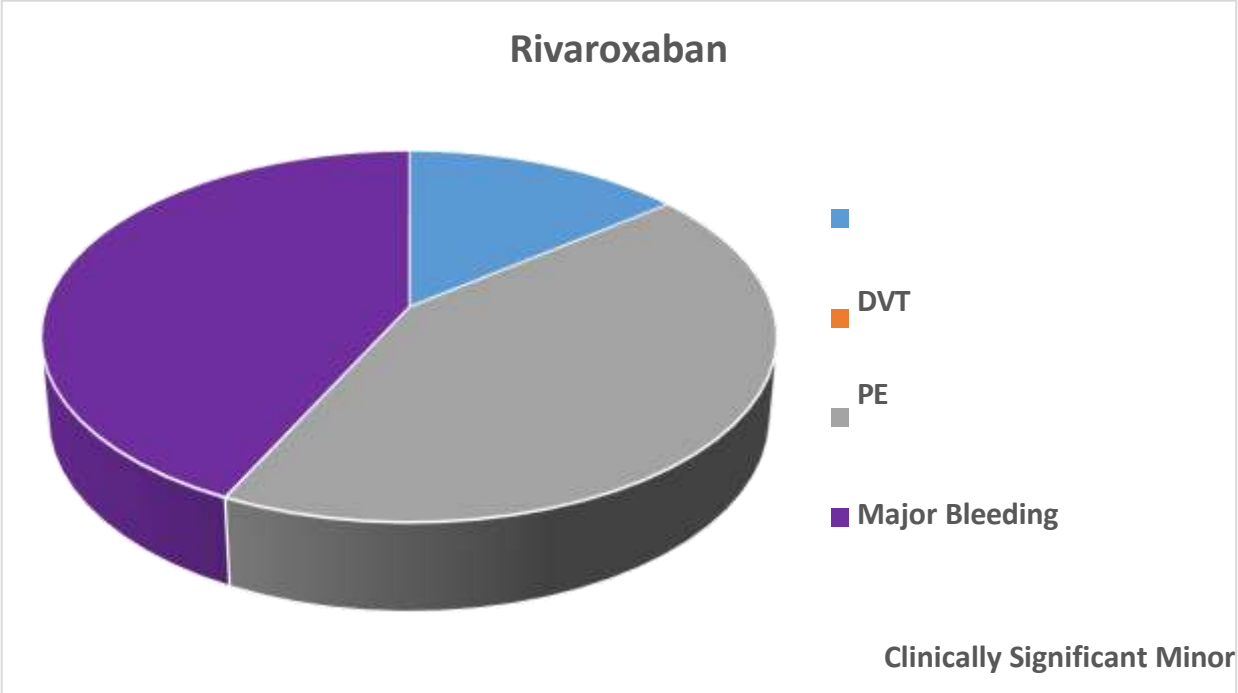
i. **Aspirin Group**

S.No.	Age Group	No. of Patients	Complications			
			DVT	PE	Major Bleeding	Clinically Significant Minor Bleeding
1	45-50	3	1	-	-	-
2	51-55	10	-	-	-	2
3	56-60	8	1	-	-	-
4	61-65	3	-	-	-	-
5	66-70	1	-	-	-	-


Aspirin
DVT
PE
MajorBleeding

ii. Rivaroxaban Group

S.No.	Age Group	No.of Patients	Complications			
			DVT	PE	Major Bleeding	Clinically Significant Minor Bleeding
1	45-50	3	1	-	1	-
2	51-55	9	-	-	1	1
3	56-60	4	-	-	1	-
4	61-65	7	-	-	-	2
5	66-70	2	-	-	-	-



Among the Aspirin Group, 2 patients had DVT, 0 patients had PE, 0 patients had Major bleeding and 2 patients had Clinically significant minor bleeding.

Among Rivaroxaban Group, 1 patient had DVT, 0 patients had PE, 3 patients had Major bleeding and 3 patients had Clinically significant minor bleeding.

DISCUSSION

The study included 50 participants with an average age of 56.22 years. Of these, 58% (29 participants) were female and 42% (21 participants) were male. The gender distribution showed 60% females (15 out of 25) in the aspirin group and 56% females (14 out of 25) in the rivaroxaban group. These findings contrast with David R. Anderson et al.'s study, which reported older participants (mean age 62.8 years) and a slightly lower proportion of females (52.2%).[6]

During the six months follow-up study DVT was observed in 3 (6%) patients. Two (8%) in Aspirin group and one (4%) in Rivaroxaban group. The P value using Chi-square test of Independence is >0.05 (p=0.551). It is statistically insignificant and demonstrate that there is no significant association between the occurrence of DVT and the specific anticoagulant chosen. In the study conducted by David R. Anderson et al., During the 90-day follow-up, blood clot complications occurred in 0.64% of patients (11 out of 1707) taking aspirin and 0.70% (12 out of 1717) taking rivaroxaban. Statistical analysis showed aspirin performed similarly to rivaroxaban in preventing serious postsurgical clots (P<0.001 for noninferiority), though it wasn't significantly better (P=0.84).[7]

In this study there are no incidents of PE. In David R. Anderson et al.'s study, one fatal pulmonary embolism occurred in the aspirin group. The patient had undergone the total knee replacement and died 31 days after Randomization 17 days after stopping aspirin prophylaxis.[8]

In this study Major Bleeding was reported in 3 (6%) cases, all of which involved Rivaroxaban, while no such complications were observed in the Aspirin group. Among the 47 cases without Major Bleeding, Aspirin was used in 25 instances, and Rivaroxaban in 22. The p-value of 0.074 indicates a statistical insignificance (p>0.05), indicating no significant association between Major Bleeding and the choice of drug. In the study conducted by David R. Anderson et al., The incidence of major bleeding was slightly higher in the aspirin group, occurring in 8 patients (0.47%), compared to 5 patients (0.29%) in the rivaroxaban group. Both treatment regimens demonstrated relatively low rates of significant bleeding complications during the study period.[9]

In this study Clinically significant minor bleeding was reported in 5 (10%) cases, with 2 (8%) instances occurring in the Aspirin group and 3 (12%) in the Rivaroxaban group. Among the 45 cases without Clinically Significant Minor Bleeding, 23 involved Aspirin, and 22 involved Rivaroxaban. The p value of 0.637 (p>0.05) suggests no statistically significant difference between the two drugs in terms of the occurrence of Clinically Significant Minor Bleeding. In the study conducted by David R. Anderson et al., The study found that combined major and

clinically relevant nonmajor bleeding events affected 1.29% of patients (22 cases) in the aspirin group, compared to 0.99% (17 cases) in the rivaroxaban group. This difference represents a slightly higher bleeding risk associated with aspirin therapy in this patient population.[10]

In a similar study conducted by Yi Ren, Shi-Liang Cao et al., including 70 patients, 34 were allocated to receive aspirin prophylaxis and 36 were allocated to receive rivaroxaban prophylaxis. They reported no cases of symptomatic VTE. The DVT rate on Doppler ultrasonography in the aspirin group was not significantly different from that in the rivaroxaban group.

When comparison is made between both the groups, our study shows Both aspirin and rivaroxaban showed comparable effectiveness in preventing blood clots following total hip or knee replacement surgery. These findings align with the study by David R. Anderson et al., which found no significant difference between aspirin and rivaroxaban in preventing serious clotting events, such as deep-vein thrombosis or pulmonary embolism, after these procedures.

In our study, the sample size was smaller compared to the study conducted by David R. Anderson et al., with 50 and 3424 participants, respectively. This discrepancy may explain the higher percentage of occurrences of DVT, major bleeding, and clinically significant minor bleeding events in our cohort. Nevertheless, our findings demonstrate that there are no significant variations in the efficacy of Aspirin and Rivaroxaban for Venous Thromboembolism prophylaxis following Total Joint Arthroplasty. Further research with larger, randomized sample sizes is needed to strengthen and expand this body of evidence.

CONCLUSION

It was observed that aspirin was not significantly different from the direct oral anticoagulant rivaroxaban in preventing symptomatic and clinically important events such as proximal deep-vein thrombosis or pulmonary embolism after total hip or knee replacement surgery. Both drugs are effective in preventing deep vein thrombosis (DVT), pulmonary embolism (PE), major bleeding, and clinically significant minor bleeding. However, aspirin, an inexpensive and prominently available generic drug, was as effective as rivaroxaban, a more expensive direct oral anticoagulant, in preventing venous thromboembolism following these surgeries.

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