

Original research article

A prospective study of pharmacological prophylaxis for venous thromboembolism in arthroplasty and hip fracture surgeries

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Abstract

Introduction: Orthopaedic surgeries like Total Knee Replacement (TKR), Total Hip Replacement (THR) and surgery of hip fractures are some of the commonly performed procedures. However, patients undergoing major elective orthopaedic surgery are in the highest risk category for thromboembolism (VTE).

Material and Methods: A prospective open label clinical trial titled, “pharmacological prophylaxis for venous thromboembolism in arthroplasty and hip fracture surgeries” was conducted in the Department of Orthopaedics, in a tertiary hospital, Mangalore between July 2021 and July 2022.

Observation and Result: The data was entered and was analyzed for descriptive statistics. Data in the form of percentage and frequency distribution will be presented in the form of tables and graphs.

Summary and Conclusion: Venous thrombo embolism (VTE), which consists of deep vein thrombosis (DVT) and pulmonary embolism, is a potentially fatal disease. Studies reported in Asian population have reported a consistent lower incidence of VTE than Western population, though the incidence of VTE had increased among Asian population.

Keywords: DVT, PE, THR, TKR, HRA

Introduction

Orthopaedic surgeries like Total Knee Replacement (TKR), Total Hip Replacement (THR) and surgery of hip fractures are some of the commonly performed procedures. However, patients undergoing major elective orthopaedic surgery are in the highest risk category for thromboembolism (VTE) ^[1]. Venous thromboembolism (VTE), which comprises deep vein thrombosis (DVT) and pulmonary embolism (PE), is a common cause of morbidity and mortality in hip fracture patients ^[2]. Patients undergoing total hip and knee arthroplasty are also at high risk for VTE ^[3].

The triad of venous stasis, hyper coagulability and endothelial injury is associated with thrombus formation. DVT usually starts in the calf veins, from where it may extend to the proximal veins and subsequently break free to cause PE. The development of symptoms depends on the extent of thrombosis, the adequacy of collateral vessels and the severity of associated vascular occlusion and inflammation. The significance of DVT lies in its ability to cause pulmonary thrombo embolism, especially in cases of proximal DVT, and also chronic venous insufficiency at later stages. Calf thrombi (distal thrombosis) carry a low risk of embolisation and chronic venous insufficiency; however, without prophylaxis, they are more likely to propagate proximally, which substantially increases the risk of pulmonary thrombo embolism. Each of these stages of VTE (e.g., calf DVT, proximal DVT, PE) may or may not be associated with symptoms ^[4].

In patients undergoing total hip (THR) or total knee replacement (TKR) or repair of a fracture of the hip, asymptomatic venographic DVT occurs in 40% to 60% of cases without prophylaxis, and symptomatic venous thromboembolism, including fatal pulmonary embolism, in up to 5%. The incidence of VTE in patients who underwent arthroplasty and major hip fracture surgeries was 13.1% and 18.1% respectively among a cohort of Japanese patients ^[1]. In addition results from a retrospective study conducted in the United Kingdom (UK) ^[5] and data from FAITH and HEALTH trials (Canada, United Kingdom, Netherlands, Norway and USA) reported an incidence of 2.25% and 2.5% for symptomatic VTE

respectively [6].

Aim and Objectives of the Study

- To find out the efficacy of Pharmacological Prophylaxis against VTE (Venous thrombo- embolism) in arthroplasty and hip fracture surgeries.
- To find out the occurrence of VTE (Venous thrombo-embolism) despite of prophylaxis in arthroplasty and hip fracture surgeries.

Material and Methods

Study Design and Study Setting

A prospective open label clinical trial titled, “pharmacological prophylaxis for venous thromboembolism in arthroplasty and hip fracture surgeries” was conducted in the Department of Orthopaedics, in a tertiary Hospital, Mangalore between July 2021 and July 2022. The ethical clearance was obtained from the Institutional Ethical Committee and a prior consent was obtained from patients before enrolling the patients as study participants.

Sample Size and Study Participants

The sample size was calculated based on alpha error of 11% and a prevalence of 43.2% from a previous study. The total sample size computed was 78 patients. All patients who reported to the department on Mondays, Wednesdays and Fridays for Total Hip Replacement, Total Knee Replacement and Hip surgeries formed the sampling frame. The nature of the study was explained to these patients and included as study participants only after providing the informed consent subject to inclusion and exclusion criteria.

Inclusion Criteria

- Patients who provided the consent.
- All patients undergoing for Total Hip Replacement, Total Knee Replacement and Hip fracture surgeries in our institution.

Exclusion Criteria

- Those not willing to be a part of the study.
- Patients who have got pre-operative venous thrombo-embolism.
- Pregnant Women Patients with GFR-30ml/min; Cirrhosis of liver and thrombocytopenia.
- Patients with existing risk factors that may predispose to thromboembolism (e.g., history of smoking, alcohol consumption, chronic venous insufficiency, stroke, varicose veins, renal insufficiency, recent myocardial infarction, heart failure etc.

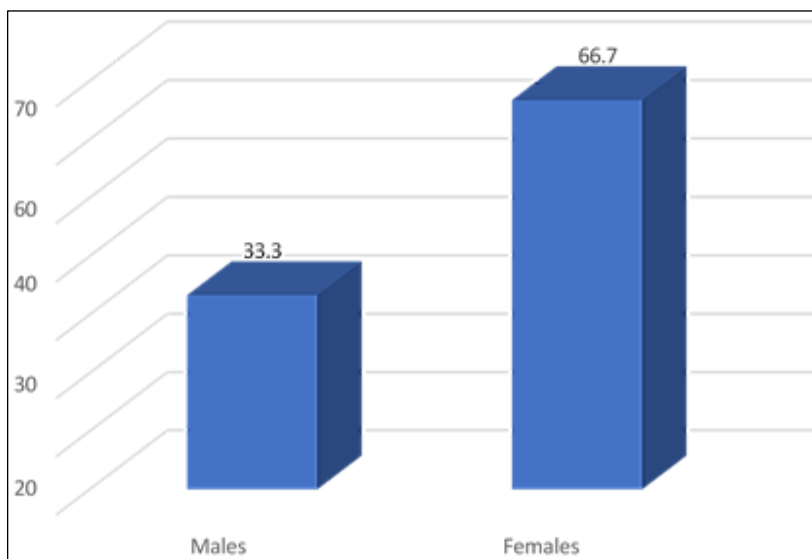
Observation and Result

The data was entered in excel spreadsheet (Windows 11, Microsoft Corp., USA) and was analysed for descriptive statistics. Data in the form of percentage and frequency distribution will be presented in the form of tables and graphs.

Results

A total of 78 patients were included in the study and data was analysed. It was found that 66.7% of patients were females and 33.3% of patients were males (Graph and Table 1). About 78.2% of patients were diagnosed with OA knee and 15.4% were diagnosed with NOF Fracture (Graph and Table 2). OA knee was bilateral in 39.7% of patients while in 25.6% of patients it was right sided. NOF fracture was seen more on the left side in 10.3% of patients while OA hip was seen on left side in 2.6% of patients. All the patients underwent recommended pre-operative procedures (PTT/aPTT and venous doppler). About 39.7% of patients underwent Bilateral Total knee replacement followed by unilateral Total Knee Replacement that was performed in 38.5% of patients. Bilateral Total Hip Replacement was performed in 1.3% of patients. About 83.3% of patients had cemented and 16.7% of patients had uncemented. In addition, all the participants received Injection Enoxaparin while its complication in the form of wound hematoma and bilateral lower limb oedema were observed only in 3.8% of patients (Graph and Table 7). None of the patients developed proximal or distal DVT, however, pulmonary embolism was observed in 1.3% of patients who died on 5th POD.

Tables and Graphs

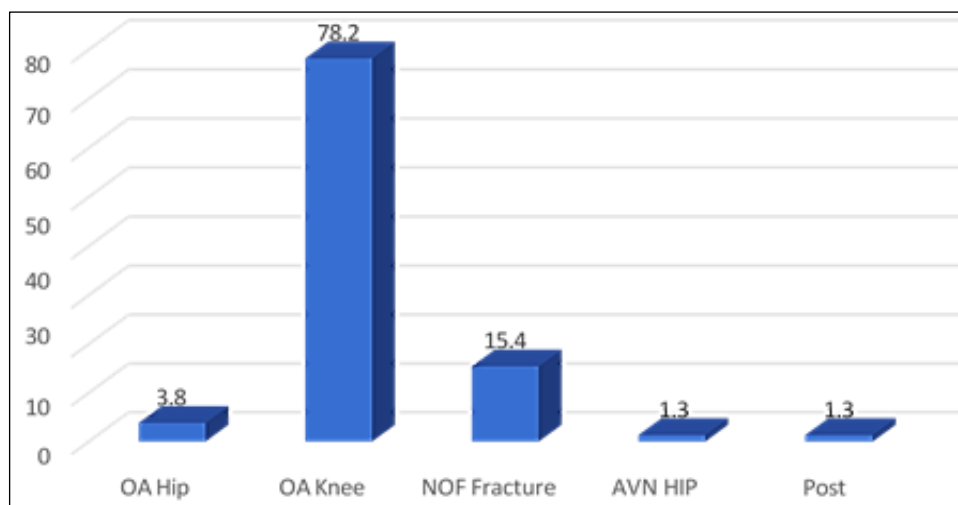


Graph 1: Distribution of participants according to gender

Table 1: Distribution of participants according to gender

	Males		Females		Total	
	N	%	N	%	N	%
Gender	26	33.3	52	66.7	78	100

N-Number; %-Percentage



Graph 2: Distribution of participants according to diagnosis

Table 2: Distribution of participants according to diagnosis

Diagnosis	N	%
OA Hip	3	3.8
OA Knee	61	78.2
NOF Fracture	12	15.4
AVN HIP	1	1.3
Post Traumatic	1	1.3

N-Number; %-Percentage

Discussion

There are not many Indian studies on lower limb VTE after major orthopaedic surgeries like lower limb Arthroplasty, as deprived the formulation of guidelines for thromboprophylaxis.

It is relevant to discuss about the American College of Chest Physicians Guidelines, prior to discussion of our study. The American College of Chest Physicians were founded in 1935. The first set of guidelines was published in 1986. The goal of these guidelines are to focus on the prevention of DVT and aggressive anticoagulation. As per the new guidelines, all primary THR and TKR patients are

considered “high risk” regardless of patient age, activity level, and co morbidities. The guidelines for thrombo prophylaxis assume greater importance in the face of insurance company liabilities and legal wrangles, apart from delivering a good health care system ^[7].

The recommendations were classified as

Grade I:- Strong recommendations, with benefits outweighing risk, burden and cost.

Grade II:- Recommendations with less certainty.

Each class of recommendation was further sub stratified:-

- a) Randomized controlled trials with consistent results and a low level of bias.
- b) Randomized controlled trials with inconsistent results.
- c) **Observational Studies:** Grade IA recommendations of LMWH, fondaparinux (pentasaccharide), and warfarin (with an adjusted international normalized ratio [INR] between 2.0 and 3.0).

Grade IA Recommendation:- Is done for total hip and knee arthroplasty.

Grade IB Recommendation:- Intermittent pneumatic compression devices recommended in TKR.

These guidelines for duration of prophylaxis have been revised in 2004 and 2008. According to 2008 guidelines, the recommended duration of prophylaxis for Grade IA rating (Chemoprophylaxis) is up to 10 to 35 days following THR and up to 10 days following TKR.

Grade IB prophylaxis recommended for TKR.

The American Academy of Orthopaedic Surgeons have slightly deviated to formulate a set of new guidelines for the prevention of symptomatic and fatal Pulmonary Embolism ^[27].

The AAOS guidelines include

1. Preoperative evaluation for a determination of “standard” and “high” risk potential.
2. To use regional anaesthesia.
3. Mechanical prophylaxis for all patients.
4. Rapid postoperative mobilisation.
5. To choose specific chemoprophylaxis agents based on the individual risk benefit profile for PE and bleeding complications.
6. Adequate patient education

Each recommendation was graded using the following system:

- A. Good evidence (level I studies with consistent findings).
 - B. Fair evidence (level II or III studies with consistent findings).
 - C. Poor evidence (level IV or V) for recommending intervention.
1. **For patients at standard risk for both PE and major bleeding complications, the recommendations (Grade of B or C, level III evidence):-** Aspirin, LMWH, fondaparinux (pentasaccharide), or warfarin (INR goal of 2.0 to 3.0).
 2. **For patients with standard risk of PE and elevated risk of major bleeding complications, recommendations (Grade C of level 3 evidence):-** Aspirin, warfarin (INR goal of 2.0 to 3.0).
 3. **For patients with elevated risk of both PE and major bleeding complications, recommendations (Grade C of level 3 evidence):-** Aspirin, warfarin (INR goal of 2.0 to 3.0) ^[27].

The most important concept in AAOS guidelines for thromboembolic prophylaxis is to assess the risk versus benefit preoperatively. However there is an inherent weakness in the AAOS guidelines to accurately assess the preoperative risk for DVT and PE. Similarly, the ACCP guidelines has been associated with disadvantages like wound hematoma, persistent wound drainage with high risk of post-operative joint infections.

Hence, the orthopaedic surgeon worldwide may prefer a risk averse method to prevent thrombo embolic phenomena following Total Joint Arthroplasty. Especially, because the rate of PE is similar regardless of the chemoprophylaxis used ^[10].

Summary and Conclusion

Background

Venous thrombo embolism (VTE), which consists of deep vein thrombosis (DVT) and pulmonary embolism, is a potentially fatal disease. Studies reported in Asian population have reported a consistent lower incidence of VTE than Western population, though the incidence of VTE had increased among Asian population.

Aim and Objectives

To find out the efficacy of Pharmacological Prophylaxis against VTE (Venous thrombo-embolism) in

arthroplasty and hip fracture surgeries with a secondary objective to determine the occurrence of VTE despite prophylaxis in arthroplasty and hip fracture surgeries.

Material and Methods

A prospective open-label clinical trial was conducted among 78 patients who reported to the Department of Orthopedics for THR, TKR and hip fractures. Data was collected in the prescribed format and were given a thorough clinical examination. All the patients underwent Doppler ultra-sonography pre-operatively and the fourth day and 4th week postoperatively. All patients were given Enoxaparin 40mg subcutaneous daily for 5 days and Tab Rivaroxaban for 4 weeks as prophylaxis against VTE.

Results

Only one patient (1.3%) had PE who died on 5th POD while none of the patient had either distal or proximal DVT. Complication to Inj Enoxaparin was observed in three patients in the form of wound hematoma and bilateral lower limb oedema.

Conclusion

VTE following THR, TKR and HRA in Indian patients is not as common as reported in the Western literature though DVT is not a non-existent entity in Indian population. A high level of suspicion and close clinical monitoring is mandatory. More trials involving a larger number of patients and at multi centers in future would be required to confirm the findings of our study.

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