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## **Incidence of venous thrombo-embolism following** arthroplasties in lower limbs in Indian population: A prospective study by using colour Doppler imaging

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#### **Abstract**

Introduction: Osteoarthritis is the most common form of joint disorder and is the leading cause of pain and physical disability in older individuals. Osteoarthritis typically presents at joints related to the knees and hips, beside the hands, spine and feet. Deep vein thrombosis (DVT) and pulmonary embolism (PE) can occur in patients after elective Total Hip Arthroplasty (THA), Total Knee Arthroplasty (TKA) and Hemi-Arthroplasty of hip. The Indian population have a low incidence of DVT and PE in comparison with the western population due to difference in ethnicity, genetic make-up and social life.

Aim: To find the incidence of venous thrombo-embolism (VTE) following lower limb arthroplasties and probable risk factors associated with the development of the disease.

Method: It is a prospective observational cohort study conducted on all the patients of either sex/gender undergoing any type of primary Arthroplasty in the lower limbs i.e., Total Hip Arthroplasty (THA), Total Knee Arthroplasty (TKA) and Hemi-Arthroplasty of hip in the department of Orthopaedics at Vydehi Institute of Medical Science and Research centre, Bangalore. A total of 100 patients who met the inclusion criteria were included in present study.

Results: Total of 100 patients was included in present study, among them 14% of the patients underwent Hemi-Arthroplasty of hip, 35% underwent THA and 51% had undergone TKA. Incidence of venous thromboembolism (VTE) in our study was found to be 6%. About 14.29% of Hemi-Arthroplasty of hip patients had VTE, 2.86% of THA and 5.88% of TKA had venous thrombo-embolism. Among the 6 cases that developed VTE, 83.3% (5 cases) had deep vein thrombosis and 16.7% (1 case) had pulmonary embolism.

Conclusion: Our results suggest that incidence of DVT and PE is low in the Indian population with a prophylactic regimen when used.

Keywords: Deep vein thrombosis, pulmonary embolism, prophylaxis, total hip arthroplasty, total knee arthroplasty, hemi arthroplasty

#### 1. Introduction

Osteoarthritis is the most common form of joint disorder and is the leading cause of pain and physical disability in older individuals. Osteoarthritis typically presents at joints related to the knees and hips, beside the hands, spine and feet [1, 2]. Arthroplasties have become effective surgical interventions for relieving the pain and improving the physical function in osteoarthritis [3]. The adverse outcomes may include acute myocardial infarction, venous thrombo-embolism (VTE), severe infections, major bleedings and stroke.

Venous thrombo-embolism (VTE) is a term used to denote deep vein thrombosis (DVT) and pulmonary embolism (PE). Venous thrombo-embolism (VTE) is a serious complication after major orthopaedic surgery. Post-operative deep vein thrombosis is a well-recognized complication following major orthopaedic surgeries on the lower limb in the Western countries. The reported incidence ranges from 45% to 84% in patients who had no prophylaxis. It remains one of the commonest causes for preventable hospital deaths in the Western world. Clinical deep vein thrombosis is incidentally found only in a minority of operated patients, and if recognized and treated adequately, almost eliminates the risk of nonfatal or fatal thrombo-embolic complications [4].

The incidence of venous thrombo-embolism is about 7 per 10,000 person-years among the community residents. The condition recurs in about 20% of patients after 5 years, but the rate varies depending on the presence of risk factors <sup>[5]</sup>. The annual incidence of idiopathic VTE in persons  $\geq$  18 years is 23 per 1,00,000 among the Caucasians, 29 per 1,00,000 among the African Americans, 14 per 1,00,000 among the Hispanics and 6 per 1,00,000 among the Asian-Pacific Islanders <sup>[6]</sup>.

The risk of developing deep vein thrombosis (DVT) extends for at least 3 months after surgery. The risk is maximum at 2-5 days post-operatively and second peak occurs around 10-13th post-operative day. Post-operative DVTs also occur in the contralateral leg after major joint surgery in approximately 25% of the patients, reflecting the systemic coagulopathy seen after surgery. The clinical assessment of these complications is unreliable and the majority of venous thrombo-embolic events are asymptomatic <sup>[7]</sup>.

Venous colour Doppler study of leg veins is being used more and more in the day-to-day practice as a diagnostic tool for diagnosing deep vein thrombosis. The ultrasound scanning has the advantage as a screening tool in detecting deep vein thrombosis, because it is performed at the bedside and is liable to detect non-occlusive thrombus.

The present study aims to find the incidence of venous thrombo-embolism (VTE) following lower limb arthroplasties in our institute and the probable risk factors associated with the development of the disease. It would also contribute to the horizon of knowledge needed for studies regarding venous thrombo-embolic disease and its prevention in the Indian population on a larger scale.

#### 2. Aims and Objective

The present study aims to find the incidence of venous thrombo-embolism (VTE) following lower limb arthroplasties in our institute and the probable risk factors associated with the development of the disease.

## 3. Material and Method

It is a prospective observational cohort study conducted on all the patients of either sex/gender undergoing any type of primary Arthroplasty in the lower limbs i.e., Total Hip Arthroplasty (THA), Total Knee Arthroplasty (TKA) and Hemi-Arthroplasty of hip in the department of Orthopaedics at Vydehi Institute of Medical Science and Research centre, Bangalore. A total of 100 patients who met the inclusion criteria were included in present study after obtaining written informed consent from the patients. Institutional ethics committee clearance was obtained prior to commencement of study.

Patients who did not undergo pre-operative colour Doppler imaging, patients who have pre-operative venous thrombo-embolism, previous surgery, revision of previous arthroplasties, known sensitivity for Heparin or LMWH and patients not willing were excluded from study.

## 3.1 Pre-operative assessment

A common protocol of detailed history taking, clinical examination, routine blood and radiological investigations and pre-operative venous colour Doppler imaging was performed as a part of the pre-operative preparation. Routine blood investigations were done for all the patients. Special attention was paid to bleeding time, clotting time,

prothrombin time and INR (International normalized ratio). Standard x-rays of the affected joints were taken accordingly All patients were subjected to pre-operative venous colour Doppler study for presence or absence of DVT, using Philips HD-7 ultrasound machine with a linear array high frequency probe of 3-12 MHz Evaluation of common femoral, superficial femoral, popliteal, anterior tibial and posterior tibial veins was done bilaterally. Assessment was done for compressibility of the veins, blood flow, augmentation and presence or absence of thrombus. Patients with findings of DVT on venous colour Doppler imaging were excluded from the study.

## 3.2 Details of Surgery

Patients then underwent required surgery according to their diagnosis and indication. Details of surgery pertaining to the type of surgery performed, type of anaesthesia administered, site of surgery, duration of surgery and duration of tourniquet (in case of TKA) were noted.

## 3.3 Post-operative period

Post operatively, all patients received pharmacological prophylaxis for venous thrombo-embolism with injectable low molecular weight heparin (enoxaparin sodium) 40 mg subcutaneously once a day for the first 2 days. First dose of enoxaparin sodium was given 10 hours after surgery. After 2 days, oral rivaroxaban was administered in a dose of 10 mg once a day for the next 3 weeks. Clinical signs and symptoms were followed for pedal oedema, calf discomfort, calf pain, warm skin and redness over skin, venous distension, calf girth (measured 10cm below tibial tuberosity), blebs over skin, Homan's sign, fever, dyspnoea, cough and haemoptysis.

Venous colour Doppler imaging for both lower limbs was performed on the 7th post-operative day to look for radiological signs of deep vein thrombosis. Evaluation of common femoral, superficial femoral, popliteal, anterior tibial and posterior tibial veins was done bilaterally. Assessment was done for compressibility of the veins, blood flow, augmentation and presence or absence of thrombus. A diagnosis of DVT was made when there was visualization of thrombosis, lack of compressibility, absence of flow or lack of augmentation. On finding presence of deep vein thrombosis, treatment was administered as per protocol decided by cardiologists at our institute.

## 3.4 End points/outcome measure

Deep vein thrombosis diagnosed on venous colour Doppler imaging on 7th post-operative day was the primary end point for determination of incidence of venous thrombo-embolism (VTE). Colour Doppler imaging was reported by radiologists at our institute. On finding presence of deep vein thrombosis, treatment was administered as per protocol decided by cardiologists at our institute. Presence of pulmonary embolism in any patient was considered an acute emergency and was administered treatment as per protocol decided by cardiologists at our institute.

#### 4. Results

Total of 100 patients were included in the study, with the age distribution from 20 years to more than 70 years with mean age of 54.71 years. Majority of them belonged to group of 50-70years of age. 55 were male patients and 45 were female patients with ratio of approx. 1:1.

**Table 1:** Age-wise distribution of the patients in the present study.

Age group	Number of cases	Percent (%)
20-29 years	3	3
30-39 years	15	15
40-49 years	11	11
50-59 years	30	30
60-69 years	26	26
More than 70 years	15	15
Total	100	100

**Table 2:** Distribution of cases according to gender.

Procedure	Male N (%)	Female N (%)	Total N (%)
Hemi-Arthroplasty	5 (35.71)	9 (64.29)	14 (14)
THA	26 (74.29)	9 (25.71)	35 (35)
TKA	24 (47.06)	27 (52.94)	51 (51)
Total	55 (55)	45 (45)	100 (100)

THA- Total Hip Arthroplasty; TKA- Total Knee Arthroplasty.

Patients with co morbidities were 5 with asthma, 17 with DM, 21 with HTN and 3 were with Hypothyroidism, and other 72 were not having any associated co-morbid condition. Previous major surgery (21%) and major trauma (14%) were the high risk factors in the patients.

Age older than 65 years (28%), bone fracture (17%) and obesity (17%) were the moderate risk factors observed in the patients. Other moderate risk factors including travel of more than 4 hours, active cancer or chemotherapy, use of birth control pills or patch or ring, hormone replacement therapy, pregnancy or recent delivery, family history of clot, heart failure, bed rest of more than 3 days and genetic or acquired clotting disorder were not found. Site of surgery in present study was Left hip, operated upon in 25% of the cases, right hip in 24% of the cases, left knee in 21% of the cases, right knee in 22% of the cases and bilateral knee in 8% of the cases.

In our study, the mean ( $\pm$  SD) duration of tourniquet was 94.53 ( $\pm$  5.85) minutes in case of unilateral TKA and 189.88 ( $\pm$  6.55) minutes in case of bilateral TKA. The mean duration of surgery for hemi-arthroplasty of hip was 63.7 ( $\pm$  7.1) minutes, THA was 87.9 ( $\pm$  8.4) minutes, unilateral TKA was 99.6 ( $\pm$  5.7) minutes and bilateral TKA was 201.9 ( $\pm$  7.0) minutes.

**Table 3:** Showing the incidence of venous thromboembolism in various surgical procedures.

Procedure	VTE		
	Total Cases	Yes (%)	No (%)
Hemi-arthroplasty	14	2 (14.29)	12 (85.71)
THA	35	1 (2.86)	34 (97.14)
TKA	51	3 (5.88)	48 (94.12)
Total	100	6 (6)	94 (94)

THA- Total Hip Arthroplasty; TKA- Total Knee Arthroplasty; VTE-Venous Thromboembolism

Among the 6 cases that developed VTE, 83.3% (5 cases) had deep vein thrombosis and 16.7% (1 case) had pulmonary embolism. In our study, 7.14% of the patients who underwent Hemi-arthroplasty of hip and 2.86% of the THA cases had asymptomatic DVT. 7.14% of Hemi-arthroplasty of hip cases and 3.92% of the TKA cases had symptomatic DVT while 1.96% of the TKA cases had symptomatic pulmonary embolism. 85.71% of the patients who underwent Hemi-arthroplasty of hip, 97.14% of the patients who underwent THA and 94.12% of the patients who had undergone TKA had no evidence of VTE.

Age more than 65 years was found to be the main risk factor in the cases that developed VTE (5 out of 6 cases, 83.3%). Previous major surgery and major trauma were found to be the most commonly found high risk factors in patients who developed VTE. Obesity and bone fracture were the moderate risk factors (33.33% each) in patients who developed VTE. The only case of pulmonary embolism had major surgery, age more than 65 years and obesity as the risk factors.

Pedal oedema, calf discomfort, calf pain, warm skin, increase in calf girth, Homan's sign, Moses sign and tachycardia were the most commonly found signs and symptoms in patients with VTE (33.33% each). The only case of pulmonary embolism presented with tachycardia, pleuritic chest pain, dyspnoea, cough and haemoptysis.

#### 5. Discussion

Despite the well-established benefits of arthroplasties, these drastic surgical procedures may result into potentially fatal complications. The adverse outcomes may include acute myocardial infarction, venous thromboembolism (VTE), severe infections, major bleedings and stroke <sup>[4]</sup>. Venous thrombo-embolism (VTE) is a term used to denote deep vein thrombosis (DVT) and pulmonary embolism <sup>[5]</sup>. Postoperative deep vein thrombosis is a well-recognized complication following major orthopaedic surgeries on the lower limb in the Western countries <sup>[8]</sup>.

Majority of the patients in our study were aged above 50 years. Mean age of patients in our study was 54.71 years. In a study by Bagaria *et al.*, the average age of the patients was 64.2 years <sup>[4]</sup>. In a study by Dhillon *et al.*, the mean age was 64 years <sup>[9]</sup>. In a study by Agarwala *et al.*, the mean age of group of patients who were given thromboprophylaxis with dalteparin sodium was 62.9 years and no thromboprophylaxis group was 61.3 years <sup>[8]</sup>. Jain *et al.* undertook a study in which average age of patients undergoing THA was 47 years and for TKA was 65 years <sup>[10]</sup>. Angral *et al.* conducted a study in which average age of patients was 55 years <sup>[11]</sup>. In a study by Chandak *et al.*, the average age of male patients was 68 years and female patients was 71 years <sup>[12]</sup>.

More than half of the patients underwent total knee arthroplasty (51%), followed by total hip arthroplasty (35%) and hemi-arthroplasty of hip (14%). Bagaria *et al.* performed THR in 15.6% of the patients and TKR in 14.9% of the patients and rest were surgeries for proximal femur fractures [4]. Fracture of neck of femur was the main indication for the hemi-arthroplasty of hip in our study.

We found the incidence of VTE to be 6% in our study, with the incidence of DVT being 5% and PE being 1%, despite giving thromboprophylaxis. Bagaria *et al*, the overall incidence of VTE was 6.12% in all the patients and 8.6% in THA patients, but no prophylaxis was administered in their study. They found an incidence of 0% in TKR group. The Overall incidence of PE was found to be 0.6% <sup>[4]</sup>. Only 1 out of 9 cases had presented as pulmonary embolism (11.1%), the rest 8 being DVT (88.9%) <sup>[5]</sup> Angral *et al*. detected DVT in 10 patients out of 150, thus an incidence of 6.6% overall. Their study included patients from multiple surgeries. The incidence of DVT in patients who underwent THR in the study was again 6.6%. No prophylaxis for DVT was given. None of the patients developed PE <sup>[11]</sup>.

Previous major surgery and major trauma were the main high risk factors in our study. Age more than 65 years, fracture of bone and obesity were found to be the moderate risk factors in our study in patients who were detected to have VTE [12]. Our study found the incidence of VTE to be 6%, which is

comparable to the studies of Bagaria *et al.* <sup>[4]</sup> Jain *et al.* <sup>[10]</sup> Angral *et al.* <sup>[11]</sup> and Chandak *et al.* <sup>[12]</sup> none of the previous studies used any form of prophylaxis, whereas we followed a protocol for thromboprophylaxis. Also, Agarwala *et al.* <sup>[8]</sup> found in their study that chemoprophylaxis is an effective way of reducing the incidence of VTE following arthroplasties. We recommend the use of thromboprophylaxis in all patients who have undergone any Arthroplasty of the lower limb, as it's a safe and easy method to keep the incidence of VTE low.

#### 6. Conclusion

The incidence of VTE in Indian population following arthroplasties in lower limbs is low as compared to the Western population. We would also recommend the use of thromboprophylaxis in all patients following lower limb arthroplasties as it's a safe and easy method of keeping the incidence of VTE low.

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**8. Conflict of interest**: There are no conflicts of interest

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