#### **ORIGINAL RESEARCH**

### A Physiological Prophylaxis of Deep Venous Thrombosis in Arthroplasty: A Prospective Study

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#### ABSTRACT

Background: A potentially lethal condition is known as venous thromboembolism (VTE), which includes pulmonary embolism and deep vein thrombosis (DVT). To determine the effectiveness of pharmacological prophylaxis against PE or DVT (Pulmonary Embolism). To ascertain the prevalence of DVT (Deep Venous Thrombosis) or PE (Pulmonary Embolism) despite prevention. On the subject, relatively few studies from India have been published, and nothing is known about the true prevalence of the disorder. Due to a sharp rise in the number of joint replacement surgeries, the topic has recently taken on more importance among Indian people. Regarding the prophylaxis for VTE in Indian patients, there are no precise recommendations.

Materials and Methods: In order to investigate the prevalence of DVT, we designed and carried out a prospective study. The current study comprised a total of fifty patients who had undergone THR, TKR, or HRA. The duplex ultra-sonography was performed on each of the patients between the seventh day and the third week of postoperative day. As a preventative measure against deep vein thrombosis (DVT), all patients received subcutaneous Enoxaparin 40 mg once day for 5 days and Asprin for 4 weeks.

Results: Only two patients or four percent of the total, revealed sonographic evidence of distal asymptomatic DVT, and both of those patients' symptoms went away on their own without any treatment. During the follow-up scan, there was no evidence of proximal DVT propagation, and there were also no incidences of pulmonary embolism.

Conclusion: DVT in patients who have undergone THR, TKR, or HRA is not nearly as common as it is reported to be in the Western medical literature. It is essential to maintain a high level of suspicion, in addition to close clinical surveillance. In our society, deep vein thrombosis (DVT) is hardly an unheard-of condition. Although low molecular weight heparin is a safe medicine, it appears that the risk of bleeding problems is higher than what is described in Western medical literature. In the future, it will be necessary to conduct additional trials that involve a greater number of patients and take place at many centres in order to corroborate the findings of our study and evaluate the actual efficacy and safety of LMWH.

Keywords: Physiological prophylaxis, thrombosis, arthroplasty, prospective study, venous thrombo embolism.

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#### **INTRODUCTION**

Total hip replacement has become the standard of care for patients with hip joint deterioration brought on by a variety of reasons, even in third-world nations. Deep vein thrombosis (DVT) is one of the most frequent side effects of total hip arthroplasty (THA), which is high-risk and

necessitates the highest level of prophylaxis (DVT).<sup>[1-3]</sup> Three factors venous stasis, increased coagulability, and endothelial damage—are associated with the development of thrombi. The patient is at the greatest risk for femoral vein blockage and activation of the clotting cascade during the insertion of the femoral component. It has been found that using cemented implants also increases the risk of developing DVT. Deep vein thrombosis, in specific cases of proximal DVT, has the potential to result in pulmonary thromboembolism; in its advanced stages, DVT can also result in chronic venous insufficiency, which is the main reason for the importance of the condition.<sup>[4-8]</sup> Calf thrombi, often referred to as distal thrombosis, are linked to chronic venous insufficiency and a low risk of embolization. On the other hand, they are more prone to spread proximally in the absence of prophylaxis, considerably increasing the risk of pulmonary thromboembolism.<sup>[8-11]</sup>

Most frequently, proximal DVT arises from a local vascular wall lesion or as an extension of distal DVT. While most proximal DVTs can resolve without any clinical consequences, those that do not have a higher chance of developing a pulmonary thrombosis than distal DVT do.<sup>[12]</sup> According to reports, the risk of getting a DVT is at its highest on the fourth postoperative day and at its second-highest level on the thirteenth day. The risk of a fatal pulmonary embolism is anticipated to be at its highest during the second week following surgery and to remain a worry for around three months. In the leg that was not operated on, deep vein thrombosis (DVT) occurs in about 20% of cases.<sup>[13-16]</sup>

Deep vein thrombosis (DVT) can occur after THA without prophylaxis in a range of 40% to 70% of cases, as can proximal DVT in 10% to 20% of cases, clinical DVT in 1% to 3% of cases, non-fatal symptomatic pulmonary thromboembolism in 2% of cases, and fatal pulmonary thromboembolism in 0.1% to 1% of cases.<sup>[17]</sup> Orthopaedic surgeons have significantly varying viewpoints regarding the utility of prophylaxis for DVT despite the fact that the incidence of DVT is relatively high, the incidence of proximal DVT is quite low, and the incidence of fatal thromboembolism is quite infrequent. This is partly because of worries about the effectiveness and negative effects of various DVT prevention techniques. As a result, there is a lot of controversy around the topic of DVT prevention as a whole.<sup>[18-21]</sup>

The majority of the DVT statistics come from numerous studies that were conducted on populations in both Europe and the United States. Deep vein thrombosis (DVT) may occur more frequently in European and American populations than to Asian cultures.<sup>[22]</sup> At our institution, for instance, the incidence of DVT following THA has been negligible. This is a result of the genetic variations that exist between populations in Asia and those in Europe and America. A diagnosis of DVT can be made using a variety of diagnostic techniques.<sup>[23,24]</sup> Doppler ultrasound is a non-invasive, economical method of providing real-time imaging. It can be used frequently as needed and matches the sensitivity and specificity of venography in terms of proximal DVT. Furthermore, it has no unfavourable side effects. Low-molecular-weight heparins, also referred to as LMWHs, are frequently used as a type of DVT prevention following a THA operation. One of the several low-molecular-weight heparins used for this particular purpose is enoxaparin.<sup>[25-27]</sup>

## **MATERIALS & METHODS**

This clinical investigation on the prospective study of pharmacological prophylaxis of deep vein thrombosis in arthroplasty was conducted in the department of orthopaedics at the Gandhi Medical College between November 2021 and August 2022. Fifty patients who were selected through a purposeful random sampling throughout this time period received prevention of deep vein thrombosis (DVT) in arthroplasty. Prior to the study's execution, each patient submitted their informed consent, and the hospital's ethical committee approved the study.

Patients who were admitted to the hospitals provided the relevant data. A standardised questionnaire and a physical exam were used to examine every patient who was a part of the

trial prior to surgery. In addition, they had additional investigations such as PT and a PTT blood tests, as well as a Doppler ultrasonography to perform a radiological screening for deep vein thrombosis (DVT). Our institute was the site of a prospective study between November 2021 and August 2022 that included fifty patients scheduled for THA, TKA, or HRA, in that sequence. Every patient gave their informed consent before receiving treatment. All of the study participants underwent a thorough clinical history and examination in addition to an interview. This was done to rule out the presence of thromboembolism risk factors, such as a history of smoking or drinking, chronic venous insufficiency, stroke, varicose veins, malignancy, renal insufficiency, recent myocardial infarction, heart failure, who were taking oral contraceptives, or who were taking steroidal medication. Using a linear array high frequency probe 9-11 MHz with a grey scale and colour Doppler mode, each patient had a preoperative examination for deep vein thrombosis (DVT) performed on both of their lower limbs. This was carried out using a Philips IU-22 ultrasound scanner. All of the Doppler reports were read by the identical radiologist who, in an effort to reduce observer bias, was unaware of the pharmacological prophylaxis and the study. The goal was to reduce observer bias by doing this.



Figure 1: Colour Doppler Ultrasound Machine, pre–Operative Doppler Scanning

Bilateral common femoral, superficial femoral, popliteal, anterior, and posterior tibial veins were all examined as part of the assessment. Their flow, compressibility, visible thrombus, and augmentation were evaluated. When thrombosis was visible, there was no flow, there was no compressibility, or there was no augmentation, DVT was diagnosed.

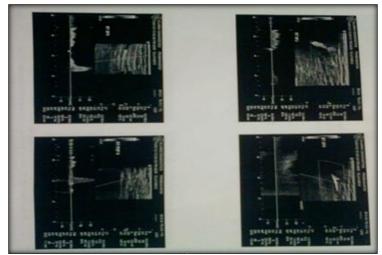


Figure 2: Normal study of Venus Doppler of Lower Limbs

Clinical evaluations of the patients included a look for further deep vein thrombosis symptoms or indications. If any, calf discomfort, edoema, and a rise in local temperature were reported. Every patient was examined for Homan's sign, or pain in the calf with dorsiflexion of the ankle, although its absence was not thought to indicate a lack of thromboembolic event. Calf and thigh circumference measurements were taken on both lower limbs for daily reference.

### **Inclusion criteria:**

All of the patients that are scheduled to undergo total hip replacement, total knee replacement, or hemi replacement arthroplasty at our facility.

## **Exclusion criteria:**

Patients who have got pre-operative deep venus thrombosis.

## RESULTS

44 was the average age of patients who underwent THR, while 61 was the average age of patients who underwent TKR. In patients undergoing THR, the most common diagnoses were avascular necrosis of the head of the femur and secondary Arthritis. In patients undergoing TKR, the most common diagnosis was primary osteoarthritis, and in patients undergoing HRA, the most common diagnosis was a fracture neck of the femur. Two patients were determined to have a case of distal DVT; however there was no instance of proximal DVT. One of these patients was a 57-year-old housewife who had undergone bilateral THR procedures for the treatment of secondary arthritis in both of her hips (Case No. 7). On the third week after surgery, colour Doppler ultrasonography revealed the presence of distal DVT in patients who were asymptomatic. The second patient was a male who was 41 years old and had undergone a THR for bilateral avascular necrosis of the femur. This patient was Case No.30. Both of his legs were affected by varicose veins. During the third week after surgery, colour Doppler ultrasonography revealed the presence of distal DVT despite the patient's lack of symptoms.

One patient was discovered to have risk factors such as varacose veins in both legs, while the second patient was found to have no known risk factors other than being 57 years old and having received a prophylactic injection of clexane 40 mg once a day subcutaneously for five days. 8 hours after the procedure, neither of the patients exhibited any signs of having suffered a pulmonary thromboembolism. They were monitored for a total of 12 weeks and 10 weeks, respectively, and there was no sign of any post-thrombotic symptoms in either group. No patient who had TKR, HRA, either preoperatively or postoperatively in both limbs was found to have a case of deep vein thrombosis (DVT).

A follow-up Doppler investigation was performed on patients who had evidence of deep venous thrombosis one week following the identification of thrombus. The purpose of this study was to rule out proximal extension of the thrombus. During the second round of Doppler testing, neither of the patients with distal DVT displayed any signs of the thrombus having spread any farther. In point of fact, the thrombosis in both individuals completely vanished after treatment. In both the TKA and the HRA procedures, none of the patients exhibited any signs of clinically apparent deep vein thrombosis or pulmonary embolism while they were in the hospital or during the first four weeks after surgery. Three of the patients were discovered to have wound haematomas. Patients who were using enoxaparin showed signs of localised bleeding, including bruises, and one patient experienced fever in conjunction with their bleeding. When enoxaparin was used, none of the patients experienced significant bleeding or a decrease in their platelet count. They needed extended antibiotic treatment that lasted for an average of seven days.

### DISCUSSION

Lack of study on lower limb VTE following major orthopaedic procedures, such as lower limb arthroplasty, has precluded Indian researchers from creating thrombo prophylaxis guidelines. It is important to understand the American College of Chest Physicians recommendations before discussing our findings. The American College of Cardiologists was founded in 1935. The first set of guidelines was published in 1986. These suggestions emphasise the need for rigorous anticoagulation and DVT prophylaxis. The regulations have undergone numerous modifications. The latest revision was from 2008. According to updated criteria, all primary THA and TKA patients are now categorised as "high risk," regardless of the patient's age, level of exercise, or co-morbidities. The criteria for thrombo prophylaxis become more important in order to provide a high-quality healthcare system as well as due to insurance company liability and legal issues.

These prophylaxis duration guidelines were labelled as having undergone changes in 2004 and 2008. The 2008 guidelines state that prophylaxis for Grade IA grading chemotherapy should last 10–35 days following THA and up to 10 days after TKA. At grade IB, TKA prevention is suggested. The American Academy of Orthopaedic Surgeons slightly deviated from their earlier recommendations in order to offer a new set of guidelines for the prevention of symptomatic and fatal pulmonary embolism. The AAOS suggests the following. Prior to surgery, weighing the risks and benefits is crucial, according to the AAOS recommendations for thromboembolic prophylaxis. Similar to the ACCP guidelines, the AAOS guidelines contain downsides such wound haemorrhage and lengthy wound drainage with a high risk of post-operative joint infections, but also have a flaw in the way they accurately calculate the preoperative risk for DVT and PE.

4% of DVTs were discovered in our series. Therefore, preoperative Doppler ultrasonography ought to be carried out to detect any DVT, particularly in patients who are getting the same or the opposite lateral joint operated on again. Our results show that, despite the small size of our study sample, the incidence of DVT in Indian patients is incredibly low and not similar to American and European populations. A high level of suspicion and close therapeutic oversight must always be maintained. Bleeding issues seem to be more prevalent in our society than in western communities, despite the fact that low molecular weight heparin is a safe medication. The ailment of DVT does not exist. Future trials involving larger patient populations and several centres will be required to confirm the findings of our analysis. To confirm the true efficacy of low molecular weight heparin. These findings hold true for both the contemporary, globalised world and other South East Asian countries that share similar socioeconomic and genetic traits. We have followed the same protocol for all total joint replacements, which entails 5 days of subcutaneous LMWH (Enoxaparin) 40mg and 4 weeks of Aspirin 75mg per day. Our research showed that the aforementioned Regimen is efficient.

#### CONCLUSION

While there is sufficient evidence in the Western literature to support routine thromboprophylaxis for patients undergoing total joint replacement and surgery for lower limb fractures, in our opinion there is not yet sufficient evidence to support the same for Indian patients undergoing major lower limb surgery. It is essential to maintain a high degree of suspicion and close therapeutic supervision. In our population, DVT is not nonexistent. Low molecular weight heparin is a safe medicine, however compared to western populations; it seems to cause higher bleeding issues. The results of our investigation would need to be confirmed in additional studies with larger patient populations and at many centres in the future to determine the effectiveness of low molecular weight heparin. Although we concur with Gillespie et al. that orthopaedic surgeons should only use pharmacological prophylaxis for high-risk patients (advanced age, past history of DVT, presence of varicose veins, obesity, malignancy, immobilisation, etc.), in whom the potential benefits clearly appear to outweigh

the risks, we recommend thrombo prophylaxis for the majority of patients undergoing TJA (Total Joint Replacement). However, it is important to maintain continuous clinical surveillance and a high index of suspicion for DVT and pulmonary embolism. Between the seventh day and the third postoperative week, all elderly and high-risk patients undergoing total joint arthroplasty or surgery for lower limb fractures should preferably undergo a duplex sonography. All positive cases should then undergo a second ultra-sonography to rule out proximal thrombus propagation. The results of this study need to be confirmed in larger-scale clinical trials in the future, which will enable orthopaedic surgeons in India, decide whether or not to give their patients having lower limb surgery chemoprophylaxis for DVT and PE.

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