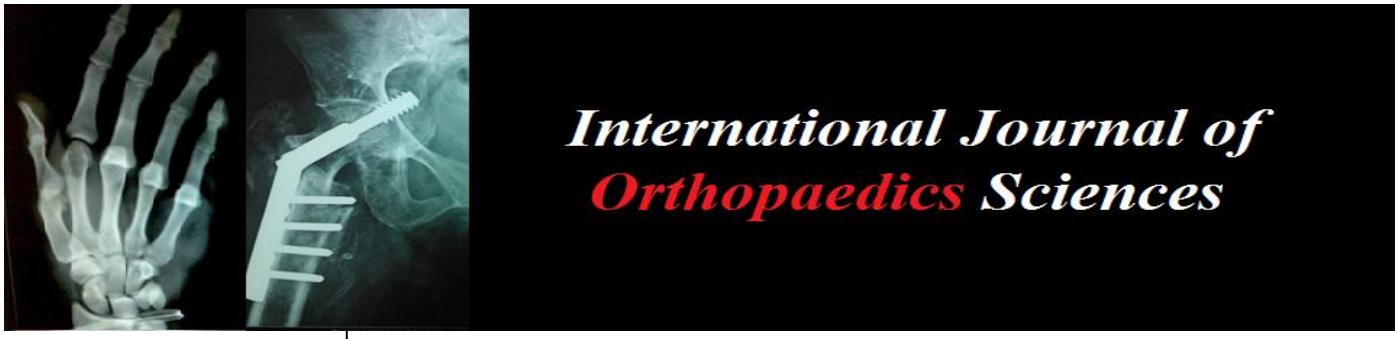

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Is thromboprophylaxis really justified among Indian population with femur shaft fractures treated with IM nailing?

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Abstract
Introduction: Venous thromboembolism (VTE), which consists of deep vein thrombosis (DVT) and pulmonary embolism, is one of the most common preventable cause of morbidity and mortality after trauma. Though most of the western countries have their guidelines for thromboprophylaxis in these patients, India still does not have these. The increasing detection of VTE among Indian population, lack of awareness, underestimation of the risk, and fear of bleeding complications after chemical prophylaxis have made deep vein thrombosis (DVT) a serious problem, hence a standard guideline for thromboprophylaxis after trauma is essential. There are many studies for thromboprophylaxis in patients underwent Joint replacement surgery. But there are no clear guidelines regarding the prophylaxis for VTE for trauma surgeries. Amongst all fracture pattern femur shaft is most notorious for incidence of fat embolism.
Materials and Methods: We carried out a Prospective Randomised study to determine the incidence of DVT. Present study included 105. Patients having Diaphyseal fracture of Femur undergoing intramedullary Interlocking Nailing. All the patients underwent duplex ultrasonography between preoperatively, 3rd Postoperative day and 6 weeks postoperative.
Results: Only six patients (7.8%) showed sonographic evidence of DVT and the majority of them resolved without treatment. There were 2 case of pulmonary embolism out of which one patient died because of Pulmonary embolism.
Conclusion: DVT following fractures of Femur in Indian patients is not as common as reported in the Western literature. A high level of suspicion and close clinical monitoring is mandatory, routine chemoprophylaxis is perhaps not justified in every patient undergoing femur fracture surgeries. More trials involving a larger number of patients and at multi centers, in future, would be required to confirm the findings of our study.

Keywords: Deep venous thrombosis, pulmonary embolism, thromboprophylaxis, trauma, Shaft femur fractures nailing

Introduction
Major orthopedic trauma (which includes spine, hip and pelvi-acetabular fractures; multiple long-bone fractures of the lower extremity) is a compelling risk factor for development of venous thromboembolism (VTE) and its potential sequelae pulmonary embolism (PE) [1]. Thromboprophylaxis by means of chemical and mechanical methods have significantly reduced morbidity and mortality in such patients [1]. Despite uncertainty about few aspects of VTE, the extensive research on this subject has helped many western surgeons to reach at some concrete conclusion; and as a result, 99% of them use thromboprophylaxis after trauma and elective orthopedic surgeries [2]. Thromboprophylaxis after trauma is still not widely practiced in India [3], the cause of which can be attributed to lack of awareness, underestimation of the problem, fear about thromboprophylaxis complications and most importantly the popular belief among surgeons that Indians have low incidence of deep venous thrombosis (DVT). Contrary to previous belief, most of the recent studies show increasing incidence of VTE among the Indian and Asian population, and it is almost equivalent to that reported in Caucasians [4-17]. Nandi *et al.* while reviewing the Chinese literature found an increasing incidence of VTE among the Chinese population, and they placed the orthopedic

Surgery of the lower limbs in the high-risk group [18]. Similarly among the Japanese population, the rate of incidence of VTE after arthroplasty surgeries was found to be increasing over the last four decades, though not equivalent to that in North America and Europe [19]. In a multinational and multi-ethnic study on Asian population, Piovella *et al.* concluded that the incidence of venographic thrombosis in the absence of thromboprophylaxis after arthroplasty and hip fracture surgery is equivalent to that in the western countries [8]. Many authors believe that the factors responsible for this changing trend are increase in life expectancy and change in dietary habits (increased fat intake) and lifestyle of the Asian/ Indian population over the last two decades [4-6, 9] Nandi *et al.* reported that other than genetic factors, certain acquired traits like dietary habits and sedentary lifestyle with reduced exercise are important factors responsible for VTE. Most of the studies which have reported very low incidence of DVT in India have been conducted in patients undergoing elective orthopedic surgery like joint replacement and used color duplex for diagnosis [20-22]. In the absence of any study in this population under the high-risk condition of trauma, it is unwise to assume that Indians are genetically protected against VTE after trauma. The reluctance among Indian surgeons to provide thromboprophylaxis to trauma patients may have serious medicolegal implications. In the present scenario, a standard guideline for providing thromboprophylaxis to trauma patients in the Indian subcontinent is urgently needed, which should be practical and acceptable for all. Also, there are medico-legal implications of not subjecting patients undergoing lower limb surgery to some kind of thromboprophylaxis, as some people consider this an act of negligence. Amongs all fracture pattern femur shaft is most notorious for incidence of fat embolism. In developing country like India many times Orthopaedic surgeon come across a situation where a Young patient who is the only earning person in the family develops pulmonary embolism while undergoing nailing intra operative or immediate postoperative period & dies leading to huge socioeconomically burden cause of which may be prevented by thromboprophylaxis. We, therefore, decided to undertake this prospective randomized study at our institution to determine the incidence of DVT & Pulmonary Embolism in Indian patients having Diaphyseal Femur fracture treated with IM IL Nailing.

Materials & Methods

A Prospective Randomised study of 105 consecutive cases having Diaphyseal fracture of Femur undergoing intramedullary Interlocking Nailing carried out over a 15 months period from May 2015 to June 2016.

All the patients randomized by computer generated chart & ooperative surgerys done in different unit into two grouos Case (Given thromboprophylaxis in the form of Low molecular weight Heparin Inj LOMO 0.6 mg Subcutaneously OD) & Control (No Chemical or mechanical thromboprophylaxis given).

Out of these 105, 50 patients got thromboprophylaxis pre & post operative & 65 patient were in control group. A prior consent was obtained from all the patients and the study was approved by the Ethical Committee of the Hospital. There were 60 male patients (Averageage-45 years, Range 25-65 years) and 55 female patients (Average age-42 years, Range 27-97 years). All the operations were carried out under regional (spinal± epidural) anesthesia. Any known risk factor associated with occurrence of DVT like past history of DVT, presence of varicose veins, obesity, malignancy etc. was recorded. Other variables e.g., age, sex, height, weight, presence of any medical problems etc. were also documented for a possible correlation with the occurrence of DVT. Note was also made of the clinical evidence of DVT before subjecting the patient to Doppler study. All the patients underwent duplex ultrasonographic assessment of both the lower limbs Preoperatively, 3rd postoperative day & 6 weeks postoperative when patient comes for 1st follow up. Duplex ultrasonography method was selected because it has a sensitivity of 100% and a specificity of 97%. It is a safe, effective and quick technique for diagnosing venous thrombosis in patients. It is well accepted by both patients and staff and is without any inherent risks The Doppler assessment included examination of bilateral common femoral, superficial femoral, popliteal, anteriortibial and posterior tibial veins. They were assessed for flow visualized thrombus, compressibility and augmentation. A diagnosis of DVT was made where there was visualization of thrombosis, absence of flow, lack of compressibility or lack of augmentation. The thrombus was classified as distal if it involved the calf veins only and as proximal if it involved the popliteal or a more proximal vein. Patients who had both a proximal and a distal thrombus were classified as having proximal thrombosis.

The patients who developed postoperative venous thrombosis diagnosed by Doppler examination were not subjected to any form of thrombolytic treatment. They were, however, kept under close clinical observation. Activated partial thromboplastin time (APTT) was closely monitored and was maintained at 1.5-2.5 times control. Tab. Warfarin-5 mg per day was commenced simultaneously and international normalized ratio (INR) was monitored every two days. When therapeutic level of INR (between 2 and 3) was achieved, Heparin infusion was discontinued. Warfarin was continued for about three to four months. A repeat Doppler study was performed in all these patients within a week of the first positive Doppler study to make sure that there was no further propagation of the thrombus.

Results

Out of 105 patients, only six patients (7.8%) showed sonographic evidence of DVT and the majority of them resolved. There were 2 case of pulmonary embolism out of which one patient died because of pulmonary embolism. Out of these six patients, only two patients had evidence of proximal DVT while the remaining four patients showed distal DVT.

Discussion

Until recently, deep vein thrombosis following lower limb surgery was considered to be a rarity in Asian patients. Dhillon *et al.*, [4] in a prospective study of 88 patients from Singapore without any prophylaxis, reported that 62.5% of the patients demonstrated venographic evidence of DVT. They further suggested that the present practice of withholding routine prophylaxis against thromboembolism in Asian patients undergoing high-risk orthopedic procedure should be reconsidered. Ko *et al.* [12] in a prospective study of 80 "low-risk" Chinese patients undergoing total knee arthroplasty (TKA) and total hip arthroplasty (THA) showed 27-31% incidence of postoperative deep vein thrombosis detected by duplex sonography. They concluded that patients who are labeled "low-risk" for DVT actually had a significant risk and suggested that the current practice of providing prophylaxis to

only patientsdeemed at "high risk" should be revised. However, Jain *et al.*, [6] reported a very low incidence of DVT following TKA and THA in Indian patients. Only two patients in their seriesof 106 patients from Northern India undergoing THA and TKA showed duplex sonographic evidence of proximal DVT. Similarly, Bagaria *et al.* [7] reported 6.12% incidence of DVT and 0.6% incidence of PE in their prospective study of 147 patients undergoing major orthopedic surgery of lower limb without any prophylaxis. They concluded that DVT has a lower incidence in Indian patients as compared with other ethnic groups. Agarwala *et al.*, [8] by using contrast venography as a diagnostic tool for DVT, however, reported 60% incidence of DVT in patients not receiving chemoprophylaxis and 43.2% incidence of DVT in patients receiving prophylaxis following major lower limb surgery in their study of 94 patients. Eighty-three percent of these patients had distal DVT and there was not a single case of pulmonary embolism.

In our study, we have observed that out of 105 patients operated for major lower limb surgery, eight patients (7.2%) demonstrated sonographic evidence of DVT out of which three patients (2.4%) had a proximal deep venous thrombosis and six patients (4.8%) had a distal deep venous thrombosis. There was 2 cases of pulmonary embolism. These results are comparable to those published by Jain *et al.* who had 1.9% rate of proximal DVT in their series of 106 patients without a single case of pulmonary embolism and with those published by Bagaria *et al.*, [7] who reported 6.2% incidence of DVT. It is rather interesting that though all our patients came from the state of Maharashtra, one of the Western Indian states with a different demographic pattern compared to the North Indian patients included in study by Jain *et al.*, the incidence of proximal DVT is around 2%. So, it may not be inappropriate to assume that the same incidence would be applicable to the Indian scenario.

From our study and those by other Indian authors (6, 7), it appears that DVT and PE in Indian patients is a fairly low incidence problem. The sample size of 105 patients in our study seems to be reasonable, as the sample size required for the estimation of incidence rate (of value 0.07) is 123 with an error of 0.045.Though the number is rather small,it is not too small to say that thromboprophylaxis is not important for all the patients. Further studies are required to confirm the findings of this research.

Conclusion

We believe that though there is enough evidence in the Western literature to advocate routine thromboprophylaxis for patients undergoing surgery for fractures of lower limb, there is not yet enough evidence to justify the same for Indian patients undergoing major lower limb surgery like femur fracture. Though it is perhaps not appropriate to make any definite recommendation about chemoprophylaxis only on the basis of our research, we strongly agree with Gillespie *et al.* [23] and advocate that the orthopedic surgeons should use pharmacological prophylaxis only for the high-risk patients (advanced age, past history of DVT, presence of varicose veins, obesity, malignancy, immobilization, etc.) in whom the potential benefits clearly appear to outweigh the risks. However, a close clinical monitoring with a high level of suspicion for DVT and pulmonary embolism must be exercised. A duplex sonography should be preferably carried out on all the elderly and high-risk patients undergoing surgery for lower limb fractures between preoperative, 3rd postoperative day and a repeat ultrasonography should be performed on all the positive cases to rule out proximal propagation of thrombus. Patients with fall in oxygen saturation or with any other signs of Pulmonary embolism should be investigated further by ventilation perfusion scan or pulmonary angiography, as available. Trials involving a larger number of patients in future are required to confirm findings of this research which would help resolve the dilemma for the orthopedic surgeons in India whether or not to subject their patients undergoing lower limb major trauma surgeries like femoral fractures to chemoprophylaxis for DVT and PE.

We have selected only shaft femur fractures, other major fractures like IT pelvic acetabulum should be also taken into account.

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