Is routine thromboprophylaxis warranted in all patients of tibial fracture managed in an above knee plaster cast- A prospective analysis based on 190 patients.

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Abstract:
Background: Deep venous thrombosis and pulmonary embolism is a well-recognized complication of leg trauma and subsequent immobilization. We prospectively evaluated the incidence of deep venous thrombosis/pulmonary embolism in our patients of tibial fracture managed conservatively and need for routine pharmacological thromboprophylaxis in these patients.

Materials and Methods: This prospective study was performed on 190 patients of stable tibial fracture who were managed on an above knee plaster cast. No means of pharmacological thromboprophylaxis was used in these patients. After 6 to 10 weeks (mean 8 weeks), all these patients were subjected to duplex Ultrasonography. Rescan was done after 10 days to look for any progression of thrombus in these patients.

Results: Venous thrombosis was seen in 11 patients in our study. Two patients were obese as per BMI, three were smokers and two had other risk factors. There was no progression of thrombus after rescan after 10 days. Incidence of deep venous thrombosis was 6% in our study.

Conclusion: We concluded that routine thromboprophylaxis is not justified in all these patients as the incidence of DVT and subsequent pulmonary embolism is not cost effective. However, in patients with high risk factors the decision to put them on thromboprophylaxis should be individualized after considering all the pros and cons of the therapy.

I. Introduction
A well-known and feared complication of prolonged immobilization is Venous thromboembolism (VTE), which may present as deep-vein thrombosis (DVT) and/or pulmonary embolism (PE).¹ ³ In our setup, most stable fractures of tibia are treated in an above knee plaster cast. It has been presumed that this method may increase the chances of venous thromboembolism because of inactivation of the ankle pump.³ Various studies previously have documented the incidence to range between 1.1% to 20% in various injuries of the lower limb managed in a plaster cast.³ ⁵ However, the real incidence of DVT in isolated fractures of tibia managed conservatively is not well published. Our objective is to assess the incidence of DVT in this group of patients and to determine whether routine prophylaxis is justified.

II. Materials and Methods
This prospective study was based on patients with leg fracture admitted in a tertiary orthopaedic and trauma care hospital from January 2013 through December 2014. There were 1035 patients of fracture tibia/tibia and fibula admitted during this period. Among these 355 patients had associated injuries who had direct or indirect effect on the period of immobilization on tibial fracture. Among rest of the 680 patients, 460 patients were managed primarily by surgical intervention either by plating, nailing or external fixation depending on soft tissue condition and stability of fracture. Decision to manage the fracture conservatively was taken in 220 patients based on evidence and stability of fracture by respective head of units. Of these 18 patients refused to participate in the study. Patients were managed conservatively on an above knee cast ranging from 6 to 10 weeks. 12 patients were lost in the follow up. Thus 190 patients were included in the study. No mode of pharmacological thromboprophylaxis was used in these patients. Written informed consent was taken from all the patients and the study was approved by the institutional ethical committee. These patients were evaluated thoroughly regarding the risk factors of thromboembolism.

There were 100 females and 90 males with a mean age of 45 years (18 to 70). Mean body mass index was taken and patients were classified as normal, obese and overweight. One of the patients was on oral contraceptives and another one had a past history of breast malignancy and was declared as cured. A total of 40

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patients were smokers and all were males. They continued to smoke during the course of treatment although to a lesser degree. The mean duration of plaster cast was 8 weeks (6 to 10 weeks). All patients were kept non weight bearing during this course of time. The patients were reviewed at the end after removal of plaster in a hospital for any clinical evidence of deep venous thrombosis. Any symptoms or signs of DVT were noted. All patients were assessed for DVT by duplex colour Doppler ultrasonography of the affected limb. Doppler was done by radiologist not below the level of a senior resident. The Doppler was considered as negative if there was normal blood flow in the femoral, popliteal, tibial and peroneal veins, with the vessel lumen fully compressible and completely filled with colour. If the vessel wall was not compressible, patient was diagnosed as having deep venous thrombosis.

III. Results

Venous duplex ultrasonography showed venous thrombosis in 11 patients in our study. (Table 1) All patients were ambulatory but non weight bearing on the affected limb. Two patients were obese as per BMI, three were smokers and two had other risk factors. Clinically none of these patients had symptoms of deep venous thrombosis. Peroneal vein was involved in 4 patients, posterior tibial and peroneal vein in 2 patients, popliteal and deep femoral vein in 4 patients and popliteal and superficial femoral vein in 1 patient. All these patients were put on enoxaparin 40 mg once daily and were rescanned after 10 days. There was no progression of thrombus in any of these patients. To summarise, Incidence of deep venous thrombosis was 6% in our study.

IV. Discussion

One of the potentially preventable cause of morbidity and mortality in orthopedic surgery is venous thromboembolism. It can lead to fatal pulmonary embolism and unfortunately, the prophylaxis is not without problems and complications. Orthopedic surgeries like total hip replacement has a very high incidence of deep venous thrombosis (40% to 80%) \(^{14}\) and fatal pulmonary embolism (clinicalPE - 4% to 10% and fatal PE 0.2 % to 5 %) therefore chemical prophylaxis is justified in these patients.

The reported incidence of DVT after injuries to the lower limb treated in a plaster cast has been 1.1% and 20%.\(^{15}\) However the risk of fatal pulmonary embolism without thromboprophylaxis after injuries of lower limb is not known.\(^{16}\) We reported an incidence of 6% of DVT in our series in contrast to Giannadakis et al (1.1% ) \(^{17}\), however the range of injuries included was variable in their series with only 11 patients having an ankle fracture. Moreover, the mean duration of immobilisation was only 14.4 days and patients with risk factors like obesity and smoking were excluded in their series. An incidence of DVT of 3.5% was found by Solis and Saxby\(^{18}\) in patients who had undergone foot and ankle surgery. Like in our study, classical signs of deep venous thrombosis were absent in their case series. We therefore believe that the classic clinical signs of DVT such as tenderness and swelling of the calf are not relevant in an orthopaedic setting involving a fracture of a lower limb. DVT was diagnosed in 17 (9%) of 183 patients who received reviparin (low-molecular-weight heparin) and in 35 (19%) of 188 who received a placebo (odds ratio 0.45) in a prospective, placebo controlled trial by Lassen et al\(^{19}\). They evaluated 440 patients who required immobilisation for at least 5 weeks after a leg fracture or Achilles tendon rupture and concluded that DVT is common with prolonged immobilisation and prophylaxis is warranted and effective.

Routine prophylaxis for all patients of tibial fracture treated conservatively can be expensive especially for a Government run health sector like ours. In our opinion, the incidence is too low to be proved to be cost effective. Moreover, the guidelines issued by the American College of Chest Physicians in 2004 advised against routine prophylaxis for patients with isolated injuries of a lower limb. It is well documented that smoking, obesity, malignancy and oral contraceptives increase the risk of venous thrombosis and whether prophylaxis in this subgroup of patients is cost effective is not yet known and more studies are recommended with focus on this subgroup of patients. At present we do not recommend routine thromboprophylaxis in our patients with tibial fracture on above knee plaster cast. However, in high risk patients the recommendation to put them on thromboprophylaxis is made on case to case basis.

V. Conclusion

We concluded that routine thromboprophylaxis is not justified in all these patients as the incidence of DVT and subsequent pulmonary embolism is not cost effective. However, in patients with high risk factors the decision to put them on thromboprophylaxis should be individualized after considering all the pros and cons of the therapy.
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Table 1: Demographics of Patients who developed Deep venous thrombosis.

<table>
<thead>
<tr>
<th>Case</th>
<th>Age</th>
<th>Gender</th>
<th>Weight Bearing Status</th>
<th>Site of DVT</th>
<th>Predisposing factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>52</td>
<td>M</td>
<td>NWB</td>
<td>Popliteal and Deep femoral vein</td>
<td>Smoker</td>
</tr>
<tr>
<td>2</td>
<td>25</td>
<td>M</td>
<td>NWB</td>
<td>Peroneal vein</td>
<td>None</td>
</tr>
<tr>
<td>3</td>
<td>63</td>
<td>F</td>
<td>NWB</td>
<td>Popliteal and Deep femoral vein</td>
<td>None</td>
</tr>
<tr>
<td>4</td>
<td>47</td>
<td>M</td>
<td>NWB</td>
<td>Posterior tibial and Peroneal vein</td>
<td>Smoker</td>
</tr>
<tr>
<td>5</td>
<td>67</td>
<td>F</td>
<td>NWB</td>
<td>Popliteal and Deep femoral vein</td>
<td>BMI -28.4</td>
</tr>
<tr>
<td>6</td>
<td>36</td>
<td>F</td>
<td>NWB</td>
<td>Peroneal vein</td>
<td>Oral contraceptive</td>
</tr>
<tr>
<td>7</td>
<td>26</td>
<td>F</td>
<td>NWB</td>
<td>Peroneal vein</td>
<td>None</td>
</tr>
<tr>
<td>8</td>
<td>29</td>
<td>F</td>
<td>NWB</td>
<td>Peroneal vein</td>
<td>Breast carcinoma</td>
</tr>
<tr>
<td>9</td>
<td>61</td>
<td>M</td>
<td>NWB</td>
<td>Posterior tibial and Peroneal vein</td>
<td>None</td>
</tr>
<tr>
<td>10</td>
<td>59</td>
<td>F</td>
<td>NWB</td>
<td>Popliteal and Deep femoral vein</td>
<td>BMI – 31.6</td>
</tr>
<tr>
<td>11</td>
<td>58</td>
<td>F</td>
<td>NWB</td>
<td>Popliteal and Superficial femoral vein</td>
<td>None</td>
</tr>
</tbody>
</table>

*BMI – Body Mass Index (kg/m²)

References