

## Original Research Article

# Deep vein thrombosis prevention with triad of soluble aspirin, pneumatic compression device and early mobilization in surgically managed proximal femur fracture: an observational study

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### ABSTRACT

**Background:** To evaluate the effectiveness of regime of thromboprophylaxis including soluble aspirin, pneumatic compression devices and early mobilization in prevention of deep vein thrombosis (DVT) with patients of proximal femoral fracture managed by internal fixation.

**Methods:** The study was an observational study conducted at tertiary care hospital of Indian armed forces with sample size of n= 50, diagnosed case of fracture proximal femur and managed operatively with soluble aspirin and pneumatic compression devices and early mobilization. Patients were observed and evaluated periodically for 12 weeks post discharge with colour doppler assessment.

**Results:** The findings at end of 2 Week, n=1 (2%, p<0.003) had findings suggested of DVT and n=49 (98%) had no signs of DVT. Next periodic evaluation at 6 weeks and 12 weeks n=50 (100% p<0.001) was devoid of any doppler findings suggestive of DVT.

**Conclusions:** The observational prospective study demonstrated the triad of soluble aspirin, pneumatic compression and early mobilization were efficacious in prevention of DVT in surgically managed cases of fracture proximal femur.

**Keywords:** Deep vein thrombosis, Aspirin, Fracture femur, Doppler

### INTRODUCTION

Venous thromboembolism (VTE), comprising of deep vein thrombosis (DVT) and pulmonary embolism (PE), has annual estimated incidence of 0.27% to 1% affecting up to 5% of population during course of their life.<sup>1,2</sup> In general surgery patients without prophylaxis against VTE, the incidence of DVT have been reported to be as high as 30% with an associated fatality rate of 1%.<sup>1</sup> The acute morbidity associated with deep vein thrombosis may include pain and swelling and in severe cases leads to arterial compromise. Acute PE may cause chest pain, dyspnea, and hypoxia. Chronic complication of VTE include post-phlebotic syndrome from DVT in up to 40% and chronic thromboembolic phenomena after PE in 1% to 4% of cases.<sup>3-5</sup>

Approximately 2,20,000 to 2,50,000 proximal femoral fractures are reported in United States of America each year. Ninety percent of these fractures occur in patients older than 50 years. In younger population, it occurs as a result of high energy physical trauma. Proximal femoral fractures in elderly patients are often pathological usually resulting from minimal to moderate physical trauma to the areas of bone significantly affected by osteoporosis.<sup>6</sup> The incidence of these fractures is 2-3 times more in females as compared to males.<sup>7</sup> They are classified on the basis of anatomical location of fractures into: Fracture neck of femur, Inter trochanteric fracture and Sub-trochanteric fracture. According to Negi et al the reported incidence rate is 8% whereas Agrawala et al reported fifty-four percent incidence of the proximal femoral fractures.<sup>8,9</sup> Risk

of sustaining the proximal femoral fractures multiplies every year after the age of 50 years. The risk factors for proximal femoral fractures include: osteoporosis, a maternal history of hip fractures, pelvic and lower extremity fractures, head injury, prolonged immobilization, excessive alcohol consumption, high caffeine intake, physical activity, low body weight, previous hip fracture, visual impairment, dementia, smoking, and the psychotropic medications.<sup>10-15</sup>

Thromboprophylaxis can be achieved by pharmacologic anticoagulation, mechanical prophylaxis and inferior vena cava filter.<sup>16</sup> Coagulopathy is observed in 25% of traumatic injury which is life threatening. Existence of anticoagulant therapy effectively treats symptoms and decreases the recurrent VTE and death. Anticoagulants like Warfarin, unfractionated heparin, low molecular weight heparins, Factor Xa indirect inhibitor Fondaparinux, and the oral IIa inhibitor Melagatran and Ximelagatran are commonly used for chemical thromboprophylaxis. Recombinant human soluble thrombomodulin is a new and highly effective antithrombotic agent.<sup>16</sup> Prophylactic placements of vena cava filters in selected trauma patients may decrease the incidence of PE. The indications for prophylactic inferior vena cava filter insertion include prolonged immobilization with multiple injuries, closed head injury, pelvic fracture, spine fracture and multiple long bone fracture.

Multiple-trauma patients are at increased risk for DVT but are also at increased risk of bleeding, and the use of heparin may be contraindicated. Sequential compression devices (SCDs) are an alternative for DVT prophylaxis. Compression devices provide adequate DVT prophylaxis with a low failure rate and no device-related complications. Immobilization is one of important reasons of VTE. The ambulant patient is far less likely to develop venous thrombosis, but also complications of inactivity like contractures, decubitus ulcers, or osteoporosis (with its associated fatigue fractures), as well as bowel or bladder complications are avoided.<sup>17</sup>

Risk stratification for deep vein thrombosis is primarily done on basis of scores by Rosendaal et al, and Bulger et al.<sup>18,19</sup> Wells clinical prediction guide quantifies the pretest probability of DVT, this model enables physician to reliably stratify patients into high, moderate, or low risk categories.

The major goal of thromboprophylaxis is to prevent propagation of thrombus, pulmonary embolism and decrease the risk of loss of venous patency, and post thrombotic syndrome (persistent leg swelling, dermatitis, recurrent cellulitis, and ulceration). The various modalities recommended for prevention of deep vein thrombosis as per American college of chest physicians (ACCP) and the American academy of orthopedic surgeons (AAOS) includes.<sup>30</sup>

(i) Pharmacological therapies: LMWH, anti-coagulants (ii) Mechanical compression devices-(a) Graduated compression stockings (GCS), (b) Intermittent pneumatic compression (IPC), (iii) Early mobilization, (iv) Vena cava filters (v) Multimodal approaches: including combination of above modalities.

**Table 1: Deep venous thrombosis risk factor scores.**

Risk factor	Score
Age 41-60 years	1
Pregnancy or postpartum within 1 month	1
History of major surgery within 1 month	1
Minor surgery	1
Varicose veins	1
Swelling of legs	1
Inflammatory bowel disease	1
Obesity (BMI) >25 kg/m <sup>2</sup>	1
Oral contraceptives, patch, or hormone replacement therapy	1
Age older than 60 years	2
Malignancy or current chemotherapy or radiation therapy	2
Major surgery (>45 min)	2
Laparoscopic surgery (>45 min)	2
Confined to bed longer than 72 hours	2
Immobilizing cast shorter than 1 month	2
Central venous access for less than 1 month	2
Tourniquet time longer than 45 minutes	2
Age older than 75 years	3
History of DVT or pulmonary embolism	3
Family history of thrombosis	3
Factor V Leiden/activated protein C resistance	3
Medical patient with risk factors of myocardial infarction, CCF, or COPD	3
Congenital or acquired thrombophilia	3
Major, elective lower extremity arthroplasty, TKR, THR	5
Stroke within 1 month	5
Multiple traumas within 1 month	5
Hip, pelvis, or leg fracture within 1 month	5
Acute spinal cord injury with paralysis within 1 month.	5
<b>Risk factor score</b>	0-1      2      3-4      5+
<b>DVT Incidence (%)</b>	2      10-20      20-40      40-80
<b>Risk level</b>	Low      Moderate      High      Very high

**Table 2: Wells score stratification grouped in either a 2 or 3 risk group scoring system**

Risk factors	Score	
Active cancer (treatment ongoing, or within 6 months or palliative)	+ 1	
Paralysis or recent plaster immobilization of lower extremities	+ 1	
Recently bedridden for more than 3 days or major surgery less than 4 weeks prior	+ 1	
Localized tenderness along the distribution of the deep venous system	+ 1	
Entire leg swelling	+ 1	
Calf swelling more than 3 cm compared with asymptomatic leg	+ 1	
Pitting edema (greater than asymptomatic leg)	+ 1	
Previous DVT documented	+ 1	
Collateral superficial veins (non-varicose)	+ 1	
Alternative diagnosis (as likely or greater than that of DVT)	- 2	
<b>Probability (3 risk group)</b>	<b>Total score</b>	<b>Probability of DVT (%)</b>
Low risk	0	5
Moderate risk	1-2	17
High risk	>2	53
<b>Probability (2 risk group)</b>		
Low risk (DVT unlikely)	<2	6
High risk (DVT likely)	2	28

**METHODS**

This was a prospective study carried out at tertiary care hospital of Indian armed forces and studied the efficacy of combined use of soluble Aspirin, mechanical prophylaxis and early mobilization in prevention of DVT in surgically managed proximal femoral fractures without use of conventional chemical prophylaxis such as LMWH.

The present study included 50 consecutive patients who sustained trauma around the hip joint and underwent internal fixation in the form of dynamic hip screw, proximal femoral nailing or cannulated cancellous screws. Inclusion and exclusion criteria (Table 3) was followed and the flow of participants is illustrated (Figure 1). It was a longitudinal study with the subjects evaluated at multiple points in time. The prophylaxis regime was risk stratified as per the recommendations of American academy of orthopedic surgeons’ recommendations for DVT prophylaxis.<sup>20</sup>

The patients were observed post operatively during hospital admission as well as up to 12 weeks post discharge from hospital. All of them received standardized DVT prophylaxis regime, early mobilization, soluble aspirin (next day from surgery and continued 4 weeks post

operatively) and application of pneumatic compression devices (KENDALL SCD EXPRESS compression system). The patients were encouraged to perform active and passive physical exercises as tolerated. Postoperative doppler ultrasound was done on HDI 4000 (Philips medical systems Inc., Boston, MA, USA) for all the patients on both the lower limbs using linear probe (5.38-12 MHz) at 2 weeks post op, 6<sup>th</sup> week, and 12<sup>th</sup> week post op to access evidence of DVT, thereby excluding any patient with clinical or subclinical DVT as a result of trauma and surgical intervention.

All patients received thromboprophylaxis using tab Disprin, pneumatic compression devices and early mobilization. A record was maintained about the involved side, the type of surgery, and the position during surgery for both the groups. Patients were mobilized in bed as tolerated postoperatively, static and dynamic exercises were started on the next day after the surgery. It was ensured that none of the patients was immobilized in bed for more than 3 days after the surgery. All the patients were examined daily for clinical signs of DVT like diffuse swelling of the leg and foot, calf tenderness (Moses’ sign) and Homan's sign (pain on passive dorsiflexion of foot).

Doppler ultrasound was performed on the 14<sup>th</sup> postoperative day on the same machine for all the patients on both lower limbs to look for DVT. The radiologist was blinded about the study and group of the patients. The Doppler assessment included examination of bilateral common femoral, superficial femoral, popliteal, anterior tibial and posterior tibial veins. They were assessed for flow, visualized thrombus, compressibility, and augmentation. A diagnosis of DVT was made when there was visualization of thrombosis, absence of flow, and lack of compressibility or augmentation. The thrombi were classified to be proximal if they were found in popliteal vein or more proximal locations, and distal if they involved tibial or calf muscle veins. Patients who had both proximal and distal thrombus were classified as having proximal thrombosis. The patients having evidence of DVT on Doppler examination were treated according to the American college of chest physicians’ guidelines.

The subjects were evaluated both clinically and for clinical as well as by duplex ultrasound studies.

**Table 3: Inclusion and Exclusion criteria**

Inclusion criteria	Exclusion criteria
Age>18-80 years undergone internal fixation of hip with dynamic hip screw and proximal femoral nailing	Skeletally immature subjects, Subjects with associated fractures around the knee were excluded, Revision surgeries Patients with pre-existing DVT, Patients with pre-existing Coagulopathy, Patients already taking aspirin/ anticoagulant. Polytrauma patients

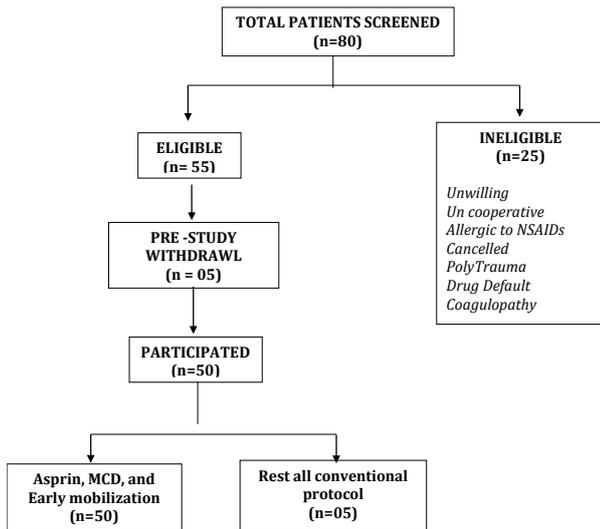


Figure 1: Participant flow for the study.

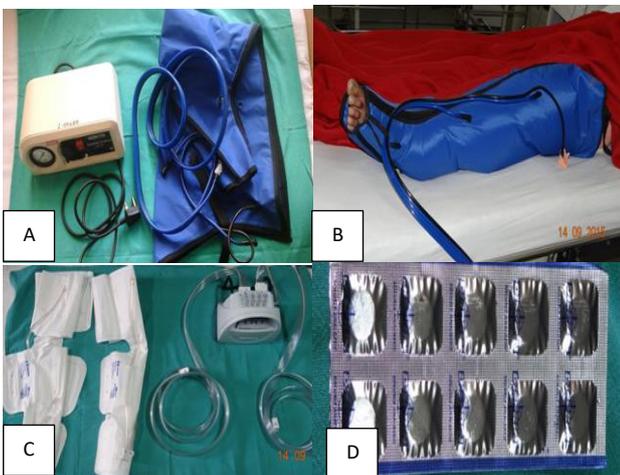


Figure 2: Mechanical compression device and aspirin. (A-C) Pneumatic compression device, (D) Soluble aspirin tablets.



Figure 3: Modes of fixation proximal fracture femur. (A) Proximal femoral nail, (B) Dynamic hip screw, (C) Cannulated cancellous screw.

**RESULTS**

The study was conducted and consecutive 50 patients as per inclusion and exclusion criteria were included. The study was prospective observational, assessment for incidence of deep vein thrombosis was carried out clinically as well as radiologically (by the Doppler evaluation).

The distribution pattern was more on higher side of male gender (60%). Out of 50 patients, 60% (30) were male and 40% (20) where female was in this study. Average age of study population was 67.38±18.95 years as shown in the Figure 4.

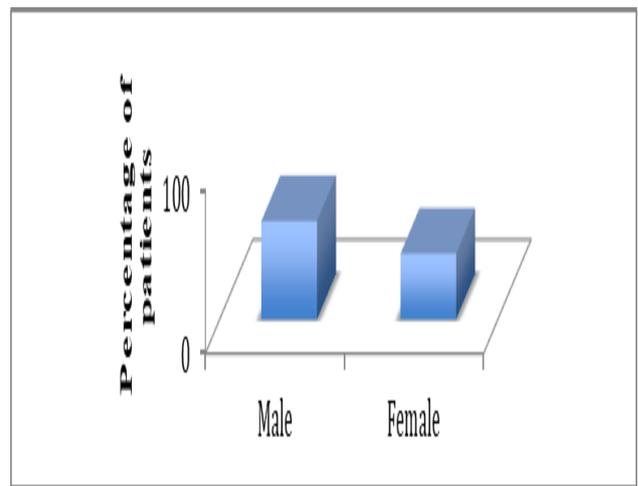


Figure 4: Gender distribution of study population.

The distribution pattern of proximal femur fracture and assessed for signs and symptoms of deep vein thrombosis, comprised mainly of Intertrochanteric fracture femur (n=42, 84%) (Table 4).

Table 4: Proximal femoral fracture patients assessed for DVT.

Diagnosis	N	Percent (%)
Basicervical fracture neck of femur	4	8
Intertrochanteric fracture femur	42	84
Nonunion fracture neck femur	1	2
Reverse oblique intertrochanteric fracture	1	2
Subtrochanteric fracture	1	2
Transcervical fracture neck femur	1	2

The patients were evaluated clinically for the signs and symptoms of deep vein thrombosis and swelling of limb was noted in n=33 (66%) and n=17 (34%) as shown in the Figure 5.

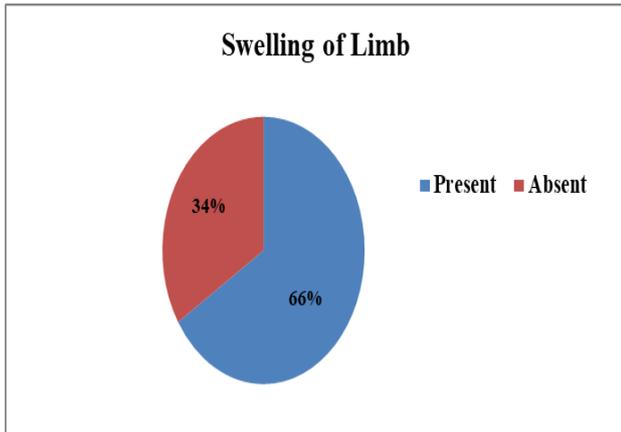


Figure 5: Incidence of swelling of limb.

Patients were managed surgically with dynamic hip screw (n=17, 34%), cannulated cancellous screw (n=2, 4%) and proximal femoral nailing (n=31, 62%). Patients were initiated with study protocol post-surgery on soluble aspirin 75 mg HS, mechanical compression device for DVT and patients encouraged for early mobilization the next post Op day (Table 5). Radiological and clinical evaluation for DVT was carried out at 2-week, 6 week and 12 weeks post operatively. The findings at 2-week suggested features of deep vein thrombosis in 1 patient (n=1, 2%, p<0.003), at 6 week and 12 week no patient had findings of DVT (n=50, 100%, p<0.001). The findings are illustrated in Figure 6.

Table 5: DVT prophylaxis regime.

DVT prophylaxis regime	N (number of patients)	Percent (%)
Early mobilization	50	100
Pneumatic compression	50	100
Soluble aspirin Prescribed	50	100

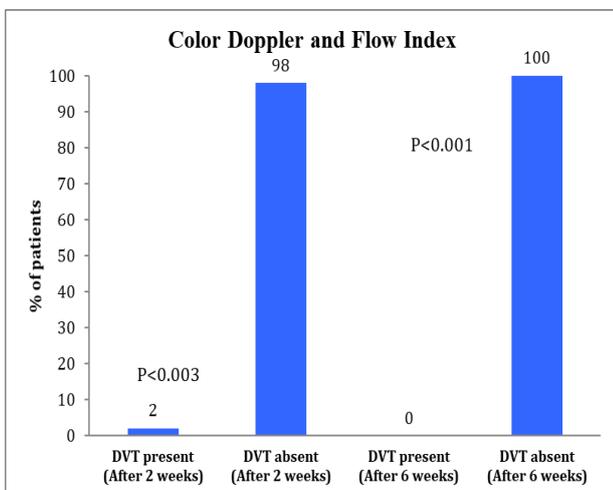


Figure 6: Assessment of DVT by color Doppler and flow index.

Two percent patients of total population showed occurrence of DVT in distal veins while 98% were free from DVT after 2 weeks of surgical intervention. All the patients were free from DVT at 6 weeks postoperatively onwards.

DISCUSSION

The present study was conducted to assess effect of soluble aspirin, pneumatic compression devices and early mobilization as deep vein thrombosis prophylaxis regime in patients with proximal femoral fracture managed by internal fixation. This was a prospective observational study conducted in department of orthopedics, military hospital, Kirkee, Pune after obtaining ethical committee approval.

Patients with a proximal femoral fracture are at particularly high risk for both deep venous thrombosis and pulmonary embolism requiring some form of preoperative and postoperative thromboembolic prophylaxis.<sup>21</sup> The elderly population (age>50 years) mainly suffers from proximal femoral fracture. This large group of patients are at high risk for the development of deep venous thrombosis (DVT) with 91% of incidence and prevalence of fatal pulmonary embolism following hip fracture has been reported up to 7.5%.<sup>22-24</sup>

This prospective study was designed to evaluate effect of different modalities of prophylaxis for DVT in patients with proximal femoral fracture. Out of 50 patients, 60% were male and 40% were female with mean age of 67.38±18.95 years. A study performed by Li et al included 41% of male and 59% of female in study aged 65-97 years. This difference might be related to difference between the total numbers of subjects involved in study. Li T et al included 82 number of patients with proximal femur fracture.<sup>25</sup> Sartoretti et al revealed that 80% of patients with femur fractures presented with cardiovascular, 41% with pulmonary, 67% with gastrointestinal and 71% with neurologic disorder or complains. In our study, 52% of patients with femur fractures were associated with either one complains like diabetes mellitus, hypertension, cancer whereas 48% of patients were not associated with any co morbid condition.<sup>26</sup> Swelling of limb was observed in 66% of patients with proximal femur fracture while 44% were free from such clinical sign. Kazmi et al found that all the patients with proximal femoral fracture developed edema postoperatively.<sup>27</sup> Holm et al also found thigh swelling in postoperative proximal femoral fracture patients.<sup>28</sup>

Intertrochantric fracture femur was found in 84% (n=42) of patients with proximal femoral fracture. Westrich et al assessed pneumatic compression with aspirin for thromboembolic disease prophylaxis in patients with hip fracture. Findings of this study suggested that only 1% of high-risk population was associated with DVT 3 months after surgical intervention.<sup>29</sup>

In present study, all patients were enrolled for early mobilization, pneumatic compression and soluble aspirin as prophylaxis regimen for DVT. DVT was assessed by colour Doppler and flow index at 2 and 6 weeks postoperatively. We found DVT was absent in 98% of patients at 2 weeks postoperatively. Moreover, 6 weeks after surgical intervention all the patients were free from deep vein thrombosis, findings of our study are consistent with reported data. This study supports the literature that prophylaxis regime (soluble aspirin, mechanical prophylaxis and early mobilization) for DVT in patients with proximal femoral fracture is useful in prevention of progression of thromboembolic disease. Serial colour Doppler examination revealed that 100% patients were free from DVT.

## CONCLUSION

Venous thromboembolism (VTE) and pulmonary embolism (PE) are common complication in patients undergoing orthopedic surgery, especially proximal femoral fracture fixation. In many patients, postoperative deep vein thrombosis (DVT) of the lower limbs is often asymptomatic whereas fatal PE is the first clinical manifestation of postoperative VTE.

It is inappropriate to depend on early diagnosis to initiate the treatment for thromboembolism. Prophylaxis is strategy of choice to decrease incidence of VTE after surgery. When risk of bleeding complications is less pharmacological prophylaxis is preferred while prophylaxis with mechanical methods is used in patients at high risk of bleeding complications.

The results from our study suggest that by combination of pharmacological as well as mechanical procedures provide prophylaxis of postoperative VTE. Risk for VTE has been adequately evaluated and the benefit of thromboprophylaxis established by using ultrasound technique.

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