



ISSN: 2395-1958
IJOS 2018; 4(1): 179-182
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www.orthopaper.com
Received: 21-11-2017
Accepted: 25-12-2017

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Evaluation of Efficacy of LMWH in Preventing DVT in Elderly Patients with Osteoporotic Hip Fracture

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DOI: <https://doi.org/10.22271/ortho.2018.v4.i1c.28>

Abstract

Background: As the geriatric population is rising, the incidence of osteoporotic fractures, especially hip fracture also increasing. Elderly patients with lower limb fracture especially osteoporotic hip fracture are at high risk for the development of deep vein thrombosis. Incidence of life threatening complications following DVT are also very common and ranges from 0.1% to 0.8% and may as high as 7% in patients undergoing hip surgery.

Method: In our study total 50 patients with osteoporotic hip fracture who gone for hip surgery were included and all the patients were started with LMWH (Enoxaparin) prophylactically to prevent DVT. Monitoring of all patients was done, in terms of development of sign and symptom of DVT. Diagnostic test Colour Doppler test were performed for making the diagnosis of DVT. Data were collected and analysis of the data was done to established the efficacy of LMWH in prevention of DVT and related complication in the target population.

Results: In our study out of total fifty patients with osteoporotic hip fracture, 28(56%) patients had fracture neck of femur and 22(44%) patients had intertrochanteric fracture femur. In our study two (4%) patients had wound haematoma, one (2%) patient had minor bleeding from wound and two (4%) patients had superficial wound infection which resolved easily without any further intervention. In our study six (12%) patients had DVT, out of that only two (4%) had symptomatic (swelling and leg pain) DVT while remaining four (8%) didn't had any symptom. No life threatening complication was found in any of our patients.

Conclusion: Our study shows very low incidence of DVT in patients who were receiving prophylactic treatment in the form of LMWH, hence it is evident that LMWH is a cynosure in preventing DVT in geriatric population and likewise.

Keywords: Venous thromboembolism, Hip Fracture, Deep vein thrombosis, Pulmonary embolism

1. Introduction

It has been seen there is increase in prevalence of DVT in the society and the major cause of which is rising number of elderly patients. This prevalent complication has got economic burden that's why prompt diagnosis and immediate treatment is essential to give better possible results in our treatment modality. To reduce morbidity, preventing pulmonary embolism and to prevent post thrombotic syndrome, anti-coagulant and thrombolytic agents has been used ^[1].

Low Molecular Weight Heparins were approved for prophylactic use in 1993, for THR and after that they have been inculcated in practice by many surgeons. Enoxaparin is the most ordinarily used LMWHs in North America which is administered by subcutaneous route. Since then LMWHs are being globally studied and found to be profusely effective as well as safe ^[2]. LMWHs (~4.5kd) are separated from standard heparin by precipitation with ethanol, gel filtration chromatography, partial de-polymerization with nitric acid and many other enzymatic and chemical means to choose the moieties that have an active sites for binding of ATIII (Fig. 1). In comparison to conventional heparin which have molecular weight of approx. 15 kD, the average molecular weight of LMWH is 4.5Kd. The anti-factor Xa activity is maximum around molecular weight 5.4Kd. As the polysaccharide side chain length is decreased from 18 U to 13U approx., the ability of molecule to form complex with AT III is preserved but the aPTT prolonging nature is lost.

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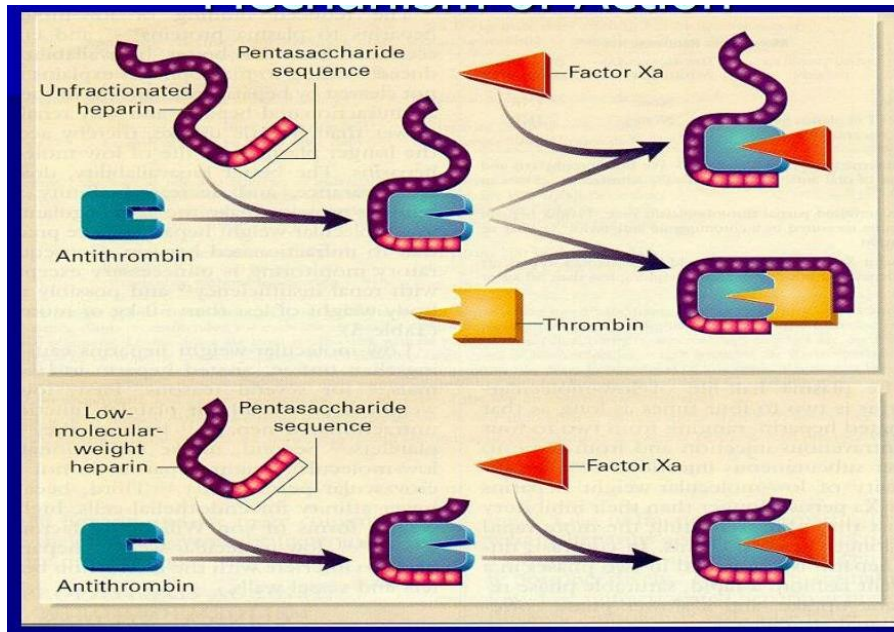


Fig 1: UFH and LMWH: Comparison of Mechanism of Action

LMWHs and standard heparins are different from each other in terms of their pharmacokinetic and pharmacodynamics properties. Factor Xa inhibition test is widely used to determine the biological activity of LMWH, in which antithrombin acts as a catalyst [3]. LMWH have better pharmacokinetic profile as compared to standard heparin and added advantage of dose adjustment according to weight without laboratory monitoring. LMWH have better bioavailability by subcutaneous route as compared to standard heparin. Therefore, response variation is minimal. LMWH have longer half-life of 4-6 hours as compared to standard

heparin ($t^{1/2}$ 1 hour) which makes it more remarkable for once daily administration.

Occurrence of DVT is quite to an extent determined by duration and timing of prophylactic agents. Most of the surgical patients when given early prophylaxis in the form of LMWH have shown lower incidence of DVT in postoperative period. Study by Hull *et al* demonstrated maximum effect of LMWH when started within 8 hours of surgery [4]. Most studied clinical criteria to predict DVT is Wells' scoring [5, 10]. (table 1)

Table 1: Wells' clinical criteria for determining DVT risk.

	Clinical Features	Score
1	Recent major Surgery in last one month or Recumbency of more than 3 days	1
2	Swelling of entire leg	1
3	Pitting type edema	1
4	Active cancer disease in last 6 months	1
5	Paresis, paralysis or cast in lower limb	1
6	Superficial collateral veins (non varicose)	1
7	Calf diameter of affected limb >3 cm large in comparison to opposite leg at 4 inches below the tibial tuberosity	1
8	Tenderness along the deep venous system	1
9	Differential diagnosis other than or likewise or more than DVT	2

Pre –test probability and frequency of DVT based on Wells' scoring system

Score	Probability	Frequency of DVT (%)
0	Low	03
1-2	Medium	17
>=3	High	75

Recommendations of ACCP for extensive orthopedic surgical procedure

In order to prevent DVT and subsequent complications in orthopedic patients, who are undergoing extensive surgical procedures, ACCP advised umpteen measures in 2012, which were based on clinical guidelines in 9th edition for preclusion of thrombosis and antithrombotic treatment [6].

- Patients who are undergoing surgery for Hip fracture, Fondaparinux, LMWH, LDUH (low dose unfractionated heparin), aspirin, dose adjusted VKA or IPC device is favored over no prophylaxis for about 14 days.

- Prophylaxis should commence within 12 hours before or after surgical procedure in those patients who are on LMWH.
- LMWH is preferred over other substitute agents irrespective of consequent use of IPC device or treatment duration.
- During the outpatient period, thromboprophylaxis should be encouraged for about 35 days commencing from the day one of surgery.
- Post-operatively, both IPC device as well as an antithrombotic agent is advised during the stay in

hospital.

- In those patients who are at higher bleeding risk, no prophylaxis or IPC device is preferred as compared to pharmacological measures.
- In uncooperative patients, dabigatran or apixaban (or if former two are not available the rivaroxaban or dose adjusted VKA) is advised.

Present study was done in order to assess the effectiveness of LMWH (ENOXAPARIN) in geriatric patients suffering from osteoporotic hip fracture in DVT prevention.

Materials & Methods

The present study was performed in the Orthopaedics Department of Hind Institute of Medical Science, Safedabad, Barabanki. Fifty patients who suffered from hip fracture following trivial trauma and presented in OPD/IPD/Emergency department of Orthopaedics during the period of October 2015 to April 2016 were taken in to account during the study with informed consent from the patients for inclusion in the study. The protocol received approval from Ethical committee of the institution. Our study includes osteoporotic fracture neck of femur and osteoporotic intertrochanteric fracture both.

Eligible candidates who were included in the study are male and female patients with osteoporotic hip fracture age more than 60 years.

Patients were excluded from the study if : 1) They were younger than 60yr of age; 2) Polytrauma patients; 3) Patients with Pregnancy; 4) Patients having active bleeding; 5) Documented history of bleeding disorder; 6) Previous hemorrhagic stroke or ophthalmologic, brain, or spinal surgery in last three months; 7) If they are planning to use an epidural or intrathecal catheter for six hours or more after surgery; 8) Patients have known history of hypersensitivity to low-molecular-weight heparins or heparin; 9) Serum creatinine concentration above 2 mg per dL; 10) Platelet count less than 100,000 per cubic mm; 11) Non-compliant patients or patients who have refused for consent.

On admission detailed clinical examination along with routine investigation for surgical fitness that includes routine blood count, viral markers, ECG, X-ray chest, PT, aPTT etc, of all the patients done, and prophylactic anticoagulant that is Enoxaparin 40mg subcutaneously once a day started. The initial dose was administered 12±2 hours preoperatively and the next dose 12 to 24 hours after surgery and continued for fourteen-day post operatively, as per recommendation of ACCP for DVT prophylaxis in hip fracture ¹⁶.

Colour Doppler Ultrasound of all the patients done on day one of admission, and then at 7th and 14th day post-operatively. Data were collected and analysis of outcome was done.

Results

As per our study Male: female ratio is 2:3. (Table - II)

Table II

Number of Male patients	Number of Female patients
20 (40%)	30 (60%)

Out of fifty patients, 28(56%) patients have fracture neck of femur and 22(44%) patients have Intertrochanteric fracture. (Table - III).

Table III

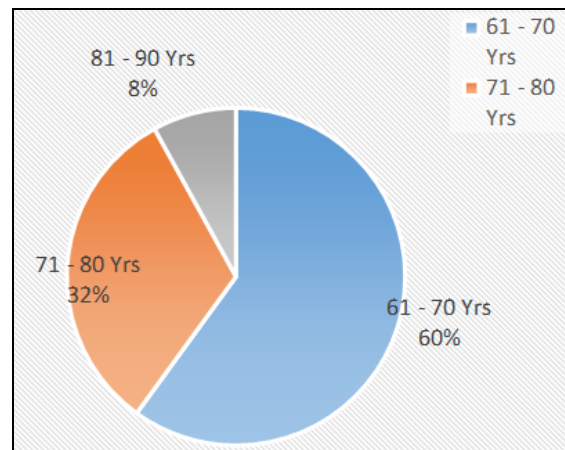
Patients with fracture Neck of Femur	28 (56%)
Patients with Intertrochanteric fracture	22 (44%)

The mean age of the patients in the study group was 69.48 years. The range in-group was 30 years with the minimum age of 61 years to maximum age of 90 years. Overall, the maximum numbers of the cases were between the ages of 61-70 years' age group 30(60%). Number of patients in 61-70 years' age group were 30 (60%), 71-80 years' age group were 16(32%) and 81-90 years' age group were 4(8%). (Table - IV, Graph - 1)

Table IV

Age group	No. of Patients
61 – 70	30 (60%)
71 – 80	16 (32%)
81 – 90	4 (8%)

As per our study 2(4%) patients had wound hematoma, 1 (2%) patients had minor wound bleeding and 2(4%) patients had superficial wound infection which resolved easily without any further intervention, remaining 45(90%) patients were don't had any complication. (Table - V)

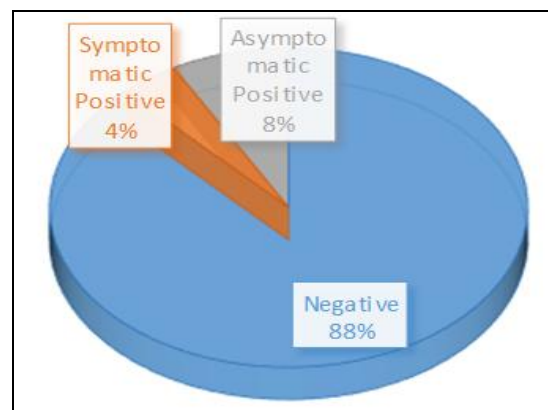


Graph 1: Age Distribution

Table V

Complications	Total No. of Patents (50 = 100%)
Wound Hematoma	2 (4%)
Wound Bleeding	1 (2%)
Superficial Infection	2 (4%)
No complication	45 (90%)

As per our study 6(12%) patients had DVT. Out of that only 2 (4%) had symptomatic DVT while remaining 4 (8%) patients having DVT, were asymptomatic. (Table – VI, Graph – 2)



Graph 2: Incidence of DVT

Table VI

Total No. of Positive Cases	Asymptomatic	Symptomatic
6 (12%)	4 (8%)	2 (4%)

Discussion

Those patients who have undergone lower limb orthopedic surgeries are very much prone to DVT and therefore this topic has always been a field of interest for orthopedicians who are devoted to decrease the risk factors as well as bypassing the side effects due to some anticoagulants [7]. In this study, we used LMWH (ENOXAPARIN) as thromboprophylactic agent in all the patients and Colour Doppler was used for diagnosis of DVT prevalence in the concerned population. Results of our study shows only 6 patients developed DVT out of 50 patients who received LMWH for DVT thromboprophylaxis. Incidence of DVT in our study was 12% out of which only 4% have symptomatic (swelling and leg pain) DVT while rest 8% cases of DVT were asymptomatic. The study published by Jain *et al* [8] shows lesser incidence of DVT after THA and TKA in Indian population as shown by duplex sonography and the result is comparable to the study done by us. In a similar study done by Bagaria *et al.*, a study of 147 patients who underwent extensive orthopedic surgical interventions like fixation of proximal femoral fracture and arthroplasty, malignancy, immobility > 72 hours, obesity, surgical duration >2 hours are considered as major risks factors for occurrence of VTE in Indian scenario [9].

As the age increases, the incidence of DVT is also found to increase, although age being an uncertain risk factor. According to our study, the patients who were suffering from DVT were having the mean age of 69.48 years (age group 61-90 years) and none of them had any prior risk factor for occurrence of DVT.

Low molecular weight heparin (LMWH) which is currently recommended being one of the preferred drugs for thromboprophylaxis has many potential disadvantages like increase in the total cost of treatment and bleeding complications.

In our study 2(4%) patients had wound hematoma, 1 (2%) patients had minor wound bleeding and 2(4%) patients had superficial wound infection which resolved easily, remaining 45(90%) patients were don't had any complication. McNally *et al.* have also stated increased incidence of bleeding complications like excessive bruising around the wound and increased wound bleeding or hematomas with the use of LMWH which has discouraged their everyday use in joint replacement surgeries [10].

As compared to Dhillon *et al* study which showed higher incidence of DVT with no thromboprophylaxis, our study has lesser incidence of DVT in those patients who have received thromboprophylaxis [11]. Out of 88 patients 55(62.5%) developed DVT. Of which 26(76.5%) patients had TKR, 9(14%) THR and 20(50%) had fracture neck femur. Results of our study depicts that use of LMWH as thromboprophylactic agent has considerably lower incidence of DVT.

Conclusion

Though western literature encourages the use of thromboprophylaxis in routine practice, there is no any suitable evidence to implement its routine use in Indian population. We strongly advocate use of thromboprophylaxis for the high risk patients, however we cannot recommend routine use of thromboprophylaxis depending on our study results. So, a close monitoring with a high level of suspicion

for development of clinical sign and symptom of DVT and PE, should be exercised. Duplex sonography should be preferably carried out in all the high risk patients and a repeat ultrasonography should be done in all the positive patients to exclude the possibility of dislodgement of thrombus at proximal site.

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