Safety And Feasibility Of Outpatient (OPD) Treatment Of Deep Vein Thrombosis With Low Molecular Weight Heparin: A Prospective Study

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Abstract

Deep vein thrombosis is a serious life-threatening disease which can lead to significant mortality and morbidity if not properly treated. Standard treatment of deep vein thrombosis has been the heparin therapy after hospitalization and strict monitoring of partial thromboplastin time (PTT) to avoid bleeding complications. Since the advent of low molecular weight heparins which provide a great safety margin as regards bleeding complications and have longer half-life and more predictable pharmacological response, they are used frequently in the treatment of deep vein thrombosis. As the bleeding complications are minimal and no laboratory monitoring is required, they can be given on OPD basis in a fixed dose depending on the weight of the patient.
The authors have treated 50 patients of deep vein thrombosis limited to the femoral vein with low molecular weight heparin (Bemiparin) with good results and without any significant complications.

INTRODUCTION

Deep vein thrombosis (DVT) is a significant cause of morbidity and mortality with an incidence of 500,000 cases per year1. Increasing age, obesity, prolonged immobility, pregnancy, puerperium, and estrogen therapy are major patient risk factors for DVT. Major gynecological orthopaedic, and especially pelvic surgeries carry a 40 to 50 % risk of developing DVT if prophylactic measures are not taken.2

Heparin has been the standard initial therapy for DVT since the 1940s. Admission to hospital has been deemed necessary for patients with DVT in order to treat them with dose-adjusted heparin administered parenterally.3

Low molecular weight heparins (LMWH) have better bioavailability, long plasma half-life, a less complicated mechanism of clearance, a more predictable anticoagulant response to fixed doses and also reduced platelet-associated side effects. Hence, LMWH can be given once a day without any laboratory monitoring.3,4

Many studies have shown that there is no difference between in-hospital administration of UFH and home administration of LMWH as regards to major bleeding, thromboembolism and death.5-7

In the present study the authors have used Bemiparin in a fixed dosage depending on weight, once a day, on OPD basis in patients of deep vein thrombosis limited to the femoral vein.

MATERIALS AND METHODS

The study was carried out in 50 patients with acute deep vein thrombosis presenting to the Department of Surgery or Accident and Emergency Department. Diagnosis was made on the basis of clinical signs and symptoms of DVT and confirmed by color Doppler examination.

All patients were subjected to routine laboratory investigations along with prothrombin time, partial thromboplastin time and platelet counts as baseline and repeated after one week or as per requirement. Only patients who had a thrombus limited to the femoral vein and who lived within 10km from the hospital having easy access to the hospital as regards facility for transportation were included in the study.

Patients were given low molecular weight heparin (Bemiparin) in the dose of 5000 anti Xa IU/day if the body weight was less than 50kg, 7500 anti Xa IU/day for 50-70kg weight and 10000 anti Xa IU/day if the body weight was

>70kg for 7 to 10 days once a day subcutaneously. Oral anti-coagulants were stared on the third day and the dose was titrated to keep the International Normalized Ration (INR) between 2 and 3. Oral anticoagulants were continued for a period of 6 months.

Patients were examined for subjective relief of symptoms like pain and swelling. The circumference of both limbs was measured on the 7th and 14th day. Any complication like bleeding and thrombocytopenia was noted. Patients were kept on regular follow-up for 6 months and INR was maintained between 2 and 3. All the patients were advised graduated elastic compression stockings.

All patients were told to report in Emergency in case of any bleeding episode like hematemesis, melena, hematuria, excessive menstruation in females and easy bruisability. Doppler USG was repeated at three months and six months. The data obtained in terms of clinical improvement, bleeding complications, recurrent thromboembolism and Doppler USG was tabulated, analysed and subjected to statistical analysis.

OBSERVATIONS

This prospective study was carried out in the Department of General Surgery, Pt. B.D. Sharma PGIMS, Rohtak between August 2007 to July 2011. Fifty cases of deep venous thrombosis (DVT) proved by color Doppler ultrasound (USG) were included in the study. The patients of DVT were given LMWH (Bemiparin) injection subcutaneously once a day depending on weight. The following observations were made:

1. Age & sex distribution

The age of patients ranged from 15 years to 70 years, with a mean of 32.50 years. The maximum number of patients was in the 3rd and 4th decade of life. No case was seen below 15 years. There were 26 females and 24 male patients in our study. Female-to-male ratio was 1.08:1. Deep venous thrombosis was more commonly seen in the left leg (56% of cases) while right leg was involved in 44%, with a ratio of 1.3:1. In the present study, the weight of the patients ranged from 52 to 97kg, with a mean of 58.04kg.

2. Presenting symptoms

Pain and swelling were the most consistent presenting features present in all the cases. Raised skin temperature was seen in 24 cases (48%). Discoloration of limb was seen in 6 cases (12%).

3. Duration of symptoms

The maximum number of patients (48%) had symptoms for 6-10 days before coming to hospital. Ten cases (20%) came to hospital within 5 days of symptoms. Ten patients presented between 11-15 days. Six patients (12%) had symptoms for more than 2 weeks.

4. Predisposing causes

Table 1

Showing predisposing causes (n=50)

Predisposing causes	No. of cases	Percentage
Puerperium/pregnancy	10	20
Previous history of IHD	2	4
Trauma	2	4
Previous history of DVT	4	8
Postoperative general surgery	2	4
Gynecological and orthopedic surgery	6	12
No predisposing cause	24	48

In our study, 10 patients (20%) were in puerperium and this was found to be the most common cause of DVT. No predisposing cause could be found in 24 patients (48%). Two patients had previous history of ischemic heart disease, 4 patients were having previous history of DVT and another 6 patients had history of orthopedic surgery. Two patients had history of abdominal surgery while two had history of prolonged bed rest after trauma.

5. Clinical signs

Calf tenderness was present in all the patients and Homan's sign was positive in 96%. Mid calf circumference was higher in the affected leg as compared to the normal leg in all the cases. The maximum difference between mid calf circumferences (more than 3cm) was noted in 36 patients (72%). All patients of DVT had a difference of more than 1.5 cm in mid calf circumference.

6. Site of DVT on color Doppler ultrasound

Sixteen cases (32%) had a thrombus extending up to the distal femoral vein. In the present study, the maximum number of patients had calf vein thrombosis (68%).

7. Relief in pain following treatment

Fifty percent of pain relief was seen in 42 cases (84%) within one week and 8 cases (16%) showed pain relief within two weeks. Hundred-percent relief in pain was achieved within 7 days in 28% of patients. The maximum number of our cases (32 patients; 64%) had pain relief within a period of 8-14 days of treatment.

8. Complications

Table 2

Showing complications (n=50)

	No. of cases	Percentage
Thrombocytopenia	-	-
Minor bleeding	5	10
Major bleeding	-	-
Pulmonary embolism	-	-

None of the patients had pulmonary embolism or major bleeding. Mortality in the present series was nil. There was no incidence of thrombocytopenia. Five patients (10%) had episodes of minor bleeding. Three patients had excessive menstrual flow and 2 had hematomas at the injection site.

9. Color Doppler study at 3 months and 6 months
All patients showed partial recanalisation of thrombus on color Doppler at 3 months of follow-up. At 6 months of follow-up 40 (80%) patients showed complete recanalisation, while 10 (20%) patients showed partial recanalisation of the thrombus.

DISCUSSION

The incidence of deep venous thrombosis (DVT) in the United States is about 159 per 100,000 or about 398,000 per year.8 Patients affected represent many risk groups in a variety of clinical settings.

Unfractionated heparin (UFH) has been the anticoagulation of choice for initial treatment of DVT for several decades.9 However, its use was associated with various side effects like bleeding, thrombocytopenia and hypersensitivity. The development of low molecular weight heparins (LMWHs) has led to a re-evaluation of the standard treatment of DVT. Compared with unfractionated heparin, LMWHs have a longer half-life, less inter-individual variability in anticoagulant response to fixed doses, and a more favorable antithrombotic-to-hemorrhagic ratio. The present study was conducted to evaluate the efficacy and safety of low molecular weight heparin (Bemiparin) as outpatient treatment in the management of deep venous thrombosis.

Table 3

Comparison of age with different studies

Author	Mean age (years)
Harenberg et al.	63.7
Levine et al.	57
Gangireddy et al.	65
Present study	35.56

Increased age along with other predisposing causes is a risk factor for venous thromboembolism (VTE).10,11 Inactivity and reduced exercises associated with increasing age may lead to stasis of blood in veins leading to DVT.12 In a study conducted by Harenberg et al., the mean age of patients receiving LMWH was 63.7 years.13 In a clinical trial by Levine et al., the mean age of patients receiving LMWHs was 57 years5, while Gangireddy et al. reported the mean age of patients as 65 years14. Patients in the present study were in a younger age group mainly because of more of female patients in puerperium. Most of these women were below the age of 30 years. There are also regional differences in the age-related incidence of DVT.11

Deep venous thrombosis is more common in women than in men15. Pregnancy and intake of oral contraceptives lead to this increased incidence. Female-to-male ratio in our study was 1.08:1. In a study by Harenberg et al., female-to-male ratio was 1.6:1.13 Fowkes et al. reported the same incidence in men and women.16 The combination of venous stasis and change in levels of clotting factors accounts for the increased incidence of DVT in pregnancy and puerperium.15

Obesity is a risk factor for development of DVT. In the present study, the weight of the patients ranged from 52 to 97kg with a mean of 58.04kg. In a clinical trial by Lindmarker et al., the mean weight of patients receiving LMWHs was 76.8kg.17 In a study by Harenberg et al., the mean weight of patients receiving LMWHs was 75.8kg.13 The mean weight of patients in our study was comparatively lower, possibly because of a higher number of young females belonging to rural areas, who have lower body weight compared to the urban population. Another possible reason may be geographical variation in the body weight of the patients.

Incidence of thrombosis in the left leg is higher than in the right leg. The factors responsible for this are compression of the left-sided vein by the right iliac artery, an overdistended bladder, gravid uterus and congenital webs within the vein. In our study, the ratio of left leg to right leg involvement in DVT was 1.3:1. In the various clinical trials conducted, the ratio of left leg to right leg involvement in DVT ranged from 1.2:1 to 4.3:1.13,17,18

The cardinal features of venous thrombosis of the legs are pain and swelling. Pain is usually, but not always, associated with swelling of the legs. Pain and swelling were present in all the cases in the present study. Fever, discoloration of skin, numbness and tingling sensation were not features specific to the diagnosis of DVT. A high degree of clinical suspicion in patients presenting with pain and swelling of the

leg along with the predisposing factors is crucial for the diagnosis of DVT.19

Puerperium was the main predisposing factor responsible for 20% of cases of DVT in our study. In a trial of 204 patients, Lindmarker et al. did not have any patient in puerperium or pregnancy.17 The cause of the increased incidence of DVT in puerperium in our study may be decreased mobility of the patients after deliveries because of socio-cultural factors. In rural areas, women are not allowed to walk or move out, up to one month after delivery. Moreover, during pregnancy, the concentration of fibrinogen, prothrombin, factor VII, Stuart factor, Christmas factor, and antihemophilic factor are elevated and remain elevated till early puerperium, and the risk of DVT is increased. The gravid uterus may retard venous flow from legs and pelvis.18

Activating clotting factors generated at the sites of tissue trauma or in association with malignant tumors enter the circulation and result in fibrin generation in the areas of venous stasis. This mechanism of clot formation in veins accounts for the risk of DVT associated with trauma, surgery or malignancy.10 In a study by Hull et al., 95 out of 432 patients studied (21.9%) were suffering from cancer.20 In a clinical trial by Lindmarker et al., 16 out of 206 patients (7.9%) were associated with malignancies.17 In our study no patient of DVT was suffering from cancer.

Four percent of patients had trauma as a cause of DVT. In the present study, two patients who had DVT were suffering from multiple injuries. Bratt et al. had 7.4% of patients associated with trauma, while Charbonnier et al. had 8%.13 Immobility associated with trauma leads to venous stasis and tissue trauma leads to activation of coagulation factors, leading to DVT.10

There was history of laparotomy in two patients (4%) in our study. Factors associated with tissue trauma are responsible for increased chances of DVT in these patients. Nineteen percent of patients of DVT studied by Lindmarker et al. were associated with previous surgery.17 In a study of 651 patients by Charbonnier et al., 14.9% of patients gave history of surgery.20 Immobility leading to venous stasis is one of the main causative factors leading to DVT. Two patients (4%) were bedridden after trauma in the present study. In the study conducted by Charbonnier et al., 11.2% of patients were immobile.21 Fourteen percent of patients studied by Hull et al. had associated chronic obstructive pulmonary disease (COPD).20 Congestive heart failure and immobility because of COPD may lead to venous stasis.10

Calf tenderness and Homan's sign may be present, but are not specific for the diagnosis of DVT.12,15 Calf tenderness was present in 100% of patients in the present study. Homan's sign was positive in 96% of cases in our study. In all the cases, the difference between the mid calf circumferences was more than one centimeter. The maximum of the patients (72%) had a difference of mid calf circumference of 3cm between affected and normal limbs. Swelling and painful leg are the cardinal features of DVT. A difference in maximum circumference >1.4cm in men and 1.2cm in women should raise the suspicion of DVT22.

Fifty-percent pain relief and 100% pain relief was achieved in most of the cases within two weeks. Fifty-percent decrease in the swelling (as measured by mid calf circumference) was achieved in all patients within two weeks. There was no mortality in the present study. Lensing et al. had a mortality of 7.1% among patients receiving UFH and 3.9% among patients getting LMWH.23 However, Holm et al. found no fatalities in any of the patients getting LMWH or unfractionated heparin (UFH).24

There was no incidence of pulmonary embolism in the present series. In the clinical trial by Levine et al., 2 patients receiving UFH and one patient receiving LMWH, out of 253 and 247 patients respectively, had pulmonary embolism.5 In the clinical trial by Harrison et al., out of 89 patients who were treated at home with low molecular weight heparin, one patient had pulmonary embolism.25

Table 4

Comparison of bleeding complications

Author	Major bleeding (%)	Minor bleeding (%)
Holm et al.	-	-
Levine et al.	2	-
Hull et al.	0.5	-
Harrison et al.	1.2	-
Present study	-	10

There was no incidence of major bleeding in the present study; however, minor bleeding was noticed in 10% of cases. Holm et al. also had no incidence of major bleeding in any of the patients in their trail.26 In a study by Levine et al., 2 patients receiving LMWH had major bleeding complications as compared to 1.2% of patients getting UFH. Hull et al. found major bleeding in 5% of patients receiving UF and 0.5% in patients receiving LMWH.27 Harrison et al. reported major bleeding in 1.2% of patients studied by them.25

There was no case of recurrent DVT in the present study. In a study conducted by Levine et al. no incidence of new DVT was found, but 6.7% of patients getting UFH and 5.3% of patients receiving LMWH had symptomatic recurrent thromboembolism. There was an absolute difference of 1.4 % in favor of LMWH.5 There was no incidence of thrombocytopenia in the present study. Lindmarker et al. detected an incidence of thrombocytopenia of 1% in patients receiving UFH and 0% incidence in the group receiving LMWH.17 No patient in the study conducted by Bratt et al. had thrombocytopenia.28

The incidence of minor bleeding was 10% in the present study. In the study conducted by Lindmarker et al., the incidence of minor bleeding was 2% in patients receiving UFH and 4% in patients receiving LMWH.17 Koopman et al. found an incidence of minor bleeding of 7.5% in patients receiving UFH and of 26.5% in patients receiving LMWH.29 The dose of LMWH used in the above mentioned study was 12,300 IU/ day for the weight range of patients from 50 to 70 kg, whereas in our study dose of LMWH was adjusted according to the weight. The difference in the incidence of minor bleeding between different studies may be because of the difference in the dosage used or because of a difference in response to heparins between the populations studied.

All the patients in the present study showed improvement on the color Doppler after 3 months of the treatment. Harenberg et al. noticed regression of thrombi in 73% of patients receiving UFH and in 71% of patients receiving LMWH.13 All the patients were advised graduated elastic compression stockings in the present study as this helps in preventing post-thrombotic syndrome.30

Oral anticoagulants do not act immediately because time is required for normal coagulation factors already present in the plasma to be cleared. By reducing effective protein-C levels, oral anticoagulants might tilt the haemostatic balance towards coagulation rather than anticoagulation in the first 24 to 48 hours. So there is a risk of increase of thrombosis if oral anticoagulants are started without achieving therapeutic levels of partial thromboplastin time.31 Moreover, for proximal DVT, a longer period of heparin administration is helpful and warfarin may be delayed until 3 to 7 days after starting heparin.10 In our study, oral anticoagulants were started on third day while Levine et al. started oral anticoagulants on the second day.5 Low molecular weight heparin is safe, effective and convenient in the treatment of deep vein thrombosis and it has made home treatment of this disease feasible.32

Hence, outpatient treatment of deep vein thrombosis with low molecular weight heparin is effective and safe especially in patients where the thrombus is limited to femoral vein. It is not associated with any increased incidence of complications and it causes a lot of saving in terms of hospitalization and convenience for the patient.

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