ORIGINAL RESEARCH

A Comparative Study on Benefit Risk Analysis of Deep Venous Thrombosis Prophylaxis with and Without Enoxaparin among Patients with Proximal Femoral Fractures

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ABSTRACT
Background: The incidence of DVT in traumatic injuries is as high as 5-63%. An autopsy study found 20% death of PE and 65% of fatality of injured patients by DVT. Proximal femoral fracture are at a high risk of perioperative DVT and guidelines have recommended mechanical and pharmacological prophylaxis for patients undergoing surgery for hip fracture. But it remains controversial whether patients with proximal femoral fracture can benefit from thromboprophylaxis specially in Indian population. Our aim is to find out the role of enoxaparin in thromboprophylaxis, its adverse effects and surgery on different time span from date of injury on incidence of DVT.
Materials and Methods: Two arm observational study done on 100 patients presenting with proximal femur fracture above age of 40 years of either sex. Enoxaparin was given to group A and no pharmacological prophylaxis to group B. All patients were managed by anatomical reduction and fixation aiming to osteosynthesis. Serial colour doppler were done on admission and in postoperative ($5^{th}, 7^{th}$)days and during follow up(1st,2nd,3rd) months.
Results: out of 100 patients, most patients were 71-80 years old [28 (28.0%)]. 15 (30.0%) patients were 51-60 years of age in Group-A and 15 (30.0%) patients were 71-80 years of age in Group-B. Male population [61 (61.0%)] was higher than the female population [39 (39.0%)]. Normal Colour doppler finding at 5th Post-op Day was equal in both Group A and Group B [49 (98.0%)]. Cumulative incidence of DVT at 3month follow up were in Group A = 6% and in Group B = 8% which was not statistically significant. (P = 0.6966). 2 patients had headache and 1 patient had wound sokage in group A.
Conclusion: Routine thromboprophylaxis is not recommended in Indian patients with proximal femur fractures. Further studies needed regarding genetic, racial and ethnic effect in these patients.
Keywords: Deep vein thrombosis, proximal femur fractures.

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INTRODUCTION

Trauma patients are at high risk for deep vein thrombosis (DVT) and subsequent pulmonary embolism (PE) which are collectively referred to venous thromboembolism (VTE).[1] The incidence of DVT in patients with traumatic injuries is as high as 5-63%. Previous reports have shown that the incidence of VTE is up to 15% in trauma patients on prophylaxis.[2] An autopsy study found 20% death of PE and 65% of fatally injured patients by DVT. Therefore, it will increase the likelihood of progression to death, which is preventable and it shows the need for prophylaxis.[3] Moreover, the inevitable delay of surgical intervention due to transfer from primary care facilities could add to the risk of preoperative DVT.[4] It remains controversial whether patients with proximal femoral fracture can benefit from thromboprophylaxis before surgery specially in Indian population.[5,6] Some studies have shown that even established thrombi in Asian patients resolve spontaneously without any long-term consequences.[7,8]

Patients with proximal femoral fracture are at a high risk of perioperative deep venous thrombosis.[9] This risk has been well documented by previous studies.[1,2,10,11,12] and guidelines have recommended mechanical and pharmacological prophylaxis for patients undergoing surgery for hip fracture. Pulmonary embolism (PE) is an obstruction of the pulmonary artery or its branches by a thrombus (sometimes due to fat or air). The most likely source of thrombus in pulmonary arteries is an embolization from deep veins of the legs. Normally, there is a balance of procoagulant and anticoagulant factors in the blood that prevents thrombus formation intravascularly. One or more factors of the triad of Virchow can lead to the formation of DVT.[11,12]

Triad of Virchow

- Venous stasis (for example, immobility and congestive heart failure[CHF]
- Endothelial injury (for example, surgery and trauma)
- Hypercoagulability (for example, OCP, cancer, thrombophilia)
- Venous stasis is the most important factor, but the presence of endothelial injury and/or hypercoagulability increases the risk of DVT. Hospitalized patients are at risk of venous stasis, and with the presence of other factors, they are at increased risk of DVT compared to patients in community.

MATERIALS & METHODS

We had done a two-arm observational study on 100 patients presenting with proximal femoral fractures at trauma center and out patient department of R.G. Kar medical college and hospital for 16 months from April 2021 to July 2022. Patients more than 40 years and not allergic to enoxaparin were included in the study.

Exclusion Criteria

1. DVT diagnosed at the time of admission.
2. Having bilateral fracture.
3. Not fit for surgery or having known renal disease.
4. Known thromboembolic disease.
5. Patients who are already on anticoagulation therapy

The study population was then allocated into two groups:

Group A

50 patients receiving enoxaparin 40 mcg subcutaneously once daily.

Enoxaparin will be stopped 12 hours begore surgery and will be resumed again 24 hours after surgery and continued till discharge.

Group B

50 patients who will be on conservative management but no enoxaparin before or after definitive surgery

All patients were undergone surgery by means of anatomical reduction and fixation by various means (cannulated cancellous screw, dynamic hip screw, dynamic compression screw, closed reduction and nailing, proximal femoral plate). Bilateral lower limb venous colour Doppler on day of admission before surgery and at 5th and 12th postoperative period for detection of deep vein thrombosis in the study group. As there is increase evidence of DVT between 2nd and 10th

postoperative period.2 An expert orthopaedician will monitor all the study patients twice a day and if DVT is clinically suspected at any time colour Doppler will be done within 8 hours. Intraoperative blood loss estimation will be done by subtracting weight of dry mop and normal saline lavage from weight of wet mop and sucker machine collection.

Need for perioperative blood transfusion, post-operative suction drain collection and any wound complications shall be recorded. Postoperative blood for haemoglobin, PCV, platelet count, aPTT and INR shall be sent on day 3. Post operatively all patients shall be advised active and passive mobilization even in non-ambulatory patients. After discharge patient will be followed up monthly with clinical examination and bilateral lower limb venous colour Doppler

Statistical Analysis

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and Graph Pad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate.

Once a t value is determined, a p-value can be found using a table of values from Student's t-distribution. If the calculated p-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favor of the alternative hypothesis.

P-value ≤ 0.05 was considered for statistically significant

RESULTS

In our study, out of 100 patients, most of the patients were 71-80 years old [28 (28.0%)]. 15 (30.0%) patients were 51-60 years of age in Group-A and 15 (30.0%) patients were 71-80 years of age in Group-B. Age was not significantly associated with Group (p=0.9537). mean age was slightly higher in Group-A [60.5400± 11.3213] compared to Group-B [59.8400± 12.0566] but this was not statistically significant (p=0.7654).

Table 1: Association between Age in group: Group

GROUP			
Age in group	Group-A	Group-B	TOTAL
$\leq$50	10	14	24

Row	%	41.7	58.3	100.0
Col %		20.0	28.0	24.0
51-60		15	12	27
Row	%	55.6	44.4	100.0
Col %		30.0	24.0	27.0
61-70		12	9	21
Row	%	57.1	42.9	100.0
Col %		24.0	18.0	21.0
71-80		13	15	28
Row	%	46.4	53.6	100.0
Col %		26.0	30.0	28.0
TOTAL		50	50	100
Row	%	50.0	50.0	100.0
Col %		100.0	100.0	100.0

Chi-square value: 1.5714; p-value: 0.6659;

We found that male population [61 (61.0%)] was higher than the female population [39 (39.0%)]. Male: Female ratio was 1.56:1. Sex was not significantly related with Group (p=0.8375)

Table 2: Association between Sex: Group

GROUP			
Sex	**Group-A**	**Group-B**	**TOTAL**
Female	19	20	39
Row %	48.7	51.3	100.0
Col %	38.0	40.0	39.0
Male	31	30	61
Row %	50.8	49.2	100.0
Col %	62.0	60.0	61.0
TOTAL	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 0.0420; p-value: 0.8375;

We observed that, higher number of patients had DM in Group-A [20 (40.0%)] compared to Group-B [15 (30.0%)] but this was not statistically significant (p=0.5653).

Table 3: Association between Comorbidities: Group

GROUP			
Comorbidities	**Group-A**	**Group-B**	**TOTAL**
DM	20	15	35
Row %	57.1	42.9	100.0
Col %	40.0	30.0	35.0
DM+HTN	4	4	8
Row %	50.0	50.0	100.0
Col %	8.0	8.0	8.0

HTN	15	14	29
Row %	51.7	48.3	100.0
Col %	30.0	28.0	29.0

It was found that, majority number of patients had DHS in Group-A [21 (42.0%)] compared to Group-B [8 (16.0%)] though it was not statistically significant (p=0.0633).

Table 4: Association between Type of surgery: Group

GROUP			
Type of surgery	Group-A	Group-B	TOTAL
CHS	3	3	6
Row %	50.0	50.0	100.0
Col %	6.0	6.0	6.0
closed reduction and nailing	13	14	27
Row %	48.1	51.9	100.0
Col %	26.0	28.0	27.0
DCS	1	4	5
Row %	20.0	80.0	100.0
Col %	2.0	8.0	5.0
DHS	21	8	29
Row %	72.4	27.6	100.0
Col %	42.0	16.0	29.0
Open reduction and nailing	10	19	29
Row %	34.5	65.5	100.0
Col %	20.0	38.0	29.0
Proximal Femoral plate	2	2	4
Row %	50.0	50.0	100.0
Col %	4.0	4.0	4.0
TOTAL	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 10.4577; p-value: 0.0633;
In our study, Normal Colour doppler finding at 5th Post-op Day was equal proportion in both Group A and Group B [49 (98.0%)] which was not statistically significant (p=1.0000).

Table 5: Association between Colour doppler finding at 5th Post-op Day: Group

GROUP			
Colour doppler finding at 5th Post-op Day	Group-A	Group-B	TOTAL
DVT	1	1	2
Row %	50.0	50.0	100.0
Col %	2.0	2.0	2.0
Normal	49	49	98
Row %	50.0	50.0	100.0
Col %	98.0	98.0	98.0
TOTAL	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 0.0000; p-value: 1.0000;

Odds Ratio: 1.0000 (0.0608, 16.4446)

We showed that, higher number of patients had Normal Colour doppler finding at 12th Post-op Day Group-A [47 (94.0%)] compared to Group-B [46 (92.0%)] though it was not statistically significant (p=0.9000).

Table 6: Association between Colour doppler finding at 12th Post-op Day: Group

GROUP			
Colour doppler finding at 12th Post-op Day	**Group-A**	**Group-B**	**TOTAL**
DVT	2	3	5
Row %	40.0	60.0	100.0
Col %	4.0	6.0	5.0
NA	1	1	2
Row %	50.0	50.0	100.0
Col %	2.0	2.0	2.0
Normal	47	46	93
Row %	50.5	49.5	100.0
Col %	94.0	92.0	93.0
TOTAL	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: .2108; p-value: 0.9000;

In Group-A, 20 (40.0%) patients had DVT and 47 (94.0%) patients had Normal in Colour doppler finding at 12th Post-op Day.
In Group-B, 3 (6.0%) patients had DVT and 46 (92.0%) patients had Normal in Colour doppler finding at 12th Post-op Day.
Association of Colour doppler finding at 12th Post-op Day with Group was not statistically significant (p=0.9000).

It was found that, slightly higher number of patients had Normal Colour doppler finding at 1st Month FU in Group-A [47 (94.0%)] compared to Group-B [46 (92.0%)] which was not statistically significant (p=0.5577). In our study, slightly higher number of patients had Normal Colour doppler finding at 2nd Month FU in Group-A [49 (98.0%)] compared to Group-B [48 (96.0%)] which was not statistically significant (p=0.5577). We observed that, slightly higher number of patients had Normal Colour doppler finding at 3rd Month FU in Group-A [49 (98.0%)] compared to Group-B [48 (96.0%)] which was not statistically significant (p=0.5577).

The Cumulative incidence of DVT in Group A at 3 month follow up= 6%. Cumulative incidence of DVT in Group B at 3 month follow up= 8%. Difference in cumulative incidence of DVT in the two groups was not statistically significant at 3 months. (P = 0.6966).

Table 7: Association between Colour doppler during follow-up: Group A

		Group-A	TOTAL
Colour doppler finding on Admission	Normal	50	50
Colour doppler finding at 5th Post-op Day	DVT	1	1
	Normal	49	49
Colour doppler finding at 12th Post-op Day	DVT	2	2
	NA	1	1
	Normal	47	47
Colour doppler finding at 1st Month FU	NA	1	1
	Normal	49	49
Colour doppler finding at 2nd Month FU	NA	1	1
	Normal	49	49
Colour doppler finding at 3rd Month FU	NA	1	1
	Normal	49	49

**Table 8: Association between Colour doppler during follow-up: Group B**

		Group-A	TOTAL
Colour doppler finding on Admission	Normal	50	50
Colour doppler finding at 5th Post-op Day	DVT	1	1
	Normal	49	49
Colour doppler finding at 12th Post-op Day	DVT	3	3
	NA	1	1
	Normal	46	46
Colour doppler finding at 1st Month FU	NA	1	1
	Normal	49	49
Colour doppler finding at 2nd Month FU	NA	1	1
	Normal	49	49
Colour doppler finding at 3rd Month FU	NA	1	1
	Normal	49	49

Cumulative incidence of DVT in Group A at 3 month follow up= 6%
Cumulative incidence of DVT in Group B at 3 month follow up= 8%

Difference	2.0%
95% CI	-9.3% to 13.5%
Chi-squared	0.152
DF	1
Significance level	P = 0.6966

Difference in incidence of DVT in the two groups was not statistically significant at 3 months.

Cumulative incidence of DVT in the two groups
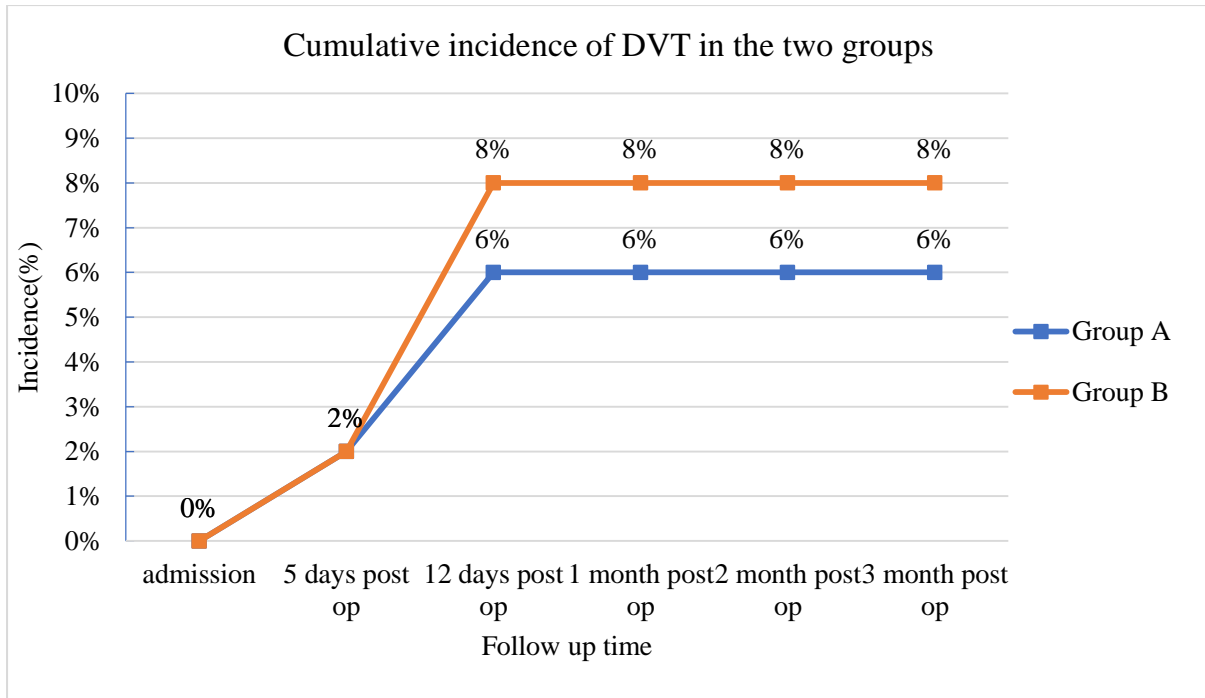
In our study Unequal variance two sample T- test showed non-significant difference in duration from injury to surgery among those who had DVT from those who did not T(7.16)= 0.87, p=0.41.

DVT incidence	No of patients	Average duration from injury to surgery(days)	Std Dev of injury to surgery	P value
no	93	7.139784946	3.658199242	0.41
yes	7	6	3.31662479	
Grand Total	100	7.06	3.631567544	
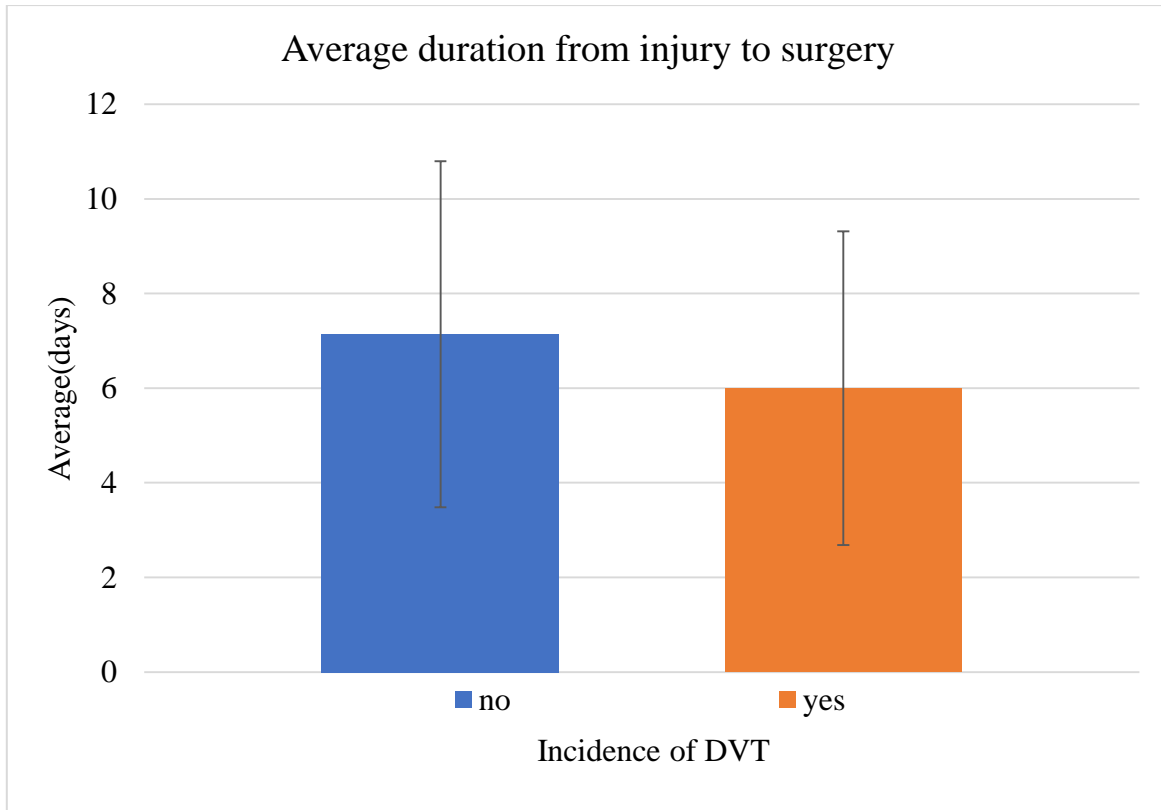
In our study, lower number of patients had Requirement of perioperative blood product transfusion in Group-B [47 (94.0%)] compared to Group-A [46 (92.0%)] but this not statistically significant (p=0.6803).

Table 9: Association between Requirement of perioperative blood product transfusion: group

GROUP			
Requirement of perioperative blood product transfusion	**Group-A**	**Group-B**	**TOTAL**
No	32	30	62
Row %	51.6	48.4	100.0
Col %	64.0	60.0	62.0
Yes	18	20	38
Row %	47.4	52.6	100.0
Col %	36.0	40.0	38.0
TOTAL	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 0.1698**; p-value:** 0.6803;
Odds ratio: 1.1852 (0.5281, 2.6601)

We found that, higher number of patients had wound soakage and headche in Group-A [1 (2.0%)] and it was statistically significant (p<0.0001).

Table 10: Association between Adverse effect: Group

GROUP			
Adverse effect	**Group-A**	**Group-B**	**TOTAL**
Headache	2	0	2
Row %	100.0	0.0	100.0
Col %	4.0	0.0	2.0
NA	0	50	50
Row %	0.0	100.0	100.0
Col %	0.0	100.0	50.0
None	47	0	47
Row %	100.0	0.0	100.0
Col %	94.0	0.0	47.0
wound soakage	1	0	1
Row %	100.0	0.0	100.0
Col %	2.0	0.0	1.0
TOTAL	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 100.0000; **p-value:** <0.0001;

In our study, mean Duration of injury in Day was slightly higher in Group- B [3.8600± 1.9589] and Group- A [3.8600± 1.9796] which was not statistically significant (p=1.0000).

Table 11: Distribution of mean Duration of injury in Day: Group

		Number	**Mean**	**SD**	**Minimum**	**Maximum**	**Median**	**p-value**
Duration of injury in Day	Group-A	50	3.8600	1.9796	0.0000	8.0000	4.0000	1.0000
	Group-B	50	3.8600	1.9589	0.0000	8.0000	4.0000	

We found that, mean Duration from admission to surgery was slightly lower in Group- B [3.1400± 1.8184] and Group- A [3.2600± 1.8273] though it not statistically significant (p=0.7427).

Table 12: Distribution of mean Duration from admission to surgery: Group

		Number	**Mean**	**SD**	**Minimum**	**Maximum**	**Median**	**p-value**
Duration from admission to surgery	Group-A	50	3.2600	1.8273	0.0000	7.0000	3.0000	0.7427
	Group-B	50	3.1400	1.8184	0.0000	8.0000	3.0000	

Our study showed that, mean Hb on Admission was slightly higher in Group- A [10.1200± 1.6492] and Group- B [9.5800± 2.1768] which was not statistically significant (p=0.1652).

Table 13: Distribution of mean Hb on Admission: Group

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Hb on Admission	Group-A	50	10.1200	1.6492	6.0000	13.0000	10.0000	0.1652
	Group-B	50	9.5800	2.1768	5.0000	14.0000	9.5000	

We showed that, mean Hb at 3th Post-op Day was slightly higher in Group- A [9.0400± 1.5774] and Group- B [8.8600± 1.7614] but this was not statistically significant (p=0.5916).

Table 14: Distribution of mean Hb at 3th Post-op Day: Group

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Hb at 3th Post-op Day	Group-A	50	9.0400	1.5774	6.0000	12.0000	9.0000	0.5916
	Group-B	50	8.8600	1.7614	6.0000	13.0000	8.5000	

We showed that, mean INR on Admission was slightly lower in in Group- A [1.2740± .1084] and Group- B [1.2860± .0904] though it was not statistically significant (p=0.5492). we observed that, mean INR at 3th Post-op Day was slightly higher in Group- A [1.1780± .1217] and Group- B [1.1620± 1497] and it was not statistically significant (p=0.5589).

Table 15: Distribution of mean INR on Admission: Group

		Number	Mean	SD	Minimum	Maximum	Median	p-value
INR on Admission	Group-A	50	1.2740	.1084	1.0000	1.4000	1.3000	0.5492
	Group-B	50	1.2860	.0904	1.0000	1.4000	1.3000	

Table 16: Distribution of mean INR at 3th Post-op Day: Group

		Number	Mean	SD	Minimum	Maximum	Median	p-value
INR at 3th Post-op Day	Group-A	50	1.1780	.1217	1.0000	1.4000	1.2000	0.5589
	Group-B	50	1.1620	.1497	0.7000	1.4000	1.2000	

We showed that, mean Total Blood Loss was higher in Group- A [228.5300± 145.1274 (ml)] and Group- B [203.6880± 131.3817 (ml)] and it was not statistically significant (p=0.3718).

Table 17: Distribution of mean Total Blood Loss in ml: Group

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Total Blood Loss in ml	Group-A	50	228.5300	145.1274	30.1000	545.0000	234.2500	0.3718
	Group-B	50	203.6880	131.3817	21.4000	469.0000	225.7000	

DISCUSSION

In our study, out of 100 patients, most of the patients were 71-80 years old with a higher male population than the female population. Male: Female ratio was 1.56: 1. We observed that, higher number of patients had DM in Group-A compared to Group-B but this was not statistically significant. In our study, Normal Colour doppler finding at 5th and 12th Post-op Day was equal.

slightly higher number of patients had Normal Colour doppler finding at 1st Month, 2nd Month and 3rd Month FU in Group-A compared to Group-B which was not statistically significant and the cumulative incidence DVT in both groups is not creating any statistical significant difference.

We showed that there is no statistical significant difference from duration of injury to surgery to those who have DVT and who did not.

In our study, lower number of patients had Requirement of perioperative blood product transfusion in Group-B not receiving any enoxaparin compared to Group-A but this not statistically significant.

2 patients had headache and one patient had wound soakage after operation in group A. which was statistically significant. No post operative complaints were present in group B.

Our study showed that, mean Hb on Admission and Hb at 3th Post-op Day was slightly higher in Group- A and Group- B which was not statistically significant.

Total blood loss was higher in group A than in group B but does not have any statistical significance.

Mean INR at 3th Post-op Day was slightly higher in Group- A and Group- B as compared to INR on admission days. But the change is non significant.

CONCLUSION

We concluded from our finding that deep venous thrombosis prophylaxis with enoxaparin among patients with proximal femoral fractures is not required routinely because in patients who are on enoxaparin there is no statistical significant difference in incidence of DVT with those patients who are not on any chemical thromboprophylaxis. This may be due to

1. Prevalence of DVT is less in Indian population.[10]

2. Due miss diagnosis specially in asymptomatic patient as false negativity is high with usg.[28]

3. May be due to racial, ethnic or genetic cause.

So in Indian population regular use of thromboprophylaxis is not recommended in all proximal femoral fracture patients. Further study is needed to know the relation of genetic ethnic and racial factors on incidence of DVT among Asian population and western countries where incidence of DVT is high and regular thromboprophylaxis is recommended.[4,7]

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