Original Research Article

Incidence of DVT following medial open wedge high tibial osteotomy (MOW-HTO): Prospective study

Mohd Abdul Naser[1], Hari Chaudhari[2], Muzaffar Patel[3*]

[1]Associate Professor, [2]Assistant Professor, [3]Resident, Department of Orthopaedics, Indian Institute of Medical Science & Research, Jalna-431202, Maharashtra, INDIA.
Email: patelmb786@gmail.com

Abstract

Background: High tibial osteotomy (HTO) is an established procedure for the treatment of medial compartment osteoarthritis of knee with varus deformity and it has become a popular procedure. In elective knee surgeries such as total knee arthroplasty (TKA) and HTO, it is well recognized that those are associated with a substantial risk of developing deep vein thrombosis (DVT) which carries a risk of fatal pulmonary embolism. **Materials and Methods**: In this prospective study, we analysed 110 patients, operated with MOW-HTO, for medial compartment osteoarthritis, for evidence of DVT, after dividing the patients into a trial group which received chemoprophylaxis in the form of Fondaparinux and a control group which did not receive any DVT prophylaxis. **Results:** At postoperative day 6, overall DVT was diagnosed in 6 (15.78%) patients in control group and in 5 (7.1%) patients in fondapariux group ($P > 0.05$). All patients with DVT were asymptomatic clinically. Proximal DVT was diagnosed in only 1 patient (2.5%) in control group, however none of the patient in fondapariux group had proximal DVT ($P>0.05$). There was no case of symptomatic DVT and symptomatic PE in either group during the entire study period. Among demographic characteristic, age and body mass index (BMI) showed association ($P<0.5$) with postoperative incidences of DVT in univariate analysis, however multivariate analysis showed patients with age more than 55 years had significant correlation with post- operative DVT. Incidences of overall DVT diagnosed by Doppler USG and CT venography were not different statistically. **Conclusion:** Our data demonstrates that the incidences of DVT following MOW-HTO were lower than incidences following TKA in Asian patients. therefore it would not be advisable to use routine chemoprophylaxis following MOW-HTO in a low DVT incidence population

Key words: High tibial osteotomy, osteoarthritis of knee, deep vein thrombosis, pulmonary embolism

[*]**Address for Correspondence:**
Dr Muzaffar Patel, Resident, Department of Orthopaedics, Indian Institute of Medical Science & Research, Jalna-431202, Maharashtra, INDIA.
Email: patelmb786@gmail.com

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INTRODUCTION

High tibial osteotomy (HTO) is an established procedure for the treatment of medial compartment osteoarthritis of knee with varus deformity[1,2,3] and it has become a popular procedure. In elective knee surgeries such as total knee arthroplasty (TKA) and HTO, it is well recognized that those are associated with a substantial risk of developing deep vein thrombosis (DVT) which carries a risk of fatal pulmonary embolism.[4,5] Incidences of DVT following TKA are well documented with huge variation, with much lower prevalence in Asia than in the West, regardless of chemoprophylaxis use.[3,4,5,6] However, there exists a paucity of data regarding incidences of DVT after the HTO.[6,7,8,9,10] Few dedicated studies have been done to estimate the prevalence of DVT and venous thromboembolism (VTE) after a lateral close wedge high tibial osteotomy (LCW-HTO), reported high incidences of proximal DVT and symptomatic pulmonary embolism.[11,12] However these studies reported the incidences of DVT after LCW-HTO in the Western population, moreover, all

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subjects from both studies received chemothromboprophylaxis hence no comparative data has been available about incidences of DVT following LCW-HTO without chemoprophylaxis. Moreover, there have been no reports of the incidence of DVT following medial open wedge high tibial osteotomy (MOW-HTO) regardless of region of a study performed. The aim of our prospective study was 1) to estimate the incidence of DVT following MOW-HTO in Asian patients and to compare with the incidence of DVT following TKA in the same region. 2) to assess the need of chemoprophylaxis in the prevention of DVT following HTO in this cohort. We hypothesized that 1) incidences of DVT following HTO would be lower than the incidences following TKA in Asian patients. 2) Prevalence of DVT following HTO would be lower in Asia than in the West. 3) Chemoprophylaxis would reduce the incidences of DVT after MOW-HTO in Asian patients.

MATERIALS AND METHODS

Study design: This was a prospective, comparative study completed in a single surgeon's practice. The institutional review board granted approval for this study, written, informed consent was obtained from all subjects before surgery. The study group comprised all subjects undergoing MOW-HTO procedure for medial compartment osteoarthritis of knee with varus deformity. The criteria for exclusion included: patients with history of previous DVT or VTE, steroid, hormonal therapy, patients with documented congenital or acquired bleeding disorders, such as hemophilia, anticoagulation therapy, patients with history of recent trauma or surgery to concern limb, patients with diagnosed acute or chronic DVT pre-operatively, patients with contraindication to fondaparinux serum creatinine above 2 mg/dl and platelet count below 100,000 per cubic millimeter.[13,14] All subjects were operated for MOW-HTO using Tomofix® plate (Dupey-Synthes, Davos, Switzerland) under general anesthesia. The tourniquet time was recorded for each patient. A single suction drain was used to measure postoperative blood loss. Graduated compression stocking were used postoperatively for both lower limb in all patients. Active quadriceps and ankle motion exercise were initiated in immediate post operative period. Active and passive knee ranges of motion exercise (ROM) were started on postoperative day 1. Suction drain was removed on postoperative day 2 and patients were allowed to walk with support of crutches as tolerable. Allogenic blood transfusion was given to patient whose postoperative hemoglobin was below 8 gram/dl or if patient developed intolerable symptoms of anemia, with 1 unit given for each gram/dl loss. All patients were divided into two groups, (A) Fondaparinux group- This group comprised all patients who were operated from May 2016 to July 2019. Every patient of this group received 2.5mg of fondaparinux subcutaneous injection at 6 hours after surgery and further daily, till postoperative day 5. (B) Control group – This group comprised all patients who were operated from July 2019 to July 2020; Patients from this group did not receive chemoprophylaxis for prevention of DVT. Clinical symptoms of calf pain, increase in calf circumference, presence of Homan sign, were evaluated daily in postoperative period until patient was discharged. Any shortness of breath, chest pain, blood-streaked sputum suggestive of pulmonary embolism also looked for. All patients were instructed about symptoms of DVT and PE and were advised to follow up in case of development of any of these symptoms after discharge. All patients were followed up for 3 months.[15,16]

Radiological study: All patients underwent routine doppler ultrasonography (USG) preoperatively to detect preexisting DVT. At postoperative day 6 all patients were investigated with either doppler USG or CT venography, randomly. Doppler USG was planned to repeat in case, if patient reported any symptoms suggestive of DVT throughout 90 days of follow up. Ventilation Perfusion lung scan (V-P scan) was planned to confirm only in case of patient reported any symptoms suggestive of PE.

Outcomes measures: Efficacy outcomes were recorded as proximal or distal DVT. Thrombi confined to popliteal vein or above were classified as proximal DVT and calf vein thrombi were classified as distal DVT. Safety outcomes were recorded as major and minor bleeding incidences during hospitalization and outpatient visits. Major bleeding included clinically overt bleeding which require transfusion of two or more than 2 units of blood or blood products, bleeding with serious or life threatening clinical event or requiring surgical intervention.[14] Minor bleeding included subtle bleeding which did not meet the criteria for major bleeding and like ecchymosis larger than 5 centimeter, prolonged wound hemorrhages or any hematoma requiring aspiration.

Statistical Analysis: Statistical analysis was performed using SPSS software version 12.0 (SPSS Inc. Chicago, IL). The data was expressed as mean+_ SD. The differences of demographic variables such as age, BMI, tourniquet time were evaluated by independent sample 'T' test. Relationship between development of DVT and other variable (age group, BMI group, and gender) were evaluated by chi-square test.

RESULT

From May 2016 to July 2019, a total of 134 patients undergoing elective MOW-HTO were enrolled in the study, out of which 24 patients were excluded because they had one of the exclusion criteria. A total of 110 patients were prospectively followed up, of which Fondapariux group and control group had 70 patients and 40 patients respectively. None of the patient had preoperative DVT. The treatment groups were comparable with respect to demographic characteristic, including age, gender, body mass index (BMI), and tourniquet time and varus correction angle (Table 1). Doppler USG was used for 55 patients to investigate DVT, and remaining 55 patients were investigated with CT venography. At postoperative day 6, overall DVT was diagnosed in 6 (15.78%) patients in control group and in 5 (7.1%) patients in fondapariux group (P > 0.05). All patients with DVT were asymptomatic clinically. Proximal DVT was diagnosed in only 1 patient (2.5%) in control group, however none of the patient in fondapariux group had proximal DVT (P>0.05) (Table 2). There was no case of symptomatic DVT and symptomatic PE in either group during the entire study period. Among demographic characteristic, age and body mass index (BMI) showed association (P<0.5) with postoperative incidences of DVT in univariate analysis (Table 3), however multivariate analysis showed patients with age more than 55 years had significant correlation with post- operative DVT. (Table 4). Incidences of overall DVT diagnosed by Doppler USG and CT venography were not different statistically (Table 5). Postoperatively, there was no incidence of fatal bleeding or bleeding required reoperation in either group. However, 4 (5.7%) patients from fondapariux group and 1 (2.5%) patient from control group required postoperative blood transfusion (P>0.05). Minor bleeding incidences were recorded in 5 (7.1%) patients only from fondapariux group, while than in control group did not show any minor bleeding complication (Table 6).

Table 1: Demographic data of the study patients

Characteristics	Fondaparinux group (N=70)	Control group (N=38)	P value
Age (years)	54.9 (±8.9)	53.1 (±7.7)	
Sex (M: F)	11:59	10:25	
BMI (Kg/m^2)	25.8 (±2.9)	26.7 (±3.1)	
Tourniquet time (min)	43.7 (±8.8)	47.6 (±10.8)	P> .05
Correction angle (°)	9.1 (±3.3)	8.2 (±3.4)	
Preop Hb (g/dL)	13.1 (±1.4)	13.2 (±1.7)	

Table 2: Prevalence of DVT by day 6

Event	Fondaparinux group (N=70)		Control group (N=38)		P value
	No.	%	No.	%	
Total DVT	5	7.1	6	15.78	P>0.05
Prox DVT	0	0	1	2.6	P>0.05
Symptomatic DVT	0	0	0	0	P>0.05
Symptomatic PE	0	0	0	0	P>0.05

Table 3: Risk factors analysis for DVT

Risk factor	DVT		P value
	Positive	Negative	
Age group (<50, 50-60, >60)			0.044
BMI	28.4 (±2.3)	25.8 (±2.9)	0.002
Female sex	11.0%	89.0%	>0.05
Touniquet time	44.9 (±12.5)	45.0 (±9.3)	>0.05
Correction angle	9.6 (±3.5)	8.7 (±3.3)	>0.05

Table 4: Multivariate analysis of risk factors for DVT

Risk Factor	B	SE	Wald	dF	P Value	Exp(B)	95% CI for Exp(B)	
							Lower	Uppper
Age (>55)	2.181	1.077	4.099	1	0.043	8.857	1.072	73.180

Table 5: Comparison of Doppler USG and CT Venography

Parameter	Ultrasonography (n=52)	CT venography (n=56)	P value
DVT	3 (5.8%)	7 (12.5%)	>0.05

Table- 6: Safety outcomes analysis of study patients

Parameter	Fondaparinux group (N=70)	Control group (N=38)	P Value
Major bleeding			
Fetal bleeding	0	0	P>0.05
Reoperation	0	0	
Transfusion ≥ 2U	4 (5.7%)	1 (2.8%)	
Minor bleeding			P>0.05
Ecchymosis	2 (2.9%)	0	
Aspiration	3 (4.3%)	0	

Table 7: Incidence of symptomatic DVT and PE reported following MOW-HTO

Author	Years	Country	Chemo-prophylaxis	No. patients	Symptomatic DVT (%)	PE (%)
Brus Miller[18]	2009	North America	Aspirin (325mg)	46	4-5%	0%
Buntoeng Pongsoipetch[2]	2009	Thailand	No	45	0%	0%
Irafan Esenkaya[3]	2005	Turkey	LMWH	58	3.4%	1.7% Nonfatal PE
Mehmet Asik[19]	2005	Turkey	No	65	3%	0%
Guntur Spahn[17]	2003	Germany	No	85	1.8-3.3%	0%

DISCUSSION

There are numerous reports describing the incidence of DVT and symptomatic PE following TKA in the literature,[4,5,6,7,8,9,10] however very few paper only from the Western literature regarding thrombotic complication after HTO.[11,12] To our best knowledge, this would be the first study, reporting incidence of DVT and symptomatic PE following HTO in Asian population. Furthermore, this is the first study regarding DVT following medial open wedge HTO since previous studies utilized lateral closed wedge HTO. A meta-analysis done by Kanchanabat *et al.*[9] reported low incidence of symptomatic PE and DVT following TKA in Asian patients. He reported, the incidence of symptomatic PE was 0.5% and the incidences of overall DVT, proximal DVT, and symptomatic DVT were 42.5%, 8.7% and 2.7%, respectively in Asian patient without chemoprophylaxis. Similar meta-analysis done by author and K Y Cho *et al.*[6] reported 40.4% incidences of overall DVT and 5.8%, 1.9% and 0.01% incidences of proximal DVT, symptomatic DVT and symptomatic pulmonary embolism, respectively. Our study recorded 15.78% and 2.5% incidences of overall DVT and proximal DVT respectively and no incidence of symptomatic DVT or PE was recorded during the study in control group, which suggested, prevalence of DVT and PE were much lower after HTO than TKA. TKA procedure is more traumatic, which involves more surgical dissection, deal with both femur and tibia, intamedullary reaming, and longer operation time than that of HTO; those could be the reasons for higher incidences of VTE after TKA. Many studies regarding HTO reported 1-5% of symptomatic DVT as a one the complication following MOW-HTO.[2,3,17,18,19] (Table-7). However, diagnosis of post-operative DVT is difficult due to surgical pain and odema after HTO, resulting into varied report of the incidences of symptomatic DVT following MOW-HTO. Furthermore, most of post operative DVT remained subclinical hence the incidences of DVT are generally underestimated; sometimes fatal PE may be the first indication of thrombosis. So a dedicated study to estimate the incidence of overall DVT following MOW-HTO is needed. A prospective study regarding DVT after LCW-HTO along with chemoprophylaxis reported 41% incidences of overall DVT and 18.5%, 6% and 1.2% incidences of proximal DVT, symptomatic DVT and symptomatic pulmonary embolism, respectively.[11] Similar study reported 9.7% incidences of overall DVT and 3%, 3.1% incidences of proximal DVT and symptomatic DVT respectively following LCW-HTO with chemoprophylaxis.[12] There was no incidence of symptomatic pulmonary embolism. These reports suggested high risk of DVT and PE after HTO in Western region even with chemoprophylaxis. Our study recorded 7.1% incidences of overall DVT along with chemoprophylaxis, however no incidence of symptomatic DVT or symptomatic PE were recorded in either chemoprophylaxis or control group. It suggested that prevalence of overall DVT after HTO was lower in Asia than in West. Moreover the incidences of proximal DVT,

symptomatic DVT and symptomatic PE were extremely rare in Asian population even without chemoprophylaxis; it was also concordance with geographical variation of DVT prevalence following TKA as demonstrated by literature. The proposed reason for this low prevalence of DVT in Asia would be ethnic difference, low prevalence of obesity and low-fat dietary pattern.[20,21] Moreover current study followed more aggressive postoperative mobilization program than these Western studies. Direct comparison of our result to Western reports was actually difficult because of different HTO procedures performed. LCW-HTO surgical procedure involves more surgical dissection, fibular osteotomy and violation of antero-lateral compartment of leg which could have contributed to possibly higher incidence of DVT in previous Western studies after LCW-HTO as compare to MOW-HTO. In contrast a meta-analysis of complication after MOW-HTO and LCW-HTO done by Smith *et al.*, reported no difference in the incidences of symptomatic DVT following these different HTO procedure,[22] however the authors evaluated only symptomatic DVT, they did not mention about incidences of overall or proximal DVT following HTOs. Many risk factors like old age, female sex, obesity intake oral contraceptive are documented for post-operative DVT.[7,10,20,21] Univariate analysis, in our study demonstrated positive correlation of increasing age and obesity with the incidence of postoperative DVT. However multivariate analysis showed age more than 55 years has significant correlation, regardless of use of chemoprophylaxis. Previous studies also highlighted age and obesity for risk factors.[7,10.20.21] It would be advisable to use routine chemoprophylaxis in these high-risk patients even in low incidence population. In chemoprophylaxis group, incidences of overall DVT were reduced from 15% to 7.1% and proximal DVT reduced from 2.5% to 0%. Many reports has shown similar efficacy of chemoprophylaxis using fondaparinux,[7,23] in both Asian as well as Western population. Nevertheless we could not show statistical significant reduction in DVT incidence with chemoprophylaxis. In contrast, there exists a concern of increase in bleeding incidences in postoperative period[23] Actually patients who required blood transfusion more than 2 units were more 4 (5.7%) in chemoprophylaxis group than 1 (2.5%) in control group. Similarly incidences of minor bleeding were seen in only chemoprophylaxis group. Safety analysis showed, although bleeding complications were little more in chemoprophylaxis group, there was no statistical significance. In this cohort, proximal and symptomatic DVT following MOW-HTO were extremely rare, even without chemoprophylaxis. Although the chemoprophylaxis could reduce overall incidence of DVT, it could not reach the statistical significance, hence considering risk of bleeding complication, it would not be advisable to use routine chemoprophylaxis following HTO in a low incidence population. However, selective use of chemoprophylaxis could be preferred in high-risk patients such as obesity to optimize cost-benefit ratio.

Limitations of our study were, first, it was a non-randomized controlled trial. However demographic characteristics' of both groups were matched. Second, as CT pulmonary angiogram or ventilation perfusion lung scan have not done routinely to all patients, we could not report the incidence of asymptomatic pulmonary embolism. Third, there was a heterogencity of DVT diagnostic modality during study. However, incidence of overall DVT diagnosed during our study by Doppler ultrasonography and CT venography were not different significantly. It showed, Doppler USG has almost equal sensitivity and specificity to venography.[24] Moreover American College of Radiology (ACR).[25] appropriateness criteria recommends Doppler USG as a most cost effective method for evaluation for proximal DVT and it is less invasive, easily available and can be repeated at any time as compare to venography. Fourth, our study could not predict the prevalence of VTE following LCW-HTO in Asian population or MOW-HTO in Western population either.

CONCLUSION

Current study demonstrates the incidences of DVT following MOW-HTO were lower than incidences following TKA in Asian patients. Prevalence of overall, proximal and symptomatic DVT and symptomatic PE were lower, even without chemoprophylaxis in Asia than in West. Chemoprophylaxis could not reduce overall incidence of DVT significantly. Moreover proximal and symptomatic DVT following MOW-HTO were extremely rare, even without chemoprophylaxis; therefore it would not be advisable to use routine chemoprophylaxis following MOW-HTO in a low DVT incidence population. However, selective use of chemoprophylaxis could be preferred in high-risk patients to optimize cost-benefit ratio.

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