Enoxaparin versus No Anticoagulation Prophylaxis after Total Knee Arthroplasty in Thai Patients: A Randomized Controlled Trial

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Background: There has been some controversy about routine use of thromboprophylaxis after total knee arthroplasty (TKA) in Asian patients.

Objective: To compare the efficacy and safety of enoxaparin in preventing venous thromboembolic diseases after TKA in Asian patients.

Material and Method: We randomized 50 patients undergoing primary TKA into two equal groups, 25 patients received once daily subcutaneous enoxaparin injections as thromboprophylaxis and 25 control patients did not receive anticoagulation. The primary outcome was deep vein thrombosis (DVT) identified by color Doppler ultrasonography and/or pulmonary embolism (PE). All significant bleeding complications were recorded.

Results: Deep vein thrombosis occurred in only one patient in the control group (4%) and in none in the enoxaparin group (0%, p = 0.31). No patient in both groups had clinical signs of PE. No patient had significant bleeding complications. One patient in enoxaparin group had a minor bleeding complication (4%) and also a surgical wound complication.

Conclusion: We concluded that the incidence of thromboembolic diseases after primary TKA in Thai patients is very low. Enoxaparin had no significant benefit in reducing venous thromboembolic complications after TKA in Asian patients, however it is safe in term of bleeding complications. We do not recommend routine use of enoxaparin as thromboprophylaxis after TKA in Asian patients.

Keywords: Asians, deep vein thrombosis, enoxaparin, knee arthroplasty, low-molecular-weight-heparin, thromboprophylaxis

Venous thromboembolism (VTE) is considered a serious complication after total knee arthroplasty (TKA)[1]. Postoperative VTE, consisting of deep vein thrombosis (DVT) or pulmonary embolism (PE) are life-threatening in patients after surgery. The incidence of VTE following TKA varies among different parts of the world[2]. In western populations, most studies reported high incidence of DVT ranging from 46 to 84%[1,3-5] and the incidence of PE ranges from 1.7 to 3.4%[1]. Routine chemoprophylaxis for DVT is considered standard of care after joint replacement[6,7] in western populations. Whereas, In Asian countries, the incidence of DVT ranges from very low; 4.4%[8], to high 61%[9], therefore routine VTE prophylaxis is still controversial in Asian population[10,11].

Several forms of thromboprophylaxis after TKA have been recommended such as low-molecular-weight heparin (LMWH), fondaparinux, dabigatran, apixaban, rivaroxaban, low-dose unfractionated heparin, adjusted

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dose vitamin K antagonist, aspirin, or an intermittent pneumatic compression device. Among these, LMWH is more popular than other agents[6]. However, like other anticoagulants, LMWH carries a risk of postoperative bleeding. Previous studies reported major bleeding rates ranging from 1.3% to 1.6%[12,13] which suggest that this can be a major concern.

We conducted the present prospective, double-blind, randomized controlled trial to evaluate risks and benefits of venous thromboprophylaxis with enoxaparin in Asian patients who underwent primary TKA.

Material and Method

From October 2012 to June 2014, there were 110 patients who undergoing elective primary knee replacement at our center. We included 103 patients scheduled for elective primary TKA aged between 50 and 85. Exclusion criteria were history of DVT or PE, history of haemorrhagic stroke or gastro-intestinal bleeding, renal impairment, the use of anticoagulants, allergy to enoxaparin. Fifty-eight patients were excluded from the study due to: refusal to participate [38], previous use of anticoagulants [18], history of previous DVT [2]; only 50 patients left in the study. All 50 patients were studied prospectively. Randomization was achieved by using a casual figures table, and sequentially numbered sealed envelopes. The study protocol was approved by the Mahidol University Ethics Committee and all patients signed written informed consents. All patients were diagnosed as primary osteoarthritis of knee. Primary TKA was performed by three experienced orthopaedic surgeons. The present study had been registered with the Thai Clinical Trials Registry (no. TCTR20140527001).

The 50 eligible patients (41 women and 9 men) were randomized into 2 equal groups. Group 1 received once daily a subcutaneous injection of 40 mg Enoxaparin sodium starting 24 hours after surgery. This was continued for seven to ten days. Group 2 received no prophylaxis. The patient demographic data, preoperative functional knee score (Oxford Knee Score), operative data (operative time, intraoperative blood loss), length of stay and complications (wound infection, surgical site hematoma) were recorded.

All patients received regional anesthesia with single-shot femoral nerve block combined with spinal anesthesia. All prosthesis were cemented,

fixed bearing, posterior stabilized knees (NexGen; LPS, LPS-flex, Gender Solutions; Zimmer, Warsaw, Indiana). Patellar were not resurfaced in any patients. We used intramedullary guide for the femoral cut and extramedullary guide for tibial cut. One dose of antibiotic prophylaxis with Cefazolin or Clindamycin was given before the operation. The operated leg was exsanguinated before inflation of the tourniquet with over 150 mmHg systolic pressure. The postoperative protocol included compressive dressing in the first 24 hours, drain was removed in 48 to 72 hours after operation, continuous passive movements was initiated on second day, followed by active mobilization and full weight-bearing ambulation.

Thromboembolic events assessment

The overall incidence of DVT was assessed by bilateral color Doppler ultrasonography on sixth to tenth day after surgery. The ultrasonography was performed by two radiologists who were blinded whether prophylaxis was used or not. Primary endpoint depended on positive diagnosis of thrombosis or loss of compressibility of a vein. Thrombi were classified by location (operated or non-operated leg), size (small <5 cm; large ≥5 cm) and anatomical site (proximal, distal). Proximal DVT referred to thrombi located at or extended above the popliteal vein. Thrombi located below popliteal vein were classified as distal DVT. Clinical signs of DVT were evaluated using score (Table 1) ranging from zero (low suspicious) to five (high suspicious). Clinical signs of PE were also evaluate using score (Table 2) ranging from zero to three (low to high suspicious). Serum D-dimer level was recorded at the third and seventh day after operation.

Bleeding assessment

Bleeding events were recorded and classified as major and minor. Major bleeding was defined as the presence of grade three hematoma which requiring operative removal, and bleeding that was fatal or involved a critical organ. Minor bleeding was defined as bleeding other than major bleeding or grade two hematoma. Total blood loss was calculated from the sum of intraoperative blood loss and postoperative blood loss recorded from a drainage system. The total unit number of blood transfused was also evaluated. Clinical assessment of surgical site hematoma was

Table 1. Deep-vein-thrombosis (DVT) clinical signs scoring system

Clinical signs	Score (point)
Swelling (circumferential diameter increase > 2 cm)	1
Warmth	1
Discolored skin	1
Visible surface vein	1
Positive Homan sign (Calf tenderness)	1

Table 2. Pulmonary embolism (PE) clinical signs scoring system

Clinical signs	Score (point)
Sudden dyspnea or tachypnea	1
Chest pain	1
Cough of haemoptysis	1

performed on the third and seventh days after surgery using hematoma grading scale from zero to three (Table 3).

Study endpoints

Primary endpoints were the incidence of DVT detected by color Doppler ultrasound, the presence of high clinical suspicious for PE which was objectively confirmed and major bleeding events. Secondary endpoints were DVT clinical scores, minor bleeding events, hematoma grading scores, total blood loss and total number of blood transfusions.

Table 3. Haematoma grading score used for evaluation of haematoma and haemarthrosis

Description	Grade
No haematoma or haemarthrosis	0
Minor haematoma around the wound with no haemarthrosis	I
Moderate haematoma around the wound extending to the calf, thing or popliteal region with haemarthrosis with no rehabilitation restriction	II
Severe haematoma or haemarthrosis threatening wound healing, requiring knee aspiration or reoperation and causing delay rehabilitation	III

All patients were clinically evaluated or telephone interviewed between three to six months after surgery to evaluate late DVT, post-thrombotic syndrome, readmission of any reason or other adverse events.

Data analysis

Intergroup comparison were determined using the chi-squared test, Student's t-test and Mann-Whitney-U test. Differences were considered significant when the p-value was <0.05.

Results

Patient demographics data and operative findings were summarized in Table 4. Intergroup differ-

Table 4. Patient demographics data and operative characteristics

Characteristic	Control (n = 25)	Enoxaparin (n = 25)	p
Age (years)	70 (6.8)	72 (6.9)	0.25
Women	21 (84%)	20 (80%)	0.71
Comorbidities			
HT	23 (92%)	19 (76%)	0.12
NIDDM	8 (32%)	9 (36%)	0.76
Ischemic heart disease	2 (8%)	1 (4%)	0.55
Previous history of inactive cancer	1 (4%)	0	0.31
Body Mass Index	26.9 (4.7)	29.1 (8.8)	0.28
Preoperative Oxford Knee Score	26.4 (7.6)	23.1 (7.9)	0.14
Operative time (minutes)	124.3 (22.3)	135.2 (26.7)	0.12
Length of hospital stay (days)	9.3 (1.6)	9.8 (2.1)	0.34

Data are number (%) or mean (SD)

Table 5. Summarized of mean D-dimer level and mean DVT clinical score.

D-dimer level/ DVT clinical score	Control (n = 25)	Enoxaparin (n = 25)	p
Mean D-dimer level in μg/ml (SD)			
3 days after surgery	0.65 (0.9)	0.76 (0.7)	0.66
7 days after surgery	1.9 (1.7)	2.0 (1.8)	0.78
Mean DVT clinical score (SD)			
3 days after surgery	1.08 (0.7)	1.00 (0.8)	0.72
7 days after surgery	0.72 (0.7)	0.76 (0.7)	0.78

ences were not significant for all items. Mean BMI was 26.9 in the control group and 29.1 in the enoxaparin group. There was no significant differences in BMI among the two groups ($p = 0.28$).

Thromboembolic events

There was one DVT in the control group (4%) which was distal with a large thrombusin the operated leg. It was asymptomatic and required no treatment. No patient in the enoxaparin prophylaxis group developed DVT. Although patients with enoxaparin prophylaxis had lower incidence of DVT than patients without, there was no statistically significant difference ($p = 0.312$). No patient developed clinical signs or symptoms of pulmonary embolism in both groups. Mean D-dimer level and mean DVT clinical score were summarized in Table 5.

There were no significant intergroup differences between the two groups. Two patients who developed DVT had D-dimer levels of 1.2 and 4.38 μg/ml at third and seventh day after surgery respectively, and had zero DVT clinical scores at third and seventh day after surgery, we repeated Doppler ultrasonography at three-month and found that the thrombus had resolved spontaneously.

Bleeding related events

No patient had major bleeding complications in both groups. Minor bleeding occurred in one patient (4%) in the enoxaparin group and none in the control group ($p = 0.31$). Total blood loss, total amount of blood transfusions and the hematoma grading score were summarized in Table 6.

Minor bleeding rate, mean amount of blood transfusion and mean postoperative hematoma score at day 7 were higher in the patients receiving enoxaparin prophylaxis, but there were no significant differences between the two groups.

The one patient who had minor bleeding from grade II surgical site hematoma, had a superficial wound infection and required prolonged hospital stay (19 days). There were no other complications in both groups. At three to six-month follow-up, all patients in both groups had no sign of late DVT or post-thrombotic syndrome.

Discussion

Our study showed that the incidence of thromboembolism after primary TKA in Thai patients was very low with or without enoxaparin prophylaxis.

In the western literatures, without prophylaxis, the incidence of DVT after TKA has been reported to

Table 6. Summarized of mean total blood loss, blood transfusion and mean hematoma grading score

Bleeding parameters	Control (n = 25)	Enoxaparin (n = 25)	p
Mean total blood loss in milliliter (SD)	595 (180)	567 (255)	0.27
Mean amount of blood transfusion in unit (SD)	0.44 (0.5)	0.48 (0.5)	0.90
Mean hematoma grading score (SD)			
3rd day after surgery	0.32 (0.4)	0.24 (0.4)	0.53
7th day after surgery	0.40 (0.5)	0.64 (0.5)	0.13

range from 46% to 84%[1,3-5], and the incidence of PE ranged from 1.7 to 3.4%[1]. In the Asian literature, a substantial variation exists in the incidence of DVT without prophylaxis. Several Asian reports suggest a low incidence of DVT[8]; however, a number of studies[9] suggest comparable incidence of DVT to those in Western countries. With enoxaparin as thromboprophylaxis after TKA, the incidence of DVT ranges from 29% to 33%[14,15] and the incidence of PE from 0.6% to 2.3%[16,17]. Our study reported low incidence (4%) of DVT in patients without prophylaxis and no case (0%) of DVT in patients with enoxaparin as prophylaxis and no patients with clinical signs of PE were found in both groups. Although the incidence of DVT in the non-prophylactic group is higher than in enoxaparin group, there was no significant statistical difference. We noted that our study population had lower body mass index (BMI 28) compared to populations from western countries (BMI 43.6 and 44.7)[18]. We believe that the lower incidence of thromboembolic events in Thai patients may associated with lower BMI. Frederick et al[19] studied risk factors for VTE and stated that overweight individuals may be at increased risk of VTE. In western literatures, studies about risks and benefits of enoxaparin as a thromboprophylaxis after TKA reported significant reduction in DVT[14,15]. There are scarcely any studies from Asia dealing with this subject. A study from Korea[20], reported very low incidence of DVT and PE after TKA with or without enoxaparin and suggested that enoxaparin had no benefit in reducing thromboembolism related events in Asian patients. However, it was a retrospective study included only clinically significant thromboembolism related events. With a prospective randomized controlled study design, including asymptomatic DVT detected by color Doppler ultrasonography, our study confirmed that the incidence of VTE is very low in Thailand. We used color Doppler ultrasonography for detecting DVT because it is non-invasive, safe, convenient and has a high accuracy[21,22].

The patient who developed DVT in the present study was 73-year-old female, BMI was 26, operative time was 145 minutes, D-dimer level was 1.2 and 4.38 μg/ml at third and seventh day after surgery, and DVT clinical score was zero at both third and seventh day after surgery. We could not identify correlation between DVT with any risk factors. The elevated D-dimer level in this patient confirmed the diagnosis of DVT, however, many patients in our study had elevated D-dimer levels without ultrasound-detectable DVT. Our data suggested that clinical evaluation has low accuracy in making diagnosis of DVT in Thai patients and that D-dimer has a better negative predictive value than positive predictive value. Wells et al[23] studied D-dimer in patients who were suspected of DVT and concluded that DVT could be ruled out in a patient who is clinically unlikely to have DVT and who has a negative D-dimer test.

For bleeding events, our study showed that there was no major bleeding event in both groups. Only one patient (4%) in the enoxaparin group had a minor bleeding event from a surgical site hematoma and also developed wound complication later and prolonged hospital stay (19 days). However, this minor bleeding incidence was not statistically significant compared to the control group. There was higher mean hematoma score and more blood transfusion in the enoxaparin group than in the control group, but this was not significantly different. Surprisingly, there was higher total blood loss in the control group than in the enoxaparin group, but without significant difference. The reported major bleeding incidence in the literatures ranged from 1.3% to 1.6%[12,13] which was higher than in the present study (0%). Liu and Chu et al[24] designed a trial to assess timing of enoxaparin administration in prevention of DVT after knee replacement surgeries. They found that administration of enoxaparin 24 hours after operation was safer for prevention of bleeding than 12 hours after operation, and was equally effective in prevention of DVT. In our study, we also started enoxaparin at 24 hours after surgery.

There were some limitations in the present study. First, the small number of patients in our study could not show any statistical significant difference in all parameters. We found that calculated sample size base on the incidence of venous thromboembolic events from the past literature was higher than in our study. Second, we used color Doppler ultrasonography to detect DVT which is operator dependent and had low sensitivity in detecting distal DVT[25]. Some patients with muscular vein DVT could have been missed. However, the prospective double-blind randomized controlled design is strength of the present study.

Conclusion

The present study showed that the incidences of thromboembolic events after primary TKA in Asian patients is very low. We believe that it is also low among the general Thai population in comparison to the West. Enoxaparin had no significant benefit in reducing venous thromboembolic complications after TKA in Asian patients, however it is safe in term of causing bleeding. We do not recommend routine use of enoxaparin as thormboprophylaxis after TKA in Asian patients. Each patient characteristics should be taken into consideration for deciding which one would be benefited from enoxaparin prophylaxis. Further studies should include a largerstudy population.

What is already known on this topic?

Venous thromboembolism is considered a serious complication after TKA. In Western population, most studies reported high incidence of VTE following TKA and routinely used of anticoagulant prophylaxis is recommended. However, in Asian countries, the incidence of VTE following TKA are varied and routine VTE prophylaxis is still controversial.

What is this study adds?

Thisstudy confirms the low incidence of VTE following TKA in Thai patients, and the benefit of anticoagulant prophylaxis after TKA is not clear. The recommendation of VTE prophylaxis after TKA in western country may not be applied to Asian population.

Authors' contributions

TI carried out the surgery, conceived the study, participated in the sequence alignment and drafted of the manuscript and performed the statistical analysis. NT carried out the surgery and participated in the design of the study. NS carried out the surgery and participated in the sequence alignment. ST carried out the ultrasonography and participated in the sequence alignment. MK participated in the design of the study and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

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การศึกษาการให้ยาต้านการแข็งตัวของเลือด Enoxaparin เพื่อป้องกันการเกิดลิ่มเลือดอุดตันหลอดเลือดดำในผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมในคนไทย

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ภูมิหลัง: ปัจจุบันการใช้ยาต้านการแข็งตัวของเลือดเพื่อป้องกันการเกิดลิ่มเลือดอุดตันหลอดเลือดดำในผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมในคนเอเชียยังเป็นที่ถกเถียงกัน ไม่มีแนวทางที่ชัดเจน

วัตถุประสงค์: เพื่อเปรียบเทียบประสิทธิภาพและความปลอดภัยของยา enoxaparin ในการป้องกันการเกิดลิ่มเลือดอุดตันในหลอดเลือดดำในผู้ป่วยชาวเอเชียที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าเทียม

วัสดุและวิธีการ: สุ่มผู้ป่วย 50 รายที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าเทียมเป็นสองกลุ่ม ๆ ละ 25 ราย โดยกลุ่มแรกได้รับยา enoxaparin ฉีดใต้ผิวหนังวันละครั้ง และกลุ่มที่สองไม่ได้รับยา โดยผลลัพธ์หลักของการศึกษาคือพบลิ่มเลือดอุดตันในหลอดเลือดดำที่ขาโดยการวินิจฉัยจากอัลตราซาวด์ หรือพบลิ่มเลือดอุดตันในปอด และการเกิดเลือดออกผิดปกติจนต้องได้รับการรักษา

ผลการศึกษา: พบการเกิดลิ่มเลือดอุดตันในหลอดเลือดดำที่ขาในกลุ่มที่ไม่ได้รับยาป้องกัน 1 รายคิดเป็นร้อยละ 4 แต่ไม่พบในกลุ่มที่ได้รับยาป้องกัน โดยไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ (p = 0.31) ไม่พบการเกิดลิ่มเลือดอุดตันในปอดในทั้งสองกลุ่ม ไม่พบเลือดออกผิดปกติจนต้องได้รับการรักษาในทั้งสองกลุ่ม พบผู้ป่วย 1 รายในกลุ่มที่ได้รับยาป้องกันเกิดเลือดคั่งบริเวณแผลผ่าตัดและภาวะแทรกซ้อนของแผลผ่าตัด

สรุป: อุบัติการณ์ของการเกิดลิ่มเลือดอุดตันในหลอดเลือดดำในผู้ป่วยที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าเทียมในคนไทยค่อนข้างต่ำ ประโยชน์ของการให้ยา enoxaparin เพื่อป้องกันการเกิดลิ่มเลือดอุดตันในผู้ป่วยชาวเอเชียที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าเทียมยังไม่ชัดเจน ภาวะแทรกซ้อนจากยาเรื่องเลือดออกผิดปกติต่ำ ยามีความปลอดภัยในการใช้งาน แต่ไม่แนะนำให้ใช้ยา enoxaparin เพื่อป้องกันลิ่มเลือดอุดตันในผู้ป่วยเอเชียที่ผ่าตัดเปลี่ยนข้อเข่าเทียมทุกราย