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Original Article

Thromboembolic disease after knee arthroplasty is rare in Southern Iran

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ABSTRACT

Background: Thromboembolic disease (TED) after knee arthroplasty occurs infrequently in Iran. The aim of this study was to examine the incidence of TED in patients with osteoarthritis undergoing knee replacement in Southern Iran while on prophylaxis.

Materials & methods: In a case series study from January to December 2012, 100 consecutive total knee arthroplasty (TKA) candidates were evaluated for TED by clinical evaluation and Doppler sonography preoperatively and 2 months postoperatively and by clinical evaluation one year after surgery. The patients in this study randomly received either warfarin or enoxaparin prophylactically.

Results: A total of 77 women and 23 men with mean age of 67 years (52–82 years) entered the study. The average hemoglobin drop of 2.7 g with warfarin and 3.3 with enoxaparin was observed. No case of TED, pulmonary embolus (PE), major bleeding, post-thrombotic syndrome, or hemarthrosis was observed.

Conclusion: No clinically significant DVT was found using either enoxaparin or warfarin prophylaxis after TKA in Southern Iran. Relatively excessive postoperative bleeding was observed, particularly with enoxaparin.

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1. Introduction

Thromboembolic disease (TED) is a potentially serious complication after joint replacement. The reported incidence of this condition varies from 40% to 80% without the use of prophylactic chemotherapy or physical modalities. Pulmonary emboli (PE), which may be fatal in 2% of cases, have been asymptomatic in 10%–20% and symptomatic in 0.5%–3% of patients.^{1–3} Anticoagulants can lower the TED risk down to 15%–30%.^{4,5} Warfarin is probably the most predictive agent

for thromboembolism prophylaxis following total knee arthroplasty (TKA).⁶ The drug is safe, inexpensive, efficient, and can be administered orally. However, the need for its prolonged use of several weeks, its delayed onset of action, its potential to cause drug interactions, and the requirement of frequent INR monitoring are untoward effects.⁷

In contrast, low-molecular-weight heparin (LMWH) can be given for a shorter period of time and does not require regular monitoring of coagulation factors. However, it has the potential for antiplatelet antagonism, is associated with an increased incidence of bleeding, is expensive, and requires

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administration by the subcutaneous route. In addition, its use with epidural anesthesia has been associated with major neurologic complications.^{7,8}

The newer oral anticoagulants that exert their action on factor Xa or through the direct inhibition of thrombin do not require coagulation monitoring, but are more expensive than warfarin. There is also no medication available for the rapid reversal of their effects. There have been multiple studies comparing this group of oral agents with enoxaparin with variable outcomes.^{9–11} The bleeding tendency with these agents has been reported to be greater than enoxaparin in some papers, and less in others.^{12,13} A meta-analysis performed by Dahl et al suggested a greater bleeding risk of up to 40% in association with enoxaparin than with these newer agents.¹⁴

The incidence of TED may be different in various populations or ethnic groups. There may also be a relationship between TED and the amount of postoperative bleeding in knee arthroplasty patients. The purpose of this study was to examine the occurrence rate of TED in a case series of patients with knee osteoarthritis while on prophylaxis following knee arthroplasty in our particular population and geographic location. At the same time, we compared the effect of warfarin with LMWH in that cohort.

2. Materials and methods

We conducted a prospective study of patients with knee osteoarthritis undergoing TKA by the senior author with one particular implant and with similar perioperative care from January–December 2012. The study was conducted to evaluate the incidence of thromboembolic disease. All patients in the study were candidates for TKA, were 50 years of age and older with knee osteoarthritis who had none of the exclusion criteria. All patients provided informed consent to randomly receive either warfarin or enoxaparin for TED prophylaxis at their own expense. They also agreed to pay for preoperative and postoperative Doppler sonography. Excluded from the study were patients younger than 50 years of age, patients with inflammatory or crystal arthritis, patients taking regular aspirin or other anti-inflammatory medications or any anti-coagulant for cardiac problems, and patients with a prior history of thromboembolic disease. For the study, TED prophylaxis was restricted to pharmaceutical measures with warfarin or enoxaparin (i.e., no mechanical prophylaxis). Simple randomization was conducted by providing warfarin to the first and every other patient and enoxaparin to the second and every other patient. This was continued until the calculated 100 cases were reached that would be appropriate for the number of TKAs performed in a year at the main referral clinic of the senior author in the Southern part of Iran.

Prophylaxis was provided with “LMWH” by way of a single subcutaneous injection of 40 mg of enoxaparin administered a few hours postoperatively. This was continued with a daily dose of 40 mg for five consecutive days in one group. The other group received 5 mg of warfarin in the immediate postoperative period and single daily doses of warfarin for one month. The target INR was 1.7–2.0 for this group of patients.

Study patients completed general health status, arthritis, and outcome questionnaires (SF36 and WOMAC), as well as a Knee Society Score (KSS) survey.^{15,16,17}

The procedures were all performed by a single surgeon using similar technique, under general anesthesia, and using a uniform type of prosthesis [cemented NexGen Legacy Posterior-Stabilized (NexGen LPS; Zimmer, Warsaw, Indiana)] using intramedullary femoral and extramedullary tibial guides, without any patellar resurfacing. All the cases were performed under tourniquet control. Sources of bleeding were fully cauterized with the tourniquet deflated before wound closure. All patients received uniform postoperative care, including soft cotton bandaging, active knee motion and ambulation within the first 24 h of surgery with the help of a physiotherapist. Continuous passive motion (CPM) was not administered. All patients were discharged with a small tensor bandage around the knee on the fifth postoperative day. The first postoperative clinic follow-up visit was two weeks after surgery. The second visit was two months after surgery, in which a repeat Doppler ultrasound was obtained (all patients received color Doppler ultrasound two weeks prior to surgery and again 2 months after TKA). Sonographic studies were all performed by one radiologist or sonographer with special interest and expertise in vascular sonography. The sonographer was blinded to the type of TED prophylaxis that the patients were receiving.

Any time that TED was suspected in the early days or weeks following surgery, additional Doppler ultrasound was obtained prior to the 2-months follow-up visit.

At the one-year follow-up visit, patients received a clinical evaluation for possible post-thrombotic syndrome (PTS) and were asked questions regarding leg or chest pain, leg swelling, ulceration, or any other symptom or sign suggestive of TED.

Patients paid all expenses for the medications and sonographs required for the study with no contribution from any drug company or third party. No funding was provided by any research or pharmaceutical center or company for the study.

3. Results

The 100 patients with primary knee osteoarthritis included 23 men and 77 women with an average age of 67 years and 11 months (52–80 years). There were 13 patients younger than 60 years of age, 72 between 60 and 74 years of age, and 15 older than 75 years of age.

In terms of risk factors for TED, the average BMI was 29.1 (20.3–39.3). This value was 27.2 for men (39% normal weight, 35% overweight, 26% obese) and 29.7 for women (10.4% normal weight, 44.1% overweight, 45.5% obese). Overall, in accordance with WHO criteria, 42% of patients were overweight and 41% were obese,¹⁸ whereas 40 patients from the warfarin and 43 from the LMWH group were classified as either overweight or obese (Table 1).

Other risk factors for TED in study patients included prominent varicose veins in the lower limbs in four patients, wheelchair ambulatory status in six patients, and breast cancer in four patients. One patient had a history of cerebrovascular accident (CVA), but was on no medication. A previous history of thromboembolic disease was not present in any patient. Patients had other associated diseases that were not

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