Original Article

Prevention of Deep Vein Thrombosis Associated with Temporary Transvenous Cardiac Pacemakers by Enoxaparin

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Background: The purpose of this prospective study is to quantify the risk of lower limb deep venous thrombosis (DVT) in patients requiring temporary transvenous femoral pacing and to evaluate the use of different enoxaparin dosages (prophylactic or therapeutic) for thrombus prevention. Transvenous temporary cardiac pacemaker, with catheters frequently used along the femoral vein is useful to relieve difficult bradyarrythmias and some tachyarrythmias. Up to one-third of patients receiving transfemoral pacing develop asymptomatic DVT. At present, there are no recommendations for thrombus prophylaxis in these patients. Besides, the efficacy in this specific condition has not been studied.

Methods: Sixty consecutive patients who underwent transvenous femoral pacing and had no contraindication to low molecular weight heparin (LMWH) therapy were divided into 3 groups each group consisted of 20 patients. Group I received prophylactic enoxaparin (1mg/kg/day; subcutaneously), group II received therapeutic enoxaparin (1 mg/kg/day every 12 hours; subcutaneously), and group III consisting of patients who were not treated with enoxaparin was considered as control group. Patients were evaluated daily for clinical features of DVT. Color Doppler sonography imaging was performed on both lower limbs of all patients within 24 hours after removal of the temporary pacemakers.

Results: Of the sixty patients, two who belonged to group III, had definitive evidence of right lower limb DVT by color Doppler sonography. These two cases of DVT were asymptomatic and had thrombosis of femoral vein. No evidence of thrombus was detected in contra lateral lower limb. No DVT was detected among patients who received prophylactic or therapeutic doses of enoxaparin. No heparin related complications were detected in this study. There were no significant difference in the clinical characteristics among 2 groups (I, II) and control group. Correlations of age and gender with occurrence of DVT were not significant (P= 0.512, 0.737).

Conclusions: This study showed that DVT is a common complication of femoral pacing, and that its incidence can be reduced with the use of prophylaxis and therapeutic intravenous enoxaparin.

Keywords: Pacemaker, prophylactic,therapeutic , deep vein thrombosis, enoxaparin

Introduction

Transvenous temporary cardiac pacing is used in the emergency treatment of patients with medically refractory bradyarrythmias and certain tachyarrythmias. The transfemoral route is frequently utilized due to its technical simplicity and perceived low incidence of complications.[1]

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Pacemaker as a foreign body in vein, which injures endothelium of vessels, increases the rate of thrombosis. Up to one-third of patients receiving transvenous cardiac pacemakers develop asymptomatic deep venous thrombosis (DVT).[2,3]

DVT is a blood clot which forms in a deep vein, most commonly in veins of the calf or thigh, and partially or completely obstructs blood flow. The clot may breaks off, travel to the vessels in the lung, causing a life-threatening pulmonary embolism (PE).[4] PE can present

as an acute problem that leads immediately at onset to dyspnea, hemoptysis, pleuritic chest pain or even hypotension and decreased level of consciousness, or can be a chronic problem with repeated small size pulmonary emboli. Furthermore, it can produce chronic pulmonary hypertension and RT sided failure.[5,6]

PE and DVT account for hundreds of hospitalization annually world wide; the death rate among nonselected patients is as high as approximately 15-18%.[2,8] Previous limited studies have described an incidence of asymptomatic DVT in the lower limbs of 25 to 34% in association with transfemoral pacing.

Full anticoagulation is the best treatment for DVT. In this case, heparin is usually preferred because of its immediate action, whereas warfarin may not become fully effective for a considerable period of time. Heparin is the cornerstone of treatment for DVT and acute PE. At present, there are no recommendations for thrombus prophylaxis for these patients, and heparin efficacy has not been studied in this specific condition.[9,10]

In this prospectively designed study, we determined the incidence of lower limb DVT associated with temporary transvenous femoral pacemakers by color Doppler ultrasonography. The efficacy and risks of prophylactic and therapeutic anticoagulation (with enoxaparin) for the prevention of DVT in these patients has been evaluated.[11]

Patients and Methods

The studied populations were 60 consecutive patients at 3 wards of Nemazee hospital, CCU I, CCU II and cardiology ward, who received temporary cardiac pacemaker within one year. The patients consisted of 23 women and 37 men aged from 52 to 70 years. The pacemaker was in place between 3 to 8 days in different patients. Patients were excluded if they had any risk factor for occurrence of DVT, such as: malignancy, previous history of DVT, pulmonary emboli or thrombosis of any cause, contraindication for use of heparin, and unstable vital signs. The patients divided into 3 following groups each group consisted of 20 patients. Group I patients received 1 mg/kg/day prophylactic doses of enoxaparin, as a single subcutaneous injection at the time of pacemaker insertion followed by single daily injection of enoxaparin at 9:00 am on subsequent days prior to removal of the pacemaker.

Group II patients received therapeutic doses of enoxaparin (1 mg/kg/every 12 hours).The first dose was injected at the time of insertion of the pacemaker and then continued on following days until 6 hours prior to removal of the pacemaker.

Group III patients received no enoxaparin, and were considered as the control group.

Daily examination was carried out for all 60 patients to detect any sign or symptoms in favor of DVT or PE. Anticoagulation discontinued 6 hours before removal of the pacemaker. Patients were reviewed daily until 48 hours after the removal of pacemaker for the presence of clinical features suggestive of DVT, pulmonary embolism, or complications related to anticoagulation. All patients gave written, informed consent to the study protocol, which was approved by human research ethics committee of Nemazee hospital.

Temporary pacemaker was inserted through a 6 fr or 7 fr homeostatic sheath in the right femoral vein.[12] The pacing wire (Cordis Europe, the Netherlands) was advanced under fluoroscopic guidance into the right ventricle and positioned to a stable pacing threshold.

Ventricular pacing initiated in accordance with the patients condition using an external generator. In all patients the venous sheath was left in site and the patients rested in bed.

Color Doppler ultrasound system (LOGIQ 7 PRO; GE Yokogawa medical system, Tokyo, Japan) with a 5-10 MHz transducer of both lower extremities was used 24 hours after removal of the temporary pacemakers in all 3 groups by an expert radiologist blinded to 3 groups and their medication and using unique sonographic equipment.[13,14]

Doppler sonography of left legs was done as a control for right legs of the same patient.

The studied vessels included iliac veins, common femoral veins, popliteal veins and superficial femoral veins.

A diagnosis of DVT was made if at least one of the following criteria was fulfilled. They comprised of direct visualization of thrombus, lack of venous compressibility, the absence of detectable flow with augmentation test, and the absence of phasic flow in the common femoral vein with respiration.[15]

Statistical analysis

Data were registered and analyzed using the Statistical Package for Social Sciences (SPSS for windows; version 13). Results describing quantitative measures were expressed as mean ± SD. Statistical analysis was performed using 2-sided fisher's exact test for continuous variable. Multiple regression analysis by stepwise logistic regression was used to determine independent variables associated with DVT. P values <0.05 were considered statistically significant.

Results

The patients consisted of 23 women and 37 men aged from 52 to 70 years.Table1 shows the baseline characteristics of the studied patients. Mean age of the patients assessed in 3 groups were 57.8, 64.1 and 54.2, respectively. There were no identifiable differences in clinical characteristics among patients treated with the two heparin dosing schedules and the control group. Of the 60 patients evaluated, DVT was found in 2 (10%) patients.

Study groups I, II showed no evidence of DVT with normal Doppler sonography images in all patients, whereas 2 patients in group III

Table1: Baseline clinical characteristics of 3 different groups

Characteristics	Group1	Group2	Group3	Total
Mean age (years)	57/8	64.1	54.2	58.5
Men	12	10	15	37
Women	8	10	5	23
Sinus node disease	4	7	6	17
Complete heart block	10	2	3	15
Trifascicular block	2	2	0	4
Drug Toxicity	4	4	6	14
Hyperkalmia	0	5	5	10
DVT risk factor	0	0	0	0
Homodynamic instability	0	0	0	0
Bleeding complication	0	0	0	0

had evidence of DVT. One was a 61 years old man who developed leg size difference (right leg circumference was 2.5 cm more than left leg) 7 days after insertion of temporary cardiac pacemaker. The other patient was a 70 years-old man who developed size difference in lower extremities (right leg circumference was 3.3 cm more than that of the left leg) 8 days after insertion of temporary cardiac pacemaker.

In daily follow up of all patients in 3 groups, we did not detect any evidence of bleeding tendency (gross bleeding to warrant discontinuation of heparin).

In regard to age, comparison of patients showed 6.66% risk of DVT in patients aged between 60-70 years, while no DVT was detected in those aged between 50-59 years. Furthermore, comparison of patients according to gender showed 5.9% risk of DVT for male patients. There was no significant difference in clinical factors associated with DVT between patients who received enoxaparin and those who did not (P= 0.971). Moreover, there was no significant statistical correlation between the time of inserting pacemaker and the occurrence of DVT in patients who developed DVT (P=0.107). The correlation between age and gender with emergence of DVT were not significant (P=0.512 and 0.737, respectively).

Discussion

Temporary pacemaker is an artificial pacemaker that substitutes or overrides a faulty conduction system. The device is inserted by threading a lead or wire through a vein into the right ventricle of the heart. At the other end, the wire in patient's body is attached to a power source which stimulates the heart to contract. Duplex ultrasound has gained acceptance as the screening device for investigation into DVT, with an acceptable sensitivity and specificity for the symptomatic and asymptomatic high-risk patients.[9,10]

According to present study, insertion of transfemoral vein temporary cardiac pacemakers in right lower extremities, increases the risk of deep vein thrombosis in the limb (10%),which is decreased by using enoxaparin.

No DVT was found in the contra-lateral limb, suggesting that thrombosis was directly related to the transfemoral pacemaker rather than to other patients' risk factors or environmental causes.

We did not exclude pre-existent thrombus; however, previous investigations have reported a significant incidence, and this confounder was controlled for by the negative study of the contra-lateral limb.[13,14]

Similar to a previous report,[15] all instances of DVT in this study were asymptomatic. We found lesser risk of DVT in comparison with some previous studies which reported higher risk even up to 64%.[16]

In this study, the use of prophylactic and therapeutic enoxaparine dosages were the only significant independent negative predictors for DVT associated with transfemoral pacing. However, in another study therapeutic heparin use resulted in an 85% relative risk reduction for DVT when compared with prophylactic heparin.[14] According to our results, prophylactic dose of enoxaparin for prophylaxis of DVT resulted in a reduction of DVT relative risk. However, there are some limitations of this study which should be considered when interpreting our findings. These consist of performing the study at a single medical center and the low population samples used. Further researches on larger population samples are thus warranted.

DVT is a common complication of transfemoral temporary pacing and the high incidence of occurrence should be considered before deciding upon the site of entry for a temporary pacemaker.[13] Anticoagulation treatment is effective in the prevention of DVT associated with temporary transvenous femoral pacemakers. DVT incidence can be safely reduced by using paraphylaxis and therapeutic intravenous enoxaparin dosages.

In regard to complication, there is no significant difference between patients receiving therapeutic amount and those treated with prophylactic dosing.

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