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#### Original article

# Hematoma complicating permanent pacemaker implantation: The role of periprocedural antiplatelet or anticoagulant therapy

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#### ABSTRACT

*Background*: Periprocedural management of antiplatelet or anticoagulant therapy at the time of device implantation remains controversial.

Methods: We reviewed all cases for whom a pacemaker was implanted in our institution between January 2008 and June 2009. In addition, beginning in June 2009, we prospectively collected data from all patients admitted to our institution, for whom a pacemaker was placed. Clinical characteristics and anticoagulant/antiplatelet drug use were evaluated.

Results: A total of 574 patients underwent a permanent pacemaker implantation. Of these, 20 patients (3.6%, 9 women) experienced a hematoma on pacemaker pocket site. Patients were aged between 35 and 79 years (mean  $60.6\pm12$  years). The frequency of hematoma formation was significantly higher (p<0.001) in those who used warfarin than in those who did not. Aspirin (ASA), clopidogrel, dual antiplatelet therapy (DAT), and bridging to low-molecular-weight heparin (LMWH) did not increase the risk of hematoma formation (p>0.05). Eleven pocket revisions for hematoma evacuation were needed in 9 patients (1.6%), six of whom were on warfarin therapy (p>0.05). Co-morbidities were similar in patients with and without hematoma (p>0.05).

*Conclusion:* The frequency of hematoma is within acceptable ranges after pacemaker placement. The use of warfarin seriously increases the risk of hematoma. Bridging to LMWH safely prevents thromboembolism.

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#### Introduction

Pocket hematoma is a common complication following device implantation accounting for 14–17% of all reoperations [1,2]. Aspirin and/or clopidogrel use are increasing due to the rising incidence of coronary and peripheral artery diseases. Warfarin use is increasing due to the high frequency of prosthetic valve or atrial fibrillation. The risk of pocket hematoma is between 12% and 23% in patients on oral anticoagulation therapy who are bridged to intravenous heparin [3,4]. For comparison, the rate of hematoma formation is approximately 2% in patients who are not receiving any anticoagulation and 4% among patients who have interruption of oral anticoagulation without bridging [4]. Many risk factors and controversial reports for a hematoma were declared in the literature. We aimed to evaluate the effect of antiplatelets and

#### Methods

**Patients** 

We reviewed all cases admitted or discharged from our institution between January 2008 and June 2009 for whom a pacemaker was implanted. In addition, beginning in June 2009, we prospectively collected data from all patients admitted to our institution, for whom a pacemaker was placed. General risk factors such as age and sex, and clinical risk factors such as diabetes mellitus, hypertension, and coronary/peripheral artery disease were evaluated for whether they predicted the risk of hematoma. Collection and analyses of data were authorized by the ethics committee of the hospital.

Device implant procedures

The cardiac device implantations or exchanges were performed according to the standard technique described in the literature

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anticoagulants on hematoma formation complicating pacemaker placement. \\

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[5–7]. In all new implants, venous access was achieved with a first rib approach under fluoroscopic guidance to the extra-thoracic portion of the subclavian vein. No added precautions or differences in techniques were performed for patients on anticoagulation compared with non-anticoagulated patients [8,9].

#### Management

According to our institutional protocol, we did not discontinue aspirin (ASA), clopidogrel, or dual antiplatelet therapy (DAT) before the implantation. Warfarin was routinely discontinued before the procedure and the operation was performed when prothrombin time international normalized ratio (INR) decreased below the value of 1.4. Low-molecular-weight heparin (LMWH) bridging was performed twice a day (BID) to patients with prosthetic valves. It was discontinued 12 h before the procedure and restarted 24 h after the procedure.

Post-implantation, the electrode position was confirmed by analyzing the intra-cardiac electrocardiogram, evaluating pacing thresholds, and by chest X-ray. Pacemaker parameters were recorded on the day of discharge. Once discharged from hospital, patients were followed up at a dedicated pacemaker clinic after four to six weeks.

#### Outcomes

Hematoma was defined as a swelling of pacemaker pocket with or without tenderness and pain. Pacemaker pocket swellings without pain and tenderness were followed conservatively. The hematomas causing a pain and/or tenderness and that were increasing in size were evacuated. Cold and compression therapy was applied for those who did not require drainage.

#### Statistical analysis

Categorical measures were summarized by using counts and percentages; continuous variables were summarized by using either means with standard deviations or medians with an interquartile range, depending on data skew. Univariate comparison between continuous variables was performed with the Student T test or Mann–Whitney U test, and for categorical data, comparison was performed with the Chi-square test or Fisher exact test. Logistic analysis was applied for multivariate analysis. A p-value <0.05 was considered statistically significant. All statistical studies were carried out using NCSS (Number Cruncher Statistical System) 2007 and PASS 2008 Statistical Software Program (Kaysville, UT, USA).

#### Results

#### Baseline characteristics

A total of 574 patients (282 male) underwent a permanent pacemaker implantation. The average age was 67 years. Forty eight out of 574 patients had prosthetic valve/s. Patients with hematoma were significantly younger than patients without hematoma (p=0.037). Clinical features such as hypertension, diabetes mellitus, chronic renal failure, coronary/peripheral artery diseases, and cerebrovascular accident were similar in patients with and without hematoma (p>0.05). Moreover, the frequency of placement of prosthetic valve/s was not significantly different within the two groups (p=0.287) (Table 1). Pacing was DDD(R) or VVI(R) in 83.8% and 16.2% of cases, respectively.

 Table 1

 Clinical features of pacemaker implanted patients owing to the hematoma formation.

Characteristics	Hematoma formation	
	(+) Percent (n = 20)	(-) Percent (n = 554)
Sex M:F	55%:45% (11:9)	49%:51% (271:283)
Age	Mean $60.6 \pm 12$ years	Mean $68 \pm 15.6$ years
Hypertension	75% (15)	67% (372)
Diabetes mellitus	45% (9)	30% (167)
Chronic renal failure	0% (0)	7% (43)
Coronary artery disease	40% (8)	43% (239)
Peripheral artery disease	5% (1)	10.1% (56)
Cerebrovascular accident	0% (0)	3.4% (19)
Prosthetic valve	15% (3)	8.1% (45)

Periprocedural antiplatelet or anticoagulation therapy

One hundred ninety six patients (34.1% of all pacemaker implanted patients) were on ASA only ( $122.4\pm13.7\,\mathrm{mg}$ ), 37 patients (6.4%) were on clopidogrel only (75 mg), and 24 patients (4.2%) were on DAT ( $132\,\mathrm{mg}$  of ASA and 75 mg of clopidogrel). Fifty nine out of 574 patients (10.3%) were on warfarin therapy (Table 2). By multivariate analysis warfarin was the only therapy that significantly increased the risk of hematoma formation (p < 0.001).

The practice during the study period was to discontinue warfarin 3-4 days before device implantation and then reinitiate it 1-2 days after the procedure. The median INR among these patients at time of implant was 1.3 (1.1-1.4); 1.31 in the hematoma group and 1.28 in the group without hematoma.

Forty eight patients with prosthetic valve/s and one patient with ischemic stroke, who were on warfarin, were bridged to LMWH BID until the evening before the procedure (Table 2). The LMWH was restarted the next morning after the procedure and continued BID until the INR achieved  $\geq$  1.8. Warfarin was usually restarted 30–36 h after the procedure.

#### Outcomes

Twenty patients (3.6% of all patients, 9 women) experienced hematoma formation. Of these, 9 patients (1.6% of all patients) required 11 surgical evacuations for the hematoma. The median time from the operation to the formation of hematoma was 5 days (2–7 days). The effect of anticoagulants on the rate of hematoma evacuation is given in Table 3. Warfarin and LMWH bridging therapies did not increase the rate of hematoma drainage in patients with hematoma owing to the pacemaker implantation (p > 0.05).

#### Discussion

The important findings of our report are: warfarin therapy significantly increases the risk of hematoma after pacemaker placement; LMWH bridging is safe for preventing ischemic complications in high-risk warfarin-interrupted patients.

**Table 2**Therapeutic characteristics of pacemaker implanted patients according to the formation of the hematoma.

Medications	Hematoma formation		
	(+) Percent (n = 20)	(-) Percent (n = 554)	
Aspirin	15% (3)	35%(193)	
Clopidogrel	10% (2)	6.3% (35)	
DAT	5% (1)	4.1% (23)	
Warfarin	60% (12)	8.5% (47)	
LMWH bridging	15% (3)	8.3% (46)	

DAT, dual antiplatelet therapy; LMWH, low-molecular-weight heparin.

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