



# Impact of body mass index on the development of pocket hematoma: A retrospective study in Chinese people

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## Abstract

**Background** Pocket hematoma is one of the major complications associated with cardiovascular implantable electronic devices (CIEDs) implantation. The aim of this study is to evaluate the impact of body mass index (BMI) on the occurrence of pocket hematoma after CIEDs implantation. **Methods** The study is a retrospective review of 972 patients receiving CIEDs implantation between 2008 and 2012 in a tertiary hospital. **Results** Twenty two patients (2.2%) developed severe pocket hematoma requiring re-intervention. The hematoma rate (4.6%,  $n = 15$ ) of patients with a BMI of  $< 23 \text{ kg/m}^2$  was significantly higher compared with that of patients with a BMI of  $\geq 23 \text{ kg/m}^2$  (1.1%,  $n = 7$ ,  $P < 0.001$ ). In multivariate regression analysis, a BMI  $< 23.0 \text{ kg/m}^2$  may be associated with the development of severe pocket hematoma. An increase of  $1.0 \text{ kg/m}^2$  in BMI was associated with lower incidence of hematoma formation (OR: 0.84; 95% CI: 0.74-0.95;  $P = 0.006$ ). **Conclusion** BMI  $< 23 \text{ kg/m}^2$  was associated with a higher incidence of pocket hematoma, requiring re-intervention. The data support that great care must be taken when patients were with a lower BMI received CIEDs implantation.

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**Keywords:** Hematoma; Pacemaker; Body mass index; Complication

## 1 Introduction

With expanding indications for cardiovascular implantable electronic devices (CIEDs) [bradycardia pacemakers (PMs), implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapeutic devices with pacing only (CRT-P) and defibrillator (CRT-D)], the number of eligible recipients has increased significantly. Pocket hematoma is an infrequent complication associated with the CIED, with an incidence rate ranging from 2% to 5%,<sup>[1,2]</sup> accounting for 14%–17% of early reoperations.<sup>[3,4]</sup> Pocket hematoma is associated with localized pain, longer hospital stays, the risk of reoperations and an increased possibility of infection.<sup>[2,5]</sup>

The effect of antiplatelet and anticoagulation therapy on the formation of pocket hematoma has been widely researched.<sup>[2,5,6]</sup> Previous studies have shown that complica-

tion rates increase with complex devices, including ICDs and CRTs.<sup>[7–9]</sup> Furthermore, it has also been reported that chronic kidney disease is an independent risk factor for pocket hematoma formation.<sup>[10,11]</sup> Research studies have also suggested that the patients' left ventricular function did not affect the formation of pocket hematoma,<sup>[2]</sup> unlike surgical experience.<sup>[2,12]</sup> Previous studies have demonstrated that a lower body mass index (BMI) was associated with a higher incidence of post-CIED procedural complications.<sup>[13–16]</sup> However, the relationship between BMI and the development of pocket hematoma has not been comprehensively studied.

The aim of this study is to evaluate the impact of BMI on the incidence of pocket hematoma. We conducted a retrospective analysis of patients receiving procedures with CIEDs using data from the Department of Cardiology at the Chinese PLA General Hospital between 2008 and 2012.

## 2 Methods

### 2.1 Study population

This study retrospectively reviewed 990 consecutive procedures involving CIEDs at the Department of Cardiol-

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ogy, Chinese PLA General Hospital, between 2008 and 2012. Of these, patients who were not followed for three months or died from causes unrelated to their operations within the first three months were excluded, resulting in 972 procedures available for analysis.

## 2.2 Study protocol

The indications for operations were based on the prevalent international guidelines, with the surgical strategy remaining unchanged during the period of the study. Puncture of the subclavian vein was used under local anesthesia in almost all of the patients except for two cases that received cephalic vein cut down instead. Pacemaker generators were routinely placed subcutaneously with careful hemostasis.

A course of prophylactic antibiotic treatment with either penicillin or a first generation cephalosporin was started 0.5–2 h prior to the implantation until the third day after the procedure. We stopped any unnecessary medication which may cause hematoma, such as aspirin, warfarin, plavix, etc.

Severe pocket hematoma was diagnosed as palpable swelling of the pocket causing pain and prolonged hospitalization (i.e.,  $\geq 1$  day than the scheduled hospital discharge), whether or not accompanied by anticoagulation treatment cease, reoperation, evacuation, or blood transfusion. According to recommendations of “Appropriate body-mass index for Asian populations and its implications for policy and intervention strategies”, the cut-off point (BMI = 23 kg/m<sup>2</sup>) was chosen as the public health action point for many Asian populations.<sup>[17]</sup> Therefore, the patients were grouped into two categories according to their baseline BMI value: BMI < 23 kg/m<sup>2</sup> and  $\geq 23$  kg/m<sup>2</sup>. Renal insufficiency was defined as a glomerular filtration rate (GFR) < 60 mL/min per 1.73 m<sup>2</sup>. The GFR was calculated using a modification of the diet in renal disease study equation.<sup>[18]</sup>

All the patients had their wounds assessed daily by a cardiologist or an experienced cardiology trainee. Patients were discharged and followed for three months after the procedure at the implant center. All pocket hematoma cases were treated with aggressive external compression and/or needle drainage. Using this approach, pocket evacuation was only performed in one case.

The researchers retrospectively reviewed the patient files for selected clinical and procedural characteristics that might be related to severe hematoma. The clinical variables included age, gender, BMI, diabetes, hypertension, atrial fibrillation, past history of myocardial infarction, coronary artery disease, renal insufficiency, platelet count, international normalized ratio (INR), heart failure, left ventricular ejection fraction (LVEF), and the use of antiplatelet (aspirin or clopidogrel) or anticoagulation therapy (warfarin or

low-molecular weight heparin). The procedural variables also included the type of implant device and the implanter's level of experience (cardiologist or trainee).

## 2.3 Statistical analysis

Statistical analysis was performed using SPSS version 10.0 (Chicago, IL, USA). The data were expressed as the mean  $\pm$  SD. Categorical variables were represented by frequencies, which were compared by  $\chi^2$  test or Fisher's exact test as appropriate. Univariate and multivariate logistic regressions were done with stepwise procedures to construct a final best fit logistic regression model to determine the predictors in the development of the pocket hematoma. This method specifies the significance level at  $P \leq 0.25$  for entering and exiting an explanatory variable in the stepwise model. We estimated the ORs and the 95% CIs for different levels of exposure. Potential predictors with  $P < 0.05$  on univariate analysis were included in the multiple regression model using a stepwise approach, and predictors with  $P < 0.05$  in the multivariable model were retained. The final model selection was based on clinical and statistical significance. Log-rank analysis was used to determine the influence of pocket hematoma on hospital stay.  $P < 0.05$  was considered statistically significant.

## 3 Results

A total of 972 CIEDs procedures ( $69.7 \pm 13.3$  years, male 68%) were enrolled in the study. The mean BMI of all the patients was  $24.2 \pm 3.5$  kg/m<sup>2</sup>. Eight hundred and fifty four (87.9%) underwent new implantations, with the remaining 12.0% undergoing replacement. One hundred and twenty eight (13.2%) were on aspirin, fifteen (1.5%) were on clopidogrel and ten (1.0%) were on both. Only three of the patients were on bridging subcutaneous enoxaparin and ten were on therapeutic warfarin therapy. The mean glomerular filtration rate (GFR) of the study population was  $82.3 \pm 23.2$  mL/min per 1.73 m<sup>2</sup>.

Of all the procedures, 584 (60.1%) were performed by a cardiologist and 388 (40.0%) by a trainee. All ICDs and CRT devices were implanted by cardiologists. The hematoma rate in bradycardia pacemaker implantations was 5 of 452 (1.1%) in procedures performed by cardiologists and 7 of 388 (1.8%) of implantations carried out by trainees ( $P > 0.05$ ).

The hematoma rate was 10 out of 132 (7.6%) in ICD and CRT device implantations and 5 out of 452 (1.1%) in bradycardia PM implantation when the devices were implanted by cardiologists ( $P < 0.01$ ).

In total, 2.2% ( $n = 22$ ) of the population developed se-

vere pocket hematoma, which was diagnosed at the mean time of  $5.5 \pm 8.5$  days (minimum one days and maximum 43 days) and needed re-intervention. Ninety one percent of hematoma cases ( $n = 20$ ) developed within the first week of the procedure. No heparin or warfarin was administered to patients with pocket hematoma. Eight (36%) patients with pocket hematoma were on aspirin and three patients were on both aspirin and clopidogrel.

Log-rank analysis revealed that patients with hematoma showed significantly longer post-procedure hospital stays ( $4.0 \pm 4.2$  days vs.  $17.6 \pm 8.4$  days,  $P < 0.001$ ) compared with patients without hematoma. Baseline clinical characteristics, the types of devices used, and the relevant rates of hematoma are listed in Table 1.

Patients were grouped into two categories according to the baseline BMI value: BMI  $< 23.0$  kg/m<sup>2</sup> ( $n = 338$ , 34.8%) and BMI  $\geq 23.0$  kg/m<sup>2</sup> ( $n = 634$ , 65.2%). Compared with patients in the BMI  $< 23.0$  kg/m<sup>2</sup> category, patients in the BMI  $\geq 23.0$  kg/m<sup>2</sup> category showed a higher prevalence of hypertension, and significantly lower rate of hematoma development (all  $P < 0.001$ ). No differences in the two categories were present in the age, gender, number of patients afflicted with diabetes, atrial fibrillation, history of myocardial infarction, coronary artery disease, renal insufficiency, platelet count, INR, New York Heart Association (NYHA)

heart failure function class and device type. Baseline characteristics by different BMI are shown in Table 2.

Of all the patients, 16.1% ( $n = 156$ ) were associated with renal insufficiency. Of these patients, 10.2% ( $n = 16$ ) showed severe hematoma. Among patients undergoing dual antiplatelet therapy with aspirin and clopidogrel, 3 out of 15 (33.3%) of them developed severe hematoma.

In total, 13% ( $n = 126$ ) of all patients underwent an ICD or CRT procedure, with the remaining 87.0% undergoing bradycardia pacemaker implantation (single or dual-chamber pacemaker). Almost 9% ( $n = 11$ ) of patients underwent the ICD or CRT procedure and 1.3% ( $n = 11$ ) of patients were treated with bradycardia PM developed severe pocket hematoma ( $P < 0.001$ ).

Pocket hematoma added 320 additional hospital treatment days, accounting for a mean extension in hospital stay of 14.5 day/patient. Pocket hematoma was treated with aggressive external compression and/or needle drainage. Using this approach, pocket evacuation was only performed in one case.

The univariate analysis showed that eight predictors were associated with higher incidence of severe pocket hematoma warranting re-intervention (Table 3). After adjusting for confounders, the following factors; BMI  $< 23.0$  kg/m<sup>2</sup>, dual antiplatelet therapy, complex devices, and renal insuf-

**Table 1. Baseline clinical characteristics, including the type of devices patients had in relation to the occurrence of hematoma.**

	Total, $n = 972$	With hematoma, $n = 22$	Without hematoma, $n = 950$	<i>P</i> -value
Age, yrs	69.7 $\pm$ 13.3	70.9 $\pm$ 9.1	69.7 $\pm$ 13.4	0.560
Male sex, %	68.0	68.1	68.0	0.990
BMI (% $< 23$ kg/m <sup>2</sup> )	34.8	68.1	34	0.001
Diabetes, %	21.5	18.2	21.6	0.700
Hypertension, %	58.1	36.3	58.6	0.040
Atrial fibrillation, %	32.3	45.4	32.0	0.180
MI history, %	12.3	36.4	11.7	0.001
CAD, %	42.6	63.6	42.1	0.040
Renal insufficiency, mL/min per 1.73 m <sup>2</sup>	82.3 $\pm$ 23.2	61.5 $\pm$ 32.6	82.0 $\pm$ 23.6	0.008
Platelet count ( $\times 10^9$ /L)	164.1 $\pm$ 46.5	136.7 $\pm$ 71.5	164.5 $\pm$ 47.1	0.210
INR	1.1 $\pm$ 0.2	1.1 $\pm$ 0.1	1.1 $\pm$ 0.2	0.430
Previous heart failure history, %	19.1	72.7	17.9	0.000
LVEF	0.7 $\pm$ 3.6	0.5 $\pm$ 0.2	0.7 $\pm$ 3.3	0.130
Complex device, %	13.6	50.0	12.7	0.000
Device replacement, %	12.1	31.8	11.7	0.004
Post-procedure hospital stay, day	4.1 $\pm$ 4.4	17.6 $\pm$ 8.4	4.0 $\pm$ 4.2	0.000
Infection, %	0.2	4.5	0.1	0.000

Data are presented as mean  $\pm$  SD or percent. Atrial fibrillation is defined as any previous episode of atrial fibrillation; complex device is referred to ICD or CRT-P or CRT-D; renal insufficiency is defined as a glomerular filtration rate  $< 60$  mL/min per 1.73 m<sup>2</sup>. BMI: body mass index; CAD: coronary artery disease; CRT-D: cardiac resynchronization therapy devices with defibrillator; CRT-P: cardiac resynchronization therapy devices with pacing; INR: international normalized ratio; LVEF: left ventricular ejection fraction; MI: myocardial infarction.

**Table 2. Baseline characteristic of patients by BMI categories.**

	BMI < 23 kg/m <sup>2</sup> (n = 338, 34.8%)	BMI ≥ 23 kg/m <sup>2</sup> (n = 634, 65.2%)	P-value
Age, yrs	69.2 ± 14.4	70.2 ± 12.4	0.290
Male	218 (64.5%)	443 (69.8%)	0.080
BMI	20.5 ± 1.9	26.2 ± 2.3	< 0.001
Diabetes	68 (20.1%)	143 (22.6%)	0.600
Hypertension	172 (50.9%)	395 (62.3%)	< 0.001
Atrial fibrillation	95 (28.0%)	196 (30.9%)	0.360
MI history	40 (11.8%)	84 (13.2%)	0.530
CAD	146 (43.2%)	273 (43.1%)	0.960
Renal insufficiency, mL/min per 1.73m <sup>2</sup>	82.6 ± 28.6	81.2 ± 19.9	0.420
Platelet count (× 10 <sup>9</sup> /L)	167.6 ± 56.8	165.4 ± 45.6	0.470
INR	1.1 ± 0.3	1.1 ± 0.1	0.210
No heart failure history	278 (82.2%)	516 (81.4%)	0.740
LVEF	0.6 ± 0.1	0.7 ± 3.7	0.290
Complex device	45 (13.3)	81 (12.8)	0.530
Device replacement	47 (13.9%)	75 (11.8%)	0.350
Hematoma	15 (4.4%)	7 (1.1%)	< 0.001

Data are presented as mean ± SD or n (%). Atrial fibrillation is defined as any previous episode of atrial fibrillation; complex device is referred to ICD or CRT-P or CRT-D; renal insufficiency is defined as a glomerular filtration rate < 60 mL/min per 1.73 m<sup>2</sup>. BMI: body mass index; CAD: coronary artery disease; CRT-D: cardiac resynchronization therapy devices with defibrillator; CRT-P: cardiac resynchronization therapy devices with pacing; INR: international normalized ratio; LVEF: left ventricular ejection fraction.

**Table 3. Univariate analysis of predictors of pocket hematoma formation.**

	OR (95% CI)	P-value
Age	1.01 (0.97–1.03)	0.810
Male vs. female	1.10 (0.33–3.70)	0.880
Lower BMI (< 23 kg/m <sup>2</sup> )	0.30 (0.14–0.66)	0.003
Coronary artery disease	2.68 (1.18–6.07)	0.020
MI history	5.60 (2.51–12.49)	0.001
LVEF	0.99 (0.90–1.10)	0.890
Hypertension	0.81 (0.59–1.12)	0.209
Renal insufficiency	0.97 (0.953–0.982)	0.001
Aspirin vs. no aspirin	2.73 (0.76–9.81)	0.120
Clopidogrel vs. no clopidogrel	8.25 (0.93–72.84)	0.060
Dual AP therapy	10.38 (2.74–39.29)	<0.001
Complex device	14.87 (6.47–34.17)	<0.001
INR	0.85 (0.112–6.48)	0.870
Previous heart failure history	2.68 (1.98–3.64)	<0.001
Device replacement	2.73 (1.12–6.63)	0.027
Diabetes	1.11 (0.44–2.77)	0.830

Complex device is referred to ICD or CRT-P or CRT-D; renal insufficiency is defined as a glomerular filtration rate < 60 mL/min per 1.73 m<sup>2</sup>. AP: antiplatelet; BMI: body mass index; CRT-D: cardiac resynchronization therapy devices with defibrillator; CRT-P: cardiac resynchronization therapy devices with pacing; INR: international normalized ratio; LVEF: left ventricular ejection fraction.

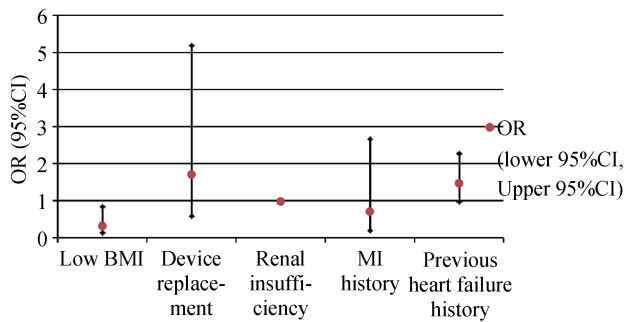
iciency, were found to be independent predictors of severe pocket hematoma in multivariate regression analysis (Table 4, Figure 1).

In multivariate regression analysis, after adjusting for past histories of heart failure, renal insufficiency, dual AP therapy, device replacement and device complexity, lower BMI (< 23.0 kg/m<sup>2</sup>) was determined to be a risk factor for pocket hematoma formation (OR: 0.32; 95% CI: 0.12–0.84; P = 0.02). An increase of 1.0 kg/m<sup>2</sup> in BMI levels was associated with lower incidence of hematoma formation (OR: 0.84; 95% CI: 0.74–0.95; P = 0.006).

**Table 4. Multivariate analysis of predictors of pocket hematoma formation.**

	Odds ratio (95% CI)	P-value
Low BMI (< 23.0 kg/m <sup>2</sup> )	0.32 (0.12–0.84)	0.020
Dual AP therapy	18.01 (3.05–103.18)	0.001
Device replacement	1.72 (0.57–5.19)	0.340
Renal insufficiency	0.98 (0.97–0.99)	0.030
Complex device	8.51 (2.58–28.05)	0.001
MI history	0.72 (0.19–2.65)	0.620
Previous heart failure history	1.48 (0.96–2.27)	0.070

Complex device is referred to ICD or CRT-P or CRT-D; renal insufficiency is defined as a glomerular filtration rate < 60 mL/min per 1.73 m<sup>2</sup>. AP: antiplatelet; BMI: body mass index; CRT-D: cardiac resynchronization therapy devices with defibrillator; CRT-P: cardiac resynchronization therapy devices with pacing; MI: myocardial infarction.



**Figure 1. Predictors of pocket hematoma formation.** Renal insufficiency is defined as a glomerular filtration rate < 60 mL/min per 1.73 m<sup>2</sup>. BMI: body mass index; MI: myocardial infarction;

## 4 Discussion

Pocket hematoma is one of the major complications related to the CIED procedure.<sup>[7,12]</sup> A significant increase in CIEDs implantations will result in a corresponding increase in the number of reported complications associated with the procedure. The pocket hematoma is associated with local discomfort, prolonged hospital stays and an increased risk of re-intervention and related risk of infection.

In our study, we observed that dual antiplatelet therapy, complex devices and renal insufficiency are independent predictors of pocket hematoma, which need re-intervention. The study demonstrated that patients with hematoma endured a longer hospital stay and a higher infection rate, compared to patients without hematoma. The above findings are in accordance with the results from previous studies.<sup>[5,7-11]</sup>

A recent study demonstrated that device replacements are associated with a significant risk of complications.<sup>[7]</sup> However, this study illustrated that device replacement did not increase hematoma rates compared with patients who received device implantation in the multivariate analysis. This is probably due to the small sample size or the comparatively reduced dosage of antiplatelet or anticoagulation therapy.

BMI is widely used as an estimate of general adiposity. A linear relationship was observed between BMI and body fat mass.<sup>[19]</sup> A lower BMI is associated with a thin subcutaneous fat layer. Previous studies have shown that a lower BMI was associated with a higher incidence of post-CIED procedure complications.<sup>[13-16]</sup> Our study demonstrates that a BMI of < 23.0 kg/m<sup>2</sup> was associated with development of severe hematoma which needs re-intervention. An increase of 1.0 kg/m<sup>2</sup> in BMI was associated with lower incidence of hematoma formation. The association between a comparatively lower BMI and hematoma formation might be attrib-

uted to the thin subcutaneous layer. Similarly a hematoma may lead to more severe tension in patients with a lower BMI. A recent prospective study described obesity (BMI ≥ 30 kg/m<sup>2</sup>) as a protective factor in the development of pocket hematoma.<sup>[5]</sup>

Today, most pulse generators are implanted deep inside the adipose tissue and lying on the pectoralis fascia, which obviates dissection of deeper tissues with a shorter operation time. The overall incidence of hematoma with the above approach is approximately 2%–5%. Hypothetically, this is less likely with the submuscular approach in healthy vascularized patients. According to Knepp's study,<sup>[20]</sup> almost 40% of the cases involving generator-repositioning are due to hematoma. After repositioning, the generator in the submuscular plane, no hematoma was reported.

Gold, *et al.*<sup>[21]</sup> reported that the overall complication rate due to subcutaneous approach was comparable to the submuscular approach. However, patients in the subcutaneous group weighed on an average of 2.8 kg more than those in the submuscular group, and the mean BMI was much higher compared with our study. In patients with a lower BMI, CIEDs placement in the submuscular plane might be an alternative, to reducing the rate of bleeding.

Previous studies have suggested that hematoma is more common when done by an individual with a lesser level of implanting experience.<sup>[12]</sup> However, this was not in accordance with the findings of this study, probably due to the comparatively reduced use of antiplatelet or/and anticoagulant therapy in our study sample.

There are several limitations associated with this study. First, because of the small number of outcomes and the retrospective nature of the subgroup analysis, we cannot exclude the possibility that the statistical significance is due to the occurrence of a type I error inflation. In addition, our research did not compare the differences in gender. Second, there were fewer patients undergoing antiplatelet or/and anticoagulation therapy in this study compared with other research studies involving pocket hematoma. As a result, the incidence rate of pocket hematoma might be underestimated. However, we excluded the influence of oral antiplatelet and anticoagulation therapy when analyzing the effects of BMI. To the best of our knowledge, this study is the first to address the impact of BMI on the development of pocket hematoma.

## 5 Conclusions

Our study demonstrates that a BMI < 23.0 kg/m<sup>2</sup> was associated with a higher incidence of pocket hematoma, which needs re-intervention after a CIED procedure. The

data support that great care must be taken when patients received CIEDs implantation with a lower BMI.

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