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# Cardiac device implantations in obese patients: Success rates and complications

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**Background:** Obesity is associated with increased complications and potentially worse outcomes for various cardiac interventions. This study analyzed the success rate and complication rates associated with implantation of cardiac implantable electronic devices (CIEDs) in obese patients.

**Hypothesis:** Success rates are lower and complication rates higher in obese patients.

**Methods:** Consecutive patients undergoing CIED implantation between 2011 and 2015 in our hospital were included. Patients were categorized into obese and nonobese groups according to body mass index (BMI); cutoff was 30 kg/m$^2$. Patient characteristics, complication rates, procedural duration, and fluoroscopy data were compared between the 2 groups.

**Results:** A total of 965 patients (mean age, 69.0 $\pm$ 12.9 years; 67% male) were included. Of these, 249 (25.8%) patients were classified obese and 716 (74.2%) nonobese. Mean BMI was 34.7 $\pm$ 4.7 kg/m$^2$ vs 25.1 $\pm$ 3.0 kg/m$^2$, respectively. There was no difference in procedural success rates between the 2 groups (97.2% vs 97.1%, respectively). Major complications were significantly lower in the obese group compared with the nonobese group (11 [4.4%] vs 62 [8.7%]; $P < 0.05$). Procedural duration and fluoroscopy duration were not different between the 2 groups, but the total dose-area product was significantly higher in obese patients vs nonobese patients (4012 $\pm$ 5416 cGcm$^2$ vs 2692 $\pm$ 5277 cGcm$^2$; $P < 0.005$).

**Conclusions:** CIED implantation can be safely and effectively achieved in patients with BMI >30 kg/m$^2$. However, total radiation dose was significantly higher in the obese group, emphasizing that efforts should be made to reduce radiation exposure in these patients.

**KEYWORDS**

Obesity, Cardiac implantable electrical devices, CIED, complications, radiation dose

## 1 | INTRODUCTION

Obesity is defined by the World Health Organization as a body mass index (BMI) >30 kg/m$^2$. Worldwide, the number of people that meet this definition has more than doubled since 1980; in 2014, approximately 13% of the world's population was considered obese. This is far from being a problem of only high-income countries; the number of obese people is mostly increasing in low- and middle-income countries, especially in urban settings.[1]

Obesity is a well-known risk factor for the development of atrial and ventricular arrhythmias. It is associated with arrhythmogenic diseases such as hypertension, heart failure, and coronary artery disease. Obesity also seems to be an independent risk factor for the development of cardiac arrhythmias, as ventricular arrhythmias were observed more often in obese patients, even in the absence of left ventricular dysfunction.[2] Moreover, obesity is associated with global biatrial endocardial remodeling characterized by left atrial enlargement, interstitial atrial fibrosis, conduction abnormalities, and increased propensity for atrial fibrillation.[3,4] As a consequence, obese patients are at high risk of being implanted with a cardiac pacemaker or implantable cardioverter-defibrillator (ICD). Yet implantation of

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these devices in obese patients can be challenging. Anesthesia can be difficult, mostly because of ventilation problems[5]; puncture of the subclavian or axillary vein is more difficult because neck landmarks can be obscured[6]; and visualization of lead placement can be impaired due to limited image quality, despite higher radiation doses.[7]

To evaluate the safety and efficacy of various cardiac device implantations in obese patients, a retrospective analysis of 965 consecutive patients undergoing these procedures in the Charité University Hospital in Berlin, Germany, was performed. The goal was to compare procedural success, complications, and total radiation dose needed for the implantation.

## 2 | METHODS

### 2.1 | Study design

This study is based on a retrospective chart review, approved by the institutional ethics committee, of 965 patients undergoing cardiac implantable electronic device (CIED) implantation in the Charité University Hospital in Berlin, Germany. The procedures were performed between 2011 and 2015.

Patient demographics were obtained, including weight, height, relevant comorbidities, and fluoroscopy time. Radiation dose was measured as dose-area product (DAP). Procedure-related complications were recorded at the time of discharge and at the first follow-up visit 6 weeks after implantation.

Obesity was defined as a BMI >30 kg/m$^2$. To maintain consistency regarding potential machine-related differences, reviewed procedures were performed in a single-catheter laboratory with the same x-ray system by the same 5 operators.

### 2.2 | CIED implantations

Device implantations were performed after an evaluation by an electrophysiology expert and according to the indications of the current European Society of Cardiology guidelines.[8]

A prophylactic dose of cefazolin was administered at the time of the procedure. For periprocedural anesthesia, propofol and/or midazolam were used. Oxygen (medium flow, 2 L/min) was administered via nasal cannula. There was continuous monitoring of blood pressure, pulse oximetry, heart rate, and electrocardiography throughout the entire procedure, until the complete awakening of the patient.

The major approach for lead insertion was subclavian vein puncture (>90%). Axillary vein puncture or cephalic vein cut-down were used as alternative venous accesses. Upon successful vein puncture or cut-down, a guidewire was inserted and positioned in the vena cava. For the implantation of multiple leads, this procedure was repeated. Lead insertion sheets were advanced over the wires. Only active fixation leads were used. Lead placement was performed under fluoroscopic guidance. Right atrial leads were preferably placed anteriorly at the ostium of the right atrial appendage. Right ventricular leads were preferably placed in the mid-septal region. If a stable and effective lead position could not be achieved in the mid-septal region, right ventricular leads were placed in the apex of the right ventricle. Left ventricular leads for biventricular stimulation were positioned basally in a lateral branch of the coronary sinus.

Pacing threshold, sensing, and impedance were recorded to ensure good placement. A subcutaneous pocket was used for pacemaker insertion, whereas ICD or cardiac resynchronization therapy defibrillator (CRT-D) devices were placed submuscularly.

### 2.3 | Definition of complications and follow-up

Routine chest radiography was performed 6 hours after the procedure to rule out pneumothorax, hemothorax, and lead dislodgement. Device interrogation was again performed routinely 6 weeks after implantation.

According to severity and clinical relevance, complications were classified as major or minor. Major complications included local infections requiring re-intervention, re-interventions within 6 weeks after implantation, major surgical-site bleeding, pneumothorax or pericardial effusion requiring drainage, implantation-related systemic infection or endocarditis, generator-lead connection problems or lead dislocation, and procedure-related death.

Surgical-site bleeding was classified as major in the following cases: the necessity of surgical re-intervention, a hemoglobin drop of >3 g/dL, the necessity for blood transfusion, and a prolonged hospitalization.

Wound-healing disorders were defined as all cases of wound dehiscence or possible superficial infection, which were treated non-surgically but required a prolonged phase of wound surveillance, delayed suture removal, or additional antibiotic treatment.

### 2.4 | Statistical analysis

For the description of patient baseline characteristics and procedural data, values are presented as absolute numbers and percentages for categorical variables or mean ± SD for continuous variables. For comparison of categorical variables among obese and nonobese patients, $\chi^2$ tests were used. The independent sample *t* test was used to compare continuous variables.

For the comparison of procedure-related complications, additionally adjusted odds ratios (ORs) were calculated by using logistic regression models. In all models, age, sex, type of device implantation, and left ventricular ejection fraction were used as covariables. For major and minor bleeding and lead dislodgment, ORs were additionally adjusted for different types of anticoagulation. For infections, ORs were additionally adjusted for diabetes mellitus. For all tests, a level of significance of 5% was determined.

All analyses were performed using SPSS software version 22.0 (IBM Corp., Armonk, New York).

## 3 | RESULTS

### 3.1 | Patient characteristics

The study included 965 patients. A total of 249 patients (25.8%) were classified as obese and 716 patients (74.2%) were classified as nonobese. Mean BMI was 25.1 ± 3.0 kg/m$^2$ vs 34.7 ± 4.7 kg/m$^2$. The mean age was 69.0 ± 12.9 years, with 67% being male patients.

**TABLE 1** Patient baseline characteristics

| Parameter | Total, N = 965 | Obese Patients, n = 249 | Nonobese Patients, n = 716 | Significance | *P* Value |
|---|---|---|---|---|---|
| Age, y | 69.2 ± 13.0 | 67.0 ± 10.8 | 69.9 ± 13.6 | *P* < 0.050 | <0.001 |
| Height, cm | 171.5 ± 9.5 | 171.9 ± 9.5 | 171.4 ± 9.5 | NS | 0.427 |
| Weight, kg | 81.4 ± 19 | 102.6 ± 17.9 | 74.0 ± 12.8 | *P* < 0.001 | <0.001 |
| Male sex | 649 (67.3) | 171 (68.7) | 478 (66.8) | NS | 0.579 |
| Arterial hypertension | 766 (79.4) | 217 (87.1) | 549 (76.7) | *P* < 0.001 | <0.001 |
| Dilated cardiomyopathy | 147 (15.3) | 42 (17.0) | 105 (14.8) | NS | 0.401 |
| AF | 428 (44.4) | 102 (41.0) | 326 (45.6) | NS | 0.205 |
| CAD | 510 (52.9) | 136 (54.6) | 374 (52.3) | NS | 0.529 |
| HF | 579 (60.1) | 163 (65.5) | 416 (58.2) | *P* < 0.050 | 0.043 |
| NYHA class | | | | | |
| 0 | 2 (0.4) | 2 (0.6) | 0 (0.0) | NS | 0.059 |
| 1 | 71 (14.3) | 57 (16.3) | 14 (9.5) | | |
| 2 | 187 (37.6) | 130 (37.1) | 57 (38.5) | | |
| 3 | 222 (44.6) | 152 (43.4) | 70 (47.3) | | |
| 4 | 16 (3.2) | 9 (2.6) | 7 (4.7) | | |
| DM | 299 (31.0) | 102 (41.0) | 197 (27.5) | *P* < 0.001 | <0.001 |
| COPD | 143 (14.9) | 47 (18.9) | 96 (13.5) | *P* < 0.050 | 0.039 |
| CKD | 401 (41.6) | 112 (45.0) | 289 (40.4) | NS | 0.203 |
| LVEF, % | 41.2 ± 15.3 | 39.7 ± 14.8 | 41.8 ± 15.4 | NS | 0.050 |
| OAC | 477 (49.4) | 117 (47.0) | 360 (50.3) | NS | 0.361 |
| Antiplatelet therapy | 556 (57.7) | 156 (62.7) | 400 (55.9) | NS | 0.065 |

Abbreviations: AF, atrial fibrillation; BMI, body mass index; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HF, heart failure; LVEF, left ventricular ejection fraction; NS, not significant; NYHA, New York Heart Association; OAC, oral anticoagulation; SD, standard deviation.

Data are presented as n (%) or mean ± SD.

Detailed characteristics of the studied population are shown in Table 1.

### 3.2 | Success rates and complications

The analyzed procedures included 72 (7.4%) 1-chamber pacemaker implantations and 215 (22.2%) 1-chamber ICD implantations; 339 (35.1%) 2-chamber pacemaker implantations and 69 (7.1%) 2-chamber ICD implantations; and 32 (3.3%) 3-chamber pacemaker implantations and 238 (26.4%) CRT implantations.

The total procedure time (107.5 ± 72.4 minutes vs 97.4 ± 55.9 minutes; *P* = not significant) and overall success rates (97.2% vs 97.1%; *P* = not significant) were not significantly different between the 2 groups (Table 2).

The number of major complications was significantly lower in obese than nonobese patients (11 [4.4%] vs 62 [8.7%], *P* < 0.05; OR: 2.2, 95% confidence interval: 1.1-4.4). Further analysis according to the type of complications showed a significantly lower rate of major bleedings (1 [0.4%] vs 24 [3.4%], *P* < 0.05; OR: 10.4, 95% confidence interval: 1.3-80.2) and pneumothoraces (0 [0%] vs 13 [1.8%]; *P* < 0.05) in obese patients (Table 3).

### 3.3 | Radiation exposure

We observed a significantly higher DAP in obese patients compared with nonobese patients, whereas procedural duration and fluoroscopy time were not statistically different (Table 4).

## 4 | DISCUSSION

Obese patients represent a relevant proportion of patients undergoing cardiac device implantation. In our study including consecutive patients in our hospital, >25% of patients presented with a BMI >30 kg/m$^2$.

Two previous studies evaluated the potential influence of obesity on outcomes and complication rates of ICD and CRT implantations. One smaller study including 58 patients with BMI >30 kg/m$^2$ found no difference in procedural success rates and complication rates for ICD and CRT implantations in nonobese vs obese patients.[9] The other study represents a subanalysis from the US National Cardiovascular Data Registry-ICD Registry. In this analysis, obese patients also did not exhibit more complications compared with normal-weight patients, whereas being underweight was associated with a higher complication rate.[10]

Our study including ICD, CRT-D, and pacemaker implantations not only confirms the finding that CIED implantation is safe and effective in obese patients, it seems that obesity may even have a protective effect on the development of pneumothorax and major bleeding.

Although it has been shown that a higher BMI is associated with a longer time taken for venous access and the use of more contrast,[11] we found a lower rate of pneumothoraces in the obese patient group. This was despite the fact that the obese patients in our study had a significantly higher rate of chronic obstructive lung disease, a well-known risk factor for the development of pneumothorax after CIED implantation.[12] So even though surface landmarks are obscured in overweight patients, the larger distance from the surface

**TABLE 2** Procedural data

| Procedure | Total, N = 965 | Obese Patients, n = 249 | Nonobese Patients, n = 716 | Significance |
|---|---|---|---|---|
| Procedure duration, min, mean ± SD | 100.0 ± 60.7 | 107.5 ± 72.4 | 97.4 ± 56.0 | NS |
| Procedure success | 939 (97.1) | 242 (97.2) | 697 (97.1) | NS |
| 1-chamber pacemaker | 72 (7.4) | 19 (7.7) | 53 (7.4) | NS |
| 2-chamber pacemaker | 339 (35.1) | 81 (32.7) | 258 (36) | NS |
| CRT-P | 32 (3.3) | 9 (3.6) | 23 (3.2) | NS |
| 1-chamber ICD | 215 (22.2) | 58 (23.4) | 157 (21.9) | NS |
| 2-chamber ICD | 69 (7.1) | 12 (4.8) | 57 (7.9) | NS |
| CRT-D | 238 (26.4) | 69 (27.8) | 169 (23.6) | NS |
| Implantation on the left side | 845 (88.2) | 215 (87) | 630 (88.6) | NS |
| Subclavian vein puncture | 918 (96.7) | 238 (97.5) | 680 (96.5) | NS |

Abbreviations: CRT-D, cardiac resynchronization therapy defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; ICD, implantable cardioverter-defibrillator; NS, not significant; SD, standard deviation.

Data are presented as n (%) unless otherwise noted.

**TABLE 3** Procedure-related complications

| Complication | Total, N (%) | Obese Patients, n (%) | Nonobese Patients, n (%) | Significance, $\chi^2$ | Adjusted OR[1] (95% CI), Nonobese vs Obese | Significance |
|---|---|---|---|---|---|---|
| Pocket hematoma | 48 (5) | 6 (2.4) | 42 (5.9) | $P < 0.05$ | 2.6 (1.0-6.3)[2] | 0.043 |
| Minor bleeding | 31 (3.2) | 4 (1.6) | 27 (3.8) | NS | 2.3 (0.8-7.0)[2] | 0.135 |
| Major bleeding | 20 (2.1) | 1 (0.4) | 24 (3.4) | $P < 0.05$ | 10.2 (1.3-80.3)[2] | 0.028 |
| Lead dislodgement | 25 (2.6) | 6 (2.4) | 19 (2.7) | NS | 1.2 (0.4-3.3) | 0.794 |
| Acute renal failure | 15 (1.6) | 6 (2.4) | 9 (1.3) | NS | 0.5 (0.1-1.5) | 0.187 |
| Pericardial effusion | 11 (1.1) | 2 (0.8) | 9 (1.3) | NS | 1.7 (0.3-8.9) | 0.499 |
| Anesthesia-related complications | 11 (1.1) | 1 (0.4) | 10 (1.4) | NS | 4.0 (0.5-32.0) | 0.197 |
| Pneumothorax | 13 (1.5) | 0 (0) | 13 (1.8) | $P < 0.05$ | NA[3] | |
| Wound-healing disorders | 7 (0.7) | 1 (0.4) | 6 (0.8) | NS | 1.7 (0.4-15.5)[4] | 0.656 |
| Device infections | 6 (0.6) | 1 (0.4) | 5 (0.7) | NS | 1.3 (0.1-13.5)[4] | 0.808 |
| Hemothorax | 2 (0.2) | 0 (0) | 2 (0.3) | NS | NA[3] | |
| Subclavian vein thrombosis | 2 (0.2) | 0 (0) | 2 (0.3) | NS | NA[3] | |
| Any major complication | 73 (7.6) | 11 (4.4) | 62 (8.7) | $P < 0.05$ | 2.1 (1.0-4.4)[5] | 0.047 |

Abbreviations: CI, confidence interval; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HTN, hypertension; LVEF, left ventricular ejection fraction; NA, not available; NS, not significant; OAC, oral anticoagulation; OR, odds ratio.

[1] All logistic regression models are adjusted for age, sex, type of device implanted, LVEF, DM, COPD, and HTN.

[2] Additional adjustment for OAC, antiplatelet drugs, and renal failure.

[3] None of the obese patients suffered the complication; therefore, an OR could not be calculated.

[4] Additional adjustment for renal failure and procedural duration.

[5] Any complication was adjusted for all of the above covariates.

of the skin to the lung due to subcutaneous fat seems to be protective. This theory is supported by 2 cohort studies showing that the risk of pneumothorax after CIED implantation increased with decreasing BMI.[11,13]

Additionally, obese patients in our study had fewer major bleedings compared with patients of normal weight. Similar results, contradicting the working hypothesis that overweight and obese patients are at a higher risk of bleeding after cardiac interventions, were observed in 2 studies each including >9000 patients undergoing percutaneous coronary intervention. In both trials, patients with a BMI >30 kg/m$^2$ had a significantly lower risk of bleeding compared with normal-weight patients.[14,15] Similar findings were observed after

**TABLE 4** Fluoroscopy data

| | | Total, N = 880 | Obese Patients, n = 230 | Nonobese Patients, n = 650 | Significance |
|---|---|---|---|---|---|
| Fluoroscopy duration, min/sec | N; mean ± SD | 878; 13/58 ± 16/00 | 230; 14/44 ± 15/50 | 648; 13/42 ± 16/04 | NS |
| DAP, cGcm$^2$ | N; mean ± SD | 867; 3048 ± 5348 | 230; 4013 ± 5417 | 637; 2699 ± 5284 | <0.005 |

Abbreviations: DAP, dose-area product; NS, not significant; SD, standard deviation.

coronary artery bypass surgery, where fewer postoperative bleedings occurred in obese patients.[16]

Obese patients are known to have increased levels of procoagulant factors and decreased fibrinolytic activity.[17,18] Additionally, there may be a tendency of underdosage of anticoagulants in these patients. We can only hypothesize if similar effects lead to the observations made in our study. An alternative theory is that hematomas may be concealed and more distributed in overweight patients. They may less likely cause tension on the surrounding tissue and sutures, and thus not require re-intervention as often as in lower-weight patients.

Despite these findings, CIED implantation in obese patients is not without negative implications. Although procedure and fluoroscopy times were not prolonged, the procedures were characterized by significantly higher radiation doses, measured as DAP. Therefore, strategies to reduce patient dose while preserving acceptable image quality are especially needed in this patient group. Those strategies should include fluoroscopy frame rate reduction (to 2–4 frames per second), avoidance of unnecessary cine loops, asymmetric collimation, and image integration. Additionally "low dose" programs with optimized exposure system settings and image processing can be established in cooperation with the equipment manufacturers.[19]

### 4.1 | Study limitations

This study has some important limitations. It is a retrospective single-center study performed in a teaching hospital, and the drawn conclusions may not be applicable to other institutions. Second, patients were followed up only for 6 weeks after implantation; therefore, differences between the studied groups regarding long-term complications such as infections or lead dislodgements may have been missed. The event rates, especially in some of the distinct complication subtypes, are relatively low. Because of this, the calculated ORs for those complication subtypes must be evaluated with caution.

## 5 | CONCLUSION

Success rates of CIED implantations were not significantly different in obese patients, whereas the number of acute major complications was significantly reduced. CIED implantation can be safely and effectively achieved in patients with a BMI >30 kg/m$^2$, and obesity might even be a protective factor. However, total radiation dose used for CIED implantation was significantly higher in the obese patient group, which emphasizes that all efforts should be made to reduce radiation exposure in these patients.

## Conflicts of interest

The authors declare no potential conflicts of interest.

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