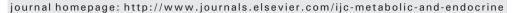
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# Heart failure as a strong independent predictor of delirium after pacemaker operations☆



Haruhiko Higashi <sup>a</sup>, Shinji Inaba <sup>a</sup>, <sup>\*</sup>, Makoto Saito <sup>a</sup>, Manami Yamaoka <sup>b</sup>, Rikako Yanagimoto <sup>b</sup>, Nami Okiura <sup>b</sup>, Yuka Gen <sup>b</sup>, Yumiko Kojima <sup>b</sup>, Takumi Sumimoto <sup>a</sup>

- <sup>a</sup> Department of Cardiology, Kitaishikai Hospital, Ozu, Japan
- <sup>b</sup> Department of Nursing, Kitaishikai Hospital, Ozu, Japan

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#### ABSTRACT

Background: Postoperative delirium is a common and serious condition in the clinical setting that has been linked to increased mortality and worse outcomes. Some patients after pacemaker operations may suffer from delirium; however, this condition has not been clarified. The aim of this study was to investigate the prevalence and predictors of delirium after pacemaker operations such as initial permanent pacemaker implantation or pacemaker generator replacement.

Methods: We retrospectively evaluated 192 consecutive patients who underwent pacemaker operations. According to the Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV) criteria, patients were divided into two groups: patients with delirium and patients without delirium after pacemaker operation. The two groups were compared in terms of patient characteristics, clinical settings, and environmental factors.

Results: Forty patients (20.8%) suffered from delirium after pacemaker operations and were significantly older than patients without delirium (85.3  $\pm$  6.4 years vs. 80.8  $\pm$  8.4 years, p = 0.0014). Temporary pacing before permanent pacemaker implantation (30% vs. 11%, p = 0.0019) and intensive care unit admission (28% vs. 12%, p = 0.014) were more common in patients with delirium. Moreover, patients with delirium had more frequent heart failure than patients without delirium (78% vs. 41%, p < 0.0001). Multiple regression models showed heart failure as an independent predictor of delirium after pacemaker implantation.

Conclusions: Delirium after pacemaker operations was not uncommon and heart failure was a strong independent predictor of such a condition.

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#### 1. Introduction

Delirium is the most common psychiatric disorder after cardiac-related operations, and the risk factors for its development are complex and multifactorial [1–7]. Clinical studies revealed that postoperative delirium is associated with prolonged and more costly hospital stay [8–10], impaired cognition [11–14], and worse clinical outcomes [14–16]. Therefore, prediction of postoperative delirium could be useful for clinical management. However, delirium after pacemaker operations has not been addressed. Therefore, the aim of the present study was to clarify the prevalence and contributing factors to the development of delirium after pacemaker operations.

#### 2. Methods

#### 2.1. Study population

This study was a retrospective evaluation of 192 consecutive patients who underwent pacemaker operations (109 permanent pacemaker implantations and 83 generator replacements) in Kitaishikai Hospital between July 2010 and September 2014. Our institution did not perform both the biventricular pacemaker implantation and implantable cardioverter-defibrillator (ICD). Therefore, there was no case undergoing biventricular pacing and/or ICD including generator replacement of these in the present study. All pacemakers in the present study were 2 single-chamber atrial pacemakers, 32 single-chamber ventricular pacemakers, and 158 dual-chamber pacemakers. 109 permanent pacemaker implantations were performed due to sinus node dysfunction (n = 34) or atrioventricular block (n = 75). Informed consent was obtained and the institutional review board of the hospital approved the retrospective use of the patients' data.

<sup>★</sup> The authors have no conflicts of interest to disclose.

<sup>\*</sup> Corresponding author at: Department of Cardiology, Kitaishikai Hospital, 2632-3 Tokunomori, Ozu, Ehime 795-8505, Japan. Tel.: +81 893 25 0535; fax: +81 893 25 0465. E-mail address: inaba226@gmail.com (S. Inaba).

#### 2.2. Pacemaker operations and delirium

Pacemaker operations were defined as initial permanent pacemaker implantation or pacemaker generator replacement. Delirium was defined as using an algorithm based on the Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV) criteria [17]. In brief, postoperative delirium was diagnosed as disturbances of consciousness and acute change in cognition, or development of a perceptual disturbance after operation. According to the criteria, patients were divided into two groups: patients with delirium after operation (delirium group), and patients without delirium after operation (non-delirium group). The two groups were compared in terms of patient characteristics, clinical settings, and environmental factors.

#### 2.3. Diagnosis of heart failure before pacemaker operations

Heart failure was defined as a combination of the presence of the typical signs or symptoms of heart failure, such as breathlessness at rest or during exertion, ankle edema and pulmonary crepitations, and confirmation by objective evidence of cardiac dysfunction (chest X-ray, echocardiography). This definition is according to the previously reported guideline [18]. Two experienced cardiologists, H.H. and S.I., who were blinded to the subjects' identity and clinical profile, evaluated the chest X-ray images. In addition, patients who had been under medical treatment for heart failure before admission were included. Before pacemaker operation, all patients were administered with 7.5 mg of pentazocine and 12.5 mg of hydroxyzine pamoate intramuscularly for sedation.

#### 2.4. Statistical analysis

Data analysis was performed using StatView 5.0 (SAS institute, Cary, North Carolina) and SPSS version 20.0 (SPSS, Inc., Chicago, Illinois), Categorical variables are presented as number and percentage. Continuous variables are expressed as mean  $\pm$  standard deviation. The patient characteristics were compared using the Mann-Whitney test for continuous variables, and Chi-square test for categorical variables. Univariate regression analysis was performed to determine the contributing factors of delirium after pacemaker operations using simple logistic regression with the odds ratio and 95% confidence interval. Multiple regression analysis was performed to evaluate the independence and robustness of heart failure using different models: utility (age, intensive care unit admission, temporary pacing, heart failure), laboratory (age, albumin, HDL-C, heart failure), comorbidity (age, previous PCI, dementia, heart failure), and cardiac function (age, LVEF, heart failure). Covariates were entered into each model on the basis of associations in the univariate analysis with p values < 0.05. Harrell's C statistic and Model Chisquare were used to evaluate the model [19]. Values of p < 0.05 were considered statistically significant.

#### 3. Results

#### 3.1. Clinical characteristics and history

The patients' clinical characteristics and history are shown in Table 1. The study population comprised 192 patients: 109 of them received initial permanent pacemaker implantation and 83 of them received generator replacement operation. There were 40/192 (20.8%) patients who suffered from postoperative delirium. The delirium group was significantly older than the non-delirium group (85.3  $\pm$  6.4 years vs. 80.8  $\pm$  8.4 years; p = 0.0014). Gender, body mass index, and coronary risk factors (i.e., hypertension, dyslipidemia, diabetes, and smoking history) did not differ between the two groups. The frequency of developing delirium was markedly higher in patients with heart failure than those without heart failure (78% vs. 41%, p < 0.0001).

**Table 1** Clinical characteristics of patients who underwent pacemaker operation (n = 192).

| Variable  | Delirium<br>(+)<br>(n = 40) | Delirium<br>(-)<br>(n = 152) | p value  |
|---|-----------------------------|------------------------------|----------|
| Initial pacemaker implantation                    | 23 (58)                     | 86 (57)                      | 0.92     |
| Age (years)                                       | $85.3 \pm 6.4$              | $80.8 \pm 8.4$               | 0.0014   |
| Male sex  | 19 (48)                     | 64 (42)                      | 0.54     |
| Body mass index (kg/m <sup>2</sup> )              | $23.2 \pm 2.9$              | $23.1 \pm 3.5$               | 0.89     |
| Hypertension                                      | 32 (80)                     | 120 (79)                     | 0.88     |
| Hyperlipidemia                                    | 24 (60)                     | 72 (47)                      | 0.16     |
| Smoking history (current or former)               | 12 (30)                     | 45 (30)                      | 0.96     |
| Current cigarette use                             | 1 (3)                       | 7 (5)                        | 0.55     |
| Diabetes  | 18 (45)                     | 51 (34)                      | 0.18     |
| Chronic kidney disease                            | 25 (63)                     | 95 (63)                      | -        |
| Patient history                                   |                             |                              |          |
| Previous coronary artery bypass graft surgery     | 1 (3)                       | 4 (3)                        | 0.96     |
| Previous percutaneous coronary intervention       | 7 (18)                      | 7 (5)                        | 0.0053   |
| Previous stroke                                   | 7 (18)                      | 25 (16)                      | 0.87     |
| Dementia  | 12 (30)                     | 21 (14)                      | 0.016    |
| Any arterial fibrillation or flutter <sup>a</sup> | 13 (33)                     | 37 (24)                      | 0.30     |
| Heart failure                                     | 31 (78)                     | 63 (41)                      | < 0.0001 |
| Left ventricular ejection fraction (%)            | $57.6 \pm 13.1$             | $62.6\pm10.7$                | 0.025    |

Values are expressed as mean  $\pm$  SD or n (%).

#### 3.2. Baseline characteristics and operation-related data

The baseline characteristics of patients on admission are shown in Table 2. Postoperative delirium was more frequent in patients admitted to the intensive care unit compared with the patients who were not admitted to the intensive care unit (28% vs. 12%, p = 0.014). The number of days from admission to operation and operation time were not different between the two groups. The time of operation was significantly longer in the patients with permanent pacemaker implantation compared with generator replacement (99.5  $\pm$  30.3 min vs. 53.0  $\pm$  27.4 min; p < 0.0001). However, the operation time in the delirium group was almost similar to that in the non-delirium group (79.2  $\pm$ 

**Table 2** Baseline characteristics and operation-related data (n = 192).

| Variable                                      | Delirium<br>(+)<br>(n = 40) | Delirium<br>(-)<br>(n = 152) | p value |
|---|-----------------------------|------------------------------|---------|
| Intensive care unit admission                 | 11 (28)                     | 18 (12)                      | 0.014   |
| Temporary pacing before operation             | 12 (30)                     | 16 (11)                      | 0.0019  |
| Heart rate (number/min)                       | $59.9 \pm 21.7$             | $56.5 \pm 17.0$              | 0.43    |
| Systolic blood pressure (mmHg)                | $140.7 \pm 26.3$            | $139.9 \pm 26.4$             | 0.84    |
| Diastolic blood pressure (mmHg)               | $67.0 \pm 14.8$             | $65.2 \pm 14.9$              | 0.85    |
| Laboratory data                               |                             |                              |         |
| Albumin (g/dL)                                | $3.7 \pm 0.5$               | $3.8 \pm 0.4$                | 0.050   |
| Hemoglobin (g/dL)                             | $11.8 \pm 1.4$              | $12.7 \pm 7.7$               | 0.20    |
| Total bilirubin (mg/dL)                       | $0.6 \pm 0.3$               | $0.6 \pm 0.2$                | 0.69    |
| Fasting glucose (mg/dL)                       | $110.1 \pm 36.8$            | $99.6 \pm 31.0$              | 0.027   |
| Hemoglobin A1c (%)                            | $5.9 \pm 0.8$               | $5.8 \pm 0.7$                | 0.22    |
| Total cholesterol (mg/dL)                     | $161.1 \pm 34.0$            | $167.9 \pm 33.0$             | 0.25    |
| High density lipoprotein cholesterol (mg/dL)  | $47.9\pm13.1$               | $52.9\pm12.7$                | 0.037   |
| Triglyceride (mg/dL)                          | $97.4 \pm 44.2$             | $94.8 \pm 43.5$              | 0.61    |
| Low density lipoprotein cholesterol (mg/dL)   | $93.7 \pm 27.7$             | $96.3 \pm 27.9$              | 0.45    |
| Brain natriuretic peptide (pg/mL)             | 367.3 ± 420.8               | 309.2 ± 501.2                | 0.050   |
| Days from admission to operation (days)       | $3.4 \pm 4.5$               | $3.2 \pm 4.9$                | 0.60    |
| Operation time (min)                          | $79.2 \pm 42.9$             | $79.4 \pm 35.5$              | 0.72    |
| Use of sleeping drug the day before operation | 17 (43)                     | 64 (42)                      | 0.96    |
| Use of sedation just before operation         | 40 (100)                    | 152 (100)                    |         |

Values are expressed as mean  $\pm$  SD or n (%).

<sup>&</sup>lt;sup>a</sup> Includes paroxysmal arterial fibrillation or flutter.

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