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Original article

## Prognosis of super-elderly healthy Japanese patients after pacemaker implantation for bradycardia

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### ABSTRACT

**Background:** The prognosis of super-elderly patients (age  $\geq 85$  years) who undergo bradycardia pacemaker (PM) implantation remains unknown.

**Methods:** We retrospectively enrolled 868 patients (men 49.0%,  $76.6 \pm 10.6$  years) who could walk unassisted and whose expected life expectancy was more than 1 year, receiving their first bradycardia PM implantation between January 1, 2006, and June 30, 2013. Clinical outcomes were compared between super-elderly patients ( $n = 201$ , mean age  $88.6 \pm 3.2$  years) and younger patients ( $n = 667$ ,  $73.0 \pm 9.3$  years).

**Results:** At the end of a median 1285-day follow-up, 128 patients (14.7%) died, of which 54 were cardiac deaths (42.2%). Mortality rates were similar between the groups (16.4% vs. 14.2%, log-rank  $p = 0.56$ ) and across different indications for implantation (atrio-ventricular conduction disturbance or sick sinus syndrome,  $p = 0.59$ ), initial rhythms (sinus rhythm or persistent atrial fibrillation,  $p = 0.62$ ), pacing modes (dual chamber pacing or VVI pacing,  $p = 0.26$ ), and ventricular lead positions (septum or apex,  $p = 0.52$ ). On Cox proportional hazard model analysis, hypertension [hazard ratio (HR) = 1.74, 95% confidence interval (CI) = 1.19–2.54,  $p = 0.004$ ], diabetes mellitus (HR = 2.18, 95% CI = 1.51–3.14,  $p < 0.001$ ), history of myocardial infarction (HR = 3.59, 95% CI = 2.49–5.16,  $p < 0.001$ ), and history of stroke (HR = 2.26, 95% CI = 1.51–3.37,  $p < 0.001$ ) were independent predictors for mortality.

**Conclusions:** The mortality rate of super-elderly patients who had no critical illnesses and were healthy enough to walk unassisted at the time of PM implantation was not inferior to that of younger patients. Prognosis was determined by comorbidities, but not by age, PM indication, initial rhythm, pacing leads, or mode.

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### Introduction

Japan has one of the longest life expectancies in the world. In 2014, for the first time, one in four of Japan's 127 million people was over 65 years old (precisely, 25.1%; the global average is 7.8%) [1]. The rate of elderly people over 65 years is increasing annually. In 2014, the population aged over 80 years numbered 9.5 million

(7.7%), and who aged over 90 years was 1.8 million (1.4%); these groups are estimated to increase to 16.2% and 5.0%, respectively, in 2050. "Super-elderly" patients over 85 years (beyond the average life expectancy in Japan, which was 83 years overall, 80.0 years in men, and 87.0 years in women in 2012) [2], are no longer rare in Japan.

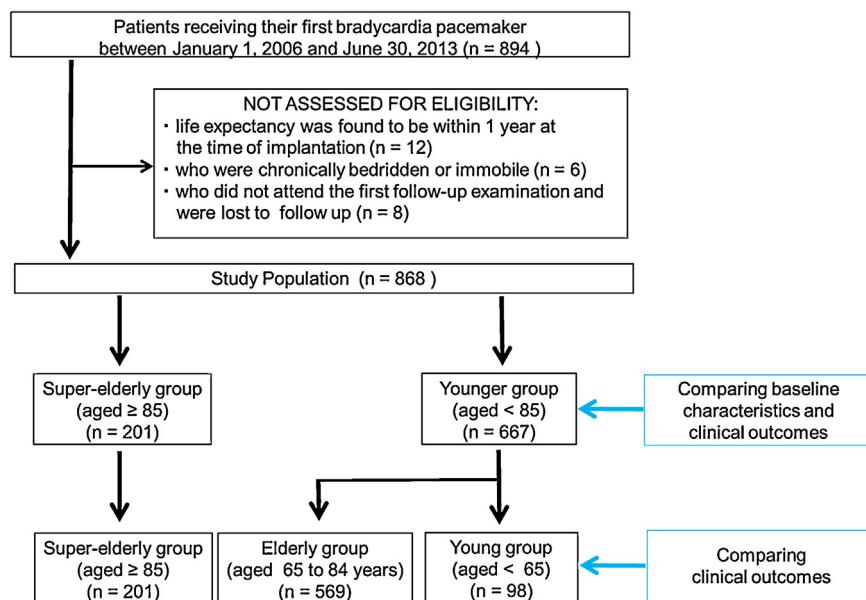
The number of cardiac pacemaker (PM) implantations has increased steadily since the PM was first introduced in 1958. In 2010, approximately 57,500 PMs were implanted in Japan (36,000 new device implantations and 21,000 exchanges) [3]. As the population ages, the number of people of advanced age who require PM implantation has been increasing. However, no previous study has reported the long-term prognosis of super-elderly patients

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**Fig. 1.** Patient selection flow. After excluding patients whose life expectancy was found to be within 1 year at the time of implantation ( $n = 12$ ), who were chronically bedridden or could not move by themselves ( $n = 6$ ), and who did not attend even the first follow-up outpatient appointment and were lost to follow-up ( $n = 8$ ), we ultimately enrolled 868 eligible patients.

needing PM. Therefore, we frequently encounter the difficult question of whether there is a benefit to super-elderly patients to undergo PM implantation, especially from the viewpoint of increasing medical cost.

The aim of the present study was to assess whether the prognosis of super-elderly patients (aged  $\geq 85$  years) who require PM implantation was comparable to that of younger patients.

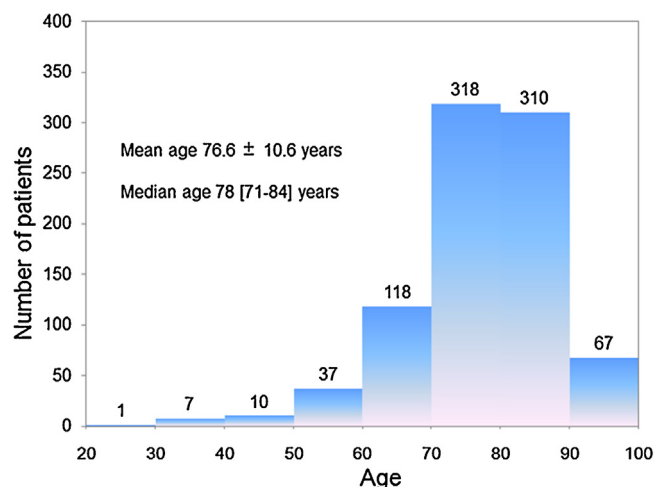
## Materials and methods

### Study population

We retrospectively enrolled 868 patients (men 49.0%,  $76.6 \pm 10.6$  years) receiving their first bradycardia PM between January 1, 2006 and June 30, 2013. We first identified 894 consecutive patients who received a PM during this period for chronic pacing according to the guidelines of the Japanese Circulation Society [3]. We excluded patients whose life expectancy was found to be within 1 year at the time of implantation ( $n = 12$ , mainly because of advanced malignancy, among whom six were over 85 years, five were between 65 and 85 years, and one was under 65 years), who were chronically bedridden or could not move by themselves ( $n = 6$ , all of them over 85 years), or who did not attend even the first follow-up outpatient appointment and were lost to follow-up [ $n = 8$ , six patients (all 65–85 years) changed residence and two patients (one over 85 years and one under 65 years) were followed up by another hospital]. After exclusion, we ultimately enrolled 868 eligible patients (Fig. 1). The age distribution of the study population is shown in Fig. 2. Baseline characteristics and clinical outcomes were compared between the super-elderly group (aged  $\geq 85$  years) and the younger group (aged  $< 85$  years). In addition, we divided the younger group into two additional groups, an elderly group aged 65–84 years and a young group aged  $< 65$  years (Fig. 1). Clinical outcomes were also compared among the three groups. This study conforms to the ethical principles of the Declaration of Helsinki. The requirement of informed consent was waived because all data were anonymously catalogued. The study protocol was approved by the institutional review boards of the Japanese Red Cross Musashino Hospital. The information disclosure document of this study has been published on the hospital website.

### Data collection

The following demographic and clinical data were obtained from medical records: age, sex, height, weight, initial vital signs [including systolic and diastolic blood pressure (BP) on admission, heart rate], laboratory data on admission, concomitant diseases [hypertension (BP  $\geq 140/90$  mmHg or a history of hypertension and taking antihypertensive medications), diabetes mellitus (DM), history of stroke, history of myocardial infarction], the indication for PM implantation (atrio-ventricular conduction disturbance or sick sinus syndrome), initial heart rhythm (sinus rhythm or persistent atrial fibrillation), pacing mode (dual chamber pacing or VVI pacing), and the position of the leads (septum or apex). Pacing mode was determined as follows: (1) dual chamber pacing for atrio-ventricular conduction disturbance or sinus bradycardia, and (2) VVI pacing for persistent atrial fibrillation or specific reasons such as implantation in elderly patients to shorten the procedure time. Each operator selected the position of the leads. The



**Fig. 2.** The age distribution of the study population.

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