Characteristics and Incidence of Patients With Tricuspid Valve Prolapse After Micra Transcatheter Pacing System Implantation

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Abstract

Background: The characteristics and incidence of patients with tricuspid valve (TV) prolapse after leadless pacemaker implantation are unknown. **Methods and Results:** We retrospectively identified 35 of 85 patients with sufficient echocardiographic TV imaging before and after Micra transcatheter pacing system (Micra TPS) implantation. The post-procedure incidence of TV prolapse was 8.6%, and the cause of prolapse was chordae tendineae rupture. Patients with TV prolapse had significantly longer procedure times and more deployments than patients without TV prolapse. **Conclusions:** TV prolapse after Micra TPS implantation is not a rare complication and is accompanied by frequent deployments and prolonged procedure times.

Title:

Characteristics and Incidence of Patients With Tricuspid Valve Prolapse After Micra Transcatheter Pacing System Implantation

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Short title:

Tricuspid Valve Prolapse After Micra Implantation

Conflict of Interest:

Conflicts of interest: Dr. K. Yamamoto has received lecturer's fees from Otsuka Pharmaceutical Co., Ltd.; Daiichi-Sankyo Co., Ltd.; and Novartis and research grants from Abbott; Otsuka Pharmaceutical Co., Ltd.; Medtronic Japan Co., Ltd.; Daiichi-Sankyo Co., Ltd.; Boston Scientific Co., Ltd.; Biotronik Japan Inc.; Japan Lifeline Co., Ltd.; Mitsubishi Tanabe Pharma Co., Ltd.; Fukuda Denshi; Takeda Pharmaceutical Co., Ltd.; Ono Pharmaceutical Co., Ltd.; and Novartis. The remaining authors have reported no relationships that could be construed as a conflict of interest.

IRB Information:

This study was approved by the Institutional Review Board of Tottori University Hospital (Reference no.22A120).

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Abstract

Background:

The characteristics and incidence of patients with tricuspid valve (TV) prolapse after leadless pacemaker implantation are unknown.

Methods and Results:

We retrospectively identified 35 of 85 patients with sufficient echocardiographic TV imaging before and after Micra transcatheter pacing system (Micra TPS) implantation. The post-procedure incidence of TV prolapse was 8.6%, and the cause of prolapse was chordae tendineae rupture. Patients with TV prolapse had significantly longer procedure times and more deployments than patients without TV prolapse.

Conclusions:

TV prolapse after Micra TPS implantation is not a rare complication and is accompanied by frequent deployments and prolonged procedure times.

Keywords: Micra transcatheter pacing system; leadless pacemaker, tricuspid valve prolapse; chordae tendineae rupture

Introduction

The Micra transcatheter pacing system (Micra TPS; Medtronic, Minneapolis, MN, US), a type of leadless pacemaker (LP), is a novel technology that has been rapidly gaining popularity worldwide in recent years as a treatment for bradycardia. Notably, LPs are superior to conventional transvenous pacemakers in that they are associated with fewer complications. However, because the Micra TPS is a relatively new device, unknown complications may occur.

Tricuspid regurgitation (TR) is one of the well-known complications after transvenous pacemaker implantation. Several studies have shown that the incidence of TR as a complication of transvenous pacemaker implantation is approximately 20%.[1,2] By contrast, one meta-analysis showed no evidence of an increase in the prevalence of significant TR up to 1 year after leadless pacemaker implantation.[3] However, several centers have experienced a few cases of TV prolapse due to chordae tendineae rupture and worsening of TR after Micra TPS implantation.[4,5,6]The clinical characteristics of patient groups with TV prolapse caused by Micra TPS implantation are unknown.

We herein present three cases of this complication at the time of Micra TPS implantation in our hospital and investigate their clinical characteristics and incidence.

Methods

Study Population and Design

We retrospectively enrolled 85 consecutive patients who underwent implantation of Micra TPS (Micra VR or Micra AV) from May 2018 to August 2022 at our institution. Of these, we included 35 patients with sufficient echocardiographic images before and after the implantation to evaluate the right heart system. We compared the patients with and without TV prolapse after the implantation. The present study was approved by the Institutional Review Board of Tottori University Hospital.

The patients' medical records were retrospectively reviewed to analyze.

Echocardiographic studies were performed on each patient approximately 1 week before implantation and 1 to 3 months thereafter. The studies were performed by echocardiologists or echocardiographers using commercially available echocardiographic systems (Vivid Series; GE Healthcare, Chicago, IL, USA and EPIQ Series; Philips Healthcare, Amsterdam, Netherlands).Assessment and quantification of valvular function and morphology were performed based on the current guidelines.[7] TV leaflet motion was analyzed in all available views.

Implantation Procedure

All Micra TPS devices were implanted by experienced cardiac electrophysiologists according to current procedure guidelines. The procedures were performed in the catheterization laboratory with the patients under moderate sedation. The devices were intended to be implanted primarily in the mid-septal region of the right ventricle (RV), but they were implanted in the anterior septal region if deployment was difficult. Projection views (45° left anterior oblique and 30° right anterior oblique) were used to evaluate the final placement of the Micra TPS in the RV chamber. The Micra TPS was recaptured and repositioned if the electrical measurements were not with in recommended values (pacing threshold at <1.0V/0.24ms, pacing impedance 400-1500Ω) and/or inadequate fixation.[8]

Statistical Analysis

Categorical variables are presented as number and percentage. Continuous variables are presented as mean and standard deviation. Student's t test and the Mann–Whitney U test were used to compare continuous variables, whereas Fisher's exact test was used to compare categorical variables. All statistical tests were two-sided, a P-values of <0.05 were considered statistically significant. Statistical analyses were performed using R software version 3.4.0 (The R Foundation for Statistical Computing, Vienna, Austria).

Results

Table 1 shows the background information of the patients with and without TV prolapse after Micra TPS implantation who had echocardiographic images sufficient to evaluate the right heart system. There were no significant differences in age, sex, body mass index, pacemaker indication between the two groups. Patients with TV prolapse after Micra TPS implantation had significantly longer procedure times (111.7±39.5 vs. 51.6±22.7 min, P<0.001) and more deployments (7.0±3.5 vs. 2.2±2.2, P=0.001) than those without TV prolapse. No patient had severe valvular regurgitation on preoperative echocardiography.

Table 2 shows the clinical manifestations of three cases of TV prolapse after Micra TPS implantation. In all three patients, the indication for Micra TPS implantation was complete atrioventricular block, and the device location was in the RV mid-septum. Prolapse of the TV septal leaflet due to chordae tendineae rupture was observed in all three patients (Figure 1). They required more than five deployment attempts, which is more than the number of deployment attempts in the patients without TV prolapse at follow-up. In two of the three patients, TR progressed to severe after Micra TPS implantation, but only Case 3 required surgical TV repair and was reported previously.[4]

Discussion

We have herein presented three cases of TV prolapse as a complication after Micra TPS implantation and investigated their clinical characteristics. This is the first report of multiple cases of TV prolapse associated

with Micra TPS implantation at a single center. We found that the incidence of TV prolapse due to chordae tendineae rupture induced by Micra TPS implantation was 8.6%. We specifically found that TV prolapse was accompanied by a significantly higher number of deployment attempts and longer procedure times.

TR is a well-known complication of cardiac implantable electronic devices. Acute tricuspid valve injury after transvenous pacemaker implantation is thought to be caused by leaflet perforation, laceration, or tearing of the tricuspid complex.[9] On the other hand, worsening TR in the acute phase after LP implantation has rarely been reported in prior clinical trials. Haeberlin et al.[3] reported that the majority of patients did not show a significant change in TV function after LP implantation, and the number of required LP deployments did not predict an increased incidence of TR in their analysis. In this way, the mechanism of worsening TR after LP implantation is still debatable.

Subvalvular tissue damage is considered unlikely with the Micra fixation tine in ex vivo.[10] However, in our study, early postoperative worsening TR was associated with rupture of TV chordae tendineae. It suggests mechanical damage to TV or subvalvular tissue, rather than functional dysfunction associated with right heart system remodeling. Similar cases have been reported at other centers and it is important to recognize that this complication can occur with Micra TPS implantation in vivo.[4,5,6] Mechanisms for TV prolapse as a mechanical complication of Micra TPS implantation may include damage to tricuspid complex due to device manipulation, pushing during deployment, traction during retrieval and trapping between the device cup and body during recapture. Transesophageal echocardiography may be useful for detecting the damage to TV or subvalvular tissue during the Micra TPS implantation. However, it is not feasible for procedure under sedation without intubation and ventilator management. On the other hand, intracardiac echocardiography may be more useful modality in that it can be used regardless of sedation depth to assess the damage to TV or subvalvular tissue during implantation.

This study had several limitations. First, the present study was subject to a selection bias. This is because of the small number of patients in a single-center retrospective study and the exclusion of patients with insufficient echocardiography to evaluate TV. Second, the number of patients with TV failure after Micra TPS implantation was too small to identify independent predictors of failure. Prospective studies with large numbers of patients are needed to accurately determine the incidence of TV prolapse after LP implantation and to identify its prognostic factors.

Conclusions

TV prolapse after Micra TPS implantation is not a rare complication and is accompanied by frequent deployments and prolonged procedure times.

Legends for Tables and/or Figures

Table 1. Patient characteristics

All data are presented as mean ± standard deviation or n (%).

AV, atrioventricular; Micra TPS, Micra transcatheter pacing system; E, peak mitral early filling velocity; e', mitral annular velocity; E/e', peak mitral early filling velocity to mitral annular velocity ratio; LAD, left atrial dimension; LAVI, left atrial volume index; LVDd, left ventricular end-diastolic dimension; LVDs, left ventricular end-systolic dimension; LVEF, left ventricular ejection fraction; LVMI, left ventricular mass index; LVOT VTI, left ventricular outflow tract velocity time index; RVDd, right ventricular end-diastolic dimension; RV, right ventricular; SV, stroke volume; TTE, transthoracic echocardiography; TV, tricuspid valve; NA, not applicable.

P-values of <0.05 were considered statistically significant.

Table 2. Clinical manifestations of three patients with TV prolapse after Micra TPS implantation

Micra TPS, Micra transcatheter pacing system; M, male; F, female; CAVB, complete atrioventricular block; RV, right ventricular; TV, tricuspid valve; TR, tricuspid regurgitation.

Figure 1. Transthoracic echocardiography findings.

(A–C) Case 1. (D–F) Case 2. (G–I) Case 3.

(A, D, G) Preoperative transthoracic echocardiography shows no flail leaflet of the tricuspid valve. (B, E, H) Flail STL with chordae tendineae rupture and TR flow. (C, F, I) Flail STL observed by three-dimensional transthoracic echocardiography.

ATL, anterior tricuspid leaflet; PTL, posterior tricuspid leaflet; RA, right atrium; RV, right ventricle; STL, septal tricuspid leaflet; TR, tricuspid regurgitation.

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