First reported implantation of a VDD leadless pacemaker and a subcutaneous defibrillator in a patient with congenitally corrected transposition of the great arteries

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Introduction

Entirely subcutaneous implantable cardioverter-defibrillators (S-ICD™ system; Boston Scientific Corp, Marlborough, MA) provide effective defibrillation and reduce the risk of infection or lead-related problems.[1–3] S-ICD systems may be a valid alternative to transvenous implantable cardioverter-defibrillator (ICD) in patients in whom bradycardia pacing or cardiac resynchronization therapy (CRT) is not required.[4,5] The Micra™ AV Transcatheter Pacing System (Medtronic Inc, Minneapolis, MN) is a recently approved leadless pacemaker enabling atrioventricular (AV) synchronized pacing, which may, in theory, compensate the S-ICD's inability to pace. In this report we describe a case of combined S-ICD and VDD leadless pacemaker (LP) implantation in a patient with a history of pacemaker lead endocarditis, occlusion of both subclavian veins, and congenitally corrected transposition of the great arteries (CCTGA). A previous report described a patient with CCTGA in whom a VDD LP alone was implanted.[6] To our knowledge this is the first case of a combined LP and S-ICD implantation in a patient suffering from CCTGA.

Case report

A 62-year-old male patient with CCTGA presented to the emergency department with signs of congestive heart failure (NYHA class III), a reduced ejection fraction of 25% of the right systemic ventricle, and sepsis.

In 1991, a transvenous dual-chamber pacemaker had been implanted for high-grade AV block via the right subclavian vein. As heart failure had progressed with declining anatomic left ventricular ejection fraction despite optimal medical therapy, an ICD was indicated for primary prevention. In 2014 a CRT-defibrillator was implanted for primary prevention via the left subclavian vein, while the right-sided pacemaker was left in place.

In 2020, a pacemaker lead endocarditis was diagnosed based on positive blood cultures and echocardiographic finding of vegetations. Both devices and all 5 leads were explanted. A temporary lead was placed in the subpulmonary left ventricle (SLV) via the external jugular vein and connected to an external pacemaker to ensure backup ventricular pacing during antibiotic therapy.

Following 6 weeks of antibiotic treatment and sterile blood cultures, a preoperative venography of the subclavian veins revealed a near-complete occlusion of both vessels

KEY TEACHING POINTS

- Leadless pacemaker implantation in congenitally corrected transposition of the great arteries is challenging but feasible.
- VDD leadless pacemaker and subcutaneous implantable cardioverter-defibrillator can be safely combined without cross-interaction.
- A combined implantation of VDD leadless pacemaker and subcutaneous implantable cardioverter-defibrillator may be a valuable option for selected patients.

KEYWORDS Congenital heart disease; Device reimplantation; Heart failure; Leadless pacing; Subcutaneous defibrillator
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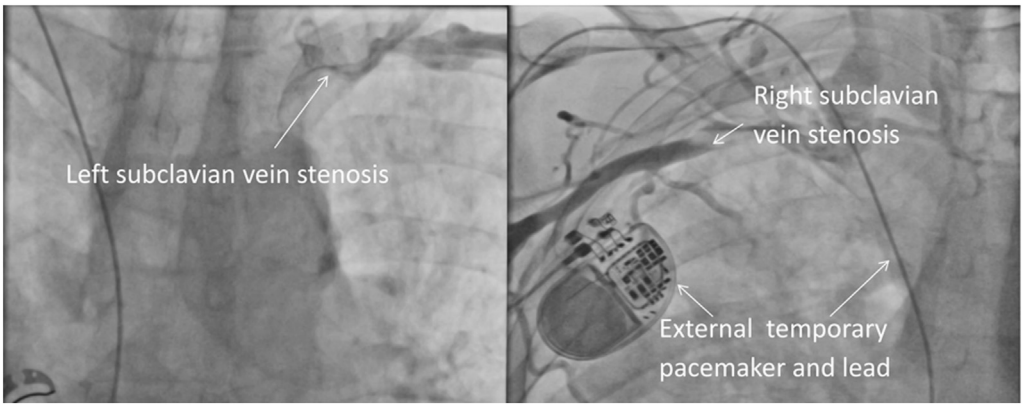

Figure 1 Occlusion of the right and left subclavian veins. Venograms were taken 6 weeks after extraction of the right-sided pacemaker and left-sided cardiac resynchronization therapy-defibrillator with all respective leads. A temporary single lead was placed into the anatomic right ventricle (congenital left ventricle) and connected to an externally placed pacemaker.

(Figure1). Thus, the patient was evaluated for S-ICD placement. Preimplantation electrocardiographic screening showed suitability for primary, secondary, and alternative vectors when measured in the right parasternal position. For bradycardia pacing, implantation of an epicardial device was regarded as surgically high risk. Therefore, we decided to implant an AV synchronized leadless pacemaker (Micra AV) and an S-ICD device (Boston Scientific A209, Electrode 3401 SQ-1) simultaneously (Figure 2).

The patient underwent general anesthesia and the implantation was performed by 2 experienced operators. The S-ICD position was acquired with a chest radiograph and a device tester. The LP was inserted via a right femoral venous delivery sheath. Owing to the lack of trabeculae in the SLV, the LP fixation was technically challenging and the device dislocated multiple times before it was successfully placed in the right ventricular midseptum. The R-wave signal measured 11.5 mV and the capture threshold was determined as 0.38 V at 0.24 ms pulse width. The device was programmed in a VDD/S pacing mode (1.88 V amplitude at 0.24 ms pulse width), with a lower rate limit of 60 beats per minute (bpm) and an upper rate limit of 120 bpm. Vectors 1 and 2 were chosen for mechanical atrial sensing. The temporary lead was removed via the jugular vein. S-ICD implantation immediately followed LP implantation. The S-ICD was implanted using a 2-incision technique with the S-ICD lead in a right parasternal position. No complication occurred during the procedure. However, we omitted S-ICD testing at the end of S-ICD implantation, since the patient required catecholamine support after nearly 4 hours of procedure time under general anesthesia. Following a synchronous 10 joule shock, a shock impedance of 38 ohms was measured. All 3 shock vectors were evaluated and no signs of cross-talk between the S-ICD and the LP were detected. The S-ICD

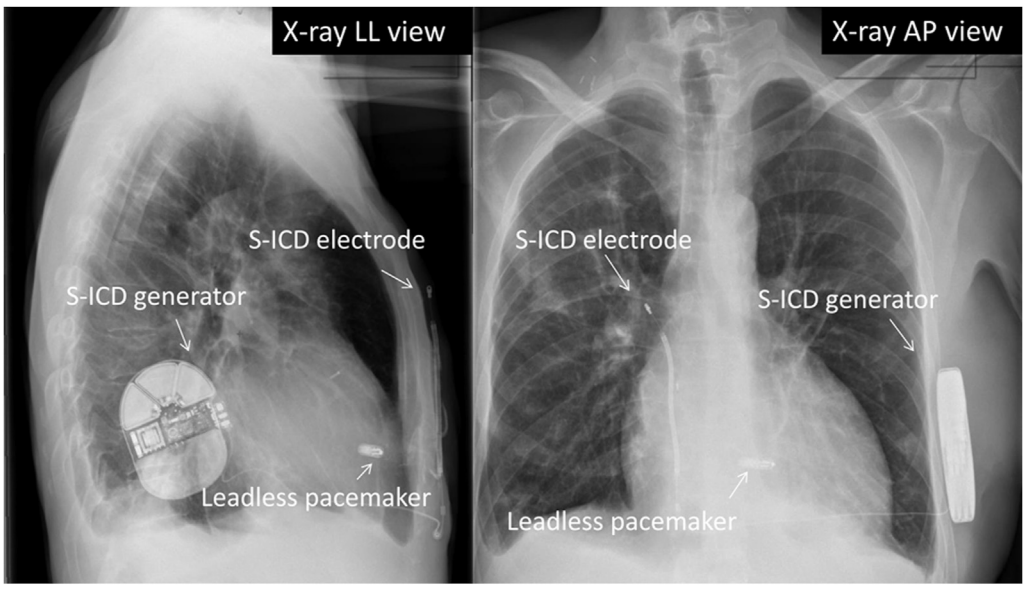

Figure 2 Chest radiograph after the implantation. The images taken in left-lateral (LL) and anteroposterior (AP) view show the position of subcutaneous implantable cardioverter-defibrillator (S-ICD) and leadless pacemaker after the implantation.

Table 1 Pacing site and ejection fraction

	QRS duration	Ejection fraction
CRT stimulation	157 ms	30%–35%
RV pacing	175 ms	30%–35%
LP pacing	144 ms	30%–35%

LP = leadless pacemaker; RV = right ventricular.

generator automatically selected the primary vector as the optimal sensing configuration and SMART Pass programming was activated. Therapeutic settings were programmed as follows: 80 joule output, standard polarity, conditional zone 220 bpm, shock zone 250 bpm, and postshock pacing was programmed off. Even when the LP was pacing at maximum output, no oversensing by the S-ICD occurred. Postprocedural chest radiographs documented adequate positioning of the devices and the subcutaneous lead (Figure 2).

At 3 months follow-up, the LP showed regular AV synchronous pacing with normal test results. The percentage of ventricular pacing was 100% without mode-switch episodes. S-ICD interrogation measured normal values for impedance and no arrhythmic events. Despite loss of cardiac resynchronization therapy, the depressed left ventricular function did not decline further compared to preimplantation.

Discussion

To our knowledge, this is the first report of a simultaneous VDD LP and S-ICD implantation in a patient with CCTGA. Previous reports[7,8] describe possible combination of a single-chamber leadless pacemaker and a subcutaneous defibrillator implantation; however, no report describes the novel LP with atrial sensing capability and the S-ICD in a patient with CCTGA. In our case, the implantation of LP in a CCTGA patient was particularly challenging because of absent trabeculae in the SLV, which complicated fixation of the device in the ventricle. No interactions between LP and S-ICD were recorded during cross-talk testing even at maximum pacing amplitude, including double counting or T-wave oversensing by the S-ICD.

According to the information on ejection fraction and clinical heart failure symptoms available to us from the time prior to CRT-defibrillator implantation, the patient appeared to have not responded with significant clinical improvements to CRT stimulation. Therefore, we were not concerned that his heart failure symptoms or ejection fraction would deteriorate following replacement of the CRT device with our combined LP and S-ICD approach. For the same reason, we regarded an alternative surgical approach with pericardial ICD lead placement riskier than the minimally invasive LP plus S-ICD approach. Notably, ejection fraction did not decline and QRS interval length did not increase following replacement of CRT pacing with right ventricular LP pacing within the follow-up period (Table 1).

At 3 months follow-up, the Micra AV device enabled AV sequential pacing with stable sensing and threshold values (Figure 3). Since we did not test the S-ICD response to induced ventricular tachycardia and ventricular fibrillation (VF) during implantation, and no arrhythmias occurred during the follow-up period, we cannot comment on the safety during ventricular tachycardia/VF and LP pacing. In theory, VF undersensing by the LP may result in pacing spikes misinterpreted by the S-ICD as ventricular excitations, which could impede VF detection and prevent shock delivery. Conversely, leadless pacemaker dysfunction or dislocation could result after S-ICD shock delivery. At this point, limited safety data exist, but single patient reports seem to confirm safety of the device combination.[9]

In the near future, LP and S-ICD devices will be able to communicate with each other, thus mitigating some of the potential risks discussed above. The new LP EMPOWER™ (Boston Scientific), for example, combined with an S-ICD, will be able to deliver antitachycardia pacing therapy, thereby replicating key functions of contemporary transvenous ICD devices.

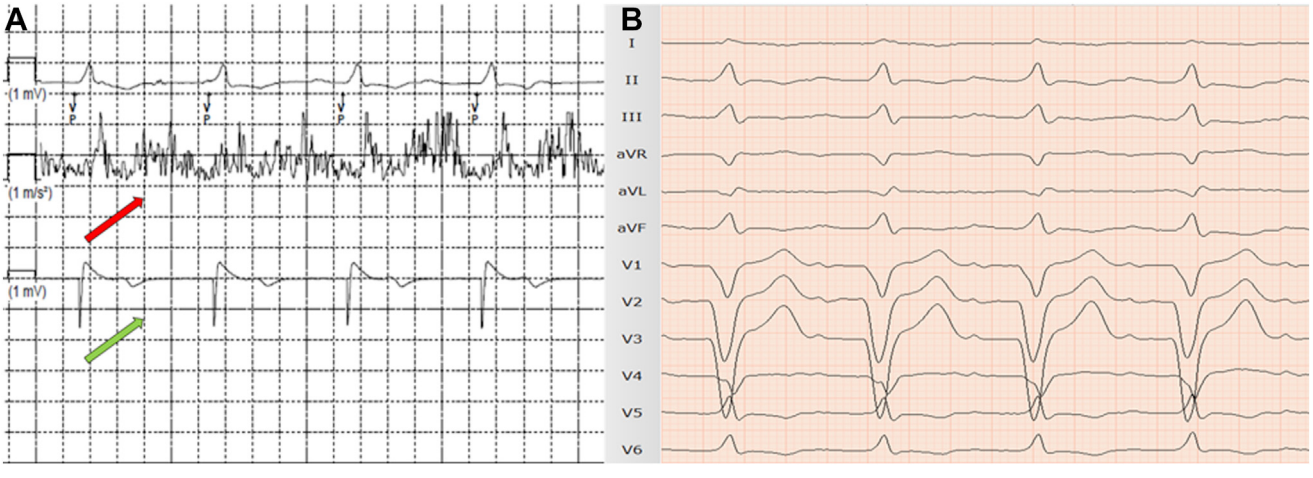

Figure 3 Leadless pacemaker–stimulated electrocardiogram (ECG). Figure shows **A:** intracardiac electrogram (*green arrow*) and atrial sensing curve (*red arrow*) recorded by leadless pacemaker and **B:** 12-lead ECG showing VDD pacing.

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