



Combined leadless pacemaker and subcutaneous implantable cardioverter-defibrillator to manage recurrent transvenous system failures

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Introduction

The leadless pacemaker (LPM) and subcutaneous implantable cardioverter-defibrillator (S-ICD) are rapidly growing alternatives to the transvenous pacemaker (PM) and implantable cardioverter-defibrillator (ICD) because of their ability to avoid common complications associated with the insertion and long-term presence of transvenous leads in the cardiovascular system. Owing to their peculiar features, they appear to be particularly suitable for patients with limited venous access or those who are at high risk of infection. Here, we describe the case of a patient needing pacing who underwent repeated heart surgeries and epicardial system revisions. When ICD indication arose, the decision was taken to implant a leadless pacemaker and an S-ICD to prevent sudden cardiac death.

Case report

In September 2017, a 46-year-old man was referred to our department for syncope due to sustained ventricular tachycardia at a rate of 170 beats per minute. Synchronized electrical cardioversion was performed to interrupt the arrhythmia. His medical history included a previous surgical correction of multiple interventricular septal defects and the intrathoracic implantation of a single-chamber pacemaker, probably for a congenital atrioventricular block, at the age of 2 years. In 1987, he also underwent implantation of a biological prosthesis for aortic valve replacement, and a new single-chamber pacing system was implanted in an abdominal position, together with a new epicardial lead. In 1994, the aortic valve was again replaced with a mechanical prosthesis.

Subsequently, he underwent replacement of the PM generator approximately every 3 years, owing to suboptimal electrical parameters

of the epicardial lead. In 2010, a worsening dilated-hypokinetic cardiomyopathy was diagnosed, and implantation of a transvenous cardiac resynchronization therapy (CRT) system was attempted. However, the procedure failed owing to the lack of suitable venous accesses. The systolic function further declined and in 2015 the decision was taken to adopt an epicardial approach through sternotomy, in order to initiate biventricular pacing. However, the patient showed no response to CRT; the ejection fraction further declined to 15%, combined with a stable NYHA III functional class. Moreover, the resynchronization therapy had to be discontinued after 1 year owing to the failure of the right ventricular lead. Since the results of the resynchronization therapy were unsatisfactory, no further attempts were made to restore biventricular pacing; an LPM (Micra, Medtronic plc, Mounds View, MN, USA) was successfully implanted in another hospital to ensure antibradycardia pacing. The electrical parameters were optimal (pacing threshold 0.75 V at 0.24 ms, programmed output 2.5 V at 0.24 ms, projected longevity of more than 8 years with expected pacing of 100% in the VVI 60 bpm mode, no measurable sensing owing to lack of stable ventricular rhythm on pacing inhibition).

During the hospital stay, the patient's eligibility for heart transplantation was confirmed and he was placed on the waiting list. In order to protect him from sudden cardiac death, implantation of an ICD was considered. However, we excluded the implantation of a transvenous ICD after CT angiography had confirmed bilateral subclavian vein occlusion. Moreover, any epicardial approach was ruled out in order to spare the patient a fifth sternotomy or thoracotomy. The use of a wearable defibrillator was also excluded because of the expected long waiting time on the transplantation list (patient classified as UNOS Status 2). Thus, the only viable approach was to implant an S-ICD, although the surface ECG screening based on the dedicated ECG morphology tool revealed that the T-waves of the paced rhythm exceeded the boundaries of the template (Fig. 1). An S-ICD (model Emblem A219, Boston Scientific, Natick, MA, USA) was then implanted (Fig. 2). The implantation procedure was successful and no T-wave oversensing was observed after activation of the SMART PASS filter, an algorithm designed to reduce the amplitude of lower frequency signals while maintaining an appropriate sensing margin [1] (Fig. 3). During S-ICD testing, VF was successfully recognized both by the S-ICD and by the LPM system; no inappropriate pacing occurred during the arrhythmia. As intervention by the LPM pacing was correctly inhibited during VF, it was deemed unnecessary to

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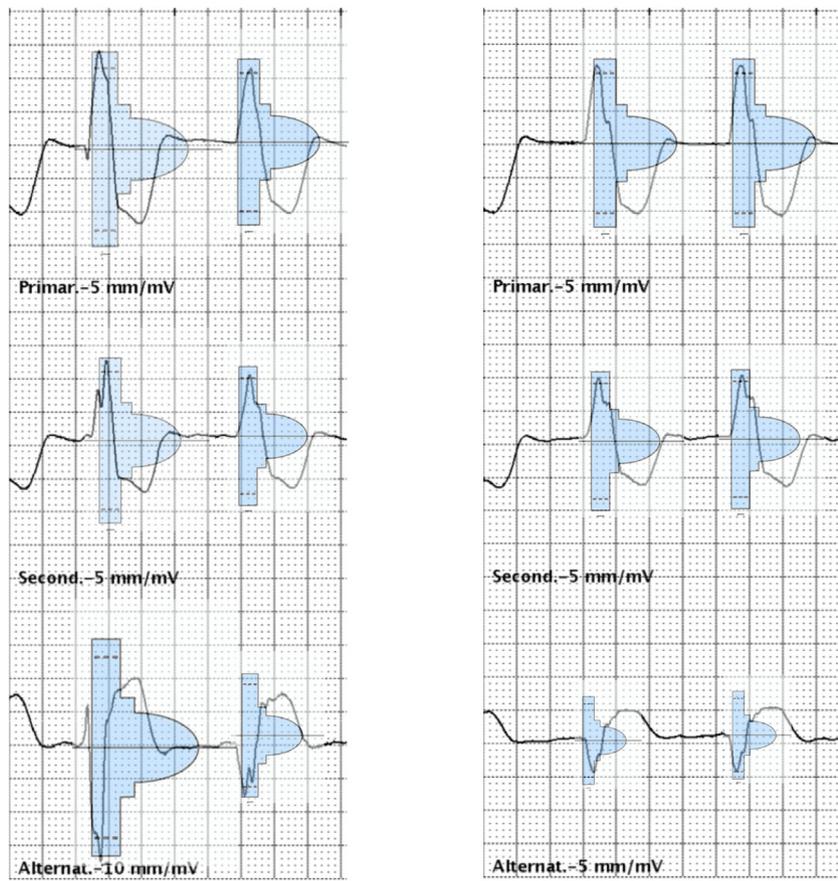


Fig. 1. Sensing channels during the automated S-ICD screening test. Left signals were acquired in the recumbent position (first QRS is a fusion beat with a premature ventricular contraction); right signals were acquired in the orthostatic position. No PM spike is evident, owing to the low-amplitude bipolar output, but the T-wave is over-represented. The ECG screening tool is superimposed for didactic purposes.

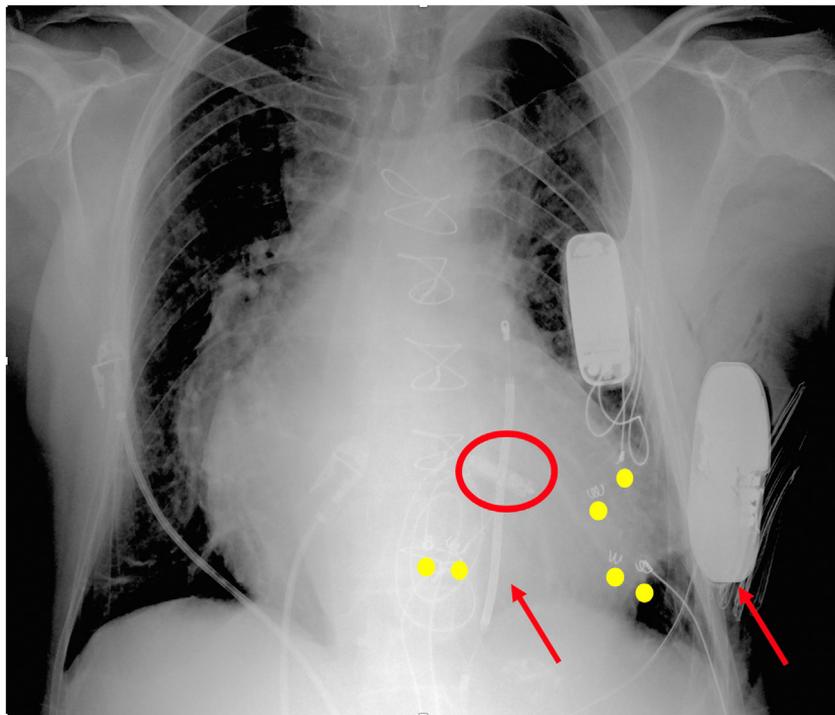


Fig. 2. Chest X-Ray after S-ICD implantation. The LPM is marked by the red circle. Yellow dots mark the abandoned epicardial leads. Red arrows mark the S-ICD system. The other device in the left hemithorax is an abandoned intrathoracic pulse generator (see text for details).

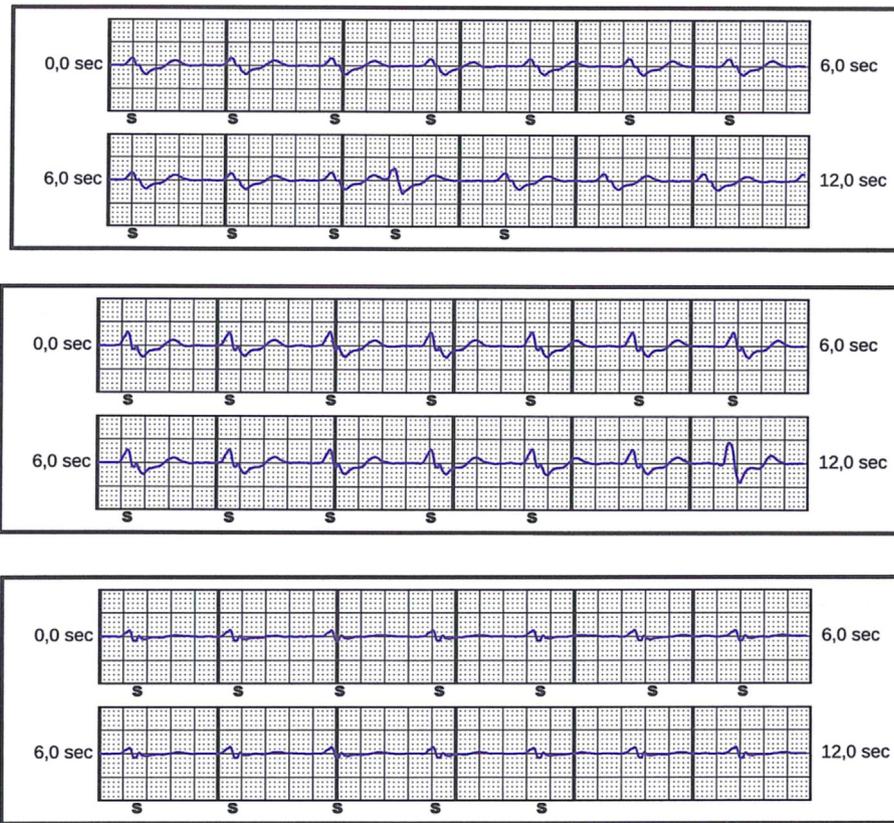


Fig. 3. *in vivo* signals after activation of the SMART PASS filter. No T-wave oversensing is present.

repeat S-ICD test during high-output asynchronous pacing. The postoperative course was uneventful and the patient was discharged 3 days after the procedure. During a 12-month follow-up, the patient remained free from system-related events, he did not experience arrhythmic episodes and no appropriate or inappropriate therapies were delivered.

Discussion

Congenital atrioventricular block is often a challenge for cardiac electrophysiologists. First pacemaker implantation during childhood is usually performed through an epicardial approach, in order to minimize catheter stretching caused by physiological growth. However, subsequent pacemaker implantation and lead revision procedures required in order to provide decades of pacing during adult age often give rise to problems of vascular access. In the case reported here, the patient had chronic bilateral subclavian vein occlusion, which was probably of congenital origin or due to repeated heart surgery at a very young age. Moreover, his cardiomyopathy progressively worsened, with theoretical indications for CRT and ICD implantation for secondary prevention. In this case, multiple epicardial pacing systems failed over time, probably owing to unfavorable chest anatomy as well as possible progressive epicardial fibrosis, which is a common finding in very advanced dilated cardiomyopathies. Consequently, CRT had to be abandoned. Although not the first choice for younger patients, LPM implantation was much easier and better tolerated than a further epicardial attempt or other off-label approaches, such as a femoral system. No further attempt to restore cardiac resynchronization was considered (including *ad hoc* programming of the existing CRT system to “pace on sense” on LV lead only) because of the lack of clinical response even during the short period of correct biventricular stimulation. In contrast, the new LPM device had optimal electrical parameters, ensuring an acceptably long life even in the presence of constant ventricular pacing.

Concerning protection from tachyarrhythmic events, very limited experience of the use of S-ICD in pacemaker recipients is available [2,3]. The only known contraindication is the need for unipolar pacing, owing to the high risk of double counting of pacemaker spikes. However, as the LPM implements fixed bipolar pacing, compatibility was theoretically guaranteed. A few other pitfalls were present in this particular case. First of all, the patient presented with ventricular tachycardia which could potentially respond to antitachycardia pacing, a painless therapy not provided by current S-ICD systems. Moreover, the signal screening test which is routinely performed prior to S-ICD implantation, had failed, implying a substantial risk of double counting of the paced rhythm due to T-wave oversensing. However, as the patient was completely pacemaker-dependent, even in the worst scenario of fixed double counting of QRS complexes, conservatively programming the pacemaker at VVI 60 bpm would have maintained the S-ICD sensed rate abundantly below the therapy window (170 bpm). In recent years, a customized high-pass filter, called SMART PASS, has proved able to significantly reduce T-wave oversensing and inappropriate shocks in S-ICD patients [1]. In our case, too, *in vivo* activation of the SMART PASS filter led to the complete suppression of T-wave oversensing, thereby allowing limitless pacemaker programming without the risk of inappropriate therapies. To the best of our knowledge, only a very small number of cases of simultaneous LPM and S-ICD implantation have been reported in the literature [4–6], and this is the first attempt at S-ICD implantation after screening failure in a permanently paced heart.

Conclusions

A totally extravascular PM and ICD system may constitute a bailout solution in highly selected patients without a suitable vascular access. S-ICD implantation can be considered even in the presence of a failed screening test in totally pacemaker-dependent patients.

Disclosures

Michele Arupi is an employee of Boston Scientific. No other conflict of interest to declare.

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