Three varieties of sense-B-noise, a novel cause of inappropriate shocks in patients treated with a subcutaneous cardioverter-defibrillator

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INTRODUCTION

The subcutaneous cardioverter-defibrillator (S-ICD), located outside the cardiovascular system, has been developed to provide primary or secondary protection against sudden cardiac death. That feature allows for a reduction in the rate of lead-related complications and infections, typical of transvenous systems. For that reason, S-ICD therapy expanded worldwide. It was adopted in Poland in 2014 [1] and is successfully used nowadays in selected patients not requiring cardiac pacing [2]. Nonetheless, a significant rate of inadequate shocks due to oversensing of T-waves, noise, and myopotentials remains an issue despite improvements in sensing algorithms.

Sensing and detection of the device rely on three electrical poles – two on the lead (distal sensing ring A and proximal sensing ring B) and the third on the can. Signals recorded between any two of them are called sensing vectors (primary [B to can], secondary [A to can], or alternate [A to B]). Recently, a novel clinical entity of inappropriate sensing has been identified in some of S-ICD recipients despite no apparent mechanical lead failure. It was named "sense-B-noise", as it is related to sensing vectors involving sensing ring B (primary or alternate). Clinical presentation is related to oversensing of noise in ECG signals, and inappropriate shocks delivered by the device. The phenomenon has been so far described in one series of six cases, where intermittent signal saturation, diminished QRS amplitudes, and disappearance of the artifacts after the inappropriate shock were deemed typical of that new entity [3]. Those characteristics may be important for differential diagnosis with other possible reasons for inappropriate shocks, such as, for example, electromagnetic interference (EMI).

METHODS

We present a series of three patients, who received S-ICD systems in our Department and who suffered from complications that were diagnosed as sense-B-noise during follow-up. Each of those three patients had a slightly different clinical picture of the same underlying problem.

RESULTS AND DISCUSSION

The first male patient with hypertrophic cardiomyopathy received an S-ICD in 2016 at the age of 39 for primary prevention of sudden cardiac death (SCD). Preoperative screening was positive for all three sensing vectors. The implanted system consisted of an A219 S-ICD device and 3401 lead (neither of them subject to any recall). The alternate sensing vector with 1x gain and Smart Pass filter on, as well as 210/230 bpm detection zones (conditional/non-conditional, respectively) were programmed. In 2018 he was admitted to a hospital in his residence area for inappropriate shocks (IAS) due to suspected noise. The first IAS occurred at an underground train station but the other three during transfer to the hospital; all of them without any symptoms suggestive of arrhythmia. The noise could not be reproduced with any maneuvers and was not consistent with EMI, and X-ray imaging did not reveal any lead failure. During surgical inspection, no abnormalities were found, so the system was explanted in one block (with the lead connected to the can), exchanged

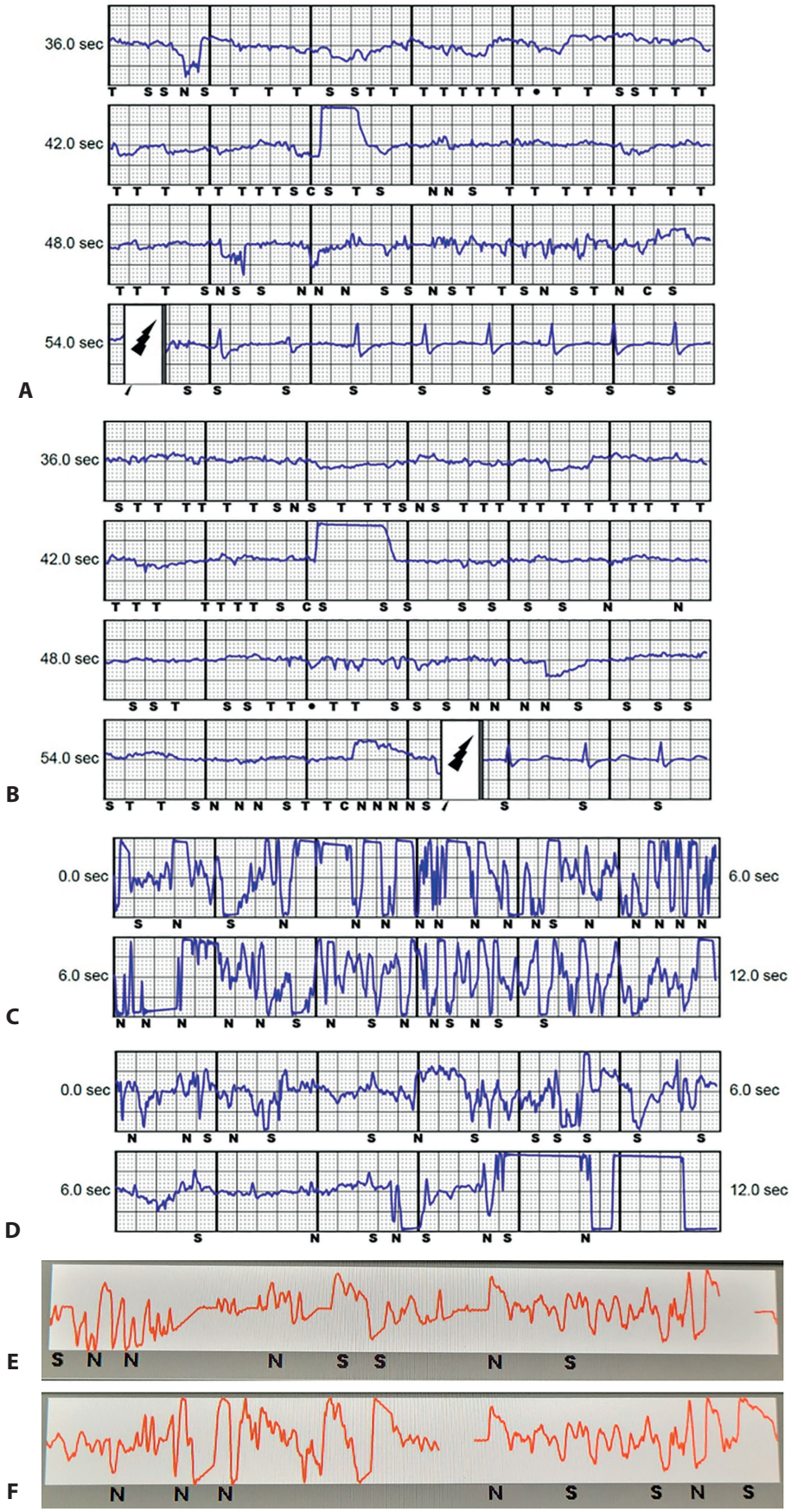

Figure 1. A, B. Two examples of inappropriate shocks due to noise oversensing in a patient with a subcutaneous implantable cardioverter-defibrillator (Patient 3, primary sensing vector). Note the noise itself, with a reduction of QRS amplitude, signal saturation, and normalization of signals immediately after shocks. **C, D.** Two examples of noise recorded as non-sustained episodes, without high-voltage therapy (Patient 2, alternate sensing vector). **E, F.** Similar noise observed during device interrogation and body position change from supine to sitting (Patient 3, alternate sensing vector)

for a new one, and the explanted system was sent to the manufacturer for investigation. No system failure was reported, the manufacturer proposed, as an explanation, sense-B-noise, and that diagnosis was finally accepted by our clinical team.

The second male patient with non-ischemic cardiomyopathy and left ventricular ejection fraction (LVEF) of 30% received an S-ICD for primary prevention in 2020 at the age of 40 (A219 device, 3401 lead, alternate sensing vector with 1× gain, Smart Pass on, 220/250 bpm detection zones). All three vectors were positive on screening. The lead was later subject to a recall, and the patient was included in the remote monitoring system. During follow-up, non-sustained episodes of noise were recorded by the device (Figure 1), all of them during the patient's normal life activity, with no suspected EMI. There was no apparent lead damage on X-ray imaging. The noise could not be reproduced with any provocative maneuvers. The manufacturer, similar to the first case, suggested sense-B-noise as the possible explanation and offered reprogramming to the secondary sensing vector as a solution. The patient refused to have the device reprogrammed and requested system replacement (being previously informed about the lead recall issue). His device was extracted in one block, and a new system was implanted during the same surgical procedure. Inspection of the explanted system by the manufacturer did not reveal any failure, and the sense-B-noise issue was again reported to us as the final diagnosis.

The third male patient received his S-ICD system in July 2022 for primary prevention (A219 device, 3501 lead, no recall, 210/230 bpm detection zones). He was 34 years old and suffered from heart failure due to left ventricular non-compaction. His LVEF was 10% at the moment of implantation despite optimal medical therapy. All three vectors were acceptable on pre-implant ECG screening, and the primary vector was automatically selected by the device (1× gain, Smart Pass on). The patient experienced 11 inappropriate shocks in December 2022, during normal activity at home, with no evidence of EMI. Oversensing of noise, with reduction of QRS amplitude, signal saturation, and normalization of signals immediately after shocks were found in recordings of the episodes at device interrogation (Figure 1). Those features are typical of sense-B-noise, so, on the basis of our previous experience, that was the initial diagnosis. But during interrogation of the device, the same noise could be seen in the live ECG window (alternate sensing vector active at that time), which was less indicative of sense-B-noise, but rather of lead failure. No apparent lead damage was found on the chest X-ray. The patient requested discontinuation of S-ICD therapy, his LVEF had improved to 45% by that time, and therefore the system was explanted and returned to the manufacturer for inspection. Thorough investigation did not reveal any electrical or mechanical failure of the lead or any other part of the system, so the sense-B-noise was eventually considered the most likely diagnosis reported back to us by the manufacturer.

Available data regarding that new clinical entity (the sense-B-noise issue) are scarce, and the manufacturer has not yet officially released any report on the evidence collected so far.

In the only available case series [3], patients had oversensing of noise and inappropriate shocks, which was also the case in our patients 1 and 3. What was different in our patient 3 is that the same noise could be observed during device interrogation although randomly (most likely during body position change). Our initial suspicion of lead failure was not confirmed either by X-ray or inspection of the explanted system by the manufacturer, and sense-B-noise was accepted as the final diagnosis. Conversely, patient 2 had non-sustained episodes of noise, without shocks, which has not been reported before. It is not known whether non-sustained episodes might foretell the sustained ones, with inappropriate shocks, or, in other words, if the sense-B-noise phenomenon might be progressive in the course of time.

The absence of mechanical lead failure in S-ICD recipients does not exclude noise oversensing. On the other hand, recorded noise is not always consistent with lead failure. Therefore, the sense-B-noise issue should be remembered and included in differential diagnosis in S-ICD patients presenting with inappropriate shocks. At the moment, there are no data on how to solve this problem, and any further guidance from the manufacturer is keenly awaited. As for now, we deemed the recommendation to reprogram the device into the secondary vector unsatisfactory. As long as we do not understand the nature of the phenomenon, we cannot accept any partial solution that does not offer absolute certainty that it will work.

Article information

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