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Case Report

Air entrapment as a cause of early inappropriate shocks after subcutaneous defibrillator implant: A case series

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ABSTRACT

Inappropriate shock (IAS) is the most frequent device-related complication among patients with subcutaneous implantable cardioverter-defibrillator (S-ICD). Air entrapment (AE) has been described as an underdiagnosed cause of early postimplant IAS. We report 6 consecutive cases of early IAS after S-ICD implant, in whom the electrogram analysis (EGM) and/or chest radiography (CXR) were consistent with AE.

1. Introduction

The subcutaneous implantable cardioverter-defibrillator (S-ICD) is an established therapy for the prevention of sudden cardiac death (SCD) in patients not in need of cardiac pacing [1]. Previous observational [2,3] and randomized [4] studies showed that S-ICD was associated with lower rate of device-related complications and higher rate of inappropriate shock (IAS) when compared to transvenous ICD (TV-ICD) [4,5]. Following the technological improvement of S-ICD system, the annual IAS rate is decreased from 13% to 3.1% [2–5]. Among S-ICD recipients, the most common causes of IAS were T wave oversensing, oversensing of ventricular tachycardia/ventricular fibrillation below the therapy zone, low amplitude signals, and myopotentials [2–4]. Previous case reports described subcutaneous air entrapment (AE) as a potential cause of early IAS [6–11]; and a recent systematic review showed an aggregate AE incidence of 1.2% causing IAS [12]. We aimed to describe the clinical characteristics, implant techniques and management of consecutive patients who underwent S-ICD implant at our Institution and experienced at least one IAS due to air entrapment.

2. Materials and methods

2.1. Database

Data for this study were sourced from the Monaldi Hospital Rhythm Registry (NCT05072119) [13], which includes all patients who underwent ICD implant, both S-ICD and TV-ICD, and followed up at our Institution through both outpatient visits, every 3–6 months, and remote device monitoring from January 1, 2015 to date. The local institutional review boards approved the study (ID 553–19), and all patients provided written informed consent for data storage and analysis.

2.2. Study population

From a cohort of 170 consecutive patients who received S-ICD from January 1, 2015 to 1 July 2022 and was followed at our Institution, we included 6 consecutive S-ICD patients (3.5%) who experienced at least one IAS due to air entrapment. The baseline characteristics of the study population was shown in Table 1. The S-ICD implant and IAS' characteristics of the study population are summarized in Table 2.

2.3. Case presentation

2.3.1. Patient 1

In 2016, a 42-year-old male with a history of resuscitated

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Table 1
Baseline characteristics of the study population.

Patient	Sex	Age	Pathology	S-ICD Indication
1	Male	42	VT	Secondary Prevention
2	Male	59	HCM	Primary Prevention
3	Male	61	Brugada syndrome	Primary Prevention
4	Female	63	HFrEF	Primary Prevention
5	Male	48	HFrEF	Primary Prevention
6	Female	76	HCM	Primary Prevention

HCM: Hypertrophic cardiomyopathy, HFrEF: Heart failure with reduced ejection fraction; S-ICD: subcutaneous implantable cardioverter-defibrillator; VT: ventricular tachycardia.

sudden cardiac arrest and no other risk factors, underwent S-ICD implant (Device: A219 EMBLEM S-ICD; Lead: 3401; Boston Scientific, MA, USA) for secondary prevention of SCD, after excluding the reversible causes of life-threatening arrhythmias. The procedure was performed following the three-incisions technique without preventive manoeuvres to prevent air retention. Defibrillation threshold testing was successfully performed. The primary sensing vector (from proximal electrode ring to can) was programmed. Before the discharge, 48 h following the procedure, the patient experienced a shock. Post-implant CXR was not performed. The device interrogation showed a continuous baseline shift and oversensing of low-amplitude signals, followed by shock. The S-ICD sensing vector was reprogrammed with no further events.

2.3.2. Patient 2

In 2018, a 59-year-old male with end-stage hypertrophic cardiomyopathy and a dysferlin-deficiency underwent S-ICD implant (Device: A219 EMBLEM S-ICD; Lead: 3501; Boston Scientific, MA, USA) for the primary prevention of SCD. A two-incision technique with a digital dissection of the tunnelled track was performed. No preventive manoeuvres to prevent air retention were provided. The primary sensing vector was programmed. Defibrillation threshold testing was successfully performed. Six hours following the procedure, the patient experienced a shock. Post-implant CXR was not performed. Device interrogation revealed an abrupt baseline shift with low signal amplitude compatible with the diagnosis of subcutaneous AE. S-ICD was switched off for 24 hours until EGM analysis demonstrated the resolution of spontaneous and provoked artifacts. The patient did not experience further IASs at the follow-up.

2.3.3. Patient 3

In 2020, a 61-year-old man with Brugada syndrome at high arrhythmic risk underwent S-ICD implant (Device: A219 EMBLEM S-ICD; Lead: 3501; Boston Scientific, MA, USA) for the primary prevention of SCD. A two-incision technique was performed including saline flushing of the pocket and skin massage of the surgical field to expel residual subcutaneous air. The tunnelled track was obtained with the digital dissection of tissues. The primary sensing vector was programmed Defibrillation threshold testing was successfully performed. Post-implant CXR was not performed. Twelve hours after the implant, the patient received 4 IASs. At the mobilization, 12 h following the procedure, the patient experienced four consecutive shocks. The device interrogation revealed a continuous baseline shift and frequent oversensing of low-amplitude signals compatible with the diagnosis of subcutaneous AE. The S-ICD was switched off to prevent further events until complete aerial reabsorption. Seven days after, EGM analysis did not show residual artifacts and the S-ICD was reactivated with no further IASs.

2.3.4. Patient 4

In 2021, a 63-year-old female with dilated cardiomyopathy and severe reduction of global systolic function, despite the optimal medical therapy, underwent S-ICD implant (Device: A219 EMBLEM MRI S-ICD; Lead: 3501e; Boston Scientific, MA, USA). The procedure was performed following the two-incision technique. All measures for the prevention of AE supported by the S-ICD manufacturer, including saline flushing of the pocket and skin massage of the surgical field to expel residual subcutaneous air, were performed. The primary sensing vector was programmed Defibrillation threshold testing was successfully performed. Post-implant CXR was not performed. During sleep, 12 h following the procedure, the patient experienced a shock. At EGM analysis, the classical features of AE were shown. The S-ICD sensing vector was reprogrammed with no further events.

2.3.5. Patient 5

In 2022, a 48-year-old male with ischemic dilated cardiomyopathy and severe left ventricular dysfunction despite optimal medical therapy underwent S-ICD implant (Device: A219 EMBLEM MRI S-ICD; Lead: 3501e Boston Scientific, MA, USA) for the primary prevention of SCD. A two-incision technique with digital dissection of the tunnelled track was performed. The saline flushing of the pocket and skin massage of the surgical field was performed to expel residual subcutaneous air. Defibrillation threshold testing was not performed to avoid the related complication; however, the impedance measurement with a synchronous 10J shock revealed a low-voltage impedance. The primary sensing vector was programmed. Twelve hours following the procedure, the patient experienced three consecutive shocks. ICD interrogation and CXR were performed. EGM analysis demonstrated continuous baseline shift and oversensing of low-amplitude signals, followed by multiple shocks (Fig. 1), meanwhile the CXR was negative. AE was considered the most probable cause and S-ICD was switched off. After 4 days, EGM analysis did not demonstrate further spontaneous or provoked artifacts, suggesting the resolution of AE. S-ICD was turned on with no further IASs.

Table 2
Characteristics of S-ICD implant and IAS.

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
S-ICD generation	Second generation	Second generation	Second generation	Third generation	Third generation	Third generation
Implant technique	Three-incision	Two-incision	Two-incision	Two-incision	Two-incision	Two-incision
Time to IAS	48 hours	6 hours	12 hours	12 hours	12 hours	24 hours
Number of IAS	1	1	4	1	3	1
Chest X-ray	Not performed	Not performed	Not performed	Not performed	Negative	Positive
EGM analysis	Typical features of AE	Typical features of AE	Typical features of AE	Typical features of AE	Typical features of AE	Typical features of AE
Management	Sensing vector changing	ICD switched off	ICD switched off	Sensing vector changing	ICD switched off	ICD switched off
Time to IAS resolution	Not evaluated	1 day	7 days	Not evaluated	4 days	3 days

AE: air entrapment; EGM: electrogram; IAS: Inappropriate Shock; S-ICD: subcutaneous implantable cardioverter-defibrillator.

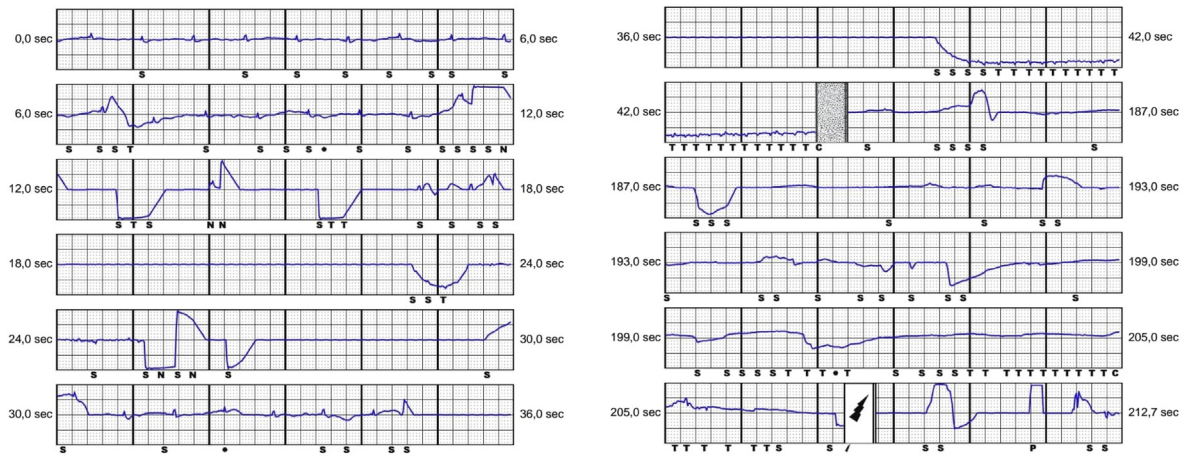

Fig. 1. EGM analysis showing typical artifacts of air entrapment.

2.3.6. Patient 6

In 2022, a 76-year-old woman with hypertrophic cardiomyopathy and a high SCD risk score underwent S-ICD implant (Device: A219 EMBLEM MRI S-ICD; Lead: 3501e Boston Scientific, MA, USA). The implant procedure was based on two-incision technique with digital enlargement of the tunnelled track. The saline flushing of the pocket and skin massage of the surgical field was performed to expel residual subcutaneous air. Defibrillation threshold testing was successfully performed. Twenty-four hours following the procedure, the patient experienced a shock. ICD interrogation and CXR were performed. EGM analysis demonstrated an abrupt baseline shift with a decrease in signal amplitude followed by an inappropriate 80-J discharge; CXR showed subcutaneous emphysema around the proximal electrode. The ICD was switched off to prevent further events. After 72 hours, when complete aerial reabsorption at CXR and sensing normalization at device interrogation occurred, ICD was reactivated with no further IAS.

3. Discussion

In 1979, Kreis et al. firstly described the dysfunction of a cardiac implantable electronic device due to AE in a unipolar pacemaker recipient [14]. Even if AE was not investigated and reported as an independent cause of IAS among S-ICD patients included in the clinical studies [3–5]; 14 case reports described this early complication after S-ICD implant [15] and it was included as a cause of IAS in 14 cohort studies [12]. However, the real incidence of IASs due to AE is still unknown, as it was considered a rare complication. Over the last seven years, 3.5% of our study population including S-ICD patients experienced IAS due to AE. IAS due to AE is reported as an early post-procedural complication [3], normally occurring in the first 72h after the device implant, although some exceptional cases of late inappropriate therapies associated with AE are described in the literature [12]. In our population, all events occurred in the first 48 hours from the S-ICD implant and in 66% of cases in less than 24 hours.

The association between AE and the S-ICD implant technique is controversial. According to some authors [16], the two-incision technique, not including the superior parasternal incision, reduce the air entrapment around the distal electrode. In contrast, other authors [17] considered this technique at increased risk of AE due to the use of a tear-away sheath to pass the lead up subcutaneous tract in the parasternal region. This latter theory seems to be supported by the higher rate of early post-implant IAS with the 2-incision technique, presumably because of AE, in the UNTOUCHED trial [3].

In our casuistry, we showed a higher incidence of IAS due to air entrapment with the two-incision technique (4%) than with the three-incision procedure (2%).

The S-ICD manufacturer suggests some precautions for procedural prevention of AE(12); however, no specific recommendations regarding its management and follow-up have been provided.

The digital dissection of the subcutaneous parasternal track should be avoided, as it increases the risk of AE and, prior to closing the incisions, the air in the subcutaneous space should be eliminated through normal saline injection and skin massaging. No information exists regarding how much these prevention measures reduce the incidence of AE and IAS due to AE in patients receiving an S-ICD. Moreover, even if such practices reduce the probability of AE, they do not prevent completely this complication, as in Case 4.

After the procedure, the device interrogation can early detect AE before switching on the S-ICD. Since, IAS due to AE sometimes occurs after patients' mobilization for the rise of the air, we suggest performing such interrogation during provocative maneuvers in both supine and orthostatic positions.

In addition, when an early IAS occurs, we suggest suspecting AE and performing antero-posterior and latero-lateral supine CXR and an S-ICD interrogation.

CXR permits the visualization of the air around the electrodes or rarely the generator, meanwhile, the EGM analysis shows a typical pattern characterized by a baseline shift with low amplitude signals eventually followed by one or more inappropriate shocks. The device interrogation can confirm the diagnosis despite a negative CXR, as in Case 5.

The management options are reprogramming the sensing vector or, if the signal from other vectors is not appropriate, switching off the device followed by serial assessment until air reabsorption is confirmed.

4. Conclusions

This case series highlights the relevance of air entrapment as a cause of early IAS following S-ICD implant. Further studies are necessary to demonstrate the effectiveness of the proposed intra-procedural measures to prevent this complication.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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