

Sudden arrhythmic death in patients with syncope and implantable cardiac monitor



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Introduction

In patients with unexplained syncope, an implantable cardiac monitor (ICM) is an effective tool to guide treatment decisions.¹ If the ICM detects an arrhythmia associated with symptoms, implantation of a permanent pacemaker for bradycardic syncope or an implantable cardioverter-defibrillator for ventricular arrhythmias is indicated.^{2,3} However, in the absence of symptoms, the case can be less clear despite findings of significant arrhythmias. Specifically, the evidence underlying guideline recommendation of permanent pacing for >6 seconds of asymptomatic sinus pause or atrioventricular (AV) block remain unclear.² Indeed, whether shorter duration of asymptomatic sinus pause or AV block would increase the risk of sudden arrhythmic death in patients with a history of syncope remains poorly studied. In this case series, we analyzed deaths from a large clinical study of syncopal patients with ICM, with the aim of identifying cases of sudden arrhythmic death and clarifying whether significant untreated arrhythmias were detected earlier.

Methods

The Observation of Clinical Routine Care for Patients with BIOTRONIK Implantable Cardiac Monitors (ICMs) study (BIO|STREAM-ICM; [NCT04075084](https://clinicaltrials.gov/ct2/show/study/NCT04075084))⁴ is an ongoing all-comers study observing the clinical course

KEY FINDINGS

- In 580 patients with history of syncope and an implanted cardiac monitor, 6 of 28 deaths (21%) were sudden cardiac deaths.
- In 3 of 6 sudden cardiac deaths, an arrhythmia was recorded at the time of death.
- In 5 of the 6 cases, a “warning arrhythmia” was observed that might have justified the implantation of a pacemaker or implantable cardioverter-defibrillator.

and treatment of patients with any indication for an ICM. This study has local ethics committee approval from all participating institutions. All subjects receive a BioMonitor ICM (Biotronik) with remote monitoring and remain in the study until a diagnosis is made and/or the ICM is explanted. The current analysis was limited to patients with syncope or presyncope reported as the main indication for the device. All patients provided informed consent, and data closure was May 15, 2024. Standard ICM settings for arrhythmia detection are >3 seconds for pause, <40 beats/min for bradycardia, and >180 beats/min for tachycardia. The home monitor sends a daily message including up to 6 episodes of arrhythmia to the server. If a death occurred after the daily transmission, postmortem device interrogation would be required to prove or disprove an arrhythmic death.

We analyzed the description of all patients' deaths from the study's adverse event reporting and categorized them as nonsudden death (noncardiovascular or cardiovascular nonarrhythmic), sudden cardiac death (SCD), or unclear. SCD was taken as all cases of either documented

KEYWORDS Cardiac syncope; Sudden cardiac death; Implantable cardiac monitor; AV block; SA block; Mortality (Heart Rhythm 0² 2024;5:821–824)

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Table 1 Details of sudden cardiac deaths

| ID | Sex, age (y) | Baseline | FU after ICM implantation (d) | Arrhythmia/event |
|----|--------------|--|-------------------------------|--|
| 1 | Male, 85 | Paroxysmal AF | 13 116 552 | Slow AF with ventricular intervals >3 s 16 beats nonsustained VT of 170 beats/min Death due to VT of 250 beats/min (lasting for 10 min and 45 s) |
| 2 | Female, 90 | Sick sinus syndrome, 1° AV block and right bundle branch block | 150 459 | Asymptomatic sinus arrest of 5 s with a single escape beat resulting in a pause of 3.2 s Death during sinus arrest |
| 3 | Male, 78 | Hypertensive cardiomyopathy | 333 337 | Sinus arrest of >15 s with escape rhythm of 25 beats/min Death during sinus arrest |
| 4 | Female, 87 | Ischemic heart failure | 124 137 | AV block lasting for 13 s with an escape rhythm of 36 beats/min Death after witnessed collapse at home; no ECG available |
| 5 | Male, 80 | Permanent AF | 21 42 136 | AV block of >20 s with escape rhythm of 40 beats/min Pacemaker implantation Death after collapsing in the street; no ECG available |
| 6 | Male, 84 | Permanent AF | — 541 | No arrhythmias recorded by ICM Death after failed out-of-hospital resuscitation; no ECG available |

AF = atrial fibrillation; AV = atrioventricular; FU = follow-up; ICM = implantable cardiac monitor; VT = ventricular tachycardia.

arrhythmia or unexpected death within 1 hour of symptom onset in the absence of an identifiable cause of death.⁵ All ICM electrograms transmitted by remote monitoring of the patients with SCD were screened for significant arrhythmias between implant date up to the time of death.

Results

By the data closing date, 580 patients with an indication of syncope or presyncope were enrolled. They were 65 ± 17 years of age and 263 (45%) were females. Cumulative follow-up duration was 818 patient-years. There were 28 (4.8%) deaths, including 15 nonsudden (10 noncardiovascular and 5 terminal heart failure), 7 of unclear cause (3 involved a fall or accident in public place and 4 occurred at the patients’ residence), and 6 SCDs. Of the 7 deaths of unclear cause, no cause of death was available despite efforts to obtain a death certificate, and no remote monitoring transmissions or ICM memory interrogations were available to prove or rule out arrhythmia as the cause of the event.

Of the 6 SCDs (21.4% of all deaths, 1% of enrolled patients), fatal arrhythmia was transmitted by remote monitoring in 3 cases. In the remaining 3 cases, there was 1 out-of-hospital arrest and 2 observed SCDs without postmortem ICM interrogation. Postmortem remote monitoring reviews of all events since ICM implantation found

significant arrhythmia in 5 of the 6 SCDs prior to their deaths (Table 1 and Figure 1). Patient 1 had a 16-beat run of nonsustained ventricular tachycardia (VT) and died of a documented sustained VT, possibly triggered by acute ischemia as evident from ST-segment elevation changes. Patients 2 and 3 had sinus arrest episodes of 5 and >15 seconds with escape rhythm and died later during documented sinus arrest. Patients 4 and 5 had episodes of third-degree AV block of 13 and 20 seconds in duration with escape rhythm. Patient 5 received a pacemaker with no evidence of pacemaker failure. Patient 6 had no significant arrhythmia recorded during follow-up. No rhythm data were available surrounding the time of death for patients 4, 5, and 6.

Discussion

From a total of 28 deaths in patients with an ICM and history of syncope or presyncope, our analysis identified 6 (21.4%) cases of SCD. Three of these SCDs had documented arrhythmias at the time of death. However, 5 of these SCDs had significant arrhythmias detected on remote monitoring between 4 and 436 days prior to their deaths. Only in 1 case (patient 2), the arrhythmia has been reported in the study documentation, but the decision about pacemaker implantation was postponed because the patient reported no symptoms. In all other cases, the arrhythmias shown here were found during postmortem

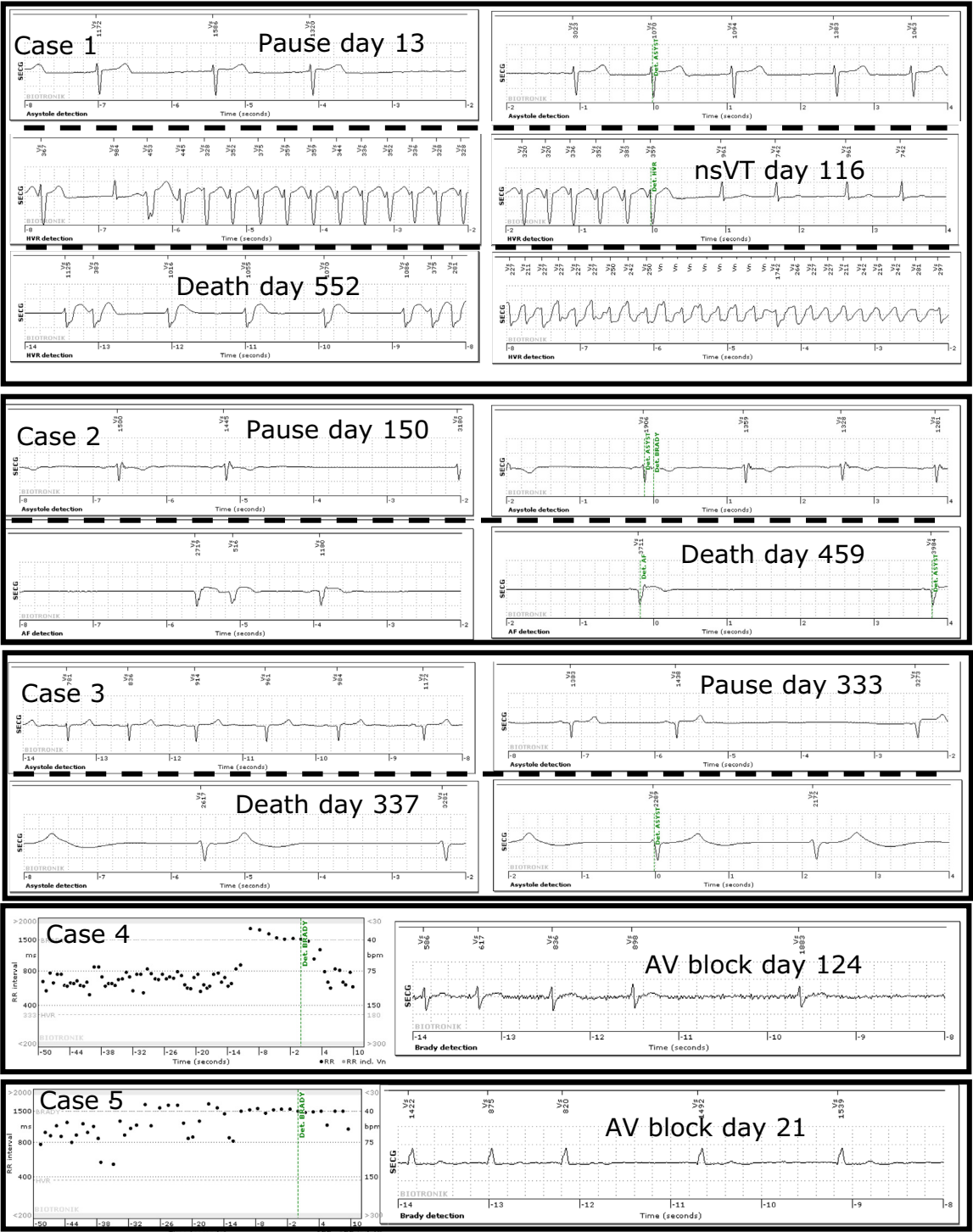


Figure 1 Electrocardiograms and cycle length plots of the episodes described in Table 1. For case 6, no electrocardiogram evidence was available. AV = atrioventricular; nsVT = nonsustained ventricular tachycardia.

screening of the remote monitoring transmissions but were not reported as adverse events. It must be assumed they were considered benign or asymptomatic, not qualifying for a reportable diagnosis, or may have been overlooked.

It is possible that some of these SCDs were preventable if the arrhythmias detected on remote monitoring were acted upon. The asymptomatic events did not have pauses longer than the guideline recommended 6-second cutoff, but it is notable that in some of these cases, the duration of AV block was in fact >6 seconds if escape rhythm was discounted from the computation. The 6 patients with SCD were between 78 and 90 years of age, while the mean age of the included study patients was only 65 years of age. Our analysis suggests that at least in elderly patients with a history of syncope, asymptomatic arrhythmic events are not always benign in nature, as others have previously reported 3- to 4-second asymptomatic advanced AV blocks prior to eventual SCD.⁶ Although our analysis is limited by the small number of deaths and the lack of detailed information about each death, it calls for further studies to delineate the burden of asymptomatic rhythm disturbances, especially in those who did not experience SCD, for a better understanding of their prognostic relevance in patients with a history of syncope or presyncope.

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Authorship: All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent: All patients provided informed consent.

Ethics Statement: This study has local ethics committee approval from all participating institutions. This study was conducted in accordance with the guidelines outlined in the Declaration of Helsinki.

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