Malfunction of an insertable cardiac monitor with a long-sensing vector attributed to a mechanical failure: A case report

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Introduction

Insertable cardiac monitors (ICMs) are widely used to elucidate unexplained syncope and cryptogenic strokes, and their efficacy has been demonstrated.[1,2] During the 2- to 4-year monitoring period, ICMs allow for follow-up through remote monitoring (RM) and early intervention when an event occurs. Although these are used for long monitoring durations, to the best of our knowledge, mechanical failures with these devices have not been previously published. We present the early detection of false-positive events immediately after a mechanical failure of the device 11 months postoperatively, in a case with an ICM for RM.

KEY TEACHING POINTS

- This is the first published report of a mechanical failure of an insertable cardiac monitor.
- Remote monitoring with insertable cardiac monitors is useful for the early detection of mechanical failures.
- The BIOMONITOR IIIm has many advantages owing to its long vector length, but its structural frailty should be considered.

Case report

The patient was a 96-year-old man with a history of an abdominal aortic aneurysm and hypertension. The patient was urgently brought to our medical facility owing to recurrent syncopal episodes. His activity of daily living was autonomous and his body mass index (BMI) was 23.2. His syncopal events mainly occurred during postprandial and orthostatic states. Therefore, neurally mediated syncope was speculated as the mechanism. However, his 12-lead electrocardiogram (ECG) showed sinus rhythm with first-degree atrioventricular block, complete right bundle branch block, and left axis deviation, which also meant left anterior fascicular block. No specific findings associated with syncope were detected by blood tests, computerized tomography, or head magnetic resonance imaging. Further, transthoracic echocardiography revealed a normal cardiac function and no severe valvular disease. No events were recorded that could have contributed to the syncope during the 24-hour Holter ECG recording. The patient expressed a desire for further investigation of the syncope and received an implantation of an ICM with a long-sensing vector (BIOMONITOR IIIm; BIOTRONIK, Berlin, Germany) at our facility.

The implantation site was marked using fluoroscopic guidance and the procedure was performed conventionally under local anesthesia. An ICM was inserted at an angle of 20 degrees to the vertebral body. The R-wave amplitude at the time of the implantation was 0.27 mV, which was adequate to visualize and discriminate the P waves and R waves (Figure 1A). The detection settings were as follows: for atrial fibrillation, low; high ventricular rate, 375 ms; bradycardia, 1714 ms; sudden rate drop, 50%; and asystole, 3 seconds. After consent for the RM was obtained, the RM was initiated 2 weeks after the ICM implantation. Thereafter, bradycardia events due to nocturnal sinus bradycardia, atrial fibrillation events due to scattered ventricular premature contractions, and T-wave oversensing were documented, but no events associated with syncope were observed.

Eleven months postoperatively, an asystole event was noted on the RM. The waveform was flat with some baseline fluctuations and high-amplitude wave noise (Figure 1B). Immediately after receiving the RM alert, we confirmed by phone that he was alive, with no symptoms. Subsequently, more than several hundred asystole events were recorded per day. During a face-to-face ICM interrogation, no waveforms were sensed at all, and mechanical contact with the

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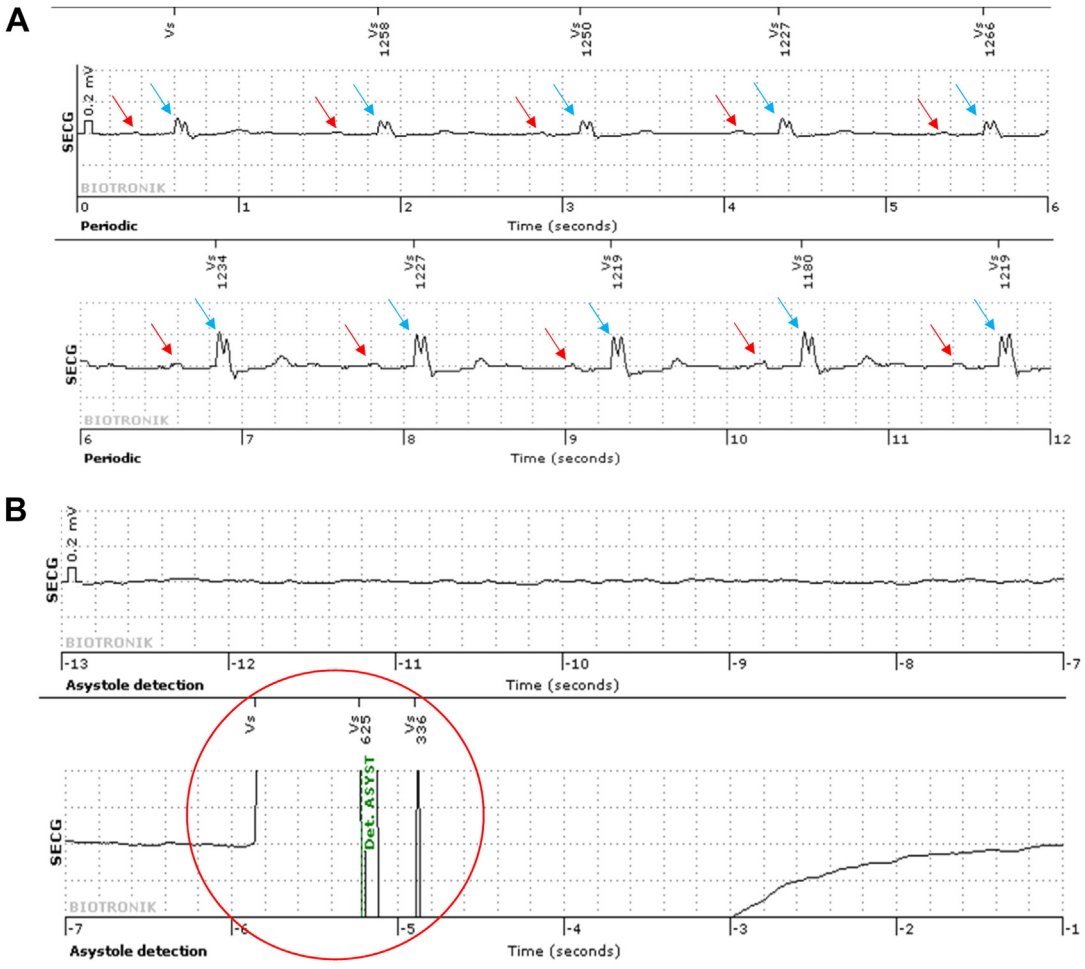

Figure 1 **A:** Subcutaneous electrocardiogram waveform immediately after the insertable cardiac monitor (ICM) implantation. Even though the QRS waveform (*blue arrows*) exhibited low and fluctuating wave amplitude values, the P wave (*red arrows*) and QRS wave were still discernible. **B:** ICM waveforms during an asystole event 11 months after the implantation. Baseline agitation is seen, but there is no QRS waveform, and a large amount of noise with high-amplitude waves is observed (*red circle*). SECG = subcutaneous electrocardiogram; Vs = ventricular sensing.

ICM implantation site reproducibly demonstrated noise on the subcutaneous ECG. Furthermore, the location of the failure could not be ascertained through a chest radiograph examination (Figure 2A). The ICM was extracted because it could not fulfill its intended purpose. Upon visual inspection of the removed ICM, air bubbles were observed in the proximal portion of the antenna's electrodes (Figure 2B). Under fluoroscopy, when tension was applied in the longitudinal direction, it was observed that the junction between the distal end of the conductor and the feedthrough in the antenna section had been severed (Figure 3A and 3B). Additionally, when the antenna section was manually bent, the conductor located at the junction with the feedthrough appeared to be severed (Figure 3A and 3C). No complications attributable to the ICM failure were observed.

Discussion

The efficacy of ICMs for determining the cause of unexplained syncope has already been reported.[3] Among the patients with a history of syncope, arrhythmias have been documented in 42% of them, 85% of which were bradycardia.[4] It has also been reported that most first syncope recurrences occur more than 30 days after the implantation of an ICM and that long-term monitoring is necessary to obtain those diagnoses.[5]

On the contrary, ICMs have a limited storage capacity and old data may be overwritten, which will result in the loss of important incidences. By initiating RM, that limitation could be overcome as episodes are transmitted automatically. It also would facilitate an early diagnosis.[6] In this case, the RM was installed and contributed to the confirmation of the failure of the ICM. RM with ICMs may be useful for not only the early diagnosis of arrhythmic events but also the early detection of mechanical defects detected as false-positive events. Patients who receive ICM implantations generally experience more false-positive alerts than other implantable cardiac devices. With concern for the analysis of ICMs using RM, it has been reported that all false asystole events are derived from R-wave undersensing, and no

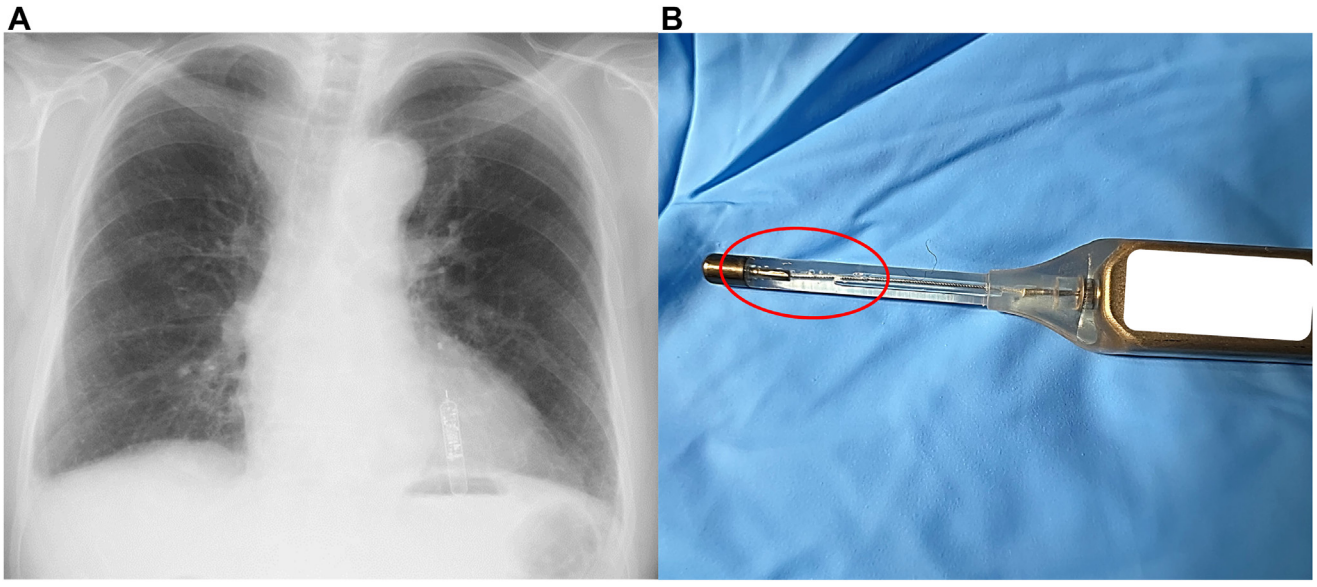

Figure 2 **A:** A chest radiograph in the anterior-posterior projection prior to the insertable cardiac monitor (ICM) extraction. No findings of a fractured ICM were observed. **B:** The BIOMONITOR IIIm (BIOTRONIK, Berlin, Germany) after removal. A bubble-like substance is seen in the silicon structure around the distal electrode (*red circle*).

false-positive events have been attributed to mechanical failure.[7]

To the best of our knowledge, this is the first published report of the mechanical failure of an ICM. However, the mechanism of the BIOMONITOR IIIm's failure could not be entirely elucidated. We did not carefully search for any abnormal visual defects of the ICM before the insertion. Therefore, we could not exclude the possibility that the ICM had a weak structure derived from any slight damage during the manufacturing process, even if its components did not appear to have been disconnected. Further, there were no problems with the implantation technique and no strong forces were applied during the insertion. Actually, the subcutaneous ECG monitoring had worked well for 11

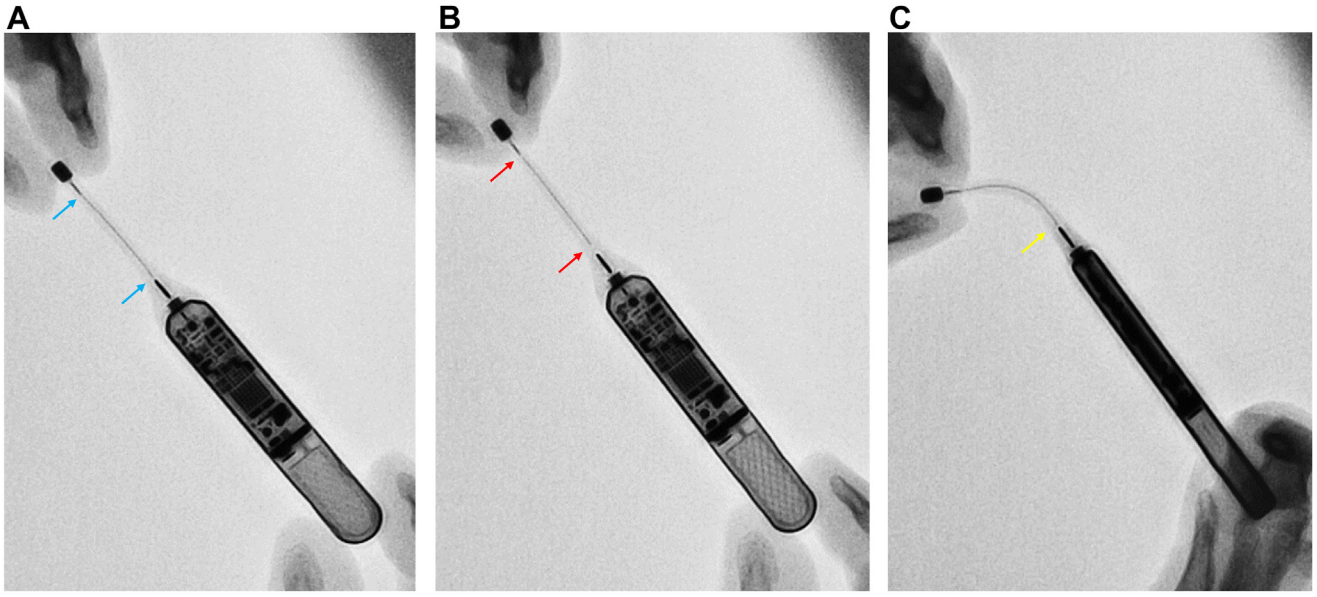

Figure 3 Fluoroscopic image of the BIOMONITOR IIIm (BIOTRONIK, Berlin, Germany) after extraction. **A:** When no tension is applied to the body, the disconnection site is difficult to see (*blue arrows*). **B:** When tension is applied in the longitudinal direction to the insertable cardiac monitor, the disconnection site appears in the conductor covered by the silicon structure (*red arrows*). **C:** When the antenna portion is manually curved, it is also found that the conductor is disconnected (*yellow arrow*).

months without any problems, which suggested that procedure-associated damage was unlikely.

Between the time of the insertion of the ICM and the failure, the patient had experienced neither any traumatic events nor any strong mechanical stress at the implantation site. Although the patient did not have a habit of getting exercise, there could have been an accumulation of daily stress on the ICM. When a longitudinal and bending tension was applied to the ICM after the removal, the silicon component elongated but the internal conductors became disconnected. Hence, it was inferred that the flexibility of the silicon structure would have been somewhat protective against external forces, but not enough to protect the internal components against repetitive mechanical stresses in some directions. Furthermore, in individuals with a slender physique, a small amount of subcutaneous tissue would not adequately buffer between the BIOMONITOR IIIm and repetitive stresses generated by the ribs, edge of the sternum, or external forces. This factor could potentially have contributed to the mechanical failure in this patient with a relatively low BMI. Therefore, we also speculated that patients with a low BMI might have a higher risk of mechanical failures of ICMs with a long-sensing vector in comparison to patients with a high BMI. Nevertheless, as a matter of fact, ICM fractures should be rare within their relatively shorter lifespan than other therapeutic cardiovascular implantable electronic devices.

Studies comparing the P- and R-wave amplitudes with the Reveal LINQ (Medtronic Ltd, Minneapolis, MN) and BIOMONITOR III have shown that the BIOMONITOR III with longer vector lengths has both higher amplitudes and better P-wave visibility.[8] With wide-spaced electrodes, the BIOMONITOR III has also been reported to function in patients with various body shapes, demonstrating acceptable R-wave amplitudes.[9,10] Although these features are helpful in clinical practice, the structural frailty of the BIOMONITOR III should be considered, since it might result in unexpected short-term monitoring periods.

Conclusion

An ICM mechanical failure should be considered when a false-positive event is detected. RM for ICMs would be helpful for the early detection of this incidence.

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