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Importance of Raw-Data Analysis When Determining the Cause of Pause Alerts Transmitted by an Implantable Loop Recorder Remote Monitoring Devices

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ABSTRACT

Introduction: Use of implantable loop recorder (ILR) for the diagnosis and documentation of cardiac arrhythmia has gained popularity during the last decade. Most ILRs are accompanied by remote monitoring (RM) devices, which allow automated daily interrogations of the ILR. These transmit arrhythmic or pause alerts to the treating clinic, enabling timely medical attention and treatment. Although ILR RM transmissions have been shown to have significant false positive alerts, a true positive alert suggesting a wrong arrhythmia diagnosis has not been shown to date.

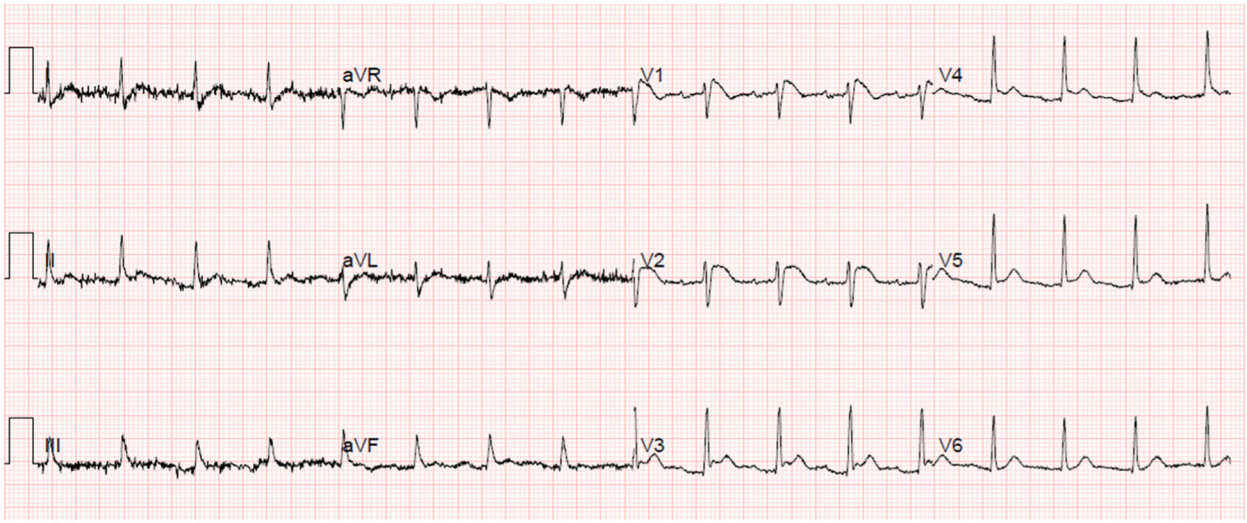
Methods and Results: We revised all ILR pause transmissions arriving to our hospital device clinic during 2024, looking for pause alerts which were initially misdiagnosed. We report a case series of patients in whom a RM pause alert has been transmitted with a suspected apparent diagnosis of sinus arrest. However, when interrogating the ILR in clinic, these episodes were diagnosed as high-degree atrioventricular block (AVB) pauses, for which an urgent permanent pacemaker (PPM) might be indicated. Review of these cases revealed that in contrast with the automated RM PDF alerts, in which the figure resolution cannot be changed (and thus small P waves may be unnoticed), the raw-data episode recording on the RM web page enables one to increase the image resolution to clearly discern initially unnoticed non-conducted P waves.

Conclusion: ILR RM pause alerts should always be reviewed via the raw-data RM web page or alternatively via ILR device interrogations, to achieve a sufficiently high-resolution image to assure these pauses are not due to AVB.

1 | Introduction

During the last decade, there has been an enormous growth of implantable loop recorder (ILR) use for long-term monitoring of patients to detect cardiac arrhythmias. This relates to patients with unexplained syncope, those with palpitations which are difficult to document, as well as for atrial fibrillation (AF) surveillance in patients post-AF ablation and post-cryptogenic stroke [1–5]. Most ILR devices are paired with a remote monitoring (RM) device consisting of a dedicated cell phone or application on the patients' own cell phone, and other home monitoring equipment. These can automatically connect with the ILR and transmit various arrhythmic findings to the responsible clinician. The development of RM for cardiac implantable electronic devices (CIEDs), including permanent pacemakers (PPM), defibrillators, and ILRs, enables timely detection of various arrhythmias and device malfunctions [1–3]. Although all CIED RM devices are associated with a significant percentage of false positive (FP) alerts, ILRs have been shown to transmit disproportionally high FP alert quantities in comparison with all other CIEDs [1, 3, 4]. This is attributed at least in part to their subcutaneous nature, which makes them prone to erroneous activations due to poor signal amplitude and somatic artifacts. In addition, their unique patient-activated alerts often

A



B

ID#	Assessment	Type	Date	Detected hh:mm	Duration hh:mm:ss	Max V. Rate	Median V. Rate	Episode Details
23		Pause	28-May-2024	02:54	00:00:04		45 bpm	ECG

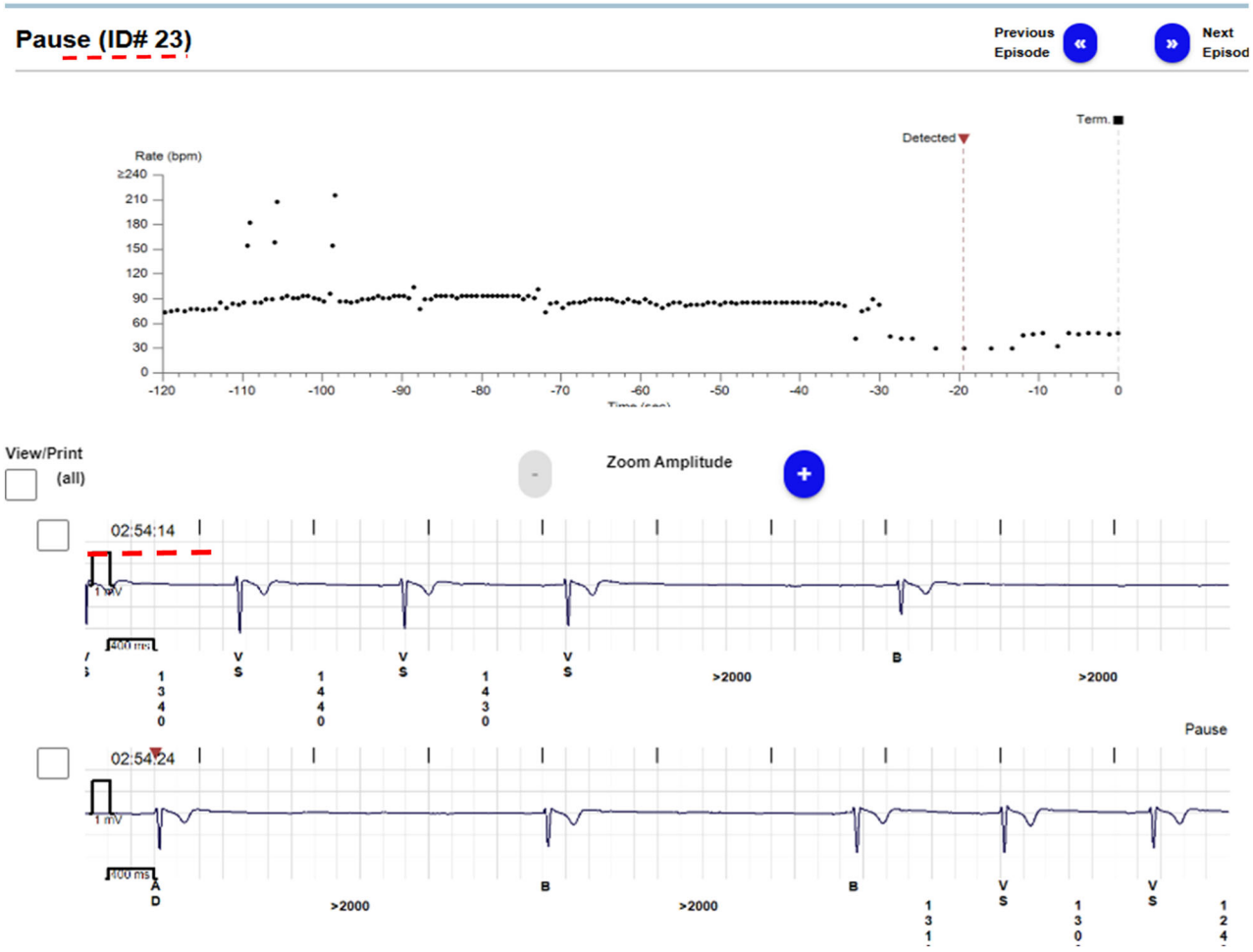


FIGURE 1 | Suspected sinus pause diagnosed as high degree AVB. A 74 y/o patient (case #1) with palpitations and Brugada pattern ECG (A) was implanted with an ILR. An ILR remote monitoring (RM) PDF alert with the interval plot of apparent sinus bradyarrhythmia (B). ILR device interrogation of the episode reveals it to represent an AVB episode, seen by sequential non-conducted P waves (marked by black arrows) (C). Magnification of the RM PDF alert (shown in 1B) still suggests sinus arrest (D). Review of the episode raw data on the RM episode web page identifies the pause as high-degree AVB, with sequential non-conducted P waves (black arrows) (E).

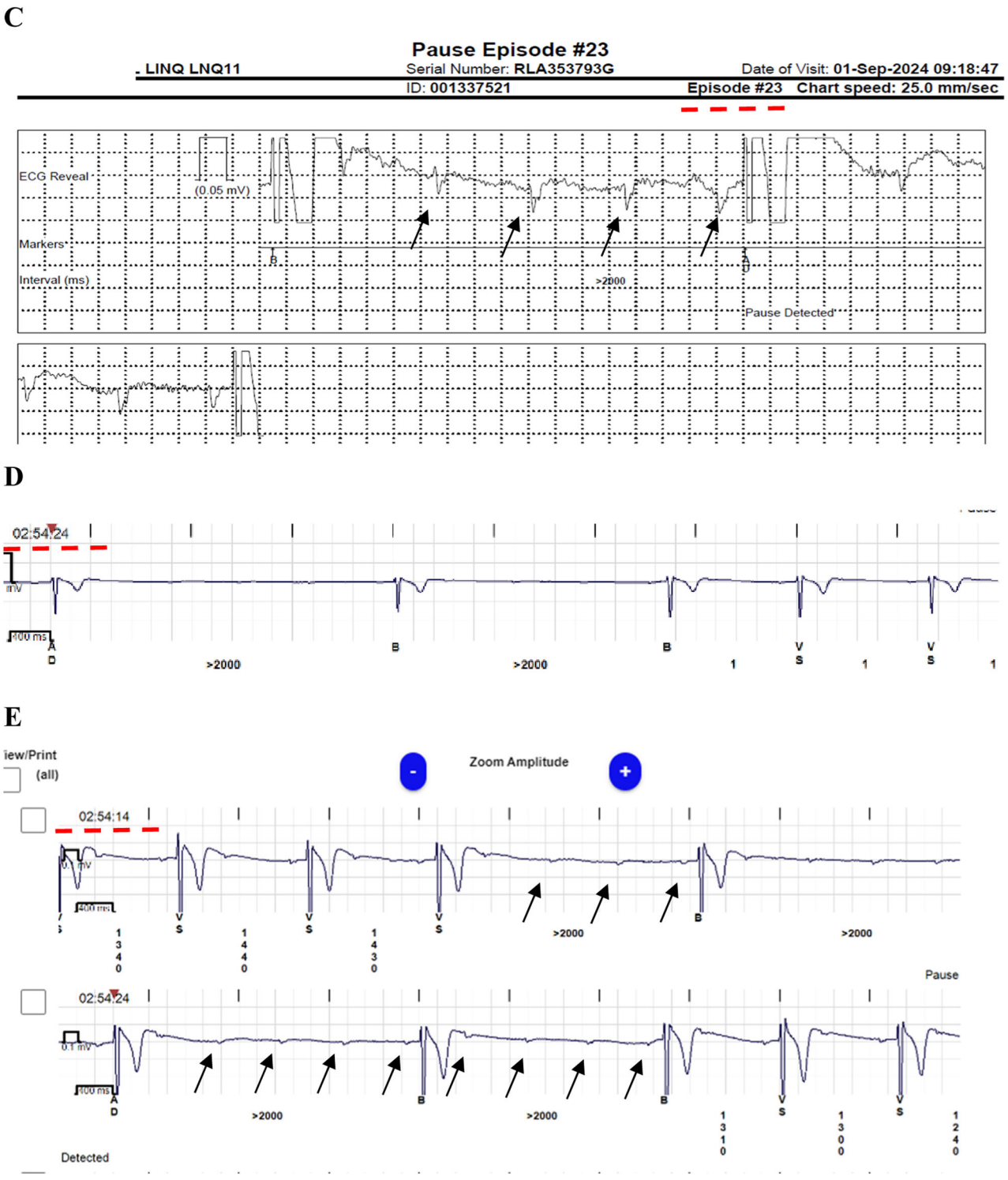


FIGURE 1 | (Continued)

do not correspond with true arrhythmias [1, 3]. As of today, multiple prior studies have shown a high percentage of FP ILR alerts [3–5], but none has shown a true positive alert with an apparently wrong diagnosis. In our study, we describe a case series of ILR RM alerts of apparently sinus pauses, which were eventually found to be transient AVB pauses.

The manuscript was approved by the Shaare Zedek Medical Center Ethics Committee.

1.1 | Case #1

A 74 y/o man with an incidental finding of a type 1 Brugada pattern on a routine electrocardiogram (ECG) (Figure 1A). The patient reported prior palpitations but denied prior syncope episodes, and there was no family history of sudden cardiac death (SCD). Continuous ECG telemetry did not reveal any arrhythmia, and thus, an ILR was implanted (Reveal Linq RLA 353793 G, Medtronic). Two years later, several episodes of

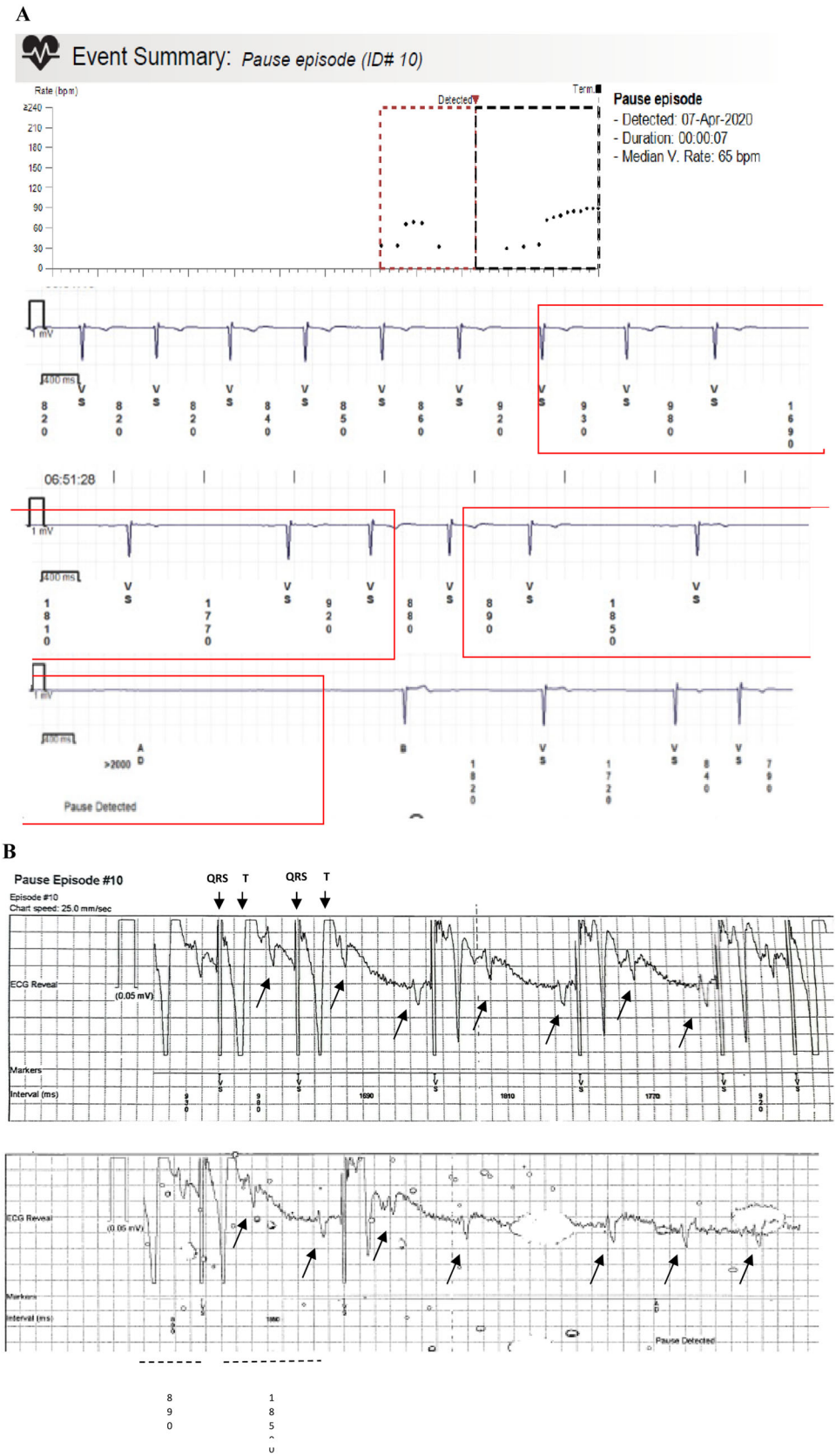


FIGURE 2 | Importance of reviewing ILR pause alerts via ILR device interrogation. A 75 y/o man implanted an ILR due to an unexplained syncope episode (case #2). An ILR RM transmits a pause alert, suggesting a 7-s sinus arrest preceded by sinus bradycardia (A). ILR device interrogation, enabling episode image enlargement with increased resolution, diagnoses the episode as a 7-s high-degree AVB pause preceded by few 2:1 AVB pauses, as seen by the non-conducted P waves (black arrows) (B). The magnified images of ILR interrogation shown in B correspond to the red boxes of the original PDF alert in A. Note the 890 ms and 1850 ms pauses preceding the 7-s pause and the giant-appearing T waves following QRS (short arrows), resulting from image magnification.

apparent sinus arrest of 3–5 s PDF alerts were transmitted by his home RM device (Figure 1B). On interrogation of the ILR device, these were found to be high-degree AVB episodes (Figure 1C). Notably, when retrospectively reviewing the case, we noticed that the magnification of the original RM PDF report could not increase its resolution and did not show AVB (Figure 1D). However, when reviewing the raw-data episode recording on the RM web page, one could increase the image resolution and clearly diagnose AVB (Figure 1E). As the patient was asymptomatic and all episodes occurred at nighttime, an EPS was performed, revealing normal infra-nodal conduction, and thus, no PPM was implanted.

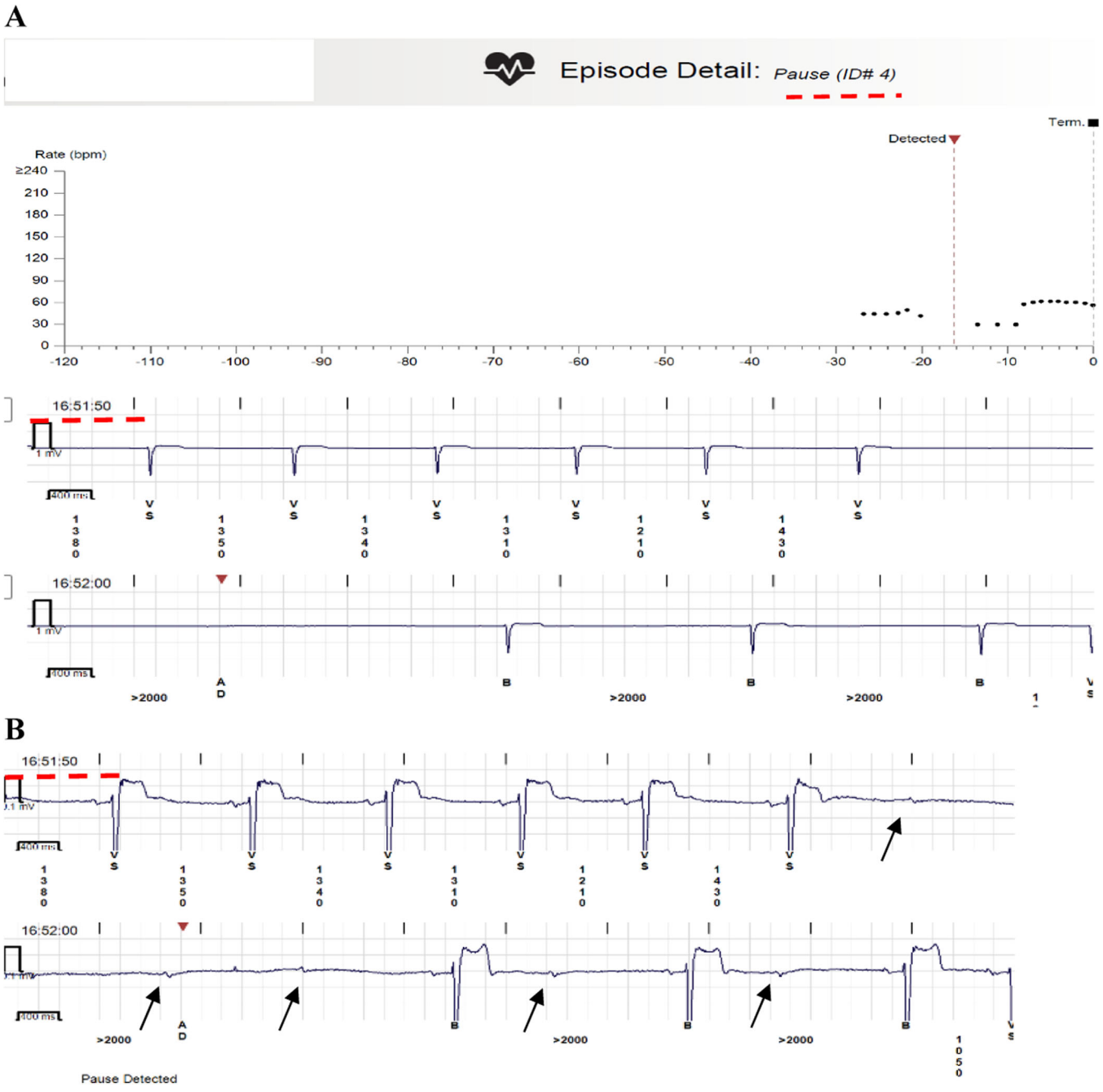


FIGURE 3 | Importance of ILR remote monitoring raw-data review of pause alerts. A 56 y/o man with unexplained syncope during exercise implanted with an ILR (case #3). ILR RM transmits a pause alert suspected as a sinus pause (A). Review of the raw-data episode in the RM web page reveals it to represent a high-degree AVB episode, with sequential blocked P waves (black arrows) (B). Another bradyarrhythmia RM alert is suspected as sinus bradyarrhythmia (C). Notably, although small sinus P waves are seen before each QRS on the RM PDF alert, there are no discernible P waves during the pause itself (C), resulting in an initial misdiagnosis of a sinus pause episode. Review of the episode raw data on the RM web page eventually diagnosed it as a 2:1 AVB episode (D).

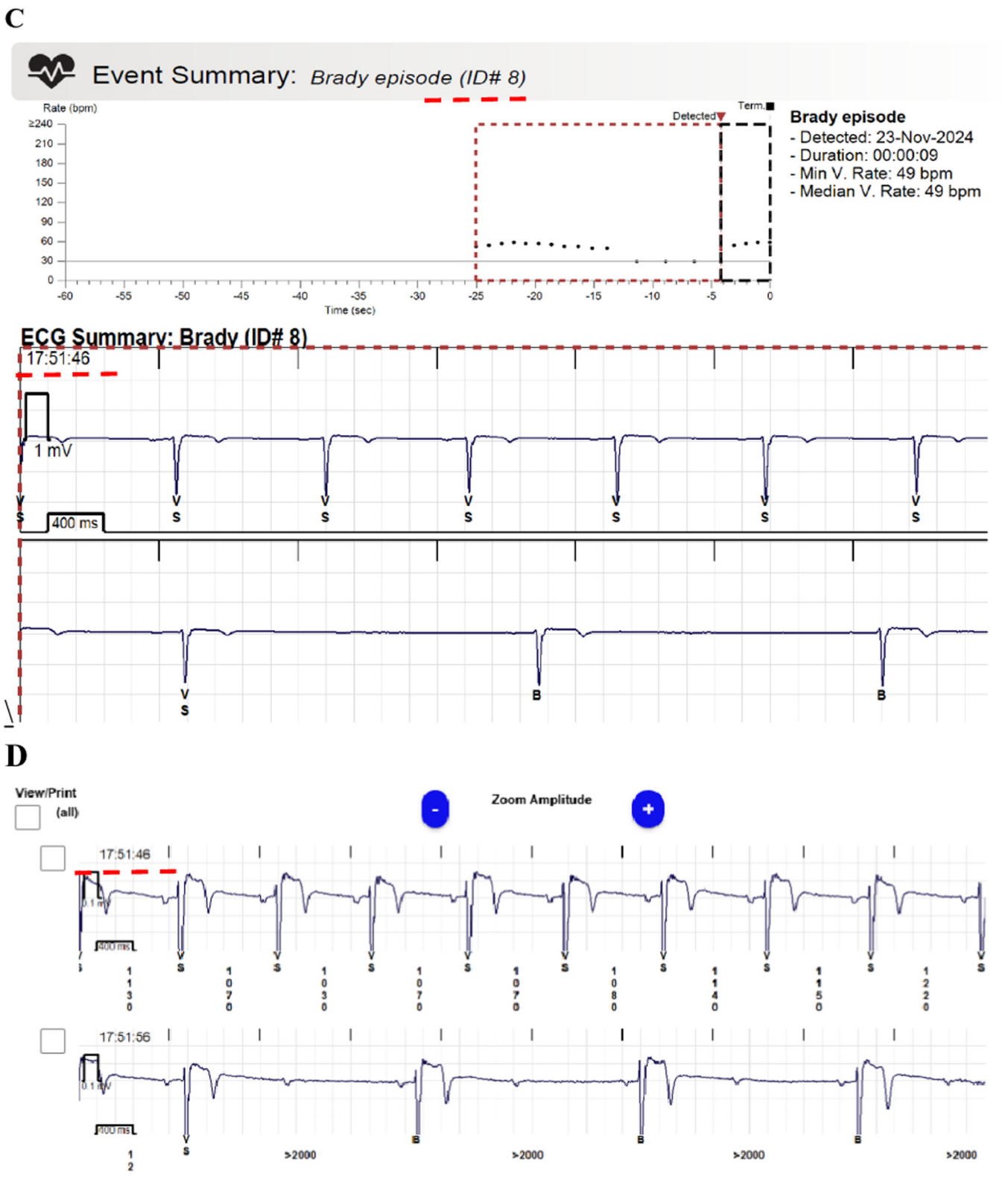


FIGURE 3 | (Continued)

1.2 | Case #2

A 75 y/o man with no cardiac background was admitted after a syncope episode while driving a car, resulting in a car accident. The patient was advised not to drive until a final diagnosis was made and treatment delivered. Cardiac evaluation including repeat ECGs, 24 h ECG Holter, trans-thoracic echocardiogram (TTE), and Treadmill test were noncontributory. Given his unexplained syncope, an ILR was implanted (Reveal Linq RLA 154733 G, Medtronic). Two months later, a RM red alert of 7 s sinus pause was transmitted (Figure 2A). The patient was called and found to be asymptomatic and thus was scheduled for clinic

interrogation a day later. ILR interrogation using an enlarged image with an increased resolution of the same episode revealed a transient high-degree AVB episode (Figure 2B), and the patient was subsequently implanted with a DDD PPM. During a 2-year follow-up, no further syncope episodes had occurred.

1.3 | Case #3

A 56 y/o man was admitted for syncope while running, resulting in a head injury. The patient had no prodrome, no prior syncope episodes or arrhythmic symptoms, and no family history of SCD. Given the exercise-related syncope, a thorough evaluation, including repeat ECGs, continuous ECG monitoring, treadmill test, TTE, and cardiac MRI, were performed and were all normal. An ILR was implanted (Reveal Linq RLA 472440 G, Medtronic). Four months later, a RM red alert due to a 7 s pause, suggestive of sinus arrest, was transmitted (Figure 3A). Using the HTML data on the RM raw-episodes web page, an enlarged and higher-resolution image of the episode showed high-degree AVB (3B). Another alert episode was reported a day later, suggesting sinus bradycardia with sinus pause, given the small but discernible P waves seen before but not during the pause itself (Figure 3C). Nevertheless, RM raw data review clearly showed a 2:1 AVB episode (Figure 3D). The patient was called and described pre-syncope episode during the same time as the alert episode without an apparent vagal trigger, and thus, a PPM was implanted.

2 | Discussion

Our study presents a case series of ILR pause alerts, which were eventually diagnosed as high-degree AVB episodes but could have been easily misdiagnosed as sinus pauses on the transmitted RM PDF alerts due to low amplitude and thus unnoticed P waves. This is in line with prior studies suggesting that ILRs have a significantly high percent of FP notifications, dominated by FP pause alerts, which are mostly due to R wave undersensing [3–5]. However, in contrast with prior studies, we show examples of true positive ILR pause alerts, as a result of transient high-degree AVB episodes, which were initially misdiagnosed as sinus pauses on the ILR RM PDF alerts. Our study emphasizes the importance of reviewing ILR pause alerts via raw-data HTML images on the RM episode web page or alternatively via ILR device interrogation, where high-resolution images can disclose possible small, non-conducted P waves. Needless to say, mistakenly diagnosed sinus arrest episodes may have led to incorrect treatment, resulting in repeat syncope episodes or even death in case of repeat AVB with a long-duration pause.

The ILRs in this case series were all Reveal Linq ones. Notably, these are the dominant ILRs used in our hospital, and we do not have significant experience with other manufacturers. However, we assume there might be similar issues with other ILR manufacturers as well, emphasizing the importance of reviewing the raw data of all ILR alerts. By no means do we infer a particular issue with this specific manufacturer.

3 | Conclusions

ILR RM devices are known to transmit a significant percent of false positive alerts. In our study we show also true positive pause alerts, due to high degree AVB, which could be easily mistaken for sinus pause alerts if one does not revise the high-resolution raw-data images. Accordingly, raw-data episode revision or ILR device interrogation is mandatory for a correct diagnosis of ILR RM pause alerts.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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