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Assessing the safety of interrogating cardiac-implantable electronic devices with brand-mismatched remote interrogators: a pilot study

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Objective Remote cardiac implantable electronic device (CIED) interrogators, originally developed for home use, have been proven to be efficacious in clinical settings, especially emergency departments. Concern exists that attempting to interrogate a CIED with the remote interrogator of a different brand, i.e., a brand-mismatched interrogator, may cause device malfunction. The aim of this study was to determine if intentionally attempting to interrogate a CIED with a brand-mismatched remote interrogator resulted in device malfunction.

Methods A total of 75 *ex vivo* CIEDs manufactured by various companies underwent attempted interrogation by a brand-mismatched remote interrogator. CIED settings were compared before and after attempted mismatch interrogation. A total of 30 *in vivo* CIEDs were then randomized for an attempted 2-minute mismatched remote interrogation by one of the two possible mismatched remote interrogators. CIED settings were compared before and after attempted mismatch interrogation.

Results Of 150 *ex vivo* brand-mismatched interrogations, no device setting changes or malfunctions occurred; no remote interrogators connected to a mismatched CIED, and no devices were turned off. In the 30 patients undergoing brand-mismatched interrogations, the mean (standard deviation) age was 71.6 (±14.7) years, 16 (53%) were male, with 24 pacemakers (80%), four pacemaker/implantable cardioverter defibrillators (13%), and two implantable cardioverter defibrillators (7%). Of the 30 mismatched interrogations performed, no device setting changes or malfunctions occurred; no remote interrogators connected to a mismatched CIED, and no devices turned off.

Conclusion In a total 180 attempted brand-mismatched CIED interrogations, no CIED malfunctions occurred. This suggests that the use of remote CIED interrogators when device manufacturer is unknown is unlikely to result in adverse CIED-related events.

Keywords Electrophysiology; Defibrillator; Cardiac resynchronization therapy devices; Artificial pacemaker; Emergency treatment

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Capsule Summary

What is already known

When patients with cardiac implantable electronic devices (CIEDs) present to the emergency department, it is crucial to determine if their CIED is malfunctioning. CIED interrogation often requires a trained professional, usually company representatives who have to travel from the nearest major city. This results in potential delays in care. Recently, remote interrogators have provided a solution to this issue. However, concern still exists regarding their safety and efficacy. Remote interrogators are brand-specific. In the event of a patient being unaware of their device manufacturer, some providers feel comfortable simply attempting to interrogate that patient's CIED with each possible remote interrogator until one device connects. However, there is concern that this strategy may cause CIED malfunction.

What is new in the current study

In our study, we test this methodology with both in vivo *and* ex vivo *devices to validate the safety of utilizing brand-mismatched remote interrogators on CIEDs.*

INTRODUCTION

The term cardiac implantable electronic device (CIED) encompasses pacemakers, implanted cardioverter-defibrillators, and combination devices. CIEDs are potentially lifesaving devices that decrease morbidity and mortality.[1,2] Roughly 200,000 pacemakers are implanted in bradycardic patients alone in the US each year,[3] and recent studies show CIED implantation rates continuing to increase worldwide.[4] Given their widespread use, it is critical for physicians in the emergency department (ED), perioperative units, and other clinical settings to be able to quickly interrogate the CIEDs of patients with complaints such as palpitations, syncope or dyspnea, or who report being shocked. However, it can be difficult for physicians in rural hospitals to access the services of an International Board of Heart Rhythm Examiners-certified professional on weekends and holidays, often a company representative based some distance away.

This problem can be addressed by remote CIED interrogators. Unlike the devices utilized by company representatives, remote CIED interrogators are "diagnosis-only" devices capable only of interrogating CIEDs, not altering their settings.[5] Hence, they can be safely used by any healthcare provider after minimal training. Each of the three major US CIED manufacturers (Abbott Laboratories, Chicago, IL, USA; Boston Scientific Corporation, Marlborough, MA, USA; Medtronic plc, Minneapolis, MN, USA) produces a brand-specific remote device capable of interrogating their CIEDs (the Merlin On-Demand, the Latitude Consult, and the Carelink Express, respectively). Each device consists of a "wand" paired to a console or tablet, which is placed in close proximity to the CIED of interest in order to perform interrogation. Remote interrogators were initially developed for home use by patients, allowing for electrophysiology clinics to monitor CIED function without the need for an in-person visit. Studies have found that remote interrogators decreased costs and saved time when used in such a manner, and a 2015 Heart Rhythm Society consensus statement described them as standard of care.[6-8] However, subsequent research has shown that remote interrogators possess utility in a variety of clinical settings as well.

Implementation of remote interrogators has been studied in a variety of clinical settings, and has been shown to be safe, efficient, and potentially time-saving compared to traditional interrogation in certain scenarios.[9,10] One facet of remote interrogator usage that has not been studied is the result of mismatch interrogation—that is, attempting to interrogate the CIED of a given manufacturer with the remote interrogation system produced by another. Anecdotally, doing so results in the remote system simply being unable to recognize, connect to, or interrogate the mismatched CIED. However, concern exists among physicians that attempting mismatched remote interrogation could cause CIED malfunction. While quite specific, these concerns are not irrelevant. Firstly, it is possible, especially in the ED, that a patient might misremember their CIED's manufacturer, resulting in an attempted remote interrogation with a mismatched system. Another scenario in which mismatched remote interrogation becomes relevant is one in which an ED patient requiring CIED interrogation is either unresponsive, or unaware of his or her CIED manufacturer, and the information cannot be found in the Electronic Medical Record. Anecdotally, some emergency physicians who are comfortable with remote interrogators simply attempt to interrogate the device with each possible remote interrogator until one connects, circumventing the time-consuming process of identifying an unknown CIED. Many physicians are leery of utilizing this

technique, worried that mismatched remote interrogation could cause CIED malfunction.

Since the safety of mismatched remote interrogation is relevant, potentially-useful, and has not been examined, we investigated whether attempting to interrogate CIEDs with brand-mismatched remote interrogators resulted in device malfunction.

METHODS

We conducted a two-phase study, evaluating brand-mismatched CIED interrogation first in nonimplanted devices (*ex vivo*), and then in patients with implanted devices (*in vivo*). This unfunded study took place in a rural community hospital in Ohio, was approved by an institutional review board, and was performed in cooperation with device manufacturers.

Ex vivo phase

In the first phase of the study, each of the three CIED major manufacturers provided a sample of 25 older and newer pacemakers, implantable cardioverter defibrillators, and combo devices. Company representatives interrogated each of their 25 *ex vivo* devices using their brand-matched programmer, recording their settings. This initial interrogation served as a baseline, and was followed by an attempted 2-minute interrogation with a brand-mismatched remote interrogator. After the first brand-mismatched interrogation, the company representative again interrogated the device and recorded its settings. This protocol was then repeated using the other possible brand-mismatched interrogator (Fig. 1). Results from before and after the 150 brand-mismatch interrogations were compared to identify any programming changes that might have occurred.

In vivo phase

The second, *in vivo* phase of the study assessed the effects of attempted brand-mismatched interrogation in patients with implanted CIEDs. Inclusion criteria were: subjects of at least 18 years of age with a CIED who were not pregnant and presented to the electrophysiology clinic for a routine visit. Patients were excluded if they had known malfunctioning devices, declined to participate, or were prisoners. After informed consent was obtained, ten patients with devices produced by each major CIED manufacturer underwent interrogation with the appropriate brand-matched programmer by a clinic technician. They were then randomized to undergo attempted mismatched remote interrogation for 2 minutes (using one of the two possible mismatched brands) by study staff. After attempted mismatch interrogation, the patient's CIED was interrogated a second time by the clinic technician. CIED settings before and after the brand-mismatched interrogation were compared (Fig. 2).

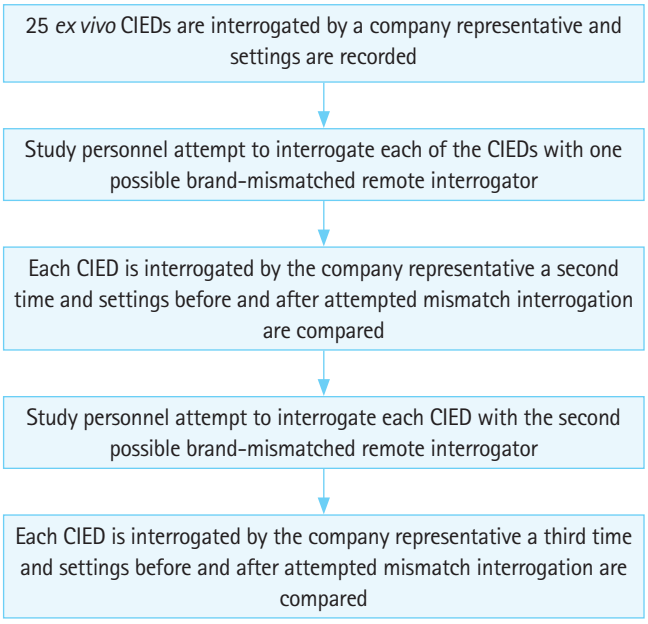

Fig. 1. Flow diagram describing the *ex vivo* phase of the study. CIED, cardiac implantable electronic device.

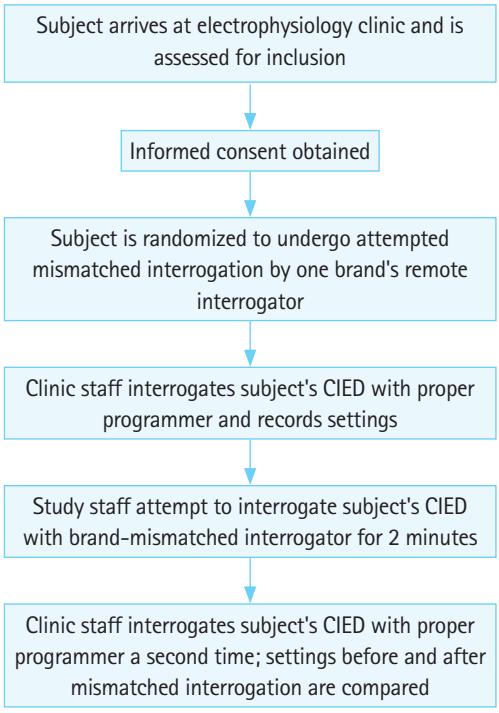

Fig. 2. Flow diagram describing the *in vivo* phase of the study. CIED, cardiac implantable electronic device.

RESULTS

Ex vivo results

Overall, in 150 *ex vivo* attempted brand-mismatched interrogations, no devices were turned off, no device settings were changed, no malfunctions occurred, and no remote interrogator was able to connect to (or extract data from) a mismatched CIED.

In vivo results

Thirty patients underwent attempted mismatched interrogation in the *in vivo* phase of the study. The mean (standard deviation) patient age was 71.6 (±14.7) years and 16 (53%) were male. CIEDs studied included 24 pacemakers (80%), four pacemaker/implantable cardioverter defibrillators (13%), and two implantable cardioverter defibrillators (7%). As a result of attempted brand-mismatched remote interrogation: no settings were changed; no devices were turned off; no malfunctions occurred; and no remote interrogator was able to connect to (or extract data from) a mismatched CIED.

DISCUSSION

The primary finding of our study is that, in a total of 180 brand-mismatched, remote CIED interrogations performed on a mix of *ex vivo* and *in vivo* devices, there were no instances of a mismatched interrogator connecting to a CIED, no instances of CIED settings being altered, and no instances of a CIED turning off. These findings support the safety and utility of remote CIED interrogators, especially in the ED setting. Specifically, our findings suggest that, if an emergency provider unintentionally attempts to interrogate a patient's CIED with a brand-mismatched remote interrogator, it is unlikely that any CIED-related adverse events will occur as a result. These findings further add to the literature surrounding remote interrogator use in clinical settings.

Remote interrogator usage has been found to be useful in a variety of clinical settings, including identifying CIED malfunction after radiotherapy, decreasing response times in perioperative areas, and reducing costs when utilized in outpatient clinics.[9-11] Perhaps the most such research has been performed in the ED, where it is crucial for emergency physicians to be able to interrogate potentially-malfunctioning CIEDs in a timely, efficient manner. This is rarely an issue in urban, academic centers, which often have electrophysiology staff available or device company representatives based nearby. However, rural EDs sometimes have to wait hours for CIEDs to be interrogated, often on weekends and holidays. Remote CIED interrogators allow rural emergency physicians to quickly interrogate CIEDs and receive an interpretation from the device company. Remote interrogators have been shown to be safe, efficient, and capable of potentially improving patient experience in the ED setting.[12-14] The increased speed inherent in remote interrogation compared to traditional interrogation is especially well-suited to the ED, as its use often allows emergency physicians to rule out device malfunction as a potential driver of symptoms. Multiple studies have shown that the vast majority of remote interrogations performed in the ED either return normal findings or findings not requiring immediate action, emphasizing their utility as a triage tool.[11,15] Because of this, remote interrogators in the ED often serve to rule out device dysfunction, decreasing clinical decision-making time and patient length of stay.

Another scenario in which remote interrogators could be of use in the ED is in identifying an unknown CIED. A previous survey of CIED patients presenting to the ED found that only 55% carried their manufacturer-issued device identification card.[16] Although not common, it is feasible that a patient could present to the ED either incapacitated or unaware of their CIED manufacturer. If the information is not available in the electronic medical record, attempting to identify the manufacturer of an unknown CIED is a lengthy, sometimes futile process often involving multiple calls to device company registries. These delays could be bypassed using a simple protocol in which ED staff attempt to interrogate an unknown CIED using each of the three possible remote interrogators until one connects, since there is no evidence of a remote interrogator being able to connect to a brand-mismatched CIED. This very strategy has proven anecdotally effective for the authors, but some emergency physicians are hesitant to utilize it, worried that mismatched remote interrogation could cause CIED malfunction. Our findings support the potential utility of this protocol.

This study has several limitations, including the fact that it was a single-center study. Furthermore, we only interrogated devices that were functional. Lastly, we did not attempt to perform mismatched interrogation malfunctioning CIEDs, due to the logistics and difficulties involved.

We found no evidence of CIED malfunction after attempted interrogation with brand-mismatched remote interrogators. These findings continue to expand the extant research related to the safety of remote CIED interrogator usage in the clinical setting, and furthermore suggest increased utility in the ED.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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