Comparing sensitivity and specificity of pacemaker ID application and cardiac rhythm management device-finder application in identifying cardiac implantable electronic device manufacturer using chest radiograph - An observational study

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Cross-sectional Study

Comparing sensitivity and specificity of pacemaker ID application and cardiac rhythm management device-finder application in identifying cardiac implantable electronic device manufacturer using chest radiograph – An observational study

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ABSTRACT

Background: Smartphone-based applications to identify cardiac implantable electronic devices (CIED) are extremely useful in circumstances, where urgent device interrogation is needed, and a device identification card is not available. Few studies have provided insights regarding the utility of these applications. We have studied two widely available applications i.e., Pacemaker ID app (PMIDa) or Cardiac Rhythm Management Device-Finder (CRMD-f) to identify device manufacturers in CIEDs.

Methods: 547 patients who underwent CIED implantation from the year 2016–2020 in our institute were enrolled. There were 438 Medtronic and 109 St. Jude’s devices. All chest radiographs were de-identified and resized into 225*225 pixels focusing on the CIED. PMIDa and CRMD-f applications were used to identify the CIED. Accuracy, sensitivity, specificity, negative predictive value, and positive predictive value for both applications were calculated and compared.

Results: Overall, CRMD-f application has higher specificity (93.58 vs. 82.5%) but lower sensitivity (53.6 vs. 55%) than PMIDa. The accuracy of both applications was comparable (61.6% vs. 60.5%). Accuracy varied with CIED model and type tested, and radiograph projection used. Accuracy is greatest with Cardiac-Resynchronization-Therapy (CRT) devices for both applications, followed by a single lead pacemaker.

Conclusion: CRMD-f has higher accuracy and specificity for CIED manufacturer identification. Both PMIDa and CRMD-f are specific tools to identify CIED but have low sensitivity.

1. Introduction

Cardiac implantable electronic devices (CIED) are increasingly being implanted across the world. With an expansion in the number of CIED implanted every year, physicians frequently encounter the need of device interrogation [1]. Timely interrogation of CIED helps with quicker diagnosis and management of patients with cardiovascular disease. Furthermore, patients with CIED need device interrogation and changes in the device parameters to safely perform emergency surgery. Emergency Department (ED) staff can now interrogate CIED with similar interrogation time and have no impact on the length of ED stay and similar 30-days outcomes when compared to the standard procedures of interrogation in ED [2,3]. However, significant time is spent in retrieving information about the device manufacturer from the medical records in circumstances when the device identification card is not available, which can potentially delay the necessary therapies for certain arrhythmias or delay the emergency treatment required.

Smartphone-based applications like Pacemaker ID application (PMIDa) and Cardiac Rhythm Management Device-Finder (CRMD-f) have been designed to aid with quicker recognition of device manufacturers so that manufacturer-specific equipment is arranged for the device interrogation. Either of the two applications needs validation studies to ascertain their usefulness in device manufacturer identification.

PMIDa is a smartphone-based application that uses neural network-driven model to recognize the device manufacturer (Fig. 1) [4]. It is also

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A single Nokia phone (13-megapixel camera) was used for all the de...

CRMD-f is a mobile-based application that was developed by Dr. Ines Sherifi and Tarun Kotia and includes a flow-chart-based inspection of CIED using the CaRDIA-X algorithm. This algorithm utilizes the fact that every device has certain unique radiographic and morphologic features such as the shape of the battery, CAN, and header position concerning the battery, presence of coils, etc., which can facilitate device identification.

2. Methods

This was a single-center, observational study approved by the Aga Khan University Hospital Ethics Review Committee (ERC Number: 2020-5101-14156). The patient enrollment period ranged from 2015 to 2020. All subjects who underwent CIED implantation during this study period and undergoing chest radiograph after the procedure at any time were enrolled in the study. Chest radiographs were obtained from the electronic medical record system of the hospital. Commonly used devices were single-lead permanent pacemakers, and 15 Cardiac Resynchronization Therapy (CRT) devices. Device models interrogated are as shown in Table 1. Chest radiograph projection was anteroposterior in 87 (14.6%) and posteroanterior in 460 devices (76.8%).

PMIDs sensitivity in identifying device manufacturers was 55% and specificity was 82.5%. PMIDa negative predictive value (NPV) was 31% and the positive predictive value (PPV) was 92.6%. CaRDIA-X algorithm carried a sensitivity of 53.6% and specificity of 93.58% with an NPV of 33.4% and PPV of 97% (Table 2 and Fig. 4).

When compared to PMIDa, the accuracy of CRMD-f was lower for Medtronic (56.6% vs. 57.9%) and higher for St. Jude Medical (94.4% vs. 75.2%). CRMD-f had 100% accuracy for single-lead PPM and CRTs. PMIDa also correctly identified 100% of CRTs. PMIDa had higher accuracy with AP-projection when compared to PA-projection (72.4% vs. 59.3%), whereas CRMD-f had higher accuracy with PA-projection (98.5 vs. 94%). (Table 3).

4. Discussion

Cardiology staff on-call often gets called for urgent interrogation of CIED. This entails consults from ED or peri-operative areas. Often, our patients fail to show CIED identity cards in emergency situations. In such circumstances, where urgent interrogation and programming of CIED are needed and the manufacturer name and device type are not known, either a PMIDa or CRMD-f with CaRDIA-X algorithm can be used to identify the device manufacturer.

In this study, we have used CRMD-f mobile application instead of manual CaRDIA-X flow-chart and compared it with PMIDa. Our study points towards variability concerning the manufacturer, device type, and X-ray projections used. Overall, CRMD-f had higher specificity (93.58 vs. 82.5%) but relatively lower sensitivity (53.6 vs. 55%) than PMIDa. We compared our sub-group accuracies to the one demonstrated in Chudow et al. study and found the interpretations mentioned in Table no. 3. In essence, when compared to the manual CaRDIA-X flowchart used in Chudow et al. the CRMD-f application had greater accuracy for St. Jude’s Medical and single lead ICDs whereas a lesser accuracy for Medtronic CIED. Based on the device type, both the studies reported lesser accuracy with PPM in comparison to ICDs.

Chudow et al. looked at the head-to-head comparison of the accuracy
of various machine learning algorithms in identifying CIED. The study used a manual CaRDIA-X flow-chart whereas our study used a mobile phone application-based CaRDIA-X algorithm. Chudow et al. reported an average accuracy of 88% for ICDs and 80% for PPMs with a variability of 71–99% depending upon the manufacturer being tested. Likewise, PMIDa had an overall accuracy of more than 75% (range: 51–100%). The manual CaRDIA-X flow-chart was reported to be time-consuming and cumbersome when compared to PMIDa [8]. This brought us to the testing of CRMD-f which is an application-based CaRDIA-X flow-chart and allows quicker user interface and identification of the device. In comparison to Chudow et al. study, we demonstrated lesser sensitivity and specificity, pointing towards inter-study variability.

The respective accuracies of our study and Chudow et al. for Medtronic devices were: 57.9 vs. 96% (PMIDa) and 56.6 vs. 72% (CRMD-f vs. manual CaRDIA-X flow chart). For pacemakers overall, the accuracies were 52.5 vs. 83% (PMIDa) and 50.6 vs. 88% (CRMD-f vs. manual CaRDIA-X flow chart). Both the studies individually demonstrated relatively higher accuracy for ICD vs. PPM when using PMIDa (This
owing to their greater familiarity with devices and algorithms. An variability with the electrophysiologists showing best performance, accuracy-variability amongst physicians of 62.3%
magnifies anterior structures (including CIED). Involves taking picture of the device and an AP projection theoretically yields higher accuracy (98.5% vs. 94%). This is likely because PMIDa is superior to PMIDa in terms of output because it not only identifies the (99.6% vs. 72%) [9]. However, other studies [8,10] including ours show variable accuracies pointing towards the variable performance of neural network-based AI performs better than the cardiologists to identify CIED (99.6% vs. 72%) [9]. However, other studies [8,10] including ours show variable accuracies pointing towards the variable performance of neural networks. The accuracy in the difference of accuracy across the studies. Our study is one of the few studies testing AI for CIED identification using chest radiograph and the first one from a low-middle income country.

Provenance and peer review
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Ethical approval
Ethical review committee of the Aga Khan University Hospital. ERC Number: 2020-5101-14156.

Consent
Consent not applicable as no direct intervention or interaction with human subjects.

Author contribution
Pirbhat Shams: Study conceptualization and design of the project. Manuscript writing and revision. Muhammad Mehdi and Jamshed Ali: Data collection, data analysis and presentation and literature review. Intisar Ahmed, Sheema Saadia, Sameen Iqbal: Literature review, statistical analysis and first draft. Aamir Hameed Khan: Critical review of the manuscript. Yawer Saeed: Supervised from conceptualization to execution. Final editing and critical review of the manuscript.

Registration of research studies
1 Name of the registry: clinicaltrial.gov
2 Unique Identifying number or registration ID: NCT04957108
3 Hyperlink to your specific registration (must be publicly accessible and will be checked): https://register.clinicaltrials.gov/prs/app/action/LoginUser?ts=1&cx=jg9qo4 (Publicly available).

Guarantor
Dr. Yawer Saeed.

<table>
<thead>
<tr>
<th>Device characteristic</th>
<th>PMIDa was correct Shams et al.</th>
<th>PMIDa accuracy Chudow et al.</th>
<th>CRMD-Finder was correct Shams et al.</th>
<th>CaRDIA-X accuracy Chudow et al.</th>
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</thead>
<tbody>
<tr>
<td>Medtronic St. Jude Medical</td>
<td>57.9%</td>
<td>96%</td>
<td>56.6%</td>
<td>72%</td>
</tr>
<tr>
<td>St. Jude Medical</td>
<td>75.2%</td>
<td>89%</td>
<td>94.4%</td>
<td>84%</td>
</tr>
<tr>
<td>Dual chamber PPM</td>
<td>52.1%</td>
<td>52.5%</td>
<td>49.7%</td>
<td>50.6%</td>
</tr>
<tr>
<td>Single lead PPM</td>
<td>71.4%</td>
<td></td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>CRT</td>
<td>100%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single lead ICD</td>
<td>75.4%</td>
<td>95% (For all ICDs)</td>
<td>93.4%</td>
<td>88% (For all ICDs)</td>
</tr>
<tr>
<td>Anterior-posterior projection</td>
<td>72.4%</td>
<td></td>
<td>94%</td>
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<tr>
<td>Posterior-anterior projection</td>
<td>59.3%</td>
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<td>98.5%</td>
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Declaration of competing interest

None of the authors has any conflict of interest to reveal.

Acknowledgment

None.

References


