

Purpose: To evaluate the outcome of patients with DR-ICDs and active RM.

Methods: A total of 283 patients with 91,632 RM transmissions collected over a 15-month follow-up (FU) and who were enrolled in the LION registry were included in the analysis. Atrial arrhythmia burden subgroups were defined as AB = 0 (no AB on any day during FU) versus AB > 0 (AB > 0 on at least one day during FU). Only patients (n=274) with a minimum of 45 RM transmissions and additional historical information of atrial fibrillation (AF) occurrence prior to enrolment were included in the analyses.

Results: Of the 274 patients fulfilling the predefined criteria, 36.1% (99 patients) with AB > 0 and 63.9% (175 patients) with AB = 0 during FU were identified. Based on the following baseline characteristics, subjects with AB > 0 differed from those without AB (p < 0.05): They were more frequently in a NYHA functional class ≥ III (AB = 0: 15% vs. AB > 0: 31%, p = 0.003), had a lower mean LVEF (AB = 0: 36.6 ± 13.6% vs. AB > 0: 33.1 ± 12.2%, p = 0.047) and had more frequently a history of AF (AB = 0: 13% vs. AB > 0: 40%, p < 0.001). Furthermore, subjects with AB during FU were older (AB = 0: 65.1 ± 10.8 years vs. AB > 0: 67.5 ± 10.1 years; p = 0.071). There was no substantial difference between groups with respect to gender, body mass index, secondary prevention indication, non-cardiac medical history, and medication. Of the 211 patients without a history of AF, 28.0% (59 patients) developed de novo high rate atrial arrhythmias during FU. For 36.5% (23 patients) with a history of AF, an AB = 0 was detected during the observational period.

Conclusions: Due to their greater morbidity, the occurrence of atrial arrhythmia reflects an important issue for ICD patients. In this case, an optimal anticoagulation therapy might be potentially helpful in preventing the occurrence of embolic stroke. In our cohort, patients with AF detected by RM suffered from progressive heart failure, low ejection fraction, and had a previous history of AF. In addition, RM-based recording of AF might help to initiate a more individual anticoagulation strategy to prevent bleeding in course of continuous anticoagulation therapy.

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Comparison of Kardia Mobile (one lead ECGs records) with 12-lead ECGs in 100 consecutive patients with various cardiovascular disorders

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Introduction: Recent advancement in the technological industry resulted in the development of novel remote monitoring solutions. Among others, Kardia Mobile is a smartphone-dependent device that enables 1-lead ECG recording. It provides a rapid insight into the patient's state during the occurrence of troubling symptoms (including chest pain, palpitations, dyspnea). Although such technology may potentially revolutionize the diagnostic processes, the data verifying its reliability remain scarce.

Purpose: To evaluate the accuracy of Kardia Mobile by comparing its readings with standard 12-lead ECG.

Methods: A total of 100 patients of a tertiary care centre were included in the trial. Each patient had a 1-lead AliveCor ECG and a 12-lead ECG performed consecutively. Only one physician was responsible for ECG recording during the whole trial. ECGs were then independently evaluated by 3 teams comprised of two cardiologists and one internal medicine specialist. Investigated parameters included: quality of the ECG, rhythm assessment (sinus rhythm, atrial fibrillation, atrial flutter or pacemaker rhythm), presence of pathological Q wave and PQ, RR and QT measurements. Results were analyzed using adequate statistic tests.

Results: 99 Kardia Mobile ECGs and 100 standard 12-lead ECGs were examined. Quality of AliveCor ECGs was compared with that of 12-lead ECGs (6 vs 0 – poor, 41 vs 1 – acceptable, 52 vs 99 – good, p < 0.001). Sensitivity and specificity of rhythm assessment based on Kardia Mobile ECGs was 98.4% and 74.2% for sinus rhythm (p = 0.018), 92.8% and 100% for atrial fibrillation (p = 0.317), 100% and 100% for atrial flutter (p value not applicable), 56.3% and 100% for pacemaker rhythm (p=0.008). Mean PQ, RR and QT measurements in Kardia Mobile ECGs and 12-lead ECGs were 160 ms vs 180 ms (p < 0.001), 853 ms vs 880 ms (p = 0.031) and 393 ms vs 400 ms (p < 0.001) respectively.

Conclusions: Based on Kardia Mobile ECGs, an indicative assessment of leading rhythm and certain measurements may be performed. Kardia Mobile showed very high accuracy in detecting atrial fibrillation. Nevertheless, additional research is needed to verify clinical utility of this system.

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Design of an alerts regrouping and management tool for CIED remote monitoring

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Background: International Guidelines recommend, with a high level of evidence, remote monitoring for patients with an Implantable Cardioverter Defibrillator (ICD). To do so, healthcare management has to be redesigned in order to take into account the amount of data made available. Each remote monitoring system allows the triggering of alerts in case of a clinical or technical event, such as therapies, arrhythmias, lead or device dysfunction. The aim of this work was to make all the alerts from the five remote monitoring systems arrive on a single computing tool and to design their management.

Methods: This tool runs two different loops to recover all the data from the remote monitoring websites and transcribes them in a linked database. It connects to the websites like any user would do it. The first loop recovers all the patients' data while the second one recovers all the new alerts' data. The medical staff only needs to login to this tool to access and manage daily alerts, to write every reaction and/or intervention related to them, and then the tool will generate a medical report for each one.

Results: Regrouping all alerts on a single tool is feasible. The recovering of the alerts is exhaustive. Management of alerts is eased from the point of view of traceability and communication to medical correspondents, for each step: reception of the alert, medical diagnosis, reaction, intervention, semi automating of medical reports. Conclusion: This is the first description of a functional tool for medical management of alerts in remote monitoring of ICD patients.

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Outcomes and costs of remote patient monitoring among patients with implanted cardiac defibrillators: an economic model based on the PREDICT RM database

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Introduction: Remote patient monitoring (RPM) of implantable cardioverter-defibrillators (ICD) has been associated with reduced rates of all-cause rehospitalizations and mortality but continues to be underutilized. To determine if RPM has economic benefits in addition to clinical benefits, we conducted an analysis of the clinical outcomes and costs of RPM versus no RPM.

Purpose: We hypothesized that use of RPM is associated with better health outcomes and lower hospitalization costs over the lifetimes of ICD recipients.

Methods: An economic model was used to simulate individual patients using a time-to-event approach to evaluate the clinical outcomes and costs of RPM from a US Medicare perspective. Events considered were first rehospitalization, subsequent rehospitalizations, and death. Patient characteristics and clinical inputs to the model were taken from the Medicare cohort of the PREDICT RM database, created by linking the ACCF ICD Registry, the Boston Scientific ALTITUDE RPM database, and Medicare claims data. Times to first rehospitalization and death were extrapolated using regression analyses based on patient characteristics and, for mortality, history of first rehospitalization. Hospitalization costs by DRG were obtained from the Medicare 2016 Inpatient Prospective Payment System. DRG codes were mapped to ICD-9 codes to assign utility decrements. Costs and benefits were discounted at 3.5% per year. The model assumed a lifetime time horizon up to 25 years.

Results: Use of RPM was associated with reduced mortality. With RPM, average life expectancy increased from 6.37 to 7.08 years (8.5 months), and average quality-adjusted life years (QALYs) increased from 5.26 to 5.85 (7.1 months). RPM patients had 0.05 fewer subsequent rehospitalizations per patient-year (PY), and hospitalization costs were lower by \$716/PY. With longer life expectancies, however, the average RPM patient experienced 0.64 additional subsequent rehospitalizations with an increased lifetime hospitalization cost of \$2,784. This yields an incremental cost-effectiveness ratio of \$4,718/QALY, making RPM a high-value intervention based on the ACC/AHA 2014 consensus statement.

Conclusions: Use of RPM is associated with better health outcomes and value over a patient's lifetime.