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ORIGINAL ARTICLE

Smartphone-based cardiac implantable electronic device remote monitoring: improved compliance and connectivity

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Aims Remote monitoring (RM) is the standard of care for follow up of patients with cardiac implantable electronic devices. The aim of this study was to compare smartphone-based RM (SM-RM) using patient applications (myMerlinPulse™ app) with traditional bedside monitor RM (BM-RM).

Methods and results The retrospective study included de-identified US patients who received either SM-RM or BM-RM capable of implantable cardioverter defibrillators or cardiac resynchronization therapy defibrillators (Abbott, USA). Patients in SM-RM and BM-RM groups were propensity-score matched on age and gender, device type, implant year, and month. Compliance with RM was quantified as the proportion of patients enrolling in the RM system (Merlin.net™) and transmitting data at least once. Connectivity was measured by the median number of days between consecutive transmissions per patient. Of the initial 9714 patients with SM-RM and 26 679 patients with BM-RM, 9397 patients from each group were matched. Remote monitoring compliance was higher in SM-RM; significantly more patients with SM-RM were enrolled in RM compared with BM-RM (94.4 vs. 85.0%, $P < 0.001$), similar number of patients in the SM-RM group paired their device (95.1 vs. 95.0%, $P = 0.77$), but more SM-RM patients transmitted at least once (98.1 vs. 94.3%, $P < 0.001$). Connectivity was significantly higher in the SM-RM, with patients transmitting data every 1.2 (1.1, 1.7) vs. every 1.7 (1.5, 2.0) days with BM-RM ($P < 0.001$) and remained better over time. Significantly more SM-RM patients utilized patient-initiated transmissions compared with BM-RM (55.6 vs. 28.1%, $P < 0.001$).

Conclusion In this large real-world study, patients with SM-RM demonstrated improved compliance and connectivity compared with BM-RM.

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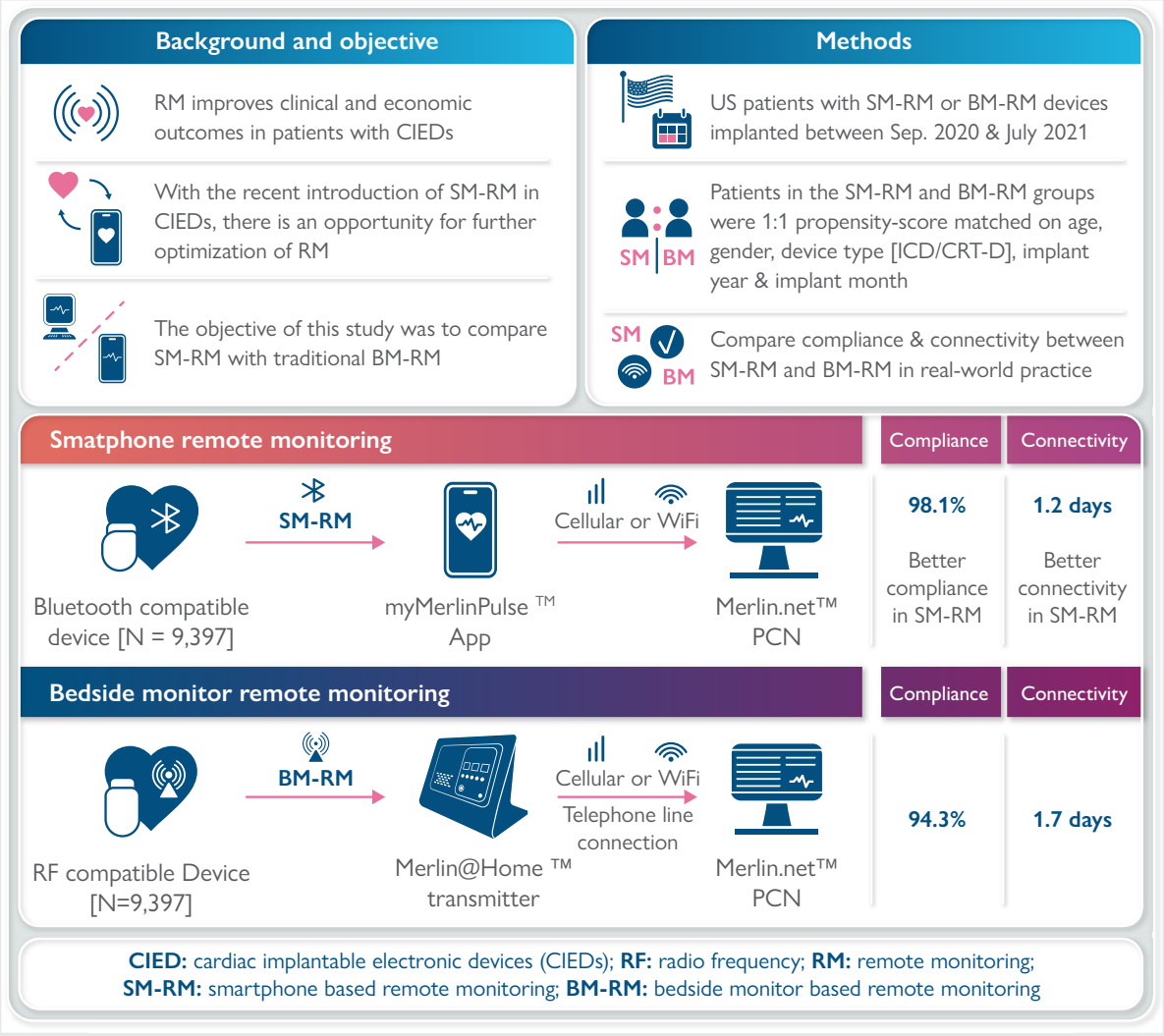
Graphical Abstract



Keywords Bluetooth • Radio frequency • Cardiac implantable electronic devices • Compliance • Connectivity • Patient-initiated transmissions

Introduction

Remote monitoring (RM) in patients utilizing cardiac implantable electronic devices (CIEDs) is associated with better clinical outcomes and reduced healthcare utilization.[1,2] Prompt enrolment in RM may lead to further improvement in patient survival.[1–3] With the advent of a more global society and the frequency of travel, the current paradigm of performing RM of CIEDs via a bedside monitor may lead to gaps in monitoring, during which important clinical events can be missed. Furthermore, the recent worldwide coronavirus disease (COVID-19) pandemic has highlighted the importance of effective telemonitoring.[4] In parallel, smartphones have evolved as the primary mechanism for mobile connection, with some countries reporting 80% penetration rate for smartphones as the primary mode of using the internet.[5–7] This adoption is universal across different age groups, with high usage among older adults.[8]

Traditionally, implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators used radiofrequency technology and required a bedside monitor for RM. The recently released Gallant™ and Entrant™ (Abbott, Chicago, IL, USA) families of devices utilize Bluetooth® and Wi-Fi/cellular technology along with a specially developed myMerlinPulse™ smartphone application (app) (Abbott) to connect to the RM system.

In this study, we aimed to compare smartphone-based RM (SM-RM) with traditional bedside monitor RM (BM-RM) in real-world practice. We compared patient compliance with RM, connectivity between the patient and clinician, utilization of patient-initiated transmissions, and timeliness of event transmission between the two RM paradigms.

Methods

Study cohort

All US patients above 18 years of age, registered in the Abbott patient device tracking database, who received an Abbott RM-capable implantable cardioverter or cardiac resynchronization therapy defibrillator between September 2020 and June 2021 were included in this retrospective study and followed through July 2021. The cohort start date corresponded to the US release of SM-RM following the US Food and Drug Administration approval of the technology in July 2020.

Patients were dichotomized into those receiving the latest generation device (Gallant™ ICD and CRT-D devices) with Bluetooth® technology as SM-RM and those with previous generation device with radiofrequency technology and bedside monitor BM-RM. Patients in the SM-RM and BM-RM groups were 1:1 propensity-score matched on age, gender, device type, implant year, and implant month. A sub-analysis was also performed on patients within the SM-RM group who participated in the Abbott SyncUP™ RM support pilot program, which assists patients with RM initiation. With SyncUP™, an Abbott support expert will enrol a patient with a newly implanted SM-RM device in the RM system, educate them on their new device, and confirm connection to the myMerlinPulse™ smartphone app.

Connectivity, transmission times, and transmission frequency were evaluated in those patients who were registered in the Merlin.net™ RM network (Abbott, Chicago, IL, USA) and paired their implantable device with a smartphone for SM-RM and a bedside monitor for BM-RM. Data from Merlin.net™ were de-identified prior to analysis and publication, as defined by HIPAA in 45 CFR Sec.164.514(b) implementation specifications: requirements for de-identification of protected health information. The study was a retrospective analysis of deidentified data and thus exempt from institutional review board approval. Deidentified health information can be used without authorization or any other permission specified in the Health Insurance Portability and Accountability Act Privacy Rule, and this study was therefore exempt from informed consent procedures.

Technology

Merlin.net™ patient care network (PCN) is a web application used by the implanting/referring clinics to remotely monitor and manage patients with Abbott cardiac rhythm management devices. After device implantation the first step in patient management by the clinic is to help the patient sign up to the Merlin.net™ PCN by entering the patient and device data. A patient's unique Merlin.net™ PCN number is automatically assigned by the system upon first being signed up.

Patients in the BM-RM group received the Merlin@home™ transmitter which transmits data to Merlin.net™ PCN for remote care patient management. For this data transmission type, patients need an electrical outlet and a telephone landline, cellular adaptor, or broadband service (see Supplementary material online, *Figure S2*).

The Gallant™ device for patients in the SM-RM group utilizes Bluetooth® technology. Bluetooth® technology enables communication between the Gallant™ device and the myMerlinPulse™ smartphone app, which then transmits data to the Merlin.net™ PCN via WiFi or cellular service (see Supplementary material online, *Figure S2*). The myMerlinPulse™ smartphone app is available for both the Android and iOS operating system. Smartphone-based RM was achieved either through the patient's compatible smartphone with the myMerlinPulse™ app installed or through a smartphone provided by Abbott. The Abbott-provided smartphone is a pre-configured Android operating system smartphone set up to function only as a remote transmitter. Patients who did not have an app-compatible smartphone or who were not comfortable with installing the app on their personal phone, were provided with this smartphone. Only patients enrolled in SM-RM group participated in the Abbott SyncUP™ RM support pilot program. Other than the patients participating in the pilot SyncUP™ RM program, patients in the SM-RM and BM-RM groups received the same education on the use of the RM system.

There are several types of transmissions that can occur within SM-RM or BM-RM including daily connectivity checks (occurs at a pre-specified time), scheduled transmissions (occurs at a pre-specified time), physician-initiated unscheduled transmissions, and patient-initiated transmissions. Daily connectivity checks send data from the device to Merlin.net™ every day regardless of the presence of any alerts. If an activated alert condition is triggered, a full transmission with all alerts, stored episodes, and diagnostics is transmitted during the daily check. Scheduled transmissions occur on a schedule set by the clinic for each patient. Unscheduled transmissions can be initiated by the clinician or the patient at any time and are sent to Merlin.net™ immediately. Scheduled, unscheduled, and patient-initiated transmissions contain a full transmission.

Socio-economic status

Area deprivation index (ADI) scores were derived from the patients' five-digit zip codes when available and used as a proxy for the anonymized patient's socio-economic status (SES). Area deprivation index is a zip-code based indicator of neighbourhood socio-economic disadvantage consisting of neighbourhood financial strength, economic hardship and inequality, and educational attainment.[9] Socioeconomic data for evaluating ADI were gathered from American community survey 5-year estimates data (2015–19). The ADI has been examined in various studies for its association with health outcomes.[9–12] The ADI scores were categorized into tertiles, with the first ADI tertile representing the highest SES level, and the third ADI tertile representing the lowest SES level.

Objectives and endpoints

Compliance

There are three stages to participation in RM: (i) signing up (enrolling) for the Merlin.net RM system, (ii) pairing myMerlinPulse™ app (for SM-RM) or Merlin@Home™ (for BM-RM) with the implanted device, and (iii) transmitting data at least once; this includes any type of transmission—a daily connectivity check, scheduled or unscheduled transmission, or a patient-initiated transmission. In order to fully evaluate RM compliance, we compared proportions of patients completing each of these stages between the SM-RM and BM-RM groups. Stages 1–3 were also evaluated separately in those <75 and ≥75 years of age.

Connectivity

Device connectivity was defined as the median number of days between consecutive transmissions for each patient. Follow-up period was defined as the number of days between device implant and the last transmission. Device connectivity was calculated in patients with at least two transmissions over the follow-up period. The effects of age, gender, and mobile device type on device connectivity in SM-RM and BM-RM were studied. Additionally, a subgroup analysis was performed in patients with available SES data to examine the effects of SES level on device connectivity.

Episode transmission time

Clinical event transmission timing from episode to availability in Merlin.net™ was calculated separately for three groups of EGM rhythms: (i) auto mode switch (AMS) or atrial tachyarrhythmia (AT)/atrial fibrillation, (ii) non-sustained ventricular tachycardia or supraventricular tachycardia (SVT), and (iii) ventricular tachycardia (VT) or ventricular fibrillation (VF). Median time from episode detection to transmission and to availability within Merlin.net™ was reported. Only episodes associated with physician-activated alerts are transmitted during daily device checks. If an alert is not activated by the physician, the corresponding episode EGM will only be sent during the next full transmission.

Patient initiated transmissions

Frequency of patient-initiated transmissions and median utilization of patient-initiated transmissions per patient were evaluated. The proportion of patients with >10 patient-initiated transmissions during the study period was calculated.

Statistical analysis

Matching was achieved using a greedy matching algorithm with a calliper width of 0.25 (MatchIt package-v4.2.0[13]). Robustness of the matching algorithm was confirmed by ensuring that standardized mean difference was below 0.1 for all variables.

Values for device connectivity and patient-initiated transmissions were reported as median [interquartile range (IQR)] across the study cohort

and across each group. Median was used due to the data having a non-normal distribution. Proportions were compared using the χ^2 test.

Stability of connectivity over time was evaluated using the Wilcoxon Signed-rank test to test whether there were any differences in the average days between transmissions between SM-RM and BM-RM in the first 6 months.

Linear mixed-effects models were built to evaluate the effect of age, gender, and mobile device on the device connectivity (lme4 package-v1.1.27.1[14]). The patient ID was treated as the random effect in the models to account for the variations of the repeated measurements from each patient. Additionally, in a subgroup analysis of patients with SES, linear mixed-effects models were built to evaluate the effect of age, gender, mobile device, and SES on the device connectivity (lme4 package- v1.1.27.1[14]).

RStudio version 1.4.1103 (Boston, MA, USA) with R version 4.1.1 was used for statistical analysis.

Results

The study population included 36 393 patients implanted from September 2020 to June 2021, with SM-RM and BM-RM used in 9714 (26.7%) and 26 679 (73.3%) patients, respectively (*Figure 1*). After 1:1 propensity score matching, there were 9397 patients in each group (*Figure 1*). Patient characteristics are summarized in *Table 1*.

Compliance

Significantly more patients with SM-RM were enrolled in RM compared with BM-RM (94.4 vs. 85.0%, $P < 0.001$), similar number of patients in the SM-RM group paired their device (95.1 vs. 95.0%, $P = 0.77$), and more SM-RM patients transmitted at least once (98.1 vs. 94.3%, $P < 0.001$) (*Table 2*). Patients ≥75 years of age had similar compliance rates for SM-RM and BM-RM as those below 75 (see Supplementary material online, *Table S1*). Notably, compliance within SM-RM was further improved in patients utilizing the SyncUP™ program when compared with patients not part of the SyncUP™ program, both in pairing the device (99.2 vs. 92.9%, $P < 0.001$) and transmitting at least once (98.6 vs. 97.8%, $P = 0.01$) (*Table 3*).

Connectivity

Connectivity was significantly higher in the SM-RM group, with patients transmitting data every 1.2 (1.1, 1.7) days vs. every 1.7 (1.5, 2.0) days with BM-RM ($P < 0.001$; overall) and remained better over time (*Figure 2*). Within SM-RM and BM-RM there was no difference in connectivity between men and women [fixed effect coefficient: 0.13 (−0.05–0.32), $P =$ 0.08 vs. 0.06 (−0.08–0.20), $P = 0.19$] and between age groups [age <75 and age ≥75; fixed effects coefficient: 0.12 (−0.07–0.30), $P = 0.11$ vs. 0.00 (−0.13–0.14), $P = 0.48$] (*Figure 3*). Additionally, within SM-RM, patients using their own mobile device had significantly better connectivity compared with those using an Abbott-provided mobile device [fixed effects coefficient: −0.54 (−0.71 to −0.36), $P < 0.001$; *Figure 3*].

In a subgroup analysis of patients in BM-RM with available SES data, there was no difference in connectivity between lowest SES and medium SES [fixed effects coefficient: −0.07 (−0.25–0.12), $P = 0.24$] and between lowest SES and highest SES [fixed effects coefficient: −0.06 (−0.25–0.12), $P = 0.25$] (see Supplementary material online, *Figure S3*). The full model incorporating SES information also showed no difference between men and women and between age groups, similar to the model without SES information. However, for connectivity in SM-RM patients with available SES data, although there was no difference between lowest SES and medium SES tertiles [fixed effects coefficient: −0.16 (−0.38–0.06), $P = 0.07$], patients in the highest SES tertile had significantly better connectivity than lowest SES tertile [fixed effects coefficient: −0.19 (−0.41–0.02), $P = 0.04$] (see Supplementary material online, *Figure S3*). The full model also showed no difference between men and women but did find that connectivity in younger patients (<75) was significantly better than in older patients (≥75) [fixed effects coefficient: 0.22 (0.02–0.41), $P = 0.02$]. As in the model without SES, the model with SES found that patients using their own mobile device had significantly better connectivity compared with those using an Abbott-provided mobile device [fixed effects coefficient: −0.47 (−0.66 to −0.29), $P < 0.001$; Supplementary material online, *Figure S3*].

Episode transmission time

The median time from episode to Merlin.net™ was faster in SM-RM compared with BM-RM for all EGM rhythm types: AMS or AT/, non-sustained VT or SVT, and VT or VF (*Table 4*). Further, these episodes were also viewed by a clinician within a similar amount of time [~1 (0.6–2) days] both in SM-RM and BM-RM.

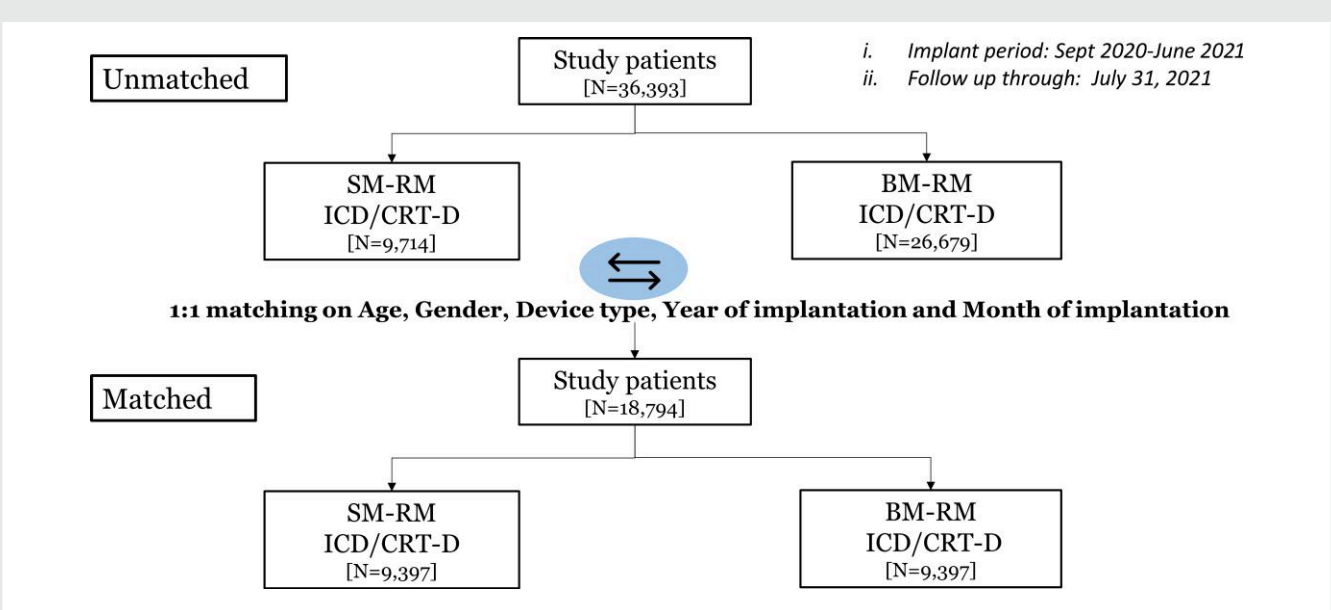


Figure 1 Cohort diagram.

Table 1 Descriptive table with matched and unmatched data reported

	Before matching			Propensity score matched (1:1)		
	SM-RM ($n = 9714$)	BM-RM ($n = 26\,679$)	SMD	SM-RM ($n = 9397$)	BM-RM ($n = 9397$)	SMD
Follow-up (days)	121 (75–183)	203 (125–282)		119 (75–180)	126 (80–189)	
Age (years)	69 (60–77)	70 (62–78)	0.12	69 (60–77)	69 (61–77)	<0.1
Age category						
Age <75	6618 (68%)	17 045 (64%)		6391 (68%)	6398 (68%)	
Age ≥75	3086 (32%)	9599 (36%)		3006 (32%)	2999 (32%)	
Missing or N/A	<100	<100		0 (0%)	0 (0%)	
Gender			<0.1			<0.1
Female	2670 (27%)	7611 (29%)		2668 (28%)	2580 (27%)	
Male	6735 (69%)	18 086 (68%)		6729 (72%)	6817 (73%)	
Missing or N/A	309 (3.2%)	982 (3.7%)		0 (0%)	0 (0%)	
Device type						
CRT-D	4392 (45%)	13 204 (49%)	0.09	4267 (45%)	4328 (46%)	<0.1
Dual chamber ICD	3572 (37%)	9493 (36%)	<0.1	3452 (37%)	3552 (38%)	<0.1
Single chamber ICD	1750 (18%)	3982 (15%)	0.08	1678 (18%)	1517 (16%)	<0.1
Implant month						
Sep-2020	60 (0.6%)	3636 (14%)	0.51	59 (0.6%)	59 (0.6%)	<0.1
Oct-2020	254 (2.6%)	3419 (13%)	0.38	228 (2.4%)	228 (2.4%)	<0.1
Nov-2020	542 (5.6%)	3064 (11%)	0.20	505 (5.4%)	501 (5.3%)	<0.1
Dec-2020	661 (6.8%)	2569 (9.6%)	0.11	613 (6.5%)	601 (6.4%)	<0.1
Jan-2021	911 (9.4%)	2630 (9.9%)	<0.1	851 (9.1%)	842 (9.0%)	<0.1
Feb-2021	994 (10%)	2336 (8.8%)	<0.1	937 (10.0%)	931 (9.9%)	<0.1
March-2021	1283 (13%)	2847 (11%)	<0.1	1249 (13%)	1257 (13%)	<0.1
April-2021	1488 (15%)	2197 (8.2%)	0.21	1478 (16%)	1498 (16%)	<0.1
May-2021	1694 (17%)	2007 (7.5%)	0.32	1676 (18%)	1673 (18%)	<0.1
June-2021	1827 (19%)	1974 (7.4%)	0.35	1801 (19%)	1807 (19%)	<0.1
Implant year			0.74			<0.1
Year-2020	1517 (15.6%)	12 688 (47.6%)		1405 (15.0%)	1389 (14.8%)	
Year-2021	8197 (84.4%)	13 991 (52.4%)		7992 (85.0%)	8008 (85.2%)	
Mobile device						—
Patient's device	5913 (61%)	0 (0%)		5740 (61%)	0 (0%)	
Manufacturer-supplied device	3801 (39%)	0 (0%)		3657 (39%)	0 (0%)	

BM-RM, bedside monitor-based remote monitoring; SM-RM, smartphone-based remote monitoring; SMD, standardized mean difference.

Patient-initiated transmissions

Significantly more SM-RM patients utilized patient-initiated transmissions compared with BM-RM (55.6 vs. 28.1%, $P < 0.001$). The median number of patient-initiated transmission sent per patient in the SM-RM group was 1 (1–3) and 1 (1–2) in the BM-RM group ($P < 0.001$). Within the patient population utilizing patient-initiated transmissions, 7% of the patients had 10 or more such transmissions in the SM-RM group compared with 2% within the BM-RM group ($P < 0.001$). Moreover, the percentage of patients utilizing patient-initiated transmissions was significantly higher in the first month (SM-RM: 96.7% and BM-RM: 98.5%) compared with 6 months (SM-RM: 4% and BM-RM: 3%) after implant. Significantly more patients with age <75 utilized patient-initiated transmissions compared with those with age ≥75 both in SM-RM (57.2 vs. 52.2%, $P < 0.001$; *Figure 4*) and BM-RM groups (29.5 vs. 25.2%, $P < 0.001$; *Figure 4*). Within the patient populations utilizing patient-initiated transmissions in SM-RM and BM-RM, comparatively higher number of patients with age <75 (SM-RM: 7.5% and BM-RM: 2.1%) had 10 or more such transmissions compared with age ≥75 group (SM-RM: 5.8% and BM-RM: 1.7%) (*Figure 4*).

Discussion

The primary aim of this large real-world study was to evaluate and compare the compliance, connectivity, episode transmission time, and utilization of patient-initiated transmissions between SM-RM and traditional BM-RM.

Main study findings

We observed that significantly more patients with SM-RM were enrolled in RM compared with BM-RM (94.4 vs. 85.0%, $P < 0.001$), and more SM-RM patients transmitted at least once (98.1 vs. 94.3%, $P < 0.001$). Compliance within SM-RM was further improved in patients utilizing the SyncUP™ program (for RM initiation). Connectivity was significantly higher in the SM-RM group, with patients transmitting

Table 2 Participation in remote monitoring by Telemetry (compliance: SM-RM vs. BM-RM)

	Propensity score matched (1:1)		
	SM-RM ($n = 9397$)	BM-RM ($n = 9397$)	*P*-value
Enrolled in remote monitoring	94.4% (=8869/9397)	85.0% (=7988/9397)	<0.001
Paired bluetooth device or bedside monitor	95.1% (=8431/8869)	95.0% (=7585/7988)	0.765
Transmitted at least once	98.1% (=8271/8431)	94.3% (=7150/7585)	<0.001

BM-RM, bedside monitor-based remote monitoring; SM-RM, smartphone-based remote monitoring.

Table 3 Participation in remote monitoring by SyncUP™ status (compliance)

	Propensity score matched [1:1]		
	SM-RM (non-SyncUP) ($n = 6318$)	SM-RM (SyncUP™) ($n = 3079$)	*P*-value (SyncUP™ vs. non-SyncUP)
Paired Bluetooth device or bedside monitor	92.9% (=5377/5790)	99.2% (= 3054/3079)	<0.001
Transmitted at least once	97.8% (=5259/5377)	98.6% (=3012/3054)	0.01

SM-RM, smartphone-based remote monitoring.

data every 1.2 (1.1, 1.7) days vs. every 1.7 (1.5, 2.0) days with BM-RM ($P < 0.001$; overall) and remained better over time. The median time from episode to Merlin.net™ was faster in SM-RM compared with BM-RM for all EGM rhythm types and significantly more SM-RM patients utilized patient-initiated transmissions compared with BM-RM.

Compliance

A previous investigation of real-world data from a large CIED RM system reported that only 61% of patients with RM-eligible devices were enrolled in RM and 79% of these patients transmitted data.[15] In this analysis, a much higher proportion of CIED patients were enrolled in RM. Even with traditional BM-RM, the enrolment rate was 85% and SM-RM led to a further increase to 94.3%.

Remote monitoring has been established to be beneficial in the follow-up of patients with CIEDs.[2,16] Remote monitoring is associated with various advantages including rapid response to patient and device events,[17–19] fewer in-person evaluations,[18,20–22] and cost reductions.[1,23] Moreover, various studies have also identified a mortality benefit.[2,16,24] This evidence has led to publication of guidelines to inform clinical practice on remote interrogation and monitoring for CIEDs.[25] The higher utilization of RM among CIED patients in this study could be attributed to the timeframe that includes both the shift in clinical practice due to the publication of overwhelming evidence for benefit of RM and also the expanded use of RM during COVID-19 pandemic.

Connectivity

Connectivity overall was improved in SM-RM over BM-RM (*Figure 2*) which could be attributed to the use of Bluetooth technology in SM-RM, which allows transmission from anywhere and not just from home where a bedside monitor is traditionally located for BM-RM. This result was confirmed in a subset of the population with at least 6 months of follow-up (see Supplementary material online, *Figure S4*). Additionally, connectivity was not affected by age or sex in either group, with older adults still transmitting every 1.3 days in the SM-RM group (*Figure 3*). Consistent with our findings, a recent study that specifically evaluated mobile health use among older adults found that a significant portion of older adults already utilize mobile technology, that they are willing to engage with mobile technology for health reasons, and that their overall attitude toward mobile technology is positive.[8] We found that within SM-RM, patients who used their own device had better connectivity than those using an Abbott-provided mobile device for RM (*Figure 3*). We speculate that patients using their own phones for RM may be more familiar with smartphone use and may be more likely to carry their smartphones with them for other uses, while those utilizing Abbott-provided smartphone devices for RM could be using smartphones for the first time and/or using them only infrequently. Separately, using percentage of scheduled RM transmissions that were successfully transmitted, a recent study[26] in pacemaker patients also reported that the SM-RM had improved success rate over BM-RM.

Another notable observation is that more SM-RM patients utilized patient-initiated transmissions. Healthcare personnel may be concerned that patient-initiated transmissions can increase unnecessary workload. However, with a median of a single transmission per patient, the added burden is limited. In addition, the percentage of patients utilizing patient-initiated transmissions was significantly higher in both groups in the first month (SM-RM: 96.7% and BM-RM: 98.5%) when compared with 6 months (SM-RM: 4% and BM-RM: 3%) after implant. One explanation is that the feedback from the device clinic, in response to the patient-initiated transmissions that occurred during the first month, could have led to a lower rate of subsequent patient-initiated transmissions.

Transmission and review times

Timeliness of episode transmission and assessment is key to reaping full benefits of RM. Several previous trials have reported on the efficacy and timeliness of episode transmissions.[27] The median time from alert to review by the clinician, in the Evolution of Management Strategies of Heart Failure Patients with Implantable Defibrillators (EVOLVO) trial,[20] was 1.4 days. The median delay from device-detected events to clinical decisions was 2 (1, 4) days in the RM group of the TRUST[18] and

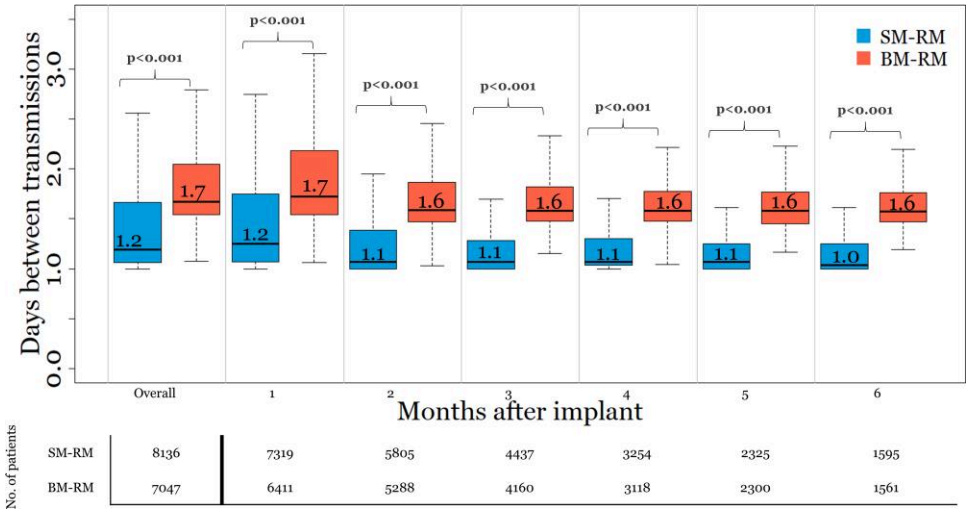


Figure 2 Connectivity overall and over time (6 months) (horizontal solid lines and values refer to the median values) for patients who were compliant/adopted remote monitoring and transmitted more than once.

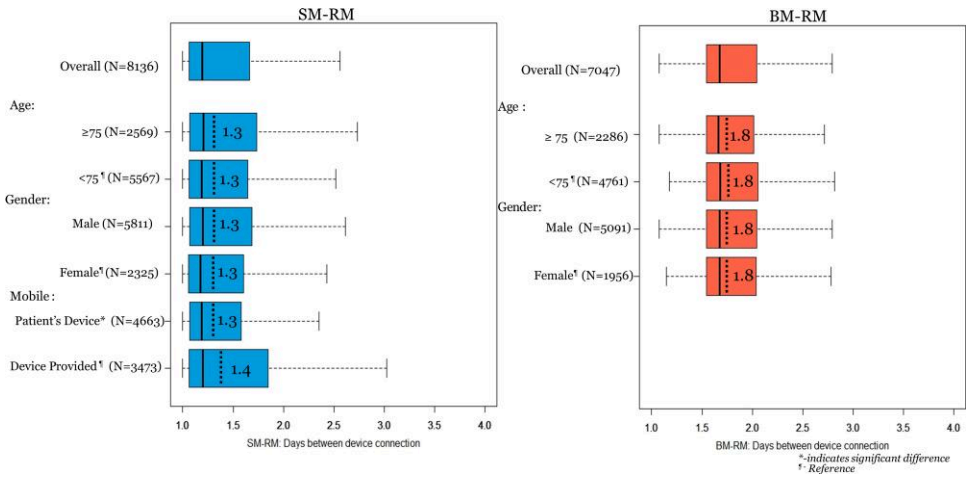


Figure 3 Effect of age, gender, and mobile device on connectivity in smartphone-based RM and bedside monitor RM arms (dotted line and value refer to estimated marginal means).

Monitoring Resynchronization Devices and Cardiac Patients (MORE-CARE) randomized controlled trial.[28] Comparatively, in this study, the median time from episode to review by clinician was lower [~1 (0.6, 2) days] in both SM-RM and BM-RM. Moreover, the median time from episode to Merlin.net™ was faster in SM-RM compared with BM-RM for all EGM rhythm types (*Table 4*). The observed variability in transmission timing across the different EGM rhythm types could be attributed to differences in alert programming for events considered more urgent (e.g. VT/VF) and those considered less urgent (e.g. AMS).

Clinical implications

Telemedicine and telemonitoring are an integral part of the healthcare system, and their application has increased exponentially[29] in 2020–21 during the COVID-19 pandemic[30–32] prompting regulatory changes needed for its rapid deployment.[30] Owing to the recent technological advances, 'digital health'-based RM is rapidly evolving into a more established role in clinical practice.[33,34] However, this transition also made health care disparities more evident[35] in certain settings; for example, female sex and median household income (<$50 000 per year) were independently associated with less telemedicine and video use, respectively.[36] Moreover, it was also reported that technology literacy from providers and patients was an additional barrier for telehealth implementation ('digital divide').[37] Interestingly, when we explored the effect of gender and socio-economic factors on connectivity in sub-group of patients in SM-RM there was no difference between men and women (see Supplementary material online, *Figure S3*), regardless of SES, as assessed by SES. However, in the overall population, patients in the

Table 4 Clinical event transmission timing (time from episode to Merlin.net™ availability)

	SM-RM			BM-RM			*P*-value comparing SM-RM vs. BM-RM transmission times
EGM rhythm type	Time median (IQR)	Patients	Episodes	Time median (IQR)	Patients	Episodes	
AMS or AT/AF	4.2 days (1.10–13.7)	2531	82 160	5.9 days (1.6–17.1)	2493	92 711	<0.001
NSVT or SVT	17.1 h (10.7–56.4)	2830	114 462	24.3 h (12.9–158.1)	2224	87 032	<0.001
VT or VF	13.1 h (7.31–23.0)	935	12 133	14.2 h (8.6–30.8)	818	10 872	0.005

AMS, auto mode switch; AT, atrial tachyarrhythmia; AF, atrial fibrillation; NSVT, non-sustained ventricular tachycardia; SVT, supraventricular tachycardia; VT, ventricular tachycardia; VF, ventricular fibrillation.

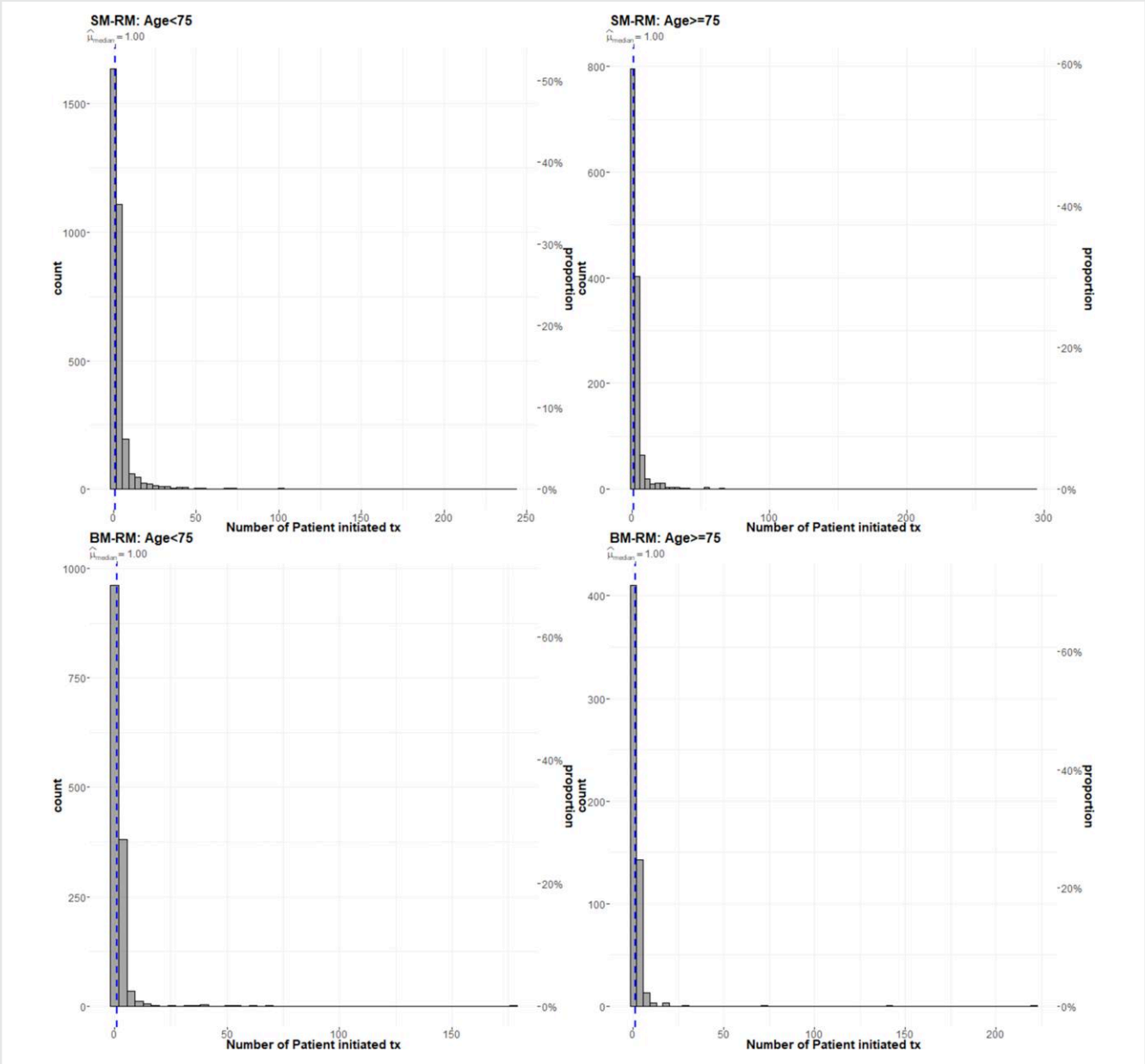


Figure 4 Histogram for patient-initiated transmission by Telemetry type and age groups (patients with >10 transmissions are represented by the rightmost bar in each plot).

highest SES tertile had significantly better connectivity than those in the lowest SES tertile [fixed effects coefficient: −0.19 (−0.41–0.02), $P = 0.04$] (see Supplementary material online, *Figure S3*). The lower connectivity in the low-SES group may have resulted from lower rates of smartphone or broadband adoption in this population,[38] an observation similar to that of the telemedicine study.[36] As a matter of fact, despite the general increase in digital literacy, there are still patient subgroups, particularly among the elderly, with limited confidence in digital technology, requiring dedicated education in the use of such tools.[39] Personalized RM device setup programs like SyncUP™ are designed to educate people about technology, while simultaneously helping reduce the 'digital divide' and take burden off physician and clinic staff as well.

While both SM-RM and BM-RM enable RM of CIEDs and are therefore beneficial, our results support SM-RM as the preferred RM option. Smartphone-based RM led to higher uptake of RM, improved connectivity, and faster episode transmission compared with BM-RM. This could be attributed to several factors. First, using a smartphone is simpler for the patient because it is a device that is already used every day for other purposes. Second, this platform improves communication with the healthcare provider and therefore the patient may be motivated to use it. Third, it facilitates monitoring even when the patient is not at home. Finally, the use of this smartphone solution engages patients in their own care. With smartphones becoming ubiquitous in everyday life as well as in healthcare, CIED RM via smartphones is a natural next step in the evolution of RM technology. Additionally, SM-RM allows the patient to assume a greater role in their own care.[40] The recent worldwide COVID-19 pandemic has highlighted the importance of effective telemonitoring and has further catalyzed the use of smartphone technology for healthcare delivery. We note that since the study follow-up is limited, these observations could be considered hypothesis-generating and should be further evaluated with a longer follow-up.

Limitations

Although the study groups were matched on age, gender, device type, month of implantation, and year of implantation, there could still be an inherent selection bias. Information on patient clinical characteristics is limited and may impact the efficacy of RM. In addition, analysis was limited to the American population and may not represent the variability in other parts of the world based on cell phone signal, data availability for transmission based on cell phone plans, and cultural factors. Socio-economic data were derived from 5-year estimates and may have changed for patients by the time they were included in the current study. The study was not designed to measure clinical outcomes associated with different modalities of RM. Future studies exploring the effect of RM modality on clinical outcomes are warranted. Finally, the study time frame took place during the COVID-19 pandemic where standards for patient follow-up shifted from alternating between in-office and remote visits to only remote visits.[4,41] By matching patients on month and year of implant, we ensured that this would have affected both groups equally.

Conclusions

In a large, real-world study of patients with implantable cardioverter defibrillators or cardiac resynchronization therapy defibrillators, we found that SM-RM leads to higher compliance with RM, improved connectivity, and more timely transmission of meaningful events compared with traditional bedside RM. Given that patient outcomes are driven by connectivity and compliance, smartphone-based RM should be the preferred methodology of monitoring. Future investigation into the effect of RM modality on patient outcomes would further support these findings.

Supplementary material

Supplementary material is available at *European Heart Journal – Digital Health*.

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Data availability

The data underlying this article cannot be shared publicly due to privacy and ethical concerns.

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