OPEN ACCESS Freely available online

Journal of Clinical & Experimental Cardiology

Research Article

The First Pilot Study on Remote Monitoring of Implantable Cardiac Electronic Devices in South Korea: Rationale and Study Protocol of a REMOTE-CARE

YouMi Hwang[1*], Hannah Bae[2]

[1]Department of Cardiology, The Catholic University of Korea, Suwon-si, Republic of Korea; [2]Department of Economics, University of California San Diego, San Diego, CA, United States

ABSTRACT

Background: Previous studies have demonstrated that remote cardiac device monitoring reduces unnecessary outpatient visits and increases patient satisfaction. As domestic research on remote monitoring in Korea is lacking, there is a need for more evidence in order to develop remote monitoring-related policies or insurance standards. Based on our previous research on patient requirements for remote monitoring, we designed the first Korean study on remote cardiac device monitoring, including a 1-year follow-up period, to examine the patient satisfaction, medical safety, and efficacy of remote monitoring.

Methods: The REMOTE-CARE study is a single university hospital observational survey study that will include 100 cardiac implantable electronic devices, including Pace Makers (PMs), Implantable Cardioverter Defibrillators (ICD), and Cardiac Resynchronisation Therapy (CRT), compatible with the Biotronik home monitoring system. All study participants will be provided cardio messenger smart for remote monitoring during enrolment. Regular in-office visits will be planned every 6 months-12 months for patients with PM and every 3 months-6 months for those with ICD and those undergoing CRT. The time/medical cost efficacy and satisfaction index will be evaluated using electronic medical records during the 12 months follow-up period. Pre and post-questionnaires will be administered before and at 1 year after remote monitoring, respectively.

Discussion: The REMOTE-CARE study is the first prospective study to provide further insights on domestic remote monitoring applications based on patient perspectives in South Korea. The study will also provide evidence for developing policy or insurance standards for remote monitoring in Korea.

Registration: The REMOTE-CARE study is registered at ClinicalTrials.gov with study ID NCT04557111. This study was approved by the Institutional Review Board (IRB) of the Catholic University of Korea St. Vincent's Hospital (Suwon, South Korea; IRB No. VC20DISF0160).

Keywords: Artificial; Cardiac resynchronisation therapy devices; Defibrillators; Implantable; Remote monitoring; Pacemaker

Abbreviations: CIED: Cardiac Implantable Electronic Device; CM: CardioMessenger Smart; COVID-19: Coronavirus Disease 2019; CRT: Cardiac Resynchronisation Therapy; ECG: Electrocardiogram; ICD: Implantable Cardioverter Defibrillator; IRB: Institutional Review Board; PM: Pace Maker; RM: Remote Monitoring

Correspondence to: YouMi Hwang, Department of Cardiology, The Catholic University of Korea, Suwon-si, Republic of Korea, Tel: +82-31-249-7548; E-mail: youmi0607@naver.com

Received: 30-Jun-2023, Manuscript No. JCEC-23-25332; **Editor assigned:** 03-Jul-2023, PreQC No. JCEC-23-25332 (PQ); **Reviewed:** 17-Jul-2023, QC No. JCEC-23-25332; **Revised:** 14-Jan-2025, Manuscript No. JCEC-23-25332 (R); **Published:**09-Apr-2025, DOI: 10.35248/2155-9880.25.16.945

Citation: Hwang Y, Bae H. (2025) The First Pilot Study on Remote Monitoring of Implantable Cardiac Electronic Devices in South Korea: Rationale and Study Protocol of a REMOTE-CARE. J Clin Exp Cardiolog. 16:945.

INTRODUCTION

Previous studies have shown that remote device monitoring is safe; it decreases unnecessary outpatient visits and increases patient satisfaction [1-6]. There has been a substantial increase in Remote Monitoring (RM) after the Coronavirus Disease 2019 (COVID-19) pandemic in many countries [7-10].

There is a lack of domestic evidence suitable for developing policy or insurance standards in Korea, as research or experience of RM of Cardiac Implantable Electronic Devices (CIEDs) is lacking. In a previous study, we demonstrated the patient requirements of RM in Korea [11] and, after the pre-RM survey study; we planned the first survey-based prospective RM study in Korea.

To date, several trials have examined the safety and efficacy of RM in other regions [12-14]. Although telemedicine and RM are not synonymous, the use of the latter, included in telemedicine, has been limited in Korea owing to reluctance towards telemedicine due to the unique medical insurance system in Korea. Unlike many other countries, Korea's medical service is state-led, allowing all citizens to receive health examinations, diagnoses, and treatments by applying the National Health Insurance System (NHIS) to all citizens. It is an advanced medical system that reduces excessive medical expenses for people by differentiating the patient's medical expenses according to the severity of the disease or the patient's economic situation. Therefore, unlike in the United States or Japan, in Korea, patients receive high-quality medical care and treatment at a relatively lower cost burden, which benefits most people [15-18]. Additionally, elderly or low-income patients are classified into medical beneficiary to receive NHIS specified medical cost support by the country with minimizing personal burden of medical expenses [19]. However, the consequence of this national insurance system is that patients are concentrated in university or large hospitals. There is a concern that the concentration of patients and the profit gap between hospitals will worsen if telemedicine is implemented. Therefore, compared to Western countries, insurance applications and the domestic introduction of new medical technologies or treatments have been delayed in Korea.

Before 2020, there was a stigma on telemedicine in Korea. As the demand and need for telemedicine have grown since the COVID-19 pandemic, there has been an increased interest in telemedicine. Remote medical services have begun to be widely used with the recent commercialisation of wearable Electrocardiogram (ECG) devices [20-22]. The introduction of RM services for CIEDs that have already been verified abroad has accelerated. However, data on patient demand for RM in Korea are scarce, and experience of RM among medical experts is lacking. Thus, this study aims to provide appropriate grounds for the introduction of RM in Korea in a timely manner.

This REMOTE-CARE study will be the first prospective study in Korea to provide:

- Evidence of RM from a patient perspective,
- Evaluate the efficacy and safety of RM compared to conventional in-office visits, and
- Evaluate the saved medical expenses of the patients in comparison to increased work load of the medical staff.

MATERIALS AND METHODS

Study design and study population

This single-university-hospital prospective pilot study will evaluate the efficacy and safety of RM of CIEDs, along with patient experience of RM, using a specially designed survey on hospital visits. Patients with Biotronik (Berlin, Germany) CIED implants compatible with the Biotronik Home monitoring system will be included in the study. The overall study process is illustrated in Figure 1. To compare conventional in-office visits, CIED care, and RM care, patients who had experienced outpatient treatment with a CIED implanted for at least 6 months prior will be enrolled. Calculating the number of study participants for statistical analysis is difficult, as this is only a pilot study examining the medical staff's work intensity and whether introduction RM is possible. For this reason, we aim to enrol 100 participants in this study, followed by at least 12 months of RM-based follow-up. Participants who want to discontinue RM or are lost during follow-up will be excluded from the study analysis.

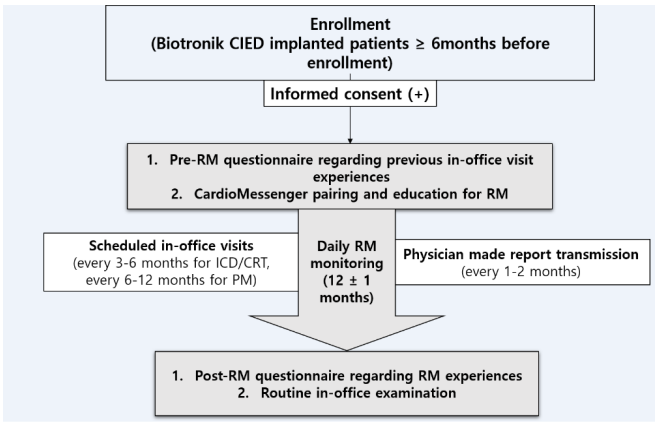

Figure 1: Study process flowchart.

This study was approved by the Institutional Review Board (IRB) of the Catholic University of Korea St. Vincent's Hospital (Suwon, South Korea; IRB No. VC20DISF0160) as version 1 on 10 September, 2020. The study protocol was registered at ClinicalTrials.gov, with study ID NCT04557111 (REMOTE-CARE study). The IRB will independently monitor the study protocol and process, and conduct audits every 6 months from the enrolment of the first patient. This study will be conducted in accordance with the declaration of Helsinki and is supported with funding from Biotronik.

Data collection and follow-up

After obtaining documentation of informed written consent from the all participants, they will be requested to complete a questionnaire ('Survey on telehealth patient experience' by YouMi Hwang, 2021, modified version; Table 1) regarding their prior experiences with conventional in-office visits before using RM. After completing the pre-RM questionnaire, the patients or

their caregivers will receive CardioMessenger Smart (CM), which will be immediately paired to their CIEDs, and instructions for CM and RM use will be provided. Following this, daily RM will be initiated.

Table 1: Survey on telehealth patient experience (YouMi Hwang, 2021, modified version).

Questions					
1. How long does it take from home to the hospital?	<30 minutes	30 minute~60 minutes	1 hour-2 hours	2 hours-3 hours	>3 hours
2. How much time does it take you to attend a cardiology clinic?	<1 hour	1 hour~2 hours	2 hours~3 hours	3 hours~4 hours	>4 hours
3. What transportation do you use to travel to the hospital?	Public transportation	Own car	Taxi	Multiple choices	
4. What is your labour situation now?	Have a job	Unemployed	Others		
5. Do you need to be accompanied by caregivers to attend the clinic?	Yes	No			
6. What is the labour situation of your accompanying person?	Have a job	Unemployed	Others		
7. Do you or the accompanying person have any expenses when traveling to the hospital?	Yes	No			
8. How much do you spend per hospital visit	<$10	$10~20	$20~30	$30~40	>$40
9. Do you have discomfort similar to before the CIED implantation?	Yes, I have some discomfort	No, I'm satisfied			
10. How many times have you called the clinic between the last visit and the current visit?	Never	Once	>2 times		
11. How often have you attended the emergency room related to your CIED since the last visit?	Never	Once	>2 times		
12. Was the explanation of your condition sufficient	Yes	No			

during the in-office visit?		
13. It would be better to check the device status by phone or e-mail rather than visiting the hospital in person.	Yes	No

During the 12 months RM period, primary investigators will review all RM events and send brief summary reports of their CIED status every other month by the patients' preferred means (mail, e-mail, or multimedia messaging service) to improve adherence to RM. Any unexpected visits or admission during the study period will be classified into the following: Device-related, patients' cardiovascular condition-related, non-cardiovascular condition-related events. Additionally, these will be divided into either physician-driven (RM-based) or patient-driven hospital visits.

During the study, routine clinic follow-ups will be scheduled every 6 months-12 months for PM recipients and every 3 months-6 months for patients with an Implantable Cardioverter Defibrillator (ICD), except for those on warfarin treatment or those with other relevant medical issues.

RESULTS

After at least 12 months of RM, patients will be asked to complete a second survey using both the 'Survey on telehealth patient experience by YouMi Hwang, 2020 (Table 1) and a modified Korean version of the HoMASQ by YouMi Hwang, 2020 (Table 2). Clinical information will be recorded, including past medical history, indications for CIED implantation, and types and modes of CIEDs. Hospital visiting times will be noted when the patient consults at the outpatient clinic desk and this information will be automatically recorded in the Electronic Medical Records (EMR). Clinic consultation times, when the physician starts and ends the consult with each patient, will also be automatically registered in the EMR. Medical costs will be requested and analysed through the EMR throughout the study period to estimate each patient's medical expenses and the insurance payment required for each hospital visit. Additionally, the physician's time consumed during RM monitoring will be measured in hours per year.

Table 2: Survey on patient satisfaction with remote monitoring (modified Korean version by YouMi Hwang, 2020 from HoMASQ; Europace.

Question	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1. There was much overall discomfort using remote monitoring					
2. I feel my health and the CIED were better cared for with remote monitoring than with conventional in-office visits					
3. It was not easy to use cardio messenger					
4. Using cardio messenger caused an inconvenience in my daily life					
5. Remote monitoring has helped me manage my health					

6. I am satisfied with the use of remote monitoring
7. Remote monitoring has advantages in terms of time and cost compared to visiting the hospital
8. I want to continue remote monitoring
9. I would like to recommend remote monitoring to other patients with CIED

The primary endpoint will be the estimation of satisfaction after RM. The secondary endpoints will include time, economic and qualitative evaluation comparisons (including cardiovascular death and hospital admissions related to pre-existing cardiovascular disease) between contact medical care and RM for CIED recipients and medical personnel.

All files and data generated by this protocol will be stored in a secured safe box or as copied files with passwords with only the investigator's accessibility. Data from this study will not be openly accessible because of personal identifiers or sensitive information included.

Remote patient monitoring system

CM is a device that collects information through wireless technology, encodes the collected biometric data, and transmits it to a medical institution. It will be utilised in this study to deliver the data from the device implanted in the user (patient) to the attending physician. This study may also use the successor model of the CM family. The package provided to participants will consist of the CM device and a power supply module. The CM receives information from the paired CIED once daily, typically at night. Study participants will be asked to charge it at night to ensure it works the following day. While on long business trips or traveling, patients will be asked to carry it with them and keep the CM connected to a charger at night-time near their bedside. The trans-server is used for communication with the CIED, and the data received from the device are encrypted and sent to the website using the data module. The website can be accessed only with a single ID and password given to the registered medical practitioner (in this study, only YMH) and does not contain any personally identifiable information other than information related to the patient's device. If there is an event, such as a periodic overall CIED check-up, change in the patient's rhythm, or change in the device, an alert is automatically sent to the registered medical staff, which can immediately monitor the event as soon as it is transmitted to the website.

Statistical analysis

Continuous variables will be expressed as means ± standard deviations. Categorical variables attained by the survey will be described using numbers and frequencies and multiple-choice analysis, as appropriate. A paired t-test will be applied for pre- and post-RM measurements. All tests will be two-sided, and a p-value of $p<0.05$ will be considered statistically significant. Statistical analyses will be performed using R version 4.05 statistical software (R Foundation for Statistical Computing, Vienna, Austria) and Stata, version 16 (StataCorp, Cary, NC, USA).

DISCUSSION

This study will provide evidence for developing policy or insurance standards for RM in Korea. Patients with CIEDs need regular follow-ups for their underlying cardiac conditions, alongside planned check-ups for the implanted devices, as CIEDs are implanted due to an underlying arrhythmia or structural heart disease. We previously demonstrated that the clinic consultation time is short despite long travel and waiting times.

Owing to Korea's unique medical insurance system, despite the development of medical technology, new medical technologies have been introduced much later compared with other medically developed countries. This is attributed to the medical policy of South Korea, which ensures national health insurance benefits for all Korean citizens. While there is an advantage of providing expensive and precise medical technologies, procedures, and drugs to many people at low prices, the number of patients is too large compared to the size of the medical staff who offers high levels of medical services? Thus, there are time and physical constraints to provide appropriate services. Accordingly, proper communication between patients and medical staff and individualised patient care is difficult in the current situation in Korea. Narrowing the knowledge gap between patients and physicians within such a short in-office consultation time is almost impossible. Assessing the patient's problems and addressing CIED-associated events during a short period, with

many patients in waiting, presents a heavy burden for the medical staff. Additionally, there may be a difference in perspective between patients with CIED and the physicians, as patients may feel they need to receive adequate attention or care. The abovementioned factors may lead to dissatisfaction by patients and physicians and inadequate CIED recipient's knowledge regarding their disease status. The result of this may be poor compliance from the patient regarding care and self-administered treatments. Although the number of CIED recipients is gradually increasing due to an aging population, it is not a desirable direction for medical treatments for either party. For individualised and optimised patient management, the need for RM of CIEDs is greater than ever. To effectively utilise RM, cooperation from patients and their guardians and a sufficient understanding and education regarding RM and their disease are essential. Patient awareness and collaboration may contribute to the diverse results highlighted in previous research investigating patient satisfaction. This study will provide the first real-world evidence of patient experience with RM and patient satisfaction in Korea.

Although an RM system for heart disease is necessary in Korea, the RM system for heart disease is mistaken for the remote treatment of patients, which is not true. The importance and essence of the RM is early detection of medical problem and possible early management by communicating with actively engaged patients and the caregivers. Thus, RM system needs the participants (both physician and the patients/caregivers) bidirectional cooperation to reach the targeted result, which is a patient-tailored-medicine. However, the RM system still has several issues, including legal issues with the personal information in the patients' data and safety, and legal concerns. Besides, possible problems during remote patient management, disagreements between various institutions and industries are not settled yet. In Korea, patients with heart failure or transplanted cardiac devices are supposed to undergo monitoring in their daily life. However, because of the aforementioned issues, only face-to-face visits for routine monitoring and medical interventions or treatments during hospital visits are possible.

As we do not have any domestic references or data regarding RM of CIEDs, the REMOTE-CARE study will be the first prospective study in Korea to provide evidence of RM from a patient perspective, evaluating the efficacy and safety of RM compared to conventional in-office-visits. It will provide the basis for estimating the effect of reducing medical expenses of the patients and the insurance system vs. to the increased out-of-office work intensity of the medical staff.

CONCLUSION

This study has a few limitations. Only a few participants will be included in this study as it is the first regional RM trial assessing the patient's and physician's points of view on RM utilisation. Investigators will evaluate the safety and the cost-effectiveness of RM compared to conventional in-office visits. The results of this study will provide an important starting point for the introduction of RM in Korea. Further, if the advantages of RM are proved in Korea, it will be possible to conduct a large-scale study that can influence the establishment of RM domestically. We believe that this study can be used to introduce RM in Korea by setting reasonable insurance policy applicable to the country and reducing the stigma surrounding telemedicine.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the Institutional Review Board (IRB) of the Catholic University of Korea St. Vincent's Hospital (Suwon, South Korea; IRB No. VC20DISF0160) as version 1 on 10 September, 2020. The study protocol was registered at ClinicalTrials.gov, with study ID NCT04557111 (REMOTE-CARE Study). This study will be conducted in accordance with the declaration of Helsinki. All patients will provide written informed consent.

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

COMPETING INTERESTS

The authors declare that they have no competing interests.

FUNDING

This study was funded by Biotronik Ltd.

AUTHORS' CONTRIBUTIONS

Protocol contributor, original manuscript: YMH.

Statistical consultation and figure arrangement: HB.

ACKNOWLEDGMENTS

We sincerely thank JG Choi for their full support during the project and GH Lee and JA Hwang for their support of remote monitoring and dedication to patient education. We would like to thank Editage (www.editage.co.kr) for English language editing.

REFERENCES

1. Ruiz Diaz MA, Egea Garcia M, Munoz Aguilera R, Vinolas Prat X, Silvestre Garcia J, Alvarez Orozco M, et al. Patient satisfaction with remote monitoring of cardiac implantable electronic devices: The VALIOSA questionnaire. BMC Health Serv Res 2020;20(1):1-9.
2. Lopez-Liria R, Lopez-Villegas A, Leal-Costa C, Peiro S, Robles-Musso E, Bautista-Mesa R, et al. Effectiveness and safety in remote monitoring of patients with pacemakers five years after an implant: The poniente study. Int J Environ Res Public Health. 2020;17(4): 1431.

3. Maciąg A, Mitkowski P, Mazurek M, Kazmierczak J, Nowak K, Grabowski M, et al. Patient perspective and safety of remote monitoring of implantable cardioverter-defibrillators in the Polish Nationwide Multicenter Registry: The Medtronic CareLink network evaluation. Kardiol Pol. 2020;78(11):1115-1121.
4. Catalan-Matamoros D, Lopez-Villegas A, Tore-Lappegard K, Lopez-Liria R. Patients experiences of remote communication after pacemaker implant: The NORDLAND study. PLoS One. 2019;14(6):e0218521.
5. Caughron H, Bowman H, Raitt MH, Whooley MA, Tarasovsky G, Shen H, et al. Cardiovascular implantable electronic device lead safety: Harnessing real-world remote monitoring data for medical device evaluation. Heart Rhythm. 2023;20(4):512-519.
6. Ricci RP, Morichelli L, Quarta L, Sassi A, Porfili A, Laudadio MT, et al. Long-term patient acceptance of and satisfaction with implanted device remote monitoring. Europace. 2010;12(5):674-679.
7. Holtzman JN, Wadhera RK, Choi E, Zhao T, Secemsky EA, Fraiche AM, et al. Trends in utilization and spending on remote monitoring of pacemakers and implantable cardioverter–defibrillators among Medicare beneficiaries. Heart Rhythm. 2020;17(11): 1917-1921.
8. Magnocavallo M, Vetta G, Bernardini A, Piro A, Mei MC, Di Iorio M, et al. Impact of COVID-19 pandemic on cardiac electronic device management and role of remote monitoring. Card Electrophysiol Clin. 2022;14(1):125-131.
9. de Larochelliere H, Champagne J, Sarrazin JF, Steinberg C, Philippon F, Roy K, et al. Findings of remote monitoring of implantable cardioverter defibrillators during the COVID-19 pandemic. Pacing Clin Electrophysiol. 2020;43(11):1366-1372.
10. Diemberger I, Vicentini A, Cattafi G, Ziacchi M, Iacopino S, Morani G, et al. The impact of COVID-19 pandemic and lockdown restrictions on cardiac implantable device recipients with remote monitoring. J Clin Med. 2021;10(23):5626.
11. Hwang YM, Kim JH. The first survey on patient needs for remote monitoring of cardiac implantable electronic device in South Korea. Medicine. 2022;101(23): e29414.
12. Bautista-Mesa RJ, Lopez-Villegas A, Peiro S, Catalan-Matamoros D, Robles-Musso E, Lopez-Liria R, et al. Long-term cost-utility analysis of remote monitoring of older patients with pacemakers: The PONIENTE study. BMC Geriatrics. 2020;20(1):1-2.
13. Wintrich J, Pavlicek V, Brachmann J, Bosch R, Butter C, Oswald H, et al. Remote monitoring with appropriate reaction to alerts was associated with improved outcomes in chronic heart failure: Results from the OptiLink HF study. Circ Arrhythm Electrophysiol. 2021;14(1):e008693.
14. Tajstra M, Sokal A, Gadula-Gacek E, Kurek A, Wozniak A, Niedziela J, et al. Remote supervision to decrease hospitalization rate (RESULT) study in patients with implanted cardioverter-defibrillator. EP Europace. 2020;22(5):769-776.
15. Hovanesyan A, Rubio E, Novak E, Budoff M, Rich MW. Comparison of rate of utilization of Medicare services in private versus academic cardiology practice. Am J Cardiol. 2017;120(10):1899-902.
16. Baker MC, Hahn EN, Dreyer TR, Horvath KA. Succeeding in medicare's newest bundled payment program: Results from teaching hospitals. Healthcare 2023;11(1):100672.
17. Sasai Y, Suzuki Y, Takeuchi Y. An analysis of the current condition of the medical insurance system in Japan. J Oral Sci 2019;61:481-482.
18. Nakatani H, Kondo T. Characteristics of a medical care program for specific diseases in Japan in an era of changing cost-sharing. Health Policy. 2003;64(3):377-389.
19. Kim YK. Forecasting the future reimbursement system of korean national health insurance: A contemplation focusing on global budget and Neo-KDRG-based payment systems. J Korean Med Sci 2012;27 Suppl:S25-S32.
20. Saghir N, Aggarwal A, Soneji N, Valencia V, Rodgers G, Kurian T. A comparison of manual electrocardiographic interval and waveform analysis in lead 1 of 12-lead ECG and Apple Watch ECG: A validation study. Cardiovasc Digit Health J. 2020;1:30-36.
21. Bray JJ, Lloyd EF, Adenwalla F, Kelly S, Wareham K, Halcox JP. Single-lead ECGs (AliveCor) are a feasible, cost-effective and safer alternative to 12-lead ECGs in community diagnosis and monitoring of atrial fibrillation. BMJ Open Qual. 2021;10(1): e001270.
22. Kleiman R, Darpo B, Brown R, Rudo T, Chamoun S, Albert DE, et al. Comparison of electrocardiograms (ECG) waveforms and centralized ECG measurements between a simple 6-lead mobile ECG device and a standard 12-lead ECG. Ann Noninvasive Electrocardiol. 2021;26:e12872.