The first survey on patient needs for remote monitoring of cardiac implantable electronic device in South Korea

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Abstract

Background/Aims: Studies showed that remote device monitoring reduced unnecessary outpatient visits and increased patient satisfaction. As there was no local research on remote monitoring (RM) in Korea, there was a lack of evidence for policy or insurance standards due to the lack of domestic data despite high demand by domestic arrhythmia experts. To establish the basis for patient satisfaction, economic efficiency, and safety of wireless monitoring, a survey-based study was planned.

Methods: This was a single-university hospital survey. The satisfaction index was evaluated using a questionnaire to investigate patient satisfaction in outpatient clinics, economic efficiency (measured as home-to-clinic time, waiting time, and actual clinic time), and demand for RM in patients with implantable cardiac devices. The questionnaire was adopted and modified from the Survey on Telehealth Patient Experience by Bas-Villalobos, 2006 (modified Korean version 2.0 by You Mi Hwang, 2020).

Results: Surveys were answered by 171 patients. The mean age of these patients was 71.2 ± 12.4 years. Based on the survey, home to clinic time was usually less than one h, mean waiting time in the hospital until clinic time ranged 42.6 ± 24.5 minutes, and mean clinic time ranged 3.1 ± 1.7 minutes. Based on the survey, patients favored RM over hospital visits with cardiac implantable electronic device follow-up mainly because of long travel times from home to clinic.

Conclusion: Based on the survey results, there is a clear need for RM in patients who have cardiac implantable electronic devices.

Abbreviations: AF = atrial fibrillation, AVB = atrioventricular block, CHF = congestive heart failure, CIED = cardiac implantable electronic device, CRT-D = cardiac resynchronization therapy with defibrillator, EMR = electronic medical record, ICD = Implantable cardioverter defibrillator, PPM = permanent pacemaker, RM = remote monitoring, SSS = sick sinus syndrome, VF = ventricular fibrillation.

Keywords: artificial, cardiac resynchronization therapy devices, defibrillators, implantable, pacemaker

Key Messages

Competency in Medical knowledge: Since remote monitoring is a powerful tool for optimal patient care, especially in cardiology patients, there has been increasing expert demand for remote monitoring of CIED recipients in Korea. However, there is no preexisting Korean data regarding the patient perspective on this issue. This is the first Korean survey on patient needs regarding remote device monitoring after COVID-19 pandemic situation.

Translational Outlook: To activate remote monitoring of CIED in Korea, domestic experience via trial and error is
needed. Since there is a clear need for RM from both patient and expert perspectives, we should move on to the next step to apply RM in Korea. To establish an RM system suitable for Korea, cardiologists, policymakers, and industrialists must work together toward the common goal of optimal CIED recipient care.

1. Introduction

Studies have shown that remote device monitoring is performed to reduce unnecessary outpatient visits and increases patient satisfaction.[1–4] There is a lack of evidence however, suitable for policy or insurance standards in Korea, as there has been no research or increased experience on remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) locally despite the need for domestic arrhythmia experts. However, medical care is required for patients who live with these devices. We shifted the standard point of view to instead evaluate patients’ perspectives of present practice in outpatient clinics and conducted a survey-based study.

2. Purpose

This study was designed to investigate patient satisfaction, discomfort with current “hospital visit,” and the demand for RM, based on surveys.

3. Methods

3.1. Study design and study population

This is a single university hospital observational study that evaluated CIED recipients’ needs and discomfort via a survey regarding hospital visits. Patients who had experienced ≥2 outpatient clinic visits with device programming were asked to complete the questionnaire after they consented to participate in the study. The usual clinic follow-up was 6 to 12 months for pacemaker patients and 3–6 months for implantable cardioverter defibrillator patients.

3.2. Data collection methods

Clinical information, including medical history, indications for CIED implantation, and types and modes of CIEDs were recorded. Hospital visit time was noted when the patient consults at the outpatient clinic desk and was automatically recorded in the electronic medical record system (EMR). Clinic time was also automatically recorded by the EMR when the physician started and finished the consult with each patient. A questionnaire survey was administered to consenting patients during outpatient office visits. Clinical information and questionnaire results were reviewed and analyzed as study endpoints. The primary endpoint was to define the need for RM. Secondary endpoints included time, economic, and qualitative evaluations of contact medical care in CIED recipients.

3.3. Survey administration

The questionnaire was adopted and modified for this study from “Survey on telehealth patient experience” by Bas-Villalobos, 2006 (modified Korean version 2.0 by You Mi Hwang, 2020, Supplementary File 1, http://links.lww.com/MD/G762). The questionnaire was focused on transportation time, hospital time or clinic time (Q1–3, 3 questions; transportation and time economy categories), economic factors, including manpower and cost expenditure for hospital visits (Q4–8, 5 questions; socioeconomic cost categories), any discomfort after CIED implantation, and requirement of medical measures between routine CIED follow-up (Q9–11, 3 questions; medical needs and satisfaction categories). In addition, patient selection regarding non-contact medical care (RM) versus contact medical care (conventional) for and CIEDs their specified reasons were investigated (Q12–15, 4 questions; demand on noncontact medical care).

3.4. Ethical considerations

This study was approved by the Catholic University of Korea St. Vincent’s Hospital of Institutional Review Board (Suwon, South Korea; Institutional Review Board No. VC20OISI0241).

3.5. Statistical analysis

Continuous variables were expressed as mean ± standard deviation. The categorical variables attained by the survey were described using frequencies and multiple-choice analysis, as appropriate. Statistical analyses were performed using R version 4.05 statistical software (R Foundation for Statistical Computing, Vienna, Austria) and SPSS for Windows version 25.0 (IBM Corporation, Armonk, NY).

4. Results

4.1. Patient characteristics

Surveys were performed on 171 patients. The mean age was 71.2 ± 12.4 years, and 94 patients (56.7%) were male. Indications for CIEDs were: sick sinus syndrome (SSS) in 72 patients (42.1%) high degree and complete atrioventricular block (AVB) in 21 (12.3%) and 59 (34.5%), respectively; dilated cardiomyopathy (DCMP) in 6 (3.5%); ischemic cardiomyopathy (ICMP) in 1 (0.6%); hypertrophic cardiomyopathy (HCM) in 5 (2.9%), Brugada syndrome in 1 (0.6%); and idiopathic ventricular fibrillation (VF) in 6 patients (3.5%). One hundred fifty-two patients had pacemakers (single chamber pacemaker in 18 [10.6%] and dual chamber pacemaker in 134 [78.3%]) and 19 patients had an implantable cardioverter defibrillator (ICD) (single-chamber ICD in 12 [10.6%], dual chamber ICD in 5 [2.9%], and cardiac resynchronization therapy with defibrillator [CRT-D] in 2 [1.2%]) (Table 1). Patients in the study had their CIEDs for 34.3 ± 5.8 months on average. The specified medical history and prescribed medications of the study population are summarized in Supplementary Table, http://links.lww.com/MD/G763.

4.2. Results of survey

4.2.1. Transportation and time economy categories. Based on the survey, home to hospital travel time was <1 hour in the majority of the patients (76%), while home to clinic time varied (within 1 hour in 12 [7.0%], 1–2 hours in 53 [31.1%], 2–3 hours in 56 [36.7%], 3–4 hours in 31 [18.1%], and >4 hours in 19 [11.1%]). Seventy-three patients came to the hospital using their own car (42.7%), 72 (42.1%) by public transportation, 16 (9.4%) by taxi, and 10 via various means of transportation.
4.3. Socioeconomic cost categories

Occupational status showed that 119 patients (69.6%) were unemployed, whereas 52 (30.4%) had jobs. More than half of the patients needed assistance from caregivers when visiting the hospital (92 patients, 53.8%) and these visiting caregivers had regular employment with 45 patients (26.3%). Patient transportation expenditures ranged from <10 dollars to >40 dollars per visit (Fig. 2).

4.4. Medical needs and satisfaction categories.

Based on the survey, 135 patients (78.9%) were satisfied with the CIEDs and were free of symptoms. More than 90% of patients had no events that required unscheduled hospital visits or consultations (Fig. 3 and Table 2).

4.5. Demand for noncontact medical care

One hundred and forty-six patients (85.4%) favored RM over hospital visits for their CIED follow-up, mainly because of time

| Table 1 | Characteristics of the patients and CIEDs. |
|---------|-----------------------------------------|
|         | No. (%)                                 |
| Sex     |                                        |
| Male    | 94 (56.7)                               |
| Indication for CIED |                        |
| SSS     | 72 (42.0)                               |
| CAVB    | 59 (34.5)                               |
| HAVB    | 21 (12.3)                               |
| DCMP    | 6 (3.5)                                 |
| ICMP    | 1 (0.6)                                 |
| BRS     | 1 (0.6)                                 |
| HCMP    | 5 (2.9)                                 |
| idiopathic VF |                         |
| Device  |                                        |
| Dual chamber pacemaker | 134 (78.3) |
| Single chamber pacemaker | 18 (10.6) |
| Dual chamber ICD | 5 (2.9) |
| Single chamber ICD | 12 (7.0) |
| CRT-D   | 2 (1.2)                                 |
| Mean time with CIED | 34.3±5.8 mo |

BRS = Brugada syndrome, CAVB = complete atrioventricular block, CIED = cardiac implantable electronic device, CRT-D = cardiac resynchronization therapy with defibrillator, DCMP = dilated cardiomyopathy, HAVB = high degree atrioventricular block, HCMP = hypertrophic cardiomyopathy, ICD = implantable cardioverter defibrillator, ICMP = ischemic cardiomyopathy, SSS = Sick sinus syndrome, VF = ventricular fibrillation.

Figure 1. Time-transportation used for hospital visit or clinic visit (responses of Q1–3, measured waiting time and clinic time by EMR) EMR=electronic medical record.
wasted travelling from home to clinic. In contrast, 25 patients (14.6%) preferred hospital visits because of direct communication with the physician (Fig. 4 and Table 3).

5. Discussion

Patients with CIEDs are a special group of patients in the cardiology field, since they need regular medical workup regarding their disease status alongside check-ups for implanted devices. They usually have underlying arrhythmia or structural heart disease as an indication for CIED implantation. Although the majority of CIED recipients benefit from CIEDs and experience a better life after CIED implantation, based on patient surveys, they may have some concerns and uncertainty regarding their devices. In Korea, the national health insurance system is well established and its wide coverage enables high-quality medical services with relatively low costs to beneficiaries of the insurance. This in turn causes tighter insurance regulations and delays regarding the introduction of new medical technologies. In addition, there is a large preference for regular hospital visits due to low medical costs as an insurance benefit, which causes an increase in the number of patients per clinic, especially in tertiary or academic hospitals. As a result, clinic time per patient is short in many of these university or tertiary hospitals. Since the communication time between the patient and the physician is short, patient counseling during clinic visits is limited in many situations. As confirmed in this study, despite a long travel time and waiting time, the actual clinic consultation time was short. In reality, it is difficult and almost impossible to resolve existing information imbalances between patients and physicians within this short clinical time. Checking the patient’s problems and addressing CIED-associated events quickly is a huge burden for the medical staff as well. The above-mentioned factors may lead to dissatisfaction with patients/physicians, inadequate CIED recipient management, and eventually, may worsen patient clinical outcomes. For individualized and optimized patient management, the need for RM of CIEDs is required among experts. However, there has been no investigation into these needs from the patient perspective. This study is the first survey on patient demand for RM. Presently, CIED RM is not available in Korea for several reasons, such as issues regarding protection of personal information, various restrictions on telemedicine from hospitals, industry partners, and policy makers. These factors led to a lack of domestic evidence of CIED telemedicine on medical/economic effects. Ultimately, it is hoped that this study will serve as a basis for representing the needs of patients as well as medical staff, thereby providing an opportunity for CIED RM to be widely applied in Korea.

Telehealth in the medical field is rapidly growing. Telehealth applications enable reduction of the information gap between medical experts and patients. Since it can be applied to diverse fields and specialties, its usefulness has been reported for both
diagnosing and monitoring various medical conditions.\textsuperscript{[5–12]} Telehealth is also widely used for monitoring various cardiac diseases\textsuperscript{[13–16]} and, regarding patients with CIED, has been used for remote monitoring.\textsuperscript{[17]} The extent of RM of CIEDs goes beyond monitoring the device parameters and providing information on patients’ condition.\textsuperscript{[18–20]} RM in CIEDs utilizes unidirectional communication from the CIED recipients to their physicians, and the CIEDs can be monitored on a daily basis. Although remote medical intervention (bidirectional communication) is impossible with CIED RM, experiences show enhanced patient satisfaction.\textsuperscript{[2]} Timely management of unexpected cardiac events or CIED-related events can be achieved by home monitoring of CIEDs.\textsuperscript{[3,4,18,20,21]} To achieve optimal RM, there is a prerequisite: dedicated, well-experienced personnel, facilities, and adequate education for medical experts/caregivers/patients are required. Despite these prerequisites, RM of CIEDs reduced medical costs via lower required manpower in experienced centers\textsuperscript{22,23} and this seems a reasonable medical option, especially given the present COVID-19 pandemic situation.\textsuperscript{[24]} RM of CIEDs is itself not the best measure for patient care; however, it can be a powerful tool for individualized and optimal patient management. To realize this in Korea, domestic experience via trial and error is needed. Since there is a clear need for RM from both patient and expert perspectives, we should move on to the next step to apply RM in Korea. To establish an RM system suitable for Korea, cardiologists, policymakers, and industrialists must work together toward the common goal of optimal CIED recipient care.

5.1. Study limitations
This study had several limitations. First, it was performed in a single university hospital, with a relatively small number of patients representing all CIED recipients seen within. Second, despite the aim of the study being to reflect CIED recipient needs for RM, the survey was adopted and revised by a physician and had the limitation of not fully representing patient opinions, with some respondents expressing confusion on reading the questionnaire regarding their experience on their overall medical condition (even if the investigator double-checked). Another
The limitation was the discrepancy between actual in-hospital waiting time and EMR-based in-hospital waiting time because the EMR-based record is activated only when patients register their visit at the outpatient clinic front desk. In this situation, underestimation of waiting time could be an issue, but this is not expected to affect the current report. Finally, the survey results may have been affected by the COVID-19 pandemic. The concerns of patients and caregivers regarding COVID-19 must have been largely reflected in the survey. This also reflected present realities though and was not expected to affect the interpretation of the results of this study.

5.2. Interpretations and conclusion

In conclusion, based on the survey, the time consumption for hospital visits was the biggest inconvenience for CIED recipients. Most patients with CIED had no unexpected hospital visits or need for consultation between clinic visits. More than 50% of the patients needed accompanying caregivers for routine clinic visits. There was a socioeconomic overconsumption in current practice based on questionnaires and there was a clear need for RM for patients with CIEDs. It is expected that this study will serve as a basis for speeding up the realization of RM due to having a common need by both patients and medical experts.

Table 2

| Question                                                                 | ICD/CRT-D (19) | Pacemaker (152) |
|--------------------------------------------------------------------------|----------------|-----------------|
| Q9. After CIED, do you have similar discomfort as before the CIED implantation? | 3 (15.8)       | 33 (21.7)       |
| Q10. Have you called the clinic between the last visit and the current visit? | 0 (0)          | 12 (7.9)        |
| Q11. Have attended the emergency room or admitted related to CIED?       | 0 (0)          | 8 (5.3)         |

CIED = cardiac implantable electronic device, CRT-D = cardiac resynchronization therapy with defibrillator, ICD = implantable cardioverter defibrillator.

Table 3

| Device                  | No. (%)       |
|-------------------------|---------------|
| ICD/CRT-D               | 17 (89.5)     |
| Pacemaker               | 129 (84.9)    |
| CRT-D = cardiac resynchronization therapy with defibrillator, ICD = implantable cardioverter defibrillator. |

Figure 4. There is a clear demand for noncontact medical care in CIED recipients, mainly because conventional medical care is time-consuming, based on their experiences (Q12–14). CIED = cardiac implantable electronic device.

Q12. What do you think is the best option for CIED monitoring?

- non-contact medical care (Remote monitoring for CIED)
- contact medical care (Conventional)

Q13. What is the reason for preferring non-contact medical care?

- Concerned about contact with others
- Long travel to hospital and long waiting time
- Cost
- Others

Q14. If possible, what is the most preferred option for remote monitoring?

- by mail
- by phone call
- by MMS or e-mail
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