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Remote Monitoring of Cardiac Implantable Systems in Those Over 80 Years of Age

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Abstract

Introduction: Remote Monitoring (RM) is increasingly employed in all types of Cardiac Implantable Devices (CIED). However, there are no data on the acceptance of RM by the elderly population.

Aim of the study: The aim of our study was to ascertain how patients over 80-years-of age, with a CIED, perceive one of the commercially available RM systems (i.e., Home Monitoring® (HM), Berlin, Germany), and what concerns or technical problems the system presents.

Methods: The study was designed as a descriptive, retrospective, single-center study. The study population consisted of all consecutive patients over 80-years-of age who were identified from our CIEDs database and who had undergone implantation of a Pacemaker (PM) or an Implantable Cardioverter-Defibrillator (ICD) between the years of 2009 and 2018 and using a HM system. All patients fulfilling entry criteria were approached with a request to complete a survey.

Results: One hundred and twenty-three patients (48 with a PM, 75 with an ICD) were identified and questioned during the survey. A total of 110 (89%) valid surveys were obtained. Most of the patients (92%) were satisfied with the necessity of undergoing ambulatory follow-up only once a year. All patients (100%) reported that they were satisfied with the HM system. However, 43% of patients were completely unaware of any health-related benefits associated with its use. Among the most frequently reported personal benefits of HM were a sense of safety and security (44%) and saving on travel expenses and time (27%). Of the respondents, 95% reported that they had not been afraid when they first started using the HM system. Before and after device implantation, 24% and 99% of patients, respectively, reported receiving information from a doctor. None reported receiving information from a nurse.

Conclusion: The HM system was well accepted by those over 80-years-of-age. Almost half of the patients did not have a complete understanding of the many benefits of the HM system in terms of their health. These results highlight the need for better patient education on remote monitoring technology, with one option being to delegate more of this education to specially trained nurses.

Keywords: Remote monitoring; Implantable electronic devices; Elderly; Education

Introduction

The clinical impact of Cardiac Implantable Electronic Devices (CIED) is well documented and is, therefore, the main reason for their implantation in patients of all age categories [1]. Because the indication criteria for CIED implantation are getting broader, the number of patients with cardiac implants continues to rise, and since the average life expectancy is simultaneously increasing, the number of patients over 80-years-of age, for whom such a procedure is indicated, is also steadily increasing [2].

Whether CIED patients are entirely dependent on the devices or not, all those who use this modern technology must undergo regular check-ups of system functionality as well as assessments of their clinical condition [3,4]. Although modern technologies for Remote Monitoring (RM) are currently widely available, they seem to be underused, especially in patients who might truly benefit, such as the elderly or people with physical disabilities [5]. RM is intuitively underused in elderly patients due to general skepticism regarding the ability of the elderly to handle and operate modern technologies. This is made worse by the fact that there is no data on the acceptance of RM technologies in the elderly population (i.e., 80+years).

The aim of our study was to ascertain how patients over 80-years-of age, with a CIED, perceive one of the commercially available RM systems (i.e., Home Monitoring® (HM), Berlin, Germany), and what concerns or perhaps technical problems the system presents. The second goal was to determine what and/or who is the main source of information on the HM system used in the elderly at our institution.

Materials and Methods

Setting

The study was performed in the largest cardiac center involved in telemonitoring of patients in the Czech Republic. At the present time, there are more than 3000 patients being followed remotely in our database. Regarding CIEDs, as a standard of care in our institution, all mentally competent patients receive an HM system and are offered to continue with remote follow-up of their device using this technology with only one in-office visit per year, unless a specific demand for an earlier check-up arises.

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Study design and participants

The study was designed as a retrospective, descriptive, single-center study. The study population consisted of 123 alive patients over 80-years-of age who were identified from our Home Monitoring database and who had undergone implantation of a Pacemaker (PM, n=48) or an Implantable Cardioverter-Defibrillator (ICD, n=75) between the years of 2009 and 2018. Patients with a PM or an ICD were monitored using the Home Monitoring® system (HM, Biotronik, Germany) starting immediately after device implantation, and regular follow-ups were conducted once a year unless extra visits were initiated either by the patient or by the physician based on remotely retrieved data requiring medical intervention.

All patients were approached via a phone call with a request to join the study. Informed consent was given orally at the time of the interview, and data processing was done anonymously. Patients who did not give informed consent or were not mentally capable of participating in the interview were excluded from the study. Both the survey structure and particular questions were designed to correspond with the aim of the study. This approach was dictated by the lack of validated questionnaires, which specifically address the quality of life and acceptance of RM technologies in the literature. Patients who agreed to take the survey were interviewed using prepared questions with possible answers read to them during the initial oral interview. The average interview lasted 18.3 ± 8.1 minutes (12-30 min). A total of 110 (89%) valid surveys were obtained, 44 (92%) from patients with a PM, and 66 (88%) from patients with an ICD.

Study questions

Our primary goal was to ascertain how octogenarians with CIEDs perceive telemedical systems used during remote follow-up of their device. Specifically, we looked at the acceptance of remote monitoring, benefits, concerns, and problems related to the use of an HM system and also accentuated the personal benefits. The second goal was to determine what and/or who was the main source of information on the HM system used by the elderly at our institution and try to assess the type and extent of patient education.

Statistical analysis

Standard descriptive statistics were used to describe the clinical characteristics and outcomes of the individual surveys within the two patient groups. Categorical parameters were expressed using absolute and relative frequencies; continuous parameters were presented using the mean ± standard deviation and/or the median (5^{th}–95^{th} percentile). The nonparametric Mann-Whitney U test was used to assess the statistical significance of the differences of continuous parameters between the two patient groups. Categorical parameters were assessed using Fisher's exact test. A p-value of<0.05 was considered statistically significant. Calculations were performed using the SPSS Statistics program for Windows, version 24.0.0.0 (IBM Corp., Armonk, NY, USA).

Results

The basic descriptive characteristics of the cohort are given in Table 1 patients with an ICD had a substantially higher occurrence of ischemic heart disease or dilated cardiomyopathy (accompanied by the low left ventricular ejection fraction), arterial hypertension, and hyperlipoproteinemia. On the other hand, patients with a PM were older and were mostly women (Table 1).

Types of CIEDs

Patient groups also differed in terms of the implant device (Figure 1). Dual-chamber devices (2D) were by far the most common in the PM group, whereas biventricular devices were much more common in the ICD group (p<0.001).

Acceptance of the number of ambulatory follow-ups and HM system satisfaction

The overwhelming majority of PM (89%) and ICD (94%) patients were satisfied with the limited number of planned ambulatory follow-ups (i.e., once a year). Although most patients found the number of ambulatory follow-ups convenient, 11% of PM patients and 6% of ICD patients said they would welcome more frequent visits to the arrhythmology ambulatory unit.

Satisfaction with the HM system was 100% in both groups (p=1.0). All these patients were delighted with the HM system, and looking back, they reported that they were glad this modern technology had been offered to them.

Benefits, concerns, and problems related to the use of an HM system

Only two patients (representing less than 2%) out of the whole cohort correctly answered that the HM system serves to prevent their clinical condition from suddenly worsening. On the other hand, most patients (54%) thought that HM was designed to serve as an emergency system that monitored their clinical condition 24 hours a day, 365 days a year, with the potential for an immediate response by medical personnel (24-hour surveillance). Alarmingly, a significant proportion of patients (43%) was completely unaware of any health-related benefits associated with the use of the HM system (Figure 2).

The patients were instructed to give a mark to the HM system on a scale of 1 to 5 (1=very beneficial, 5=completely unbeneficial). Patients

Parameters	PM (n=44)	ICD (n=66)	P-value
Age (years)	84.9 ± 4.3	82.7 ± 4.3	0.034
Men	17 (38.6%)	44 (66.7%)	0.004
Arterial hypertension	17 (38.6%)	43 (65.2%)	0.006
Coronary artery disease	5 (11.4%)	44 (66.7%)	<0.0001
Dilated cardiomyopathy	0 (0%)	13 (19.7%)	0.002
Atrial fibrillation	23 (52.3%)	35 (53.0%)	0.938
Diabetes	23 (52.3%)	28 (42.4%)	0.310
Hyperlipoproteinemia	8 (18.2%)	26 (39.4%)	0.018
Previous cardiac surgery	4 (9.1%)	22 (33.3%)	0.003
Stroke	2 (4.5%)	4 (6.1%)	0.732
Left ventricular ejection fraction	62 ± 7	32 ± 11	<0.0001
Stationary CardioMessenger	44 (100%)	53 (80.3%)	0.002

Table 1: A comparison of the basic clinical data from patients with an implanted Pacemaker (PM) *vs*. an Implantable Cardioverter-Defibrillator (ICD), who were followed using a Home Monitoring® system (HM, Biotronik, Germany) and agreed to participate in the study.

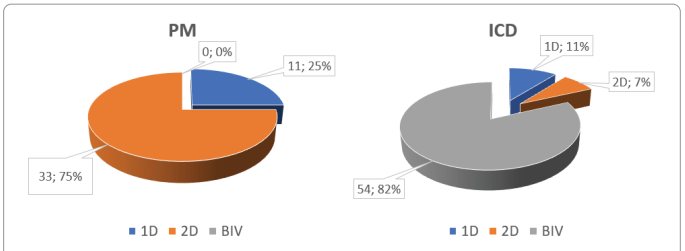

Figure 1: The structure of implanted devices in the Pacemaker (PM) and Implantable Cardioverter-Defibrillator (ICD) groups. 1D=Single-Chamber Devices, 2D=Dual-Chamber Devices, BIV=Biventricular Devices.

with a PM found HM very beneficial (mark 1) in 100% of cases. Patients with an ICD rated the HM system similarly: 94% of patients found it very beneficial (mark 1), 5% of patients found it beneficial (mark 2), and only 1% of patients (p=0.8) found it somewhat beneficial (mark 3). From their personal perspective, the HM system generally gave patients a feeling of safety and security (55% of all patients), especially when the green indicator light was ON (or the "OK" text on the mobile unit). Patients reported that the light on the patient unit represented positive feedback, and they regularly checked to see whether it was still green. Patients also appreciated the time and money saved on travel and the time saved not waiting at the clinic (33% of all patients). They also reported that HM provided a sense of calm, comfort, and well-being (15% of all patients), nonetheless, a significant number of patients (21%) could not describe any personal benefits (Figure 3). No significant differences were observed between the PM and ICD groups (p=0.89). The vast majority of the patients were not afraid of and had no concerns about using the HM system for the very first time, with no significant difference between patients in the PM (95%) and the ICD group (97%, p=0.677).

Technical problems related to the HM unit occurred in only 7% of patients in the PM group and 9% of patients in the ICD group (p=0.67). However, none of the problems were clinically dangerous, let alone life-threatening. The interviews revealed that most of the problems were user-related (e.g. forgot to plug the unit into a power source, forgot to take the patient unit with them when traveling, which prevented data transfer, preventing the doctor from having access to their data, etc.). Patients also reported that they sometimes had to search for a suitable place in their homes with a sufficient GSM signal for the patient unit. One patient reported that during a summer storm, lightning damaged his home unit (Cardio Messenger), and it had to be replaced. None of the PM patients reported any acute problems, whereas 14% of ICD patients reported that they were contacted by their doctor at least once for an event related to their device. The main reason for contact (in 7 out of 9 cases) was a low battery, indicating replacement of the device. In one case, the patient was contacted due to inadequate detection of ventricular arrhythmia during ongoing atrial fibrillation, and the other case was caused by new-onset atrial fibrillation, which required anticoagulation therapy.

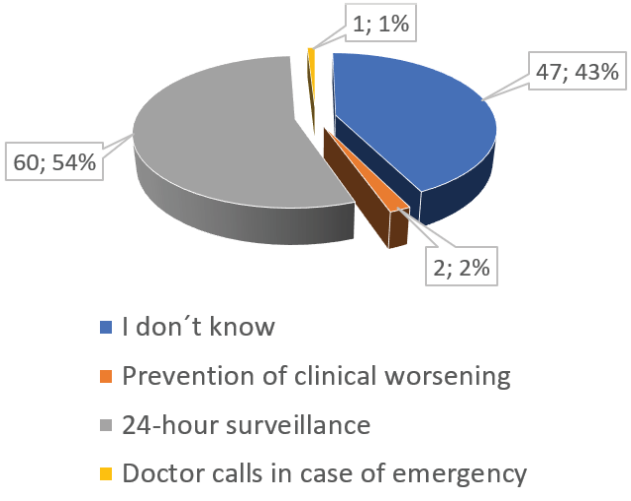

Figure 2: Patient views on the benefits of Home Monitoring (HM system), in terms of its effect on health.

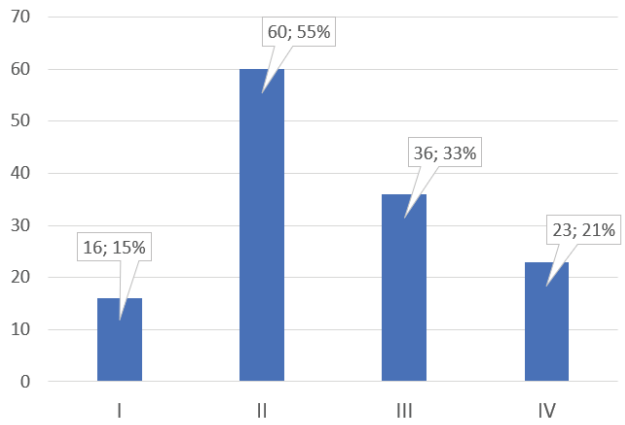

Figure 3: Patient views on the personal benefits of the Home Monitoring system (several options could have been selected by the patients during the interview). I=Contentment, serenity, or "sense of well-being," II=Safety or security, III=Savings on travel expenses and time, IV=No personal benefits.

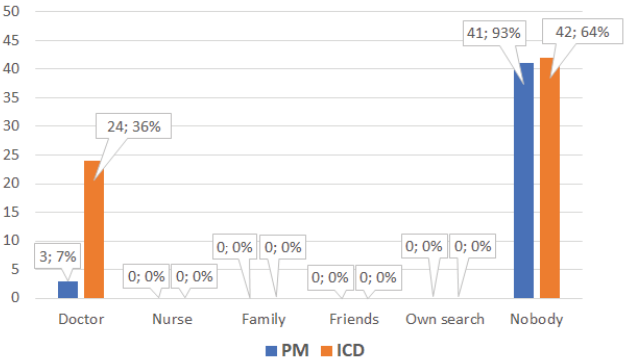

Figure 4: Sources of patient education before device implantation (several options could have been selected by the patients during the interview). PM–Pacemaker, ICD–Implantable Cardioverter-Defibrillator.

Psychological problems

Six percent of the patients in both groups reported that the HM system caused them some degree of psychological stress (e.g. concerns about loss of connection, concerns about data transfer, fear of forgetting to carry the patient mobile unit or loss of power to the unit). Three patients in the PM group (3% of all patients), for instance, reported that they did not fully trust HM, in part because they did not completely understand its function. Additionally, they also reported that they were never sure whether remote monitoring was working because they had no meaningful feedback aside from the green indicator light on the HM unit. On the other hand, four ICD patients (4% of all patients) reported that they were concerned that the HM unit would malfunction, and they experienced a sense of foreboding that "something bad would happen", either with the HM unit or with their ICD.

Patient education and sources of patient information

Ninety-three percent and 64% of patients in the PM and ICD groups, respectively (p<0.001), reported that neither the doctor nor nurse provided them with any information or education on HM technology before the implantation procedure. Only 7% and 36%

of patients in the PM and ICD groups, respectively ($p<0.001$), were educated or informed about the availability of HM technology by the doctor. None of the patients in either group sought information on CIED implantation from his or her family, friends, books, newspapers, or the internet (Figure 4).

All patients in the PM group and 98% of patients in the ICD group received information on HM technology after the implantation procedure prior to discharge from the hospital. Nurses were not involved in patient education after device implantation, and it was, again, doctors who were the primary source of information. One patient in the ICD group reported that he did not receive any information even after device implantation, and two patients sought additional information in their families (Figure 5).

Almost every patient (99%) said that they relied on their family to help them understand the HM information brochure provided post-discharge. Only 9% of patients with a PM and 6% of patients with an ICD reported that they looked for more specific information about HM post-discharge. All patients with a PM cited the Internet as their main source of additional information about HM, whereas ICD patients obtained HM information from the Internet (50%), from a specialist doctor (33%), or from the "other people" they knew (17%). The main reason why PM patients sought more information post-discharge was curiosity (67%) and the desire to have more information (33%). For patients with an ICD, curiosity was the main reason (67%), while insufficient information being provided during hospitalization (33%) was the second most common reason.

Discussion

The notable outcomes of our study can be summarized as follows: (1) patients over 80-years-of age very much appreciate the opportunity to use RM systems and RM of their CIEDs was generally very well accepted; (2) although the vast majority of the patients were satisfied with their RM system, they did not have a full understanding of its clinical benefits; and (3) doctors, not nurses were mainly involved in the education process. Regarding this 3rd point, some patients, even after being instructed by doctors at the facility where the CIED implantation was performed, subsequently looked for more information either on the Internet, from their general practitioners, or from doctors in specialized ambulatory units; unfortunately, there was no guarantee that any of these sources were up-to-date on telemedicine. Therefore, it is very likely that patients encountered incomplete, inaccurate, or possibly out-of-date information as they sought to better understand their HM system.

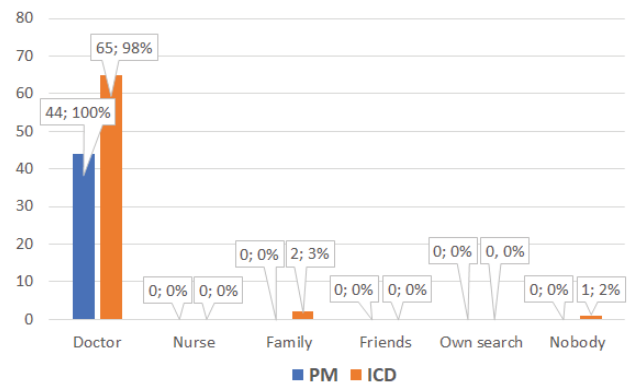

Figure 5: Sources of patient education after device implantation before discharge from the hospital (several options could have been selected by the patients during the interview). PM–Pacemaker, ICD–Implantable Cardioverter-Defibrillator.

Clinical benefits of the HM system

The impact of remote monitoring of CIEDs has been investigated in many studies. These studies have consistently shown benefits such as improved clinical conditions, decreased morbidity and number of hospitalizations, significantly decreased number of ambulatory visits, earlier detection of adverse technical events, and better allocation of health care resources [6-10]. With respect to mortality, the TRUECOIN [11] study evaluated data from 2405 patients who were monitored in the TRUST [12], ECOST [13], and IN-TIME [14] trials and showed that HM reduces all-cause mortality, by 38%, in patients with an ICD, at one year. Moreover, the ECOST study showed cost-effectiveness in the context of the French health insurance system. In the Czech Republic, the authors of a cost analysis study on HM in patients with an ICD also reached the same conclusion [15].

The effect of the degree of understanding on the acceptance of the HM system

The results of our study indicate that patients over 80-years-of age were unlikely to have adequate information about all the benefits of remote monitoring of their CIED. They often mistakenly thought that HM was used for 24-hour monitoring of their clinical condition (emergency surveillance) and were often completely unaware of the potential of HM to positively affect their health. It is perhaps safe to assume that it was, in fact, the ignorance of the clinical benefits of remote monitoring that led approximately one-tenth of the patients in both of our study groups to prefer more frequent ambulatory follow-ups. The French study EUDCAT (included patients aged 63.9 ± 12.8) found that the degree of understanding of remote monitoring systems was directly linked to the degree of acceptance [16]. EDUCAT was also the first observational study to show that the degree of overall understanding of HM was closely related to the patient's age and confirmed the importance of comprehensive education and training during the introduction of HM into the patient's daily life. However, so far, there have been no studies looking specifically at patients over 80-years-of age, with the goal of addressing the potential concerns and problems of this age group. The steadily increasing population of those over 80-years-of age is often overlooked, but changing demographics and the ever-increasing average age of patients should compel us to give consideration to their needs as they are related to medical technology, and as in this study, remote monitoring [17].

Health benefits of the HM system from the patient's perspective

The main finding in our study was that even patients aged 80+appreciated the remote monitoring system. During the survey, they often emphasized that they were delighted to have the opportunity to use modern technologies, which had not been (made) available to them in the past. However, almost every patient said that they relied on their family to help them understand the HM information brochure provided post-discharge. The patients in our study admitted that they did not understand the technical details of data transfer, but they were happy that everything seemed to work well, and that it gave them a sense of security. In light of some of the educational failures, it was to be expected that only 2% of the patients were fully aware of the HM system's health benefits, and 43% of the patients failed to see any clinical benefits of HM.

The European Society of Cardiology (ESC) stated in their 2016 guidelines for heart failure that a high portion of deaths among patients with heart failure, especially those with milder symptoms, occur suddenly and unexpectedly [18]. ICDs provide both effective prevention of bradycardia and correction of potentially lethal ventricular arrhythmias. These same guidelines for heart failure management also state that patients should be included in multidisciplinary care programs designed to reduce the risk of rehospitalization and all-cause mortality. These guidelines literally emphasize, in the context of telemedical care (class of recommendation IIb, level of evidence B), that automatic, daily multiparameter CIED monitoring using an HM system should now be actively recommended to patients with chronic heart failure and, therefore, should become the standard of care for these patients.

One of the reasons to implement HM systems is to enable patients to live a full life of as high a quality as possible with a minimal sense of limitations, for example, the need for frequent ambulatory follow-up visits [19]. The patients we studied also appreciated the added sense of safety and security (55%) HM brought them. Many patients also reported that they found "the green light" on the HM unit comforting, in that the indicator light gave them a sense of safety. They believed that if the light was on, they were all right.

Patient education and sources of information

Our findings show that although patients were educated by a doctor before discharge and received an HM information brochure, almost 10% of them subsequently looked for additional information. Even though our patients were over 80-years-old, they reported looking for additional information on the internet. They also sought more information from other specialist doctors or people they knew. Interestingly, more than half of the patients look for more information out of pure curiosity. Others wanted to have more information to supplement the information given during discharge, which may have been insufficient due to time constraints.

The fact that almost 100% of patients received some education in the hospital after implantation procedure before discharge was in a sharp disparity with the general level of understanding and knowledge of what kind of clinical benefits the HM system can add on top of the presence of CIED alone. This area is where the role of the nurse-educator comes into use–nurses can instruct patients on the use and care of the HM systems and educate the patient's family, both before device implantation and after discharge from the hospital. Nurses can work with each patient individually and take the time needed to fully educate them on HM. This type of nursing position (i.e. heart failure nurse or clinical nurse specialist) is commonplace in clinical and nursing practice in Western European countries, much like the echocardiography specialist or nurse-specialist in anticoagulation therapy. Unfortunately, no system for education and implementation of nurse competencies has been created that would lead to the creation of the nurse-specialist position in the Czech Republic. Therefore, remote monitoring system education falls on doctors, who must give patients the required information about remote monitoring in a minimal amount of time. It can be assumed, especially in patients over 80-years-of age, that more time is needed for proper patient education if we want them to fully understand the function and benefits of remote monitoring systems. Based on the results of our study, we have created a nurse-led educational program aimed at the most common issues of living with CIEDs that are being followed remotely and also on the impact of HM technology on the patient´s life and clinically relevant events. This education is based on nurse-led verbal communication with all patients using remote monitoring, handed-out brochure summarizing the main advantages of the HM system, and a short video available on YouTube (https://www.youtube.com/watch?v=QwBcZ_Ne144&feature=youtu.be, in the Czech language). We are now running a trial evaluating the impact of this specific education approach.

The relation between the "degree of understanding" and patients´ concerns

In our study, 5% of patients with a PM and 3% of patients with an ICD were afraid of using HM for the first time. This could have easily been the result of insufficient education. The previously mentioned EDUCAT study noted that approximately 50% of patients with an ICD had depression or anxiety caused by chronic disease as well as the knowledge that they were at risk of life-threatening arrhythmias or sudden cardiac death [16,20]. Another source of panic disorders or anxiety in the majority of these patients was the knowledge that there is a continuous risk of an unexpected electrical discharge, either appropriate or inappropriate [21,22].

The few PM patients in our study who did not trust HM reported that they were not sure whether their remote monitoring system was working because they had no feedback, even though the green light on the HM unit was on. On the other hand, our patients with an ICD reported a sense of foreboding "something bad would happen," relative to a potential failure of the patient HM unit or their ICD. While remote monitoring has become the preferred standard of ICD follow-up, its effect on the mental state of patients and the extent of education needed to help offset some of these concerns, especially in patients older than 80-years-of age, is not well known [23]. We believe that establishing patient trust in the remote monitoring system is the first step towards full acceptance of this modern technology. Again, there is enormous potential for nurses in this area. Nurses can educate patients in both groups; they can also be more proactive with patients and provide post-discharge care as needed. Nurses can also facilitate regular contact with patients and, if needed, provide more information about remote monitoring technology, or answers questions that might stem from its daily use. In this sense, it might also help those patients who want more contact with a health professional as a social event.

Study strengths and limitations

To our knowledge, this is the first study to evaluate the general acceptance of RM systems in the elderly population with CIEDs that focused on the daily application of this kind of telemedicine. Another strength of our study is the mixture of patients with both ICDs and PMs, giving the most complex picture of their fears, hopes, and possible expectations. The study highlights the necessity of a proper education process that focuses on telemonitoring and the potential for this process to be performed by specially educated nurses. The weak point of the trial is that it explored only patients already actively using the HM system, which included only patients who were deemed mentally capable of handling and accepting HM based on their pre-implantation screening. However, (1) these would be the patients most likely to use remote systems in daily clinical practice, and (2) even this presumably highly compliant population of 80+patients showed significant misunderstandings regarding HM technology. If the technology is to be offered to all-comers, the problems associated with a lack of understanding and inadequate education would most likely be even more pronounced. Not all 80+patients from our database were included; however, we strongly believe that the almost 90% of patients that were included, constitute a robust body of evidence capable of offsetting any bias towards our conclusions. Last, due to the absence of any standardized questionnaires, none were used.

Conclusion

Home Monitoring systems are well accepted, even in patients over 80-years-of age. Potential psychological stress appears to be exclusively a result of patients not fully understanding the system and its functions. In our patients, the primary source of information about telecare came from a doctor working in a specialist implant facility. Even though most patients may not have understood the specific clinical benefits of the Home Monitoring system in terms of their health, they nevertheless accepted it and viewed it very positively. These results show a need for improved education of remotely monitored CIED patients not only during the initial learning phase, which usually occurs during hospitalization but also during follow-up care. This is the area where we see a clear opportunity for technicians or nurse-specialists educated in telemedicine to provide supplemental information, while also making sure each patient fully understands the information they were given.

Recommendations

The authors advocate for the creation of a specific nurse-led educational program aimed at remote technologies used for the daily multiparametric follow-up of PMs and ICDs. The senior nurse, educated in all different types of telemonitoring as well as considerable experience regarding everyday use, should run such programs. These programs should mainly include information on device start-up, everyday care of patients' units, common technical problems, and FAQs. The clinical benefits of the RM systems should be thoroughly explained. This would eventually lead to greater adherence to their usage. Multimodal educational approaches (personal communication, brochures, educational video available on the Internet) should always be used for better learning and memorization. The nurse should also be ready to answer all subsequent questions that patients have during the life-long time of their devices, including malfunctions, inappropriate therapy, and other technical issues, in conjunction with the doctors dealing with the ambulatory CIEDs follow-ups.

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Conflicts of Interest

The authors report no conflicts of interest. The authors alone are responsible for the writing and content of this article.

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