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Remote Monitoring of Implantable Pacemakers: In-Office Setup Significantly Improves Successful Data Transmission

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ABSTRACT

Background: Remote wireless follow-up of implanted pacemakers (PM) has become an attractive method of follow-up. Although wireless PM follow-up has several advantages compared with transtelephonic and office-based follow-up, its utility depends on successful transmission.

Hypothesis: Initial in-office setup of wireless PM will improve transmission rate as compared with home setup.

Methods: A total of 202 consecutive patients from 2 medical centers were included in this retrospective study. Patients in the home setup group (N = 101) had traditional home setup of wireless PM, whereas patients in the in-office group (N = 101) had setup of PMs by allied health professionals during the postoperative office visit. Successful transmission was defined as successful initial wireless transmission of PM data by 2 months postimplant.

Results: Of the 101 patients in the home setup group, 22 (22%) patients had successful transmission. Of the 101 patients in the in-office group, 92 (91%) patients had successful transmission ($P < 0.0001$). Logistic regression analysis showed that that the in-office group was independently associated with successful transmission (odds ratio: 114.5; 95% confidence interval: 32.1-408.4; $P < 0.0001$).

Conclusions: In patients implanted with PM capable of remote wireless data transmission, initial home setup of the wireless monitoring device was frequently unsuccessful. In-office PM setup was associated with a significantly higher rate of successful transmission.

Introduction

Cardiovascular implantable electronic devices (CIEDs) include implantable cardioverter-defibrillators and pacemakers (PMs). Follow-up of CIEDs can be office-based or remote. Remote follow-up include transtelephonic and wireless transmissions of device data. Transtelephonic transmission of PM data has been used clinically since 1971.[1] However, it provides only basic information such as battery status (based on paced rate that is different and elective replacement indicator rate with magnet application), capture and sensing, and limited electrocardiogram rhythm strip. Although these data are helpful, they are insufficient for optimal clinical care.

Until recently, remote wireless follow-up has been available only for implantable cardioverter-defibrillators but not PMs.[2–5] Although wireless PM follow-up is feasible and has several advantages compared with traditional transtelephonic follow-up, the rate of successful wireless transmission is unknown.[6–10]

Wireless PM transmission can occur only after synchronization (pairing) of the implanted PM with the external transmitter unit, which is usually performed at home as recommended by the device manufacturer. In clinical practice, however, we encountered unsuccessful initial wireless transmissions from several patients. Therefore, we sought to examine the rate of successful wireless transmissions among patients with newly implanted PMs and hypothesized that initial in-office setup of wireless PMs will improve wireless transmission.

Methods

This was a retrospective study of 202 consecutive patients implanted with the Accent RF PM (St. Jude Medical, St. Paul, MN) from 2 centers (Kaiser Permanente Medical Center at Redwood City, CA and at San Jose, CA). Patients

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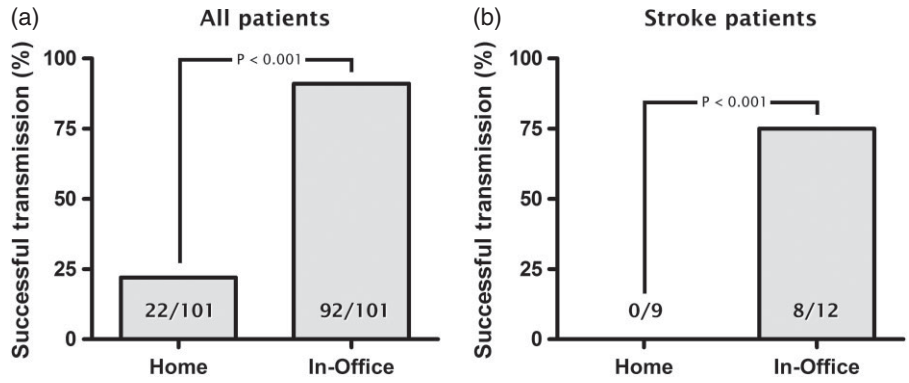

Figure 1. (A) Comparison of successful remote transmission rates (within the first 2 months) between the home setup and the in-office setup groups. (B) Comparison of successful remote transmission rates (within the first 2 months) in patients with a prior stroke, between the home setup group (n = 9) and the in-office setup group (n = 12).

were divided into 2 groups: home setup and in-office setup. The Accent RF PM is capable of remote wireless transmission using existing telephone landline or optional cellular adapter. Conventionally, after implantation of the PM, patients receive a home transmitter unit shipped from the manufacturer with written instructions and a DVD on how to pair the PM. The pairing process begins with manually turning on the transmitter unit and plugging it into an analog telephone jack. After the monitor has "booted up," it begins to beep. The start button is then pressed and held for 5 seconds while the monitor is positioned within 2 feet of the PM. The "read" icon will light up as the transmitter pairs with the implanted PM. Thereafter, pairing information is automatically sent to the monitoring center of the manufacturer, and the beeping stops. Only after successful pairing can wireless transmission and monitoring occur.

Since June 2011, after a series of failed wireless transmissions, PM allied health professionals at the 2 centers began pairing remote wireless PM transmitters at the 1-week postimplant office visit (in the manner recommended by the device manufacturer). Patients in this group were categorized as in-office. Patients in the home setup group (prior to June 2011) had traditional home setup of wireless PM transmitters by patients or their proxy as suggested by the device manufacturer (after receiving their wireless transmitters by mail between 7 to 10 days postimplant). These patients also attended the 1-week postimplant office visit. Patients in both groups received routine teaching about the wireless PM unit by allied health professionals prior to device implant. Thus, the home setup group consisted of all wireless PM patients prior to June 2011, and the in-office group consisted of all wireless PM patients after June 2011.

Clinical data were obtained by review of the electronic medical record (EMR). The Kaiser Permanente EMR system (Epic HealthConnect; Epic Systems Corp., Verona, WI) is an integrated system that includes progress notes, operative reports, discharge summaries, diagnoses, and problem lists. Coronary artery disease, diabetes mellitus, hypertension, hyperlipidemia, atrial fibrillation, heart failure, and stroke were recorded for each patient if the condition was present. Pacing indication, device, and mode of function were recorded based on information at the time of PM implant.

The primary outcome was successful initial transmission, defined as successful wireless transmission by 2 months postimplant. We chose the 2-month time point to account for variations in receipt of the wireless monitor unit, which typically occurs within 1 month. In cases of unsuccessful transmission, we spoke with each patient for possible causes, and a final determination was made by the study investigators. A χ^2 test was used to determine statistical differences in baseline characteristics and transmission success. For univariable analyses, 95% confidence interval (CI) was calculated by the binomial exact method. Logistic regression was used to determine independent predictors of successful transmission.

The study protocol was approved by the Kaiser Permanente Northern California institutional review board with waiver of informed consent.

Results

A total of 202 patients were included in the study. The Table 1 shows the baseline characteristics of patients. The mean age was 77 years, and the majority of patients had multiple medical comorbidities. Patients in the 2 groups were similar except for a higher prevalence of diabetes mellitus (39.6% vs 25.7%, $P = 0.036$) and lower prevalence of dual-chamber pacing mode (71.3% vs 83.2%, $P = 0.044$) in the home setup group.

Of the 101 patients in the home setup group, only 22 (22%) patients had successful transmission (95% CI:14%-31%). Of the 101 patients in the in-office group, 92 (91%) patients had successful transmission ($P < 0.0001$, 95% CI: 84%-96%) (Figure 1). Reasons for unsuccessful transmission in the control group included not opening the transmitter package (34 patients), inability to complete the pairing process (39 patients), and lack of landline telephone access (6 patients). Patients who did not open the wireless transmitter package either could not remember that it was part of the wireless PM system (N = 15) or were afraid that it may interfere with the PM (N = 19). Inability to complete pairing was mostly due to fear that pairing would interfere with the PM (N = 30). For example, 29 patients who were unable to complete the pairing process unplugged the wireless unit after hearing a normal electronic tone emitted by the

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Table 1. Baseline Characteristics.

Variable	In-Office Setup, N = 101	Home Setup, N = 101	*P* Value
Age, y	76.3 ± 11	78.2 ± 12	0.258
Male gender	61 (60.4%)	59 (58.4%)	0.774
Medical history			
Hypertension	78 (77.2%)	82 (81.2%)	0.488
Hyperlipidemia	67 (66.3%)	74 (73.3%)	0.283
Diabetes mellitus	26 (25.7%)	40 (39.6%)	0.036
Atrial fibrillation	44 (43.6%)	44 (43.6%)	1.000
Coronary artery disease	35 (34.7%)	34 (33.7%)	0.882
Heart failure	20 (19.8%)	24 (23.8%)	0.495
Stroke	12 (11.9%)	9 (8.9%)	0.489
Indication for pacemaker			
Atrioventricular block	49 (48.5%)	59 (58.4%)	0.158
Sinus node dysfunction	47 (46.5%)	36 (35.6%)	0.116
Bradycardia	5 (5.0%)	6 (5.9%)	0.757
Pacing mode			
DDD	84 (83.2%)	72 (71.3%)	0.044
VVI	17 (16.8%)	19 (18.8%)	0.713
Other	2 (2.0%)	7 (6.9%)	0.088

Abbreviations: DDD, dual-chamber pacing; VVI, ventricular pacing.

wireless transmitter as part of the pairing process. Thus, these patients effectively aborted pairing before completion. When the wireless unit was brought to the office, all 29 had normal function and were successfully paired with the PPM. Reasons for unsuccessful transmission in the in-office group included lack of landline telephone access (7 patients) and defective wireless monitor (2 patients). Because patients with a history of stroke may have cognitive or motor deficits that prevent successful transmitter setup, we examined transmission rate in this population. Among 21 patients who had a history of stroke, 0 of 9 patients in the home setup group were able to transmit (95% CI: 0%-34%), whereas 8 of 12 in the in-office group had successful transmission ($P = 0.002$, 95% CI: 35%-90%) (Figure,1B)

Logistic regression analysis showed that that the in-office group was independently associated with successful transmission (odds ratio [OR], 114.5; 95% CI: 32.1-408.4; $P < 0.0001$) after adjusting for all variables given in the Table 1 . In addition, patients with a history of stroke were less likely to have successful transmission (OR: 0.052; 95% CI: 0.01-0.28; $P = 0.001$), after controlling for all variables in given the Table 1.

Discussion

To our knowledge, our study is the first to examine the rate of successful transmission in wireless PM patients. We found that the traditional home setup of a wireless transmitter, as recommended by the manufacturer, results in exceptionally poor transmission rates in patients implanted with a remote wireless PM. Furthermore, patients with a history of stroke may have particular difficulty with transmission. In-office pairing of PM is associated with a substantial improvement in transmissions. These findings suggest that in-office setup of wireless PM may result in more effective patient follow-up.

Because wireless transmitters are mailed to patients 1 to 2 weeks postimplant by the device manufacturer, pairing it to the implanted PM has been traditionally performed at home by patients or their proxy. Several obstacles can occur in this workflow that can lead to failed transmission. We found that many patients simply did not open the package containing the transmitter because of fear that pairing would interfere with the pulse generator. Other patients aborted the setup after hearing the normal electronic tone generated by the transmitter during the pairing process. These events occurred despite routine teaching about the wireless PM unit by allied health professionals preimplant. Schoenfeld et al found a significantly higher rate of successful transmission in their study.[4] Several factors can account for this difference. First, they studied patients with implantable cardioverter-defibrillators. Remote event detection in these patients is generally considered critical and a standard of care. Thus, successful transmission is emphasized more strongly by patients and clinicians. Second, their study excluded patients without landline telephone access. Third, patients in their study were required to contact the device technical support center for feedback after each transmission, thereby enabling immediate troubleshooting. Our study did not have this requirement. Finally, the mean age in their study was 64 years, which is much younger than our study.

In patients with prior stroke, transmission rate was particularly poor in the home group. Several reasons may account for this. First, stroke patients may have language or cognitive deficits, making home pairing difficult. Second, motor deficits might interfere with physical setup of the wireless unit. Finally, stroke patients may be more likely to reside in chronic nursing or assisted-living facilities and have less support for proper transmitter setup. Thus, it may be reasonable to consider in-office pairing of wireless PM even more strongly in this population.

Prior studies have found that wireless CIED systems enabled increased detection of clinically important arrhythmias.[3,6–9] Furthermore, remote wireless PM monitoring has been shown to significantly lower the number of ambulatory visits during long-term follow-up.[10] These published studies suggest that remote wireless PM monitoring is an attractive method of follow-up. The 2008 Heart Rhythm Society and European Heart Rhythm Association expert consensus on the monitoring of CIEDs state that outpatient remote PM follow-up can replace routine office visits.[11] These recommendations, however, are likely based on the assumption that the majority of patients can successfully transmit data wirelessly. Our study shows that home pairing of remote PM (the standard of care for remote wireless PM patients) may not be reliable. Extrapolating data from the study by Crossley et al, our 22% transmission rate would translate to missing 211 of 271 clinically actionable events

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in 602 patients over 1 year.[7] By employing in-office pairing, successful transmission improved substantially because we were able to both overcome patients' fears about pairing and provide more education about their wireless PM during the pairing process.

Our study has strengths and limitations. Study strengths include simple study end points and thorough chart review facilitated by a robust electronic medical records system. Study limitations include the retrospective study design, relatively small sample size, short follow-up, and use of PM clinic with allied health professionals. We chose the 2-month time point for successful transmission to account for variations in receipt of the wireless monitor unit. In clinical practice, all patients had office visits at 3-months postimplant, and causes for unsuccessful transmissions would have been rectified. Another potential limitation is the increased prevalence of diabetes mellitus in the home setup group, as diabetic retinopathy may impair proper device pairing. However, the home setup group had only 1 additional diabetic patient with retinopathy, which unlikely affected the result. Another potential limitation is our practice setting, which consisted of physicians and allied health professionals. Although a PM clinic with allied health professionals was optimal in both device pairing and patient education, wireless device pairing by physicians may be too time intensive and thus not be feasible in PM clinics without allied health professionals. In addition, our study patients were elderly and may be prone to memory deficits and discomfort with technology. Younger patients undergoing PM implant may have higher transmission rates. Another potential limitation is that home setup may have increasing successful transmission over time simply because of improved patient teaching, thereby reducing the difference between the home and in-office groups. However, we consistently provided thorough teaching in a standard fashion to both groups, making this limitation less likely. Nonetheless, our study demonstrates the potential limitation of the remote wireless PM system and describes a method to overcome this limitation. Finally, our study is applicable to only 1 model of 1 manufacturer, and the results may not be applicable to other models or manufacturers. At the time of the study, there was only 1 manufacturer in the United States with a remote wireless PM system.

Conclusion

In patients implanted with a remote wireless PM, the initial home setup of the wireless monitoring device was frequently unsuccessful, with less than one-fourth of patients completing transmission within the first 2 months. The in-office PM setup was associated with a significantly higher rate of successful transmission. Careful patient selection is probably indicated to maximize the utility of remote wireless PMs. Furthermore, larger randomized studies may be helpful to confirm the findings of the current study.

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