

Clinical application of remote monitoring in post-pacemaker implantation follow-up.

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Abstract

This study aims to evaluate the clinical application values of Remote Monitoring (RM) in post-pacemaker implantation follow-up. A total of 105 patients implanted with Dual-Chamber Pacemaker (DCPM) in our hospital were divided into the HM group (n=59, implanted the HM system, Biotronik, German) and the control group (group N, n=46). The Average Outpatient Follow-Up Times (AOFT), alarm events, all-cause mortality, stroke rate, cardiogenic readmission rate, arrhythmia, and heart functions between the two groups within 12 mon after the implantation were then compared. The follow-up lasted 359.21 ± 17.23 d, and 26452 pieces of data were accumulatively obtained by the HM system network center, including daily data alarm events (n=813), among which "Missing messages>7 d" accounted for 37.98%, and "mode switching" accounted for 20.83%. Compared with group N, AOFT of each patient in group RM was significantly less ($P<0.01$); the patients with new-onset stroke or re-admitted were less ($P<0.05$); the patients with new-onset atrial fibrillation were more ($P<0.05$); the patients with NYHA III were less ($P<0.05$), but the mortality, patients with new-onset atrial tachycardia, ventricular tachycardia, or ventricular fibrillation, and LVEF showed no significant difference. RM could be safely and effectively applied in following up the DCPM patients, and could effectively reduce the outpatient follow-up times, detect asymptomatic arrhythmic events, effectively reduce the occurrence of cardio-cerebrovascular events through timely intervention, and improve heart functions and readmission risk.

Keywords: Remote, Pacemaker, Follow-up.

Accepted on May 11, 2017

Introduction

Cardiac pacing is one therapeutic method using low-energy electrical pulses to temporarily or long-termly stimulate the heart so as to produce action potentials and to achieve systole. In recent years, with continuous developments of cardiac pacing technologies and further researches about the mechanisms of arrhythmia, cardiac pacing indications have also been continuously developed, and the implantation of Pacemaker (PM) has gradually become an important treatment means, and been increasingly accepted by patients. The increased amount of PM implantation increases cardiac outpatients [1], and due to its special working features, regular follow-up would be particularly important. The origin of remote monitoring [2] and the application of the first pacemaker-telephone transmission monitoring system [3,4] had made Home Monitoring (HM) much more important after pacemakers were implanted. HM could determine the operating parameters and understand patients' clinical conditions through evaluating basic PM parameters [5], thus providing real-time monitoring and whole-procedure tracking

in early detecting abnormal alarm events and preliminarily testing asymptomatic events [6], providing evidence for reducing the time management and treatment of patients with atrial arrhythmia [7], reducing clinic visits, hospitalization times, and patients' cost [8-10], together with saving resources and assessing health outcomes in advance [11], as well as achieving the requirements-based follow-up, increasing patients' postoperative safety, and reducing the workload of clinicians. It plays important roles in as-soon-as-possibly dealing with adverse situations. This study analysed the clinical applications of HM-PM in postoperative follow-up through comparing it with conventional pacemakers.

Methods

Subjects

105 patients implanted DCPM in our hospital from September 2013 to May 2015 were selected, and randomly divided into the non-RM group (group N) and the RM group. This study was conducted in accordance with the declaration of Helsinki.

This study was conducted with approval from the Ethics Committee of Wuhan University. Written informed consent was obtained from all participants.

Inclusion criteria: 1) Aged 18-80 y old, suffered from atrioventricular block, sick sinus syndrome, or sinus bradycardia, in levels I-III of NYHA, and could complete the follow-up in accordance with the requirements; 2) implanted the DCPM with or without home monitoring function (Biotronik, Germany), and the surgery succeeded immediately; 3) signed the informed consent, could master the purposes and usage of the RM system, which was put to use within 72 h after the surgery, and the RM network center could receive the patient's information. **Inclusion criteria:** age between 18 y and 80 y old, who diagnosed as atrioventricular block, sick sinus syndrome or sinus bradycardia, and were implanted artificial cardiac pacemaker. **Exclusion criteria:** 1) with non-reversible causes resulted ventricular fibrillation or cardiac arrest caused by unstable hemodynamics-resulted sustained ventricular tachycardia; 2) with organic heart disease-associated spontaneous sustained ventricular tachycardia, regardless of stable or unstable hemodynamics; 3) unexplainable syncope, and cardiac electrophysiology revealed sustained ventricular tachycardia or ventricular fibrillation that could induce hemodynamic instability; 4) in level IV of NYHA, and could not tolerate the surgery; 5) suffering from mental diseases; 6) Self-monitoring.

Table 1. Home monitoring network alarm parameters setting.

Device	Patient options applied
Yellow	Missing messages>7 d
Yellow	Mode switching exceeding the preset threshold>20 times/d
Red	Regular intracavity ECG
Yellow	P wave<50% of safe value
Yellow	Ventricular rate exceeding the preset threshold
Yellow	Mode switching exceeding the preset threshold>10%/d
Yellow	Ventricular premature contraction exceeding the preset threshold>100 times/h
Yellow	Invalid right ventricular pacing threshold
Yellow	Ventricular pacing threshold exceeding the preset threshold>30%
Yellow	Right ventricular pacing threshold exceeding the preset threshold>3.0 V
Yellow	R wave<50% of safe value
Yellow	Atrial load exceeding the preset threshold>5%

Follow-up and observation indexes

Each patient with RM was performed remote real-time network-monitoring *via* the home monitoring center, and if any abnormalities were found, the patient would receive phone call to guide the intervention, and clinic follow-up at any time if necessary; if no special alert occurred, each patient should be clinically followed up in the 3rd and 12th month. The patients in group N were performed regular clinical follow-up in the 1st,

PM selection

Pacemaker models: The patients in group RM were randomly one of the three models (Estella DR-T, EviaDR-T, and Philos II DR-T, Biotronik) and open the functions of HM; the patients in group N were randomly implanted one of the three models (Estella DR, Evia DR, and Philos II DR, produced by the same company while without RM function).

Composition and settings of RM

The RM system consisted of three parts. 1. The mobile terminal (Cordio Messenger CM), 2. GSM network and 3. Network Service Center. The RM-PM had one built-in antenna and independent medical bands, so each patient would have a mobile phone-like CM, which could monitor the working conditions of PM as long as the CM was within 20 cm to 2 m of the patient; any abnormalities would be immediately send out *via* the GSM network to the specialized service center, and the doctors in charge and the patient's family members would also be informed in different ways, including telephone, short messages or emails; since some old people could not be connected by mobile phone or internet, the relatives would be connected. The alarm setting parameters of the RM network referred to Table 1 (Home Monitoring network alarm settings).

3rd, 6th, and 12th month (The follow-up included the time, alarm event, mortality rate, incidence of stroke, readmission rate, arrhythmia, echocardiography and 6 MWT).

The average follow-up times of each patient, number of death, number of new-onset stroke, number of cardiogenic readmission, and cardiac functions (level of heart function by NYNA, LEVF (%), left ventricular end-diastolic diameter

(LVEDD, mm), and 6 MWT) between the two groups within 12 mon of the implantation were then analysed and compared.

Statistical analysis

SPSS19.0 statistical software was used for the data analysis. The measurement data that met or approached normal distribution were expressed as mean ± standard deviation; the intergroup comparison of measurement data used the t test; the count data were performed the χ² test or the Fisher exact rate test, with P<0.05 considered as statistically significant.

Results

A total of 105 patients were collected, with 59 and 46 patients divided into group RM and N, respectively; one patient in group RM refused to use RM or telephone follow-up due to extreme anxiety 4 mon after the PM implantation. Eventually, 105 patients were enrolled.

General situation

The comparison of preoperative basic information between the two groups showed no significant difference (P>0.05), so these two groups were comparable, Table 2.

Table 2. Comparison of basic information between the two groups (x ± s, %).

Group	RM	N	P
N	59	46	
Age (y)	72.22 ± 7.33	69.83 ± 7.41	0.079
M	30 (64.5)	26 (59.43)	0.311
Hypertension	19 (36.80)	17 (41.91)	0.565
Diabetes	13 (16.78)	10 (20.95)	0.514
CHD	31 (66.65)	35 (75.12)	0.356
N	59	46	
Post-stenting	11 (18.15)	8 (11.23)	0.432
Atrial fibrillation (Af)	0 (0)	2 (2.51)	0.513
Atrial or Ventricular premature contraction (AV)	6 (15.43)	4 (12.43)	0.771
LVEF	58.93 ± 8.71	58.29 ± 8.65	0.885
LVEDD	52.26 ± 6.15	53.47 ± 6.89	0.16
NYHA I	30 (59.63)	23 (53.83)	0.491
NYHA II	14 (30.12)	17 (33.81)	0.789
NYHA III	4 (11.35)	8 (13.43)	0.896
6 MWT	445.51 ± 67.97	439.54 ± 75.12	0.753

AF: Atrial Fibrillation; AT: Atrial Tachycardia; VT: Ventricular Tachycardia; LVEF Left Ventricular Ejection Fraction; LVEDD: Left Ventricular End-Diastolic Diameter; 6 MWT: 6 Minutes Walking Distance.

Follow-up

The follow-up lasted 359.21 ± 17.23 d, and a total of 26452 pieces of information was collected through the RM system, 813 pieces of alarm event prompts, among which the alarm of "Missing messages for more than 7 d" ranked the maximum number, accounting for 37.98%. The telephone follow-up revealed that most cases were caused by "not timely charging the CM machine-caused system shutdown and no signal"; furthermore, a small number of patients did not carry the CM machine in their daily outdoor activities, and some patients turned off the machine in the daytime while only turned it on at night. Three patients reported the malfunction of their CM machine in the telephone follow-up, and after inspected by the manufacturer's technicians, it was found that the machine could work normally, so the patients were told to maintain adequate electric quantity of the machine; after restarted the machine, data could be normally received. Mode switching exceeding the preset threshold>20 times/d were 157 pieces, which took 21.92% and the specific alarm events were summarized in Table 3.

The results showed that: the average follow-up times of each patient in group RM were significantly lower than group N (P<0.01); the cases of cardiogenic readmission in group RM were fewer than group N (P<0.05); the cases of atrial fibrillation detected in group RM were more than group N (P<0.05); LVEDD in group RM was reduced than group N (P<0.05), which meant cardiac function improvement; the cases with NYHA III in group RM were less than group N (P<0.05); the death rate, detection of atrial tachycardia, ventricular tachycardia, and ventricular fibrillation, LVEF, and cases with NYHA I, II, and III showed no significant difference (Table 4). The results of 6 MWT in both groups were significantly increased than those before the surgery (P<0.01), and the improvement in group RM was better than group N (P<0.05) Table 5.

Table 3. Summary of alarm events reported by the RM network.

Alarm event	Pieces	The number of cases
Missing messages>7 d	296	18
Mode switching exceeding the preset threshold>20 times/d	157	31
Regular intracavity ECG	110	56
P wave<50% of safe value	50	6
Ventricular rate exceeding the preset threshold	47	36
Mode switching exceeding the preset threshold>10%/d	28	3
Ventricular premature contraction exceeding the preset threshold>100 times/h	18	18

Invalid right ventricular pacing threshold	15	2
Ventricular pacing threshold exceeding the preset threshold>30%	11	5
Right ventricular pacing threshold exceeding the preset threshold>3.0 V	8	3
R wave<50% of safe value	5	4
Atrial load exceeding the preset threshold>5%	2	2

Table 4. Follow-up results ($x \pm s$, %).

Groups	RM	N	P
N	59	46	-
Death	0	0	-
Unscheduled visits(Unplanned visits)	5	27	
Average follow-up times of each patient	2.08 \pm 1.05	4.10 \pm 0.79	0.001
Cardiogenic readmission	1 (2.5)	6 (15.6)	0.045
AF	11 (24.5)	2 (5.24)	0.023
AT	21 (53.8)	16 (42.1)	0.303
VT	4 (25.3)	3 (20.4)	0.515
LVEF	61.22 \pm 6.88	57.43 \pm 6.99	0.047
LVEDD	52.30 \pm 6.74	56.34 \pm 5.71	0.023
NYHA I	13 (33.33)	10 (26.32)	0.501
NYHA II	24 (61.54)	21 (52.63)	0.44
NYHA III	1 (2.59)	7 (16.0)	0.042
NYHA IV	1 (2.6)	2 (5.26)	0.541
6 MWT	466.64 \pm 57.34	435.25 \pm 74.69	0.013

AF: Atrial Fibrillation; AT: Atrial Tachycardia; VT: Ventricular Tachycardia; LVEF Left Ventricular Ejection Fraction; LVEDD: Left Ventricular End-Diastolic Diameter; 6 MWT: 6 Minutes Walking Distance; CHD: Coronary Heart Disease.

Table 5. Comparison of 6MWT before and after the surgery ($x \pm s$, m).

Group	N	Before	After	p
RM	59	436.51 \pm 70.01	466.64 \pm 56.34	0.002
N	46	432.84 \pm 74.22	435.25 \pm 74.69	0.003
P		0.734	0.013	

Discussion

With the developments of medical technologies, the usage of implantable cardiac pacemakers has been increased year by year, but some patients' follow-up could not be guaranteed due to many reasons such as distance, time, etc. so the loss rate is high [12]. In order to prevent the phenomenon of emphasizing the implantation while ignoring the follow-up, pacemakers with remote monitoring have undoubtedly become the best choice for outpatient clinicians to reduce unnecessary follow-

up [13]. The fixed daily event transmission of the RM system (Biotronik, Germany) could effectively improve the reference of event detection, so the detection rate of early asymptomatic clinical events would also be increased. Many studies had reported the clinical benefits of this RM system when applied matching with implantable cardiovascular devices [14], and the degree of satisfaction could be as high as 96.3% [15]. Compared with other remote monitoring devices, Biotronik's RM was relatively simple and easy to understand, so no complicated operation would be required by patients, and the remote monitoring had been proven safe and effective [16].

Among the alarm events collected by RM in this study, the reason ranking the first place was the "Missing messages", accounting for 37.98% of the total alarm events, exhibiting bigger difference from other large-sample studies [17], which might be caused by the patients' insufficient understanding of the functions and roles of this system, as well as insufficient understanding of the benefits that could be produced. Meanwhile, such reasons that many patients needed to travel frequently, did not want others to know their disease, or inconvenient carrying, could also not be ruled out; these patients could not carry the CM device with them constantly, or could not charge the device in time. The latest mobile terminal "Cardio Messenger Smart 3G" had been available in Japan in May 2015, which was equipped with a new-generation rechargeable built-in battery so as to facilitate patients' carrying during their daily activities or travel, as well as to ensure the continuous daily monitoring and patients' life convenience. The alarm event ranking the second place was the "mode switching"; according to the preset pacemakers, when the heart rate was >160 beats/min, the PM mode would automatically switch from DDDR to DDIR in order to prevent over-rapid atrial rate and subsequent ventricular rate. In this study, HM had at least one alarm of "mode switching, and the patients with frequent occurrence were all contacted by their chief doctors for clinic follow-up, among who 21 patients were diagnosed as paroxysmal atrial tachycardia, 11 as paroxysmal atrial fibrillation, and only one patient exhibited obvious symptoms of heart palpitations; the patients that occurred atrial fibrillation had all been applied timely and early intervention with antiarrhythmic drugs. Guedon et al. [17] reported that the incidence of atrial fibrillation among the HM-alarm events was 22.9%, and among the 141 patients, the new-onset cases were 58; in this study, the incidence of atrial fibrillation was 23.1%, close to the above study and better than group N. The roles of HM for arrhythmia lie in early diagnosis and early intervention, and the diagnostic time of arrhythmia by HM could be four months ahead of ordinary PMs [18]. Another study found that compared with traditional follow-up, remote follow-up reduced the clinical decision time by doctors from 36 d to 2 d [8]. Through the Internet, chief doctors would need only 1.1 min/d to monitor 100 patients with HM-PM [19], indicating that HM could bring the benefits of treatment time for both the clinicians and patients, so the clinicians would have enough time for the early symptomatic intervention, thus reducing such related complications mainly as arrhythmias,

especially atrial arrhythmia-atrial fibrillation-, induced stroke [20].

There's one study included 628 cases who have implanted dual chamber pacemaker showed that 141 cases (22.5%) had more than one atrial fibrillation event within 180 d, which was 58 d earlier than predicted; 38 cases (27.0%) have more than 10% atrial fibrillation events within 30 d, and 27 cases (14.9%) left until 180 d with significant difference ($P < 0.05$). During the 180 d follow-up, the atrial fibrillation load was decreased from 12.9% to 2.5% in 141 subjects, with the significant difference after 130 d post-surgery. 433 patients were followed up for 27 months, the results showed that the home monitoring system reduced the risk of inappropriate shocks in 52% patients, and reduced the risk of re-hospitalization in 72% patients because of inappropriate shocks [17]. In addition, the home monitoring system reduced the ICD battery charge and discharge by 76%. Therefore, the serious adverse events could be monitored by ICD family monitoring system rather than the traditional model. Another research analysed 73 alarm events recorded by 17 patients and found that there were 5 patients had more than one atrial fibrillation during the first 1~3 months of follow-up, a total of 5 patients (14.3%) were at least 1 times the incidence of event records. The home monitoring system could find the atrial fibrillation (AF) 76 d earlier in 3 months' follow-up; and 83 d earlier in 6 months' follow-up. The results showed that more AF patients were founded in home care group than control group ($P < 0.05$), which provided evidence for early prevention of stroke patients.

After DCPM, a large number of patients might appear atrioventricular non-synchronous conduction. One study [21] confirmed the width of QRS wave was an independent risk factor for atrial fibrillation, and through observing the QRS duration, RM could timely adjust AV intervals depending on patients' conditions, select appropriate AV intervals, and improve cardiac hemodynamics and systolic functions so as to make the patients obtain more benefits. Lots of Chinese reports had confirmed that after DCPM, the optimized AV interval settings could improve the patients' hemodynamic parameters and cardiac functions. Most patients would exhibit such relevant changes as heart rate increasing and heart rate variability reduction before the occurrence of heart failure, and RM's special function of "Heart Failure Monitoring" could inform clinicians to guide the treatments according to the patients' conditions before they appeared the symptoms of heart failure, to adjust their treatment programs, to reduce the incidence of heart failure, thus further reducing patients' readmission rate and mortality, as well as improving their long-term life qualities. The study results of TRUST showed that RM could reduce patients' clinic follow-up times by 45% while without affecting the mortality [8]. In this study, the average follow-up times per patient in group RM was significantly reduced than the control group (Table 3); consistent with the above study; however, due to the shorter follow-up period, this study had no death case, but it could be seen from the results that the number of the patients readmitted into hospitals in group RM was significantly reduced than the control group (Table 3). This might be related to the in-

advance discovery of asymptomatic cardiac events and timely drug interventions. Because RM could record special cardiac events in time, and 99% of these cardiac events would be reported to the monitoring center within 5 min, and then the patients' clinicians and their families would be informed *via* telephone, SMS, or e-mail, so the detection rate of such asymptomatic cardiac events, particularly arrhythmia, was greatly increased.

The home care system have shown the same safety and effectiveness as outpatient follow-up, which could monitor wire electrode dysfunction and found the clinical alarm events, and saved the costs of patients during the follow up, as well as the workload of doctors, which can also improve the satisfaction and compliance of patients. Remote monitoring could strengthen the connection between the doctors and patient, the patient would feel safety when they realized that the doctors would know what happened to them after the implantation of pacemaker. According to different alarm level, the patients would follow up according to the alarm level would be telephoned when necessary. However, when pacing parameters need to be adjusted, the patient had to come to the doctor. The home care system would be replaced by GSM in the future which could be adjusted parameters.

Acknowledgements

This study was supported by the Key Technology Projects of Hubei Province, NO.2013BCB013; general projects of NSFC: NO.81270249, NO.81570306.

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