Feasibility study of a non invasive Cardiac Rhythm Management System

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Abstract- This paper discusses the trial results of a personalised Cardiac Rhythm Management (CRM) system using a smart phone (PDA) and a wireless ECG sensor. The system is used in a trial to record and diagnose abnormal cardiac arrhythmias. This novel approach uses standard mobile phones, off-the-shelf ECG sensors and personalised feedback to the patient when compared to a conventional clinical Holter and event monitor systems. The preliminary results are discussed of an ongoing trial conducted with the Royal North Shore Hospital in Sydney Australia. The results indicate the viability of the system for commercial purposes.

Index Terms – Cardiac rhythm management, remote tele-monitoring, smart phones, wireless ECG sensors.

1. Introduction

Cardiac rhythm disorders impact millions of people each year. Some arrhythmias are difficult to diagnose because they occur sporadically in otherwise healthy adults and do not pose a threat to heart health. Other arrhythmias however, could indicate more serious, potentially life-threatening problems. Identifying and managing cardiac rhythm disorders is a field in cardiology called Cardiac Rhythm Management (CRM). It may involve the use of artificial pacemakers and/or implantable cardioverter-defibrillators as well as anti-arrhythmic drugs [1].

To capture relatively frequent arrhythmias a Holter monitor may be used. This is a portable device for continuously monitoring the electrical activity of the heart for 24 hours or more. A Holter monitor records the electrical signals from the heart via a series of electrodes attached to the chest. The number and position of electrodes varies by model, but most recording systems employ from three to eight electrodes [2].

To monitor patients with cardiac symptoms that only occur sporadically (e.g. once or twice a month) a cardiac event monitor can be used. Event monitors are activated only when the arrhythmia occurs or symptoms are felt. The advantage is that these recorders may be used for a longer period. This type of device only records cardiac events for typically 30-60 seconds. The recordings can then be transmitted via the telephone to ECG technicians for further processing.

The Personal Health Monitor system developed by our team at the University of Technology, Sydney is a flexible CRM system that can be used either as a Holter monitor or an event monitor. The system is different from conventional Holter and Event monitor systems since it uses standard mobile phones and wireless ECG sensors. It is not limited to just recording ECG arrhythmias but offers a range of other functionalities, that make it a personal health monitoring system for people that need to make life style changes such as lose weight, lower the blood pressure or monitor their blood glucose level.

In this paper we focus on the use of the Personal Health Monitor system for CRM management which is being trialled by the Cardiology Department of the Royal North Shore Hospital in Sydney, Australia. The aims of the trial are to:

- Demonstrate that the detection of important cardiac arrhythmias is feasible using the Personal Health Monitor system utilising the Internet.
- Investigate whether the use of the Personal Health Monitor provides clinically meaningful reassurance to patients with suspected arrhythmias and heart disease.
- Obtain feedback from patients and cardiologists regarding usability and practicability of the software/hardware used.
- Obtain feedback on the usefulness/efficiency of rehabilitation in cardiac patients and elderly using the personal health monitor application.

The trial is an Observational Cohort Study. Two hundred patients with suspected or confirmed cardiac arrhythmias will be recruited over 2 years and technical, clinical and psychological experiences will be recorded. The value and significance of this research comes from assessing how easily available and economical non-proprietary technology for the detection of cardiac arrhythmias and vital signs will enhance clinical management via the internet. This will extend the applicability of present technologies especially for patients in remote locations.

This paper presents the preliminary results of the PHM trial with 70 patients. Section 2 presents an overview of the PHM system. Section 3 focuses on the remote assessment of arrhythmia data by the specialist. Section 4 discusses the trial results from both the patient's and cardiologist's viewpoint. Finally, section 5 concludes this paper.

2. Personal Health Monitor System

The Personal Health Monitor (PHM) provides personalised, intelligent, non-intrusive, real time health monitoring using wireless sensors and a mobile phone [3-5]. The wireless sensors can be either attached to the user's body (for example ECG and Accelerometer) or can be external devices, such as a blood pressure monitor or a weight scale, that are used when required. The sensors are Bluetooth enabled or integrated into the mobile phone. On the phone, the Personal Health Monitor software analyses, in real-time, the data received from the sensors. The phone gives immediate feedback and personalised advice to the user based on the analysis of sensor data collected.

Fig. 1 Personal Health Monitor System

The PHM offers the following functionalities which makes it attractive for cardiac rhythm management:

Ambulatory monitoring: Using small sensors and a mobile phone it allows convenient, non intrusive monitoring for a prolonged period of time, while users carry on with their normal daily routines. The user needs a Microsoft Windows mobile phone, and may buy or rent the sensors. The user can download the software onto the mobile phone and use it just like any other windows mobile application.

Multiple sensors: The PHM system supports the following sensors: ECG, Fall detector, Pulse Oximeter, Blood Pressure, Weight and Blood Glucose. The PHM uses off-the-shelf sensors which are widely available on the market and their technology is mature. The advantage of off-the-shelf sensors is that health professionals trust these devices since they are FDA, TGA and/or CE, approved.

Instant feedback: The Personal Health Monitor analyses and stores biosignals and activity data on the phone and provides instant personal feedback to the user. If required, the phone can be set, in the event of a cardiac arrest, to loudly play a message with pre-set CPR instructions for any bystander, so that they know how to assist.

Personalisation: Each user has different needs and preferences and the PHM application can be configured to the patients' and health professionals' needs and requirements.

Arrhythmia detection: The PHM application can detect and record various arrhythmias and can react to serious arrhythmias such as ventricular fibrillation/ tachycardia. The ECG signal quality (Fig. 2) is in the vast majority of cases of sufficient quality for a cardiologist to make an assessment.

Fig. 2 ECG trace from PHM system

Reminders and logs: The Personal Health Monitor software allows the users to set reminders for their measurements and to keep logs of their activities.

Communication: The sensor data and analysis can be instantaneously sent to the Health Care data server using 3G or any other Internet connection available on the phone. The PHM application can also be configured to provide alerts which automatically ring or SMS pre-assigned numbers in emergency situations, such as when it detects a life threatening arrhythmia or a fall. The PHM application can use either wireless or wired communication for synchronising data.

Remote configuration: The specialist can remotely configure the PHM application for each user by changing variables such as threshold levels for a particular sensor (e.g. max heart rate). In this way, the Personal Health Monitor software can be customised to the needs of each user or clinician.

2. Remote Assessment via Health Care data server

One of the strengths of the PHM system is remote monitoring and assessment of patients. The patient can upload the data instantaneously via 3G or any other Internet connection available on the phone to the www.PersonalHealthMonitor.net website. The health professional is notified of new data and can assess the results. Currently, the ECG assessment consists of heart rate variability (HRV) analysis and ECG traces. Additional information is shown such as the max/min and average heart rate, RR intervals, as well as, the arrhythmia symptoms detected for that ECG trace (e.g. ectopic beats). This allows the specialist to quickly assess the relevant traces. HRV time domain summaries are generated for the purpose of assessing autonomic regulatory effects on heart rate.

The cardiologist can annotate ECG traces and HRV summaries which will then be added to a report specific for the patient. Figure 4 shows an example of such a report. Other physiological data can also be recorded and shown in graphical format.

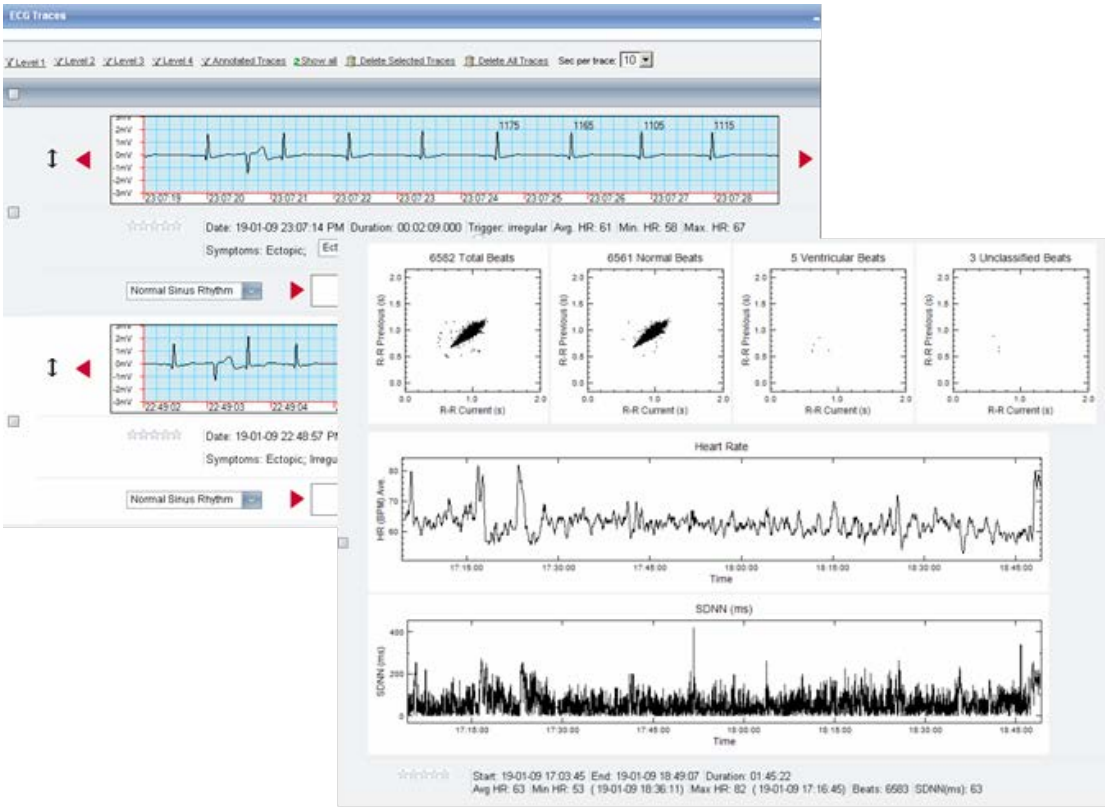

Fig. 3 ECG trace and Heart Rate Variability (HRV) assessment

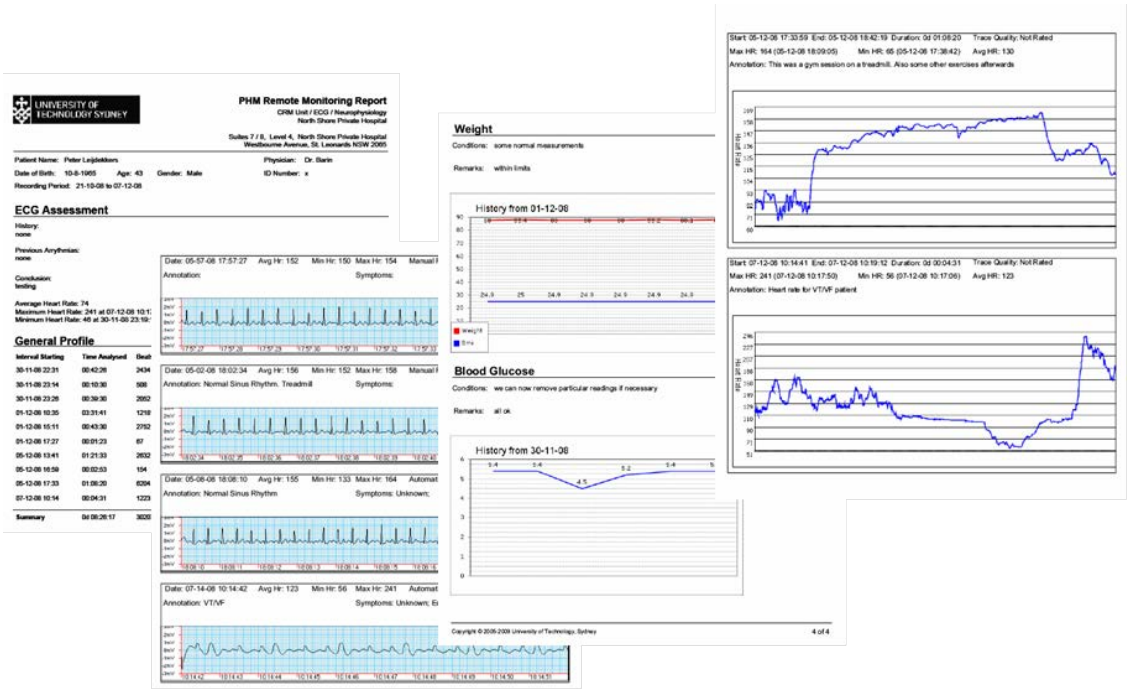

Fig. 4 Reports

3. Trials

This section presents the preliminary results of trails being conducted with the Royal North Shore Cardiology department in Sydney Australia. The trial runs over a period of 2 years (2008-2010) and aims to test it on 200 patients.

3.1. Process

The cardiologist screens potential subjects. Subjects with low risk cardiac conditions and suspected arrhythmias are recruited. Selected patients are instructed how to use the personal health monitor application and sensors. On average, 30 minutes are needed to instruct a patient, and a 5 page user guide is given for reference. The patients use the Personal Health Monitor when they wish to do so. Our recommendation is to wear it for one full day (usual Holter period) and when they feel symptoms. The patients keep the personal health monitor till they capture an event and most keep it for 2-4 weeks. For economical and practical reasons (e.g. 3G is expensive in Australia, not all patients have Internet connection), the data is uploaded to the website when the patient returns the equipment. The cardiologist examines the traces immediately in case the system has detected an important arrhythmia, or during the next appointment with the patient. The patient fills in the questionnaire after they return the equipment or after feedback from the cardiologist.

3.1. Preliminary results from the patient surveys

At the time of writing, over 70 patients aged from 21 to 90 (Average age 56.6) have used the system and 47 patients (23 males, 24 females) have been surveyed about their experience with the PHM system. Our survey consists of 48 questions (a mix of open and closed questions). This paper focuses on 12 Likert-scale questions where the respondents indicate how closely their feelings match the question or statement on a rating scale.

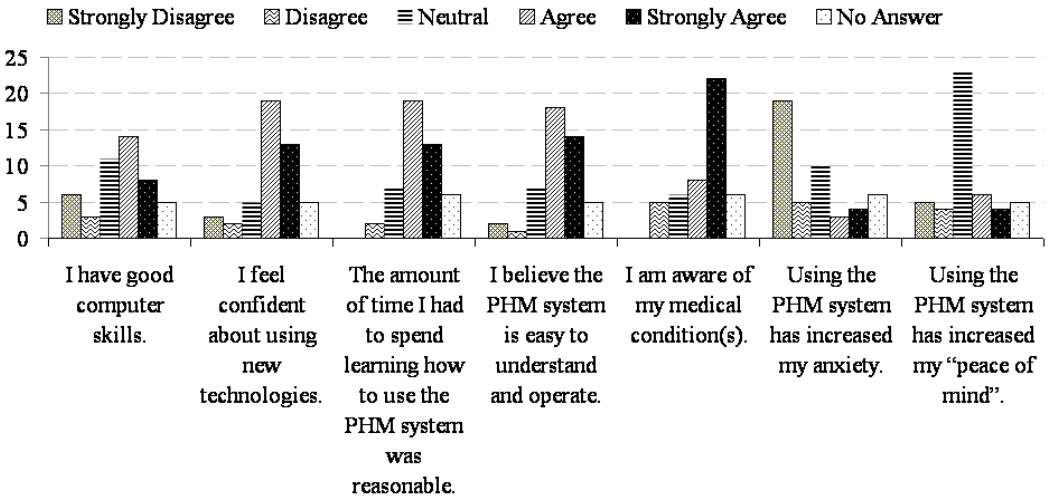

Fig. 5 Evaluation of the PHM system (y-axis = number of answers)

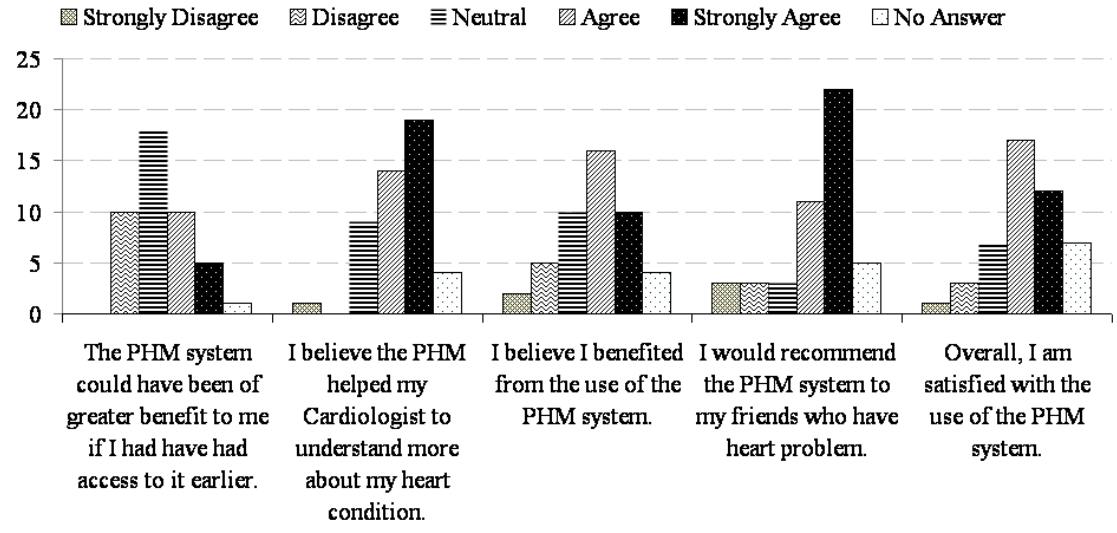

Fig. 6 Evaluation of the PHM system (y-axis = number of answers)

Most patients have reasonable computer skills and are confident about using new technologies. One of them, a 91 year old female has never used a mobile phone and despite this, she finds the PHM application easy to use

and manages to record numerous ECG traces.
The vast majority of our patients find the PHM easy to use and consider the time spent learning how to use the PHM reasonable. Approximately 25% of the patients give a phone call a day or two after the first meeting to make sure they are doing the right thing and potential issues are clarified over the phone within a few minutes.
Most are aware of their health condition and wish to capture the arrhythmia and be able to show it to the cardiologist. The use of the PHM does not increase the anxiety for most patients. The few exceptions correspond to a feature in the PHM software that will play a loud voice message when the heart rate is too low or too high. This feature was added after one patient fainted due to a low heart rate. It seemed like a good idea at that time but it was quickly disabled since it led to more anxiety amongst other patients. The feature can now be enabled on specific request by the patient or cardiologist. The patients are neutral about the fact whether the PHM increases their peace of mind. For those at higher risk tend to agree that it brings piece of mind.
Most patients believe that the PHM helps their cardiologist understand their condition. Overall, they are satisfied with the use of the PHM and they benefit from it. They would recommend it to their friends that have a heart condition.
The survey contains several questions about the Holter monitor. 21 patients out of 47 surveyed used a Holter monitor previously and the vast majority find the PHM more convenient (89.3%) and easier to use (90.5%) compared to a Holter monitor. Only 54.6% find the PHM more comfortable than a Holter monitor which surprises us. A possible explanation can be that we use a fairly bulky phone (i-mate JasJam) and patients do not use this as their daily phone therefore carrying 2 mobile phones which might have an impact on the comfort. In the near future we migrate to a far slimmer mobile phone (HTC Diamond) which will hopefully improve the comfort level.
Several patients, especially women, develop some rash or skin irritation where the electrodes are placed and several find the ECG monitor slightly inconvenient. Some patients appreciate the online access to their ECG data, which improves their understanding of their heart condition. Some patient feedback:

"It had picked up Supra Ventricular Tachycardia (SVT) which I have had but never been able to capture it. I am now on medication and have had reduced symptoms and feel a lot more confident to be able to get back in shape and go forward".

"I think the monitor is an excellent diagnostic tool. As I informed you I have had the symptom for six years and more but have never been able to demonstrate it to any doctor, GP of specialist. Now with your assistance that has been done and that is very reassuring".

3.2. Cardiologist experience

The PHM provides another tool for the efficient diagnosis and characterisation of heart arrhythmias, a very common disorder in clinical medicine. Previous clinical experience has confirmed the efficacy of ambulatory monitoring, but this smart phone based system will broaden the application of the technology to other conditions outside the realm of heart disease. Furthermore, careful selection of suitable patients will enhance the confidence of patients and acceptance of appropriate reassurance or treatment. The survey confirms the general satisfaction of patients with the system in assisting their diagnosis. It does not create undue anxiety.

Clear advantages of PHM include:
- Diagnosis of an unsuspected arrhythmia (e.g. heart standstill).
- Confirmation of a suspected arrhythmia (e.g. ectopic beats).
- Readily accessible low-cost technology which may be used as an adjunct to established monitoring systems.
- Option to remotely review tracings via the internet and website which is user friendly.
- Potential for linkage with other bio-markers (e.g. oxygen saturation, blood pressure and body position) using Bluetooth enabled systems.

Disadvantages include:
- The need to select patients who are not averse to using mobile phone technology.
- Tailoring of alert algorithms to avoid excessive anxiety in patients.
- Provision of surveillance manpower to skilfully screen traces and alerts (further automation may help).

The utility and feasibility of PHM has been demonstrated in the trial with individual cases such as:

Patient A who had suspect minor arrhythmias but the extent to which they occurred (atrial fibrillation) led him to be treated with anticoagulation to avoid strokes. (Fig. 7)

Patient B who collapsed while wearing the device and was admitted to hospital with no abnormal findings. Review of the recordings which were forwarded to the treating Emergency Unit revealed periods of heart standstill for which he received a pacemaker. He has remained well since. (Fig. 8)

Fig. 7 Patient A - Atrial fibrillation with typical variable ventricular (heart) rate

Fig. 8 Patient B: Junctional bradycardia with marked heart rate slowing corresponding to fainting symptoms

3. Conclusion

This paper presented a novel Cardiac Rhythm Management application using standard mobile phones and wireless ECG sensors which are Bluetooth enabled. To date, the application has been trailed on 70 low risk heart patients and the preliminary results show the commercial potential of this system for identifying and diagnosing arrhythmia abnormalities. The Personal Health Monitor system can be used as either a Holter and/or Event monitor but offers many more features which make it a multi purpose device for health monitoring. Areas where the PHM system has potential application are:

- Cardiac Rehabilitation: After a heart attack or a coronary bypass surgery the patient is involved in a personalised rehabilitation programme where the PHM application instructs and motivates patients to follow their exercise prescription and keeps track of their progress. It also monitors the relevant biosignals and provides immediate and comprehensive feedback to the patient and caregivers [7].
- Community Healthcare: Patients are remotely monitored by a home nursing or healthcare provider. Patients are given the PHM and additional equipment such as a weight scale, blood pressure monitor or glucose diabetes monitor and need to take their measurements according to a predefined schedule. The PHM will automatically remind the patient and once the data is collected it is automatically uploaded to the healthcare data centre for review by the staff.
- Monitoring of Lifestyle changes: For people that need to make lifestyle changes such as losing weight, fitness surveillance and blood pressure control. The PHM application can be used to monitor their progress without repeated visits to clinics or hospital departments.
- Athletic performance: Exercise enthusiasts and elite athletes may use the PHM application to monitor their sporting progress, or symptoms related to activity, particularly when exercising in remote areas.

We believe that the use of this system will be easily extended after further experience in real world situations measuring bio-data in selected groups of people. Because it employs mature technology the PHM system is unlikely to encounter limits on purely technical grounds. Its value in general community and clinical use will be further clarified by studies looking at cost effectiveness.

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