Remote Monitoring of Cardiac Rhythm Management Devices in Vietnam
The role of the Biomedical Engineer

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Abstract— **Cardiac rhythm management (CRM) manufacturers of pacemakers, implantable defibrillators, offer remote monitoring of their high end products. In the West, the responsibility for monitoring devices is given to a device nurse at the cardiac center. The nurse performs daily checks of any reported issue by the manufacturer and act upon any alert reported by the device. With the patient group numbering hundreds of patients, a device nurse can be supported by reimbursement for remote monitoring.**
The situation is different in Vietnam. The number of implant patients at a typical implant center is barely in the low hundreds. Patients are typically not actively followed and irregularly come back for follow-ups. Currently there is no reimbursement program for automated follow-ups.
In developing the first Remote Monitoring program for Vietnam, we had to factor in these differences and have developed an alternative approach. A biomedical engineer at the distributor assumes the duty of the device nurse and works with the patients' cardiologists. The engineer will review the daily reports and study alerts reported by the devices or the automatic analysis programs of the manufacturer. When appropriate, the cardiologist will be alerted. The cardiologist will contact the patient to come in for a follow-up. The engineer will not deal directly with the patient, except on technical matters, such as malfunctioning remote monitor.
This has enabled us to create a new model for the care of CRM patients in Vietnam. With daily report by the device, the patient does not need to visit the cardiologist, except for a yearly visit, unless contacted. Since the Home Monitoring reports had been analyzed prior to the visit, recommendations about therapy or device parameter changes will be discussed with the cardiologist before the patient arrives.

Keywords— **Pacemaker, defibrillator, remote monitoring, biomedical engineer.**

I. Introduction

Cardiac Rhythm Management (CRM) devices have been life savers for patient with cardiac electrical conduction problems. They consist of

- bradycardia devices: pacemakers for symptomatic patients with a slow heart rate or episodes of heart block,
- tachycardia devices: cardioverter defibrillators (ICD) for episodes of ventricular tachyarrhythmia
- Cardiac resynchronization therapy (CRT) devices for heart failure with dissynchrony between the ventricles.
- ICD and CRT patients are considered high risk patients who deserve close follow-ups.

Patients in Vietnam can now have these devices implanted at major cardiac centers throughout Vietnam. As the number of patients increases, the Vietnamese cardiologist is fast encountering the same problem that has faced his colleagues in the West. With the implanted devices reaching longevities in excess of 15 years, and requiring regular follow-ups, every 3 to 6 months, throughout their service life to maintain optimal performance, the workload of the busy cardiologist can easily reach overload conditions.

From the patient point of view, the current overload conditions at all major hospitals in Vietnam have caused a major degradation of services. A consultation with the cardiologist can only accommodate a routine device follow-up. Beyond checking the battery status of the device, the cardiologist has barely time to look over the ever increasing amount of diagnostics stored in these devices.

One approach to solving this problem has been the open CRM clinic that one hospital has adopted. On a particular day of the week, patients implantd with a CRM device of a particular manufacturer can present themselves, without appointment, at the clinic and request a device follow-up. A clinical engineer of the CRM distributor will perform the follow-up and a quick analysis of the data stored in the device. The results are summarizeds for and recommendations made to the cardiologist on duty. The latter will review the recommendations, discuss the results with the patient, approve any program change and if necessary write a new prescription. If further analysis of the data is needed, this is performed later at the distributor office, and if warranted, the patient is contacted to come back the following week to update the device parameter set after review and discussion with the cardiologist on duty.

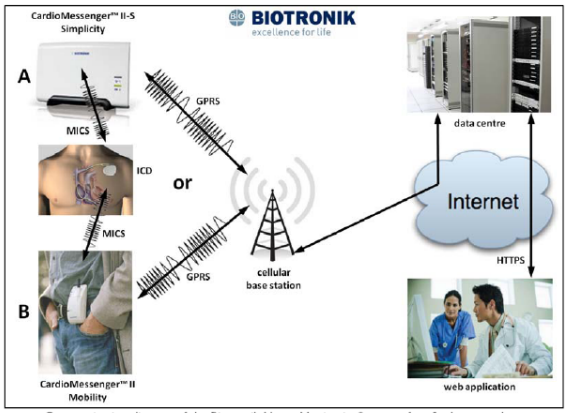
This open clinic strategy can be adopted at cardiac hospitals only. The clinic at a general hospital does not yield a sufficient number of CRM patients for the CRM distributor to assign a clinical engineer for the half day of clinic.

In this paper we would like to present an alternative approach to follow-up that is aimed at the high-end devices in patient at high risks.

II. Remote Monitoring

A typical cardiac clinic in the West has a patient group numbering in the hundreds, if not thousands. All CRM manufacturers now offer remote monitoring (RM) programs to allow the device nurse at the clinic to follow patients remotely and the nurse will contact the patient to come in only for an actionable intervention.

The high end devices all have a short range wireless communication unit built-in. This allows the implanted device to communicate with a patient device, typically placed at the bedside. It is connected to a telephone landline or to the cellular phone network. Periodically, from 1 to 90 days, the implanted device will send a summary of its status along with supporting data to the patient device to be forwarded to a monitoring center. The center will repackage the information and make it available on-line to the device nurse and other approved staff at the cardiac clinic for review. The implanted device can also send unscheduled alerts as needed.



Communication diagram of the Biotronik Home Monitoring® system for **A**: the second generation bedside monitor and **B**: the second generation wearable mobile monitor

Fig. 1 Example of the Biotronik Remote Monitoring system [1]. In Vietnam, we use the device shown in B, at the bedside.

Since patients at the cardiac implant centers in Vietnam come from all over the country, and not necessarily from the local area, such a RM system should relieve the workload of the cardiologist. However, just as in the West, the busy Vietnamese cardiologist is overwhelmed by the technology (getting on line daily) and the amount of data to be reviewed. In the West, the device nurse has taken over these responsibilities. With the large population of patients, the device nurse can be supported by the reimbursement for remote monitoring. In Vietnam, there is no reimbursement for remote monitoring. As a result no device nurse is available. Thus a new operational model is needed for RM in a third world country like Vietnam.

III. The Vietnamese Remote Monitoring Model

With the consent of the cardiologists and their patients, we have setup the following Remote Monitoring system:

- Based on Biotronik Home Monitoring® system, Berlin, Germany
  - Designed for high end pacemakers, for ICDs and CRT devices.
  - Low power transmission from the implanted device to the patient unit, CardioMessenger II® (CM II). It is in the Medical Implant Communication Service (MICS) band, 402-405 MHz [2]. In addition to measurements, multi-channel electrograms are also sent periodically or following detection and treatment of tachyarrhythmia episodes.
  - Communication between the CM II and the monitoring center in Berlin, Germany, is over the cellular GPRS (General Purpose Radio Service, so called 2.5G) network [3]. Home Monitoring® is the only remote monitoring system with GPRS as the standard method for communication with the monitoring center.
  - The GPRS message between the CM II and the monitoring center is prepaid and included in the price of the CM II. At this time, the patient does not incur any additional charge.
  - The data is analyzed and repackaged by the monitoring center. Various levels of alert are generated from analyses of the data or from therapy reports by the implanted device.
  - Authorized personnel can access the data using a protected internet account hosted by a dedicated Biotronik server in Berlin, Germany.
- An experienced Biomedical Engineer working for the Biotronik CRM distributor in Vietnam will review the data and alert the cardiologist when needed.

The Biomedical Engineer (BE), a clinical engineer with extensive experience with Biotronik CRM products, assumes the role of the device nurse in the West. The BE will review the data the Biotronik monitoring center makes available on the web. Since the number of patients is fairly modest at this time, in addition to reacting to the alarms generated by the analysis program at the monitoring center, and/or the implanted device, the BE can also be proactive and perform trend analyses and correlations of various data to arrive at preliminary diagnoses. These are then reviewed with the treating cardiologist of the particular patient. From his experience with implanted device, the BE can make recommendations for

- Adjustment of the implanted device parameter for optimal operation, like other clinical engineers.
- Recommendation on therapy adjustment. For example anti-coagulant for patients with newly discovered atrial fibrillation, shift in therapy to focus on atrial tachyarrhythmia, increased dosage of beta blocker due to increase in ventricular early systole (VES/PVC), ...
- Recommendation for referral to an Electro Physiologist for ablation of certain focal tachyarrhythmia

As noted, these are recommendations made to the treating cardiologist, never to the patient. So, effectively, the BE is working under the supervision of the cardiologist. The cardiologist is responsible for contacting the patient and making arrangement for subsequent device follow-ups. The advantage of the approach is that, by the time the patient comes to the hospital, the cardiologist knows what adjustments to the implanted device are needed and would have ready any prescription change.

The only communication the BE has with the patient is with regard to the operation of the CM II unit.

The patient no longer has to go for periodic follow-ups, which typically are routine [4, 5], and only needs to come to the clinic when contacted by the cardiologist for an actionable event, or yearly. Patients are very appreciative of this VIP treatment, especially in the overcrowded situation in Vietnam since the patient has priority due to his "requested by the doctor" appointment status.

IV. Contributions of the Biomedical Engineer

The BE key contribution, beyond what a device nurse would provide in response to alerts by the device or the monitoring center, is his analyses of the data. In this section we would like to present a couple of examples of this.

A. Arrhythmic storm

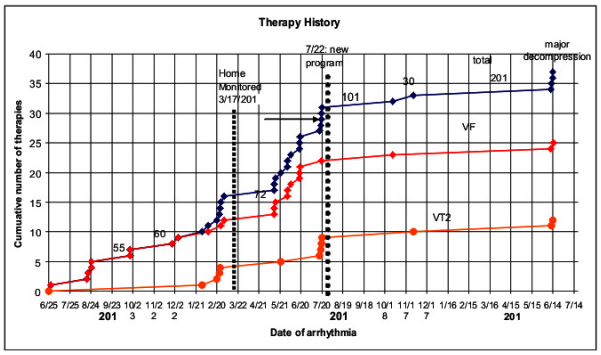


Fig. 2 Patient with arrhythmic storm.
The number on the top curve is the number of days between episodes.

The male patient has been implanted a Biotronik Lumax 300 HF-T, a three chamber ICD with CRT for heart failure in June of year 1. For the first 7 months, he had a number of episodes of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT) that were detected and treated with burst pacing (anti-tachycardia pacing, ATP) or with shocks, most often aborted since the arrhythmia broke before charging of the shock capacitors were completed. A few episodes every other month was considered acceptable. However, starting about the 8th month, in late January of year 2, he started to have this string of tachyarrhythmia episodes, an arrhythmic storm (the strict definition of a storm is a string of episodes over a 24 hour period. We have expanded the definition here). This was unsettling. About March of year 2, we started the new RM program. The patient agreed to join. In May of the second year, he started having this long arrhythmic storm. We redoubled our effort to find a way to stop the storm using the 30 seconds of 3 channels of electrogram pre-episode we received each time an episode of arrhythmia was detected. We worked with his cardiologist trying to alter his prescription, but the storm continued unabated. After 4 month of RM, we finally uncovered the cause of his storm. The symptom in the pre-arrhythmia electrogram is delayed depolarization after a pacing pulse at normal voltage, but not at high voltage. We speculated that the right ventricular lead was implanted close to a re-entry circuit.

Fig. 3 Delayed depolarization; high pacing voltage; anodal stimulation

In order to achieve resynchronization of the two ventricles, it is necessary to pace both the left and right ventricles >98% of the time. The Lumax 300 HF-T allows us to pace the right ventricle anodically from the right ventricular ring (normal pacing is bipolar with the tip being the cathode, and the ring the anode) in conjunction with pacing the left ventricle (cathode) with a higher voltage (than normal) pulse. The ring being remote from the myocardium can simultaneously capture a large area of the myocardium, which we believe would include the whole arrhythmic re-entry circuit. The programming change was made on July 22 of year 2, and the arrhythmic storm stopped!

It was the ability to collect all the pre-arrhythmia electrograms that allowed us to uncover the cause of the storm. Without RM, the patient would have to come in for a follow-up immediately after each episode, a major inconvenience for the patient. A good understanding of electrophysiology and the device allowed the solution formulation.

B. Prediction of acute decompensation episode

Except for patients who need an ICD due to a genetic condition, such as Brugada or Long QT Syndrome, most patients with an ICD have heart failure, along with CRT patients. For these patients, acute decompensation [6] is a serious and constant threat. One early indication of acute decompensation is a growing pulmonary edema. It has been proposed that transthoracic impedance be used as an early warning of acute decompensation [7]. An automated alarm was proposed. The resulting high rate of false alarm has led to the failure of the DOT-HF [7] trial. It has been suggested that transthoracic impedance should require a review by an experienced operator prior to a diagnosis.

Transthoracic impedance is measured in the Biotronik Iforia 5 series of ICD. However the information is available only through RM for fluid edema diagnosis and can be used for predicting an imminent episode of decompensation. We would like to report an episode of decompensation that we were able to predict and avoid the patient a hospital stay.

The patient was implanted with a single chamber Biotronik Iforia 5 VR-T. He also signed up for the Biotronik Home Monitoring® program.

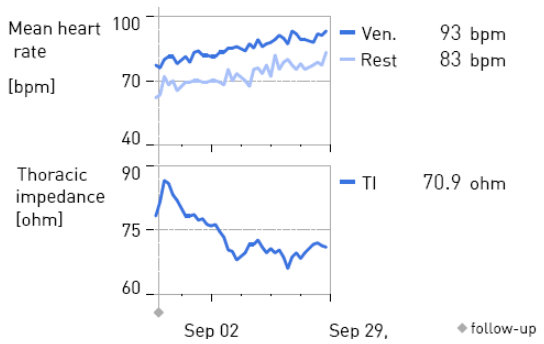


Fig. 4 Heart Rate and Thoracic Impedance report.

Since we just started monitoring this patient and this is our first patient with Thoracic Impedance measurement, we were gun-shy to the increase in fluid accumulation indicated by the decrease of the Thoracic impedance. We could have alerted the cardiologist around Sept 9, but at that time, with the rest heart rate hovering about 70 bpm, we did not feel comfortable, in view of the DOT-HF failure [7]. We waited until the daily rest heart rate, measured at 02:00, crossed the 80 bpm threshold before alerting the cardiologist. Following our Sept 27 report, the cardiologist confirmed the pulmonary edema and initiated an intensive diuretics regimen that saved the patient from a hospital stay. Since then the patient has not experienced such a low impedance concurrent with a high resting heart rate.

Because this is our first experience the transthoracic impedance, and the decompensation occurred too shortly after the implant of the device, we will need further episodes with additional patients before we can generalize this result.

V. Conclusion

In this paper we have presented a model for Remote Monitoring developed for Vietnam taking into account the different operating environment. The Biomedical Engineer, an experienced clinical engineer, has assumed the role of the device nurse in the West. The BE reports his analyses and recommendations to the cardiologist, who is responsible for the interactions with the patient. Thanks to his technical training and experience, the Biomedical Engineer can do more than his device nurse counterpart. With a good understanding of electrophysiology and the devices, by analyzing trends and correlations between the parameters that are received from the remote monitoring system, the BE can be proactive in support of the cardiologist.

Thus, at this early stage of the Vietnamese Remote Monitoring program, the patient is getting first class follow-up, on par and possibly better than in the West! We are monitoring patients with pacemakers, ICD and CRT devices.

Conflict of Interest

Northwest Signal Processing, Inc. (NSPI) and Systolic Medical Products operate as the distributor of Biotronik CRM products in Vietnam. The author is a principal of NSPI.

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