

Telemedicine Framework for Manufacturer Independent Remote Pacemaker Follow-Up

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Abstract

Due to international standards each implantable cardiac pacemaker reacts to the application of a permanent magnet by changing the pacing rate in a predefined way depending on the depletion level of its battery. The purpose of this study has been to use a routine ECG recording to verify in a telemedicine framework whether the pacemaker works correctly or if further examination is indicated.

The system has been implemented prototypically and has been evaluated in a clinical pilot trial on 24 consecutive patients with a total of 17 different pacemaker models from 6 different manufacturers.

The promising results indicate that the presented follow-up concept, which can be handled by general practitioners, has the potential to work as an efficient screening method and may spare a significant number of patients the burden of having to travel to specialized hospitals which are often far away from patients' homes.

1. Introduction

Pacemaker (PM) implantation is only the first step in the care of pacemaker patients. According to international guidelines [1] PM follow-ups have to be performed several times a year, depending on the duration of PM implantation, the patient's general condition and the results of previous follow-ups. In the course of most of these follow-ups – so-called “basic follow-ups” – mainly the depletion level of the battery and the basic function of the pacemaker are assessed. Only in a minor number – so-called “extended follow-ups” – more comprehensive procedures are necessary in order to adjust PM settings to the individual needs of the patient as well as to optimise the pacing system concerning power source utilization.

To guarantee as much security as possible for the patients, guidelines recommend performing basic and extended follow-ups alternately [1].

Currently in Austria only “extended follow-ups” are performed in specialized cardiological departments.

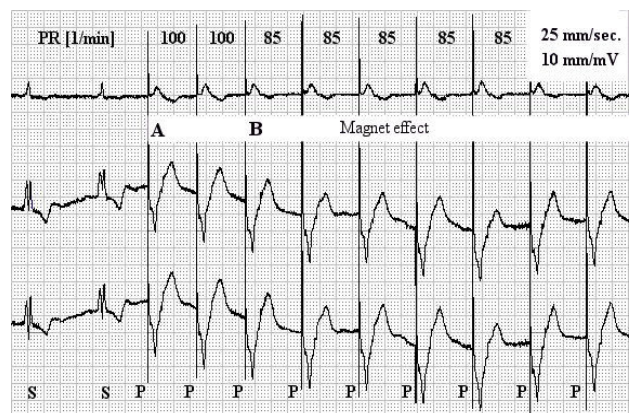


Figure 1. Example of an ECG sequence recorded during magnet placement from a patient with a Medtronic Kappa pacemaker; A: magnet takes effect (PR=100 min⁻¹); B: after the 3rd stimulus the PR lowers to 85 min⁻¹ indicating BOL.

Therefore company specific, cost intensive PM programming systems, which allow communicating with the implanted PM telemetrically, are required. This implies a huge personal effort for the departments and long travel burdens for the usually elderly persons to undergo this routinely performed examination.

The general idea of the project is to shift a significant number of basic pacemaker follow-ups from follow-up centers to caregivers located in the patient's vicinity. This is based on the fact, that “basic follow-ups” can be performed without the necessity of manufacturer specific PM programming devices.

Shifting tasks from specialized clinics to the health care providers in the vicinity of the patients implies an increased effort on communication and collaboration between both participants in general which can be supported by a telemedicine framework. In the case of the proposed PM follow-up framework the face to face contact as well as data acquisition will be shifted from the specialist to the primary care physicians. This means that the patient and its data can be separated. The specialist

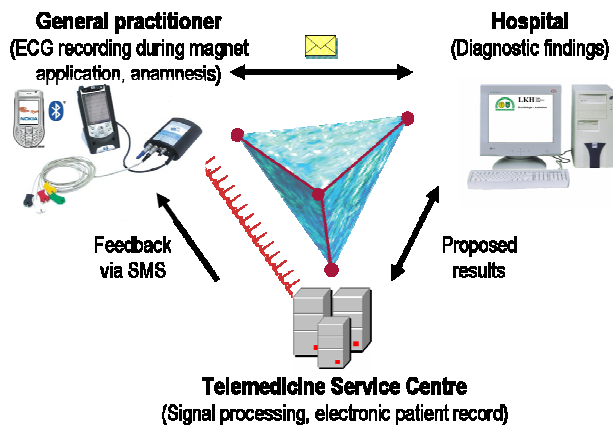


Figure 2. Overview of the telemedical framework for manufacturer independent, collaborative pacemaker follow-up.

only has to review the data and give the feedback to the primary care physician who is in direct contact with the patient.

The aim of the project has been to verify whether a telemedicine framework can be used to separate patient and data ways, to establish a new way of communication and collaboration between specialists and health care providers as well as to transfer routinely “basic follow-ups” from the specialized cardiologic department to caregivers in the vicinity of the patients. This could be convenient for the patients and disburden the specialists at the same time.

2. Methods

Due to the international standards each device reacts to the application of a permanent magnet by changing the pacing rate in a predefined way depending on the depletion level of the battery and on the type and manufacturer of the PM (Figure 1). Therefore a routine two channel ECG recording can be used to verify whether the PM works correctly or if further examination is indicated. A comprehensive list of all PM specifications can be found in [2]. This information is used to check the depletion level of the PM battery system automatically by matching the pacing intervals during magnet placement with the device specific information, which is stored in the central pacemaker database. This database contains the individual patterns for begin of life (BOL), elective replacement indicator (ERI), and end of life (EOL) for every pacemaker. The underlying algorithm has already been evaluated and published in [3].

Figure 2 shows a general overview of the developed telemedicine framework for remote, manufacturer independent PM follow-up.

The framework supports the collaboration between the

cardiologist at the PM clinic and the physician at the point-of-care (rural hospitals or primary care physician) and comprises of the following components at the participating sites:

- a. Rural hospital or primary care physician
 - Face to face patient contact
 - A mobile, PDA based PM follow-up system supports the physician in data acquisition
- b. Specialized cardiologist at the PM-Clinic
 - Data review via web-interface
 - PC with access to the Internet, or mobile client (PDA)
- c. Remote follow-up centre
 - Web-service providing the PM follow-up system infrastructure and remote ECG signal processing unit

2.1. Data acquisition

Mobile ECG acquisition is supported by a PDA based ECG signal recording unit, provided by g.tec Guger Technologies OEG (Graz, Austria). The mobile biosignal amplifier provides a two channel ECG recorder. Each channel is sampled with 256Hz and the ECG can be stored directly on the PDAs memory card. The data acquisition equipment is shown in Figure 3.

A specially developed, PersonalJAVA [4] based software running on the PDA guides the user through the data acquisition process. After login, the user selects the appropriate patient and opens a new follow-up session. Thereafter the user is asked to record a standard two channel ECG. During the recording a permanent magnet is placed above the pacemaker case to trigger the magnet mode for a period of about 30 seconds. It is important to collect as much information as possible for every recording, so that signal processing can be done in a reliable way. The ECG has to be assigned to the patient. Thereafter the user is asked to fill in the anamnesis form. Typically the physician is asked about the general condition of the patient and the condition of the wound. Finally the dataset is stored locally on the PDA waiting to be sent to the telemedicine service centre.

Moreover, the PDA provides a mobile client, in order to have access to relevant patient data via mobile web browser (IE for Pocket PC), as well as to get the final decision and feedback of the PM follow-up, made by the specialist at the hospital.

2.2. Data transmission and storage

The PDA is connected to a 3G UMTS mobile phone (phone model: Nokia 6630) via a Bluetooth connection. Unfortunately no UMTS card for PDAs was available at the moment this study was performed. Thus the mobile phone acts as a modem for the PDA to establish the



Figure 3. Data acquisition and transmission equipment. ECG signals are recorded with a mobile biosignal acquisition system (g.mobilab, g.tec – Guger Technologies OEG) that is connected with a PDA. A mobile phone is used for sending the ECG to the telemedicine service centre.

connection with the telemedicine service centre. Necessary settings and configuration establishing the Bluetooth connection between PDA and mobile phone as well as to initialise a connection to the internet is done by the software itself. After data acquisition the user triggers the data transfer simply by pressing a “send” button. Thereafter locally stored ECG files are sent to the telemedicine service centre via File Transfer Protocol (FTP). Appropriate anamnesis data is transmitted over Hypertext Transfer Protocol (HTTP) in parallel. UMTS connection guarantees a theoretical upload rate up to 64 kBit/s.

On the server side incoming files and data are stored and managed by the application-server automatically. The files as well as anamnesis data are registered in the database and assigned to the patient waiting to be fetched and processed by the signal processing unit.

2.3. Automatic ECG signal processing and feedback

Upon the arrival of new datasets, data processing starts automatically in order to extract all pacemaker relevant information from the ECG (pacing spikes are detected, spontaneous and paced beats are classified, and the RR-intervals are calculated). A matching process correlates the PM specific stimulation patterns for BOL-, ERI- and EOL-indication to the sequence of RR-intervals. The correlation coefficients give an estimation on the depletion level of the battery of the PM. Regarding the overall outcome, three different cases were classified:

- “ok”: the BOL stimulation sequence has been

detected definitely.

- “replace”: the ERI / EOL stimulation sequence has been detected definitely.
- “undefined”: In spite of repeated ECG recording no appropriate stimulation sequence could be identified.

The result of the signal processing is sent to the data acquisition unit immediately via SMS. If the result of the automatic algorithm is “undefined”, the user is asked to record the ECG with temporally magnet application once again. In case of “replace” the patient has to be assigned to the specialised PM clinic immediately for further examination. “ok” indicates a successfully performed “basic PM follow-up”, waiting to be confirmed by the cardiologist.

2.4. Data review (final decision)

The preliminary report is proposed to the cardiologist via web-interface and includes patient related data, information about the implanted pacemaker as well as the results of the remote signal processing together with specific sections of the ECG showing the magnet effect. Based on the outcome and the patient’s follow-up history, a date for the next follow-up is suggested. Relevant parameters as well as critical episodes of the ECG are highlighted automatically in order to focus cardiologist attention. A screenshot of a preliminary report is shown in Figure 4.

After acceptance or correction of the suggested values for depletion level and next follow-up date a final report is generated. In case of an unclear situation the cardiologist can order the patient to an “extended follow-up” to the hospital immediately. The final report is stored in the file system, accessible to authorized users, and can be sent to the primary care physician. The general practitioner informs the patient about the results of the follow-up.

In course of the pilot trail the proposed telemedicine framework for remote PM follow-up has been evaluated in clinical environment. Previous to routinely PM follow-up the patients were asked to undergo the remote follow-up procedure described above. The examination has been performed separately without the presence of the cardiologist. The feedback and results of the remote follow-up system have also been hidden to the cardiologist and compared to the standard decision.

3. Results

The presented telemedical framework for manufacturer independent remote pacemaker follow-up has been evaluated in a clinical pilot trial with 24 consecutive patients (10 female, age 75 +/- 13 years) on four days. A total of 17 different PM models from 6 different

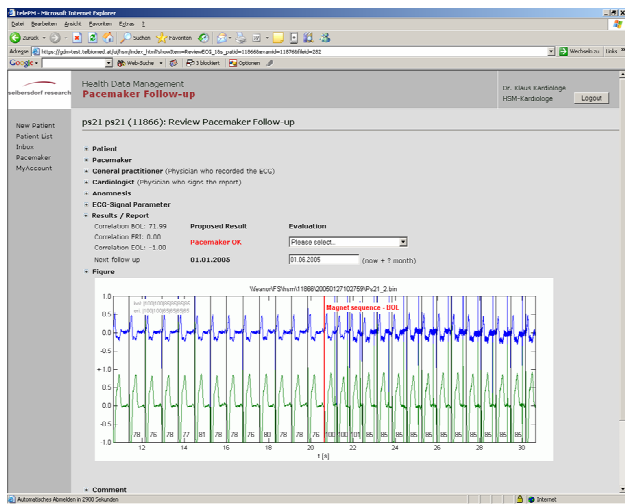


Figure 4. Screenshot of the preliminary report that is presented to the cardiologist via web-interface.

manufacturers (Biotronik, Medtronic, Vitatron, St. Jude, ELA, Intermedics) were analyzed. The mean implantation duration was 16 months (min: 0 month, max: 132 month). 17 out of 24 patients were classified as “OK”. In spite of repeated ECG recording and analysis 7 PM were classified as “UNDEFINED”. In the course of the standard follow-up procedure all PM were classified as “OK” by the cardiologist.

Overall 58 ECGs (file size 63 +/- 17 kByte) were recorded and sent to the telemedical service centre via the 3G UMTS network. Averaged transmission time was 9 +/- 2.8 seconds, averaged signal processing time was 9 +/- 4 seconds. During the study period there were no problems with signal transmission or the availability of the UMTS network. Feedback of the results of the signal processing unit via SMS was available within a maximum of five minutes.

4. Discussion and conclusions

The presented application provides a prototype of a manufacturer independent, remote PM follow-up framework. The results of the pilot trail were limited due to the following factors:

- To perform an automatic analysis of the magnet effect it is essential that the typical stimulation pattern for each depletion level of the battery and pacemaker are stored in the database. Because of a lack of database update 7 patients (6 PM) could not be analysed online because the PM were not registered in the database. Hence the examination could not be performed prospectively.

- A correct identification of the pacing spikes is essential for identifying the stimulation pattern within the ECG. In the pilot trail, the ECG recording device used supports a sampling rate of 256 Hz, which seems to be too low – especially in case of bipolar stimulation – to detect the pacing spikes correctly. Hence 7 PM could not be evaluated.

Further studies should also include a respective patient group (pacemakers with identified problems). Nevertheless the results indicate that the presented follow-up concept, which can be handled by general practitioners, has the potential to work as an efficient screening method and may spare a significant number of patients the burden of having to travel to specialized hospitals which are often far away from patients’ homes.

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