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Initial experiences with a telemedicine framework for remote pacemaker follow-up

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Abstract— **According to international guidelines implanted cardiac pacemakers (PM) have to be checked periodically to ensure that they are working correctly. To spare a significant number of patients the burden of traveling to specialized PM clinics a telemedicine framework has been developed prototypically. A mobile, Personal Digital Assistant (PDA) based PM follow-up unit provides the caregiver at the point-of-care with the necessary infrastructure to perform a basic PM follow-up examination remotely. In case of detected malfunction of the PM the patient is ordered to the hospital for further examination.**

The system has been evaluated in a clinical pilot trial on 44 patients with a total of 23 different PM models from 8 different manufacturers. The initial results indicate the potential of the concept to work as an efficient, manufacturer independent screening method with the ultimate goal to increase the safety, quality and efficiency of PM therapy.

I. Introduction

THE increasing number and the high complexity of implanted cardiac pacemakers (PM) require new strategies in therapy management and follow-up. Mainly medical and financial benefits are expected with this approach. Particularly the use of information and communication technologies (ICT) provide a great opportunity to enhance the safety of patients, to increase the efficiency in the therapy management, and to reduce the burden for patients of traveling to the physician's office or specialized PM centers to undergo periodical follow-up visits.

After implantation of a pacemaker careful follow-up and continuity of care are required. The main goals of PM follow-up are to identify potential problems and malfunction with the pacing system and to determine the current depletion level of the battery [1]. The decision how often a patient's pacemaker should be monitored is in the responsibility of the patient's physician. The follow-up interval may vary over time from a single up to four times a year, depending on the time passed since implantation and the circumstances of the individual patient.

Today, mostly "extended PM follow-up" examinations are performed in PM follow-up clinics. For this purpose, manufacturer specific programming systems are used to communicate with the PM telemetrically. This enables the cardiologist to interrogate the programmed parameters and to adjust the PM's settings to the individual needs of the patient, which is particularly necessary at the beginning of the PM's life cycle. Based on the provided information in combination with patient's general condition the physician is able to act accordingly.

Transtelephonic monitoring (TTM) provides routine testing of PMs' basic functions conveniently at home, using a standard telephone [2]. The patient is equipped with a portable ECG recording system. In predefined intervals, the patient records an ECG in free-running and magnet mode and transmits the data via the standard telephone line to a service centre. The transmitted ECG is converted to a hard copy for review and interpretation by the physician. In case of identified problems the patient is ordered to the PM clinic for an extended follow-up examination. This service is very common in the US and Canada and is provided by special cardiac monitoring centres, hospitals, and outpatient clinics.

Upcoming pacing systems will have integrated monitoring features to provide the physician with diagnostic data at a distance. In a particular system the data are transmitted wirelessly from the PM to a modified mobile phone which forwards them to the central service centre automatically [3]. In Austria, these systems are currently evaluated in clinical trials.

Today, in Austria only extended follow-ups are performed in specialized PM clinics routinely. This implies significant investments (personnel, equipment, and logistics) in those institutions and long travel burdens for the predominantly elderly patients. The general idea of the present project is to provide the caregiver at the point-of-care with an efficient screening method to identify possible problems with the

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pacing system and to send patients to the specialized institutions only in case of good reason.

II. METHODS

Due to international standards each PM reacts to the application of a magnet by changing the pacing rate in a predefined way depending on the depletion level its battery (magnet effect). In this mode a predefined sequence of pacing pulses – which strongly depends on the type and manufacturer of the PM - is applied to the patient's heart. Hence, the depletion level of the battery can be determined by the means of a surface ECG recording. In our previous research we developed an algorithm which allows the assessment of a PM's battery status by interpreting the magnet effect automatically [4].
Moreover, the signal processing unit was integrated into a web based PM follow up concept, where ECGs could be uploaded and analyzed automatically [5]. However, this system lacked in terms of mobility which is one of the major aspects in providing ubiquitous medical care.

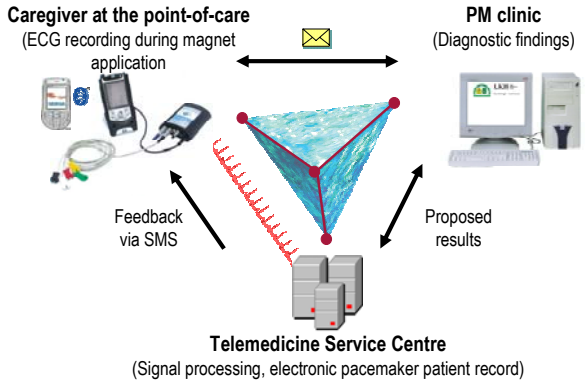

Fig. 1: Overview of the telemedicine framework for manufacturer independent, collaborative pacemaker follow-up.

To provide the caregiver at the point-of-care with an adequate communication interface a mobile PM follow-up unit has been developed (figure 2). A Personal Digital Assistant (PDA) acts as mobile client which is connected to a Universal Mobile Telecommunications Service (UMTS) enabled mobile phone (phone model: Nokia 6630) via a Bluetooth connection. Hence, the mobile phone acts as a modem for the PDA to establish the wireless internet connection to the telemedicine service centre.

A specially developed, JAVA based software running on the PDA guides the user through the PM follow-up procedure. After login and authentication process, the user selects the appropriate patient and a new follow-up session is initialized. Thereafter the user is asked to record a standard 2-lead ECG. Mobile ECG acquisition is supported by a PDA based ECG signal recording unit, provided by g.tec – Guger Technologies OEG (g.mobilab, g.tec Guger Technologies OEG, Graz, Austria).

Firstly, an ECG is recorded in non-magnet mode for about 30 seconds. Secondly, a magnet is placed above the PM case to trigger the magnet mode for a period of about 30 more seconds. Thereafter the magnet is removed and the PM switches back in the predefined mode. Finally data concerning the general condition of the patient is acquired and sent to the telemedicine service centre via the UMTS mobile network.

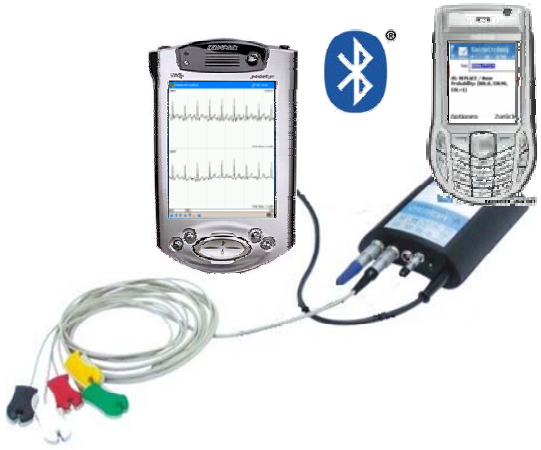

Fig. 2: Mobile pacemaker follow-up unit. ECG signals are recorded with a mobile biosignal acquisition system (g.mobilab, g.tec – Guger Technologies OEG) that is connected with a PDA. A mobile phone is used for transmitting the ECGs to the telemedicine service centre over the UMTS network.

Received files and examination data are stored and managed by the central application server (Zope 2.6.1, Zope Corporation, Fredericksburg, Virginia, USA) waiting to be fetched and processed by the signal processing unit (MATLAB 7.0, The MathWorks Inc., USA). The algorithm extracts all relevant information from the ECG. Namely, the pacing spikes are detected and the intervals between the pacing spices, representing the magnet effect, are calculated. Once the magnet rate is determined a matching process compares the PM specific stimulation patterns for begin of life (BOL), elective replacement indicator (ERI) and end of life (EOL) with the identified sequence. The results provide an estimation of the depletion level of the battery of the PM and give information about the general condition of the pacing system. The results of the signal processing are stored into the central database (Interbase, Version 6.0, Borland Software Corporation, USA) and are sent to the caregiver at the point-of-care via SMS immediately. Regarding the magnet effect, three different cases were classified:

- "ok": the BOL stimulation sequence has been detected definitely. The result has to be confirmed by the cardiologist.
- "notok": the ERI / EOL stimulation sequence has been detected definitely. The patient has to be admitted to

the PM clinic immediately for further examination

- "undefined": no appropriate stimulation sequence could be identified. The user is asked to repeat the examination.

According to the overall concept, preliminary results have to be reviewed, confirmed or corrected by the cardiologist. Hence, processed ECGs are listed in the so called "Inbox". A preliminary report summarizes patient related data, information about the implanted PM as well as the results of the ECG processing. Additionally, the recorded ECG could be accessed via web. Relevant parameters as well as critical episodes of the ECG are highlighted in order to focus the cardiologist's attention (figure 3).
After acceptance or correction of the suggested results the cardiologist appoints the next follow-up. Finally a PDF - report is generated and stored into the database. However, in case of detected problems or an unclear situation the patient is admitted to the PM clinic for further examination.

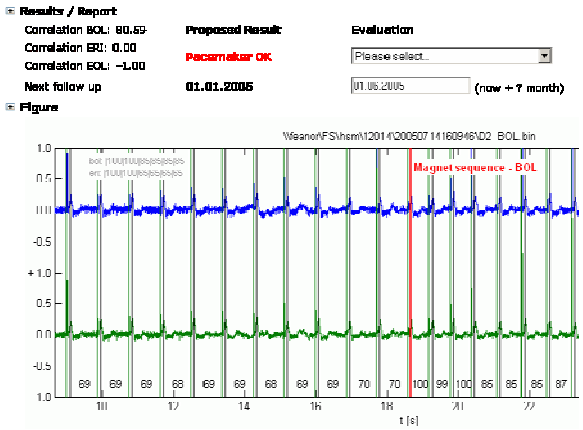

Fig. 3: Screenshot of the preliminary report that is presented to the cardiologist via web-interface. Relevant parameters as well as critical episodes of the ECG are highlighted.

The main goals of the telemedicine framework are to establish collaboration between the caregiver at the point-of-care and the specialist at the hospital, to provide an open platform for data management and to make the data accessible for the responsible physician via web portal. The system has been implemented as a fully web based application, hosted by a central monitoring centre, and comprises of:

1) Core Services: A combination of a web and an application server manages core services like user management, data management and general security issues. Additionally, features like PDF - report generation or an integrated ECG viewer are provided as callable functions implemented on JAVA servlet and JAVA applet technology.

2) Electronic Pacemaker Patient Record (EPPR): Basically, the EPPR provides the functionality of an electronic health record and adds special services for the management of PM therapy related data. Patient data, results of previous performed PM follow ups, and general medical history are stored and linked in a central database. ECGs and PDF reports are retained on the file server and linked to the corresponding database items.

3) Web-Portal: The web portal provides the user with an interface to access and manage the data stored into the EPPR. After login the data can be accessed and/or managed according the users' permissions.

4) Interoperability: Data are exchanged by remote procedure call (RPC). This standardized, XML based protocol provides a fast and secure data exchange over the internet. ECG files are uploaded by standard file transfer protocol (FTP).

The proposed telemedicine framework for remote PM follow-up has been evaluated in a clinical environment. The main goal of the study was to evaluate the feasibility of the remote follow-up concept. The second goal was to adapt and optimize the signal processing unit regarding accuracy. Therefore two mobile ECG recording systems have been used. The first device provided a sampling rate of 256 Hz (setting 1); the second device has been extended to provide a sampling rate up to 1024 Hz (setting 2).

III. Results

The results of the comparison between expert and automated classification for all ECGs are summarized in Table I. Results are presented as means +/- SD.

TABLE 1
SUMMARIZED RESULTS OF THE CLINICAL EVALUATRION OF THE MOBILE PACEMAKER FOLLOW-UP UNIT.

	setting 1		setting 2	
Number of Patients	24		20	
Age [years]	75 +/- 13		78 +/- 9	
Recorded ECGs	55		66	
File size [kByte]	63 +/- 17		236 +/- 31	
Sampling frequency [Hz]	256		1024	
Transmission time [s]	9 +/- 2		73 +/- 34	
Results	Expert	BSP	Expert	BSP
Magnet effect found and classified correctly	43	33	52	48
Undefined	12	22	14	18

In the first setting (setting 1) 24 patients (10 female, age 75 +/- 13 years) were examined on four consecutive days. Overall 55 ECGs with an averaged file size of 63 +/- 17 kByte (sampling rate of 256 Hz) were recorded and transmitted to the telemedicine service centre via the UMTS network. All transmissions succeeded on the first try; averaged transmission time was 9 +/- 2.8 seconds and feedback via SMS was available within a maximum of five

minutes. 33 out of 55 ECGs were classified correctly. 22 files couldn't be processed due to problems in detecting the pacing spikes correctly. A sampling rate of 256 Hz seems to be too low – especially in case of bipolar stimulation.
Hence, 20 more patients (11 female, age 78 +/- 9 years) were recruited. The sampling rate was increased up to 1024 Hz (setting 2). 66 ECGs were recorded and transmitted to the monitoring centre. In all cases automated signal transmission and processing succeeded at once. 48 out of 66 ECGs were classified correctly; in 18 cases no appropriate magnet effect was found.

The overall average expenditure of time per patient was 15, minutes including preparation for the ECG recording, the follow-up procedure itself, and the idle time to receiving the feedback.

IV. Discussion

The telemedicine framework has been designed to establish an active collaboration between the caregiver at the point-of-care and the cardiologist at the PM clinic. By separating the data acquisition process from the data evaluation process, the patient does no longer have to attend a PM clinic to undergo the routine PM check.
Basically, our developed concept is comparable to TTM. The key features are:

- The presented system provides an efficient method to access the working status of the PM independent on the manufacturer. The follow-up procedure could be easily performed by a caregiver in predefined intervals.
- Using the PDA based PM follow-up unit along with UMTS based data transmission provides a high level of mobility. Due to the ubiquitous availability of the UMTS network in Austria a wired internet access is not longer necessary to perform the examination. This could be convenient for bedridden patients - PM follow-up could be performed in the course of a house visit of the caregiver.
- Immediate and automatic analysis of the transmitted ECG provides a timely feedback of the working status of the PM. In case of unsatisfactory signal quality or a deficient magnet effect the examination could be repeated. On the other hand, if a malfunction of the pacing system is indicated, the patient could be admitted to the hospital for further examination immediately.
- Examination data are stored and managed electronically within the EPPR. Moreover, the EPPR has been designed to provide continuous data storage for documentation purposes. Data could be accessed and managed via the telemedicine framework in a comfortable way.

The promising results approved the overall feasibility of the telemedicine framework. Data transmission succeeded in all cases at once. The second goal could also be reached. By increasing the sampling rate from 256 Hz to 1000 Hz the accuracy of the signal processing algorithm could be increased from 76% (33 out of 43) to 92% (48 out of 52).

Managing PM data electronically is associated with a huge effort for the cardiologist, because every company uses their own, proprietary software and PM programming system. Moreover, modern pacing systems provide a huge amount of diagnostic data which requires new strategies in data management. This becomes more and more important, since modern PMs are able to transmit diagnostic data automatically from the device to the central database.
Our developed telemedicine framework provides an open platform with standardized interfaces to integrate, store, manage, and document PM therapy and PM follow-up related data electronically from different sources.

V. Conclusion

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 PM clinics. Nevertheless, the ultimate goal ultimate goal to increase the safety, quality and efficiency of PM therapy seems to be achievable in the near future.

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