Pacemaker (PM) implantation is only the first step of therapy for patients suffering from several heart rhythm diseases like bradycardia, sick sinus syndrome, and AV-node dysfunction. Since patients' welfare depends on proper PM system function, careful and regular follow-ups are crucial. The major goals of PM follow-up are to identify abnormal system functions, lead/electrode problems, and to detect critical battery depletion at the earliest possible stage. Currently, in Austria PM follow-ups are provided only in specialised clinics. As a consequence, many of the predominantly elderly patients have to travel for quite a distance and a small number of PM follow-up centres have to carry the whole workload.

The general idea of the project is to shift a significant number of “basic PM followups” from follow-up centres to caregivers located in the patient’s vicinity. This is possible because “basic PM follow-ups” can be performed without the necessity of manufacturer-specific PM programming devices.

To comply with international standards, each device reacts to the application of a 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. Therefore, a routine ECG recording can be used to verify whether the PM works correctly or if further examination is indicated. Only in case of patient-reported symptoms, or an indicated malfunction of the pacing system determined by analysing an ECG recording during magnet application, the patient is admitted to the PM clinic for further examination.

Therefore, an advanced, multidisciplinary collaboration between the caregiver at the point-of-care and the specialists at the hospital is needed which can be provided by an appropriate IT infrastructure.

System Architecture

Basically, the telemedicine framework supports the collaboration between the cardiologist at the hospital and
the primary care physician at the point-of-care. It supports the following processes at the participating sites:

1. Data acquisition:
According to the follow-up schedule, the patient frequents the general practitioner (GP) to undergo the follow-up procedure. The GP records a surface ECG in freerunning and magnet mode using a mobile, PDA-based ECG recording system. Additionally, general clinical data concerning the health status of the patient are collected.

2. Data transmission:
Specially developed software running on the the PDA guides the user through the PM follow-up procedure. The collected data are transmitted to the telemedicine service centre via the mobile network. UMTS connection guarantees a theoretical upload rate up to 64 kBit/s.

3. Data processing: In the telemedicine service centre, the data are processed automatically. Relevant information about the working status of the PM is extracted from the ECG.

4. Immediate feedback: In case of insufficient signal quality, the GP is informed to repeat the ECG recording.

5. Data review: Based on the results of the automatic signal processing, a preliminary report is generated which is provided to the cardiologist via the webportal. The preliminary report is reviewed, confirmed or corrected by the cardiologist.

6. The final report is provided to the GP.

Only in case of an indicated malfunction of the pacing system or in case of an undefined situation, the patient is admitted to the PM clinic for further examination.

Results and Discussion

The proposed telemedicine framework has been developed and used to prove the feasibility of the described collaborative PM follow-up concept in the course of a clinical pilot trial. The experience obtained during this project shows that the following aspects are of crucial importance with respect to safety, quality and efficiency of PM therapy:

- **Collaboration:** An efficient PM therapy management requires a multidisciplinary collaboration between the surgeon, the cardiologist and the caregiver at the point-of-care.

- **Telemedicine Support:** Telemedicine is defined as providing medical care at a distance. By separating the data acquisition process from the data evaluation process, the patient no longer has to attend a PM clinic to undergo the routine PM check. This increases the convenience for patients and unburdens the specialists at the same time.

- **Central Data Management:** Besides providing an efficient screening method, the framework provides an electronic pacemaker patient record (EPPR) where the patient data and PM therapy-related data are stored and managed. The system has been designed to provide continuous data storage and documentation from implantation to explaining it to the PM. Participating caregivers have access to the data in an uncomplicated way for patient care, clinical decision-making, report generation, statistics and research. The web-based architecture provides for easy and familiar access to the data using a standard web browser.

Future Directions

Based on the promising results of the pilot trial, the presented telemedicine framework has been enhanced and is currently evaluated in the course of a multi-centre study in which more than 400 patients will take part (http://h-elga.at). Because the EPPR evolved as the central element for data management in PM therapy, the next steps will be the integration of the EPPR into the hospital information system (HIS) to enable its usage in routine care.
The figure depicts the general concept: the EPPR serves as the central hub for PM therapy-relevant data from different sources. As such, the EPPR will provide interfaces to PM manufacturer-specific, programming devices, telemedicine systems as well as to device and patient registries. The EPPR will merge the data and will give the physician the possibility to access the information via a single, central web-portal.

The most challenging part in such a system is to ensure unique patient identification, data integrity, and data security for all components. To fulfil these requirements, the EPPR has been designed to operate as a subsystem of an existing IT infrastructure of a regional hospital group. This configuration will allow the EPPR to exchange data with the HIS using standardised communication protocols (e.g. HL7) as well. Basically, the EPPR stores all kinds of source data and PM therapy-relevant data are summarised in medical reports which are sent to the HIS for long-term storage. The regional master patient index of the group will enable the collaboration of several cardiology centres, thus providing best possible care near to the PM-patients’ home in case of problems. A modular system architecture allows one to adapt the EPPR to the terms of use in routine care and in clinical research.

Conclusion

The rapidly increasing number of pacemakers, ICDs and other implantable devices requires new strategies in the management of therapy and follow-up. The results obtained so far indicate that the presented telemedical pacemaker follow-up concept has the potential to work as a manufacturer-independent screening method and may spare a significant number of patients the burden of having to travel to specialised pacemaker clinics. To use such telemedical concepts in routine care, they will have to be fully integrated into the existing IT infrastructure at the partnering institutions to ensure data consistency and integration with existing workflows and processes.

Figure: The Electronic Pacemaker Patient Record (EPPR) serves as a central crossroads and offers several interfaces to devices and external services.

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