Remote Monitoring: Good or Bad?

Advances in Remote Monitoring: from telephone Transmitter to Blue Tooth Technology

Renato P. Ricci
Rome, Italy
First ECG remote monitoring (Einthoven, March 22, 1905)

ECG transmission through the telephone line from the Hospital to the ECG lab (2 km)
The Radio Doctor: Maybe!

1924: Nobel Prize to Einthoven for ECG
Transtelephonic pacemaker monitoring (70s)

Available data:
- ECG streep
- Pulse duration
- Pulse interval

Main purposes:
- Battery status monitoring
- Avoid long travelling
ICD implantation rate in Italy - EURID form
85% of industry data

ICD implant rate per million since 1990 to 2006

A.I.A.C. Italian ICD Registry
Actual number of device follow-ups at our institution
Main limits of in-hospital device follow-up

- Delayed detection of system malfunctions or early battery depletion (mainly for devices in advisory)

- Delayed awareness of diagnostic data stored in the device memory such as atrial and ventricular arrhythmias, ICD interventions, heart rate, spontaneous rhythm behaviour, daily activity, HRV.

- Delayed reaction to changes in clinical status, mainly if asymptomatic

- Delayed evaluation of drug therapy effects

- Health Care Source waste for unnecessary visits.
New technology for remote control of ICD and pacemaker patients

- Home Monitoring™ System (Biotronik)
- Housecall Plus Remote Patient Monitoring System™ (St Jude Medical)
- Medtronic Carelink Network™ manual
- Medtronic Carelink Network™ wireless
- Merlin.net System (St Jude Medical)
- Latitude System™ (Boston Scientific)
Home Monitoring™ System

Patient wearing either a pacemaker or an ICD equipped with an antenna for long distance telemetry.

The transmitter sends on a daily basis or in case of trigger events the data collected by the device via GSM (mobile phone) network in the form of encrypted SMS messages to a Service Center.

They receive alert messages via sms or e-mail and may check their patients on the secure website.

The Service Center decodes, analyzes and organizes the data and posts them on a secure website.
For each patient, on clinical basis, trigger events may be selected in order to have the medical staff aware of them as early as possible.

In case of events, the Service Center sends sms messages, e-mail and faxes either to the physician responsible for the patient or to a dedicated nurse.

### Event types: Kronos (default settings)

| System integrity | Atrial pacing impedance < 250 ohm or > 1500 ohm  
|                  | RV pacing impedance < 250 ohm or > 1500 ohm  
|                  | LV pacing impedance < 250 ohm or > 1500 ohm  
|                  | BiV pacing impedance < 200 ohm or > 750 ohm  
|                  | Impedance of last shock < 25 ohm or > 110 ohm  
|                  | ERI  
|                  | Special implant status (incl. VT/VF detection inactive)  
| Episode diagnostics | VT1 detected  
|                     | VT2 detected  
|                     | VF detected  
|                     | SVT detected  
|                     | 30 J shock ineffective  
| CHF diagnostics | Ventricular pacing < 90 %  
|                   | Mean ven. heart rate at rest > 90 ppm  
|                   | First mode switching since last follow-up  
|                   | First mode switching per day  
|                   | Duration of mode switching >= 75 % (18 h)  
|                   | Mean VES / h >= 50  

Home Monitoring™ Flow Chart (Biotronik)
Transmission time from pacemaker to patient’s physician

<table>
<thead>
<tr>
<th>Transmission time</th>
<th>≤ 1’</th>
<th>≤ 3’</th>
<th>≤ 15’</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periodic</td>
<td>67 %</td>
<td>97 %</td>
<td>98 %</td>
</tr>
<tr>
<td>Patient-activated</td>
<td>69 %</td>
<td>97 %</td>
<td>99 %</td>
</tr>
</tbody>
</table>

- 100 % of the messages correctly transmitted
- 92 % of the patient days actually monitored
Organizational aspects

Human Sources

Nurse
- Patient training and education
- Web site data entering
- HM data and alert reviewing
- Data screening
- Submitting critical cases to the physician
- Contact with the patients
- Monitoring of patient compliance and therapy benefits

Physician
- Informed consent submission
- Overview and check
- Clinical judgement in critical cases
Patients followed by HM at our Institution

245 patients enrolled between April 2006 and September 2008

<table>
<thead>
<tr>
<th>Pacemaker</th>
<th>ICD</th>
<th>ICD-CRT</th>
</tr>
</thead>
<tbody>
<tr>
<td>182</td>
<td>34</td>
<td>29</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reaction time to the first AF alert</th>
<th>Median (days)</th>
<th>Interquartile interval (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median time from the last in-hospital follow-up visit to the detection and the first intervention for AF</td>
<td>50</td>
<td>10 244</td>
</tr>
<tr>
<td>Median value of reaction time to AF in advance to the scheduled follow-up</td>
<td>148</td>
<td>75 170</td>
</tr>
</tbody>
</table>

Case Report: Asymptomatic AF recurrence

Sinus rhythm restored. No further AF recurrences

Real time transmission of a fast VT in the VF window
ATP delivery during charge interrupted VT (patient asymptomatic)
The Housecall Plus™ System

- Receiver:
  - Computer
  - Build-in modem
  - Flat screen
  - Key board
  - Printer

- Transmitter:
  - For patient / Referrals
  - Phone connection
Housecall Plus™ System

- Analog phone lines
- Interactive and real time remote follow-up (for ICDs only)
- Ability to alternate between voice and data modes
- Access to all information stored in device (ICD only)
- Printed Reports and Database Connectivity
Remote follow-up duration

3 follow-ups for each patient, the first in-hospital from a remote room, the others from patient’s home

<table>
<thead>
<tr>
<th>Time to Interrogation</th>
<th>Interrogation</th>
<th>Time to Call End</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5 ± 4.0</td>
<td>8.2 ± 1.1</td>
<td>2.2 ± 1.6</td>
<td>13.9 ± 9.6</td>
</tr>
</tbody>
</table>

*House Call Plus: S. Filippo Neri (Rome) Preliminary Experience*
Clinical application in ICD patients
- Routine follow-up
- Symptoms
- ICD Therapy Delivery
- Patients needing frequent follow-up

Specific advantage
- Phone contact between the patient and the nurse / physician

Limitations
- No automatic analysis or automatic alert to the physician
- Need to exactly schedule the date and the time of the follow-up
The patient puts the Carelink Monitor antenna on the device to interrogate.
The Monitor sends the data through a standard telephone line to a secure web site.
The physician may check the data on the Carelink Clinician website.
**Clinical application in ICD patients**
- Routine follow-up
- Symptoms
- ICD Therapy Delivery
- ICD Sound Alerts

**Patient needs**
- Standard telephone line to send the interrogation

**Limitations**
- No automatic analysis or automatic alert to the physician
- Not available abroad
CARELINK Device Monitoring: Arrhythmic Episodes

Male, 61, post-MI DCM, NYHA Class III, EF 28%, CRT-D in primary prevention

The pt received a night shock. In the morning he called the center and sent a transmission.
M, 65, DCM, NYHA Class II, EF 23%, QRS = 160 ms, CRT-D in primary prevention

Audible alert on March 28 at noon.

- The transmission of stored data revealed an episode of possible fluid accumulation associated with a reduction of the patient activity.
- Contacted by phone, the pt reported worsening of HF symptoms.
M, 65, DCM, NYHA Class II, EF 23%, QRS = 160 ms, CRT-D in primary prevention

The diuretics dosage was increased.

The review of device data after 1 week permitted to observe an improvement of fluid and activity indices.
Medtronic CareLink Network™ (wireless devices)

Scheduled follow-ups

Transmission scheduling
Automatic interrogation
Transmission to the web center
Data available for the physician

Care Alerts

Automatic transmission of data to the Carelink monitor.
Physician immediately alerted by phone
### Transmissions:

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Status</th>
<th>Battery</th>
<th>Next Send</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-Jul-2008</td>
<td>11:01</td>
<td>Viewed</td>
<td>3.03 V</td>
<td>Not Scheduled</td>
<td>Virtuoso™ DR</td>
</tr>
<tr>
<td>2-Jul-2008</td>
<td>08:29</td>
<td>Viewed</td>
<td>3.13 V</td>
<td>Not Scheduled</td>
<td>Virtuoso™ DR</td>
</tr>
</tbody>
</table>

### Event Summary:

- **15-Oct-2008 12:25**: Possible Fluid Accumulation
- **13-Oct-2008 18:26**: Patient Alert, Possible Fluid Accumulation, 1 VT/VF, 1 Shock, 1 Shocks Delivered for an Episode
- **30-Jul-2008 13:22**: No Events
- **12-Jul-2008 11:01**: 39 VT/VF, 19 Shocks
- **2-Jul-2008 08:29**: Patient Alert, 2 VT/VF, 1 Shock, 1 Shocks Delivered for an Episode
Here's a list of today's Alerts. What would you like to do?

<table>
<thead>
<tr>
<th>Patients</th>
<th>Transmission Reports</th>
<th>Location</th>
<th>Comments</th>
<th>Alerts</th>
<th>Episodes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stewart, Charlie</td>
<td>03-29-2007, 05:49 PM</td>
<td>San Francisco</td>
<td></td>
<td>2 Alerts</td>
<td>2 Episodes</td>
</tr>
<tr>
<td>Stewart, Charlie</td>
<td>03-29-2007, 06:19 PM</td>
<td>San Francisco</td>
<td></td>
<td>2 Alerts</td>
<td></td>
</tr>
<tr>
<td>Parker, Peter</td>
<td>03-29-2007, 06:59 PM</td>
<td>Los Angeles</td>
<td></td>
<td>3 Alerts</td>
<td>0 Episodes</td>
</tr>
<tr>
<td>Parker, Peter</td>
<td>03-29-2007, 07:53 PM</td>
<td>Los Angeles</td>
<td></td>
<td>3 Alerts</td>
<td>0 Episodes</td>
</tr>
<tr>
<td>Anderson, Thomas</td>
<td>03-30-2007, 06:52 AM</td>
<td>San Diego</td>
<td></td>
<td>0 Alerts</td>
<td>2 Episodes</td>
</tr>
<tr>
<td>Anderson, Thomas</td>
<td>03-30-2007, 07:55 AM</td>
<td>San Diego</td>
<td></td>
<td>0 Alerts</td>
<td></td>
</tr>
<tr>
<td>Stewart, Charlie</td>
<td>03-30-2007, 08:58 AM</td>
<td>San Francisco</td>
<td></td>
<td>1 Alerts</td>
<td>1 Episodes</td>
</tr>
<tr>
<td>Anderson, Thomas</td>
<td>03-29-2007, 03:46 PM</td>
<td>San Diego</td>
<td></td>
<td>0 Alerts</td>
<td>1 Episodes</td>
</tr>
<tr>
<td>Michaels, John</td>
<td>03-29-2007, 07:59 PM</td>
<td>San Diego</td>
<td></td>
<td>0 Alerts</td>
<td>0 Episodes</td>
</tr>
<tr>
<td>Martin, Mark</td>
<td>03-29-2007, 09:08 PM</td>
<td>Los Angeles</td>
<td></td>
<td>0 Alerts</td>
<td>0 Episodes</td>
</tr>
<tr>
<td>Young, Dorothy</td>
<td>03-29-2007, 09:17 PM</td>
<td>San Diego</td>
<td></td>
<td>0 Alerts</td>
<td>0 Episodes</td>
</tr>
<tr>
<td>Tan, Sandy</td>
<td>03-29-2007, 09:31 PM</td>
<td>San Diego</td>
<td></td>
<td>0 Alerts</td>
<td>0 Episodes</td>
</tr>
<tr>
<td>Scott, Michael</td>
<td>03-30-2007, 06:49 AM</td>
<td>Los Angeles</td>
<td></td>
<td>0 Alerts</td>
<td>0 Episodes</td>
</tr>
</tbody>
</table>
Merlin.net system. Self-limited VF episode
still not available in Europe
Conclusions

- Technology for remote monitoring of implantable devices dramatically improved during the last few years and is now based on wireless data collection and transmission and on internet use. Analog and GSM phone lines are utilized according to manufacturer preference.

- Remote monitoring of implanted devices has been demonstrated feasible and reliable and may be introduced in standard clinical practice.

- A tailored organization involving several professionals should be developed in order to optimize health care source utilization and patient management.

- Home monitoring may deeply impact on treatment strategies for patients with implanted devices.

- Clinical studies are needed to demonstrate if such new strategies may improve patient overall clinical outcome.