Remote Monitoring in a Collaborative Health Care Model

- 계명대학교 심장내과 조교수 황종민 -
Follow-up of CIED

- Establish and maintain appropriate CIED function and optimal programming
- Identify device-related risk (e.g., impending lead failure)
- Aside from direct therapeutic ability, CIEDs have a sophisticated capacity to identify, quantify, and present patient condition
  - e.g., arrhythmias, hemodynamic parameters
- Attention to these may facilitate device and/or disease management.
- This requires mechanisms for CIED monitoring that permit timely retrieval of important diagnostic data.
- Hence postimplant follow-up is important.
Follow-up of CIED

• Traditionally, calendar-based schedule of in-person evaluation (IPE)
• A recent survey in the US indicated that only a fraction of patients were seen regularly after implant
• Frequent in-office evaluation generates a large service commitment and challenges patient compliance.
• Another major limitation is that patients remain unmonitored between scheduled appointments, irrespective of frequency
• Hence recorded data remain concealed for extended periods.
Follow-up of CIED

• This is important if clinical intervention based on these data would prevent patient morbidity and/or mortality, most obviously with system component failures.

• A mechanism for performing continuous surveillance and rapid problem recognition and notification, without overburdening device clinics, is desirable.
What is remote monitoring

• IPE: In-Person Evaluation
• Remote interrogation (RI)
  • routine, scheduled, remote device interrogations structured to mirror in-office checkups
  • Practically all information obtained during an in-office device checkup
  • important exception is measuring the pacing capture threshold

• Remote monitoring (RM)
  • Automated transmission of data based on prespecified alerts related to device functionality and clinical events

• The terms RI and RM are often used interchangeably, with RM being the colloquially accepted term for both
Transtelephonic monitor (TTM)

In the beginning...
Remote technologies

- **Transtelephonic**
  - Scheduled follow-up

- **Inductive**
  - Scheduled follow-up

- **Automatic**
  - Electrophysiologist
  - Heart failure MD

Slotwiner et al 2015 HRS Expert Consensus Statement on remote interrogation and monitoring for CIED
Enhanced security with data encryption and pacemaker protection

Use of Bluetooth low energy is designed to minimize battery drain of the pacemaker.¹

Automatic notifications inform patients of transmission status

Upgradeable throughout lifetime of device

• Elimination of bedside communicator
  • Easier to pair devices (“plug and play”)
  • Data transfer not limited to certain hours of day
  • No headaches when patients travel
  • Inform patients when there are connectivity issues
  • Link to other healthcare apps
    • Medication adherence
  • Two way notification between doctors and patients regarding device related issues
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Name of technology</th>
<th>Pacemaker</th>
<th>ICM</th>
<th>ICD/CRT</th>
<th>Mode of transmission</th>
<th>Interface</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic (Minneapolis, MN)</td>
<td>CareLink</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗ ○</td>
<td>Web ○</td>
</tr>
<tr>
<td>Abbott (Abbott Park, IL)</td>
<td>Merlin.net patient care network</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗ ○</td>
<td>Web ○</td>
</tr>
<tr>
<td>Boston Scientific (Marlborough, MA)</td>
<td>Latitude home monitoring system</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗ ○</td>
<td>Web ○</td>
</tr>
<tr>
<td>Biotronik (Berlin, Germany)</td>
<td>Home Monitoring</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗ ○</td>
<td>Web ○</td>
</tr>
<tr>
<td>LivaNova (Sorin) (London, England)</td>
<td>SmartView hot spot</td>
<td>Not available in Canada</td>
<td>N/A</td>
<td>✗</td>
<td>✗ ○</td>
<td>Web ○</td>
</tr>
</tbody>
</table>

## Remote monitoring in Asia-Pacific

### Table Remote monitoring of cardiac implantable electronic devices in major countries/regions in Asia-Pacific

<table>
<thead>
<tr>
<th></th>
<th>Australia and New Zealand</th>
<th>China</th>
<th>Hong Kong</th>
<th>India</th>
<th>Japan</th>
<th>South East Asia</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Pacemaker with RM</td>
<td>15</td>
<td>1.7</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>% ICD with RM</td>
<td>40</td>
<td>14.2</td>
<td>&lt;5</td>
<td>&lt;1</td>
<td>50</td>
<td>&lt;1</td>
</tr>
<tr>
<td>% CRT/CRTD with RM</td>
<td>30</td>
<td>8.6</td>
<td>&lt;10</td>
<td>&lt;1</td>
<td>50</td>
<td>&lt;1</td>
</tr>
<tr>
<td>No. of RM centers</td>
<td>120</td>
<td>250</td>
<td>9</td>
<td>NA</td>
<td>400</td>
<td>3</td>
</tr>
<tr>
<td>No. of Implanting centers</td>
<td>200</td>
<td>1200</td>
<td>24</td>
<td>NA</td>
<td>2000</td>
<td>NA</td>
</tr>
<tr>
<td>Data surveillance</td>
<td>Technicians</td>
<td>Nurses</td>
<td>Physicians</td>
<td>Industry Technicians</td>
<td>Physicians</td>
<td>Physicians</td>
</tr>
<tr>
<td>Reimbursement</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Additional cost (%) per unit</td>
<td>15</td>
<td>20</td>
<td>20</td>
<td>NA</td>
<td>5</td>
<td>20</td>
</tr>
</tbody>
</table>

Data shown are the maximum reported from any of the four providers of remote monitoring devices. CRT, cardiac resynchronization therapy; CRTD, cardiac resynchronization therapy and defibrillator; ICD, implantable cardioverter defibrillator; NA, data not available; RM, remote monitoring.
# Evidence of RM

<table>
<thead>
<tr>
<th>Study Name or Author</th>
<th>Year</th>
<th>Study Size</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Randomized Trials: Pacemakers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PREFER Trial</td>
<td>2009</td>
<td>897 pts</td>
<td>Mean time to first diagnosis of clinically actionable events was shorter in the RM arm (5.7 months) than in the control arm (7.7 months)</td>
</tr>
<tr>
<td>COMPAS Trial</td>
<td>2011</td>
<td>538 pts</td>
<td>RM was safe (major adverse events 17.3% in RM arm vs. 19.1% in control arm) and reduced in-office visits by 56%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>RM allowed earlier detection of clinical and device-related adverse events</td>
</tr>
<tr>
<td><strong>Randomized Trials: ICDs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRUST Trial</td>
<td>2010</td>
<td>1339 pts</td>
<td>In-hospital device evaluation was 2.1 per patient-year in the RM arm vs. 3.8 per patient-year in the control arm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Overall adverse event rate was 10.4% in both groups at 12 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>RM advanced by &gt;30 days the detection of arrhythmia onset</td>
</tr>
<tr>
<td>CONNECT Trial</td>
<td>2011</td>
<td>1997 pts</td>
<td>RM reduced the time to a clinical decision: 4.6 days vs. 22 days (in-office)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>RM reduced mean length of stay: 3.2 days vs. 4.3 days (in-office arm)</td>
</tr>
<tr>
<td>EVATEL Trial</td>
<td>2011</td>
<td>1501 pts</td>
<td>No differences in major cardiovascular events between RM (28.9%) and control group (28.4%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• RM reduced Inappropriate Device Therapy: 4.7% vs. 7.5% in the Control Group</td>
</tr>
<tr>
<td>ECONST Trial</td>
<td>2012</td>
<td>433 pts</td>
<td>RM was as safe as standard FU (major adverse events 40.3% (RM) vs. 43.3% (control arm))</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical</td>
<td>RM reduces appropriate and inappropriate shocks by 71% and increased battery longevity</td>
</tr>
<tr>
<td>EVOLVO Trial</td>
<td>2012</td>
<td>Clinical</td>
<td>RM reduced emergency department or urgent in-office visits: 4.4 vs. 5.7 in the control arm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>200 pts</td>
<td>RM reduced health care use and increased efficiency of health care</td>
</tr>
<tr>
<td>REFORM Trial (2nd analysis)</td>
<td>2013</td>
<td>155 pts</td>
<td>RM safely reduced the ICD FU visits by 58% during 27 months after implantation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• RM had a favorable impact on quality of life</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• RM had no impact on mortality and hospitalization rate</td>
</tr>
<tr>
<td>INTIME Trial</td>
<td>2014</td>
<td>716 pts</td>
<td>RM was associated to a reduction of the worsening of clinical status: 18.9% (RM) vs. 27.2% (control)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• RM reduced 1-year all-cause mortality from 8.7% (control group) to 3.4% (RM)</td>
</tr>
<tr>
<td><strong>Registries</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AWARE</td>
<td>2007</td>
<td>11624 pts</td>
<td>RM improved safety and optimized allocation of health resources</td>
</tr>
<tr>
<td>ALITIITUDE</td>
<td>2010</td>
<td>185778 pts</td>
<td>RM was associated to 50% increase of 1-year and 5-year survival both in ICD and CRT-D patients</td>
</tr>
<tr>
<td>Home Guide Registry</td>
<td>2013</td>
<td>1650 pts</td>
<td>RM was highly effective in detecting and managing clinical events in CIED pts (RM sensitivity 84.3%; PPV 97.4%); RM detected 95% of asymptomatic and 73% of actionable events</td>
</tr>
<tr>
<td>MERLIN</td>
<td>2015</td>
<td>269,471 pts</td>
<td>RM was associated with improved survival, in recipients of ICDs, CRTDs and also pacemakers; this effect was “dose-dependent relationship” with level of adherence to RM</td>
</tr>
</tbody>
</table>
• 897 pacemaker patients were randomized to remote follow-up or in-office visits and TTM to determine the time to first diagnosis of a clinically actionable events

• Clinically actionable events were found, on average, two months earlier in the remote arm than in the control arm

AT/AF episodes >48 h or longer were the 2nd most frequent CAE reported (after NSVT)
TRUST Trial

Suneet Mittal 2019 HRS
Hospitalization - atrial arrhythmias & stroke:
(OR = 0.33; 95% CI: 0.14-0.87; p = 0.02)
The HeartLogic algorithm alerted a median of 34 days before a HFE.
Multisensor Algorithm

At nominal HeartLogic Threshold = 16
- HF Event Rate was 10 times higher in the IN Alert State than OUT of Alert State
  - IN Alert = 0.80 events/patient-year
  - OUT of Alert = 0.08 events/patient-year
- 17% of patient-days IN Alert State

Event Rate Ratios range between 8.4 and 12.6 across all thresholds

Gardner RS et al. ESC-HF 2017
Suneet Mittal 2019 HRS
RM and All-Cause Hospitalization

**Hospitalization Risk**
- HR: 0.82
- 95% CI: 0.80 - 0.84
- p < 0.001

**Mean Length of Stay, days**
- RM: 5.3 (9.6)
- No RM: 8.1 (15.7)
- p < 0.001

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Piccini JP, Mittal S et al. 2016 Heart Rhythm Journal
Suneet Mittal 2019 HRS
RM and Survival

Varma N, Mittal S et al. JACC 2015; 65: 2601-2610
Suneet Mittal 2019 HRS
**RM and Survival - Defibrillators**

**Survival, ICD**

- **Number at Risk**
  - High: 18,605, 17,597, 10,345, 4,305, 361
  - Low: 18,854, 17,703, 11,786, 5,667, 714
  - None: 45,139, 40,080, 24,601, 10,827, 1,325

**Probability of Survival**

- **RM Adherence**
  - High
  - Low
  - None

**Survival, CRT-D**

- **Number at Risk**
  - High: 14,217, 13,342, 7,454, 2,744, 206
  - Low: 13,602, 12,572, 7,712, 3,363, 367
  - None: 31,704, 27,448, 15,748, 6,335, 671

**Probability of Survival**

- **RM Adherence**
  - High
  - Low
  - None

**HR Comparison**

- **RM High vs. None**
  - HR: 2.5
  - [2.3–2.7], p<0.001

- **RM High vs. Low**
  - HR: 1.4
  - [1.3–1.5], p<0.001

- **RM Low vs. None**
  - HR: 1.8
  - [1.7–1.9], p<0.001

- **RM High vs. None**
  - HR: 2.4
  - [2.2–2.6], p<0.001

- **RM High vs. Low**
  - HR: 1.5
  - [1.4–1.6], p<0.001

- **RM Low vs. None**
  - HR: 1.6
  - [1.5–1.7], p<0.001

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*Varma N, Mittal S et al. JACC 2015; 65: 2601-2610*

*Suneet Mittal 2019 HRS*
RM and Survival - Pacemakers

**Survival, Pacemaker**

- **Probability of Survival**
- **RM Adherence**
  - High
  - Low
  - None
- **Years from Implant**
  - 0, 1, 2, 3, 4

**Number at Risk**

- **RM High vs. None**
  - HR: 2.3 [2.1–2.4], p<0.001
- **RM High vs. Low**
  - HR: 1.6 [1.3–1.5], p<0.001
- **RM Low vs. None**
  - HR: 1.4 [1.5–1.7], p<0.001

**Survival, CRT-P**

- **Probability of Survival**
- **RM Adherence**
  - High
  - Low
  - None
- **Years from Implant**
  - 0, 1, 2, 3, 4

**Number at Risk**

- **RM High vs. None**
  - HR: 2.1 [1.8–2.5], p<0.001
- **RM High vs. Low**
  - HR: 1.2 [0.9–1.5], p<0.111
- **RM Low vs. None**
  - HR: 1.7 [1.5–2.1], p<0.001

*Varma N, Mittal S et al. JACC 2015; 65: 2601-2610*

Suneet Mittal 2019 HRS
# RM Guideline

## HRS Remote Monitoring Consensus Statement Recommendations

<table>
<thead>
<tr>
<th>Device and Disease Management</th>
<th>Class of Recommendation</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>RM should be performed for surveillance of lead function and battery conservation.</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Patients with a CIED component that has been recalled or is on advisory should be enrolled in RM to enable early detection of actionable events.</td>
<td>I</td>
<td>E</td>
</tr>
<tr>
<td>RM is useful to reduce the incidence of inappropriate ICD shocks.</td>
<td>I</td>
<td>B-R</td>
</tr>
<tr>
<td>RM is useful for the early detection and quantification of atrial fibrillation.</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>The effectiveness of RM for thoracic impedance alone or combined with other diagnostics to manage congestive heart failure is currently uncertain.</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>

Slotwiner et al 2015 HRS Expert Consensus Statement on remote interrogation and monitoring for CIED
### HRS Remote Monitoring Consensus Statement Recommendations

<table>
<thead>
<tr>
<th>Device Follow-Up Paradigm</th>
<th>Class of Recommendation</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.</td>
<td>I</td>
<td>A</td>
</tr>
</tbody>
</table>

Slotwiner et al 2015 HRS Expert Consensus Statement on remote interrogation and monitoring for CIED
Implementing RM

Slotwiner et al. 2015 HRS Expert Consensus Statement on remote interrogation and monitoring for CIED

Interim report generation & communication with other health care providers, including heart failure data.
Implementing RM

Slotwiner et al 2015 HRS Expert Consensus Statement on remote interrogation and monitoring for CIED
• Needs active participation of patients

• Needs multidisciplinary team
  ✓ Allied Professional
    • Nurse, technician, ancillary staff
  ✓ Electrophysiologist
  ✓ Nurse Practitioner / Physician Assistant
  ✓ Heart Failure Physician
  ✓ IT Support
  ✓ Manufacturers
  ✓ Third Party

• Device Clinic Team
  ✓ Dedicated, Trained, Protected time
RM – Patient activated, compliance

Place the antenna of your Patient Monitor over your device to transmit via a standard phone line (Internet connection not required)

Your information is stored in a secure databank

Your clinic reviews your data on the clinician Website
Medtronic Get Connected - Enhanced Service Solutions

DESIGNED TO ALLEVIATE CLINICIAN BURDEN AND IMPROVE PATIENT EXPERIENCE

NEW PATIENTS

Medtronic CareLink™ Network
GET CONNECTED SERVICE – Launched 2017

Guides patients through the process of order, setup and first transmission with their remote monitor – freeing up clinic time at no additional cost

✓ Pacemakers
✓ ICDs
✓ CRTs

EXISTING PATIENTS (WITH AN EXISTING MONITOR)

Medtronic CareLink™ Network
STAY CONNECTED SERVICE – Launched 2018

Provides troubleshooting and support for patients experiencing issues with connectivity, monitor equipment, or who just want to explore new monitor options

✓ Pacemakers
✓ ICDs
✓ CRTs
✓ ICMs

Lynn M. Brewer HRS 2019
Partnering with 3rd Party Vendors

- Important to create expectations – who is doing what?
- Patient Education
- New Patient Workflow
- Compliance Reports
- Optimizing Alert Programming
- Disconnected Monitor Workflow
- Different Billing Platforms
RM with dedicated Device team!
RM in Collaborative Health Care

Remote Monitoring of Cardiac Implantable Electronic Devices.
한국 부정맥 환자들은 반차로 사서 티코차럼티는솔로

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한국 부정맥 환자들은 반차로 사서 티코차럼티는솔로