New Paradigms of Devices for arrhythmias management: a European view

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No conflict of interest to declare
Arrhythmias and devices:

1. Ventricular arrhythmias
2. Supraventricular arrhythmias
Management of arrhythmias

Manage Arrhythmias

Device diagnostics provide information to assess arrhythmias:
- AT/AF total minutes/day
- V Rate During AT/AF and VT/VF
- Non-sustained and Treated VT episodes/day
- Episode Logs and Stored EGMs

Device features to help manage arrhythmia episodes include:
- SmartShock Technology™
- ATP During Charging™
- PainFREE™ Rx Programming Strategies
- Conducted AF Response
- Ventricular Sense Response
- Atrial Tracking Recovery
- Reactive ATP
- Atrial Preference Pacing
- Post Mode Switch Overdrive Pacing
Manage/Optimize Drug Therapies

Optimal drug therapy may include Beta blockers, ACE Inhibitors/ARBs, Aldo-blockers, Hydralazine/Nitrates and Diuretics.

Device diagnostics provide the clinician with trends to aid in monitoring drug therapies, including:

- Episode logs with detailed episode information (i.e. time of episode, duration, rate)
- Average V Rates and Heart Rate Variability to monitor and/or adjust heart failure medications
- AT/AF Trends to evaluate efficacy of anti-arrhythmic drugs as well as risk for stroke and need for anticoagulation
Silent AF and devices: problems...

1. Stroke
2. Inappropriate shocks
3. Heart Failure worsening

Timely treatment is a challenge!
The killer !!!

Thrombus in LAA
The pernicious bond Stroke-AF

- AF stroke is more severe compared to stroke from other causes
- AF pts had twice mortality compared to SR pts
- But…

3 out of 4 AF-Strokes could be prevented …
How to prevent?

Traditional approach

Pz. Con FA evidenziata (%)

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 ECG</td>
<td>2.7%</td>
</tr>
<tr>
<td>ECG multipli</td>
<td>6.8%</td>
</tr>
<tr>
<td>Holter 24 h</td>
<td>11.8%</td>
</tr>
<tr>
<td>Holter 7 giorni</td>
<td>17.5%</td>
</tr>
</tbody>
</table>

Jabaudon D, Stroke 2004; 35: 1647-1651
AF detection

Standard methods of AF monitoring have a low sensitivity and a low negative predictive value!
Today we must take advantage of the device!!!
# Thromboembolic risk

**Table 3.** Risk of Ischemic Stroke or Systemic Embolism after the 3-Month Visit, According to Baseline CHADS<sub>2</sub> Score and According to Whether Subclinical Atrial Tachyarrhythmias Were or Were Not Detected between Enrollment and the 3-Month Visit.

<table>
<thead>
<tr>
<th>CHADS&lt;sub&gt;2&lt;/sub&gt; Score</th>
<th>No. of Patients</th>
<th>Subclinical Atrial Tachyarrhythmias between Enrollment and 3 Months</th>
<th>Hazard Ratio for Ischemic Stroke or Systemic Embolism with Subclinical Atrial Tachyarrhythmias (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Present</td>
<td>Absent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>no. of patients</td>
<td>no. of events</td>
</tr>
<tr>
<td>1</td>
<td>600</td>
<td>68</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>1129</td>
<td>119</td>
<td>4</td>
</tr>
<tr>
<td>&gt;2</td>
<td>848</td>
<td>72</td>
<td>6</td>
</tr>
</tbody>
</table>

* The P value for trend is 0.35.
AF burden

Botto G,...Boriani G JCE 2009
AF treatment

Antithrombotic therapy before and after the evaluation of the ANGELS (Anticoagulation Use Evaluation and Life Threatening Events Sentinels) of AF reports in the active intervention arm.

Silent AF and inappropriate shocks...

74% of Inappropriate ICD Shocks are due to AF

...therefore, inappropriate shocks are life-threatening!
For all these problems...

1. Stroke
2. Inappropriate shocks
3. Heart Failure worsening

Timely treatment is crucial!
Remote Monitoring

Patient

Transmitter

GSM

Web site

Centro Servizi

SMS/E-mail/Fax
Remote Monitoring

Alarm!

Physician reaction

Timely treatment
Remote Monitoring and Atrial Fibrillation

TRUST study

Several AF episodes are silent, therefore:

Follow-up in outpatient clinic → Late diagnosis → Greater risk of events

Remote monitoring → Early diagnosis → Lower risk of events
Home Monitoring in Patients with Implantable Cardiac Devices: Is There a Potential Reduction of Stroke Risk? Results from a Computer Model Tested Through Monte Carlo Simulations

RENATO P. RICCI, M.D.,* LOREDANA MORICHELLI, M.S.N.,* ALESSIO GARGARO, Ph.D.† MARIA T. LAUDADIO, Ph.D.,† and MASSIMO SANTINI, M.D., F.A.C.C., F.E.S.C.*

(Odds Ratios [95% CI] of 2-years stroke incidence)

(J Cardiovasc Electrophysiol, Vol. 20, pp. 1244-1251, November 2009)
Reduction of inappropriate shocks!

Home Monitoring® significantly reduces inappropriate shocks (52%) and related hospitalizations (72%)

Kacet S et al. ECOST Study. Presented in Hot Line Session at ESC 2011 Congress
Supraventricular arrhythmias

Chi-square = 4.63, p = 0.031

Remote monitoring patients

Conventional fup patients

Marcantoni L, ...Bertini M. JCM 2015
Who takes more advantage from remote monitoring?

<table>
<thead>
<tr>
<th></th>
<th>Number of patients</th>
<th>Number of events</th>
<th>Odds ratio (95% CI)</th>
<th>p value</th>
<th>p Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tele-monitoring</td>
<td>Control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤67 years</td>
<td>182</td>
<td>170</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;67 years</td>
<td>151</td>
<td>161</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LVEF within 3 months of enrolment*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤25%</td>
<td>168</td>
<td>166</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;25%</td>
<td>150</td>
<td>151</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>274</td>
<td>262</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>59</td>
<td>69</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>History of atrial fibrillation*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.044</td>
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<tr>
<td>No</td>
<td>257</td>
<td>238</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>76</td>
<td>92</td>
<td></td>
<td></td>
<td>0.003</td>
</tr>
<tr>
<td>ICD</td>
<td>143</td>
<td>131</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>CRT-D</td>
<td>190</td>
<td>200</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE/ARB use at enrolment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>26</td>
<td>45</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>307</td>
<td>286</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>333</td>
<td>331</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*IMfluence of Home Monitoring on The clinical Management of heart failure patients with impaired left ventricular function (IN-TIME) Hindricks et al Lancet 2014
What Affects CRT Retention?

Timely treatment reduces heart failure worsening!

Optimize CRT Therapy

Device diagnostics provide information on percent of CRT:
- Percent Pacing Trend
- Histograms
- Capture Management® Trends

Device features provide tools for ensuring CRT:
- Complete Capture Management
- AdaptivCRT™*
- CardioSync™ Optimization*
- Conducted AF Response
- Ventricular Sense Response
- Atrial Tracking Recovery

*Available beginning with the Viva™ CRT-D device models.
Remote monitoring of implantable devices: Should we continue to ignore it?

Matteo Bertini, Lina Marcantoni, Tiziano Toselli, Roberto Ferrari

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Improvement of clinical status ... 
Reduction of mortality

Primary endpoint: modified Packer score
At study end, a patient is classified “worsened” in case of
- Death
- Overnight hospitalization for worsening heart failure
- Worsening in NYHA class
- Deterioration in the patient’s global self-assessment

<table>
<thead>
<tr>
<th></th>
<th>HM arm</th>
<th>Control arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>worsened</td>
<td>18.9%</td>
<td>27.5%</td>
</tr>
<tr>
<td>improved or unchanged</td>
<td>81.1%</td>
<td>72.5%</td>
</tr>
</tbody>
</table>

p < 0.05 x² test

Major secondary endpoint: all-cause mortality

Death: 3.4%
Deaths: 8.7%

Hindricks et al Lancet 2014
2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

The Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology was constituted by representative groups of experts from the different cardiological areas involved in the management of patients with cardiac rhythm disturbances.

But... Guidelines do not mention what to do with AF diagnosed with devices!
ARTESiA: Design

- Pacemaker or implanted defibrillator
- CHA\textsubscript{2}DS\textsubscript{2}-VASC score $\geq$ 3
- $\geq$ 1 episode of SCAF lasting $\geq$ 6 minutes (and $<$ 24 hours)
- No history of clinical AF

Apixaban 5 mg BD
2.5 mg BD in selected patients

3,719 patients

Double-blind

ASA (80–100 mg/day)

Primary outcome: ischaemic stroke or SE

SCAF, subclinical atrial fibrillation.
Clinicaltrials.gov identifier: NCT01938248
In day-life clinical practice: What to do with Silent AF in device memory?

- Don’t ignore device memory on AF!!!
- Confirm that is really AF > 5 min
- Check $\text{CHA}_2\text{DS}_2\text{Vasc}$ score:
  
  1. $\text{CHA}_2\text{DS}_2\text{Vasc}= 0$ No OAC
  2. $\text{CHA}_2\text{DS}_2\text{Vasc}= 1$ No OAC for AF 5min-24h, Debatable for AF>24h
  3. $\text{CHA}_2\text{DS}_2\text{Vasc}= 2$ OAC if AF>24h
  4. $\text{CHA}_2\text{DS}_2\text{Vasc} \geq 3$ OAC if AF>5 min
• Technology has improved the connection between patient and healthcare clinicians

• Device data will become a “vital sign”
Take home message

Do not ignore the technology, but use it for the benefit of the patient!
Thanks!
Thanks!