Novel Diagnostic-Derived Big Data Applications

Paul Ziegler
Senior Principal Scientist and Technical Fellow
Medtronic Diagnostics Research
“Big data is like teenage sex; everyone talks about it, nobody really knows how to do it, everyone thinks everyone else is doing it, so everyone claims they are doing it”.

Dan Ariely, Duke University

“The definition of Big Data is a moving target”
MEDTRONIC CARELINK NETWORK

Serving over 9888 clinics and 1,030,000 patients in 64 countries

• 16.5 million total device transmissions
# AVAILABLE PARAMETERS

<table>
<thead>
<tr>
<th>Diagnostics</th>
<th>Programming</th>
<th>Demographics</th>
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</thead>
<tbody>
<tr>
<td>AF burden</td>
<td>Indication</td>
<td>Age</td>
</tr>
<tr>
<td>V rate during AF</td>
<td>Sensitivity</td>
<td>Gender</td>
</tr>
<tr>
<td>Day/night HR</td>
<td>Pacing info</td>
<td>Geography</td>
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<td>HR variability</td>
<td>Algorithms</td>
<td></td>
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<tr>
<td>Activity</td>
<td>Shocks</td>
<td></td>
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<td>Impedance</td>
<td></td>
<td></td>
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<tr>
<td>% A &amp; V Pacing</td>
<td></td>
<td></td>
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<tr>
<td>Therapies delivered</td>
<td></td>
<td></td>
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EXAMPLE 1: DEVICE DATA IN ISOLATION
AF Incidence and Type

141,231 pts CareLink

77,345 pts (55%) ICD

47,783 pts (62%) No AF

29,562 (38%) AF

20,748 pts (27%) PAF

6,928 pts (9%) PER

1,886 pts (2%) CAF

14,597 pts (23%) PAF

7,992 pts (13%) PER

4,148 pts (6%) CAF

63,886 pts (45%) CRT-D

26,737 pts (42%) AF

37,149 pts (58%) No AF

*p<0.001
EXAMPLE 2: DEVICE DATA WITH CLINICIAN INPUT
AF Incidence in Cryptogenic Stroke

Real-World Experience with Insertable Cardiac Monitors to Find Atrial Fibrillation in Cryptogenic Stroke

Paul D. Ziegler\textsuperscript{a}  John D. Rogers\textsuperscript{b}  Scott W. Ferreira\textsuperscript{c}  Allan J. Nichols\textsuperscript{d}
Shantanu Sarkar\textsuperscript{a}  Jodi L. Koehler\textsuperscript{a}  Eduardo N. Warman\textsuperscript{a}  Mark Richards\textsuperscript{e}

\textsuperscript{a}Medtronic Cardiac Rhythm Heart Failure, Mounds View, Minn., \textsuperscript{b}Scripps Clinic, La Jolla, Calif., \textsuperscript{c}St. Louis University, St. Louis, Mo., \textsuperscript{d}Ohio Health Heart and Vascular Physicians, Columbus, Ohio, \textsuperscript{e}ProMedica Physicians Cardiology, Toledo, Ohio, USA
REAL-WORLD INCIDENCE OF AF IN CRYPTOGENIC STROKE

Results

- 1247 patients included
- 53% male
- Age: 65.3±13.0 years
- Follow-up: 182 days
- AF detection rate
  - 12.2% at 6 months

Monitoring for only 30 days misses 62% of patients with AF at 6 months

EXAMPLE 3: DEVICE DATA WITH CLINICIAN INPUT

AFinder

CHA\textsubscript{2}DS\textsubscript{2}-VASc

Score: 0

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHF or LV dysfunction</td>
<td>HF symptoms or EF ≤ 35%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>≥ 140/90 mmHg</td>
</tr>
<tr>
<td>Age</td>
<td>≥ 75 years</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Yes</td>
</tr>
<tr>
<td>Stroke or TIA</td>
<td>Yes</td>
</tr>
<tr>
<td>Vascular Disease</td>
<td>Peripheral/Cerebral/Coronary Vasculopathy</td>
</tr>
<tr>
<td>Age</td>
<td>≥ 65 years</td>
</tr>
<tr>
<td>Sex category</td>
<td>Female</td>
</tr>
</tbody>
</table>

Back to patient
Improving Atrial Fibrillation Detection in Patients with Implantable Cardiac Devices by Means of a Remote Monitoring and Management Application

Figure 2. Classification of patients according to AF occurrence during the observation period and according to how cardiologists got knowledge about AF, through AFinder web-application and/or through device diagnostics evaluation during standard follow-up, i.e., in-hospital visits or remote monitoring. AF = atrial fibrillation.
EXAMPLE 4: DEVICE DATA FROM CLINICAL STUDIES
Clinical Classification of AF

- 1195 patients included
- Multiple clinical studies
- Clinician assessment of AF compared to device assessment of AF

**Figure 1**
Distribution of AF Burden in Patients With Documented AF According to the Clinical AF Classification

EXAMPLE 5: DEVICE DATA WITH GOVERNMENT RECORDS
AF Type and Mortality

The Epidemic of Inadequate Biventricular Pacing in Patients With Persistent or Permanent Atrial Fibrillation and Its Association With Mortality

Kevin T. Ousdigian, MS; P. Peter Borek, MD; Jodi L. Koehler, MS; J. Thomas Heywood, MD; Paul D. Ziegler, MS; Bruce L. Wilkoff, MD, FHRS

- 54,019 patients
- 2645 centers
- 124,497 patient-years of follow-up
- Device data linked to Social Security Death Registry
EXAMPLE 6: DEVICE DATA WITH MEDICAL RECORDS
AF and Stroke Risk

- Why does data need to be collected prospectively?
- CareLink – World’s largest collection of continuous rhythm monitoring data
- Veteran’s Administration – World’s largest user of CareLink and extensive EMR data
COST EFFICIENT ANALYSIS

- **TRENDS Study**
  - Prospective design
  - Patients enrolled = 2813
  - Strokes observed = 51
  - “Usable” strokes = 40

- **VA Collaboration**
  - Retrospective design
  - Patients included = 10,011
  - Strokes observed = 360
  - “Usable” strokes = 187

Cost of generating “usable” stroke data was **0.27%** of the cost in TRENDS.
AF BURDEN AND SHORT-TERM RISK OF STROKE

AF temporal proximity: The risk of stroke was highest within 5 days of the AF episode (OR=17.4, 95%CI: 5.4-73.1) and the risk declined steadily with longer periods after the episode of AF, declining to background risk by 31 days.

Relationship between temporal proximity of AF and unadjusted odds ratio for stroke using 5 day periods

Turakhia, Ziegler et al. Circ Arrhythm Electrophysiol. 2015;8:1040-1047
CONCLUSION

- Unprecedented volumes of continuously monitored physiologic data are now available

- Device data by itself may have limited utility

- Combining device data with clinical data can be a cost-effective means of addressing important research questions
  - Clinician input
  - Clinical studies
  - Government records
  - Medical records
  - Claims data