The Israeli ICD Registry- Update

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On behalf of the Israeli ICD Registry Scientific Committee

Jan 11, 2013
Jul 2010-Dec 2012

Total Number of Procedures
N=5280

New Implants
N=3448
Primary = 74%
Secondary = 26%

Generator Change
N= 1278
Primary= 58%
Secondary= 42%

Lead Related/other
N=554
Lead only= 505
System removal 19
Pocket revision= 30
Reason(s) for ICD Implantation

Primary Prevention
- MADIT II/SCDHFT (74%)
- MADIT I/MUSTT (19%)
- High Risk Familial Disease (3%)
- Other (4%)

Secondary Prevention
- VT (42%)
- VF (35%)
- Syncope with high Risk Features (10%)
- Syncpe with induced VT (7%)
- Unknown etiology (5%)
- Other (1%)

Other (4%)

Syncope with induced VT (7%)

Unknown etiology (5%)

Other (1%)

VF (35%)

VT (42%)

Primary Prevention

Secondary Prevention
Baseline Characteristics of New Implants

<table>
<thead>
<tr>
<th>variable</th>
<th>All n=2388</th>
<th>Primary n=1743</th>
<th>Secondary n=645</th>
<th>P</th>
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<tbody>
<tr>
<td>Age</td>
<td>64±13</td>
<td>64±15</td>
<td>64±12</td>
<td>0.86</td>
</tr>
<tr>
<td>Female</td>
<td>17</td>
<td>18</td>
<td>16</td>
<td>0.4</td>
</tr>
<tr>
<td>Old MI</td>
<td>64</td>
<td>65</td>
<td>63</td>
<td>0.3</td>
</tr>
<tr>
<td>&lt; 40 days</td>
<td>8</td>
<td>6</td>
<td>13</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Non ischemic CM</td>
<td>22</td>
<td>25</td>
<td>14</td>
<td>&lt;0.001</td>
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<tr>
<td>HCM</td>
<td>6</td>
<td>6</td>
<td>7</td>
<td>0.3</td>
</tr>
<tr>
<td>ARVD</td>
<td>0.6</td>
<td>0.3</td>
<td>1.5</td>
<td>0.001</td>
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<tr>
<td>Primary Electrical Disease</td>
<td>3</td>
<td>1.4</td>
<td>8</td>
<td>&lt;0.001</td>
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<tr>
<td>Atrial Fibrillation</td>
<td>21</td>
<td>20</td>
<td>22</td>
<td>0.44</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>36</td>
<td>38</td>
<td>31</td>
<td>0.003</td>
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<tr>
<td>Hypertension</td>
<td>60</td>
<td>61</td>
<td>56</td>
<td>0.04</td>
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<td>Dialysis</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>0.9</td>
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<tr>
<td>Smoking</td>
<td>31</td>
<td>30</td>
<td>32</td>
<td>0.57</td>
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</table>
New Implants

Device Type

- Single: 17%
- Dual: 28%
- CRTD: 39%
- CRTD w plug: 16%

- Single: 20%
- Dual: 41%
- CRTD: 39%
Device Type and Gender

- All: 61 (ICD) + 53 (CRTD)
- Male: 62 (ICD) + 55 (CRTD)
- Female: 52 (ICD) + 49 (CRTD)

- Primary: 47 (ICD) + 45 (CRTD)
- Male: 57 (ICD) + 43 (CRTD)
- Female: 51 (ICD) + 49 (CRTD)

National ICD Registry
Trends of New Implants

<table>
<thead>
<tr>
<th>Year</th>
<th>1st half</th>
<th>2nd half</th>
<th>Total</th>
<th>1st half</th>
<th>2nd half</th>
<th>Primary</th>
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<tr>
<td>2010</td>
<td>671</td>
<td>768</td>
<td>615</td>
<td>694</td>
<td>700</td>
<td>517</td>
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<tr>
<td>2011</td>
<td>487</td>
<td>0</td>
<td>590</td>
<td>445</td>
<td>512</td>
<td>517</td>
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<tr>
<td>2012</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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</tbody>
</table>
Follow-up Studies
Follow-up

Patient Details: Center: Rambam  |  Patient Identifier: 23288095  |  Last name: Abu Tarif  |  First name: Hamad  |  Year of Birth: 1968  |  Sex: Male

**Follow-up**

*Date Information Obtained:*

*Center:*

Information obtained through:
- Check-up at the clinic:
  - No
  - Yes
- Patient's file / Hospital records:
  - No
  - Yes
- Other interview:
  - No
  - Yes

**Deceased Information**

*Deceased:*
- No
- Yes
- Lost to follow up
- Death date:
- Reason:

**NYHA**

Last known NYHA Functional:

National ICD Registry
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Options</th>
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</thead>
<tbody>
<tr>
<td>First Therapy Delivered by Device Since Last FU</td>
<td>First Appropriate Therapy</td>
<td>No, Yes, Unknown</td>
</tr>
<tr>
<td></td>
<td>Therapy Type</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Date of 1st appropriate therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Date unknown</td>
<td>Yes, No</td>
</tr>
<tr>
<td></td>
<td>First Appropriate Shock</td>
<td>No, Yes, Unknown</td>
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<tr>
<td></td>
<td>Date of 1st appropriate shock</td>
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<tr>
<td></td>
<td>Date unknown</td>
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<td></td>
<td>First Inappropriate Therapy</td>
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<tr>
<td></td>
<td>Therapy Type</td>
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<td></td>
<td>Date of 1st inappropriate therapy</td>
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</tr>
<tr>
<td></td>
<td>Date unknown</td>
<td>Yes, No</td>
</tr>
<tr>
<td></td>
<td>Cause</td>
<td></td>
</tr>
<tr>
<td></td>
<td>First Inappropriate Shock</td>
<td>No, Yes, Unknown</td>
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<td></td>
<td>Date of 1st inappropriate shock</td>
<td></td>
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<tr>
<td></td>
<td>Date unknown</td>
<td>Yes, No</td>
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</table>

Additional Therapies Delivered by Device Since Last FU

<table>
<thead>
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<th>Description</th>
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<tr>
<td>Appropriate</td>
<td>No, Yes, Unknown</td>
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<td>ATP</td>
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### Completed Sub-studies

<table>
<thead>
<tr>
<th></th>
<th>Title</th>
<th>Author</th>
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<tbody>
<tr>
<td>1</td>
<td>Sex Differences in Implantable Cardioverter Defibrillator Implantation Indications and Outcomes: Lessons from the Nation-wide Israeli-ICD Registry</td>
<td>Guy Amit</td>
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<tr>
<td>2</td>
<td>Role of defibrillation threshold testing prior to ICD implantation</td>
<td>Moti Haim</td>
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<tr>
<td>3</td>
<td>Renal Function and Clinical Outcomes of Patients Undergoing ICD or CRTD Implantation</td>
<td>Moti Haim</td>
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<tr>
<td>4</td>
<td>Prognostic Value of Programmed Electrical Stimulation for Primary Prevention Implantable Cardioverter-Defibrillator Implantation</td>
<td>JE. Schliamser</td>
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<tr>
<td>5</td>
<td>Clinical Characteristics and Outcomes of Elderly Patients Treated with ICD and CRTD in a Real World Setting</td>
<td>M. Suleiman</td>
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<tr>
<td>6</td>
<td>Outcome of Patients with Advanced Heart Failure who Receive Device-Based Therapy for Primary Prevention of Sudden Cardiac Death</td>
<td>M. Suleiman</td>
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<tr>
<td>Suggested sub-Studies</td>
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<td>-----------------------</td>
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<tr>
<td>1. Outcomes of Patients who Received Appropriate Shocks as Compared to Patients who Received Inappropriate Shock or no Shock</td>
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<td>2. Is Dual-Chamber ICDs Associated with Increased Long Mortality when Compared with Single-Chamber Defibrillators: a subanalysis of the Israeli ICD Registry?</td>
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<td>3. Do Patients with End-Stage Kidney Disease Benefit from Prophylactic ICD Therapy?</td>
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<td>4. Syncope Significance in Patients Implanted with ICDs for Primary Prevention of Sudden Death</td>
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<td>5. Development of Models for the 6 Months and one Year Mortality after ICD Implantation</td>
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</table>
# Suggested sub-Studies

1. Outcomes of patients who received appropriate shocks compared to patients who received inappropriate shock or no shock.

6. Frequency of inappropriate shocks in patients with single vs dual chamber ICD.

7. Rates of upgrade of plugged CRT-D device to full CRT in clinical practice and the potential clinical and economic impact of the use of plugged CRT-D device at initial implant.

8. Impact of lead or pocked revision on clinical outcomes in patients with ICD/CRTD.


10. Atrial fibrillation (new, paroxysmal and chronic) and outcome in patients implanted with ICD/CRTD.
<table>
<thead>
<tr>
<th></th>
<th>Suggested sub-Studies</th>
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<tbody>
<tr>
<td>11.</td>
<td>Outcomes in CRTD Recipients with Atrial Fibrillation</td>
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<tr>
<td>12.</td>
<td>Outcomes in ICD recipients who have pacemaker indications</td>
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<tr>
<td>13.</td>
<td>Racial disparity in the utilization of implantable cardioverter-defibrillators and Cardiac resynchronization therapy among Israeli patients</td>
</tr>
<tr>
<td>14.</td>
<td>Outcomes in ICD recipients with Genetic inherited arrhythmogenic disease in the real world settings</td>
</tr>
</tbody>
</table>
Clinical Characteristics and Outcomes of Elderly Patients Treated with Implantable Cardioverter-Defibrillator and Cardiac Resynchronization Therapy in a Real World Setting
HF OR DEATH (COMBINED) BY AGE GROUPS

Total Population

Adj HR=1.66 (1.11-2.49) P=0.01
Adj HR= 2.25 (1.51-3.34) P<0.001

P(\text{log\_rank})= 0.04
Event-free Survival

Adj HR = 2.58 (1.47-4.51) P<0.001
Adj HR = 3.74 (2.14-6.53) P<0.001

P (log rank) < 0.0001
Event-free Survival

TIME (DAYS)

1: ≤ 65
2: 66–75
3: > 75

P (log rank) = 0.93

Adj HR = 1.01 (0.54-1.83) P = 0.98
Adj HR = 1.30 (0.72-2.33) P = 0.38
VTVF OR DEATH (COMBINED) BY AGE GROUPS

P(log_rank) = < 0.001

Adj HR = 1.95 (1.24-3.07) P = 0.003
Adj HR = 2.78 (1.80-4.31) P < 0.001
LETHAL OUTCOME BY AGE GROUPS IN CRTD PATIENTS

P(log_rank) = 0.75

Adj HR=1.01 (0.50-2.35) P=0.82

Adj HR=2.07 (1.02-4.20) P=0.04
REINTERVENTION BY AGE GROUPS

\[ P(\text{log_rank}) = 0.70 \]
Major Findings

- >50% of new implants are in patients >65 yo and >20% in patients >75 yo
- Elderly patients have a higher risk profile and were more likely to receive CRTD device and have their device implanted for secondary prevention indication
- Elderly patients had a similar low re-intervention rate as younger patients.
- The risk of both HF and arrhythmic outcomes was attenuated among elderly patients implanted with CRT-D devices.
Outcome of Patients with Advanced Heart Failure who Receive Device-Based Therapy for Primary Prevention of Sudden Cardiac Death
Cumulative probability of HF or Death
Total Population

Adj HR = 1.01 (0.50-2.35) P = 0.82

P(log_rank) = 0.005
Cumulative probability of HF or death in ICD patients

Adj HR = 3.2 (1.7-6.3) p < 0.001
Cumulative probability of HF or death in CRTD patients

Adj HR = 0.9 (0.5-1.8) p=0.92

P(log_rank) = 0.74
Cumulative probability of death or appropriate device therapy for VT/VF

\[ P(\text{log_rank}) = 0.02 \]
NYHA change during FU

- No change: 78 (ICD: 58, CRTD: 20)
- Increased: 17 (ICD: 8, CRTD: 9)
- Decreased: 4 (ICD: 38, CRTD: 0)

P<0.001 for the comparison between ICD and CRTD.
Major Findings

• Patients with advanced HF who receive ICD for primary prevention of SCD are at increased risk of recurrent HF hospitalization

• High baseline NYHA class was not associated with recurrent HF hospitalization in patients implanted with CRTD

• Higher baseline NYHA was associated with reduced ventricular arrhythmias risk regardless of device type

• CRTD implantation was associated with higher rate of functional class improvement as compared to implantation of an ICD
תודות

המרכזיים המשתתפים – רופאים, אחיות וטכנאים

ניצני החברות

המעوثת למחקרי לווייתן דם

פרופ' אלין גולדנברג

שלומית, נטלי, ליזי ואורית

יו"ר וחברי הוועד והועדה המעים

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