The Case for a Pacemaker and ICDs re-use Programme in Africa

Mahmoud U. Sani
Bayero University Kano &
Aminu Kano Teaching Hospital, Kano, Nigeria.
<table>
<thead>
<tr>
<th>I.</th>
<th>II.</th>
<th>III.</th>
<th>IV.</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have received (a) research grant(s) / in kind support</td>
<td>I have been a speaker or participant in accredited CME/CPD ...</td>
<td>I have been a consultant / strategic advisor etc. ...</td>
<td>I am a holder of (a) patent / shares / stocks or ownership...</td>
</tr>
<tr>
<td>A</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>... from current sponsor(s)</td>
<td>... from current sponsor(s)</td>
<td>... for current sponsor(s)</td>
<td>... related to presentation</td>
</tr>
<tr>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
Global Cardiovascular Disease Mortality

Mendis S. J Hypertension. 25, 1578-1582
Cardiovascular Disease Burden

- Overwhelming majority of deaths due to CVD occur in low and middle income countries
- About 1-2 m die each year due to lack of access to Pacemaker or ICD globally (WHO)

Joshi R J Am Coll Cardiol. 2008 Dec 2;52(23):1817-25.
### Cardiovascular Topics


George A Mensah, Gregory A Roth, Uchechukwu KA Sampson, Andrew E Moran, Valery L Feigin, Mohammed H Forouzanfar, Mohsen Naghavi, Christopher JL Murray, for the GBD 2013 Mortality and Causes of Death collaborators

<table>
<thead>
<tr>
<th>CV Cause</th>
<th>No. deaths 1990</th>
<th>No. deaths 2013</th>
<th>Death rate (per 100 000) 1990</th>
<th>Death rate (per 100 000) 2013</th>
<th>% change in death rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHD</td>
<td>138308</td>
<td>258939</td>
<td>91</td>
<td>93</td>
<td>2</td>
</tr>
<tr>
<td>Hypertensive HD</td>
<td>37525</td>
<td>86035</td>
<td>27</td>
<td>33</td>
<td>22</td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td>28917</td>
<td>53742</td>
<td>13</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>Rheumatic HD</td>
<td>23625</td>
<td>25239</td>
<td>10</td>
<td>7</td>
<td>-37</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>529880</strong></td>
<td><strong>958713</strong></td>
<td><strong>328</strong></td>
<td><strong>330</strong></td>
<td><strong>1</strong></td>
</tr>
</tbody>
</table>

In 2013, Cardiovascular disease caused 11% of all deaths

Age-adjusted mortality rate unchanged from 1990 to 2013

~250 000 people in SSA may have SCD/year
Sudden cardiac death in Africa

Poor Healthcare systems
Lack of EMS services/defibrillation
Lack of skilled doctors to make the diagnosis
Lack of autopsy data
Limited specialised investigations to confirm the diagnosis (echocardiography, MRI, EP testing, genetic testing)

Limited treatment options (Pacemakers, ICDs, drugs)
Access to pacemakers/ICDs is highly skewed

Mond HG. *PACE* 2008 Sep;31(9):1202-12.
Pacemaker Implants - Sub Saharan Africa

- No Complete Data
- South Africa 39 implants/million (1998 Survey)
- Pacemaker implantation rate is generally <10/million
- Limited centers that can implant devices especially ICDs
Barriers for Pacemaker/ICDs Implantation

- Clinical expertise – Not widely available
- Availability of x-ray equipment with fluoroscopy and aseptic conditions
- **Availability/affordability** of the pacemakers/ICDs
Affordability of Pacemakers and ICDs

- Pacemaker generator - US$2 500–3 000 and leads cost US$800–1 000
- ICD generator costs US$20 000–40 000 and leads cost over US$10 000.

The PASCAR Task Force for Pacemakers and ICDs Re-use seeks to address this barrier of cost through collaboration with stakeholders and NGOs by seeking of donations of used pacemakers for re-use in the Sub Saharan African countries.
Are Pacemakers/ICDs Safe for Reuse?
Heart Rhythm Society members
Concerns on Pacemaker & ICD re-use

What are your greatest concerns regarding the re-utilization of post-mortem pacemakers or ICDs? Please mark all that apply:

- Infection
- Device malfunction
- Religious
- Ethical
- None, I have no concerns about re-use of post-mortem devices
- Other

Crowford TC et al.....abstract at HRS congress
Safety of Pacemaker Reuse
A Meta-Analysis With Implications for Underserved Nations

Timir S. Baman, MD; Pascal Meier, MD; Joshua Romero, BA; Lindsey Gakenheimer; James N. Kirkpatrick, MD; Patricia Sovitch, NP; Hakan Oral, MD; Kim A. Eagle, MD

• 18 clinical trials
• 2270 patients
• 1⁰ endpoint – pacemaker infection or device erosion
• 2⁰ endpoint – device malfunction – defect in the structural or electrical integrity of the pulse generator
• Infection rates – 1.97%; no difference between re-used & new devices (OR 1.31 (0.50 – 3.41), P 0.58)
• Device malfunction rates 0.68% (0.27 – 1.28%).
• Risk of malfunction higher in the reuse group (OR 5.8 (1.93 – 17.47), p = 0.002)
Conclusion.......... Pacemaker reuse has an overall low rate of infection and device malfunction and may be a safe and efficacious means of treating patients in underserved nations
Performance of re-used pacemakers and implantable cardioverter defibrillators compared with new devices at Groote Schuur Hospital in Cape Town, South Africa

Zimasa V Jama, Ashley Chin, Motasim Badri, Bongani M Mayosi

Abstract

Objectives: Little is known about the performance of re-used pacemakers and implantable cardioverter defibrillators (ICDs) in Africa. We sought to compare the risk of infection and the rate of malfunction of re-used pacemakers and ICDs with new devices implanted at Groote Schuur Hospital over a 10-year period. The outcomes were incidence of device infection, device malfunction, early battery depletion, and device removal due to infection, malfunction, or early battery depletion.

Methods: This was a retrospective case comparison study of the performance of re-used pacemakers and ICDs in comparison with new devices implanted at Groote Schuur Hospital over a 10-year period. The outcomes were incidence of device infection, device malfunction, early battery depletion, and device removal due to infection, malfunction, or early battery depletion.

Results: Data for 126 devices implanted in 126 patients between 2003 and 2013 were analysed, of which 102 (81%) were pacemakers (51 re-used and 51 new) and 24 (19%) were ICDs (12 re-used and 12 new). There was no device infection, malfunction, early battery depletion or device removal in either the re-used or new pacemaker group over the median follow up of 15.1 months (interquartile range (IQR), 1.3–36.24 months) for the re-used pacemakers, and 55.8 months (IQR, 20.3–77.8 months) for the new pacemakers. In the ICD group, no device infection occurred over a median follow up of 35.9 months (IQR, 17.0–70.9 months) for the re-used ICDs and 45.7 months (IQR, 37.6–53.7 months) for the new ICDs. One device delivered inappropriate shocks, which resolved without intervention and with no harm to the patient. This re-used ICD subsequently needed generator replacement 14 months later. In both the pacemaker and ICD groups, there were no procedure-related infections documented for the respective follow-up periods.

Conclusion: No significant differences were found in performance between re-used and new pacemakers and ICDs with regard to infection rates, device malfunction, battery life and device removal for complications. Pacemaker and ICD re-use is feasible and safe and is a viable option for patients with bradyarrhythmias and tachyarrhythmias.

Methods
• Re-used devices (cases) matched by age, gender and date of implantation on a 1:1 basis to patients with new devices (controls).

• Date of implantation (same month for pacemaker, same year for ICDs)

• Median follow up
  - 15.1 months for reuse
  - 55.8 months for new
<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Pace maker Group</th>
<th>ICD Group</th>
</tr>
</thead>
</table>
| There was no | - device infections  
- pacemaker malfunction  
- early battery depletion  
- explantation due to infection, malfunction and/or early battery depletion | There was no  
- device infections  
- procedure-non-related infections during follow up |
Figure 2. Views of general population and patient population with pacemakers and implantable defibrillators relative to device reuse.
The of Need for an RCT on Pacemaker and ICD Re-use
Clinical Study Protocol

Project My Heart Your Heart:
Prospective Evaluation of the Safety and Efficacy of Cardiac Pacemaker Reuse in Low to Middle Income Countries

March 24, 2015, 2015
Version: A

A Joint Collaborative between The University of Michigan Cardiovascular Center, Pace4Life, World Medical Relief, and Pan-African Society of Cardiology, and Physicians to Determine the Safety and Efficacy of Cardiac Device Reutilization in Low and Middle Income Countries
Clinical Study Protocol

Project My Heart Your Heart:
Prospective Evaluation of the Safety and Efficacy of Cardiac Pacemaker Reuse in Low to Middle Income Countries

March 24, 2015, 2015

A Joint Collaborative between The University of Michigan Cardiovascular Center, Pace4Life, World Medical Relief, and Pan-African Society of Cardiology, and Physicians to Determine the Safety and Efficacy of Cardiac Device Reutilization in Low and Middle Income Countries
FDA Approval of Export Permit for Pacemaker re-use

- Ghana
- Sierra Leone
- Philippines
- Nicaragua
- Pakistan
Ethics of Pacemaker Re-use

The ethical and legal issues involve

- retrieval of a still usable pacemaker/ICD from a deceased patient
- selection of the patient to receive such a pacemaker or ICD
- consent of the next of kin or the living will of the patient.
- Informed consent of the recipient
- Recipient country’s approval for pacemaker reuse
• It is cost effective.
• Consistent with the principles of justice and beneficence
• Consistent with a commitment to stewardship of resources and the Common Good
• Used pacemakers with adequate battery life should be properly sterilized for use by the patients in LMICs who cannot afford the cost of a new pacemaker.
Conclusion

- The French philosopher Voltaire wrote that “the best is the enemy of the good,” a saying often invoked in the context of resource-limited health care.

- In our case, an over-emphasis on offering the best therapy - a new pacemaker - may impede the substantial benefits that can be gained from an otherwise effective treatment, particularly when the current alternative for the target population is no treatment at all.