Gender Biases in Implantable Cardiac Defibrillators (ICDs)

BMED 2110 Project Phase 2 - Deliverable 3 - Presentation

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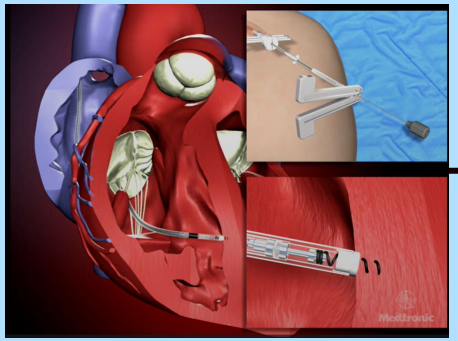
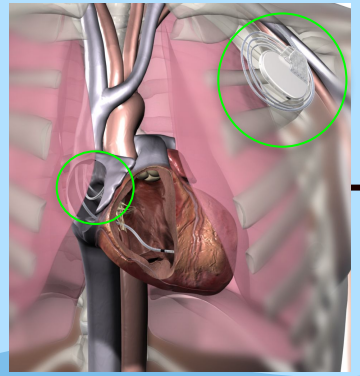
Problem: Biases present in ICDs pose significant risks to female patients

1. What are ICDs used for?
   - Prevention of arrhythmias
2. How do ICDs work?
   - electrical pulses sent to corrects heart rhythm
3. What is the process of incision?
   - leads sent through veins in arm and directed to heart
   - ICD placed under muscles in the chest
4. What category of medical science is this?
   - Cardiology



Thickness of ventricular wall makes a major difference in lead attachment

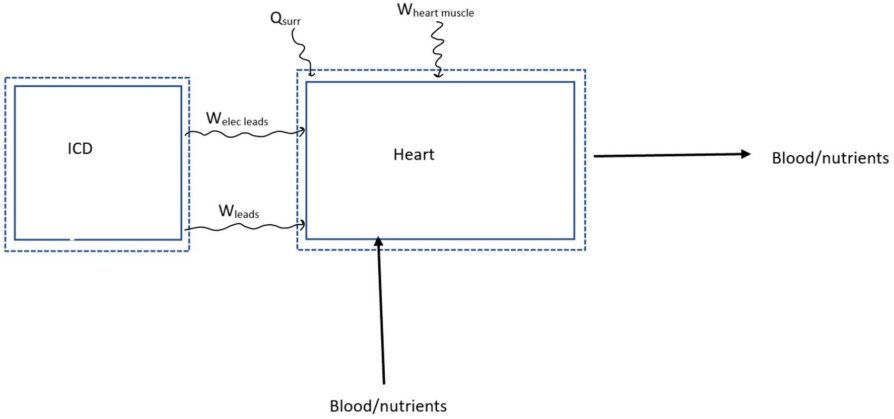


ICD positioned in body where women anatomy is different than men

BIAS

1. What is the main threat posed by the current model?
    - High risk of complications in women
2. What causes this bias?
    - Anatomical and physiological differences between male and female hearts were not taken into account during the clinical trial phase: exclusion of women in clinical trials
    - 1 in 3 subjects of a cardiovascular disease linked trial are female, yet heart disease is the leading cause in death in women.
    - Women have been excluded from clinical trials historically due to concerns over their propensity to metabolize drugs faster as a result of their typically smaller size than men, and the dramatic shifts in their endocrine system during life events such as pregnancy, puberty and menopause, which are considered confounding variables
    - This exclusion is dangerous! By failing to account for anatomical differences, as a result, female patients experience 32% higher odds of an adverse event during or post op, with 2% of these events ending in death.

Quantitative Analysis



$$\Delta(U+KE+PE) = Q + W - \Delta(H+KE+PE)$$

$$\Delta H = Q + W$$

$$\Delta H = Q + W_{heart\ muscle} + W_{electric\ ICD} + W_{leads\ on\ heart\ tissue}$$

Energy Balance Equation: $\Delta H = Q_{surr} + W_{heart\ muscle} + W_{Electric\ ICD} + W_{leads}$

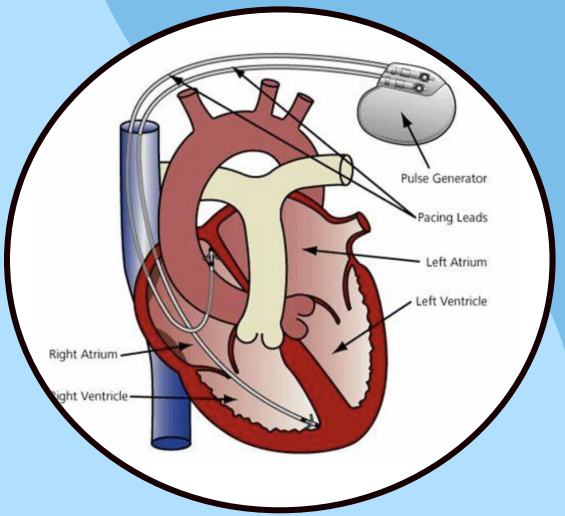
Male: $\Delta H = \frac{100J}{s} \times 60s + \frac{1027.05J}{s} \times 60s + 40J + 3381.36J = 71044.39J$

Female: $\Delta H = \frac{100J}{s} \times 60s + \frac{1157.24J}{s} \times 60s + 35J + 3381.36J = 78850.76J$

The differences in energy produced by the same ICD are due to the different flows for male and female patients. The energy of the patient's heart can be modeled with the system above to the left and the calculations above on the right.

New Recommendations

1. Smaller leads
   - The female heart is 90% the size of a male heart and the heart walls are 90% the thickness of male heart walls
   - Sizing down the leads by 10% should reduce the risk of cardiac perforation
2. Electric regulation done by ICDs
   - ICD, which is more geared towards male anatomy, does not take into account the much larger ejection fraction and the faster rate of the female heart, or the smaller cardiac output
   - Delivering lower levels of shock and monitoring for a wider range of arrhythmias can be more effective and pose less risks to female patients
3. Analysis of bias
   - Through further research on the complications that are more common in women, and further analysis on anatomical differences, we will continue to eliminate the bias' in the current model of ICDs.



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