**Computer Trials for Medical Devices**

*Abstract:*  
**Introduction:**  
Clinical trials for Implantable Cardioverter Defibrillators (ICDs) rely on historical data to formulate hypotheses and estimate statistics. This process can be assisted by early and fast large-scale experiments on computer models of the heart. We sought to estimate, using model-based analysis, the specificity and sensitivity of two different algorithms for discriminating between Ventricular Tachycardia (VT) and SupraVentricular Tachycardia (SVT), as a first step in planning a trial for comparing devices running the two algorithms.

**Methods:**  
This model-based trial aims to evaluate the specificity and sensitivity of two VT/SVT discrimination algorithms (DA): Rhythm ID (RHID, Boston Scientific) and PR Logic + Wavelet (PRLW, Medtronic). We created a computer model of cardiac electrical activity, and used it to simulate 11,400 arrhythmia episodes [atrial Flutter (AFL), atrial fibrillation, other SVT, sustained and non-sustained VT and VF]. We implemented the two DA in software using the open literature. Each episode is run through both DA.

**Results:**  
Simulations took less and a day to complete. The table shows the specificity and sensitivity of both DA by arrhythmia type. Atrial flutter and Other SVT had worst specificity, and showed the most difference between DA.

**Conclusion:**  
This model-based analysis can guide clinical trial investigators in the calculation of effect size, sample size, and choice of eligibility criteria.

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|  | ***Rhythm ID*** | ***PR Logic + Wavelet*** | ***P*** |
| ***Arrhythmia*** | *Specificity* | |  |
| *Atrial fibrillation* | *99.8* | *99.6* | *0.31* |
| *Atrial flutter* | *58.3* | *79.33* | *<0.0001* |
| *Other SVT* | *96.3* | *99.7* | *<0.0001* |
| *Non-sustained VT* | *100* | *99.8* | *0.3171* |
| *Premature Ventricular Complex (PVC)* | *100* | *100* | *1* |
|  | *Sensitivity* | |  |
| *Ventricular fibrillation* | *100* | *100* | *1* |
| *Ventricular flutter* | *100* | *100* | *1* |