**Computer Trials for Medical Devices**

*Abstract:*  
**Introduction:**  
Clinical trials for 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.

**Methods:**  
We created a computer model of cardiac electrical activity that reuses real patient EGMs and varies the rate. We simulated 11400 arrhythmia episodes (the cohort) distributed between Atrial Flutter (Aft) and fibrillation, Other SVT, Sustained and Non-sustained VT and VF. This model-based trial aims to analyze VT/SVT discrimination algorithms (algos). We implemented two algos based on the open literature, Rhythm ID (RHID) and PR Logic + Wavelet (PRLW), but excluded Onset discriminator, post-shock detection and re-confirmation. Episodes (eps) were fed to both algos. We studied 3 effects: which arrhythmias cause the lowest specificity, how the Rate of Inappropriate Detection (RInD) changes with cohort characteristics, and how the values of VF cut-off rate (CO) and therapy delay (DL) affect RInD.

**Results:**  
In our implementation of the algos, RHID and PRLW had 100% sensitivity. Worst specificity occurred for Aft eps (58.3% and 79.33% resp., p < .001) and Other SVT (96.3% and 99.7% resp., p < .001). No significant difference was found for other arrhythmias.

The figure shows how RInD varies as we vary the distribution of arrhythmias in the cohort.

Specificity was improved by increasing DL of RHID and NB of PRLW, at all CO values. Beyond DL = 10 or NB = 30 no increase is seen.

**Conclusion:**  
This model-based analysis demonstrates the experiments possible with a computer model for early validation of basic trial assumptions.