COMPARISON OF DIGITAL 12-LEAD ECG AND DIGITAL 12-LEAD HOLTER ECG RECORDINGS IN HEALTHY MALE SUBJECTS

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Background: Numerous publications on Thorough QT (TQT) studies display a wide range in ECG variability. Our meta-analysis study investigating the effects of (a) the baseline correction method (b) the design (c) the ECG recording method demonstrated that only the ECG recording method had a significant impact on data variability and it appears that digitally recorded 12-lead bedside ECG are superior when compared to digital 12-lead Holter ECG recordings (Naseem et al, 2009).

Methods: To investigate this further we used the ECG data from a first into human study investigating the safety and tolerability of a new medicinal product in which bedside and 12-lead Holter recording methods were employed simultaneously. Standard 12-lead triplicate digital ECGs were recorded using MAC1200 machines at specified time points and in addition, continuous 12-lead Holter ECG recordings were made in 34 healthy male subjects (25.7±7.5 years) on a baseline and a treatment day when they received active treatment or placebo. Prospective 12-lead ECG snapshot extraction was done at the same time points as the standard ECG with retrospective ECG analysis by specialist cardiologists. We examined the differences in SD for both data sets. This provided an opportunity to explore variability in data which owing to the simultaneous acquisition are attributable to experimental noise.

Results: The results were consistent with published data. The standard deviations for RR, QT, QTcF/B were higher for data sets derived from Holter ECG traces.

Conclusion: The advantage of using 12-lead Holter devices in TQT studies is that they provide a continuous data acquisition available for retrospective ad hoc analyses. On the other hand, they make precise ECG acquisition more difficult leading to an increased variability due to RR/QT hysteresis as described by Malik et al. 2009 and Naseem et al. 2009.

Key words: Safety, ECG, 12-lead ECG, 12-lead Holter, pharmacology, clinical trial methodology.

Conflict of interest: None