

# Toxicology and Clinical Pharmacology

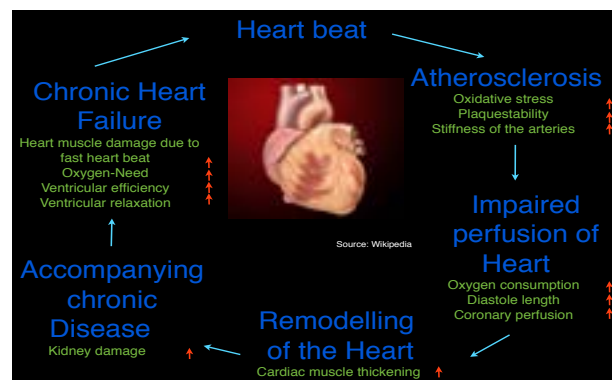
## & Generic Drugs and Biosimilars

December 14-16, 2017 Rome, Italy

### Evaluation of heart rate measurements in clinical studies: A prospective cohort study in patients with heart disease

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The purpose of this study was to evaluate the measurement of heart rate undertaken in clinical studies by (1) assessing the repeatability and reproducibility of heart rate measurements by various methods and under various conditions and (2) determining whether a single heart rate measurement at rest is representative of the circadian and inter-day variation of heart rate. Methods Prospective cohort study in 102 patients with various types of heart disease at Duisburg Heart Center, Germany between 2011 and 2012. The heart rate measurements were based on self-assessment, ECG tracings at rest, and bicycle stress ECG in the office as well as 24-h Holter ECG. Results show that office measurements and self-assessment at rest as well as 24-h Holter ECG and self-assessment at rest are highly correlated, but no correlation between self-assessment and office recordings/24 h recordings under exercise conditions was seen. Coefficient of variability was below 10% for the self-assessment and for office measurements at rest. There were no differences in coefficient of variability during the day and within the 6 days for self-assessment of heart rate at rest and circadian variation was normal. We conclude that at rest heart rate measurements by various methods agree sufficiently and inter-day/circadian variation is adequately represented. Under exercise conditions self-assessment of heart rate is not valuable and use of 24 h Holter as well as stress ECG recordings is necessary. Thus, self-reported heart rate measurements by the patient at rest seem to be reliable, but should be used in clinical studies only for heart rate assessment at rest.



#### Recent Publications

1. Albanese M, Neofytou M, Ouarrak T, Schneider S, Schöls W (2016) Evaluation of heart rate measurements in clinical studies: a prospective cohort study in patients with heart disease. *Eur J Clin Pharmacol.* 72(7):789-795.
2. Albanese M, Stappert G, Chondros K, Schoels W (2017) Early treadmill ECG stress testing after percutaneous coronary intervention following hemostasis with the AngiosealTm vascular closure device: a prospective single-center cohort study. *J. Clin. Trials.* 7:2.

#### Biography

Marco Albanese, MD Senior Consultant for Cardiology and Endocrinology at the Hirslanden St. Anna Klinik in Lucerne/Switzerland. Prior to this he was Senior Consultant for Internal Medicine at the Regionalspital Surselva/Switzerland from 2014-2016. From 2007-2014 he was Consultant for Interventional Cardiology at the Heartcenter Duisburg/Germany. He received his MD and degrees from the University of Padova School of Medicine/Italy in 1990. Further clinical training was in Internal Medicine at the Krethl Klinik/University of Heidelberg/Germany through Board Certification in Internal Medicine. He then did post-doctoral research at the NIH-NLBI-MDB/USA on LCAT-transgenic mouse models. He had further training in Endocrinology at the Deutsche Klinik für Diagnostik/Germany and in Cardiology at the Herzzentrum Duisburg/Germany.

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