

The BEAUTIFUL trial: Facts and Figures

BEAUTIFUL is the first international, multicentre, randomized, double-blind study to evaluate the effects of pure heart rate reduction with ivabradine (Procoralan®)* on the reduction of cardiovascular events in patients with stable coronary artery disease (CAD) and left ventricular dysfunction (LVD).

Patients were enrolled in the BEAUTIFUL trial if they were having documented stable CAD with associated LVD with heart rate ≥ 60 beats per minute (bpm). These patients were randomized to receive ivabradine or placebo in addition to their current treatment considered optimal by their physician. Ivabradine was chosen for the BEAUTIFUL trial because it is the only agent that provides pure heart rate reduction and thus fully preserves the force of contraction. This leads to anti-ischemic efficacy and an improvement in the ventricular function which is beneficial for CAD patients, particularly for those with LVD. After a 2 week run-in period patients were randomized to receive ivabradine 5 mg bid or placebo. If after 2 weeks the heart rate was ≥ 60 bpm, the patient was switched to 7.5 mg bid. Patients with a heart rate that dropped below 50 bpm, or who showed signs of bradycardia, were discontinued. The goal was for each patient to maintain a heart rate of between 50-60 beats per minute for 18-36 weeks. The primary objective of BEAUTIFUL is to determine whether by adding ivabradine to these patients' current therapy results in a further reduction in cardiovascular and total mortality and morbidity.

BEAUTIFUL was initiated in 2005 under the guidance of the Executive Committee. Almost 11,000 patients from 33 countries have been enrolled in the BEAUTIFUL trial. The study is now completed and the final results will be released in the coming months at a leading international congress. A recent publication in *Cardiology* provides full details of the study population.⁵

BEAUTIFUL

MorBidity-mortality EvAIUaTion of the I_f
Inhibitor ivabradine in patients with coronary
disease and left ventricULar dysfunction

The baseline characteristics are, 83% male with a mean baseline heart rate of 72 bpm and a mean age of 65 years. Previously documented myocardial infarction (MI), diabetes mellitus, metabolic syndrome are present in 88%, 37% and 40% respectively. Most of these patients are taking beta-blockers (87%), antithrombotics (94%), usually aspirin, angiotensin converting enzyme inhibitors or angiotensin receptor blockers (91%), lipid lowering drugs (76%). There was no large difference in resting heart rate between patients treated with or without beta-blockers: 71.1bpm and 74.6 bpm.

BEAUTIFUL is a landmark trial because it will be the first to assess the effect of pure heart rate reduction with ivabradine on cardiovascular outcome in optimally treated patients with CAD and LVD. The results of the BEAUTIFUL trial are eagerly awaited by the scientific community.

**Depending on the country ivabradine is available as Procoralan[®], Coralan[®], Coraxan[®] and Corlentor[®]*