Safety and tolerability of Bisoprolol treatment in children

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Introduction: Bisoprolol is a widely used beta-blocker in adults due to its pharmacokinetics and cardioselective properties. However, its safety and efficacy is unknown in children. The aim of this retrospective study was to determine the safety and tolerability of bisoprolol in a large paediatric population.

Methods: The indications, the dosage and outcome of 184 consecutive children commenced on Bisoprolol treatment between October 2003 and May 2014 were retrospectively reviewed.

Results: Indications for Bisoprolol were long QT syndrome (n= 59), hypertrophic cardiomyopathy (n=34), ventricular arrhythmias (n=22), supraventricular tachycardia (n=19), atrial arrhythmias (n=17), aortic root dilation (n=11), cardiac dysautonomia (n=10), hypertension (n=6), repolarization abnormalities with a family history of SADS (n=2), ARVC (n=2), LV diastolic dysfunction (n=1) and CPVT (n=1).

Bisoprolol treatment was started at a median age of 12.8 years (range 0.4-18.8 years) in 176 patients. Median starting dose was 1.25mg (range 0.625mg-10mg) in 174 patients. The initial dose was higher when converted from another beta blocker. The dose was up-titrated as tolerated and clinically-indicated. 150 patients were on Bisoprolol at their last clinical appointment with a median dose of 2.5mg (range 1.25mg-10mg).

Side effects were documented in 39 patients (21.2%): lethargy and/or tiredness (n=22); dizziness/lightheadedness (n=4); headaches (n=2); sleep disturbance (n=5); epigastric pain and dizziness (n=2); blurred vision (n=1); worsening eczema (n=1); decreased exercise tolerance (n=1), unknown (n=1).

Bisoprolol was discontinued in 54 patients (at a median 4.45 months (range 2 days – 5.04 years): due to side effects in 23 (12.9%); no longer required in 20 (successful RFA n=8, scheduled RFA n=2, no arrhythmia/symptoms recurred n=4, deceased n=2, on Berlin Heart n=2, heart transplantation n=2); it was not effective in 7; patient's non-compliance in 3; changed to another medication once prescription run out in 1.

Conclusions: Bisoprolol is safe and relatively well tolerated in children. Further prospective studies are required to establish its efficacy in specific paediatric indications.