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Congenital Heart Disease

EFFECTS OF BOSENTAN ON PEAK OXYGEN CONSUMPTION, HEMODYNAMICS AND FUNCTIONAL CLASS IN FONTAN PATIENTS: A RANDOMIZED, PLACEBO CONTROLLED, DOUBLE BLIND STUDY

Moderated Poster Contributions

Hall C

Saturday, March 29, 2014, 4:15 p.m.-4:30 p.m.

Session Title: Congenital Heart Disease: New Insights into Fontan Comorbidities

Abstract Category: 11. Congenital Heart Disease: Therapy

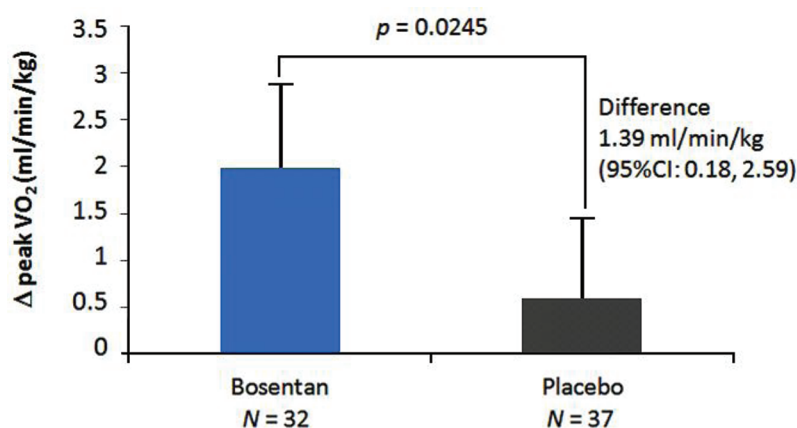
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Background: The Fontan procedure has greatly improved survival for children with univentricular heart. However, complications such as reduced exercise capacity are seen more frequently as these patients get older. Several factors have been suggested responsible for the exercise intolerance e.g. a mild elevation in pulmonary vascular resistance. The aim of this study was to examine the safety and effect of the pulmonary vasodilator Bosentan on exercise capacity in clinically stable Fontan patients.

Methods: Seventy-five patients ≥ 12 years were randomized 1:1 to oral Bosentan or placebo for 14 weeks. Patients and investigators were blinded to randomization. At baseline and after treatment, the patients underwent exercise test and functional classification.

Results: Sixty nine patients (92 %) completed the study. The primary endpoint peak oxygen consumption increased in the Bosentan group compared to placebo (1.99 vs. 0.60 ml/kg/min, $p=0.02$). The improvement was supported by higher peak pulmonary blood flow (0.86 vs. 0.29 l/min, $p=0.03$) and longer exercise duration (28.2 vs. 4.8 seconds, $p=0.04$). Nine patients improved one functional class in the Bosentan group vs. none in the placebo group, $p=0.0085$. No serious adverse effects were seen and no patients had liver enzyme levels at or above three times the upper reference limit.



Conclusions: Bosentan was safe to use for 14 weeks, improved exercise capacity and time, pulmonary blood flow as well as functional class in stable Fontan patients.