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Safety And Short-Term Efficacy Of Transition From Bosentan To Macitentan In Patients With Pulmonary Arterial Hypertension: Preliminary Results

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Introduction:Macitentan (Opsumit) is an orally active, potent, second-generation dual endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH). Macitentan's effectiveness was established in the pivotal SERAPHIN study in 2013. While peripheral edema, hepatotoxicity, and anemia appear to be class effects of the ERAs, clinical trials of macitentan indicate that its unique pharmacokinetics decrease the incidence of these side effects significantly compared to previous ERAs. We aimed to evaluate the safety and short-term efficacy of transition from bosentan to macitentan in patients with PAH.**Methods:**This is a single institution, 24 weeks prospective study. Patients on bosentan therapy were switched to oral macitentan 10 mg once daily. Patients on combination treatment continued sildenafil. Patients were evaluated at baseline, 12 and 24 weeks. Endpoints included: change from baseline in 6-minute walk distance (6-MWD), WHO functional class (WHO FC), baseline oxygen saturation, oxygen saturation after 6-MWD test, systolic pulmonary artery pressure (sPAP) measured by echocardiography, brain natriuretic peptide (BNP) levels, incidences of adverse events (AE).**Results:**6 patients (mean age:20.8±5.1years(12-26), body weight:55.2±16.1kgs(27-73), 4 females, 2 males) completed 24 weeks of macitentan therapy. 4 had Eisenmenger syndrome, 2 had residual PAH after surgery. Median follow-up period:13 years (7-23). All patients were in WHO FC II. 4/6 patients were on monotherapy (bosentan), 2/6 patients were on combination therapy (bosentan and sildenafil). Patients were on bosentan therapy for 7.7±2.7years (6-13). One patient with Down syndrome could not complete 6-MWD test. Macitentan significantly improved exercise capacity (6-MWD) from baseline (mean:469 m), at week 12 (mean:510 m, +41 m), at 24 week (mean:519 m,+50 m) ($p<0.05$) and oxygen saturation after 6-MWD test from baseline (mean:%81), at week 12 (mean:%83), at 24 week (mean:%87) ($p<0.05$) and decreased sPAP measured by echocardiography from baseline (mean:100 mmHg), at week 12 (mean:85 mmHg,-15mmHg), at 24 week (mean:85 mmHg,-15mmHg) ($p<0.05$). There was no significant change in WHO FC, baseline oxygen saturation, BNP levels. None of the patients had AE (peripheral edema, anemia, hepatotoxicity).**Conclusions:**In this short term preliminary study, transition from bosentan to macitentan significantly improved exercise capacity (6-MWD), oxygen saturation after 6-MWD test, hemodynamic parameters and well tolerated without any AE.