

HEMODYNAMIC EFFICACY OF BERAPROST THERAPY IN SYSTEMIC SCLEROSIS-RELATED PULMONARY ARTERY HYPERTENSION

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ABSTRACT

Backgrounds: Systemic sclerosis-related pulmonary artery hypertension (SSc-PAH) is a poor prognostic condition. Beraprost, an oral prostacyclin analogue, is the only PAH-specific drug in the National list of Essential Drugs (NLED) available for medicare in Thailand. However, the efficacy of beraprost in treating SSc-PAH has never been established.

Objective: To evaluate the short term hemodynamic efficacy of beraprost therapy in SSc-PAH.

Methods: A study was conducted in functional class (FC) II-III SSc-PAH patients. Beraprost was administered in up-titration strategy to the maximum or maximally-tolerated dose. Right heart catheterization (RHC), symptoms, and N-terminal pro B-type natriuretic peptide (NT-proBNP) were evaluated at baseline and end of study. Primary end point was hemodynamic changes. Secondary end point was non-hemodynamic changes (symptoms and NT-proBNP).

Results: A total of 21 patients were enrolled, 14 patients were completely evaluated (2 denied re-evaluation, 2 were dead from infection during study period, 2 had severe comorbidity, and 1 was loss to follow up). The mean age was 49.6 years, 57% were female, 71% were in FC II, and 64% were diffuse SSc. The mean dose of beraprost was 201.4 µg/day and mean study duration was 13.7 weeks. Beraprost had a trend but not significantly improve hemodynamic changes. Mean pulmonary artery pressure (mPAP) was reduced from 35.1 mmHg to 32.5 mmHg ($p = 0.096$, 95% CI, -0.54 to 5.83), mean right atrial pressure (mRAP) was reduced from 8.3 mmHg to 7.3 mmHg ($p = 0.428$, 95% CI, -1.64 to 3.64), pulmonary vascular resistance (PVR) was reduced from 6.35 Wood units to 6.07 Wood units ($p = 0.639$, 95% CI, -0.95 to 1.50), and cardiac index (CI) was increased from 3.13 l/min/m² to 3.16 l/min/m² ($p = 0.927$, 95% CI, -0.69 to 0.63). There was also a trend to improve according to secondary end point. FC was improve in 5 patients and stable in 8 patients, mean NT-proBNP was reduced from 1129 pg/ml to 1050 pg/ml ($p = 0.771$, 95% CI, -496.54 to 654.68). Heart failure was developed in 3 patients and no any syncopal event happen.

KEYWORDS: Hemodynamic Efficacy, Beraprost Therapy, Systemic Sclerosis, Pulmonary Artery Hypertension.