European Journal of Heart Failure: A promising drug treatment for patients with pulmonary hypertension associated with heart disease

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The results of the SPHERE-HF study are published in the European Journal of Heart Failure*. SPHERE-HF is a multicenter academic clinical trial led by investigators at the Centro Nacional de Investigaciones Cardiovasculares (CNIC) and Hospital Clínic de Barcelona*

There is currently no specific treatment for pulmonary hypertension associated with heart disease, a highly prevalent condition with a poor prognosis. Now, a study from the Centro Nacional de Investigaciones Cardiovasculares (CNIC) and Hospital Clínic de Barcelona/IDIBAPS has shown that mirabegron, a drug that acts on the beta-3 adrenergic receptor, may have a beneficial effect on right ventricular function.

The SPHERE-HF study evaluated the beneficial potential of mirabegron in patients with pulmonary hypertension associated with heart disease. The results, published in the *European Journal of Heart Failure* do not show any improvement in pulmonary vascular resistance, the main study objective; however, they do show a beneficial effect on right ventricular function.

“Right ventricular function is a major determinant of the prognosis of patients with pulmonary hypertension associated with heart disease, so the results are encouraging and warrant continued research,” said SPHERE-HF principal investigator Dr. Ana García Álvarez, head of the Cardiology department at Hospital Clínic Barcelona, professor at Universitat de Barcelona and researcher at the CNIC and IDIBAPS.

SPHERE-HF included 80 patients with heart disease and associated pulmonary hypertension. The patients were recruited at 4 tertiary hospitals—H**ospital Sant Pau de Barcelona, Hospital Puerta de Hierro de Madrid, Hospital 12 de Octubre de Madrid, and Hospital Clínic de Barcelona**—and were randomized to receive treatment with mirabegron or placebo over a 16-week period.

The study participants were between the ages of 65 and 70 years, and approximately half had NYHA functional class III, that means a marked limitation of physical activity, with shortness of breath upon exertion.

All the patients were assessed by right heart catheterization to measure pulmonary pressures and by magnetic resonance imaging or cardiac computed tomography to evaluate right ventricular function.

All cardiac images were evaluated by blinded experts at the CNIC, under the supervision of **Dr. Inés García-Lunar**, CNIC researcher and study co-author.

The study is a continuation of preclinical research begun approximately 9 years ago by Dr. Ana García and Dr. Borja Ibáñez, Clinical Research Director at the CNIC.

Dr. Ibáñez said that “SPHERE-HF is a model of translational research, and these results suggest that beta-3 adrenergic receptor agonists have potential to improve right ventricular dysfunction, for which there is currently no treatment available suitable for chronic therapy.”

The clinical trial was made possible through competitive funding from Fundació la Marató de TV3 and a collaborative partnership of 5 Spanish centers, said Dr. Ana García.

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- García-Álvarez, A.; Blanco, I.; García-Lunar, I.; Jordà, P.; Rodriguez-Arias, J.J.; Fernández-Friera, L.; Zegri, I.; Nuche, J.; Gomez-Bueno, M.; Prat, S.; Pujadas, S.; Sole-Gonzalez, E.; Garcia-Cossio, M.D.; Rivas, M.; Torrecilla, E.; Pereda, D.; Sanchez, J.; García-Pavía, P.; Segovia-Cubero, J.; Delgado, J.F.; Mirabet, S.; Fuster, V.; Barberá, J.A.; Ibañez, B.; SPHERE-HF Investigators. β3 adrenergic agonist treatment in chronic pulmonary hypertension associated with heart failure (SPHERE-HF): a double blind, placebo-controlled, randomized clinical trial. Eur J Heart Fail. (2022) Nov 20. doi: 10.1002/ejhf.2745

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