



TRANSCATHETER PULMONARY ARTERY BANDING FOR ADULTS WITH HFREF: ACUTE AND INTERMEDIATE RESULTS FROM THE ONGOING FIRST IN HUMAN TRIAL

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Background:

PAB in infants with DCM and preserved right ventricular function has been successful in improving left ventricular function due to favorable repositioning and buttressing of the interventricular septum in systole.

Objectives:

An FIH trial to assess the safety and feasibility of transcatheter pulmonary artery banding with a novel device in adults with HFREF and preserved RV function.

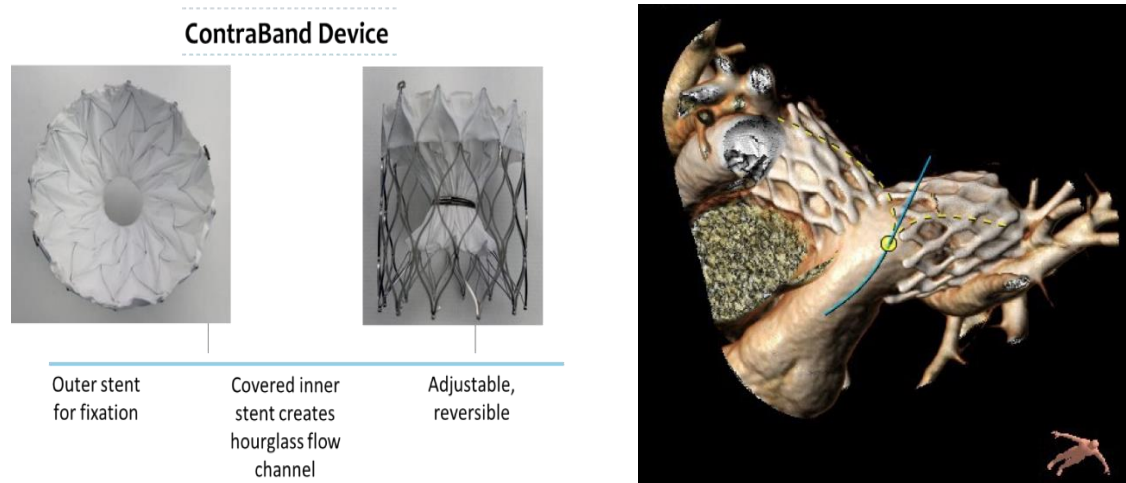
Methods:

Contraband [Restore Medical, Or Yehuda, Israel] is a novel transcatheter pulmonary arterial band, with an adjustable and reversible constriction, which is implanted in the branch pulmonary arteries [diameter 18-30mm] via an 18Fr sheath and delivery system from a femoral vein. The FIH trial includes heart failure patients with reduced LV ejection fraction, no pulmonary hypertension and preserved RV function with appropriate pulmonary artery diameters assessed by echocardiography and CT angiography. Follow up includes echocardiography at 1 and 6 months and cardiac catheterization and CT at 6 months.

Results:

12 patients [9M, 3F] of median age 63 years [45-77] and NYHA Class II and III have been enrolled so far. All implantations with 9mm [10] and 8mm [2] restrictions were successful with a 12-20mmHg increase of RV pressure to reach ~45-50% LV pressure. There was acute partial dislodgement of three bands in the LPA with no complication or loss of functionality. At median follow up of 6.2 months [0.2-11.5] all patients are alive and well with no CHF related hospitalizations. 5 patients have undergone evaluation at 6 months follow up and demonstrate, in comparison to baseline, an increase of 4.7±4.1% in LVEF, a decrease of 29.6±32.2ml and 24.4±18.3ml in LVEDV and LVESV, respectively with an average increase of 59m in the 6-

minute walk. There has been no change in RV function assessed by lateral longitudinal strain. The sample sizes are too small to assess significance at this stage.



Conclusion:

Transcatheter PAB is safe and feasible in adult HFrEF patients at 6-month median follow up with initial results demonstrating improvements in LVEF, LVEDV and LVESV and functional parameters with no reduction in RV function. All these parameters will be further assessed over 2 years and form the basis for further clinical controlled trials.

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