EARLY RESULTS OF THE INTERSHUNT IMPLANT-FREE INTERATRIAL SHUNT FOR HEART FAILURE

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Background:

Interatrial shunt to reduce left atrial pressure in patients with heart failure is being explored. We examined a new transcatheter system that creates an interatrial shunt by mechanically excising tissue, relieving left atrial pressure, without requiring energy or a permanent implant.

Objectives:

The study was designed to evaluate the safety and performance of the Percutaneous Atrial Shunt-Catheter (PAS-C) System for percutaneous shunting of the interatrial septum and reduction of heart failure related symptoms.

Methods:

Patients with NYHA Class II, III or ambulatory IV, aged 40 - 85 years of age were enrolled in this feasibility study. Screening included echocardiography, exercise right heart catheterization, brain natriuretic peptides (NT-proBNP), Kansas City Cardiomyopathy Questionnaire (KCCQ) and 6-minute walk test (6MWT). Under fluoro and echocardiographic guidance, femoral venous access with transeptal crossing was achieved. Deployment of the distal capture mechanism (InterShunt PAS-C) in the left atrium was performed to securely capture, cut and remove tissue leaving an opening with a prescribed shape and surface area in the interatrial septum.

Results:

A total of 10 patients (7 female, 3 male) were enrolled. Mean age was 69.4 ± 13.6 years. At baseline 90% patients were NYHA class III and 10% were class II. Mean LVEF was 54.8 ± 2.2%. All procedures were successful with no device or procedure related adverse events. At one month follow-up the core lab confirmed all shunts were patent with left to right flow. Mean peak exercise PCWP decreased by 4.8 mmHg (p=0.029) and mean NT-proBNP decreased by 197.6 pg/mL (p=0.037). LVEF improved by 7.8%, KCCQ score improved by 12 points (p<0.001) and 6MWT improved by 26.0 meters (p=0.001).

Conclusion:

This first in human study with the InterShunt System demonstrated procedure safety and feasibility to create an implant-free, energy-free interatrial shunt. At 30 days all shunts were patent with left to right flow and clinically relevant improvements in 6MWT, KCCQ, NT-proBNP. The ability to create an interatrial shunt without a permanent implant allows for unobstructed access to the left atrium for future procedures and the potential to reduce or eliminate the need for post procedure anti-platelet therapy. Continued follow up to determine durability and clinical benefit is needed.