

Novel, atrial flow controlling (AFR) device to support balloon atrioseptostomy (BAS) in patients with pulmonary arterial hypertension (PAH).

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Introduction: Ballon Atrioseptostomy (BAS) remains unsatisfying in both the short and long term due to both uncertainties of the form and size of the created atrial septal defect (cASD) and the frequent later closure of it. Ad-hoc makeshift devices to address these problems have been reported, but present a risk per se, and do underline the need for a systematic and less risky solution.

Methods: A device very similar to conventional ASD-occluding devices, but with a central hole in it was designed and industrially produced in different sizes of outer diameter and of the inner hole, to provide both a controlled shunt when implanted into the cASD after BAS, and lasting patency of this atrial communication.

Results: In communication with the local Ethics Committee, two patients, (a) 39 year old male with very decompensated, non-transplantable clinical state despite multitherapy, with pulmonary arterial hypertension (PAH) and right heart (RV) failure, (b) 8 year old girl with recurrent syncope despite triple, both oral and inhaled PAH-therapy, received a BAS according to the established PAH algorithm, and an AFR device to technically stabilize the BAS-created atrial septal defect.

The AFR implantation was fast, uncomplicated, remained in stable position and remained entirely patent at most recent check-up (>8 months post implantation). There was no need to repeat the BAS. Anticoagulation was provided with aspirin for 3 months. Both patients showed improved RV function. Further, patient (a) had marked clinical improvement with successful lung transplantation 2 months later; in patient (b) syncope did not occur again.

Conclusions: The AFR device functioned as intended by stabilizing the BAS result, providing patency and delivering a controlled RL-Shunt over the observation time. AFR-implantation required only small-to-moderate sized cASD. Re-BAS did not occur, and anticoagulation required only mild agents. Taken together, this lowered the BAS risks and increased the BAS benefits, thus improving BAS risk/benefit ratio. As a result, BAS in its clinical value is upgraded. This changed risk-benefit profile might allow and justify an earlier use in the treatment algorithm of these diseases. These preliminary encouraging results need to be confirmed by a larger study.