

A novel atrial flow egulator (AFR) device to control and assure blood flow after balloon atrioseptostomy (BAS) for severe, endstage pulmonary arterial Hypertension (PA)

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Introduction: PAH may progress to its final, pre-lung-transplant stage despite high-dose, multiple combined medications. A BAS may be offered to those patients that need to wait, need to improve to become eligible, or are remain ineligible to offload the venous system and right ventricle, and provide much needed extra systemic blood flow. However, size of BAS and hence resulting shunt flow are difficult to control, and BAS tend to close, with needing repeat procedures, thus leading to some neglect of this otherwise hemodynamically useful and important Intervention in the recent years.

Methods: a purpose made device was developed (Occlutech) that uses the self-centering ability of ASD-closure devices but has a fenestration tunnel of different diameters (4-10 mm) to be implanted into the defect produced by preceding BAS. A formal study protocol to achieve European CE-marking has been set up (see "PROPHET" trial at www.clinicaltrials.com), and recruitment is ongoing and europe-wide.

Patients: 8 adult patients (39-62 years) with multi-medicated terminal PAH were included and received the AFR device without complications in all. AFR remained in situ and patent in all, with 2 patients > 6 months of follow-up time. 4 patients dropped out < 6 months due to disease progression. One patient required exchange of AFR device for one with a smaller fenestration. The remaining patients all showed improvement as judged by organ parameters including NT-BNP, and clinical state, and 1 of these, the AFR device served as a bridge to transplantation with the patient receiving a lung transplant a month after intervention, with the patient remaining well to date and the - now left to right shunting- AFR device safely left in situ.

Conclusion: While the AFR-implantation after BAS is a swift and uncomplicated intervention, this is the first time that a known controlled interatrial right to left shunt flow can be achieved and appreciated in its effects within PAH treatment. Choice of fenestration width is of highest importance. Continuation of our PROPHET study is warranted to further establish the use of this important interventional hemodynamic treatment option in refractory final PAH.