ATRIAL SEPTOSTOMY WITH A PREDEFINED DIAMETER USING A NOVEL OCCLUTECH ATRIAL FLOW REGULATOR IMPROVES SYMPTOMS AND CARDIAC INDEX IN PATIENTS WITH SEVERE PULMONARY ARTERIAL HYPERTENSION.

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OBJECTIVES
A novel Occlutech atrial flow regulator (AFR) implantation gives an atrial septal predefined predictable fenestration.

BACKGROUND
Atrial septostomy relieves syncope in pulmonary arterial hypertension (PAH) by improving left heart filling, cardiac output and systemic oxygen transport despite hypoxia. Symptoms recur when small fenestrations close spontaneously.

METHODS
AFR was implanted after informed consent in patients with severe PAH presenting with syncope and right heart failure. Symptoms, hemodynamics, echocardiographic parameters, brain natriuretic peptide (BNP) levels and device patency were serially documented.

RESULTS: Eighteen patients aged 28.3±8.5 years with severe PAH underwent AFR implantation. All procedures were successful without any major complications. All patients had relief of syncope and 6-min walk distance improved significantly from 377.3 6 ±33.2 to 423 ± 31.32 m. The cardiac index (2.36±0.52 to 2.89 ± 0.56 L/min/m2) and systemic oxygen transport (367.5 ±75.5 428.0 ±67.1 ml/min/m2) also showed a significant improvement. Inferior caval vein congestion and pericardial effusion reduced due to improvement in heart failure, but other echocardiographic parameters of right ventricular function did not show significant change. The reduction in BNP levels too did not reach statistical significance. The device was patent in all patients at a median follow-up of 189 days (range 10–296 days) resulting in a significant reduction of oxygen saturations from 98±0.18 to 85.26 ±2.86% after exercise.

CONCLUSIONS
AFR implantation was feasible and safe in all patients with PAH. There was a significant improvement of symptoms, six-minute walk distance, cardiac index and systemic oxygen transport. The device maintained patency in short-term follow-up and the resultant hypoxia was tolerated well.

FIGURE 1 Occlutech AFR. This self-expanding nitinol wire mesh device is available with fenestration diameters of 4, 6, 8, and 10 mm diameter and waist lengths of 2, 5, 10 mm.
FIGURE 2  Implantation of AFR. After septal puncture with Brockenbrough needle (A), a long Mullins sheath is introduced into the left atrium (B) and the AFR is implanted under fluoroscopic guidance (C). After confirming stable device position and right to left shunt through the fenestration (D), it is released from the Flex II delivery cable (E). Enface view (F) clearly shows the fenestration.

FIGURE 3 Echocardiogram after AFR implantation. Transesophageal echocardiogram is utilized to obtain a three dimensional left atrial enface view of the device (A) and demonstrate the shunt through the device (B). Agitated saline injection during a transthoracic echocardiogram (C) is a simpler way to demonstrate shunt through the device from right atrium (RA) to left atrium (LA).