Clinical Impact of Creating a Predetermined Atrial Communication in the Management of Severe Pulmonary Hypertension using the Atrial Flow Regulator Device

Joseph J. Vettukattil[1] MBBS, MD, DNB, CCST, FRCPCH, FRSM, FRCP; Ramasamy Rajeshkumar[2]; Nagib Dahdah[3]; Dietmar Schranz[4,5]; Ata Firouzi[6]; Sven Dittrich[7]; Daniel Springmüller[8]; Vishal R. Kaley[1]; Bennett P. Samuel[1]; Kothandam Sivakumar[2]

[1]Congenital Heart Center, Spectrum Health Helen DeVos Children's Hospital, Grand Rapids, Michigan, USA

Background

- Pulmonary hypertension (PH) is a chronic progressive disease with mean pulmonary arterial pressure (MPAP) >25 mmHg, progressing to right ventricular dysfunction, heart failure, and death.
- Medical management remains challenging with unpredictable outcomes.
- The efficacy of an interatrial shunt in severe PH is recognized.
- A lack of interventional devices to create a sustainable interatrial communication led to the development of the Occlutech® Atrial Flow Regulator (AFR; Figure 1).
- We describe outcomes of AFR implantation in patients with PH (Figure 2).

Methods

- A retrospective, multi-center study was performed in patients with severe PH who underwent compassionate use of AFR in collaboration with physician implanters from 7 international centers.

Results

- Thirty-five patients underwent implantation during a period of 3 years with follow-up data available on 27 patients (females n=21, 77%).
- NYHA Class III/IV symptoms were observed in 77% of patients with syncope in all patients at baseline, 54% at short-term follow-up and only 9% at long-term follow-up with no recurrence of syncopal episodes in any patients (Figure 3).
- The average 6 minute walk test distance improved from 370 m to 434 m (N=12, F=18.91, p=0.0001) at last follow-up (Figure 4) with expected decrease in oxygen saturation (Figure 5).
- A significant decrease in mean right atrial pressure (RAP) was noted (N=11, 10.6 to 8.5 mmHg, F=15.27, p=0.0009) with trivial change in MPAP (N=11, 74.8 to 76 mmHg; S=7.5, p=0.5791) at long-term follow-up (Table 1).
- No major complications were observed except in 1 patient who had spontaneous occlusion of the fenestration, but underwent successful heart-lung transplant 1-year after AFR implantation.
- There were 4 deaths related to progressive ventricular dysfunction, severe desaturation, and co-morbidities.
- There was no correlation between RAP and outcomes, specifically in those with RAP >20mmHg, a cutoff pressure formerly considered a contraindication for atrial fenestration in PH.

Figure 1. Occlutech® Atrial Flow Regulator

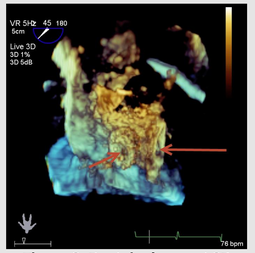

Figure 2. Post deployment 3D TEE shows a well seated AFR

Figure 3. NYHA Class (N=13)

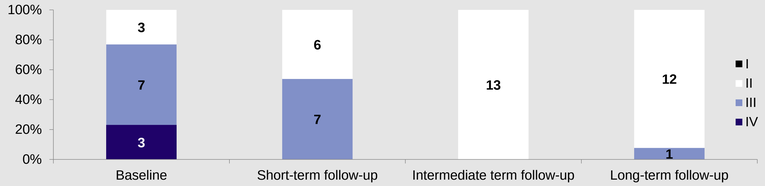

Figure 4. Change in 6MWT distance (m) N=12

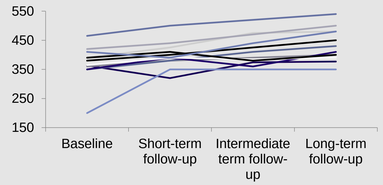

Figure 5. Oxygen Saturation (%) N=12

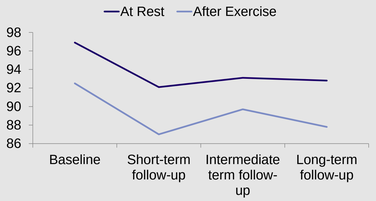

Table 1. Change in hemodynamics after AFR implantation (N=11)

	Baseline	Short-term follow-up	Long-term follow-up
Left atrial pressure (mmHg)	6.6 ± 4.2	7.1 ± 3.8	8.3 ± 3.4
Right atrial pressure (mmHg)	10.6 ± 4.4	7.5 ± 4.8	8.5 ± 4.0
Mean PA pressure (mmHg)	74.8 ± 17.4	-	76.0 ± 19.7

Conclusion

- Implantation of AFR results in significant clinical improvement in severe PH.
- Overall safety and tolerability was documented in our series, including patients with high RAP.
- This study paves the way for future trials to better determine optimal timing of intervention, device size selection, and long-term prognosis.

Clinical Implications

- The Occlutech® AFR is a novel device to create a predefined interatrial communication for decompression of the RA, which increases systemic ventricular output, and may be offered as a treatment option with optimized medical therapy for symptomatic patients with PH.
- The application of AFR may also be extended to patients with chronic refractory right and left-sided heart failure with elevated atrial pressures.

Collaborators

- [2]Department of Pediatric Cardiology, Institute of Cardio Vascular Diseases, The Madras Medical Mission, Chennai, INDIA
- [3]Division of Pediatric Cardiology, CHU Ste-Justine, University of Montreal, Montreal, Québec, CANADA
- [4]Pediatric Heart Center of Hessen, Justus Liebig University, Giessen, GERMANY
- [5]Department of Internal Medicine, Division of Cardiology, Goethe University, Frankfurt/Main, GERMANY
- [6]Cardiovascular Intervention Research Center, Rajaie Cardiovascular Medical and Research Center, Iran University of Medical Sciences, Tehran, IRAN
- [7]Department of Pediatric Cardiology, University Hospital Erlangen, Friedrich-Alexander University Erlangen-Nuernberg, Loschgestrasse, Erlangen, GERMANY
- [8]Departamento de Cardiología Pediátrica y Enfermedades Respiratorias, Hospital Clínico de la Universidad Católica de Chile, Pontificia Universidad Católica de Chile, Santiago Chile, CHILE