Outcomes of Atrial Flow Regulator Implantation in Patients with Severe Pulmonary Hypertension

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Background

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

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 (females n=21, 77%).
- NYHA Class III/IV symptoms including episodes of syncope were observed in 85% at baseline, 54% at immediate follow-up and only 8% at long-term follow-up with no recurrence of syncopal episodes in any patients (Figure 3).
- The average 6 minute walk test distance improved (370 to 434 m, F=18.91, p=0.0001; Figure 4) with significant decrease in mean right atrial pressure (RAP; 10.6 to 8.5 mmHg, F=15.27, p=0.0009), expected decrease in oxygen saturation (Figure 5) and trivial change in MPAP (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.

Figure 1. Occlutech® Atrial Flow Regulator

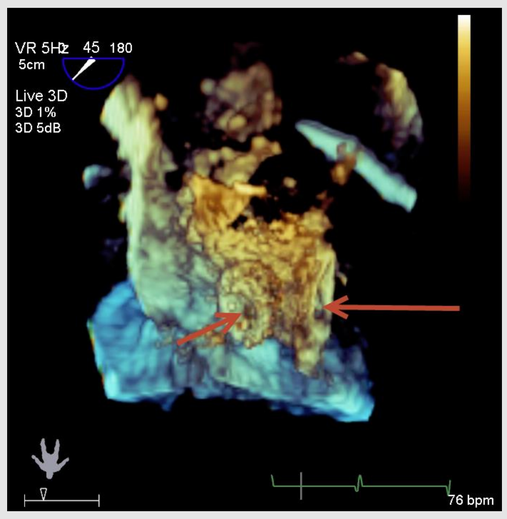

Figure 2. Post deployment 3DTEE shows a well seated AFR

Figure 3. NYHA Class (N=13)

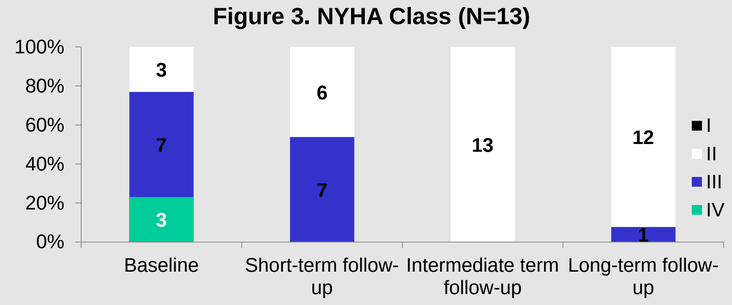

Figure 4. Change in 6MWT distance (m) N=12

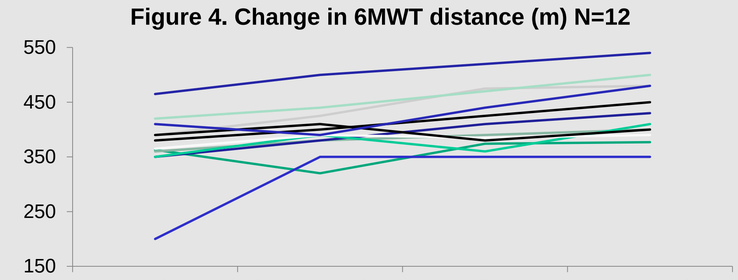

Figure 5. Mean Oxygen Saturation (%) N=12

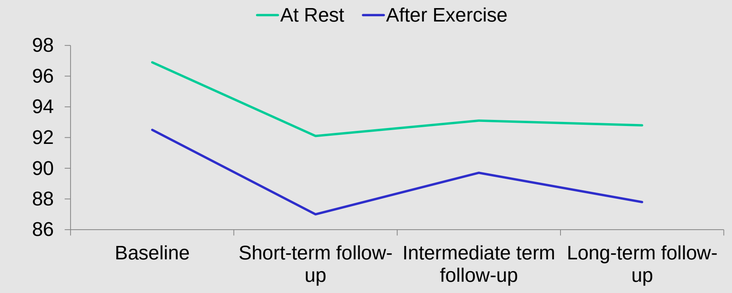

Table 1. Change in hemodynamics after AFR implantation (N=11)

	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

- 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.

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 clinical trials to determine optimal timing of intervention, device size selection, and long-term prognosis.

Collaborators

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