Atrial Flow Regulator Implantation in Children 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.
- Treatment of PH in children remains challenging due to unpredictable outcomes on medical therapy and difficulty of obtaining hearts for transplantation.
- 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), a novel nitinol-based device to create a sustainable atrial communication of predetermined size (Figure 1).

Objective

- To determine the outcome of AFR implantation in children with severe 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 4 international centers.

Results

- Thirty-five patients (29 adults and 6 children) underwent AFR implantation during a period of 3 years (Figure 2).
- All 6 children (females, n=3) had severe PH not controlled on medical therapy: 4 children on dual drug therapy, and 2 children on triple drug therapy.
- Pre-implantation NYHA Class III/IV symptoms were observed in 67% at baseline with incidence of syncope in 83% (n=5), and arrhythmias in 16% (n=1).
- One child died within 1 month of device implantation related to progressive worsening of PH.

Figure 1. Occlutech® Atrial Flow Regulator

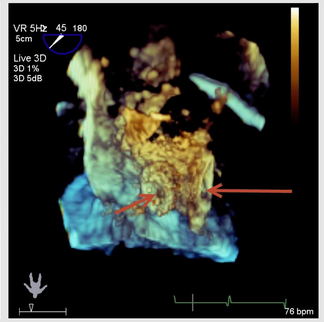

Figure 2. Post deployment 3D TEE shows a well seated AFR

Figure 3. NYHA Class (N=6)

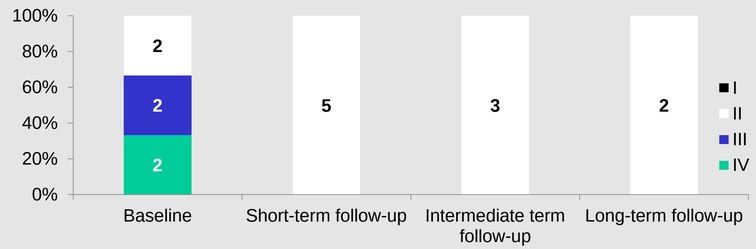

Figure 4. Change in 6MWT distance (m) N=2

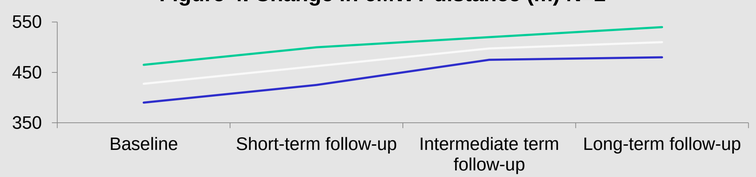

Figure 5. Mean Oxygen Saturation (%) N=5

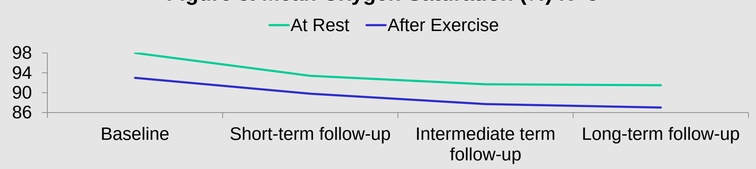

Table 1. Change in hemodynamics after AFR implantation (N=2)

Parameters	Baseline	Long-term follow-up
Left atrial pressure (mmHg)	11.2 ± 8.7	7.5 ± 0.5
Right atrial pressure (mmHg)	9.5 ± 5.3	6.5 ± 0.5
Mean PA pressure (mmHg)	68.3 ± 18.7	89.0 ± 11.0

- No other major adverse events were observed in any of the children.
- At immediate and long-term follow-up the children (n=5) were observed to have NYHA class II symptoms without recurrence of syncopal episodes in any of them.
- The average 6 minute walk test distance improved from 428 to 510 m (n=2; Figure 4) with expected decrease in oxygen saturation (n=5; Figure 5).
- No significant decrease in mean right atrial pressure (9.5±5.3 to 6.5±0.5 mmHg, n=2, p=0.3530), or increase in MPAP (68.33±18.74 to 89±11 mmHg, n=2, p=0.3108) was noted at long-term follow-up (Table 1).

Conclusion

- Implantation of AFR results in clinical improvement for children with severe PH.
- Overall safety and tolerability of implantation in children was documented in our series.
- This study paves the way for future trials to determine optimal timing of intervention, device size selection, and long-term outcomes.

Collaborators

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