Creation of a Predefined Interatrial Communication with the Occlutech® Atrial Flow Regulator: Outcomes in a Porcine Model

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Background
- Permanent interatrial communication with a defined diameter is beneficial for palliation of congenital heart conditions with obstructive lesions, failing Fontan circulation, heart failure, and pulmonary hypertension.
- The predetermined atrial communication allows for shunting, maintaining adequate cardiac output.
- Although percutaneous stent implantation and balloon dilatation are well-established techniques to create an atrial communication, they often result in complications such as spontaneous closure of the fenestration, excessive desaturation, and stent embolization.
- The lack of a safe and effective interventional device for creating a sustainable atrial fenestration led to the development of the Occlutech® Atrial Flow Regulator (AFR) device (Figure 1).

Objective
- To evaluate the safety, and efficacy of the AFR device in a porcine model.

Methods
- Eight 2.5 month old piglets weighing 35-50 kg underwent AFR implantation.
- Hemodynamic changes, device position and patency were monitored using echocardiography and fluoroscopy for 3 months.
- Tissue reaction and histopathological changes were also studied.

Results
- Eight animals were included in the study. The AFR was successfully implanted in 6 pigs; 2 were excluded from the study (Table 1).
- Device patency was demonstrable on echocardiography at 1 day after implantation (n=6).
- At 1-month follow-up, 2 pigs had spontaneous closure of the fenestration, but device patency was maintained in the remaining 4 piglets throughout the study period.
- Postmortem examination demonstrated patent shunts (Figure 2) with neoendothelialization (n=4), and slight decrease in pulmonary artery oxygen saturation 61.4 ± 5.59 to 58.7 ± 4.33 mmHg, but was not found to be significantly different at follow-up (p=0.3568). There was no statistically significant difference in the Qp:Qs before and after implantation (p=0.1881).
- No tissue reaction was noted at the implantation site (n=6).

Conclusion
- The AFR device was found to be easy to deploy, safe, and effective in creating and maintaining a permanent atrial communication.

References