

ATRIAL SEPTAL DEFECT OCCLUSION USING AN IMMEDIATE RELEASE PATCH METHOD ; EARLY CLINICAL EXPERIENCE

i2 Poster Contributions

Georgia World Congress Center, Hall B5

Monday, March 16, 2009, 9:30 a.m.-10:30 a.m.

Session Title: Endovascular and New Technologies

Abstract Category: PCI - Congenital

Presentation Number: 2505-430

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Background: The transcatheter patch (TP) is a wireless and bio-absorbable occluding device with good long term results but inconvenient patch release (48 hours). A modified TP able for immediate release (IR) was found effective and safe in experimental atrial septal defect (ASD) occlusion in piglets. Purpose of this study was the validation of the IR method in humans, in comparison to the 48 hour release method.

Methods: Ten ASDs 12-26 mm (m=23) in diameter were repaired by the IR method. The results were compared with ten matched controls corrected by the regular release method. Different factors including safety, efficacy and convenience were compared with the two **Methods:** Data from the International TP Registry for ASD occlusion was used for this study.

Results: There were no device/method problems. All ASDs in the IR group were fully occluded. All patients were able to be mobilized in 2-3 hours in the IR group and were discharged home within 24 hours. In contrast all patients in the control group had to remain still for 48 hours and were discharged home in 48-72 hours. The full occlusion rate on implantation and one month follow-up was superior in the IR group: 100-100% vs. 64-80% in the control group.

Conclusions: The IR method was more convenient for the patients as well as more operator friendly. The early results have shown superior full occlusion rates. The long term results of the IR method are expected to be similar to the ones observed in the TP registry, where the regular release method was used. A known occlusion method with good results, appears better with the IR method.