Feasibility of a Percutaneously Deployed Clip to Create and Maintain an Interatrial Communication

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Background: In many instances of congenital heart disease there is a necessity of mixing of blood from the right and left atria. A number of techniques have been described to create, enlarge or maintain a passage to allow for this mixing. We investigated the effect of a simple clip that can be placed during an interventional procedure to create and maintain a channel between the left and right atria.

Methods: Fifteen juvenile pigs (5 acute and 10 chronic) were used weighing 35-45 kg. Following anesthesia and ventilation, transseptal puncture was performed. A simple 6 winged nitinol clip was deployed through an 8F system under intracardiac echocardiographic (ICE) guidance. At full expansion the clip provided a 6mm aperture. Flow was confirmed by ICE. Follow up and pathological analysis was performed at 4 hours -12 weeks. All animals were treated with aspirin and plavix until sacrifice. Intraprocedural heparin was administered to a target ACT of >200secs.

Results: All acute animals demonstrated excellent patency by ICE at 4 hours. The 5 acute animals demonstrated neat 6 mm apertures in the device. Four devices were occluded at sacrifice (2 at 3 weeks, one each at 6 and 8 weeks). Animals sacrificed at 2, 4, 8 and 12 weeks had patent apertures, however of decreasing diameters due to progressive endocardial ingrowth. The mean ACT at implant appeared lower in the occluded (122±43secs) than that of the patent cases (191±93secs).

Conclusions: A simple clip for the creation and maintenance of interatrial communication is feasible and effective in the short term. A combination of early occlusion probably due to thrombus formation and late closure due to endocardial growth limited its effectiveness in this study. Improved design, increased initial aperture and medical therapy would likely remedy some of these issues.