BioSTARTM device achieves 90 percent closure rate for atrial septal defect in children

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A novel study by Canadian physicians reported that the BioSTARTM biodegradable implant achieved comparable closure rates to the Amplatzer Septal OccluderTM (ASO) in children with atrial septal defect (ASD). The BioSTAR device displayed successful outcomes, while avoiding issues associated with implants containing substantial amounts of metal. Results of the study, the first to compare the BioSTAR device with the ASO in children, are now available online and in the July print issue of *Catheterization and Cardiovascular Interventions*, a journal published by Wiley-Blackwell on behalf of The Society for Cardiovascular Angiography and Interventions.

ASD is a congenital heart defect where a hole is present in the wall between the two upper heart chambers. While smaller ASDs may close on their own in early life, larger defects may require surgery to close the opening. If left untreated, ASD may increase the risk of developing atrial fibrillation, heart failure, or stroke later in life. The incidence of atrial septal defects ranges from one-twentieth to one-tenth of all congenital heart lesions.

During the study period of November 1, 2007 through November 30, 2008 there were 54 children who underwent ASD closure with the ASO implant. The ASO group subjects' median data were: age of 7.4, weight of 23.3 kg, defect size of 10 mm, and balloon stretched size of 12.7 mm. The BioSTAR implant was used in 10 patients where a small to

moderate defect was anticipated by non-invasive studies. In this group, patients' median data were: age of 11, weight of 39.6 kg, defect size of 10 mm, and balloon stretched size of 11.5 mm.

Study results indicated the acute and 6-month follow up closure rate for the BioSTAR were both 90%, compared with 100% for both time periods with the ASO implants. "Our study provides evidence that the BioSTAR implant achieves comparable closure rates to the ASO device in small- to moderate-ASD," said lead study author Lee Benson, M.D., FSCAI. "Minimal foreign material remains after 6 months with the biodegradable implant, reducing the risks associated with devices containing significant amounts of metal." The study team noted that decreased long-term thrombogenicity, preserved transseptal access, decreased inflammatory response, and reduced potential of arrhythmogenicity and erosion were benefits of using biodegradable implants.

The team reported no serious complications in either group. However, statistically significant differences in the median procedure time (BioSTAR-52 minutes; ASO device-39.5 minutes) and fluoroscopy times (BioSTAR-6.7 minutes; ASO device-6.1 minutes) were observed. "Longer procedure and fluoroscopy times are a drawback of the BioSTAR implant, but should improve with familiarity with the device and deployment system," Dr. Benson concluded.

More information: "A Biodegradable Device (BioSTARTM) for Atrial Septal Defect Closure in Children." Gareth Morgan, Kyong-Jin Lee, Rajiv Chaturvedi, and Lee Benson. Catheterization and Cardiovascular Interventions; Published Online: March 1, 2010 (DOI:10.1002/ccd.22517);

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