Growth of the Atrial Septum after Amplatzer Device Closure of ASD

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Background

- Trans-catheter closure of ostium secundum ASD with the Amplatzer Septal Occluder (ASO) has largely replaced surgical closure
- The size of the ASD and the septal rims surrounding the defect are used to determine the ASO device chosen
- One classification system identifies 6 septal rims named according to the adjacent structures: aortic rim, superior vena cava rim, superior rim, posterior rim, inferior vena cava rim, and atrio-ventricular valve rim
- Recent concerns for cardiac erosions have raised attention to the use of the smallest possible device to occlude the ASD
  - Causes of erosions remain unknown, although rim size may be related
- Although pediatric patients continue to grow after device placement little is known about the growth of the septal rims over time OR the effect of somatic growth on the risk of erosion

Specific Aims

We sought to define:

1. Rims sizes/ distance of the device from the surrounding cardiac structures at time points prior to and after closure with ASO
2. The effect of somatic growth on the size of the septal dimensions after ASO placement
3. To determine if there was a relationship between these dimensions and erosions

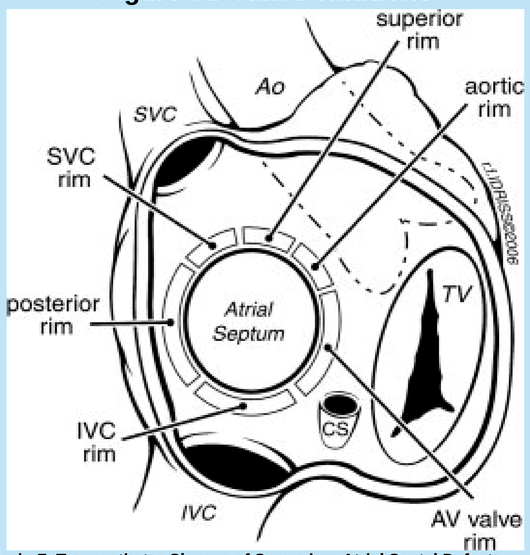
Methods

- IRB approved Retrospective Chart Review
- Inclusion Criteria:
  - Patients undergoing ASO placement from 2002 to 2009
  - Patients under the age of 13 at time of ASO placement
- Exclusion Criteria:
  - Non-Amplatzer ASD devices used
  - Multiple devices placed
- Baseline data collected included:
  - Age at placement of device
  - Size of ASD
  - Size of ASO placed
  - Height, Weight, BSA

Methods

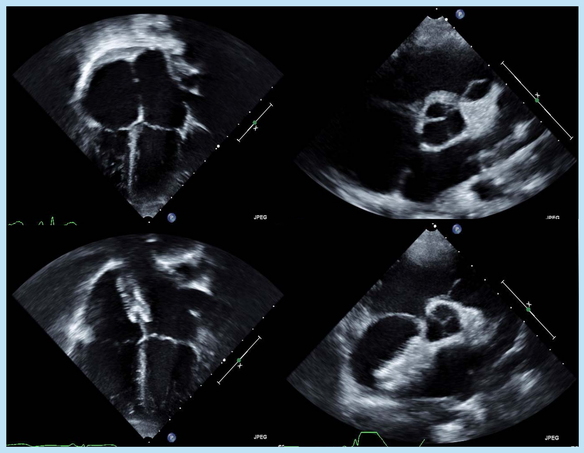
- 3 Separate trans-thoracic ECHO studies were evaluated and measurements of six septal rims were obtained (figure 1)
  - ECHO 1: PRIOR to device placement
  - ECHO 2: Immediately following Amplatzer placement
  - ECHO 3: Most recent available follow-up
- Follow-up data collected included:
  - Age, Height, Weight, BSA
- All measurements were obtained by a senior echo sonographer and confirmed
- When the device contacted the cardiac wall or aorta this was assigned a distance of 0mm

Figure #1- Rim Definitions



Amin Z. Transcatheter Closure of Secundum Atrial Septal Defects. *Catheterization and Cardiovascular Interventions.* 2006; 68:778-787

Figure #2- Rims Before and After Device



Results

- Of the 109 patients identified with ASD closure during the study period 33 met eligibility criteria
  - The majority of exclusions were due to missing ECHOs prior to our institutional shift to digital archiving
- Baseline demographics are shown in table #1
- As expected, the mean size of all rims decreased in size immediately after device placement (figure 2, and 3 ECHO 1 to ECHO 2)
- Thirty-one of 33 patients had an Aortic Rim of zero after ASO placement (figure 2)

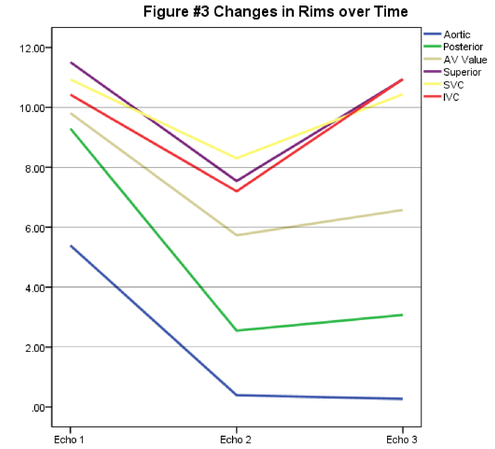
Table #1- Baseline Data

Age at device placement, (median, range)	4.5 yrs (0.4-12.2)
% Male	30%
Height (median, range)	102.4cm (55-145)
Weight (median, range)	16kg (4.1-48.6)
BSA (median, range)	0.71 (0.3-1.3)
ASD Size (median, range) Unstretched (ECHO) (n=29) Stop Flow Sized (n=20)	 11.0mm (3-29) 18mm (9.1-31.5)
QP:QS	2:1 (1:1-7.6:1)
ASD Device size	14mm (6-32mm)
Device to ASD ratio Unstretched (ECHO) (n=29) Stop Flow Sized (n=20)	 1.29 (0.9-3) 1.04 (0.9-1.3)

- Median length of follow-up was 3.9 yrs (0.02-8.1)
- To investigate long-term changes in sizes with somatic growth we analyzed all patients with greater than 1 year of follow-up available (n=28)
  - For this population median follow-up was 4.1 yrs (1-8.1)
- The change over time in distance from device to cardiac structure is shown in Figure 3
  - From ECHO 2 to ECHO 3 there was a significant increase in the size of the IVC rim
  - There was NO increase in the median size of the aortic rim from device placement to most recent follow-up
    - All aortic rims that measured zero at device placement remained zero at most recent follow-up
- The effect of growth (BSA) on distance from device to cardiac structure after device placement was investigated
  - With increase in BSA there was a significant increase in superior and IVC rims
  - With increase in BSA there was NO increase in aortic or AVV rims
  - Change in SVC and posterior rims were not consistently predictable with growth
- No episodes of erosion occurred during this study precluding evaluation of the relationship between rims size/growth and erosion

Results

Figure #3 Changes in Rims over Time



Limitations

- Retrospective single center study
- Small number of patients
- Not all data points available in all patients
- Not all patients underwent balloon stop-flow sizing

Conclusions

- The vast majority of ASDs in the studied population are not central in the septum, but proximate to the aorta
  - This relationship persists after ASO with the device remaining in close proximity to the aorta in most instances over time
- With somatic growth of the patient the atrial septum appears to grow asymmetrically, and the device position relative to the aorta remains constant
  - The majority of our devices are in contact with the aorta immediately after device placement and with patient somatic growth
- Although our study was not powered to detect a serious adverse event such as erosion, it is informative that the aortic rims were consistently zero and yet no events occurred

References

1 Amin Z. Transcatheter Closure of Secundum Atrial Septal Defects. *Catheterization and Cardiovascular Interventions.* 2006; 68:778-787
2. Amin Z, Hijzi, ZM, Bass, JL, et al. Erosion of Amplatzer Septal Occluder Device After Closure of Secundum Atrial Septal Defects: Review of Registry of Complications and Recommendations to Minimize Future Risks. *Catheterization and Cardiovascular Interventions.* 2004; 63:496-502
3. Everett AD, Jennings J, Sibinga E. Community Use of the Amplatzer Atrial Septal Defect Occluder: Results of the Multicenter Atrial Septal Defect Study. *Pediatric Cardiology*. 2009; 30:240-247
4. . Rossi, R, de Oliveira Cardoso, C, Machado, PR, et al. Transcatheter Closure of Atrial Septal Defect with Amplatzer Device in Children Aged Less than 10 Years Old: Immediate and Late Follow-up. *Catheterization and Cardiovascular Interventions.* 2008; 71:231-236