Transcatheter Closure of ostium secundum atrial septal defects with a new soft device in pediatric age: single Center experience

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Background

This perspective, observational study evaluated safety and efficacy of the GORE® Cardioform ASD Occluder (WL Gore & Associates, Flagstaff, AZ), a compliant and potentially innovative prosthesis recently approved for closure of ostium secundum atrial septal defects (ASD).

Methods

Between January 2020 and March 2022, 97 children underwent transcatheter ASD closure at our Institution; between these patients 63 with hemodynamically significant ASD were submitted to trans-catheter closure with GORE® Cardioform ASD Occluder. Primary endpoints were procedural success and safety. Secondary endpoints were closure rate and clinical safety at 1-month follow-up.

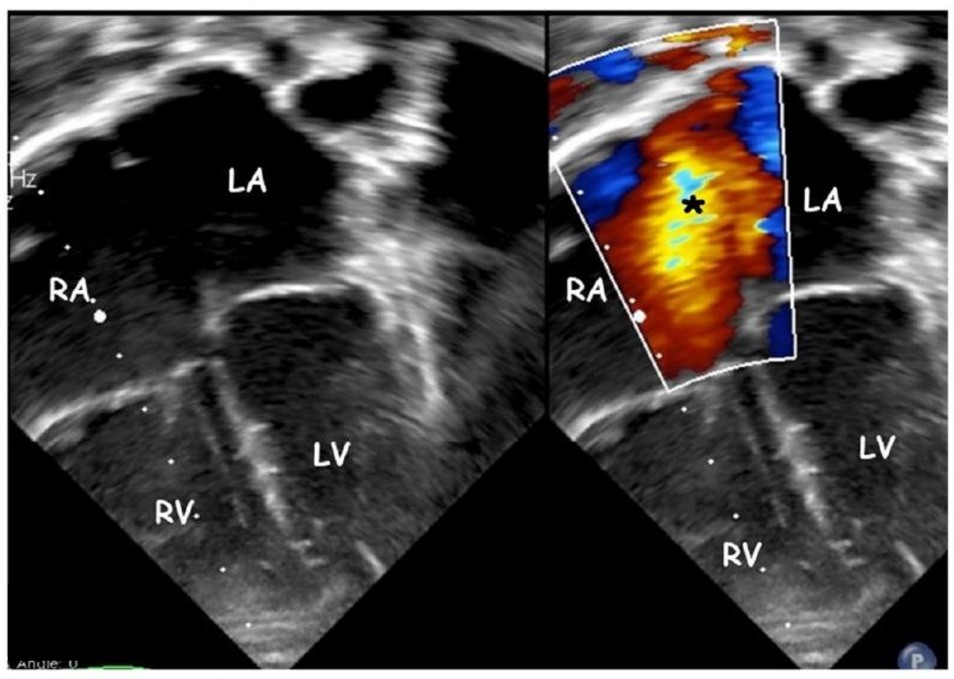

Figure 1: Transthoracic echocardiography in 4-chamber view showing a large ASD causing a significant left-to-right shunt (asterisk). ASD, atrial septal defect; LA, left atrium; LV, left ventricle; RA, right atrium; RV, right ventricle**.**

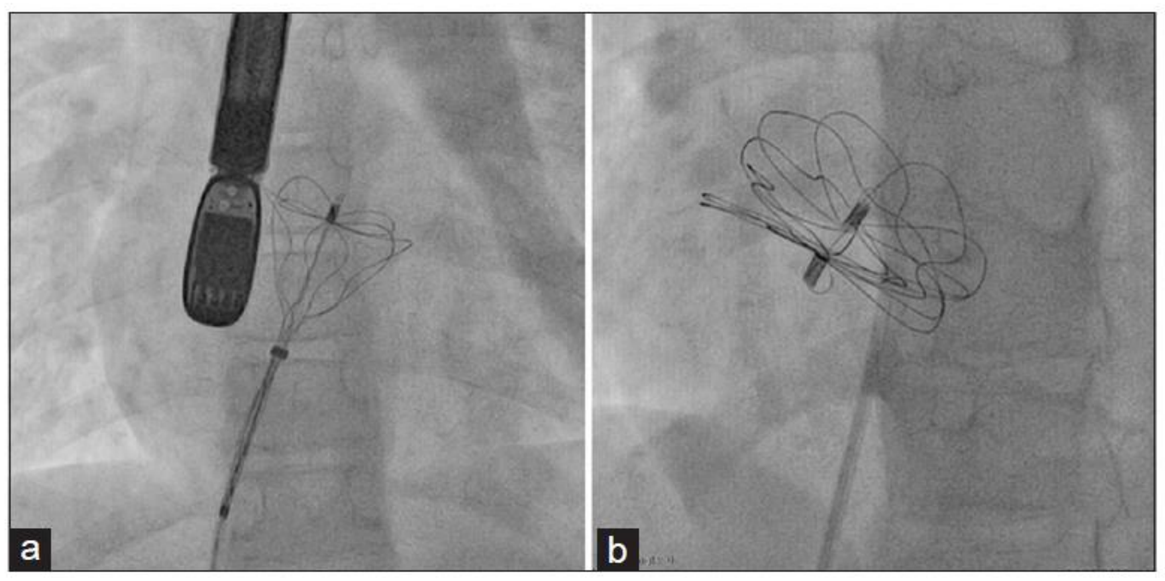

Figure 2: Fluoroscopy showing (a) deployment of the left atrial disc and the soft central waist and (b) final release of the device, well seated across the atrial septal defect

Results

Patients' age and weight were 7.0±3.5 years (range 3-17, median 6.0) and 27.0±13.8 kg (range 13-67, median 21.5), respectively. ASD diameter was 18.4±4.5 mm (median 18.5), resulting in QP/QS of 1.8±0.7 (median 1.5). Thirty-five patients (36%) were considered "surgical" candidates due to challenging septum morphology, ASD rim deficiency or ASD diameter/patient weight ratio >1.2. Device placement was successfully achieved in all but four patients (94,6%), who needed rescue or elective surgery due to device embolization (n=1), device instability (n=2) or new-onset tricuspid valve regurgitation (n=1). No cross-over with different devices was recorded. Median procedure and fluoroscopy times were 58 and 10 minutes, respectively. Major adverse events were recorded in 4.8% (3 pts). Complete closure rate was 95.2% at discharge, rising to 98.4% (62/63 pts) at 1-month evaluation, without cardiac or extra-cardiac adverse events. "Challenging" procedures were more time-consuming but as effective and safe as the "simple" ones.

Conclusions

The GORE® Cardioform ASD Occluder device was highly effective and safe in closure of ASDs with different anatomy and size, even in challenging settings.