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IMAGES IN INTERVENTION

Porous CARDIOFORM Septal Occluder Balloons Within the Right Atrial Cavity

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A 68-year-old woman presented with fatigue, atrial fibrillation, and tachy-brady syndrome requiring a pacemaker. Transesophageal echocardiography revealed an 8-mm secundum atrial septal defect with shunt fraction (Q_p/Q_s) of 2.7 (**Figure 1A**, Online Video 1). Atrial septal defect closure was undertaken with a 25-mm CARDIOFORM Septal Occluder (Gore Medical, Flagstaff, Arizona). Under transesophageal echocardiographic guidance, the device was deployed across with 2 wire helices in each atrium (**Figure 1B**, Online Video 2). One minute following deployment, fluoroscopy revealed stretching of the right atrial portion of the frame (**Figure 1C**, Online Video 3). Transesophageal echocardiography demonstrated ballooning of the device within the right atrium (**Figure 1D**, Online Video 4). Doppler ruled out obstruction of atrial inflow and outflow. We believe that a defect in the left atrial polytetrafluoroethylene membrane allowed blood to fill the right atrial half of the device via left-to-right shunting. Heparin was begun to prevent thrombosis. Fluoroscopy 1 day later demonstrated improved right atrial configuration (**Figure 1E**), suggesting spontaneous drainage. The patient was discharged on dabigatran for atrial fibrillation and defective atrial septal defect occlusion device.

The REDUCE trial showed efficacy of patent foramen ovale closure in preventing recurrent ischemic events (1). On March 30, 2018, the U.S. Food and Drug Administration approved the CARDIOFORM Septal Occluder for patent foramen ovale closure, which will increase its use. We present a novel complication associated with this device. In light of our experience, we recommend expectant management: anticoagulation to prevent device thrombosis and imaging follow-up by echocardiography and fluoroscopy.

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From the Division of Cardiovascular Medicine, University of Nebraska Medical Center, Omaha, Nebraska. Both authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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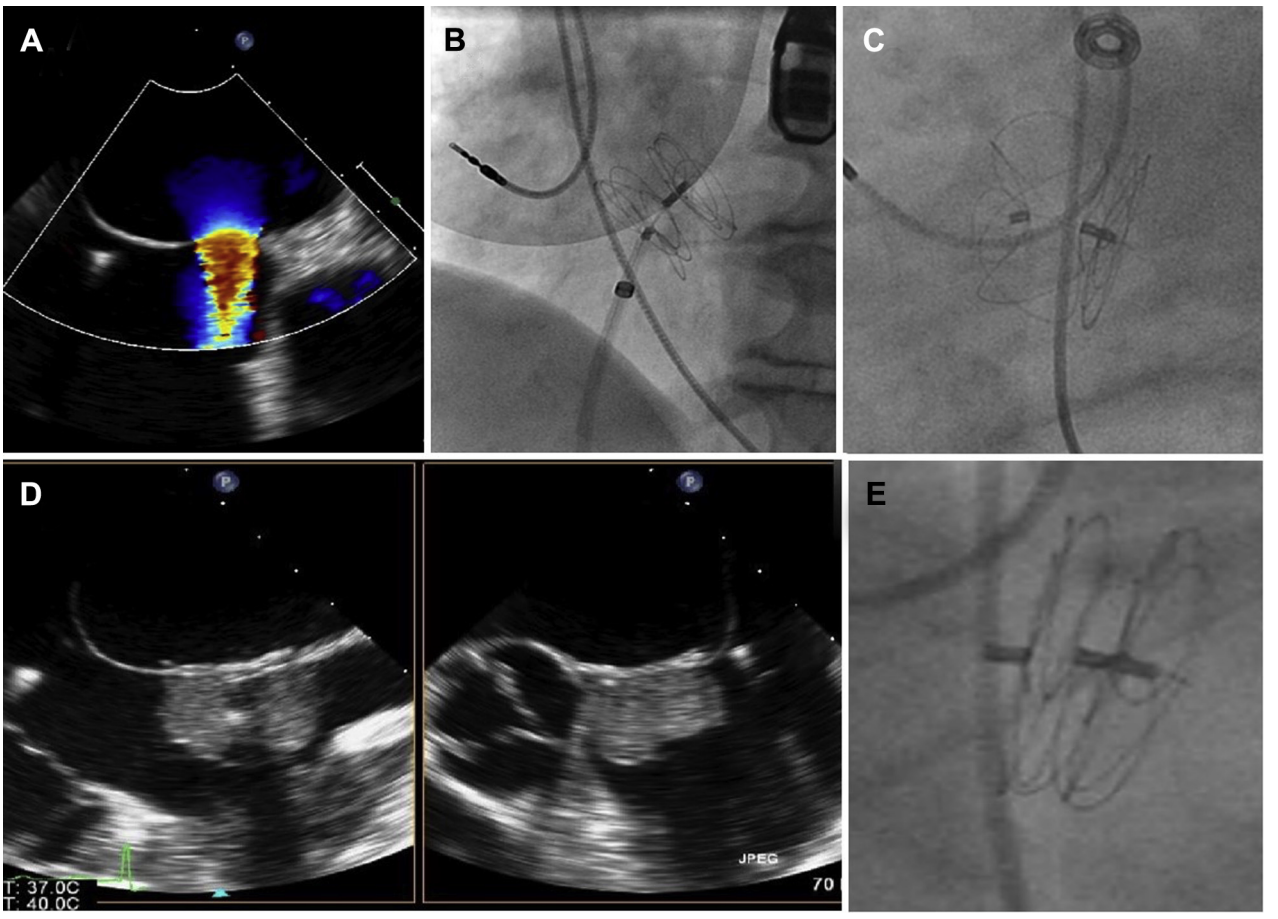
FIGURE 1 **Deployment and Malformation of CARDIOFORM Device**



(A) Secundum atrial septal defect by transesophageal echocardiography (TEE). See Online Video 1. **(B)** Successful device deployment by fluoroscopy. See Online Video 2. **(C)** Stretching of the right atrial portion of the frame by fluoroscopy. See Online Video 3. **(D)** Ballooning of the device within the right atrium by TEE. See Online Video 4. **(E)**. Fluoroscopy showing improved right atrial configuration of device the day following implantation.

REFERENCE

1. Sondergaard L, Kasner SE, Rhodes JF, et al. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. N Engl J Med 2017;377:1033–42.

KEY WORDS atrial septal defect, Gore CARDIOFORM, patent foramen ovale

APPENDIX For supplemental videos, please see the online version of this paper.