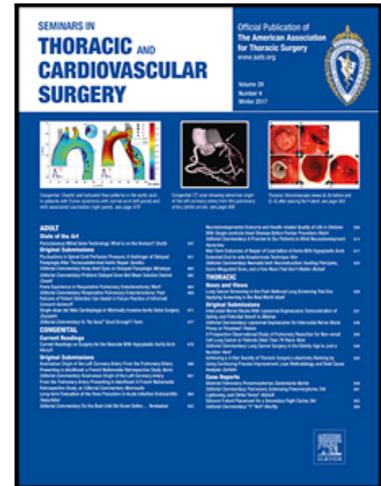


Novel Implementation of a Cerebral Protection System During Ascending Thoracic Endovascular Aortic Repair (TEVAR)

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1 **Novel Implementation of a Cerebral Protection System During Ascending Thoracic**

2 **Endovascular Aortic Repair (TEVAR)**

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39 **Central Message:**

40 TEVAR of the ascending aorta is associated with increased risk of stroke, which may be  
41 mitigated by use of cerebral protective devices.

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**58 Background:**

59 Thoracic endovascular aortic repair (TEVAR) has emerged as the standard of care for  
60 management of most descending aortopathies. Despite rapid evolution of associated devices,  
61 materials, and techniques, however, TEVAR of the ascending aorta and aortic arch is currently  
62 reserved for patients with prohibitive risk for open surgical intervention [1]. Over 80% of  
63 patients undergoing TEVAR demonstrate post-procedural radiologic evidence of stroke  
64 associated with significant neurocognitive decline, and this incidence is estimated to be even  
65 higher in ascending TEVAR [2,3]. Increasingly widespread application of transcatheter aortic  
66 valve replacement (TAVR) has encouraged the development and implementation of cerebral  
67 protection devices for prevention of intra-operative stroke. The Sentinel Cerebral Protection  
68 System (Claret Medical, Santa Rosa, CA) is currently the only FDA-approved cerebral  
69 protection device for TAVR, and preliminary data regarding its efficacy in both TAVR [4] and  
70 TEVAR of the descending aorta [5] have been promising. Here we present the first published  
71 report of cerebral protection device utilization during TEVAR for an ascending aortic aneurysm.

**72 Clinical Summary:**

73 An 85 year-old woman with a medical history significant for atrial fibrillation status post  
74 ablation with placement of permanent pacemaker/implantable cardioverter-defibrillator, also  
75 status post remote open mitral valve repair, who was referred to our institution from an outside  
76 hospital for further evaluation of a chronic ascending aortic aneurysm. A small ascending aortic  
77 pseudoaneurysm with surrounding hematoma was noted 4 years prior to her presentation at our  
78 clinic and was managed conservatively. Pre-operative CT angiography revealed an increasingly  
79 dilated ascending aorta measuring 4.2 cm, and a 20 x 12 mm distal ascending aortic  
80 pseudoaneurysm with an 8 mm neck without significant atheroma burden, with extensive

81 surrounding hyperdensity adjacent to the aortic lumen involving the aortic root, aortic arch, and  
82 thoracoabdominal aorta consistent with intramural and/or para-aortic hematoma [Figure 1]. Pre-  
83 operative transesophageal echocardiography (TEE) revealed mild to moderate aortic  
84 regurgitation, without evidence of major aortic atheroma. Given her age, prior cardiac surgical  
85 history, medical co-morbidities (STS Risk Score 8%), and elevated risk of peri-operative stroke  
86 (CHA<sub>2</sub>DS<sub>2</sub>-VASc score 5), the patient was offered endovascular repair of her pseudoaneurysm  
87 using vascular plug placement and thoracic endograft (TEVAR) placement, with utilization of  
88 the Sentinel Cerebral Protection System (SCPS).

89 **Procedure in Detail:**

90 Both radial and groin arterial access was obtained. After heparinization, the 6F SCPS was placed  
91 under fluoroscopic guidance via the right radial artery and positioned such that proximal and  
92 distal filters were within the innominate and left common carotid arteries, respectively, as  
93 previously described [6, Figure 2]. A temporary pacing wire was placed in the right ventricle.  
94 Intra-operative aortography and TEE confirmed favorable anatomy for TEVAR placement.  
95 Fluoroscopic visualization of the pseudoaneurysm neck, however, was technically difficult and  
96 the decision was made to forego vascular plug embolization. The arterial access site was  
97 preclosed with sutures. Two Cook Alpha thoracic endografts (42 x42 x 90 mm) (Indianapolis,  
98 IN) were modified on the backtable to accommodate our echocardiographic aorta measurements;  
99 both grafts were partially unsheathed and trimmed for a total length of 70 mm, and subsequently  
100 re-sheathed into the original delivery sheath. Both grafts were deployed under rapid pacing  
101 without incident, ultimately facilitating almost 2 cm of pseudoaneurysm coverage proximally.  
102 Completion aortography showed no extravasation or endoleak, and TEE confirmed successful  
103 exclusion of the pseudoaneurysm. The SCPS and endograft sheath were removed sequentially

104 without incident. There were no embolic debris noted within the SCPS filters following retrieval.  
105 The patient was awakened from anesthesia and extubated without incident, and was discharged  
106 the following day without any evidence of neurologic deficit.

107 **Discussion:**

108 Endovascular approaches to treat complex aortopathies have been attempted out of necessity  
109 when surgical repair is not an option. Despite substantial research efforts in pre-operative risk  
110 stratification and various intra-operative preventive strategies [3,6], stroke remains a major  
111 complication of TEVAR and is associated with substantial morbidity and mortality. The high  
112 stroke rates of aortic arch grafts have previously raised concern about excessive morbidity [9].  
113 Cerebral protection devices for TAVR such as the SCPS have demonstrated feasibility and  
114 efficacy for stroke risk reduction [4,8], and preliminary reports of their use in the descending  
115 aorta are promising. Here we report the first published account of cerebral protection device  
116 utilization in the endovascular management of proximal aortic arch pathology, with an excellent  
117 outcome. Further prospective studies are needed to comprehensively characterize aortic anatomy  
118 that permits the use of cerebral protection devices. Nevertheless, utilization of cerebral  
119 protection devices should be considered on a case-by-case basis for patients with elevated risk of  
120 stroke undergoing both ascending and descending TEVAR.

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162 **Acknowledgements:**

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164 During MitraClip Implantation: Initial Experience at 2 Centers, Pages 171-179, 2016, with  
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168 **Central Picture:**

169 Sentinel Cerebral Protection System utilization during ascending TEVAR.

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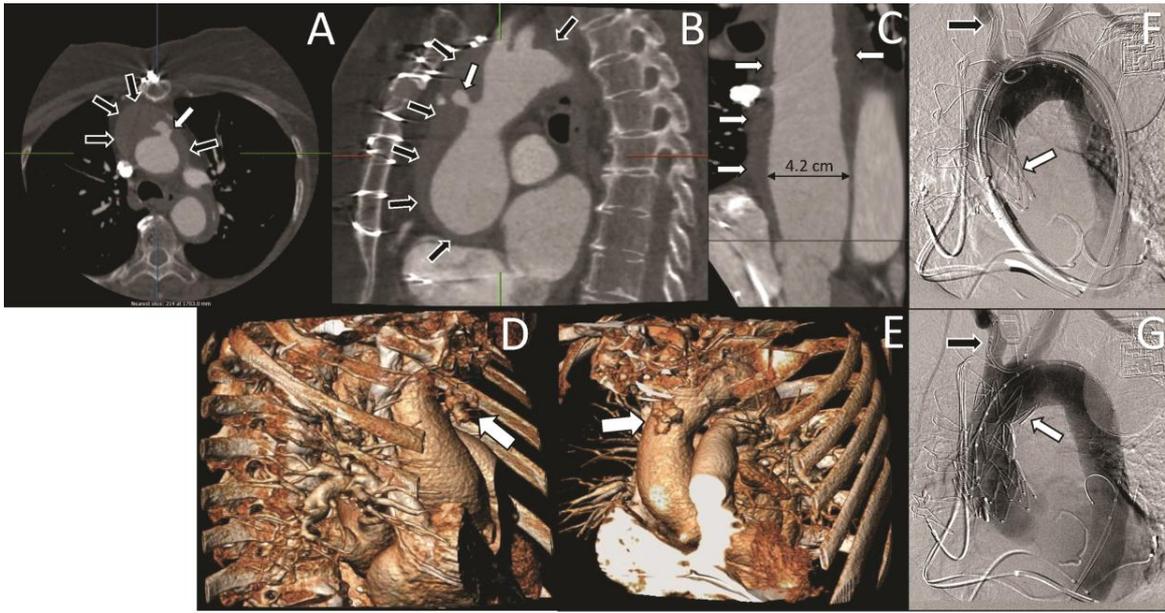


Figure 1

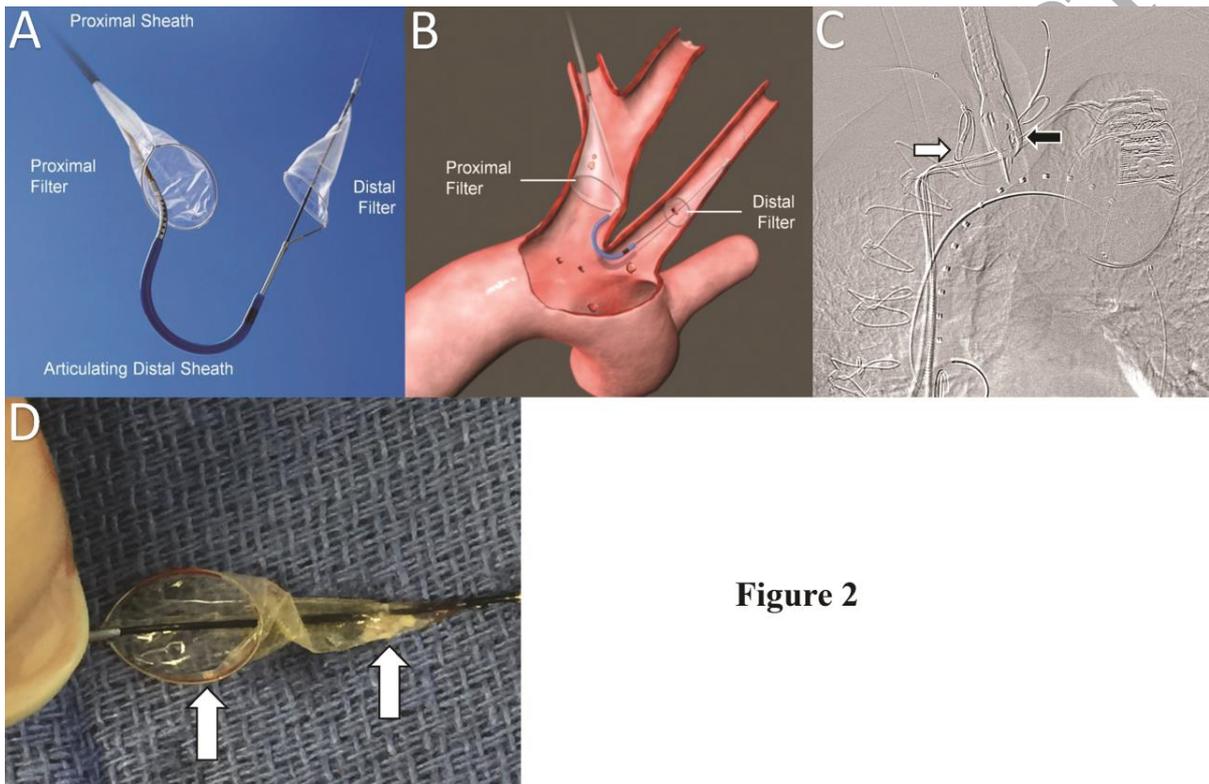


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174 **Figure #1:**

175 Axial (A) and Sagittal (B) CT imaging demonstrating aortic pseudoaneurysm (white arrows) and  
176 large intramural and/or periaortic hematoma (black arrows). (C) Elongated CT view of aorta with  
177 dimensions and with hematoma (white arrows). 3D CT reconstructions demonstrating aortic

178 pseudoaneurysm (white arrows) from right anterior (D) and left anterior (E) oblique views.  
 179 Fluoroscopic imaging of proximal (F, white arrow) and distal (G, white arrow) aortic endografts  
 180 following deployment with visible Cerebral Protection System (black arrows).  
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**Figure 2**

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 183 **Figure #2**  
 184 (A) Photograph of the Sentinel Cerebral Protection System with proximal and distal sheaths and  
 185 filters<sub>1</sub> (B) Schematic *in vivo* positioning of the Sentinel Cerebral Protection System with  
 186 proximal and distal filters within the innominate and left carotid arteries, respectively<sub>1</sub>. (C)  
 187 Confirmation of Sentinel Cerebral Protection System placement with proximal filter within the  
 188 innominate artery (white arrow), and distal filter within the left carotid artery (black arrow). (D)

189 Representative photograph of embolic debris (white arrows) following Sentinel Cerebral  
190 Protection System retrieval.

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### 193 **Video Legend**

194 Aortography highlights the proximal and distal landing zones and relevant cardiovascular  
195 anatomy for both Sentinel Cerebral Protection System and TEVAR endograft positioning. Prior  
196 to deployment of the TEVAR endografts, the Sentinel Cerebral Protection System is placed  
197 under fluoroscopic guidance via the right radial artery and positioned such that the proximal and  
198 distal filters are within the innominate and left common carotid arteries, respectively. Proximal  
199 and distal TEVAR endografts are then deployed under fluoroscopic guidance. Successful  
200 exclusion of the aortic pseudoaneurysm is noted on subsequent completion angiography. The  
201 endograft sheath and Cerebral Protection System are then removed percutaneously.

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