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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 (CHA₂DS₂-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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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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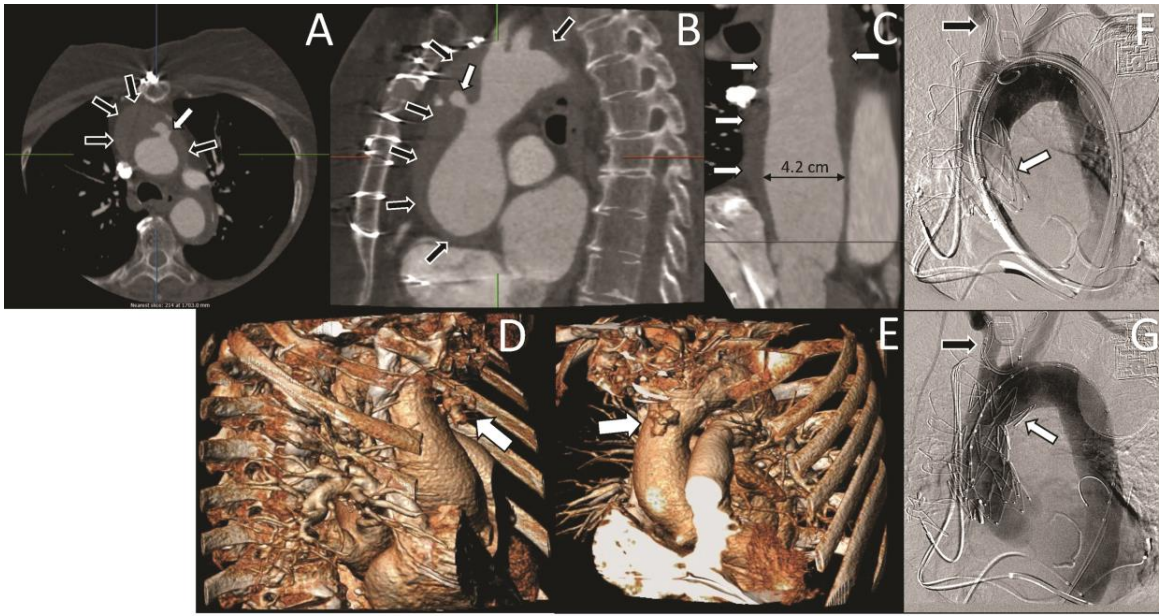


Figure 1

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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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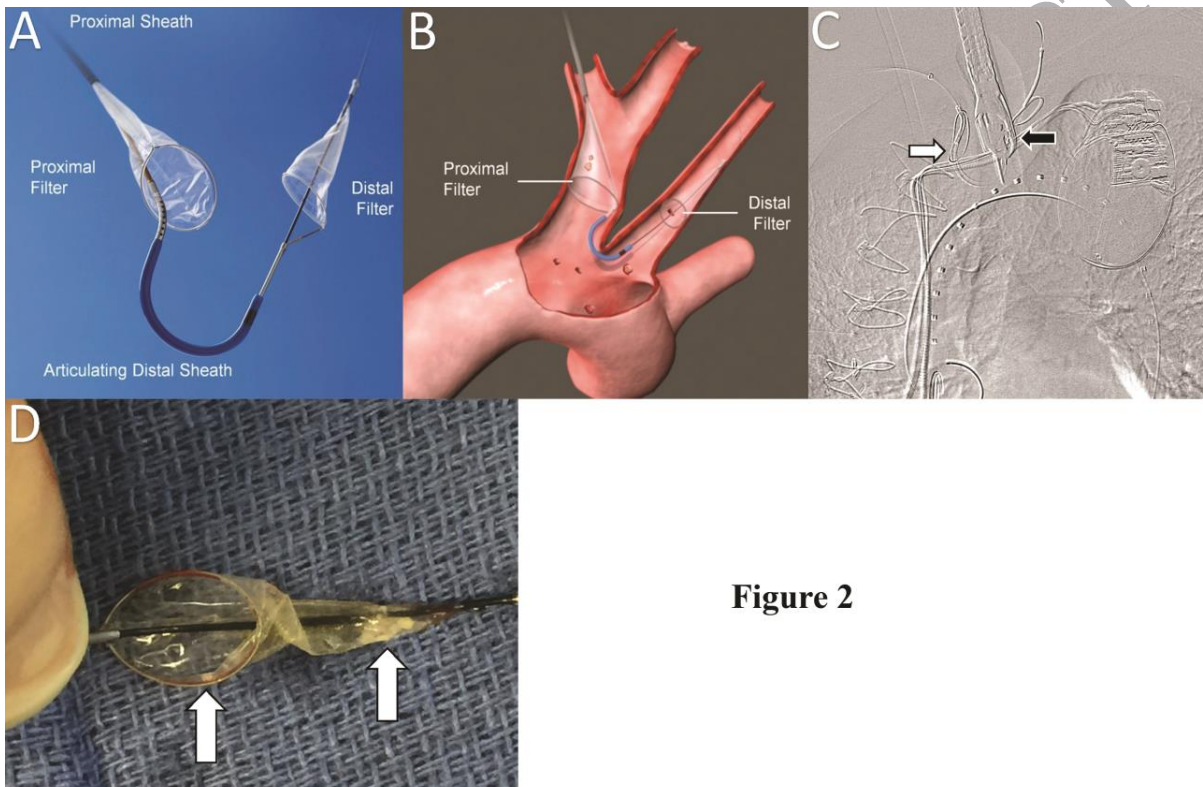


Figure 2

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 183 **Figure #2**
 184 (A) Photograph of the Sentinel Cerebral Protection System with proximal and distal sheaths and
 185 filters₁ (B) Schematic *in vivo* positioning of the Sentinel Cerebral Protection System with
 186 proximal and distal filters within the innominate and left carotid arteries, respectively₁. (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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