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Endovascular treatment of spontaneous internal carotid artery dissection with proximal embolic protection device

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2	embolic protection of	levice.
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29 Abstract

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30	Purpose. To report the feasibility and outcomes with the endovascular treatment of spontaneous
31	internal carotid artery dissections (ICAD) using proximal embolic protection device (EPD).
32	Materials and methods. Retrospective analysis from January 2017 to December 2018 of patients
33	treated for spontaneous symptomatic ICAD using proximal EPD. Indication for treatment was the
34	presence of neurological symptoms. Early outcomes measured included technical success,
35	perioperative mortality and major cardiovascular or cerebrovascular complications. Late outcomes
36	were recurrent neurological symptoms, patency and reinterventions.
37	Results. A total of 4 male patients with ICAD were included: A preoperative cerebral CT positive
38	for cerebral ischemic events was reported in all cases. In 3 patients the neurologic symptoms
39	consisted of a TIA, the remaining patient presented an amaurosis fugax and aphasia. In 2 patients
40	ICAD was associated to a carotid significant stenosis. In all patients the reported approach was
41	feasible with no complications and complete anatomic dissection resolution. At a mean follow-up of
42	18 months, all stents are patent and no restenosis recurrence or complications were registered.
43	Conclusion. The use of proximal EPDs allowed the treatment of ICAD under flow arrest
44	minimizing the risk of stroke during the endovascular maneuvers. Larger series are required to
45	validate this treatment strategy.
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55 **TEXT** 

## 56 Introduction

- 57 Internal carotid artery dissection (ICAD) is a rare disease that occurs spontaneously or following
- traumatic injuries. Spontaneous ICAD incidence is reported in 2.6 per 100 000 patients.<sup>1,2</sup> Despite
- 59 its rarity, ICAD represents a significant cause of cerebral events in young patients.<sup>3</sup> Neurological
- 60 symptoms secondary to ICAD are an indication to repair over the medical management.
- 61 Endovascular solutions showed better outcomes when compared to conventional surgery due to a
- 62 reduced incidence of early occlusion, stroke, and cranial nerve injuries.<sup>4,5</sup>
- 63 Herein we report the feasibility and outcomes of endovascular treatment for spontaneous ICAD
- 64 using proximal embolic protection device (EPD).

### 65 Materials and methods

- 66 From January 2017 to December 2018 were retrospectively analyzed patients treated for
- 67 spontaneous symptomatic ICAD. Were excluded from the study patients presenting post-traumatic
- 68 ICADs; patients addressed by conventional open surgery and patients addressed by endovascular
- 69 solutions without proximal EPD. Neurological symptom was an indication for treatment in all
- 70 cases, including: stroke, transient ischemic attack (TIA), amaurosis fugax and aphasia. All patients
- 71 underwent preoperative CTA (figure 1-2). Measured metrics included early and late outcomes.
- 72 Early outcomes comprised technical success, perioepartive mortality and major cardiovascular or
- 73 cerebrovascular complications; late outcomes were recurrent neurological symptoms, patency and
- reinterventions. Follow-up consisted of duplex ultrasound before dismission, at 1,6 and 12 months.
- 75 All patients received cardioaspirin and low-molecular-weight heparin therapy prior to the
- 76 procedure.
- 77 Informed consent for the treatment itself and the anonymous data collection and analysis was
- 78 obtained for each patient; approval of the Institutional Review Board was not required.
- 79 Technique. All procedures have been performed in the angio suite with a fixed equipment (Artis
- 80 Zeego, Siemens, Germany); under local anesthesia; and using a retrograde femoral access. After a

81 single perclose ProGlide (Abbott Vascular, Santa Clara, CA, US) access, a 9 Fr introducer sheath (Avanti; Cordis Europe, Roden, the Netherlands) was placed and general heparinization 82 administered (5000 IU). The common carotid artery (CCA) was engaged and a carotid angiography 83 84 roadmap performed. Using a hydrophilic .035 guidewire (Radifocus guidewire, Terumo, Tokyo, 85 Japan) the external carotid artery (ECA) was cannulated and the hydrophilic wire exchanged to a stiff wire (Amplatzer Super Stiff, Boston Scientific, Natick, MA, US). Over the stiff wire the 86 87 proximal EPD (MoMa, Invatec, Roncadelle, Italy) was advanced and positioned in correspondence. 88 Inflation of the ECA balloon was first performed until the balloon shape change; subsequently the 89 CCA balloon was inflated to arrest ICA antegrade circulation. A slow injection of 5cc 90 contrast/saline mixture is employed to confirm the CCA and ECA occlusion. Cerebral protection 91 was established before any wire passage across the carotid dissection. At this stage a floppy 92 steerable .014 wire (ATW, Cordis Europe Command) was employed to cross the carotid dissection 93 maintaining the true lumen. A primary carotid stenting (Carotid Wallstent, Boston Scientific) was 94 employed; stents were sized using the distal healthy carotid artery diameter as for carotid atherosclerotic disease. Stent post-dilation was used in case of residual stenosis at operator 95 96 discretion. The removal of endovascular material was followed by the aspiration of 4 x 20 ml 97 syringes with the last aspirated syringe filtered through the 40 µm filter. In case of residual debris, 98 additional aspirations were performed until no debris were visible. During the procedure, 99 neurological status was checked for clamping intolerance especially in the phase of CCA balloon 100 insufflation by waiting for 60 seconds and during blood aspiration. ECA and CCA balloons were 101 sequentially deflated and a completion angiography performed (figure 3-4).

102 **Results** 

In the study period were included a total of 4 male patients with a median age of 54 (IQR: 52-55) years. In all patients the preoperative cerebral CT was positive for cerebral ischemic events. All the treated patients reported neurological symptoms including a TIA in 3 patients and amaurosis fugax and aphasia in 1 patient. CT angiography showed in all cases an ICAD; in 2 patients the ICAD was

- 107 associated to a significant ICA stenosis. The median dissection length was 20.1 (IQR: 18-21) mm.
- 108 No significant contralateral carotid disease was detectable in all patients.
- 109 Technical success was achieved in all cases without perioperative mortality, major cardiovascular
- 110 or cerebrovascular complications. A post dilation was employed in 2 patients presenting
- 111 preoperatively significant stenosis associated with ICAD. A complete anatomic resolution of the
- 112 dissection was achieved in all patients after stent placement with no residual stenosis after
- 113 treatment. The median operative time was 48 (IQR: 41-56) minutes; the median flow reversal time
- 114 7.5 (IQR: 7-9) minutes; the median fluoro time 7 (IQR: 7-9) minutes; the median contrast volume
- 115 34 (IQR: 30-38) ml; and the median radiation exposure 310 (IQR: 294-348) µGym<sup>2</sup>. Postoperative
- 116 medication regimen consisted of dual antiplatelet therapy for 6 months followed by single
- administration. At a mean follow-up of 18 months, all stents are patent and no restenosis, recurrence
- 118 of neurological symptoms or reintervention were registered.

### 119 **Discussion**

120 Spontaneous ICADs are rare and have been associated to fibromuscular dysplasia, infections, cystic medial necrosis and connective disease.<sup>6,7</sup> Endovascular treatment in patients presenting ICAD has 121 been reported to be effective and safe.<sup>5,8</sup> Surgical treatments, on the other hand, have been 122 123 associated with the worst outcomes compared to the best medical treatments or endovascular solutions due to a higher risk of stroke and nerve injuries.<sup>4</sup> It can be argued that also the 124 endovascular approach presents potential drawbacks including the risk of stroke when crossing the 125 dissected carotid artery as well as the risk of artery perforation in correspondence of the fragile 126 dissected artery.<sup>3</sup> 127

During carotid artery stenting procedures, proximal EPDs present some advantages over distal filters or distal occlusion devices, including a reduced risk of distal embolization during the procedure, mainly related to the flow arrest before lesion crossing. These advantages are even more relevant in ICADs where wire navigation within the false lumen, without flow arrest, represents a potential risk of distal embolization. Conversely proximal EPDs allow wire navigation and ICAD

133	crossing under flow arrest with a reduced risk of distal embolization. Moreover, in case of carotid
134	disruption during the endovascular ICAD treatment, the EPDs are useful reducing the bleeding and
135	allowing the use of covered stent-grafts under flow arrest.
136	Disadvantages of proximal EPDs in ICAD are the same reported for carotid artery stenting in
137	atherosclerotic disease, for instance: requirement of large introducer sheath, risk of CCA introgenic
137	injuries and reduced imaging availability during the intervention. Moreover it should be considered
130	injuries and reduced imaging availability during the intervention. Moreover it should be considered
139	the possibility of clamping intolerance, an higher risk of access complications, the risk of carotid
140	vacuum effect and arch/carotid anatomic variants. <sup>9</sup> These proximal EPDs-related complications did
141	not occur in the present series.
142	To date, no papers reporting endovascular treatment of spontaneous ICADs with proximal EPDs
143	have been identified. In our limited experience, the stent of choice for ICAD was the Carotid
144	Wallstent (Boston Scientific) with the aim to exploit the closed-cell mesh and radial force
145	characteristics. The choice of this specific stent is consistent with most of experience reported and
1.0	
146	analyzed in the systematic review. <sup>2</sup>
146 147	analyzed in the systematic review. <sup>2</sup> Conclusion
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208 Figure Legend

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209	Figure 1. Preoperative CT MPR (A) showing a spontaneous internal carotid artery dissection; 3D
210	curved MPR showing a complex spontaneous internal carotid artery dissection with significant
211	lumen reduction (B-D).
212	Figure 2. Preoperative CT MPR showing preoperative measurements including the intended stent
213	coverage length (A); and proximal and distal landing zones (B).

Figure 3. Intraoperative angiograms showing preoperative angiography (A); proximal embolic protection device (EPD) positioning in correspondence of the external carotid artery (EIA) and common carotid artery (CCA) (B); proximal EPD balloon inflating in correspondence of the EIA and CCA (C); blood flow arrest check after balloon inflation (D); Wallstent placement and proximal EPD balloon deflation (E); final angiography (F).

Figure 4. Intraoperative angiograms showing preoperative angiography (A); proximal embolic protection device (EPD) positioning in correspondence of the external carotid artery (EIA) and common carotid artery (CCA) (B); proximal EPD balloon inflating in correspondence of the EIA and CCA (C); blood flow arrest check after balloon inflation (D); final angiography after Wallstent placement (E); proximal and distal EPD balloon deflation (F).



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