Endovascular resolution of MicroNET-covered stent inadvertent implantation from the external to common carotid artery

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MicroNET-covered stent (CGuard) is a self-expandable 2nd-generation carotid dual-layer anti-embolic ("mesh") stent with level-1 (randomized controlled trial) evidence for a profound reduction of peri-procedural cerebral embolism and elimination of lesion-related post-procedural embolism in carotid artery stenting (CAS) [1]. Clinical data demonstrate a minimized risk of 30-day death/stroke/myocardial infarction (≤ 1%) and optimal long-term outcomes with CGuard, in absence of device-related issues [2–6]. Today, competent CAS has a significant part in primary and secondary stroke prevention [7]. Also, evidence is increasing for an important role of the MicroNET-covered stent in improving the outcomes of emergency CAS in acute carotid-related strokes [8–10].

CGuard consists of a very widely open-cell (laser-cut) metallic frame (free cell area of ~22 mm^2) that is wrapped by an outer, single-fiber knitted polyethylene terephthalate MicroNET adaptable sleeve (fiber thickness ~25 µm; cell size ~0.02–0.03 mm^2; mesh fixation to the frame on stent edges [11, 12]); for a stent photograph see reference 13. CGuard combines properties of the most open-cell metallic stent frame (and thus very high conformability) with the smallest-cell anti-embolic layer [11, 12]. The MicroNET pore size is similar to that of embolic protection filters, resulting in a dense plaque coverage between the sparse struts, providing not only sequestration of the atherothrombotic plaque material but also a degree of sealing properties [13–17]. The MicroNET-covered stent shows no foreshortening or elongation and exhibits self-adaptability to the artery diameter (within the device nominal diameter; "SmartFit" characteristics) [11, 12]. The neuroprotective [1, 4, 14] stent has an increasing role in emergency management of carotid-related strokes [8–10]. Importantly, when properly implanted (post-dilatation embedded), the MicroNET-covered stent shows a normal healing profile and minimal in-stent restenosis (< 1%) [5, 6, 8, 17].

Embolic protection device use remains important in MicroNET-covered stent CAS because of the need to prevent cerebral embolism at procedural stages prior to protection by the MicroNET that is exerted only after the stent implantation and post-dilatation optimization [14]. Distal filters have several limitations relevant for cerebral safety of CAS [14, 18, 19]. Thus practical knowledge of how to effectively use proximal cerebral protection is crucial in today's competent CAS [14, 20, 21]. For procedures at the level of carotid bifurcation, double-balloon systems, enabling transient endovascular exclusion of both the external (ECA) and common (CCA) carotid artery – and thus preventing any flow towards the brain in the internal carotid artery – are preferred [13, 14, 22] , as with a mono-balloon catheter the flow exclusion may be limited to CCA-only [13]. This, in some patients, can be insufficient for any effective cerebral protection because of the residual flow from the ECA to the ICA, towards the brain [13]. However, use of the double-balloon catheter [20] is not feasible in case of severe stenosis of the ECA ostium (Figures 1 A–C) and/or when the lesion involves distal CCA [13].

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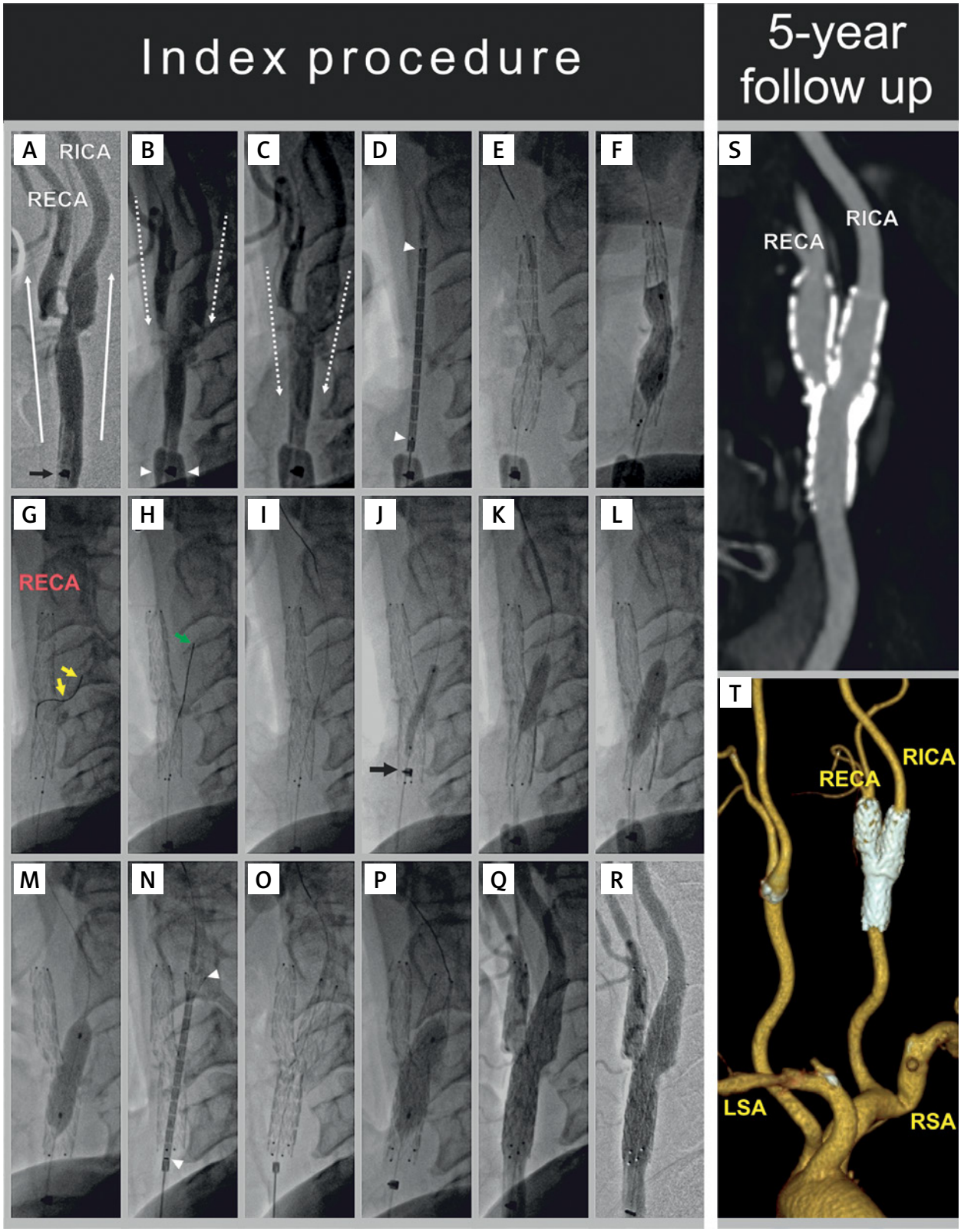

Figure 1. A 61-year-old man presenting with a recent right-hemispheric transient ischemic attack was treated, in primary prevention of carotid-related stroke, with proximal-protected stenting of the right internal carotid artery. MicroNET-covered 2nd-generation anti-embolic stent was used consistent with the PARADIGM protocol [11].

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Proximal cerebral protection – offering a "protected" lesion crossing [14, 20] – was selected due to the lesion morphology (**A**, note a large ulceration in the right internal carotid artery extending to the distal common carotid artery seen with antegrade contrast injection, white arrows, via a non-inflated mono-balloon catheter, the catheter marker is indicated with a black arrow) and symptomatic presentation, consistent with the 'tailored' CAS algorithm [18]. With the external carotid artery (RECA) tight ostial stenosis, and lesion involving also the distal common carotid artery (**A**), use of a double-balloon proximal neuroprotection system (that is our preference [8, 10, 13]) was not feasible as the balloon-wire ECA exclusion system [22] was no longer available. Contrast injection (common carotid artery, CCA balloon inflated, **B**, white arrowheads, "back" pressure 68/52 mm Hg) demonstrated – with opening the stopcock of the system – flow reversal (**B** and **C**, dotted arrows) in the right internal carotid artery (RICA, target vessel), RECA, and CCA, consistent with an effective cerebral protection. The common carotid artery lesion was crossed with a coronary wire (BMW 0.014 J) and a 10 × 30 mm self-expandable MicroNET-covered stent was positioned (**D**, white arrowheads indicate the stent edges), released (**E**), and post-dilated with a 5.5 × 20 mm balloon (**F**). As post-aspiration visualization demonstrated stent presence in RECA-CCA (rather than ICA-CCA), an attempt was made to cross from the CCA to the ostial-stenosed (*cf.,* **A**) – and now covered with the dual-layer stent – RICA. Attempts to cross with standard coronary wires (BMW 0.014" and WhisperMS 0.014") failed but crossing with a V-14 wire (with manually modified tip angulation to resolve the "wire-preferred" entry into the RICA ulcer, yellow arrows in **G**) was successful (**H**, green arrow). Effective reaching of the RICA distal extracranial segment with the angioplasty wire is shown in **I**. Insertion of a small coronary balloon through the 2 stent layers and the RICA ostial stenosis required increased support from the guiding catheter (note the catheter marker within the proximal portion of the 1st stent, **J**, arrow). Gradual opening of the RICA ostium was performed under resumed (due to extended procedure duration – at key steps) proximal protection, using a semi-compliant coronary balloon (3.5 × 15 mm, **K**) followed by non-compliant balloons (5.0 × 20 mm and 6.0 × 20 mm, **L** and **M**). With the above preparation, a second 10 × 30 mm self-expandable MicroNET-covered stent could be smoothly inserted into the RICA, positioned (**N**), and released (**O**). The stent was gradually post-dilatation optimized, up to using (finally) an 8.0 × 20 mm balloon inflated up to 20 atm at the proximal segment (**P**). No balloon inflations from the CCA to RECA were performed following the 2nd (ie., RICA-RCCA) stent implantation. The final result at the carotid bifurcation is shown in **Q** (non-subtracted image) and **R** (digital subtraction angiogram). There was no cerebral embolism and the procedure was clinically uneventful. Annual clinical and duplex ultrasound follow-ups were normal. At 5 years in-stent peak velocities remained normal (RICA – 58/28 cm/s; RECA – 82/21 cm/s; RCCA – 76/31 cm/s), and computed tomography angiography demonstrated – with the "Y" configuration of the stents – a lasting optimal anatomic result of the reconstruction of carotid bifurcation in absence of any restenosis (**S**, **T**).

We present procedural imaging demonstrating how to resolve safely and effectively – using the endovascular route – an accidental implantation of the CGuard double-layered stent into the ECA (rather than ICA), covering the (diseased) ICA ostium with the MicroNET and strut structure; this occurred in CAS employing a mono-balloon catheter with transient flow reversal for cerebral protection (Figures 1 A–R). 5-year follow-up showed a maintained excellent anatomic result (Figures 1 S-T) in the context of uneventful clinical follow-up.

In conclusion, with mono-balloon use for proximal protection in CAS/eCAS, landmark separation of the ICA and ECA is critical to avoid accidental stent placement in ECA. We show that inadvertent placement of the dual-layer MicroNET-covered stent can be resolved, using the endovascular route (same, continued procedure), by (1) crossing the MicroNET and stent strut frame and making a step-wise gradual opening onto the ICA, followed by (2) placement and optimization of another MicroNET-covered stent (appropriately positioned in the ICA; "Y" technique). This endovascular resolution was safe and effective, with an optimal clinical and anatomic result at long-term. Today, ensured separation of ICA from the ECA under mono-balloon catheter proximal cerebral protection can be practiced – along with neurovascular interventions – in a novel human stroke model [23].

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Ethical approval

Not applicable.

Conflict of interest

PM has proctored and/or consulted for Abbott Vascular, Balton, Gore, InspireMD, Medtronic and Penumbra, and serves on the European Society of Cardiology Stroke Council Scientific Documents Task Force; he has been the Polish Cardiac Society Board Representative for Stroke and Vascular Interventions. PM is Global Co-Principal Investigator in CGUARDIANS FDA IDE Trial of the MicroNET-covered carotid stent system. Other authors declare no conflict of interest.

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