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Dislocation of a cerebral protection device component during carotid stenting: A case report of favorable outcome from conservative management after failure of retrieval

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ABSTRACT

INTRODUCTION: Cerebral-protection devices (CPDs) are a well-established system for reduction of embolic risk in carotid artery angioplasty and stenting (CAS). Although rare, adverse events with CPDs are unpredictable and can be associated with serious outcomes and iatrogenic sequelae.
PRESENTATION OF CASE: We describe the unique case of dislocation of a FilterWire EX™ filter loop during right CAS. On trying to recapture the CPD filter at the end of the procedure, the filter loop suddenly detached from the guidewire and dislocated to the proximal middle cerebral artery. Attempted retrieval of the loop failed and the patient developed a transient neurological deficit caused by an acute ischemic infarction in the lenticular nucleus. No further retrieval attempt was pursued. No further dislocation of the loop or clinical event have been reported during the 16-year follow up.
DISCUSSION: This case reported a favorable outcome of conservative management for entrapped material from a CPD after iatrogenic damage from failed retrieval. No similar reports are available in the literature, and conservative management is generally not a recommended approach because of the potential complications. However, rescue retrieval attempts are as well a potential source of serious events, and no clear guidelines exist on the management of mechanical complications from CPD.
CONCLUSION: Entrapment of CPD components constitutes an adverse event with no unique solution for risk-free management. The potential risks associated with the use of protection devices are still to be fully explored, and improving the standard of care and patient safety needs to be a top priority.

1. Introduction

Cerebral-protection devices (CPDs) are an effective tool for reducing the risk of embolic complications during carotid artery angioplasty and stenting (CAS) [1,2]. However, the CPD itself may cause complications that may result in serious outcomes requiring rescue maneuvers and/or surgical removal of the device with iatrogenic sequelae [3–7].

The self-expanding, CPD FilterWire EX™ (Boston Scientific, Natick, MA, USA) has been approved for use in CAS [8] and a procedural success of 98% among patient stented under FilterWire EX protection has been reported [9]. The device consists of a 0.014" steerable guidewire mounting a polyurethane filter with 110 mm diameter pores attached to a 3.5-5.5-mm self-expanding nitinol loop. The filter is deployed distal to the lesion by retraction of a 3.9 Fr delivery sheath and is supposed to be closed and retracted using a retrieval sheath after trapping embolic debris. We report the unique case of dislocation of the nitinol loop with unsuccessful attempted retrieval of the device and subsequent ischemic infarction in the lenticular nucleus. The patient was managed in a public setting.

1.1. Presentation of case

A 55-year-old male with documented systemic atherosclerotic disease, hypertension, diabetes mellitus and a smoking history was referred by the family physician to the service of Interventional Neuroradiology for a severe (>70%) restenosis in the right internal carotid artery (ICA) 4 years after endarterectomy. He was scheduled for CAS with cerebral protection. Daily medicine included ticlopidine 250 mg, enalapril 20 mg, amiloride-hydrochlorothiazide 5 + 50 mg, ranitidine 150 mg, rapid-acting insulin 8 + 12 + 12 I.U., and long-acting insulin 8 I.U. (qd).

An 8-Fr introducer (Flexor Shuttle, Cook, Bloomington, IN, USA) was placed into the right CCA via the transfemoral approach. A FilterWire EX distal protection device was guided past the stenosis

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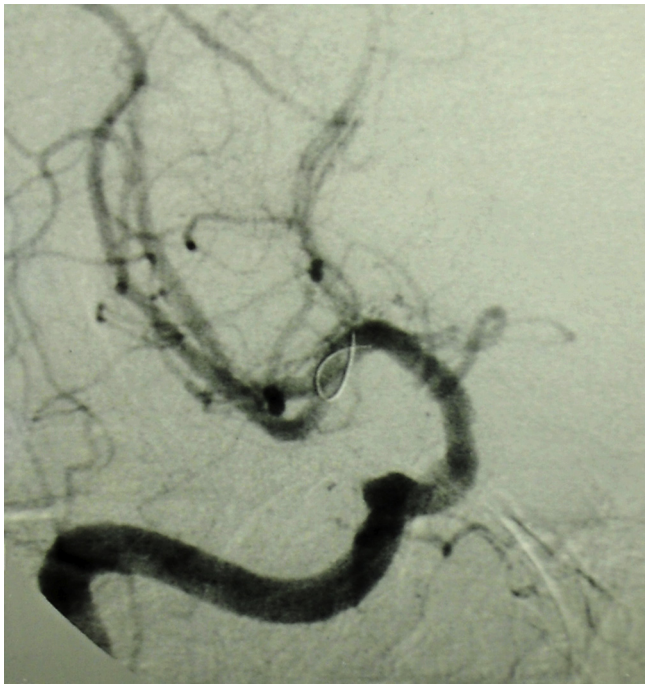

Fig. 1. Dislocation of the nitinol loop in the proximal branch of the right middle cerebral artery.

at the distal tract of the extracranial ICA and easily deployed. A 3 × 20 mm balloon was placed across the stenosis and was inflated to its nominal value. A Precise RX nitinol 8 × 21 mm stent (Cordis, Miami Lakes, FL, USA) was placed across the stenosis and the angiographic control showed a complete revascularization.

On trying to recapture the filter, when the operator moved the retrieval sheath forward on the catheter close to the device a significant resistance was encountered. During each attempt, the distal portion of the retrieval sheath would easily pass through the deployed stent but would not progress further to the loop, preventing retrieval of the distal protection device. After several failed attempts, the nitinol loop suddenly detached from the FilterWire EX guidewire and dislocated to the proximal middle cerebral artery (MCA) (Fig. 1). The operator attempted recollection of the device with a dedicated retriever passed over the FilterWire EX guidewire, that also proved unsuccessful. The operator then tried to mobilize the device by expanding a catheter guided balloon (Sentry, Target, Fremont, CA, USA) at the level of the FilterWire EX; during this maneuver the patient suddenly manifested a left facio-brachiocrural motor hemisyndrome (National Institutes of Health Stroke Scale – NIHSS 5) so it was decided to immediately interrupt the retrieval attempt. Immediate intracranial angiographic control was performed, showing reduction of caliber and delayed flow in the temporal inferior branch of the MCA. A cerebral CT scan performed immediately after the procedure showed no focal lesion; a control CT scan at 48 h revealed an acute ischemic infarct in the right anterior lenticular nucleus and small ischemic areas in the right insular-temporal cortex (Figs. 2 and 3). The patient was transferred to the Intensive Care Unit and then underwent intensive physical therapy, showing progressive improvement. He was discharged a month after the procedure on single antiplatelet therapy; the neurologic examination was negative (NIHSS 0). During the 16-year follow-up the patient remained stable and no new acute events were documented both on clinical and neuroradiological follow-up. The work has been reported in line with the SCARE criteria [10].

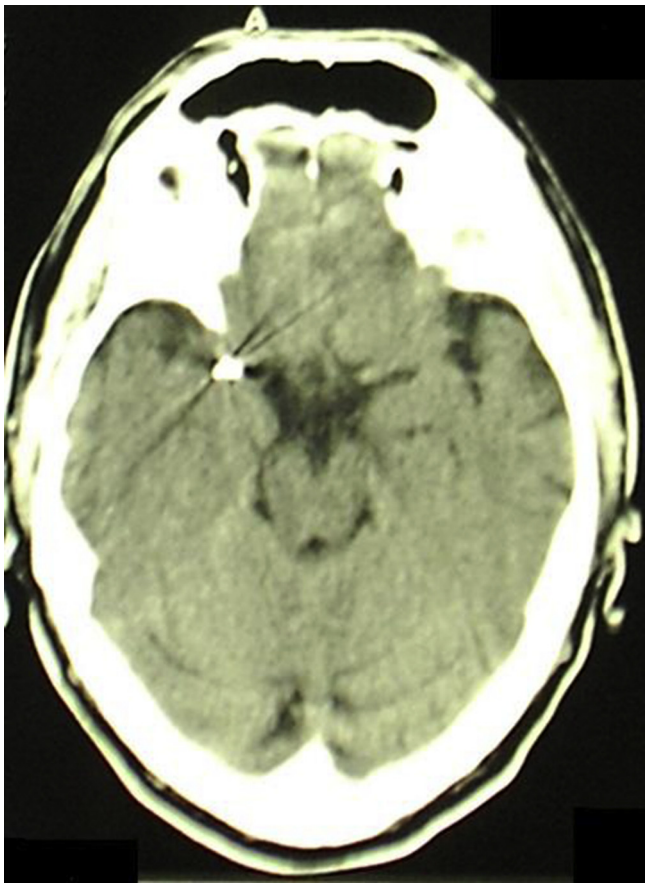

Fig. 2. Hyperdense signal in the middle cerebral artery showing the nitinol loop displacement-.

2. Discussion

CAS has become the gold standard treatment of the extracranial carotid disease for stroke prevention, providing a viable alternative to carotid endarterectomy [1,9,11]: the technique is safe, minimally invasive, and it offers specific advantages compared to endarterectomy, especially in terms of cardiovascular complications (like myocardial infarction) and patients' comfort. A recently published randomized trial involving asymptomatic patients with severe carotid stenosis proved CAS guarantees equal performance of stroke-free survival up to 5 years compared to endarterectomy [11]. Nonetheless, the risk of stroke within the 30-day periprocedural period stands higher with CAS, especially for patients aged >70 years.

In order to limit the incidence of adverse events during the procedure, nowadays it is generally advised to perform CAS under protection using one of the three different types of protection devices that are commercially available: distal occlusion devices, distal filter devices, and proximal occlusion devices. Even though the efficacy of these devices has not been proven by any large randomized trial so far, unprotected CAS is considered improper by large part of the interventional community [3,12–15]. However, the use of a CPD is not always safe. Mechanical complications related to the use of CPDs during CAS include: locking between the stent-delivering catheter and the CPD; separation of the membranous component from the CPD; inability to pass the accessory retrieval sheath through the proximal/distal terminus of the stent/the stent lumen; retained CPD; and fractured guidewire. All cases reported so far were successfully resolved, either non-invasively (by manual carotid compression technique/endovascular rescue) [4–6,16]

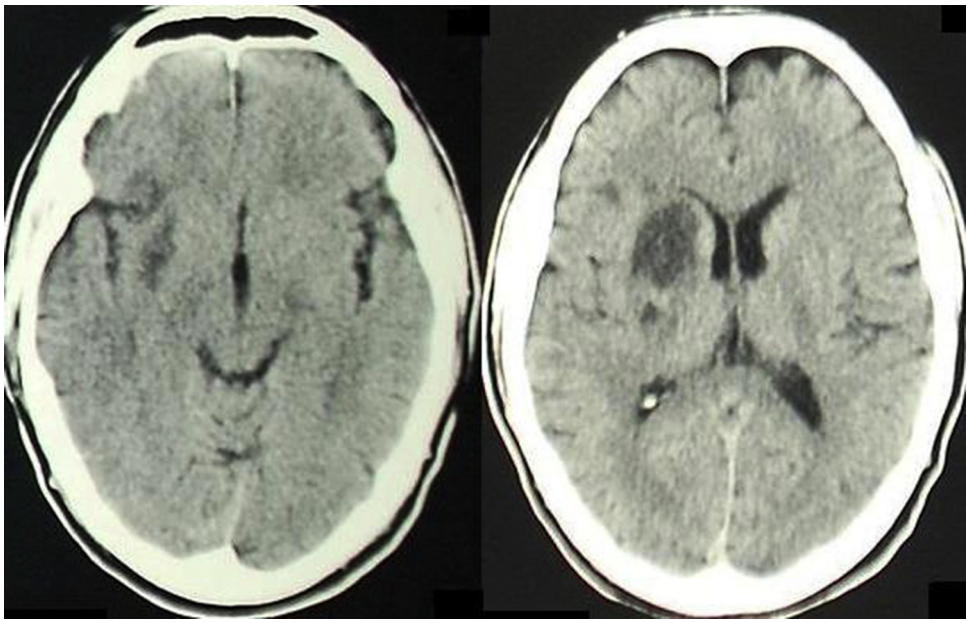

Fig. 3. Forty-eight hours CT scan showing the ischemic lesion in the right anterior lenticular nucleus and small ischemic areas in the right insular-temporal cortex.

or surgically (carotid endarterectomy and foreign body removal) [7] while our case is the first report of permanently failed retrieval with the CPD left in situ. Conservative management is generally not a recommended approach to entrapped material as potential complications range from vasospasm, thrombosis and embolism, to vessel injury including vascular dissection [3,5]. Rescue retrieval attempts, however, are as well a potential source of serious events: advancing the introducer forward in a patient with a hostile arch anatomy or carotid bifurcation angulation may be difficult or even dangerous, since aggressive movement of the introducer could elicit plaque dislodgement or vascular dissection [17]; also, withdrawal of the CPD through the stent could produce tangling with the stent strut, which could exacerbate the problem [3,12].

Although the use of CPDs during CAS is nowadays a well-established routine since its introduction in the early 2000s', no clear guidelines exist on the management of the mechanical complications. Rigorous quality assurance practices are still lacking in many low- and middle-income countries, and training and practice quality varies widely. Preventive actions should be taken prior to scheduling the use of a CPD. The severity of native coronary artery disease and the anatomic characteristics of individual patients need to be considered when simulating the procedure, and a sufficient distance between three markers of the CPD and the stenosis must be confirmed before placing the CPD. While adjusting the stenting segment, the shortest distance between three markers of the CPD and one marker of the stent-delivering catheter should be borne in mind. The operator should also be aware of the possible rescue maneuvers. We would also like to remark, as previously done by other authors [5,18], the importance of the CPD used: a fixed-basket, 1st-generation filter device like the FilterWire EZ™ Embolic Protection System is associated with a higher incidence of carotid vasospasm than is use of a newer, 2nd-generation mobile-basket filter device like the Rx Accunet Embolic Protection System (Abbott Vascular, a division of Abbott Laboratories; Abbott Park, Ill) or the SpiderFX™ Embolic Protection Device (ev3® Endovascular, Inc./Peripheral Vascular; Plymouth, Minn).

In our case, we tried a combination of different approaches first to overcome the interlocking and then to retrieve the retained loop, which caused a permanent iatrogenic damage. The amount of the possible damage, and therefore the appropriate number and method of the rescue retrieval attempts depend on highly individual parameters. For example, a sizeable body of evidence over the past 25 years has firmly estabilished the prognostic relevance of brain collaterals in determining the fate of ischemic stroke. In our patient, the state of the brain collaterals was not assessed before the intervention; such an assesment, that can be made also during the angiographic procedure (for example with the Careggi Collateral Score [19]), could have provided valuable information to help guide decision for interventional or conservative management in such an emergency situation. Collateral status assessment (through angiography methods or CT methods that include the CT perfusion study [20]) in asymptomatic patients prior to endovascular procedure is not yet part of standard routine but it can provide the clinician with a useful tool that can guide difficult decisions in emergency situations.

3. Conclusion

Entrapment of CPD components constitutes an adverse complication with no unique solution for risk-free management. Excellent clinical results were obtained with the adoption of filter protection for CAS intervention, but the potential risks associated with the use of protection devices are still to be fully explored. Improving standard of care and patient safety needs to be a top priority.

Consent

The authors declare that appropriate informed written consent for the use of personal details and images was obtained from the patient.

Author contribution

Dr. Tocco-Tussardi acquired the clinical data, helped drafting the article, revised critically the content, and gave final approval of the version to be submitted. Dr. Kulyk contributed to the present work by analysing and interpreting the data, drafting the article, and finally approving the version to be submitted. Prof. Vindigni and Dr. Avruscio contributed to the conception and design of the

Report, they revised critically the article content, and gave final approval of the version to be submitted.

Guarantor

Dr. Avruscio is the Guarantor for the present study.

Funding

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Ethical approval

Authors declare their Institution exempts the present case report from the need for ethics committee review.

Conflict of interest

The authors have no financial interest to declare or anything to disclose in relation to the content of this article.

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