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Technical Notes

Off-label use of the pipeline embolization device for reconstruction of the extracranial internal carotid artery

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ABSTRACT

Background: Internal carotid artery dissection (ICD) is a common cause of cerebral ischemia in adults. Medical management has been the standard of care; however, endovascular internal carotid artery (ICA) reconstruction has certain indications. The pipeline™ embolization device (PED) is a flow-diverting (low porosity), self-expanding, braided platinum and nickel-cobalt chromium alloy stent and is indicated for wide neck or large aneurysms of the ICA from the petrous to the superior hypophyseal segments. The flexible nature of PED stents, with their high wall coverage, makes them amenable as stents for reconstructing arterial dissections diagnosed in the tortuous segments of the extracranial ICA. We present our experience using PEDs for ICA reconstruction in cases of distal cervical or petrous segment dissection or dissecting aneurysms and review the literature on this contemporary indication of flow diverter devices.

Methods: This study was a retrospective review of patients with ICD or dissecting aneurysms who underwent endovascular reconstruction at our center using PED stent implants. Patients were selected based on pre-morbid modified Rankin Scores ≤1a and National Institutes of Health Stroke Scale (NIHSS) ≥3 and radiologic data consistent with ICA dissection.

Results: Eight patients with a mean age of 55.6 years (range: 31–82 years) and median NIHSS score of 8 (Interquartile range IQR: 2.75–16) who underwent off-label PED surgery were analyzed and are illustrated in this short series. The technical success rate was 100%, with all cases achieving reperfusions of thrombolysis in cerebral infarction grades ≥2b.

Conclusion: In our series of patients with distal cervical or petrous segment ICD or dissecting aneurysms, we found the PED to be feasible, safe, and effective in achieving arterial recanalization. Further studies will clarify the role of this technique.

Keywords: Flow diverter device, Internal carotid artery dissecting aneurysm, Internal carotid artery dissection, Pipeline embolization device

INTRODUCTION

Over the past decade, flow diverter devices (FDDs) like the Pipeline™ embolization device (PED) have gained acceptance and the Food and Drug Administration's approval as a treatment option for select intracranial aneurysms, namely, giant and large aneurysms extending from the petrous to the superior hypophyseal segments of the internal carotid artery (ICA) in adult patients.[4,13] FDDs are flexible, self-expanding stents; the purported mechanism of action is the diversion of blood flow away from the aneurysm, leading to aneurysmal thrombosis while maintaining parent vessel patency by providing a scaffold for endothelial growth.[12] Although initially developed for the treatment of aneurysms, a variety of off-label uses have been described for these flow-diverter devices, including carotid-cavernous fistulas, dissecting aneurysms, and ICA pseudoaneurysms.[5,6,17,18] Their flexible nature and high wall coverage, in addition to their availability in the desired sizes (diameters), make FDDs amenable as stents for arterial reconstruction in the tortuous segments of the extracranial ICA.[7] This facet of their application has been mentioned; but has not been widely described.[1,8,15]

Internal carotid artery dissections (ICDs) account for about 2% of acute ischemic strokes, and extracranial ICD is usually more common than intracranial ICD.[11] Dissection usually results from an intimal tear, allowing blood to dissect within the arterial wall and creating a false lumen, which can cause elongated tapered stenosis (48%), tapered occlusion (35%), or dissecting aneurysm (pseudoaneurysm) (17%).[10,16] Medical management with anti-coagulation and close neurological monitoring remains the initial treatment strategy, with good patient outcomes noted in 75% of cases, with a low mortality of 3–4%.[2,19] In select patients who fail medical management or present with stroke-like symptoms and high National Institutes of Health Stroke Scale (NIHSS) scores, endovascular treatment is indicated, especially if computed tomography perfusion scans show perfusion deficits in the affected hemisphere.[1]

Traditional carotid stents are primarily used for proximal and mid-cervical ICA dissections. However, high-cervical and skull base ICA segments and tortuous cervical ICA segments present a unique challenge. The traditional carotid stents (e.g., Wallstent; Boston Scientific, Natick, Massachusetts, USA) are ill-suited due to the rigid stent delivery systems, and traditional intracranial stents (e.g., Neuroform [Boston Scientific, Natick, Massachusetts, USA], Enterprise [Cordis Neurovascular, Miami Lakes, Florida, USA], etc.) fall short due to large pore size, stent diameter restrictions (largest being 4.5 mm), and inherent low radial force. Flow-diverter stents, like PED, with or without angioplasty, in conjunction with intracranial stents or carotid stents, can be employed for the reconstruction of long-segment ICD or ICA loop dissections encountered in ICAs with tortuous anatomy.[1] With lower porosity than traditional stents, FDDs in ICD treatment are more likely to obliterate the false lumen and thrombose pseudoaneurysms.[3] We present our institutional experience with the use of FDDs for the reconstruction of steno-occlusive lesions involving tortuous segments of the extracranial ICA and review the pertinent literature on this topic.

MATERIALS AND METHODS

We retrospectively queried our prospectively maintained institutional database of mechanical thrombectomies and carotid stent procedures from 2016 to 2022. We identified all patients at our institution with ICDs in whom we utilized FDD for vessel reconstruction. The study was approved by our Institutional Review Board (STUDY00001538). Consents were obtained from the patient or the family for endovascular therapy and carotid stent placement before the procedure. Patients' medical records and imaging data were acquired and shared under Health Insurance Portability and Accountability Act guidelines.

Clinical management

As most procedures were emergent (i.e., code stroke), no preloading antiplatelet was utilized; however, preoperative antiplatelet was given to elective cases. All treatments were performed under general anesthesia or monitored anesthesia care, and patients were given thrombolysis in cerebral infarction (TICI) score postoperatively. All patients were started on antiplatelet therapy postoperatively with combined aspirin (ASA) and P2Y12 inhibitor or Tirofiban (first 24-h) with transition to ticagrelor for P2Y12 non-responders. Patients were transferred to the neurocritical care unit after the intervention for post-operative monitoring and care.

Patient follow-up

All patients underwent a post-procedure non-enhanced computed tomography of the head (CTH) immediately and a follow-up CTH or magnetic resonance imaging 24 h after the procedure to assess the extent of infarction or any hemorrhage. Device and procedure-related complications were assessed. The neurology team completed daily NIHSS and modified Rankin scores (mRSs) at the time of discharge. Patients were seen in the neuro-intervention clinic 1–3 months after discharge.

RESULTS

Patient characteristics and presentation

Between 2016 and 2022, seven patients underwent ICA reconstruction with PED at our institution for diagnoses including tandem occlusion with cervical ICA dissection or cervical ICA pseudoaneurysm. The median age was 57 years of age (range: 31–82 years), and the median NIHSS score was 10 (Interquartile range: 4.5–16). All seven patients presented with pre-morbid baseline mRS ≤1. 5 patients presented as code stroke per the following: three patients with ICA occlusion secondary to ICD, and two patients with ICA occlusion developed intraoperative ICD from mechanical thrombectomy or angioplasty. Two patients with ICA occlusion presented after traumatic injury; one patient sustained ICA pseudoaneurysm, and another with long segment ICD. All patients achieved reperfusion, 29% TICI 2b and 71% TICI 3.

Patient characteristics and presentation, imaging findings, operative details, and postoperative management are detailed in Table 1.

Technical note

We demonstrate the utility of the PED for reconstructing segments of the extracranial ICA. ICA luminal diameter near the skull base is amenable to the PED stent, ranging from 2.5 to 5.5 mm in stent diameter [Figures 1-4]. The PED

Table 1: Summary of patient demographics and presentation, procedure details, and postoperative management in a series of seven patients presenting with lesions of the extracranial ICA reconstructed with flow-diverter devices.

Patient	Age	Sex	Baseline mRS	NIHSS	Laterality	Presentation	TICI Score	PED
1	55	M	0	3	Left	Code stroke; Lt ICA complete occlusion secondary to ICD	2b	5×20 mm*
2	63	M	0	16	Left	Traumatic; Tandem occlusion Lt M1, Lt ICA complete occlusion secondary to ICD	3	5.5 mm×20 mm
3	43	M	0	0	Right	Elective; Rt ICA pseudoaneurysm	3	4.5 mm×26 mm
4	82	M	1	10	Left	Code stroke; Lt ICA 99% stenosis, Rt ICA complete occlusion, Rt SDH	2b	5×32 mm
5	31	F	0	2	Left	Code stroke; Lt ICA complete occlusion secondary to ICD	3	5.0×35 mm*
6	78	F	0	16	Left	Code stroke; Lt ICA complete occlusion	3	4.25×16 mm*
7	60	M	0	17	Left	Code stroke; Lt ICA complete occlusion secondary to ICD	3	5 mm×25 mm*

Patient	Stent	Pre-op Antiplatelet	Post-operative Antiplatelet	Intra-operative Findings	Follow-up		
					Imaging	Results	mRS
1	6×20 mm, carotid wall stent	-	Aspirin, Clopidogrel	Lt ICA complete occlusion secondary to cervical loop dissection with pseudoaneurysm	CTA , 6 months	Lt ICA stent patent with distal flow, no filling defect of stenosis	0
2	Carotid wall stent*	-	Aspirin, Clopidogrel	ICD from ICA bifurcation to petrous segment	MRI, 3 days	Punctate hemorrhagic transformation	5
3	-	Clopidogrel	Aspirin, Clopidogrel	Cervical ICA pseudoaneurysm	CTA, 6 months	Unremarkable	0
4	8×33 mm, carotid wall stent *	Clopidogrel	Aspirin, Clopidogrel	Lt ICA carotid stent with angioplasty, ICD s/p angioplasty from cervical ICA to petrous segment	MRA, 1 day	Acute infarct at Lt MCA and ACA, persistent Rt ICA occlusion	5

(Contd...)

Table 1: *(Continued).*

Patient	Stent	Pre-op Antiplatelet	Post-operative Antiplatelet	Intra-operative Findings	Follow-up		
					Imaging	Results	mRS
5	4.5×30 mm, atlas stent	-	Tirofiban, Ticagrelor	ICD from cervical ICA to petrous segment	CTA, 18 days	Lt ICA stent occlusion	1
6	-	-	Aspirin, Clopidogrel	ICD s/p MT and angioplasty, ICD from cavernous ICA to clinoid segment	MRI, 2 days	Lt MCA and ACA watershed ischemic changes	4
7	6 mm×22 mm, carotid wall stent	-	Aspirin, Clopidogrel	ICD from cavernous ICA to petrous segment	CTH, 2 days	Watershed infarcts	3

mRS: Modified Rankin Scale, NIHSS: National Institute of Health Stroke Scale, LT: Left, RT: Right, s/p: Status post, ICD: Internal carotid artery dissection, TICI: Thrombolysis in cerebral infarction, PED: Pipeline embolization, *: Angioplasty, ICA: Internal carotid artery, MRI: Magnetic resonance imaging, CTH: Computed tomography of the head, Lt: Left, Rt: Right, CTA: Computed tomography angiography, MRA: Magnetic resonance angiography, MCA: Middle cerebral artery, MT: Mechanical thrombectomy, ACA: Anterior cerebral artery

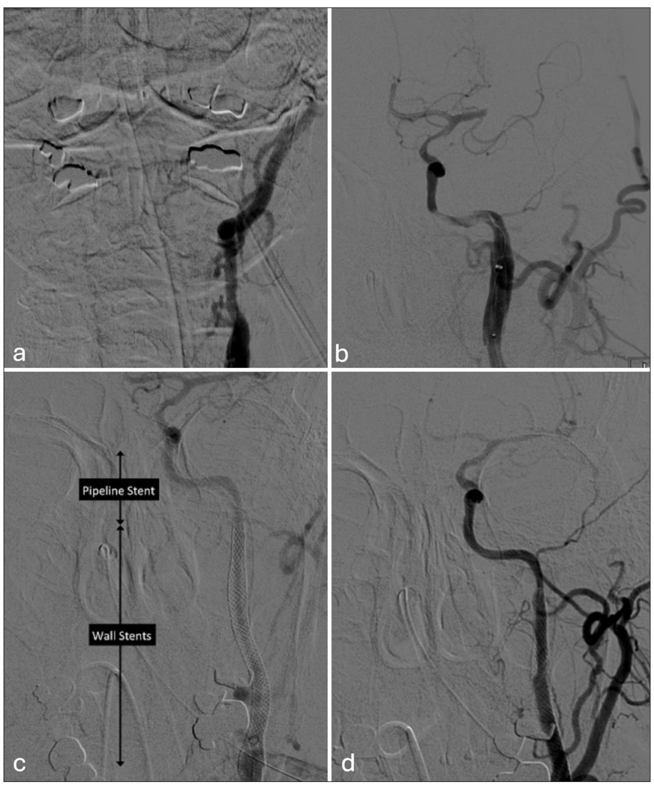

Figure 1: 82/Male. (a) An antero-posterior left common carotid runs showing complete occlusion of the left internal carotid artery (ICA) at the bulb. (b) After angioplasty and crossing of the left ICA origin, we encountered an intimal flap (possibly iatrogenic) in the petrous segment of the left ICA. (c) Endovascular reconstruction of the petrous and cervical ICA is performed by overlapping pipeline embolization device stent in the petrous ICA and carotid Wallstent in the cervical ICA. (d) Final Anterior-Posterior (A-P) common carotid artery run showing reconstructed left ICA and thrombolysis in cerebral infarction 2b reperfusion.

device has a low-profile delivery system that helps navigate tortuous segments of the ICA. In conjunction, a traditional carotid Wallstent, with the smallest stent diameter of 6.0 mm, can be utilized in long segment reconstructions that require proximal ICA stenting. The PED stent is engaged to cover the kinked distal ICA segment and conjunctive telescoping of carotid Wallstent into the proximal PED to cover the entire dissecting segment [Figure 5]. Using flow arrest as an embolic protection device, angioplasty can also be performed to expand segments stenosed secondary to the dissection and luminal clot.

DISCUSSION

In this series of patients with acute symptomatic extracranial ICA dissection, we demonstrate the feasibility of utilizing the PED stent for ICA reconstruction. Dissections involving the extracranial ICA segments can present unique technical challenges, such as conforming to the tortuous curves of the skull base segments (petrous, lacerum, and proximal cavernous) and redundant ICA anatomy.[1,15]

ICDs, near the skull base and high cervical segments, can present challenging anatomy, and navigation and deployment may not be feasible with a traditional carotid stent alone.[1] Previous authors have highlighted the combination use of overlapping FDDs with carotid wall stents for ICD treatment in Hilditch *et al*. (2019), Cohen *et al*. (2015), Amuluru *et al*.[1,8,14] Patients in all studies achieved successful recanalization post-procedure, establishing the benefit of utilizing a flexible flow-diverter device to occlude dissections in higher ICA regions with tortuous anatomy.[1,8,14]

Our case series further demonstrates the PED as a feasible, safe, and effective option to achieve arterial recanalization

Figure 2: 55/Male. (a and b) A-P and lateral views of the left common carotid artery (CCA) run showing left cervical internal carotid artery (ICA) loop dissection causing flow arrest. (c) The segment of dissection is crossed with a filter wire and a distal embolic protection device is deployed in the distal cervical ICA before the thrombectomy. Pseudoaneurysm is noted at the apex of the proximal loop. (d-f) The pipeline embolization device (PED) stent is deployed in the tortuous segment of the distal cervical ICA, covering the origin of the pseudoaneurysm. (g) A carotid Wallstent is overlapped (telescoping technique) into the proximal portion of the PED stent to complete the left ICA reconstruction. (h and i) Final A-P and lateral runs from the left CCA showing the reconstructed left ICA and thrombolysis in cerebral infarction 2b reperfusion.

of the extracranial ICA. Neurointerventionists should recognize this off-label use of PED as a bail-out strategy when traditional carotid or intracranial stents are ill-suited for reconstructing tortuous segments of the extracranial ICA.

Utility of PED

FDDs provide a suitable solution with a highly flexible and adaptable construct, low-profile delivery system, and higher

Figure 3: 31/Female. (a) Initial A-P run from the left internal carotid artery (ICA) bulb showing left ICA mid-cervical loop dissection with severe narrowing of the cervical ICA. (b) With difficulty, we crossed the dissected segment but it resulted in elongation of the intimal flap. (c, d, and e) An Atlas Neuroform stent (Stryker Neurovascular, Fremont, California, USA) is deployed in the petrous ICA, followed by two Pipeline stents in the cervical ICA, including the ICA loop. Angioplasty of the stented segment was required. (f) Final left ICA run showing reconstructed left ICA and thrombolysis in cerebral infarction 3 reperfusion. The Left A1 branch of the anterior cerebral artery was filling from the right ICA run.

wall coverage compared to traditional carotid and intracranial stents. FDDs have the advantage of opening a stenosed vessel while reconstructing the vessel wall to obliterate a false lumen and tamponade a pseudoaneurysm.[3,14] FDDs have the advantage of opening a stenosed vessel while reconstructing the vessel wall to obliterate a false lumen and tamponade a pseudoaneurysm.[9] PED mechanics allow for adaptable radial force when expanding intraluminally, contributing to its flexibility and securing apposition centrifugally against the vessel wall, offering a scaffold for endothelization and vessel reconstruction.[3,20] In conjunction with intracranial or classic carotid stents, FDDs can be strategically utilized for reconstructing tortuous ICAs, taking into consideration the ICA pathology, length of dissection, and vessel lumen diameter [Figure 5].[5]

Challenges and limitations

PED use is limited to certain vessel lumens due to the maximum device circumference of 5.5 mm. If the

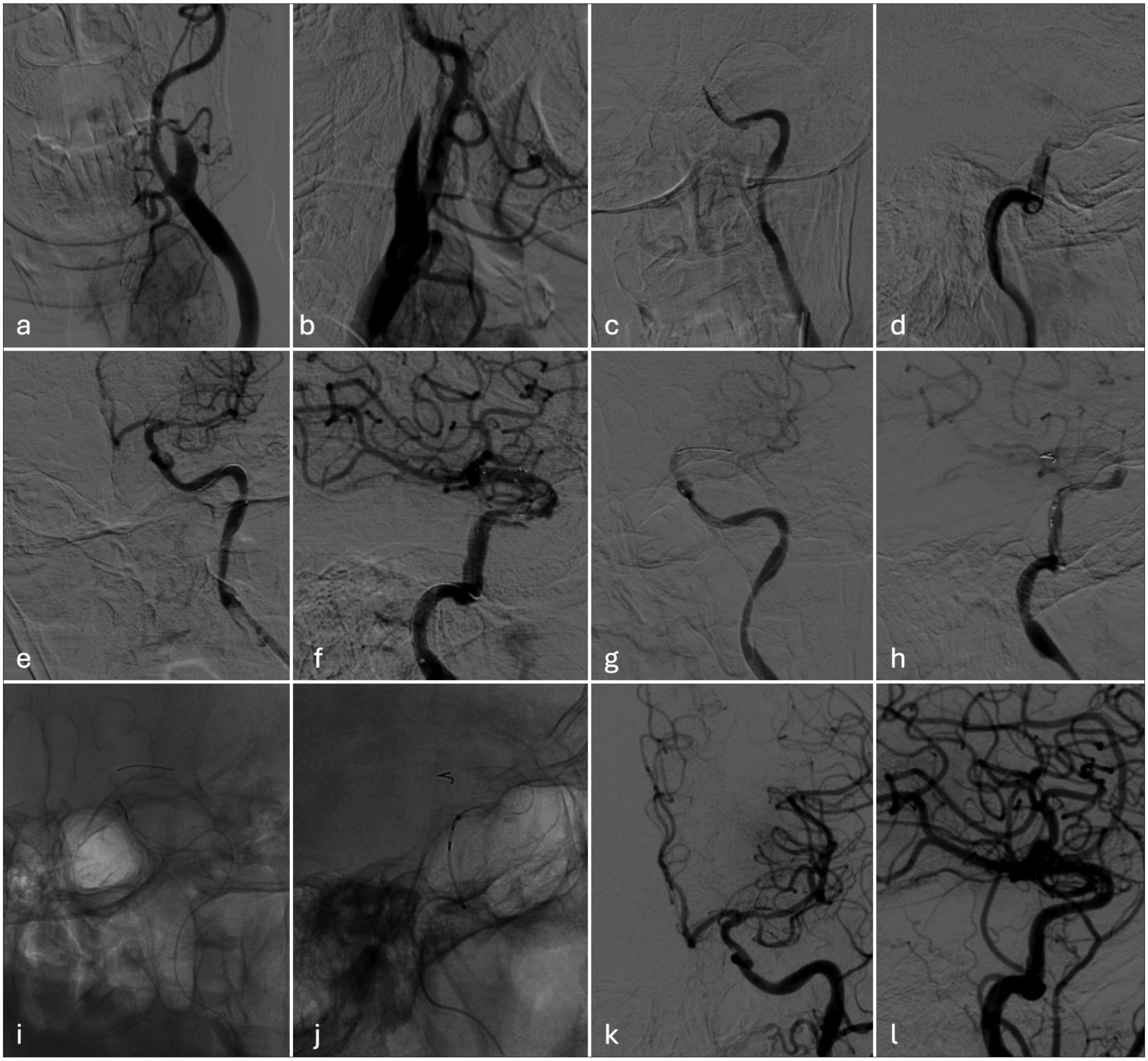

Figure 4: 78/Female (a and b) Initial A-P and lateral runs from the left common carotid artery showing pseudo-occlusion of the left cervical internal carotid artery (ICA). (c and d) The culprit for the pseudo-occlusion is a thrombus in the cavernous ICA with proximal extension into the petrous segment. (e and f) Stentriever thrombectomy is performed, and reperfusion is obtained; however, severe stenosis in the cavernous ICA is observed. A post-angioplasty run shows dissection in the left cavernous ICA. (g and h) A pipeline embolization device is placed in the cavernous ICA, extending proximally into the petrous segment to reconstruct the ICA. (i and j) Anterior-Posterior (A-P)- and Lateral X-rays as the Pipeline stent is being placed. (k and l) Final A-P and lateral left ICA runs showing reconstructed left cavernous ICA and thrombolysis in cerebral infarction 3 reperfusion.

device is inappropriately sized, patients are posed with a risk of stent migration due to poor wall apposition or incomplete treatment of ICD or pseudoaneurysm. Patients also require a strict antiplatelet regimen immediately following implantation due to the risk of stent thrombosis and vessel occlusion. Not all patients may tolerate DAPT due to pre-existing conditions (e.g., intracranial or systemic hemorrhage) or risk of bleeding, and the risk-benefit ratio for patients should be evaluated on an individual basis.

Although our vascular reconstructions were successful, our case series is restricted in the number of patients. Additional limitations of the study include its retrospective and single-center nature. Follow-up time was also varied and limited, adding to the challenges of determining the overall durability

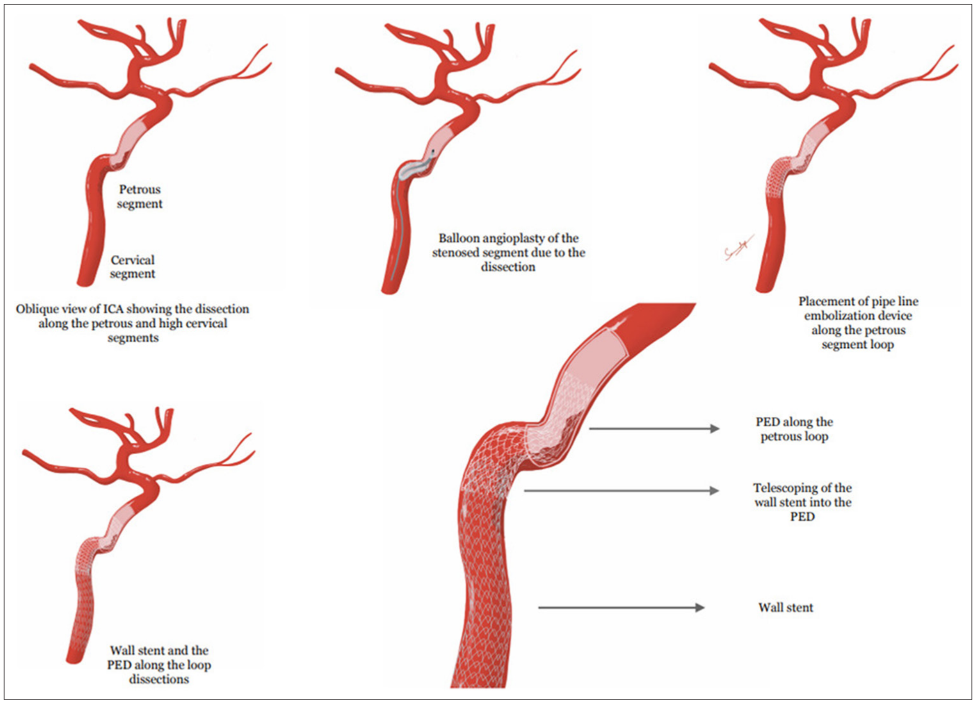

Figure 5: Schematic representation of left internal carotid artery loop dissection and the use of Pipeline embolization device (PED) stent to cover the kinked segment and conjunctive telescoping of carotid Wallstent into the proximal PED to cover the entire dissecting segment. Angioplasty is performed to expand segments stenosed secondary to the dissection and luminal clot.

and long-term clinical outcome. PED for the treatment of ICD is an off-label use with limited literature on technique, efficacy, and safety.

CONCLUSION

PED for ICD treatment is an off-label use with scarce literature on technique, efficacy, and safety. This novel approach is a useful tool for navigating tortuous anatomy and reconstructing the ICA but should be used with caution in select patients, carefully taking into consideration the PED size, adjunctive low-pressure angioplasty, and proximal telescoping of traditional carotid stents to avoid stent migration. Close consideration should be given by neuro-interventionists, especially to the risk-benefits of starting dual anti-platelet therapy when selecting patients with stroke-like symptoms for such reconstructions.

Ethical approval: This retrospective case series has received approval from the institutional review board.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent.

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