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Case Report

Usefulness of non-slip element percutaneous transluminal angioplasty scoring balloons in treating severe calcified lesions of the carotid artery for carotid artery stenting: A case report

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ABSTRACT

Background: Treatment of calcified lesions with conventional angioplasty balloons can be difficult due to insufficient lumen expansion, high dissection rates, and repeated revascularization. We report a case in which a scoring balloon was used in lesions resistant to angioplasty with a semi-compliant balloon.

Case Description: A 72-year-old man presented with severe stenosis and a highly calcified lesion in the right cervical internal carotid artery. Right carotid artery stenting (CAS) was planned to prevent future ischemic stroke events. Conventional semi-compliant balloon angioplasty was unsuccessful. Three inflations of a non-slip element (NSE) percutaneous transluminal angioplasty (PTA) scoring balloon (Nipro, Osaka, Japan) successfully achieved CAS without complications.

Conclusion: This is the first report to describe the use of this scoring balloon in *de novo* carotid artery disease. NSE PTA scoring balloon catheters can be a useful option for refractory, highly calcified stenosis.

Keywords: Balloon angioplasty, Calcification, Carotid artery stenting, Endovascular treatment, Non-slip element balloon, Predilatation

INTRODUCTION

Carotid artery stenting (CAS) is increasingly used for treating carotid artery stenosis as an alternative to carotid endarterectomy for revascularization. Managing calcified lesions using traditional angioplasty balloons can pose challenges due to limited lumen dilation, elevated dissection risks, and the need for repeated revascularization.[1,8] In the coronary artery, scoring balloons have been used for primary stenting of high-grade or concentrically calcified stenosis that is refractory to angioplasty with conventional angioplasty balloons.[2,3,6,18] The non-slip element (NSE) percutaneous transluminal angioplasty (PTA) balloon (Nipro Corporation, Osaka, Japan) is a low-profile, semi-

compliant scoring balloon designed with three triangular nylon elements that can score even a stiff plaque wall, such as calcified plaque [Figure 1a].[16] The scoring effect can prevent balloon slippage, plaque shift, and focal overstress, which contribute to safe and optimal luminal expansion, even in cases of severely calcified lesions [Figures 1b and c].[2,3,5,6,13,14,18] To the best of our knowledge, no cases in which a scoring balloon has been used to treat *de novo* carotid artery stenosis have been published.

Here, we describe the case of a patient with carotid calcified lesions who successfully underwent CAS with a scoring balloon and review the literature on carotid interventions with scoring balloons.

CASE DESCRIPTION

A 72-year-old man with a history of hypertension, diabetes mellitus, and cerebral infarction presented to our hospital with progressive left-sided hemiparesis four months previously. At the initial presentation, cranial magnetic resonance imaging/cranial and cervical magnetic resonance angiography revealed right cervical internal carotid artery (ICA) stenosis; moreover, acute and subacute infarctions in the right ICA territory were observed on diffusion-weighted image sequences [Figure 2]. A head and neck computed tomography angiogram revealed a focal area of high-grade calcified stenosis [Figure 3]. Ultrasonography of the right carotid artery revealed a hyperechoic plaque within the stent, and routine carotid angiography revealed severe stenosis of the right cervical ICA [Figure 4a, white arrow].

Right CAS was planned to prevent future ischemic stroke events. The patient was treated with 100 mg aspirin and 200 mg cilostazol daily for four weeks before the procedure.

With the patient under local anesthesia, a 7-Fr long sheath was inserted into the right femoral artery, and a 7-Fr Optimo (Tokai Medical Products, Aichi, Japan) was delivered to the right common carotid artery. An activated clotting time of 250 seconds was maintained using intravenous heparin. A distal protection device (Filter-Wire EZ; Stryker, Fremont, California, USA) was inserted into the ICA. This device crossed the stenotic lesion after inflation of the guiding catheter balloon with proximal flow control. Attempts with a 3 mm × 40 mm SHIDEN balloon dilatation catheter (Kaneka, Osaka, Japan) and a 4 mm × 40 mm SHIDEN balloon dilatation catheter were unsuccessful despite inflation to a nominal pressure of 8 atm for 45 s. An 8 × 29 mm Carotid Wallstent Monorail (Boston Scientific, Natick, MA, USA) was inserted into the ICA and did not cross the stenotic lesion. Restenosis was thought to be caused by recoil. An NSE PTA balloon with three longitudinal nylon elements attached proximally and distally to the balloon component was used as a pre-dilatation step [Figure 1a]. A 3.5 × 20 mm NSE PTA balloon was then inflated in the lesion at 8 atm for 60 s, 8 atm for 60 s, and 14 atm for 60 s to achieve successful luminal expansion [Figures 4b and c]. An 8 × 29 mm Carotid Wallstent Monorail was deployed, and a 4 × 40 mm SHIDEN balloon dilatation catheter was inflated at 8 atm for 60 s as a post-dilatation step [Figures 4d-f]. Due to the angiographic slow flow, no visible debris was aspirated from the suction catheter. The distal protection device was removed, and no visible debris was observed. Right common carotid angiography showed improved ICA flow [Figure 4g]. No periprocedural bradycardia or hypotension was observed.

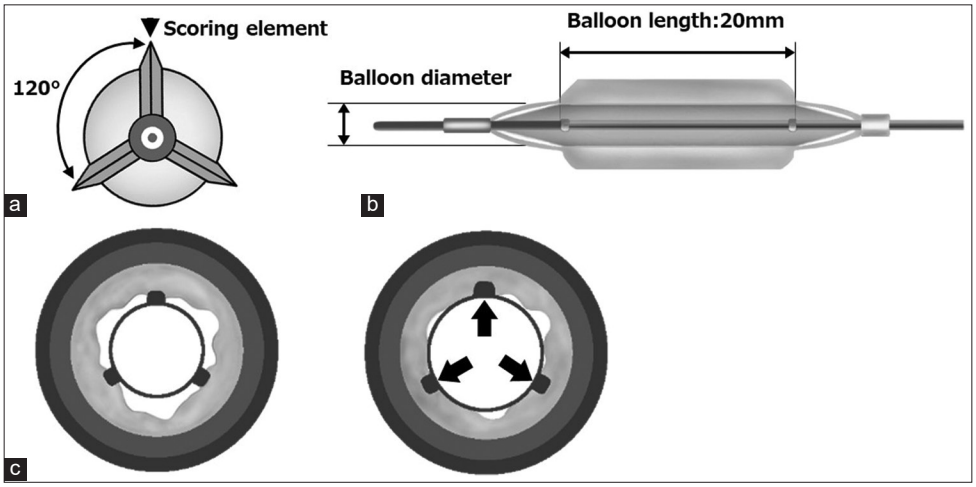

Figure 1: Non-slip element percutaneous transluminal angioplasty (NSE PTA) balloon. (a) The NSE PTA balloon is a non-slip angioplasty catheter with three nylon scoring elements for controlled scoring of the vessel wall and reducing slippage during balloon inflation. (b) Stabilization of the balloon within the lesion during inflation. (c) Provision of an effective scoring effect through high concentrated force transmission (arrow).

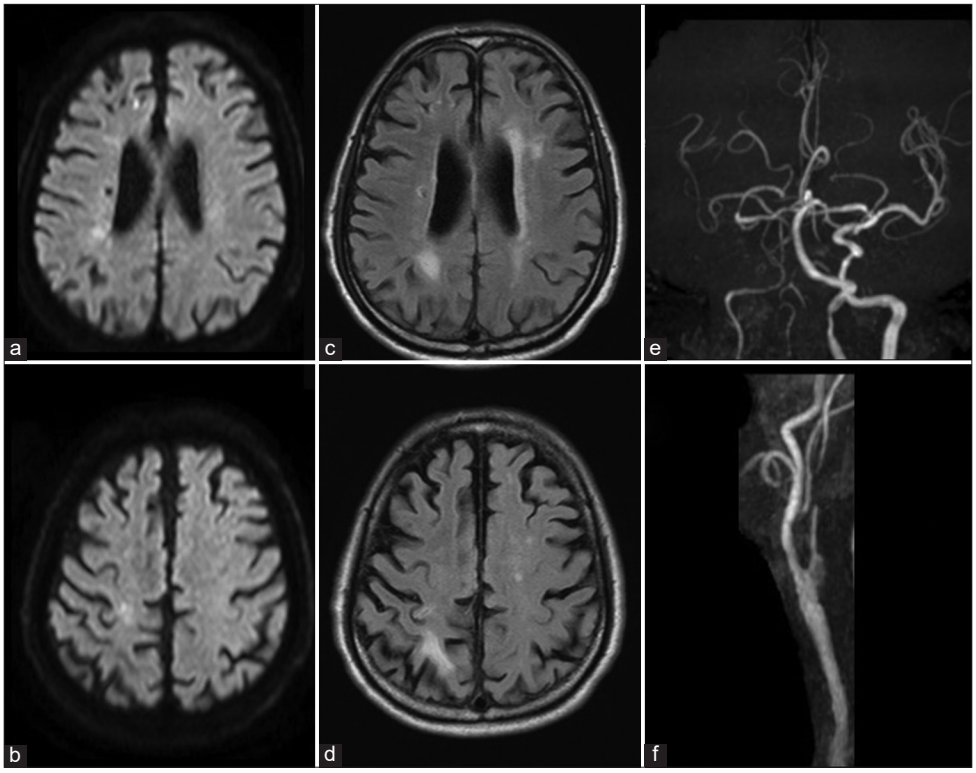

Figure 2: (a and b) Initial magnetic resonance imaging, diffusion-weighted image, (c and d) fluid-attenuated inversion recovery image, and (e and f) magnetic resonance angiography showing acute and subacute infarcts in the territory of the right internal carotid artery (ICA) and right cervical ICA stenosis.

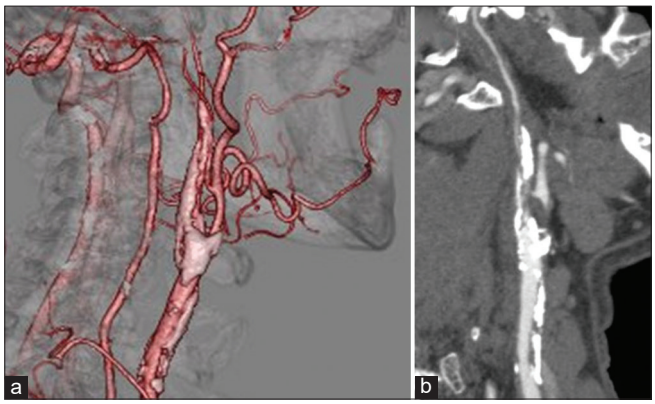

Figure 3: (a) Preoperative three-dimensional computed tomography angiography (CTA) and (b) sagittal CTA showing a right carotid artery with high-grade stenosis caused by a multifocal calcified plaque.

No postprocedural stroke events occurred [Figure 5]. The postprocedural course was uneventful without complications.

DISCUSSION

In this case, a scoring balloon was used to successfully treat a highly calcified carotid artery stenosis lesion that could not be adequately dilated using the conventional technique.

High rates of carotid plaque calcification are associated with high rates of residual stenosis and restenosis.[8] Highly calcified carotid arteries are a risk factor for stroke and major adverse events after CAS.[1] To achieve adequate stent expansion in severely calcified lesions, the radial force applied during balloon angioplasty must surpass the resistance posed by calcifications. Pre-dilatation balloons for carotid stenting, such as high-pressure, cutting, and intravascular lithotripsy balloons, have been reported to be able to treat calcified lesions.[4,7,15,20] However, cutting balloons have poor deliverability due to their bulkiness with blades around the surface of the balloon. Furthermore, CAS with cutting or intravascular lithotripsy balloons is an off-label use in Japan.

NSE PTA balloons are low-profile, semi-compliant scoring balloons with three triangular nylon elements that can score even a stiff plaque wall.[16] The scoring elements create the scoring effect (longitudinal cracks on the target lesion at regular intervals).[2,3,14,18] This tool assists in reducing balloon slippage and the risk of incomplete plaque coverage (geographic miss) when inflating the balloon.[14] Scoring balloons are expected to dilate the arteries with less dissection, thereby resulting in less vascular injury and inflammatory reaction.[5,13,14] Furthermore, the

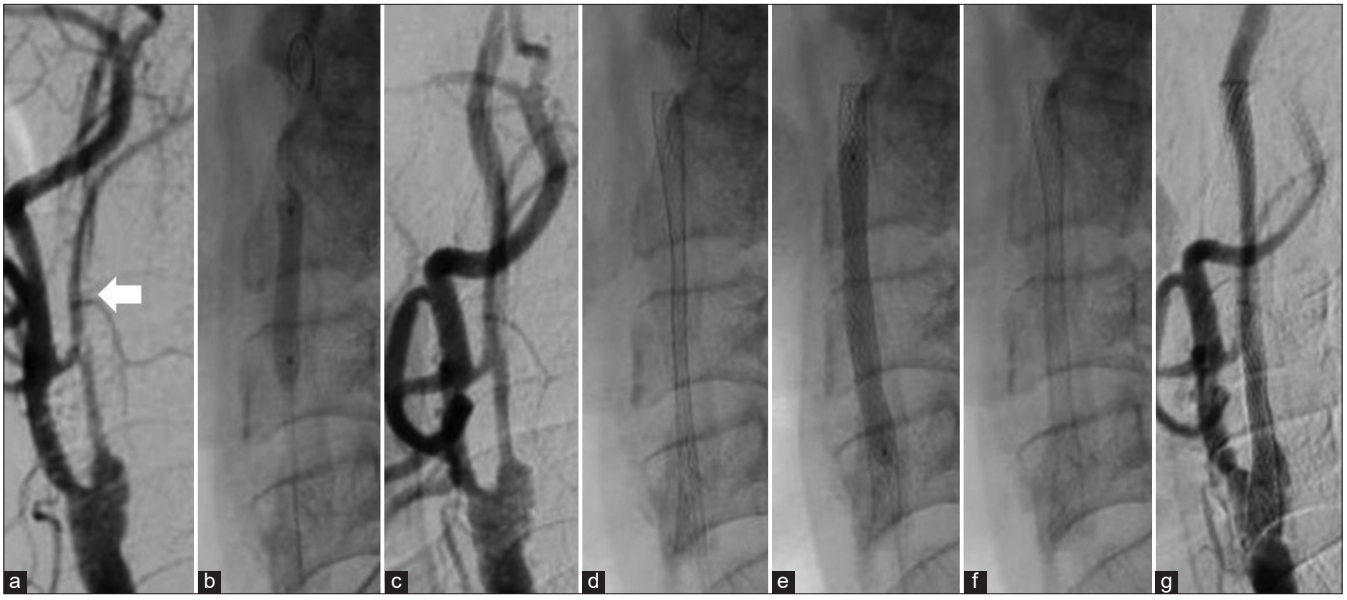

Figure 4: Intraprocedural common carotid angiograms of the patient with severe calcified stenosis of the right carotid artery who underwent carotid artery stenting (CAS) with a non-slip element percutaneous transluminal angioplasty (NSE PTA) balloon. (a) A common carotid angiogram reveals severe stenosis (white arrow) of the right cervical internal carotid artery (ICA) (white arrow). (b) An NSE PTA balloon was placed in the cervical ICA, centered on the stenotic lesion, and used for pre-dilatation in the CAS. The NSE PTA balloon was inflated three times with Filter-Wire EZ underprotection. (c) Post-PTA shows mild improvement of the stenosis. (d) Placement of an 8 × 29 mm Carotid Wallstent Monorail. (e) Post-dilatation using a 4 mm × 40 mm SHIDEN balloon dilatation catheter. (f) Post-PTA showing the dilated stent. (g) A postprocedural common carotid angiogram reveals satisfactory revascularization.

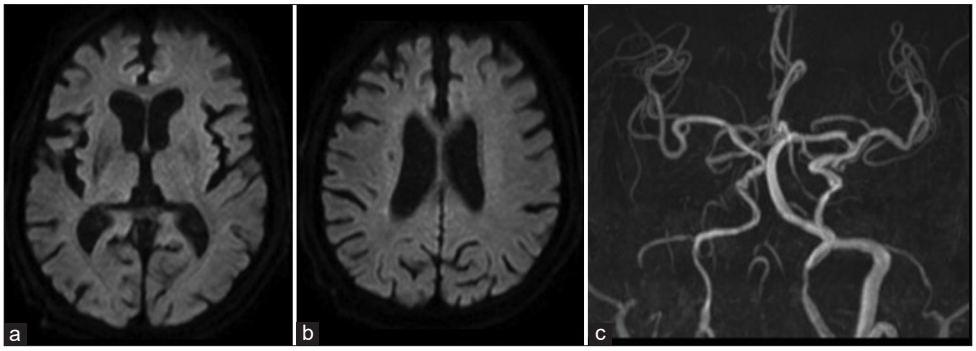

Figure 5: Postoperative magnetic resonance imaging, (a and b) diffusion-weighted image , and (c) magnetic resonance angiography showing no infarcts and improvement in the right cervical internal carotid artery stenosis.

scoring effect promotes uniform radial expansion and enables significant increases in the inner vessel diameter without causing vessel dissection, even in severely calcified lesions that are technically challenging with a conventional balloon in coronary and infrapopliteal lesions.[2,3,6,14] The use of a scoring balloon may be a therapeutic option for calcified carotid stenosis. Three cases of carotid interventions using a scoring balloon have been reported [Table 1].[9,17] The scoring effect (neointimal modification) has been demonstrated radiologically,[9] suggesting that endovascular retreatment with a scoring balloon is a useful option for both carotid and coronary in-stent restenosis.

To increase the luminal area during the initial procedure, a method that involves prolonged or multiple inflations of a scoring balloon has been reported.[10,12] Creep is a deformation that occurs under prolonged and sustained loading and can lead to material damage.[11] The mechanism of arterial dilatation by prolonged balloon or stent inflation may be because the sustained tensile stress distorts a resistant lesion by a creep phenomenon.[12,19] However, prolonged balloon inflation may lead to long-term ischemia. Therefore, if long-term ischemia was not tolerable or hemodynamics failed during ischemia, this method was not used. Multisite scores induced by multiple scoring balloon inflations can optimize balloon angioplasty

Table 1: Summary of carotid intervention cases treated with scoring balloon.

	Sorkin *et al*. 2014[17]	Sorkin *et al*. 2014[17]	Inomata *et al*. 2021[9]	Current case
Age (years)/sex	55/Male	82/Female	77/Male	72/Male
Clinical state	Symptomatic carotid ISR 6 years after the initial CAS	Symptomatic carotid ISR 8 years after the initial CAS	Asymptomatic carotid ISR 2 years after the initial CAS	Asymptomatic carotid stenosis
Plaque imaging	not available	Focal calcified plaque	Homogeneously echogenic	Calcified plaque
Scoring balloon	AngioSculpt PTCA scoring balloon	AngioSculpt PTCA scoring balloon	NSE PTA balloon	NSE PTA balloon
Endovascular procedure	Scoring balloon angioplasty alone (10atm)	Scoring balloon angioplasty alone (18atm)	Scoring balloon angioplasty for predilatation (8atm, 30 seconds) in the repeated CAS	Scoring balloon angioplasty for predilatation (8atm 60s, 8atm 60s and 14atm 60s) in the CAS
Result				
Immediate	Successful luminal expansion	Successful luminal expansion	Successful luminal expansion	Successful luminal expansion
Follow-up	Not available	Not available	No restenosis 1 year and 5 months after repeated CAS	No restenosis 3 months after CAS

CAS: Carotid artery stenting, ISR: In-stent restenosis, NSE: Nonslip element, PTCA: Percutaneous carotid transluminal angioplasty, PTA: Percutaneous transluminal angioplasty

results by obtaining a sufficient initial lumen area.[10] We achieved an adequate initial lumen area using three scoring balloon inflations. In our patients, the flexibility and low profile of NSE PTA balloons worked well, considering the high-grade stenosis, refractory, and highly calcified nature of the plaques.

CONCLUSION

This is the first report to describe the use of a scoring balloon for *de novo* carotid artery disease. NSE PTA balloon catheters can be a useful option for refractory, highly calcified stenosis.

Ethical approval

The Institutional Review Board approval is not required.

Declaration of patient consent

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

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Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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