JVIN Journal of Vascular and Interventional Neurology
OFFICIAL JOURNAL OF THE ZEENAT QURESHI STROKE RESEARCH CENTER

Instent restenosis after carotid stenting: treatment using an off-label cardiac scoring balloon

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Abstract

Background—Treatment of instent restenosis after carotid artery stenting because of circumferential or calcified lesions can be difficult and refractory to conventional balloon angioplasty. We describe the off-label use of a cardiac scoring balloon that was used for lesions refractory to angioplasty with other balloons.

Case descriptions—Two patients with a history of carotid artery stenting 6 and 8 years ago, presented with symptomatic carotid instent restenosis caused by circumferential and calcified lesions, respectively. Angioplasty with conventional compliant and noncompliant balloons was unsuccessful. An AngioSculpt percutaneous transluminal coronary angioplasty (PTCA) scoring balloon catheter (AngioScore, Fremont CA, USA) was successful in achieving vessel recanalization despite the refractory nature of these lesions. No further conventional balloons or use of cutting balloons was required.

Conclusion—The AngioSculpt PTCA scoring balloon catheter can be a useful option for treatment of refractory calcified or circumferential carotid instent restenosis.

Keywords

angioplasty; cardiac scoring balloon; carotid artery; instent restenosis

Introduction

Carotid artery stenting (CAS) has emerged as an important alternative to endarterectomy for the management of carotid stenosis [1–3]. Rates of instent restenosis after CAS vary according to literature source and definition of restenosis, ranging from 1% to 21% over 12–18 months, with its treatment dependent on vascular and plaque morphology [4,5]. Treatment of instent restenosis with conventional angioplasty balloons (compliant or noncompliant) caused by circumferential or calcified lesions can be difficult because of inadequate luminal expansion, high dissection rate, and need for repeated revascularization procedures [6–9]. To overcome these obstacles, cutting and scoring balloons have been used in multiple vascular beds in primary stenting for high-grade or concentrically calcified stenosis and for instent restenosis that is refractory to angioplasty with conventional angioplasty balloons [10–12]

Cutting balloons consist of parallel atherotomes (blades) attached longitudinally to the balloon surface that allow vessel lumen expansion with lower inflation pressures compared with conventional balloons. These athero-

Published May, 2014.

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tomes score the surrounding plaque on expansion, thereby acting like an anchor within the surrounding lesion [9,13]. These characteristics make cutting balloons useful when migration during angioplasty is unacceptable, including focal, bifurcation, and ostial lesions, or lesions that are calcified and resistant to conventional angioplasty [6,10,11,13–15].

The AngioSculpt percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA) scoring balloon catheters (AngioScore, Fremont CA, USA), used for peripheral and coronary disease, respectively, are unique angioplasty balloons that have three rectangular scoring wires that spiral around the longitudinal axis of a semicompliant balloon [16,17]. Compared with cutting balloons, AngioSculpt balloons are lower profile, more flexible given the spiral arrangement of scoring wires, and create more scoring marks per millimeter (mm) of plaque, with the ability to achieve higher nominal and burst pressures (as high as 20 atm) suited for calcified and circumferential plaque [12,18–20]. AngioSculpt PTCA balloons have received Food and Drug Administration approval for the treatment of coronary artery stenosis, including instent restenosis, and American College of Cardiology–American Heart Association classification type-C coronary lesions for the purposes of improving myocardial perfusion [17]. AngioSculpt PTA balloons have been approved for dilation of lesions in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, as well as for native or synthetic arteriovenous dialysis fistulae [16]. This report represents what is to our knowledge the first description of its off-label use for complex instent carotid restenosis.

Illustrative Cases

Case 1

A 55-year-old man with a history of bilateral CAS for pseudo-occlusions 6 years earlier presented to our clinic for annual carotid Doppler screening. Left peak systolic velocity was 675 cm/s, up from 125 cm/s 1 year earlier. On questioning, the patient described two episodes of transient loss of vision in the left eye 1 week earlier. He was admitted to the hospital from the clinic for urgent treatment of symptomatic instent carotid restenosis with commencement of dual antiplatelet therapy (aspirin, 325 mg daily; and clopidogrel, 75 mg daily) prior to intervention.

Right femoral artery access was obtained, and a selective left common carotid angiogram was performed revealing >95% instent restenosis from a circumferential, fibrotic plaque (Figures 1 and 2). After heparinization to achieve an activated coagulation time between 250 and 300 s, a 6-French Cook Shuttle (Cook, Bloomington, IN, USA) was brought into the left common carotid artery by climbing over a Vitek catheter after an Amplatz Super Stiff Exchange Wire (Cook) was positioned in the external carotid artery. An Emboshield Nav 6 (Abbott Medical, Santa Clara, CA, USA) distal embolic protection device was deployed using the exchange length microwire option allowing for an over-the-wire (OTW) angioplasty balloon. Attempts using a 2.5 mm × 15 mm Sprinter OTW balloon dilation catheter (Medtronic, Minneapolis, MN, USA) and a 2.5 mm × 20 mm Aviator Plus RX balloon catheter (Cordis, Warren, NJ, USA) were unsuccessful despite inflation to burst pressure of 14 atm. A 2.5 mm × 15 mm AngioSculpt PTCA scoring balloon catheter (inflated to pressure of 10 atm; burst pressure of 16 atm) was used for successful luminal expansion (Figures 3 and 4).

Figure 1. Anteroposterior (AP) digital subtraction angiogram (DSA) revealing high-grade, circumferential restenosis of the left internal carotid artery (ICA).

Figure 2. Lateral DSA revealing high-grade, circumferential restenosis of the left ICA.

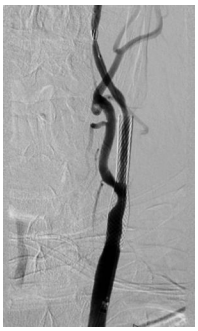

Figure 3. Post angioplasty AP DSA revealing luminal expansion after AngioSculpt (AngioScore, Fremont CA, USA).

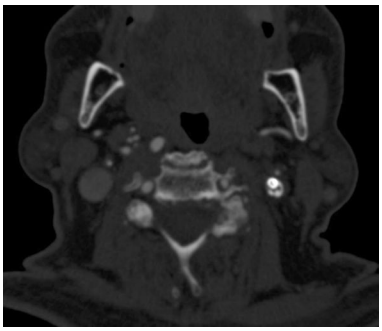

Figure 5. Axial CT angiogram revealing a left carotid artery stent with high-grade instent restenosis caused by a focal calcified plaque.

Figure 4. Post angioplasty lateral DSA revealing luminal expansion after AngioSculpt.

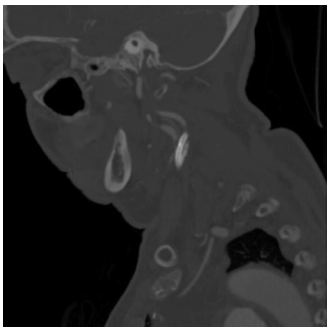

Figure 6. Sagittal CT angiogram revealing a left carotid artery stent with high-grade instent restenosis caused by a focal calcified plaque.

Case 2

An 82-year-old woman with a history of left CAS 8 years earlier for symptomatic disease presented to the emergency department with transient right-sided hemiparesis and expressive aphasia. A computed tomographic (CT) angiogram of the head and neck revealed a focal area of high-grade calcified stenosis within the stent (Figures 5–7). Given the symptomatic nature of the instent restenosis, the dual antiplatelet regimen described above was initiated, and the patient was taken for neuroendovascular intervention.

Consistent with the technique described above, right femoral artery access was obtained, a 6-French Cook shuttle was positioned in the common carotid artery, and an Emboshield Nav 6 distal embolic protection device with exchange length microwire was deployed in the internal carotid artery (ICA) for OTW angioplasty balloons. Initial angioplasty attempts with a 3.0 mm × 15mm Sprinter OTW balloon dilation catheter and a 3.0 mm × 20 mm Aviator Plus RX balloon catheter were unsuccessful. The next attempt using a 3.0 mm × 15 mm

Figure 7. Lateral DSA revealing high-grade restenosis of the left ICA.

Voyager NC coronary dilatation catheter (Abbott Medical) was unsuccessful and aborted owing to the need to approach high pressures. Finally, a 3.0 mm × 20 mm AngioSculpt PTCA scoring balloon catheter was used for successful luminal expansion when inflated to burst pressure of 18 atm (Figure 8).

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Figure 8. Post angioplasty lateral DSA revealing luminal expansion after AngioSculpt.

Discussion

The rate of instent restenosis after CAS varies according to the literature source and definition of restenosis, ranging from 1% to 21% over 12–18 months [9,21–25]. When defined as stenosis >50%, stenosis rates range from 6% to 13% at one year [4,5,26]. When defined as stenosis >80%, rates range from 2.5% to 4% [4,5,26]. Risk factors for instent restenosis include restenosis after carotid endarterectomy [9,27], residual stenosis and inadequate luminal expansion after CAS [4,28], and use of multiple stents [9,27,29]. Treatments for instent restenosis after CAS include carotid endarterectomy and stent removal [30,31], additional stent placement [9,27–29], and angioplasty utilizing conventional or cutting or scoring balloons [5,6,9,14,15,23,26].

To date, no consensus in the literature exists on management; therefore, treatment remains on a case-by-case basis. The use of cutting balloons for instent restenosis in the coronary literature has been shown to be effective for complex lesions, allowing use of fewer balloons, minimizing slippage, and lowering the need for stenting or restenting after angioplasty [6,9,31]. However, their use has not been shown to reduce long-term restenosis rates compared with conventional angioplasty balloons [6,9,13]. Shah et al [32] reported a literature review of 16 patients treated with cutting balloon angioplasty for carotid instent restenosis. Of the 11 patients that were followed up to one year, all had immediate angiographic improvement to less than 30% stenosis but eight patients went on to require subsequent retreatment with angioplasty or repeat stent placement. Long-term outcomes after treatment with cutting balloon angioplasty for carotid instent restenosis needs further exploration, particularly related to rates of restenosis [32]. In our patients, the AngioSculpt balloon's flexibility and low-profile features performed well given the high grade, refractory, circumferential or calcified nature of the plaques. Durability of such treatment will require further study.

Conclusion

To our knowledge, this is the first report describing the off-label use of this scoring balloon for carotid disease. The AngioSculpt PTA scoring balloon catheter can be a useful option for refractory, calcified, or circumferential instent restenosis.

Financial relationships/Potential conflicts of interest

Dr. Dumont, Dr. Eller, and Dr. Sorkin report no financial relationships. Dr. Hopkins receives grant/research support from Toshiba; serves as a consultant to Abbott, Boston Scientific,*Cordis, Micrus, and Silk Road; holds financial interests in AccessClosure, Augmenix, Boston Scientific,*Claret Medical, Endomation, Micrus, and Valor Medical; holds a board/trustee/officer position with Access Closure and Claret Medical; serves on Abbott Vascular's speakers' bureau; and has received honoraria from Bard, Boston Scientific, Cleveland Clinic, Complete Conference Management, Cordis, Memorial Health Care System, and the Society for Cardiovascular Angiography and Interventions (SCAI). Dr. Levy receives research grant support, other research support (devices), and honoraria from Boston Scientific* and research support from Codman & Shurtleff, Inc. and ev3/Covidien Vascular Therapies; has ownership interests in Intratech Medical Ltd. and Mynx/Access Closure; serves as a consultant on the board of Scientific Advisors to Codman & Shurtleff, Inc.; serves as a consultant per project and/or per hour for Codman & Shurtleff, Inc., ev3/Covidien Vascular Therapies, and TheraSyn Sensors, Inc.; and receives fees for carotid stent training from Abbott Vascular and ev3/Covidien Vascular Therapies. Dr. Levy receives no consulting salary arrangements. All consulting is per project and/or per hour. Dr. Mokin has received an educational grant from Toshiba. Dr. Siddiqui has received research grants from the National Institutes of Health (coinvestigator: NINDS 1R01NS064592-01A1, Hemodynamic induction of pathologic remodeling leading to intracranial aneurysms; not related to present manuscript) and the University at Buffalo (Research Development Award); holds financial interests in Hotspur, Intratech Medical, StimSox, and Valor Medical; serves as a consultant to Codman & Shurtleff, Inc., Concentric Medical, ev3/Covidien Vascular Therapies, GuidePoint Global Consulting, and Penumbra; belongs to the speakers' bureaus of Cod-

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man & Shurtleff, Inc. and Genentech; serves on an advisory board for Codman & Shurtleff; and has received honoraria from Abbott Vascular, American Association of Neurological Surgeons' courses, an emergency medicine conference, Genentech, Neocure Group LLC, Peripheral Angioplasty and All That Jazz Conference, and from Abbott Vascular and Codman & Shurtleff, Inc. for training other neurointerventionists in carotid and aneurysm stenting. Dr. Siddiqui receives no consulting salary arrangements. All consulting is per project and/or per hour. (*Boston Scientific's neurovascular business has been acquired by Stryker.)

Financial and material support

None in conjunction with this submission/study.

Contributors

Conception and design: Sorkin, Dumont; Acquisition of data: all authors; Analysis and interpretation of data: Sorkin; Drafting the manuscript: Sorkin, Dumont; Critically revising the manuscript: all authors; Final approval of the manuscript: all authors

Acknowledgements

The authors would like to thank Paul H. Dressel BFA for assistance with preparation of the illustrations and Debra J Zimmer for editorial assistance.

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