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Stent Induced Carotid Remodeling: A Balloon Sparing Technique for Carotid Revascularization

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Abstract

Background— Carotid artery stent placement is widely utilized to treat high-risk carotid stenosis patients but is associated with a greater risk of peri-procedure stroke than carotid endarterectomy in standard-risk populations. We explore a technique designed to lower this risk by avoiding the use of angioplasty intra-procedurally and allowing more gradual carotid remodeling to occur.

Methods—We compare two groups of consecutively treated subjects. The first group was treated with the traditional combination of stent placement and angioplasty (AG; 18 subjects), while the second group utilized stent insertion alone (NAG; 20 subjects). All subjects were treated at a single institution with retrospective data collection. Procedural and clinical data were collected for analysis.

Results— No differences in clinical outcome were noted between the two groups. There was a trend toward more significant immediate residual stenosis in the NAG group than the AG groups (22% versus 5%; p=0.06), but at follow up imaging, there was no difference between the groups, with the NAG group showing interval luminal gain of 7.5% accounting for the equalization.

Conclusion— Avoidance of angioplasty during carotid stent placement is associated with similar clinical and radiographic outcomes; more immediate luminal gains are observed with angioplasty versus more gradual gains with stent placement alone. Given the physiologic reasons to believe this technique could reduce peri-procedure stroke, further evaluation of this technique in a larger population is warranted.

Keywords— carotid, stent, angioplasty, stroke, remodeling.

INTRODUCTION

Carotid artery stent placement (CAS) has proven effective in preventing recurrent ischemic events in carefully selected patients with symptomatic cervical carotid artery stenosis[1] and is noninferior to and less invasive than carotid endarterectomy.[2] CAS is recommended for symptomatic patients with a low risk of endovascular intervention when the diameter of the internal carotid artery lumen is reduced by >70% by noninvasive imaging or >50% by catheter-based imaging or noninvasive imaging, and the expected rate of periprocedural stroke or death is less than 6%, according to AHA/ASA 2014 guidelines.[3] However, the CREST trial showed that carotid endarterectomy (CEA) is associated with lower peri-procedure minor stroke risk in standard-risk patients than CAS.[4] Practitioners of CAS must carefully analyze their procedural technique to minimize this risk. Traditionally in patients undergoing CAS, balloon angioplasty is performed before and after stent deployment. The inflation of a balloon within the atherosclerotic segment leads to intimal injury, potentially releasing embolic material into the lumen and promoting in-situ platelet aggregation. The degree of intimal injury is likely related to the balloon's size and the corresponding amount of luminal distention. A second factor contributing to peri-procedural stroke post-CAS is the protrusion of friable atherosclerotic material through stent struts with subsequent intra-procedural or delayed embolization intracranially. Finally, balloon angioplasty

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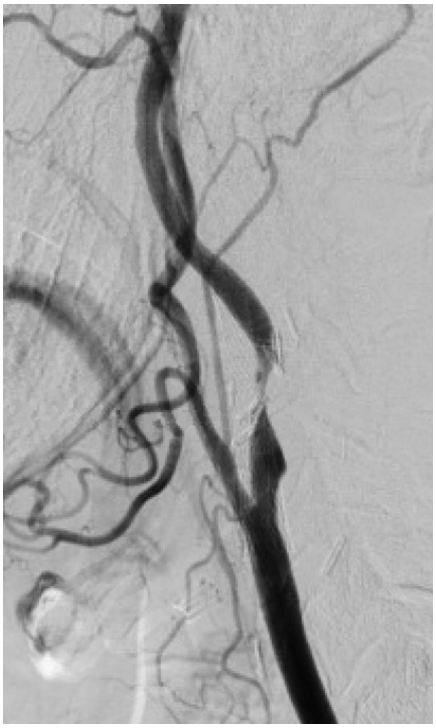

FIGURE 1: Digital subtraction angiogram showing 75% stenosis of the cervical internal carotid artery.

post-stent deployment is associated with an increased risk for hemodynamic depression, which may contribute to delayed flow failure related infarctions.[5]

To minimize the peri-procedure stroke risk associated with CAS, we utilize a technique that avoids the use of angioplasty balloons. This technique relies on the outward radial force exerted by closed-cell carotid stent systems to cause immediate but partial improvements in vessel diameter with more gradual luminal gains over time.[6] In addition, we deploy a second stent inside the first to further increase outward radial force, decrease cell size, and increase strut surface area coverage of the endothelium.

This second effect may also reduce the protrusion of plaque and/or thrombus through the stent into the vessel lumen.[7]

We report on two consecutive groups of patients undergoing carotid artery stent placement for symptomatic cervical carotid artery stenosis. The first group consists of patients undergoing stent placement with large diameter balloon angioplasty to achieve complete or nearly complete immediate resolution of the stenotic lesion. The second group consists of patients undergoing stent placement without balloon angioplasty.

METHODS

A retrospective analysis of carotid stent procedures performed between January 2016 and May 2019 at a single center was completed. The cases were separated into those in which a standard approach to CAS utilizing balloon angioplasty was performed and cases in which stent placement was performed without balloon angioplasty. Data collected included demographic information, procedural details, periprocedural outcomes, long-term clinical outcomes, and radiologic follow up imaging when available.

Procedural Details

Angioplasty

All patients were pre-treated with aspirin and clopidogrel. All procedures were performed under local anesthetic with moderate intravenous sedation. In all cases, access was transfemoral. Intravenous heparin was administered to achieve an activated clotting time of 250 to 300 seconds. A 7 French 80 or 90 cm Cook Shuttle (Cook Medical, Bloomington, Indiana, USA) sheath was navigated over a

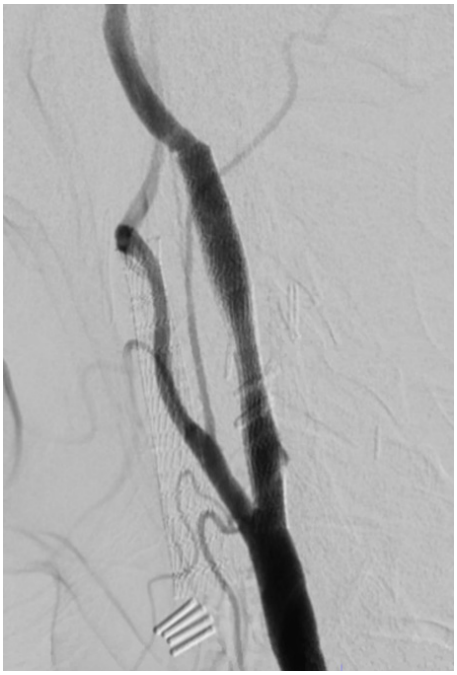

FIGURE 2A: Digital subtraction angiogram showing double stent deployment. stents extend from the internal carotid artery to the common carotid artery.

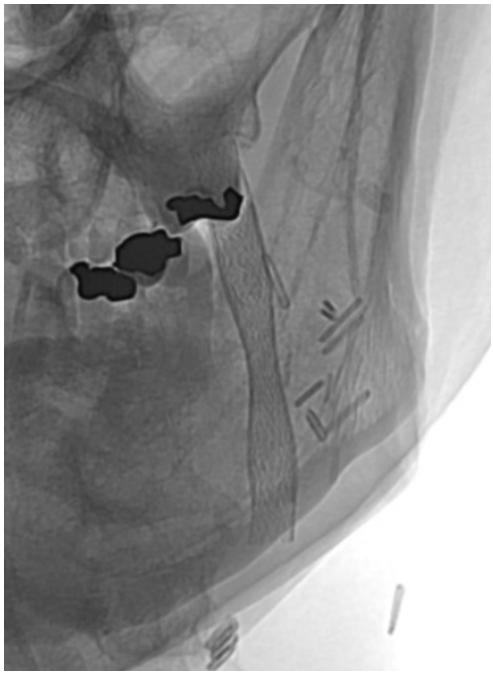

FIGURE 2B: Immediate post-stent angiography showing significantly improved flow with 40% residual stenosis.

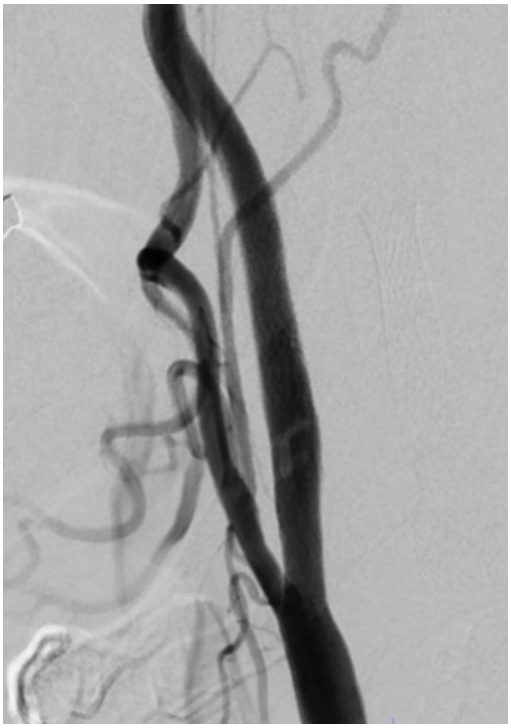

FIGURE 3: 6 month follow up angiogram showing enlarged left Internal carotid stent diameter with no residual stenosis.

120cm 6 French Select Catheter (Penumbra, Inc., Alameda, California, USA) and a 200 cm Glide (Terumo Medical, Somerset, NJ, USA) wire into the common carotid artery proximal to the target lesion. Baseline angiography of the cervical and intracranial vessels was performed. A 200cm Transcend Floppy (Stryker Neurovascular, Fremont, CA, USA) microwire was used to cross the target lesion under roadmap guidance. Over this microwire, a Spider FX embolic protection device (Medtronic, Minneapolis, Minnesota, USA) sized 1-2 mm greater than the normal vessel diameter was navigated. The filter device was deployed in the petro-cervical carotid segment. The Transcend Floppy microwire was removed. If the stenotic lesion was <2mm in diameter, a 2.5 by 20 mm Maverick (Boston Scientific, Marlborough, Massachusetts, USA) rapid exchange balloon was navigated over the filterwire and inflated to nominal pressure. The pre-stent angioplasty balloon was then removed. A tapered Xact (Abbott Vascular, Santa Clara, California, USA) stent size 2-3 mm greater than the normal vessel diameter was then deployed from the internal carotid artery into the common carotid artery. A post-stent angioplasty was then performed with a 4 or 5 mm Sterling (Boston Scientific, Marlborough, Massachusetts, USA) rapid exchange balloon to achieve minimal to no residual stenosis. Through the existing catheter, angiography was performed to assess the degree of residual stenosis and rule out intracranial emboli.

No Angioplasty

The procedural steps were as described above with the following modifications: No pre-stent angioplasty was attempted. Instead, an attempt was made to cross the lesion primarily with the stent delivery catheter. If this was unsuccessful or the lumen was <1 mm, a small diameter (2 or 2.5 mm) rapid exchange balloon (Boston Scientific) was navigated over the filter wire and inflated to nominal pressure. A tapered Xact (Abbott) stent size 2-3 mm greater than the normal vessel diameter and measuring 40mm in length was then deployed from the internal carotid artery into the common carotid artery. A second Xact (Abbott) stent size 2-3 mm greater than the normal vessel diameter and measuring 30 mm in length was then deployed within the first stent. No post-stent angioplasty was performed. Through the existing catheter, angiography was performed to assess the degree of residual stenosis and rule out intracranial emboli.

Case Example

Our patient is a 70-year-old man with a distant history of squamous cell cancer of the head and neck who had undergone tumor resection and radiation therapy. He presented in 2015 with transient left-sided weakness and facial droop. He was found to have 75% stenosis of the right common carotid artery and less than 50% stenosis of the left internal carotid artery by NASCET criteria. Given the history of neck irradiation, he was deemed high-risk for carotid endarterectomy and underwent right common CAS. He was subsequently followed clinically but began to experience episodes of impaired language and level of consciousness. In February of 2018, he was found to have > 70% stenosis of the left internal carotid artery on carotid Doppler ultrasound. On 2/29/2018, he underwent left internal CAS as described below:

Angiography of the cervical and intracranial vessels were performed, showing 75% stenosis of the cervical internal carotid artery just distal to the carotid bulb (Figure 1). A 5mm Spider Rx embolic protection device (Medtronic) was navigated into the petro-cervical carotid segment and deployed. A tapered Xact (Abbott) 8 to 10 mm by 40 mm stent was then deployed from the internal carotid artery into the common carotid artery. A second tapered Xact (Abbott) 8 to 10 mm by 30 mm stent was then deployed within the first stent (Figure 2A). A 40% residual stenosis was noted on post-stent angiography; however, the flow was significantly improved, and no angioplasty was performed (Figure 2B). Over the next 6 months, the patient continued to note episodic pre-syncopal symptoms, and a follow-up angiogram was performed on 12/12/2018 to look for posterior circulation stenosis. No significant posterior circulation stenosis was noted. However, the left internal carotid stent diameter was noted to be further enlarged compared to the immediate post-stent placement diameter with no residual stenosis present (Figure 3).

Statistical Analysis

Descriptive statistics were conducted for the sample overall and by angioplasty status, no angioplasty group (NAG) vs. balloon angioplasty group (AG). Counts and percentages are presented for the categorical variables, and median and interquartile ranges (IQR) are given for continuous variables. Chi-square or Fisher's exact tests were utilized to compare the distribution of the categorical variables by angioplasty status, with Fisher's exact tests being used when the assumptions of the Chi-square test were violated. Mann-Whitney U tests were utilized to compare differences in status for continuous variables. Baseline patient and procedure characteristics were compared between the groups; these variables included

TABLE 1: Baseline Demographics between both groups.

	No Angioplasty (n = 20)	Balloon Angioplasty (n = 18)	p-value[b]
Male	15 (75%)	11 (61%)	0.36
Race			0.21
Caucasian	15 (75%)	10 (56%)	
Other[a]	5 (25%)	8 (44%)	
Age, median (IQR)	65 (62.3 – 72.8)	65.5 (58 – 72.3)	0.85
Sided-ness			0.27
Left	11 (55%)	13 (72%)	
Right	9 (45%)	5 (28%)	
Pre-Procedure Stenosis %, median (IQR)	80 (70.0 – 90.0)	85.5 (78.8 – 90.0)	0.15

[a]: Balloon Angioplasty contained 1 Asian, all others were African American.

[b]: Chi-square or Fisher's exact test for categorical variables, Mann-Whitney U tests for continuous variables. NA: cannot calculate due to low cell counts.

TABLE 2: Post-Stenting Outcomes between Both Groups.

	No Angioplasty (n = 20)	Balloon Angioplasty (n = 18)	p-value[a]
Had a follow-up	14 (70%)	13 (72%)	0.88
Time to follow-up, median (IQR), n	77.5 (31.8 – 110), 14	56.0 (29.0 – 233.5), 13	0.94
mRS follow-up. median (IQR), n	1 (0 – 2), 11	1 (1 - 1), 11	0.56
0 - 2 mRS	9 (81.8)	10 (90.9)	0.53
3 - 6 mRS	2 (18.2)	1 (9.1)	
Stenosis, median (IQR), n			
Pre - procedure	80 (70.0 – 90.0)	85.5 (78.8 – 90.0)	0.15
Post - procedure	22.5 (5.0 – 30.0)	5 (0.0 – 21.3)	0.06
Follow-up	5 (0 – 20), 8	20 (2.5 – 40), 5	0.44
Change in Stenosis %, median (IQR), n			
Pre to Post-Op	-60 (-77.5 – -41.3), 20	-75 (-85.0 – -63.8), 18	0.009*
Post to Follow-up	-7.5 (-23.8 – 0), 8	0 (-2.5 – 32.5), 5	0.09
Pre to Follow-up	-70 (-80 – -46.3), 8	-70 (-87.5 – -42.5), 5	0.94
Procedural Complications	1 (5%)	2 (11%)	0.60
Recurrent TIA/Stroke (same side)	1 (7%)	1 (7%)	1.00

*: Significant at $p < 0.05$.

gender, race (Caucasian vs. other), age, sidedness (left vs. right), anti-platelets post-procedure (none vs. ASA + Plavix), procedural complications (yes vs. no), recurrent transient ischemic attack (TIA) or stroke (same side), Modified Rankin Scale (mRS) at discharge, and stenosis percentage pre-procedure and post-procedure. Follow-up data included if they had a follow-up visit (yes vs. no), time to follow-up (in days), mRS at follow-up, the change in mRS (from post-procedure to follow-up), stenosis percentage at follow-up, the change in stenosis percentage (pre- to post-procedure, from post-procedure to follow-up, and from pre-procedure to follow-up), and the change in stenosis from post-procedure to follow-up (improved, no change, worse). NASCET criteria were followed in determining degree of stenosis. After analyzing all follow-ups, the dataset was restricted to those who had follow-ups within 91 days. The same baseline and follow-up characteristics were analyzed for this subset. All analyses were conducted in IBM SPSS Statistics version 26 (IBM Corp. Released 2018. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.). The significance level was set at 0.05.

RESULTS

Thirty-eight consecutive subjects were identified between 2016 and 2019. The median (IQR) age was 65 (60-72) years old, 68.4% were male, and 65.8% were Caucasian. All patients had symptomatic carotid stenosis with a median severity of 82.5% (IQR 70-90%) at baseline. Eighteen subjects were included in the AG group, and 20 patients were included in the NAG group. There were no significant differences in the demographic profiles of these two groups.

There was no difference in the peri-procedural complication rate in the two groups (Table 1). Of the NAG group, 3 lesions could not be crossed primarily with the stent delivery catheter and required pre-stent angioplasty as described above. No patients in the NAG group required post-stent angioplasty. There was greater post-stent residual stenosis on immediate post-stent imaging in the NAG group (-60% NAG versus -75% AG; $p = 0.009$).

Clinical follow up was available in 27 subjects (71.1%), with radiological follow up available in 20 patients (52.6%). There was no statistical difference in the degree of functional recovery between the two groups at follow up (mRS 0-2: 81.8% in NAG versus 90.9% AG, $p = 0.53$). As noted above, there was a statistically significant difference in the immediate post-stent luminal improvement. However, while the follow up imaging showed no net change in luminal diameter in the AG, there was a trend towards continued luminal improvement in the NAG at follow up (-7.5% in NAG versus 0% in AG; $p = 0.09$). This led to equal luminal gains at follow up imaging between the two groups (70% in NAG versus 70% in AG; $p = 0.94$) (Table 2).

DISCUSSION

CAS is associated with a higher rate of peri-procedure ischemic infarctions compared to carotid endarterectomy in standard risk populations.[4] These events can occur intra-procedurally or post-procedurally. Several technique related strategies are being employed to reduce the incidence of intraprocedural infarctions: use of embolic protection devices,[8] direct carotid access to reduce aortic arch navigation-related embolism (Transcarotid Revascularization; TCAR),[9] flow reversal to remove and filter embolic particles generated during the stent placement procedure,[10] and modifications of stent design to add surface area coverage and reduce plaque protrusion and to prevent subsequent cerebral emboli.[11]

The technique described in this paper builds on a technique published 20 years ago by Roubin et al. and relies on the self-expanding properties of nickel-titanium (Nitinol) alloy stent systems.[12] Placing one stent inside another has several theoretical advantages over single stent use: the luminal surface area covered by the metal of the stent is increased. Conversely, the cell size is decreased, narrowing the window through which friable plaque can protrude into the vessel's lumen. This improved ability to "wall off" plaque may reduce the post-procedure stroke related to this protruding plaque and any emboli they cause. Two stents also increase the outward, radial force generated. This force allows for substantial luminal gains even without the use of angioplasty. While significantly less than the force of an angioplasty balloon, it was sufficient to immediately reduce the percent stenosis by 60% in our case series. The less aggressive outward force may cause less intimal damage and thus leave subintimal tissues unexposed. This, in turn, should lead to less in situ platelet aggregation and artery to artery embolism. Finally, the outward force continues beyond the procedural period and leads to continuous but gradual vascular remodeling, and shown in our illustrative case and the 7.5% reduction in stenosis seen in the NAG group at follow up.[13] There is a theoretical greater risk of thrombogenicity when overlapping two stents due to the increased luminal area covered by the metal struts. However, we did not see clinical evidence of this in our cohort.

We utilized self-expanding stents that are constructed of Nitinol, a nickel-titanium alloy. This material can sustain high-load stress, making it less susceptible to stent collapse and compression than balloon mounted stents while retaining the ability to conform to the carotid artery bifurcation contour. This may, in turn, lower the risk of intimal dissection.[14] Self-expanding stents can be either open-cell or closed-cell. Closed-cell stents provide a more continuous outward force against the arterial wall and more lesion coverage due to higher metal coverage to the vessel wall's surface area.[14,15] More lesion coverage decreases the risk of debris protrusion through the stent struts, which can potentially decrease the risk of post-procedural stroke or TIA.[16,17] There is evidence that self-expanding nitinol stents alter the baseline ventral and dorsal plaque thickness due to their radial expansion while not significantly affecting the native arterial wall.[18] The closed-cell Abbott Xact stent used in this case series provides adequate scaffolding to prevent plaque prolapse but acceptable flexibility and conformability. The Xact cell size area varies between 3.1 and 4.0 mm^2, with proximal cells being larger in diameter. Its strut thickness is 0.181 mm, and its radial force is 10.05 ± 0.75 N.[15] The use of two overlapping stents enhances the continuous outward force while reducing the cell size.

This gradual vessel remodeling approach to minimize embolic risk comes with a tradeoff of less immediate luminal gain compared to balloon angioplasty plus stent placement. However, Poiseuille's flow equation:

$$\text{Flow Rate} = (\Delta P \pi r^4)/8\eta L$$

implies flow rate $\propto r^4$, therefore despite an on average a smaller immediate improvement in cross-sectional area, the flow is exponentially increased over the pre-stent baseline. While the full luminal gain is not achieved intra-procedurally, there is a sufficient change to dramatically increase intracranial flow and reduce the risk of stroke related to hemodynamic fluctuations.[19] Secondly, in the long term, equal final luminal gains between both procedures implies continued outward vascular remodeling between the initial procedure on the follow up with an ultimately equal improvement inflow.

There is a well-described relationship between angioplasty and peri-procedural hypotension. Balloon mounted carotid stents are associated with significantly more peri-procedural hypotension than self-expanding stents.[20] Additionally, Lavoie et al. described a relationship between balloon diameter used and peri-procedural hypotension risk.[21] These studies argue for limiting the use of balloon inflation in carotid revascularization, supporting the proposed approach. Although we did not assess this in our series, this potential benefit should be explored in future research.

Our study has several key limitations: the retrospective and non-randomized nature of the data collection limits the variables available – for example, we did not collect information on hemodynamic consequences of CAS. The small sample size and lack of follow up data on all subjects limit the ability to show significance clinically between group differences. In addition, we do not have data on hemodynamic consequences included in the study. However, this preliminary study indicates NAG approach to CAS is potentially safe and achieves similar luminal improvement at follow-up. Given these promising findings and the many theoretical advantages of stent induced carotid remodeling over traditional techniques, further study is warranted.

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