Pak Heart J

SAFETY OF ADEQUATE PREDILATATION IN CAROTID ANGIOPLASTY

Asim Javed[1], Asma Shabbir[1], Sana Ahmed[1], Muhammad Abdus Salam Azad[1], Hamid Sharif[1], Salman Abdul Qayyum[1]

1 Rawalpindi Institute of Cardiology, Rawalpindi, Pakistan

Address for Correspondence:
Dr. Asim Javed
Department of Interventional Cardiology Rawalpindi Institute of Cardiology, Rawalpindi, Pakistan
Email: doctorasimjaved@gmail.com

Contribution
AJ conceived the idea and designed the study. Data collection and manuscript writing was done by AJ, AS, SA, MASA, HS, and SAQ. All the authors contributed equally to the submitted manuscript.

All authors declare no conflict of interest.

This article may be cited as: Javed A, Shabbir A, Ahmed S, Azad MAS, Sharif H, Qayyum SA. Safety of Adequate Predilatation in Carotid Angioplasty. Pak Heart J 2020;53(03):263-268.
https://doi.org/10.47144/phj.v53i3.1969

ABSTRACT

Objective: In carotid angioplasty a lot of interventionists avoid predilatation or perform predilatation using smaller diameter balloons to avoid distal embolization. The objective of our study was to determine the procedural safety and complications of predilatation of carotid artery using adequate diameter balloon in patients undergoing angioplasty.

Methodology: Symptomatic patients with greater than 50% common carotid artery (CCA) or internal carotid artery (ICA) stenosis, asymptomatic patients with 80% or more carotid stenosis, asymptomatic patients planned for Coronary Artery Bypass Graft Surgery (CABG) with bilateral severe carotid stenosis (70-99%) or a unilateral severe carotid stenosis with a contralateral occlusion undergoing CABG, were selected for carotid artery angioplasty. Cerebral angiogram was performed before and after carotid intervention.

Results: A total of 25 patients were included in this study. Adequate diameter balloon used for predilatation before stenting in all cases. Post dilatation was required in 6 (24%) patients. Distal embolic protection device was used in all patients. No complication was seen after predilatation in any case. No mortality or neurological deficit was seen in the study.

Conclusion: This study shows that proper predilatation with adequate diameter balloon, sized according to diameter of internal carotid artery, before carotid stent implantation is an effective and safe procedure. We believe that this leads to good stent expansion and full apposition with better long term outcomes. Moreover it is now important to adequately predilate carotid arteries, for proper sizing of carotid stents with close cell design, to avoid unnecessary longitudinal stent lengthening due to inadequately prepared carotid bed.

Keywords: Carotid angioplasty, Balloon, carotid stenosis

INTRODUCTION

Cerebrovascular accident is the third leading reason of mortality in the United States. Almost 750,000 people have a stroke every year, costing an almost $45 billion in treatment and loss of productivity.[1] Moderate to severe (50%–99%) carotid artery stenosis is an important public health concern.[2] Internal carotid artery stenosis causes almost 7-10 % of ischemic strokes.[3] Extracranial carotid artery stenosis is cause of approximately 20-30% of ischemic strokes. Previously, carotid artery stenosis was treated with carotid endarterectomy. However, with the low periprocedural complication rate and the increased durability, carotid artery stenting has made it a good alternative treatment approach[4] and this must be compared against the increased risk of procedural myocardial infarction, cranial nerve palsy, and access-site hematoma associated with endarterectomy.[5]

The overall technical success rate of carotid artery stenting is greater than 95%. Procedure related mortality rate varies with experience of operators but in one study suggested it as 0.6 to 4.5%, with major stroke rate being 0 to 4.5% and minor stroke rate 0 to 6.5% and rate of restenosis at 6 month as less than 5 %.[1]

CAS with embolic protection device as compared to carotid endarterectomy is considered not only feasible but also safe in asymptomatic patients undergoing CABG surgery.[6] Previous clinical trials performed suggested that patients having average or high risk for surgical complications will benefit more from carotid artery stenting with embolic protection as compared to carotid endarterectomy.[7]

The CREST Carotid Revascularization Endarterectomy vs. Stenting Trial showed that both carotid artery stenting and carotid endarterectomy had similar rates of death and stroke. During the 30 day periprocedural period however carotid angioplasty has greater risk of stroke in patients aged more than 70 years whereas patients with carotid endarterectomy had higher chances of MI.[8] ·Carotid endarterectomy (CEA) is recommended for patients with greater than 70% internal carotid artery stenosis if patients are at low risk for perioperative stroke, myocardial infarction (MI), or death.[9] The SAPPHIRE Worldwide Registry supports CAS as an alternative to CEA in patients who are at high-risk for surgery due to anatomic risk factors.[10]

Studies have shown that balloon predilatation when performed in carotid artery stenting has acceptable periprocedural complication rates[11] but most of the studies done on predilatation for carotid stenting used 2-3mm diameter balloons and therefore the purpose of our study is to use adequate diameter balloons for predilatation, sized according to diameter of internal carotid artery and to look at its procedural safety and complications.

METHODOLOGY

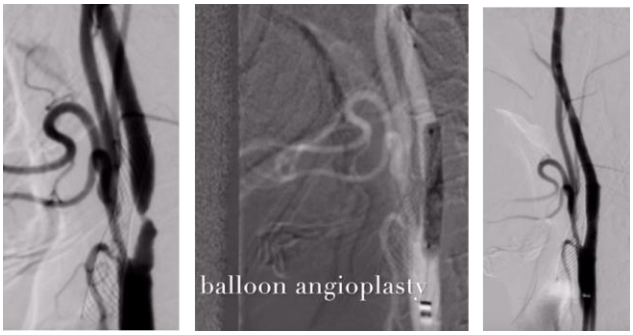
This is a cross sectional study, conducted at Rawalpindi Institute of Cardiology. Permission was taken from hospital ethical committee prior to conducting the study. Informed consent was taken from all the patients. Symptomatic patients with greater than 50% common carotid artery (CCA) or internal carotid artery (ICA) stenosis, asymptomatic patients with 80% or more carotid stenosis, neurologically asymptomatic patients planned for Coronary Artery Bypass Graft Surgery (CABG) with bilateral severe carotid stenosis (70-99%) or a unilateral severe carotid stenosis with a contralateral occlusion undergoing CABG, were selected for carotid artery angioplasty and were included in this study. Candidates for Carotid intervention amongst CABG candidates were selected based on above criteria which was adopted from ACCF/AHA CABG guidelines.[12] In CABG patients with bilateral disease, only single carotid artery with more severe stenosis was intervened with angioplasty as per ACCF/AHA CABG guidelines.[12] Complete carotid artery occlusions were not intervened.

All patients with significant carotid stenosis and candidates for carotid intervention were seen by vascular surgeon for consideration of carotid endarterectomy and carotid angioplasty was only carried out on those who were rejected by vascular surgeon due to any technical reason or comorbidities or patient refused endarterectomy and opted for carotid angioplasty. Post carotid stenting, CABG was postponed for one month to complete dual antiplatelet therapy duration after which clopidogrel was stopped and patients could undergo

CABG without increased risk of bleeding. Neurologic examination was performed at baseline pre-procedure, immediately post-procedure and before hospital discharge. Cerebral angiogram was performed before and after carotid intervention to confirm patency of cerebral vessels. Anti-hypertensives were discontinued 24 hours prior to procedure. 300mg Aspirin and 600mg clopidogrel were given as loading doses before procedure. Heparin intravenously 80 units/Kg were given at the start of procedure to all patients. All carotid interventions were performed by interventional cardiologists via trans-femoral access through 8F guide catheters. Accunet distal protection device (Abbott Vascular) was deployed as the first step before predilatation. However in very critical carotid stenosis where distal protection device could not cross, predilatation with 2mm coronary balloons at nominal pressure was performed followed by deployment of distal protection device. Carotid predilatation was then performed in all patients using adequate diameter Viatrac 14 peripheral balloons (Abbott vascular), sized according to dimeter of internal carotid artery to prepare the carotid bed proper to accept the stent. Carotid artery sizing was done on angiographic eye balling. TPM was not implanted in any case but prophylactic 0.5-1mg atropine was given to all cases prior to predilatation to avoid significant bradycardia in response to baroreceptor reflex after predilatation in carotid bulb region. In case of hypotension before predilatation, dopamine infusion was initiated to raise the blood pressure to prevent significant hypotension as a result of baroreceptor response to balloon predilatation. Acculink self-expanding carotid stent (Abbott Vascular), sized according to diameter of common carotid artery, was then deployed. Post dilatation of stent was only reserved for cases with significant residual stenosis. Distal protection device was then removed at the end of the procedure. Final check cerebral angiogram was then performed to look at the patency of cerebral vessels. Anti-hypertensive medication that was withheld 24 hours prior to the procedure was immediately restarted post procedure to keep the blood pressure under control to avoid hyper perfusion syndrome. All patients were advised dual antiplatelet therapy aspirin 75mg daily and clopidogrel 75mg daily for one month followed by lifelong aspirin.

Data analysis was done using SPSS version 24, Frequency and percentages were computed for qualitative variables that are gender, site of intervention balloon sizes and complications. Mean and standard deviations were calculated for quantitative variables such as age.

Figure 1: Right carotid intervention with predilatation using 5x20mm balloon and then stent. Also visible is Left carotid stent from previous intervention



RESULTS

A total of 25 patients were included in this study. Mean age with S.D of patients enrolled in the study was 65 ±8.38 years. 24(96%) patients were male and 1(4%) patient was female. Carotid angioplasty was done on right ICA in 14(56%) patients and left ICA in 11(44%) patients. 5 (20%) patient were detected on carotid doppler during pre CABG work up and out of these 4 patients had bilateral severe carotid disease and 1 patient had one sided total occlusion and other side 80% carotid stenosis. Adequate diameter balloons, sized according to diameter of internal carotid artery, mostly 5x20mm or 4.5x20mm were used for predilatation before stenting in all cases. Post dilatation was required in 6 (24%) patients. Distal embolic protection device, ACCUNET (Abbott Vascular), was used in all patients. Accunet 6.5mm was the commonest size used, a decision based upon diameter of internal carotid artery. No complication was seen after predilatation in any case. However transient carotid artery spasm post stenting was seen in one case and resolved with intra carotid medication. Slow flow after post dilatation of stent was seen in one case which resolved spontaneously on removal of distal protection device. No procedural or in hospital mortality or neurological deficit was seen in the study.

Table 1: Site of Carotid Intervention

SITE	Frequency	Percentage
Left ICA	11	44%
Right ICA	14	56%
Total	25	100%

Table 2: Balloon Size Used for Predilatation and Postdilatation

Balloon size	Frequency	Percentage
Predilatation		
4.5x20mm	7	28
5.0x18mm	1	4
5.0x20mm	17	68
Postdilatation		
5.0x20mm	6	24

DISCUSSION

Carotid artery stenting (CAS) is now well established as a safe and effective procedure for treatment of carotid artery stenosis. Studies such as CAPTURE trial have shown no significant difference between carotid stenting and endarterectomy procedure in terms of composite primary endpoint of periprocedural stroke, MI or death and subsequent ipsilateral stroke.[13] The Lexington study, CREST and ACT-1 state that after the perioperative period had elapsed, there was no change in rates of late ipsilateral stroke, suggesting that CAS was as affective as CEA.[14] Carotid artery lesions that are stenotic may also be heavily calcific or have a fibrous scar from past endarterectomy. A brief predilatation with balloons is helpful.[15] Experimental work done by Ohki etal showed that not only greater embolic debri was released with primary stenting without predilatation but also when lesion was predilated with large peripheral balloons which tend to form traumatic wings after deflation . Balloon predilatation is considered to create a small passage which facilitates stent delivery. Certain practices recommend using low profile coronary balloons as these balloons rewrap well without residual wings causing less risk of trauma to plaque during withdrawal of balloon. In case stenotic lesion is pre-occlusive gradual step up of balloon size is recommended by Nadeem ul Mubarak in his book “Carotid artery stenting Current practice and techniques” to minimize plaque disruption and distal embolization. In such scenarios initially predilatation is performed using 2x 40mm balloon followed by a second predilatation using 4x40mm balloon and in rare cases of calcific lesions a large 5mm balloon is used.[16] It gave good end point results as adequate predilatation not only helps in preparing path for easing stent crossing but helps in dilating calcific lesions which would not be possible with direct stenting. As forceful crossing of stents can cause major dissections in ICA, primary stenting is associated with scissoring effect of the stent struts on the plaque.[10] In our practice as seen in this study we size the predilatation balloon according to the size of internal carotid artery but never went beyond 5mm diameter and only carry out this predilatation after deployment of distal protection device and we did not see any visible distal embolization or no flow etc. as a result of this predilatation. However as mentioned above in materials and methods, if the carotid artery stenosis is very critical and it is not possible to easily pass the distal protection device across the lesion then we go with sequential predilatation procedure, whereby we predilate first with a small 2mm coronary balloon and create a small passage for the distal protection device to go across and then after its deployment we used adequately sized balloon for proper predilatation of the stenotic lesion.

According to a study published in 2012 in JACC risk of stroke and death during carotid artery stenting is more frequently associated in cases where cerebral protection is not used rather than predilatation.[17] We used distal protection device in all of our carotid interventions and reason for not using proximal protection device was non-availability of the device in our institution at the time of this study. Post dilatation is considered to be associated with thromboembolic complications therefore several times carotid artery stenting is performed without post dilatation. Most emboli are produced in post dilatation step of procedure which occurs when balloon pushes struts of the stent against atheromatous plaque.[18] Carotid artery stenting without post dilatation is considered safe and is associated with less risk of stroke.[19] We perform adequate pre-dilatation and hence avoid the risk of distal embolization due to cheese cutting effect associated with post dilatation after stent implantation. In our study we required postdilatation in only six patients (24%) and we did see one slow flow as a result of post-dilatation as explained in result section. The main purpose of cerebral protection device is to prevent embolization of atheromatous debris into cerebral circulation during the whole carotid intervention[20] and therefore we remove the protection device only at the end of the procedure as the last step. Stroke is the most feared complication of carotid revascularization that reduces the benefit of the procedure in overall stroke prevention[21] but we did not encounter this complication in any of our case. Vasospasm may be faced before or just after filter removal, and this is usually managed by observing. Rarely, the administration of a vasodilator is required. Nitroglycerin is the most commonly used drug to

treat flow-limiting vasospasm[22] and we saw this complication in only one case which resolved spontaneously with conservative approach. No reflow or slow flow as seen in one of our cases may be encountered during carotid intervention and usually occurs after post dilatation of stent. This is promptly treated with aspiration of blood column in the internal carotid artery to remove any clot or thrombus or removal of filter distal protection device in order to prevent distal embolization.[23]

This study is limited by the fact it is not a randomized control trial and that is what is required in future to compare safety and clinical outcomes of carotid angioplasty with adequate size carotid predilatation vs. direct carotid stenting.

CONCLUSION

This study shows that proper predilatation with adequate diameter balloon, sized according to diameter of internal carotid artery, before carotid stent implantation is an effective and safe procedure. We believe that this leads to good stent expansion and full apposition with better long term outcomes. Moreover it is now important to adequately predilate carotid arteries for proper sizing of carotid stents to avoid unnecessary longitudinal stent lengthening due to inadequately prepared carotid bed with closed cell type of stents.

REFERENCES

1. Higashida RT, Meyers PM, Phatouros CC, Connors JJ 3rd, Barr JD, Sacks D. Technology Assessment Committees of the American Society of Interventional and Therapeutic Neuroradiology and the Society of Interventional Radiology. Reporting standards for carotid artery angioplasty and stent placement. J Vasc Interv Radiol. 2004;15(5):421-2.
2. Abbott AL, Paraskevas KI, Kakkos SK, Golledge J, Eckstein HH, Diaz-Sandoval LJ, et al. Systematic review of guidelines for the management of asymptomatic and symptomatic carotid stenosis. Stroke. 2015;46(11):3288-301.
3. Khandelwal P, Chaturvedi S. Carotid disease management: surgery, stenting, or medication. Curr Cardiol Rep. 2015;17(9):625.
4. Dieter R S,Laird JR, Carotid Artery Stenting: Update Int J Cardiovasc Intervent. 2005;7(3):126-33.
5. Bonati LH, Dobson J, Featherstone RL, Ederle J, van der Worp HB, de Borst GJ, et al. Long-term outcomes after stenting versus endarterectomy for treatment of symptomatic carotid stenosis: the International Carotid Stenting Study (ICSS) randomised trial. Lancet. 2015;385(9967):529-38.
6. Polydorou AD, Megaloikonomos P, Moutiris JA, Polydorou V, Antypa E, Testembasi E et al. Carotid angioplasty in asymptomatic patients undergoing CABG surgery. Int Angiol. 2010;29(3):239-43.
7. Rosenfield K, Matsumura JS, Chaturvedi S, Riles T, Ansel GM, Metzger DC, et al. Randomized Trial of Stent versus Surgery for Asymptomatic Carotid Stenosis. N Engl J Med. 2016;374(11):1011-20.
8. Gahremanpour A, Perin EC, Silva G. Carotid Artery Stenting versus Endarterectomy Texas Heart Inst J. 2012;39(4):474-87
9. Moresoli P, Habib B, Reynier P, Secrest MH, Eisenberg MJ, Filion KB. Carotid Stenting Versus Endarterectomy for Asymptomatic Carotid Artery Stenosis: A Systematic Review and Meta-Analysis. Stroke. 2017;48(8):2150-7.
10. Massop D, Dave R, Metzger C, Bachinsky W, Solis M, Shah R, et al. Stenting and angioplasty with protection in patients at high-risk for endarterectomy: SAPPHIRE Worldwide Registry first 2,001 patients. Catheter Cardiovasc Interv. 2009;73(2):129-36.
11. Sahin M, Yazicioglu MV, Acar G, Demir S, Kalkan ME, Ozkan B, et al. Safety of balloon pre-dilatation in the treatment of severe carotid artery stenosis. Eur Rev Med Pharmacol Sci. 2013;17(6):788-93.
12. Hillis LD, Smith PK, Anderson JL, Bittl JA, Bridges CR, Byrne JG, et al. 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2011;124(23):e652-735.
13. Khosravi A, Bideh FZ, Roghani F, Saadatnia M, Khorvash F, Nejati M, et al .Carotid arterial stent implantation follow-up and results in 50 patients: preliminary report. Electron Physician. 2018;10(2):6400-5.
14. Naylor AR. Endarterectomy versus stenting for stroke prevention. Stroke Vasc Neurol. 2018 Feb 24;3(2):101-6.
15. Exaire JE, Yadav JS. Predilatation, stent selection, and postdilatation. In: Bhatt DL, editor. Guide to Peripheral and Cerebrovascular Intervention. London: Remedica; 2004. Available from: https://www.ncbi.nlm.nih.gov/books/NBK27343/
16. Al-Mubarak N, Roubin GS, Iyer SS, Vitek JJ, New G. Techniques of carotid artery stenting:

the state of the art. Semin Vasc Surg. 2000;13(2):117-29.
17. Kypta A, Buchmayr G, Grund M, Kammler J, Kerschner K, Leisch F, et al. TCT-197 Carotid Artery Stenting with or without Predilatation, protected or unprotected: Acute Results and Complications. J Am Coll Cardiol. 2012;60(17 Supplement):B58.
18. Ogata A, Sonobe M, Kato N, Yamazaki T, Kasuya H, Ikeda G, et al. Carotid artery stenting without post-stenting balloon dilatation. J Neurointerv Surg. 2014;6(7):517-20.
19. Spacek M, Zimolova P, Veselka J. Carotid artery stenting without post-dilation. J Interv Cardiol. 2012;25(2):190-6.
20. Chaer, RA, Trocciola S, DeRubertis B, Lin SC, Kent C, Faries PL. Cerebral ischemia associated with PercuSurge balloon occlusion balloon during carotid stenting: Incidence and possible mechanisms. J Vasc Surg. 2006;43:946-52
21. Huibers A, Calvet D, Kennedy F, Czuriga-Kovács KR, Featherstone RL, Moll FL, et al. Mechanism of Procedural Stroke Following Carotid Endarterectomy or Carotid Artery Stenting Within the International Carotid Stenting Study (ICSS) Randomised Trial. Eur J Vasc Endovasc Surg. 2015;50(3):281-8.
22. Malik RK, Vouyouka A, Salloum A, Marin ML, Faries PL. Tips and techniques in carotid artery stenting. J Vasc Surg. 2009;50(1):216-20.
23. Roffi M, Baumgartner RW, Eberli FR. Images in cardiology. No reflow during carotid stenting. Heart. 2006;92(4):538.