

Percutaneous Angioplasty and Stenting of Carotid Artery: Study of 18 Cases

NAM Momenuzzaman, F Begam, KN Khan, A Dey, DK Adhikary, ZM Ilius, KM Sohail, F Haque
MU Amin, R Rahman, Sk. Mallick, SMZ Haque
Department of Cardiology, United Hospital, Dhaka.

Abstract:

Key words:
Carotid artery
disease; Carotid
angioplasty

Background: Carotid angioplasty & stenting is becoming an emerging therapeutic option for carotid revascularization. The use of cerebral protection system has expanded the area of application of the procedure worldwide.

Purpose: To assess the feasibility, success rate, safety as well as in-hospital & early 30 days outcome in patients undergoing percutaneous carotid intervention.

Methods: A retrospective, observational study where a total of 18 (Eighteen) consecutive patients who presented with symptomatic and > 70 % carotid artery stenosis & asymptomatic but > 90% stenosis underwent percutaneous carotid intervention. All of them had coronary artery disease; CABG was done in 3 patients & PCI in 9 patients. Three of them had previous stroke (Ischemic) & 7 had TIA.

Results: Technical and angiographic success was achieved in all patients. Carotid artery obstruction diminishes from 85 ± 14 % to 10 ± 5 % ($p < .001$). Mean lesion length was 12 ± 3 mm and mean time of carotid occlusion during balloon inflation was 10 ± 2.5 sec. distal protection devices used in all patients. No major stroke or death occurred during procedure. One patient developed No-flow because of obstruction of distal protection device which was managed by thrombosuction. One patient developed TIA. All patients were discharged from hospital after an average of 3 days & all of them were prescribed dual antiplatelet therapy for 6 months. During follow-up one patient died secondary to acute myocardial infarction and one patient developed major stroke.

Conclusion: Percutaneous angioplasty and stenting associated with distal protective devices appear feasible, effective and almost safe endovascular treatment modality for carotid artery stenosis.

(*Cardiovasc. j.* 2010; 2(2) : 218-222)

Introduction:

Cerebrovascular disease is the third leading cause of death in United States behind heart disease & cancer and it is associated with 700000 strokes per year resulting in huge morbidity & a significant economic burden to the society.¹ Several studies have shown that ischemic events are four times more frequent than hemorrhagic events and approximately 20-30% of all ischemic strokes are attributable to extracranial carotid occlusive disease.² Consequently management of carotid artery stenosis has been intensely studied for decades.

Carotid endarterectomy (CEA) has been shown to be superior to medical treatment in reducing overall risk of stroke in patients with CAS.^{3,4} Although endarterectomy is considered to be the gold standard treatment for CAS, the approach is not free of complication. In the NACET (North

American Symptomatic Carotid Endarterectomy Trial) study population, 5.8% of patients suffered from perioperative stroke & death & it was also reported that subgroups of patients at high risk had mortality & morbidity rates of upto 18%.^{3,5} Carotid angioplasty is an evolving technology to treat carotid artery disease. Since the first carotid angioplasty was performed by Kerber in 1980, the number of procedures has constantly been increasing. Although early studies of carotid angioplasty have been associated with a higher stroke risk following angioplasty when compared to CEA, recent clinical trials have suggested the equivalency of carotid angioplasty with CEA as a consequence of refinements in carotid angioplasty technique.^{6,7}

The SAPPHERE trial has received greatest attention in this regard. This prospective trial evaluating high risk patients with CAS randomized

to either carotid stenting or CEA, revealed a statistical benefit in major adverse event rate (combined death, stroke, acute myocardial infarction) in favour of carotid stenting (5.8%) when compared to CEA (12.6%) at 30 days.⁶ The CARESS trial, a randomized trial, demonstrated that there was no significant difference in 30 day combined all cause mortality & stroke rate between carotid stenting (2%) and CEA (2%). This report concluded that the 30 days risk of stroke or death following carotid stenting with cerebral protection devices is equivalent to CEA. A recent update of this trial has indicated that there was no significant difference in one-year combined all cause mortality & stroke rate between CEA (13.6%) & carotid stenting (10%).⁸ Significantly the CARESS trial included a patient population that was not limited to high risk patients. Inclusion of all patients as candidates for carotid artery angioplasty & stenting, not just high risk patients, is the trend in this field.

In this paper we present our experience about the feasibility, efficacy, safety and in-hospital & early 30 days clinical outcome in first 18 patients who underwent percutaneous carotid intervention.

Materials and Methods:

Patient population-

From August 2003 to July 2008, a total of 18 patients (16 male, 2 female; mean age, 55 + 5 years; age range, 49- 70 years) were undergone carotid angioplasty & stenting for carotid occlusive disease. Neurological status of all patients was evaluated before & after the procedure. Those patients with Ischaemic heart disease presented with previous ischaemic cerebral events (stroke, transient ischaemic attack etc.) were selected for carotid angiogram and patients with angiographic evidence of > 70% diameter stenosis were selected for carotid stenting. All patients were on dual antiplatelet therapy (DAT) with aspirin (75 mg/day) & clopidogrel (75 mg/day), starting at least 72 hours before the procedure. DAT were continued for at least six months after carotid artery stenting.

All patients received detailed information about potential risks & benefit of the procedure and an informed written consent was taken in all cases. Exclusion criteria included patient unwillingness or inability to give informed consent, intracranial haemorrhage, known malignant tumor, severe renal failure, and allergy to contrast media.

Procedure:

Under local anaesthesia, percutaneous access was gained with the seldinger technique through the right femoral artery or rarely through left femoral artery. A bolus of unfractionated heparin (70 IU/kg) was given intravenously; further boluses were given as needed to maintain the activated clotting time between 200- 250 seconds. Blood pressure & ECG were monitored continuously. Glyceryl trinitrate, atropine, and positive inotropic drugs were also readily available.

Angiography of the extracranial carotid systems, as well as of the intracranial circulation was done routinely in standard projections. The patient's neurological status was monitored constantly throughout the procedure. During stenting. Distal protection devices was used in all cases. Self expandable nitinol stents were deployed and then postdilated with a balloon according to the size of the internal carotid artery in some cases.

After the procedure, all patients were monitored in the intensive care unit overnight. Usually the sheath was removed on the same day after the activated clotting time returned to normal and the patients were routinely discharged on the 2nd or 3rd day after intervention. The patients were followed up carefully for any neurological events one month after the procedure.

Results:

Demographic and clinical characteristics of the patients-

Demographic & clinical characteristics of the patients are given in table-I. The mean age of the population was 55 (+5.5) years. Among the population, 14 patients had diabetes mellitus & Dyslipidaemia, 12 patients were smoker and same no. of patients had history of hypertension. Eight patients had positive family history of IHD.

All the patients in this study had coronary artery disease (CAD). Among them, nine had undergone PCI, 3 patients undergone CABG and rest were on medical management. Regarding neurological symptoms, in this study 7 patients had history of transient ischaemic attack (TIA), 6 patients had suffered from previous cerebral ischaemic strokes, 3 patients had history of syncope and others had nonspecific symptom like vertigo, dizziness & presyncope.

Table-I
Demographic Profile and Risk Factors

| | Sex | No | % |
|-----------------------|----------|-----------|-----|
| Age (years) | Male | 16 | 89 |
| | Female | 2 | 11 |
| | 0 | | |
| Age (years) | Range | 50-70 | |
| | Mean | 55 (±5.5) | |
| CAD (AMI, PTCA, CABG) | | 18 | 100 |
| Diabetes | | 14 | 78 |
| HTN | | 12 | 67 |
| Dyslipidaemia | | 14 | 78 |
| Smoking | Yes / No | 12 / 06 | |
| Positive FH | | 8 | |

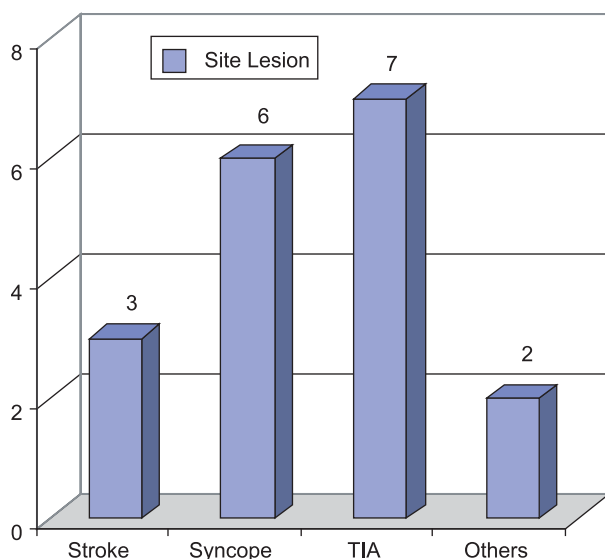


Fig-1: Initial Neurological presentation.

Procedural & angiographic characteristics:

These data are given in table-II. In this study, 7 patients had stenosis in right carotid system, 9 patients had stenosis in left carotid system and rest 2 had stenosis in both carotid system. Baseline lesion stenosis was 85 % (±8.8) in right carotid & 86% (±11.1) in left carotid system. Almost all the lesions were located at bifurcation of common carotid artery & proximal part of internal carotid artery.

Angiographic success was obtained in almost all the patients (100%) with mean residual stenosis of 10(±5)%. Predilatation was necessary to deliver the distal protection devices in 6 patients. We used distal protection devices in all the cases

(Angioguard & Spider). Self expandable Nitinol stents were used in all the cases according to the size of the CCA & ICA. In stent balloon dilatation was necessary in all patients.

Procedural success was attained in all the cases. During procedure, 6 patients developed transient bradycardia & hypotension at time of balloon catheter inflation in carotid stents which was managed by atropine Inj. & I/V saline infusion and vasopressor. No patient required temporary pacemaker. One patient developed drowsiness, disorientation & restless during procedure due to no-flow phenomenon because of blockage of protection device by atheromatous debris which was managed by thrombosuction catheter device. Two patients developed headache after placement of stent probably due to hyperperfusion syndrome. All the patients leave the hospital without any neurological sequelae after an average of 2.5 days.

Table-II
Procedural characteristics.

| Involved Vessel | Distal Protection Device | Stent size Diameter (mm) | Stent size Length (mm) | Post stenosis procedural % |
|-----------------|--------------------------|--------------------------|------------------------|----------------------------|
| Rt Carotid | yes | 6 / 7 | 30 / 40 | 5 (8.4) |
| Lt Carotid | yes | 6 / 7 | 30/40 | 10 (6.2) |
| Both | yes | 6 / 7 | 30/40 | 5 (10.6) |

Table-III
Lesion morphology (Angiographic)

| Vessel involved | No | Stenosis | Site of Stenosis | |
|-----------------|----|------------|------------------|-----------------------|
| | | | Proximal | Ostio-proximal to ICA |
| Right Carotid | 7 | 85 (8.8) | 0 | 7 |
| Left carotid | 9 | 86 (11.1) | 1 | 8 |
| Both | 2 | 86.2 (9.2) | 0 | 2 |

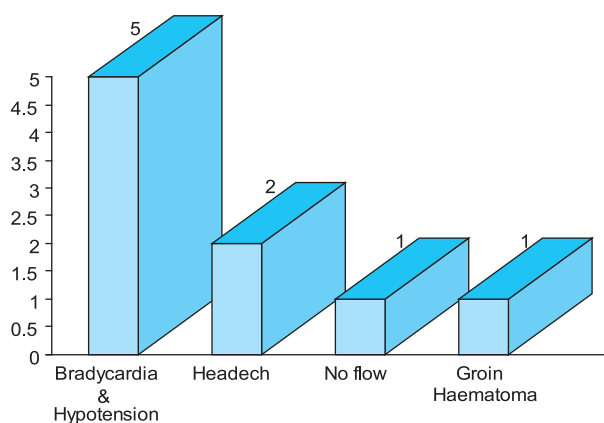


Fig-2: Peri-procedural complication

Follow-Up:

All the patients were followed up later on. During one month follow-up, one patient developed TIA. One patient who experienced No-flow during procedure developed major stroke and that patient later on died of complications from stroke. All other remaining patients were asymptomatic & did not develop any neurological complication.

Discussion:

The aim of this paper was to report our experience with carotid angioplasty & stenting in first 18 patients. The study population consisted of all the patients in whom carotid stenting was undertaken. All the patients in our study had CAD as observed in other reports of carotid stenting where there was a high incidence of concomitant CAD.^{9,10} Although all of our patients had CAD, no periprocedural cardiac complications were observed. The less invasive approach associated with percutaneous treatment and the fact that it is performed under local anaesthesia, seems to limit cardiac complications in patients with combined carotid & coronary artery disease. It is noted that major adverse events (stroke, acute myocardial infarction, or death) have been reported in 8 – 10% of patients with severe CAD undergoing carotid endarterectomy.¹¹ In the NASCET trial, cardiac complications occurred in 4% of the patients.³

Angiographic & technical success was excellent in our study. Our complication rate, consisting of one patient with TIA & one patient with major stroke, is similar to the rates reported by other investigator.^{9,10,12,13} and may be better than those reported in carotid endarterectomy trials in patients with similar clinical characteristics. Neither the presence of concomitant severe CAD nor the patient's age was predictors of in-hospital events.

During procedure distal protection devices were used in all the cases and a significant reduction in immediate complications has been reported when distal protection devices (DPD) are used.¹⁴ In our study, one patient developed no-flow during procedure due to blockage of pores of DPD by atheromatous debris and that patient later on developed major stroke. The possibility of late onset neurological complications after carotid stenting is reported by Wholey and colleagues.¹⁵

Carotid stenting carries the risk of vagal stimulation in the carotid sinus at the time of balloon inflation, resulting in bradycardia & hypotension or even asystole. These clinical signs normally respond promptly to balloon deflation, asking the patient to cough, or intravenous injection of atropine or vasopressor infusion. The six patients in our study with bradycardia are in contrast with data from other authors,^{12,16} who reported significant bradycardia in 67% and 71% of patients, respectively. Of the 33 patients in the series of Smedema and Saaiman, three developed asystole for a maximum of 10 seconds and four experienced bradycardia for a maximum of 20 seconds.¹⁷ The in-hospital and one month follow up results in our population are similar to those reported by others.^{9,12,18}

Conclusion:

Carotid angioplasty with stent implantation appears to be a reliable, safe and efficient method of treating occlusive carotid artery disease. In our experience, the risks do not seem greater than those of surgery and might be lower in patients who are at high surgical risk. However carotid angioplasty is technically demanding and should be performed by well trained multidisciplinary teams using a clearly defined protocol for patient selection. The results of ongoing randomized studies comparing surgery and angioplasty will help to define further the role of stenting in the treatment of carotid artery stenosis especially in asymptomatic carotid occlusive disease.

References:

1. Thom T, Hasase N, Rosamond W, et al. Heart disease and stroke statistics- 2006 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation* 2006; 113: e85-151.
2. Wolf PA, Kannel WB, McGee PC. Epidemiology of strokes in North America. In: Barnett HJM, Stein BM, Mohr JP, Yatsu FM, eds. *Stroke: Pathology, Diagnosis and Management*. Vol 1. Churchill Livingstone, 1986:1929.
3. Barnett HJ, Taylor DW, Eliasziw M, et al. Benefit of carotid endarterectomy in patients with symptomatic moderate or severe stenosis. North American Symptomatic Carotid Endarterectomy Trial Collaborators. *N Eng J Med* 1998; 339: 1415-25.
4. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. *JAMA* 1995; 273: 1421-8.

5. Winslow CM, Solomon DH, Chassin MR, et al. The appropriateness of carotid endarterectomy. *N Eng J Med* 1988; 318: 721-7.
6. Yadav, Jay S, Wholey, Mark H, Kuntz, Richard E, Pierre et al. Protected Carotid artery Stenting versus Endarterectomy in High Risk Patients. *N Eng J Med* 2004; 351 (15): 1493-1501.
7. CAVATAS investigators. Endovascular versus surgical treatment in patients with carotid stenosis in the Carotid & Vertebral Artery Transluminal Angioplasty Stenting (CAVATAS); A randomized trial. *The Lancet* 2001; 357: 1729-1737
8. CARESS Steering Committee. Carotid Revascularization using Endarterectomy or Stenting Systems (CARESS) ; Phase I clinical trial. *J Endovasc Ther* 2003; 10(6): 1021-30
9. Henry M, Amor M, Henry I, et al. Angioplasty and stenting of the external carotid arteries. *J Endovasc Surg* 1998; 5: 293-304.
10. Shawl F, Kadro W, Domanski MJ, et al. Safety and efficacy of elective carotid artery stenting in high risk patients. *J Am Coll Cardiol* 2000; 35: 1721-8.
11. Al-Mubarak N, Roubin GS, Liu MW, et al. Early results of percutaneous intervention for severe coexisting carotid and coronary artery disease. *Am J Cardiol* 1999; 84: 600-2,A9.
12. Yadov JS, Roubin GS, Iyer S, et al. Elective stenting of extracranial carotid arteries. *Circulation* 1997; 95: 376-81.
13. Mathur A, Roubin GS, Iyer SS, et al. Predictors of stroke complicating carotid artery stenting. *Circulation* 1998; 97: 1239-45.
14. Reimers B, Carvaja N, Mashiri S, et al. Cerebral protection with filter device during carotid artery stenting. *Circulation* 2001; 104: 12-15.
15. Wholey MH, Tan WA, Toursarkissian B, et al. Management of neurological complication of carotid artery stenting. *J Endovasc Ther* 2001; 8: 341-53.
16. Gil-Peralta A, Mayol A, Gonzalez Marcos JR, et al. Percutaneous transluminal angioplasty of the symptomatic atherosclerotic carotid arteries. *Stroke* 1996; 27: 2271-2273.
17. Smedema JP, Saaiman A. Carotid stent-assisted angioplasty. *S Afr Med J* 1997; 87: 9-14.
18. Roubin GS, New G, Iyer S, et al. Immediate and late clinical outcome of carotid artery stenting in patients with symptomatic and asymptomatic carotid artery stenosis: a 5 years prospective analysis. *Circulation* 2001; 103: 532-7.