January 2008

Endovascular stenting for carotid artery stenosis: results of local experience at Aga Khan University Hospital, Karachi

Muhammad Azeem Uddin
Aga Khan University, muhammad.azeemuddin@aku.edu

Tanveer ul Haq
Aga Khan University, tanveer.haq@aku.edu

Ishtiaque Ahmed Chishty

Zafar Sajjad
Aga Khan University, zafar.sajjad@aku.edu

Basit Salam
Aga Khan University, basit.salam@aku.edu

Original Article

Endovascular stenting for carotid artery stenosis: Results of local experience at Aga Khan University Hospital, Karachi

Muhammad Azeem Uddin, Tanveer ul Haq, Ishtiaque Ahmed Chishty, Zafar Sajjad, Basit Salam
Department of Radiology, Aga Khan University Hospital, Karachi.

Abstract

Objective: To evaluate the results, complications and initial follow-up of patients after percutaneous stent placement for carotid artery disease.

Methods: A retrospective study was carried out on patients treated with carotid artery stenting at the Radiology Department of Aga Khan University Hospital, Karachi, from September 2002 to December 2005. The patients were selected according to the institutional guidelines for Carotid Angioplasty and stenting. Preliminary angiogram was performed in all patients followed by stent deployment. Distal protection device was used in 12 patients. All patients underwent pre and post procedure independent neurological examinations. Follow-up consisted of serial duplex ultrasonography and clinical assessment.

Results: Total of 18 stentings were carried out on 17 patients, with one patient having bilateral carotid stenting. There were 14 males and 3 females with an age range of 13 to 68 years. Technical success rate of stent deployment was 100%. Two patients developed Transient Ischaemic Attack (TIA) with transient monoparesis. One patient had confusion and TIA (Hemiparesis) during the preliminary angiogram before stenting. One patient acquired asystole during the procedure; however, he recovered with resuscitation. Five patients had transient bradycardia and hypotension. All these patients recovered with conservative therapy. No stroke or death occurred in any of our patients who underwent this procedure.

Conclusion: The initial experience revealed satisfactory results with low morbidity rate (JPMA 58:11;2008).

Introduction

Carotid artery stenosis is responsible for up to 10-30% of all ischaemic strokes.[1] The risk of carotid-related stroke can be significantly reduced by re-establishing the arterial lumen through carotid endarterectomy (CEA). Percutaneous carotid angioplasty with stenting (CAS) has emerged as an alternative to CEA for restoring the patency of the carotid lumen. Preliminary data from clinical trials indicates that CAS has a safety and efficacy profile similar to CEA.[2] Trials are ongoing, however, to settle this question definitively.

CAS has been successfully performed at AKUH since last few years. The cases were performed according to the institutional guidelines and protocols, developed after a consensus meeting held on October 29, 2001 that was attended by a vascular surgeon, radiologist, cardiologist and neurologists.

Patients and Methods:

The diagnosis of carotid artery stenosis was initially established on Carotid Doppler study. MRI or CT scanning of the Brain was carried out to exclude intracranial pathology. Neurological history was taken and the patients underwent detailed neurological examination. The patients undergoing Carotid Artery Stenting (CAS) were selected according to stringent inclusion and exclusion criteria (Table1) based on institutional guidelines for CAS. All the patients identified for CAS had detailed counseling by their neurologist as well as by the interventional neuro-radiologist performing the procedure. The purpose of counseling was to inform the patient and family about this relatively new treatment modality. Patients were educated about procedural indications, costs, potential complications, expected outcomes and possible alternatives. A written informed consent was obtained in all cases.

Basic laboratory investigations were performed before performing complete intra- and extra-cranial 4-vessel cerebral angiograms. These included CBC with platelet counts, serum creatinine, electrolytes, PT and APTT. Anti-hypertensive medications were withheld on day of procedure. Aspirin 325 mg/day was started at least 3 days before procedure and was advised to be continued indefinitely. Clopidogrel 300 mg was given a day prior and 75 mg a day to be taken for 6 weeks post procedure. No Warfarin was used during procedure and if the patient was already on Warfarin then it was discontinued at least 3 days prior and was not resumed until 1 week after. Heparin 3000 - 5000 units were given intravenously during the procedure. Atropine 1 mg stat was given intravenously if any bradycardia was encountered.

All procedures were done electively under local

Table 1. Carotid artery stenting; inclusion and exclusion criteria.

	Inclusion Criteria
1.	Carotid Artery stenosis of 70 - 99%, ipsilateral to hemispheric/retinal ischaemia (TIA, Amaurosis fugax or non-disabling stroke) occurring within the past 6 months.
2.	Asymptomatic carotid artery stenosis of >80% in patients due to undergo coronary artery bypass grafting (CABG).
3.	Carotid dissection / Trauma leading to pseudoaneurysm formation.
	Exclusion Criteria (Absolute)
1.	Symptomatic carotid stenosis of <70%.
2.	Asymptomatic carotid artery stenosis of >80% in patients due to undergo coronary artery bypass grafting (CABG).
3.	Complete carotid occlusion by angiography.
4.	Associated thrombosis in carotid artery.
5.	Associated significant intracranial ICA or MCA stenosis.
6.	Evolving stroke or stroke within the past 48 hours.
7.	Intracranial mass, infection, aneurysm or AVM.
8.	Recent (last 6 months) intracranial hemorrhage.
9.	Severe disabling stroke or dementia (Modified Rankin Score 4 - 6)
	Exclusion Criterias (Relative)
1.	Associated common carotid artery stenosis (Discrete Lesion).
2.	Renal failure (serum creatinine >2 mg %)
3.	Long stenosis (> 5 cm)
4.	Very tortuous carotid artery.
5.	Heavily calcified plaques.
6.	Age > 80 years.
7.	Pre-existing stent within target artery.
8.	Unstable angina.

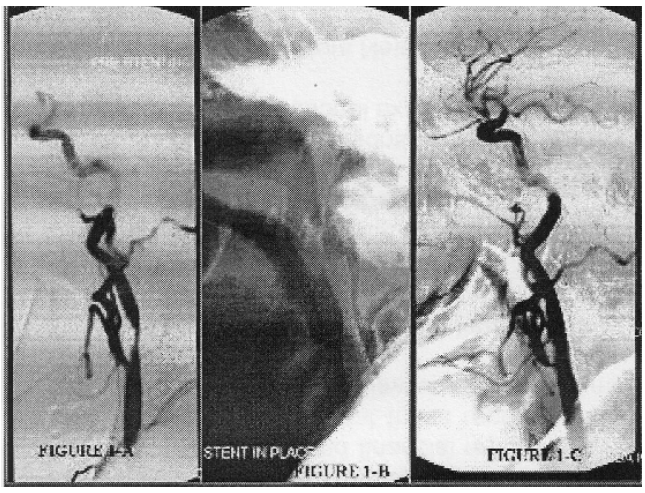

Figure 1 a, b & c. Digital subtraction angiogram (DSA) of Right Carotid Bifurcation showing about 85% stenosis involving proximal internal carotid artery (1-A). Non-subtracted image (1-B) after stent deployment shows residual stenosis. Post dilatation angiogram (1-C) shows no residual stenosis with free flow of contrast.

anaesthesia; conscious sedation was needed in some cases. Preliminary angiogram was performed in all patients using right femoral approach. A distal protection device (Angioguard, Cordis) was then deployed just proximal to the petrous portion of internal carotid Artery followed by stent deployment. Self-Expanding Nitinol Stent (SMART, Cordis) was used in all patients except the two patients with post traumatic pseudoaneurysm in which a balloon mounted covered stent-graft was deployed. Post deployment balloon dilatation was performed in all patients (Figure 1). All patients underwent pre and post procedure independent neurological examinations. Follow-up consisted of serial duplex ultrasonography and clinical assessment at 3, 6 and 12 months after the procedure. The duplex ultrasonography was used to look for the patency of stent and development of in-stent stenosis while the clinical benefit was judged by clinical assessment.

Results

Seventeen patients underwent Carotid Artery Stenting (Table 2). There was a significant male predominance with a male to female ratio of 14:3. The age range was from 13 to 68 years. Fifteen of these patients were symptomatic (TIAs) while two had asymptomatic carotid artery stenosis. One of these two had a post traumatic pseudoaneurysm while the other had a total (100%) occlusion on the contra lateral side. Total of 18 stentings were carried out on 17 patients, with one patient having bilateral carotid stenting.

Preliminary angiography showed 15 patients to have

Table 2. Results

Description	Data
Total # of Patients.	17
Male : Female	14 : 3
Age Range (years)	13 - 68
Symptomatic / Asymptomatic	15 / 2
Athero-sclerotic Disease	15
Pseudo-aneurysm	2
Total # of Stenting	18
Technical Success	100%

Table 3. Complications

Description	# of Patients
Minor	
TIAs	2
Transient Hypotension	5
Transient Bradycardia	5
Transient Asystole	1
Major	
Stroke	0
Procedure Related Death	0

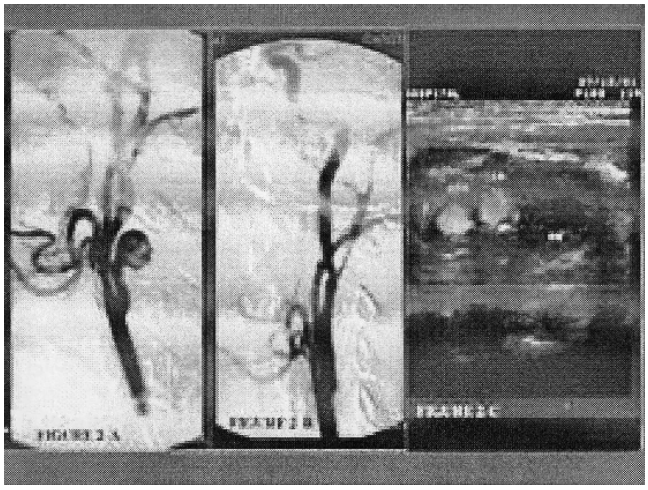

Figure 2 a, b & c. Patient with post-traumatic pseudoaneurysm involving left ICA. Digital Subtraction Angiogram film of left carotid bifurcation before (2-A) and after (2-B) stent deployment. Follow-up Carotid Doppler (2-C) shows thrombosis of pseudo-aneurysm (AN) with free flow in ICA and ECA.

atherosclerotic disease resulting in > 90% stenosis in 6 patients, 81-90% stenosis in 5, and 70-80% stenosis in 4 patients. Two patients had 60% stenosis with associated post traumatic pseudo aneurysm (Figure-2). All these patients underwent endovascular stenting using self-expanding metallic stents in 16 carotids while the two patients having post-traumatic pseudo aneurysm were treated with covered stent-grafts. It was interesting to note that contra lateral disease producing >70% stenosis was found in 6 of these 17 patients.

Technical success was defined as successful stent deployment leaving less than 20% residual stenosis. Technical success rate of stent deployment was 100%. However all of the cases required post dilatation with balloon, during which 5 developed transient bradycardia and hypotension (Table 3). One patient developed asystole. All were managed conservatively with intravenous Atropine and other supportive measures. Two patients developed Transient Ischaemic Attack (TIA) with transient monoparesis. One patient had confusion and TIA (Hemiparesis) during the preliminary angiogram before stenting. No stroke or death occurred in any of our patients. The patients were admitted overnight and were discharged on the following day. They were advised to avoid vigorous neck manipulation or deep neck massage. The follow-up consisted of clinical assessment and carotid doppler examination at 3, 6 and 12 months after the procedure. The follow up in our patients ranged from 1 to 24 months with an average of 6 months. To date the follow up did not revealed any case of restenosis.

Discussion

Stroke remains a major complication of atherosclerotic cerebrovascular disease, with extracranial carotid occlusive disease accounting for nearly one third of all events. Ischaemic stroke is the commonest reason for admission to a neurology ward in Pakistan as other part of the world.[1]

One third of all strokes that occur annually world wide are due to extracranial carotid atherosclerosis. In Pakistan carotid artery occlusive disease is responsible for up to 25% of these strokes. In a local study carotid artery occlusive disease was found to be the second most common cause of ischaemic stroke in Pakistan.[3]

In the past, there has been considerable controversy over the appropriate treatment of carotid artery stenosis in both symptomatic and asymptomatic patients. The major reasons for this include slowly evolving knowledge of the natural history of atherosclerotic carotid artery disease, along with a delay in definitive studies documenting proven benefits of surgical endarterectomy over standard medical therapy.

Established extracranial carotid artery stenosis demonstrates disease progression in approximately 20 - 40% of cases. In one prospective natural history study of 232 patients with mild (<50%) and moderate (50 - 79%) carotid stenosis followed with annual carotid duplex ultrasonography for a mean of 7 years, 23% demonstrated disease progression. One half of these patients progressed to severe stenosis (80 - 99%) or occlusion. Risk of progression to either 80 - 99% stenosis or occlusion was more likely in patients whose initial stenosis was categorized as 50 - 79% rather than <50%.[4]

Several trials have shown carotid endarterectomy to be superior to medical management for the prevention of stroke in patients with symptomatic or asymptomatic carotid artery stenosis.[5-9]

During the past decade, carotid angioplasty with stenting has been used to treat patients at high surgical risk. Percutaneous transluminal balloon angioplasty for carotid artery stenosis was first reported in 1980.[10]

The advantages of stenting over simple angioplasty include avoiding plaque dislodgment, intimal dissection, elastic recoil and later stenosis. However, the role of percutaneous angioplasty and stenting was initially limited by the risks of compression of the stent and embolization of plaque debris to the brain.[9,11-16] Nickel-titanium (Nitinol) crush - resistant stents and emboli protection devices have been developed to address these problem.[17]

CAS is being done worldwide in both high and low risk patients with symptomatic carotid artery stenting. A number of factors contribute to the risk of revascularization in patients with carotid stenosis. Factors such as restenosis, previous radiation, previous radical neck dissection, cranial

nerve palsies, severe cardiac or pulmonary disease, location of the lesion (high or low) and contra lateral occlusion make surgical endarterectomy particularly high risk. Severely tortuous vessels, poor arterial access, coagulation and platelet disorders, and severe calcification make percutaneous intervention difficult and high risk. Certain factors such as age, severe stenosis with a string sign, presence of thrombus and acute stroke contribute to risk for either surgery or stenting.

The North American Symptomatic Carotid Endarterectomy Trial (NASCET)[18-19] and the Asymptomatic Carotid Atherosclerosis Study (ACAS)[20] demonstrate the efficacy of carotid endarterectomy (CEA) in reducing the risk of stroke and death in selected patients. SAPPHIRE Trials (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy) were conducted to determine a revascularization strategy for patients with severe carotid artery stenosis and coexisting conditions that would have excluded them from other trials of carotid endarterectomy.[21] Preliminary three year data from SAPPHIRE and final three year data from the U.S. Carotid Feasibility Study (USFS) presented at the 2005 Transcatheter Cardiovascular Therapeutics meeting, demonstrate the long term durability of carotid artery stenting (CAS) for the prevention of stroke versus carotid endarterectomy (CEA) in high risk surgical patients.

The SAPPHIRE trial demonstrated that CAS was non-inferior to CEA. This is important new data which suggests the long-term durability of CAS in this patient population". Data from the SAPPHIRE, USFS and CASCADE clinical trials also suggests that emboli protection is effective in preventing major strokes during carotid stenting. Approximately two thirds of the minor ipsilateral strokes that occurred in these trials resolved with time.

In our series majority of patients (15/17) were surgical high risk either due to difficult anatomy or associated co-morbid disease. The primary reason for this being the fact that surgery has remained the treatment of choice at our institution for a long time and only the difficult cases were referred initially for CAS. However, with increasing confidence on endovascular techniques and increasing awareness of the patients and the physicians more uncomplicated cases also underwent CAS. Like all developing nations, cost has been an important limitation in patient's referral for CAS. Distal embolic protection device (Angioguard, Cordis) was not used in 3 (3/15) patients primarily to reduce the procedural cost. Its use was not justified in two patients (2/17) with post traumatic pseudoaneurysm. The most critical time for distal embolism is at the time of crossing the lesion. Three patients in our series developed transient complications and recovered with conservative therapy. The technical success of 100 % was achieved in all cases. However as stated in the Quality Improvement document of the society of Interventional Radiology, "any procedure that has 'stroke' as a routine potential risk should be performed only by medical professionals with appropriate training and experience".[22]

Conclusion

CAS can be an alternative to surgical endarterectomy but requires further randomized trials to prove it. It is a less invasive and safer means than CEA for reducing the risk of stroke in appropriately selected patients.

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