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# ORIGINAL ARTICLES

## CAROTID ARTERY STENTING: AFIC-NIHD REGISTRY STUDY

**Abdul Hameed Siddiqui, Sohail Aziz, Hamid Sharif, Muhammad Qaiser Khan, Syed Mohammad Imran Majeed**

Armed Forces Institute of Cardiology & National Institute of Heart Diseases, Rawalpindi

## ABSTRACT

***Objective***: To report management, procedural outcome, short and long term results of carotid artery stenting in patients with significant carotid artery stenosis.

***Study Design:*** Descriptive observational study.

***Place and Duration of Study***: Adult cardiology departments of Armed forces institute of cardiology / National institute of heart diseases (AFIC/NIHD) from January 2005 to December 2013.

***Patients and Methods***: We studied 168 patients from Jan 2005 to Dec 2013 who underwent carotid artery stenting with significant coronary stenosis. Significant lesion was defined as 70% stenosis as documented by non-invasive imaging or 50% as documented by catheter angiography in symptomatic patients and 70% as documented by validated Doppler ultrasound or at least 60-70% by catheter angiography in asymptomatic patients. A 7 or 8F multipurpose guiding catheter was used to cannulate internal carotid artery depending upon type of deployment. We used either right coronary Judkin or JB diagnostic with railroad technique. The lesion was crossed with an appropriate sized distal protection device which was then deployed in the internal carotid artery at least 2.5 cm distal to the lesion. Predilatation was done in critical narrowing cases followed by placement of self-expanding tapering carotid stent across the lesion. Direct stenting was done only when the lesion was considered suitable. Post dilatation was done subsequently to ensure that not more than 20% of residual stenosis was left. Mean age of patients was 65 ± 8.4 years. Majority of patients were males (78.9%). Embolic protection device was used in all cases.

***Results:*** The procedural success rate was 97.03%.The 30 day event rate of primary end points-death, stroke or myocardial infarction was 4.16%. Two patients (1.19%) died after discharge. Stroke occurred in 5 patients (2.97%), in three ipsilateral to the stenting and in two contralateral. One patient developed stroke during the procedure, two after the procedure but before discharge and two after discharge but within 30 days.

***Conclusion:*** Carotid artery stenting is a safe procedure for significant carotid artery stenosis as an alternative to carotid endarterectomy with low complication rate.

## INTRODUCTION

Stroke is the third most common cause of death in North America and carotid artery stenosis is the cause in about 20% to 25% of strokes and risk depends upon severity of the carotid stenosis[1]. 75% to 94% stenosis is associated with a stroke risk of 27% in symptomatic patients and 18.5% in asymptomatic patients according to the North American Symptomatic Carotid Endartecrectomy Trial (NASCET)[2]. Carotid endarterectomy (CEA) emerged in 1954[4] and remained sole treatment modalitytill 90s. Endovascular techniques and devices were developed and balloon angioplasty initially followed by carotid artery stenting (CAS) was started with reasonable success and low complication rate. This soon emerged as a potential alternative to CEA. Advancement in endovascular technology and with increasing expertise of interventional cardiologist, carotid artery stenting has challenged CEA as a preferred treatment option for carotid artery stenosis.

**Correspondence: Dr Abdul Hameed Siddiqui,** Classified Cardiologist, AFIC/NIHD, Rawalpindi
*Email: adahsahs@gmail.com*

## PATIENTS AND METHODS

We studied 168 consecutive patients undergoing carotid artery stenting from Jan 2006 to Dec 2013 at Armed Forces Institutes of Cardiology were. A7 or 8F arterial sheath was passed in the femoral artery and 7 or 8F multipurpose appropriate guiding catheter mounted on 6F right Judkin mostly or JB diagnostic catheter at times, placed depending upon compatibility of distal protection device and its sheath. We advanced guiding catheter by railroading (mother and child technique) over a 0.035 inch guide wireup the aorta and then slided into the internal carotid artery.

Right Judkin or JB curve helped in the railroad technique to engage the internal carotid artery and were then removed along with guide wire. A carotid arteriogram was obtained in antero-posterior and lateral projections. The lesion was crossed with an appropriate size distal protection device which was then deployed in internal carotid artery (ICA) distal to the lesion. Predilatation was performed in selected cases with 3 mm coronaryballoon. The self expanding tapering carotid stent was placed across the lesion and deployed. Post dilatation if required was done ensuring not more than 15-20% residual stenosis was left behind. A repeat arteriogram in similar projection was obtained, after guide wire and protection device were retrieved. A temporary pacing wire was used in earlier cases. Pressure bandage was done at access site. Arterial and venous sheaths were removed 4 hours after the procedure. Strict monitoring of blood pressure was ensured in the 12-24 hour post procedure period to avoid hypo or hypertension. Technical success was defined as the ability to access the carotid artery to successfully stent the lesion with less than 20% residual stenosis. Study end points were defined as occurrence of minor or major stroke or death within 30 days of index procedure.

## RESULTS

The average age of the patients was 65 ± 8.4 years. There was male predominance (78.9%). Embolic protection device was used in all cases. In five patients procedure was abandoned because of failure to engage the guiding catheter in common carotid artery(three patients) and due to failure to cross the tortuous vessel (two patients). 163 out of 168 achieved technical success (97.03%). The 30 day event rate of primary end points-death, stroke or myocardial infarction was 4.16%. Two patients (1.19%) died after discharge of seemingly non-neurological causes. Stroke occurred in 5 patients (2.97%), in three ipsilateral to stenting and in two contra-lateral to it. One patient developed stroke during the procedure, two after the procedure but before discharge and two after discharge but within 30 days. One patient developed bull neck swelling due to vessel rupture and leakage of blood. He had to be intubated for 72 hours before haematoma resolved and patient could be extubated. Restudy of carotid artery showed no obvious leakage of blood in the neck. One patient developed pericardial effusion with temporary wire prior to stenting and procedure had to be abandoned. He didn't turn up for second attempt.

**Table-1: Showing baseline characteristics of patient who underwent carotid artery stenting (n=168).**

| Characteristics | No |
|---|---|
| Carotid Artery involved | |
| Right internal carotid artery | 100(61.3%) |
| Left internal carotid artery | 63(38.7%) |
| Embolic protection device 163 (100%) | |
| Accunet (Abbott Vascular) | 154(94.4%) |
| Spider X (Medtronic) | 9(5.60%) |
| Total stents deployed = 163 (97.02%) | |
| Acculink stents | 153(93.8%) |
| Others | 10(6.14) |
| Pre-dilatation | 60(37%) |
| Direct | 103(63%) |
| Post-dilatation | 93(57%) |

**Table-2: Showing size of embolic protection device (EPD).**

| | |
|---|---|
| Accunet 4.0 | 2 (1.19%) |
| Accunet 4.5 | 9 (5.35%) |
| Accunet 5.5 | 19 (11.30%) |
| Accunet 6.5 | 103 (61.30%) |
| Accunet 7.5 | 20 (11.9%) |
| Spider X | 8 (4.76%) |
| EZ | 7 (4.16%) |

## DISCUSSION

Although randomized trials of CAS and CEA have produced somewhat conflicting results, systematic meta-analysis have shown that most of these differences were related to heterogeneity amongst patient population using different end points and level of experience of different operators. In Carotid and Vertebral Artery Trans-luminal Angioplasty study (AVATAS) cumulative incidences of primary endpoints (restenosis >70%) in angioplasty and CEA groups respectively were 21.7% and 30.7% at 1 year and 7.5% and 10.5% at 5 years[5]. Patients who received stents had a significantly lower

incidence of re-stenosis than did patients who received angioplasty alone. The stenting and angioplasty with protection in patients at high risk for endarterectomy (SAPHIRE) trial, the primary end point of composite of death, stroke or myocardial infarction within 30 days or death or ipsilateral stroke from day 31 through 1 year was reached by 20 patients assigned to CAS and 32 patients assigned to CEA[3]. At 1 year carotid revascularization was repeated in fewer patients who had undergone CAS than in patients who had undergone CEA. The CREST trial was designed to overcome confounding factors in earlier trials. In this trial only one kind of stent and embolic protection filter was allowed and rigorous training criteria were used to standardize operator skill. Overall in CREST, the rate of stroke, death and MI were lower than or equal to corresponding rates in previous trials for both CAS and CEA procedures. The rates of any peri-procedural stroke or death associated with CAS & CEA were 2.5% versus 1.4% for asymptomatic patients and 6% versus 3.2% for symptomatic patients; all of these rates are less than or equal to current American Heart Association "acceptable risk"guidelines for patients who undergo these procedures[6,7]. The lower risk of strokes than in similar trials is probably due to the use of embolic protection devices (EPDs) in 96% of patients, the use of same EPD and stent system in all patients and higher standard for interventionalist training.

In our study EPDs were used in all cases. Acute myocardial infarction has been consistently shown to be more frequent after CEA than CAS. In 2010, Illuminati and associates evaluated the effectiveness of elective coronary angiography and percutaneous coronary intervention (PCI) before CEA in reducing the incidence of postoperative MI. They randomly assigned 426 CEA candidates either to coronary angiography with possible PCI before CEA or to CEA without angiography or PCI. The primary endpoint was the combined rates of postoperative MI and complications of angiography and PCI. No postoperative MI was observed in PCI group but 9 myocardial events including one fatal MI were observed in the no-PCI group[8]. In our study no myocardial infarction occurred in patients undergoing CAS. We used preferably one brand of device for logistic reason as there was not enough volume for the multiple companies to keep sufficient stents and DPDs on the shelf. Initially Boston scientific devices were used but later on Abbott Vascular replaced it because of ease of availability. Our technical success rate was 97.03% which is comparable to various studies done previously. The death rate in our study was 1.19% which is less than other studies. This may be because of lack of proper follow up. There were two pericardial effusions caused by 6F temporary lead one of which required urgent aspiration because of tamponade and other settled conservatively. One patient died in 2005 after a failed attempt at CAS because of incompatibility of stent and distal protection device. He was hospitalized with acute coronary syndrome and was found to have triple vessel coronary artery disease and was awaiting bypass surgery. One patient had bilateral carotid stenting in stages. One patient had persistent hypotension which settled following day with Saline infusion.

## CONCLUSION

We conclude that CAS is an acceptable alternative to CEA if performed by experienced hands at experienced centers particularly for patients who are at high surgical risk and is probably preferable for patients younger than 70 years of age.

### Conflict of Interest

This study has no conflict of interest to declare by any author.

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