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ORIGINAL ARTICLE

Role of Cerebral Protection In Carotid Angioplasty And Stenting

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Aim: To study the role of protective devices in improving the efficacy of percutaneous transluminal angioplasty (PTA) and stenting, in the treatment of symptomatic atherosclerotic stenosis of carotid arteries.

Materials and Methods: This study was performed in a teritiary care center in a period of 4 years, which included 66 patients. A majority of the patients presented with transient ischaemic attacks, with the youngest being 19 years and oldest was 82 years. Preprocedural workup with Doppler, MR angiogram and Digital subtraction angiogram was done in all the patients. The degree of stenoses was classified on the basis of the NASCET (North American Society Carotid Endarterectomy Trial) trial. PTA and stenting with self expandable stent and balloon was done in all the patients under local anaesthesia. Cerebral protective devices were used in all the patients and the patients were regularly followed up at intervals of 1, 3, 6 and12 months.

Results:PTA and stenting with cerebral protection was done in all the patients. Technical successs was achieved in all the patients. Four patients had filter choking. Major stroke occurred in one patient. No deaths occurred in our study. Bradycardia occurred in 3 patients, hypotension in 4 patients and puncture site haematoma in 2 patients. The results of the present study were analysed and compared with the literature.

Conclusion: PTA and stenting is effective for the management of carotid artery stenosis with higher success rate and less complications. The role of cerebral protection in avoiding migration of the plaque material and thus preventing cerebral circulation was emphasized.

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Introduction

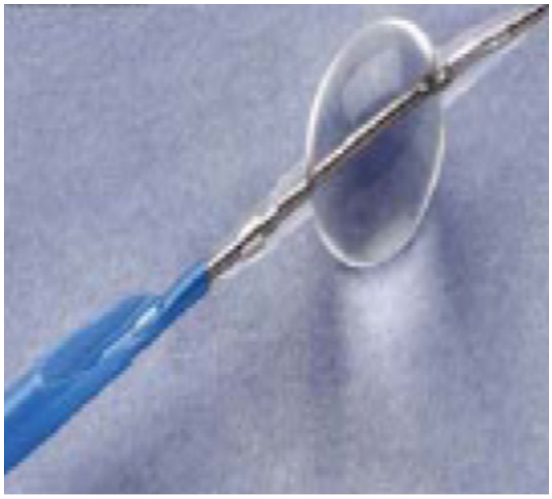
One of the important limitations of carotid artery stent placement in stenotic disease is the potential risk of developing embolic stroke by the plaque dislodgement of atheromatous material [1],[2].The role of cerebral protection devices have gained popularity in the recent years in preventing the adverse events of carotid artery stenting .Cerebral protection can be done using various types of balloons and filters. In our study, we share our experience with the use of cerebral protection devices in sixty six patients who underwent carotid artery stent placement and the results were studied and analysed with those from the literature review.

Materials and Methods

The study was conducted in our institution, which is a tertiary care centre, in a period of 4

years. 66 patients were included in the study, the youngest being 19 years and oldest was 82 years. Among the 66, 48 were male patients and 18 were females (M:F=4:1.5) . Four of the patients underwent PTA and stenting of both the carotids .Preprocedural workup was done in all the patients. All the patients underwent either Doppler or MR angiogram for the assessment of the carotid stenoses. These patients subsequently underwent Digital substraction angiography. Colour doppler was performed in ALOKA SSD 5500 and the stenoses was assessed, based on direct measurement using callipers on the machine and velocity criteria derived from spectral analysis. MRA was done with the 3D Time of Flight and phase contrast sequences and stenoses were assessed on the post processed MIP (Maximum intensity projection) and VR (Volume rendered) images.

Digital subtraction angiogram was performed using Advantax LCN+ (GE BIPLANE SYSTEM) by femoral catheterization. The degree of stenoses was measured using the NASCET criteria, where the smallest luminal diameter at the level of stenosis was compared to the normal arterial diameter distal to the stenosis. 33 patients had 30-69% stenosis and 37 patients had more than 70% stenosis. All the procedures were done under local anaesthesia. The femoral artery was accessed with a 7F sheath and 5000 I.U. of heparin was given intravenously. 1 mg of Atropine was given intravenously prior to the dilatation. Thecarotid artery was accessed and the stenosis was crossed with a 0.035" guide wire. A self expandable stent was used in all the cases. The stenosis was post dilated over the stent with approximately sized balloon and the entire length was dilated to oppose the stent to the vessel wall.



Table/Fig 1 -Distal occlusion balloon device-Percusurge

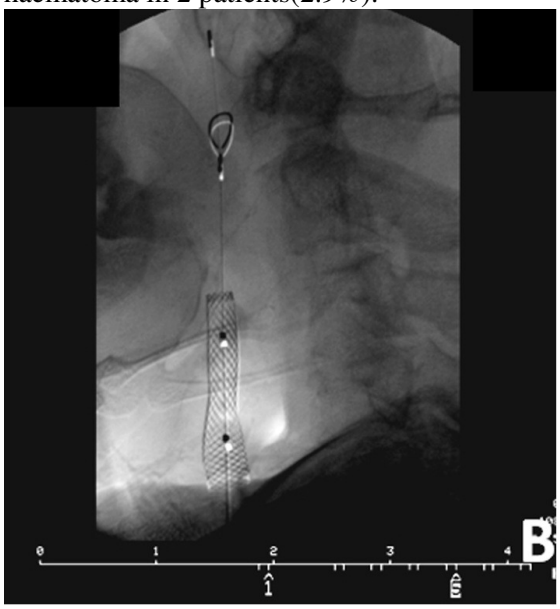
Protection devices in the form of the EPI filters were used in 56 patients, Percusurge in 3 patients, Emboshield in 2 patients and spider in 5 patients. Associated co morbidities were also present in these patients, which included hypertension (61 patients), Diabetes mellitus (43 patients), TIA(56 patients) Vertebro basilar insufficiency (05 patient), Major stroke (01 patient) and minor stroke in 17 patients.
Premedication was given to all the patients in the form of oral aspirin (150mg) and clopidogrel (75mg) 4 days prior to the procedure, intravenous Glycopyrrolate (0.4 mg) prior to angioplasty and heparin (5000 I.U.(intravenous) prior to the guide wire placement.

Table/ Fig 2 -Volume Rendered image of the pre-angioplasty angiogram showing 99% of stenosis of the internal carotid artery distal to CCA bifurcation

Results

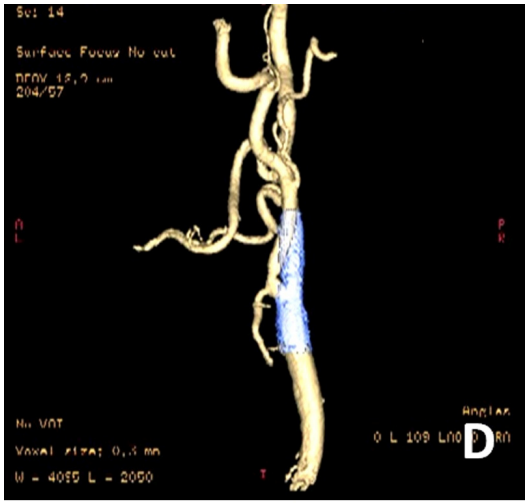
Technical success was achieved in all our patients without any major complications or restenoses.

Four patients had filter choking, from which one was severe, but the carotid flow was normal after the removal of the filter. We had no deaths in our study. Minor complications like carotid spasm were seen in four patients (5.7%), bradycardia in 3 patients (4.3%), hypotension in 4 (5.7%) and puncture site haematoma in 2 patients(2.9%).

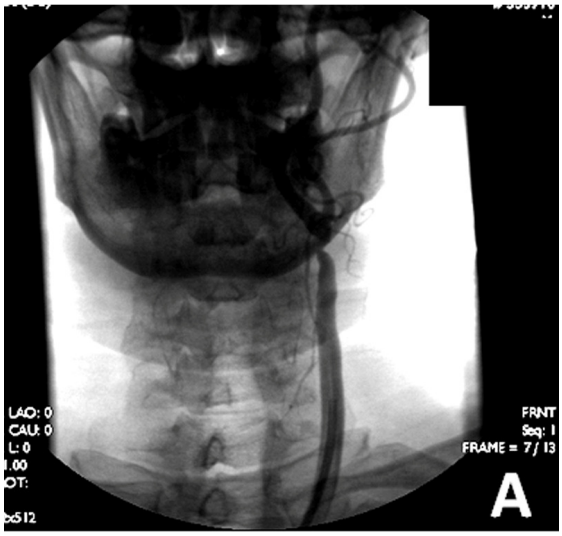


Table/Fig 3-Lateral view of the stent with the EPI filter deployed at the level of C1 vertebral body.

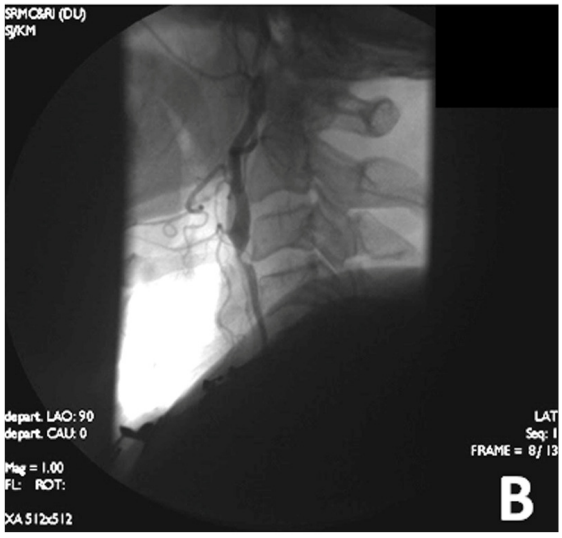
Table/Fig 4- Post stenting angiogram (AP view) revealing adequate result.



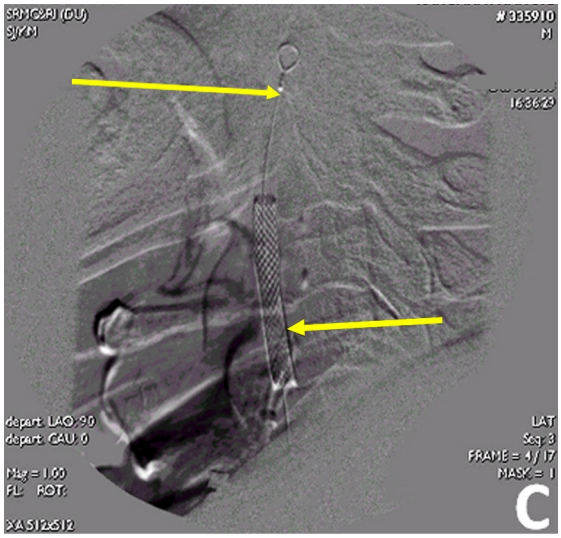
Table/Fig 5 Volume Rendered image of the post-angioplasty angiogram showing opening up of the stenotic segment and the stent in situ.



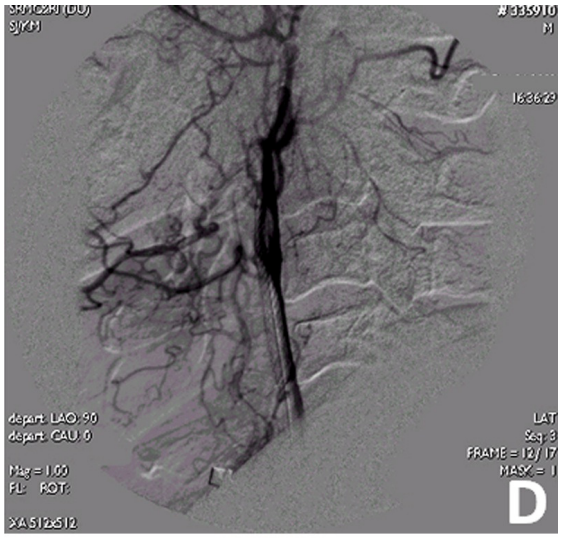
Table/Fig 6- Left common carotid injection revealing a tight stenosis of the distal CCA



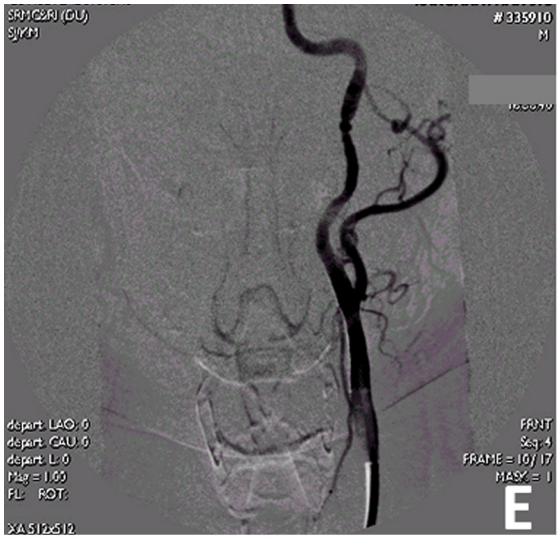
Table/ fig 7: Left common carotid injection revealing a tight stenosis of the distal CCA on lateral view



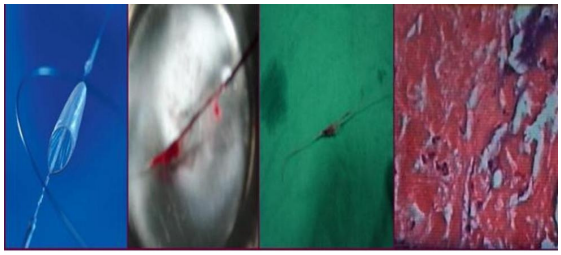
Table/ fig 8: Lateral view of the Lt CCA with the stent and filter in position



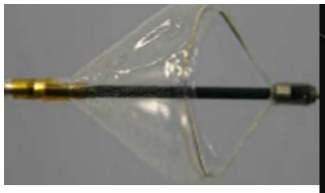
Table/Fig 9- Lateral view of the Lt CCA with the stent and filter in position and reduced flow distal to the filter



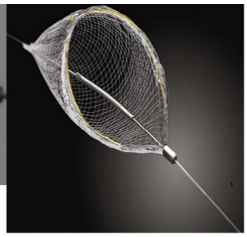
Table/Fig 10- Angiogram (AP view) after removal of the filter revealed increased flow in the left CCA



Table/Fig 13: Embolic material collected in the filter device with histology examination



Table/Fig 11: Abbott EmboshieldPRO filer Device



Table/Fig 12: SpiderFX filter device

Discussion

Carotid angioplasty with or without stenting is a minimally invasive alternative to open endarterectomy. The most common complication of PTA and stenting is an embolic shower causing stroke. This can be prevented by the use of the cerebral protection devices. Percutaneous transluminal angioplasty and stenting is a very successful and effective procedure and has pushed carotid endarterectomy to the back seat in recent years. The protection devices avoid the migration of plaque material distally, henceforth, preserving the cerebral circulation and the impending complication rate. The role of these devices is emphasized in the present study.

Stroke is the third leading cause of disability worldwide [5]. Carotid artery disease is responsible for one third of all ischaemic strokes [7]. A third of these patients die and another third are permanently disabled [7]. Thus, the management of carotid artery disease is undergoing thorough scientific evaluation.

Randomized prospective surgical trials like NASCET and ESCT have shown a significant reduction in the risk of stroke in symptomatic patients with carotid stenosis, who undergo carotid endarterectomy versus optimal medical therapy [3],[4] . In the NASCET study, symptomatic patients with greater than 70% stenosis had a 2 year cumulative risk of stroke of 26%, with optimal medical therapy versus

9% risk with carotid endarterectomy (CEA). For major stroke and death, a risk reduction of 10.6% was identified with surgery. A reassessment by the American Heart Association Stroke Council indicated that CEA is three times as effective as medical therapy by itself in reducing the frequency of stroke [5].

While the demonstrated utility of surgery for improving outcome in the patients with severe carotid stenoses is an important advance, complication rates, while acceptable, leave room for improvement. Carotid artery balloon angioplasty and stenting offer the same efficacy and less morbidity. It's advantages over surgery include, the ability to monitor the neurological status during the entire procedure, to reach very high cervical and petrous level stenosis and to avoid the 7.6% risk of cranial nerve injury as reported in NASCET. Other indications for considering an endovascular approach include such conditions as radiation-induced carotid fibrosis, fibromuscular dysplasia and severe medical co-morbidity. Contralateral carotid occlusion has also been proposed as an indication for angioplasty and stenting. Dissection, with or without pseudoaneurysm, may also occasionally be treated effectively with angioplasty and stenting.

Since its development by Gruentzig in early 1970, the use of balloon angioplasty for the treatment of atherosclerotic and other stenoses has gained wide acceptance [6]. The CAVATAS study compares the surgery and angioplasty [7]. A large number of series of carotid angioplasty and stenting studies have been published. The major ones include those by Theron etal [8], Diethrich etal [9] and Henry etal [10].

The most important persistent risks shared by the CEA and PTA procedures are stroke and death [11] Wholey etal [12] published a review of 2048 PTAS procedures. These results show that CEA and PTAS are nearly equal in terms of procedure related deficits and stroke. Thus, the role of cerebral protection devices came into existence, in an attempt to prevent stroke which is the most worrisome complication of the procedure. Different studies conducted by Wholey etal , Al-Mubarak etal and Kasturp etal showed a reduction of about 50 % in the stroke rate by using a protective device during the carotid artery stenting procedure [13],[14],[1]

A majority of the patients who were included in our study had associated co morbidities, which further added to the risk factor of the occurrence of stroke in these patients. Hence, the intraprocedural risk of distal migration of the embolic material during carotid arterial stenting was high in this group. Distal protective devices have been shown to be safe and effective in preventing distal embolisation. They are categorised as Distal occlusion Balloons and Filters. Distal occlusion balloon is of lower crossing profile, but causes temporary cessation of blood flow during the procedure. We used Percusurge which is of this type in three patients in the initial period. Though we did not encounter any adverse effects in these three patients, this temporary cessation may not be tolerated in all the patients. The series published by Henry etal [15] is the first clinical experience using the PercuSurge Guidewire system.

The largest consecutive series of carotid stent implantation using filter devices for cerebral protection, emphasizing the reduction in the risk of embolisation, was published by Bernhard Reimers [16]. Filter devices maintain the antegrade flow as against the interrupted flow caused by the distal occlusion balloons. The filter devices were used in 63 patients. EPI (Embolic protection Incorporated cerebral protection device) by BOSTON scientific were used in 56 patients. Emboshield by Abbot was used in 2 patients and Spider by ev3 was used in 5 patients.

In the study by Reimers etal, macroscopic debris was seen in 53% of their cases. Embolic material was demonstrated in the device in 28 of our cases. Major cardiac events occurred in 2.3% of their series, but we did not encounter any such events in our study.

Zahn etal, in their study, compared the effectiveness of both the distal occlusion balloon and Filter Embolic protective devices and showed that Filter Embolic protective device is by far the most preferred choice [17]

Major adverse effects like spiral dissection, subocclusive ostial stenosis and intracranial haemorrhage were reported in the literature (18.) None of these were seen in our study. Minor complications like transient carotid spasm were encountered in four of our patients (5.7%), but the flow was completely restored after the filter removal. In these cases, large particles of debris are lodged in the devices. All the patients were followed up at regular intervals for a period of 3 years. Major stroke occurred in one patient in our study. There was no incidence of any other major events or restenosis in any of the cases in the study group.

Conclusion

Cerebral protection devices are safe and effective methods for preventing distal embolization by thus, decreasing the potential risk of stroke with the carotid artery stenting procedure, thereby increasing the efficacy of the procedure, making it widely acceptable for treatment of the cases of symptomatic carotid stenosis.

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