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Carotid Stenting for Severe, Symptomatic and High-Surgical-Risk Stenosis, a Clinical Series

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Abstract

Background: *A significant number of randomized trials with long term follow up has been modifying the role of carotid stenting for symptomatic as well as asymptomatic carotid stenosis.*

Method: *In this retrospective study a series of high-surgical-risk symptomatic carotid stenosis managed with carotid stenting performed under standard protocol of general anaesthesia with distal filter protection and closed cell self-expanding nitinol stent was reviewed. Inclusion criteria were symptomatic carotid stenosis>70%, clinically significant cardiac disease, severe pulmonary disease, contralateral carotid occlusion, contralateral laryngeal nerve palsy, recurrent stenosis after carotid endarterectomy, previous radical neck surgery or radiotherapy to the neck. Follow up ultrasound was done at 6 and 24 months.*

Results: *40 cases aged 50 to 85 years fulfilled the inclusion criteria. There were no stroke, myocardia infarct or death perioperatively or within 30 days. There was one unsuccessful intervention due to tight 99% stenosis precluding passage of filter wire. There was one asymptomatic recurrent stenosis>50% detected at two years in a case with prior radiation.*

Conclusion: *Carotid stenting with distal filter protection is safe and effective for severe, symptomatic and high-surgical-risk carotid stenosis.*

Introduction

Indications for carotid stenting is evolving. Recent publication of the long term follow up results of Second Asymptomatic Carotid Atherosclerosis Study (ACST-2) study has shed more light in the management of carotid stenosis where outcome of carotid stenting and endarterectomy produced no significant difference with mean follow up of five years.[1] The investigators concluded that both carotid stenting and endarterectomy were equally effective for asymptomatic carotid stenosis >60%. Prior to this study there have been multiple randomized control trials comparing carotid endarterectomy vs stenting for symptomatic or asymptomatic carotid disease. Some studies favoured endarterectomy and some studies favoured stenting. Meta analysis appears to favour endarterectomy for non disabling ischemic events. As a neurosurgeon practising both endarterectomy as well as stenting, the author has been performing carotid stenting for high risk cases post Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE)[2-3]trial era. One important lesson learned from the Endarterectomy Versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S)[4-5] trial, the Carotid Revascularization Endarterectomy vs Stenting Trial (CREST)[6] as well as the SAPPHIRE trial is that the use of distal protection devices, the stents and the operators' familiarity with the implants matters significantly. This retrospective study reviews the outcome of 40 consecutive cases with symptomatic, high-surgical-risk carotid stenosis>70% stenosis using a standardized intervention protocol under general anaesthesia.

Methods

This is a retrospective study of a prospectively maintained data base of cases with symptomatic severe stenosis >70% measured by North American

Symptomatic Carotid Endarterectomy Trial (NASCET)[7-8]methodology.Inclusion criteria for the purpose of this study were symptomatic carotid stenosis>70%, clinically significant cardiac disease, severe pulmonary disease, contralateral carotid occlusion, contralateral laryngeal nerve palsy, recurrent stenosis after carotid endarterectomy, previous surgery involving extensive neck dissection or radiotherapy to the neck. The caseswere expected to be able to survive more than two years. Prior to surgery double antiplatelet therapy with aspirin and clopidogrel was administered for 5 days. General endotracheal anaesthesia was given followed by standard femoral puncture. 6F Shuttle sheath (Cook Medical, USA) was introduced into common carotid artery proximal to the stenotic segment. Full anticoagulation with intravenous heparin was administered following placement of the guide catheter. Monorail EZ Filter Wire 0.014" (Boston Scientific, USA) was then manipulated pass the stenotic segment and deployed in the distal internal carotid artery. Once the filter is deployed, intravenous atropine 0.5mg was given. When the heart rate accelerates, a monorail Sterling balloon (Boston Scientific, USA) will be deployed and inflated for pre-dilatation. Monorail exchange for a carotid Wall stent (Boston Scientific, USA) was then performed and the stent deployed, covering entire stenotic segment of the internal carotid artery distally and common carotid artery proximally. Post dilatation was then performed if necessary to fully expand the stent. The EZ Filter Wire (Boston Scientific, USA) was then retrieved, with enough subtotal closure of the loop without dislodging the clot/atheroma debris. Post stenting the cases were maintained on double antiplatelets for 1 month followed by single antiplatelet indefinitely. Follow up was done clinically at 30 days followed by 6 monthly intervals with ultrasound at 6, 12 and 24 months. Perioperative stroke was defined by neurological deficit persisting more than 24 hours. Myocardial infarction was defined by two out of three criteria of chest pain, electrocardiographic changes or elevation of cardiac enzymes.

Result

40 cases, 9 female and 31 male, aged 50 to 85 years fulfilled the inclusion criteria. There was no stroke, myocardia infarct or death perioperatively or within 30 days. Demographics and outcome of the study population is listed in Table 1. There was one unsuccessful intervention (2.5%) due to tight 99% stenosis precluding passage of EZ Filter Wire (Boston Scientific, USA). Carotid endarterectomy was performed subsequently by the author the next day without complication. There was one (2.5%) asymptomatic recurrent stenosis>50% detected at two years by U/Sin a case with prior radiation for nasopharyngeal carcinoma. This patient elected to have conservative follow up rather than salvage angioplasty or endarterectomy. One 79 year-old case died from unrelated abdominal sepsis two yearspost stenting.

Table 1. *Demographics and outcome of the study population*

Age	Gendre	Side	Outcome	Complication	
70	m	L	Good	nil	
72	f	L	Good	nil	
69	m	R	Good	nil	
50	m	L	Good	nil	
74	m	L	Good	nil	
52	f	L	Good	nil	
71	m	L	Good	nil	
63	m	L	Good	nil	
60	m	R	Good	nil	
58	m	L	Good	nil	
61	m	R	Good	nil	
64	f	R	Good	nil	
77	m	L	Good	nil	
77	m	R	Good	nil	
71	m	R	Good	nil	
65	f	R	Good	nil	
66	f	R	Good	nil	
67	m	L	Good	nil	
54	m	L	Good	nil	
70	m	R	unsuccessful	nil	Unable to cross tight stenosis. Followed by uneventful endarterectomy
66	m	L	Good	nil	
66	m	R	Good	nil	
71	m	R	Good	nil	
68	m	L	Good	nil	
79	m	R	Good	nil	died from unrelated cause at follow up
65	m	R	Good	nil	
85	m	L	Good	nil	
62	f	R	Good	nil	
53	m	R	Good	nil	
60	m	L	Good	nil	
60	m	R	Good	nil	
59	f	L	Good	nil	
63	f	L	Good	nil	
53	f	R	Good	nil	
66	m	L	Good	nil	
64	m	R	Good	nil	
70	m	R	Good	nil	
63	m	R	Good	nil	
71	m	R	Good	nil	
66	m	R	Good	nil	

Discussion

Carotid endarterectomy or endovascular stenting for carotid stenosis has been studied in multiple randomized trials. For asymptomatic carotid stenosis more than 60% by (NASCET) criteria, carotid endarterectomy was proven to be superior to best medical therapy by Asymptomatic Carotid Atherosclerosis Study (ACAS)[9] and Asymptomatic Carotid Surgery Trial (ACST-1)[10].In the recently published ACST-2 study, which was a randomized trial of carotid endarterectomy vs stenting in severe asymptomatic carotid stenosis greater than 60% by NASCET criteria, there was no statistically significant difference in outcome. The investigators concluded that "serious complications are uncommon after competent stenting and endarterectomy, and the long term effects of these two carotid artery procedures on fatal or disabling stroke are comparable".[1] This study put the two treatment modalities in equipoise once again, at least for asymptomatic carotid stenosis.

The role of carotid endarterectomy in symptomatic carotid stenosis has been well established by randomised control trials. In patients with symptomatic atherosclerotic carotid stenosis greater than 70% by NASCET criteria, the value of endarterectomy was established by the results of NASCET and the European Carotid Surgery Trial (ECST)[11]. In NASCET, the estimate of any ipsilateral stroke at 2 years for patients with symptomatic high grade stenosis was 26% in the medical arm and 9% in the surgical arm. For symptomatic carotid stenosis in the moderate category (50% to 69% stenosis), NASCET and ECST demonstrated moderate but significant benefits for endarterectomy compared to best medical therapy. NASCET investigators reported that the five-year rate of any ipsilateral stroke was 15.7 percent among patients treated surgically and 22.2 percent among those treated medically.[8]Out of abundance of caution, the inclusion criteria to intervene for this case serieswas set for high grade stenosis >70% by NASCET criteria.

The first major randomised control trial for direct comparison of endarterectomy versus stenting was the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS).[12-13] In this trial, three-quarters of the cases in endovascular group received balloon angioplasty alone without stenting. The rates of major outcome events within 30 days of first treatment did not differ significantly between endovascular treatment and surgery. No substantial difference in the rate of ipsilateral stroke was noted with survival analysis up to 3 years after randomization. The investigators concluded that endovascular treatment had similar risks and effectiveness at prevention of stroke at three years compared with endarterectomy. Subsequently carotid stenting became a popular choice for the treatment of carotid stenosis for several years.

The Stent-Supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy (SPACE)[14] trial compared stenting vs endarterectomy for patients with symptomatic carotid stenosis greater than 70% by NASCET criteria. For SPACE trial, surgeons must submit results for 25 consecutive endarterectomy procedures. Interventionist must have performed a minimum of 25 stenting or angioplasty procedures. Use of protection devices, pre-dilatation, and balloon was at the discretion of the interventional physician. The outcome of ipsilateral ischaemic strokes up to 2 years after the procedure and any periprocedural stroke or death did not differ between the carotid artery stenting and the carotid endarterectomy groups. In the Endarterectomy Versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) trial, the 30-day incidence of any stroke or death was 3.9% after endarterectomy and 9.6% after stenting.The 30-day incidence of stroke or deaths was 25% for stenting without distal protection compared with 7.9% with protection device. In fact, the study was temporarily stopped at one stage due to the excessive complication rate of stenting without distal protection. It is worth mentioning that in the EVA-3S trial, there were five different stents and seven different distal protection devices used in various stages of the study.[4-5] In the Carotid Revascularization Endarterectomy vs Stenting Trial (CREST), where the outcomes of stenting with those of carotid endarterectomy among patients with symptomatic or asymptomatic extracranial carotid stenosis were compared, it was reported that there was no significant difference in the estimated 4-year rates of the composite primary outcome of stroke, myocardial infarction and death. During the periprocedural period, there was a higher risk of stroke with stenting and a higher risk of myocardial infarction with endarterectomy. The 224 interventionists in the trial were certified after satisfactory evaluation of their

endovascular experience, carotid-stenting results, participation in hands-on training, and participation in a lead-in phase of training. For carotid-artery stenting arm in the CREST trial, the protocol specified use of the RX Acculink stent (Abbott Vascular Solutions, IL, USA) and, whenever feasible, the RX Accunet embolic-protection device (Abbott Vascular Solutions, IL, USA).[6]In the International Carotid Stenting Study (ICSS) the number of fatal or disabling strokes as well as cumulative 5-year risk did not differ significantly between the stenting and endarterectomy groups for symptomatic carotid stenosis greater than 50%.[15]All these randomized trial data suggest that the outcome of carotid stentingcould be different with the use of different distal protection devices or stents.Meta-analysisof the pooled data from randomized trials favoured endarterectomy in view of lower rate of non disabling ischemic event.[16-17] As a result endarterectomy became the preferred choice for routine unilateral carotid stenosis>50%.

On the contrary, in the SAPPHIRE trial, where high risk patients were randomized for stenting or endarterectomy, stenting was found not to be inferior to endarterectomy and that no significant difference could be shown in the long term outcomes between the two carotid interventional procedures. It is worth noting that in the SAPPHIRE trial, the selection of interventionist or surgeon was very stringent. Surgical investigators had a median annual volume of 30 endarterectomies (range, 15 to 100). The total experience of interventional physicians with this procedure was a median of 64 procedures; range, 20 to 700. Only self-expanding, nitinol stent (Smart or Precise, Cordis, USA) and an emboli-protection device (Angioguard or Angioguard XP Embolic Capture Guidewire, Cordis, USA) was allowed. When the long term follow up results of SAPPHIRE was published, stenting with distal filter protection was adoptedby the author for high-surgical-risk cases with carotid stenosis > 70% stenosis.[2-3]

The author had prior experience with various distal protection devices and stents over the years and found EZ Filter Wire (Boston Scientific, USA)combination with monorail carotid Wallstent (Boston Scientific, USA)easy to use with low complication rate and good results.

While local anaesthesia can be used for carotid stenting procedure, in this current series general anaesthesia was utilized for elimination of unintended movements to facilitate exact stent placement. The presence of an anaesthesiologist for hemodynamic control during the procedure was very helpful to minimise perioperative cardiac events. Occasionally profound bradycardia or even cardiac arrest may occur during balloon dilatation of the carotid artery, therefore prophylactic administration of atropine and closed monitoring by anaesthesiologist was important. Distal protection with filter wire was chosen in this series for ease of deployment and to minimise the duration of flow arrest. An industry sponsored study demonstrated that carotid stenting with the Wallstent plus Filter Wiredistal protection was non-inferior to endarterectomy at 1-year, in asymptomatic stenosis >80%, and symptomatic stenosis >50%, forhigh-surgical-risk patients.[18]

The results of the current series, albeit with small number of cases,was encouraging. The success rate was 97.5% and there was no major complication of stroke, myocardial infarct or death. It appears that with prior training and proficiency in the use of distal protection devices and stents as exemplified in SAPPHIRE and CREST trials, complications with carotid stenting could be reduced to a level comparableto endarterectomy.

Conclusions

Carotid stenting with distal filter protection is safe and effective for severe, symptomatic and high-surgical-risk carotid stenosis.

Disclosures

Consent was obtained from every case for carotid stenting with full disclosure on the option of endarterectomy. Consent for this retrospective review was waived by institutional review board of Spine and Brain Surgery Clinic, Mt Elizabeth Medical Centre as patients' data were not disclosed and kept fully confidential. The study was self-funded and the author has no financial or other interest in any of the implant companies mentioned in this study.

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