Original Article

Stent-assisted Percutaneous Angioplasty for Extra-cranial Carotid Disease: Experience at Singapore General Hospital

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Abstract

Introduction: This study aims to analyse the results of carotid stenting in a tertiary referral centre in Singapore. Materials and Methods: Retrospective analysis of all carotid artery stenting (CAS) cases in a single centre from March 1997 to December 2008 was performed. Sixty successful procedures were performed in 61 patients, with bilateral stenting in 1 patient, and 2 failed procedures. The majority were Chinese (78.7%) and males (77.0%), with a high proportion having hypertension (82.0%) and hypercholesterolaemia (78.7%). The majority (91.8%) of patients were high surgical risk candidates, primarily due to cardiac risk factors. Ten patients (16.4%) had prior neck irradiation for nasopharyngeal carcinoma, and 3 patients each (4.9%) had previous endarterectomy and contralateral occlusion. A distal embolic protection device was used in 71.7% of cases. Results: Technical success was 96.8%. The 30-day stroke and death rate was 13.8%, comparable to reported results for this high surgical risk population. Conclusion: CAS is a technically feasible and a relatively safe alternative to endarterectomy to treat extracranial carotid stenosis, especially in patients who are inoperable or at high surgical risk.

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Keywords: Carotid stenting, High surgical risk

Introduction

The NASCET[1,2] and ESCT[3,4] randomised controlled trials established benefits of carotid endarterectomy (CEA) over medical therapy in a selected group of patients with symptomatic high grade extracranial carotid artery stenosis. Building on these results, the findings of the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS)[5] and SAPPHIRE[6] trials demonstrated equipoise between CEA and carotid angioplasty with or without carotid stenting (CAS) in a randomised symptomatic standard risk cohort (CAVATAS), and in a high surgical risk cohort (SAPPHIRE). We conducted an analysis of our carotid stenting cases to analyse the benefits in our local patients, as well as the international patients referred to our service.

Materials and Methods

A retrospective analysis of all patients who underwent carotid artery stenting at our institutes from March 1997 to December 2008 was performed. A total of 62 procedures were attempted in 61 patients. The demographics of the study population is summarised in Table 1. The majority of the patients were Chinese (78.7%) and males (77%), with about two-thirds having hypertension and hypercholesterolaemia. About half of patients (49%) also suffered from diabetes mellitus.

In 1 patient, bilateral carotid stenting was performed. In 2 patients, the attempted stenting procedure was unsuccessful, giving an overall technical success rate of 96.8%, and a total of 60 procedures successfully performed.

All patients who underwent stenting were symptomatic, having suffered from an ipsilateral minor stroke (67.2%) or transient ischaemic deficit (31.1%). No asymptomatic patients were treated in this cohort of patients. Over 96% of patients (96.4%) had severe carotid stenosis (defined

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Table 1. Patient Demographics

Study period	**March 97 to December 08**
Number of patients	61
Number of procedures	62
Number of failed procedures	2
Number of bilateral procedures	1
Total number of stented segments	66
Demographics	
Age (y): mean ± SD (range)	66.9 ± 10.1 (46.0-91.2)
Male, n (%)	47 (77 %)
Female, n (%)	14 (23 %)
Chinese, n (%)	48 (78.7 %)
Malay, n (%)	2 (3.3%)
Indian, n (%)	6 (9.8%)
Other races, n (%)	5 (8.2%)
Co-morbidities	
Coronary heart disease, n (%)	27 (44.3%)
Hypertension, n (%)	50 (82.0%)
Diabetes mellitus, n (%)	30 (49.2%)
Hypercholesterolaemia, n (%)	48 (78.7%)
Current/past history of smoking, n (%)	24 (39.3%)
Prior neck radiation therapy, n (%)	10 (16.4%)
Presenting symptoms	
Asymptomatic, n (%)	0 (0%)
TIA, n (%)	19 (31.1%)
CVA, n (%)	41 (67.2%)

CVA: cerebrovascular accident; TIA: transient ischaemic attack

on NASCET measurements as ≥70% stenosis) without occlusion.

A team approach consisting of neurologists, neurosurgeons, neuroradiologists and cardiologists, was adopted for all patients. All the patients were also assessed routinely for cardiac fitness for surgery. Prior imaging consisted of duplex carotid ultrasound examination and CT or MRI in all patients. Angiography, conventional (performed earlier in our experience) and MR or CT angiograms (in subsequent patients) were also obtained as part of the pre-treatment work-up. The patients were seen by a neurologist prior to the procedure, and baseline neurological status was

Table 2. High Risk Factors for CEA[6-8]

Anatomy related factors	**Co-morbidity related factors**
Inaccessible lesions – below clavicle or superior to C2 level	Older age group (>80)
Previous neck radiotherapy	Clinically severe cardiac disease: - Severe (Class 3 or 4) angina or CCF - Left main or greater than 1 coronary artery disease - Poor LV ejection fraction (<30%) - Recent AMI (<1 month) - Need for urgent coronary artery bypass surgery within 30 days
Previous carotid surgery or radical neck dissection	Severe chronic pulmonary disease
Contralateral carotid occlusion	Severe renal disease
Contralateral laryngeal nerve palsy	

AMI: acute myocardial infarction; CCF: congestive cardiac failure; LV: left ventricular

performed. Early in the experience of the team, unless there were strong contraindications to CEA, most patients were first assessed by the neurosurgeon and only referred to the endovascular therapist when CEA was considered high-risk (Table 2). However, over the last few years, with increasing medical awareness, patients have often queried about available treatment options. Thus, we now routinely discuss both CEA and CAS as treatment strategies concurrently. Informed consent was then taken from the patient by the endovascular team quoting both international and local team results.

As a result of this approach, the majority (56/61, 91.8%) of patients accepted for CAS were high-risk surgical candidates. Ten patients (10/61, 16.4%) had prior neck irradiation for nasopharyngeal carcinoma (NPC). Two lesions were deemed surgically inaccessible. In 2 additional cases, the consultant surgeon felt that the distal circulation was unsuitable for CEA – one of these patients had bilateral foetalised PCAs with terminal basilar artery hypoplasia, and the other had a very small distal ICA. A further 3 patients (4.9%) had recurrent stenosis after previous CEA. Three patients were inoperable due to a contralateral occlusion. One of these patients also had a prior CEA, and prior neck irradiation for NPC. The majority of the high-risk patients were due to cardiac risk factors. A small group of patients (5/61, 8.2%) had self-requested for CAS, and were otherwise of normal surgical risk. These results are summarised in Table 3.

The stenting procedure was performed in a well-equipped

Fig. 1a.

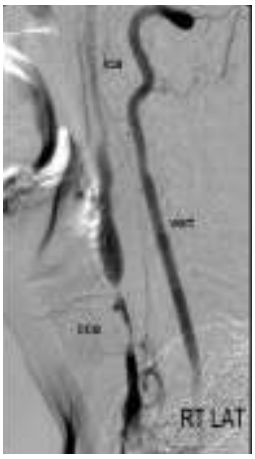

Fig. 1b.

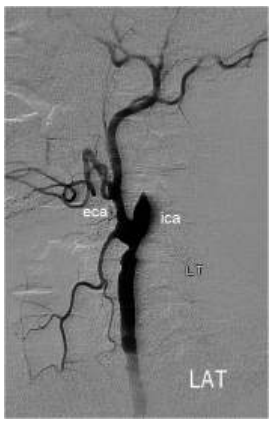

Fig. 1c.

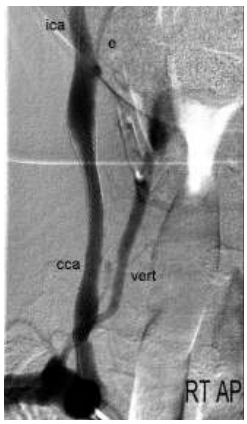

Fig. 1d.

Fig. 1e.

Fig. 1. A 49-year-old Chinese male had radiotherapy for NPC 10 yearrs before current presentation, tumour in remission. The patient presented with recurrent right-sided TIAs and amaurosis fugax. Carotid endarterectomy had been performed 8 months prior to the procedure but the symptoms had recurred. (1a,b): AP and lateral digital subtraction conventional angiograms of the right common carotid artery (rcca) reveal severe stenosis just proximal to a dilated segment (d) of CCA and proximal ICA reflecting the vein graft from previous CEA. The ECA origin is labelled (eca). 1c: Occlusion of the contralateral ICA. (1d,e): Protected stenting was performed with a 8 x 36mm Wallstent, predilation with a 4mm and postdilation with a 5.5-mm balloon. AP and lateral angiographic images after stenting show acceptable 10% residual stenosis in the stented segment.

Table 3. Lesion and Procedural Statistics

High surgical risk	56/61 (91.8%)
- Irradiation for nasopharyngeal carcinoma, n (%)	10/61 (16.4%)
- Restenosis after previous carotid endarterectomy	3 (4.9%)
- Contralateral occlusion	3 (4.9%)
- Surgically inaccessible location	2 (3.3%)
- Surgery declined by surgeon for anatomical reasons	2 (3.3%)
Normal surgical risk (patient's preference)	5 (8.2%)
Embolic Protection Device - No	17/60 (28.3%)
Embolic Protection Device - Yes	43/60 (71.7%)
EPD type	
- EPI Filterwire EZ (Boston Scientific, Natick, MA)	33 (76.7%)
- Miscellaneous	10 (23.3%)
Predilatation	59 (98.3%)
Postdilatation	54 (90.0%)
Severity of carotid stenosis on baseline Doppler	
Severe, ≥70% ipsilateral diameter reduction, n (%)	55 (96.5%)*
Severe, ≥70% contralateral diameter reduction, n (%)	6(13.6%)*
Occlusion, contralateral n (%)	3 (6.8%)*
Hospital stay (days) mean ± SD (Range)	4.6 ± 5.3 (1.0-28.0)
Technical success rate	96.8% (60 of 62)

* Patients with unavailable data excluded

angiography suite in all cases. The right common femoral artery was punctured and diagnostic angiography performed for the target vessel. If prior conventional angiography had not been performed, the contralateral carotid artery was also catheterised. The intracranial circulation was reviewed at the time of angiography as a baseline.

A long sheath or guidecather (80-90cm long, 6-8 French diameter) was advanced into the common carotid artery (CCA) over a 0.035/0.038 inch exchange-length support guidewire which was placed in the ipsilateral external carotid artery after prior selection with a diagnostic catheter system. Variations to this technique included a "bare-back" method, without the use of a guide sheath (first 10 cases) and direct cannulation of the target carotid artery over a co-axial catheter system. The lesions were then crossed with guidewires or, in cases after 2002, with a distal embolic protective device (EPD, 43/60 procedures-71.6%). The

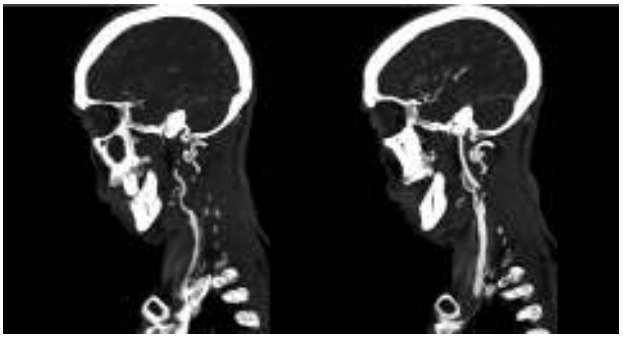

Fig. 2a.

Fig. 2b.

Fig. 2c.

Fig. 2d.

Fig. 2. A 67-year-old male presenting with sudden onset of bilateral lower limb weakness, greater on the right, which resolved after several minutes. Mild left foot weakness was documented on clinical examination by a neurologist. MRI brain showed leukoaraiosis but no acute infarct. US carotids revealed occlusion of the right ICA and 90% stenosis of the left ICA. (2a): Occlusion of right ICA and severe stenosis of left ICA demonstrated on pre-procedure CT angiogram. (2b): Digital subtraction catheter angiogram performed just prior to stenting. (2c): Positioning of a SMART stent across the stenosis. Note that the lesion has already been crossed with a distal embolic protection device which is fully deployed. (2d): Good flow post stenting with no significant residual stenosis. No complications were encountered, the patient discharged after 2 days, and no further neurological symptoms have occurred up to the last (18 months) follow-up visit.

EPI Filterwire EZ (Boston Scientific Corporation, MA, USA) was the predominant EPD used (33/43 cases-76.7%). Balloon pre-dilatations (1.5-4.0 mm diameter) of the stenotic segment were performed in all but 1 patient. In this latter case, the stenosis (65% severity) was deemed wide enough for primary stenting. Self-expandable stents were then deployed taking into consideration the need to match the diameter of the normal ICA or CCA diameter. Balloon post-dilatations (3.0-6.0 mm diameter) were performed in 54 of 60 procedures (90%). Over the years, as techniques and instrumentation improved there has been gradual decrease in the diameter and crossing profile of the balloons, stents and EPDs as well as a switch from an over the wire technique to a rapid exchange technique.

A neurologist performed daily assessment until the patient was discharged. Aspirin 100 mg every morning was started pre-procedure and continued for life. In earlier patients in whom aspirin was contra-indicated, ticlopidine 250 mg was substituted. In later patients, in addition to the aspirin, clopidogrel 75mg starting 3 days prior to the procedure or a single stat dose of 375 mg on the day of the procedure was used. Clopidogrel continued for 6 weeks post-procedure. Patients were reviewed in the clinic at 2 weeks, 4 weeks, 3 months, 6 months and 1 year after the procedure. Imaging follow-up with Doppler ultrasound was performed at Day 1, 4 weeks, 6 months post-procedure and subsequently every year.

Results

A total of 66 stents comprising of 46 Wallstents (Boston Scientific Corporation, MA, USA) – 70%, 15 precise stents (Cordis, NJ, USA) and 5 other stents were deployed in 61 patients. A total of 31 right and 29 left extracranial carotid stenoses were treated. Technical success rate was 96.8% (60/62). Two failures were related to the inability to maintain the guiding catheter in the common carotid artery due to unfavourable aortic arch anatomy. Successful balloon angioplasty (pre-dilatation) without stenting was performed for the first case.

Six patients had 2 overlapping stents deployed. Residual mild peri-procedure stenosis was accepted in 43 (72.7%) of procedures. These stenoses were all 30% or less, except for one patient in whom a 40% residual stenosis was accepted. One patient developed moderate (50-60%) intra-stent restenosis at 2-year follow-up but was asymptomatic, and did not require any secondary intervention. Follow-up of this latter patient recently, at the 3-year mark, revealed a stable lesion, and no clinical symptoms.

There was no statistically significant difference between an initially more severe presentation, and final outcome. Among those who had initially presented only with transient ischaemic attack (TIA), 5.3% (1 of 19) suffered

Table 4. Procedural Complications

Minor complication	
Bradycardia/hypotension	11 (18.3%)
Groin haematoma	3 (5.0%)
Major complication	30-day outcome
Death, n (%)	2 (3.5%)
Procedural stroke, n (%)	6 (10.3%)
- Distal embolic protection device (EPD) used	5/43 (11.6%)
- No distal EPD used	1/17 (5.9%)
No. of defaulters	2 (3.4%)

a major complication. Among those who presented initially with stroke, 17.1% (7 of 41) developed major complications (Fisher's exact test – P = NS). There were also no significantly increased odds of major complication including mortality among patients with the co-morbidities of diabetes mellitus, hypertension, ischaemic heart disease, renal impairment, hyperlipidaemia or cigarette smoking compared to those without these co-morbidities.

There were 6 procedure related acute minor or major strokes (10.3%). The morbidity and mortality data is summarised in Table 4. One infarct occurred on the contralateral side due to procedure related hypotension secondary to bradycardia. This patient had a previous right hemiparesis secondary to left MCA infarction, with good functional recovery many years prior to the latest presentation. She presented with hemispheric TIAs symptomatic to the right carotid territory. Carotid US revealed moderate left (65%) ICA stenosis and severe (90%) right ICA stenosis. Post-right ICA stenting, a dense left territorial infarct (ie. right hemiparesis) developed. This was attributed to an episode of hypotension during the procedure, with reduced perfusion through the moderately stenosed contralateral left ICA.

Another patient developed an acute ipsilateral central retinal artery occlusion (CRAO) post-procedure and was documented to have reduced ipsilateral vision the next day. No further neurological events have occurred up to the 8th follow-up year. Of the remaining 4 (all ipsilateral) infarcts, 2 improved significantly with conservative management, while the other 2 remained significantly disabled because of their stroke. They could not walk independently and required assistance in some activities of daily living. For cases where an EPD was used, 5 of the 43 cases (11.6%) were complicated by a peri-procedural stroke (within 30 days). For the earlier cases where an EPD was not used, a stroke occurred in 1 of 17 cases (5.9%) – Fisher's exact test, P = NS.

Table 5. Clinical and Angiographic Features Associated with Increased Procedural Risks after Carotid Stenting (modified from Roubin et al[8])

Clinical	Advanced age
	- Age 80 years or older
	Decreased cerebral reserve
	- Dementia
	- Prior (remote) stroke
	- Multiple lacunar infarcts
	- Intracranial microangiopathy
Anatomical	Excessive tortuosity
	- 2 or more right-angle curves within 5 cm of the target lesion
	Heavy calcification
	- Concentric circumferential calcification with width of 3mm or more.
	Very severe stenosis
	- 90% or greater.

Two mortalities occurred within 30 days of the procedure. One of the early patients developed a stent occlusion on Day 2 and was successfully treated with intra-arterial Urokinase. Repeat Doppler ultrasound confirmed restored flow although there was reduced flow velocity. The patient however died of an acute myocardial infarction on the 7th post-procedure day. One patient developed a groin haematoma after a failed closure device deployment at the puncture site. Despite multiple attempts at control of the puncture site, the wound continued to ooze and a groin haematoma developed. The patient succumbed to an acute myocardial infarct the next day despite eventual control of the groin haematoma and blood transfusions.

Discussion

Since the first percutaneous carotid angioplasty was performed by Kerber in 1980,[9] there has been tremendous improvement in interventional technology and materials which have transformed a technique initially developed as a palliative treatment of inoperable patients into a therapeutic option for all patients. CAVATAS[5] which randomised symptomatic patients to balloon angioplasty or CEA, reported a similar incidence of stroke in both strategies at 30-days and 3-years follow-up. Similar results are reported by Roubin et al[10] in a 5-year prospective study of the clinical outcomes of CAS.

Our technical success rate (96.6%) is comparable to other reported studies.[10-14] The 30-days combined stroke and death rate of 13.8% (including minor strokes) is, however, on the high side, compared to the 30-days overall stroke and death rate of 10% in the CAVATAS trial[5] and 5.8% in the SAPPHIRE trial.[6] This may be related to the following factors: i) the small sample size, ii) learning curve of the operators, iii) the fact that the majority of patients were symptomatic high-risk patients and had been assessed to be unsuitable for surgery, and iv) patient selection, in that some patients treated with CAS may not be actually suitable for the procedure.

What is the risk of carotid revascularisation? Kumar et al[15] reported on 50 patients who underwent CEA in our institution over an 11-year period, with a combined neurological complication rate of 8% and a further 4% experiencing transient cranial nerve injury; there were however no deaths. A comparison of the combined neurological complication rate of CEA (8%)[15] versus CAS (10.3%) (Table 4) suggests very similar adverse neurological event rates.

Of note too is that despite a comprehensive carotid Doppler screening programme within our institution for all patients presenting with cerebral ischaemic events, there is a relatively low number of patients who were treated by either CEA or CAS. This may reflect the generally lower incidence of extra-cranial carotid disease in Asian populations presenting with TIA or ischaemic stroke (9-30%) versus Western counterparts (30-60%).[16] This lower incidence of the disease locally may support channelling both CEA and CAS to specialised centres where expertise is readily available.

The reported rates of complications following CEA vary. For the randomised controlled trials, the rates of any stroke or death at 30 days for "any-risk CEA" range between 3.9% in EVA-3S[17] to 9.9% in CAVATAS.[5] For high-risk patients, the risk of carotid endarterectomy can be significantly higher. In the SAPPHIRE trial,[6] CEA carried a combined death, stroke and MI risk at 30 days of 12.6% versus 5.8% for CAS with distal protection. American registries, for example, ARCHER[18] and BEACH,[14] conducting CAS trials for high surgical risk patients used a historical weighted average control of 14.5% 30-day stroke or death rate after (high-risk) CEA.[7]

It is empirical that patient selection may predetermine the outcome of any form of therapy. As the body of knowledge regarding CAS continues to accumulate, a clearer picture has emerged with respect to identifying patients who are high-risk not only for CEA but also CAS.[8,12,13,19] These characteristics which may be associated with higher risk can be divided into clinical and angiographic and are detailed in Table 4. Vitek[11] also emphasises proper patient selection based on technical aspects of the procedure to decrease morbidity and mortality. Retrospectively, 62.5% of the cases in this cohort with periprocedural complications (5 of the 8) had 1 or more of these characteristics which would put them in high-risk category even for CAS (5 of these had severe stenosis of more than 90%, one additionally being aged more than 80 years).

The use of EPD during CAS can potentially reduce the incidence of distal embolism.[20-22] These devices can be divided into 2 major groups: balloon occlusive devices and filter devices. We have preferentially used filter devices, most often the Boston Scientific EZ Filterwire for its ease of use and design advantage of being able to conform to a range of vessel diameters.

However, the use of filters themselves presents technical issues which may complicate the entire procedure. Eckert[23] in an editorial comment concluded after a review of 10 papers that the complication rates between unprotected 2.0% and protected 3.2% CAS did not warrant a strong recommendation for routine use of EPD. In our study, there appears to be a higher proportion of strokes with the use of the embolic protection device compared to without its use. However, the differences are not significant, probably due to the small sample size. At the very least, this data does not support the notion that usage of the distal embolisation filter is definitely beneficial in high-risk candidates.

Limitations of Study

While there was an attempt to review the long-term follow-up of the patients who underwent CAS in our cohort, many defaulted, the follow-up period varying from 6 days to 10 years (3.4% defaulter at 1 month). Some of them returned to their countries of origin and could not be contacted. The small sample size also limits analysis of the effects of co-morbidities on the final outcome.

Conclusions

CAS is a technically feasible and a relatively safe alternative to CEA to treat extracranial carotid stenosis, especially in patients who are inoperable or at high surgical risk. Recent randomised trials,[17,24] however, have yet to show conclusively the non-inferiority of CAS over CEA although high volume single centre series continue to report adverse event rates comparable to or better than CEA.[10,13] The question of what to do with surgical high-risk patients still remains and perhaps will never be answered without a randomised controlled trial of intervention versus best medical treatment.

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