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Comparison between Carotid Stenting and Carotid Endarterectomy in Early Outcome

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ABSTRACT

Carotid artery stenting (CAS) is a widely used method in prevention of stroke for carotid artery stenosis as an alternative to surgical treatment. Initial studies reveal higher morbidity and mortality rates for CAS than acceptable standards for carotid endarterectomy (CEA). The aim of this study was to compare results in a series of CAS with concurrent risk-matched group of CEA patients. The study included two groups of 50 patients with internal carotid artery stenosis. We compared early outcome (30 days after procedure) in risk-matched groups of patients that underwent these procedures. Post procedural complications were equally frequent in both groups. There was no significant difference in peri-operative complication rates ($P=0.871$). Comparison of these two methods shows that CAS and CEA are competitive methods for treatment of carotid artery stenosis. Particularly in symptomatic patients with high risk for surgery CAS is alternative treatment.

Key words: carotid artery stenosis, carotid stenting (CAS), carotid endarterectomy (CEA)

Introduction

Stroke is the third leading cause of death as well as a cause of permanent disability. Carotid endarterectomy (CEA) is considered standard for prevention of stroke related to carotid artery stenosis. There are two trials that are referenced the most in daily practice decision for carotid stenosis: North American Symptomatic Carotid Endarterectomy Trial (NASCET) and Asymptomatic Carotid Atherosclerosis Study (ACAS)^{1,2}. They concluded that there was a benefit to CEA in patients with symptomatic and asymptomatic carotid occlusive disease surgery. The benefit of CEA over the best medical treatment has been clearly demonstrated in patients with symptomatic carotid stenosis.^{2,3} The risk of stroke or death for symptomatic patients with severe stenosis within 30 days of CEA was 6.8% in ECST and 5.8% (NASCET). In the NASCET trial high-risk groups had mortality and morbidity rates up to 18%.^{2,3} Carotid angioplasty combined with stenting (CAS) is another treatment option.^{4,5} Since the first CAS was performed development of new stents and devices for cerebral protection have improved procedural safety and contributed in increasingly usage of this technique specially in high risk pa-

tients. In the last decade vascular surgeons have changed their point of view in managing severe carotid artery stenosis. In current clinical practice CAS is a viable alternative for patients who are at high risk for surgery.

Materials and Methods

Between October 2008 and May 2010, we retrospectively analyzed 100 symptomatic carotid artery stenosis patients, divided into two groups. Mean age for CAS was 69 (95% C.I. 67–71) and 72 (95% C.I. 70–74) for CEA. Diabetes mellitus has been equally frequent in both groups ($P=0.096$). There were 50 patients undergoing CAS and 50 patients undergoing CEA, with higher risk patients in the CAS group. Risk factors for CEA patients are as shown in Table 2.

The primary criterion for treatment was symptomatic severe ($>70\%$) internal carotid artery (ICA) stenosis. Average stenosis in patients was 83% (95% C.I.: 78%–87%) in the left ICA and 82% (95% C.I.: 77%–87%) in the right ICA. Patients with recurrent carotid stenosis, previous

TABLE 1
ODDS RATION FOR CAS AND CEA PATIENTS

Patients	CAS	CEA	OR	p
postoperative complications				
yes	5	7	0.91 (95% C.I. 0.26–3.12)	0.880
no	33	42		
diabetes mellitus				
yes	23	14	2.21 (95% C.I. 0.96–5.1)	0.06
no	26	35		
Symptoms				
Yes	24	29	0.38 (95% C.I. 0.16–0.91)	0.03
no	26	12		

TABLE 2
RISK FACTORS FOR CEA PATIENTS

Risk factor	Prevalence (N)	p
smoking		
yes	14	<0.001
no	35	
Alcohol		
Yes	14	0.003
no	35	
H.L.P.		
Yes	39	<0.001
no	11	
H.A.		
Yes	41	<0.001
no	8	

cervical radiation therapy or tracheostomy were excluded from the present study in both series, resulting in 50 CAS procedures and 50 CEA patients to be matched. All patients underwent preoperative duplex ultrasound (US) 1 month before carotid revascularization, cerebral computed tomography and carotid angiography. Duplex US criteria for 70% stenosis is a peak systolic velocity (PSV) of more than 200 cm/s and for 90% stenosis PSV of more than 300 cm/s. Plaque characteristics were defined by ultrasound. Carotid angiography was used to define site, degree and length of stenosis with vessel measurements in order to select proper size of balloon and stent in cases of CAS⁶. Duplex velocity criteria were previously validated against angiography as a gold standard using the NASCET criteria.

Patients undergoing CAS were always confirmed by angiography ICA stenosis during the stent procedure. All patients scheduled for CAS received full antiplatelet therapy consisting of acetylsalicylic acid (mean dosage of 100 mg/d) and clopidogrel (75 mg/d) for at least 30 days after a 300 mg loading dose, 12 hours before the procedure⁷. For patients undergoing CEA antiplatelet medication was not interrupted for surgery. CAS was performed by interventional radiologists with experience in endovascular procedures, using a standardized protocol. In-

travenous heparin (100 U/kg) was routinely given before selective catheterization of the common carotid artery. CAS was performed in all cases after proper placement of cerebral protection device (CPD) in the distal ICA under roadmap guidance. Predilation was performed when needed. After CPD deployment, a self-expandable nitinol stent was selected depending on operator preference, lesion characteristics and placed across the stenosis. During the dilation phase, atropine (mean dosage, 1 mg IV) was used in procedures at the discretion of the anesthesiologist. Procedural success for CAS was defined as complete stent deployment with resolution of stenosis or with residual stenosis of less than 30% at the completion angiogram. CEA was performed under local or general anesthesia at discretion of the anesthesiologist. Systemic heparinization was always used during the procedure at the same dosage as CAS and reversed after declamping of the ICA^{8,9}. Longitudinal and eversional arteriotomy was performed. Duplex US of the operated vessel was performed within 1 month, and procedural success for CEA was defined as presence of residual stenosis less than 30%. Early complications were stroke, death, cardiac events and local complications. Perioperative stroke was defined as any new neurological event persisting more than 24 hours and occurring within 30 days from the procedure. Transient ischemic attack (TIA) was defined as any new neurological focal event with complete recovery within 24 hours. Restenosis was defined as carotid stenosis of at least 50% after intervention at follow-up Duplex examination (using PSV 125 cm/s as threshold). For CAS, and for CEA complications during procedure were differentiated whether occurring within the first 24 hours or later. For 24 hours after the procedure (either CAS or CEA) patient was monitored continuously, and in the case of symptoms or uncertainty the patient was examined by a neurologist and the necessary diagnostic imaging was performed (CT scan or magnetic resonance)^{10,11}. Clinical and duplex examination was performed before discharge. Patients were instructed to inform the vascular surgeon or general practitioner when any new symptoms occurred after hospital discharge.

Results

Continuous variables are presented with median and 95% confidence intervals due to the absence of normal distribution (Kolmogorov-Smirnov test). Odds ratio was calculated for categorical variables. Difference within categorical variables was calculated with χ^2 -test. Data processing was done by using *MedCalc* v. 11.2.1.0. (MedCalc Inc. Mariakerke, Belgium). Mean age for CAS 69 (95% C.I. 67–71) and 72 (95% C.I. 70–74) for CEA. Post-procedural complications were equally frequent in both groups (12 patients). There was no significant difference in perioperative complication rates ($P=0.871$). 16 patients had restenosis after CEA. Thirty-Day outcome in CAS group were 2 stent thrombosis immediately during the procedure, which was resolved with intraarterial thrombolysis, 1 dissection, 3 major strokes, 1 intra-

cerebral hemorrhage and minor complications as hematoma on puncture site and nausea. In CEA group there were 2 pulmonary edema in dilative cardiomyopathy, 3 minor strokes, 2 intracranial hemorrhages, 2 myocardial infarction, 2 minor stroke and 1 thrombosis.

Conclusion

The critical safety objective of carotid intervention is the avoidance of stroke. On the basis of several trials^{1,2} CEA is generally considered the standard therapy for severe carotid artery disease. Recent trials have concentrated on investigating CAS, however there is no general agreement whether it should be accepted as an alternative therapy to CEA^{13–15}. Perioperative outcome is shown in Table 1. There were no significant differences in the overall rate of local complications between the two groups. Hematoma requiring revisions were more frequent in the CEA group. The results of ongoing trials with comparison of CAS and CEA will provide a higher level of evidence regarding the risks and benefits of CAS. The experiences of the CAS Registries are currently supplying more data about long term results^{16,17}. Experience with CAS optimized our learning curve and the results obtained supported our conviction of offering CAS as the first choice to patients with severe carotid stenosis¹⁸. The very infrequent periprocedural strokes were presumably

related to small emboli released during the manipulation of the arch, previous to catheter access into the common carotid artery, before embolic filter protection was in place and at the post-dilatation of the stent¹⁹. Despite the fact that embolic protection devices allowed operators to protect the procedure^{20–22}. Long-term stroke prevention in our treated patients is the hallmark of successful carotid intervention. On the basis of the current evidence, CAS with cerebral protection, can be considered equal if not superior to CEA in high-risk patients^{23,24}. On the basis of our results careful selection of patients and good preparation for endovascular procedure can make both procedures competitive. There are now many more medication to treat hypertension, dyslipidemia, coronary heart disease and diabetes. Clopidogrel, a new generation of anti-platelet anti-aggregation drugs used widely for CAS in addition to aspirin, reduces the risk of myocardial infarction. We have to be familiar with the pathology, anatomy, hemodynamics.^{2,4} These, combined with correct patient and lesion analyses, should indicate good results in treatment with both procedures. Comparison of these two methods shows that CAS and CEA are competitive methods for treatment of carotid artery stenosis. Particularly in symptomatic patients with high risk for surgery CAS is alternative treatment. Periprocedural and in-hospital results are encouraging enough in daily practice to use both methods in prevention of stroke.

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KOMPARACIJA RANIH REZULTATA KAROTIDNOG STENTIRANJA I ENDARTEREKTOMIJE

SAŽETAK

Karotidno stentiranje (KAS) je široko prihvaćena metoda liječenja stenoza karotidnih arterija u svrhu prevencije infarkta mozga, alternativa kirurškom zahvatu. Početne studije su pokazale visok morbiditet i mortalitet kod KAS-a za razliku od prihvaćenih kriterija za karotidnu endarterektomiju (KEA). Cilj ove studije je komparirati rezultate u bolesnika nakon KAS-a sa sličnom skupinom bolesnika nakon KEA. Studija uključuje dvije skupine od 50 bolesnika sa stenozom unutarnje karotidne arterije. Usporedili smo rane komplikacije (30 dana nakon zahvata) kod bolesnika kojima je učinjen zahvat. Komplikacije su bile podjednako učestale u obje skupine bolesnika. Nije bilo statistički značajne razlike ($p=0,871$). Rezultati pokazuju da su karotidno stentiranje i endarterektomija jednako kvalitetne metode liječenja stenoza karotidnih arterija. Kod simptomatskih bolesnika s visokim rizikom za operaciju karotidno stentiranje je metoda izbora.