

Editor's Choice — Comparison of Early Outcomes and Restenosis Rate Between Carotid Endarterectomy and Carotid Artery Stenting Using Propensity Score Matching Analysis

Seon-Hee Heo ^a, Kyoung-Won Yoon ^a, Shin-Young Woo ^a, Yang-Jin Park ^a, Young-Wook Kim ^a, Keon-Ha Kim ^b, Chin-Sang Chung ^c, Oh-Young Bang ^c, Dong-Ik Kim ^{a,*}

^a Division of Vascular Surgery, Samsung Medical Centre, Sungkyunkwan University School of Medicine, Seoul, South Korea

^b Department of Radiology Samsung Medical Centre, Sungkyunkwan University School of Medicine, Seoul, South Korea

^c Department of Neurology, Samsung Medical Centre, Sungkyunkwan University School of Medicine, Seoul, South Korea

WHAT THIS PAPER ADDS

This propensity score matched analysis of unselected patients with carotid stenosis reconfirms the findings of previous randomised controlled trials (RCT) that carotid endarterectomy was associated with a lower 30 day incidence of major adverse clinical events and restenosis than carotid artery stenting. This suggests that RCT findings from selected study populations can be generalised to clinical practice.

Objective/Background: Despite randomised evidence, the debate continues about the preferred treatment strategy for carotid stenosis in routine clinical practice. The aim of this study was to compare early outcomes and restenosis rates after carotid endarterectomy (CEA) and carotid stenting (CAS) in unselected patients using propensity score matching (PSM).

Methods: The 30 day incidence of major adverse clinical events (MACE; defined as stroke, transient ischaemic attack, myocardial infarction, or death) and procedure related complications, as well as restenosis rates during follow-up were compared between unselected patients undergoing CEA or CAS between January 2002 and December 2015 at a single institution. PSM was used to balance the following factors between the CEA and CAS cohorts: age, sex, hypertension, diabetes, dyslipidaemia, smoking, atrial fibrillation, previous percutaneous coronary intervention or coronary artery bypass grafting, valvular heart disease, contralateral carotid occlusion, degree of carotid stenosis, and symptomatic status. Statistical comparisons of outcomes were based on logistic regression analysis and log rank test.

Results: Of 1184 patients (654 CEA and 530 CAS), 452 PSM pairs of CEA and CAS patients were created. The CAS group showed a relatively higher 30 day incidence of MACE (7.5% vs. 2.4%; odds ratio [OR] 3.261, 95% confidence interval [CI] 1.634–6.509; $p = .001$) but a lower incidence of procedure related complications (1.5% vs. 5.3%; OR 0.199, 95% CI 0.075–0.528; $p = .001$). During a mean follow-up of 49.1 months (range 1–180 months), restenosis rates were higher after CAS than after CEA (1.5% vs. 1.0% at 12 months and 5.4% vs. 1.2% at 24 months, respectively; $p = .008$).

Conclusion: This PSM based observation reconfirmed previous trial results in both asymptomatic and symptomatic patients with carotid artery stenosis in routine clinical practice: CEA showed lower 30 day MACE and mid-term restenosis rates than CAS.

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INTRODUCTION

Atherosclerotic stenosis of the internal carotid or intracranial arteries is associated with 8–16% of ischaemic strokes.^{1–3} Carotid endarterectomy (CEA) and carotid artery stenting

(CAS) have been compared as treatment modalities of internal carotid artery (ICA) stenosis in many studies. Previous meta-analyses demonstrated that CAS significantly increases the risk of minor stroke but decreases the risk of myocardial infarction (MI).^{4,5} In addition, recent randomised controlled trials (RCTs) with long-term results showed no significant differences in the risk of 30 day post-operative stroke, MI, or death between the two procedures.^{6,7} Despite many reports, the efficacy debate continues between these two treatment modalities. Can these results be uniformly applied to an individual institution? The aim of this study was to evaluate

* Corresponding author. Division of Vascular Surgery, Samsung Medical Centre, 81, Irwon-ro, Gangnam-gu, Seoul 06351, Republic of Korea.

E-mail address: dikim@skku.edu (Dong-Ik Kim).

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early outcomes of CEA versus CAS and restenosis rate during the follow-up period. To balance demographic and clinical characteristics and to adjust for selection bias and confounding factors between the two groups, propensity score matching (PSM) was applied in the analysis.^{8–10}

MATERIALS AND METHODS

Study enrollment and data collection

This study was approved by the Institutional Review Board of Samsung Medical Centre. Informed consent was waived for this retrospective review. From January 2002 to December 2015, 1488 cases of CEA or CAS were performed at a single institution and were included in this study. Demographic and clinical data of enrolled patients were retrospectively collected from electronic medical records.

Among the 1488 cases of CEA ($n = 840$) or CAS ($n = 648$), 47 cases of CEA co-performed with a coronary artery bypass grafting (CABG) operation and 38 cases of CAS performed without embolic protection devices (EPD), three cases of technical failure, and 109 patients who received sequential treatment with CEA or CAS for each of two carotid arteries were excluded from this study.

Procedures

Indications for treatment of ICA stenosis at the authors' institution are ICA stenosis $> 50\%$ in symptomatic (presence of neurological or ocular symptoms) patients and $> 70\%$ in asymptomatic patients, unless totally occluded. All patients who underwent carotid revascularisation had computed tomography angiography, magnetic resonance angiography, or conventional angiography before the procedure. The degree of stenosis was calculated according to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) measurement criteria.^{11,12}

When deciding treatment modality between CEA or CAS, CAS was selected for patients with an unfavourable carotid anatomy for CEA (prior ipsilateral radiation therapy to neck, previous ablative neck surgery, contralateral vocal cord paralysis, presence of a tracheostomy stoma, high lesion above the C2 vertebral body), high surgical risk of CEA (old age, severe heart failure, severe pulmonary function disorder), the preference of the patient, and for the purpose of the clinical trial.

All CEAs were conducted using conventional endarterectomy technique under general anaesthesia, and carotid shunts were used routinely (Pruitt-Inahara® Carotid Shunts; LeMaitre Vascular, Burlington, MA, USA). In symptomatic patients, antiplatelet agent was continued before the CEA procedure and all CEA procedures were performed with intravenous unfractionated heparin (50–60 units/kg body weight) during the CEA procedure. The carotid artery was closed primarily or with processed bovine pericardial patch (Vascu-Guard; Synnovis Surgical Innovations, St. Paul, MN, USA) according to the surgeon's preference. CAS was performed under local anaesthesia with antiplatelet therapy (100 mg aspirin and/or 75–300 mg clopidogrel) before the procedure and intravenous unfractionated heparin (50–60

units/kg body weight) during the procedure. Several types of EPD were applied for all CAS during the study period. After CEA or CAS, single or dual antiplatelet therapy or warfarin was continued unless contraindicated.

Endpoints and definition

The primary endpoint for this study was the 30 day post-operative incidence of a major adverse clinical event (MACE), a composite outcome that defined any clinical stroke, TIA, MI, or death. Any clinical stroke was defined as an acute neurological event with focal symptoms and signs, lasting for 24 hours or more, that were consistent with focal cerebral ischaemia. MI was defined as one or more of the following: documentation of electrocardiographic changes indicative of acute MI; new elevation in troponin more than three times the upper level of the reference interval in the setting of suspected myocardial ischaemia. Secondary outcome included the 30 day incidence of procedure related complication, such as cerebral hyperperfusion syndrome, bleeding required re-operation, cranial nerve injury, and restenosis rate during the follow-up period. Cerebral hyperperfusion syndrome was included with severe ipsilateral headache with hypertension, seizures, and intracranial haemorrhage on image study,^{13,14} without any further confirmative examination by transcranial Doppler.¹⁵ For patients complaining of unusual prolonged headache or showing abnormal neurological signs after CEA or CAS, neurological examinations and further management were performed by neurologists. Cranial nerve injury was determined on the basis of the symptomatic presentation after the revascularisation procedure showing injury of hypoglossal, recurrent laryngeal, superior laryngeal, and marginal mandibular branch of facial nerve.^{16,17}

Duplex ultrasonography was routinely performed at 1, 6, 12, and 24 months after revascularisation and then every year during the follow-up period. Seventy percent or more diameter reducing stenosis or occlusion and peak systolic velocity above 300 cm/s detected by duplex ultrasonography were considered restenosis.^{18,19}

Statistical analysis

The primary predictive variable for the analysis was revascularisation technique (CEA vs. CAS). Because this study was designed as a retrospective observational study and there were likely to be non-random differences between the CEA and CAS groups, the PSM technique was used to reduce possible selection bias and confounder effects and to create two balanced groups.

PSM matching using zero matching tolerance, and a 1:1 matching algorithm without replacement was conducted by a professional biostatistics team. Matching factors were as follows: age, sex, hypertension, diabetes, dyslipidaemia, smoking, atrial fibrillation, previous percutaneous coronary intervention or CABG, valvular heart disease, contralateral carotid occlusion, degree of carotid stenosis, and symptomatic status. Age (years) was categorized into four groups: ≤ 60 , 61–70, 71–80, and > 80 . Degree of carotid stenosis was divided into two groups: $< 70\%$ and $\geq 70\%$.^{11,20} Symptomatic was defined as the presence of

neurological or ocular symptoms within 6 months prior to CEA or CAS.²¹ Use of antiplatelet or anticoagulant medication was not included in the matching factors. A covariate balance test was conducted after PSM, and matching factors were compared between the two groups in the same manner. It was considered that the standardised mean difference was < 10% and the variance ratio was around 1.0 when pursuing balancing. To perform subgroup analysis according to the symptomatic status, a matched group was made using same matching factor except symptomatic status, in the same manner.

Before PSM, matching factors were compared for all patient using Fisher's exact test and chi-square test. In the matched group of patients, comparisons of early outcomes were performed using logistic regression analysis, and restenosis rate during the follow-up period was performed using Kaplan–Meier estimates and the log rank test. All *p* values were two sided and statistical significance was defined as *p* < .05.

RESULTS

A total of 1184 patients who underwent CEA (*n* = 654) or CAS (*n* = 530) were included in the study. The demographic and clinical characteristics of the overall group of carotid revascularisation patients are shown in the Table 1. There was a higher incidence of symptomatic cases in the CAS group than in the CEA group (55.5% vs. 35.5%; *p* < .001). Dyslipidaemia, previous CABG, contralateral carotid artery occlusion, and degree of stenosis were also significantly different between two groups (Table 1).

Matching was conducted between the CEA and CAS groups. Four hundred and fifty two CEA patients (69.1% of the CEA patients) and 452 CAS patients (85.3% of the CAS patients) who had same propensity score were able to be matched. The 202 unmatched CEA patients and 78 unmatched CAS patients were excluded from the statistical analysis after PSM. A homogeneity test revealed that there was no significant difference in the incidence of covariates between the two matched groups (Table 1).

In total, 452 pairs of matched patients were analysed for the comparison of outcomes. The CAS group had a higher 30 day incidence of MACE (7.5% vs. 2.4%; odds ratio [OR] 3.261; 95% confidence interval [CI] 1.634–6.509; *p* = .001) (Table 2). However, the incidence of procedure related complications was higher in the CEA group (Table 2). During the mean follow-up period of 49.1 months (range 1–180 months), 17 patients (2.6%) and 28 (5.3%) patients had developed restenosis in the CEA group and CAS group, respectively. The median interval between treatment and detection of restenosis was 18 months (interquartile range [IQR] 7.3–25 months). The CAS group showed a higher restenosis rate (1.5% vs. 1.0% at 12 months, 5.4% vs. 1.2% at 24 months; *p* = .008 log rank test) than the CEA group (Fig. 1)

The result of subgroup analysis according to symptomatic status is given in Tables S2 and S3 and Fig. S1 (see Supplementary Material). The CAS group showed a higher 30 day incidence of MACE (5.6% vs. 1.7% [OR 3.384, 95% CI 1.066–3.979; *p* = .039] in asymptomatic patients and 11.6% vs. 2.4% [OR 5.298, 95% CI 2.005–13.999; *p* = .001] in symptomatic patients) and lower incidence of procedure related complications in the asymptomatic and symptomatic groups. In the subgroup analysis for restenosis rate, the CAS group showed a higher restenosis rate than the CEA group (asymptomatic patient group; *p* = .035), but there was no statistically significant difference in the symptomatic patient group.

DISCUSSION

For treatment of patients with carotid artery stenosis, CEA and CAS have been compared in several meta-analyses, with similar conclusions. Murad et al. demonstrated that, compared with CEA, CAS was associated with a significant increase in the risk of any stroke and mortality, but there was a decrease in the risk of peri-procedural MI.⁵ Another study showed that CAS was associated with elevated risk for stroke and exhibited a marginal trend toward higher death and disabling stroke rates. In contrast, CEA presented with higher rates of MI and cranial nerve injury.^{4,5}

Table 1. Demographic and clinical characteristics of overall and propensity score matched group of carotid revascularisation patients.

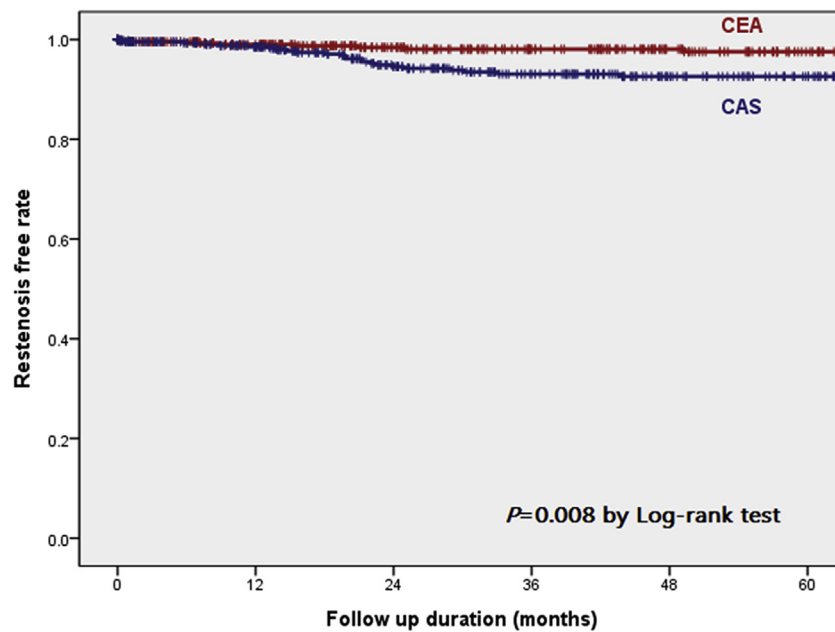
Characteristics	Overall group			Matched group		
	CEA (<i>n</i> = 654)	CAS (<i>n</i> = 530)	<i>p</i>	CEA (<i>n</i> = 452)	CAS (<i>n</i> = 452)	<i>p</i> ^c
Age (y)			.5 ^a			.894
≤ 60	111 (17.0)	96 (18.1)		78 (17.3)	85 (18.8)	
61–70	284 (43.4)	211 (39.8)		188 (41.6)	179 (39.6)	
71–80	231 (35.3)	193 (36.4)		165 (36.5)	165 (36.5)	
> 80	28 (4.3)	30 (5.7)		21 (4.6)	23 (5.1)	
Sex (female)	96 (14.7)	87 (16.4)	.459 ^a	66 (14.6)	76 (16.8)	.361
Symptomatic	232 (35.5)	294 (55.5)	< .001 ^a	206 (45.6)	221 (48.9)	.318
Hypertension	500 (76.5)	403 (76.0)	.922 ^a	349 (77.2)	348 (77.0)	.937
Diabetes	264 (40.4)	236 (44.5)	.167 ^a	190 (42.0)	209 (46.2)	.203
Dyslipidaemia	477 (72.9)	347 (65.5)	.007 ^a	308 (68.1)	299 (66.2)	.524
Smoking	320 (48.9)	264 (49.8)	.808 ^a	229 (50.7)	220 (48.7)	.549
Atrial fibrillation	37 (5.7)	23 (4.3)	.371 ^a	22 (4.9)	18 (4.0)	.518
Previous PCI or CABG	191 (29.2)	97 (18.3)	< .001 ^a	99 (21.9)	95 (21.0)	.746
Valvular heart disease	8 (1.2)	6 (1.1)	1.000 ^b	5 (1.1)	4 (0.9)	1.000
Contralateral carotid occlusion	44 (6.7)	60 (11.3)	.008 ^a	35 (7.7)	49 (10.8)	.109
Degree of stenosis ≥ 70%	538 (82.3)	505 (95.3)	< .001 ^a	427 (94.5)	428 (94.7)	.883

Note. Data are *n* (%). CEA = carotid endarterectomy; CAS = carotid artery stenting; PCI = percutaneous coronary intervention; CABG = coronary artery bypass grafting. ^a Chi-square test. ^b Fisher's exact test. ^c Marginal homogeneity test.

Table 2. Thirty day post-operative outcomes of propensity matched group of carotid revascularisation patients, stratified by procedure.

Outcome	All matched group		OR (95% CI)	p
	CEA (n = 452)	CAS (n = 452)		
MACE	11 (2.4)	34 (7.5)	3.261 (1.634–6.509)	.001
Any stroke	7 (1.5)	24 (5.3)	3.565 (1.502–8.461)	.004
Transient ischaemic attack	4 (0.9)	8 (1.8)	2.018 (0.598–6.812)	.258
Myocardial infarction	0	0	NA	NA
Death	0	3 (0.7)	NA	NA
Procedure related complication	24 (5.3)	7 (1.5)	0.199 (0.075–0.528)	.001
Hyperperfusion syndrome	11 (2.4)	7 (1.5)	0.631	.350
Bleeding required re-operation	2 (0.4)	0	NA	NA
Cranial nerve injury	11 (2.4)	0	NA	NA

Note. Data are n (%). OR = odds ratio; CI = confidence interval; CEA = carotid endarterectomy; CAS = carotid artery stenting; MACE = major adverse clinical event; NA = not available.



Number at risk

CEA	452	(4)	369	(2)	291	(1)	238	(0)	193	(1)	152
CAS	452	(1)	370	(13)	284	(4)	227	(1)	170	(0)	140

Figure 1. Restenosis free rate of propensity score matched group of carotid revascularisation patients during the follow-up period.

In contrast, recently published, long-term, multicentre RCTs found different results. In the International Carotid Stenting Study (ICSS), the authors insisted that the long-term risk of fatal or disabling stroke was similar for CEA and CAS for symptomatic carotid stenosis. They also found that procedure related stroke or death, as well as ipsilateral stroke, were more frequent in the stenting group.⁶ In contrast, the CREST trial found no significant difference between CAS and CEA with respect to the risk of peri-procedural stroke, MI, death, or subsequent ipsilateral stroke.⁷

In the present single-centre experience, CEA showed a lower 30 day incidence of MACE and lower restenosis rate during the follow-up period than CAS for revascularisation of carotid artery stenosis. The difference in the 30 day incidence of MACE was mainly attributed to the difference in any incidence of stroke. In the current study, there were very low 30 day post-operative incidences of MI and death. Echocardiograms were routinely checked before the

procedure for the evaluation the coronary artery disease. If the patient had coronary artery disease, coronary intervention or coronary artery bypass grafting was performed before the carotid revascularisation in most patients. This might be the reason why the 30 day incidence of MI was lower than in other studies. There were three deaths in the CAS group and none in the CEA group within 30 days of the procedure, although this difference was not statistically significant. Causes of death in the CAS group were progression of lung cancer, hospital acquired pneumonia, and left middle cerebral artery total infarction.

During the mean follow-up period of 49.1 (range 1–180) months, 2.6% of patients in the CEA group and 5.3% of patients in the CAS group had developed restenosis, respectively. The median interval between treatment and detection of restenosis was 18 months (IQR 7.3–25 months). In a meta-analysis of 55 reports, the overall incidence of restenosis after CEA was 6–14%²²; in another

study, the rate of restenosis was 10% within the first year, 3% in the second, and 2% in the third year after CEA.²³ In a secondary analysis of CREST, carotid restenosis or occlusions occurred at similar rates after CAS (6.0%) and CEA (6.3%) at 2 years after randomisation,¹⁹ but 2 year data from the SPACE trial showed still higher carotid restenosis after CAS than after CEA (10.7% vs. 4.6%).²⁴

Although recent multicentre RCTs concluded that CAS and CEA have comparable outcomes for the treatment of carotid artery stenosis, the present results favour CEA over CAS. These conflicting results indicate that different procedure related risks for the two procedures should be weighted before selecting an approach for an individual patient. In addition, given the present findings, the treatment, characteristics, and supportive environment of each institution may play an important role in choosing the best treatment modality.

Study limitations

This study has several limitations. First, it was conducted as a retrospective observational study at a single centre, and the outcomes of other RCTs or meta-analyses should be considered in future studies. Second, patients were not matched on the covariate of pre-operative use of antiplatelet and anticoagulation medications, and plaque morphologies and time intervals between event and revascularisation procedure in symptomatic patients despite being crucial parameters determining outcome of stenting and CEA. Finally, longer term follow-up data are needed for further evaluation.

CONCLUSION

CEA was associated with a lower risk of any clinical stroke within 30 days post-procedure and lower restenosis rate during the follow-up period in this single-centre experience.

CONFLICT OF INTEREST

None.

FUNDING

None.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.ejvs.2017.08.006>.

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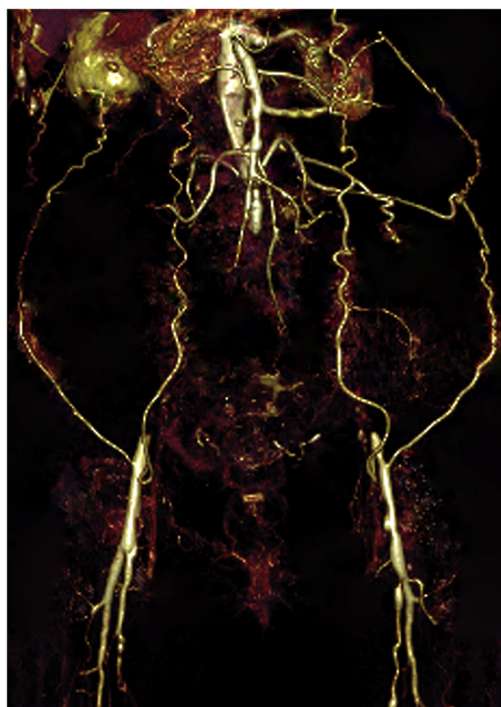
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COUP D'OEIL

Collateral Circulation in Chronic Aortic Occlusive Disease

Zhongzhi Jia, Guomin Jiang *

Department of Interventional Radiology, No. 2 People's Hospital of Changzhou, Nanjing Medical University, Changzhou 213003, China



A 76 year old man presented with weakness in both legs. There was no sensory loss or coldness, and he reported no claudication. He had suffered from type 2 diabetes mellitus and hypertension for 20 years. Chronic aorto-iliac occlusive disease (AIOD) was diagnosed by computed tomography angiography. He was prescribed walking exercises and dual anti-platelet therapy. The image demonstrates various collateral pathways maintaining blood flow to the lower extremities in AIOD, including proximally internal thoracic inferior epigastric-thoraco-epigastric arterial arcades, distally lumbar deep circumflex iliac arteries linking to the external iliac arteries. Patients can be treated conservatively without intervention when supported by such well formed collateral pathways.

* Corresponding author. Department of Interventional Radiology, No. 2 People's Hospital of Changzhou, Nanjing Medical University, Changzhou 213003, China.

E-mail address: 747094035@qq.com (Guomin Jiang).

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