



Recommendations for Carotid Stenting in Korea

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Carotid artery angioplasty with stenting (CAS) is being performed in many hospitals in Korea. Most of the guidelines which are being used are similar, but the practical aspects such as techniques are different between hospitals. For example, usage of various protective devices, the oral antiplatelet regimen prior to procedure and placing of temporary pacemaker to prevent bradycardia are different between hospitals. In this article, we summarize and propose the guidelines for CAS which is currently being accepted in Korea. These guidelines may be helpful in providing protocol to neurointerventionalist who perform CAS and to standardize the process including reporting of CAS in the future comparative trials in Korea.

Key Words : Guideline; Carotid artery; Angioplasty; Stenting

Since the publication of guidelines review in 2006 and preliminary guidelines in 2007 from the Korean Society of Interventional Neuroradiology (KSIN) [1, 2], new study results are needed to be mentioned for carotid artery stenting (CAS). The most outstanding change was publication of Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) [3, 4].

CREST showed no significant difference between the stenting and endarterectomy group overall in the rates of a composite outcome that included major periprocedural complications (such as stroke, myocardial infarction, or death) and ipsilateral stroke over a 4-year follow-up period. According to the results of CREST, American College of Cardiology (ACC)/American Heart Association (AHA) recommended CAS as an alternative to CEA for symptomatic carotid stenosis [5]. However, debates still remain about the comparative efficacy of CAS and carotid endarterectomy (CEA) [6].

While there are many comparative trials in European and North American medical societies [3, 7–10], there have not been any large comparative trials between CAS and CEA in Asia or Korea. Ethnicity may play a role in the characteristics of carotid stenosis. For example, the pattern of carotid bulb stenosis in Koreans is different from westerners; apical type of carotid bulb stenosis is more common in Koreans than body type which is more common in western countries and related with hyperlipidemia [11]. Such anatomical preference results in difference in baroreceptor

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Received November 11, 2014;

accepted after revision January 19, 2015.

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responses during carotid stenting [12]. Thus, the consensus about guidelines of CAS is needed to prepare a large trial in Korea or Asia.

The purpose of this document is to summarize and suggest the guidelines of CAS which can be generally accepted in Korea. Furthermore we want to standardize the reporting of CAS procedures so that CAS and CEA will be fairly compared in future clinical trials conducting in Korea or Asia. This document is a consensus statement of the Task Force Team of the Korean Society of Interventional Neuroradiology. This document describes the indication, contraindication, eligibility of operator, and standard reporting system for the use of CAS in Korea.

Pre-Procedural considerations

Patient selection

Patients can be selected according to multiple factors such as degree of stenosis, presence of symptoms, patient age, and presence of factors related with high risk of complications from CAS [13]. Various endarterectomy and stent trials have defined symptomatic patients as those with symptoms of acute ischemic stroke or transient ischemic stroke within 90 to 180 days of trial entry [13–15]. For purpose of consistency, it is recommended that symptomatic patients be defined as those with neurological or ocular symptoms within 6 months (180 days) [14]. On pooling data from the ECST, NASCET and Veterans Affairs trial, endarterectomy was of marginal benefit in those with 50–69% stenosis (in this document, all reporting of the degree of stenosis follows the NASCET criteria) and was highly beneficial in those with 70% stenosis or greater without near occlusion [16, 17]. ACC and AHA reported in their guidelines that CAS is indicated as an alternative to CEA for a patient with symptomatic carotid stenosis of more than 50% as documented by catheter angiography [5]. The “2013 Clinical Practice Guideline for Stroke” in Korea recommended the same guideline as ACC/AHA in terms of stenosis degree [18]. However in 2008 the Health Insurance Review & Assessment Service (HIRA) in Korea announced the indication of insurance coverage for CAS as more than 70% narrowing and 50% narrowing with surgically high risk or unsuitable patients [19]. Therefore, the indication for CAS in Korea needs to be broadened to the patients without surgically high risk. The Korean HIRA also allowed the insurance coverage as more than 50% narrowing in the special cases of ulcerative plaque, restenosis after CEA, tandem lesion, dissection,

fibromuscular dysplasia, Takayasu’s arteritis, and stenosis after radiotherapy. In the cases of flow disturbance due to dissection, arterio-venous fistula, and pseudoaneurysm, CAS is included in the insurance coverage by HIRA regardless of stenosis degree.

In the asymptomatic carotid stenosis, the evidence does not show either CEA or CAS having a clear benefit compared with treatment by medication alone. The only large, well-constructed, randomized, controlled trial published to date comparing surgical endarterectomy with medical therapy in asymptomatic carotid stenosis is the Asymptomatic Carotid Atherosclerosis Study (ACAS) [13, 20]. ACAS reported that the patients with more than 60% stenosis have absolute risk reduction of 5.9% for CEA as compared to medical therapy over a 5-year period. In contrast to CEA, there is no randomized controlled trial between CAS versus medical therapy. In the SAPHIRE and CREST, some enrolled patients were asymptomatic patients [16]. ACC/AHA reported that CAS might be considered for highly selected patients with asymptomatic stenosis of more than 60% by angiography. HIRA allowed the insurance coverage for patients with more than 80% narrowing for CAS and all cases for CEA in asymptomatic stenosis. In this document, we followed the HIRA guideline in asymptomatic stenosis [21].

2011 ACC/AHA guideline reported that it is reasonable to choose CEA over CAS when revascularization is indicated in older patients [5]. In CREST and CaRESS trial, CAS was better than CEA in the patients with less than 70-years-old and less than 80-years-old [3, 22]. It is probably due to proportional relation between old age and unfavorable arterial pathoanatomy for CAS. We followed the age guideline of CaRESS trial (<80 years).

In endarterectomy trials, patients at high risk for complications from the treatment have been identified [14]. In SAPHIRE trial, clinically significant cardiac disease, severe pulmonary disease, contralateral carotid occlusion, contralateral laryngeal nerve palsy, previous radiation therapy or radical surgery of neck, recurrent stenosis after endarterectomy, and older than 80 years are categorized as high risk group of CEA [7]. High cervical ICA lesion or CCA lesions below the clavicle and severe tandem lesion are also included in the high risk group for CEA [23]. CAS also has high risk group such as the patients who have a severely tortuous carotid artery which makes it difficult to pass the device for CAS or who have acute thrombi in the stenotic site that can migrate during the passage of the

CAS devices. Inclusion and exclusion criteria must be reported regarding age, categorization of patients as symptomatic or asymptomatic, type of symptom, degree of stenosis, technique for measuring the degree of stenosis, and presence and type of high-risk comorbidities.

In the conclusion of patient selection, we recommend the following inclusion criteria for CAS.

- A. Patients with symptomatic carotid artery stenosis more than 50% (NASCET criteria) and less than 80-years-old without high risk factors contraindicating CAS and more than 80-years-old with high surgical risks.
- B. For symptomatic patients, CAS should be performed by the interventionist with established periprocedural stroke and mortality rates of less than 6%.
- C. Patients with asymptomatic carotid artery stenosis more than 80% (NASCET criteria) and less than 80 years old without high risk factors contraindicating CAS.
- D. For asymptomatic patients, CAS should be performed by the interventionist with established periprocedural stroke and mortality rates of less than 3%.

Pretreatment evaluations

Pretreatment evaluations should include assessment of the degree of stenosis using imaging diagnosis (duplex US, CTA, or MRA), and neurological assessment (NIH stroke scale, Barthel index, and Rankin scale). Laboratory tests pertaining to blood homeostasis, renal function, and cardiac enzyme within 72 hours before the procedure are required to be included, the same standard applied to endarterectomy trials [13]. A baseline brain CT or MRI scan should be obtained to document any preexisting infarction or intracranial hemorrhage.

Treatment Description

Previous operator experience is needed in the procedure report. Medical therapy may need to be adjusted for angiography. Patients with preexisting renal disease may be admitted 1 day early for intravenous hydration or vasodilator therapy [13].

Antiplatelet and anticoagulation regimen

Oral enteric-coated aspirin (325 mg/day or 100 mg/day) and clopidogrel (75 mg/day) have been recommended before and after the procedure, but the

optimal duration of antiplatelet therapy has not been established [24]. In the CREST, patients received aspirin (325 mg, twice daily) and clopidogrel (75 mg, twice daily) at least 2 days before CAS. When CAS was scheduled for within 48 hours, 650 mg of aspirin and 450 mg of clopidogrel were given 4 or more hours before the procedure [3]. According to the WFITN anticoagulation protocol, aspirin 100 mg and clopidogrel 75 mg are administered 3 days before the procedure and dual-therapy for three months with aspirin to be continued indefinitely after the procedure [25]. At least 3 days before CAS, 100 mg of aspirin and 75 mg of clopidogrel are commonly used in Korea [25]. After CAS, it is common to use dual antiplatelet of aspirin and clopidogrel for one to three months and then change to a single antiplatelet therapy with aspirin indefinitely [24]. A resistance test for Aspirin and Clopidogrel before the procedure is usually performed because Clopidogrel resistance is more common in Koreans. If there is resistance, additional roading or change of the regimen is considered. Heparin is typically given during the procedure and may be given with or without glycoprotein IIb/IIIa inhibitor. As a single agent, heparin is usually given as a 2,000- to 4,000-unit bolus according to the patient's body weight with maintenance dose of 1000-unit/hour with control of ACT between 250–300 [24, 25].

To control blood pressure antihypertensive medication is recommended before and after CAS. Neurological examination should be done and documented within 24 hours before and after CAS [5]. The procedure is usually performed under conscious sedation which allows continuous monitoring of the patient's neurological status. Although patients may have been selected for CAS based on previous noninvasive imaging study, the final determination of stenosis degree should be made from the catheter angiographic findings at the time of intervention [5].

Access to target lesion

Access is usually via the common femoral artery, although carotid or the brachial artery can be used [16]. A 7- or 8-Fr guiding system with 80–90 cm length is usually used for CAS. Within the guiding system, 5-Fr angiographic catheter with 110–125 cm length is coaxially introduced to reach the target lesion [16]. Then IV bolus Heparin is administered in the manner previously mentioned and continuous stream of heparinized flush (1000 units per liter) is used with either a pressurized bag or an electronically driven pump [26]. After the guiding catheter is placed in the

distal common carotid artery, angiographic runs of carotid artery with the anteroposterior and lateral projections are done. For better evaluation of the stenosis and lesion site, oblique projection or 3D rotational angiography may be used [27].

Protection device

Cerebral protection devices have been widely used as a necessary means to prevent migration of emboli and stroke during CAS although many controversies still exist [28]. There are two kinds of protection devices, distal embolic protection devices (EPD) and proximal cerebral protection devices. EPD is advanced across the target lesion and positioned distally in the artery to establish cerebral protection. In contrast to EPD, the proximal cerebral protection device provides protection before crossing the region of stenosis.

1) EPD

There are two kinds of distal embolic protection devices such as distal filter device and distal protection balloon. A distal filter device is placed in the ICA between the target lesion and the brain to capture any debris during the CAS procedure. When the stenosis is too tight to pass the protection device, balloon angioplasty with a 2–3 mm balloon catheter can be used prior to filter device placement [1]. When placing protection device, it is important not to advance the tip of the device beyond the cavernous portion of internal carotid artery because the intracranial portion of the carotid artery is prone to dissection. Currently the distal protection balloon is not widely used in Korea.

2) Proximal cerebral protection device

Only one kind of proximal cerebral protection device is available in Korea which is a single catheter system comprising of cerebral protection and guiding sheath to perform stent placement and removal of debris by blood aspiration [29]. It is positioned and cerebral protection with flow cessation is established before the guide-wire or device is placed across the carotid stenosis. Slow inflation of the ECA and CCA balloons is observed under fluoroscopy until the balloon shape is observed to change from circular to cylindrical shape. Flow cessation is confirmed by stagnation of 5 cc of slowly injected contrast/saline mix and the establishment of carotid artery back pressure. Aspiration of 60 cc of blood is completed with the last 20 cc filtered through a 40 micrometer filter to evaluate for atherothrombotic debris. If debris is noted, additional 20 cc aspirates are completed until no further debris is

visible.

Predilatation

The decision to pre-dilate the lesion using balloon angioplasty depends on the type and size of stent being used, the narrowest lumen diameter, and the morphological configuration of stenotic segment [13]. Many operators perform routine predilatation with 3–4 mm diameter/2–4 cm length balloon. Some operator prefer long balloon such as 3–4 cm length to prevent “watermelon seed effect” (sliding of balloon to normal diameter lumen) and to determine stent length [30].

Stent

A self-expandable stent is recommended rather than a balloon-expandable stent which can be compressed by external force. In terms of stent length, the stent margin should optimally extend 1 cm beyond the proximal and distal margins of the stenotic plaque. The stent diameter should be 1 to 2 mm larger than the largest vessel diameter that the stent will need to contact the parent vessel wall.

Post-deployment balloon angioplasty can be performed to closely contact the stent and vessel wall and further expand regions of residual stent narrowing. Some operators, however, do not advocate routine post-deployment angioplasty other than for obvious gaps between the stent and vessel wall, because this additional intervention might increase the risk of embolic complications and worsens restenosis rates related to intimal injury [13].

The technical success has been described as a stent placement resulting in improvement of the stenosis by >20%, with final residual stenosis <50% using NASCET criteria [13]. Iatrogenic vasospasm may occur during the procedure, but usually resolves soon after removal of the guide-wire from the internal carotid artery. Such spasm is usually relieved by waiting a while. If the vasospasm compromises the normal flow in the carotid artery, intra-arterial nimodipine or nitroglycerin can be used.

When bradycardia is observed or expected by stimulating baroreceptor during pre and post stent balloon dilatation, it is recommended to instruct the patient to cough, administer atropine 0.25–0.5 mg IV, or a combination of these methods. When hypotension is observed, it is recommended to make a patient in head-flat position, administer IV hydration, atropine, sometimes IV vasopressors (such as phenylephrine or dopamine), or a combination of these [31–33].

The patient is usually monitored in the intensive care

unit for 12 to 24 hours after the procedure. After successful revascularization, lowering of the mean arterial pressure to 10 to 20% below baseline may be desirable to prevent cerebral hyperperfusion injury.

When a new neurologic symptom develops during or after the procedure, an MRI including diffusion imaging and gradient echo sequence is advised in order to rule out a new embolic lesion or hyperperfusion syndrome.

Post-treatment Evaluation

Post-treatment evaluation should include the perioperative (within the first 30 days) stroke, death, and myocardial infarction. Long term evaluation for stroke recurrence or restenosis in the treated vessel for 2 to 5 years is also necessary. Neurological assessment including the NIH stroke scale in the perioperative period, Barthel index, and modified Rankin scale after 90 days should be performed. Regular follow-up may also be required on the outpatient clinic by neurologist as well as neurointerventionalist at 6 months and 12 months after the procedure and yearly thereafter for 2 to 5 years. Assessment of long-term mortality is also included.

Post treatment radiological evaluation is a matter of debate [34, 35]. Doppler ultrasonography (US) and computed tomography angiography (CTA) are usually used. Doppler US is a useful screening method because of low cost, no radiation effect and no contrast media administration. But, shortcomings are operator dependent, possible non-accessibility and poor visualization of stented lumen. Furthermore, there are no standard diagnostic criteria for restenosis after CAS. CT angiography is an effective tool in the visualization of the stented lumen and relatively accurate in the measurement of in-stent restenosis. A combination of both diagnostic methods is recommended according to the patient's and doctor's preference and hospital's availability

Reporting of Complication

Complications within 30 days of the procedure are considered perioperative and procedure related complications. A stroke as a complication of the procedure may be caused by intracranial embolism, hemorrhage, or hyperperfusion injury. A stroke may be described as reversible and minor versus major, or permanent and minor versus major. A reversible stroke is a neurological complication having a duration of >24 hours and <

30 days, and permanent stroke is >30 days.

A minor deficit is a neurological deterioration evidenced by an increase of the NIHSS of <4 points without the presence of aphasia or hemianopsia, or complete recovery within one month. A major deficit is an increase of the NIHSS of ≥ 4 points or the presence of aphasia or hemianopsia or residual deficit beyond 1 month. A transient deficit can be described when the neurological complication has completely subsided within 24 hours. Neurologic deficits should be listed as ipsilateral or contralateral. Myocardial infarction and death which is related with stroke should be described.

Other complications such as puncture related or contrast media related events also should be described as minor or major according to the severity [13].

Qualification and training for CAS

There are many international guidelines covering the qualifications and training of operators performing CAS [36, 37]. However, most of these guidelines are for the western population. The epidemiology of carotid stenosis for the Korean or Asian population is different from western people. Thus, the guidelines covering qualifications and training for CAS for Asian patients should be different from western patients.

We propose a method of training of CAS in our society (KSIN). KSIN can nominate CAS proctors who can help assist inexperienced members who did not experience less than 10 cases. The selection processes include application and review and nomination. Application is done by experienced operator who performed more than 30 cases during the last two years and submit the outcome results including 90 days mRS to the Society. The society TFT reviews the applicants and finally proctor is nominated in the executive committee. Therefore, if a member request a help to assist the CAS procedure, KSIN dispatch an available proctor to the hospital. The applicant with proctor reports the procedure process, result and final outcome to the Society. The Society regularly reviews the proctor's outcome and rearranges the proctorship based on the patient outcome reported by the applicant.

Conclusion

CAS is an active treatment method for carotid arterial stenosis and it has many advantages as compared to CEA. Although the ACC reported that CAS is an alternative treatment to CEA in their guideline after release of the results of CREST, CAS is not accepted as

an equal to CEA as a treatment option especially in the surgical society [6]. We thought that CAS is not currently in the state of competence to CEA but they are complementary to each other.

In order to obtain and maintain for CAS as a well-founded comparison to CEA, the efficacy, safety, and durability of stroke prevention should be verified through a large randomized multicenter study. Furthermore, the continuous efforts for further establishment of formal indication, reporting standards, and qualification and training methods for operator are needed for improvement of clinical results of CAS and a future comparative study of CAS versus CEA in Korea.

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