Review

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Recent Update of Guidelines for Neurointerventional Procedures

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Treatment guidelines of the neurointerventional procedures are continuously updated. However, these guidelines differ between countries and even medical societies within the same country because of the differing interests and patient groups. The differences between guidelines are confusing to many neurointerventionalists. Recently "Clinical Research Center for Stroke" in Korea updated "Clinical Practice Guidelines for Stroke" for the patients in Korea. So we introduce those guidelines and compare several recent guidelines of international medical societies for neurointerventionalists.

Key Words : Guideline; Neurointervention; Stenting; Aneurysm

Since the preliminary guidelines were published in 2007 [1−6], there have been many changes in the practice environments of the neurointerventional field [7]. Expertise in this field requires long training background [8]. There are two major things in recognizing the changes in the practice pattern of neurointervention in Korea. One is the review process of imported products from foreign countries. The more complicated review process in the government organizations takes more time to get insurance coverage or even non-insurance coverage which can allow usage in patients by predetermined non-insurance cost. The other thing is the indication of the procedures.

Compared to rapid development and application of useful new products in abroad, renewal of application for the insurance coverage for the new products becomes more difficult year-by-year in Korea. For example, protective devices for carotid stenting or glue for fistular embolization is not included in insurance coverage because there is no re-evaluation system if the item is not accepted and not further recognized by the Health Insurance Review & Assessment Service (HIRA).

In contrast to situation in Korea, treatment guidelines of the neurointerventional procedures are continuously updated in the literature worldwide. Although many countries refer to those guidelines, some guidelines published in the regional Society may defer from others because they adopt different medical evidences. Such differences between guidelines are sometimes confusing to neurointerventionalists because indication of procedure and products may depend on the situation of their own countries.

Recently "Clinical Research Center for Stroke (CRCS)" in Korea reported "Clinical Practice Guidelines for Stroke" for the patients in Korea [9]. Those guidelines were updated in 2013. Some

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members of Korean Society of Interventional Neuroradiology (KSIN) were involved in the establishment of the guidelines. We introduce and review those guidelines and compare several recent guidelines of international medical societies for management of carotid artery stenosis, intracranial artery stenosis, and unruptured intracranial aneurysms. In addition, we also discuss some current issues regarding administrative process related with procedures and devices ruled by government.

Carotid Artery Stenosis

After publication of the results of the Carotid Revascularization Endarterectomy versus Stenting trial (CREST), the American College of Cardiology (ACC) and the American Heart association (AHA) announced the following guideline for carotid artery stenosis [10, 11].

> *CAS is indicated as an alternative to CEA for symptomatic patients at average or low risk of complications associated with endovascular intervention when the diameter of the lumen of the internal carotid artery is reduced by more than 70% as documented by noninvasive imaging or more than 50% as documented by catheter angiography and the anticipated rate of periprocedural stroke or mortality is less than 6% (class 1; level of evidence B).*

CAS; Carotid Artery Stent, CEA; Carotid Endarterectomy

The recommendation that CAS can be used as an alternative to CEA is a change from previous guidelines.

The "2013 Clinical Practice Guidelines for Stroke" in Korea recommend similar guidelines to AHA/ACR as follows:

In symptomatic patients with more than 50% narrowing, CAS is an alternative to CEA when anticipated rate of periprocedural stroke or mortality is less than 6%

In 2008 the HIRA in Korea followed the indication of CAS as follows:

1. *In symptomatic patients with more than 70% narrowing.*
2. *In symptomatic patients with more than 50% narrowing patients in special conditions such as surgically high risk or unsuitable patients.*

In patients with symptomatic carotid stenosis, consensus opinions of guidelines are as follows. First, symptomatic narrowing more than 50% with NASET criteria can be an indication of CAS except HIRA. Second, in surgically high risk patients or surgically unsuitable conditions such as radiation-induced stenosis or restenosis, CAS is recommended. Third, CAS can be performed by the interventionist with established periprocedural morbidity and mortality rates of less than 6%.

In the case of asymptomatic carotid stenosis, the guideline is more complicated because the best medical treatment should be included as a treatment option. According to the results of CREST, ACA/AHA recommended that prophylactic CAS might be considered in highly selected patients with asymptomatic carotid stenosis (class IIb; level of evidence, B). However, they also mentioned that its effectiveness compared with medical therapy is not well established. In the CREST, even though the statistical power was weak due to the small number of events, the risk of stroke and death was not significantly different between CAS and CEA for the asymptomatic carotid stenosis.

The European Society of Cardiology (ESC) guideline recommends that CAS may be considered as an alternative to CEA for asymptomatic carotid stenosis in high-volume centers with documented death or stroke rate < 3% (class IIb; level of evidence, B) [12].

In asymptomatic carotid stenosis, not only CAS and CEA but also medical treatment should be included in comparative studies in the future.

Intracranial Artery Stenosis

Intracranial atherosclerotic disease (ICAD) accounts for 10−15% of all ischemic strokes, with an increased incidence in Asian, Black and Hispanic populations [13, 14]. Due to its increasing prevalence, ICAD may represent the most common stroke etiology worldwide [15]. The trial of Warfarin versus Aspirin for Symptomatic Intracranial Disease (WASID) was a randomized, double blind, and controlled study to compare warfarin with aspirin for the management of ICAD in patients with 50−99% symptomatic stenosis [16]. In the WASID trial, more than 70% stenosis was one of the strongest predictors related to subsequent stroke.

In the WASID trial, medical treatment was not enough to prevent recurrence of the stroke. In 2005, after publication of results of WASID trial, the Wingspan (Stryker Neurovascular, Fremont, CA, USA) stent was approved by the FDA as the stent for the management of intracranial artery disease (ICAD) [17].

Approval of the Wingspan stent subsequently made it possible to conduct the first prospective, randomized, controlled trial for patients with symptomatic ICAD comparing stent placement with medical treatment, known as SAMMPRIS - Stent placement versus Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis [18].

Unexpectedly, however, the SAMMPRIS trial was halted owing to higher than expected 30-day stroke rates for patients with stents compared to patients with aggressive medical treatment. In the SAMMPRIS trial, the 30-day stroke and death rate in the stent group was 14% and 5.8% in the medical management group. Even though the final results of the SAMMPRIS trial were not addressed (presentation of the final results are planned for the Fall of 2013) [17], the primary results disappointed most interventionists because the trial did not prove the effectiveness of the intracranial stenting for the patients who were resistant against medical treatment. However, endovascular therapy might be still the best therapeutic option in some subgroups of ICAD. Future trials will give more comprehensive information to augment the SAMMPRIS trial.

Hussain et al. [17] reviewed 59 published literatures regarding ICAD from 2000 to 2011. They introduced recently updated guidelines of several medical societies such as the American Academy of Neurology (AAN), the Stroke Council of the AHA and the University of Oxford, and the Centre for Evidence Based Medicine (CEBM) for treatment of symptomatic ICAD. We summarize the guidelines which apply to the field of the Neurointervention.

1. *In patients with symptomatic 70-99% intracranial stenosis who are not on maximal medical therapy, medical therapy is recommended over angioplasty and stent therapy (AHA level B, class IIa; CEBM level 1b, grade B).*
2. *In patients with symptomatic 70-99% intracranial stenosis who have failed aggressive maximal medical therapy, angioplasty or stent therapy may be considered (AHA level B, class IIB, CEBM level 2b, grade B).*

There is insufficient evidence to compare the efficacy of angioplasty to the use of balloon mounted, drug eluting or self-expanding stent systems.

The "2013 Clinical Practice Guidelines for Stroke" in Korea recommend treatment for intracranial stenosis as follows. It seems more practical and reasonable to apply angioplasty and/or stenting for the Korean patients because the incidence of intracranial stenosis is more common in Korea and the procedures are performed more often in Korea [19].

In patients with symptomatic more than 50% intracranial stenosis who have failed medical therapy, angioplasty or stent therapy may be considered. (level of evidence IV and grade of recommendation C according to US Agency for Health Care Policy and Research)

In 2008, HIRA in Korea announced the indication of insurance for intracranial stent as follows:

1. *Symptomatic more than 70% narrowing patients (ICA, vertebral artery, basilar artery)*
2. *Some special condition such as arterial dissection*
3. *In the case that is not included in the above 1 or 2, every case should be reviewed individually.*

There must be an important issue to be considered. Wingspan and Gateway balloon which has been approved by FDA in the United States failed to approve its efficacy in SAMMPRIS. Wingspan is self-expanding stent which is accompanied by the introducer with olive tip [20]. Gateway balloon is not the monorail system which can make the complicated procedure simple and reduce the procedural risk. That may be the reason why most coronary devices are developed as having the balloon expandable stent and the monorail system.

Unruptured Intracranial Aneurysm

Among many guidelines for neurointerventional procedures, those covering the treatment of unruptured intracranial aneurysms (UIA) are the most controversial. The discrepancy between the guidelines and practical decision-making has been mostly due to the undefined natural history of UIA. However, recently there have been a number of elegantly designed studies that are bringing consensus to the treatment guidelines.

The incidence of unruptured aneurysm in several studies including autopsy population is about 1~6% [21]. The annual risk of rupture of an UIA has been estimated by several investigations to range from 0.1 to 8%, leading to much controversy regarding the appropriate management of these lesions [21]. The rupture rate varies according to the size of the aneurysm and its location. The International Study of Unruptured Intracranial Aneurysms (ISUIA) investigator reported [22] the 5-year cumulative rupture rates for patients who did not experience Subarachnoid hemorrhage. Table 1 compares aneurysms located in the anterior and posterior circulations in the ISUIA results. In the

Table 1. Rupture Rates According to the Aneurysm Size in Anterior and Posterior Circulations in ISUIA

	Anterior Circulation	Posterior Circulation
Size of Aneurysm	% of Rupture Rates	% of Rupture Rates
Less than 7 mm	0	2.5
7−12 mm	2.6	14.5
13−24 mm	14.5	18.4
25 mm or greater	40	50

ISUIA, the mortality and morbidity rates 30days after treatment were 1.8 and 12% in the surgical group and 2 and 7.4% in the endovascular group of patients who did not experience SAH. These results suggest that small aneurysms less than 7 mm located in the anterior circulation without a previous SAH histories are relatively safe and not likely to rupture easily. It is better to observe rather than treat this group of aneurysms. These results, however, are opposed by many studies. Juvela et al. [23] reported that the rupture rate of small aneurysms (2−6 mm) was 20% during their follow up period (mean 18.1, median 19.7, range 0.8−38.9 years). They suggested such aneurysms be surgically treated regardless of their size, if it is technically possible, and if the patient's concurrent diseases are not contraindications. Joo et al. [24] also reported large amounts of ruptured aneurysms (71.8%) in aneurysms smaller than 7 mm in diameter.

Several recent studies from Japan [25, 26] suggested the race/ethnicity factor contribute the risk of rupture in small size aneurysms. In "The Natural Course of Unruptured Cerebral Aneurysm in a Japanese Cohort", the rupture rate of small aneurysms less than 7 mm is higher than the results of ISUIA [26]. The overall rupture risk was 0.95% per year in Japan study and 0.36% vs. 0.34% per year in aneurysms with the size smaller than 5 mm.

In the treatment of UIA, several other factors should be considered as risk factors for aneurysm rupture. Patient-specific factors to be considered include cigarette smoking, history of hypertension and family history of SAH, and aneurysm-specific factors include multiplicity of aneurysms, lobulated aneurysm or daughter sac, and growth during follow up [27].

Komotar et al. [21] reported the guidelines for the surgical treatment of unruptured intracranial aneurysms based on the discussion of the first annual J. Lawrence pool memorial research symposium. It can be the guideline for treatment of UIA in the United States as follows:

1. *With rare exceptions, all symptomatic unruptured aneurysms should be treated.*
2. *Small, incidental aneurysms less than 5 mm in diameter should be managed conservatively in virtually all cases.*
3. *Patients younger than 60 years of age with aneurysms larger than 5 mm should be offered treatment.*
4. *Large, incidental aneurysm larger than 10 mm should be treated in nearly all patients younger than 70 years of age.*

The "Joint Committee on Guideline for the Management of Stroke: in Japan reported the guideline for treatment of UIA in the Japanese guideline for the management of Stroke 2009 as follows. Considering the natural history of UIA, the following aneurysms are recommended for treatment when patient's remaining life is more than 10 years.

1. *Larger than 5 mm*
2. *Less than 5 mm in the cases of symptomatic aneurysms, aneurysms located in A-Com, P-com, or posterior circulation, and the aneurysms that have large dome to neck ratio or bleb.*

The CRCS in Korea reported the guideline for the treatment of UIA in the "2013 Clinical Practice Guidelines for Stroke" as follows:

1. *All symptomatic aneurysms should be considered for treatment.*
2. *Non-symptomatic extra-dural aneurysm should not be considered for treatment.*
3. *Considering the natural history of UIA, the following aneurysms are recommended for treatment when patient's remaining life is more than 10 years.*
   1) *Larger than 5 mm*
   2) *Aneurysms located in posterior circulation, A-Com, or P-Com.*
   3) *The patients who have family history or the history of previous SAH.*
   4) *The aneurysm which is enlarged or change of shape during follow up period.*
   5) *The patients younger than 50 years old who have hypertension and multiple aneurysms.*
   6) *Aneurysms which have large aspect or size ratio, multilobular shape, or bleb.*
4. *The patients with severe psychological disturbances secondary to harboring an unruptured aneurysm.*

There are still controversies in the management of small UIA. There are also many factors affecting rupture of small size aneurysm such as location, aneurysm or patient-specific factors. In the management of small UIA less than 5 mm, it is recommended to consider the benefit-risk balance and to discuss this with patient or family and get informed consent.

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