Carotid Artery Stenting
First Consensus Document of the ICCS-SPREAD Joint Committee

Alberto Cremonesi, MD; Carlo Setacci, MD; Angelo Bignamini, MD; Leonardo Bolognese, MD; Francesco Briganti, MD; Germano Di Sciascio, MD; Domenico Inzitari, MD; Gaetano Lanza, MD; Luciano Lupatelli, MD; Salvatore Mangiafico, MD; Carlo Pratesi, MD; Bernard Reimers, MD; Stefano Ricci, MD; Gianmarco de Donato, MD; Ugo Ugozolli, MD; Augusto Zaninelli, MD; Gian Franco Gensini, MD

Background and Purpose—The prevention of stroke and the correct treatment of carotid artery stenosis represent today a major debate in cardiovascular medicine. Beside carotid endarterectomy, carotid angioplasty and stenting is becoming more widely performed for the treatment of severe carotid obstructive disease, and is now accepted as a less invasive technique that may provide an alternative for selected patients, particularly those with significant comorbidities. An Italian multidisciplinary task force, in which converged the most representative scientific societies involved in carotid treatment, was created to provide neurologists, radiologist, cardiologists, vascular surgeons, and all those involved in prevention and treatment of carotid disease with a simple, clear and updated evidence-based consensus document.

Summary of Review—This First Consensus Document of the ICCS (Italian Consensus Carotid Stenting)/SPREAD group addressed the main issues related to methodology, definition of symptomatic and asymptomatic carotid stenosis, indication and procedures for carotid artery stenting, including the use of devices for preventing procedural embolic complications. Special attention was paid to credentials and competency for physicians qualifications to perform vascular angioplasty and stent placement, including training, acceptable complication rates and certification.

Conclusions—As any guideline or consensus statement, also this document is valid as long as the evidence on which it is based remains up-to-date. In such a fast-evolving field of medicine as the management of carotid stenosis, it is mandatory to stimulate a continuous and fruitful discussion among all the professionals involved in this very evolutionary field. (Stroke. 2006;37:2400-2409.)

Key Words: carotid stenosis • consensus statement

The problems associated with the treatment of carotid atherosclerotic disease today represent a major matter of debate in cardiovascular medicine. In the first part of 2005, the Italian Society of Interventional Cardiology (SICI-GISE, http://www.gise.it) appointed a special task force to address this subject. This multidisciplinary working group represents a convergence of delegates designated by the representative scientific societies involved in carotid treatment: (1) SICI-GISE, Italian Society of Interventional Cardiology; (2) SIC, Italian Society of Cardiology; (3) ANMCO, National Association of Hospital Cardiologists; (4) AINR, National Association of Neuroradiology; (5) SICVE, Italian Society of Vascular and Endovascular Surgery; (6) SIN, Italian Society of Neurology; and (7) SIRM, Italian Society of Medical Radiology.

The task force also included several members of the SPREAD group, a multidisciplinary association representing >30 scientific societies and patient organizations in the field of cardiovascular disease, which, during the last 7 years, has released 4 editions of evidence-based guidelines for stroke prevention and treatment (http://www.spread.it).

The SICI-GISE and SPREAD groups decided to combine their efforts to attempt to provide neurologists, radiologists, cardiologists, vascular surgeons, and all those involved in the prevention and treatment of carotid disease with a simple, clear, and updated evidence-based consensus statement. The last update on data review was undertaken in November 2005; consequently, future updates will be needed when subsequent reviews indicate major changes in the available evidence.
This first consensus document of the ICCS (Italian Consensus Carotid Stenting)/SPREAD group addressed the main issues related to methodology, the definitions of symptomatic and asymptomatic carotid stenosis, and indications and procedures for carotid artery stenting (CAS), including the use of devices for preventing procedural embolic complications. The general methodology included the evaluation and “considered judgment” not only of strong and weak results of randomized clinical trials but also the weight of the evidence, the methodological quality of the studies, and their transferability to different settings. Special attention was paid to credentials and competency for physician qualifications to perform vascular angioplasty and stent placement, including training, acceptable complication rates, and certification.

Clearly, this represents only the first consensus statement produced by the joint ICCS/SPREAD group, as several studies and registries in progress may produce in the near future further evidence capable of inducing remarkable changes in the statements on which agreement may be reached by the group. Despite this, we considered it appropriate to offer to the clinical/scientific community this document, both to provide, to the best of our knowledge, what is shared by clinicians and other professionals deeply involved in this field and to stimulate fruitful discussion among all professionals involved in this very evolutionary field. This group is aware that the positions expressed are tailored for healthcare structures and policies applicable in Europe, and these may not necessarily be applicable or equally appropriate for other healthcare systems, such as those in the United States or other areas of the world.

Methodology

Grading of Evidence

Although a consensus statement does not need formal grading of external evidence, nevertheless, this consensus group, in view of the already existing documentation, decided to grade the recommendations issued. Because different grading methods are in use, some based more on size and statistics and others also concerned with applicability, a double grading system was indicated for easier comparability across different documents.

The first grading system (Table 1) is the same as that used in SPREAD,1 which integrates the principles of the SIGN (Scottish Intercollegiate Guideline Network)2 with the statistical considerations suggested by the CEBM (Centre for Evidence-Based Medicine) methodology and allows one to clearly distinguish between recommended best practice based on consensus without evidence (GPP) and limited external evidence (D).3 These grades are reported in boldface type. For comparative purposes, a second grading system, based on the article by Sackett,4 is reported in square brackets. A representative grading of evidence in this system is given in Table 2. Although no direct equiva-

<table>
<thead>
<tr>
<th>Levels of Evidence</th>
<th>Grading of Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++ High-quality meta-analyses without heterogeneity; systematic reviews of RCTs each with small CIs; or RCTs with very small CIs and/or very small α and β</td>
<td>A At least 1 meta-analysis, systematic review, or RCT rated as 1++ and directly applicable to the target population; or</td>
</tr>
<tr>
<td>1+ Well-conducted meta-analyses without clinically relevant heterogeneity; systematic reviews of RCTs; or RCTs with small CIs and/or small α and β</td>
<td>A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results</td>
</tr>
<tr>
<td>1– Meta-analyses with clinically relevant heterogeneity, systematic reviews of RCTs with large CI, or RCTs with large CI and/or α or β</td>
<td>B A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+</td>
</tr>
<tr>
<td>2++ High-quality systematic reviews of case-control or cohort studies; high-quality case-control or cohort studies with very small CIs and/or very small α and β</td>
<td></td>
</tr>
<tr>
<td>2+ Well-conducted case-control or cohort studies with small CIs and/or small α and β</td>
<td>C A body of evidence including studies rated as 2+, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++</td>
</tr>
<tr>
<td>2– Case-control or cohort studies with large CIs and/or large α or β</td>
<td></td>
</tr>
<tr>
<td>3 Nonanalytic studies, eg, case reports, case series</td>
<td>D Evidence level 3 or 4; or</td>
</tr>
<tr>
<td>4 Expert opinion</td>
<td>Extrapolated evidence from studies rated as 2++; or</td>
</tr>
<tr>
<td>– Meta-analyses with clinically relevant heterogeneity; systematic reviews of trials with large CIs; trials with large confidence intervals and/or large α and/or β</td>
<td>Evidence from trials classified as − regardless of the level</td>
</tr>
</tbody>
</table>

GPP Recommended best practice based on the clinical experience of the guideline development group, without research evidence
TABLE 2. Levels of Evidence and Grading of Recommendations, AHCPR (Agency for Health Care Policy and Research)* System

<table>
<thead>
<tr>
<th>Levels of Evidence</th>
<th>Grading of Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>I Evidence from large, well-conducted RCTs</td>
<td>A Good evidence: evidence from well-conducted RCTs or cohort studies (levels I–III)</td>
</tr>
<tr>
<td>II Evidence from small, well-conducted RCTs</td>
<td></td>
</tr>
<tr>
<td>III Evidence from well-conducted cohort studies</td>
<td></td>
</tr>
<tr>
<td>IV Evidence from well-conducted case-control studies</td>
<td>B Fair evidence: evidence from other types of studies (levels IV and VI)</td>
</tr>
<tr>
<td>V Evidence from uncontrolled or poorly controlled studies</td>
<td></td>
</tr>
<tr>
<td>VI Conflicting evidence, but tending to favor the recommendation</td>
<td></td>
</tr>
<tr>
<td>VII Expert opinion C Expert opinion (level VII)</td>
<td></td>
</tr>
</tbody>
</table>

*Currently the Agency for Healthcare Research and Quality (AHRQ).

Evidence between gradings can be established, in general terms, grade [A] includes grades A, most of B, and a few of C; grade [B] includes some of B, most of C, and a few of D; grade [C] includes some of C, all of D, and all of GPP.

**Structure and Procedure of Consensus Development**

This consensus statement is a result of the collaboration of the Italian scientific societies and multidisciplinary working groups presently involved in stroke prevention and management. All of these scientific entities were represented by their relevant leaders in the Writing Committee. The Writing Committee assembled the material into a draft document, evidenced and reconciled discrepancies, verified the consistency of grading with the methodology, submitted the subsequent drafts for formal approval by the participating societies and interdisciplinary bodies, received and, where appropriate, incorporated documented dissent positions, organized and managed revisions submitted by independent guideline users, and wrote this first document. The consensus procedure followed the Rand technique, corrected to account for possible documented dissent positions, always possible in such a fast-evolving field. Details on the consensus procedure are available at http://www.spread.it/iccs.

**Legal Considerations on the Expressed Recommendations**

Clinical guidelines aim at providing physicians an updated and weighed synthesis of the current best external evidence, adapted to local conditions. Guidelines cannot offer thought-proof mechanisms for improving medical care. However well linked to the evidence, they need to be interpreted sensibly and applied with good judgment. Recommendations are issued on the basis of population statistics and may not necessarily be applicable to the individual case. The acceptable standards of clinical care derive from responsible customary practice, not from guidelines. Therefore, clinical guidelines cannot be used to mandate, authorize, or exclude treatment options: the mere fact that a guideline exists does not itself establish that compliance with it is reasonable under all circumstances or that noncompliance is negligent. On the other hand, complying with the recommendations of a guideline is, in the vast majority of cases, the most appropriate and effective clinical behavior: modern, evidence-linked, clinical guidelines seek to make the strengths, weaknesses, and relevance of research findings transparent to clinicians. Their appropriate interpretation and application in the individual case are likely to generate better clinical care—and a safer medicolegal strategy—than either uncritical disregard or unthinking compliance.

**Definition of Symptomatic Carotid Stenosis**

All of the studies performed on carotid endarterectomy (CEA) used, as a definition for “symptomatic carotid stenosis,” a functional definition, which may or may not be shared, but which remains the only definition applicable for a rational comparison of clinical outcomes among different studies. A carotid stenosis is defined as “symptomatic” when it is correlated with at least 1 clinical episode of ipsilateral ocular or cerebral ischemia in the previous 6 months. Although it is not possible to be completely sure that the stenosis is the actual cause of the episode, careful neurological work-up can reasonably exclude different causes (ie, cardiac embolism and lacunar ischemia not attributable to artery embolism). The 6-month period has been arbitrarily chosen in clinical trials (ECST, NASCET, ACST), and in the future it should probably be changed, according to a recent analysis of these trials that has shown that, even a few weeks after the event, the risk associated with a symptomatic carotid lesion is not substantially different from that associated with an asymptomatic one. Until further evidence becomes available, however, it is wise to use the old definition to make both recommendations and results comparable with those of the main trials.

However, a concept that has evolved in recent years is equally important, and that is the one of individual risk. This has become substantially more relevant in relation to the fast-increasing application of carotid interventions, mainly endovascular, in asymptomatic carotid stenoses (those detected in a subject but not compatible with the aforementioned definition of symptomatic). The other concept that accompanies that of individual risk of stroke is the one of intrinsic safety of the procedure as performed in a definite center, as discussed later. The same calculations of advantages and disadvantages of an intervention as applied to the studies of CEA should also be applied to the studies on carotid stenting, with the same rigorous classification, attribution, and statistical techniques to produce
the NNT (number of patients needed to treat to prevent 1 negative outcome) for the different conditions considered, directly comparable with those already available for endarterectomy. Similarly, assessment of surgical risk should be produced, resulting in a proper and directly comparable estimation of the associated risk and possibly, for determining models for subjects at higher medical, surgical, and endovascular risk, to guide the clinical decision based on an actual documented and weighed trade-off between benefits and risks for the individual subject at the individual center with the specific procedure anticipated.

Establishing the Indication for Surgical or Endovascular Treatment

Recommendation 1: Grade GPP [C]
Each structure having available teams capable of performing CEA and CAS (as recommended in this consensus document) should set standard operating procedures (SOPs) on the choice of procedure to be applied. Except when indications are clearly established for either procedure, the choice will be performed by a team including an expert on stroke and experts on all disciplines involved, coordinated by a team coordinator chosen according to the local SOPs. The decision should take into account the locally evaluated risks of periprocedural and post-procedural complications with either procedure, as well as the patient’s preferences and the locally available facilities and resources. The local risk rate should be communicated to the patient or the patient’s representative at the time of obtaining informed consent.

Recommendation 2: Grade GPP [C]
A structure having available teams capable of performing CEA or CAS exclusively should evaluate each individual potential patient according to the same procedures indicated for a structure capable of performing both procedures, with the assistance of those external experts as needed. It will then be decided whether to perform the locally available procedure or to refer the subject to a structure able to perform the alternative procedure as needed. Information on the alternative procedures available and their relative risks and benefits should be given in any case to the subject, at the time of seeking informed consent.

Establishing the indication for CAS or CEA is a condition for which the principles of multidisciplinary integration find a paradigmatic application but also for which no direct literature support is available. Indeed, in all of the trials performed on CAS/CEA, the indication to intervention was based on the available procedures and protocol, rather than according to an evidence-based, preset standard procedure. Consequently, only rational considerations are available to issue a recommendation. It is nevertheless of major relevance that all participating clinicians exhibit in their respective field that “proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice.”

The items to be considered in this event are as follows:

- The structure of the local team and the applicable SOPs;
- The objective condition of the patient, established through an intensive collaboration that shall include at least 1 physician expert in stroke prevention and management; a neurologist expert in cerebrovascular diseases; an expert in vascular surgery; an expert in imaging; an expert in endovascular procedures; and an expert in overall patient management within the structure;
- The number of individuals in the team is relatively unimportant, because each individual can have >1 field of expertise (eg, the expert in stroke prevention and management can easily be the neurologist expert in cerebrovascular diseases);
- The team should have a coordinator. The exact background of the individual is relatively unimportant, so long as this person is authoritative and is able to establish good interaction with colleagues and patients alike.

It is the responsibility of the team coordinator to promote the preparation and continuous update of the team’s SOPs, to evaluate the extent of resource requisition within the specific structure (in collaboration with management), to establish procedures for investigating and understanding the patient’s predicaments and preferences that may influence the final decision, and to obtain the patient’s informed consent to the procedure, whichever it may be, in a form acceptable to the structure’s ethics committee and incorporated into the SOPs.

It is the collective responsibility of the team to keep track of the best external evidence available, to weigh the recommendations of the best external evidence against the structure’s facilities, and to record the team’s performance and estimate the local breakpoint of CAS-associated risks and CEA-associated risks for any given condition. These estimates should be considered when recommending either procedure in a specific case. It is also the team’s collective responsibility to take the reasoned decision not to apply the recommendations indicated in this document in a specific case. It is also suggested that the team maintain a log of each decision and of the main items leading to the actual choice to prevent later disputes.

Once the basic approach of teamwork to establish the indication for CAS or CEA is accepted, a structure having available teams capable of performing CEA or CAS exclusively should evaluate each individual patient according to the same procedures indicated for a structure able to perform both procedures, with the help of external experts. The treatment options (in-house or external hospital) should be decided according to the best balance between the subject’s benefits and risks that should emerge from the multidisciplinary evaluation. Information on the alternative procedures available and their relative risks and benefits should be given in any case to the subject at the time of seeking informed consent.

The consensus panel is aware that no scientific data support this model in an evidence-based–medicine approach. For this reason, further studies of the feasibility and economy of this method of establishing the indication for surgical or endovascular treatment should be performed.

CAS: Recommendations

Recommendation 3: Grade A [A]
Given that current evidence is still insufficient, endarterectomy should not be systematically replaced with endovascular procedures for the elective correction of carotid stenosis.
Recommendation 4: Grade B [A]
CAS, if performed with adequate procedural quality levels, should be used instead of endarterectomy in the presence of severe vascular or cardiac comorbidities or specific conditions.

Explanatory Note to Recommendation 5
Conventionally, high risk for surgery is suspected in the presence of:

Specific conditions:
- contralateral laryngeal nerve palsy;
- radiation therapy to the neck;
- previous CEA with recurrent restenosis;
- high cervical internal carotid/below the clavicle common carotid lesions;
- severe tandem lesions;
- age >80 years
- severe pulmonary disease.

Severe vascular and cardiac comorbidities:
- congestive heart failure (New York Heart Association class III/IV) and/or known severe left ventricular dysfunction;
- open heart surgery needed within 6 weeks;
- recent myocardial infarction (>24 hours and <4 weeks);
- unstable angina (Canadian Cardiovascular Society class III/IV);
- contralateral carotid occlusion.

This definition of high risk, however, is not evidence based and is not universally shared.

Recommendation 5: Grade D [B]
CAS should be avoided when the presence of endoluminal thrombotic or thromboembolic material is suspected or in the presence of markedly tortuous supra-aortic vessels.

Recommendation 6: Grade D [B]
CAS should be performed with adequate cerebral protection, unless contraindicated in the individual case. An extensive analysis of the available documentation yielded the following considerations:

- The documentation comparing CAS and CEA is extremely mixed for quality, end points, selection criteria, techniques for evaluating outcome (often not adequately specified in terms of who determined outcome and how outcome was determined)16–22;
- There is substantial, clinically relevant heterogeneity among the different studies (eg, incidence rates substantially variable across studies and in comparison with the reference studies);
- There are serious methodological objections to the selection criteria, randomization procedures, and outcome evaluation even for the most recent of these studies23;
- There are substantial, clinically relevant discrepancies on those conditions conventionally considered to pose a high risk for surgery and not for stenting; eg, preliminary data from the CREST study suggest that patients >80 years of age have high stroke rates with stenting24;
- The main studies comparing CEA and CAS, at variance with those that evaluated CEA, do not include a medically treated control group; therefore, medical management should be considered an alternative option to stenting for patient at high risk for surgery.

On the basis of the aforementioned considerations and the latest Cochrane Review,16 the systematic switch from CEA to CAS remains “not indicated” for grade A10 until new, high-quality, unbiased information becomes available. According to this meta-analysis, although there was serious heterogeneity for 4 of 5 of the tested outcomes, there was no difference between techniques at 30 days for death or any stroke (odds ratio [OR] CAS/CEA, 1.33; 95% confidence interval [CI], 0.86 to 2.04); for death or disabling stroke (OR, 1.22; 95% CI, 0.61 to 2.41); or for death, any stroke, or myocardial infarction (OR, 1.04; 95% CI, 0.69 to 1.57). The same was seen at 1 year for death or any stroke (OR CAS/CEA, 1.01; 95% CI, 0.74 to 1.44). Instead, the risk of cranial nerve lesions was significantly in favor of CAS, with an OR=0.1 (95% CI, 0.06 to 0.26).16 Additional information is expected to be gathered from the randomized studies in progress: ICSS (CAVATAS 2) for symptomatic patients25 and ACST 2 for asymptomatic subjects.

In the presence of controversial and contradictory external evidence, the multidisciplinary team should carefully evaluate any subject for whom CEA or CAS is being planned, taking into consideration the performance index of the surgical and interventional team in the specific risk class, the presence of multiple risk factors, and the patient’s preferences. It is suggested that validated individual risk models, as are available for CEA, be rapidly developed for CAS as well.

Because it is likely that in any given center a number of subjects with carotid stenosis will not have a definite indication for surgery or endovascular treatment, these patients may, with their consent, be randomized to the comparative investigations currently in progress. Additional information is expected to be gathered from the randomized studies in progress: ICSS (CAVATAS 2)25 and SPACE26 for symptomatic stenosis, EVAST37 for severe symptomatic stenosis, and CREST24 for both symptomatic and asymptomatic subjects.

For the time being, this consensus statement does not take a definite position on specific procedures and devices to be used during stenting, also in view of the rapid evolution of the field. Cerebral protection and relevant devices, type of stenting, and the ultrasonography/imaging profile of the stenosis and of the plaque are all items deserving an adequate discussion, although to date, none of them, except cerebral protection, are sufficiently supported by evidence.

With the current evidence, it appears that stenting procedures are less prone to periprocedural risks when adequate cerebral protection is applied with a device the interventionist is familiar and expert with and trained on.27–33 This statement, however, is supported essentially by case series, some quite large but probably not bias-free.34 Additional information should also be obtained from the ongoing studies, although they are not randomized as to the application of cerebral protection devices or techniques.35
CAS: Acceptable Complication Rates and Risk Certification

Recommendation 7: Grade C [A]
In patients with symptomatic carotid stenosis >50% estimated according to NASCET, CEA or CAS can be performed if the upper limit of the 90% CI for 30-day complications (any stroke and death by any cause) of the last years’ performance of the center is certified ≤6% (and should be ≤2% for death or disabling stroke). Neurological complications should be evaluated by a physician expert in cerebrovascular diseases.

Recommendation 8: Grade C [A]
In patients with asymptomatic carotid stenosis ≥60% estimated according to NASCET, CEA or CAS can be performed if the upper limit of the 90% CI for 30-day complications (any stroke and death by any cause) of the last years’ performance of the center is certified ≤3% (and should be ≤1% for death or disabling stroke). Neurological complications should be evaluated by a physician expert in cerebrovascular diseases.

Recommendation 9: Grade GPP [C]
In patients with asymptomatic carotid stenosis, the multidisciplinary team should consider the option not to intervene, instead assigning the best current medical treatment.

Background
A procedure of CAS or CEA is performed to prevent a future cerebrovascular event. However, most subjects with carotid stenosis, including those classified as “symptomatic,” will never experience a stroke before dying of another cause: the 3-year stroke risk for a medically treated, symptomatic carotid stenosis of 70% to 99% (NASCET method) is ≈20%. On the contrary, the procedure itself can cause disabling strokes and death. The objective of setting certified limits to the risk of short-term cerebrovascular events is to balance the benefits and risks for the subject, so that he or she does not incur a greater intervention-related risk than a stenosis-related risk.

Interventional Risks
The only sensible measure of interventional risk is the short-term, periprocedural (30-day) incidence of cerebrovascular events. A longer observation period would be advisable; however, there is currently no way to distinguish among procedure-induced events, spontaneous events, and independent and unrelated events. On the other hand, although early events might also be completely independent in origin, assigning the early events to the intervention increases the margin of safety for the subject.

The benefit from CEA is minor in symptomatic patients with 50% to 69% stenosis (NNT=22 to prevent ipsilateral stroke, nonsignificant to prevent disabling stroke and death) and noticeable for 70% to 99% stenosis (NNT=6 and 14, respectively), excluding patients with carotid near-occlusion, for whom the benefit from endarterectomy is marginal. The benefit of endarterectomy is still greater in patients with a high risk score according to current models (NNT=3) and little if any in patients with a low risk score (NNT=100). Similar evaluations for carotid stenting, with similarly reliable estimates, are still lacking.

The risk rate for patients subjected to conventional endarterectomy has been conventionally established at 6% for any complication and at 2% for disabling strokes and death for symptomatic stenosis. For symptomatic stenoses, it has been set at 3% for any stroke and death by any cause and at 1% for disabling strokes and death. Although this is a restrictive evaluation, in the absence of more widely evaluated definitions, these figure remain the yardstick by which to estimate the interventional risk.

However, procedural safety has increased remarkably during the last few years, as shown by a number of large case series, so these same figure cannot be considered a reliable central estimate of risk but rather the upper acceptable limit for risk. This should be reflected in the recommendation, and this recommendation should, for the time being, be applicable to both CAS and CEA, so long as the 2 procedures remain comparable in outcome as discussed previously.

Asymptomatic stenosis deserves an additional consideration. In asymptomatic patients, the overall benefits of CEA or CAS over the best current medical treatments are still not conclusively established. This consensus group recommends that the multidisciplinary team also formally consider for these patients the option not to intervene, prescribing instead the best current medical treatment and taking into account the patient’s preferences as well as the individual disease-associated and procedure-associated risks.

Risk Certification
For transparency toward the public and correctness toward the patients, the surgical/interventional risks should properly be certified by external auditing. To this aim, each group should state in advance who is in charge of the external audit of the results. It would be advisable that a neurologist with experience in cerebrovascular diseases, and in particular, in postinterventional neurological problems, is involved. Where such professional expertise is not available, a physician with experience in cerebrovascular diseases can be appointed so long as he or she is not a member of the interventional group and does not have any common commitment with the group. The neurologist (or physician expert on stroke) must see every single patient before the procedure, the day after the procedure, and 1 month afterward. If a neurological deficit is still present at 30 days, then a formal assessment of the residual disability at 6 months is also required.

Data should be stored in a database, to be analyzed yearly with appropriate standardized statistical descriptions and analysis by independent personnel. The risk rate, as derived from these yearly analyses, should be incorporated into the information to be given to the patient before obtaining the informed consent to the procedure, as previously indicated. In case different teams are present at the same center, each team should be independently certified as to the risk of events. Data should be publicly available. A possible audit procedure as identified by this consensus group can be found at http://www.spread.it/iccs.

CAS: Training and Expertise
Recommendation 10: Grade GPP [C]
Once the basic skill for catheter-based intervention has been achieved by the already-active interventionist, the minimum recommended training to achieve competence is as follows:
1. At least 150 procedures of supra-aortic vessel engagement (during diagnostic as well as interventional procedures) within 2 years, of which at least 100 as the primary operator;
2. At least 75 carotid stenting procedures, of which at least 50 as the primary operator, within a 2-year fellowship.

**Recommendation 11: Grade GPP [C]**
The minimum requirement to maintain technical skill (competence) is the number of 50 carotid stenting procedures performed and documented by each primary operator per year.

**Background**
There is insufficient firm external evidence supporting the concept that training and competency are an essential background for any medical activity; this is a self-evident statement and constitutes the personal physician’s contribution to evidence-based clinical decisions. 14 Nevertheless, there is some supporting indirect evidences that theoretical training significantly facilitates making more appropriate clinical decisions, 15-19 including training by computer simulation in the carotid stenting area. 44,45 In the specific field of CAS, relatively small series of cases have shown that the “learning curve” of carotid stenting flattens after \( \approx 80 \) interventions with regard to procedural risk and after \( \approx 160 \) interventions with regard to procedural time (an item not so irrelevant, because it is related to the patient’s discomfort and resource requisition). 46

Once it was established that competence and training are key factors that may affect the patient safety, recent multispecialty consensus statements have supported a series of recommendations, tailored, however, for the United States. 47–49 These statements can be taken as a valuable reference, but the ICCS/SPREAD panel has expressed the necessity that these training recommendations be adapted to the Italian and European environment, taking into account the differences existing in the different countries (learning steps to specialization and credentialing procedures).

### TABLE 4. CAS: Advanced Cognitive Skills Regarding Physiopathology, Assessment, and Treatment of Carotid Artery Disease and Stroke

<table>
<thead>
<tr>
<th>Causes of stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embolization (cardiac, carotid, aortic, other)</td>
</tr>
<tr>
<td>Vasculitis</td>
</tr>
<tr>
<td>Arteriovenous malformation</td>
</tr>
<tr>
<td>Intracranial bleeding (subdural, epidural)</td>
</tr>
<tr>
<td>Space-occupying lesion</td>
</tr>
<tr>
<td>Causes of stenotic carotid artery lesions</td>
</tr>
<tr>
<td>Atherosclerosis</td>
</tr>
<tr>
<td>Fibromuscular dysplasia</td>
</tr>
<tr>
<td>Spontaneous dissection</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

**Clinical manifestations of stroke**
- Knowledge of stroke syndromes (classic and atypical)
- Distinction between anterior and posterior circulation events

**Natural history of carotid artery disease**
- Associated pathology (eg, coronary and peripheral artery disease)
- Diagnosis of stroke and carotid artery disease
- History and physical examination
  - Neurological
  - Nonneurological (cardiac, other)
- Noninvasive imaging
  - Duplex ultrasound
  - Magnetic resonance angiography
  - Computed tomographic angiography
- Angiographic anatomy (arch, extracranial, intracranial, basic collateral circulation, common anatomic variants, and nonatherosclerotic pathological processes)

**Knowledge of alternative treatment options for carotid stenosis and their results (immediate success, risks, and long-term outcome)**
- Pharmacotherapy (antiplatelet agents, anticoagulation, lipid-lowering agents, etc)
- CEA
  - Results from major trials (NASCET, ACAS, ECST, ACST)
  - Results in patients with increased surgical risk
  - Stent revascularization
  - Results with and without distal embolic protection

**Case selection**
- Indications and contraindications for revascularization to prevent stroke
- High-risk criteria for CEA
- High-risk criteria for percutaneous intervention

**Role of postprocedural follow-up and surveillance**

---

**TABLE 3. CAS: Basic Cognitive Skills**

- Physiopathology of vascular diseases, atherosclerosis, and thrombosis
- Systemic manifestations of atherosclerosis
- Cardiovascular risk factors and their prevention and management
- Physiopathology, clinical manifestations, natural history, evaluation, and management of peripheral arterial disease, renal artery stenosis, extracranial cerebrovascular disease, aortic and peripheral artery aneurysms, and other arterial diseases
- Physiopathology, clinical manifestations, evaluation, and management of venous thromboembolism
- Prothrombotic disorders, including inherited and acquired hypercoagulable states
- Physiopathology, clinical manifestations, evaluation, and treatment of chronic venous insufficiency and lymphedema
- Preoperative evaluation and perioperative care of the vascular surgery patient
- Noninvasive vascular tests, including duplex ultrasonography of peripheral arteries and veins, carotid arteries, renal arteries, and physiological tests of the peripheral circulation
- Magnetic resonance and computed tomographic angiography
- Conventional contrast angiography
- Diagnostic criteria and technical limitations for each test
before an interventionist is credentialed as primary operator to perform CAS. With this perspective, the interventionist should be knowledgeable about all of the complex diagnostic and therapeutic process related to carotid pathology, from basic cognitive skills for vascular medicine physicians (Table 3) to specific advanced cognitive and technical requirements for performing CAS (Tables 4 and 5).

One of the main topics that remains poorly defined is the procedure recommended for maintaining competence. Participation in continuing medical education events and programs may be appropriate, so long as scientific societies actively participate in determining and assuring quality standards and program content. E-learning can also be appropriate, so long as the technique guarantees the participation of active trainees and the correctness and security of the verification procedures.

Within the area of competence, a special segment is the technical skill required. Because all of these procedures are strongly operator dependent, the minimum technical skill should also be validated by independent and period-ical certification, either by the individual colleges or by an interdisciplinary body.

### TABLE 5. Technical Requirements for Performance of CAS

<table>
<thead>
<tr>
<th>Angiographic skills</th>
<th>Vascular access skills</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Selection of guidewires and angiographic catheters</td>
</tr>
<tr>
<td>Interventional skills</td>
<td>Appropriate manipulation of guidewires and catheters</td>
</tr>
<tr>
<td>Guide catheter/sheath placement</td>
<td>Use of “closed-system” manifold</td>
</tr>
<tr>
<td>Deployment and retrieval of embolic protection devices</td>
<td>Predilation and postdilation</td>
</tr>
<tr>
<td>Stent positioning and deployment</td>
<td>Recognition and management of intraprocedural complications</td>
</tr>
<tr>
<td>Cerebrovascular events</td>
<td>Stroke or cerebrovascular ischemia</td>
</tr>
<tr>
<td>Embolization</td>
<td>Hemorrhage</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>Dissection</td>
</tr>
<tr>
<td>Seizure and loss of consciousness</td>
<td>Cardiovascular events</td>
</tr>
<tr>
<td>Arrhythmias</td>
<td>Hypotension</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Myocardial ischemia/infarction</td>
</tr>
<tr>
<td>Vascular access events</td>
<td>Bleeding</td>
</tr>
<tr>
<td>Ischemia</td>
<td>Thrombosis</td>
</tr>
<tr>
<td>Management of vascular access</td>
<td>Proper sheath removal and attainment of hemostasis</td>
</tr>
<tr>
<td>Closure device utilization</td>
<td></td>
</tr>
</tbody>
</table>

**Training**

Training can be divided into 3 segments:

- Standard medical and specialty training, which is standardized by country and often, within the specific country, by the individual school of medicine;
- Specific training for the procedure: interventional laboratory training (including preceptorship, proctorship, and computer-aided training);
- Specific training with individual devices.

Once the standard skill for catheter-based intervention has been achieved by the already-active interventionists, the ICCS/SPREAD panel recommends the following specific training as a minimum to achieve the basic competence and technical skill as the primary operator for performing carotid stenting:

1. At least 150 procedures of supra-aortic vessel engagement (during diagnostic as well as interventional procedures), of which ≥100 as the primary operator;
2. At least 75 carotid stenting procedures, of which ≥50 as the primary operator; within a 2-year fellowship.

These numbers appear different in comparison with the learning curve reported in the literature and also in comparison with the numbers given in specific articles on training, competence, and credentialing standards. Nevertheless, the position of this consensus panel is based on the assumption that carotid stenting must be performed only by high-level and well-trained interventionists. Being aware that baseline technical backgrounds are different among the various specialty components, this consensus panel states that these are general recommendations, and consequently, the scientific societies may propose specific individual training programs to their associates that are oriented to focus their teaching activities on improving the real needs of each specialty.

For maintaining technical skill (competence), the minimum requirement should be 50 carotid stenting procedures per year, performed and documented by each operator. This implies that a log be maintained of each procedure performed and that this log be reviewed periodically by independent experts. These experts may be the same individuals who validate the incidence of events by site, as mentioned in the section on acceptable limits for periprocedural and postsurgical complications in this consensus document.

Although virtual reality can be considered an essential component in accelerating the learning process and may help considerably in avoiding procedural errors during and after actual training, the ICCS/SPREAD panel considers that, for the time being, no virtual reality training may replace the training in the interventional theater because of the implicated responsibility and extreme variability of individual cases. Therefore, actual interventional theater training is recommended, with the guidance and under the supervision of an expert credentialed interventionist, who shall be responsible for presenting the candidate for certification, with a log of performed interventions, efficacy information, and neurologist-confirmed, short-term outcomes.

The specific training on individual devices should be the manufacturer’s responsibility. For this reason, device-related, hands-on sessions, as well as preceptorships and/or proctorships, must be managed by manufacturers. The specific training package must have been previously approved by the
same bodies that have the authority to certify the carotid training program. Interventionists failing to participate in specific device training should not use that device for their interventions.

**Future Tasks**

As with any guideline or consensus statement, this document is valid so long as the evidence on which it is based remain up to date. In such a fast-evolving field of medicine as management of carotid stenosis, this time can be quite short. The statements contained in this consensus document are scheduled to be reviewed every 6 months, and a full update is planned to be performed yearly.

The procedures anticipated for interim review consist of an update of the literature. Changes to this document will be inserted only if absolutely needed on the Web site; changes of grading will not be inserted. The need to review new topics will be formalized.

The yearly update will result in inclusion/elimination of recommendations as needed, updating of grading if new evidence has emerged, and insertion of new topics anticipated at the interim reviews. The procedures anticipated for such updating are the same used to develop this document.

**Disclosures**

None.

**References**


Carotid Artery Stenting: First Consensus Document of the ICCS-SPREAD Joint Committee

Alberto Cremonesi, Carlo Setacci, Angelo Bignamini, Leonardo Bolognese, Francesco Briganti, Germano Di Sciascio, Domenico Inzitari, Gaetano Lanza, Luciano Lupattelli, Salvatore Mangiafico, Carlo Pratesi, Bernard Reimers, Stefano Ricci, Gianmarco de Donato, Ugo Ugogetti, Augusto Zaninelli and Gian Franco Gensini

Stroke. 2006;37:2400-2409; originally published online August 10, 2006;
doi: 10.1161/01.STR.0000236101.09480.b7

Stroke is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2006 American Heart Association, Inc. All rights reserved.
Print ISSN: 0039-2499. Online ISSN: 1524-4628

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://stroke.ahajournals.org/content/37/9/2400

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Stroke can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Stroke is online at:
http://stroke.ahajournals.org//subscriptions/