ΑΝΑΣΚΟΠΗΣΗ

ΕΛΛΗΝΙΚΗ ΑΓΓΕΙΟΧΕΙΡΟΥΡΓΙΚΗ
Τεύχος 13, 2008 (98-107)

The ESVS guidelines for carotid disease Is there anything to change in everyday practice?

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Guidelines Committee Chairman

1. GUIDELINES COMMITTEE

Chairman:	C.D. Liapis
Reviewers Coordinator:	Sir P. Bell
Coordinators:	D. Michailidis A. Nikolaides J. Sivenius, J. Fernandes e Fernandes G. Biasi L. Norgren

2. BRIEF HISTORICAL OVERVIEW...

- The ESVS Guidelines project was launched at the first meeting on 17 Sept 2005, in Helsinki, Finland.
- Primary aim of the guidelines: to cover the whole range of vascular diseases, starting with carotids.
- The Plan was to develop the first set of guidelines within 24 months following the above meeting & have them ready for publication by the end of 2007.
- In order to produce a credible document, expertise from other disciplines or societies was sought from:
  - Neurology
  - Radiology
  - Cardiology
- The document was founded on established strategies evidence based, where applicable, and examining the shortcomings of the levels of evidence. Critical issues were also included.

3. GUIDELINE PROCESS I

- Definition of the subject
- Structure of the subject
- Literature search (non structured vs Cochrane)
- Subjects of controversy
- Critical issues
- Each chapter is concluded by a list of recommendations.
- Strength of recommendations is graded A-C
- The document has already been promoted in the EJVES, the ESVS website and on CD/DVD

4. DIVISION OF LABOUR I

Four working group sectors:

Committee Chairman: C Liapis (Gr)

Sector	**Coordinator(s)**
Investigations:	A Nicolaides (Cy)
Indications:	G Biasi (It)
Prevention:	D Mikhailidis (UK) J Sivenius (Fi)
Treatment:	L Norgren (Swe)

5. DIVISION OF LABOUR II

2 reviewers (or more) for each group, namely:

- B Norrving (Swe) (Neurologist)
- J Powell (UK) (Angiologist)
- F Becker (Fr) (Neurologist)
- H-C Diener (Ger) (Neurologist)
- W Hacke (Ger) (Neurologist)

The Reviewers Coordinator: Sir P Bell (UK)

6. WORKING GROUPS

Composition based on:

- Expertise in the working sectors: particularly from participants already involved in this type of activity that could lead the way for the ESVS project.
- Geographical spread: to amalgamate the best of the differences in the various countries.

7. PARTICIPATION PREVENTION

Coordinators: D Mikhailidis / J Sivenius

Name	**Participation**	**Discipline**
1. D Mikhailidis	Coordinator	Clinical Biochemistry Vasc Disease Prevention
2. J Sivenius	Coordinator	Neurology
3. N Angelides		Vascular Surgery
4. D Bergqvist		Vascular Surgery
5. S Daskalopoulou		Clinical Biochemistry Vascular Disease Prevention
6. H-C Diener	Reviewer	Neurology
7. G Gerotziafas		Hematology (Antiplatelet / Antithrombotic)
8. W Hacke	Reviewer	Neurology
9. M Kaste		Neurology
10. N Kadoglou		Internal Medicine/ Cardiology
11. D Leys		Neurology
12. T Mätzsch		Vascular Surgery
13. F Moll		Vascular Surgery
14. E Petridou		Hygiene/ Epidemiology
15. S Ricci		Vascular neurologist
16. M Schachter		Internal Medicine
17. T Schroeder		Vascular Surgery
18. H Sillesen		Vascular surgery
19. W Staszkiewiecz		Vascular Surgery/ Angiology
20. C Stefanadis		Cardiology
P Bell	Reviewers' Coordinator	Vascular Surgery

8. PARTICIPATION INVESTIGATIONS

Coordinator: A Nicolaides

Name	Participation (Writer/ Reviewer)	Discipline
1. A Nicolaides	Coordinator	Vascular Surgery
2. A Al-Kutoubi		
3. M Averkiou		
4. J Brunkwall		Vascular Surgery
5. F Becker	Reviewer	Vascular Medicine
6. J Fernandes e Fernandes		Vascular Surgery (Cardio-vascular Dept)
7. G Geroulakos		Vascular Surgery
8. P Gaines		Radiology
9. M Griffin		
10. A Katsamouris		Vascular Surgery
11. L Mendes Pedro		Vascular Surgery (Cardio-vascular Dept)
12. W Paaske		Cardiothoracic and Vascular Surgery
13. J-B Ricco		Vascular Surgery
14. M Salmasi		
15. J Swedenborg		Vascular Surgery
16. D Thomas		
17. L Vlachos		Radiology
18. B Norrving	Reviewer	Neurology
P Bell	Reviewers' Coordinator	Vascular Surgery

9. PARTICIPATION INDICATIONS

Coordinator: G Biasi

Name	Participation	Discipline
1. G Biasi	Coordinator	Vascular Surgery
2. E Bastounis		Surgery
3. P Cao		Vascular Surgery
4. J Beard		Vascular Surgery
5. F Benedetti-Valentini		Vascular Surgery
6. M Brown		Neurology
7. A Cremonesi		Cardiology
8. P Dimakakos		Vascular Surgery
9. A Froio		
10. P Gaines		Radiology
11. G Gensini		Cardiology/ Internal med
12. J Kakisis		Vascular Surgery
13. K Katsenis		Vascular Surgery
14. D Kiskinis		Vascular Surgery
15. A Halliday		Vascular Surgery
16. M Lavitrano		Pathology/ immunology
17. T Mätzsch		Vascular Surgery
18. R Naylor		Vascular Surgery
19. B Norrving	Reviewer	Neurology
20. J Powell	Reviewer	Vascular Medicine
P Bell	Reviewers' Coordinator	Vascular Surgery

10. PARTICIPATION TREATMENT

Coordinator: L Norgren

Name	Participation	Discipline
1. L Norgren	Coordinator	Vascular Surgery
2. K Balzer		Vascular Surgery
3. J-P Becquemin		Vascular Surgery
4. A Cremonesi		Cardiology
5. P Dimakakos	Reviewer	Vascular Surgery
6. P Gaines		Radiology
7. C Karkos		Vascular Surgery
8. K Katsenis		Vascular Surgery
9. K Konstantinidis		Vascular Surgery
10. T Kotsis		Vascular Surgery
11. M Heikkinen		Vascular Surgery
12. M Horrocks		Vascular Surgery
13. T Mätzsch		Vascular Surgery
14. B Norrving	Reviewer	Neurology
15. H Pärsson		Vascular Surgery
16. D Raithel		Vascular Surgery
17. J Salenius		Vascular Surgery
18. C Setacci		Vascular Surgery
P Bell	Reviewers' Coordinator	Vascular Surgery

11. PROGRESS

- After several meetings (mainly of the Co-ordinators) in Athens, London, Crete, Lisbon and Prague in 2006, and after careful thought and discussions:
- The individual chapters are now complete and were presented at the Council Meeting on Thursday 20 and at the Guidelines Committee Meeting on Friday 21 September.
- Following presentation and approval by the General Assembly, the document was submitted for publication to the EJVES

12. DOCUMENT DETAILS

- 80 pages
- 3 tables – 2 figures
- 26 Recommendations (divided in 72 subcategories)
- 33 Grade A
- 18 Grade B
- 21 Grade C

13. GRADING OF RECOMMENDATIONS

Grade	Recommendation
A	Based on Randomized Controlled Clinical Trial
B	Based on well conducted clinical studies
C	Based on evidence obtained from expert committee reports or opinions

AHCPR. United States Department of Health and Human Services. Agency for Health Care Policy and Research. Rockville MD, AHCPR, 1993

14. GUIDELINES: PREVENTION

Recommendation 1. Lipid lowering therapy

Statins are recommended in patients with ischemic stroke, TIA, asymptomatic carotid stenosis >50% and/or comorbid coronary artery disease, or evidence of an atherosclerotic origin. The target goal is an LDL-C of <2.6 mmol/l, and < 1.8 mmol/l for very high-risk persons with multiple risk factors [A].

15. GUIDELINES: PREVENTION

Recommendation 2. Antithrombotic therapy for symptomatic carotid stenosis

- All patients with symptomatic carotid artery stenosis should be given antiplatelet therapy and this should be continued in the long term [B].
- Antiplatelet therapy should be started before carotid endarterectomy [C].

Critical issue: There is no clear evidence supporting the choice of a specific antiplatelet agent.

16. GUIDELINES: PREVENTION

Recommendation 3. Antithrombotic therapy for asymptomatic carotid stenosis

Antiplatelet therapy is recommended in patients with asymptomatic carotid stenosis if there are no contraindications [C].

17. GUIDELINES: PREVENTION

Recommendation 4. Treatment of elevated blood pressure

Antihypertensive treatment is recommended for both prevention of recurrent stroke and other vascular events in persons who have had an ischemic stroke or TIA.

An absolute target BP level is uncertain and should be individualized. Target blood pressure level is <140/90mmHg. In patients with diabetes or impaired renal function the target should be <130/80mmHg [A].

Critical issue: The optimal drug regimen remains uncertain; however available data supports the use of diuretics and ACE inhibitors.

18. GUIDELINES: PREVENTION

Recommendation 5. Risk factor modifications

- Patients should be advised to quit smoking [B].
- Excessive intake of alcohol should be avoided [C].
- Weight reduction is recommended in overweight individuals [C].
- Increased physical activity is recommended [C].

19. GUIDELINES: PREVENTION

Recommendation 6. Diagnosis of carotid artery disease

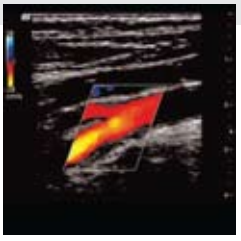
Patients with appropriate neurological and ocular symptoms, with or without audible bruit at the carotid bifurcation or with evidence of atherosclerotic disease in other territories should be referred for assessment at a properly accredited Vascular Laboratory [A].

Carotid bifurcation disease is more likely to be present if there is evidence of atherosclerotic disease in other territories

20. GUIDELINES: DIAGNOSIS

Recommendation 7. Diagnosis of presence and grading of carotid stenosis

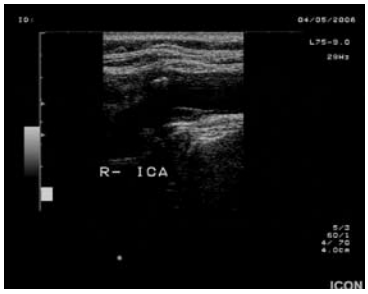
Colour-flow duplex scanning is the investigation of choice for the diagnosis and measurement of carotid stenosis, provided that objective criteria are used, by experienced operators. The velocities detected should be mentioned in the report as well as whether the percent stenosis reported refers to the angiographic ECST or NASCET method [B].



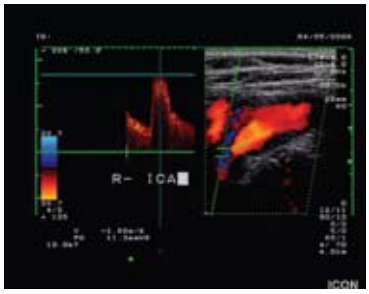
21. GUIDELINES: DIAGNOSIS

Recommendation 8. Plaque characteristics

Surface ulceration, low GSM (<25), heterogeneous appearance of the plaque and the juxta-luminal location of the echolucent area after image normalisation are ultrasonographic indicators of plaque vulnerability and should be considered in the selection of appropriate therapy and the frequency of follow up [B].



Carotid Stenosis 50%



GSM 17

22. GUIDELINES: DIAGNOSIS

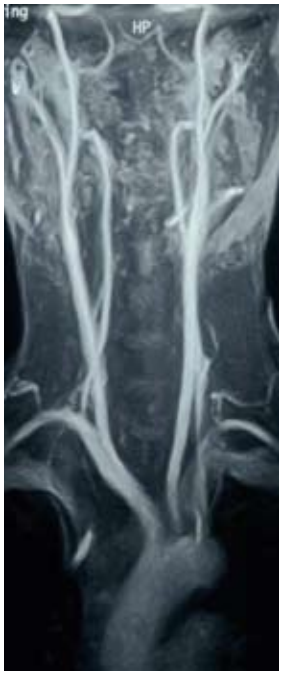
Recommendation 9. Carotid arteriography

Carotid arteriography should be performed only in cases where the results of noninvasive tests are inconclusive or when CAS is considered [C].

Critical issue: Data derived from CTA including plaque structure, quantification of degree of stenosis at the carotid bifurcation and arch anatomy should be further investigated.

23. GUIDELINES: DIAGNOSIS

Recommendation 10. Magnetic resonance angiography



- MRA is indicated for the detection of carotid stenosis only in cases where carotid duplex is ambiguous [B].
- MRA is the angiographic investigation of choice for the imaging of intrathoracic and intracranial vessels [C].

Critical issue: Data derived from MRA of the carotid including plaque structure, haemodynamics of the carotid bifurcation and wall shear stress should be further exploited.

24. GUIDELINES: DIAGNOSIS

Recommendation 11. Brain imaging and intracranial angiography

Combining brain imaging with CT or MR intracranial angiography provides valuable information on aortic arch and intracranial vascular anatomy [C].

25. GUIDELINES: INDICATIONS

Recommendation 12. Neurological symptomatology and degree of carotid stenosis

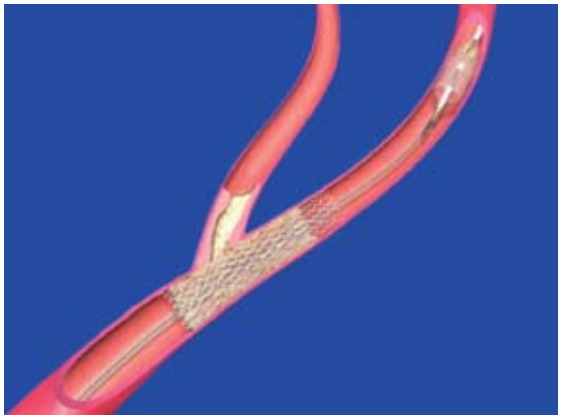
- The operative treatment of carotid disease is indicated in symptomatic patients with 70% (NASCET) stenosis [A] and and could be beneficial in patients with 50-69% (NASCET) stenosis [A]. The peri-operative stroke/death rate should be <6%. Carotid endarterectomy (CEA) is contraindicated for symptomatic patients with less than 50% stenosis [A].
- CEA should be done within 2 weeks of the patient's last symptoms [A].
- CEA can be recommended for asymptomatic patients under 75 years of age with 70% to 99% stenosis if the risk associated with surgery is less than 3% [A].
- In asymptomatic women under 75 years of age, the benefit from CEA is moderate [A]. The life expectancy should be at least 3 years, with the benefit becoming significant only over time [A].

Critical issue:

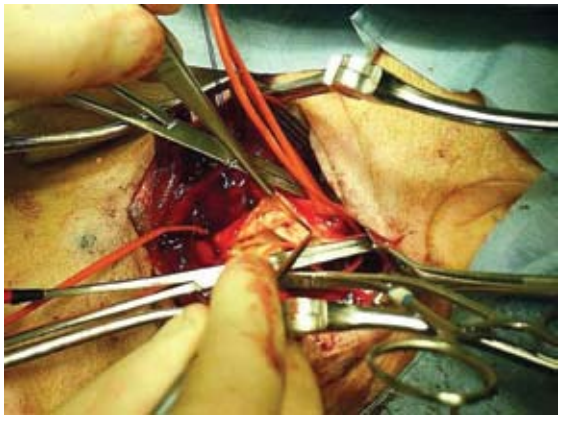
- The assumption that a patient can be treated with CAS when he has indication to CEA (carotid stenosis greater than 50% in symptomatics or 70% in asymptomatics) is not demonstrated.
- There is no randomized evidence on the specific threshold in the degree of stenosis over which there is indication to CAS (neither in symptomatic nor asymptomatic patients).

26. GUIDELINES: INDICATIONS

Stenting



or Endarterectomy?



27. GUIDELINES: INDICATIONS

Recommendation 13. Treatment options influenced by medical comorbidities

- There is currently insufficient evidence to support a widespread change in clinical practice away from recommending CEA [A].
- High risk patients suitable for CEA should be offered stenting within the confines of the ongoing CAS trials [B].
- For asymptomatic patients at "extremely" high risk (several medical comorbidities at the same time), the best medical treatment should be offered, instead of invasive intervention [C].
- CAS is associated to higher risk of embolization in octogenarians [B]. CEA is preferred in octogenarians without increased risk of embolization and with an acceptable rate of neurological and cardiac complications [C].

28. GUIDELINES: INDICATIONS

Recommendation 14. Treatment options according to vascular and local anatomical features.

- CAS is indicated in case of contralateral laryngeal nerve palsy, previous radical neck dissection, cervical irradiation, with prior CEA (restenosis), with high bifurcation or intracranial extension of a carotid lesion [A].
- CAS is not indicated in cases with long, multifocal lesions or an angulated internal carotid artery (ICA), extensive aortic or brachiocephalic trunk plaque, severe tortuosity or calcification of the aortic arch vessel and the ICA [C].

29. GUIDELINES: INDICATIONS

Recommendation 15. Treatment options according to carotid plaque morphology

- Plaque morphology should be assessed in all cases before invasive treatment [B].
- A GSM value lower than 25 is a predictor of stroke during CAS, as is related to a higher embolization rate during the procedure [B]. Carotid plaque echolucency (GSM <25) predicts the risk of stroke in carotid stenting irrespective of brain protection device and learning curve [B].
- Echolucent carotid plaques with a GSM <25 should be treated by surgery [C].
- In cases of echolucent (GSM<25) plaques in patients at increased risk due to anatomical and medical conditions (see above), an endovascular procedure can be performed using a proximal brain protection device and stents with a closed-cell design [C].
- More data are required for the routine use of brain protection devices during CAS [B].

Critical issue:

- The brain protection device (BPD) used during the endovascular procedure cannot protect from late embolization. The selection of carotid plaques at lower embolic potential is essential to reduce late complications.
- There is no randomized trial demonstrating the superiority of one stent compared to others (tapered vs. straight, open- vs. closed-cell) in the reduction of neurological complications.

30. GUIDELINES: TREATMENT

Recommendation 16. CEA in symptomatic patients

Carotid endarterectomy should be performed in patients with symptomatic severe stenosis (ECST >80%, NASCET >70%) and without contra-indications [A].

31. GUIDELINES: TREATMENT

Recommendation 17. CEA in asymptomatic patients

Carotid endarterectomy in asymptomatic patients reduces the stroke risk considerably [A].
In a centre with a stroke and death rate of < 3% surgery can be considered [A].

Critical issue: Data are required to establish the lower limit of grade of stenosis to justify surgery.

32. GUIDELINES: TREATMENT

Recommendation 18. CAS in symptomatic patients

The available level I evidence suggests that for symptomatic patients surgery is at present the best option [A].

Critical issue: More evidence is required to establish the role of CAS in symptomatic carotid artery disease.

33. GUIDELINES: TREATMENT

Recommendation 19. CAS in asymptomatic patients

CAS should not be offered to asymptomatic patients outside well-conducted clinical trials [C].

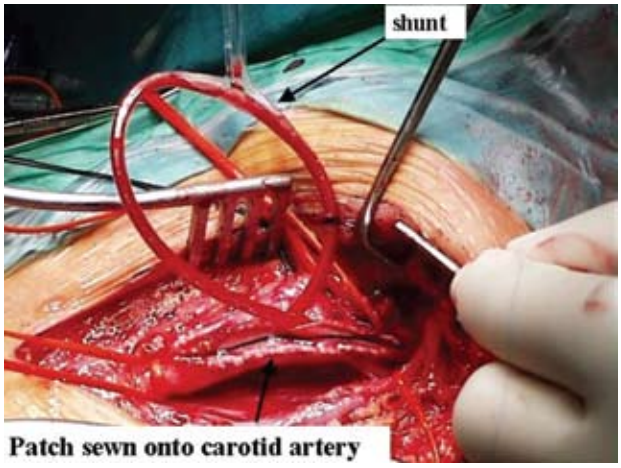
Critical issue: Any benefit from CAS in asymptomatic patients with carotid artery stenosis is still to be demonstrated.

34. GUIDELINES: TREATMENT

Recommendation 20. Shunting

There is no evidence for the routine use of shunts during carotid endarterectomy [A].

Critical issue: There is still insufficient evidence from randomized controlled trials to support or refute the use of routine or selective shunting during carotid endarterectomy. Further, there is little evidence to support the use of one form of monitoring over another in selecting patients requiring a shunt. A large, randomized controlled trial (3000-5000 patients) would be required to assess whether shunting reduces the risk of perioperative and long-term death and stroke.



35. GUIDELINES: TREATMENT

Recommendation 21. Patch angioplasty

Evidence suggests that carotid patch angioplasty reduces the risk of occlusion and restenosis, as well as the risk of combined stroke/death [A].

Critical issue:

- As differences between the outcomes with different patch materials are small, more data than currently available will be required for firm conclusions to be made.
- Until further evidence is available, the choice of the CEA technique should depend on the experience and familiarity of the individual surgeon.
- More data from randomized trials are required to establish any potential benefit from the use of local anesthesia.

36. GUIDELINES: TREATMENT

Recommendation 22. Quality control of CEA

- Completion evaluation of the results of CEA in the form of either ultrasound or arteriography is advisable [B].

37. GUIDELINES: TREATMENT

Recommendation 23. Improving the CAS outcome

- Validated training programmes should be developed [B].
- Cerebral protection devices are probably of benefit [B].

Critical issue:

- Type of cerebral protection has still to be defined.
- The ideal stent has yet to be developed.

38. GUIDELINES: TREATMENT

Recommendation 24. Simultaneous management of peripheral arterial and carotid disease

A carotid stenosis which has been asymptomatic for 6 months need not delay the operative treatment of peripheral vascular disease [C].

39. GUIDELINES: TREATMENT

Recommendation 25. Simultaneous management of coronary and carotid artery disease

Until data from randomised trials are available, the surgical approach to the patient with simultaneous severe coronary and carotid artery disease should be individualized, based on the specific risk profile of each patient [C].

40. CONCLUSIONS

- Implementation of the guidelines into everyday practice enhances the quality of care provided by the vascular specialists.
- The guidelines improve inter-specialty relations by giving a clear signal of the intentions and the level of practice by vascular surgeons.

41. ACKNOWLEDGEMENTS

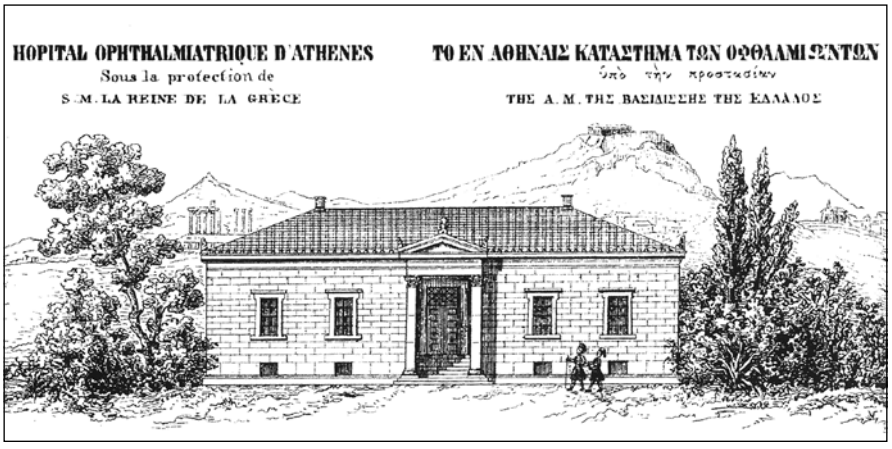
To the Coordinators, Reviewers and all participants for their invaluable contributions

- ***Special thanks for support and involvement***

To the ESVS Secretary General and all the Executive Committee.

42. ESVS GUIDELINES FOR ANEURYSMS

- There is a controversy on indications for the treatment of aneurysms.
- The existing literature's results need to be conveyed through guidelines to vascular surgeons.
- The ESVS will continue the initiative and be the first among the vascular scientific societies in that aspect .



Το Οφθαλμιατρείο Αθηνών (σχέδιο Χριστιανού Χάνσεν, 1843)