# Indicazioni alla ricostruzione carotidea nella stenosi asintomatica – Indikation zur Carotis-Rekonstruktion bei asymptomatischer Stenose

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**ISCRIZIONI: entro il 16.4.2013**

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**ANMELDUNG: innerhalb 16.4.2013**

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SCUOLA EUROPEA DI SCIENZE DELLA SALUTE

**TRATTAMENTO DELLE PATOLOGIE VASCOLARI SOPRAAORTICHE: NUOVE STRATEGIE**

*CONVEGNO INTERUNIVERSITARIO*

AUTONOME PROVINZ BOZEN · SÜDTIROL
Abteilung 23 Gesundheitswesen
PROVINCIA AUTONOMA DI BOLZANO · ALTO ADIGE
Ripartizione 23 Sanità

TRIANGULUM

EUROPÄISCHE SCHULE FÜR GESUNDHEITSWISSENSCHAFTEN

**DIE BEHANDLUNG SUPRAAORTALER GEFÄSSPATHOLOGIEN: NEUE STRATEGIEN**

*INTERUNIVERSITÄRE TAGUNG*

**Bolzano - 20 aprile 2013**
SALA CONGRESSI dell'Ospedale Regionale di Bolzano

**Bozen - 20. April 2013**
KONGRESS-SAAL des Regionalkrankenhauses von Bozen

# Setting high-impact clinical research priorities for the Society for Vascular Surgery

**Table V.** Final group scoring
SVS clinical research priorities (in order of priority 1-9)

| *Rank* | *Score ($)* | *Clinical research question* |
|---|---|---|
| 1 | 178 | Define optimal management of asymptomatic carotid stenosis |
| 2 | 168 | Compare effectiveness of medical vs invasive therapy (open or endovascular) for claudication |
| 3 | 129 | Compare effectiveness of initial open vs endovascular infrainguinal revascularization for critical limb ischemia |
| 4 | 62 | Develop and compare effectiveness of clinical strategies to reduce cardiovascular and other perioperative complications (eg, wound) after vascular intervention |
| 5 | 61 | Define the effectiveness of strategies to enhance arteriovenous fistula maturation and durability |
| 6 | 47 | Develop best practices for management of chronic venous ulcer |
| 7 | 36 | Define optimal adjunctive medical therapy to enhance the success of lower extremity intervention |
| 8 | 32 | Identify and evaluate medical therapy to prevent abdominal aortic aneurysm growth |
| 9 | 7 | Evaluate ultrasound vs computed tomographic angiography surveillance postendovascular aneurysm repair |

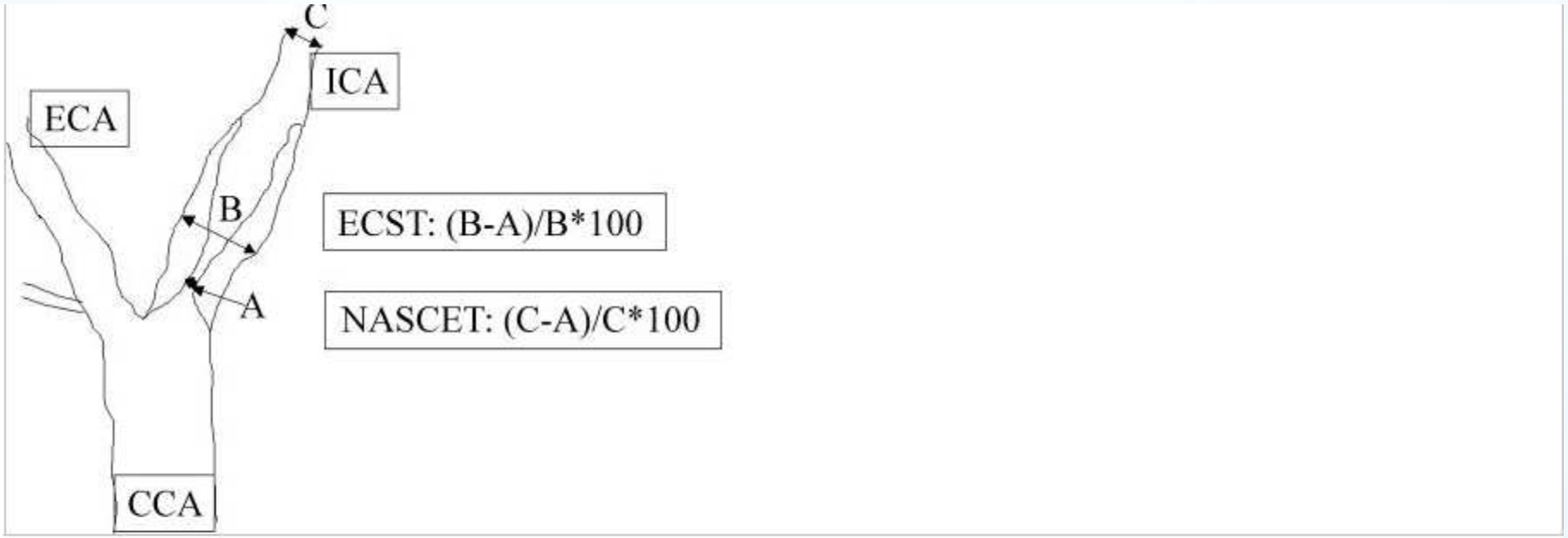
Other questions listed in Table IV received no votes during final scoring exercise.

**C5 Define clinical and anatomic characteristics in asymptomatic carotid stenosis patients that place them at high risk for stroke**
**C3 Compare effectiveness of invasive intervention (CEA or CAS) with medical therapy for asymptomatic carotid stenosis**

**J Vasc Surg 2013;57:493-500**

# Crucial points

- Definizione del grado di stenosi
- Definizione della placca “a rischio”
- Valutazione dei costi-benefici del trattamento chirurgico
- Linee guida nazionali ed internazionali
- Casistica del Reparto di Chirurgia e Vascolare di Bolzano
- Take home messages

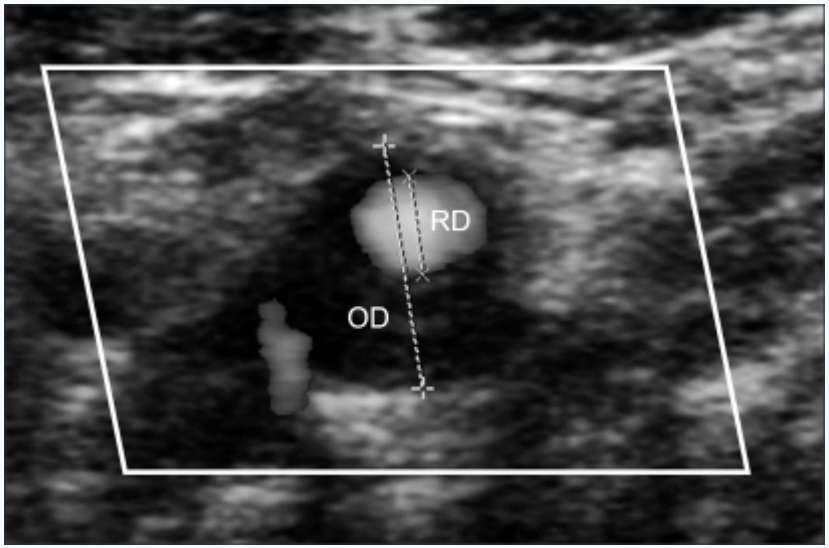



**Angiographic Methodology of Grading Carotid Stenosis**

Grading can be done in relation to the carotid bulb (ECST method) or the distal internal carotid stenosis (NASCET method). CCA, common carotid artery; ECA, external carotid artery; ICA, internal carotid artery.

**Umrechnung von distalem (NASCET) zu lokalem (ECST) Stenosemaß gemäß den Formeln nach Rothwell und Nicolaides.**

| NASCET% | ECST%-Rothwell N%x0,6+40%] | ECST%-Nicolaides [N%x0,57+43%] |
|---|---|---|
| 30 | 58 | 60 |
| 40 | 64 | 66 |
| 50 | 70 | 72 |
| 60 | 76 | 77 |
| 70 | 82 | 83 |
| 80 | 88 | 89 |
| 90 | 94 | 94 |
| 100 | 100 | 100 |




Calculation of carotid stenosis% on a transverse scan color flow ultrasonography image of the internal carotid artery: residual diameter (RD) indicates the shortest diameter of residual lumen of the most stenotic segment of the internal carotid artery and original diameter (OD) indicates a diameter from the outer media-to-outer media in a same plane and a same direction with RD.

# Linee guida SICVE

- L’estrema variabilità dei criteri ultrasonografici proposti in letteratura per classificare la stenosi è indicativa di quanto la metodica sia operatore e macchina dipendente. Per tale motivo è necessaria una validazione locale dei criteri ultrasonografici per classificare la stenosi comprensiva di un programma di controlli della qualità nel tempo. La validazione presuppone la collaborazione tra laboratorio, chirurgo vascolare e angioradiologo.

***Raccomandazione grado A***

**Tabelle 2:** **Stenosegraduierung der A. carotis interna nach aktualisierten DEGUM Kriterien Abkürzungen: ACA: A. cerebri anterior. ACC: A. carotis communis. ACI: A. carotis interna.**

| Stenosegrad (NASCET-Definition) [%] | | 10 | 20 - 40 | 50 | 60 | 70 | 80 | 90 | Verschluss |
|---|---|---|---|---|---|---|---|---|---|
| Stenosegrad alt (ECST-Definition) [%] | | 45 | 50 - 60 | 70 | 75 | 80 | 90 | 95 | Verschluss |
| **Haupt-kriterien** | 1. B-Bild | +++ | + | | | | | | |
| | 2. Farb-Doppler-Bild | + | +++ | + | + | + | + | + | +++ |
| | 3. Systolische Spitzengeschwindigkeit im Stenosemaximum [cm/s] ca. | | | 200 | 250 | 300 | 350-400 | 100-500 | |
| | 4. Systolische Spitzengeschwindigkeit poststenotisch [cm/s] | | | | | >50 | <50 | <30 | |
| | 5. Kollateralen und Vorstufen (Periorbitalarterien / ACA) | | | | | (+) | ++ | +++ | +++ |
| **Zusatz-kriterien** | 6. Diastolische Strömungsverlangsamung prästenotisch (ACC) | | | | | (+) | ++ | +++ | +++ |
| | 7. Strömungsstörungen poststenotisch | | | + | + | ++ | +++ | (+) | |
| | 8. Enddiastolische Strömungsgeschwindigkeit im Stenosemaximum [cm/s] | | | bis 100 | bis 100 | über 100 | über 100 | | |
| | 9. Konfetti-Zeichen | | | | (+) | ++ | ++ | | |
| | 10. Stenoseindex ACI/ACC | | | ≥2 | ≥2 | ≥4 | ≥4 | | |

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# Risk stratification for stroke in ACAS

- severity of stenosis
- echolucent (hypoechoic) plaque type
- low grayscale median (GSM)
- increased percentage of echolucent plaque components
- the presence of discrete white areas (DWAs) without acoustic shadowing
- clinical risk factors
- brain infarction on computed tomography

# Risk stratification for stroke in ACAS

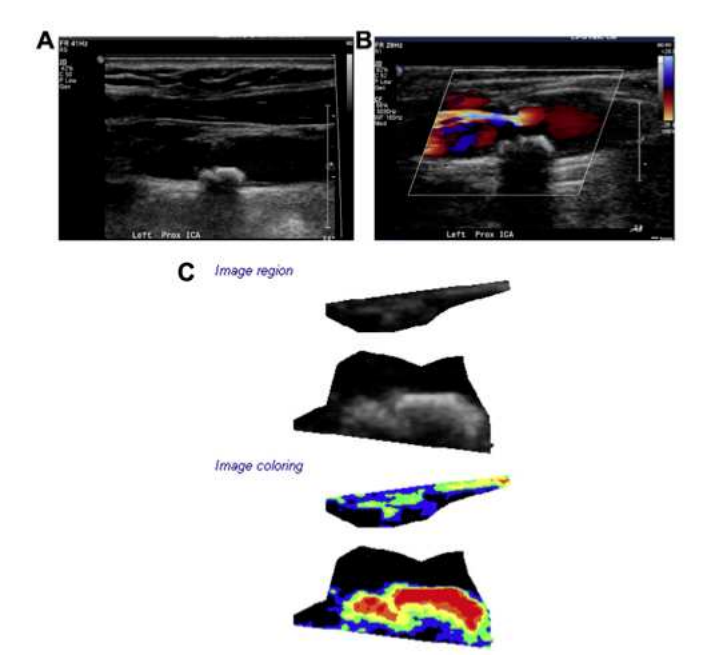
- Transcranial Doppler can identify a subgroup of patients with microembolic signal
- Contrast enhanced ultrasound (CEUS) appears to be one of the most promising tools for the stratification of the carotid plaque vulnerability

**Arch Neurol 2010;67:180–186**

**Int Angiol 2012;31:565-71**

# Risk stratification for stroke in ACAS

- the size of juxtaluminal black (hypoechoic) area (JBA)




**J Vasc Surg 2013;57:609-18**

# Risk stratification for stroke in ACAS

- Mild cognitive impairment/rapid progressive dementia
- Identification of embolic signals on TCD
- The presence of a thin fibrous cap (MR)
- Neovascularaization (MR, IVUS)
- Intraplaque hemorrhage (MR, IVUS)

J Cardiovasc Surg 2013;54:55-9

# Risk factors most significantly associated to unstable plaques

- hypertension (p=0.009, OR 2.29),
- low HDL-cholesterol (p=0.01 OR 2.21)
- the ratio of total to HDL-C >5 (p=0.03, OR 2.07)

**Atherosclerosis. 2010;208(2):572-80**

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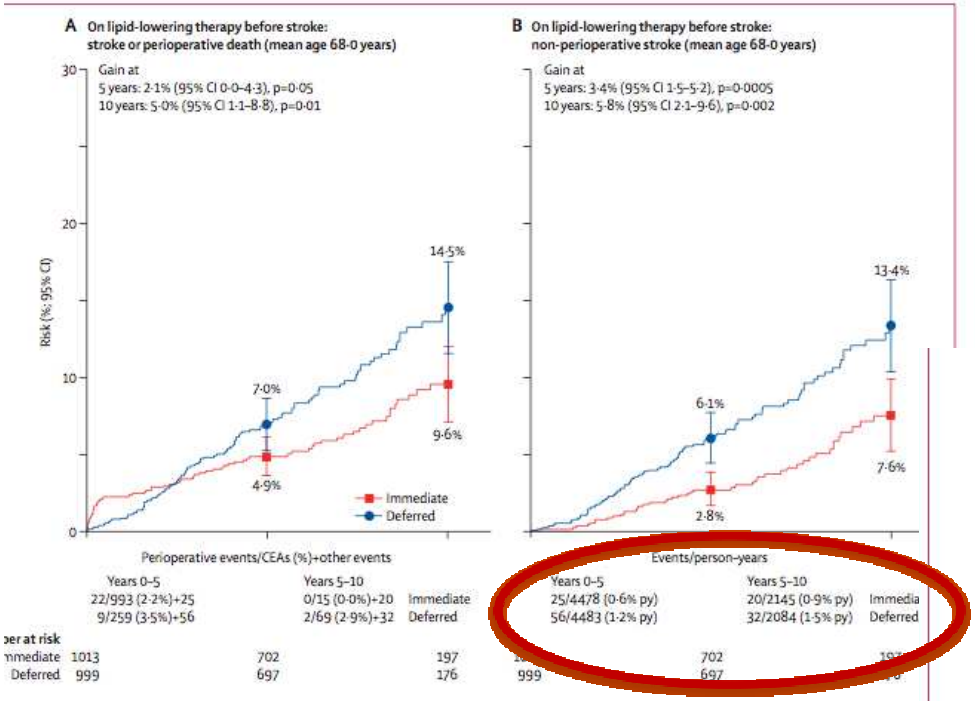
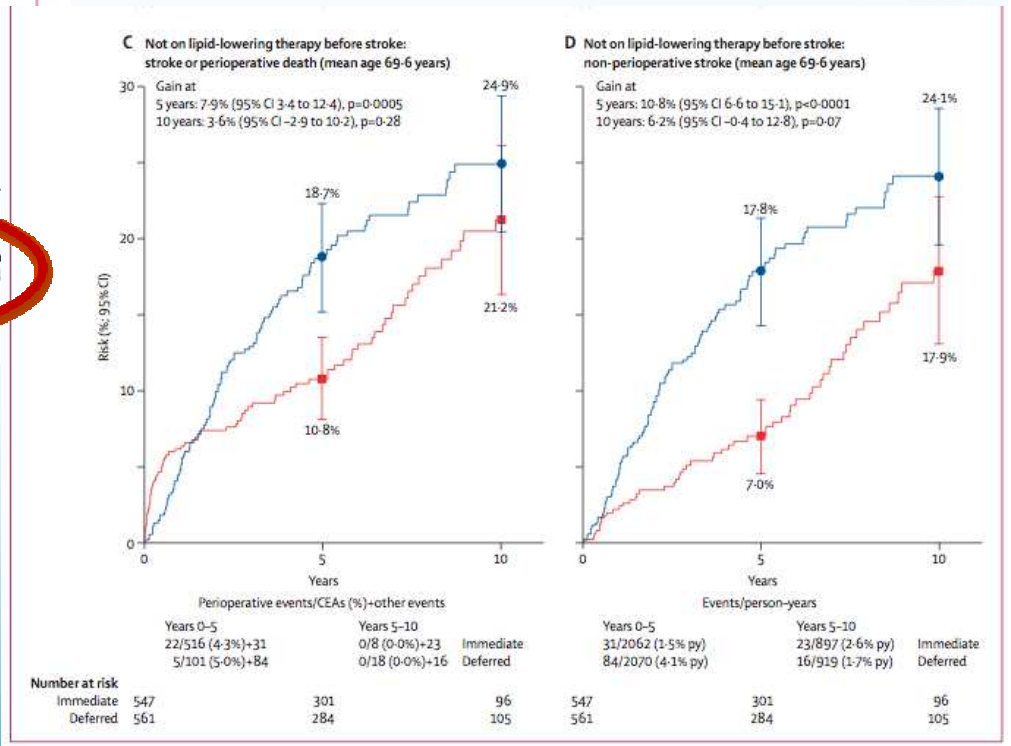
# 10-year stroke prevention after successful carotid endarterectomy for asymptomatic stenosis (ACST-1)

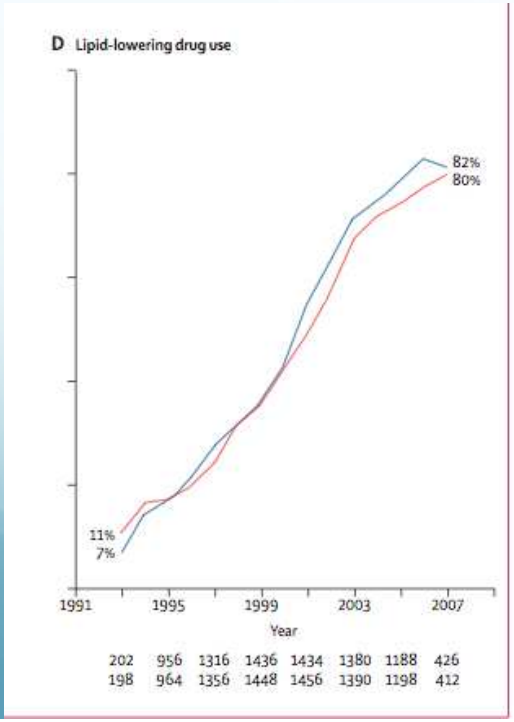



**Lancet 2010; 376: 1074–84**

# BMT and prevention of stroke in ACAS

- the annual risk of stroke has dropped significantly to **<1% per year** with medical therapy alone, raising serious questions as to the benefit of any revascularization procedure




**Stroke 2009;40:e573-e583**

# BMT and prevention of stroke in ACAS

- The any territory annual ischemic stroke risk was **0.4%** in 50% to 99% ACAS and **0.5%** per year for 70% to 99% ACAS patients.
- The risk of ischemic stroke was not significantly increased in patients with ACAS 70% to 99% (hazard ratio, 1.5; 95% confidence interval, 0.7-3.5).
- mean follow-up was 6.2 and 6.0 years

**Stroke**. 2013 Apr;44(4):1002-7

# Metanalysis

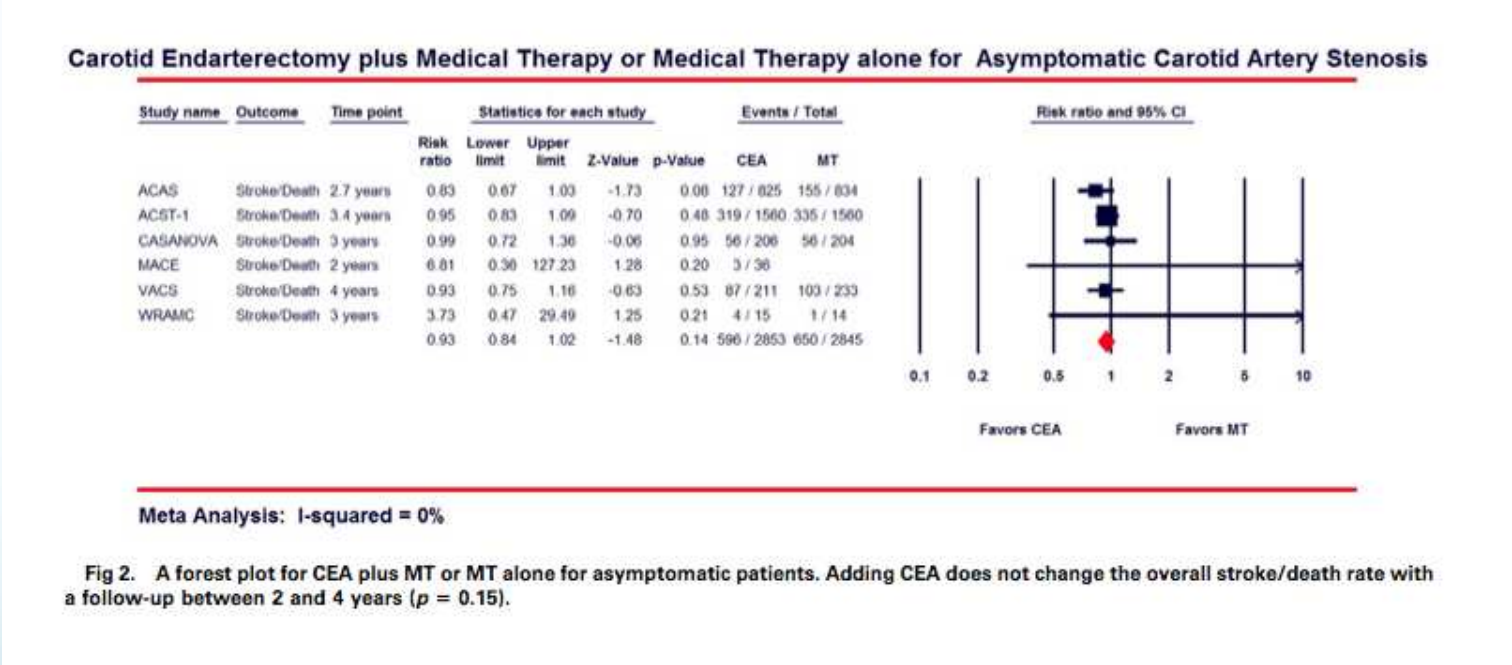



Fig 2. A forest plot for CEA plus MT or MT alone for asymptomatic patients. Adding CEA does not change the overall stroke/death rate with a follow-up between 2 and 4 years ($p = 0.15$).

**Journal of Cardiothoracic and Vascular Anesthesia, 26, 2012: pp 835-844**

# Modelling the cost-effectiveness of carotid endarterectomy for asymptomatic stenosis

- In the ACST, early endarterectomy was predicted to be cost-effective in those below 75 years of age, using a threshold of £20 000 per quality adjusted life-year (QALY).
- If background any-territory stroke rates fell below 1 per cent per annum, early endarterectomy would cease to be cost-effective.

**British Journal of Surgery 2013; 100: 231–239**

# Studi in corso

- SPACE-2 Int J Stroke. 2009 Aug;4(4):294-9
- CREST-2 ?
- TACIT ?

# The perioperative hazards of CEA

| Perioperative mortality and morbidity | | |
|---|---|---|
| Total number of CEAs† | 1532 | 447 |
| Stroke death | 11 | 2 |
| Cardiac death | 5 | 0 |
| Other death | 1 | 1 |
| Disabling stroke | 9 | 5 |
| Non-disabling stroke | 18 | 8 |
| Non-fatal myocardial infarction | 10 | 1 |
| Any perioperative stroke or death | 44 | 16 |
| % of total number of CEAs (95% CI) | 2·9% (2·1–3·8) | 3·6% (2·2–5·7) |

This table includes only CEAs done within 10 years of randomisation. CEA=carotid endarterectomy *Kaplan-Meier time-dependent percentages; denominators at these times are shown in figure 2. †Ipsilateral or contralateral (bilateral=two CEAs) first or subsequent CEAs.

*Table:* Surgical compliance, mortality, and morbidity

**Lancet 2010; 376: 1074–84**

# Risk index for predicting perioperative stroke, myocardial infarction, or death risk in asymptomatic patients undergoing carotid endarterectomy

**Table III.** Risk factors associated with combined 30-day stroke, myocardial infarction (MI), and death after carotid endarterectomy (CEA) in asymptomatic patients on multivariate analysis

| *Risk factor* | *Adjusted OR* | *95% CI* | *Regression coefficients* | *Points assigned* |
|---|---|---|---|---|
| Age, years | | | | |
| <60 | Reference | Reference | Reference | 0 |
| 60-69 (vs <60) | 0.75 | 0.50-1.12 | −0.29 | −1 |
| 70-79 (vs <60) | 0.84 | 0.57-1.24 | −0.17 | −1 |
| ≥80 (vs <60) | 1.52 | 1.03-2.26 | 0.42 | 2 |
| Dyspnea at moderate exertion or rest | | | | |
| No | Reference | Reference | Reference | 0 |
| Yes | 1.43 | 1.10-1.86 | 0.36 | 2 |
| Previous peripheral revascularization or amputation | | | | |
| No | Reference | Reference | Reference | 0 |
| Yes | 1.80 | 1.33-2.45 | 0.59 | 3 |
| COPD | | | | |
| No | Reference | Reference | Reference | 0 |
| Yes | 1.73 | 1.27-2.36 | 0.55 | 3 |
| Recent angina within 1 month | | | | |
| No | Reference | Reference | Reference | 0 |
| Yes | 2.05 | 1.21-3.47 | 0.72 | 4 |
| Dependent functional status | | | | |
| No | Reference | Reference | Reference | 0 |
| Yes | 2.77 | 1.68-4.58 | 1.02 | 5 |

**Table IV.** Estimated risk of combined 30-day stroke, myocardial infarction (MI), or death after carotid endarterectomy (CEA) in asymptomatic patients

| *Total points for the patient* | *Estimated risk percentage for the patient* | *Risk tier categorization* | *N (%)* |
|---|---|---|---|
| −1 | 1.18 | Low | |
| 0 | 1.44 | | |
| 1 | 1.75 | <3% | 15,249 (86.2%) |
| 2 | 2.13 | | |
| 3 | 2.6 | | |
| 4 | 3.15 | Intermediate | |
| 5 | 3.82 | | 2233 (12.6%) |
| 6 | 4.63 | 3-6% | |
| 7 | 5.6 | | |
| 8 | 6.75 | High | |
| 9 | 8.13 | | |
| 10 | 9.75 | | |
| 11 | 11.66 | >6% | |
| 12 | 13.88 | | |
| 13 | 16.45 | | 210 (1.2%) |
| 14 | 19.38 | | |
| 15 | 22.7 | | |
| 16 | 26.4 | | |
| 17 | 30.47 | | |
| 18 | 34.86 | | |
| 19 | 39.53 | | |

**J Vasc Surg 2013;57:318-26**

# Crucial points

- Definizione del grado di stenosi
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# Linee guida SICVE

***Pazienti asintomatici***

In pazienti con rischio **chirurgico < 3%** e spettanza di vita di almeno 5 anni

-Indicazioni dimostrate :

stenosi ≥ 60% (NASCET) complicata o non, indipendentemente dall'asse carotideo controlaterale

***Raccomandazione grado A, livello I a***

# Leitlinie zur Diagnostik, Therapie und Nachsorge der extracraniellen Carotisstenose

| Nr. | Text der Empfehlung | Grad* | LoE° |
|---|---|---|---|
| A | Patienten sollen vor und nach einer CEA ASS einnehmen, eine Dauertherapie mit ASS soll nicht unterbrochen werden | ↑↑ | 1 |
| B | Die medikamentöse und nicht-medikamentöse Basistherapie zur Verhinderung arteriosklerotischer Komplikationen soll sich an den entsprechenden LL und Standards orientieren (Lipidstoffwechsel, antihypertensive Therapie und Diabetes mellitus Therapie, lifestyle modification) | ↑↑ | 1 |
| C | Die CEA soll bei Patienten mit einer 60-99%igen asymptomatischen Carotisstenose erwogen werden, da das Schlaganfallrisiko bei diesen Individuen gering, aber statistisch signifikant reduziert wird | ↑↑ | 1 |
| D | Der Nutzen der CEA bei Patienten mit asymptomatischer Carotisstenose besteht nur, wenn die Behandlung mit einer Komplikationsrate von weniger als 3% durchgeführt wird | ↑↑ | 1 |
| E | Der Nutzen der CEA bei Patienten mit asymptomatischer Carotisstenose besteht vor allem für Männer und Patienten mit einer Lebenserwartung von mindestens 5 Jahren | ↑ | 1 |
| F | Der Stellenwert der Therapieverfahren (CEA, CAS, BMT) bei asymptomatischer Carotisstenose sollte in kontrollierten Studien überprüft werden | GCP | - |
| G | Wenn bei einer asymptomatischen Carotisstenose die Indikation zur invasiven Behandlung besteht, kann CAS alternativ erwogen werden, wenn das behandelnde Zentrum zur CEA analoge Qualitätskriterien mit einer Komplikationsrate von weniger als 3% nachweislich einhält | ↔ | 2b |
| H | Bei erschwerten Bedingungen für eine CEA kann bei bestehender Therapieindikation in Zentren mit nachgewiesener Komplikationsrate <3% alternativ eine CAS erwogen werden | ↔ | 2b |

# Comparison of the five 2011 guidelines for the treatment of carotid stenosis

**Table II.** Recommendations of the 2011 carotid guidelines for patients with asymptomatic carotid artery stenosis

| *Guidelines* | *Recommendation* |
|---|---|
| ACC/AHA[1] | • Prophylactic CAS might be considered in highly selected patients with asymptomatic carotid stenosis (minimum 60% by angiography, 70% by validated Doppler ultrasound), but its effectiveness compared with medical therapy alone in this situation is not well established [class IIb; level of evidence, B]. |
| Revised SVS[2] | • Neurologically asymptomatic patients with ≥60% diameter stenosis should be considered for CEA for reduction of long-term risk of stroke, provided the patient has a 3- to 5-year life expectancy and perioperative stroke/death rates can be ≤3% [grade I; level of evidence, A].<br>• There are insufficient data to recommend CAS as primary therapy for neurologically asymptomatic patients with 70% to 99% diameter stenosis. In properly selected asymptomatic patients, CAS is equivalent to CEA in the hands of experienced interventionalists with a combined stroke and death rate <3% [grade II; level of evidence, B]. |
| ESC[3] | • In asymptomatic patients with carotid artery stenosis ≥60%, CEA should be considered as long as the perioperative stroke and death rate for procedures performed by the surgical team is <3% and the patient's life expectancy exceeds 5 years [class IIa; level of evidence, A].<br>• In asymptomatic patients with an indication for carotid revascularization, CAS may be considered as an alternative to CEA in high-volume centers with documented death or stroke rate <3% [class IIb; level of evidence, B]. |
| Australasian[4] | • There is currently no evidence to support CAS as a treatment for asymptomatic carotid stenosis. |
| NICE[5] | • Current evidence on the safety of CAS placement for asymptomatic extracranial carotid stenosis shows well-documented risks, in particular, the risk of stroke. The evidence on efficacy is inadequate in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. |

*ACC/AHA*, American College of Cardiology/American Heart Association; *CAS*, carotid artery stenting; *CEA*, carotid endarterectomy; *ESC*, European Society of Cardiology; *NICE*, UK National Institute for Health and Clinical Excellence; *SVS*, Society for Vascular Surgery.

**J Vasc Surg 2012;55:1504-8.**

# The American Academy of Neurology guidelines

Recommend that CEA for asymptomatic stenosis be considered only for patients aged 40 to 75 years, with at least a 5-year life expectancy. In addition, the surgeon’s complication rate should be reliably documented as less than 3%

**Neurology 2005;65:794–801**

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# The perioperative hazards of CEA

Department of Vascular and Thoracic Surgery
of Bolzano
**1992-2012**

| **Total number of CEAs** | **1631** | **%** |
|---|---|---|
| **Asymptomatic** | **965** | **59.2** |
| **Perioperatve moratlity/morbidity** | | |
| Disabling stroke | **7** | **0.43** |
| Death | **8** | **0.49** |
| Acute miocardial infarct | **4** | **0.24** |

**1.16%**

# Incidenza di stroke in Alto Adige dati relativi alla popolazione

- 2011: 0.14%
- 2012: 0.15%

Dati forniti dall'osservatorio epidemiologico dell'Alto Adige
Dr.ssa Carla Melani

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# Take home messages

- Definire il trattamento ottimale della stenosi carotidea asintomatica rappresenta una delle priorità principali nella ricerca in chirurgia vascolare
- Definire una classificazione clinica e strumentale della placca carotidea asintomatica con precise indicazioni chirurgiche
- Ridurre se possibile la morbilità perioperatoria

# Danke/Grazie