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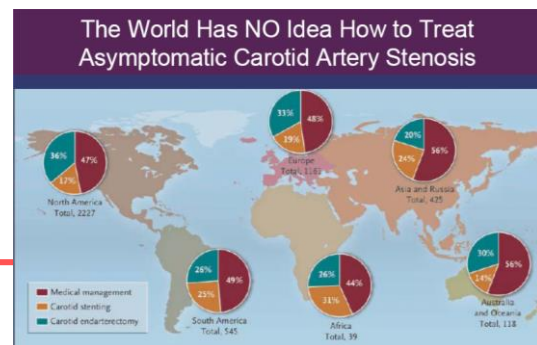
TAVOLA ROTONDA:

**Cardiovascular risk stratification in patients
with asymptomatic carotid disease**

Claudio Novali



Dibattito



- La comunità scientifica solleva il problema dell'assenza di evidenza scientifica: **TEA vs Stenting**



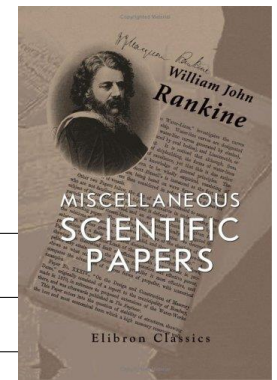
GREAT DEBATE

CAS could be **superior** or **not inferior** to **CEA**





Evidenza Scientifica



NASCET Trial *N Engl J Med* 1991

ECST Trial *Lancet* 1998

ACST Trial *Lancet* 2004

LEICESTER TRIAL *J Vasc Surg* 1998

WALLSTENT TRIAL *Stroke* 2001

EVA-3S Trial *Stroke* 2004

Cavatas

SAPPHIRE

CREST

SPACE

CAPTURE

CAPTURE 2

ICCS/CAVATAS2

ACST 2

SMART Study

Tacit

SPACE 2

Administrative Database Studies

SVS/ESVS Registries

TEA vs Stenting

Sintomatici / Asintomatici



Evidenza Scientifica

REVIEW

Annals of Internal Medicine

Management Strategies for Asymptomatic Carotid Stenosis

A Systematic Review and Meta-analysis

Gowri Raman, MD, MS; Denish Moorthy, MBBS, MS; Nira Hadar, MS; Issa J. Dahabreh, MD, MS; Thomas F. O'Donnell, MD; David E. Thaler, MD, PhD; Edward Feldmann, MD; Joseph Lau, MD; and Georgios D. Kitsios, MD, PhD

Background: Adults with asymptomatic carotid artery stenosis are at increased risk for ipsilateral carotid territory ischemic stroke.

Purpose: To examine comparative evidence on management strategies for asymptomatic carotid stenosis and the incidence of ipsilateral stroke with medical therapy alone.

Data Sources: MEDLINE, Cochrane Central Register of Controlled Trials, U.S. Food and Drug Administration documents, and review of references through 31 December 2012.

Study Selection: Randomized, controlled trials (RCTs) and prospective or retrospective nonrandomized, comparative studies of medical therapy alone, carotid endarterectomy (CEA) plus medical therapy, or carotid artery stenting (CAS) plus medical therapy for adults with asymptomatic carotid stenosis, as well as single-group prospective cohort studies of medical therapy, were reviewed.

Data Extraction: Two investigators extracted information on study and population characteristics, results, and risk of bias.

Data Synthesis: Forty-seven studies in 56 publications were eligible. The RCTs comparing CAS and CEA were clinically heteroge-

neous; 1 RCT reported more but not statistically significant ipsilateral stroke events (including any periprocedural stroke) in CAS compared with CEA, whereas another RCT, in a population at high surgical risk for CEA, did not. Three RCTs showed that CEA reduced the risk for ipsilateral stroke (including any periprocedural stroke) compared with medical therapy alone, but these results may no longer be applicable to contemporary clinical practice. No RCT compared CAS versus medical therapy alone. The summary incidence of ipsilateral stroke across 26 cohorts receiving medical therapy alone was 1.68% per year.

Limitations: Studies defined asymptomatic status heterogeneously. Participants in RCTs did not receive best-available medical therapy.

Conclusion: Future RCTs of asymptomatic carotid artery stenosis should explore whether revascularization interventions provide benefit to patients treated by best-available medical therapy.

Primary Funding Source: Agency for Healthcare Research and Quality.

Ann Intern Med. 2013;158:676-685.
For author affiliations, see end of text.

2013



Risultati



- I dati indicano il beneficio e la sicurezza della **TEA** nella prevenzione dello stroke. In particolare l'NNT si riduce nei pazienti affetti da **stenosi tra il 70 ed il 99%** sintomatici o asintomatici con un elevato punteggio di rischio di stroke.
- In pazienti asintomatici **le evidenze di equivalenza o non inferiorità dello *Stenting* carotideo rispetto all'endoarteriectomia sono ancora incerte e da definire meglio.** Nei sintomatici non è stata dimostrata alcuna superiorità dello stenting ad eccezione di una riduzione periprocedurale di rischio di infarto miocardico non fatale.

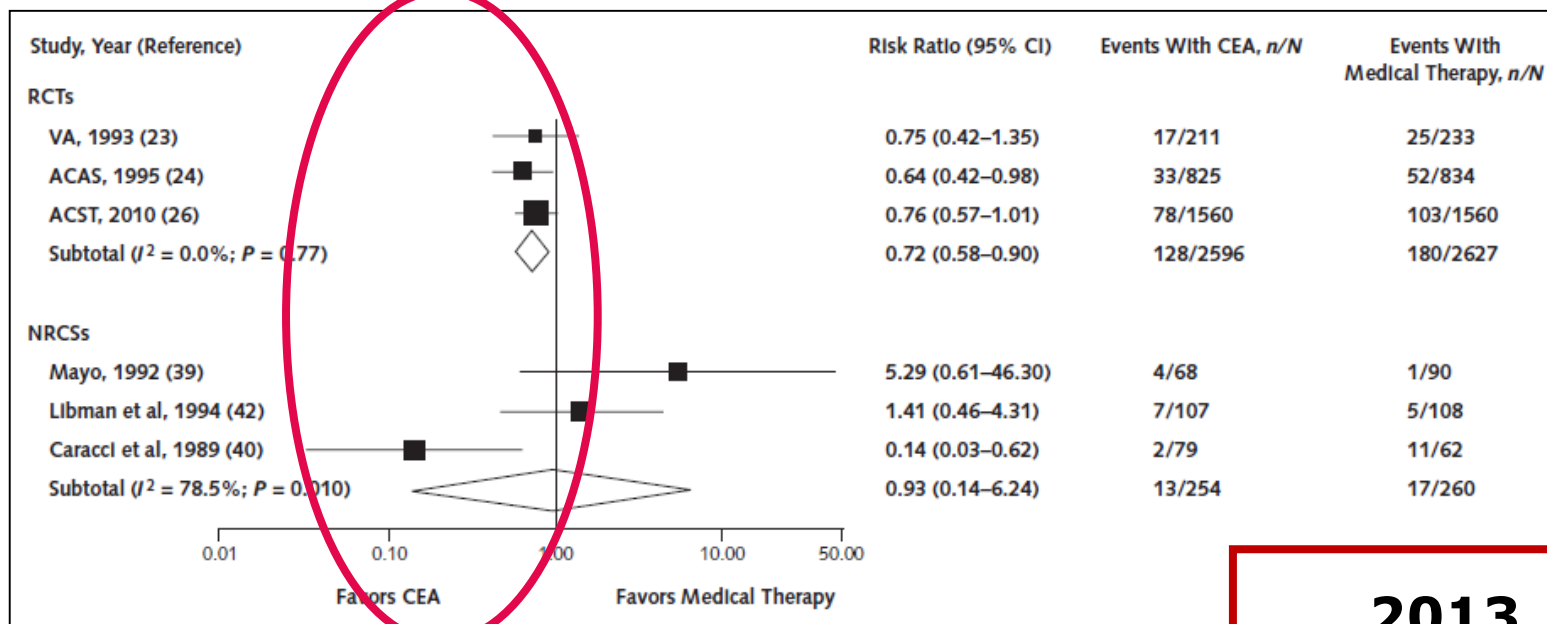
2013



Risultati



- La TEA risulta superiore alla sola terapia medica nella prevenzione dello stroke nei pazienti asintomatici ma ulteriori studi randomizzati sono necessari nel futuro.





Il miglioramento della TEA e del Management

- In numerose serie il tasso di periprocedurale di stroke/morte è risultato < **del 2%** e non aumentato nei pz > 80aa.
- **1%** /anno rischio di restenosi significativa.
- Miglior gestione periprocedurale (beta bloccanti, statine, antiaggreganti, sistemi di monitoraggio, fast track)



Mortalità **0.2%**

Morbilità **1.8 %**

2008



Le Linee Guida

Eur J Vasc Endovasc Surg (2018) 55, 3–81

Editor's Choice — Management of Atherosclerotic Carotid and Vertebral Artery Disease: 2017 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)

A.R. Naylor^a, J.-B. Ricco^a, G.J. de Borst^a, S. Debus^a, J. de Haro^a, A. Halliday^a, G. Hamilton^a, J. Kakisis^a, S. Kakkos^a, S. Lepidi^a, H.S. Markus^a, D.J. McCabe^a, J. Roy^a, H. Sillesen^a, J.C. van den Berg^a, F. Vermassen^a,
ESVS Guidelines Committee^b, P. Kolh, N. Chakfe, R.J. Hinchliffe, I. Koncar, J.S. Lindholt, M. Vega de Ceniga, F. Verzini,
ESVS Guideline Reviewers^c, J. Archie, S. Bellmund, A. Chaudhuri, M. Koelemay, A.-K. Lindahl, F. Padberg, M. Venermo

Keywords: Carotid, Vertebral, Stroke, Transient ischaemic attack, Endarterectomy, Stenting, Medical therapy, Screening, Dementia, Asymptomatic, Symptomatic, Thrombolysis, Imaging, Bypass, Surgical techniques, Complications, Patch infection, Restenosis

- Sintomatologia neurologica
- Grado di stenosi
- Comorbilità
- Caratteristiche anatomiche
- Morfologia della placca
- Tasso di complicitanze del Centro

2018



Stenosi Asintomatica - ACS



2018

ESVS guidelines (2018) therefore recommend that patients with an **'average surgical risk'** and an asymptomatic carotid artery stenosis of 60–99% **should be considered for CEA** only in the presence of one or more characteristics that may be associated with an increased risk of late ipsilateral stroke:

La TEA ha un beneficio maggiore nei pazienti asintomatici con rischio annuo di Stroke > 4% e di evento ischemico > 7%:



ACS: sotto gruppo a rischio: Criteri clinici ed imaging



2014-2018

- Infarto silente alla TAC o RMN
- Progressione della stenosi
- Ecolucenza ed instabilità della placca: da Soft (1) a Hard (5): 94% degli eventi avvengono con placche da 1 a 3.
- Emorragia intrapacca alla RMN
- Area della placca
- Insufficienza della vasoreattività cerebrale: riduzione del flusso invertito cerebrale
- Riscontro di microembolizzazione al TCD
- Storia di di TIA controlaterale
- IRC

**Rischio periprocedurale stroke/morte < 3% e
spettanza di vita > 5 anni**



ACS: Rischio cardiaco

- Assessing the risk of complications also helps guide decision making about the need for additional preoperative cardiac testing, type of revascularization, medication therapy (eg, β -blockade), or intraoperative monitoring

Predicting Medical and Surgical Complications of Carotid Endarterectomy

Comparing the Risk Indexes

Matthew J. Press, MD; Mark R. Chassin, MD, MPP, MPH; Jason Wang, PhD; Stanley Tuhim, MD; Ethan A. Halm, MD, MPH

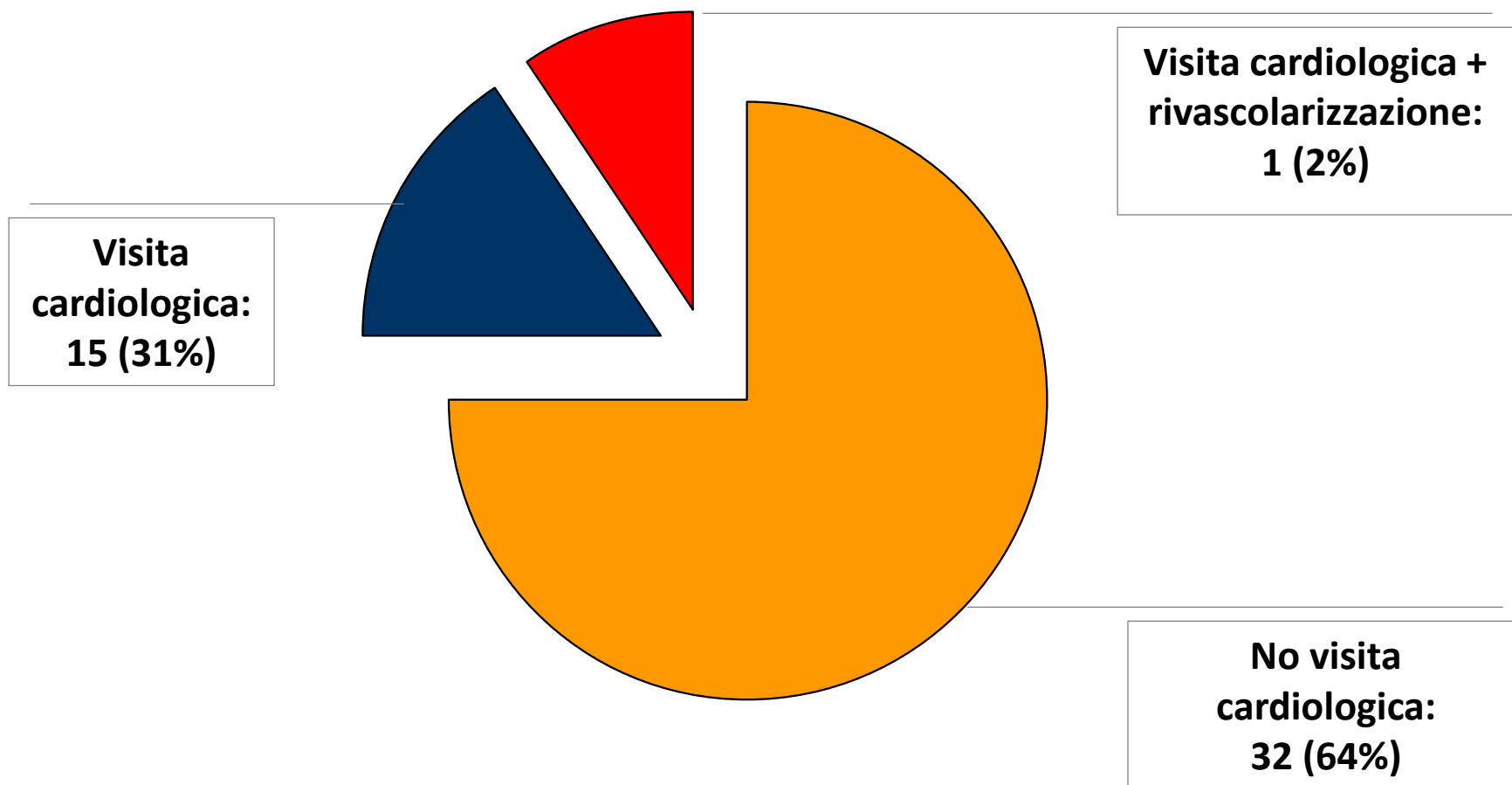
Table 3. Rates of Complication Types Within 30 Days of Surgery Among 1998 Patients Undergoing Carotid Endarterectomy

Complication	No. (%)*
Death or stroke	64 (3.2)
Cardiac	80 (4.0)
Myocardial infarction	23 (1.2)
Unstable angina	30 (1.5)
Congestive heart failure	37 (1.9)
Ventricular tachycardia	10 (0.5)
Noncardiac medical	63 (3.2)
Mechanical ventilation	45 (2.3)
Postoperative pneumonia	16 (0.8)
Sepsis	4 (0.2)
Renal failure	9 (0.5)
Deep venous thrombosis or pulmonary embolism	3 (0.2)
Gastrointestinal bleeding	4 (0.2)
Minor neurologic	138 (6.9)
Transient ischemic attack	27 (1.4)
Cranial nerve palsy†	120 (6.0)
Seizure	8 (0.4)
Wound	119 (6.0)
Wound bleeding or hematoma	108 (5.4)
Infection	16 (0.8)



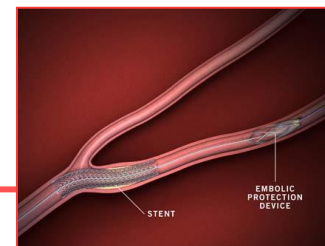
ACS: Rischio cardiaco – protocollo modello Cuneo

- da luglio 2019 a Settembre 2019: 48 carotidi in studio





ACS



2018

Carotid stenting may be considered in selected asymptomatic patients who have been deemed by the multidisciplinary team to be **“high-risk for surgery”** and who have an asymptomatic 60 - 99% stenosis in the presence of one or more imaging characteristics that may be associated with an increased risk of late ipsilateral stroke, a provided documented procedural risks are <3% and the patient’s life expectancy exceeds 5 years

Basandoci sulle attuali evidenze **non è indicato un cambio di tendenza dall’endoarteriectomia verso lo stenting** nella correzione chirurgica di scelta della **stenosi carotidea asintomatica**. Spread *Grado A*



Stenting



Indicazioni

■ Pazienti **asintomatici con gravi comorbidità** cardiache e/o polmonari

■ Pazienti **sintomatici ad alto rischio** con un documentato basso tasso di complicanze periprocedurali preferibilmente all'interno di studi controllati

■ Indicazioni **anatomiche:**

- **Pregressa radioterapia +++++**
- **Pregressa tracheostomia +++++**
- **Paralisi del nervo laringeo controlaterale +++++**
- **Estensione intracraniale della stenosi +++++**
- **Collo rigido e/ostile ++**
- **Biforcazione alta ++**
- **Restenosi +**



ACS: domande e future considerazioni



- **Dati estrapolati da RCTS basati su tecniche e materiali verosimilmente antiquati**
- **Terapia medica non ottimizzata**
- **Attuale tasso di Stroke nelle ACS**





ACS: domande e future considerazioni



- **SPACE 2**
- **CREST 2**
- **ECST-2**
- **ACTRIS**
- **ACST-2**

The results of these RCTs are eagerly anticipated and awaited in the 2020s as they will provide clarity, in a large number of patients (whilst also providing an opportunity for meta-analysis), regarding the effect of the increased use of statins, new stent designs and safer CAS techniques compared with CEA and BMT **to better inform the management of patients with asymptomatic carotid artery stenosis.**



ACS: Follow-up Post-operatorio



SPREAD 2016: Raccomandazione 13.24

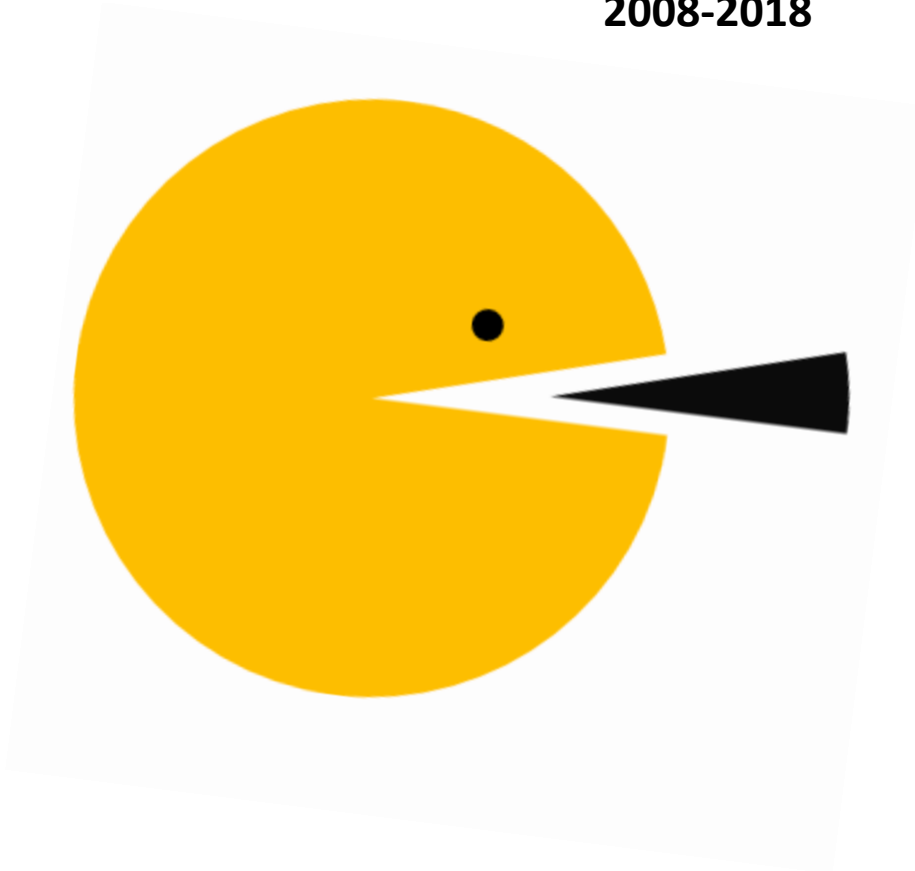
■ **È indicato che ogni Centro valuti e renda nota la propria incidenza** (dopo endoarterectomia e dopo stenting carotideo) di complicanze gravi (morte, ictus, infarto miocardico) perioperatorie, che possono condizionare l'indicazione all'intervento, specie nella stenosi carotidea asintomatica. *Grado GPP*

Nostra esperienza

Nostra Esperienza

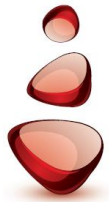


2008-2018



■ TEA: 2188

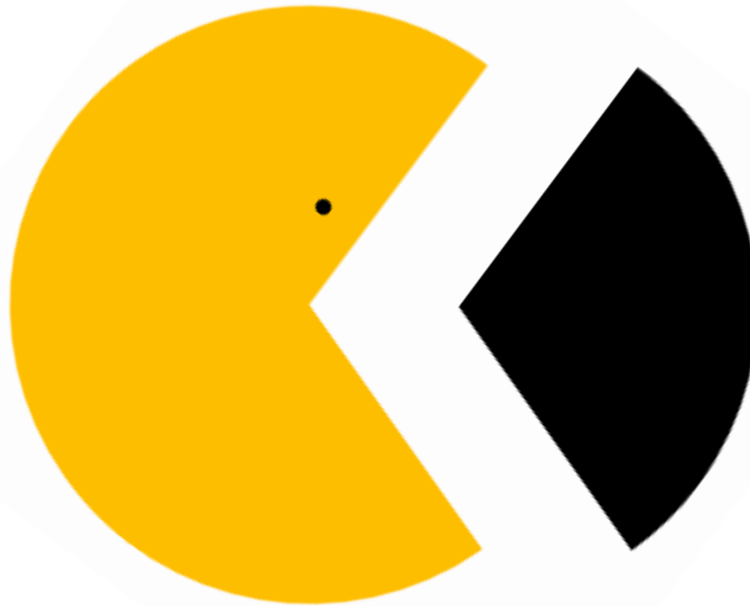
■ CAS: 121



Nostra Esperienza

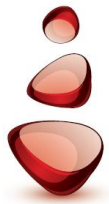


%



- Asintomatici: 1619 (74%)
- Sintomatici: 569 (26%)

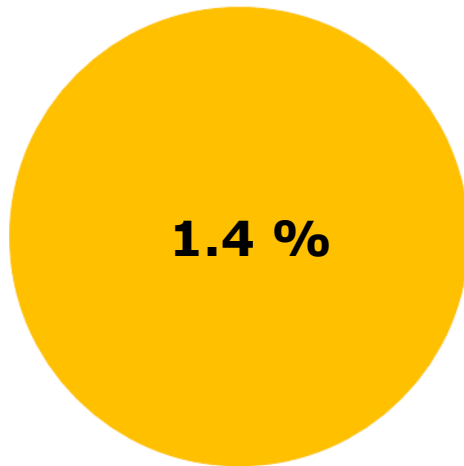




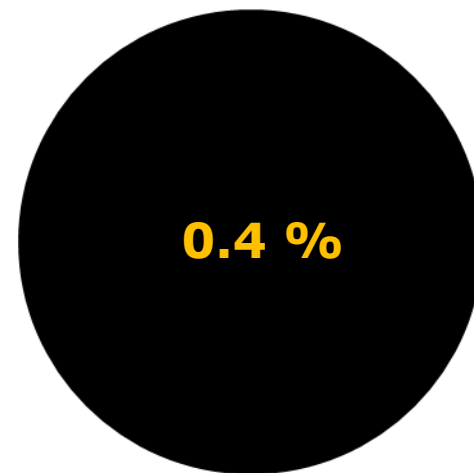
Nostra Esperienza: ACS



Major Stroke



Mortalità



grazie per
l'attenzione

