

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

JANUARY 25-27 2018 

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER, PARIS, FRANCE

2000 CAS in 20 years: what have we learned in terms of indications, CPD, type of stents?

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Vascular and Endovascular Surgery Unit

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Disclosure

Speaker name:

Enrico Cieri

- I have the following potential conflicts of interest to report:
- Consulting: Cook, Medtronic
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest



CAS Indication - Guidelines



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)

Writing Group ^a, A.R. Naylor, J.-B. Ricco, G.J. de Borst, S. Debus, J. de Haro, A. Halliday, G. Hamilton, J. Kakisis, S. Kakkos, S. Lepidi, H.S. Markus, D.J. McCabe, J. Roy, H. Sillesen, J.C. van den Berg, F. Vermassen, 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. Bellmunt, A. Chaudhuri, M. Koelemay, A.-K. Lindahl, F. Padberg, M. Venermo



3. Patologia carotidea

NZA ⁴,
IGIA ⁸

Current guideline endorsements of CEA and CAS are mainly based on trials in which patients were randomized 15 to 35 years ago !



ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline

2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease



Updated Society for Vascular Surgery guidelines for management of extracranial carotid disease

John J. Ricotta, MD,^a Ali AbuRahma, MD, FACS,^b Enrico Ascher, MD,^c Mark Eskandari, MD,^d Peter Faries, MD,^e and Brajesh K. Lal MD,^f Washington, DC; Charleston, WV; Brooklyn, NY; Chicago, Ill; New York, NY; and Baltimore, Md

Key points for a successful CAS

- Patient selection
- Medical treatment
- Intra-operative imaging
- Protection device
- Stent
- Operator experience



Age

- *Patient selection*
- Medical treatment
- Intra-operative imaging
- Protection device
- Stent
- Operator experience



➤ Clinical and angiographic risk factors for stroke and death within 30 days after carotid endarterectomy and stent-protected angioplasty: a subanalysis of the SPACE study

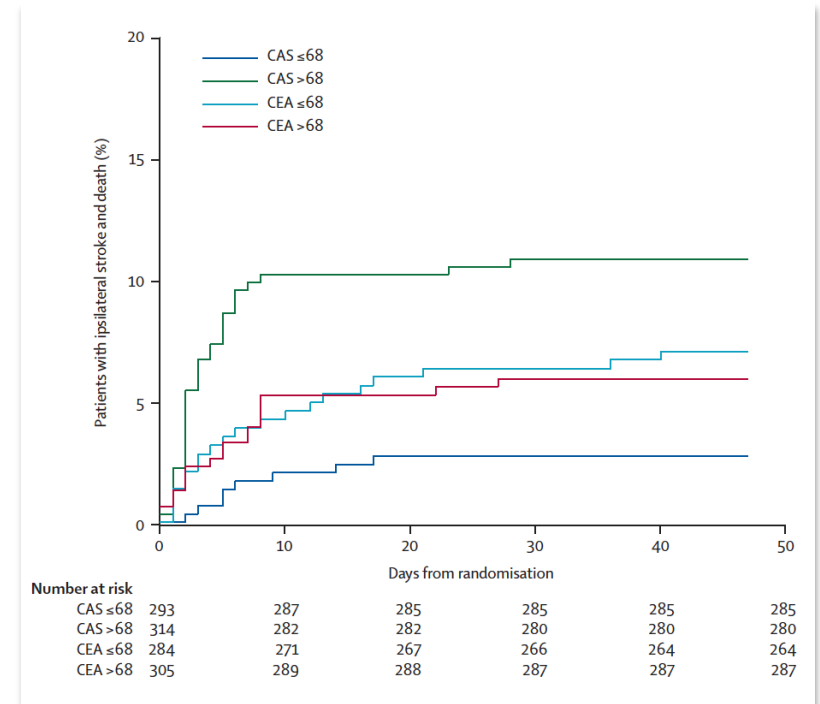
Robert Stingele, Jürgen Berger, Karsten Alfke, Hans-Henning Eckstein, Gustav Fraedrich, Jens Allenberg, Marius Hartmann, Peter A Ringleb, Jens Fiehler, for the SPACE investigators*

<http://neurology.thelancet.com> Vol 7 March 2008

1196 CAS-CEA

- Age was significantly associated with the risk of stroke and death

- The lower risk after CAS versus CEA in patients up to 68 years of age was not detectable in older patients



Gender

- *Patient selection*
- Medical treatment
- Intra-operative imaging
- Protection device
- Stent
- Operator experience



A comparative analysis of the outcomes of carotid stenting and carotid endarterectomy in women

Paola De Rango, MD,^a Gianbattista Parlani, MD,^a Valeria Caso, MD, PhD,^b Fabio Verzini, MD,^a Giuseppe Giordano, MD,^a Enrico Cieri, MD,^a and Piergiorgio Cao, MD,^a *Perugia, Italy*

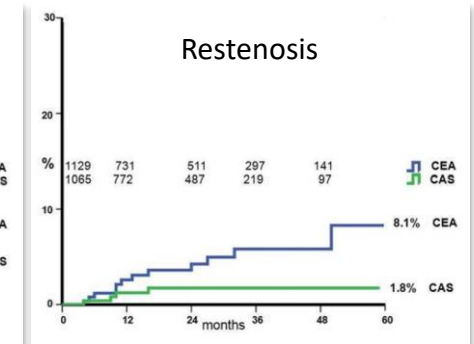
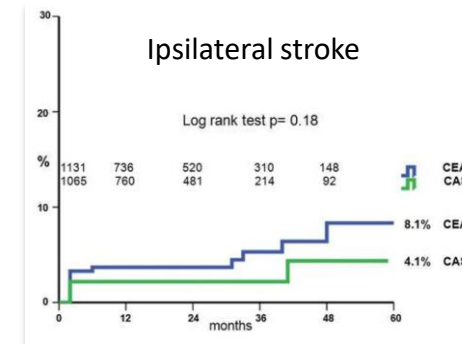
JOURNAL OF VASCULAR SURGERY
February 2010

1065 CAS- 1131 CEA

2004-2009

Women with carotid stenosis (whether symptomatic or asymptomatic) might have favourable early and late outcomes from CAS with complication rates similar and even lower than those attained with CEA

	CAS group (n = 306) n (%)		CEA group (n = 325) n (%)		OR	95% CI	P value
30-day outcomes							
Death or stroke	6	1.9	10	3	0.63	0.2-1.7	.45
Stroke	6	1.9	9	2.7	0.7	0.2-1.9	.6
Stroke in asymptomatic	3/241	1.2	7/220	3.2	0.38	0.09-1.5	.2
Disabling stroke in asymptomatic	0/241		1/220			0.0-35.6	.47
Stroke in symptomatic	3/65	4.6	2/105	1.9	2.49	0.28-30.43	.37
Disabling stroke in symptomatic	2/65		3/105		1.08	0.12-8.2	1
Disabling stroke	2	0.65	3	0.9	0.7	0.11-4.2	1
Death	—	—	2	0.6	—	—	.5
TIA	10	3.2	4	1.23	2.7	0.84-8.7	.1
Myocardial infarction	2	0.65	3	0.9	0.7	0.11-4.25	1
MACE	7	2.3	12	3.7	0.61	0.24-1.57	.35
Hematoma	5	1.6	9	2.8	0.76	0.23-2.54	.8



Previous Symptoms

- *Patient selection*
- Medical treatment
- Intra-operative imaging
- Protection device
- Stent
- Operator experience



21 registries;
More than
1.500.000
procedures

Comparable
Stroke/death rates
for “average risk”
asymptomatic
patients
undergoing CAS
and CEA

REVIEW

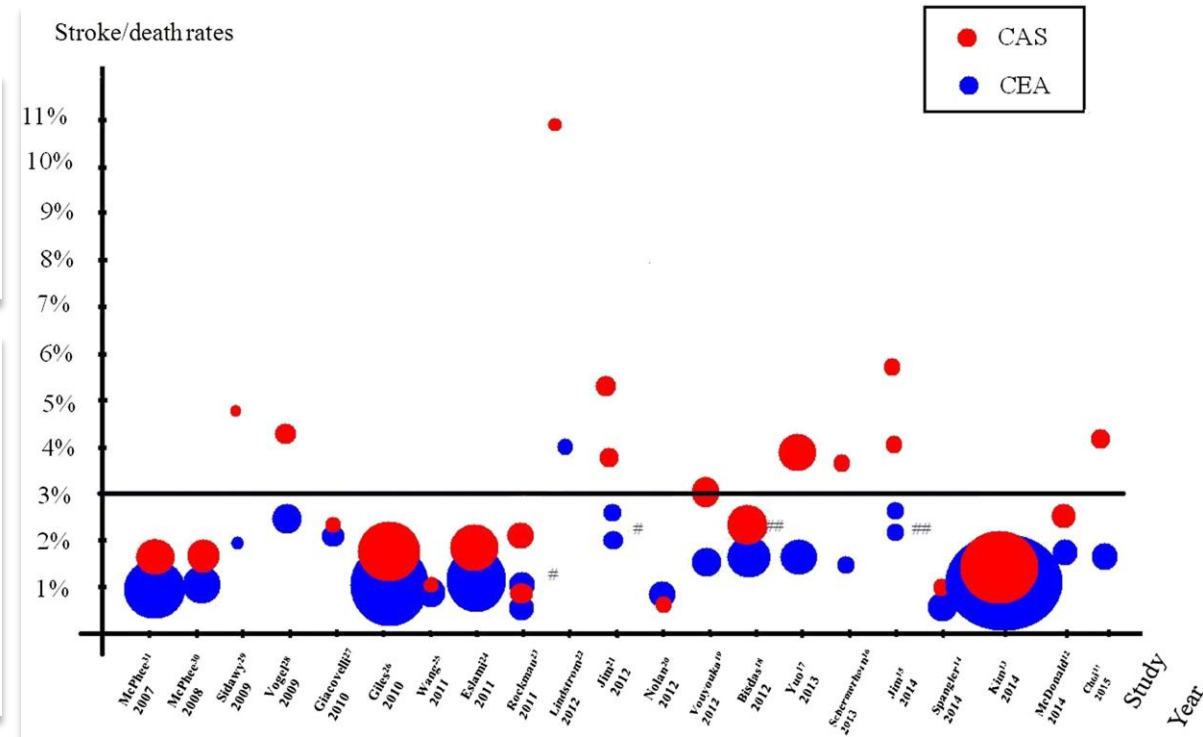
Eur J Vasc Endovasc Surg (2016) 51, 3–12

Stroke/Death Rates Following Carotid Artery Stenting and Carotid Endarterectomy in Contemporary Administrative Dataset Registries: A Systematic Review

K.I. Paraskevas ^{a,*}, E.L. Kalmykov ^b, A.R. Naylor ^b

^aSt. George's Vascular Institute, St. George's Healthcare NHS Trust, London, UK

^bDepartment of Vascular Surgery, Vascular Research Group, Division of Cardiovascular Sciences, Clinical Sciences Building, Leicester Royal Infirmary, Leicester, UK



Previous Symptoms

- *Patient selection*
- Medical treatment
- Intra-operative imaging
- Protection device
- Stent
- Operator experience



21 registries;
More than
1.500.000
procedures

**Worse
Stroke/death rates
for symptomatic
patients
undergoing CAS
compared to CEA**

REVIEW

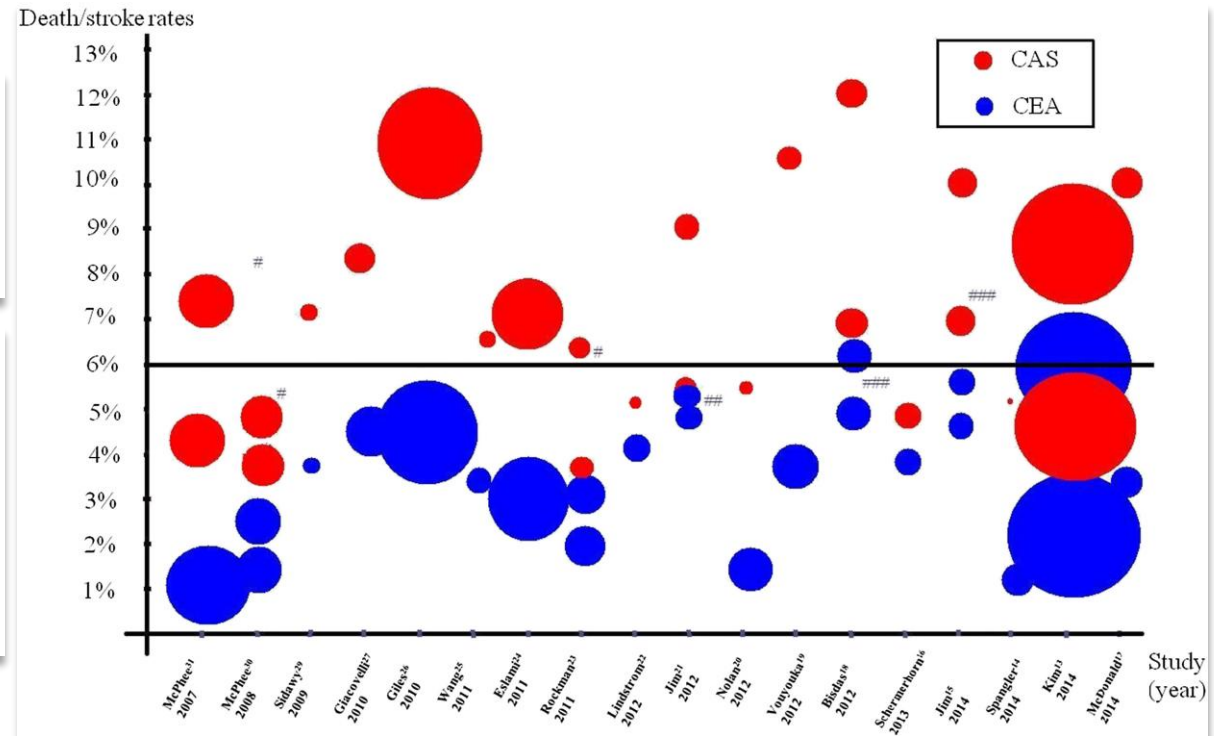
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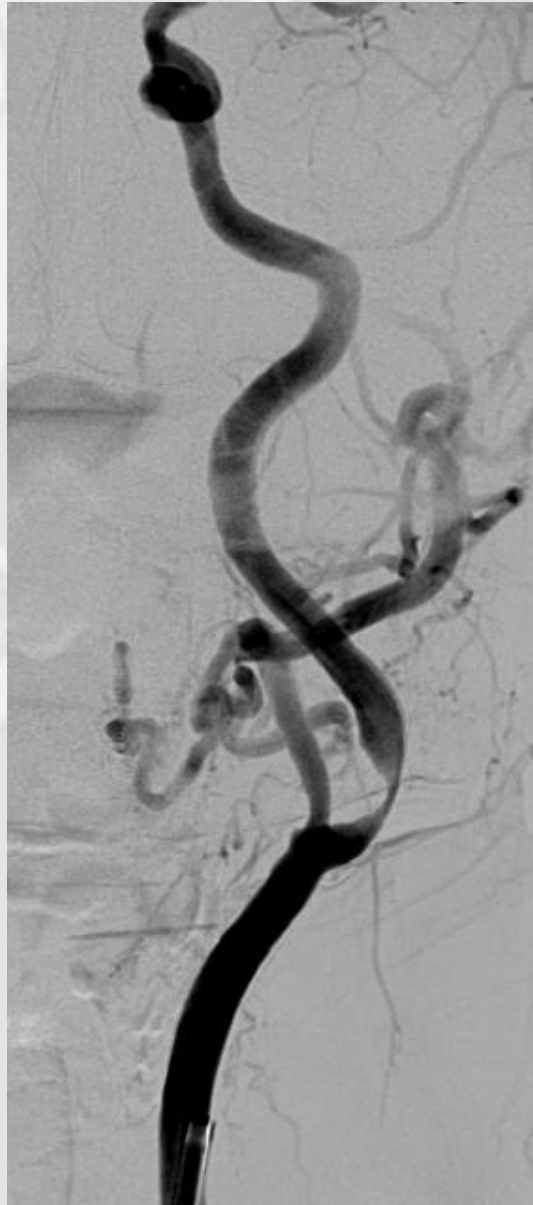
^aSt. George's Vascular Institute, St. George's Healthcare NHS Trust, London, UK

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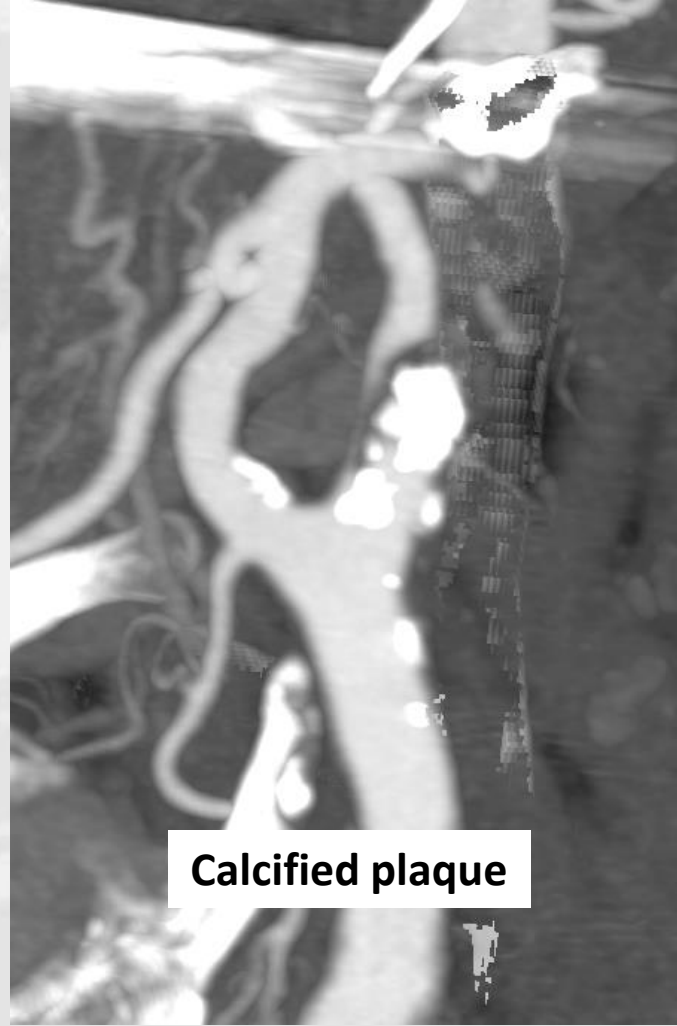


Anatomical Issues

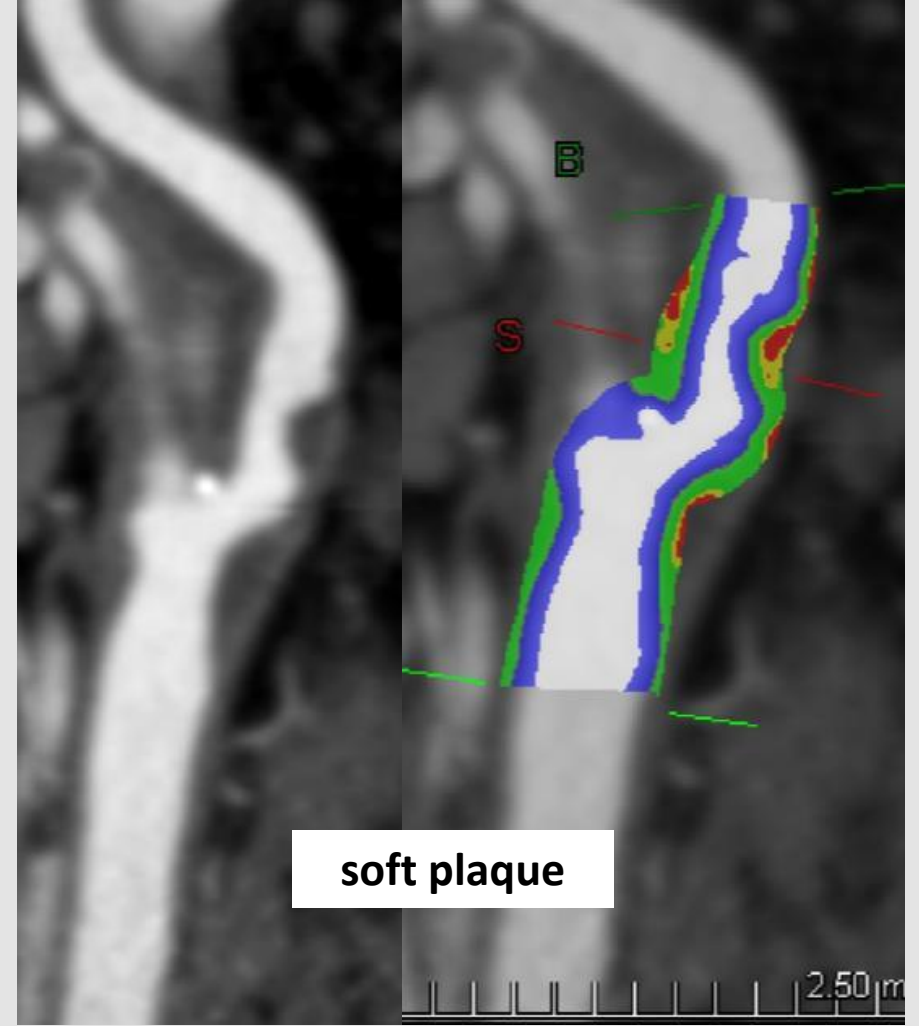
- *Patient selection*
- Medical treatment
- Intra-operative imaging
- Protection device
- Stent
- Operator experience



Plaque characteristics



Calcified plaque



soft plaque



Arch pathology



Effect of Statins

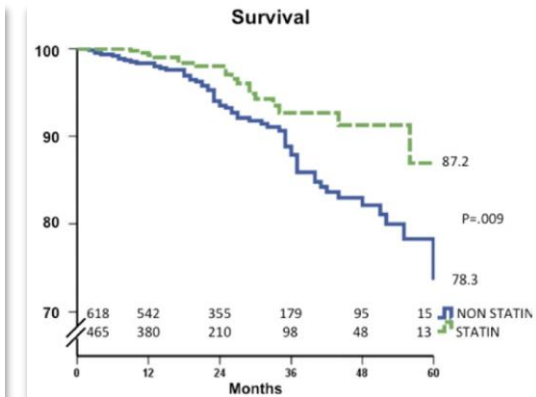
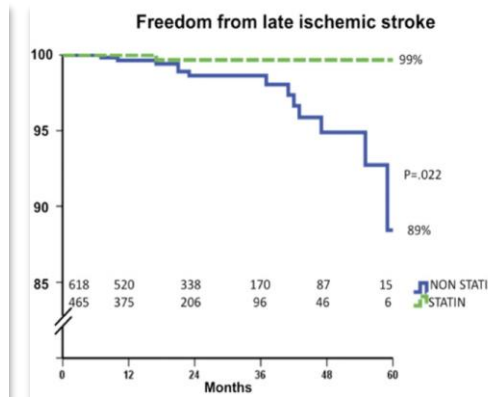
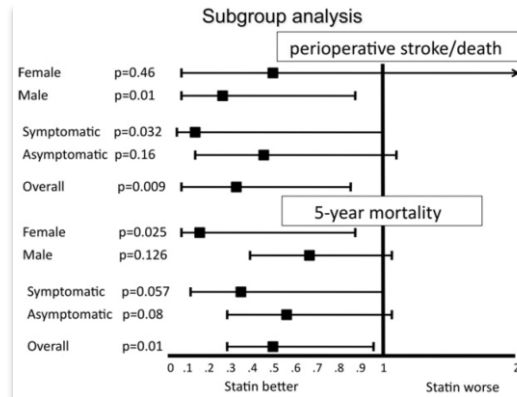
- Patient selection
- *Medical treatment*
- Intra-operative imaging
- Protection device
- Stent
- Operator experience



Effects of statins on early and late results of carotid stenting

Fabio Verzini, MD, PhD,^a Paola De Rango, MD,^a Gianbattista Parlani, MD,^a Giuseppe Giordano, MD,^a Valeria Caso, MD, PhD,^b Enrico Cieri, MD,^a Giacomo Isernia, MD,^a and Piergiorgio Cao, MD, FRCS,^c *Perugia and Rome, Italy*

JOURNAL OF VASCULAR SURGERY
January 2011



1083 CAS (2004-2009)

- Statins use is associated with decreased perioperative and late ischemic strokes risk and lower mortality rates in patients undergoing CAS
- Statins therapy should be considered part of the BMT in current CAS practice



Last Generation Hybrid Room

- Patient selection
- Medical treatment
- *Intra-operative imaging*
- Protection device
- Stent
- Operator experience

The better you look,
the more you see.

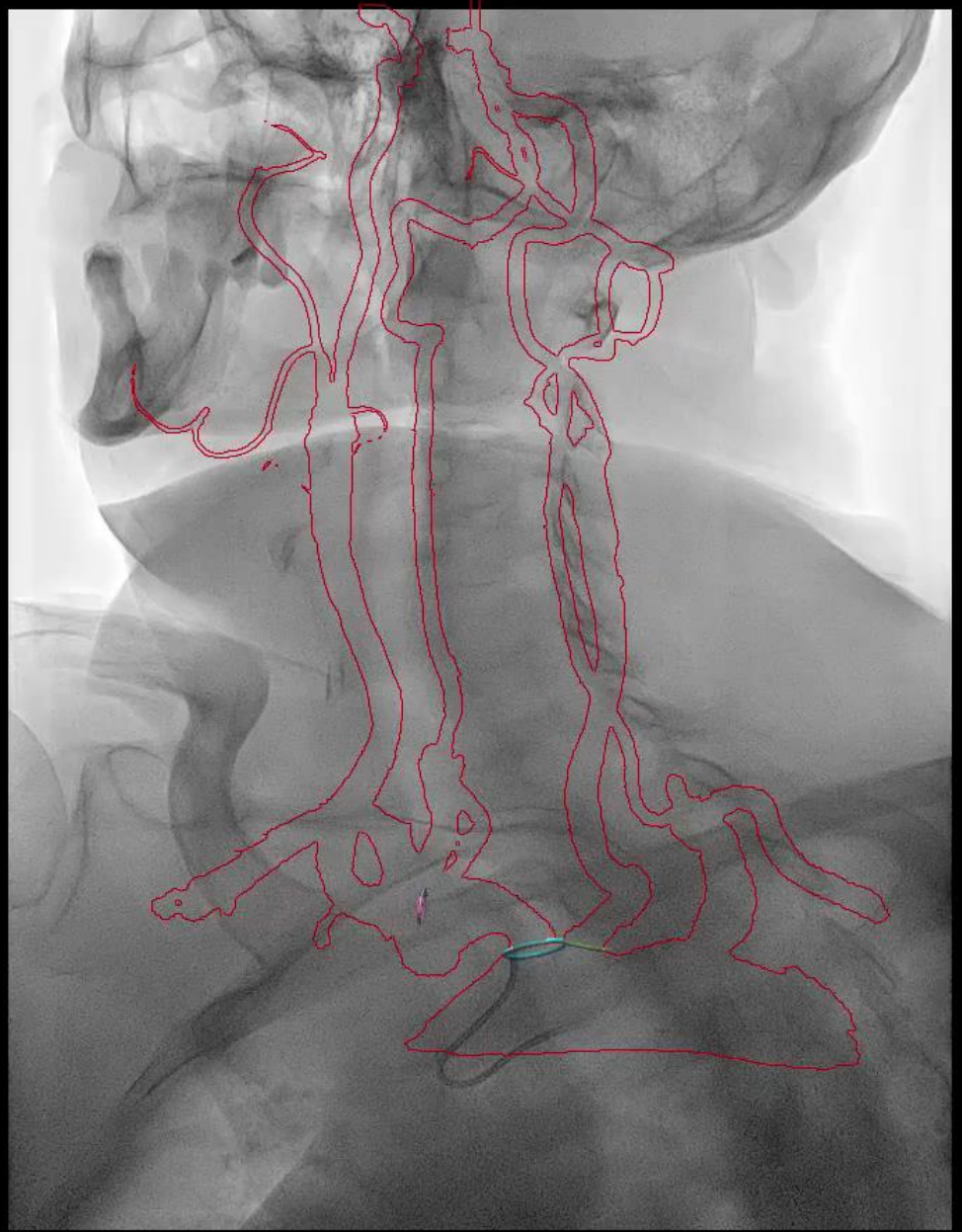
Bret Easton Ellis

quote fancy





LAO 37° CRAN 2°



158



Protection Device

- Patient selection
- Medical treatment
- Intra-operative imaging
- *Protection device*
- Stent
- Operator experience



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)

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Recommendation 63	Class	Level	References
The use of embolic protection devices should be considered in patients undergoing CAS	IIa	B	97,189,316,319
Recommendation 64			
Proximal protection devices are not recommended in patients with advanced common carotid disease, or those with external carotid artery disease (where an occlusion balloon is to be positioned in the external carotid artery) or in patients with contralateral occlusion and insufficient collateralisation	III	C	317





SKYDIVING WITHOUT PARACHUTE

Protection Device

- Patient selection
- Medical treatment
- Intra-operative imaging
- *Protection device*
- Stent
- Operator experience



National quality assurance database
13,086 CAS
2009-2014

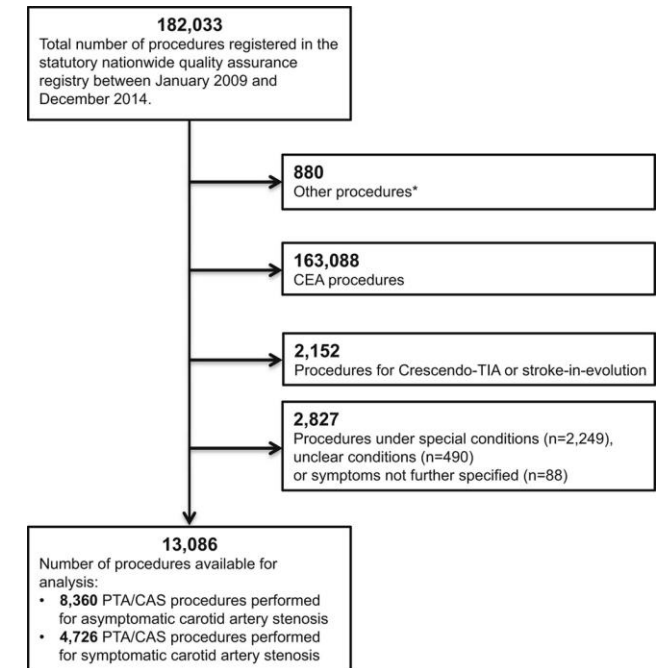
The use of CPD was independently associated with lower in-hospital risk for stroke or death

Peripheral

The Use of Embolic Protection Devices Is Associated With a Lower Stroke and Death Rate After Carotid Stenting

Christoph Knappich MD ^a, Andreas Kuehnl MD, MPH, MBA ^a, Pavlos Tsantilas MD ^a, Sofie Schmid MD ^a, Thorben Breitzkreuz ^b, Michael Kallmayer MD ^a, Alexander Zimmermann MD, MHBA ^a, Hans-Henning Eckstein MD, PhD ^a

Volume 10, Issue 12, 26 June 2017, Pages 1257-1265



Protection Device

- Patient selection
- Medical treatment
- Intra-operative imaging
- *Protection device*
- Stent
- Operator experience



3160 CAS
1997-2006

No difference in procedural adverse neurological events observed for any of the CPDs or types of CPDs

The type of embolic protection does not influence the outcome in carotid artery stenting

Vikram Iyer, MD,^a Gianmarco de Donato, MD,^b Koen Deloose, MD,^a Patrick Peeters, MD,^c Fausto Castriota, MD,^d Alberto Cremonesi, MD,^d Carlo Setacci, MD,^b and Marc Bosiers, MD,^a
Dendermonde and Bonheiden, Belgium; and Siena and Cotignola, Italy

JOURNAL OF VASCULAR SURGERY
August 2007

Comparison	Procedural events			30-day events		
	RR	95% CI	P	RR	95% CI	P
Proximal occlusion vs filter						
Unadjusted	1.28	0.30-5.37	1.00	1.52	0.75-3.13	1.00
Adjusted for RF	1.34	0.22-4.54	1.00	1.57	0.70-3.06	1.00
Adjusted for RF, ST	1.34	0.22-4.54	1.00	1.59	0.71-3.10	1.00
Distal occlusion vs filter						
Unadjusted	4.56	0.64-32.52	1.00	2.72	0.71-10.51	.96
Adjusted for RF	4.34	0.24-20.60	1.00	2.69	0.44-8.53	1.00
Adjusted for RF, ST	4.32	0.24-20.90	1.00	3.38	0.55-10.87	.54
Distal vs proximal occlusion						
Unadjusted	3.57	0.34-38.05	1.00	1.79	0.40-7.96	1.00
Adjusted for RF	3.57	0.34-38.05	1.00	1.79	0.40-7.96	1.00
Adjusted for RF, ST	3.57	0.34-38.05	1.00	1.79	0.40-7.96	1.00
Eccentric vs concentric filter						
Unadjusted	1.25	0.52-3.03	1.00	0.59	0.38-0.92	0.04
Adjusted for RF	1.31	0.56-3.41	1.00	0.61	0.39-0.95	0.06
Adjusted for RF, ST	1.33	0.55-3.57	1.00	0.76	0.47-1.22	0.51

RF, Risk factors; ST, Stent-type (open-cell or closed-cell); RR, relative risk; CI, confidence interval.



Stent configuration

- Patient selection
- Medical treatment
- Intra-operative imaging
- Protection device
- *Stent*
- Operator experience

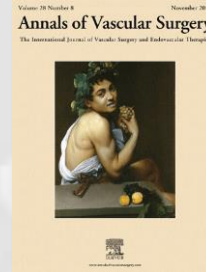


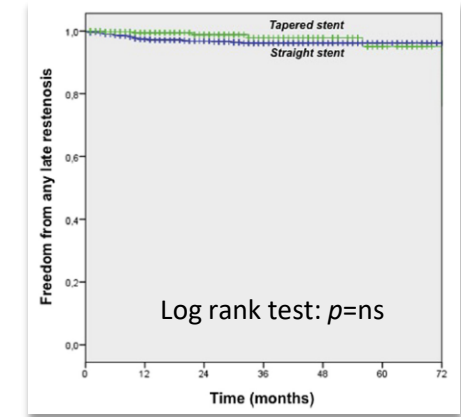
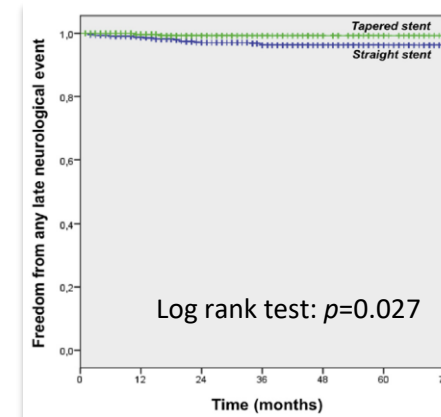
Table IV. Perioperative outcomes (at 30 days)

Outcomes	Tapered stent group (n = 485)	Straight stent group (n = 883)	P
Mortality	0	0	NA
Any neurological event	19 (3.9%)	40 (4.5%)	0.68
Ipsilateral stroke	6 (1.2%)	14 (1.6%)	0.81
Major stroke	2 (0.4%)	6 (0.7%)	0.72
TIA	13 (2.7%)	26 (2.9%)	0.87
Immediate conversion to CEA	3 (0.6%)	1 (0.1%)	0.13

Long-term Results of Tapered Stents in Endovascular Treatment of Carotid Stenosis

Gioele Simonte, Beatrice Fiorucci, Giacomo Isernia, Gianbattista Parlani, Fabio Verzini, Enrico Cieri, and Massimo Lenti, Perugia, Italy

Annals of Vascular Surgery Volume 45, November 2017



1368 CAS (2005-2012)

- The use of conic stents appears to be associated with similar perioperative results when compared with straight stents
- Late outcomes suggest a lower risk of late neurological events in patients with conical shape stents



Stent configuration

- Patient selection
- Medical treatment
- Intra-operative imaging
- Protection device
- *Stent*
- Operator experience



3179 CAS

In the symptomatic population post-procedural complication rates are highest for the open cell types and increase with larger free cell area

Does Free Cell Area Influence the Outcome in Carotid Artery Stenting?

M. Bosiers,^{1*} G. de Donato,² K. Deloose,¹ J. Verbist,³ P. Peeters,³
F. Castriota,⁴ A. Cremonesi⁴ and C. Setacci⁴

¹Department of Vascular Surgery, AZ St-Blasius, Dendermonde, Belgium, ²Department of Vascular and Endovascular Surgery, University of Siena, Italy, ³Department of Cardiovascular and Thoracic Surgery of the Imelda Hospital in Bonheiden, Belgium, and ⁴Interventional Cardio-Angiology Unit, Villa Maria Cecilia Hospital, Cotignola (RA), Italy

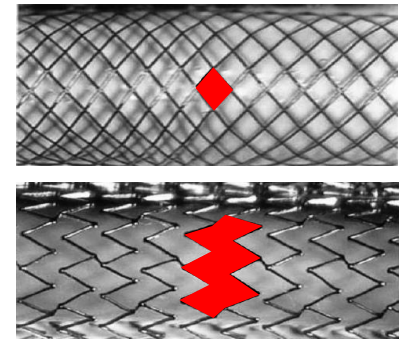
Eur J Vasc Endovasc Surg Vol 33, February 2007

Table 9. Overview of event rates related to the cell design

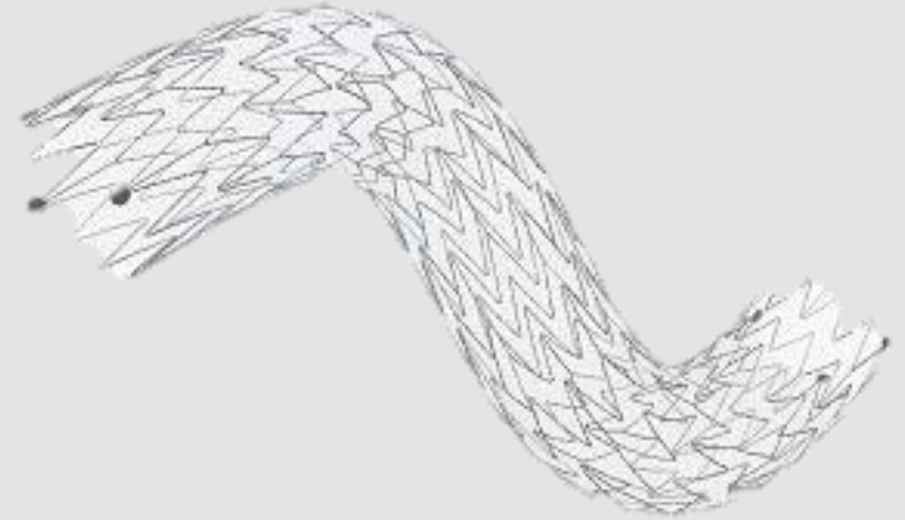
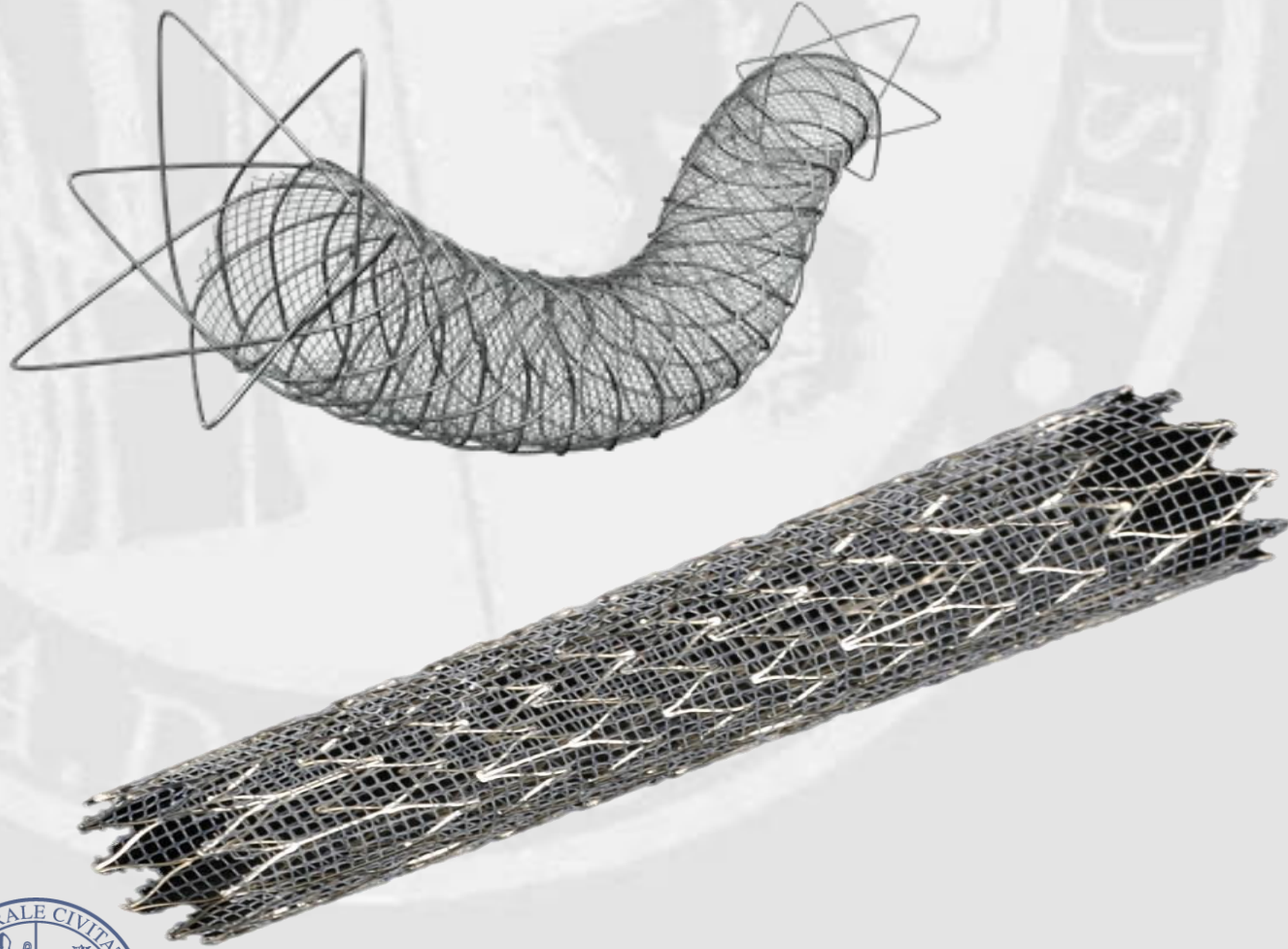
	Total population			Symptomatic population			Asymptomatic population		
	Patients	All events	Post-procedural events	Patients	All events	Post-procedural events	Patients	All events	Post-procedural events
Open cell	937	39	32	383	27	24	554	12	8
Closed cell	2242	51	29	934	21	12	1308	30	17
Total	3179	90	61	1317	48	36	1862	42	25
Cell type									
Open cell		4.2%	3.4%		7.0%	6.3%		2.2%	1.4%
Closed cell		2.3%	1.3%		2.2%	1.3%		2.3%	1.3%
Total	3179	2.83%	1.9%	1317	3.6%	2.73%	1862	2.25%	1.3%

Table 10. P-values for the test that event rates differ by cell type

Population	Outcome	p-value
Total	All events	0.005
	Post-procedural events	<0.0001
Symptomatic	All events	<0.0001
	Post-procedural events	<0.0001
Asymptomatic	All events	1.00
	Post-procedural events	1.00



Multi-layered Stent



Manufacturer	W.L. Gore and Associates*	Abbott Laboratories	Abbott Laboratories	Boston Scientific Corporation	ev3 Inc./ Covidien	Cordis Corporation	Medtronic, Inc./ Invatec
Device	GORE® Carotid Stent	ACCULINK® RX DEVICE	XACT® DEVICE	WALLSTENT® MONORAIL® DEVICE	PROTÉGÉ RX® DEVICE	PRECISE® DEVICE	CRISTALLO IDEALE DEVICE
Stent Type	Straight, Hybrid Design	Tapered, Open Cell	Tapered, Closed Cell	Straight, Closed Cell	Tapered, Open cell	Straight, Open cell	Tapered, Combination
Stent Size (mm)	10 - 10 x 40	7 - 10 x 30	8 - 10 x 30	10 x 24	7- 10 x 30	9 x 30	7 - 10 x 30
Cell Size (mm)²	0.28	16.60	4.00	1.36	10.40	9.00	3.30 (center) 13.50 (ends)
Max Fitted-in Circle Diameter (mm)	0.50	1.30	1.25	1.06	1.70	1.25	1.20 (center) 1.90 (ends)
Max Number of Fitted-in Circles per cell	1	9	2	1	3	6	1 (center) 3 (ends)

Figure 8: Manufacturer, name, cell size, and fitted in circle data. Data for the GORE® Carotid Stent is based on nominal manufacturing specifications. Competitive device information from Müller-Hülsbeck S, *et al*². Images are shown for illustrative purposes only; the stent type shown may not be the same size measured by Müller-Hülsbeck.
* Though sometimes listed as a closed cell stent, Protégé IFU describes the design as an "open lattice"³.



Learning Curve

- Patient selection
- Medical treatment
- Intra-operative imaging
- Protection device
- Stent
- *Operator experience*



Appropriateness of learning curve for carotid artery stenting: An analysis of periprocedural complications

Fabio Verzini, MD, Piergiorgio Cao, MD, FRCS, Paola De Rango, MD, Gianbattista Parlani, MD, Agostino Maselli, MD, Lydia Romano, MD, Lucia Norgiolini, MD, and Giuseppe Giordano, MD, Perugia, Italy

JOURNAL OF VASCULAR SURGERY
December 2006

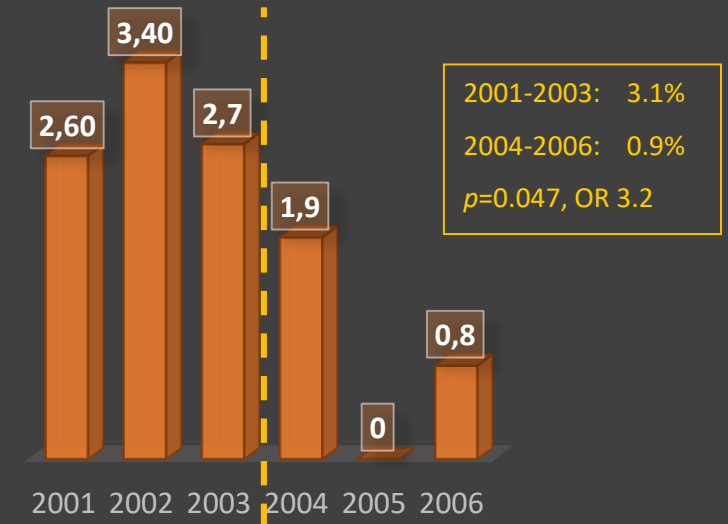
627 CAS

2001-2006

First study interval independent predictor of stroke
(HR, 3.68; 95% CI, 1.49-9.01; $P=0.005$)

The effect of the learning curve related to technical expertise and patient selection may influence the results of CAS

Perioperative major stroke & death /year



Training

- Patient selection
- Medical treatment
- Intra-operative imaging
- Protection device
- Stent
- *Operator experience*



Safety of Carotid Stenting (CAS) is Based on Institutional Training More than Individual Experience in Large-volume Centres

G. Parlani ^{a,*}, P. De Rango ^{a,*}, F. Verzini ^a, E. Cieri ^a, G. Simonte ^a, A. Casalino ^a, A. Manzone ^a, P. Cao ^b

^aUnit of Vascular and Endovascular Surgery, Hospital S.M. Misericordia, University of Perugia, Loc. S. Andrea delle Fratte, 06134 Perugia, Italy

^bVascular Surgery, Hospital S. Camillo Forlanini, Rome, Italy

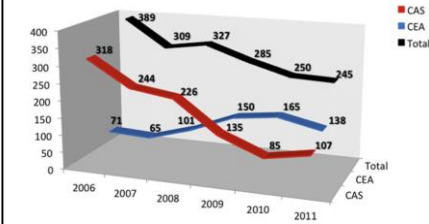
1026 CAS

2006-2012

No differences in term of stroke/death between the two teams

- Institutional experience is a primary factor driving outcomes of CAS
- Effective team-working approach can reliably improve the training of new trainees preserving CAS safety and efficacy

	Leader-operators team CAS = 683 N (%)	New-operators team CAS = 343 N (%)	OR	95%CI	P_value
Periprocedural outcomes					
Any stroke or death	18 (2.6)	4 (1.2)	0.44	0.15–1.30	0.17
Any stroke	18 (2.6)	4 (1.2)	0.44	0.15–1.30	0.17
Major stroke	6 (0.9)	0	0.99	0.98–0.99	0.18
Death	0	0	–	–	–
Intraprocedural details					
Technical failure	3 (0.4)	2 (0.6)	0.7	0.12–4.51	0.99
Conversion to CEA	5 (0.7) ^a	3 (0.9) ^b	1.2	0.28–5.05	0.99



Perugia CAS experience

January 2001- June 2016
2069 CAS

Learning Curve 2001-2004
199 CAS

No crossing
17

2004-2016
1853 CAS



Population

Characteristics	n.	%
Age	Mean 71.1 ± (SD 7.2)	
Male gender	1285	69.3
Hypertension	1446	78
Diabetes	506	27.3
CHD	440	24
Symptoms	338	18.2
Stroke	180	9.7
Contralateral Occlusion	148	8
Statins	1134	61.2
Double antiplatelet	1764	95.2



Perioperative Results

Endpoint	n.	%
Stroke	35	1.9
Asymptomatic	24	1.6
Symptomatic	11	3.2
Death	1	0.05

Backward stepwise logistic regression

(Male gender, symptoms, diabetes, hypertension, tapered stent, close cell, double antiplatelet, >80 yrs, statins)

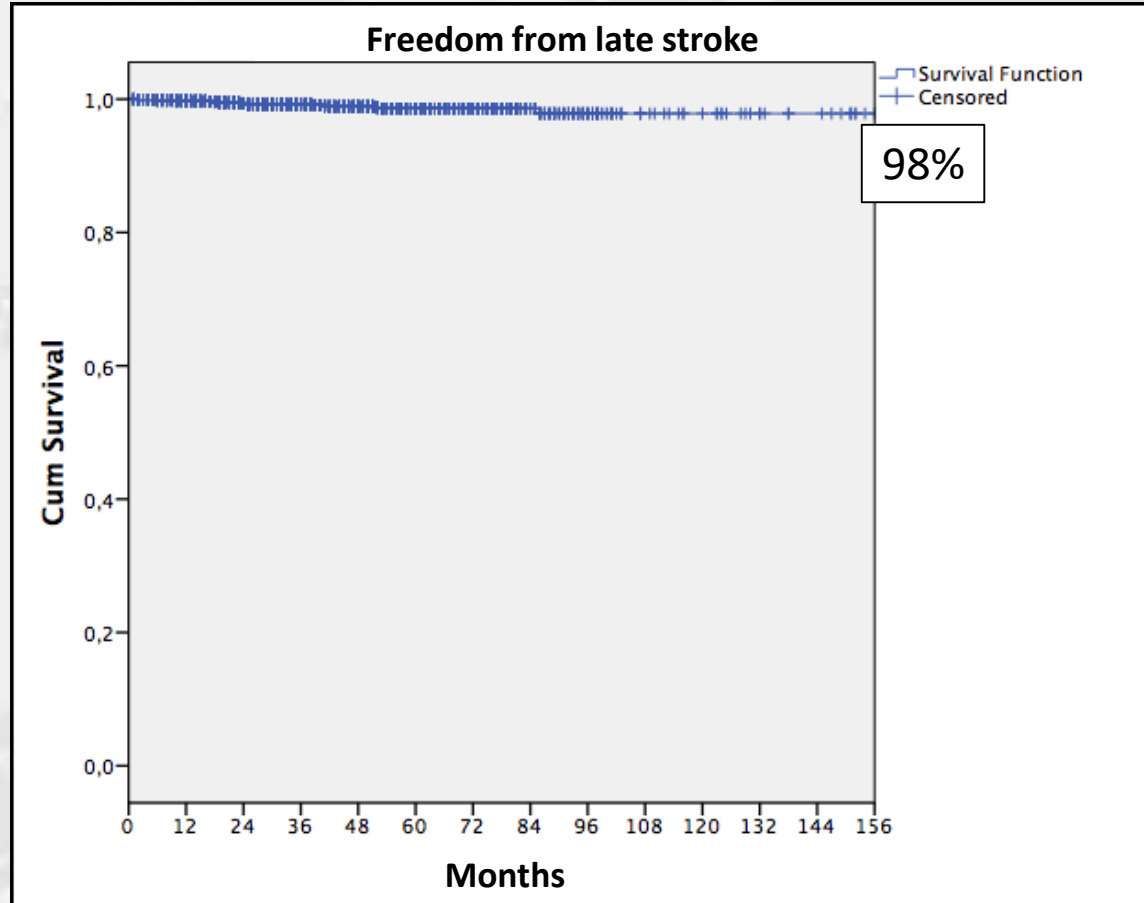
Independent predictors of perioperative Stroke

	OR	95% C.I.	<i>p</i>
Statins	0.423	0.225 - 0.794	0.007
Prev. Symptoms	2.594	1.331 – 5.054	0.005



Late Results

Mean F-U 45 ($\pm 27,7$) months

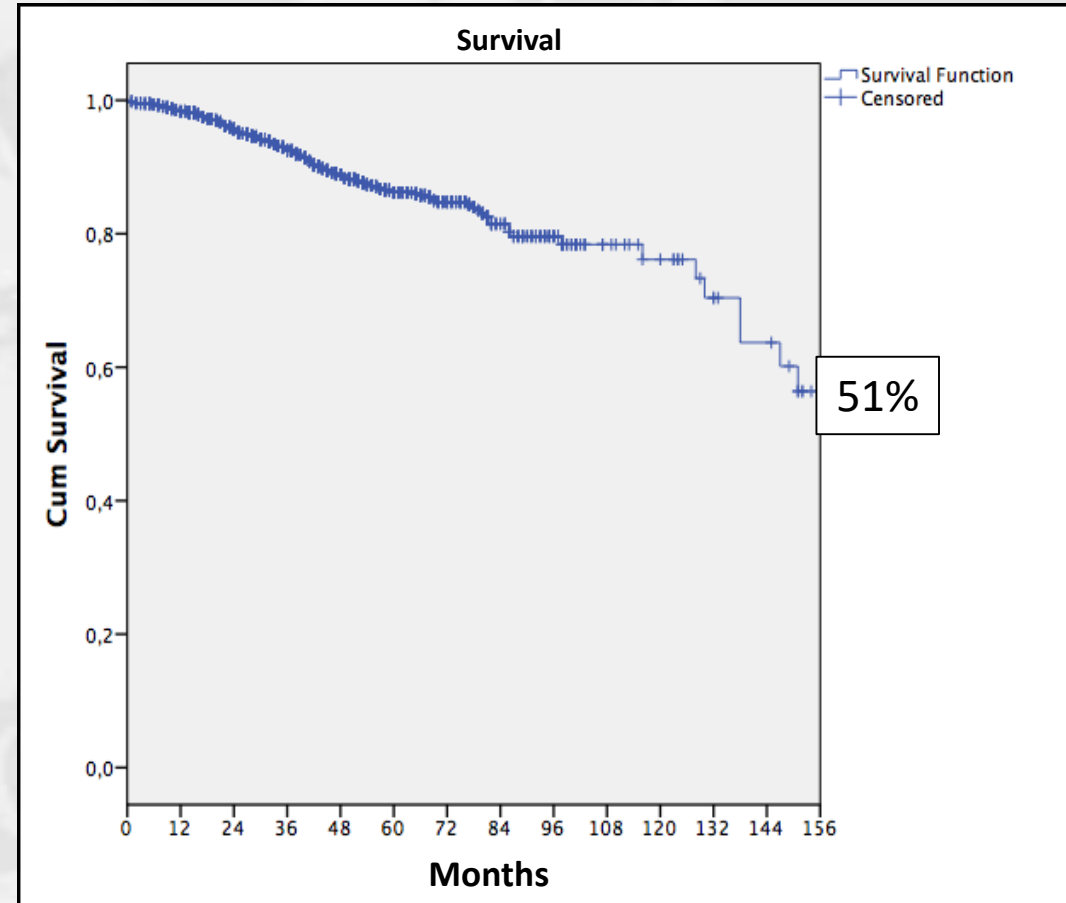


Months	12	24	36	48	60	72	84	96	108	120	132	144	156
%	99,8	99,4	99,2	98,9	98,6	98,6	98,6	97,9	97,9	97,9	97,9	97,9	97,9
N. at risk	1698	1344	1315	912	633	633	633	132	132	132	132	132	132



Late Results

Mean F-U 45 ($\pm 27,7$) months

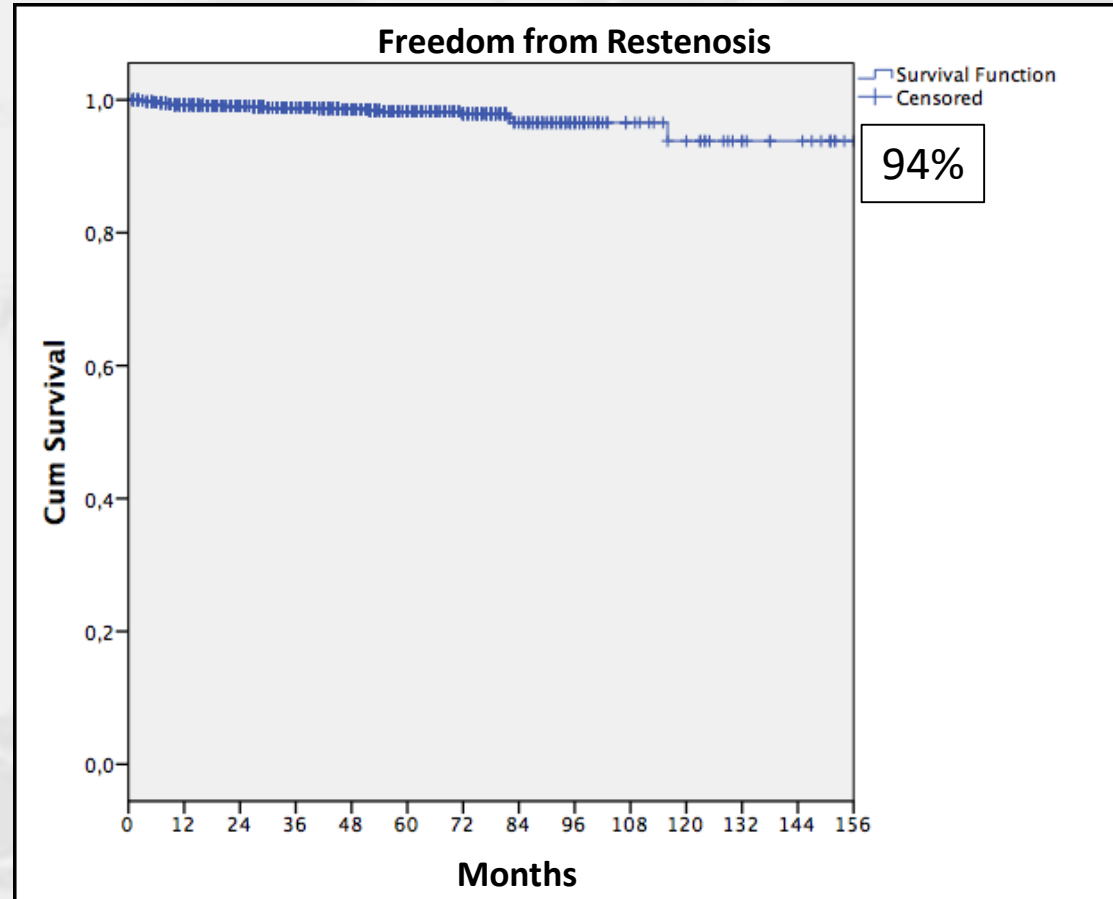


Months	12	24	36	48	60	72	84	96	108	120	132	144	156
%	98,3	95,7	92,5	88,8	86,2	84,8	81,5	79,6	78,4	76,1	70,4	63,7	50,8
N. at risk	1654	1343	1031	771	471	318	150	125	64	34	24	19	9



Late Results

Mean F-U 45 ($\pm 27,7$) months



Months	12	24	36	48	60	72	84	96	108	120	132	144	156
%	99,3	99,1	98,8	98,6	98,3	97,9	96,6	96,6	96,6	93,8	93,8	93,8	93,8
N. at risk	1685	1413	1182	809	567	285	140	140	140	34	34	34	34



Late Results

Cox regression analysis

(Male gender, symptoms, diabetes, hypertension, tapered stent, close cell, double antiplatelet, >80 yrs, statins)

Independent predictor of late Stroke

	OR	95% C.I.	<i>p</i>
Prev. Symptoms	5.07	1.46 – 17.53	0.01

Independent predictors of late Death

	OR	95% C.I.	<i>p</i>
Male gender	1.62	1 – 2.65	0.05
Prev. Symptoms	2.43	1.54 – 3.83	<0.001
Age > 80 yo	2.4	1.32 – 4.33	0.004



CAS: What have we learned?

With increasing experience and material refinements CAS represents today a valid alternative option to CEA in selected cases

Individual clinical judgment should be applied, allowing...
...a perfectly tailored strategy

