# Current Status of Carotid Interventions

## Role of CAS in 2018

#### **Piotr Musialek**



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#### Potential conflicts of interest

Speaker's name:

Piotr Musialek

Advisory Board/Consulting Research Support InspireMD, Medtronic Abbott

### Indications

### Indications

### Concepts and Tools

### Indications

- Concepts and Tools
- Outcomes

### Indications

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AHA Statistical Update Heart Disease and Stroke Statistics—2016 Update A Report From the American Heart Association	4
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Factor	Prevalence, %	PAR, %*	RR	
Cigarette smoking				
Overall	19.8	12-14†	1.9	
Men	22.3			
Women	17.4			
Hypertension		<b>‡</b>	8	
Ages 20–34 y				
Men	13.4	99		
Women	6.2	98		
Ages 35–44 y				
Men	23.2	99		
Women	16.5	106		
Ages 45–54 y				
Men	36.2	100		
Women	35.9	103		
Ages 55–64 y				
Men	53.7	100		
Women	55.8	102		
Ages 65–74 y				
Men	64.7	100		
Women	69.6	101		
Ages ≥75 y				
Men	64.1	100		
Women	76.4	101		
AF (nonvalvular)				
Overall age, y				
50-59	0.5	1.5	4.0	
60-69	1.8	2.8	2.6	
70–79	4.8	9.9	3.3	
80-89	8.8	23.5	4.8	

Factor	Prevalence, %	PAR, %*	RR	
Cigarette smoking				
Overall	19.8	12-14†	1.9	
Men	22.3			
Women	17.4			
Hypertension		+		
inerosc	lerotic C	arotic	i Stenos	5
Men	13.4	99		
Women	6.2	98		
Ages 35-44 y				
Men	23.2	99		
Women	rom	ainc		
Ages 45–54 y	rema			
Men	36.2	100		
Women	35.9	103		
Ages 55–64 y				
Men	53.7	100		
Women	55.8	102		
	rtant a	na mo	Daitiadi	2
-				
Women	risk <sup>®</sup> fact	to r <sup>in</sup> fo r		
Ages ≥75 y Men				
	schemic	ctrok	•	
AF (nonvalvular)	SCHEILIIG	SLIUK	6	
Overall age, y	0.5	4.5	4.0	
50-59	0.5	1.5	4.0	
6069 70-70	1.8 4.8	2.8	2.6 3.3	
70–79 80–89	4.8		3.3	
5U69	ŏ.ŏ	23.5	4.5	

#### Stroke Reduction with Carotid Revascularization



A. Halliday et al. (10-year ACST data) Lancet 2010

#### Stroke Reduction with Carotid Revascularization



Gain at

5 years: 5.9% (95% Cl 4.0-7.8), p<0.0001

10 years: 6-1% (95% Cl 2-7-9-4), p=0-0004

On lipid-lowering therapy before stroke: non-perioperative stroke (mean age 68-0 years)

Gain at 5 years: 3·4% (95% Cl 1·5-5·2), p=0·0005 10 years: 5·8% (95% Cl 2·1-9·6), p=0·002

#### The only way to recall Level-1 evidence would be to provide new evidence at similar level



Years Events/person-years

A. Halliday et al. (10-year ACST data) Lancet 2010

### PCR Carotid Revascularization 2018

#### **Optimized Pharmacotherapy is <b>FUNDAMENTAL**

#### but

there is ZERO! evidence today to *claim* that pharmacotherapy ALONE protects sufficiently against stroke in atherosclerotic carotid disease

### PCR Carotid Revascularization 2018

### **Optimize Current CAS studies...**

### there is **continue** ce today to *claim* that **to receive patients who develop** protects sufficiently against stroke in atheroscleratic caratid disease

### **PCR** Cardiovascular Clinic Patients are NOT "average" Carotid Stenosis Subjects

Reviewed in

Musialek & Hopf-Jensen J Endovasc Ther 2017 Musialek, Hopkins, Siddiqui Adv Intev Cardiol 2017

#### Cardiovascular Clinic Patients are NOT "average" Carotid Stenosis Subjects

#### **Fundamental Issue**

 $\neq$ 

### "People" with Carotid Stenosis

### Vascular Clinic Referral Patient

### General Popu--lation Subject

annual ipsilateral stroke risk 2.5-3.0% annual ipsilateral stroke risk ≈0.5%

Reviewed in

Musialek & Hopf-Jensen J Endovasc Ther 2017 Musialek, Hopkins, Siddiqui Adv Intev Cardiol 2017

### PCR CAS indications 2018

 Focus on treating "symptomatic" patients is not the pride but rather failure of the system

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 Focus on treating "symptomatic" patients is not the pride but rather failure of the system





Figure 1. Distribution of AQoL utility scores among 5-year survivors and Australian general population aged 70–79 years.

#### Long-Term Outcome in the North East Melbourne Stroke Incidence Study

Predictors of Quality of Life at 5 Years After Stroke

Seana L. Paul, BSc (Hons); Jonathan W. Sturm, PhD; Helen M. Dewey, PhD; Geoffrey A. Donnan, MD; Richard A.L. Macdonell, MD; Amanda G. Thrift, PhD

Utility scores range from -0.04 (state worse than death) through 0.0 (death-equivalent) to 1.0 (full health). The AQoL is valid and reliable in stroke patients.<sup>27</sup> Furthermore, it is reliable when completed by



#### Table 3. Evolution of neurological status in PARADIGM patients.

CLINICAL RESEARCH



Novel PARADIGM in carotid revascularisation: Prospective evaluation of All-comer peRcutaneous cArotiD revascularisation in symptomatic and Increased-risk asymptomatic carotid artery stenosis using CGuard<sup>™</sup> Micronet-covered embolic prevention stent system



Piotr Musialek<sup>1\*</sup>, MD, DPhil; Adam Mazurek<sup>1</sup>, MD; Mariusz Trystula<sup>2</sup>, MD, PhD; Anna Borratynska<sup>3</sup>, MD, PhD; Agata Lesniak-Sobelga<sup>1</sup>, MD, PhD; Malgorzata Urbanczyk<sup>4</sup>, MD; R. Pawel Banys<sup>4</sup>, MSc; Andrzej Brzychczy<sup>2</sup>, MD, PhD; Wojciech Zajdel<sup>5</sup>, MD, PhD; Lukasz Partyka<sup>6</sup>, MD, PhD; Krzysztof Zmudka<sup>5</sup>, MD, PhD; Piotr Podolec<sup>1</sup>, MD, PhD

#### These people

#### should have been treated before stroke, not after stroke

Patient	≤24 hrs pr	rior to CAS		fter CAS	30 days	after CA
number	NIHSS	Rankin	NIHSS	Rankin	NIHSS	Rankin
#5	6	1	6	1	6	1
#6	5	Z	5	2	3	Z
#7	1	1	1	1	1	1
#9	6	4	6	4	6	3
#13	6	3	4	2	3	2
#15	3	3	3	2	3	1
#18	9	4	4	3	3	2
# 20	1	1	1	1	1	1
# 22	2	1	2	1	2	1
# 23	4	2	3	1	Z	1
# 25	6	3	5	3	4	3
# 26	4	2	4	2	4	Z
# 28	5	2	2	2	2	2
# 33	3	1	3	1	3	1
# 41	5	3	5	3	5	3
# 44	9	4	7	4	7	3
# 48	3	1	3	1	3	1
# 50	6	3	6	3	6	3
# 55	3	2	3	2	3	Z
# 56	Z	1	2	1	2	1
# 59	3	1	1	1	1	1
# 63	4	2	4	2	4	Z
# 60	2	0	0	0	0	0
# 65	4	2	4	2	4	2
# 69	Z	Z	2	2	2	Z
# 70	5	4	5	4	5	4
# 71	3	1	3	1	3	1
# 72	1	0	1	0	1	0
# 74	6	4	6	4	6	4
# 75	2	1	2	1	2	1
# 83	3	1	3	1	3	1
# 86	Z	Z	2	2	2	Z
# 94	1	1	0	0	0	0
# 98	3	2	3	2	3	Z
# 99	2	1	2	1	2	1
	1	1	0	0	0	0
#100	1	-	_			



### Every symptomatic Carotid Stenosis ...



### Every symptomatic Carotid Stenosis ...

### ... starts as asymptomatic

### CHADS<sub>2</sub> Calculator for Atrial Fibrillation

Evaluates ischemic stroke risk in patients with atrial fibrillation

Criteria		Poss. Point		
Congestive heart failure Signs/symptoms of heart failure confirmed with objective evidence of cardiac dysfunction	Yes No	+1		
Hypertension Resting BP > 140/90 mmHg on at least 2 occasions or current antihypertensive pharmacologic treatment	Yes No	+1		
Age 75 years or older	Yes No	+2		
Diabetes mellitus Fasting glucose > 125 mg/dL or treatment with oral hypoglycemic agent and/or insulin	Yes No	+1		
Stroke, TIA, or TE Includes any history of cerebral ischemia	Yes No	+2		
Vascular disease Prior MI, peripheral arterial disease, or aortic plaque	Yes No	+1		
Age 65 to 74 years	Yes No	+1		
Sex Category (female) Female gender confers higher risk	Yes No	+1		

Results:
Total Criteria Point Count: 0
Reset Form
Stroke Risk per 100 Person Years/Warfarin Rx Interpretation
0 Points: 0.25 ON Rx; 0.49 NO Rx
1 Point: 0.72 ON Rx; 1.52 NO Rx
2 Points: 1.27 ON Rx; 2.50 No Rx
3 Points: 2.20 ON Rx; 5.27 NO Rx
4 Points: 2.35 ON Rx; 6.02 NO Rx
5-6 Points: 4.60 ON Rx; 6.88 NO Rx

• we have the duty to use **published risk criteria** 

• we have the duty to use **published risk criteria** 



#### 

### How asymptomatic is "asymptomatic" carotid stenosis?

Resolving fundamental confusion(s)-and confusions yet to be resolved

#### Piotr Musiałek<sup>1</sup>, Iris Q. Grunwald<sup>2,3</sup>

1 Department of Cardiac and Vascular Diseases, Jagiellonian University Medical College, John Paul II Hospital, Kraków, Poland

2 Neuroscience and Vascular Simulation, Anglia Ruskin University, Chelmsford, United Kingdom

3 Southend University Hospital NHS Foundation Trust, Westcliff-on-Sea, United Kingdom

### symptoms vs. sign(s) of cerebral ischemia

eg. "asymptomatic" infarct(s), retinal function, cognitive function, etc.

What is the meaning of "symptomatic" in relation to CS? The English language, in contrast to many others, differentiates between "symptoms" and "signs." A symptom is an indication of disease perceived by the patient and reported by the patient. Symptoms of CS-associated cerebral ischemia include ipsilateral TIA or clinical stroke.<sup>2,10</sup> A sign is an observable physical phenomenon indicative of the presence of a pathology or disease. Signs are detected by the physician through clinical examination and accessory investigations. A clinically-silent cerebral infarct ipsilateral to CS is a sign, not a symptom, and the patient is, strictly speaking, "asymptomatic." In such patients, however, there is evidence for an increased risk of further, clinically symptomatic, brain injury likely to occur in the absence of an intervention.<sup>2,8</sup> While the definition of stroke includes an episode of clinically manifest neurological dysfunction,<sup>10</sup> according to the same guidelines, the term "stroke" may be also used for brain infarction in the absence of clinical symptoms.10 According to some authors, patients with TIA or stroke become automatically "asymptomatic" from the point of 6 months after the event onwards.<sup>3,9,11</sup> Further confusions arise from the fact that different studies have used different time points to change the "symptomatic"/"asymptomatic" label, such as 1, 3, 4, or 12 months.<sup>12</sup> More accurate terms have been proposed, such as "recently symptomatic" and "remotely symptomatic."12 The above, and other, inconsistencies greatly confuse physicians, leading to different approaches to the same patient type by various specialties or in various medical centers or countries.

### Concepts and Tools

#### <u>Post-procedural</u> Embolization with conventional carotid stents DW-MRI post CAS

Mean total lesion area









#### **Timing of neuro-embolic events after CAS**



## CEA excludes the plaque

### In CAS, the stent should exclude the plaque too

### CGuard<sup>™</sup> embolic prevention system





## CGuard EPS 90 days/pig



12-105 LCCA-S 3 13-1689-3 1.25x H&E.tif



CA-S 3 13-1689-3 10x H&E.tif

### CGuard EPS 30 & 90 days / pig





Mean ± SD and Median Standard Histomorphology Parameters									
Parameter	Day 30				Day 90				
	BMS (n=3)		CGuard (n=9)		BMS (n=3)		CGuard (n=9)		
Injury (0-3)	$0.00 \pm 0.01$	0.00	$0.00 \pm 0.01$	0.00	0.01 ± 0.02	0.00	0.00 ± 0.01	0.00	
Inflammation (0-3)	0.43 ± 0.23	0.51	$0.41 \pm 0.22$	0.36	$0.17 \pm 0.16$	0.11	$0.09 \pm 0.08$	0.07	
Neointimal Fibrin (0-3)	$1.13 \pm 0.23$	1.00	$0.82 \pm 0.37$	1.00	$0.00 \pm 0.00$	0.00	$0.00 \pm 0.00$	0.00	
Adventitial Fibrosis (0-3)	$0.00 \pm 0.00$	0.00	$0.02 \pm 0.07$	0.00	$0.00 \pm 0.00$	0.00	$0.00 \pm 0.00$	0.00	
Neointimal Maturation (0-3)	$3.00 \pm 0.00$	3.00							
Endothelialization (0-4)	$3.67 \pm 0.42$	3.80	$3.62 \pm 0.35$	3.80	$4.00 \pm 0.00$	4.00	$4.00 \pm 0.00$	4.00	



CA-S 3 13-1689-3 10x H&E.tif

BMS = non mesh-covered CGuard nitynol frame; InspireMD data / used with permission



#### **Normal Long-Term Healing**









Musialek & Stabile EuroIntervention 2017

# mechanical **Properties**

#### RoadSaver / Casper



#### **CGuard EPS**



C. Wissgott and colleagues. *J Endovasc Ther.* 2015;22:634-39 C. Wissgott and colleagues. *J Endovasc Ther.* 2017;24:130-7




aprox 1000 um

•

•

Musialek & Stabile EuroIntervention 2017







Nerla et al.EuroIntervention 2017Musialek & StabileEuroIntervention 2017Umemoto et al.EuroIntervention 2017



Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

Nadim Al-Mubarak, MD; Gary S. Roubin, MD, PhD; Jiri J. Vitek, MD, PhD; Sriram S. Iyer, MD; Gishel New, MD; Martin B. Leon, MD



Nadim Al-Mubarak, MD; Gary S. Roubin, MD, PhD; Jiri J. Vitek, MD, PhD; Sriram S. Iyer, MD; Gishel New, MD; Martin B. Leon, MD Effect of the Distal-Balloon Protection System on **Microembolization During Carotid Stenting** 



Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

Effect of the Distal-Balloon Protection System on **Microembolization During Carotid Stenting**  Nadim Al-Mubarak, MD; Gary S. Roubin, MD, PhD; Jiri J. Vitek, MD, PhD; Sriram S. Iyer, MD; Gishel New, MD; Martin B. Leon, MD



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### **Microembolization During Carotid Artery Stenting**

A Randomized Trial of Proximal Versus Distal Cerebral Protection



Montorsi P et al. JACC 2011

### TransCarotid Artery Revascularization (TCAR)



- 1. avoiding arch
- 2. avoiding access route-dependent embolization
- 3. DYNAMIC flow reversal => ROBUST protection V





T.W., man 69 yo critical LICA stenosis

#### L haemisph stroke <u>5mo</u>

E.W., woman, 58 y, TWO recent ( <u>20d and 5d</u> ) R haemispheric minor strokes despite OMT !







Surgical Team: M. Trystula, M. Kazubudzki, J. Krzywoń, A. Brzychczy; L. Pinter Endo: P. Musialek & A. Mazurek

#### Direct carotid access CAS (TCAR) Under En Route (SilkRoad Medical) Flow Reversal





lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal



CGuard 7.0 x 30mm full endovascular reconstruction Direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal



CGuard 7.0x30mm full endovascular reconstruction direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal

#### WE, woman, 58 y, R haemispheric minor stroke x 2

#### TCAR plus CGuard







#### En Route (SilkRoad Medical) Dynamic Flow Reversal





lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal







Debris captured in the A-V shunt filter



lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal



lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal



#### **Final Result**



CGuard 7.0x30 mm full endovascular reconstruction plus NO new lesions on DW-MRI !





















Flow reversal time 7min 10sec Intolerance in the last 80sec (active aspiration still !! performed)



#### **Final Result**





#### November 13, 2017 – patient A/S, discharged home



#### Normal stent image



**Normal velocities** 



#### Double layered stents for carotid angioplasty: A meta-analysis of available clinical data

Anna Sannino, MD<sup>1,2\*</sup> | Giuseppe Giugliano, MD, PhD<sup>1,2\*</sup> | Evelina Toscano, MD<sup>1,2</sup> | Gabriele G. Schiattarella, MD<sup>1,2</sup> | Anna Franzone, MD, PhD<sup>1,2</sup> | Tullio Tesorio, MD<sup>3</sup> | Bruno Trimarco, MD<sup>1,2</sup> | Giovanni Esposito, MD, PhD<sup>1,2</sup> | Eugenio Stabile, MD, PhD<sup>1,2</sup> ©

	Event Rate	95% CI	N	
Mazzaccaro et al. 2016	6 0.08	0.01/0.62	5	
Musialek et al. 2016	6 0.00	0.00 / 0.07	101	
Shofer et al. 2015	5 0.02	0.00 / 0.21	30	
Speziale et al. 2017	7 0.03	0.01/0.06	200	-#-
CGuard	0.02	0.01 / 0.05	336	+
Bosiers et al. 2016	6 0.02	0.01 / 0.08	100	
Castagno et al. 2016	6 0.10	0.01/0.67	4	
Kedev et al. 2015	5 0.05	0.00 / 0.45	10	
Nerla et al. 2016	0.00	0.00 / 0.05	150	
Ruffino et al. 2016	6 0.02	0.00 / 0.26	23	<u> </u>
Wissgott et al. 2016	6 0.04	0.00 / 0.40	12	
Roadsaver	r 0.02	0.01 / 0.06	299	+

FIGURE 2 30-day mortality and stroke rate. Random effects event rate and 95% confidence interval for 30-day mortality and stroke (A) and relative subgroup analysis (B)



#### "Asymptomatic" carotid artery stenosis

#### (evaluate stroke risk & SIGNS of ischaemia)

#### PHARMACOTHERAPY + INERVENTIION

#### ISOLATED PHARMACOTHERAPY



#### "Asymptomatic" carotid artery stenosis

PHARMACOTHERAPY + INERVENTIION

#### ISOLATED PHARMACOTHERAPY



#### "Asymptomatic" carotid artery stenosis

PHARMACOTHERAPY + INERVENTIION

#### ISOLATED PHARMACOTHERAPY



"Asymptomatic" carotid artery stenosis



Double-layered stents //

## Stenting replaces CEAs

# Minimal invasiveness incl. TransRadial



*eg*. CGuard growth by > **130%** (Q1 2017/Q1 2018)

## • Stenting replaces CEAs!

eg. TCAR growth (coming predominantly from CEA) by > **350%** (2016/2017) CMS (US) reimbursement, both in symptomatics and HR asymptomatics already > 500 patients in ROADSTER-2 + Vascular Quality Initiative

# Minimal invasiveness incl. TransRadial

One swallow does not a summer make but many swallows do: <u>accumulating clinical evidence</u> for nearly-eliminated peri-procedural and 30-day complications with meshcovered stents transforms the carotid revascularisation field

#### Piotr Musiałek<sup>1</sup>, L. Nelson Hopkins<sup>2</sup>, Adnan H. Siddiqui<sup>2</sup>

<sup>1</sup>Department of Cardiac and Vascular Diseases, Jagiellonian University, School of Medicine, John Paul II Hospital, Krakow, Poland <sup>2</sup>Departments of Neurosurgery and Radiology, School of Medicine and Biomedical Sciences, University at Buffalo, State University of New York, Jacobs Institute, Gates Vascular Institute Kaleida Health, Buffalo, New York, USA

#### Adv Interv Cardiol 2017; 13, 2 (48): 95–106 DOI: https://doi.org/10.5114/pwki.2017.69012

#### Abstract

Atherosclerotic carotid artery stenosis (CS) continues to be a common cause of acute ischaemic stroke. Optimised medical therapy (OMT), the first-line treatment modality in CS, may reduce or delay – but it does not abolish – CS-related strokes. As per current AHA/ASA and ESC/ESVS/ESO guidelines, carotid artery stenting (CAS) is a less-invasive alternative to carotid endarterectomy (CEA) for CS revascularisation in primary and secondary stroke prevention.

Ten-year follow-up from the CREST trial in patients with symptomatic and asymptomatic CS confirmed equipoise of CAS and CEA in the primary endpoint. Nevertheless CAS – using a widely open-cell, first-generation stent and first-generation (distal/filter) neuroprotection – has been criticised for its relative excess of (mostly minor) strokes by 30 days, a significant proportion of which were post-procedural.

Atherosclerotic plaque protrusion through conventional carotid stent struts, confirmed on intravascular imaging, has been implicated as a leading mechanism of the relative excess of strokes with CAS vs. CEA, including delayed strokes with CAS. Different designs of mesh-covered carotid stents have been developed to prevent plaque prolapse. Several multi-centre/multi-specialty clinical studies with CGurad MicroNet-Covered Embolic Prevention Stent System (EPS) and RoadSaver/Casper were recently published and included routine DW-MRI cerebral imaging peri-procedurally and at 30 days (CGuard EPS).

Data from more than 550 patients in mesh-covered carotid stent clinical studies to-date show an overall 30-day complication rate of ~1% with near-elimination of post-procedural events. While more (and long-term) evidence is still anticipated, these results – taken together with optimised intra-procedural neuroprotection in CAS (increased use of proximal systems including trans-carotid dynamic flow reversal) and the positive 12-month mesh-covered stent data reports in 2017 – are transforming the carotid revascularisation field today.

Establishing effective algorithms to identify the asymptomatic subjects at stroke risk despite OMT, and large-scale studies with mesh-covered stents including long-term clinical and duplex ultrasound outcomes, are the next major goals.

Key words: carotid artery stenting, mesh, stroke, endarterectomy, neuroprotection.

#### Thursday 24 May - Morning

10:30 - 12:00

#### Carotid angioplasty evolution for 2018 *Chairperson: L.N. Hopkins*

#### ROOM 343 Level 3

10:30	Accumulating two-year clinical and duplex ultrasound evidence from the CGuard PARADIGM-Extend prospective academic trial: durability of stroke prevention	11:22	What we learned after first 122 CAS procedures using dual-layer micromesh Roadsaver stents P. Odrowaz-Pieniazek
10.00	P. Musialek	11:30	Discussion and audience interaction
10:38	<ul> <li>Discussion and audience interaction</li> <li>Dradictors of the long torus</li> </ul>	11:35	Novel angiographic algorithm to grade
10:43	Predictors of the long-term antihypertensive effect of carotid artery stenting F. Shukurov		calcification severity of carotid stenosis: development and performance in the CGuard PARADIGM trial involving highly-calcific lesions management
10:51	Discussion and audience interaction		A. Mazurek
10:56	<ul> <li>Total wrist access for carotid artery stenting</li> <li>B. Zafirovska</li> </ul>	11:43 11:48	<ul> <li>Discussion and audience interaction</li> <li>Results of hybrid repair multilevel lesions of the brachiocephalic arteries</li> </ul>
11:04	<ul> <li>Discussion and audience interaction</li> </ul>		M. Chernyavskiy
11:09	Synchronous vs. staged carotid artery stenting and open heart surgery ? a propensity score matched comparison / Marting	11:56	<ul> <li>Discussion and audience interaction</li> </ul>
	J. Martins		

One swallow does not a summer make but many swallows do: <u>accumulating clinical evidence</u> for nearly-eliminated peri-procedural and 30-day complications with meshcovered stents transforms the carotid revascularisation field

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