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Practice Patterns For Treatment Of Carotid Stenosis Are Changing Dramatically From Those In Previous RCTs: A Population Based Study

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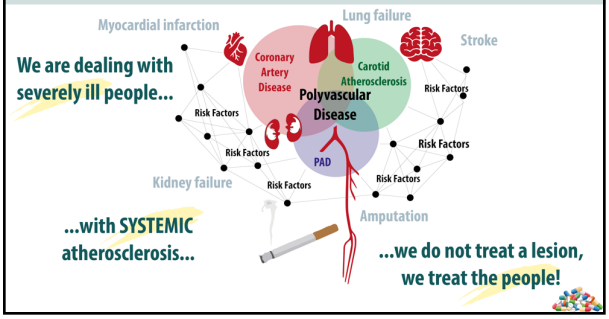
ASKLEPIOS KLINIK WANDSBEK

Disclosures

- ❑ I have the following potential conflicts of interest to report:
  - ❑ Receipt of grants/research support
  - ❑ Receipt of honoraria and travel support
  - ❑ Participation in a company sponsored speakers' bureau
  - ❑ Employment in industry
  - ❑ Shareholder in a healthcare company
  - ❑ Owner of a healthcare company
- ☑ I do not have any potential conflict of interest

No competing interests & nothing to disclose!



We are dealing with severely ill people...

...with SYSTEMIC atherosclerosis...

...we do not treat a lesion, we treat the people!

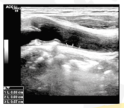
Behrendt CA, Thomalla G, Rimmele DL, et al. Editor's Choice - Prevalence of Peripheral Arterial Disease, Abdominal Aortic Aneurysm, and Risk Factors in the Hamburg City Health Study: A Cross Sectional Analysis. Eur J Vasc Endovasc Surg. 2023;65:590-598.

One out of three between 45 and 74 years of age has carotid atherosclerosis and a thickened intima

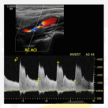
10.1016/j.ejvs.2023.01.002

30% of adults have carotid atherosclerosis!

Song P, et al. Global and regional prevalence, burden, and risk factors for carotid atherosclerosis: a systematic review, meta-analysis, and modelling study. Lancet Glob Health. 2020;8:e721-e729.



More than 1 billion worldwide!

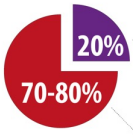


60 million with stenosis!

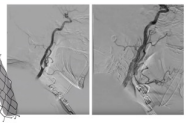
▶ 500 000 invasive procedures!

Most guidelines recommend carotid endarterectomy (CEA)...

esvs GUIDELINES
SVS | Society for Vascular Surgery
American Heart Association.
ESC

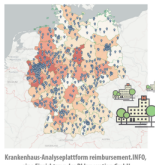


CAS



CEA

...as first line therapy PLUS best medical treatment!

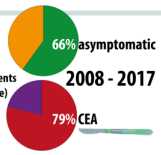


611 Hospitals

Krankenhaus-Analyseplattform reimbursement.INFO, eine Einrichtung der RI Innovation GmbH

nationwide

22 637 patients (42% female) 72.5 years



Length of stay only 4 days...

6%

30 809 procedures

...what happens after discharge?!

500 000 CEA/CAS worldwide...

Baseline characteristics

	asymptomatic		„symptomatic"		acute stroke	
	CEA	CAS	CEA	CAS	CEA	CAS
Number (n)	12 293	2 712	1 368	326	4 294	1 644
Female	42%	42%	42%	40%	41%	41%
Octogenarians	16%	15%	17%	12%	21%	16%

Considerable comorbidity burden: Critical patient selection?

van Walraven (Case Mix)	9.95	11.13	12.35	12.44	12.77	14.03
Heart failure	28%	31%	24%	24%	23%	21%
Diabetes	33%	32%	33%	32%	33%	29%
Chronic kidney failure	25%	29%	24%	22%	22%	20%
Obesity	16%	17%	14%	14%	13%	12%

1/3

Unadjusted outcomes

	asymptomatic		„symptomatic"		acute stroke	
	CEA	CAS	CEA	CAS	CEA	CAS
Number (n)	12 293	2 712	1 368	326	4 294	1 644
Female	42%	42%	42%	40%	41%	41%
30 day mortality	0.4%	0.8%	0.7%	0.9%	0.7%	2.1%
120 day mortality	1.6%	2.8%	2.0%	2.1%	2.8%	5.0%
1 year mortality	4.1%	6.2%	4.8%	6.1%	5.7%	8.4%

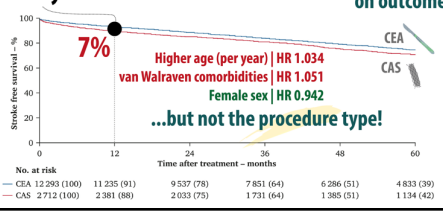
Not really surprising: 5% death after one year and 3% exhibit a stroke

30 day stroke rate	0.6%	0.8%	0.8%	2.5%	1.4%	1.2%
120 day stroke rate	1.4%	1.7%	1.7%	4.0%	2.7%	2.6%
1 year stroke rate	2.5%	3.1%	3.4%	6.4%	4.9%	4.5%
5 year stroke rate	5.9%	7.6%	11.2%	12.6%	10.4%	10.5%

Combined death or stroke rate at 1 year

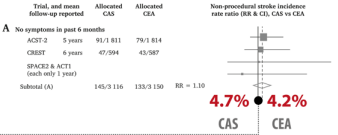
6.3% CEA vs. 8.7% CAS

Higher age & comorbidity burden has an impact on outcomes...



Bulbulia R, Halliday A.
Carotid Stenting: The Myth of Real World Evidence versus the Magic of Randomisation.
Eur J Vasc Endovasc Surg. 2023;67:97-98.

Maybe even more interesting than „is CEA or CAS better?"...



...why are stroke rates in „real world data" higher than in RCTs?

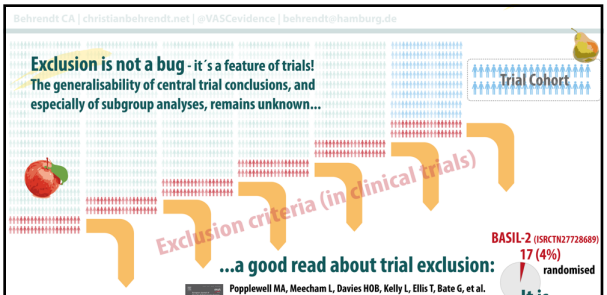
4.7% CAS vs. 4.2% CEA

7.6% +3% vs. 5.9% +2%

The most likely answer? We do not just treat a lesion...
The power of the „right pill" cannot be overestimated!

Stroke-free survival is a complex endpoint!

Exclusion is not a bug - it´s a feature of trials!
The generalisability of central trial conclusions, and especially of subgroup analyses, remains unknown...

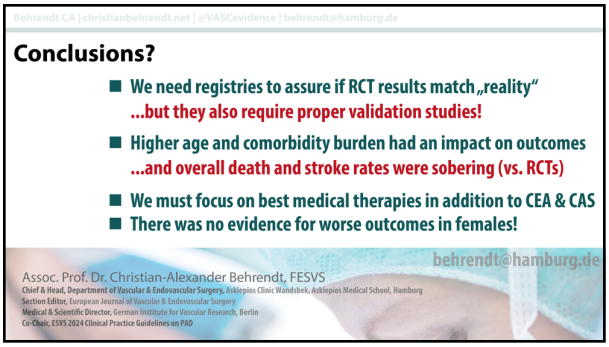


...a good read about trial exclusion:

Popplewell MA, Meecham L, Davies HOB, Kelly L, Ellis T, Bate G, et al. Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL) Prospective Cohort Study and the Generalisability of the BASIL-2 randomised controlled trial. Eur J Vasc Endovasc Surg. 2024;67:146-152.

BASIL-2 (ISRCTN27728689)
17 (4%) randomised

It is what it is!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Conclusions?
We need registries to assure if RCT results match „reality“
...but they also require proper validation studies!
Higher age and comorbidity burden had an impact on outcomes
...and overall death and stroke rates were sobering (vs. RCTs)
We must focus on best medical therapies in addition to CEA & CAS
There was no evidence for worse outcomes in females!
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