Carotid repair is best for asymptomatic carotid stenosis because medical management alone does not work

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CardioVascular Center Frankfurt - CVC,
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<table>
<thead>
<tr>
<th>Physician name</th>
<th>Company</th>
<th>Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horst Sievert</td>
<td>4tech Cardio, Abbott, Ablative Solutions, Adona Medical, Akura Medical, Ancora Heart, Append Medical, Axon, Bavaria Medizin Technologie GmbH, Bioventrix, Boston Scientific, Cardiac Dimensions, Cardiac Success, Cardimed, Celonova, Contego, Coramaze, Croivalve, CSL Behring LLC, CVRx, Dinova, Edwards, Endobar, Endologix, Endomatic, Esperion Therapeutics, Inc., Hangzhou Nuomao Medtech, Holistick Medical, Intershunt, Intervene, K2, Laminar, Lifetech, Magenta, Maquet Getinge Group, Medtronic, Metavention, Mitralix, Mokita, Neurotronic, NXT Biomedical, Occlutech, Recor, Renal Guard, Terumo, Trisol, Vascular Dynamics, Vectorious Medtech, Venus, Venock, Vivasure Medical, Vvital Biomed, Whiteswell</td>
<td>Study honoraria to institution, travel expenses, consulting fees to institution¹</td>
</tr>
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</table>
Medical management alone just does not work!

At least not for me – if I would be the patient
If you tell me:

- "Well, this is your carotid artery"
- "There is a high-grade stenosis"
- "But thank God it is still asymptomatic"
- "So, no need to do an intervention"
- "Instead, you should wait until you get a stroke or a TIA"
- And only then we should proceed and treat this stenosis

- Then I would immediately know that you are absolutely crazy!
Then I would ask Dr. Google

- And I would learn
  - that there is a significant risk of disabling stroke over the next couple of years
  - that this stenosis can easily be fixed by stenting or by surgery
  - and that after this procedure my stroke risk would be back to normal
Would I care about a periprocedural stroke risk of 1, 2, 3 or even 5%?

Of course not!

Why would I not care?

Because in my whole life I have always been one of the 95% lucky ones
Randomized trials and guidelines
We are human beeings

• Not programmed by machine learning (not yet)
• That's why some of us
  - Smoke
  - Drink 2 glass of red wine per day
  - Go skiing
  - Go high altitude mountain climbing (with a mortality of 10%)

- Prefer carotid stenosis repair
  • In order to sleep well in the years to come without fear of getting a sudden stroke
That's it!

That's why medical management alone does not work!
You disagree?

You need "data"?

Randomized trials?

How out of touch with life - and how boring!
Most of you know the data!
Surgery for Asymptomatic Carotid Stenoses is superior to medical therapy

- Randomized Trials -

Stroke %

<table>
<thead>
<tr>
<th>Study</th>
<th>Duration</th>
<th>N</th>
<th>Medical</th>
<th>Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>VA</td>
<td>48 Months</td>
<td>444</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>ACAS</td>
<td>72 Months</td>
<td>1662</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>ACST</td>
<td>60 Months</td>
<td>3101</td>
<td>15</td>
<td>12</td>
</tr>
</tbody>
</table>

P<0.06

P<0.006

P<0.00001
Surgery is good!

At least by far better than aspirin only
Some will tell you:

"Medical therapy has improved!"

"These old surgical trials are not relevant anymore!"
"Asymptomatic stenoses should be treated medically"

"In conclusion, current vascular disease medical intervention alone is now best for stroke prevention associated with asymptomatic severe carotid stenosis given this new evidence"

This conclusion is not based on randomized trials but on retrospective analyses
Medical Treatment for Asymptomatic Carotid Stenosis
Is the current annual risk really less than 1%?
These studies included many patients with mild stenoses

<table>
<thead>
<tr>
<th>Study</th>
<th>Reference</th>
<th>Patients</th>
<th>PSV</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMART</td>
<td>Goessens Stroke 2007</td>
<td>221 with ≥50% stenosis</td>
<td>150cm/sec</td>
<td>Only 96 pts had PSV ≥210, 7% had carotid repair</td>
</tr>
<tr>
<td>Oxford Vascular Study</td>
<td>Marquardt Stroke 2010</td>
<td>101 with ≥50% stenosis (Only 32 with ≥70%)</td>
<td>150cm/sec</td>
<td>Vascular death in 7.7%</td>
</tr>
<tr>
<td>ASED</td>
<td>Abbott Stroke 2005</td>
<td>202 with ≥50% stenosis</td>
<td>150cm/sec</td>
<td>TCD</td>
</tr>
</tbody>
</table>

Patients with minimal disease generally have minimal risk of stroke
ACST: Patients without and with lipid-lowering drugs

So yes, medical therapy may improve the prognosis – but in both groups, surgery and medical therapy.
However, in daily practice, best medical therapy just does not work in vascular patients

- Bissacco D et al, Medical therapy before carotid endarterectomy: Changes over a 13-year period and comparison between asymptomatic and symptomatic patients. *Angiology*. 2018;69(2):113-119
- Singh N et al, Prescribing of statins after lower extremity revascularization procedures in the US. *JAMA Netw Open*. 2021;4(12):e2136014

- A large percentage of patients (30-60%) are not treated according to guidelines despite decades of efforts
- We do not know how many get prescriptions – but don't take their meds without telling us
- This is even worse in asymptomatic patients
Even worse:
In daily practice best medical therapy may be ineffective in carotid stenosis

- 900 asymptomatic carotid arteries in 794 patients
- Mean age 72.5 yrs
- FU up to 6 yrs
- Patients were considered to have OMT if they were on aspirin and a statin with a low-density lipoprotein level that was always <100 mg/dL
- OMT failed to prevent progression of the disease or stroke

Medical therapy did not prevent progression of carotid plaque nor neurological events

Conrad MF et al.
The natural history of asymptomatic severe carotid artery stenosis

- 126 asymptomatic carotid artery stenoses in 115 patients.
- 88 (70%) had severe (70%-89%) and 38 (30%) had very severe stenoses (VSS; 90%-99%)
- 86% were taking a statin drug (28% had a low-density lipoprotein level <100 mg/dL)
- There were 31 patients (24.6%) who developed ipsilateral neurologic symptoms during a mean follow-up of 27 months, 14 (45%) were strokes.
- Outside of clinical trials Statin use was not protective against symptoms or death
... and the results of surgery are also getting better!

In Summary

• Medical therapy may have improved
• But surgery also has improved
• If there was an improvement in medical therapy, then also patients after surgery (or stent) would benefit
• Therefore, "old surgical trials" are still valid until we have the results of new trials (ECST-2, CREST-2, ACTRIS, ...)
• Also, "Optimal medical therapy"
  - is not even well defined specifically for patients with carotid stenosis
    • Which targets for blood pressure, lipids?
    • Which drugs?
  - may be ineffective in carotid stenoses
• Long term compliance in asymptomatic patients is very bad
• Therefore, surgery (in addition to medical therapy) is better than medical therapy alone
• Needless to mention that stenting is as good as surgery
Thank you for your time

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