DEBATE:
Not so:
CMS Data-based
Studies are
Flawed Models
Sinking in the
Quicksand
of Pseudo-data

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Disclosures
• I have nothing to disclose
• Dr. Veith → Purpose of a Debate
• Dr. Brott → CREST 1
• Thanks for the title!
• Thanks for the time limit!

CREST - ?? Final Word

• 2502 randomized patients → began as a symptomatic pt. trial
• "No difference in 1st endpoint" (composite)
• BUT stroke/death risk with CAS 2-fold increase
  4.8% vs 2.6% p = .01

The Landscape

Analysis of large databases in vascular surgery

Many of the current large medical databases were not created for outcomes analysis, but rather for financial or administrative purposes, such as billing and record-keeping. They contain medical data in so far as to link diagnoses and procedures with charges and billings.

Medicare Database in NEJM

Long-Term Outcomes of Abdominal Aortic Aneurysm in the Medicare Population

• Propensity match large cohorts (40,000 matched pairs!!!) Treated 2001-08 and followed through 2009
• Endpoints periop mortality and late death

MGH Study on TEVAR

<table>
<thead>
<tr>
<th>Year</th>
<th>TEVAR</th>
<th>OPEN</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>352 (25%)</td>
<td>1073 (75%)</td>
<td>1425</td>
</tr>
<tr>
<td>2005</td>
<td>777 (45%)</td>
<td>963 (55%)</td>
<td>1740</td>
</tr>
<tr>
<td>2006</td>
<td>1184 (58%)</td>
<td>866 (42%)</td>
<td>2050</td>
</tr>
<tr>
<td>2007</td>
<td>1216 (60%)</td>
<td>816 (40%)</td>
<td>2032</td>
</tr>
<tr>
<td>Total</td>
<td>3529 (49%)</td>
<td>3718 (51%)</td>
<td>7247</td>
</tr>
</tbody>
</table>

J Vasc Surgery 2010;52:768-74
Ann Surg 2010;252:603-610
### 30-Day Mortality

<table>
<thead>
<tr>
<th>Variable</th>
<th>TEVAR</th>
<th>OPEN</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort (n=11166)</td>
<td>7.4%</td>
<td>18.6%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Intact Aneurysm (n=7247)</td>
<td>5.2%</td>
<td>12%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Ruptured Aneurysm (n=1033)</td>
<td>24%</td>
<td>40%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Dissection (n=2701)</td>
<td>9.1%</td>
<td>21%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Trauma (n=185)</td>
<td>14%</td>
<td>35%</td>
<td>0.0007</td>
</tr>
</tbody>
</table>

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### Limitations Detailed

Accuracy of administrative data versus clinical data to evaluate carotid endarterectomy and carotid stenting.

CONCLUSION: Administrative data are unreliable for determining symptom status, high-risk status, and perioperative stroke and should not be used to analyze CEA and CAS.

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### Who is Being Treated?

Outcomes of carotid artery stenting and endarterectomy in the United States

Hey > 90% of these procedures are being performed in asymptomatic patients! (attn: Ann Abbott)

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### What is Symptom Status?

- **MGH DATA**
  - 1335 CEA performed 2010-15
  - 108 CAS performed 2010-15
  - 3.7% in ipsilateral symptomatic patients
  - 3.4% in ipsilateral asymptomatic patients

- **VSGNE DATA**
  - COMBINED ≈ 5K CEA and 400 CAS, 2003-13
  - 3.5% had ipsilateral symptoms
Given the uncertain timing of POA events as preoperative vs intraoperative and its apparent underestimation of the perioperative stroke rate, the use of administrative data even with the POA indicator for symptom status and non-fatal outcomes after CEA and CAS is hazardous.

Potential strategy of linking MEDPAR files to CAS certification registry to assess symptomatic status and outcomes:
- Only successful in 67%

Mortality for CAS 1.9% between 2005-07 (n ≈ 25K patients)

The “Power of Inference”
- 2004-06 study of CEA/CAS in > 10K Medicare beneficiaries
- Alloges similar results for endpoints including POST PROCEDURE STROKE
- If the data ain’t there, one can always make it up

For CAS? Does Registry Help
- Cardiologists are 1/3 operators but > 50% procedures
- Cardiology CAS → followed cardiac catheterization BUT NOT TIA/Stroke!
- Regions where cardiologists major operators had significant higher population based rates of CAS

Who is doing CAS
- Cardiologists are 1/3 operators but > 50% procedures
- Cardiology CAS → followed cardiac catheterization BUT NOT TIA/Stroke!
- Regions where cardiologists major operators had significant higher population based rates of CAS

RECENT META ANALYSIS
- Carotid Artery Stenting vs Carotid Endarterectomy:
  - Meta-analysis and Diversity-Adjusted Trial Sequential Analysis of Randomized Trials
  - Carotid Artery Stenting Versus Carotid Endarterectomy

The impact of the present on admission indicator on the accuracy of administrative data for carotid...
Stroke and death after carotid endarterectomy and carotid artery stenting with and without high risk criteria

Kristina J. Sills, MD, Abhishek Handa, MD, Frank R. Langendyk, MD, Mark C. Wyers, MD, and Mario U. Molinari, MD, PhD, Toronto, Canada

The data set has no information on severity of stenosis or anatomic risk factors that may predispose a patient to adverse outcomes with either repair method. For preoperative data, we cannot determine severity of prior stroke, lateralization, frequency of symptoms, or the temporal relationship of symptoms and surgical repair.

NSQIP “Real World” CONTEMPORARY OUTCOMES CEA

Outcomes after carotid endarterectomy: Is there a high-risk population? A National Surgical Quality Improvement Program report


• 3949 CEA in 2005-06 pvt. sector
• 30% “high risk” by SAPPHIRE criteria
• Overall adjudicated 30-day stroke/death 2.2%
• No difference in “high risk” including octogenarians (n = 750)

VSGNE Registry

Factors associated with stroke or death after carotid endarterectomy in Northern New England

Philip P. Groome, MD, Donald K. Idlette, MD, and Jack J. Coumbaris, MD, for the Vascular Study Group of Northern New England, Lebanon, NH

• 3092 CEA → 30 day S/D = 1.8%
Correlates of increased risk
• Emergency operation (RR 7.0)
• Contralateral occlusion (RR 2.8)
• PreOp Stroke (RR 2.4)

MGH Results

Clinical and anatomic outcomes after carotid endarterectomy

Saez de Person, MD, Mike A. Cavanagh, MD, Virendra J. Patel, MD, and Pritesh Patel, MD, Massachusetts General Hospital, Boston, MA

• 3014 CEA 1989-05 mean f/u 7yrs
• 30 day ipsilateral S/D → 2.2%
• 5 year survival 70%
• 5 year reintervention rate 3.4%

CAS vs CEA COMPARISONS

Thru 2007, there were 6403 procedures in SVS Reg.

CAS (30 day D/S/MI)
7.1% symptomatic
3.7% asymptomatic
Two fold increased risk (p < .002)
of death/stroke for CAS

CEA (30 day D/S/MI)
3.7% symptomatic
1.9% asymptomatic

DETAILS OF CREST

Safety of Stenting and Endarterectomy by Symptomatic Status in the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST)

Peter G. B. Neil, MD, Ian T. Smith, MD, Steve J. Shulman, MD, and CREST Investigators.

• CAS (%) 4.4
• CEA (%) 2.3
• Overall (2500 pts) 1.9 (p < .005)

• Symptomatic (1321 pts) 6.0 ± 0.9
• Asymptomatic (1181 pts) 2.5 ± 0.6

Stroke 2011;42:657-680
Can CEA get any better?

- VS had equivalent outcomes for CAS
- Symptomatic (CAS vs CEA) → 6.1% vs 1.3%, p=.01
- Asymptomatic (CAS vs CEA) → 2.6% vs 1.1%, p=.2

CONCLUSIONS

- For certain vascular interventions and hard end-points (e.g. in-hospital death), large administrative databases can be effectively used in research
- In carotid interventions, important antecedent clinical variables and outcome measures (e.g. periprocedural stroke) cannot be accurately assessed