Debate: Statins after infrainguinal treatments for CLI improve survival… but not patency

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Few Would Argue:
- Treatment with statins is good for patients with vascular disease.

The Question at Hand
Do statins have an independent effect on lower limb revascularization procedures?

Why This Question is Hard To Answer
Competing Risks
Death
Cardiac Events
Stroke
Limb Loss
Why We Have a Debate

- Randomizing patients with CLI to statins (or no statins) will never happen.
  - Too few patients would ever be able to be randomized.

- We must rely, therefore, on observational approaches.
  - In these analyses, the devil is in the details…

The Data

- Our Side: The Vascular Quality Initiative
  - All have “significant” vascular disease
    - All patients underwent a procedure

- Their Side: The REACH Registry
  - Outpatients with specific criteria for PAD
  - Not procedure-based

The Challenge:

- Observational analyses
  - Patients who are not on statins may be different than those who are on statins

- Can we measure all of these differences??
Table 2. Operative Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>All n=2,067</th>
<th>Unmatched Cohort n=1,537</th>
<th>Propensity-Matched Cohort n=530</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Statin Group n=431</td>
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<tr>
<td>Graft Side - Right</td>
<td>1,030 (48)</td>
<td>743 (36)</td>
<td>256 (50)</td>
<td>0.83 227 (54)</td>
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<tr>
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<td>Proportion Remaining Alive</td>
<td>274 (11%)</td>
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What We Found:
- Our study
- Dr. Baumgartner will explain here...

Figure 1. Cohort Creation

VSGNE Database January 2003 – December 2011

4,613 Lower Extremity Bypass Procedures

- 82 (2%) Missing Follow-Up Data
- 35 (1%) Statin Intolerant
- 1,770 (38%) Incomplete Statin Data
- 310 (7%) Non-Primary Bypasses

923 Patients with Statin Use Data

- 151 (6%) Statin only at 1 yr flu
- 274 (11%) Statin only peri-op

2,067 Patients for Analysis

- 530 (26%) No statin
- 1,537 (74%) Statin peri-operatively and 1 yr follow-up

Figure 2a. Patient Survival – Unmatched Cohort

Survival - Patients with CLI

logrank p-value=0.003

Mean follow-up = 3.1 years

Topics of Annotation
What We Found:

- This was the good news...
  - Statins were associated with better survival
- The rest of the news was pretty bland…

![Survival - Patients with Claudication]

logrank p-value=0.92
Mean follow-up = 3.3 years

![Freedom from Graft Occlusion]

logrank p-value=0.99

![Freedom from Major Amputation]

logrank p-value=0.4
**Take Home Message**

- Statin Effects are Big and Real
  - But for survival only
  - No clear independent effect on patency

- Eerily similar findings in PREVENT III
  - + effect on survival
  - No effect on patency

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**For my esteemed opponent..**

- She may try to argue for an effect of statins on patency…

**For my esteemed opponent..**

- But…
  - Their dataset is different and potentially more heterogeneous.
  - Their finding is small, and hasn’t been largely reproduced.

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**For the Audience - and Judges**

- Limits of Observational Studies

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For the Audience - and Judges

LIMITS OF OBSERVATIONAL STUDIES!