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**Answering The Big Questions:
Vascular Surgeons/Specialists Need To
Develop High Quality Evidence To Improve Care:**

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Veith Symposium
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- No disclosures

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BEST-CLI trial

- Showed value of high quality evidence
 - Provides guidance for clinical practice
 - Provides evidence for clinical guidelines
- Demonstrated how hard it is to do a randomized clinical trial
- Highlighted lack of RCT's by vascular surgeons

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Randomized Clinical Trials

- Difficult to do
- Not many

"contemporary RCTs of invasive cardiovascular interventions are relatively small and fragile, have short follow-up, and have limited power to detect large treatment effects."⁴

⁴Characteristics of Contemporary Randomized Clinical Trials
JAMA Intern Med. 2020

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Randomized Clinical Trials

- Difficult to do
- Not many
- **Not well done**

"In this systematic review, the size of contemporary surgical trials was small and the focus was on minor clinical events. Trial registration remained suboptimal and discrepancies with the published protocol and reporting bias were frequent."

⁴Characteristics of Randomized Clinical Trials
JAMA Netw Open. 2021

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Scientific Evidence - Gold standard

**Prospective Randomized
Controlled Clinical Trial - RCT**

Highest level of scientific clinical evidence


Controls for confounding variables by establishing two groups of patients who have balanced baseline characteristics

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Is there a problem here?



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- Narrow inclusion criteria
- Multiple exclusion criteria
- Limits generalizability



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Randomized Clinical Trials SVS | VQI
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- Selected Centers, Providers, and Patients
- Does a RCT Reflect Real World Evidence?



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RCT Issues SVS | VQI
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- Increasingly expensive
- Increasing regulatory issues
- Increasingly time consuming
- Increasingly complex and prohibitive
- Difficult recruitment
- Bottom Line – Delay to market (\$\$\$)



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Randomized Clinical Trials – SVS | VQI
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Still the gold standard?

- *Rethinking Randomized Clinical Trials* ...Ann Intern Med 2009
- *Clinical Trials and the Real World: Selection Bias* Cardiovasc Drugs Ther 2001
- *Practical Improvements for Medical Device Evaluation* ... JAMA 2017

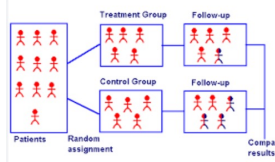


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Registry-based RCT SVS | VQI
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- Leverages pre-existing
 - Case report forms
 - Data collection methodology
- Site identification
- Allows rapid enrollment

Registry patients




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The Future of Trials

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- *The Randomized Registry Trial – the Next Disruptive Technology ...* NEJM 2013
- *Registry-based Randomized Clinical Trials – a New Clinical Trial Paradigm ...* Nature/Cardiology 2015




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Registry Based Trials

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- Mortality with Paclitaxel coated Devices in PAD – SWEDEPAD
- TASTE – thrombus aspiration for acute MI - SWEDEHEART
- SORT OUT – stent evaluation – Danish research network
- SAFE-PCI – radial vs femoral access for PCI – NCDR



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Registry-based RCT's

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Advantages

- Randomization removes confounding factors
- Large n
- More (RWE) generalizability
- Simple design
- Low cost

Disadvantages


- Variable data quality
- Need for customized endpoints, safety reporting, core lab, etc

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VQI – Registry-based RCT

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- **Cost effective**
- **Efficient**
- **Rapid enrollment**
- Site selection tool
 - Quality of data entry
 - High volume
 - Diverse patient population (URIM)
 - Different settings (academic, community, rural, etc)




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Registry Based Trials

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- Cost of TASTE – thrombus aspiration for acute MI (SWEDEHEART)
- \$400,000 vs tens of millions
- ROI – estimated at 10-20X



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Vascular controversies

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- Intervention for asymptomatic carotid stenosis
- Management of claudication
- Size threshold for AAA repair



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Vascular surgeon led clinical trials

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BY COLLABORATION AND INTEGRITY

- Need for high quality evidence
 - Provide guidance for clinical care and guidelines
- SVS Clinical Trials Task Force, Chair, Michael Conte
 - Support vascular surgeon RCT's
 - Encourage Registry-based RCT's (using VQI)

SVS + VQI



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Thank you



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