



# RAPID Phase II: OPC Results and Lessons Learned

Daniel Bertges, MD

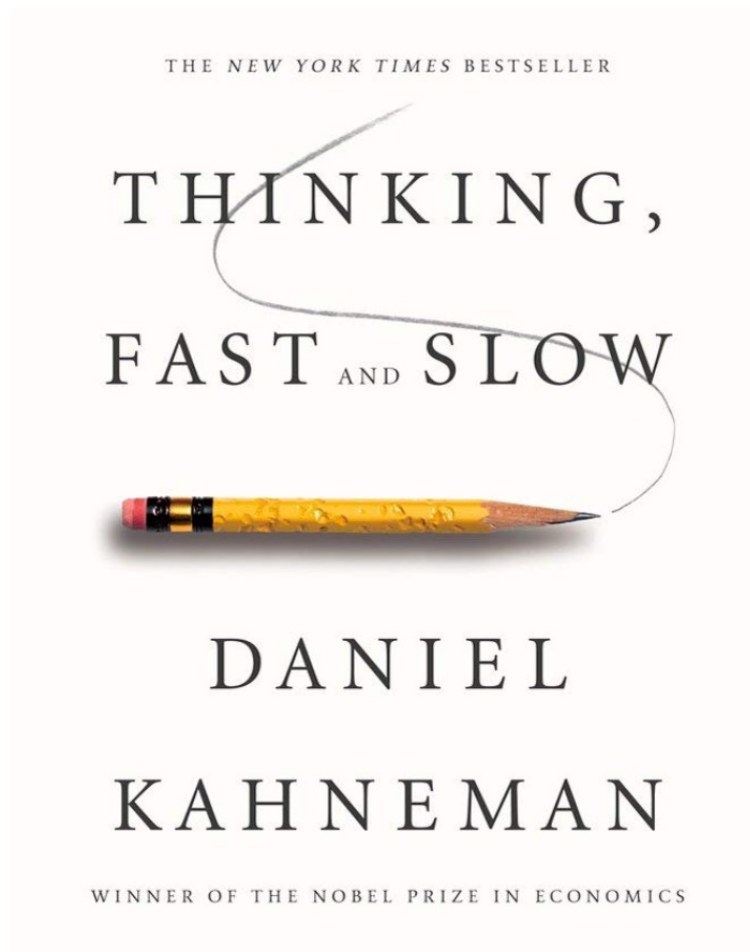
University of Vermont Medical Center

Society for Vascular Surgery

VQI PVI Registry Chair



# Lesson learned: success is not guaranteed



## The Planning Fallacy

Estimates are often closer to the best-case scenario

## The Outside View

Forecasts can be improved by consulting statistics of similar cases



# Lesson learned: doing everything is hard

## STATISTICAL ANALYSIS PLAN (SAP-001SPEED)

Protocol Number: XXXX

### SFA-Popliteal Evidence Development (SPEED)

Version Number: 1.0

Author: SPEED Statistical Team

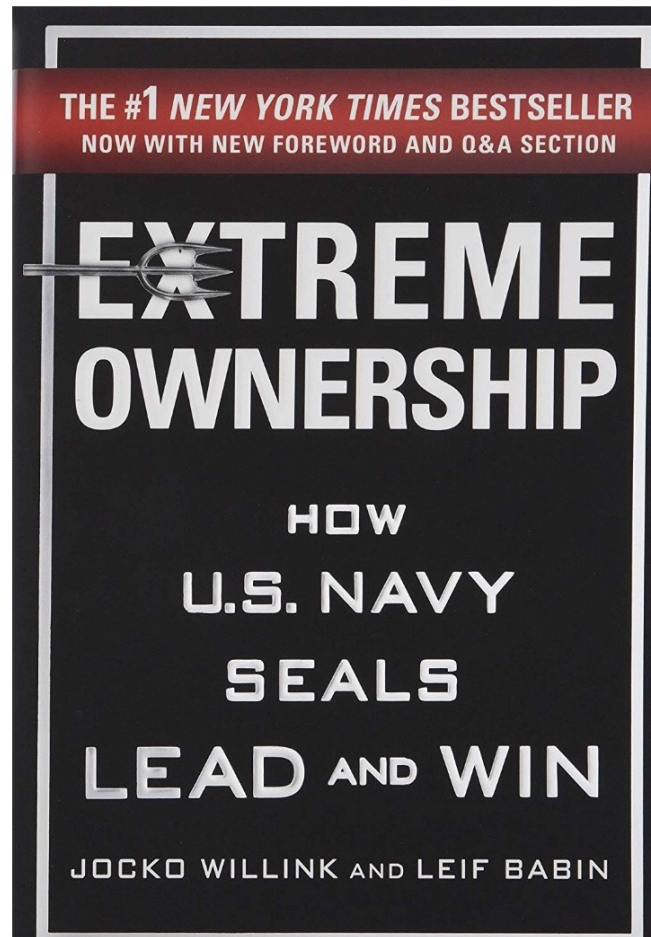
#### 3.5.1. Outcomes

The outcomes that will be evaluated are the following:

- Mortality, any cause
- Major amputation: below or above knee amputation rate of index limb
- Amputation free survival (AFS): composite of freedom from mortality and major amputation
- Target lesion revascularization (TLR): repeat intervention (open surgical or percutaneous) on the index artery(ies)
  - Open surgery: any endarterectomy or infrainguinal bypass of target lesion previously treated with PVI
  - Interventional: any angioplasty, atherectomy, stent or stent graft or thrombolysis performed on target lesion previously treated with PVI
- Target lesion occlusion: binary loss of patency or occluded at follow-up
- Target Vessel Revascularization: Any new qualifying procedure within the target vessel
- Technical failure: inability to cross lesion (with wire or device) or occlusion, or superficial femoral-popliteal artery dissection or perforation requiring treatment, or distal embolization requiring treatment, or residual stenosis  $\geq 30\%$ . Excludes access site complications. Excludes device malfunction that is not specifically captured in VQI.



# Lesson learned: physician engagement

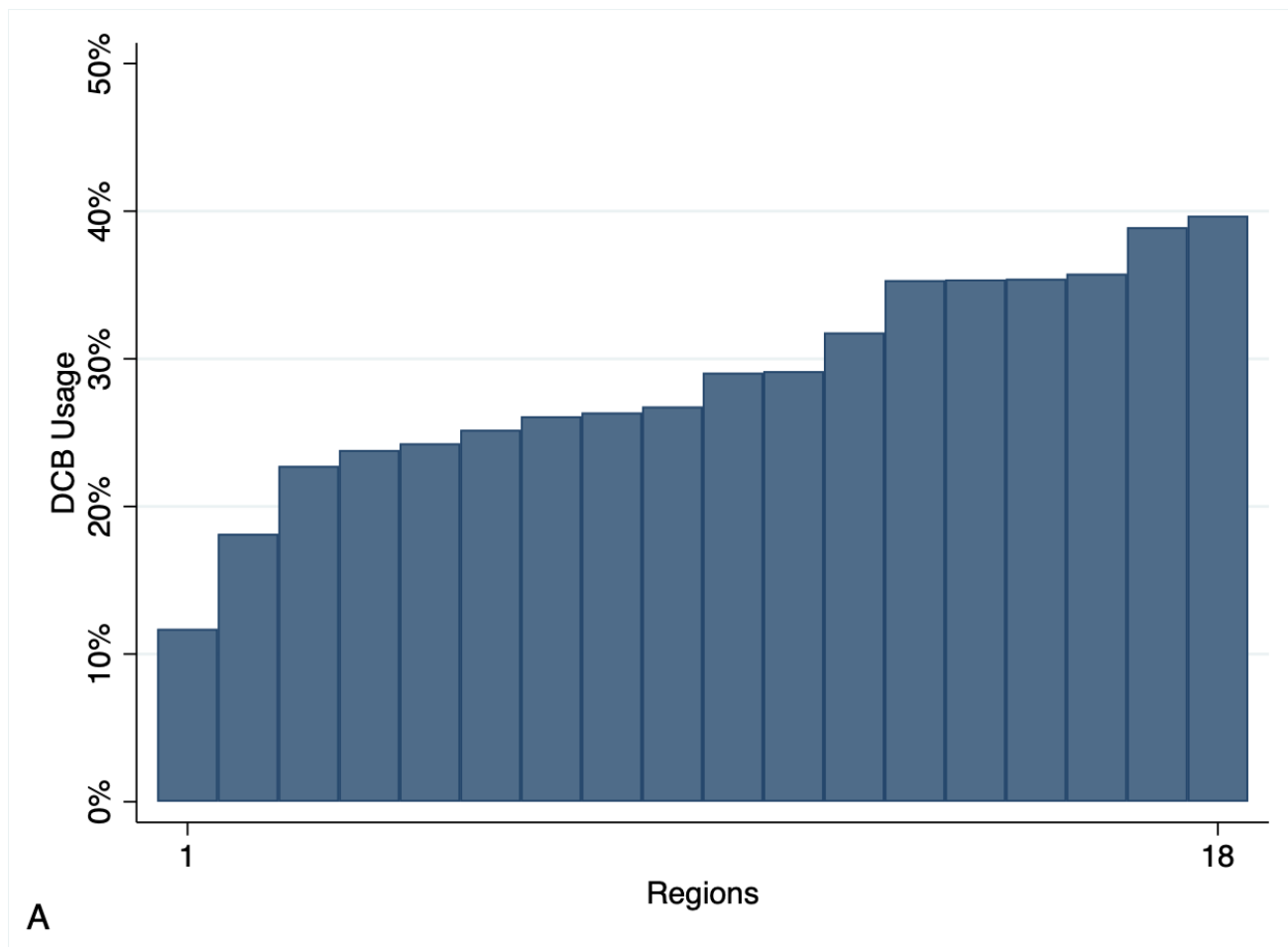


# What does it all mean?

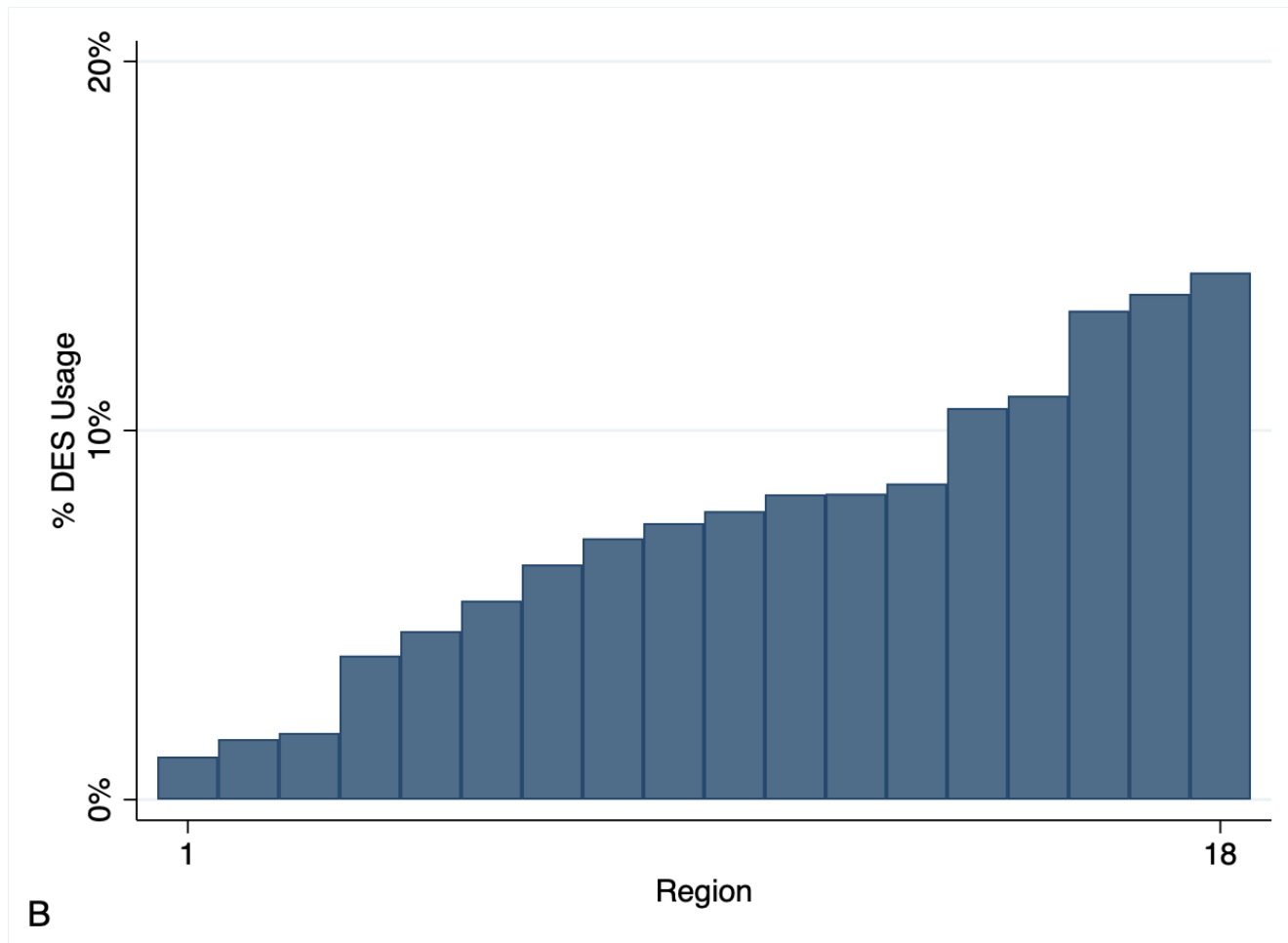
- Accurate patient selection?
- Accurate device selection?
- All devices within classes created equally?
- All devices are created equally across classes?
- For some patients and some anatomies are all devices are equal?
- Large sample sizes in registries affords the possibility of “precision medicine”



# VQI regional variation in DCB use



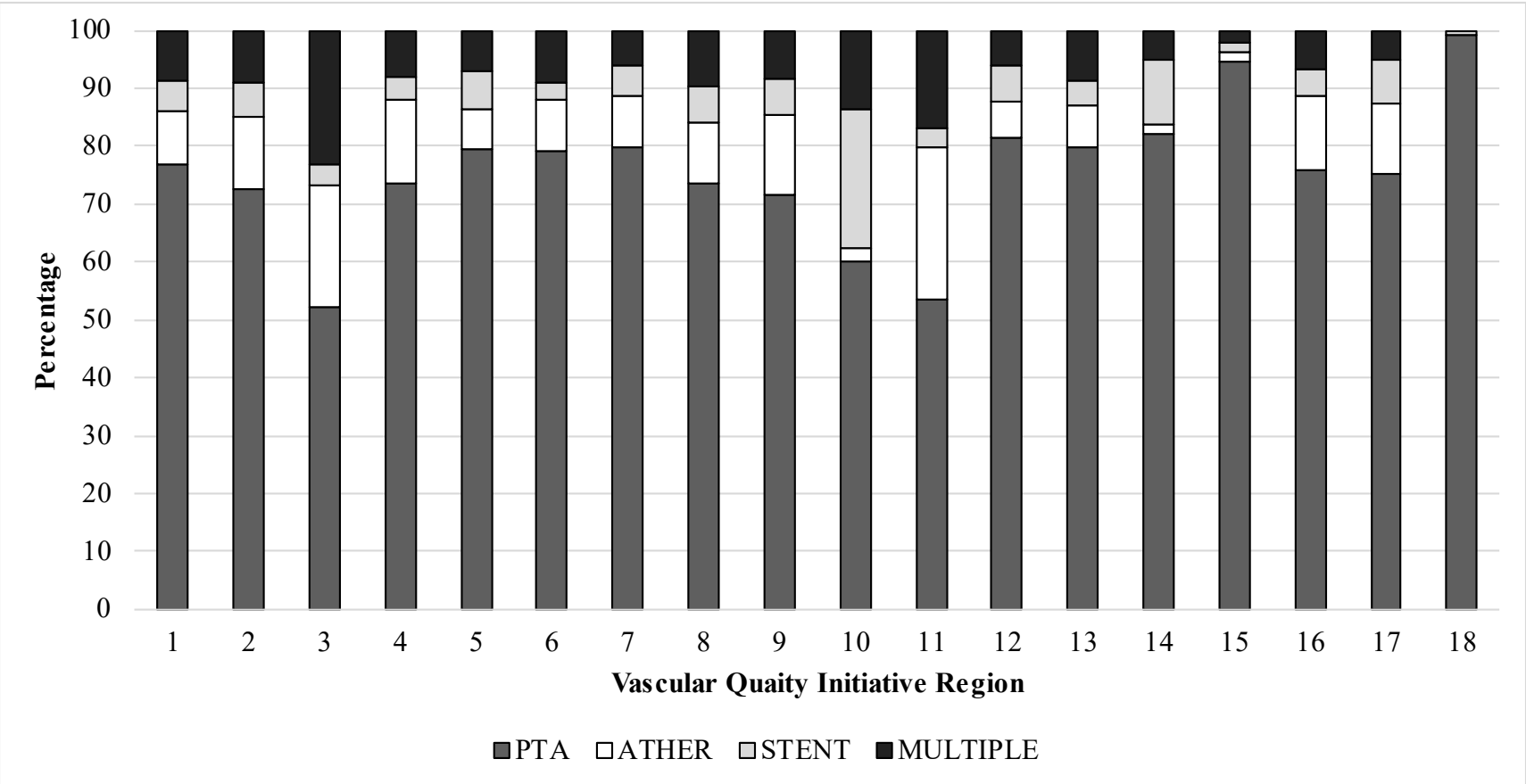
# VQI regional variation in DES use



B



# VQI regional variation in infrapopliteal PVI





# Regional variation in Medicare data

**Table 2. Hospital Characteristics of Patients Admitted for Femoropopliteal Artery Revascularization, Stratified by Treatment With Drug-Coated Devices vs Non-Drug-Coated Devices**

Characteristic	No. (%)			P Value
	Overall (N = 16 560)	Non-Drug-Coated Devices (N = 10 571)	Drug-Coated Devices (N = 5989)	
Bed size, mean (SD)	458 (342)	446 (326)	480 (367)	<.001
Femoropopliteal artery revascularization procedure volume in 2016, mean (SD)	21.6 (29.9)	19.3 (21.7)	25.6 (40.4)	<.001
Teaching status				
Metropolitan teaching	10 229 (61.8)	6428 (60.8)	3801 (63.5)	
Metropolitan nonteaching	5876 (35.5)	3843 (36.4)	2033 (33.9)	.003
Rural	455 (2.8)	300 (2.8)	155 (2.6)	
Region				
West	2336 (14.1)	1524 (14.4)	812 (13.6)	
Midwest	3719 (22.5)	2330 (22.0)	1389 (23.2)	<.001
South	6841 (41.3)	4539 (42.9)	2302 (38.4)	
Northeast	3664 (22.1)	2178 (20.6)	1486 (24.8)	
Ratio of use of drug-coated/non-drug-coated devices, mean (SD)	0.36 (0.22)	0.29 (0.19)	0.49 (0.21)	<.001

