

# Proposed CMS MEDCAC Research questions

**Sanjay Misra, MD FSIR, FAHA**

*Professor of Radiology*

Mayo Clinic Rochester

Division of Vascular and Interventional Radiology

[misra.sanjay@mayo.edu](mailto:misra.sanjay@mayo.edu)



# Sanjay Misra, MD FSIR, FAHA

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# Proposed CMS MEDCAC

## Research questions

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1. What is the role of endovascular treatment of SFA in patients with intermittent claudication versus supervised exercise therapy?
2. What is the role of endovascular SFA treatment in patients with advanced CKD
3. What is the role of endovascular treatment of infra-inguinal disease in patients with critical limb ischemia?

# Results from the **E**ndovascular **R**evascularization **A**nd **S**upervised **E**xercise for claudication study

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Farzin Fakhry, on behalf of the ERASE Trial Investigators

Erasmus Medical Center

Departments of Radiology and Epidemiology

Rotterdam, The Netherlands

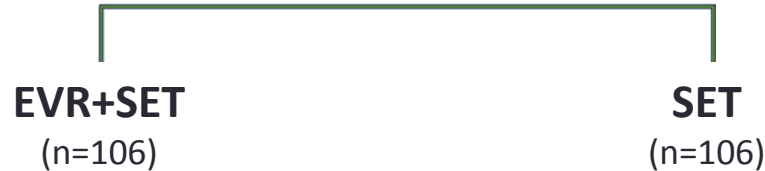
- Intermittent claudication
  - Symptomatic form of peripheral arterial disease, 20–40 million cases worldwide
- Functional- and quality of life limitations
- Supervised exercise therapy first-line treatment, endovascular revascularization increasingly performed
- Combination therapy of endovascular revascularization and exercise promising

# Study Objective

## **ERASE Trial**

To compare the clinical effectiveness of Endovascular Revascularization (EVR) plus Supervised Exercise Therapy (SET) versus the standard care of SET only in patients with intermittent claudication.

### Randomization



### Endovascular Revascularization

- Balloon angioplasty aortoiliac and/or femoropopliteal lesion
- Selective stenting

### Supervised Exercise Therapy

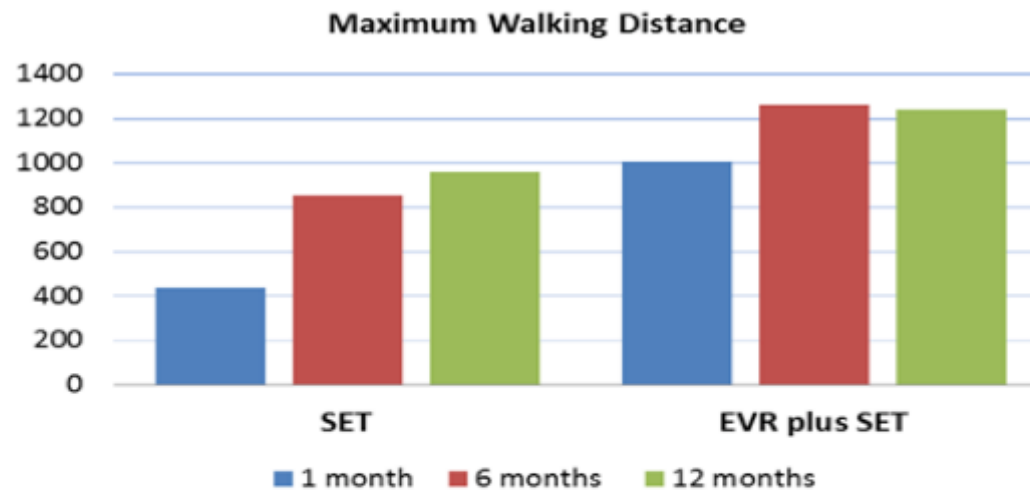
- Approximately 1 hour sessions of exercise, trained physiotherapist
- 2-3 s/wk 3 months, 1-2 s/wk 3-6 months and 1 s/4 wks 6-12 months, depending on patients' progress and preference

## Baseline characteristics of the randomized patients

		SET (n=106)	EVR+SET (n=106)
Age (years)		66 ( $\pm$ 10)	64 ( $\pm$ 9)
Gender (Male)		67%	58%
Smoking (Current/Former)		92%	93%
Hypertension		63%	60%
Diabetes		26%	16%
Dominant Lesion	Aortoiliac	51%	55%
	Femoropopliteal	49%	45%
Maximum Walking Distance (meters)		272 ( $\pm$ 124)	251 ( $\pm$ 117)
Pain Free Walking Distance (meters)		130 ( $\pm$ 77)	112 ( $\pm$ 68)
Vascular QoL score (1–7)		4.5 ( $\pm$ 1.0)	4.5 ( $\pm$ 0.9)

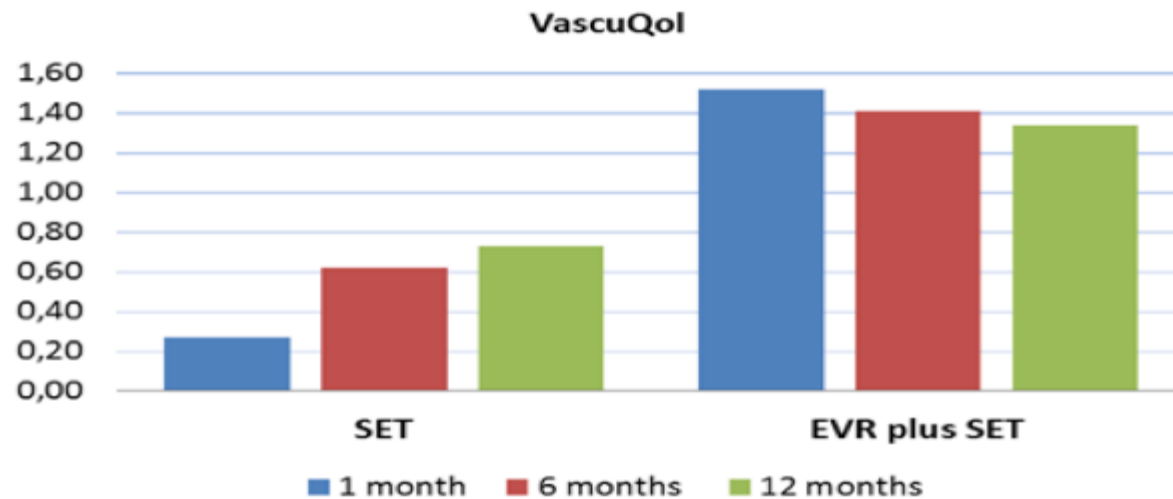


# Results



	Mean Difference EVR <i>plus</i> SET vs. SET	P-value
1 month	566 (358 ; 774)	<0.001
6 months	409 (183 ; 436)	<0.001
12 months	282 (60 ; 505)	0.001

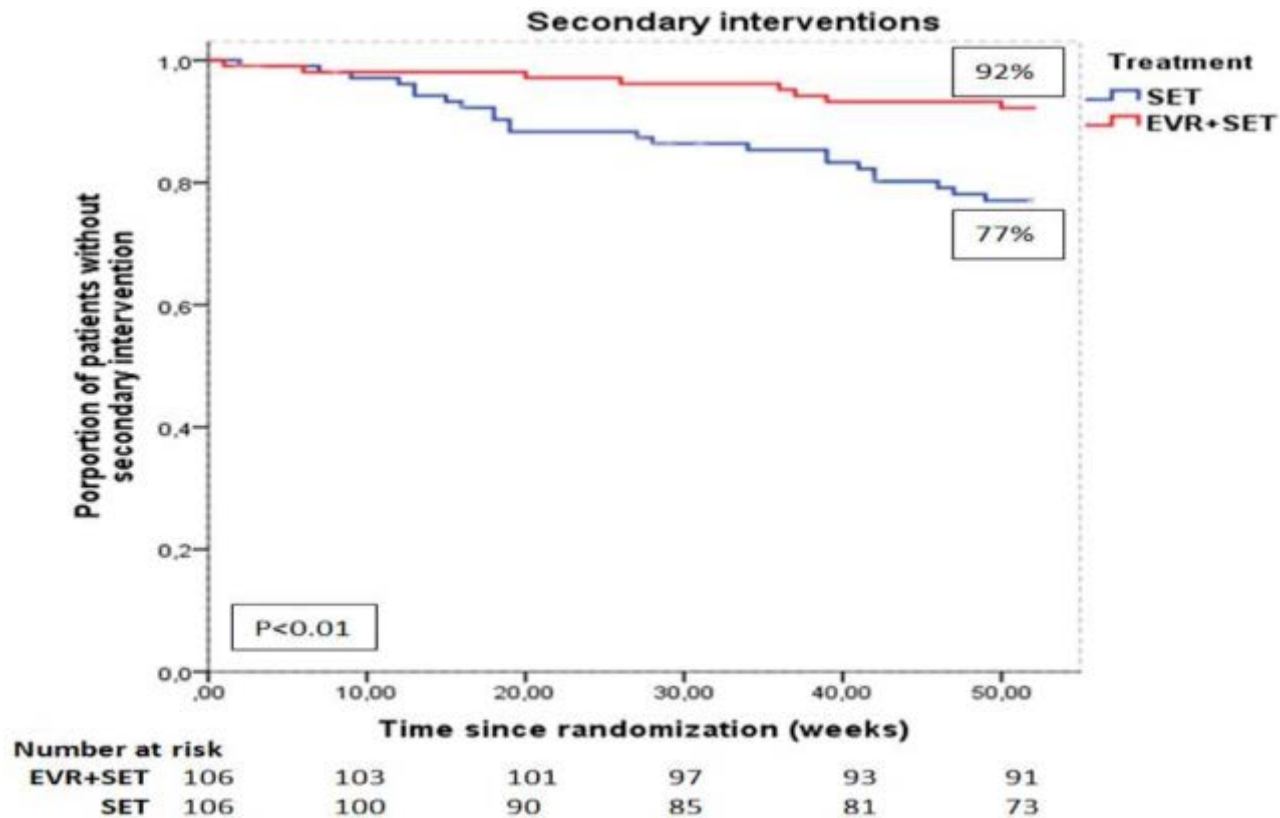
Fig. 1 Bars represent mean change (meters) compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization



	Mean Difference EVR <i>plus</i> SET vs. SET	P-value
1 month	1.25 (0.94 ; 1.56)	<0.001
6 months	0.79 (0.45 ; 1.13)	<0.001
12 months	0.62 (0.20 ; 1.03)	<0.001

Fig. 5 Bars represent mean change compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization

## Secondary interventions during follow up



# What is the role of endovascular SFA treatment in patients with advanced CKD?

- Single center experience
- 440 patients (58% male,  $72.3 \pm 10.7$  years old)
- 518 limbs who underwent percutaneous angioplasty or stent placement
- median duration of follow-up was 4.3 years (inter-quartile range from 1.4 to 4.8 years)
- GFR calculated using MDRD

## Procedural details:

Treatment, n (%)		
Angioplasty	268 (51.7)	
Stent	250 (48.3)	
Runoff to the foot, n (%)		
0	7 (1.4)	
1	133 (25.8)	
2	212 (41.2)	
3	163 (31.6)	
TASC II, n (%)		
A	119 (23.2)	
B	245 (47.7)	
C	140 (27.2)	
D	10 (2.0)	
ABI	# Data Available	Mean (SD)
Pre PT ABI, mean (SD)	301	0.57 (0.18)
Pre DP ABI, mean (SD)	307	0.56 (0.19)
Post PT ABI, mean (SD)	243	0.83 (0.21)
Post DP ABI, mean (SD)	247	0.82 (0.21)

Figure 1:

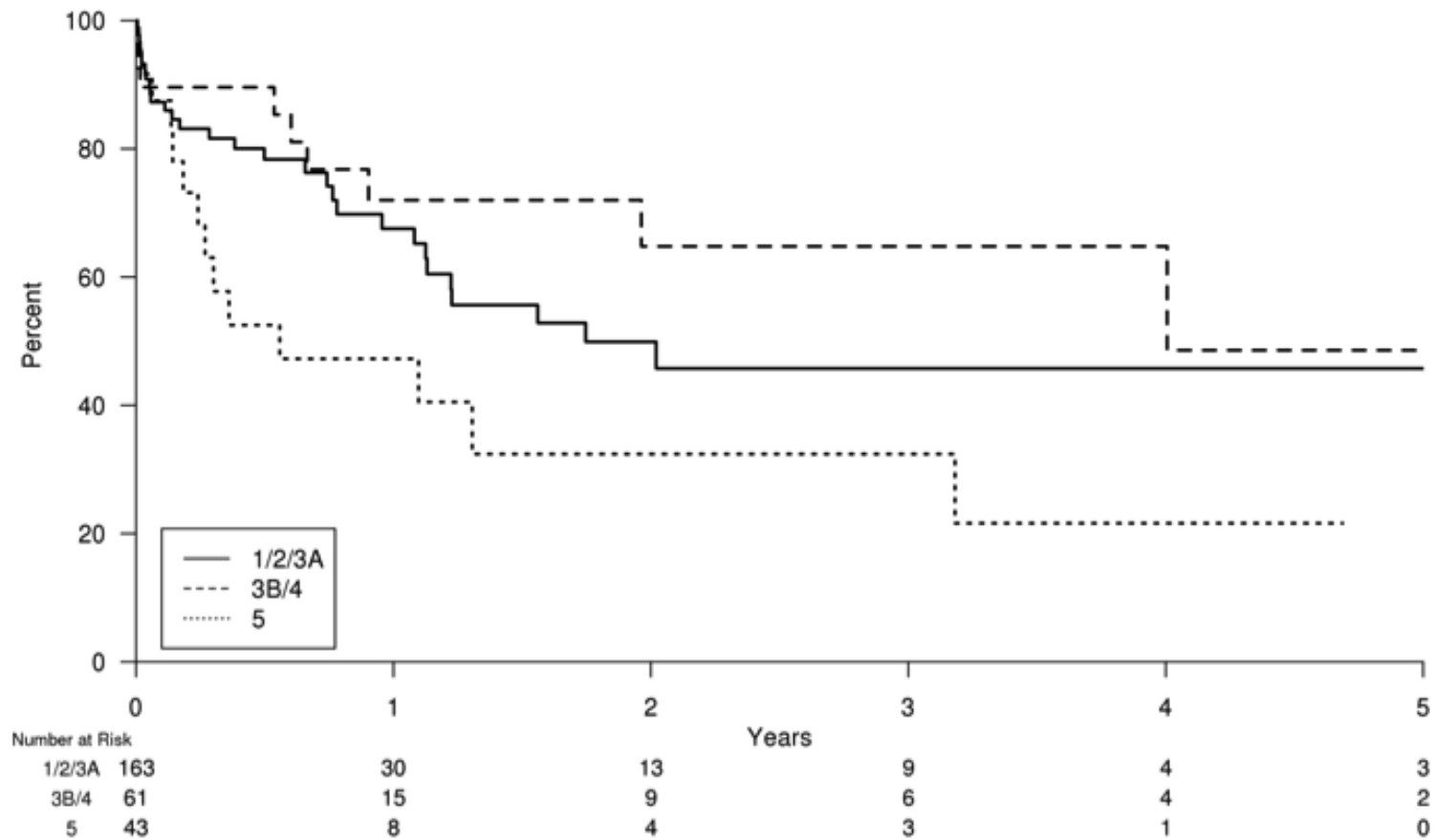
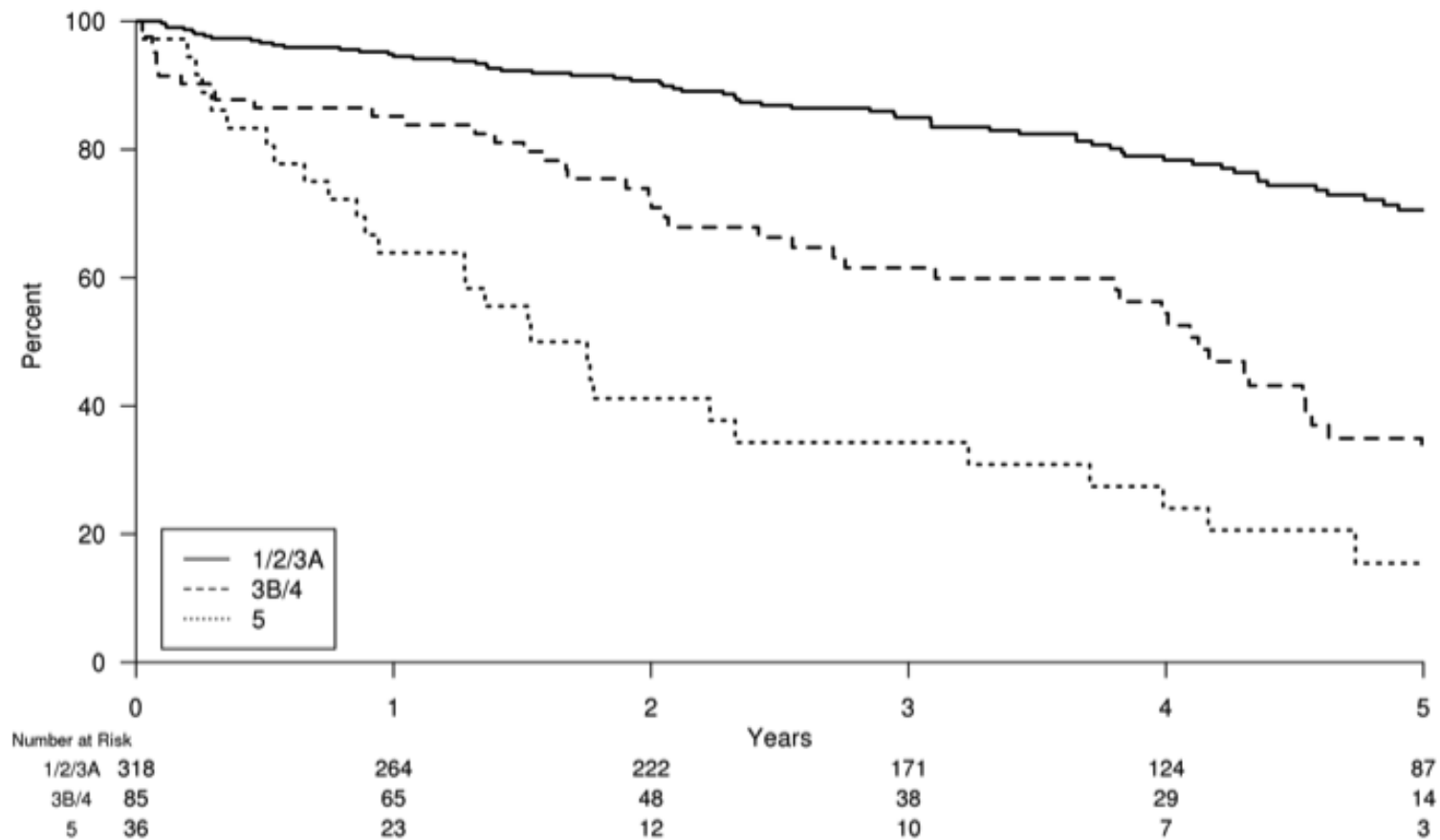


Figure 2:



# Variation in the Use of Lower Extremity Vascular Procedures for Critical Limb Ischemia

Philip P. Goodney, MD, MS; Lori L. Travis, MS; Brahmajee K. Nallamothu, MD, MPH;  
Kerianne Holman, MD, MPH; Bjoern Suckow, MD; Peter K. Henke, MD; F. Lee Lucas, PhD;  
David C. Goodman, MS, MD; John D. Birkmeyer, MD; Elliott S. Fisher, MD, MPH

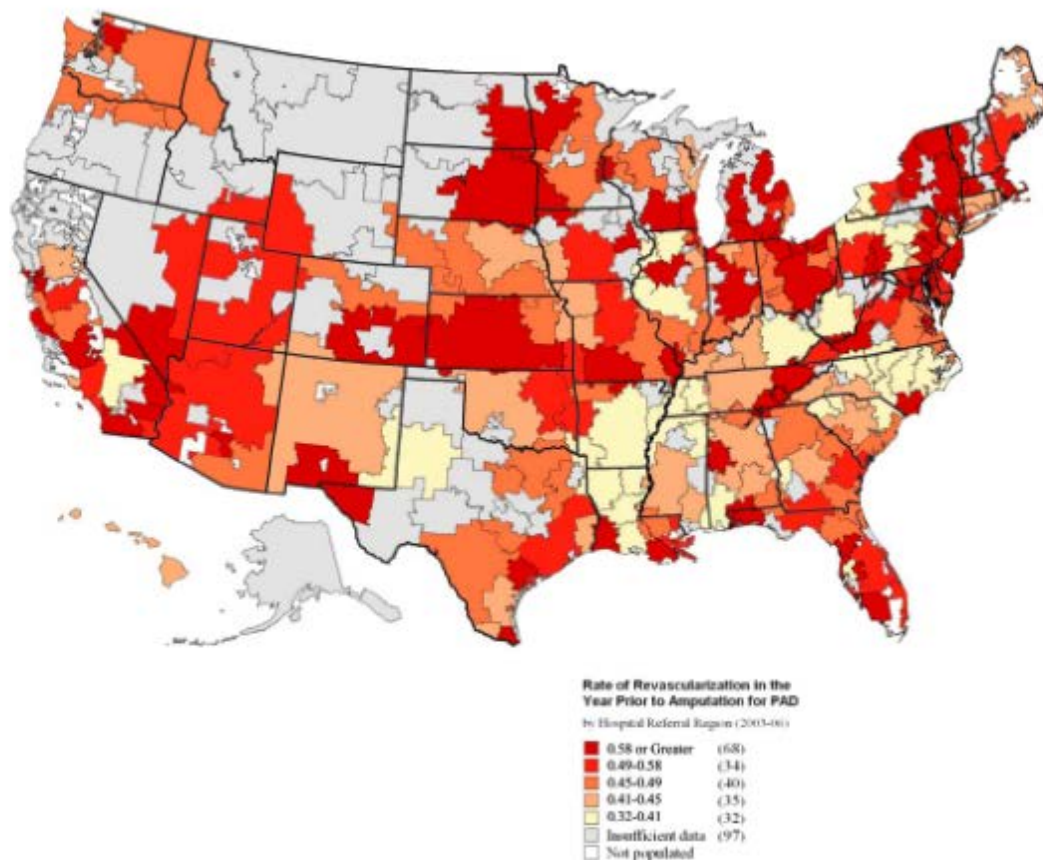
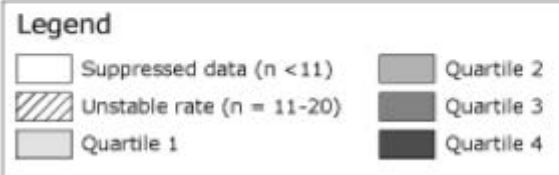
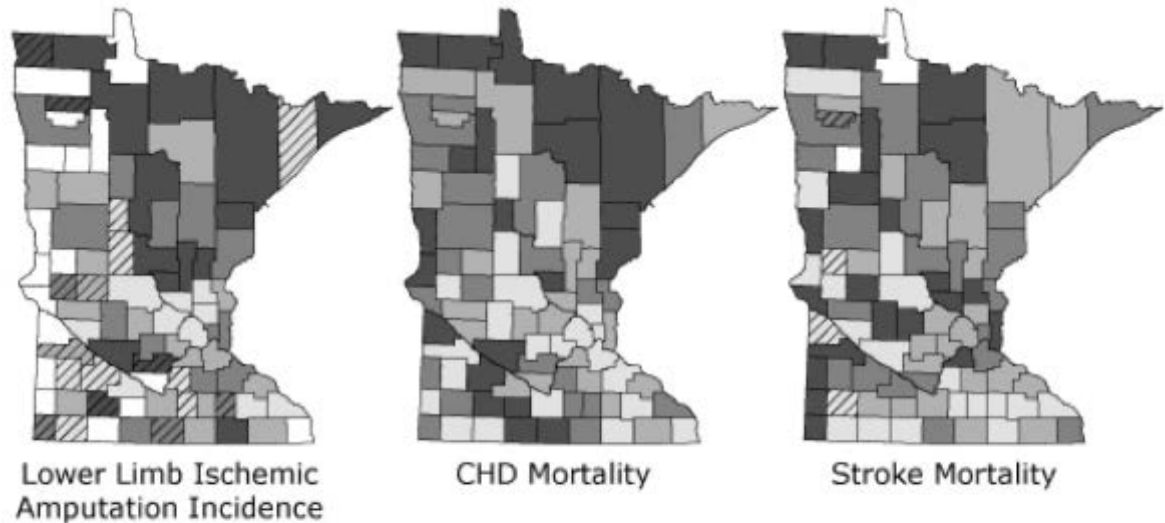


Figure 3. Map of revascularization rates, by hospital referral region, from 2003 to 2006.



# Minnesota



# Gaps in Knowledge for IC patients:

What procedural technique (PTA, BMS, DEB, DES, Stent graft, or atherectomy) is best for IC patients

What are the clinical outcomes for change in walking distance, CV mortality, all cause mortality, non-fatal MI, and stroke in IC patients

What is the role of (PTA, BMS, DEB, DES, Stent graft, or atherectomy) combined with SET versus SET for IC patients

What is the total cost of the endovascular procedures for the desired clinical outcome (walking distance, CV mortality, all cause mortality, non fatal MI, and stroke)

What are the procedural outcomes in patient specific characteristics (gender, age, race, CKD, diabetes, and others) and anatomical subsets (TASC, calcified vessels, and CTOs)

# Gaps in Knowledge for CLI patients:

What procedural technique (PTA, BMS, DEB, DES, Stent graft, or atherectomy) is best for CLI patients

What are the clinical outcomes of MALE, CV mortality, all cause mortality, non fatal MI, and stroke in these patients for the different procedural techniques

What is the role of (PTA, BMS, DEB, DES, Stent graft, or atherectomy) combined with surgical intervention (hybrid)?

What are the total cost of the above techniques

What are the procedural outcomes in patient specific characteristics (gender, age, race, CKD, diabetes, and others) and anatomical subsets (TASC, calcified vessels, and CTOs)