



# Cost-effectiveness of leg bypass vs endovascular therapy for critical limb ischemia

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# Acknowledgements



The review team developed the report's scope, study questions, and methodology in consultation with the Operational Partners (*i.e.*, topic nominators), the ESP Coordinating Center, and the technical expert panel (TEP). Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

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## Operational Partners

Operational partners are system-level stakeholders who have requested the report to inform decision-making. They recommend TEP members; assure VA relevance; help develop and approve final project scope and timeframe for completion; provide feedback on draft report; and provide consultation on strategies for report dissemination.

**Mark Wilson, MD**  
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Department of Veterans Affairs

**William Gunnar, MD**  
Former National Director of Surgery  
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## **Technical Expert Panel (TEP)**

To ensure robust, scientifically relevant work, the TEP guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress.

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# VA Evidence Synthesis Program overview

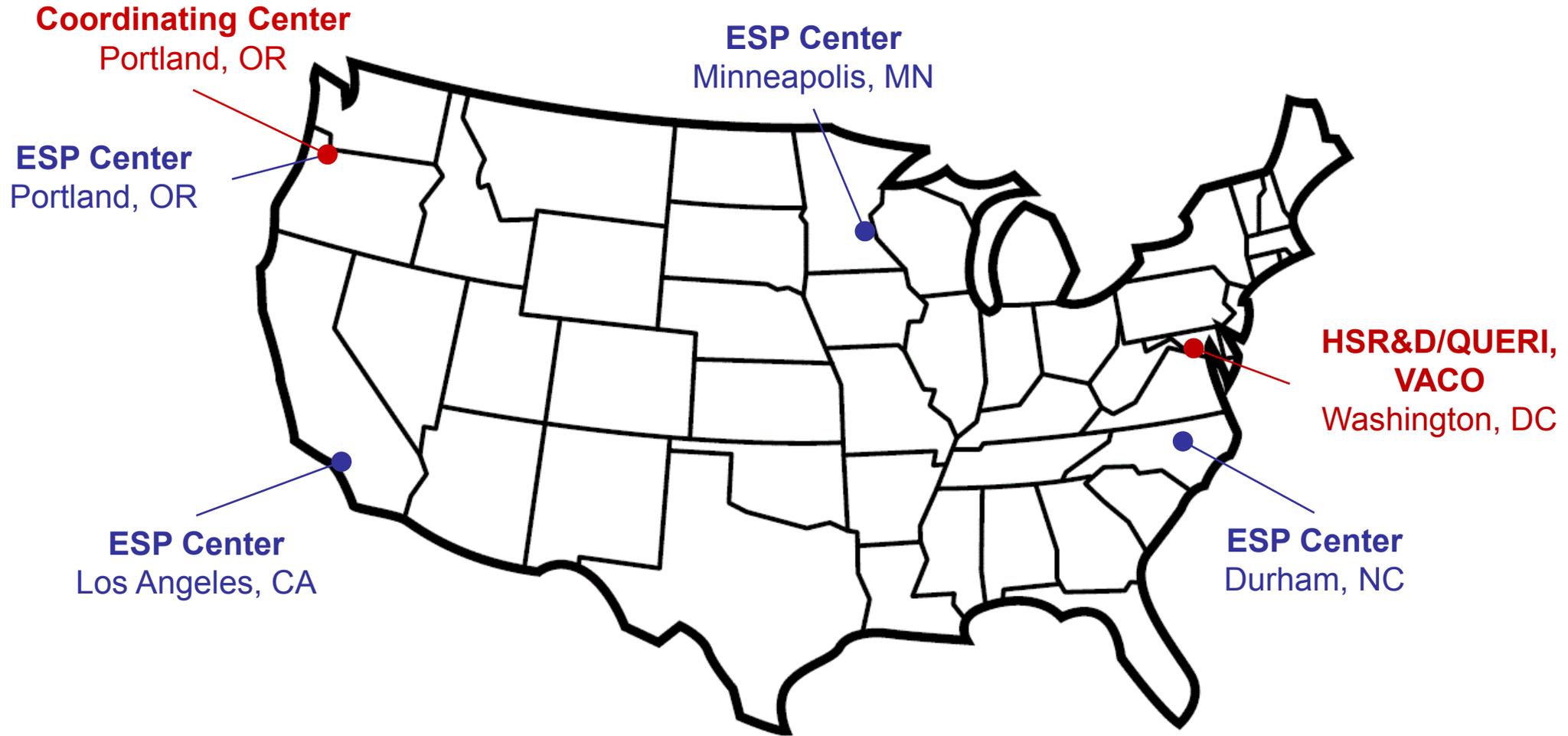


- Established in 2007
- Provides tailored, timely, and accurate evidence syntheses of VA-relevant, Veteran-focused healthcare topics. These reports help:
  - Develop clinical policies informed by evidence;
  - Implement effective services and support VA clinical practice guidelines and performance measures; and
  - Set the direction for future research to address gaps in clinical knowledge.
- Four ESP Centers across the US:
  - Directors are VA clinicians, recognized leaders in the field of evidence synthesis, and have close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration
- ESP Coordinating Center in Portland:
  - Manages national program operations and interfaces with stakeholders
  - Produces rapid products to inform more urgent policy and program decisions

To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee comprised of health system leadership and researchers.

**The program solicits nominations for review topics several times a year via the [program website](#).**

# ESP Center locations



## **Cost-effectiveness of leg bypass vs endovascular therapy for critical limb ischemia**

July 2019

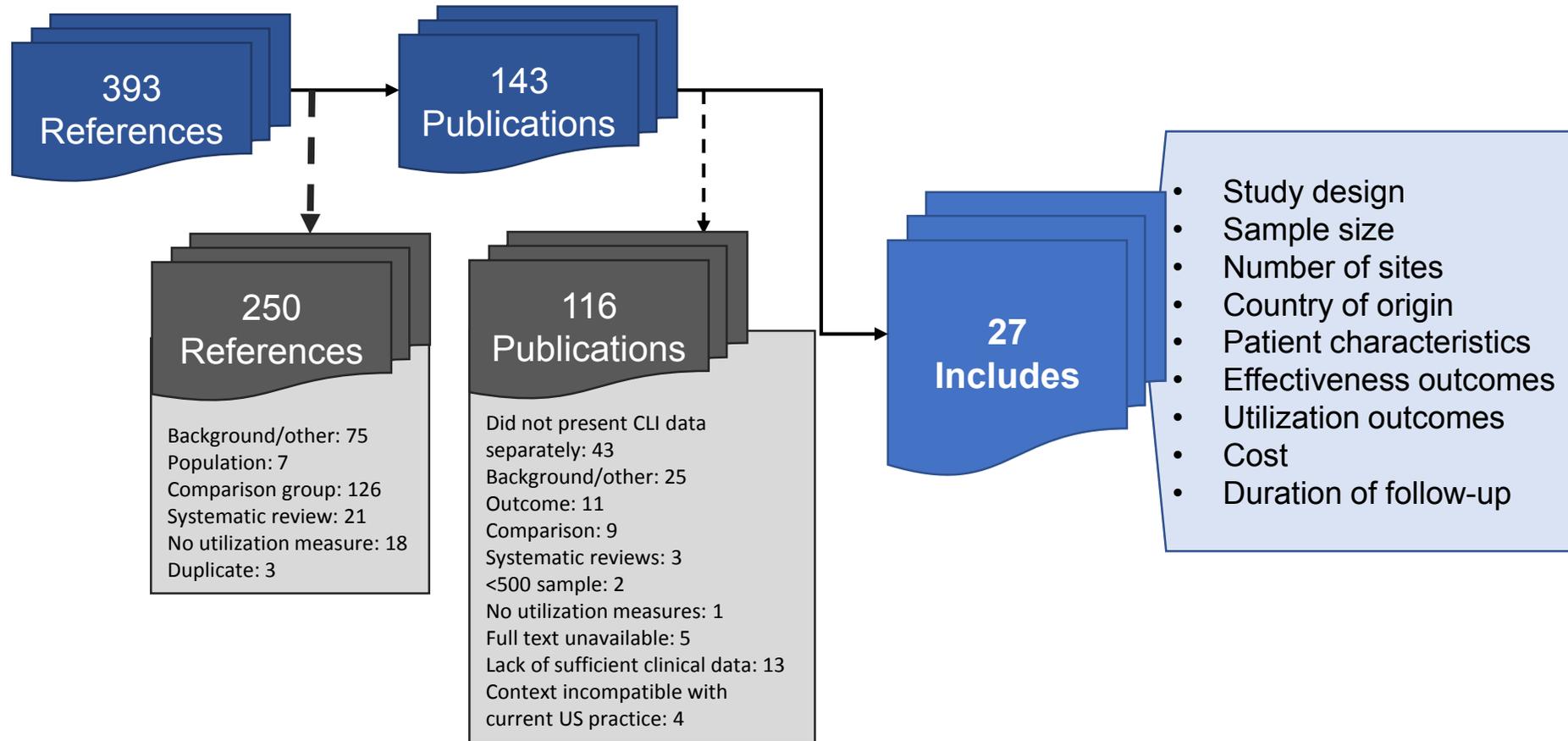
Full-length report available on ESP website:

<http://www.hsrd.research.va.gov/publications/esp/reports.cfm>

- Critical limb ischemia (CLI) is a severe form of peripheral arterial disease (PAD) marked by ischemic rest pain, tissue loss, or gangrene
- It is estimated that 1.3% of the US adult population suffers from CLI
- CLI is associated with significant morbidity, mortality, and increased utilization of healthcare resources
- Revascularization takes two primary forms – surgery or endovascular therapy
- Current guidelines from ACC and AHA do not specifically recommend endovascular or surgical therapy first for patients with CLI

- 1) Among adults with CLI, what is the cost-effectiveness of leg bypass (surgery) compared to endovascular procedures including balloon angioplasty, arterial stents, and atherectomy?
- 2) Does the cost-effectiveness of leg bypass (surgery) compared to endovascular procedures for CLI vary by patient population, setting, or time (short vs long-term)?

# Selection of Studies



*Among adults with CLI, what is the cost-effectiveness of leg bypass compared to endovascular procedures including balloon angioplasty, arterial stents, and atherectomy?*

Included studies:

- 1 RCT (BASIL study\*)
- 3 cost-effectiveness analysis models
- 15 observational studies

\*publications classified as RCT were all results from the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Study

# Key Question 1 – RCT\*

- 27 hospitals
- 452 patients
  
- Primary outcome:
  - amputation-free survival
- Secondary outcomes:
  - all-cause mortality
  - health related quality of life (HRQOL)
  - costs

\*publications classified as RCT were all results from the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Study

# Key Question 1 – RCT\* results

- No statistically significant difference in amputation-free survival and HRQOL at 1 year or 3 years
- All-cause mortality favored surgery-first treatment strategy after 2 years of follow-up (prior to 2 years there was a nonsignificant difference favoring angioplasty)

Hazard Ratio of Surgery Relative to Angioplasty  
(12 month period)

	Angioplasty (n=224)	Surgery (n=228)	Unadjusted	Adjusted*
Amputation – free survival	106	98	0.89 (0.68-1.17)	0.88 (0.66-1.16)
All-cause mortality	87	79	0.90 (0.66-1.22)	0.95 (0.69-1.29)

\*publications classified as RCT were all results from the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Study

# Key Question 1 – RCT\* results

- The surgery-first management option had more resource use by patients in the first year, but these differences disappeared in subsequent years

at 12 months

Surgery (n=228)

Angioplasty (n=224)

	Mean (SD)	Range	Mean (SD)	Range	p-value*
<b>Number of admissions to hospital</b>	2.14 (1.30)	(1-8)	2.06 (1.50)	(0-10)	0.286
<b>Total days spent in hospital</b>	46.14 (53.87)	(0-365)	36.35 (51.39)	(0-334)	<0.00001

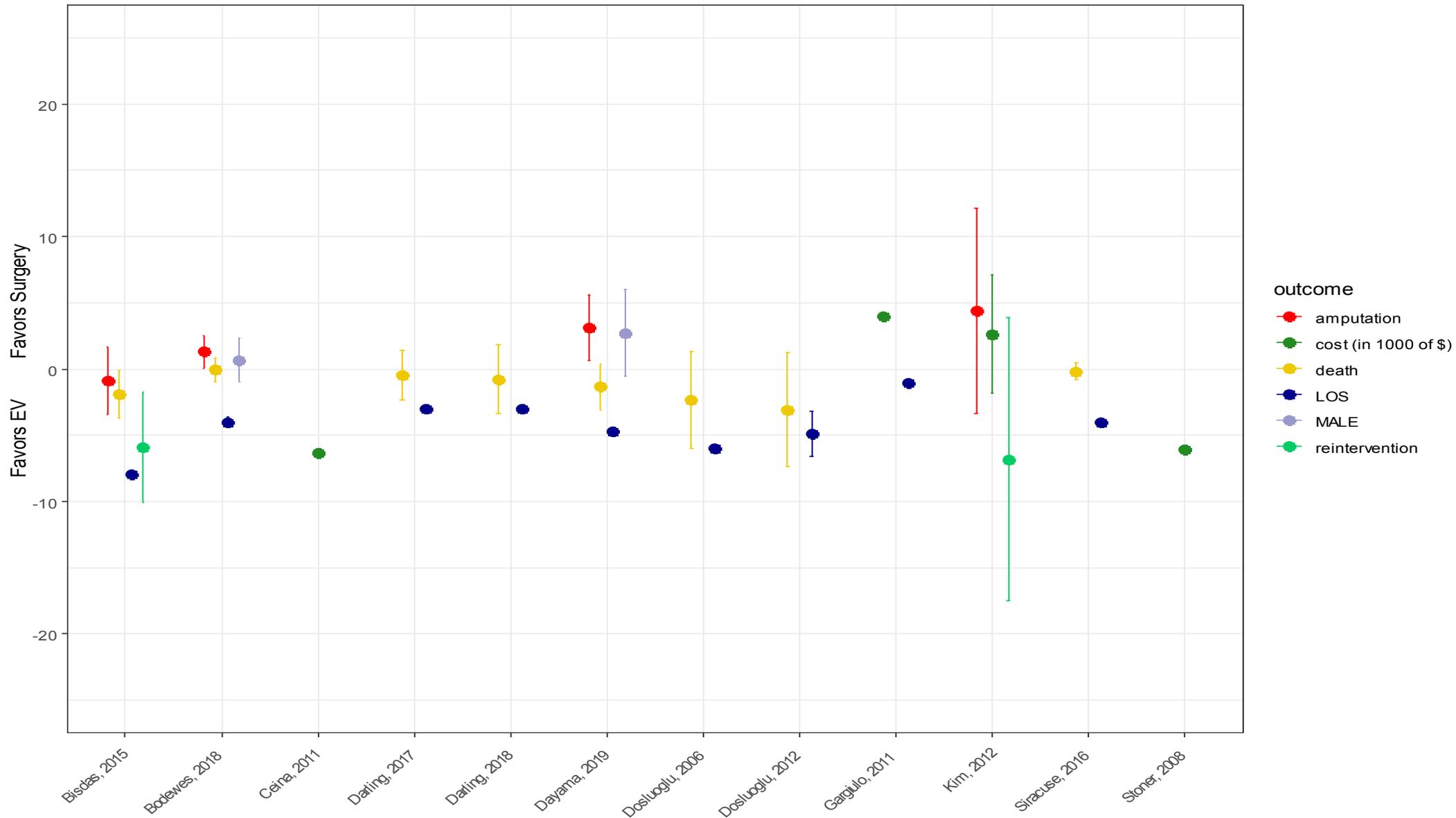
- The incremental cost-effectiveness ratio of the surgery-first management option was \$184,492 per quality-adjusted life year

\*publications classified as RCT were all results from the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Study

# Key Question 1 – Observational studies

## Short-term outcomes

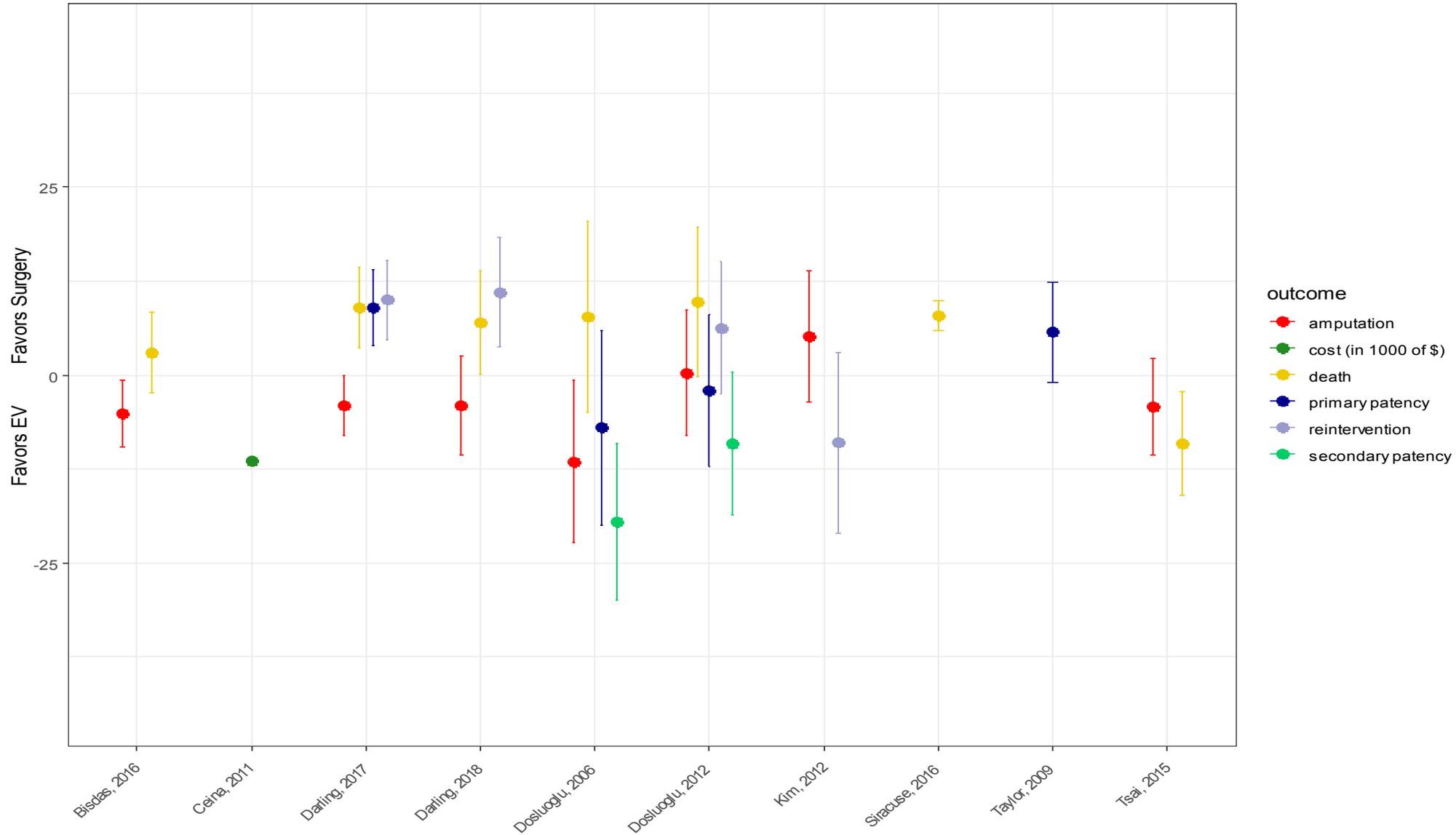
- Most favored EV over surgery, but few were statistically significant



# Key Question 1 – Observational studies

## Long-term outcomes

- mortality and reintervention favor surgery



# Key Question 1 – CEA models

- 1 from the United Kingdom (within BASIL trial):
  - incremental cost-effectiveness ratio of surgery-first approach = \$184,492 per quality-adjusted life year (QALY)
- 1 from the US:
  - incremental cost-effectiveness ratio of surgery-first approach = \$47,738/QALY
  - incremental cost-effectiveness ratio of endovascular-first approach = \$101,702/QALY
- 1 from Germany:
  - incremental cost-effectiveness ratio of surgery-first approach = €3,462.65/QALY
  - incremental cost-effectiveness ratio of endovascular-first approach = €3,431.60/QALY

*Does the cost-effectiveness of leg bypass compared to endovascular procedures for CLI vary by patient population, setting, or time (short vs long-term)?*

Included studies:

- 1 RCT (within BASIL study\*)
- 2 cost-effectiveness analysis models
- 3 observational studies

\*publications classified as RCT were all results from the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Study

# Key Question 2 – Subpopulations

- Patients with infrapopliteal disease:
  - endovascular therapy may have worse long-term outcomes
  - increased short-term utilization in the surgical group but similar utilization between groups over longer time horizons
- Patients with ESRD:
  - lower costs per year of ambulation with endovascular-first approaches compared to surgery-first
- Patients with diabetes:
  - worse outcomes for the composite of reintervention, amputation, or stenosis when treated with endovascular therapy compared to surgery
- Patients with borderline functional status:
  - a cost-effectiveness model favored endovascular-first approaches over surgery-first

# Overall Summary of Our Review

- Endovascular therapy has a lower initial length of stay. (Strength of Evidence: High)
- Endovascular therapy has lower short-term mortality. (Strength of Evidence: Low)
- Surgical therapy has lower long-term mortality. (Strength of Evidence: Very Low)
- Cost-effectiveness varies by the time horizon, where initial outcomes and utilization tend to favor percutaneous interventions, but longer term outcomes tend to favor open revascularization. (Strength of Evidence: Low)
- Endovascular therapy is less cost-effective than surgery in infrapopliteal disease. (Strength of Evidence: Low)

## Study Quality

- One RCT identified had serious limitations in terms of directness and applicability to modern care.
- Observational studies had serious limitation with respect to risk of bias.

## Heterogeneity

- Among the observational studies, a relatively consistent finding was a shorter length of stay for patients treated with endovascular therapy. Other outcomes were not as consistent.

## Applicability of Findings to VA Population

- Two publications from the same institution were specific to VA populations. It is likely that the applicability of published studies to VA patients is reasonably good. Costs, however, from non-VA institutions cannot be assumed to be applicable to VA settings.

- Studies report short-term effectiveness and resource utilization favoring endovascular therapy, but most were not statistically significant.
- Long-term outcomes were more mixed; mortality favored surgery, although concluding cause-and-effect is not possible since endovascularly-treated patients tended to be older, and may have had a shorter life expectancy regardless of therapy.
- Therefore....we conclude:
  - Clinical effectiveness and resource utilization of surgery compared to endovascular approach for critical limb ischemia is not known and won't be known until ongoing trials report results.
  - It is likely that findings will vary by time horizon, where initial outcomes and utilization tend to favor endovascular interventions, but long-term outcomes favor surgery.

# Questions?

If you have further questions, please feel free to contact:

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Full-length report and cyberseminar available on ESP website:

<http://www.hsrd.research.va.gov/publications/esp/>