



Virginia Mason™

# Vascular Surgery During COVID

Derek Nathan, MD

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December 2021

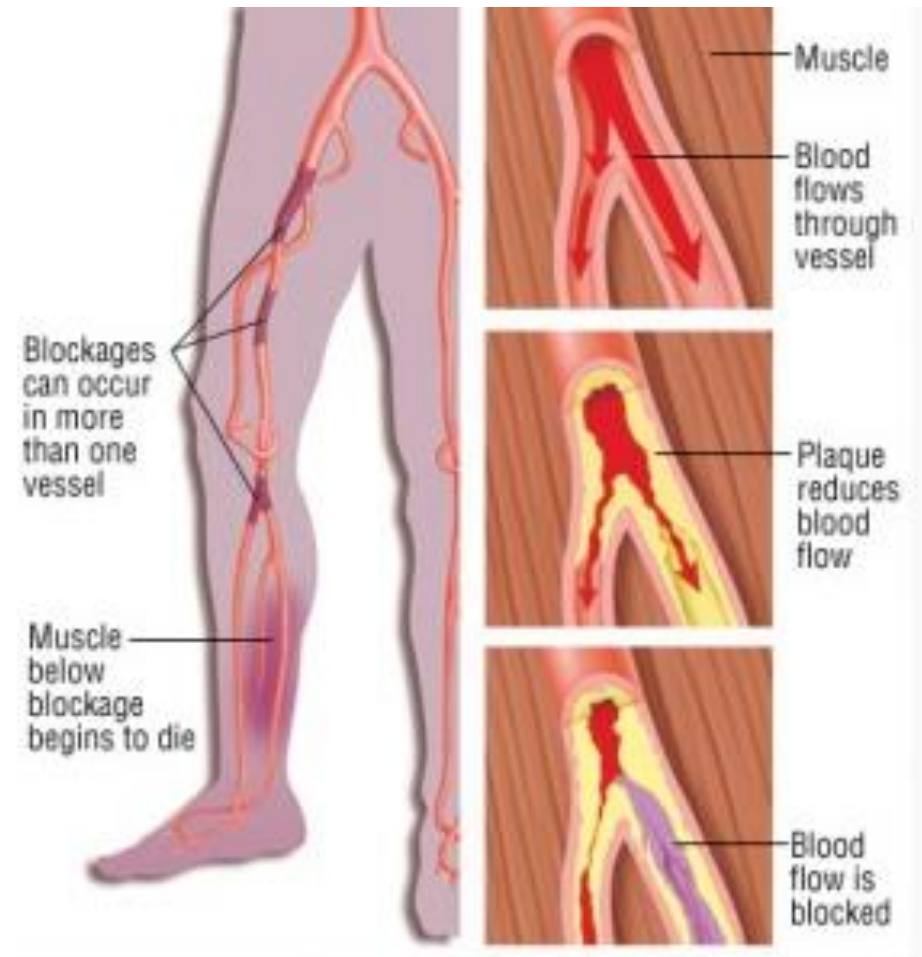
# Virginia Mason Vascular Surgery

- Dr. Damon Pierce
- Dr. Derek Nathan
- Dr. Matthew Bennett



# Outline: Vascular Surgery During COVID

- Carotid stenosis
- Aortic aneurysms
- Peripheral arterial disease



# Vascular Surgery During COVID

	hemorrhagic shock, or impending rupture	
	Revascularization for high grade re-stenosis of previous intervention	2b Postpone if possible
	Asymptomatic bypass graft /stent restenosis	1 postpone
Carotid	Symptomatic Carotid Stenosis: CEA and TCAR	3 Do not postpone
	Asymptomatic carotid artery stenosis	1 Postpone
Dialysis	Thrombosed or nonfunctional dialysis access	3 Do not postpone
	Infected dialysis access	3 Do not postpone
	Fistula Revision for Ulceration	3 Do not postpone
	Renal failure with need for dialysis access	3 Do not postpone
	Tunneled Dialysis Catheter	3 Do not postpone
	Fistula Revision for Malfunction/steal	2b Postpone if possible
	Fistulagram for malfunction	2b Postpone if possible
	AV fistula and graft placement for dialysis (ESRD, CK4, and CK5 only)	2a Consider postponing
Mesenteric	Symptomatic acute mesenteric occlusive disease	3 Do not postpone
	Chronic mesenteric ischemia	2b Postpone if possible
PVD	Acute limb ischemia	3 Do not postpone
	Limb Ischemia: Progressive tissue loss, acute limb ischemia, wet gangrene, ascending cellulitis	3 Do not postpone
	Fasciotomy for compartment syndrome	3 Do not postpone
	Peripheral Vascular Disease: Chronic limb threatening ischemia - rest pain or tissue loss	2b Postpone if possible
	Peripheral Angiograms and endovascular therapy for Claudication	1 Postpone

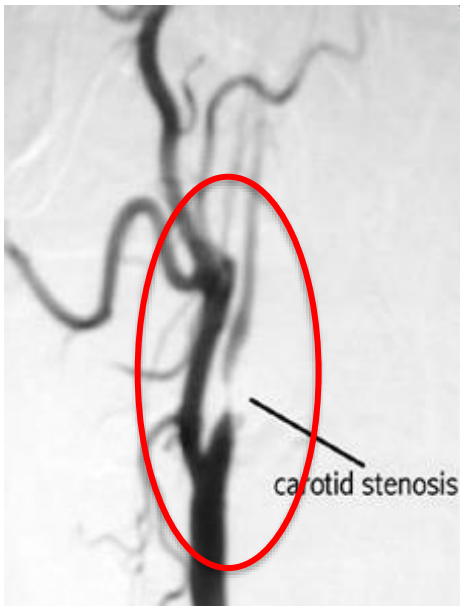


# COVID: Carotid Stenosis

- Do Not Postpone:
  - Symptomatic carotid stenosis
- Postpone:
  - Asymptomatic carotid stenosis

# Carotid Disease: Pathophysiology

- **Cerebrovascular Disease → Stroke**
- Sudden interruption of blood flow to the brain
  - Embolus / Thrombosis of cerebral artery
  - Hemorrhage



# Carotid Stenosis: Asymptomatic Disease

## Original Contributions

## Endarterectomy for Asymptomatic Carotid Artery Stenosis

Table 3.—Number of Observed Events in Median 2.7-Year Follow-up, Estimated Number and Percentage of Events in 5 Years, Reduction Due to Surgery in 5-Year Risk as a Proportion of Risk in the Medical Group (95% CI), and Large-Sample *P* Value for Treatment Group Difference, by Event Type\*

Event Type	Medical (n=834)		Surgical (n=825)		Reduction Due to Surgery in 5-y Risk as a Proportion of Risk in Medical Group (95% CI)	P
	Observed No. of Events in Median 2.7-y Follow-up	Kaplan-Meier Estimate of 5-y Event Risk, No. (%)	Observed No. of Events in Median 2.7-y Follow-up	Kaplan-Meier Estimate of 5-y Event Risk, No. (%)		
Ipsilateral stroke or any perioperative stroke or death	52	92 (11.0)	33	42 (5.1)	0.53 (0.22 to 0.72)	.004
Major ipsilateral stroke or any perioperative major stroke or death	24	50 (6.0)	21	28 (3.4)	0.43 (−0.17 to 0.72)	.12
Ipsilateral TIA or stroke or any perioperative TIA or stroke or death	102	160 (19.2)	55	67 (8.2)	0.57 (0.39 to 0.70)	<.001
Any stroke or any perioperative death	86	146 (17.5)	60	102 (12.4)	0.29 (−0.05 to 0.52)	.09
Any major stroke or perioperative death	40	76 (9.1)	28	53 (6.4)	0.30 (−0.30 to 0.62)	.26
Any stroke or death	155	266 (31.9)	127	211 (25.6)	0.20 (−0.02 to 0.37)	.08
Any major stroke or death	116	213 (25.5)	100	171 (20.7)	0.19 (−0.08 to 0.39)	.16

\*CI indicates confidence interval; and TIA, transient ischemic attack.

**Conclusion.**—Patients with asymptomatic carotid artery stenosis of 60% or greater reduction in diameter and whose general health makes them good candidates for elective surgery will have a reduced 5-year risk of ipsilateral stroke if carotid endarterectomy performed with less than 3% perioperative morbidity and mortality is added to aggressive management of modifiable risk factors.

(*JAMA*. 1995;273:1421-1428)

tional review board approval of the study protocol.

### Recruitment

Study participants were recruited from ultrasound vascular laboratories, practitioners who auscultated carotid bruits, and physicians who found carotid steno-

# Carotid Stenosis: Asymptomatic Disease

- Patients with asymptomatic  $\geq 60\%$  stenosis can be referred for carotid endarterectomy
- Surgeons should have a low complication rate
- Modest benefit at 5 years
- Medical therapy was not optimal

# Carotid Stenosis: Asymptomatic Disease

From the Society for Vascular Surgery

## Carotid endarterectomy should not be based on consensus statement duplex velocity criteria



Jesse A. Columbo, MD,<sup>a</sup> Bjoern D. Suckow, MD, MS,<sup>a</sup> Claire L. Griffin, MD,<sup>b</sup> Jack L. Cronenwett, MD,<sup>a</sup> Philip P. Goodney, MD, MS,<sup>a</sup> Timothy G. Lukovits, MD,<sup>c</sup> Robert M. Zwolak, MD, PhD,<sup>a</sup> and Mark F. Fillinger, MD,<sup>a</sup> *Lebanon, NH; and Salt Lake City, Utah*

### ABSTRACT

**Objective:** Randomized trials support carotid endarterectomy (CEA) in asymptomatic patients with  $\geq 60\%$  internal carotid artery (ICA) stenosis. The widely referenced Society for Radiologists in Ultrasound Consensus Statement on carotid duplex ultrasound (CDUS) imaging indicates that an ICA peak systolic velocity (PSV)  $\geq 230$  cm/s corresponds to a  $\geq 70\%$  ICA stenosis, leading to the potential conclusion that asymptomatic patients with an ICA PSV  $\geq 230$  cm/s would benefit from CEA. Our goal was to determine the natural history stroke risk of asymptomatic patients who might have undergone CEA based on consensus statement PSV of  $\geq 230$  cm/s but instead were treated medically based on more conservative CDUS imaging criteria.

**Methods:** All patients who underwent CDUS imaging at our institution during 2009 were retrospectively reviewed. The year 2009 was chosen to ensure extended follow-up. Asymptomatic patients were included if their ICA PSV was  $\geq 230$  cm/s but less than what our laboratory considers a  $\geq 80\%$  stenosis by CDUS imaging (PSV  $\geq 430$  cm/s, end-diastolic velocity  $\geq 151$  cm/s, or ICA/common carotid artery PSV ratio  $\geq 7.5$ ). Study end points included freedom from transient ischemic attack (TIA), freedom from any stroke, freedom from carotid-etiology stroke, and freedom from revascularization.

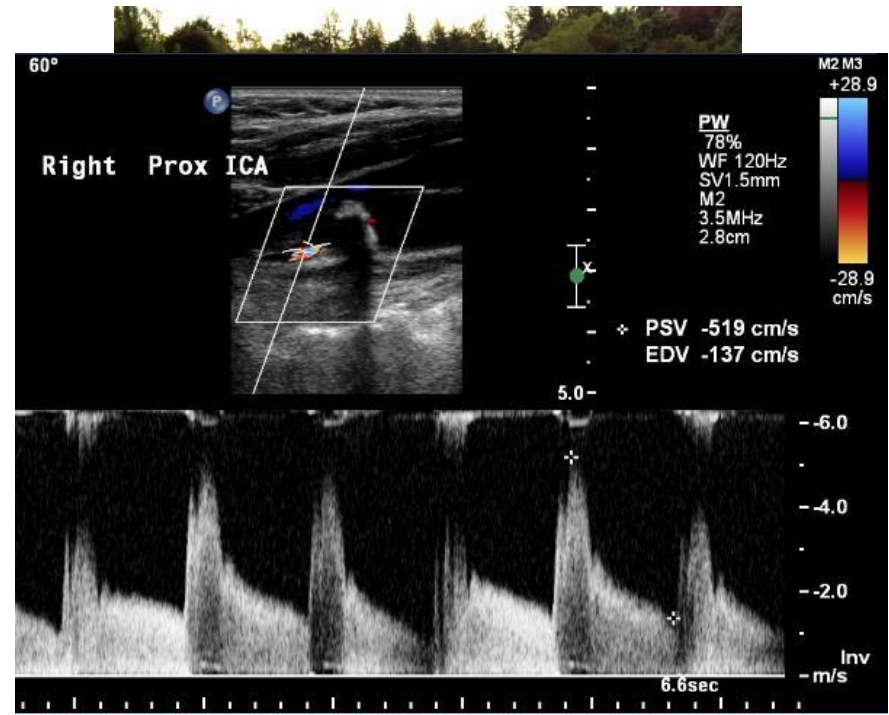
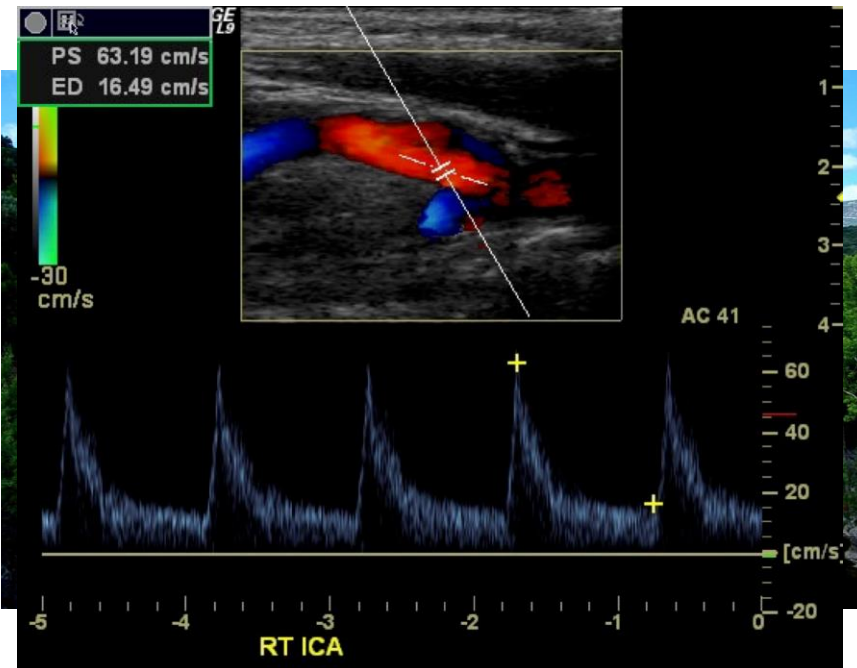
**Results:** Criteria for review were met by 327 patients. Mean follow-up was 4.3 years, with 85% of patients having  $>3$ -year follow-up. Four unheralded strokes occurred during follow-up at  $<1$ , 17, 25, and 30 months that were potentially attributable to the index carotid artery. Ipsilateral TIA occurred in 17 patients. An additional 12 strokes occurred that appeared unrelated to ipsilateral carotid disease, including hemorrhagic events, contralateral, and cerebellar strokes. Revascularization was undertaken in 59 patients, 1 for stroke, 12 for TIA, and 46 for asymptomatic disease. Actuarial freedom from carotid-etiology stroke was 99.7%, 98.4%, and 98.4% at 1, 3, and 5 years, respectively. Freedom from TIA was 98%, 96%, and 95%, freedom from any stroke was 99%, 96%, and 93%, and freedom from revascularization was 95%, 86%, and 81% at 1, 3, and 5 years, respectively.

**Conclusions:** Patients with intermediate asymptomatic carotid stenosis (ICA PSV 230-429 cm/s) do well with medical therapy when carefully monitored and intervened upon using conservative CDUS criteria. Furthermore, a substantial number of patients would undergo unnecessary CEA if consensus statement CDUS thresholds are used to recommend surgery. Current velocity threshold recommendations should be re-evaluated, with potentially important implications for upcoming clinical trials. (*J Vasc Surg* 2017;65:1029-38.)



# Carotid Stenosis

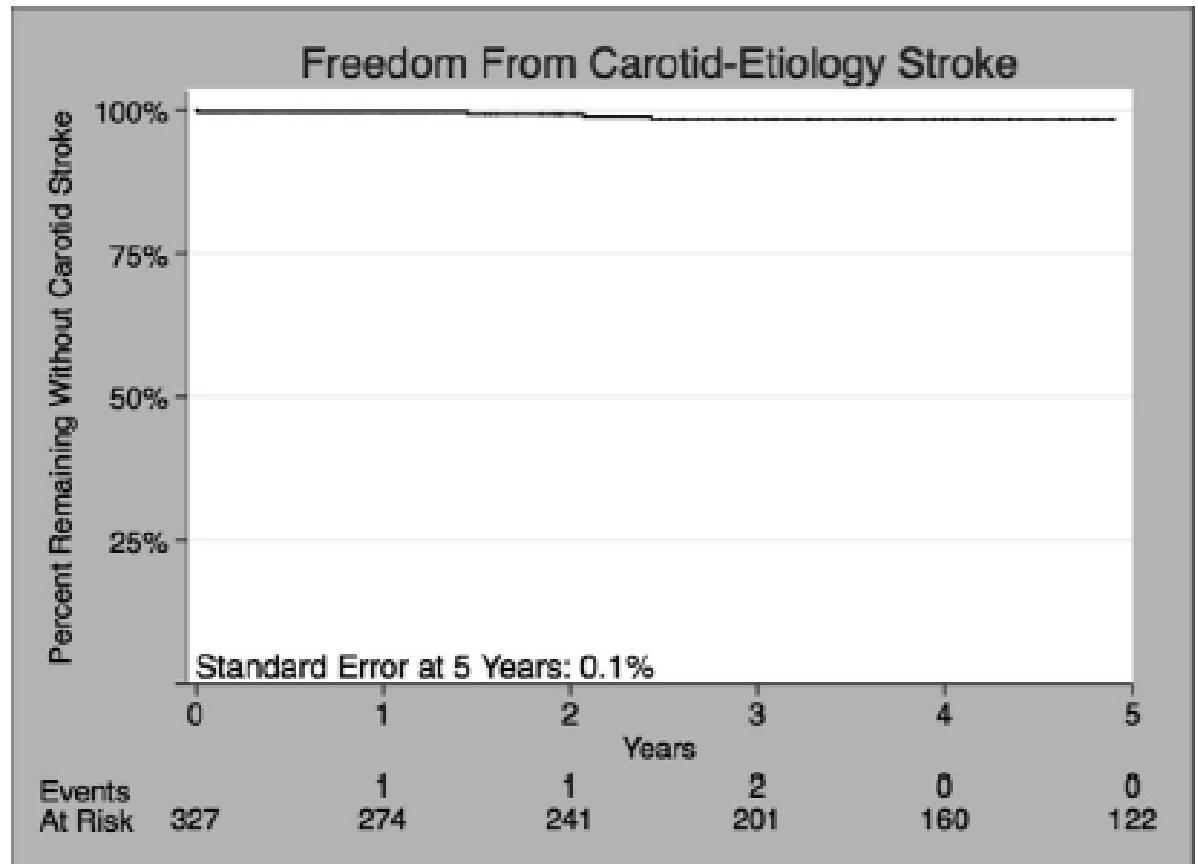
- Duplex Ultrasound



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# Carotid Stenosis: Asymptomatic Disease

- Using a higher threshold for surgery (> 80% stenosis)



**Fig 4.** The Kaplan-Meier survival estimate shows freedom from carotid-etiologic stroke during follow-up. The standard error is 0.1% at 5 years.



# Carotid Stenosis: Asymptomatic Disease

- Patients with asymptomatic  $\geq 80\%$  stenosis can be referred for carotid endarterectomy
  - Surgeons should have a low complication rate
  - Patients should have a good life expectancy
  - Ensure medical therapy optimization

# Carotid Stenosis: Asymptomatic Disease

- Number needed to treat to prevent one stroke for asymptomatic carotid disease = **20**

Incidence, outcomes, and effect on quality of life of

**Table II.** Resolution of cranial nerve injuries (CNIs) over time

<i>Type of injury</i>	<i>Present immediately post-op, No. (%)</i>	<i>Present at 1 month, No. (%)</i>	<i>Present at 12 months, No. (%)</i>
Hypoglossal (XII)	13 (24.5)	6 (11.3)	0 (0) <sup>a,b</sup>
Facial (VII)	16 (30.2)	10 (18.9)	3 (5.8)
Dysphagia/ hoarseness (IX, X)	22 (41.5)	18 (33.9)	6 (11.5) <sup>c</sup>
Horner syndrome	2 (3.8)	1 (1.9)	1 (1.9)
Any CNI	53 (100)	35 (66)	10 (19.2) <sup>d</sup>

factors were identified. Deficits resolved in 18 patients (34%) at 1 month and in 42 of 52 patients (80.8%) by 1 year. One patient died before the 1-year follow-up visit. The HRQOL evaluation showed no statistical difference between groups with and without CNI at any interval. By Likert scale analysis, the group with CNI showed a significant difference in the difficulty eating/swallowing parameter at 2 and 4 weeks ( $P < .001$ ) but not at 1 year.

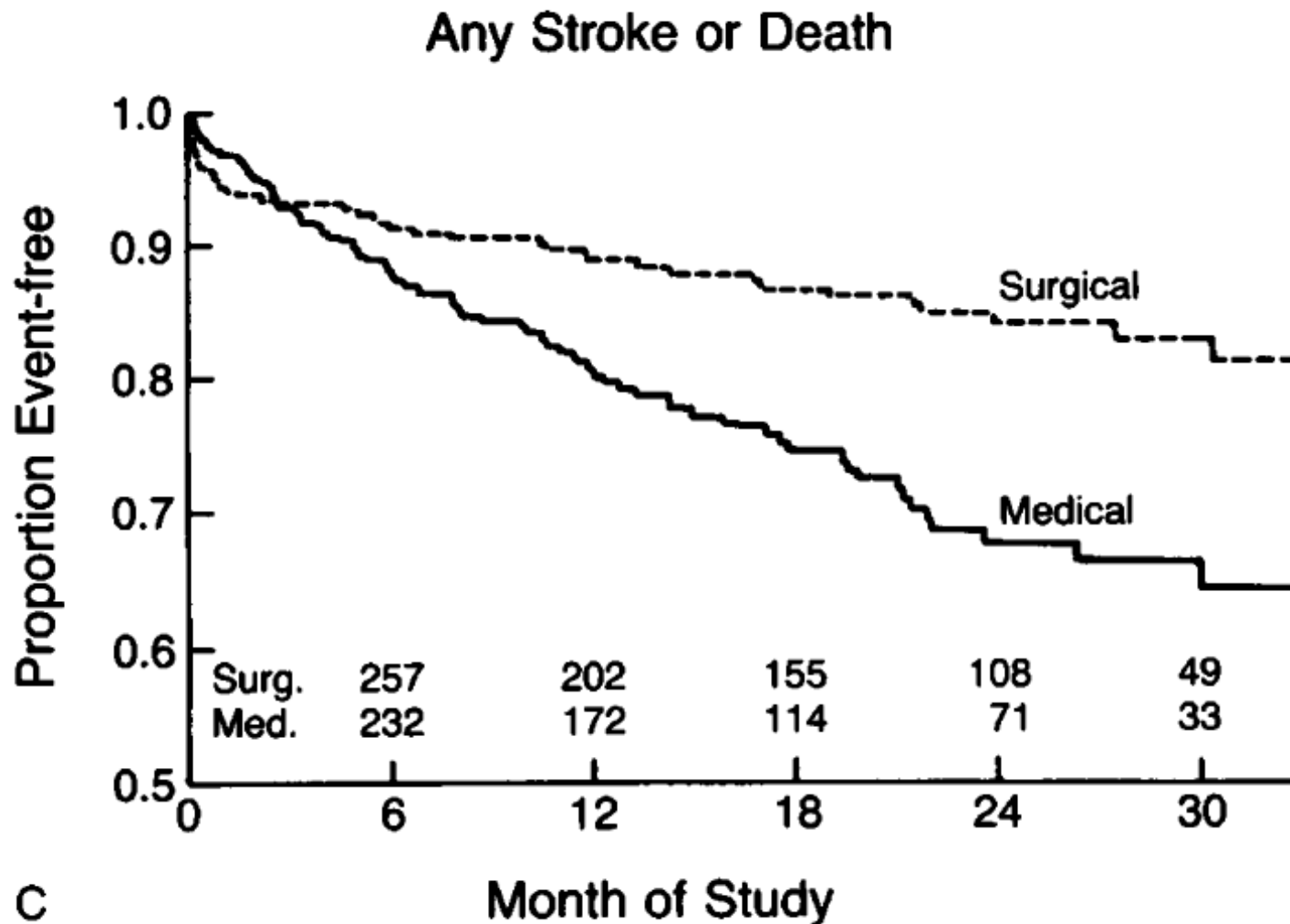
**Conclusions:** In CREST, CNI occurred in 4.6% of patients undergoing CEA, with 34% resolution at 30 days and 80.8% at 1 year. The incidence of CNI was significantly higher in patients undergoing general anesthesia. CNI had a small and transient effect on HRQOL, negatively affecting only difficulty eating/swallowing at 2 and 4 weeks but not at 1 year. On the basis of these findings, we conclude that CNI is not a trivial consequence of CEA but rarely results in significant long-term disability. (J Vasc Surg 2015;61:1208-15.)

- Cranial nerve injury rate of 4.6%

# Carotid Stenosis: Asymptomatic Disease

- Surgery is indicated
  - If surgical rate of complications is low
  - Patient has life expectancy of 5-10 years
  - Medical therapy is optimized
  - Goal is annual reduction of stroke risk

# Carotid Stenosis: Symptomatic Disease



# Carotid Stenosis: Symptomatic Disease

- General recommendation of carotid revascularization for severe symptomatic stenosis within **two weeks**

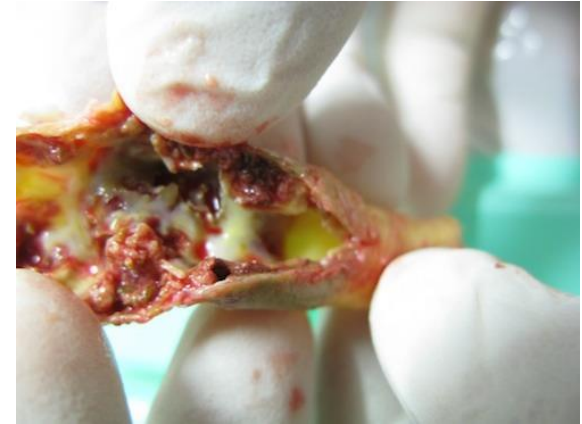
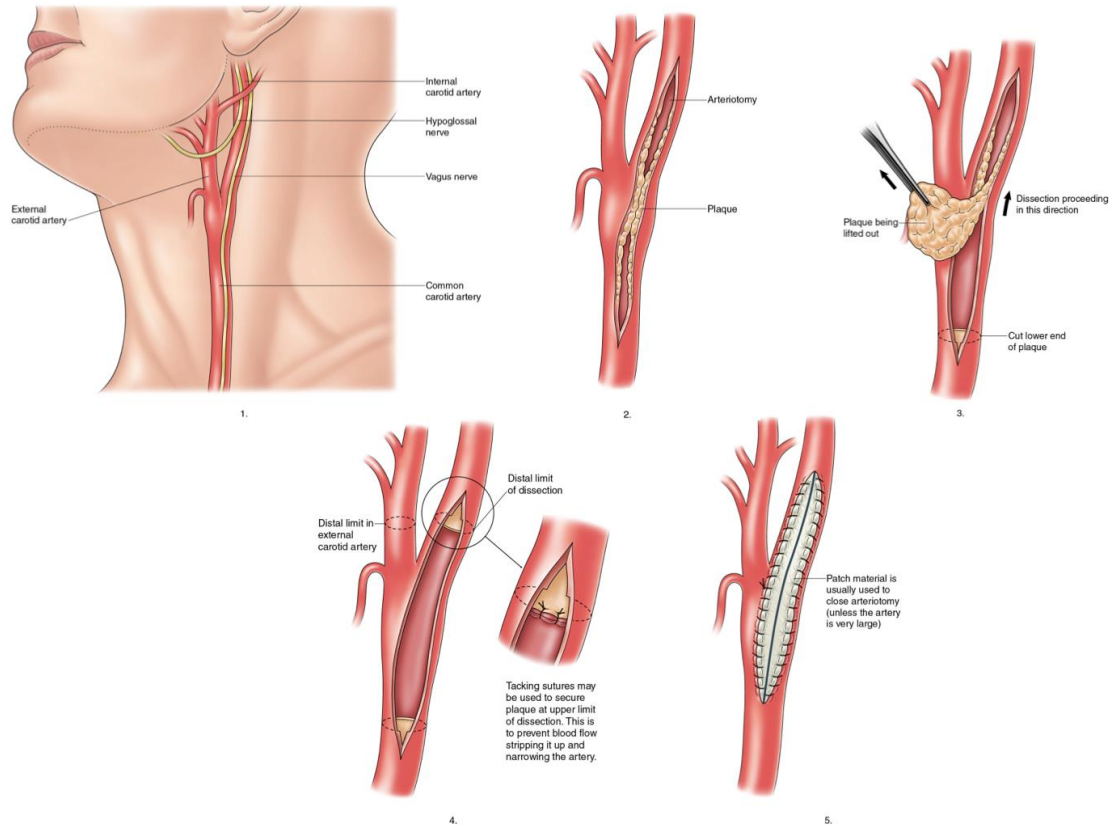
Time since randomisation	50–69% stenoses			70–99% stenoses			ALL 50–99% stenoses		
	ARR	NNT	CVA/1000	ARR	NNT	CVA/1000	ARR	NNT	CVA/1000
< 2 weeks	14.8	7	148	23.0	4	230	18.5	5	185
2–4 weeks	3.3	30	33	15.9	6	159	9.8	10	98
4–12 weeks	4.0	25	40	7.9	13	79	5.5	18	55
>12 weeks	-2.9	nil	nil	7.4	14	74	0.8	125	8

Data from Carotid Endarterectomy Trialist Collaboration (NASCET, ECST, and VA studies) Naylor AR, Eur J Vasc and Endovasc Surg 2008

# Symptomatic Carotid Stenosis

- Patients with symptomatic high-grade stenosis (70-99%) should undergo urgent carotid endarterectomy
  - Stroke reduction at two years is 9% versus 26%
- Surgeons should perioperative morbidity and mortality rates similar to those in trial

# Surgical Management

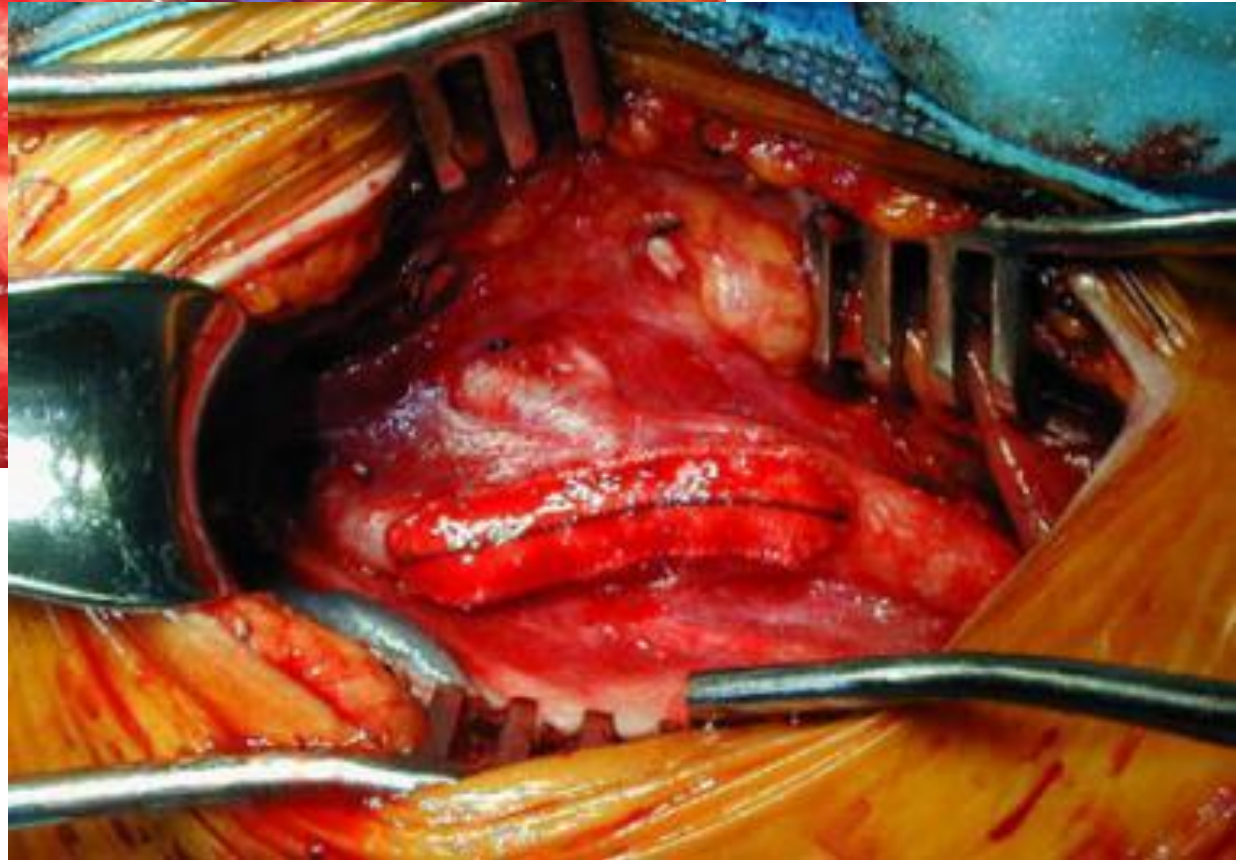
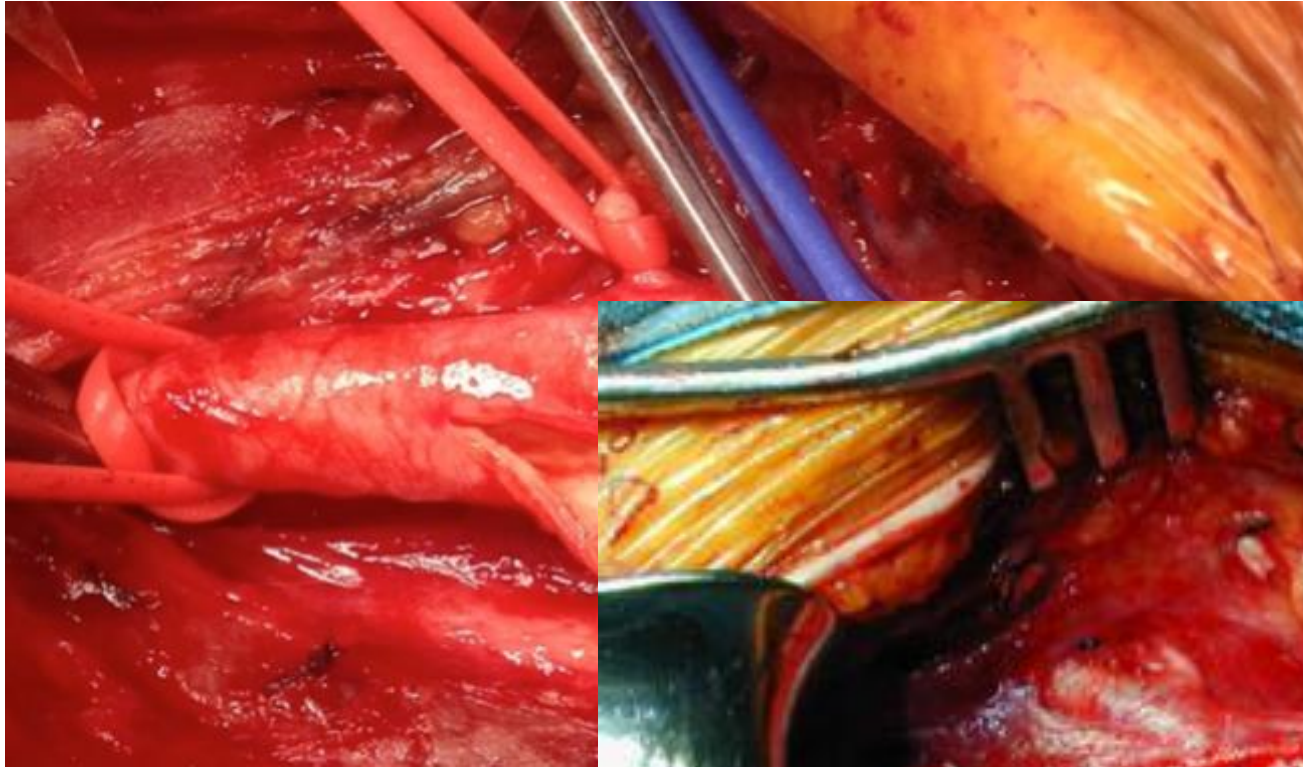


REMOVED CAROTID ARTERY PLAQUE

*c/o Vascutek UK*



# Surgical Management



# Surgical Management

- **Carotid Endarterectomy**
  - Typical 1 day hospitalization
    - ~90% home POD #1
    - Reason for >1d stay usually BP related
  - Post-op Follow-up
    - 1 , 6 , 12 , 18 , 24 months with duplex
    - Yearly thereafter

# Endovascular Management



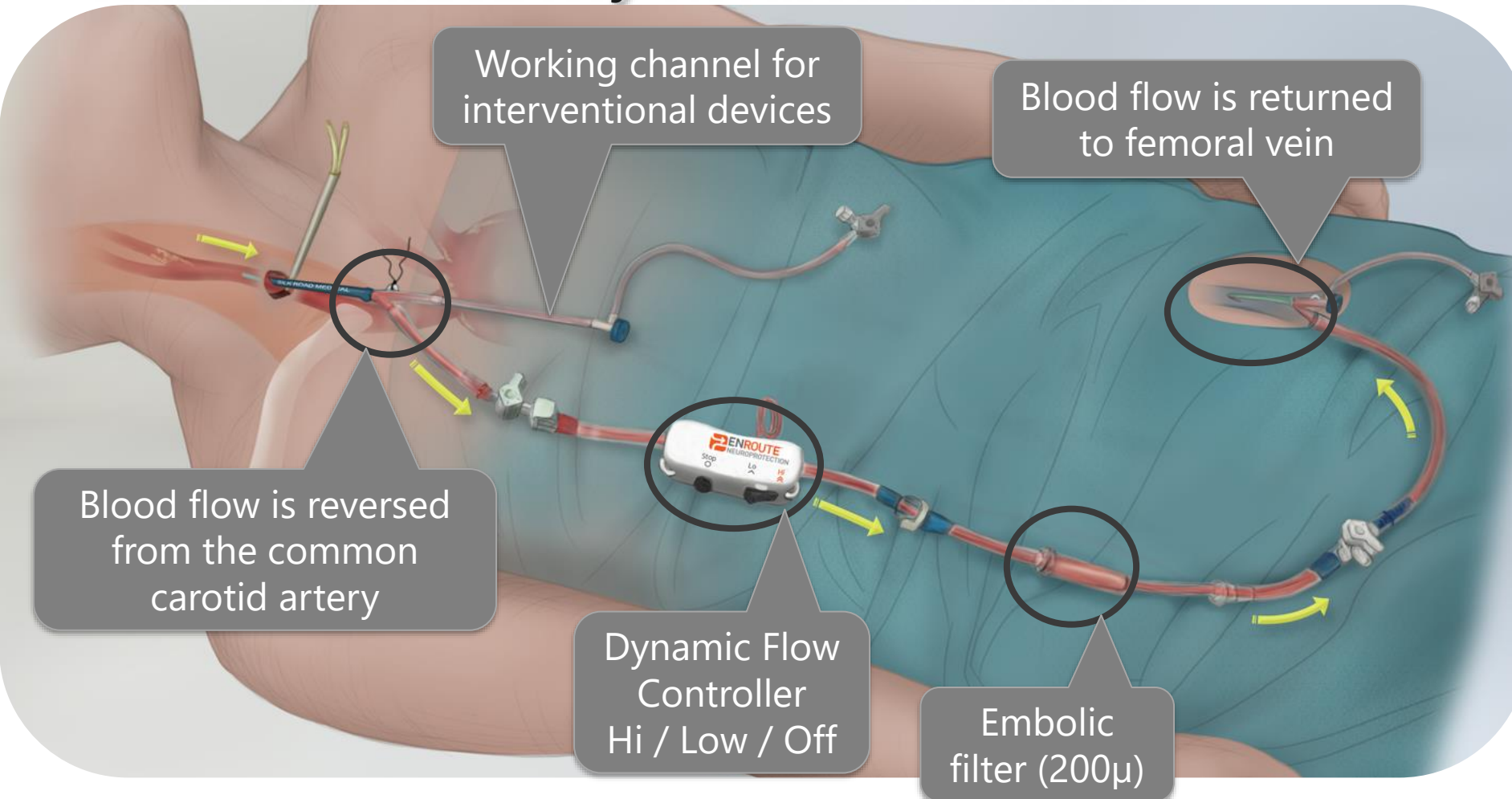
- Transfemoral filter-protected CAS\* requires 3 steps that create embolic risk
  1. Advancing a catheter through the aortic arch
  2. Navigating the lesion before neuroprotection established
  3. Inadequate neuroprotection from misaligned filters and manual extraction

# Carotid Stenting Versus Endarterectomy

- Stenting *vs.* CEA for Treatment of Carotid Artery Stenosis (***CREST Trial***)
  - *Symptomatic **and** Asymptomatic severe disease*
  - Randomized to stenting vs endarterectomy
  - 30-d stroke/death/MI rate 7.2% *vs.* 6.8%
  - **Ten Year Data equivocal**

# New Frontiers

## Trans Carotid Artery Revascularization





# New Frontiers

## Trans Carotid Artery Revascularization



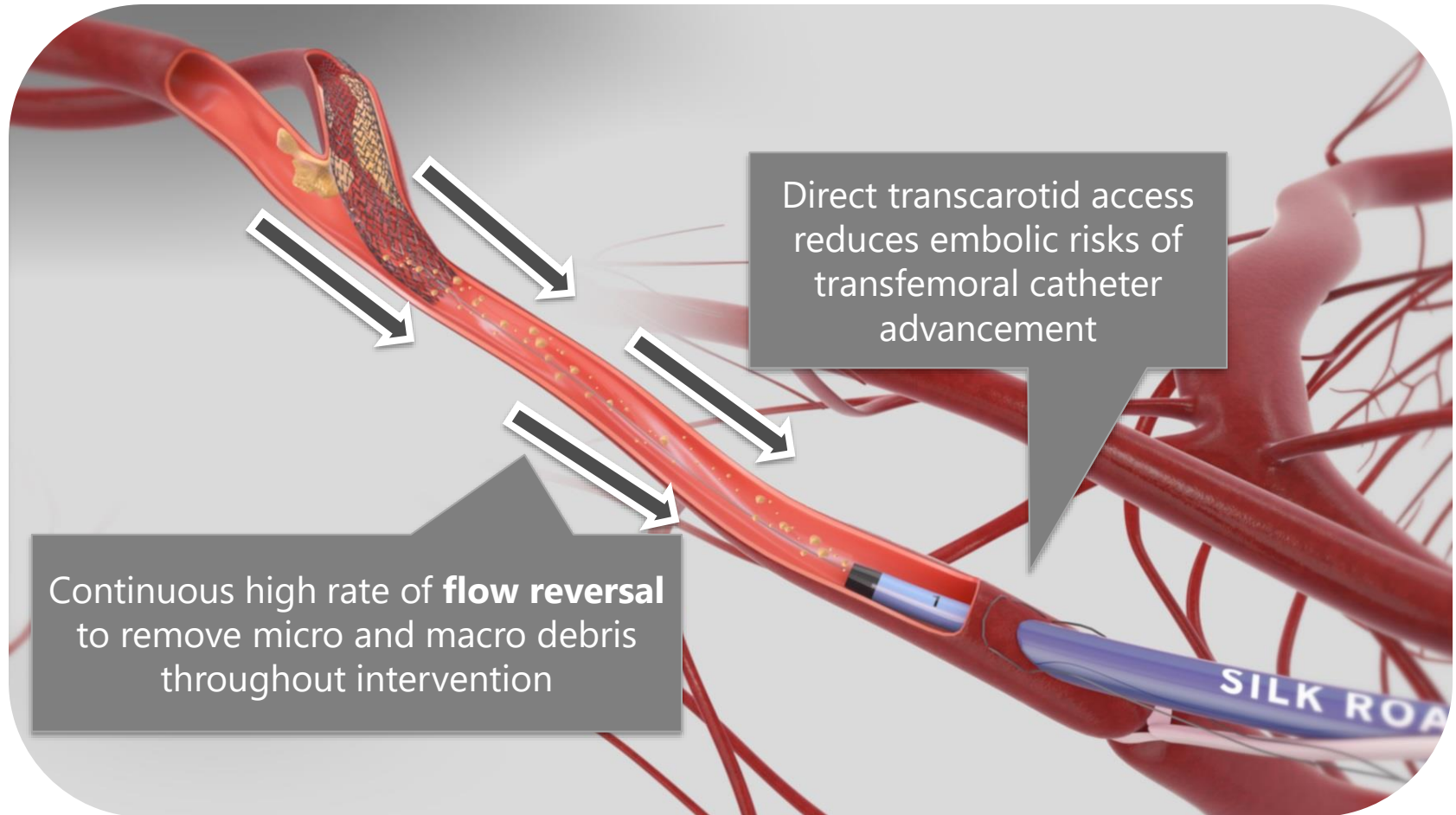
# New Frontiers

## Trans Carotid Artery Revascularization

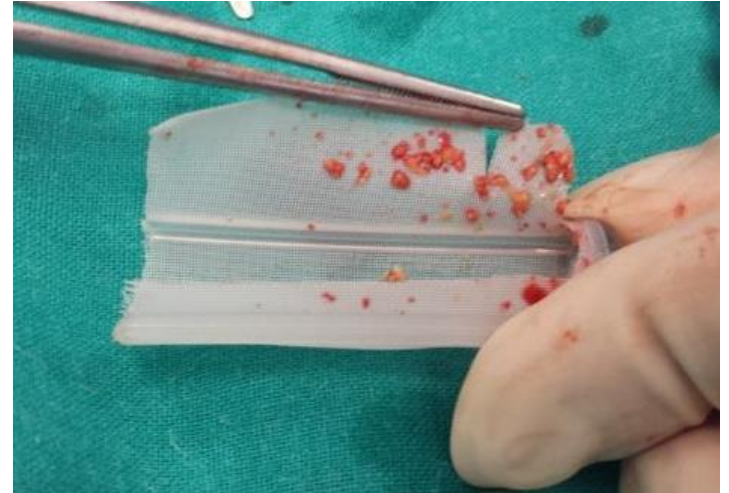
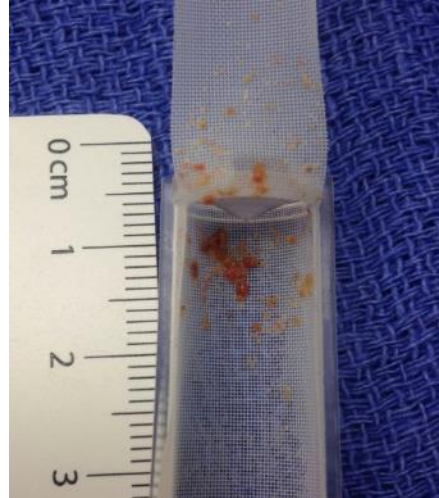
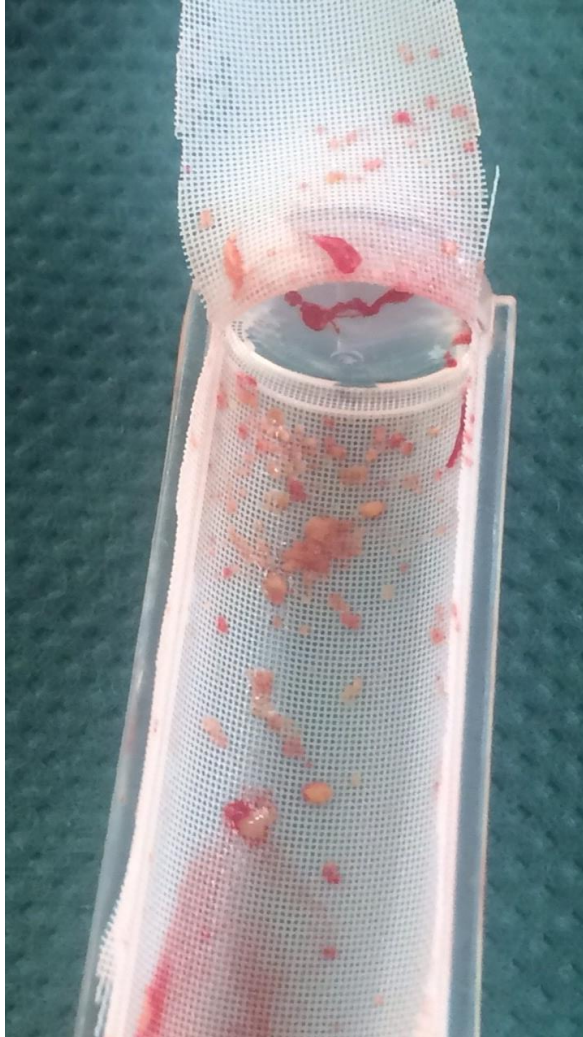




# New Frontiers

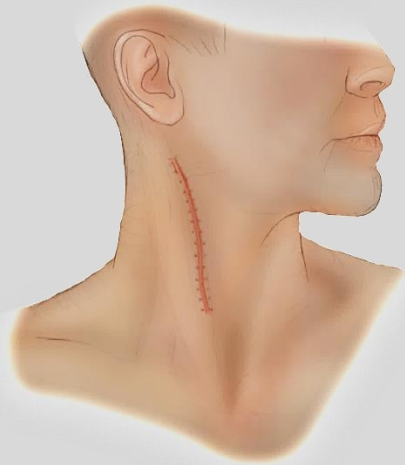


# New Frontiers

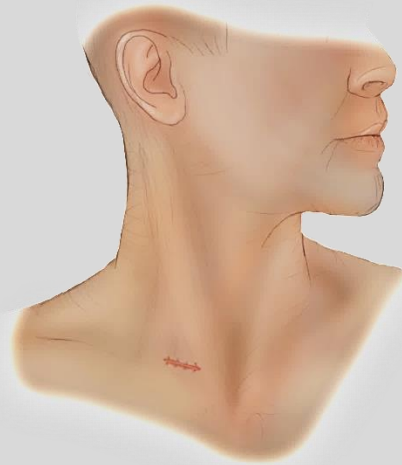




# New Frontiers



**CEA**



**TCAR**

**Reduced rate and severity of cranial nerve injury**

CREST – 2.1% unresolved at 6mths<sup>6</sup>  
ROADSTER – 0% unresolved at 6mths

Local anesthesia can improve recovery time

**Cosmetic result of a less invasive procedure**

Smaller scar in a less obvious location than with surgery



# New Frontiers

Demographics and Technical Results	
High Surgical Risk Pivotal ITT	ROADSTER (n=141)
Age	72.9 ±9 (40, 90)
Age ≥75	47%
Age ≥80	28%
Female	35%
Symptomatic	26%
Local Anesthesia	53%
Reverse Flow Time (median)	10 minutes
Acute Device Success	99%
Technical Success	99%
Procedural Success	96%

**Acute Device Success**

ENROUTE NPS delivered, reverse flow established, device removed from vasculature.

**Technical Success:**

Acute Device Success with successful introduction of interventional tools.

**Procedure Success**

Technical Success without the occurrence of MAE 30-days post procedure.

of a physician. Please refer to package insert for indications,

Clinical Results		
High Surgical Risk Pivotal ITT	ROADSTER (n=141)	
S/D/MI*	5	3.5%
Major Stroke	0	0%
Minor Stroke	2	1.4%
Death	2	1.4%
MI	1	0.7%
Stroke & Death	4	2.8%
Cranial Nerve Injury	1	0.7%
CNI Unresolved 6 mths	0	0.0%
*Hierarchical	Primary Endpoint All stroke, MI & death at 30-days	



# New Frontiers



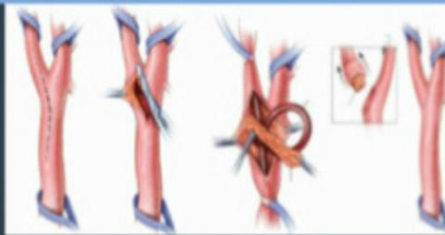
CREST-2 offers three  
***STROKE PREVENTION OPTIONS***

1



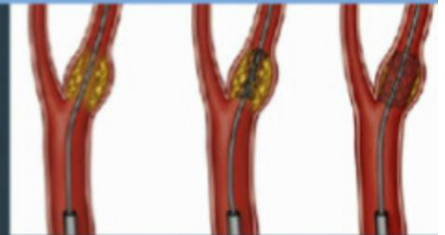
Medical Management

2



Carotid Endarterectomy  
+ Medical Management

3



Carotid Artery Stenting  
+ Medical Management

# Vascular Surgery During COVID



AMERICAN COLLEGE OF SURGEONS

Inspiring Quality:  
Highest Standards, Better Outcomes

100+years

## COVID 19: Elective Case Triage Guidelines for Surgical Care

### Vascular Surgery

Category	Condition	Tier Class
AAA	Ruptured or symptomatic TAAA or AAA	3 Do not postpone
	Aneurysm associated w/infection or Prosthetic graft infection	3 Do not postpone
	AAA > 6.5 cm	2b Postpone if possible
	TAAA > 6.5 cm	2b Postpone if possible
	AAA < 6.5 cm	1 Postpone
Aneurysm peripheral	Peripheral aneurysm, Symptomatic	3 Do not postpone
	Peripheral aneurysm, Asymptomatic	2a Consider postponing
	Pseudoaneurysm Repair: Not candidate for thrombin injection or compression, rapidly expanding, complex	3 Do not postpone
	Symptomatic non-aortic intra-abdominal aneurysm	3 Do not postpone
	Asymptomatic non-aortic intra-abdominal aneurysm	2a Consider postponing
Aortic Dissection	Acute aortic dissection with rupture or malperfusion	3 Do not postpone
Aortic emergency NOS	AEF with septic/hemorrhagic shock, or signs of impending rupture	3 Do not postpone
Bypass graft complications	Infected arterial prosthesis without overt sepsis, or	3 Do not postpone

# Abdominal Aortic Aneurysms (AAA)

- Do NOT Postpone
  - Ruptured or symptomatic AAA
  - Infected AAA
- Postpone if possible
  - AAA > 6.5 cm
- **Postpone**
  - AAA < 6.5 cm



# COVID: Abdominal Aortic Aneurysms (AAA)

- Abdominal aortic aneurysm rupture is 15<sup>th</sup> leading cause of death overall and 10<sup>th</sup> leading cause of death in men older than 55 years



# AAA Natural History

- VA study (n=200)
- Patients with  $\geq$  5.5 cm AAA at prohibitive risk of or refused repair

## Rupture Rate of Large Abdominal Aortic Aneurysms in Patients Refusing or Unfit for Elective Repair

Frank A. Lederle, MD

Gary R. Johnson, MS

Samuel E. Wilson, MD

David J. Ballard, MD, PhD

William D. Jordan, Jr, MD

John Blebea, MD

Fred N. Littooy, MD

Julie A. Freischlag, MD

Dennis Bandyk, MD

Joseph H. Rapp, MD

Atef A. Salam, MD

for the Veterans Affairs Cooperative Study #417 Investigators

**R**UPTURE OF ABDOMINAL AORTIC aneurysm (AAA) can be prevented by elective surgical repair, but because most AAA never rupture,<sup>1</sup> elective repair is re-

**Context** Among patients with abdominal aortic aneurysm (AAA) who have high operative risk, repair is usually deferred until the AAA reaches a diameter at which rupture risk is thought to outweigh operative risk, but few data exist on rupture risk of large AAA.

**Objective** To determine the incidence of rupture in patients with large AAA.

**Design and Setting** Prospective cohort study in 47 Veterans Affairs medical centers.

**Patients** Veterans (n=198) with AAA of at least 5.5 cm for whom elective AAA repair was not planned because of medical contraindication or patient refusal. Patients were enrolled between April 1995 and April 2000 and followed up through July 2000 (mean, 1.52 years).

**Main Outcome Measure** Incidence of AAA rupture by strata of initial and attained diameter.

**Results** Outcome ascertainment was complete for all patients. There were 112 deaths (57%) and the autopsy rate was 46%. Forty-five patients had probable AAA rupture. The 1-year incidence of probable rupture by initial AAA diameter was 9.4% for AAA of 5.5 to 5.9 cm, 10.2% for AAA of 6.0 to 6.9 cm (19.1% for the subgroup of 6.5-6.9 cm), and 32.5% for AAA of 7.0 cm or more. Much of the increased risk of rupture associated with initial AAA diameters of 6.5-7.9 cm was related to the likelihood that the AAA diameter would reach 8.0 cm during follow-up, after which 25.7% ruptured within 6 months.

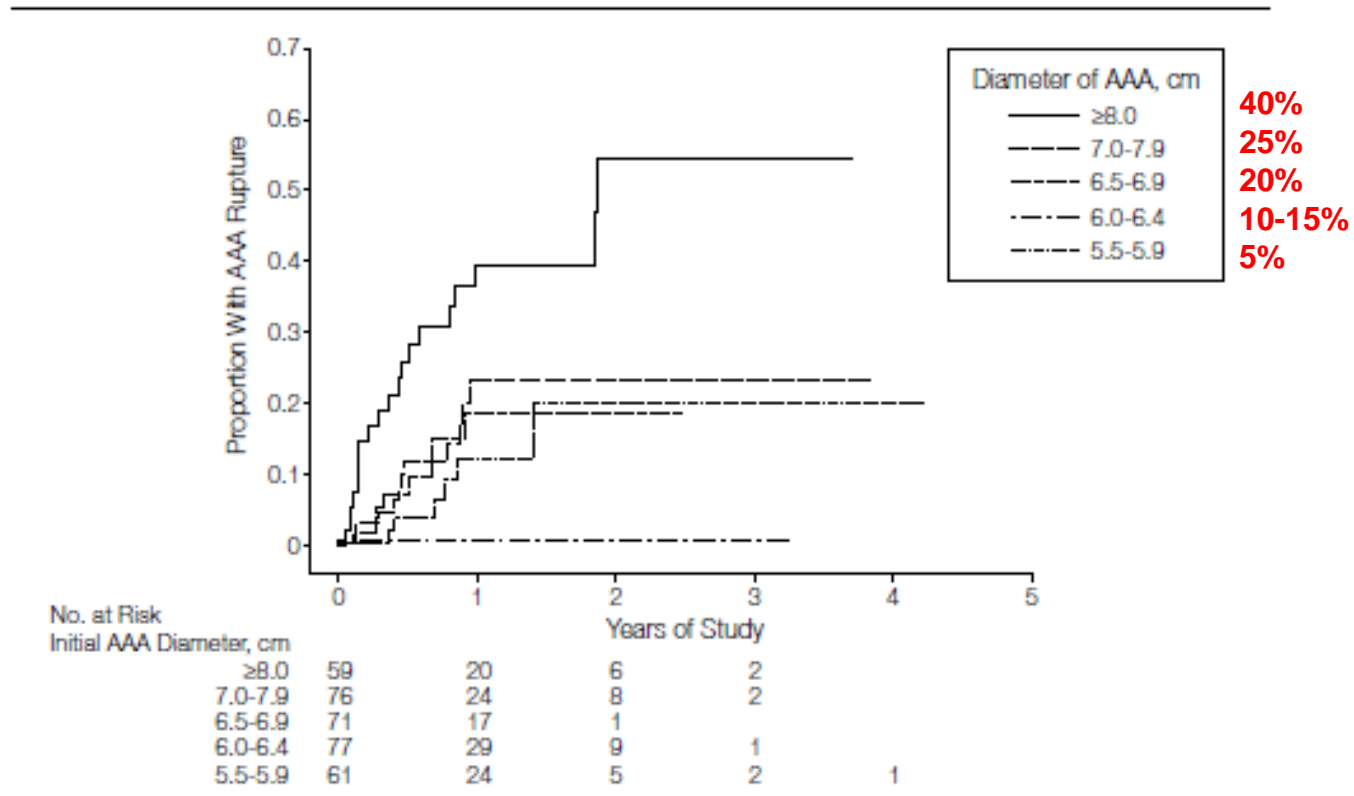
**Conclusion** The rupture rate is substantial in high-operative-risk patients with AAA of at least 5.5 cm in diameter and increases with larger diameter.

JAMA. 2002;287:2968-2972

www.jama.com

# AAA Natural History

- Annual rupture risk by aneurysm diameter



Patients could be evaluated in more than 1 stratum, but events are counted only once. The 6.0-6.4-cm and  $\geq 8.0$ -cm strata each differed significantly from all other strata (all  $P < .01$ ). The other 3 strata did not differ significantly from each other (all  $P > .20$ ).

# AAA Natural History

- VA population
- Older study from 2002
- What about more recent data?  
Different patient population?

# AAA Natural History

- Over 3000 patients with AAA that met size threshold for repair
  - > 5.5 cm men
  - > 5.0 cm women
- Kaiser Permanente Data

From the Western Vascular Society

## The natural history of large abdominal aortic aneurysms in patients without timely repair

Elizabeth M. Lancaster, MD, MAS,<sup>a</sup> Rebecca Gologorsky, MD,<sup>b</sup> Michaela M. Hull, MS,<sup>c</sup> Steven Okuhn, MD,<sup>d</sup> Matthew D. Solomon, MD, PhD,<sup>e,f</sup> Andrew L. Avins, MD, MPH,<sup>f,g</sup> John L. Adams, PhD,<sup>c</sup> and Robert W. Chang, MD,<sup>f,h</sup> *San Francisco, Oakland, Pasadena and South San Francisco, Calif*

### ABSTRACT

**Objective:** Contemporary data on the natural history of large abdominal aortic aneurysms (AAAs) in patients undergoing delayed or no repair are lacking. In this study, we examine the impact of large AAA size on the incidence of rupture and mortality.

**Methods:** From a prospectively maintained aneurysm surveillance registry, patients with an unrepaired, large AAA ( $\geq 5.5$  cm in men and  $\geq 5.0$  cm in women) at baseline (ie, index imaging) or who progressed to a large size from 2003 to 2017 were included, with follow-up through March 2020. Outcomes of interest obtained by manual chart review included rupture (confirmed by imaging/autopsy), probable rupture (timing/findings consistent with rupture without more likely cause of death), repair, reasons for either no or delayed (>1 year after diagnosis of large AAA) repair and total mortality. Cumulative incidence of rupture was calculated using a nonparametric cumulative incidence function, accounting for the competing events of death and aneurysm repair and was stratified by patient sex.

**Results:** Of the 3248 eligible patients (mean age,  $83.6 \pm 9.1$  years; 71.2% male; 78.1% white; and 32.0% current smokers), 1423 (43.8%) had large AAAs at index imaging, and 1825 progressed to large AAAs during the follow-up period, with a mean time to qualifying size of  $4.3 \pm 3.4$  years. In total, 2215 (68%) patients underwent repair, of which 332 were delayed >1 year; 1033 (32%) did not undergo repair. The most common reasons for delayed repair were discrepancy in AAA measurement between surgeon and radiologist (34%) and comorbidity (20%), whereas the most common reasons for no repair were patient preference (48%) and comorbidity (30%). Among patients with delayed repair (mean time to repair,  $2.6 \pm 1.8$  years), nine (2.7%) developed symptomatic aneurysms, and an additional 11 (3.3%) ruptured. Of patients with no repair, 94 (9.1%) ruptured. The 3-year cumulative incidence of rupture was 3.4% for initial AAA size 5.0 to 5.4 cm (women only), 2.2% for 5.5 to 6.0 cm, 6.0% for 6.1 to 7.0 cm, and 18.4% for >7.0 cm. Women with AAA size 6.1 to 7.0 cm had a 3-year cumulative incidence of rupture of 12.8% (95% confidence interval, 7.5%-19.6%) compared with 4.5% (95% confidence interval, 3.0%-6.5%) in men ( $P = .002$ ).

**Conclusions:** In this large cohort of AAA registry patients over 17 years, annual rupture rates for large AAAs were lower than previously reported, with possible increased risk in women. Further analyses are ongoing to identify those at increased risk for aneurysm rupture and may provide targeted surveillance regimens and improve patient counseling. (J Vasc Surg 2021; ■:1-9.)

**Keywords:** Abdominal aortic aneurysm; Aortic aneurysm rupture; Natural history

# AAA Natural History

- Low incidence of rupture

**Table V.** Cumulative incidence of confirmed and probable AAA rupture based on first large size

	12 months		24 months		36 months	
	%	95% CI	%	95% CI	%	95% CI
5.0 to 5.4 cm (women) n = 567	2.7	1.6-4.2	3.8	2.5-5.7	5.3	3.6-7.4
	389 at risk <sup>a</sup>		292 at risk <sup>a</sup>		207 at risk <sup>a</sup>	
5.5 to 6.0 cm n = 1576	1.7	1.2-2.5	2.5	1.9-3.4	3.1	2.3-4.1
	710 at risk <sup>a</sup>		469 at risk <sup>a</sup>		349 at risk <sup>a</sup>	
6.1 to 7.0 cm n = 669	5.1	3.6-6.9	6.1	4.5-8.1	6.9	5.1-9.0
	218 at risk <sup>a</sup>		142 at risk <sup>a</sup>		109 at risk <sup>a</sup>	
>7.0 cm n = 436	18.8	15.3-22.6	19.3	15.7-23.1	19.3	15.7-23.1
	47 at risk <sup>a</sup>		22 at risk <sup>a</sup>		17 at risk <sup>a</sup>	

AAA, Abdominal aortic aneurysm; CI, confidence interval.

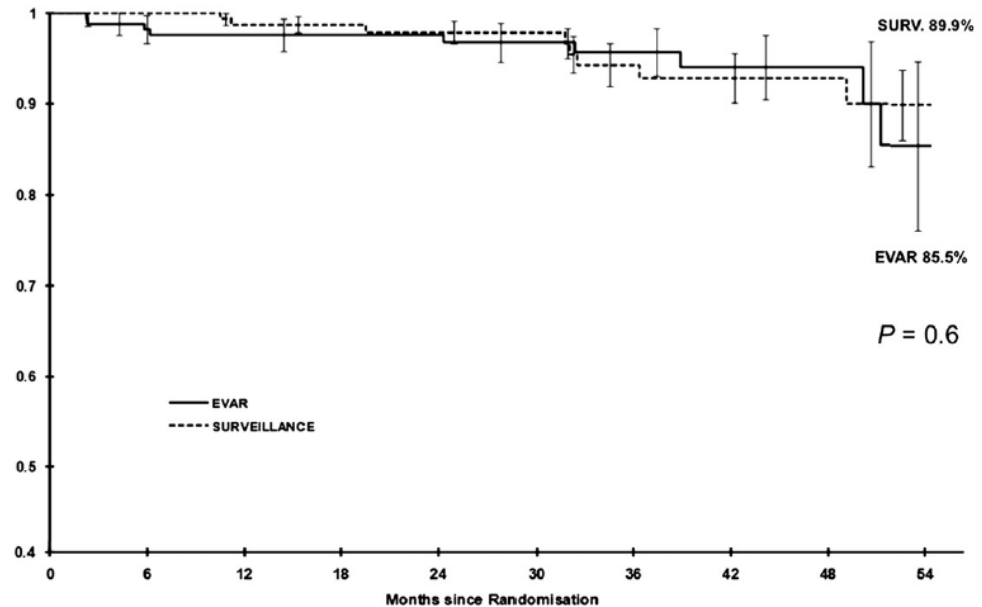
<sup>a</sup>Number of patients at risk at end of noted time period.



# AAA: Indications for Repair

- Size threshold
  - No benefit to endovascular repair of smaller (< 5.5 cm aneurysms)
  - Surveillance is required

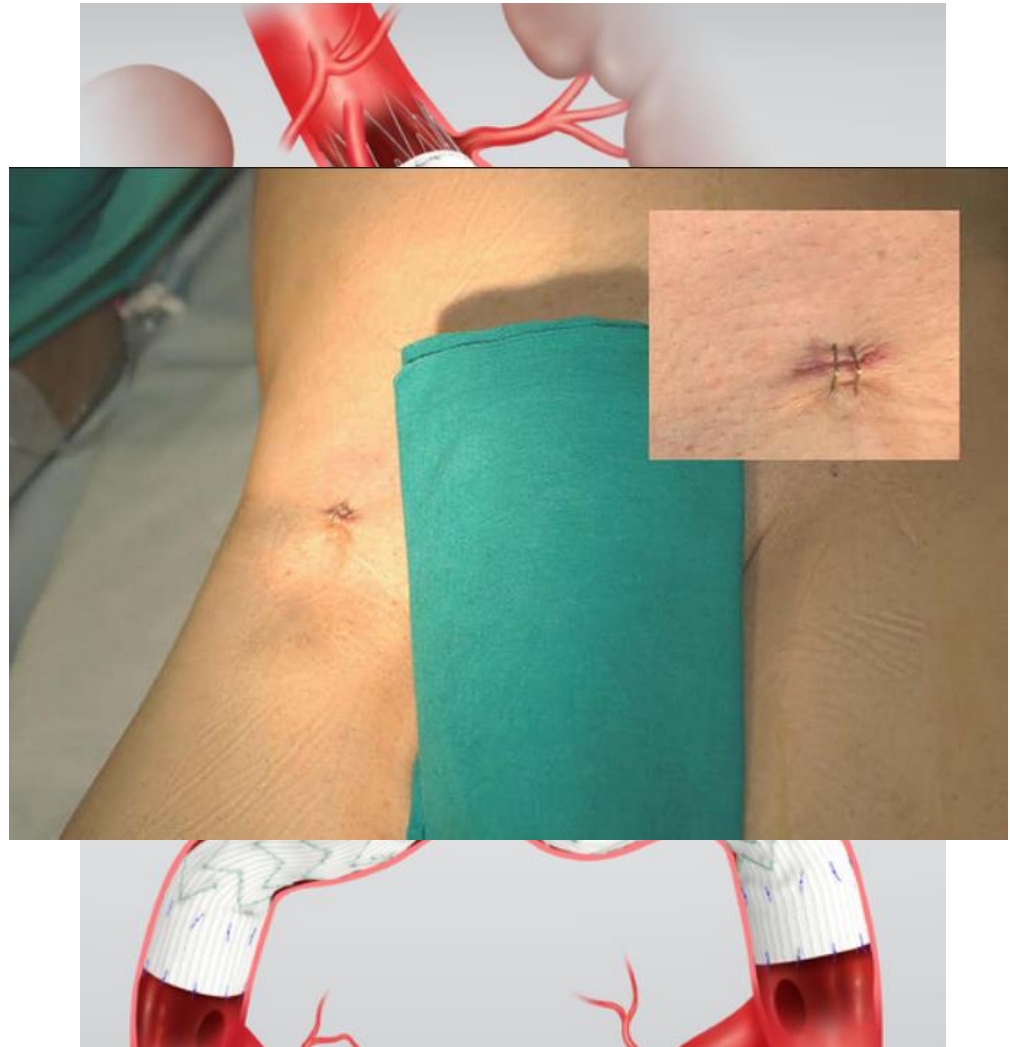
Eur J Vasc Endovasc Surg (2011) 41, 13–25



rysm-related mortality, aneurysm rupture and major morbidity rates were similar. Kaplan–Meier estimates of aneurysms growth  $\geq 5$  mm at 36 months were 8.4% in the EVAR group and 67.5% in the surveillance group (HR 10.49; 95% CI 6.88–15.96;  $p < 0.01$ ). For aneurysms under surveillance, the probability of delayed repair was 59.7% at 36 months (84.5% at 54 months). The probability of receiving open repair at 36 months for EVAR feasibility loss was 16.4%.  
**Conclusion:** Mortality and rupture rates in AAA  $< 5.5$  cm are low and no clear advantage was shown between early or delayed EVAR strategy. However, within 36 months, three out of every five small aneurysms under surveillance might grow to require repair and one out of every six might lose feasibility for EVAR.

# Abdominal Aortic Aneurysm and Repair

- Endovascular repair
  - Minimally invasive
  - Low morbidity and mortality



# Endovascular Versus Open Repair: 30-Day Outcomes

## Outcomes Following Endovascular vs Open Repair of Abdominal Aortic Aneurysm

A Randomized Trial

**Table 3.** All Outcome Measures

Outcomes	No. (%) of Patients		P Value
	Endovascular Repair (n = 444)	Open Repair (n = 437)	
All-cause mortality	31 (7.0)	43 (9.8)	.13
Before AAA repair	2 (0.5)	1 (0.2)	>.99
Within 30 d after repair	1 (0.2)	10 (2.3)	.006
Within 30 d after repair or during hospitalization	2 (0.5)	13 (3.0)	.004
AAA diameter <5.5 cm	1 (0.5)	5 (2.6)	.10
AAA diameter ≥5.5 cm	1 (0.4)	8 (3.2)	.02
After 30 d or hospitalization	27 (6.1)	29 (6.6)	.74

procedure and has been reported to reduce perioperative mortality, hospital stay, and intensive care unit (ICU) stay. However, more frequent reinterven-

needed to fully assess the relative merits of the 2 procedures.

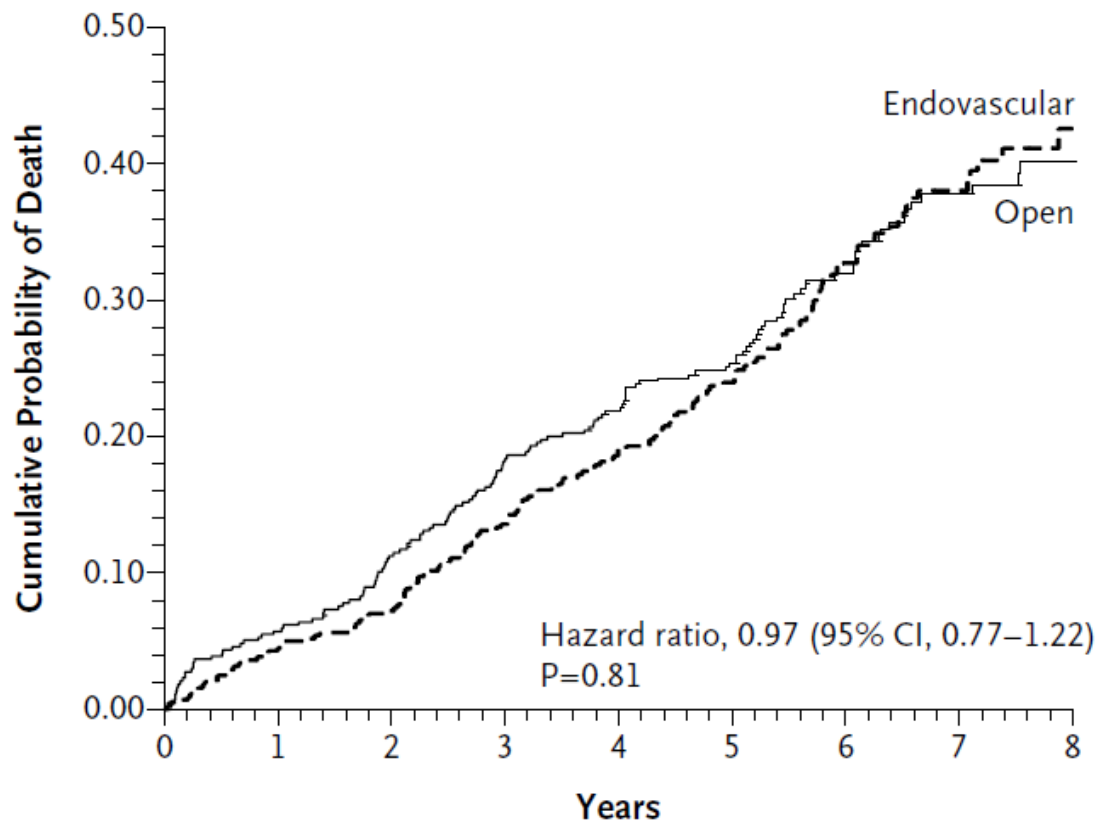
**Trial Registration** [clinicaltrials.gov](http://clinicaltrials.gov) Identifier: NCT00094575

*JAMA.* 2009;302(14):1535-1542

[www.jama.com](http://www.jama.com)

# Endovascular Versus Open Repair: Mid-Term Outcomes

- Mid-term outcomes of open repair versus endovascular therapy are similar



# Endovascular Versus Open Repair: Long-Term Outcomes

- In patients who survive beyond 8 years, open repair is superior



## Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial



Rajesh Patel, Michael J Sweeting, Janet T Powell, Roger M Greenhalgh, for the EVAR trial investigators\*

### Summary

Lancet 2016; 388:2366-74

Published Online

October 12, 2016

[http://dx.doi.org/10.1016/S0140-6736\(16\)31135-7](http://dx.doi.org/10.1016/S0140-6736(16)31135-7)

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\*The EVAR trial investigators are listed in the appendix

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See [Online](#) for appendix

**Background** Short-term survival benefits of endovascular aneurysm repair (EVAR) versus open repair of intact abdominal aortic aneurysms have been shown in randomised trials, but this early survival benefit is lost after a few years. We investigated whether EVAR had a long-term survival benefit compared with open repair.

**Methods** We used data from the EVAR randomised controlled trial (EVAR trial 1), which enrolled 1252 patients from 37 centres in the UK between Sept 1, 1999, and Aug 31, 2004. Patients had to be aged 60 years or older, have aneurysms of at least 5.5 cm in diameter, and deemed suitable and fit for either EVAR or open repair. Eligible patients were randomly assigned (1:1) using computer-generated sequences of randomly permuted blocks stratified by centre to receive either EVAR (n=626) or open repair (n=626). Patients and treating clinicians were aware of group assignments, no masking was used. The primary analysis compared total and aneurysm-related deaths in groups until mid-2015 in the intention-to-treat population. This trial is registered at ISRCTN (ISRCTN55703451).

**Findings** We recruited 1252 patients between Sept 1, 1999, and Aug 31, 2004. 25 patients (four for mortality outcome) were lost to follow-up by June 30, 2015. Over a mean of 12.7 years (SD 1.5; maximum 15.8 years) of follow-up, we recorded 9.3 deaths per 100 person-years in the EVAR group and 8.9 deaths per 100 person-years in the open-repair group (adjusted hazard ratio [HR] 1.11, 95% CI 0.97-1.27, p=0.14). At 0-6 months after randomisation, patients in the EVAR group had a lower mortality (adjusted HR 0.61, 95% CI 0.37-1.02 for total mortality; and 0.47, 0.23-0.93 for aneurysm-related mortality, p=0.031), but beyond 8 years of follow-up open-repair had a significantly lower mortality (adjusted HR 1.25, 95% CI 1.00-1.56, p=0.048 for total mortality; and 5.82, 1.64-20.65, p=0.0064 for aneurysm-related mortality). The increased aneurysm-related mortality in the EVAR group after 8 years was mainly attributable to secondary aneurysm sac rupture (13 deaths [7%] in EVAR vs two [1%] in open repair), with increased cancer mortality also observed in the EVAR group.

**Interpretation** EVAR has an early survival benefit but an inferior late survival compared with open repair, which needs to be addressed by lifelong surveillance of EVAR and re-intervention if necessary.

# Endovascular Versus Open Repair: Long-Term Outcomes

	Endovascular repair (N=626)		Open repair (N=626)		Hazard ratio (95% CI)		p value†
	n/N (%)	Rate per 100 person-years	n/N (%)	Rate per 100 person-years	Unadjusted	Adjusted*	
<b>Total mortality</b>							
All patients	466/626 (74%)	9.3	444/626 (71%)	8.9	1.05 (0.92-1.19)	1.11 (0.97-1.27)	0.14
0-6 months	26/626 (4%)	8.5	45/626 (7%)	15.0	0.57 (0.35-0.92)	0.61 (0.37-1.02)	0.06
>6 months to 4 years	126/600 (21%)	6.7	116/581 (20%)	6.3	1.07 (0.83-1.38)	1.13 (0.87-1.47)	0.35
>4-8 years	135/474 (28%)	8.3	129/464 (28%)	8.0	1.03 (0.81-1.31)	1.07 (0.83-1.37)	0.62
>8 years	179/339 (53%)	14.9	154/333 (46%)	12.7	1.18 (0.95-1.47)	1.25 (1.00-1.56)	0.048
<b>Aneurysm-related mortality</b>							
All patients	56/626 (9%)	1.1	45/626 (7%)	0.9	1.24 (0.84-1.83)	1.31 (0.86-1.99)	0.21
0-6 months	14/626 (2%)	4.6	30/626 (5%)	10.0	0.46 (0.24-0.87)	0.47 (0.23-0.93)	0.031
>6 months to 4 years	12/599 (2%)	0.6	8/581 (1%)	0.4	1.48 (0.60-3.62)	1.46 (0.56-3.83)	0.44
>4-8 years	14/474 (3%)	0.9	4/464 (1%)	0.2	3.46 (1.14-10.52)	3.11 (0.99-9.72)	0.05
>8 years	16/339 (5%)	1.3	3/333 (1%)	0.2	5.50 (1.60-18.89)	5.82 (1.64-20.65)	0.0064

\*Hazard ratios adjusted for age, sex, maximum aneurysm diameter, forced expiratory volume in 1 s, log creatinine, statin use, body-mass index, smoking status, systolic blood pressure and total cholesterol; 77 individuals excluded due to missing data. †p value adjusted for covariates.

**Table 1: Deaths from any cause and aneurysm-related causes, according to time since randomisation in the intention-to-treat population**



# Endovascular Aneurysm Repair and Unfit Patients

## Endovascular aneurysm repair and outcome in patients unfit for open repair of abdominal aortic aneurysm (EVAR trial 2): randomised controlled trial



*EVAR trial participants\**

### Summary

**Background** Endovascular aneurysm repair (EVAR) to exclude abdominal aortic aneurysm (AAA) was introduced for patients of poor health status considered unfit for major surgery. We instigated EVAR trial 2 to identify whether EVAR improves survival compared with no intervention in patients unfit for open repair of aortic aneurysm.

**Methods** We did a randomised controlled trial of 338 patients aged 60 years or older who had aneurysms of at least 5.5 cm in diameter and who had been referred to one of 31 hospitals in the UK. We assigned patients to receive either EVAR (n=166) or no intervention (n=172). Our primary endpoint was all-cause mortality, with secondary endpoints of aneurysm-related mortality, health-related quality of life (HRQL), postoperative complications, and hospital costs. Analyses were by intention to treat.

**Findings** 197 patients underwent aneurysm repair (47 assigned no intervention) and 80% of patients adhered to protocol. The 30-day operative mortality in the EVAR group was 9% (13 of 150, 95% CI 5–15) and the no intervention group had a rupture rate of 9.0 per 100 person years (95% CI 6.0–13.5). By end of follow up 142 patients had died, 42 of aneurysm-related factors; overall mortality after 4 years was 64%. There was no significant difference between the EVAR group and the no intervention group for all-cause mortality (hazard ratio 1.21, 95% CI 0.87–1.69, p=0.25). There was no difference in aneurysm-related mortality. The mean hospital costs per patient over 4 years were UK£13 632 in the EVAR group and £4983 in the no intervention group (mean difference £8649, SE 1248), with no difference in HRQL scores.

**Interpretation** EVAR had a considerable 30-day operative mortality in patients already unfit for open repair of their aneurysm. EVAR did not improve survival over no intervention and was associated with a need for continued surveillance and reinterventions, at substantially increased cost. Ongoing follow-up and improved fitness of these patients is a priority.

*Lancet* 2005; 365: 2187–92

Published online June 17, 2005  
DOI:10.1016/S0140-6736(05)66628-7

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\*Trial participants listed at end of EVAR trial 1<sup>10</sup>

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# Definition of “Unfit” for Surgery

## **Recommended guidelines for assessment of patient fitness for open repair and suitability for EVAR Trial 1 or 2**

Patient fitness for open repair is decided at the local level, however, these guidelines may provide some assistance.

### **Cardiac status**

Normally, patients presenting with the following cardiac symptoms would not be recommended for any surgical intervention:

- MI within last 3 months
- Onset of angina within the last 3 months
- Unstable angina at night or at rest

Normally, patients presenting with the following symptoms would be unsuitable for open repair (EVAR Trial 1) but may be suitable for EVAR Trial 2:

- Severe valve disease
- Significant arrhythmia
- Uncontrolled congestive cardiac failure

### **Respiratory status** (no constraints for EVAR Trial 2)

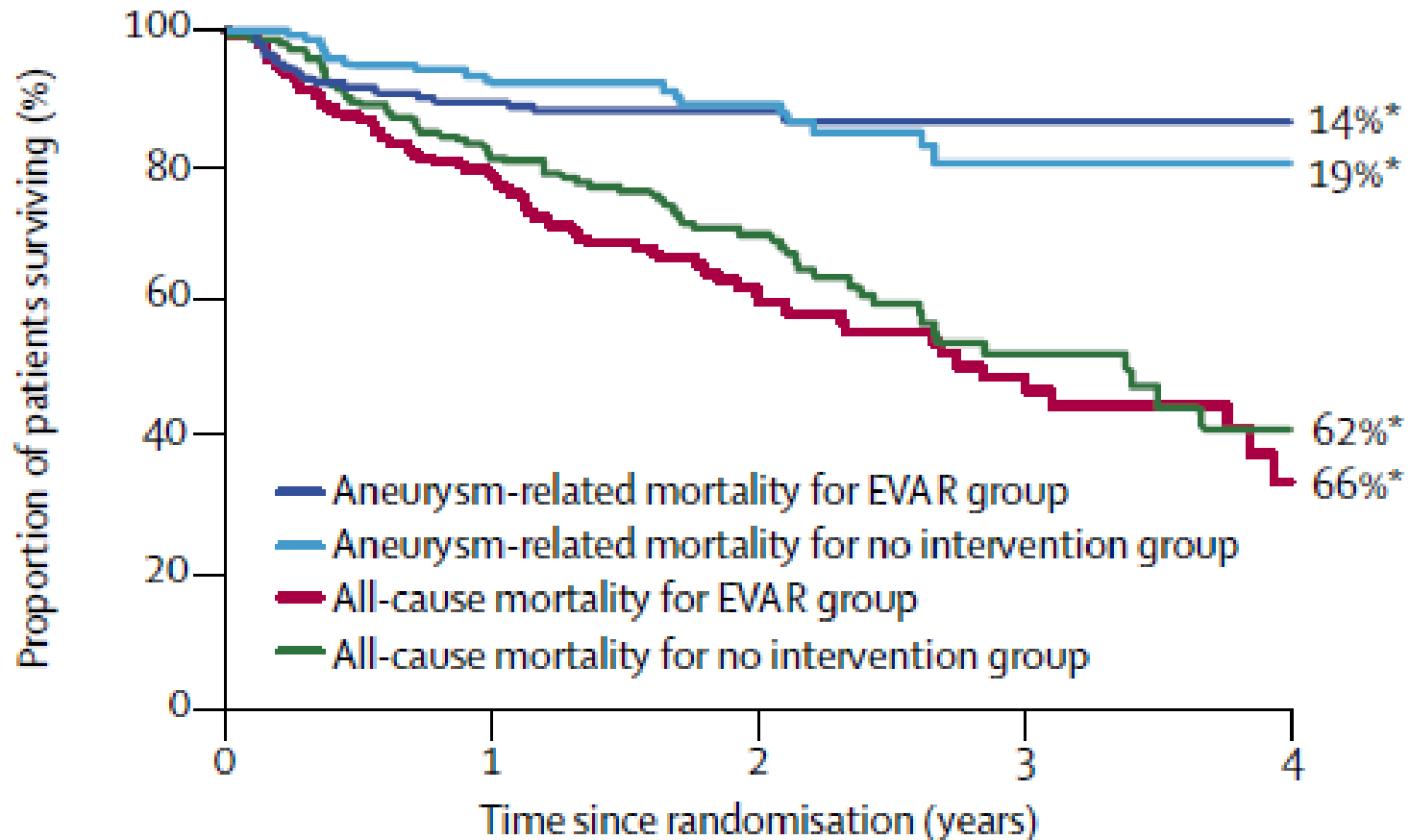
Open repair (EVAR Trial 1) would not be recommended for patients presenting with the following respiratory symptoms:

- Unable to walk up a flight of stairs without shortness of breath (even if there is some angina on effort).
- $FEV_1 < 1.0$  L
- $PO_2 < 8.0$  KPa
- $PCO_2 > 6.5$  KPa

### **Renal status** (no constraints for EVAR Trial 2)

Open repair might not be recommended for patients presenting with serum creatinine levels greater than  $200\mu\text{mol/L}$ . These patients may be suitable for EVAR Trial 2.

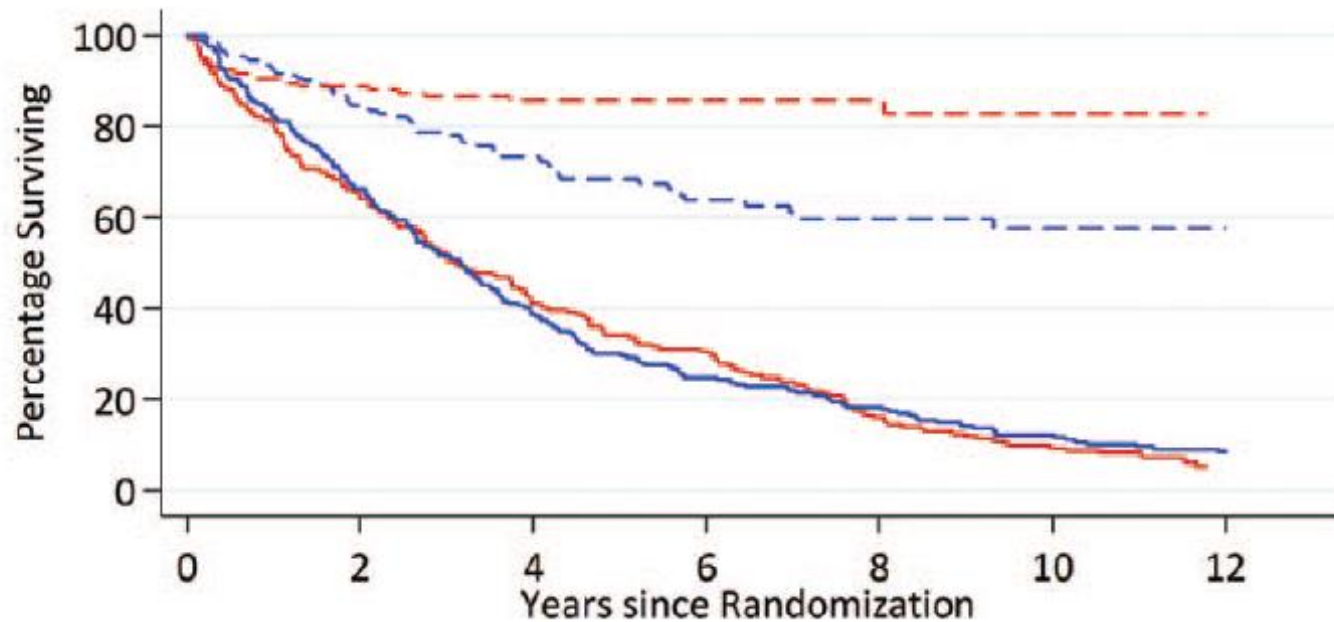
# Endovascular Aneurysm Repair and Unfit Patients



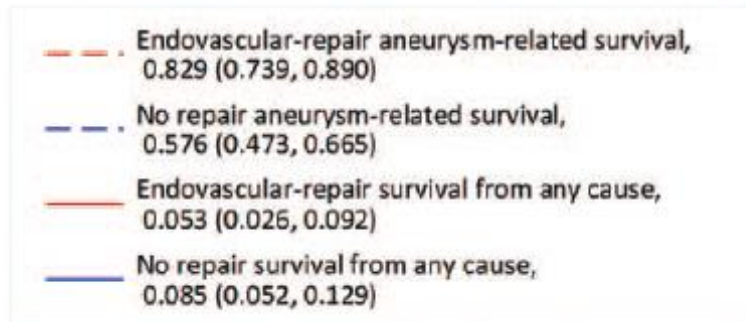
## Number at risk

	0	1	2	3	4
No intervention	172	139	71	29	9
EVAR	166	129	58	23	6

# Long-Term Data on EVAR and Unfit Patients



Number at risk		0	2	4	6	8	10	12
Endovascular repair	197	127	81	59	31	18	6	
No repair	207	137	80	51	38	25	15	



# Long-Term Data on EVAR and Unfit Patients

**TABLE 3.** Comparison of Baseline Characteristics for those Individuals who Survived  $\geq 8$  Years after Randomization Versus those who did not in EVAR Trial 2

Baseline Characteristic*	Did Not Survive >8 yrs (N = 334)	Survived >8 yrs (N = 69)	P	
			Univariate†	Multivariate‡
Age (yrs)	77.2 (6.6) [0]	74.9 (6.1) [0]	0.0049	0.013
No. of males (%)	287 (86) [0]	60 (87) [0]	0.82	–
AAA diameter (cm)	6.7 (1.0) [0]	6.6 (1.2) [0]	0.028	0.12
Body Mass Index (kg/m <sup>2</sup> )	26.2 (4.7) [2]	27.8 (4.8) [0]	0.010	0.017
Diabetes (%)	47 (14) [3]	12 (18) [1]	0.47	–
Smoking status (%)	[0]	[0]	0.96	–
Current	58 (17)	12 (17)		
Past	255 (76)	52 (75)		
Never	21 (6)	5 (7)		
History of cardiac disease§ (%)	233 (70) [0]	52 (75) [0]	0.35	–
Systolic blood pressure (mm Hg)	139 (21) [0]	139 (24) [0]	0.91	–
Diastolic blood pressure (mm Hg)	79 (12) [3]	80 (12) [0]	0.41	–
Ankle-brachial pressure index (mean of both legs)	0.98 (0.20) [24]	1.01 (0.21) [1]	0.52	–
FEV <sub>1</sub> (% predicted)	63.6 (26.1) [12]	70.1 (24.1) [1]	0.06	0.0038
eGFR¶	57 (21) [1]	63 (17) [1]	0.0084	0.0043
Serum cholesterol (mmol/L)	4.8 (1.1) [19]	4.8 (1.3) [1]	0.99	–
Statin use (%)	138 (41) [1]	30 (43) [0]	0.76	–
Aspirin use (%)	186 (56) [1]	41 (59) [0]	0.59	–

\*Continuous variables presented as mean (SD). Categorical variables presented as number (%). Data in squared brackets indicate number of patients with missing data.

†P value calculated from a Wilcoxon rank-sum nonparametric test for continuous variables and a  $\chi^2$  test for categorical variables.

‡P value calculated from a multivariate logistic regression model including predictors significant at  $P < 0.10$  in univariate analyses.

§Cardiac disease defined as previous history of any of the following: myocardial infarction, angina, cardiac revascularization, cardiac valve disease, significant arrhythmia, or uncontrolled congestive cardiac failure.

¶eGFR calculated by the abbreviated MDRD equation:  $186 \times (\text{Creat}/88.4) - 1.154 \times (\text{Age}) - 0.203 \times (0.742 \text{ if female})$ . Units mL/min/1.73 m<sup>2</sup>.



# EVAR and Unfit Patients

- No benefit to endovascular aneurysm repair in unfit patients

# Implications and Future Directions

- United Kingdom National Institute for Health and Care Excellence recommends against elective endovascular repair of abdominal aortic aneurysms
  - Endovascular repair in ruptured aneurysms
  - Endovascular repair for complex aneurysms

# Vascular Surgery During COVID



AMERICAN COLLEGE OF SURGEONS  
*Improving Quality*

PVD	Acute limb ischemia	3 Do not postpone
	Limb Ischemia: Progressive tissue loss, acute limb ischemia, wet gangrene, ascending cellulitis	3 Do not postpone
	Fasciotomy for compartment syndrome	3 Do not postpone
	Peripheral Vascular Disease: Chronic limb threatening ischemia - rest pain or tissue loss	2b Postpone if possible
	Peripheral Angiograms and endovascular therapy for Claudication	1 Postpone



	Surgical Procedures for Claudication	1 Postpone
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Bypass graft complications	Infected arterial prosthesis without overt sepsis, or	3 Do not postpone
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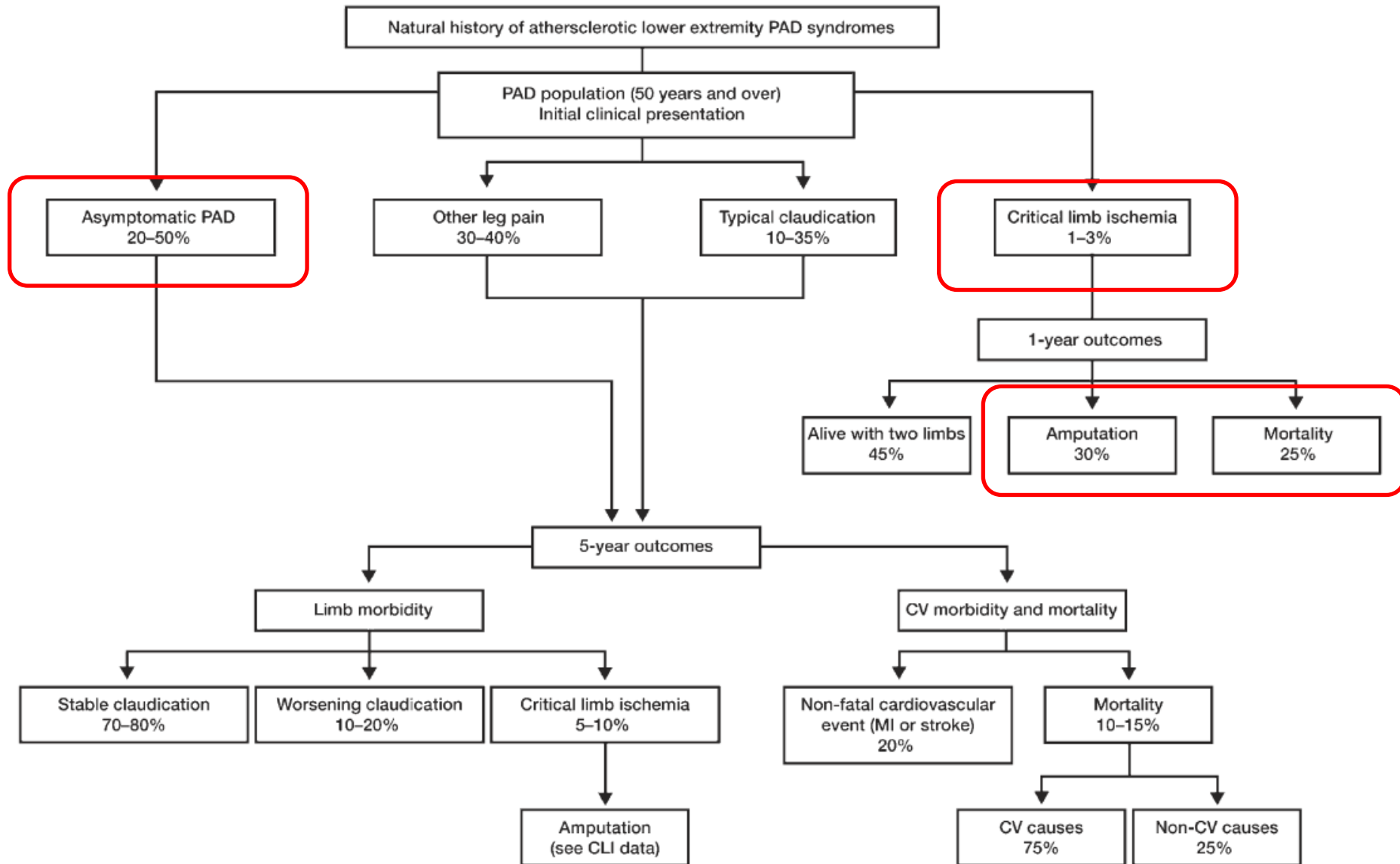
# COVID: Peripheral Artery Disease

- DO NOT POSTPONE
  - Acute limb ischemia
  - Worsening gangrene or infection
- Postpone if possible
  - Rest pain or tissue loss
- Postpone
  - Claudication

# Peripheral Arterial Disease

- Peripheral arterial disease affects 20% of people over 60 years of age
  - Defined by ankle brachial index  $\leq 0.9$
- Prevalence expected to increase as population ages

# Context: Epidemiology of Peripheral Arterial Disease





# Context: Classification of Peripheral Arterial Disease

- Asymptomatic disease
- Symptomatic disease
  - Claudication
  - Critical limb ischemia: rest pain, ulcer, gangrene



# Context: Classification of Peripheral Arterial Disease

- Asymptomatic disease
- Symptomatic disease
  - Claudication
  - Critical limb ischemia: rest pain, ulcer, gangrene



# Context: Classification of Peripheral Arterial Disease

- Asymptomatic disease
- Symptomatic disease
  - Claudication
  - Critical limb ischemia: rest pain, ulcer, gangrene



# Context: Claudication

- Claudication: pain with ambulation
  - Affects quality of life
  - Low risk of limb loss
  - **Medical therapy is treatment**





# Context: Claudication

## MORTALITY OVER A PERIOD OF 10 YEARS IN PATIENTS WITH PERIPHERAL ARTERIAL DISEASE

MICHAEL H. CRIQUI, M.D., M.P.H., ROBERT D. LANGER, M.D., M.P.H., ARNOST FRONEK, M.D., PH.D.,  
HEATHER S. FEIGELSON, M.P.H., MELVILLE R. KLAUBER, PH.D., THERESA J. McCANN, M.P.H.,  
AND DEIRDRE BROWNER, M.P.H.

Table 3. Relative Risk of Death among Subjects with Various Categories of Large-Vessel Peripheral Arterial Disease (LV-PAD).\*

CAUSE OF DEATH	UNILATERAL LV-PAD (N = 34)	BILATERAL LV-PAD (N = 30)	ASYMPTOMATIC LV-PAD (N = 49)	SYMPTOMATIC LV-PAD (N = 18)	MODERATE LV-PAD (N = 49)	SEVERE LV-PAD (N = 18)	ISOLATED POSTERIOR TIBIAL LV-PAD (N = 31)	OTHER LV-PAD (N = 33)
	<i>relative risk (95% confidence interval)</i>							
All causes	3.3 (1.9–5.9)	2.9 (1.5–5.5)	2.7 (1.6–4.5)	4.7 (2.3–9.6)	2.8 (1.6–4.8)	3.9 (1.9–8.0)	2.9 (1.6–5.4)	3.4 (1.9–6.0)
CVD	5.5 (2.5–12.1)	5.8 (2.5–13.3)	4.7 (2.3–9.8)	11.2 (4.5–27.9)	4.8 (2.3–10.3)	8.4 (3.4–20.8)	4.2 (1.7–10.4)	7.0 (3.2–14.9)
CHD	5.5 (2.0–15.2)	7.2 (2.6–19.7)	5.6 (2.3–13.5)	11.4 (3.6–35.8)	5.6 (2.2–14.2)	8.9 (3.0–26.8)	5.5 (1.8–16.7)	6.8 (2.7–17.5)

\*CVD denotes cardiovascular disease, and CHD coronary heart disease. Relative risks have been adjusted for age, sex, number of cigarettes smoked per day, systolic blood pressure, HDL cholesterol level, LDL cholesterol level, logarithm of the triglyceride level, fasting plasma glucose level, body-mass index, and selection criterion.

whom we followed prospectively for 10 years.

**Results.** Twenty-one of the 34 men (61.8 percent) and 11 of the 33 women (33.3 percent) with large-vessel peripheral arterial disease died during follow-up, as compared with 31 of the 183 men (16.9 percent) and 26 of the 225 women (11.6 percent) without evidence of peripheral arterial disease. After multivariate adjustment for age, sex,

revealed a 15-fold increase in rates of mortality due to cardiovascular disease and coronary heart disease among subjects with large-vessel peripheral arterial disease that was both severe and symptomatic.

**Conclusions.** Patients with large-vessel peripheral arterial disease have a high risk of death from cardiovascular causes. (N Engl J Med 1992;326:381-6.)

# Context: Claudication and Exercise

- CLEVER trial

**Table 3. Six-Month End Points and Risk Factors**

	OMC (n=20)	SE+OMC (n=38)	ST+OMC (n=41)	SE vs OMC [95% CI] (P)	ST vs OMC [95% CI] (P)	SE vs ST [95% CI] (P)
<b>Primary end point</b>						
Change of PWT from baseline to 6 mo, mins	1.2±2.6 (−4.1, 8.6)	5.8±4.6 (−0.4, 16.9)	3.7±4.9 (−4.7, 14.6)	4.6 [2.7–6.5] (<0.0001)*	2.5 [0.6–4.4] (0.021)*	2.1 [0.0–4.2] (0.042)
<i>P</i> , nonparametric analysis				<0.001*	0.019*	0.002
Multiple imputation analysis	1.0±2.8 (−9.5, 8.60)	6.1±4.6 (−0.4, 16.9)	3.6±4.9 (−4.7, 14.6)	5.1 [4.5–5.7] (<0.001)*	2.6 [2.0–3.2] (0.017)*	2.5 [1.9–3.1] (0.028)
<b>Secondary end points</b>						
Change in COT from baseline to 6 mo, min	0.7±1.1 (−0.6, 3.3)	3.0±2.9 (−0.8, 10.7)	3.6±4.2 (−0.3, 17.9)	2.2 [1.2–3.3] (0.003)	2.9 [1.5–4.3] (0.006)	0.7 [0.9–2.3] (0.425)
Change in hourly free-living steps from baseline to 6 mo, n†	−5.6±109.4 (−268.2, 168.9)	72.6±138.7 (−185.2, 425.7)	114.3±273.9 (−192.6, 976.4)	78.3 [0.7–157.2] (0.0625)	120.0 [3.5–236.5] (0.1024)	41.7 [73.4–156.8] (0.4661)
Change in ABI from baseline to 6 mo	0.01±0.10 (19) (−0.24, 0.12)	0.03±0.11 (36) (−0.23, 0.37)	0.29±0.33 (40) (−0.12, 1.59)	0.0 [0.0–0.1] (0.578)	0.3 [0.2–0.4] (<0.001)	0.3 [0.2–0.4] (<0.001)
<b>Risk factors (change from baseline)</b>						
LDL cholesterol, mg/dL	−4.4±42.3	−3.6±17.4	−9.3±24.7	<i>P</i> =0.813	<i>P</i> =0.686	<i>P</i> =0.474
HDL cholesterol, mg/dL	7.9±15.4	5.6±8.4	0.4±8.5	<i>P</i> =0.551	<i>P</i> =0.061	<i>P</i> =0.013
Hemoglobin A <sub>1c</sub> , %	−0.09±0.27	0.01±0.50	0.01±0.35	<i>P</i> =0.344	<i>P</i> =0.303	<i>P</i> =0.977
Fibrinogen, g/dL	31.7±64.1	−15.0±84.5	−2.0±89.1	<i>P</i> =0.043	<i>P</i> =0.151	<i>P</i> =0.541
Systolic blood pressure, mm Hg	−5.8±20.7	−0.95±19.1	−5.6±21.9	<i>P</i> =0.381	<i>P</i> =0.974	<i>P</i> =0.323

OMC indicates optimal medical care; SE, supervised exercise; ST, stent revascularization; CI, confidence interval; PWT, peak walking time; COT, claudication onset time; ABI, ankle-brachial index; LDL, low-density lipoprotein; and HDL, high-density lipoprotein. Values are mean±SD (minimum, maximum) when appropriate. *P* values are based on ANCOVA with adjustment for study center, baseline cilostazol use, and baseline value of the end point.

\*One-sided *P* value.

†Adjusted with pedometer logs.

(*Circulation*. 2012;125:130-139.)

exercise did  
better!



# Context: Claudication and Overuse of Intervention

- Of ~ 200,000 patients diagnosed with claudication, 3% underwent treatment within six months of diagnosis

From the Society for Vascular Surgery

## Overuse of early peripheral vascular interventions for claudication

Caitlin W. Hicks, MD, MS,<sup>a</sup> Courtenay M. Holscher, MD,<sup>b</sup> Peiqi Wang, MD, MPH,<sup>b</sup> James H. Black III, MD,<sup>a</sup> Christopher J. Abularrage, MD,<sup>a</sup> and Martin A. Makary, MD, MPH,<sup>b,c</sup> *Baltimore, Md*

### ABSTRACT

**Objective:** Guidelines from the Society for Vascular Surgery and the Choosing Wisely campaign recommend that peripheral vascular interventions (PVI) be limited to claudication patients with lifestyle-limiting symptoms only after a failed trial of medical and exercise therapy. We sought to explore practice patterns and physician characteristics associated with early PVI after a new claudication diagnosis to evaluate adherence to these guidelines.

**Methods:** We used 100% Medicare fee-for-service claims to identify patients diagnosed with claudication for the first time between 2015 and 2017. Early PVI was defined as an aortoiliac or femoropopliteal PVI performed within 6 months of initial claudication diagnosis. A physician-level PVI utilization rate was calculated for physicians who diagnosed >10 claudication patients and performed at least one PVI (regardless of indication) during the study period. Hierarchical multivariable logistic regression was used to identify physician-level factors associated with early PVI.

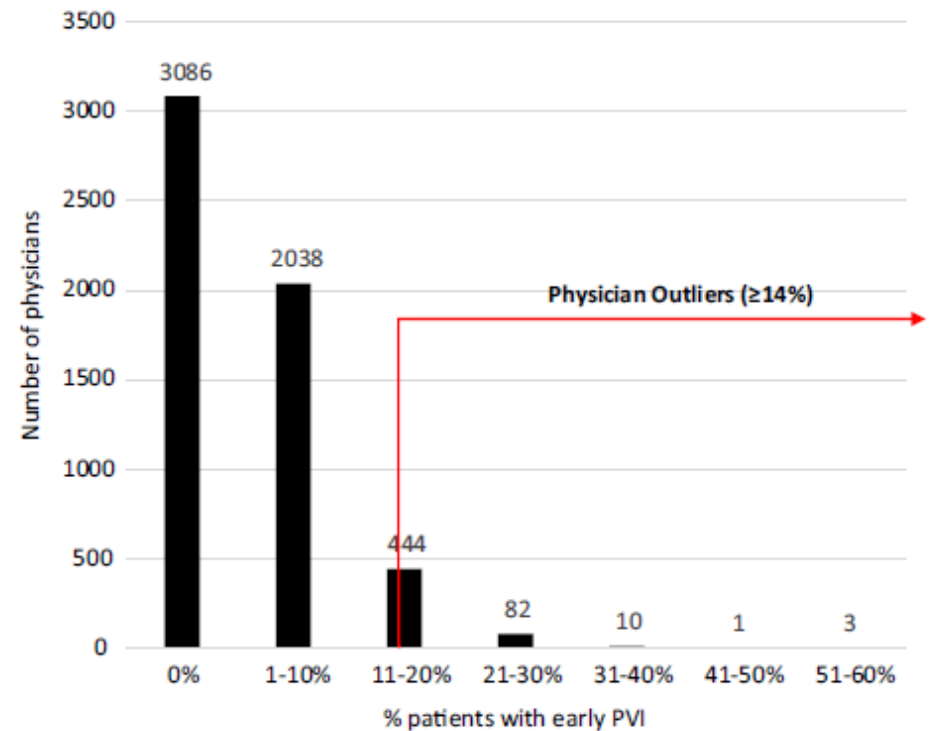
**Results:** Of 194,974 patients who had a first-time diagnosis of claudication during the study period, 6286 (3.2%) underwent early PVI. Among the 5664 physicians included in the analysis, the median physician-level early PVI rate was low at 0% (range, 0%-58.3%). However, there were 320 physicians (5.6%) who had an early PVI rate  $\geq 14\%$  ( $\geq 2$  standard deviations above the mean). After accounting for patient characteristics, a higher percentage of services delivered in ambulatory surgery center or office settings was associated with higher PVI utilization (vs 0%-22%; 23%-47%; adjusted odds ratio [aOR], 1.23; 48%-68%: aOR, 1.49; 69%-100%: aOR, 1.72; all  $P < .05$ ). Other risk-adjusted physician factors independently associated with high PVI utilization included male sex (aOR, 2.04), fewer years in practice (vs  $\geq 31$  years; 11-20 years: aOR, 1.23; 21-30 years: aOR, 1.13), rural location (aOR, 1.25), and lower volume claudication practice (vs  $\geq 30$  patients diagnosed during study period;  $\leq 17$  patients: aOR, 1.30; 18-29 patients: aOR, 1.35; all  $P < .05$ ).

**Conclusions:** Outlier physicians with a high early PVI rate for patients newly diagnosed with claudication are identifiable using a claims-based practice pattern measure. Given the shared Society for Vascular Surgery and Choosing Wisely initiative goal to avoid interventions for first-line treatment of claudication, confidential data-sharing programs using national benchmarks and educational guidance may be useful to address high utilization in the management of claudication. (*J Vasc Surg* 2019;■:1-10.)

**Keywords:** Claudication; Peripheral vascular intervention; Utilization

# Context: Claudication and Overuse of Intervention

- Of  $\sim 6,000$  physicians, five percent had an intervention rate two standard deviations above the mean ( $\sim 14\%$ )



**Fig.** National distribution of physician-level early peripheral vascular intervention (PVI) rate.

# Context: Claudication and Overuse of Intervention

- Performance of intervention of office based laboratory (OBL) predicted overtreatment
  - Re-imbursement \$10,000 in OBL versus \$1,000 in hospital setting for atherectomy

# Context: Claudication and Overuse of Intervention

- Medicare B data
- Atherectomy is associated with high rate of re-intervention and higher rate of amputation than with medical therapy

## High Reintervention and Amputation Rates After Outpatient Atherectomy for Claudication

Dipankar Mukherjee, MD, Brian Contos, BS, Erica Emery, MS, more...

[Show all authors](#) ▾

First Published May 1, 2018 | Research Article | [Find in PubMed](#) |



<https://doi.org/10.1177/1538574418772459>

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### Abstract

Outpatient use of atherectomy for peripheral arterial disease has grown rapidly and outcomes are poorly understood. We analyzed outcomes of atherectomy done for claudication, comparing office and hospital outpatient settings. Analysis of Medicare Part B claims data was performed for incident femoral–popliteal or tibial–peroneal atherectomy from 2012 to 2014. Longitudinal analysis assessed services 18 months before, during, and up to 18 months after the incident peripheral vascular intervention (PVI). Differences between office-based and hospital outpatient-based settings were assessed using  $\chi^2$  and Fisher exact tests. Comparing procedure settings, significant differences in race (femoral–popliteal:  $P = .04$ , tibial–peroneal:  $P = .001$ ), chronic renal failure (femoral–popliteal:  $P = .002$ ), and hypertension (femoral–popliteal:  $P = .01$ , tibial–peroneal:  $P = .006$ ) were found. Nine hundred twenty-four patients undergoing femoral–popliteal atherectomy were analyzed (262 office based, 662 hospital outpatient based); 42.7% of office-based and 36.9% of hospital outpatient-based femoral–popliteal atherectomy patients had repeat PVI within 18 months ( $P = .10$ ). Major amputation was performed in 2.3% and 3.2% of patients in office and hospital outpatient settings, respectively ( $P = .47$ ). Four hundred twenty-three patients undergoing tibial–peroneal atherectomy were analyzed (202 office based, 221 hospital outpatient based); 46.5% of office-based and 38.9% of hospital outpatient-based tibial–peroneal atherectomy patients had repeat PVI within 1 year ( $P = .11$ ). Major amputation was performed in 5.0% and 8.1% of patients in office and hospital outpatient settings, respectively ( $P = .19$ ). Our study demonstrates higher than expected rates of major amputation for patients undergoing peripheral arterial atherectomy with regard to previously reported rates. Further studies may be required to prove the efficacy and safety of atherectomy for occlusive disease in the femoral–popliteal and tibial–peroneal segments to ensure outcomes are not worse than the natural history of medically managed claudicants.

# Context: Claudication and Overuse of Intervention

- Medicare data
- African-American patients in low-income counties more likely to undergo intervention

## Race and socioeconomic differences associated with endovascular peripheral vascular interventions for newly diagnosed claudication



Caitlin W. Hicks, MD, MS,<sup>a</sup> Peiqi Wang, MD, MPH,<sup>b</sup> William E. Bruhn, BS,<sup>b</sup> Christopher J. Abularrage, MD,<sup>a</sup> Ying W. Lum, MD, MPH,<sup>a</sup> Bruce A. Perler, MD, MBA,<sup>a</sup> James H. Black III, MD,<sup>a</sup> and Martin A. Makary, MD, MPH,<sup>b,c</sup> *Baltimore, Md*

### ABSTRACT

**Background:** Despite guidelines cautioning against the use of endovascular peripheral vascular interventions (PVI) for claudication, more than 1.3 million PVI procedures are performed annually in the United States. We aimed to describe national rates of PVI for claudication, and identify patient and county-level risk factors associated with a high rate of PVI.

**Methods:** We used the Medicare claims database to identify all Medicare beneficiaries with a new diagnosis of claudication between January 2015 and June 2017. A hierarchical logistic regression model accounting for patient age, sex, comorbidities; county region and setting; and a patient race-county median income interaction was used to assess the associations of race and income with a high PVI rate.

**Results:** We identified 1,201,234 patients with a new diagnosis of claudication for analysis. Of these, 15,227 (1.27%) underwent a PVI. Based on hierarchical logistic regression accounting for patient and county-level factors, black patients residing in low-income counties had a significantly higher odds of undergoing PVI than their white counterparts (odds ratio [OR], 1.30; 95% confidence interval [CI], 1.20-1.40), whereas the odds of PVI for black versus white patients was similar in high-income counties (OR, 1.06; 95% CI, 0.99-1.14). PVI rates were higher for low versus high-income counties in both the black (OR, 1.46; 95% CI, 1.31-1.64) and white (OR, 1.19; 95% CI, 1.12-1.27) groups. There were no significant associations of Hispanic, Asian, North American native, or other races with PVI in either low- or high-income counties after risk adjustment (all  $P \geq .09$ ).

**Conclusions:** In the Medicare population, the mean rate of PVI of 12.7 per 1000 claudication patients varies significantly based on race and income. Our data suggest there are racial and socioeconomic differences in the treatment of claudication across the United States. (*J Vasc Surg* 2020;72:611-21.)

**Keywords:** Claudication; Peripheral artery disease; Race; Socioeconomic status; Disparities; Medicare

# Context: Critical Limb Ischemia

- Critical limb ischemia
  - Rest pain or tissue loss (ulcer or gangrene)
  - Most severe form of peripheral artery disease
  - “End Stage” Peripheral Arterial Disease



# Context: Critical Limb Ischemia

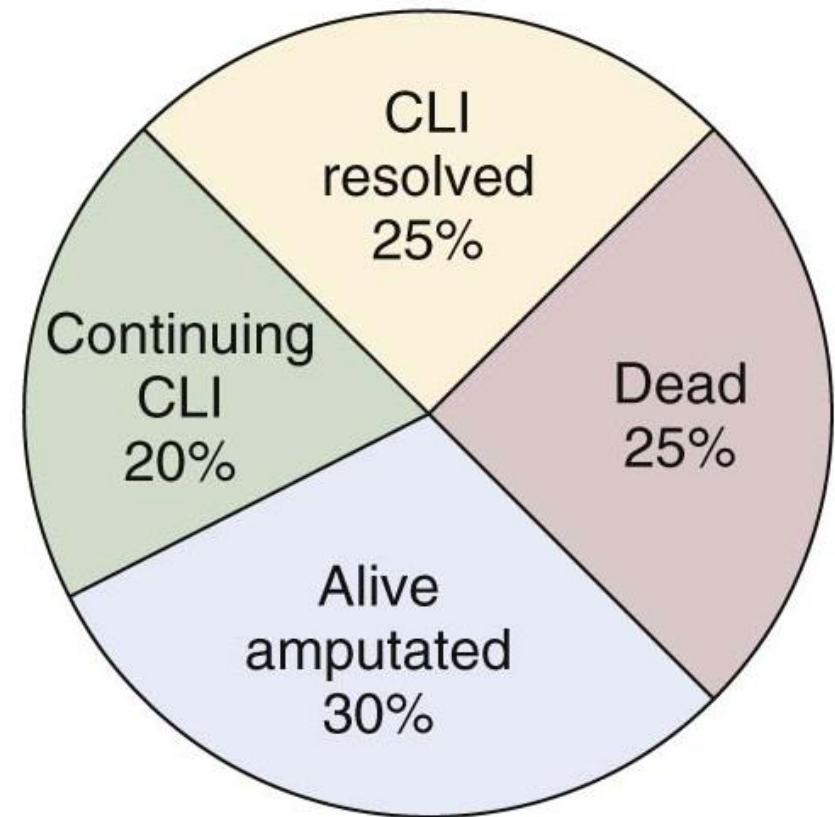
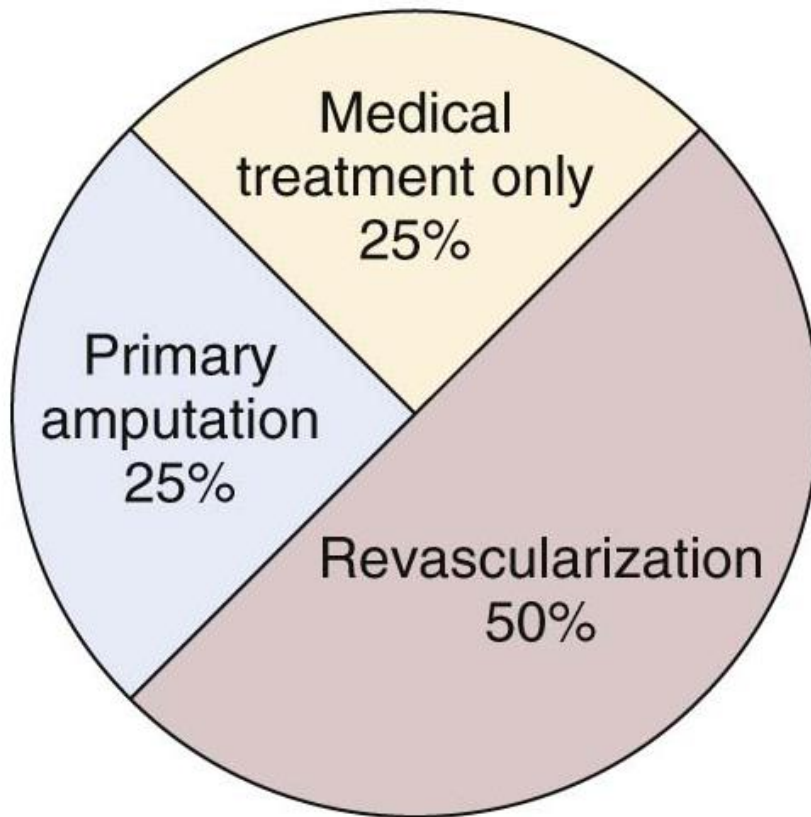
- 2001 Medicare expenditures for cost of PAD related treatment:

\$4.4 Billion

- More than congestive heart failure and cerebrovascular disease

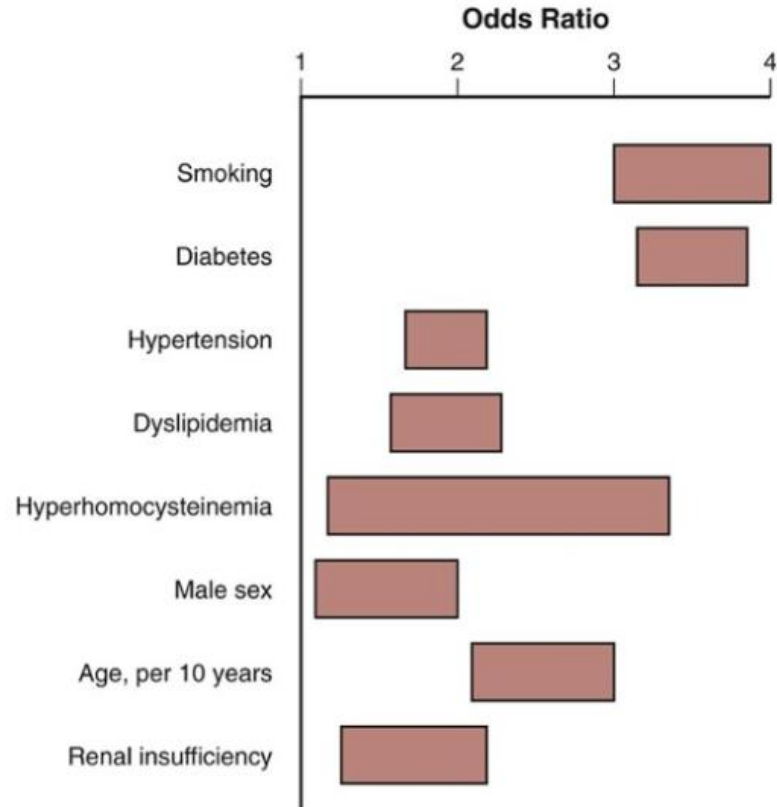
# Context: Critical Limb Ischemia

Primary treatment → A year later

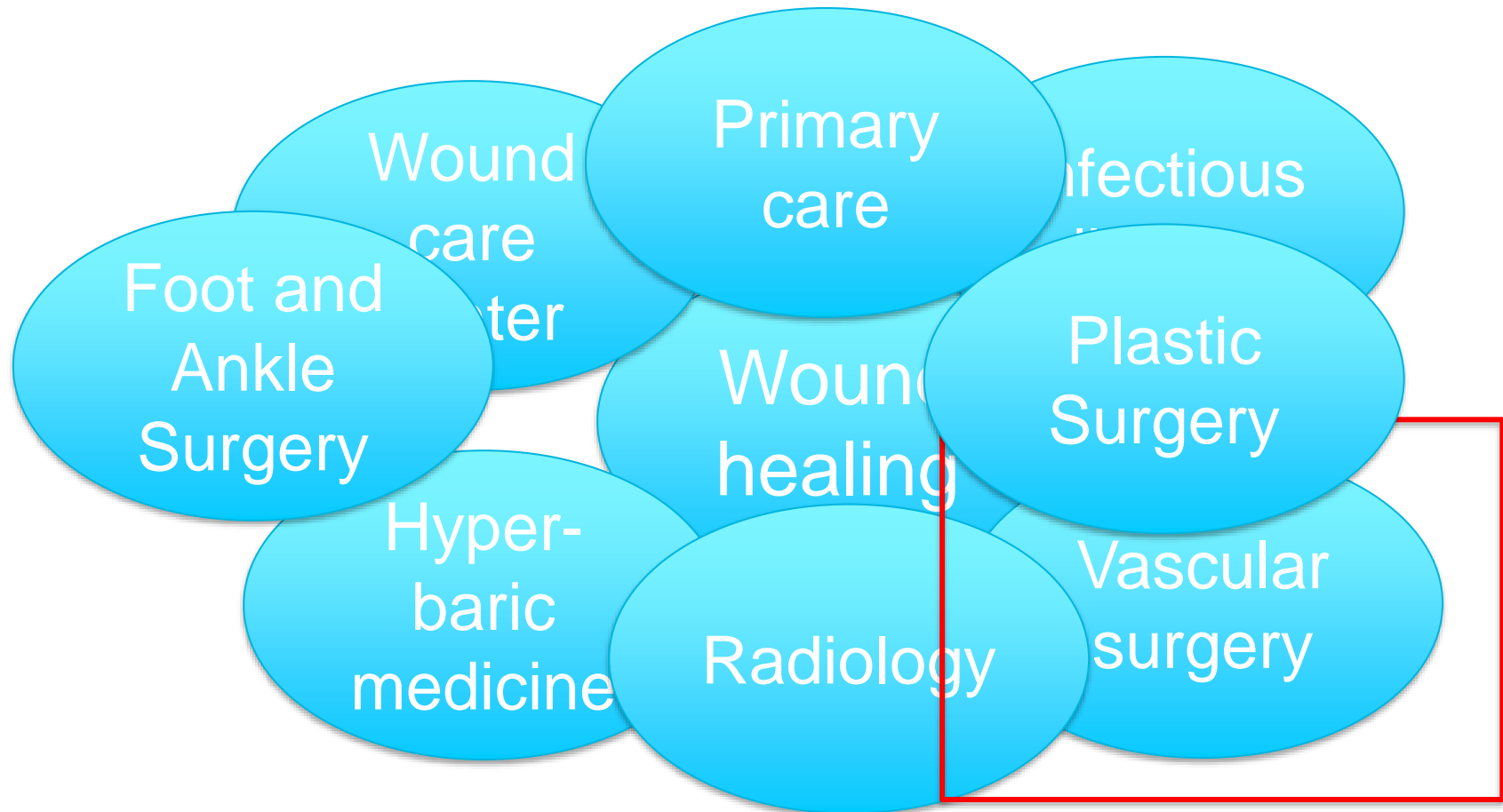


# Treatment: Medical Therapy

- Treat the underlying disease process
- Address modifiable risk factors

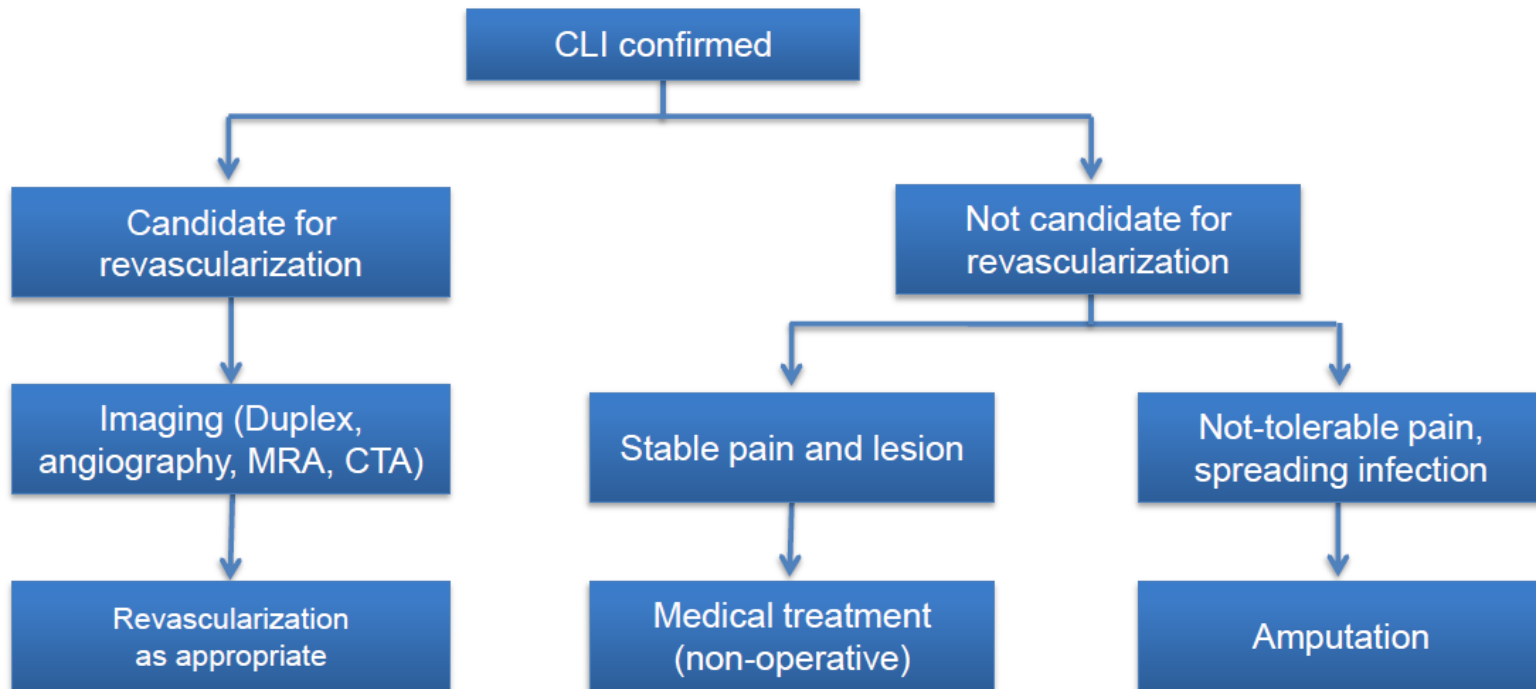


# Limb Salvage: Multidisciplinary Approach



# Treatment: Algorithm

## Algorithm for the Treatment of CLI



Reprinted from *Journal of Vascular Surgery*, Vol. 45(1), Norgren L, Hiatt WR, Dormandy MR, Harris KA, and Fowkes FGR, on behalf of the TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II), S5-S67, 2007, with permission from Elsevier.

TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg*. 2007 Jan;45 Suppl

# Endovascular Operating Room





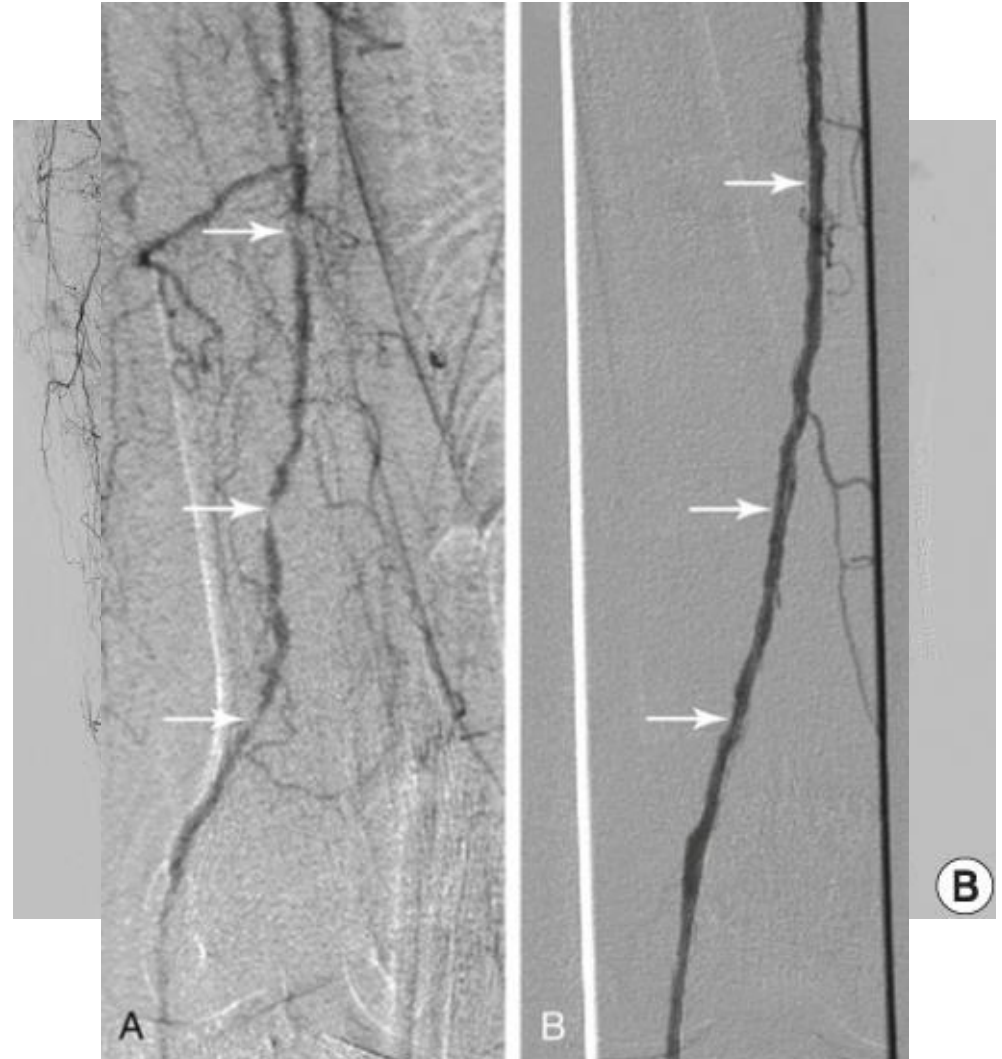
# Treatment: Endovascular Therapy

- Endovascular therapy
  - Relatively non-invasive
  - Can be done with conscious sedation



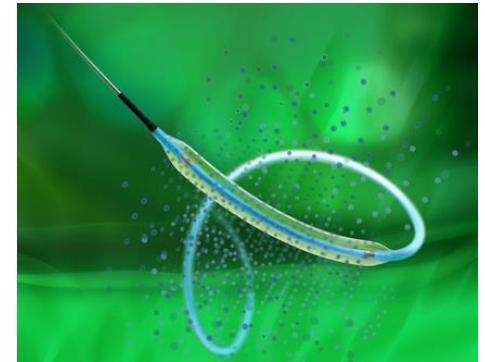
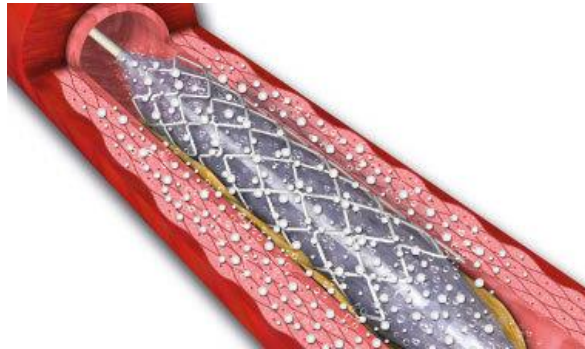
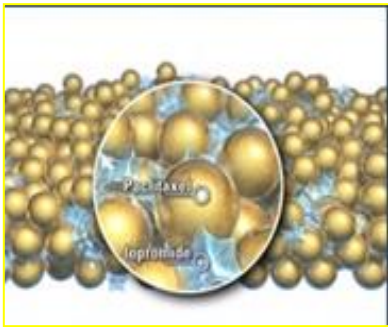
# Treatment: Endovascular Therapy

- Endovascular therapy
  - Diagnostic angiogram
  - Therapeutic angioplasty, stenting, and other modalities



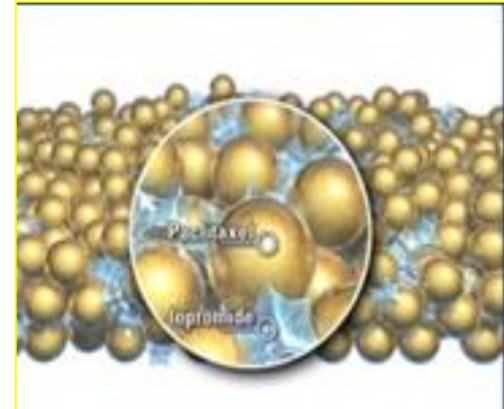
# Treatment: Advances in Endovascular Therapy

- Atherectomy - remove/debulk plaque
- Drug-eluting balloons (DEB)
- Drug-eluting stents (DES)



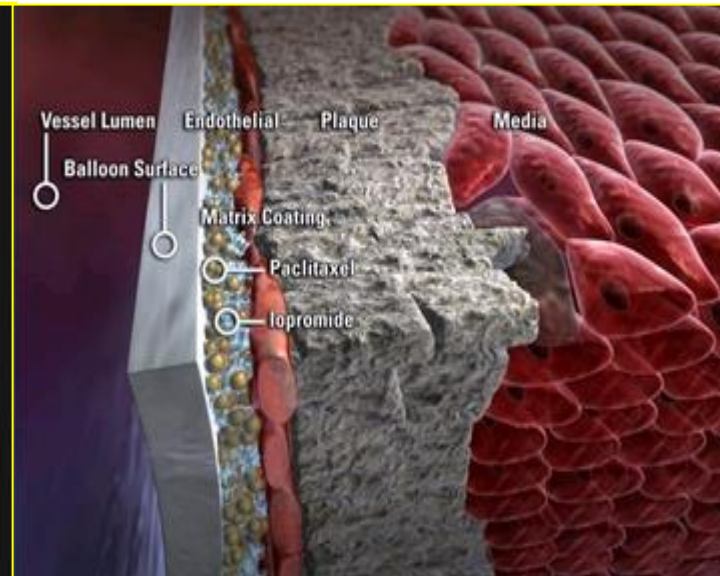
# Treatment: Drug Eluting Technology

Paclitaxel+Hydrophilic Spacer (urea,sorbitol)



The hydrophilic spacer leads to:

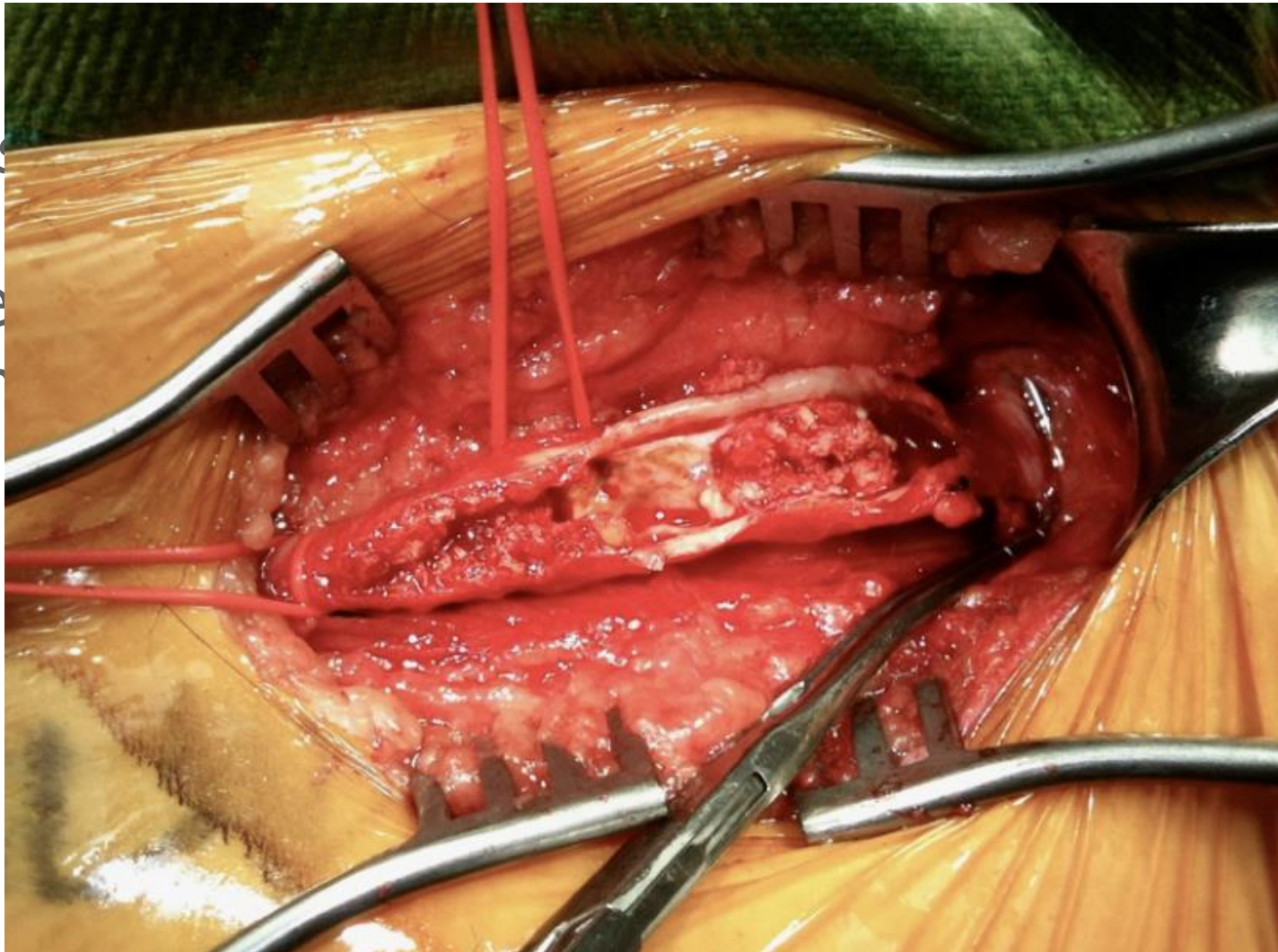
- Porous coating with a high contact surface between the lipophilic drug molecules and the vessel wall.
- Drug release through vessel contact following balloon expansion.
- High bioavailability of paclitaxel on the target side for rapid drug absorption by the vessel wall





# Treatment: Limitations of Endovascular Therapy

- Balloon dilatation
- Stent placement



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1  
d and

1. Fitzgerald P. *Circulation*. 1992. 86:64-70.
2. Scheinert D. *J Am Coll Cardiol*. 2005;45:312-315.

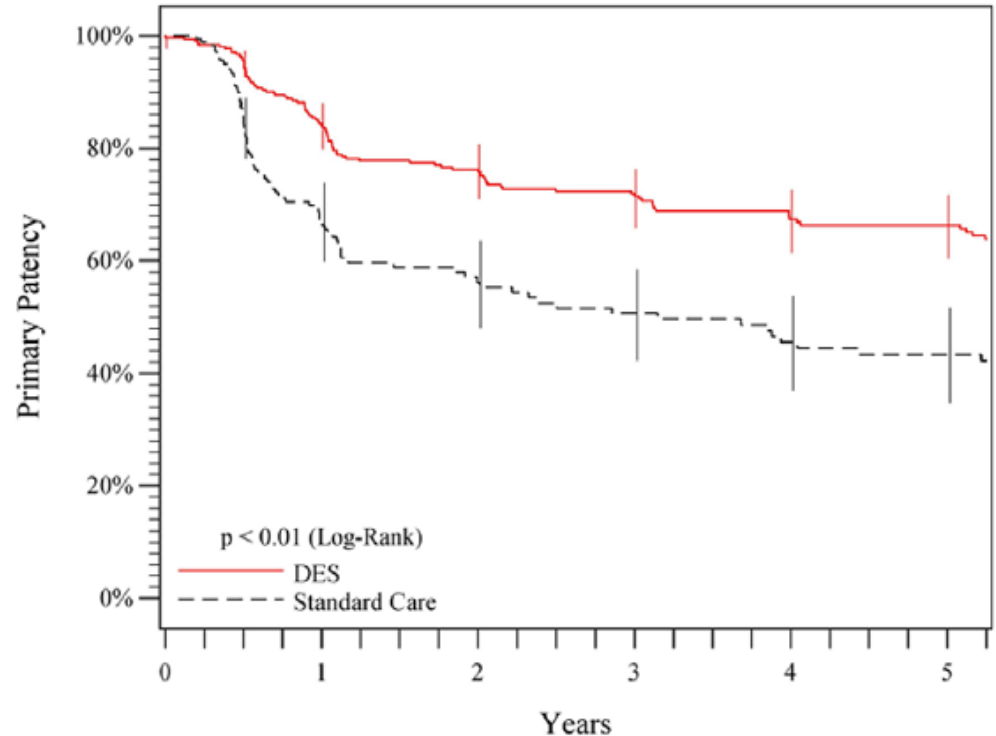
# Treatment: Limitations of Endovascular Therapy

- Drug eluting technology has not translated to below the knee
- Signal of danger: increased mortality with drug eluting stents



# Treatment: Drug Eluting Stents

- Drug eluting stents provide sustained patency and durability



Years Post-procedure	Primary Patency ± Standard Error		Cumulative Failed		Remaining at Risk	
	Standard Care	DES	Standard Care	DES	Standard Care	DES
0	100.0 ± 0.0%	99.7 ± 0.3%	0	1	183	318
1	67.4 ± 3.6%	84.4 ± 2.1%	57	48	108	246
2	56.2 ± 4.0%	76.3 ± 2.5%	73	71	64	199
3	50.7 ± 4.2%	71.5 ± 2.7%	79	83	52	163
4	45.5 ± 4.3%	67.4 ± 2.9%	84	92	44	137
5	43.4 ± 4.4%	66.4 ± 2.9%	86	94	38	109

# Treatment: Drug Eluting Stents

- Drug eluting stents increase mortality
- 90% of patients are claudicants

## Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Konstantinos Katsanos, MD, PhD, MSc, EBIR; Stavros Spiliopoulos, MD, PhD; Panagiotis Kitrou, MD, PhD; Miltiadis Krokidis, MD, PhD; Dimitrios Karnabatidis, MD, PhD

**Background**—Several randomized controlled trials (RCTs) have already shown that paclitaxel-coated balloons and stents significantly reduce the rates of vessel restenosis and target lesion revascularization after lower extremity interventions.

**Methods and Results**—A systematic review and meta-analysis of RCTs investigating paclitaxel-coated devices in the femoral and/or popliteal arteries was performed. The primary safety measure was all-cause patient death. Risk ratios and risk differences were pooled with a random effects model. In all, 28 RCTs with 4663 patients (89% intermittent claudication) were analyzed. All-cause patient death at 1 year (28 RCTs with 4432 cases) was similar between paclitaxel-coated devices and control arms (2.3% versus 2.3% crude risk of death; risk ratio, 1.08; 95% CI, 0.72–1.61). All-cause death at 2 years (12 RCTs with 2316 cases) was significantly increased in the case of paclitaxel versus control (7.2% versus 3.8% crude risk of death; risk ratio, 1.68; 95% CI, 1.15–2.47; —number-needed-to-harm, 29 patients [95% CI, 19–59]). All-cause death up to 5 years (3 RCTs with 863 cases) increased further in the case of paclitaxel (14.7% versus 8.1% crude risk of death; risk ratio, 1.93; 95% CI, 1.27–2.93; —number-needed-to-harm, 14 patients [95% CI, 9–32]). Meta-regression showed a significant relationship between exposure to paclitaxel (dose-time product) and absolute risk of death ( $0.4 \pm 0.1\%$  excess risk of death per paclitaxel mg-year;  $P < 0.001$ ). Trial sequential analysis excluded false-positive findings with 99% certainty (2-sided  $\alpha$ , 1.0%).

**Conclusions**—There is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs. Further investigations are urgently warranted.

**Clinical Trial Registration**—URL: [www.crd.york.ac.uk/PROSPERO](http://www.crd.york.ac.uk/PROSPERO). Unique identifier: CRD42018099447. (*J Am Heart Assoc.* 2018;7:e011245. DOI: 10.1161/JAHA.118.011245.)

# Treatment: Drug Eluting Stents

- Should not be placed in claudicants
- Should be reserved for patients at risk for limb loss who have no other options

# Treatment: Surgical Therapy

- Surgical bypass
- Inflow, outflow, conduit



# Treatment: BASIL Trial

- Endovascular therapy versus surgical bypass for critical limb ischemia

- Randomized controlled trial
- Long-term follow-up

Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: An intention-to-treat analysis of amputation-free and overall survival in patients randomized to a bypass surgery-first or a balloon angioplasty-first revascularization strategy

Andrew W. Bradbury, BSc, MD, MBA, FRCSEd,<sup>a,b</sup> Donald J. Adam, MD, FRCSEd,<sup>a</sup> Jocelyn Bell, PhD,<sup>b</sup> John F. Forbes, PhD,<sup>c</sup> F. Gerry R. Fowkes, PhD, FRCPE,<sup>d</sup> Ian Gillespie, MD, FRCR,<sup>c</sup> Charles Vaughan Ruckley, ChM, FRCSEd, CBE,<sup>e</sup> and Gillian M. Raab, PhD,<sup>g</sup> on behalf of the BASIL trial Participants,\* *Birmingham and Edinburgh, United Kingdom*

*Background:* A 2005 interim analysis of the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial showed that in patients with severe lower limb ischemia (SLI; rest pain, ulceration, gangrene) due to infrainguinal disease, bypass surgery (BSX)-first and balloon angioplasty (BAP)-first revascularization strategies led to similar short-term clinical outcomes, although BSX was about one-third more expensive and morbidity was higher. We have monitored patients for a further 2.5 years and now report a final intention-to-treat (ITT) analysis of amputation-free survival (AFS) and overall survival (OS).

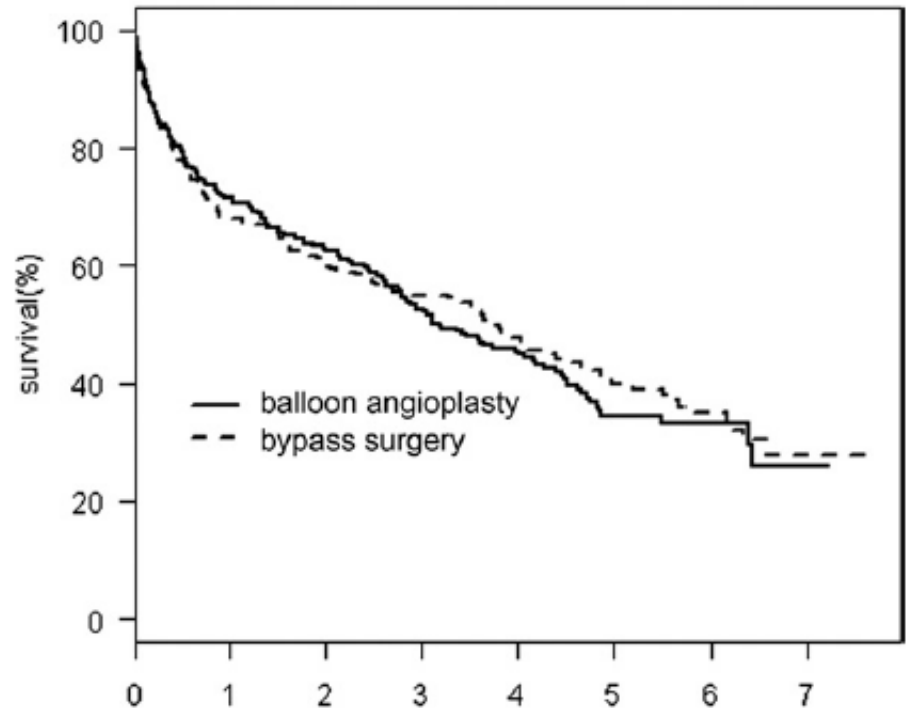
*Methods:* Of 452 enrolled patients in 27 United Kingdom hospitals, 228 were randomized to a BSX-first and 224 to a BAP-first revascularization strategy. All patients were monitored for 3 years and more than half for >5 years.

*Results:* At the end of follow-up, 250 patients were dead (56%), 168 (38%) were alive without amputation, and 30 (7%) were alive with amputation. Four were lost to follow-up. AFS and OS did not differ between randomized treatments during the follow-up. For those patients surviving 2 years from randomization, however, BSX-first revascularization was associated with a reduced hazard ratio (HR) for subsequent AFS of 0.85 (95% confidence interval [CI], 0.5-1.07;  $P = .108$ ) and for subsequent OS of 0.61 (95% CI, 0.50-0.75;  $P = .009$ ) in an adjusted, time-dependent Cox proportional hazards model. For those patients who survived for 2 years after randomization, initial randomization to a BSX-first revascularization strategy was associated with an increase in subsequent restricted mean overall survival of 7.3 months (95% CI, 1.2-13.4 months,  $P = .02$ ) and an increase in restricted mean AFS of 5.9 months (95% CI, 0.2-12.0 months,  $P = .06$ ) during the subsequent mean follow-up of 3.1 years (range, 1-5.7 years).

*Conclusions:* Overall, there was no significant difference in AFS or OS between the two strategies. However, for those patients who survived for at least 2 years after randomization, a BSX-first revascularization strategy was associated with a significant increase in subsequent OS and a trend towards improved AFS. (*J Vasc Surg* 2010;51:5S-17S.)

# Treatment: BASIL Trial

- No difference in survival between endovascular therapy and surgical bypass

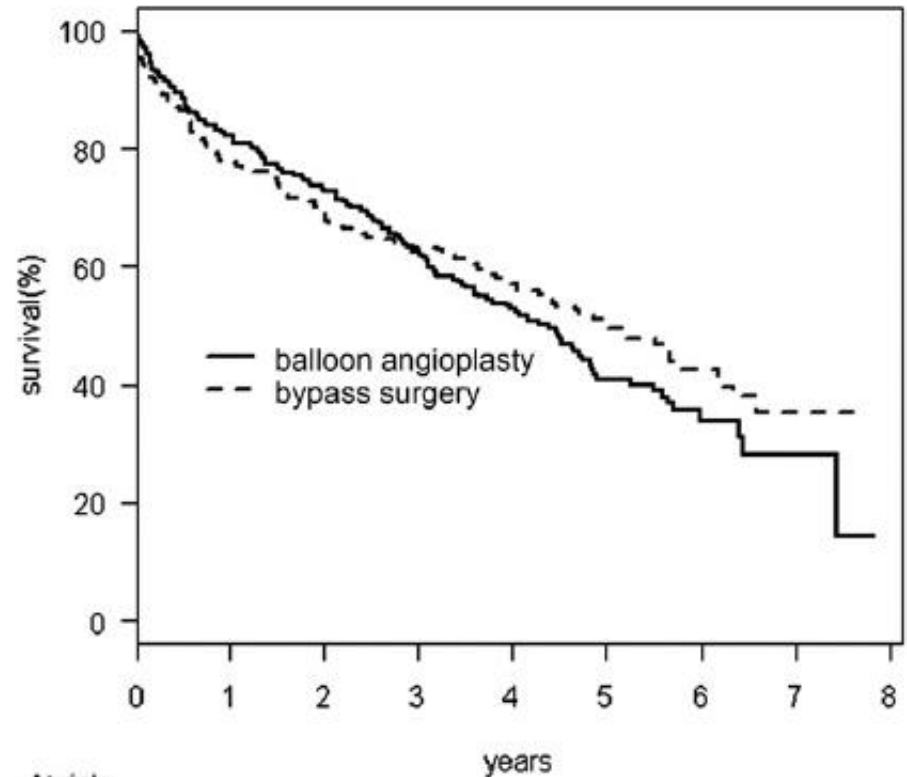


At risk	years							
	0	1	2	3	4	5	6	7
Balloon angioplasty	224	160	139	117	87	41	16	5
Bypass surgery	228	154	138	124	93	53	24	6



# Treatment: BASIL Trial

- No difference in limb salvage between endovascular therapy and surgical bypass



At risk	0	1	2	3	4	5	6	7	8
Balloon angioplasty	224	184	162	139	101	49	19	7	
Bypass surgery	228	175	155	142	110	63	31	7	

# Treatment: BEST CLI Trial



[ABOUT BEST-CLI](#) [STUDY SITES AND LEADERSHIP](#) [STUDY DESIGN](#)  
[PUBLICATIONS AND PRESS](#) [CONTACT](#)

## Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia

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Important information about critical limb ischemia and clinical trials.

#### CLINICALTRIALS.GOV

[Clinicaltrials.gov has up-to-date information on the current status of this trial »](#)

# Summary: PAD

- Optimize medical therapy in patients
- Reserve revascularization for claudicants who have disabling claudication and have failed medical therapy
  - No drug eluting stents
- Revascularize patients at risk for limb loss as long as benefits exceed risks

**Table II.** Operative cases performed since instituting COVID-19 vascular surgery guidelines (March 17, 2020-April 13, 2020)

Pt. No.	Operation	Case notes	Hospital (ICU) LOS, days	Complications
1	Aortofemoral bypass for acute thrombosis of left common iliac artery	Intraoperative consultation; thrombosis occurred during spine exposure performed by general surgery	4 (1)	None
2 <sup>a</sup>	Open repair of ruptured juxtarenal AAA with temporary abdominal closure	None	13 (13)	Ischemic colitis, respiratory failure, myocardial infarction, death
2 <sup>a</sup>	Second-look exploratory laparotomy with sigmoid colectomy	None	NA	NA
2 <sup>a</sup>	Exploratory laparotomy, creation of sigmoid colostomy, abdominal closure	None	NA	NA
3	Lower extremity angiogram for chronic limb-threatening ischemia	Already inpatient at consultation, with open minor amputation already performed for wet gangrene by general surgery	11 (0)	None
4	Carotid artery GSW repair using Dacron interposition graft	None	8 (3)	None
5	Above-the-knee amputation for wet gangrene	None	6 (0)	None
6	Intraoperative consultation for arterial hemorrhage during orthopedic surgery	None	7 (0)	None
7	Endovascular repair of ruptured AAA	None	4 (1)	None
8	Femoral artery repair after VA-ECMO decannulation	Already inpatient at consultation	Remained an in-patient	None
9	Brachial artery GSW repair with GSV interposition graft	None	4 (2)	None
10	Brachial artery GSW repair with GSV interposition graft	None	3 (1)	None
11	Subclavian angiogram and removal of CVC from SCA with balloon angioplasty for hemostasis	COVID-19 positive	Remained an in-patient	None
12	Infected AV graft ligation and excision	None	Remains inpatient	None
13 <sup>b</sup>	SFA GSW repair with GSV interposition graft, 4 compartment fasciotomies	None	4 (1)	None
13 <sup>b</sup>	Fasciotomy washout and closure	None	None	None
14	Radial artery injury primary repair with thrombectomy	None	2 (0)	None

AAA, Abdominal aortic aneurysm; AV, atrioventricular; CVC, central venous catheter; GSV, greater saphenous vein; GSW, gunshot wound; ICU, intensive care unit; LOS, length of stay; NA, not applicable; Pt. No., patient number; SCA, subclavian artery; SFA, superficial femoral artery; VA-ECMO, venoarterial extracorporeal membrane oxygenation.

<sup>a</sup>Patient 2 underwent three separate procedures.  
<sup>b</sup>Patient 13 underwent two separate procedures.

- Single Acader Trauma Weekly
- Surgical decrease 15 cases
- Clinic decrease 40 patients

during 

attle, Wash  
 Washington State has been on the obtained from Italian surgeons in iton State, we implemented new involved significant changes to our understood.  
 y instituted new vascular surgery j consultation volume data were Washington State case and death ise volumes were collected from  
 thin the UW Medicine system has 215%, respectively. After instituting 6 (from 43.1 patients to 1.5 patients to 4.25 cases per week), and our ultations were completed as tele-surgical volume has also decreased

ar surgical practice in a large ac- and decreased staff and trainee immediate increase in emergency es, although preserving resources, ; new modes of education delivery. re for the next crisis. (J Vasc Surg

# Vascular Surgery in COVID

- 1103 vascular interventions across 57 centers in 19 countries

- Increased mortality observed

## Outcomes of Vascular and Endovascular Interventions Performed During the Coronavirus Disease 2019 (COVID-19) Pandemic

*The Vascular and Endovascular Research Network (VERN)  
COVID-19 Vascular Service (COVER) Tier 2 Study*

*Ruth A. Benson, BSc, MBChB, PhD and Sandip Nandhra, MBBS, MD*

**Objective:** The aim of the COVER Study is to identify global outcomes and decision making for vascular procedures during the pandemic.

**Background Data:** During its initial peak, there were many reports of delays to vital surgery and the release of several guidelines advising later thresholds for vascular surgical intervention for key conditions.

**Methods:** An international multi-center observational study of outcomes after open and endovascular interventions.

**Results:** In an analysis of 1103 vascular intervention (57 centers in 19 countries), 71.6% were elective or scheduled procedures. Mean age was  $67 \pm 14$  years (75.6% male). Suspected or confirmed COVID-19 infection was documented in 4.0%. Overall, in-hospital mortality was 11.0% [aortic interventions mortality 15.2% (23/151), amputations 12.1% (28/232), carotid interventions 10.7% (11/103), lower limb revascularisations 9.8% (51/521)]. Chronic obstructive pulmonary disease [odds ratio (OR) 2.02, 95% confidence interval (CI) 1.30–3.15] and active lower respiratory tract infection due to any cause (OR 24.94, 95% CI 12.57–241.70) were associated with mortality, whereas elective or scheduled cases were lower risk (OR 0.4, 95% CI 0.22–0.73 and 0.60, 95% CI 0.45–0.98, respectively). After adjustment, antiplatelet (OR 0.503, 95% CI: 0.273–0.928) and oral anticoagulation (OR 0.411, 95% CI: 0.205–0.824) were linked to reduced risk of in-hospital mortality.

**Conclusions:** Mortality after vascular interventions during this period was unexpectedly high. Suspected or confirmed COVID-19 cases were uncommon. Therefore an alternative cause, for example, recommendations for delayed surgery, should be considered. The vascular community must anticipate longer term implications for survival.

**Keywords:** abdominal aortic aneurysm, carotid endarterectomy, COVID-19, peripheral arterial disease, vascular surgery

*(Ann Surg 2021;273:630–635)*

The coronavirus disease 2019 (COVID-19) pandemic has impacted vascular services in unprecedented ways.<sup>1</sup> Some national and international surgical bodies had initially recommended limiting surgery to only the most severe or late-stage presentations of certain vascular conditions, such as crescendo transient ischaemic attacks, ischaemic limbs with tissue loss or rest-pain, and abdominal aortic aneurysms (AAA) larger than the global standard treatment thresholds of 5.5 cm (that is 6.5–7 cm for asymptomatic AAA).<sup>2–4</sup> The reduction in hospitals' capacity to treat non-COVID-19 pathologies, coupled with staff shortages and resource limitations, have led to considerable deviations from the established gold standards of vascular surgical care.<sup>5–7</sup>

In addition to an estimated overall mortality rate of up to 15% for those with a severe COVID-19 infection and a surgical pathology, it is now recognized that there are significant increases in “excess deaths” due to the pandemic for patients without COVID-19, that is, delayed treatments for cancer, or delayed presentation of patients with cardiovascular disease.<sup>8,9</sup> Many specialities have reported vastly reduced or delayed presentation for serious pathologies such as myocardial infarctions.<sup>10</sup> A number of international studies are currently investigating surgical interventions and clinical outcomes specifically in patients diagnosed with COVID-19,<sup>11</sup> however, little is known about the outcomes of any patients undergoing cardiovascular surgery during the pandemic, irrelevant of COVID-19 diagnosis.

The prospective Vascular and Endovascular Research Network (VERN) COVID-19 Vascular Service (COVER) Study was therefore developed to prospectively document outcomes for all vascular procedures performed during the pandemic, in COVID-19 positive and negative patients worldwide. COVER is a 3-tier global collaborative research project supported by multiple international vascular organizations.<sup>12,13</sup> The primary aim of this analysis was to report in-hospital outcomes during the first months of the COVID-19 pandemic worldwide. The secondary aims were to compare in-hospital mortality

# Vascular Surgery in COVID

- Increased mortality: Pre vs post pandemic

	Pre-pandemic Reported In Hospital Mortality	COVER Reported In Hospital Mortality
Carotid intervention	1% (17)	10.7%
Lower limb Revascularisation	1–5% (18)	9.8%
Amputation	7.70% (18)	12.1%
Aortic intervention	Elective: 3% (19) Emergency: 40.9% (18)	Elective: 10.5% Emergency: 33.3%
EVAR	Elective: 0.5% (19) Emergency: 22.6% (18)	Elective: 9.8% Emergency: 24.4%

- Carotid: 1% vs 10%
- PAD: 1-5% versus 10%
- Amputation 8% versus 12%
- Aorta elective repair: 3% versus 10%



# Vascular Surgery in COVID

**TABLE 2.** Changes Due to COVID 19 Pandemic

	Carotid (n = 103)*	Lower Limb (n = 521)†	Amputation (n = 232)‡	Aortic (n = 151)§
Choice of procedure a deviation from normal practice due to COVID pandemic?	5 (4.9%)	34 (8.1%)	20 (9%)	7 (4.8%)
Confirmed COVID Positive Patients	2 (1.9%)	7 (1.3%)	3 (1.3)	0 (0%)
Suspected COVID Positive Patients	2 (1.9%)	6 (1.2%)	13 (5.6%)	4 (2.7%)
Postoperative destination				
Ward	67 (65%)	364 (71.9%)	198 (87.6%)	70 (47.3%)
Stepdown ward from critical care unit	5 (4.9%)	44 (8.7%)	5 (2.2%)	9 (6.1%)
Level 2/High dependency unit	20 (19.4%)	47 (9.3%)	12 (5.3%)	30 (20.3%)
Level 3/Critical care	11 (10.7%)	34 (6.7%)	5 (2.2%)	36 (24.3%)
Died in theatre	0 (0%)	0 (0%)	0 (0%)	3 (2.0%)
Day case	0 (0%)	17 (3.4%)	6 (2.7%)	0 (0%)
Destination after surgery a change in practice due to COVID pandemic?	3 (2.9%)	8 (1.6%)	7 (3.1%)	3 (2.1%)
Mode of anesthesia				
Local anesthesia	23 (22.3%)	221 (43.8%)	23 (10.2%)	33 (22.6)
Spinal/Epidural	0 (0%)	58 (11.5%)	56 (24.9%)	11 (7.5%)
Peripheral Nerve Block	0 (0%)	3 (0.6%)	54 (24.0%)	0 (0%)
General Anesthesia	80 (77.7%)	222 (44.0%)	92 (40.9%)	102 (69.9%)
Mode of anesthesia a change in practice due to COVID pandemic	0 (0%)	3 (0.6%)	13 (5.8%)	2 (1.4%)

- “Second mortality effects of healthcare during Pandemic”

# Thank You

Thank you very much  
for your attention

# Questions?

Virginia Mason would like to thank you for joining us and if you have any further questions,

please don't hesitate to contact us

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# Thank You!





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