

**Aggressive Interventions Including  
Atherectomy In Claudicants Leads To More  
Harm Than Good**

VEITH SYMPOSIUM  
November 23, 2024, Session 107, 9:26 AM – 9:31 AM.

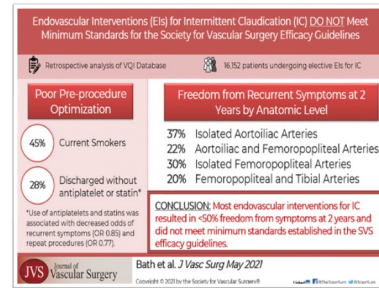
Dipankar Mukherjee  
Chief of Vascular Surgery  
INOVA Fairfax Hospital  
Falls Church, VA.

Nothing to disclose.

**Introduction**

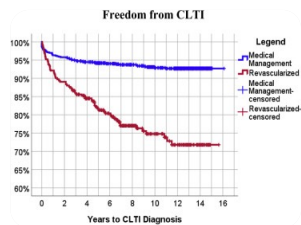
- PAD in 10 million or 12 % of US adult population .
- 20% of adults >70 years have PAD.
- Incidence of DM expected to double by 2030.
- Interventions for PAD double every decade.
- CLI in 1.3% of PAD patients with 5 yr survival of < 30%.
- Most interventions therefore for claudication.
- In 2008 CMS introduced changes in OPPS and the OBL was born.
- Most PAD interventions now done in the OBL.

**Discussion**



**Discussion**

**Revascularization of intermittent claudicants leads to more chronic limb-threatening ischemia and higher amputation rates.**  
Madabhushi, Davenport et al. IC revascularization associated with progression to CLTI (HR 2.9, 95% CI 2.0-4.2) and Amputation (HR 4.5, 95% CI 2.2-9.5)



- 3 years (13% vs 6%;  $P < .001$ )
- 5 years (18% vs 8%;  $P < .001$ )
- 10 years (27% vs 10%;  $P < .001$ ).

IVS 2021, Sep; 74 (3) : 771 - 777

**Revascularization for claudication: Changing the natural history of a benign disease!**

Robert A McCready, O William Brown, Charles F Goodson.  
J Vasc Surg 2024 Jan 79(1): 159-166.

- Google scholar and PubMed search for manuscripts on conservative therapy vs intervention for claudication revealed:
- Early improvement in claudication symptoms, however over the long-term conservative therapy results in similar or better improvement in walking distance
- High reintervention rates up to 43% for Tibial atherectomy results in high rates of acute and chronic limb threatening ischemia.
- Amputation rates up to 11 % on long term follow-up.
- Higher adverse CV events including MI .
- Practitioners should inform patients of higher adverse consequences of intervention as part of the informed consent process.

Outcomes of Revascularization for Claudication

**Table I.** Revascularization vs conservative therapy in claudication

| Study                                      | Number of patients                    | Measured outcomes (readmission/walking)   | Follow-up | Reintervention and amputation  |
|--|---------------------------------------|---|-----------|--|
| Ahmadatos (2011) meta analysis of 9 trials | 875                                   | No difference in outcomes                 | 12 months | NA   |
| Spronk <sup>2</sup> (2009) <sup>2</sup>    | 151                                   | No difference in outcomes                 | 12 months | NA   |
| Frans <sup>3</sup> (2012)                  | 8 trials systematic review            | No difference in outcomes                 | 6 months  | NA   |
| Fakhy <sup>4</sup> (2012) <sup>5</sup>     | 151                                   | No difference in outcomes                 | 7 years   | SET group intervention rate: 47%<br>PCI group reintervention rate: 73% |
| Becker <sup>6</sup> (2011)                 | 56                                    | Greater improvement in conservative group | 6 years   | NA   |
| Djerf <sup>7</sup> (2020) IRONIC trial     | 158                                   | No difference in outcomes                 | 5 years   | Conservative group interventions, 33<br>PCI group reinterventions, 1%  |
| Murphy <sup>8</sup> (2015) CLEVER trial    | 111 patients with aorticiliac disease | No differences in outcomes                | 18 months | NA   |

Outcomes of Revascularization for Claudication

**Table II.** Outcomes of revascularization for claudication

| Study                            | Number of patients                                    | Follow-up | Reinterventions/patency/ outcomes   | Major amputations   |
|----------------------------------|---|-----------|---|---|
| Mukhejee <sup>9</sup> (2018)     | 924 patients with atherosclerosis                     | 18 months | At 18 months 47% performed in OBL had reinterventions   | For tibial atherosclerosis: Performed in OBL 5%<br>Performed in-hospital 8.1% |
| Lumsden <sup>10</sup> (2015)     | 148 patients with prosthetic femoropopliteal bypasses | 12 months | At 12 months: Primary patency, 76.5%<br>Major graft reintervention, 22%<br>Graft infection rate, 2.9% | 2%  |
| Bath <sup>11</sup> (2021)        | 16152 patients with PCI database                      | 2 years   | At 2 years: Recurrent symptoms of IC, 68%<br>Reintervention rate, 25%                                 | NA  |
| de Rubertis <sup>12</sup> (2007) | 463 patients with PCI for IC                          | 2 years   | At 2 years: Primary patency, 62.4%<br>Secondary patency, 79.3%<br>Reintervention rate, 17%            | 0.5%  |
| Gunnarsson <sup>13</sup> (2020)  | 775 patients with PCI or bypasses                     | 8 years   | At 8 years: 32% required reintervention   | 6.7%  |
| Saraladitis <sup>14</sup> (2017) | 515 patients  | 5 years   | 21.8% with reintervention   | 2.8%  |
| Apley <sup>15</sup> (2020)       | 11887 VQJ database (2003-2017)                        | 1 year    |   | 0.3%  |

Outcomes of Revascularization for Claudication

|                                 |   |  |   |
|---------------------------------|---|--|---|
| Masduziyah <sup>16</sup> (2021) | 328 patients with revascularization   | 3, 5 and 10 years                            | Risk of CLTI with revascularization:<br>3 years 10%<br>5 years 18%<br>10 years 19%<br>Risk of amputation with revascularization:<br>3 years 3%<br>5 years 6%<br>10 years 11%<br>Risk of CLTI with conservative treatment:<br>3 years 6%<br>5 years 6%<br>10 years 10%<br>Risk of amputation with conservative treatment:<br>5 years 1%<br>5 years 1%<br>10 years 2% |
| College <sup>17</sup> (2018)    | 176 patients with revascularization, 278 patients with conservative treatment | 5 years                                      | Revascularization group: intervention required, 46%<br>Major amputation, 6.3%<br>Conservative group: intervention required, 29%<br>Major amputation, 0.7%   |
| Bosmans <sup>18</sup> (2019)    | 476 patients with SET or revascularization                                    | 2, 4 years                                   | All 2 years: SET group: reintervention rate, 21%<br>Revascularization group: reintervention rate, 30%   |
| Mazzei <sup>19</sup> (2010)     | 178 patients with SET alone, PCI alone or SET and PCI                         | No difference in outcomes among the 3 groups | NA  |

CLTI Chronic limb threatening ischemia, NA Not available, PCI percutaneous intervention, SET supervised exercise therapy, Standardized confidence size

Outcomes of Revascularization for Claudication

|                               |  |         |  |   |
|-------------------------------|--|---------|--|---|
| Siracuse <sup>20</sup> (2012) | 218 patients   | 5 years | Freedom from restenosis: Bypasses 70%, PCI 42%<br>Freedom from claudication: Bypasses 70%, PCI 36%<br>Freedom from reinterventions: Bypasses, 77%; PCI, 66%    | None  |
| Levin <sup>21</sup> (2020)    | 10,427 patients VSCNE                                | 1 year  | Reintervention at 1 year: PCI group 14%<br>Femoropopliteal bypasses, 10%<br>Suprainguinal bypasses, 7%   | PCI group: 6%<br>Infringuinal bypasses, 6%<br>Suprainguinal bypasses, 7%          |
| Scall <sup>22</sup> (2011)    | 230 patients   | 3 years | 9.4%   | Stent graft group (SPA occlusive disease), 3%<br>Femoropopliteal bypass group, 8% |
| Martian <sup>23</sup> (2015)  | 76 patients  | 1 year  | Progression to CLTI or ALI: BMS 9%, SC, 17%  | BMS group 7%  |
| Fashandi <sup>24</sup> (2018) | 3925 patients with PCI or surgical revascularization | 30 days | MALE rate: PCI group 3.2%<br>Surgical group 4%<br>Return to the OR: PCI group 1.0%<br>Surgical group 7.9%<br>MACE rates: PCI group 1.0%<br>Surgical group 2.0% |   |

Outcomes of Revascularization for Claudication

**Table II.** Continued

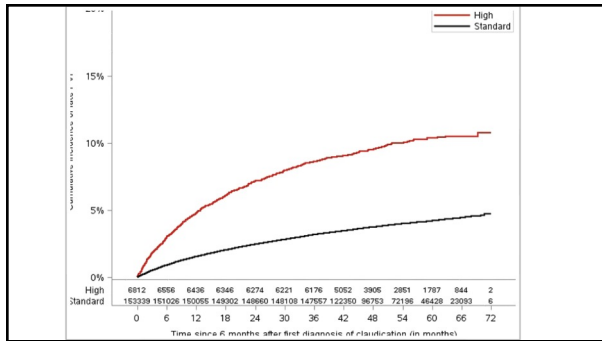
| Study                                   | Number of patients  | Follow-up | Reinterventions/patency/ outcomes   | Major amputations  |
|---|---|-----------|---|--|
| Jamson <sup>25</sup> (2003)             | 253 patients (50A limbs)<br>PCI in 272 limbs<br>Surgical bypasses in 52 limbs | 81 months | 50% of limbs required further intervention<br>5 year primary patency, 27%<br>secondary patency, 45%<br>Major complications, 11.8%<br>CLTI development, 12.2%<br>Patients with initial mild/moderate IC who had deterioration of symptoms during follow-up, 23%<br>Died from complications from repeat treatment, 4% | 6.6% amputation rate   |
| Levin <sup>26</sup> (2021) VQJ Database | 5347 infra-inguinal bypasses<br>22% to tibial arteries                        | 1 year    | Return to the OR: Femoropopliteal bypasses, 3.6%<br>Tibial bypass, 6.6%   | Major amputation/ death: Femoropopliteal bypasses, 6.7%<br>Tibial bypasses, 9.8% |

All: Acute limb ischemia, BMS bare metal stent, CLTI, critical limb-threatening ischemia, IC, intermittent claudication, MACE, major adverse cardiac events, MALE, major adverse limb event, OBL, office-based locations, OR, operating room, PCI, percutaneous intervention, SPA, superficial femoral artery, SC, stent graft, VQJ, Vascular Quality Initiative, VSCNE, Vascular Study Group of New England

Early Peripheral Vascular Interventions for Claudication in High Reimbursement Settings Are Associated With Higher Rates of Late Intervention and Progression to Chronic Limb-threatening Ischemia

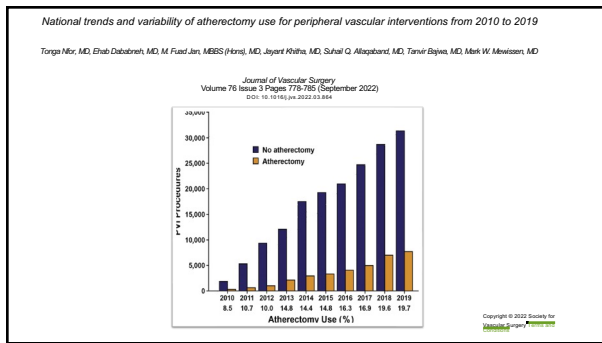
Rebecca A. Sorber Chen DunQingwen Kawaji James H.  
Black III Martin A. Makary Caitlin W. Hicks

JVS, Vol 75, 6, E241-242, June 2022



Absence of Long-Term Benefit of Revascularization in Patients With Intermittent Claudication: Five Year Results From the IRONIC Randomized Controlled Trial.  
Henrik Djerf, Johan Millinger et al Circ Cardiovasc Interv 2020 Jan13(1)

- SET vs PCI
- SF 36 primary outcome
- Vascular QOL, Treadmill walking distance secondary end points.
- Revascularization strategy was superior at 1-2 years however this early advantage was lost by 5 years.
- SF 36 greater improvement in SET group.
- No difference in Treadmill walking distance.
- Revascularization strategy cost x 2/ patient \$13,098 vs \$6965 (P=0.02)



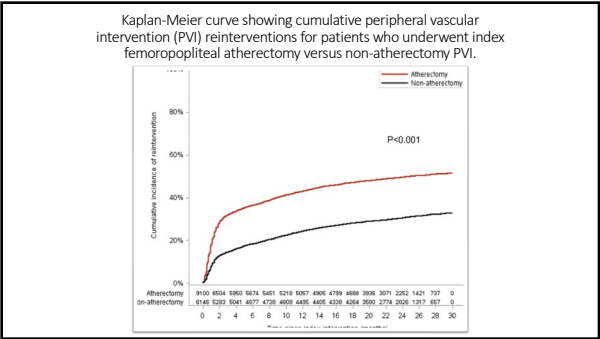
### Discussion

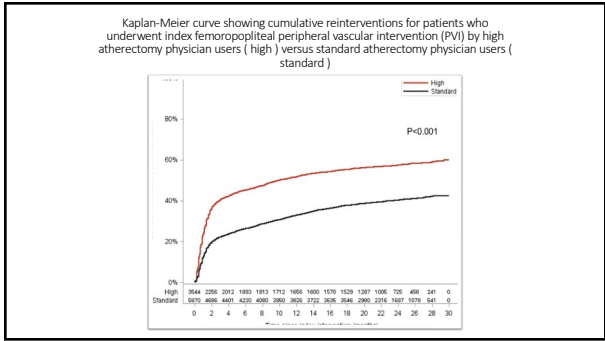
- In the United States, atherectomy use in PVI has more than tripled between 2010 and 2019.
- We found wide regional variability in atherectomy use that was not driven by patient factors.
- Nonclinical factors were a more dominant driver of atherectomy use.
- PVI performed in an office setting was the single strongest predictor of atherectomy use.
- The pattern of migration of PVI to the outpatient setting might have been influencing physicians' decisions regarding the use of atherectomy during PVI compared with commonly accepted clinical factors.

Index atherectomy peripheral vascular interventions performed for claudication are associated with more reinterventions than non-atherectomy interventions.

Qingwen Kawaji MD, ScM, Chen Dun MHS, Christi Walsh MSN, CRNP, Rebecca A. Sorber MD, David P. Stonko MD, MS, Christopher J. Abularraje MD, James H. Black MD, Bruce A. Perler MD, MBA, Martin A. Makary MD, MPH and Caitlin W. Hicks MD, MS

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Atherectomy in Peripheral Vascular Interventions:  
Time to Follow the Guidelines

- Interventional community does not need more professional guidelines, what we need is to adjust the "moral compass" and to follow the already existing AUC and guideline/consensus documents ( 78910 ).
- 8-fold higher atherectomy use in OBL/ASC versus in-patient setting should be a warning sign to clinicians to follow the Hippocratic principles of delivering "the right procedure, for the right patient, at the right time," no matter where they are performed.
- OBL/ASC centers should be held to similarly high standards of care as inpatient facilities, with quality assurance metrics in place, including peer review for appropriateness of PVI and review of device selection/utilization.
- CMS policy changes for OBL/ASC PVI reimbursement and their unintended consequences should be periodically re-examined. Furthermore, randomized, comparative device trials are critically needed to determine the value and cost effectiveness of atherectomy devices in specific lesion subsets.

Dmitriy N. Feldman MD and Andrew J.P. Klein MD  
JACC: Cardiovascular Interventions, 2021-03-22, Volume 14, Issue 6, Pages 689-691, Copyright © 2021 American College of Cardiology Foundation

RE-IMBURSEMENT for VALUE BASED CARE

- CMS mandate for re-imbursement for value - based care from 2030.
- Metrics for value still being determined.
- Some facts are well established and undeniable.
- SET for claudication now re-imbursed by Medicare.
- Interventions for claudication are of low value and likely to be targeted for denial for payment.
- Indiscriminate use of ATHERECTOMY will be questioned.
- Perhaps this will change provider behavior.

THANK YOU