From the Western Vascular Society

# Optimal medical management before lower extremity bypass for claudication in the veteran population

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## ABSTRACT

**Objective:** Optimizing medical management through glucose control, smoking cessation, and drug therapy (ie, antiplatelet and statin agents) is recommended as first-line therapy for patients with claudication. The aims of this study were to determine how frequently veterans with claudication received optimal medical management (OMM) before undergoing elective open lower extremity bypass procedures nationwide and whether preoperative OMM was associated with improved surgical outcomes.

**Methods:** We reviewed all patients within the Veterans Affairs (VA) Surgical Quality Improvement Program database who underwent elective open lower extremity bypass procedures for claudication at nationwide VA medical centers from 2005 until 2015. We defined OMM as a claudicant's having documentation of receiving all of the following within 12 months before surgery: prescriptions for antiplatelet, statin, and smoking cessation therapy (if a smoker) and monitoring of hemoglobin $A_{1c}$ (if diabetic). Outcome measures included occurrence of any 30-day VA Surgical Quality Improvement Program complication, amputation-free survival, and 30-day and 1-year mortality. We used multivariate regression and Cox proportional hazards models incorporating inverse probability treatment weighting to analyze the effect of OMM on outcome measures after adjusting for patient-level confounding.

**Results:** Among 10,271 lower extremity bypass procedures performed, 2265 (22%) were undertaken in claudicants with a median age of 63 years (interquartile range, 58-68 years). Of claudicants, 839 (37%) were diabetic, and 1333 (59%) patients smoked within 12 months before surgery. OMM was achieved in only 581 (26%) claudicants before they underwent surgery, although adherence to individual components was variable: antiplatelet, 55%; statin, 63%; smoking cessation, 58%; and hemoglobin $A_{1c}$ monitoring, 92%. In risk-adjusted analyses, there were no statistically significant differences in complication rates, amputation-free survival, or mortality outcomes among patients who received OMM compared with non-OMM patients.

**Conclusions:** Only a quarter of veterans with claudication were documented as receiving OMM within the year before undergoing open lower extremity bypass across nationwide VA medical centers, highlighting the need for strategies to ensure that medical therapy is intensified before surgical revascularization. Nevertheless, our data showed that documentation of preoperative OMM did not lead to improved short- or long-term postoperative outcomes in these patients, suggesting that more objective measures of medical management are needed to ensure that peripheral arterial disease goals are achieved. (J Vasc Surg 2019;69:545-54.)

**Keywords:** Peripheral artery disease; Intermittent claudication; Lower extremity bypass; Glucose control; Drug therapy; Smoking cessation

Peripheral arterial disease (PAD) is a highly prevalent disease, affecting between 8 and 10 million Americans and accounting for >500,000 hospitalizations in the United States every year, and the rates of intervention for PAD have been steadily rising.[1,2] Intermittent claudication (IC) is one of the earliest manifestations of PAD with the onset of exercise-induced muscle ischemia in the extremities. More than a third of patients with PAD present with IC as their initial symptom, although it is estimated that >50% remain asymptomatic, and only 20% to 30% of patients with claudication symptoms will progress to critical limb ischemia (CLI) during a 15-year period.[3,4] Moreover, it is well established that patients with IC or asymptomatic PAD have an increased risk of concomitant coronary artery disease and cerebrovascular disease, with >20% incidence of suffering a myocardial infarction (MI) or stroke within 5 years of diagnosis.[3] As such, the diagnosis of PAD is considered a coronary artery disease equivalent and an independent predictor of both short-term and long-term mortality.

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Given the significant morbidity and mortality associated with PAD, optimal medical management (OMM) is recommended for all patients who present with claudication. OMM strategies for IC aim to prevent progression of PAD, to improve limb function, and to reduce cardiovascular morbidity and mortality, irrespective of whether the patient requires lower extremity revascularization.[5] Specifically, practice guidelines for IC based on class I evidence currently recommend a complete history and physical examination, reduction of modifiable risk factors, supervised exercise programs, and antiplatelet and statin therapy.[2,6] Tobacco use and uncontrolled diabetes are the two modifiable risk factors most often targeted, given that they have the largest risk related to the development and progression of PAD.[2] The benefits of antiplatelet therapy are centered on the ability of these agents to reduce the risk of nonfatal MI, ischemic stroke, and cardiac-related death among patients with PAD. Statin therapy is critical for the control of hyperlipidemia as well as pleiotropic benefits independent of cholesterol lowering that have been shown to improve walking distance in claudicants over time.[7] Together, nearly all evidence-based OMM algorithms developed for IC include antiplatelet therapy, statin therapy, and risk factor modification focused on smoking cessation and glycemic control before consideration of surgery.[2,5]

Whereas all patients with claudication should receive OMM, it is unclear how often these treatment goals are successfully achieved before patients undergo surgical revascularization. Importantly, the decision to offer a higher risk open surgical revascularization vs lower risk endovascular intervention is typically made when claudication is lifestyle limiting and attempts at providing OMM or other nonoperative treatments do not appear successful. However, even when OMM is documented before patients undergo revascularization procedures, it is uncertain whether patients receive improved mortality and limb-specific outcomes after surgery. The Veterans Affairs (VA) Health Care System is the largest integrated health care system in the United States, which allows comprehensive assessment of medical management delivered before surgery. This study was designed to identify how often veterans were documented to have received OMM before undergoing open surgical revascularization and to determine whether short- and long-term postoperative outcomes were improved when these treatment goals were achieved. We hypothesized that achieving OMM before open surgical revascularization for claudication would be associated with improved survival and limb-related outcomes after surgery.

## ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of prospectively collected Veterans Affairs Surgical Quality Improvement Program data
- **Take Home Message:** In a group of 2265 claudicants, those achieving optimal medical management before a lower extremity bypass procedure had complication rates, amputation-free survival, and mortality similar to patients who were not medically optimized.
- **Recommendation:** Medical therapy should be intensified prior to performing lower extremity bypass in claudication patients, but this strategy by itself may not improve long-term outcomes.

## METHODS

**Study design and cohort.** A retrospective cohort study was conducted among patients who underwent open lower extremity revascularization for claudication at nationwide VA medical centers (VAMCs) located within every Veterans Integrated Service Network between 2005 and 2015. The VA Surgical Quality Improvement Program (VASQIP) database was used to identify all veterans who underwent open lower extremity revascularization procedures. This database contains a comprehensive list of preoperative patients' demographics, comorbidities, laboratory data, operative information, complications, and postoperative outcomes. Patients were identified using *Current Procedural Terminology* codes specific for lower extremity surgical bypass procedures (35521, 35546, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654,35656, 35661, 35663, 35665, 35666, 35671). In addition to procedure codes for lower extremity bypass, each patient was required to have an *International Classification of Diseases, Ninth Revision* diagnosis code for claudication (443.9, 440.21). Patients with VASQIP variables or *International Classification of Diseases, Ninth Revision* codes (459.9, 440.22, 440.23, 440.24) that indicated presence of CLI (rest pain or gangrene) were excluded from analysis (Fig 1). In addition, we excluded patients who were recorded in the VASQIP database as having a wound at the time of surgery as well as those who underwent lower extremity bypass for indications associated with aneurysms, arterial embolism, venous insufficiency, or trauma. VASQIP data were then linked by patient identifiers (ie, scrambled Social Security number file) to available prescription and laboratory data within the Veterans Health Administration Corporate Data Warehouse for the 12-month period before bypass surgery. Our protocol for this study was approved by the Institutional Review Board for the Salt Lake City VA and University of Utah, and informed consent was waived. In addition, we received a data use agreement to use VASQIP data for this analysis from the VA Surgical Quality Data Use Group.

**Exposure—OMM.** The main exposure variable for the analysis was defined by whether OMM processes were documented in the electronic health record for each

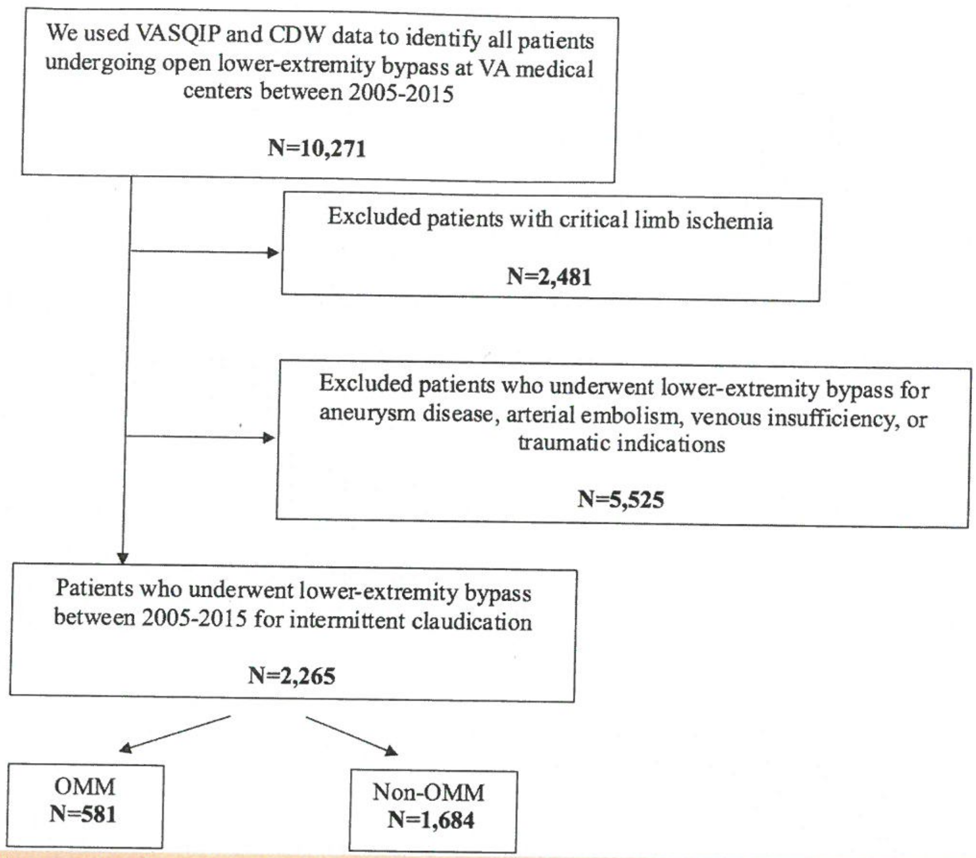


**Fig 1.** Identification of cohort of patients for analysis who underwent lower extremity bypass for claudication in Veterans Affairs (*VA*) medical centers (VAMCs) between 2005 and 2015. *CDW,* Corporate Data Warehouse; *OMM,* optimal medical management; *VASQIP,* Veterans Affairs Surgical Quality Improvement Program.

patient before the patient underwent bypass surgery for claudication. In this study, we determined that OMM was achieved if patients had evidence of medical management processes within the following four domains during the 12-month period before surgery:

1. Prescription of any oral antiplatelet therapy (eg, aspirin, dipyridamole, triflusal, clopidogrel, prasugrel, ticagrelor, ticlopidine, cilostazol, or vorapaxar) or documentation that an antiplatelet agent was in the patient's outpatient medication list;
2. Prescription of any hydroxymethylglutaryl-coenzyme A reductase inhibitor (statin) agent (eg, atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, or simvastatin) or documentation that a statin medication was in the patient's outpatient medication list;
3. Documentation in the VASQIP of the patient's being a current smoker, a prescription for any type of medication-based smoking cessation therapy (eg, nicotine replacement therapy [patches, gum, lozenges, or spray], varenicline, bupropion, nortriptyline), or documentation that one of these agents was in the patient's outpatient medication list; and
4. Documentation in the VASQIP of the patient's being diabetic or laboratory evidence that a glycated hemoglobin (hemoglobin $A_{1c}$) determination was ordered within 12 months before surgery.

If patients were not diabetic or smokers, OMM was defined only by whether antiplatelet and statin therapy was prescribed before surgery.

**Outcome measures.** The primary outcomes for this analysis included all-cause mortality and amputation-free survival (AFS) after bypass surgery for claudication. AFS was defined as the proportion of patients alive without having any amputation after an open lower extremity revascularization procedure. Survival outcomes were estimated at 30-day, 1-year, 3-year, and 5-year end points after date of surgery. Secondary outcomes included any documentation of surgical site infection, graft complications, cardiac complications, postoperative bleeding, and reoperation within 30 days. These 30-day postoperative outcomes were nurse abstracted and validated for inclusion in the VASQIP database.

**Statistical analysis.** We first calculated the proportion of patients achieving OMM before undergoing elective lower extremity bypass for claudication for each year of the study period. Next, we compared patients' characteristics between those who achieved OMM and those who did not. For continuous variables, an unpaired *t*-test or Wilcoxon rank sum test was used,

**Table I.** Characteristics of patients who underwent lower extremity bypass for claudication, stratified by whether optimal medical management (*OMM*) was documented within the year before surgery

| Variable | OMM (n = 581) | Non-OMM (n = 1684) | *P* value[a] |
|---|---|---|---|
| Age, years | | | |
| Mean (SD) | 64.4 (8.3) | 63.1 (7.6) | <.001 |
| Median (IQR) | 63 (59-70) | 63 (58-67) | — |
| Range | (42-91) | (39-92) | — |
| White | 392 (67) | 1150 (68) | .33 |
| Male sex | 575 (99) | 1671 (99) | .64 |
| BMI, kg/m$^2$ | | | |
| Mean (SD) | 28.4 (5.1) | 27.4 (5) | <.001 |
| Median (IQR) | 26 (23-30) | 27 (24-31) | |
| Range | (14.9-45.5) | (12.5-47.4) | — |
| Current smoker within 1 year | 186 (32) | 1147 (68) | <.001 |
| DM with oral medication or insulin controlled | 242 (42) | 587 (35) | .003 |
| CHF within 30 days preoperatively | 7 (1) | 13 (1) | .34 |
| Angina within 1 month preoperatively | 15 (3) | 18 (1) | .009 |
| MI within 6 months preoperatively | 3 (1) | 6 (0) | .70 |
| History of HTN on medication | 523 (90) | 1408 (84) | <.001 |
| CVA or stroke with neurologic deficit | 40 (7) | 81 (5) | .06 |
| History of severe COPD | 111 (19) | 322 (19) | .99 |
| Dyspnea | 75 (13) | 221 (13) | .14 |
| Acute renal failure preoperatively | 0 (0) | 3 (0) | .57 |
| Dialysis preoperatively | 10 (2) | 19 (1) | .27 |
| Ascites | 0 (0) | 3 (0) | .57 |
| >10% weight loss in last 6 months | 9 (2) | 17 (1) | .29 |
| Bleeding disorder | 68 (12) | 108 (6) | <.001 |
| ASA class | | | |
| 1 | 0 (0) | 0 (0) | .35 |
| 2 | 11 (2) | 43 (3) | — |
| 3 | 486 (84) | 1431 (85) | — |
| 4 | 84 (14) | 210 (12) | — |
| 5 | 0 (0) | 0 (0) | — |
| Emergent case | 4 (1) | 21 (1) | .27 |
| Steroid use for chronic condition within 30 days preoperatively | 8 (1) | 18 (1) | .55 |

*ASA*, American Society of Anesthesiologists; *BMI*, body mass index; *CHF*, congestive heart failure; *COPD*, chronic obstructive pulmonary disease; *CVA*, cerebrovascular accident; *DM*, diabetes mellitus; *HTN*, hypertension; *IQR*, interquartile range; *MI*, myocardial infarction; *SD*, standard deviation. Values are reported as number (%) unless otherwise indicated.
[a]*P* value <.0167 indicates statistical significance.

depending on the normality of the variable distribution. For categorical variables, a $\chi^2$ test was used or a Fisher exact test if the expected cell count in any of the factor-level combinations was less than five. Outcomes were also summarized and stratified by optimization group. All survival outcomes (1 year, 3 years, 5 years, median AFS, and 30-day and 1-year mortality) and their 95% confidence intervals (CIs) were estimated using the Kaplan-Meier method. Multivariate logistic regression was used to construct the propensity score for OMM based on 21 variables in Table I. Subsequently, inverse probability of treatment weighting with the propensity scores was used to assign an OMM weight to each patient, calculated as

$$e/(Z * e + (1\text{-}Z) * (1\text{-}e))$$

where *e* is propensity score and $Z = 1$ with OMM and 0 otherwise. Observations with propensity score outside of the overlapping range of the two groups were removed. After weighting patients, we used logistic regression to estimate the effect of OMM on binary outcomes and Cox proportional hazards regression models

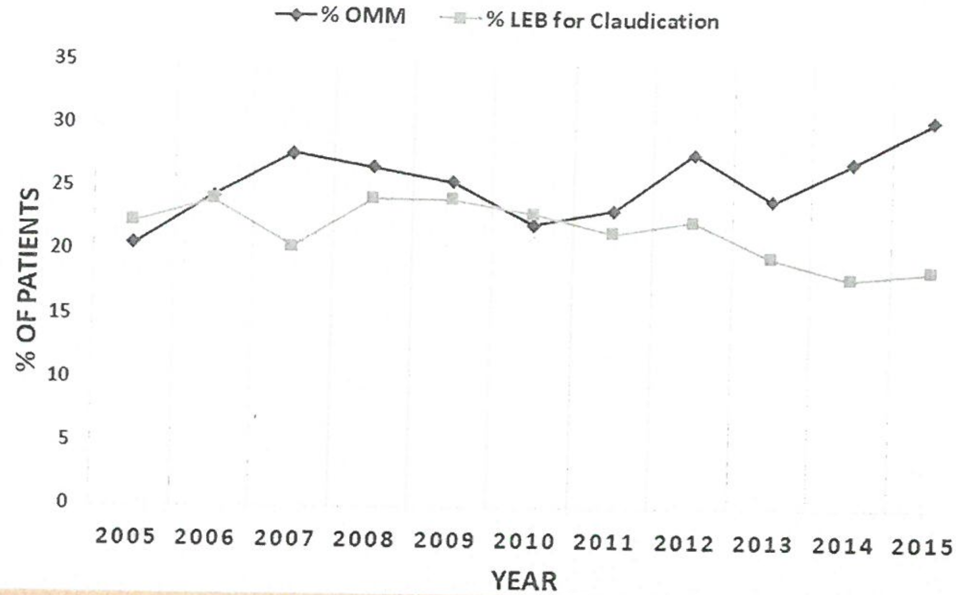


**Fig 2.** Trends in the proportion of veterans who underwent lower extremity bypass (*LEB*) for claudication and were documented to be receiving optimal medical management (*OMM*) within the year before surgery between 2005 and 2015. Whereas the proportion of bypass cases for claudication has decreased over time, the adherence to OMM has recently increased.

to analyze the effect of OMM on survival outcomes. Firth's bias-reduced logistic regression was used for the postoperative bleeding outcome because of few events.[8] All models adjusted for clustering of cases within facilities. We also tested for the presence of an interaction between OMM and time. Finally, we performed sensitivity analyses to examine outcomes among different subgroups of patients, including claudicants in the mildly obese (body mass index [BMI] >25 kg/m$^2$) and moderately to severely obese (BMI >30 kg/m$^2$) categories, claudicants in different age strata (<55 years, 55-65 years, and >65 years), and claudicants who underwent tibial bypass surgery. The Bonferroni method was used to adjust for multiple comparisons by diagnosis type, so that a *P* value of .0167 was used to assess statistical significance. Statistical analyses were conducted in R (version 3.4; R Foundation for Statistical Computing, Vienna, Austria), and all tests were two sided.

## RESULTS

Among 10,271 patients who underwent a lower extremity bypass across nationwide VAMCs between 2005 and 2015, we identified 2265 (22.1%) veterans undergoing bypass surgery for IC symptoms (Fig 1). During this time, the number of patients undergoing percutaneous interventions for IC significantly increased, whereas the proportion of lower extremity bypass procedures undertaken for IC declined slightly from 24% to 18% (Fig 2). This cohort included an equal distribution of patients who underwent surgery at VAMCs located within all 23 Veterans Integrated Service Networks across the United States. Components of medical management documented among veterans in this cohort are shown in Table II. A total of 1249 (55%) patients were documented as receiving antiplatelet therapy, and 1484 (66%) patients were documented as receiving statin therapy within the year before surgery. There were 829 (37%) claudicants with either type 1 or type 2 diabetes. Of the total cohort, 2095 (92%) were either nondiabetic or, if diabetic, had $HbA_{1c}$ measured within the year before surgery. The mean (±standard deviation) $HbA_{1c}$ level reported was 6.9% ± 1.6%. Among 1304 (58%) current smokers, 186 (32%) patients were prescribed a smoking cessation agent. Together, a total of 581 (25.7%) patients within this cohort were found to have achieved all components of OMM before undergoing surgery. During the entire study period, however, the proportion of patients documented as achieving OMM increased from 20% in 2005 to 30% in 2015 (Fig 2).

Baseline characteristics of patients at the time of lower extremity bypass are summarized in Table I, stratified by whether OMM was achieved. Full adherence to four domains of OMM did not differ significantly by sex or race. Patients with documentation of OMM were older, had a higher BMI, and had a higher prevalence of bleeding disorders than patients in the non-OMM group. In addition, OMM was associated with a higher proportion of diabetics and patients with angina symptoms. As might be expected, patients documented as achieving OMM were less likely to be current smokers.

Despite being documented as receiving OMM before surgery, there were no differences in 30-day or long-term outcomes among the cohort relative to patients in the non-OMM cohort. There was no significant difference in our Kaplan-Meier survival analysis between

**Table II.** Components of medical management received by patients undergoing lower extremity bypass for claudication (N = 2265)

| Component of medical management | |
|---|---|
| Documentation of antiplatelet therapy within 1 year before surgery | 1249 (55) |
| Documentation of statin therapy within 1 year before surgery | 1484 (66) |
| If DM, $HbA_{1c}$ level reported within 1 year before surgery | 2095 (92) |
| If DM, $HbA_{1c}$ values reported within 1 year before surgery | |
| Mean (SD) | 6.9 (1.6) |
| Median (IQR) | 6.4 (5.8-7.6) |
| If smoker, documentation of smoking cessation agent within 1 year before surgery | 1304 (58) |
| OMM | 581 (26) |

*DM*, Diabetes mellitus; *$HbA_{1c}$*, glycated hemoglobin; *IQR*, interquartile range; *OMM*, optimal medical management; *SD*, standard deviation. Values are reported as number (%) unless otherwise indicated.

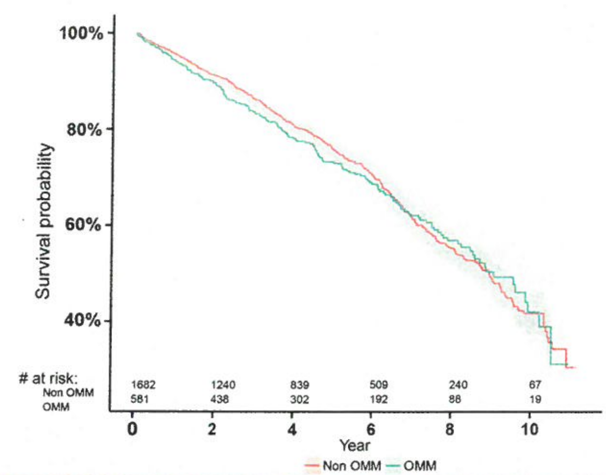


**Fig 3.** Kaplan-Meier survival estimate analysis among patients with preoperative optimal medical management (*OMM*) and those without OMM. No statistically significant difference in survival after lower extremity bypass surgery was identified among patients with preoperative OMM and those without OMM ($P = .78$ using log-rank test). Standard error <10% for all time points.

groups (Fig 3) as well as no difference in Kaplan-Meier AFS analysis up to 10 years after surgery (Fig 4). This was also found to be true for patients in different BMI and age strata (Table III). These findings for primary and secondary outcomes were confirmed in risk-adjusted analyses, summarized in Table IV. There was also no significant difference between OMM and non-OMM groups in the rate of 30-day postoperative complications, which included surgical site infection, graft failure, adverse cardiac events, postoperative bleeding, or need for reoperation. There also was no significant interaction effect between OMM and time on any of the outcomes. Finally, there was no significant difference in primary or secondary outcomes between OMM and non-OMM groups when cases were evaluated by whether patients underwent proximal vs distal bypass procedures (Table V).

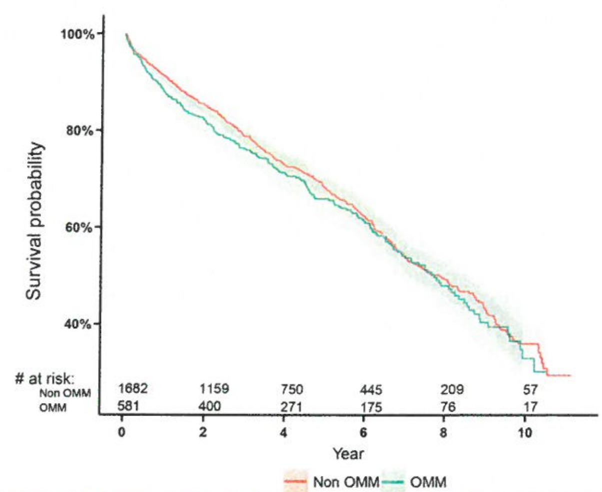


**Fig 4.** Kaplan-Meier amputation-free survival (AFS) estimate analysis among patients with preoperative optimal medical management (*OMM*) and those without OMM. No statistically significant difference in AFS after lower extremity bypass surgery was identified among patients with preoperative OMM and those without OMM ($P = .82$ using log-rank test). Standard error <10% for all time points.

## DISCUSSION

It is well established that all patients with claudication related to PAD should receive OMM to prevent progression of disease, to improve limb function, and to reduce cardiovascular morbidity and mortality, irrespective of whether they require lower extremity revascularization. Using data from across nationwide VAs, however, we found that only 26% of veterans who underwent lower extremity bypass for claudication during a 10-year period had evidence of achieving this goal within the year before undergoing surgery. Moreover, patients who were documented as achieving OMM before surgery did not have improved short- or long-term outcomes, including all-cause mortality and AFS. This study provides long-term survival data for a large cohort of male patients with PAD and suggests that efforts are needed to ensure that medical management is intensified before open revascularization procedures as well as to verify that objective goals of medical management for PAD are being achieved.

The management of patients with PAD has evolved to encompass many different therapeutic strategies, including surgical revascularization, exercise therapy, and medical managment.[2,9-11] In general, medical management includes a combination of both cardiovascular

**Table III.** Postoperative outcomes among patients undergoing lower extremity bypass for claudication, stratified by body mass index (*BMI*), age groups, and whether preoperative optimal medical management (*OMM*) was achieved

| | BMI strata | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | BMI <25 kg/m² (n = 537; 24%) | | | BMI 25-30 kg/m² (n = 751; 33%) | | | BMI >30 kg/m² (n = 977; 43%) | | |
| | OMM | Non-OMM | *P* value | OMM | Non-OMM | *P* value | OMM | Non-OMM | *P* value |
| 1-year AFS | 91.3 | 88.4 | .552 | 96.6 | 93.2 | .313 | 93.8 | 91.7 | .559 |
| 3-year AFS | 78.3 | 77.0 | .844 | 89.8 | 83.2 | .188 | 81.8 | 79.7 | .670 |
| 5-year AFS | 73.9 | 70.7 | .643 | 83.1 | 76.9 | .281 | 76.6 | 74.7 | .740 |
| Postoperative cardiac complication | 0.00 | 2.04 | .329 | 1.69 | 2.31 | .238 | 3.13 | 3.29 | .944 |
| Postoperative SSI | 8.7 | 7.7 | .817 | 15.3 | 10.3 | .240 | 20.3 | 15.9 | .352 |
| | Age strata | | | | | | | | |
| | <55 years (n = 257; 11%) | | | 55-65 years (n = 1265; 56%) | | | >65 years (n = 743; 33%) | | |
| | OMM | Non-OMM | *P* value | OMM | Non-OMM | *P* value | OMM | Non-OMM | *P* value |
| 1-year AFS | 100.0 | 90.9 | .206 | 92.0 | 92.9 | .750 | 95.5 | 89.1 | .104 |
| 3-year AFS | 87.5 | 81.7 | .561 | 81.6 | 82.9 | .754 | 83.3 | 77.8 | .301 |
| 5-year AFS | 81.3 | 77.2 | .706 | 79.3 | 76.9 | .612 | 75.8 | 69.3 | .273 |
| Postoperative cardiac complication | 0.00 | 2.49 | .523 | 1.15 | 2.29 | .486 | 1.52 | 3.40 | .409 |
| Postoperative SSI | 6.25 | 13.28 | .416 | 18.4 | 12.5 | .114 | 13.6 | 11.2 | .557 |

*AFS*, Amputation-free survival; *SSI*, surgical site infection.
Values are reported as percentages.

**Table IV.** Risk-adjusted postoperative outcomes for patients undergoing lower extremity bypass for claudication, stratified by whether preoperative optimal medical management (*OMM*) was achieved

| Outcome variable | OMM (n = 581) | Non-OMM (n = 1684) | *P* value[a] |
|---|---|---|---|
| SSI | 72 (12) | 209 (12) | .66[b] |
| Graft failure | 15 (3) | 41 (2) | .25[b] |
| Cardiac complications | 15 (3) | 50 (3) | .11[b] |
| Reoperation within 30 days | 74 (13) | 207 (12) | .48[b] |
| Postoperative bleeding | 2 (0) | 4 (0) | .13[c] |
| AFS, % (95% CI) | | | .81[d] |
| 1-year | 87.6 (84.9-90.3) | 90.9 (89.4-92.2) | |
| 3-year | 76 (72.4-79.7) | 78.7 (76.5-80.8) | |
| 5-year | 65.9 (61.7-70.5) | 68.1 (65.5-70.8) | |
| Median, years (95% CI) | 7.73 (6.89-8.59) | 7.88 (7.07-8.71) | |
| Mortality, % (95% CI) | | | .36[d] |
| 30-day morality | 0.7 (0.1-1.4) | 0.6 (0.2-1) | |
| 1-year mortality | 5.7 (3.8-7.6) | 4.6 (3.6-5.6) | |

*AFS*, Amputation-free survival; *CI*, confidence interval; *SSI*, surgical site infection.
Values are reported as number (%) unless otherwise indicated.
[a]*P* value <.0167 indicates statistical significance.
[b]Logistic regression, adjusting for inverse probability of treatment weighting propensity scores.
[c]Firth's logistic regression due to rare events, adjusting for inverse probability of treatment weighting propensity scores.
[d]Cox proportional hazards regression model, adjusting for inverse probability of treatment weighting propensity scores.

risk reduction and limb-specific therapies, such as those assessed in this study. Specifically, we chose to evaluate whether there was evidence that patients with IC were appropriately treated for tobacco abuse or hyperglycemia, if needed, and received the two types of medication classes that are universally agreed to be prescribed for PAD. This was based on overwhelming evidence showing that tobacco abuse and uncontrolled diabetes are the two most important modifiable risk factors to target for PAD.[1,2,5,6,12] Smoking cessation has been shown to improve both ankle-brachial index and exercise tolerance, whereas uncontrolled diabetes has been

**Table V.** Postoperative outcomes among patients undergoing proximal and distal bypass procedures for claudication, stratified by whether preoperative optimal medical management (*OMM*) was achieved

| | Proximal bypass (n = 1932; 85%) | | | Distal bypass (n = 333; 15%) | | |
|---|---|---|---|---|---|---|
| Outcome variables | OMM | Non-OMM | *P* value | OMM | Non-OMM | *P* value |
| 1-year AFS | 95.7 | 92.9 | .215 | 87.1 | 82.8 | .541 |
| 3-year AFS | 84.1 | 82.7 | .685 | 77.4 | 71.9 | .509 |
| 5-year AFS | 78.3 | 76.0 | .543 | 77.4 | 65.6 | .182 |
| Postoperative cardiac complication | 0.72 | 2.57 | .176 | 3.23 | 3.31 | .980 |
| Postoperative SSI | 13.8 | 12.4 | .636 | 14.5 | 10.9 | .557 |

*AFS*, Amputation-free survival; *SSI*, surgical site infection.
Values are reported as percentages.

shown to be associated with progression to tissue loss and amputation.[13,14] Antiplatelet therapy has been shown to lower the risk of stroke or MI, and at least one meta-analysis involving randomized controlled trials among patients with claudication found that aspirin compared with placebo reduced the risk of arterial occlusion and need for revascularization procedures.[15] Studies have also shown that claudicants treated with statin therapy experience improvements in pain-free walking distance and physical activity tolerance.[16] However, there are other components of PAD medical management that we did not include in analysis. For example, class I evidence supports blood pressure control as a risk-reducing measure for those with PAD.[3] Most consensus guidelines specifically recommend use of angiotensin-converting enzyme (ACE) inhibitors as a medical means to reduce concomitant cardiovascular risk in PAD. Moreover, our study was not designed to evaluate adherence of patients to supervised exercise therapy or other evidence-based behavioral techniques designed for IC. This includes cognitive-behavioral interventions and counseling, which have been shown to be effective strategies for promoting smoking cessation.

Patients being managed for PAD are consistently found to have variable compliance with all of these evidence-based components of medical management despite sharing similar long-term risk with patients with coronary artery disease.[17,18] Only a quarter of claudicants in our study achieved OMM before undergoing lower extremity bypass, which is similar to the rates of medical management reported in other PAD studies. One study that evaluated 1357 patients who underwent peripheral vascular interventions for PAD in the Blue Cross Blue Shield of Michigan Cardiovascular Consortium database found that only 47% of patients were considered to have received OMM.[9] This was defined by concurrently taking an aspirin (85%) or statin (76%) and abstaining from smoking (65%) before the peripheral intervention. Another study defined OMM as taking a daily aspirin, statin, and ACE inhibitor as well as smoking abstention among a cohort of 739 patients with both claudication and CLI who underwent diagnostic or therapeutic angiography.[10] In this study, only 32% of patients met all four guideline-recommended therapies, including aspirin (88%), statin (67%), ACE inhibitors (60%), and smoking cessation (71%). The low compliance with OMM in this study was similar to ours; however, it is notable that these previous studies did not assess $HbA_{1c}$ level or determine whether efforts to control hyperglycemia were undertaken among diabetic patients in their cohorts.

Despite a low adherence to OMM in our study, it was expected that patients who were documented as receiving all of these evidence-based processes would benefit from improved long-term outcomes. Indeed, previous studies have demonstrated that compliance with OMM is associated with significant reductions in major adverse cardiovascular events, major adverse limb events, and mortality among patients undergoing management for IC or CLI. For example, it was shown that patients with PAD who adhered to OMM consisting of aspirin, statin, and ACE inhibitors and smoking abstinence before angiography had decreased cardiovascular events (hazard ratio [HR], 0.64; 95% CI, 0.45-0.89; *P* = .009), major limb events (HR, 0.55; 95% CI, 0.37-0.83; *P* = .005), and mortality (HR, 0.56; 95% CI, 0.38-0.82; *P* = .003) compared with patients receiving fewer than the four recommended therapies.[10] Another study evaluated patients with symptomatic PAD (either claudication or CLI) who were prospectively enrolled in a targeted program called Systematic Assessment of Vascular Risk (SAVR) that promoted antiplatelet agents, statins, ACE inhibitors, blood pressure control, lipid control, diabetic glycemic control, smoking cessation, and target BMI.[11] Propensity-matched PAD patients in the SAVR program were found to have a significantly lower rate of death, MI, or ischemic stroke compared with the control group (HR, 0.63; 95% CI, 0.52-0.77).[11] In addition, patients who received the intervention were less likely to have major amputation (HR, 0.47; 95% CI, 0.29-0.77), minor amputation (HR, 0.26; 95% CI, 0.13-0.54), or hospitalization because of heart failure (adjusted HR, 0.73; 95% CI, 0.53-1.00).[11] However, not all patients in this cohort were simple claudicants, and only a fraction of patients in this study underwent revascularization including arterial bypass surgery (12%) and a peripheral vascular intervention (14%).

Consensus guidelines sponsored by the Society for Vascular Surgery emphasize that surgical treatment for IC should be individualized on the basis of the patient's comorbidities, functional impairment, and anatomic factors as well as be reserved for patients who are most likely to yield predictable functional improvements with reasonable durability.[2] For suitable patients, first-line therapy recommended by guidelines consists of walking a minimum of three times per week (30-60 min/session) for at least 12 weeks. However, there are a number of factors that can drive clinicians away from conservative therapy toward early surgical revascularization for IC. In a study examining practice patterns and differences between community hospitals and academic medical centers, the authors identified several factors that push surgeons to recommend surgery, including a lack of reasonable reimbursement for medically managing claudicants compared with reimbursement for procedural or surgical treatment of disease.[19] In addition, the investigators described pressures in private practice settings to provide surgery for their patients to avoid doctor shopping or to appease referring providers. There is also emerging competition between vascular surgery and specialties such as interventional radiology and interventional cardiology to provide endovascular therapies for patients with peripheral vascular disease.[19] Whereas these competitive and financial pressures among providers in theory should be eliminated in the VA, OMM is often not achieved before surgical intervention. This highlights the need for a quality initiative to ensure that medical management is undertaken before surgical interventions for IC.

The assessment of both OMM and associated long-term outcomes among patients with claudication must account for unique characteristics intrinsic to this specific population. First, the expected effects of OMM on surgical outcomes in patients with claudication may need to be tempered compared with patients with more severe manifestations of PAD such as CLI. For example, Suckow et al[20] examined statin use in a study among PAD patients undergoing lower extremity bypass and found a survival advantage in patients taking statins with CLI (5-year survival rate, 63% vs 54%; $P = .01$) but not claudication (5-year survival rate, 84% vs 80%; $P = .59$). Second, the delivery of OMM in patients with claudication must be correlated with objective end points that are specific to their disease. This may include restricting procedures until goals are met, such as uptitration of statin agents to maximal tolerated dose and correlation with walking distances, intensification of hyperglycemic therapy to meet the $HbA_{1c}$ goal of <7%, and smoking abstinence for >3 months. For claudicants, a meta-analysis showed that open or endovascular revascularization in combination with an exercise program improved claudication-specific outcomes over medical management.[21] It may be that claudication-specific outcomes and surgical outcomes are less affected by medical management in patients with claudication compared with those with more severe symptoms related to PAD.

Our study has several limitations to discuss. First, this is a retrospective study based on administrative data and is not designed to show causality between OMM and postoperative outcomes. Second, the documentation of OMM domains shows the intent to treat or to manage, but it does not measure whether the patient's compliance with therapy was actually met. Some patients may have been taking over-the-counter medications or have dually eligible status (ie, enrolled in VA health care as well as in another health care program) and thus not have all current medications listed in their chart. Active smokers, by definition, were not medically optimized even if they were prescribed medications for smoking cessation therapy. Furthermore, we used $HbA_{1c}$ measurement as a marker of the physician's monitoring of diabetes in place of specific medical agents as we believe this marker to be more congruent with success of diabetic management. Third, our study did not measure other components of PAD management, including office-based counseling, supervised exercise therapy, and blood pressure control with the ACE inhibitor ramipril, which are also recommended in patients with PAD. Nevertheless, there are no national VA protocols regarding these management strategies, which are left up to the discretion of the provider. Fourth, our study did not have claudication-specific outcomes available, like subjective measurement of symptom improvement, gains in walking distance, or improvement in exercise tolerance. Moreover, we were unable to assess whether any cardiovascular events or intervening illnesses occurred beyond 30 days after surgery, which may have had an impact on long-term survival. Fifth, our cohort of patients undergoing lower extremity bypass was heterogeneous, and we did not stratify data on the basis of type of graft used. Sixth, our analysis was unable to control for VAMC sites that were staffed with full-time vascular surgeons vs those who rely on rotating staff, which may have confounded adherence to OMM. Last, our study included only patients with symptomatic claudication that led to bypass surgery within the VA health care system. Patients whose claudication improved with medical management, those whose disease progression was slowed to the point of avoiding surgery during the study period, and those who underwent interventions outside the VA were not included in this analysis.

## CONCLUSIONS

Whereas OMM processes were documented in only 26% of veterans with claudication within the year before open lower extremity bypass, achieving this metric was ultimately not found to be associated with improved postoperative outcomes. These results suggest that focused efforts are needed to ensure that medical management is intensified before open revascularization procedures. Moreover, these data also underscore the importance of having objective laboratory or clinical end points allowing vascular providers to confirm that OMM is achieved before surgery.

## AUTHOR CONTRIBUTIONS

Conception and design: CW, AJ, LM, BB
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Data collection: CW, AJ, LM
Writing the article: CW, BB
Critical revision of the article: CW, AJ, LM, CZ, AP, LK, BB
Final approval of the article: CW, AJ, LM, CZ, AP, LK, BB
Statistical analysis: CZ, AP
Obtained funding: BB
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