

The Association of Gender With Quality of Health in Peripheral Arterial Disease Following Peripheral Vascular Intervention

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ABSTRACT: Background. Women and men have similar prevalence of peripheral arterial disease (PAD). However, women are reported to have more severe disease and worse claudication symptoms than men. The association of the gender-related differences in PAD-specific health status following peripheral vascular intervention (PVI) has not been previously evaluated. **Methods.** We compared the clinical responses of women and men to PVI by prospectively obtaining answers to a Peripheral Arterial Questionnaire (PAQ) in 384 patients at baseline and up to 6-months follow-up post-PVI. We utilized the PAQ summary score of patients' physical function, symptoms, social function, and quality-of-life (QOL) scores to reflect patients' quality of health (QOH). Scores range from 0-100, with higher scores indicating better symptomatic and functional status. **Results.** Women (191, 49.7%) and men (193, 50.3%) were equally represented in our study. Prior to PVI, both groups had similar QOH scores (36 ± 21 vs 34 ± 20 , $P = 0.49$) for men and women, respectively. Following PVI, there was a similar and significant improvement in QOH scores increasing to 60 ± 28 vs 58 ± 29 ($P = 0.36$) for men and women, reflecting a substantial clinical improvement in both groups. **Conclusion.** In patients undergoing PVI, women and men had similar QOH scores at baseline. There was also a significant and similar improvement in QOH scores following PVI in both genders. These findings showed that PVI had similar effectiveness for improving QOH significantly and equally in both men and women with symptomatic PAD.

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Key words: peripheral arterial disease, Peripheral Arterial Questionnaire, claudication, quality of health

Lower extremity peripheral arterial disease (PAD) affects at least 8.5 million Americans above the age of 40 years.¹ Earlier studies have suggested that PAD is more common in men, but recent reports have shown that the prevalence of PAD in women is at least the same as in men, if not higher.^{2,3} PAD results in significant symptoms and impairment in ambulatory capacity, leading to functional disability and limitation in the patient's quality of life.² Specifically, women with PAD have faster functional decline and greater restriction of mobility than men with PAD.⁴ Women also have a more severe and complex disease process, and they are at increased risk for adverse outcomes following peripheral vascular intervention (PVI).⁵ In PAD revascularization trials, women are disproportionately underrepresented, and they accounted for only a third of trial participants, with limited focus on gender-related outcomes.^{6,7} To the best of our knowledge, no study has evaluated the association of gender with changes in health status following PVI. The aim of our study is to examine the gender-related differences in PAD-related health status in patients undergoing PVI for lower extremity PAD.

METHODS

Study population and data collection. The study population consisted of consecutive patients who underwent PVI between January 1, 2012 and December 31, 2012 at St John Hospital and Medical Center in Detroit, Michigan. These data are collected on an ongoing basis as a result of our participation in the multicenter quality improvement registry, BMC2-VIC, that involves 47 hospitals in Michigan. Details of the BMC2-VIC registry have been described elsewhere.^{8,9} For this analysis, all patients who underwent lower extremity PVI, and whose data were collected in the registry at our single center, were included. An on-site research coordinator collected data on demographic and clinical characteristics, procedural details, treatments, and outcomes of patients undergoing PVI procedures. Rutherford classification of chronic limb ischemia was used for clinical staging of peripheral arterial disease. This classification has 7 categories—category 0, asymptomatic; category 1, mild claudication; category 2, moderate claudication; category 3, severe claudication; category 4, rest pain; category 5, minor tissue loss; and category 6, ulceration or gangrene.¹⁰ The data were submitted electronically to the registry, and a copy of these data

was maintained at our institution. Similarly, our research nurse coordinators collected data on health status following PVI using the Peripheral Arterial Questionnaire (PAQ).¹¹ This information was collected prior to PVI and at follow-up (up to 6 months) following intervention, using the same questionnaire.

The data were collected for a total of 502 patients. Of those, 115 patients had acute limb ischemia and were excluded from the current analysis. Additionally, 3 other patients were excluded because information on gender was missing for them. Thus, the study population consisted of 384 consecutive patients with PAD who underwent PVI in the time period noted above. As a part of participation in the BMC2-VIC registry, data quality and the inclusion of consecutive procedures were ensured by ad hoc queries, random chart reviews, and a series of diagnostic routines included in the database. This study was approved by the institutional review board of the hospital.

Data definitions and endpoints. Peripheral vascular intervention (PVI) was defined as endovascular intervention on an artery in the aorto-iliac, femoro-popliteal, and below-knee arterial tree using a wide range of interventional devices at the discretion of the operator.

The PAQ is a PAD-specific tool that assesses the health status

of PAD patients over 4 weeks' duration prior to completing the questionnaire.¹¹ The PAQ comprises 6 domains: physical function, symptoms, symptoms stability, treatment satisfaction, social function, and quality of life (QOL). Scores in each domain range from 0-100; lower scores suggest worse functional status, worse quality of life, and increased frequency of symptoms.

Six questions addressed the physical limitation domain, in which patients rate the severity of restriction in different activities caused by PAD. These restrictions range from limitation in mild activities such as walking around the house, to limitation only in more vigorous activities such as jogging. Three questions in the symptoms scale domain addressed the frequency and burden of claudication and fatigue, as well as rest or nocturnal pain, if present. Change of symptoms over a 4-week period was evaluated by one question under symptoms stability domain. QOL domain focused on PAD impact on patients' enjoyment of life, satisfaction with their current symptoms, and psychologic well-being. Social functioning domain evaluated the PAD burden on patients' abilities to practice their hobbies, visit families and friends, and perform daily household chores. The summary score reflects the average scores of the domains of physical limitation, symptoms, social functioning, and quality of life. In our study, we utilized the PAQ summary score

Table 1. Baseline Characteristics of Study Population^a

| Patients/Gender | Men n=193 (50.3) | Women n=191 (49.7) | P Value |
|---------------------------------|------------------------|-----------------------|---------|
| Age, mean (SD) | 74.8 ± 10.1 | 75.9 ± 11.4 | 0.29 |
| Diabetes | 106 (55.2) | 95 (49.7) | 0.28 |
| Coronary artery disease | 122 (63.2) | 110 (57.6) | 0.26 |
| Hypertension | 187 (96.9) | 181 (94.8) | 0.29 |
| Hyperlipidemia | 179 (93.2) | 163 (85.3) | 0.01 |
| Congestive heart failure | 46 (23.8) | 49 (25.7) | 0.68 |
| CVD/TIA | 49 (25.5) | 54 (28.3) | 0.54 |
| Atrial fibrillation | 37 (19.2) | 25 (13.2) | 0.11 |
| Family history of premature CAD | 34 (17.9) | 27 (14.2) | 0.33 |
| COPD | 60 (31.1) | 55 (28.9) | 0.65 |
| Renal failure on dialysis | 14 (7.3) | 11 (5.8) | 0.56 |
| Prior PVI procedure | 105 (54.4) | 98 (51.3) | 0.54 |
| Prior surgical procedure | 63 (32.6) | 35 (18.3) | 0.001 |
| Current smoker | 54 (28.0) | 58 (30.4) | 0.61 |
| Former smoker | 113 (58.5) | 84 (44.0) | 0.004 |

| Patients/Gender | Men n=193 (50.3) | Women n=191 (49.7) | P Value |
|--|------------------------|-----------------------|---------|
| Lesion location | | | |
| Above knee only ^b | 81 (42.3) | 94 (50.2) | 0.11 |
| Below knee only ^c | 45 (23.6) | 31 (16.6) | 0.95 |
| Above and below knee ^d | 67 (35.1) | 62 (33.2) | 0.72 |
| Rutherford category | | | |
| 0 | 0 | 0 | |
| 1 | 0 | 0 | |
| 2 | 2 (1.1) | 0 | |
| 3 | 80 (43.2) | 74 (40.4) | |
| 4 | 41 (22.2) | 61 (33.3) | |
| 5 | 59 (31.9) | 43 (23.5) | |
| 6 | 3 (1.6) | 5 (2.7) | |
| CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; CVD/TIA = cerebrovascular disease/transient ischemic attack; PVI = peripheral vascular intervention; SD = standard deviation. | | | |
| ^a Values are mean ± SD and n (%). | | | |
| ^b Iliac or femoral artery lesions. f | | | |
| ^c Popliteal artery or below-knee artery lesions. | | | |
| ^d Both above-knee and below-knee lesions in same patient. | | | |

to represent the quality of health (QOH) of the patients. The PAQ has been validated against different health status questionnaires in patients with PAD who underwent PVI.¹² The changes in PAQ scores after revascularization have been shown to reflect substantial sensitivity of the PAQ to clinical improvement.¹¹

The primary outcome of interest for this study was the difference in the change in QOH scores following PVI between men and women. The change score was described as the difference between the baseline PAQ summary score pre-PVI and up to 6 months post-PVI.

Statistical analysis. Descriptive statistics were calculated to characterize the study group. Continuous variables were described as the mean with standard deviation (SD) or median with range. Categorical variables were described as frequency distributions. Mean and median domain and overall PAQ scores were computed. The differences in scores at each time period (baseline, post-PVI) between men and women were assessed using Student *t*-test or the Mann-Whitney U test (if the data were skewed). The difference in the change in scores over time was compared between men and women using the Mann-Whitney U test. All data were analyzed using SPSS version 24.0, and a *P* value of 0.05 or less was considered to indicate statistical significance.

RESULTS

Demographics and clinical history. Of the 384 patients, half were women (*n* = 191, 49.7%) and of similar age compared with men, as shown in **Table 1**. The prevalence of comorbid conditions such as diabetes, coronary artery disease, hypertension, congestive heart failure, chronic obstructive pulmonary disease, and atrial fibrillation was similar in both groups. Hyperlipidemia was less common in women. Also, women were less likely to have a prior peripheral surgical revascularization. Rate of current smoking was similar in the 2 groups, but men were more likely to be former smokers. Above-knee-only intervention was performed slightly more in women than men (50% vs 42%), but the difference was not statistically significant. Over 99% of our study patients had severe claudication (Rutherford class 3), rest pain (Rutherford class 4), or minor tissue loss (Rutherford class 5). Rutherford classification did not differ between genders, indicating similar severity of PAD.

Post-PVI care and medications. There was no significant difference in the use of dual anti-platelet therapy, cilostazol, statins, β -blockers, and angiotensin-converting enzyme (ACE) inhibitors between the 2 groups, as shown in **Table 2**. However, women were more likely to receive additional vasodilators, including nitrates and angiotensin receptor blockers (ARBs). Women were less frequently on warfarin, likely a reflection of lower rates of atrial fibrillation in women in our study population. Patient education upon discharge regarding the benefits of smoking cessation and regular exercise was similar in both groups. Technical success, which was defined as vascular access, deployment of device(s), and \leq 30% diameter residual stenosis after revascularization,⁹ was slightly better in women compared with man (95.7% vs 89.9%). The rates of complications both at 30 days and at 1 to 6 months were similar between the 2 groups (**Appendix 1 and 2**).

Table 2. Prescribed Medications, Technical Success, and Education Upon Discharge

| Discharge Medications | Men | Women | <i>P</i> Value |
|--------------------------|------------|------------|----------------|
| Aspirin | 182 (94.3) | 178 (93.2) | 0.65 |
| DAPT ^a | 171 (88.6) | 171 (89.5) | 0.77 |
| Clopidogrel | 177 (91.7) | 181 (94.8) | 0.23 |
| Prasugrel | 5 (2.6) | 3 (1.6) | 0.48 |
| β blockers | 140 (72.5) | 133 (69.6) | 0.53 |
| ACEIs | 111 (57.5) | 100 (52.4) | 0.31 |
| ARBs | 23 (11.9) | 37 (19.4) | 0.04 |
| Statins | 161 (83.4) | 150 (78.5) | 0.22 |
| Calcium channel blockers | 65 (33.7) | 77 (40.3) | 0.18 |
| Nitrate | 25 (13.0) | 41 (21.5) | 0.03 |
| Cilostazol | 14 (7.3) | 13 (6.8) | 0.86 |
| Warfarin | 26 (13.5) | 13 (6.8) | 0.03 |
| Technical success | 170 (89.9) | 176(95.7) | 0.03 |
| Education upon discharge | | | |
| Exercise (Yes) | 157 (81.3) | 151 (80.3) | 0.79 |
| Smoking (Yes) | 193 (100) | 188 (100) | -- |

ACEIs = angiotensin-converting enzyme inhibitors; ARBs = angiotensin II receptor blockers; DAPT = dual antiplatelet therapy.

^aASA + one of the following (clopidogrel or prasugrel).

QOH at baseline and following PVI. The overall analysis of PAQ scores showed 3 notable findings. First, both groups had similar baseline scores in all PAQ domains (**Table 3**). Second, QOH scores following PVI increased substantially, from 35.9 ± 21.0 and 34.4 ± 20 at baseline to 60.2 ± 27.8 and 57.5 ± 29.0 at follow-up for men and women, respectively, (**Table 3 and Figure**). These large improvements in the post-PVI QOH scores reflect a significant clinical improvement in both groups. Third, both groups benefited equally (**Table 4**). This important finding suggests that women derived equal clinical benefit from the procedure.

We next evaluated the individual domains. Women and men had a substantial and statistically significant improvement in all PAQ scores, except in treatment satisfaction domain. The physical function score doubled in both men and women, increasing to 50.4 ± 35.7 and 45.1 ± 32.4 , respectively, while symptoms scores increased significantly, indicating lessening of claudication. The stability score also increased in both groups, suggesting that the improvements in claudication symptoms were sustained. Social function scores improved, indicating the patients were able to engage more in social activities and hobbies. In treatment satisfaction domain, the scores

Table 3. The PAQ Domains and the Summary Score in Both Groups at Baseline and Post-PVI^a

| PAQ domain | Men | | | Women | | |
|------------------------|-------------|-------------|---------|-------------|-------------|---------|
| | Baseline | Follow-up | P Value | Baseline | Follow-up | P Value |
| Physical function | 24.6 ± 24.9 | 50.4 ± 35.7 | <0.0001 | 22.4 ± 22.3 | 45.1 ± 32.4 | <0.0001 |
| Symptoms | 36.2 ± 25.9 | 66.6 ± 31.5 | <0.0001 | 33.2 ± 24.6 | 60.1 ± 33.7 | <0.0001 |
| Symptom stability | 33.7 ± 23.9 | 55.9 ± 24.9 | <0.0001 | 35.6 ± 24.3 | 53.7 ± 24.5 | <0.0001 |
| Treatment satisfaction | 81.7 ± 21.3 | 77.9 ± 25.0 | 0.06 | 82.7 ± 20.3 | 76.9 ± 26.0 | 0.008 |
| Social function | 44.7 ± 32.7 | 62.7 ± 34.8 | <0.0001 | 42.6 ± 31.1 | 61.2 ± 34.9 | <0.0001 |
| Quality of life | 38.3 ± 24.1 | 61.5 ± 29.1 | <0.0001 | 38.2 ± 23.5 | 60.5 ± 29.1 | <0.0001 |
| Summary score | 35.9 ± 21.0 | 60.2 ± 27.8 | <0.0001 | 34.4 ± 20.2 | 57.5 ± 29.0 | <0.0001 |

PAQ = peripheral arterial questionnaire; PVI = peripheral vascular intervention.

^a Values are mean ± standard deviation.

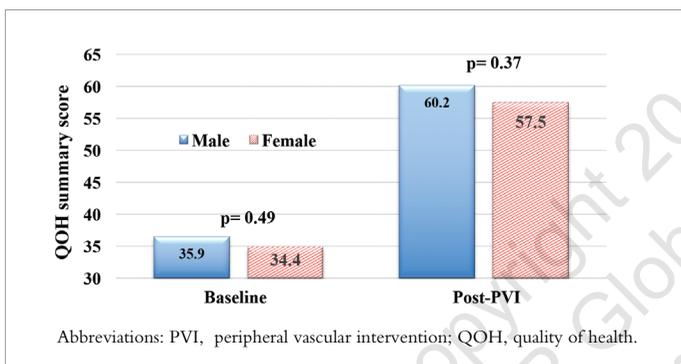


Figure. Change in Quality of Health From Baseline to Post-PVI

decreased in women but did not change in men. Overall QOH score improvement was large in women and men, appropriately reflecting a significant clinical improvement in both groups.

For readers unfamiliar with the PAQ questionnaire, we describe the PAQ scoring in one study patient in an attempt to make it easier to correlate PAQ scores with patient clinical symptoms. A 78-year-old woman was slightly limited walking around the house and moderately limited with her household chores. She had episodes of rest pain and claudication every day, and she woke at least once every night due to pain. Her summary score at baseline was 25. After intervention in right femoral, popliteal, and peroneal arteries, she had no limitation with walking around the house or with her household chores. She had claudication less than once a week and woke from sleep with leg pain less than once a week. Her summary score postintervention improved to 86.

DISCUSSION

The treatment of PAD is aimed at reducing cardiovascular risk, increasing functional performance, and improving health status.

QOL is emerging as an important measurable outcome for patients undergoing peripheral interventions.^{11,12} In general, assessing PAD-related health status provides insights into the effects of treatment on patients and may help guide the need for further therapy. Moreover, assessment of health status following PVI has become even more relevant in the current era where PVI has emerged as a common initial therapy for symptomatic PAD,^{13–15} while supervised exercise therapy continues to remain underutilized. Prior PAD studies evaluated gender disparities in mortality and morbidity following revascularization. These studies indicate that among patients undergoing PVI, women have higher adjusted rates of procedural bleeding and vascular access site complications.^{5,16} Also, several studies have demonstrated higher rates and severity of PAD, worse quality of life, and worse physical function in women compared with men with PAD.^{17,18} However, no study as of yet has assessed gender differences in PAD-related health status following PVI.

In contrast to previous studies, our study of post-PVI health status demonstrated that women had similar PAD-specific health status as reflected by similar QOH scores at baseline. The recently published Patient-centered Outcomes Related to Treatment Practices in Peripheral Arterial Disease Investigating Trajectories (PORTRAIT) study by Roumia et al elegantly assessed the differences in health status between men and women with symptomatic peripheral arterial disease upon their first presentation to a vascular specialty clinic by using the peripheral arterial questionnaire.¹⁹ They reported that women had poorer baseline health status when compared with men. However, the PORTRAIT study included a younger patient cohort with less severe disease than that of our cohort. Over 70% of PORTRAIT patients had only mild-to-moderate disease with Rutherford class < 2, while 99% of participants in our study had Rutherford class > 3. Moreover, over half of our patients had rest pain or tissue loss, while none of the PORTRAIT patients did. Overall, the PORTRAIT included patients with milder PAD managed medically, while patients from our study had more advanced disease that necessitated vascular intervention. These differences

Table 4. The Change in Each of the Six PAQ Domains and the Summary Score^a

| PAQ domain | Men | Women | P Value |
|------------------------|-------------|-------------|---------|
| Physical Function | 20.8 (58.3) | 20.8 (45.8) | 0.65 |
| Symptoms | 33.3 (47.2) | 25.0 (52.8) | 0.31 |
| Symptom Stability | 25.0 (50.0) | 25.0 (50.0) | 0.28 |
| Treatment Satisfaction | 0.0 (41.7) | 0.0 (33.3) | 0.83 |
| Social Function | 16.7 (56.3) | 25.0 (58.3) | 0.87 |
| Quality of Life | 25.0 (45.8) | 25.0 (47.9) | 0.90 |
| Summary Score | 24.4 (41.1) | 25.0 (44.3) | 0.78 |

Abbreviations: PAQ, peripheral arterial questionnaire; PVI, peripheral vascular intervention.

^a Values are mean ± standard deviation.

in demographics and PAD severity were proportionately reflected by differences in baseline PAQ scores: lower baseline PAQ scores indicating worse health status (average 30 to 40) due to severe disease in our study vs higher baseline scores (average 40 to 60) consistent with milder disease and better health status in PORTRAIT patients. These above noted differences help us explain the gender-related disparities seen in PAQ scores and health status between the 2 studies. We believe that gender-related differences in health status are more prominent in the milder form of PAD, as assessed by the PORTRAIT study and other earlier studies. However, as the disease progresses to advanced stages, especially in older patients, these significant gender-related differences in health status disappear, as elucidated in our study.

Our study showed that both men and women benefited significantly from PVI. Prior to interventions, the patients were significantly limited physically and socially, and they had poor QOH due to severe PAD. After intervention, there was significant improvement in symptoms, physical and social function, and overall QOH. Most PAQ domains increased to 60%, demonstrating better and improved health status but also indicating room for greater improvement, which is where future research should be directed.

When the net increase in the scores was compared with that seen in men, women achieved similar improvements in QOH following intervention. This is an important finding, suggesting that even in a study population like ours with advanced and severe PAD, the benefits of PVI on health status gained by women are significant, and this improvement is not impacted by gender. These findings will help the physician explain the treatment plan and outcome expectations to patients and will help patients make decisions and refine their expectations regarding improvements in QOH following PVI.

An interesting and potentially important finding of our study

concerns satisfaction of patients with their care. Despite significant physical and social limitations related to their PAD, patients reported very high satisfaction with care both pre-PVI (PAQ satisfaction score 82) and at follow-up post-PVI (PAQ score 78). This score was substantially higher than all other PAQ domains pre- and post-PVI. Further, 2 other studies of PAD utilizing PAQ observed similar findings.^{12,19} It is not immediately clear why patients with moderate or severe limitations from PAD would consistently be very satisfied with their care. Possibilities might include optimism and appreciation for personalized care provided in a specialized vascular clinic¹⁹ or with an intervention designed to improve care.¹² An opposite hypothesis could be that patients may be afraid of offending their physicians, even though the survey was anonymous.

We also noted that women had lower rates of prior surgical procedures before the index PVI. This finding, when combined with additional use of nitrates and ARBs in women, might indicate that women with symptomatic PAD were more likely to be managed medically. It remains unclear if physicians treat women with PAD medically and tend to defer revascularizations, given reported higher rates of procedural complications in this population. The design and size of our study precludes us from deriving any concrete conclusions in this regard.

Our study complements the prior vascular literature and adds to our understanding of the impact of gender on health status in severe PAD requiring PVI. Gender-related impact on health status is more pronounced in the milder form of disease. However, as disease severity increases, the PAD-related clinical health status is similar in men and women.

STUDY LIMITATIONS

This is a retrospective observational study with a moderate sample size. Limitations of observational studies would apply to our study. The results should be viewed as hypothesis generating rather than implying causation. We only had intermediate-term follow-up data on QOH following PVI. Longer follow-up data will provide better understanding of sustainability of improvement in QOH in men and women.

CONCLUSIONS

In patients receiving PVI, women and men had similar QOH scores at baseline. There was also a significant and similar improvement in QOH scores following PVI in both genders. These findings showed that PVI had similar effectiveness for improving QOH significantly and equally in both men and women with symptomatic PAD. ■

Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no conflicts of interest regarding the content herein.

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Appendix 1. Thirty-Day Outcomes and Complications

| Outcomes/Gender | Men | Women | P Value |
|--------------------------|----------|----------|---------|
| Death | 2(1.3) | 1(0.6) | 0.55 |
| MACE | 2(1.3) | 3(1.9) | 0.68 |
| Repeat procedure | 8(5.2) | 5(3.1) | 0.35 |
| New vascular procedure | 37(23.4) | 25(15.4) | 0.07 |
| Infection | 12(7.8) | 8(5.1) | 0.33 |
| Access site complication | 3(1.9) | 2(1.2) | 0.63 |
| Amputation | 8(5.1) | 9(5.6) | 0.86 |
| Myocardial infarction | 1(0.6) | 1(0.6) | 0.98 |
| TIA/Stroke | 0(0) | 1(0.6) | -- |
| Transfusion | 6(3.8) | 7(4.3) | 0.82 |

CV = cardiovascular; MACE = major adverse cardiovascular event; TIA = transient ischemic attack.

Appendix 2. One- to 6-Month Outcomes and Complications

| Outcomes/Gender | Men | Women | P Value |
|--------------------------|---------|---------|---------|
| Death | 8(4.7) | 9(5.1) | 0.86 |
| MACE | 1(0.6) | 3(1.6) | 0.33 |
| Repeat procedure | 12(6.7) | 14(7.8) | 0.71 |
| New vascular procedure | 13(7.3) | 14(7.8) | 0.87 |
| Infection | 7(4.0) | 4(2.2) | 0.34 |
| Access site complication | 1(0.6) | 1(0.6) | 0.99 |
| Amputation | 11(6.2) | 7(3.9) | 0.32 |
| Myocardial infarction | 0(0) | 0(0) | -- |
| TIA/Stroke | 1(0.6) | 1(0.6) | 0.99 |
| Transfusion | 4(2.3) | 5(2.8) | 0.77 |

CV = cardiovascular; MACE = major adverse cardiovascular event; TIA = transient ischemic attack.

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