Failure of Patients with Peripheral Arterial Disease to Accept the Recommended Treatment Results in Worse Outcomes

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Background: Strategies available to facilitate decision making for patients with peripheral arterial disease (PAD) include a Markov-based decision analysis (DA) model and the Lower Extremity Grading System (LEGS) score. Both have suggested inferior outcomes when the actual treatment received (ATX) differs from that predicted. This study focuses on patient outcomes when such discordance exists.

Methods: All patients referred for symptomatic lower extremity PAD over a 3-year period were evaluated using the DA model and the LEGS score. Calculated quality of life (cQOL) values were assigned before treatment based on patient symptom, perfusion, and amputation status and at follow-up (range 1.000 [perfect health] to .000 [death]). The primary outcome of cQOL was compared according to whether the ATX matched that proposed by the surgeon or predicted by the DA model or LEGS score. Secondary outcomes for revascularized patients included major adverse limb event with perioperative death (MALE + POD) and amputation-free survival (AFS).

Results: Among 375 procedures in 345 consecutive patients, the greatest improvement in cQOL at last follow-up (median 16 months) was observed with endovascular (0.23 ± 0.16, $n = 93$) or open (0.21 ± 0.17, $n = 137$) revascularization compared with primary amputation (0.10 ± 0.07, $n = 23$) or medical therapy (0.04 ± 0.09, $n = 122$). Multivariate regression showed discordance with the surgeon's recommendation ($P < 0.05$) and/or the DA model ($P < 0.05$) to be independent predictors of improvement failure. ATX did not always agree with that proposed by the surgeon (89% agree, $\kappa = 0.84$), the DA model (68% agree, $\kappa = 0.53$), or the LEGS score (53% agree, $\kappa = 0.32$). Improvement in cQOL was greatest when ATX was concordant with treatment proposed by the surgeon (0.18 vs. 0.08, $P < 0.01$), the DA model (0.19 vs. 0.13, $P < 0.01$), or the LEGS score (0.23 vs. 0.10, $P < 0.01$). Patient refusal to follow the surgeon's recommendations and continued smoking were associated with minimal improvement (cQOL ranges 0.05–0.07 and 0.00–0.02, respectively), while pursuing a less morbid procedure was associated with greater improvement (cQOL range 0.28–0.38). Among revascularized patients, MALE + POD was lower at 36 months after endovascular than open surgery ($21\% \pm 5\%$ vs. $36\% \pm 4\%$, $P < 0.05$), while AFS was not significantly different. Only discordance with the surgeon's recommendation was an independent predictor of MALE + POD, possibly because of limitations in sample subset size.

Conclusions: Mean cQOL improved most with direct revascularization, especially when the treatment received matched that predicted by the models or proposed by the surgeon. Type of treatment received was an independent predictor of agreement of treatment with recommendations. Patient refusal to follow the recommended treatment as well as the strategy not to revascularize claudicants who persist in smoking were associated with much less patient benefit from treatment.

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INTRODUCTION

The outcomes of treatment for peripheral arterial disease (PAD) vary greatly in terms of patient quality of life and are influenced by patient factors including comorbidities and preoperative functional status.[1-3] However, decisions intended to maximum patient outcomes are complex and can be improved. At least 2 different models have been described to assist in decision making. First, a computerized Markov decision analysis (DA) model has been offered for patients with PAD, combining individualized probabilities for all potential outcomes for each treatment with patient-derived utility analysis to define expected quality of life.[4,5] Using this model, it was observed that the treatment actually recommended by the surgeon to the patient frequently did not agree with the treatment mathematically predicted by the model to result in the best outcome.[6] The DA model was subsequently expanded to include a broader spectrum of severity of PAD as well as adding the option of endovascular revascularization.[7,8] An alternative route to decision making, the Lower Extremity Grading System (LEGS) score, derived by consensus from a panel of vascular specialists and validated on subsequent patients has also been reported to improve planning of therapy.[9,10] The LEGS score appears to be less cumbersome than the Markov model, although it does not address primary medical therapy alone as an option. Interestingly, it was reported for both the DA model and the LEGS score that patients experienced inferior outcomes when the treatment that they actually received did not match that predicted as optimal.[4,11] Satisfactory explanation for these observations has yet to be elucidated, and while it does not necessarily follow that universal concordance of treatment with these models would have led to better patient results, the potential for such tools to improve patient outcome remains intriguing.

The objective of this study is to compare decisions regarding the therapy received by patients with PAD with the therapy proposed by the treating vascular surgeon, the DA model, and LEGS score to determine why such decisions might be discordant and how such discordance affects patient outcomes. The hypotheses to be tested were that decisions regarding the best therapy for PAD often differ among the patient, the treating vascular surgeon, and existing decision-making models and that patient outcome is affected by discordance with these decisions.

MATERIALS AND METHODS

Research Design

The protocol for this retrospective case–control study including waiver of consent was approved by the Institutional Review Board of the Medical University of South Carolina and the Research and Development Committee of the Ralph H. Johnson Department of Veterans Affairs Medical Center in Charleston. The primary outcome of interest was calculated quality of life (cQOL). The secondary outcomes for patients revascularized with endovascular or open surgery included major adverse limb event with perioperative death (MALE + POD) and amputation-free survival (AFS). As MALE is presumed to indicate major undesirable and even catastrophic outcomes from intervention, POD was included in this measure. Patients were compared according to whether their actual treatment received (ATX) was concordant with the therapy initially proposed by the surgeon (SURG) or that predicted as optimal by the DA model or LEGS score. For each group, controls were defined as those with concordant treatments, while cases were defined as those with discordant treatments.

Data Collection

All patients referred to one vascular surgeon over a 3-year period for management of symptomatic lower extremity PAD including both tertiary university and Veterans Administration practices were eligible for study inclusion and included patients who were managed with primary amputation or medical therapy alone. Patients without at least one follow-up encounter more than 30 days after the initial intervention (or encounter if medical therapy only) in which the results of therapy could not be ascertained were excluded from analysis. Exceptions were patients who died or had a MALE within 30 days of intervention. The medical records of study patients were abstracted for pertinent clinical information including location and severity of symptoms as well as anatomic and demographic information. This information was used to predict the optimum type of therapy using 2 published clinical vascular surgical decision-making tools, the DA model, and the LEGS score.[4,9] In the current retrospective study, all patient treatment decisions were made before and independently of either model. The treatment recommended to the patient as well as that actually received was recorded, as were results including relief of ischemic symptoms,