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Two-Year Outcomes after Transcatheter Arterialization of the Deep Veins

To the Editor:

The PROMISE I and PROMISE II trials are prospective, multicenter studies to evaluate the safety and effectiveness of transcatheter arterialization of the deep veins in patients with chronic limb threatening ischemia and with no option for arterial revascularization. The results of the studies along with study details including eligibility criteria, data collection, and data analysis have been published^{1,2} and the study protocol is available online at NEJM.org. Here, we report the 2-year outcomes from both trials.

A total of 137 study participants underwent transcatheter arterialization of deep veins using the LimFlow System. The mean age of patients was 69 years, 68% were men, and 20% were Black. Preexisting conditions were common among patients and 75% had diabetes, 91% had hypertension, and 75% had dyslipidemia. All patients presented with Rutherford class 5 or 6 peripheral artery disease, indicating non-healing ulcers or gangrene, and were independently adjudicated as not candidates for conventional endovascular or surgical revascularization. Patient disposition and baseline characteristics are shown in Tables S1 and S2 of the Supplementary Appendix available online at NEJM.org.

At 2 years, 38 patients had major amputation and 28 patients had died, limb salvage was 68% (95% confidence interval [CI], 60 to 77) and amputation-free survival was 49% (95% CI, 41 to 59) by Kaplan-Meier estimation (Fig. 1A). Survival was 72% (95% CI, 64 to 82). Of the patients who died, 5 deaths were related to COVID-19 and 4 to chronic kidney disease or end-stage renal disease. Although patient mortality was impacted by these and other comorbid conditions, limb salvage appeared consistent between 1 and 2 years.

Wounds were independently adjudicated as healed (71%) or healing (12%) in 28 of 34 patients (82%) at 2 years (Fig. 1B), and patient-reported pain scores had improved from a median of 6 of 10 at baseline to 0 of 10, with a median decrease of 4.3 points (95% CI, 3.0 to 5.5). (Fig. 1C). Among patients who had kept their limbs through 2 years, 26 of 49 patients (53%) were Rutherford class 0 (95% CI, 38 to 67), and 38 of 49 patients (78%) improved by at least 1 class compared to baseline. At 2 years, major amputation occurred in 24 patients who had maintained patency of their stent graft at 3 months (limb salvage of 75%; 95% CI, 65 to 82) compared to 14 patients who had lost patency (limb salvage of 40%; 95% CI, 19 to 60) (Fig. S1). Additional outcomes are shown in Tables S3, S4 and S5. Representativeness of the study population is shown in Table S6.

These findings demonstrate the 2-year durability of limb salvage after transcatheter arterialization of the deep veins among surviving patients with no-option chronic limb-threatening ischemia.

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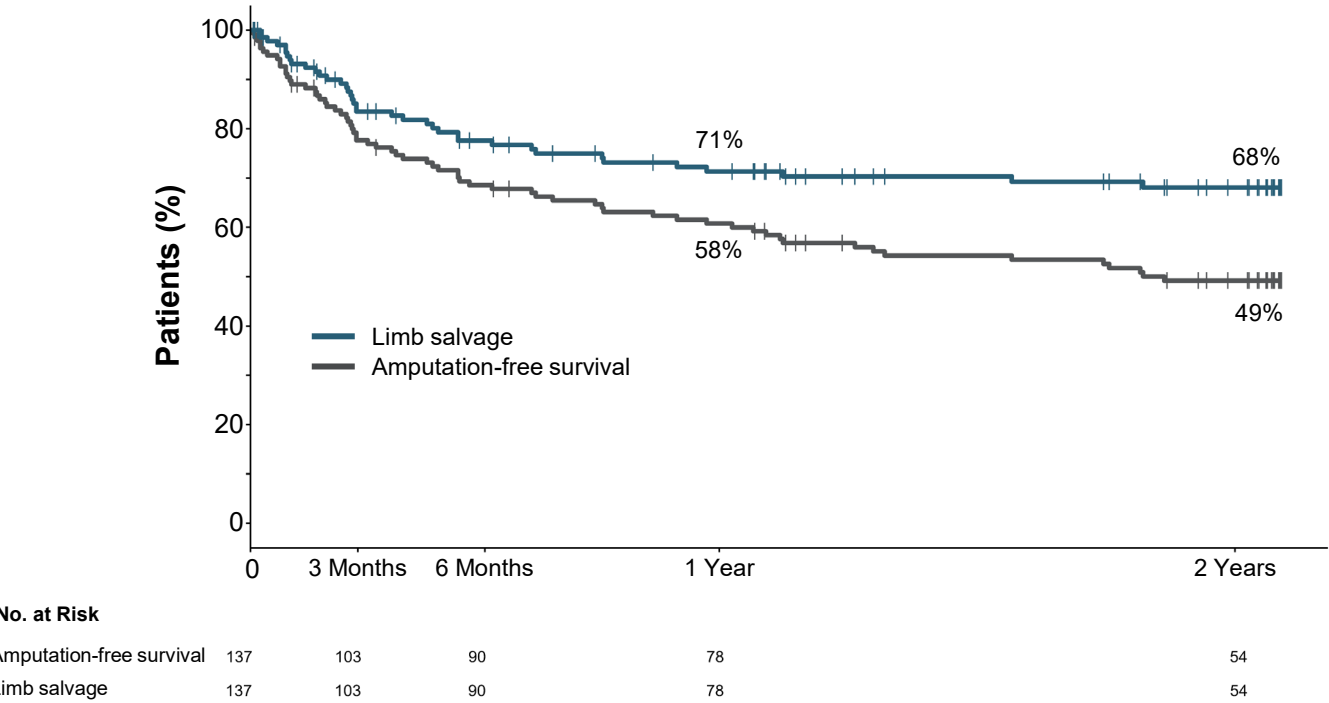
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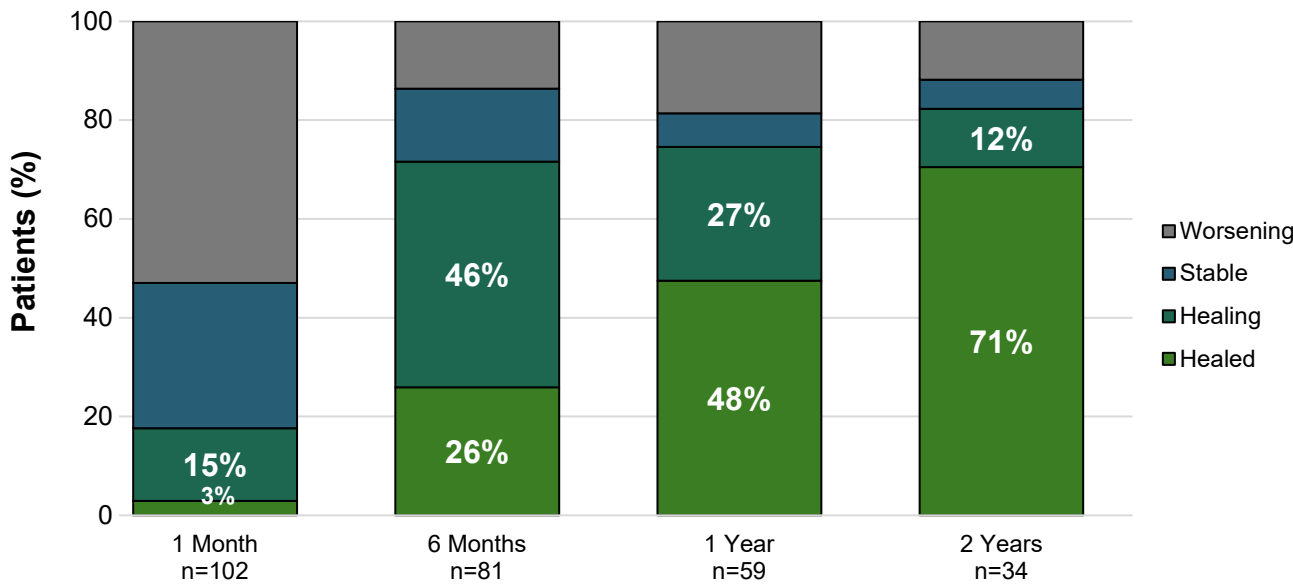
Figure 1. 2-Year Outcomes following Transcatheter Arterialization of the Deep Veins

Figure legend: Panel A shows the Kaplan-Meier estimates of limb salvage and amputation-free survival through 2 years following treatment with transcatheter arterialization of the deep veins. Panel B shows the wound status at 4 timepoints through 2 years, the assessment of which was independently adjudicated by a core laboratory. Panel C shows the patient-reported pain scores (scale of 0 to 10; 0 indicates no pain), at baseline and through 2 years. The box indicates the interquartile range, the horizontal line indicates the median, the red dot indicates the mean, whiskers represent 1.5 times the interquartile range, and black dots represent outliers.

A Amputation-free Survival and Limb Salvage



B Wound Status



C Pain Scores

