

INTRODUCTION

- Venous leg ulcers (VLU) are the most common cause of lower extremity ulceration and are characterized by slow healing trajectory and frequent recurrence, leading to significant disability, reduced quality of life, and tremendous economic burden.^{1,2}
- The U.S. prevalence of VLU ranges from 0.15% to 0.3%, equating to approximately **600,000** cases per year, and is higher among women and the elderly.^{3,4} The total annual cost of VLU treatment is estimated as **\$3.5 billion**.³
- In addition to the standard compression therapy alone, the U.K.-based Early Venous Reflux Ablation (EVRA) trial has demonstrated the clinical benefits and long-term cost-effectiveness of early intervention of surgical correction - endovenous ablation – of the superficial venous reflux from the U.K. healthcare sector perspective.^{4,5}
- Early ablation: undergoing ablation with compression within two weeks after the treating clinicians deems endovenous ablation to be clinically significant for the patient.
- Deferred ablation: receiving compression therapy alone; an ablation procedure is considered after the ulcer has healed or at least 6 months after becoming clinically eligible for it.

OBJECTIVES

- To assess the cost-effectiveness of early endovenous ablation with compression therapy among the elderly with VLU from the U.S. Medicare perspective.
- To assess the budget impact of early endovenous ablation for the VLU population from the U.S. Medicare perspective.

STUDY DESIGN

Model Overview

- **Comparators:** Early ablation vs. deferred ablation (defined above)
- **Target population:** VLU Patients aged 65 and older, with the same clinical features described in the EVRA trial
- **Perspective:** The Medicare perspective
- **Discount rate:** 3%
- **Time horizon:** 3 years
- **Decision model:** Markov model with monthly cycles (Figure 1)
- **Model outputs:** Total costs per patient, quality-adjusted life years (QALYs), and net monetary benefits (NMB) at a willingness-to-pay (WTP) threshold of \$100,000/QALY.
- **Sensitivity analysis:**
 - One-way sensitivity analysis
 - Probabilistic sensitivity analysis; the cost-effectiveness acceptability curve (CEAC).
- **Additional analysis:** budget impact analysis
 - Based on the EVRA trial, we defined patients who entered the model with an open VLU for a period of 6 weeks to 6 months, and an ankle-brachial index > 0.8.
 - Patients began in the unhealed VLU state and could stay in or transition in post-VLU (healed) or death state according to the assigned transition probabilities.

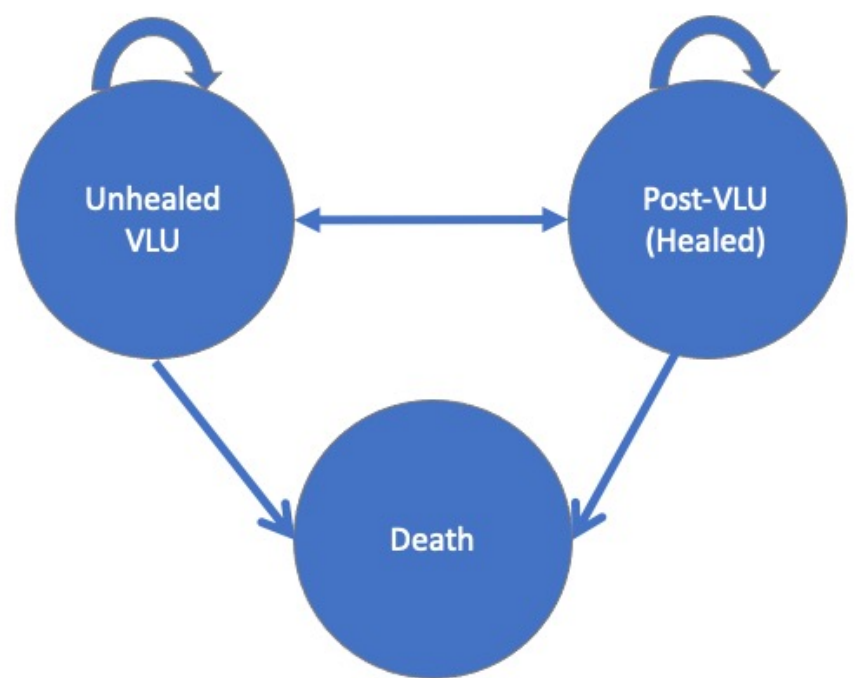


Figure 1. Markov model of VLU disease progression.

MODEL PARAMETERS

Transition Probabilities (Table 1)⁴⁻⁶

- The transition probabilities between unhealed VLU and post-VLU (healed) were derived from the healing rate and recurrence rate reported in the EVRA trial.^{10, 11}
- Most patients got healed within 6 months [85.6% in the early ablation group vs. 76.3% in the deferred ablation group].
- The recurrence rate at 3 years were 24.5% for the early ablation group vs. 29.9% for the deferred ablation group.
- The DEALE methods were applied to convert the trial data to monthly transition probabilities between states.
- The probability of healing after 12 months was assumed to be half of that between 6-12 months to account for the reality that some patients have smaller chance and take longer to heal.
- Given the insufficient evidence of VLU as a direct predictor of death, we applied the all-cause mortality for the general population aged 65 and older in the U.S.¹⁴

Cost parameter	CPT/DRG code	Medicare costs	Lower bound	Upper bound
Intervention Costs				
Endovenous radiofrequency	36475	\$1,323	\$1,059	\$1,588
Radiofrequency added on with multiple veins treatment	36476	\$314	\$251	\$377
Endovenous laser	36478	\$1,215	\$972	\$1,458
Laser added on with multiple veins treatment	36479	\$138	\$111	\$166
Mechanochemical ablation	36473	\$1,448	\$1,158	\$1,737
Mechanochemical ablation added on with multiple veins treatment	36474	\$296	\$237	\$356
Physician Payment, Facility				
Physician, evaluation, initial visit	99203	\$85	\$68	\$102
Physician, debridement, initial visit	11042	\$63	\$51	\$76
Physician, debridement, established visit	97597	\$36	\$29	\$44
Physician, compression only	99212	\$36	\$29	\$44
Facility Reimbursement				
Facility, initial visit	99213	\$86	\$69	\$104
Facility, debridement, initial visit	11042	\$220	\$176	\$264
Facility, debridement, established visit	97597	\$114	\$91	\$137
Facility, compression only	29581	\$83	\$66	\$99
Home Health				
Home health (60-day episode)	C2F2S1	\$2,808	\$2,246	\$3,370
Compression				
Compression stocking (per pair for 6 months)	A6532	\$72	\$58	\$86
Hospitalization costs				
Skin debridement with complication	571	\$10,832	\$8,665	\$12,998
Skin ulcer with complication	593	\$8,882	\$7,105	\$10,658
Cellulitis (No major complication)	603	\$5,562	\$4,449	\$6,674
Cellulitis (major complication)	602	\$9,872	\$7,898	\$11,847
Pain medication (prescription drugs)				
Amitriptyline, calculated monthly cost		\$43	\$35	\$52
Gabapentin, calculated monthly cost		\$124	\$99	\$149
Hydrocodone, calculated monthly cost		\$22	\$17	\$26

Table 2. Direct costs of venous leg ulceration (VLU) treatment.

Parameter	Monthly transition probability	Lower bound	Upper bound
Compression with Early Ablation			
Probability of healing - Month 1 to 6	0.133	0.106	0.160
Probability of healing - Month 6 to 12	0.090	0.072	0.108
Probability of healing - Month 12+	0.045	0.036	0.054
Probability of recurrence - Month 1-12	0.011	0.009	0.013
Probability of recurrence - Month 12-24	0.004	0.003	0.004
Probability of recurrence - Month 24-36	0.007	0.006	0.009
Compression with Deferred Ablation			
Probability of healing - Month 1 to 6	0.119	0.096	0.143
Probability of healing - Month 6 to 12	0.065	0.052	0.078
Probability of healing - Month 12+	0.032	0.026	0.039
Probability of recurrence - Month 1-12	0.016	0.013	0.019
Probability of recurrence - Month 12-24	0.005	0.004	0.006
Probability of recurrence - Month 24-36	0.007	0.005	0.008
All-Cause Mortality			
Mortality - Month 1-12	0.001	0.001	0.001
Mortality - Month 12-24	0.001	0.001	0.001
Mortality - Month 24-36	0.001	0.001	0.001

Table 1. Transition probability base case inputs and range for sensitivity analyses.

Costs (Table 2)⁷⁻¹¹

- Direct medical costs associated with VLU treatment were considered:
 - Endovenous ablation procedures
 - Compression therapy
 - Pain medication
 - Additional home health
 - Hospitalization associated with infections and complications of VLU
- The Medicare national average reimbursement rates in accordance with the Current Procedural Terminology (CPT) codes and the diagnosis-related groups (DRG) codes were sourced from the Center for Medicare & Medicaid Services (CMS) database and published literature.
- All monetary terms were converted to 2021 USD using the Medical Component of the Consumer Price Index.

Health Utilities

- The utilities measuring patients QOL in each state were relied on the Euro-QOL 5-Domain (EQ-5D) index scores.
- The utility for the unhealed VLU state: 0.694.¹²
- The utility for the post-VLU (healed) state: 0.75.¹³
- The utility for death state: 0.
- The utilities were adjusted to account for the impact of aging on people’s preference of QOL using the U.S. general population disutility by age (65-74 years).¹⁴

RESULTS

Base Case Results (Table 3)

Treatment	Costs	QALYs	iNMB
Compression with Early Ablation	\$15,208	1.985	/
Compression with Deferred Ablation	\$12,527	2.011	\$5,226

Table 3. Base case results. QALY, quality adjusted life years; iNMB, incremental net monetary benefits.

Sensitivity Analyses

- **One-way sensitivity analysis:** the parameter showing the greatest impact on the incremental NMB is the probability of healing, followed by the probability of recurrence.
- **Probabilistic sensitivity analysis (CEAC curve in Figure 2):**
 - Early ablation is more cost-effective in **59.2%** of the 10,000 simulations at \$100,000/QALY WTP, and it drops to 57.4% if applying \$150,000/QALY WTP.
 - Regardless of the WTP threshold, early ablation always has a greater likelihood of being cost-effective than deferred ablation.

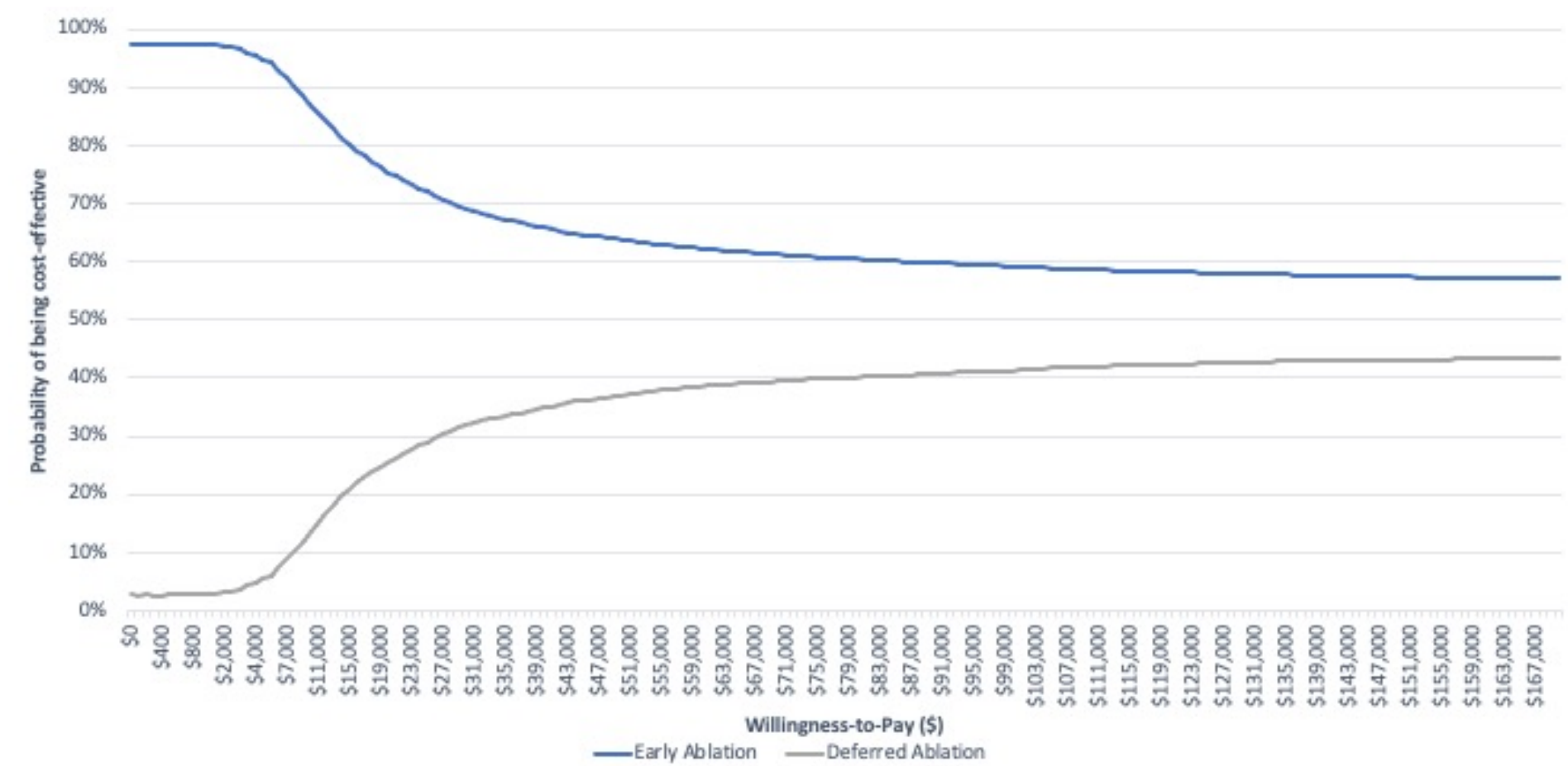


Figure 2. Cost-effectiveness acceptability curve.

Budget Impact Analysis:

- Assuming 1,000 patients with VLU in a hypothetical 1-million-member health plan, compression therapy with early ablation generated a total cost saving of **\$636,238 at 1 year**, and **\$2,680,246 at 3 years**.
- Equivalent to a per member per month (PMPM) difference of **\$0.053 at 1 year**, and **\$0.075 at 3 years**.

CONCLUSIONS

- The early endovenous ablation presents a cost-effective alternative to delayed ablation with compression therapy for Medicare VLU patients.
- Medicare should consider innovative payment models, including formulary placement, that increase incentives to deploy early endovenous ablation to all eligible VLU patients
- It’s in Medicare’s best interest to reduce long-run consequences of chronic wounds.

Study limitations:

- The clinical efficacy of early endovenous ablation were sourced from the U.K. trial, which may not represent U.S outcomes.
- The U.K. trial data were collected in a controlled setting, which potentially results in our estimates representing a lower bound since in real-world patients might gain fewer clinical benefits.
- The economic model doesn’t control for the variability in the VLU population, such as socio-demographics and minority health disparity.

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REFERENCE

