Carry the published CLTI range through assessment

Two cited US benchmarks, with an explicitly illustrative midpoint.

US CLTI disease pool

Callegari et al. 2024	Illustrative midpoint	Barnes et al. 2020
1,000,000	**1,500,000**	**2,000,000**
Published benchmark	Not a published estimate	Published benchmark

Entering assessment with active disease in the period

1,000,000 × A	**1,500,000 × A**	**2,000,000 × A**

After infection treatment and reassessment

900,000 × A	**1,350,000 × A**	**1,800,000 × A**

Meeting all treatment criteria: must be measured in each scenario

A = share entering active assessment in the stated period; it must be measured.
Infection scenario: 40% initially infected; 75% return. Retention = 60% + 30% = 90%.
The 1–2 million span is not a confidence interval. Counts after infection are not established eligibility.
Sources: Callegari et al., JAHA 2024;13:e034477. Barnes et al., ATVB 2020;40:1808–1817.
Full citations and assumptions: dga-collategene.pages.dev/funnel.html | Revised 8 September 2026

CLTI threatens limbs. It threatens lives.

CLTI prevalence benchmarks: Callegari 2024 and Barnes 2020. Outcomes: Barnes 2020.

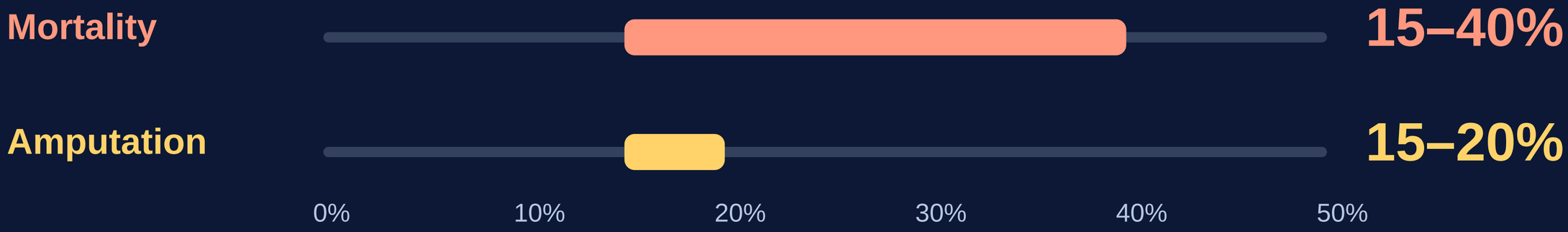
~1–2 million

~1M: Callegari 2024. ~2M: Barnes 2020 (adults >40).
Published benchmarks; not a confidence interval or incidence.

~11%

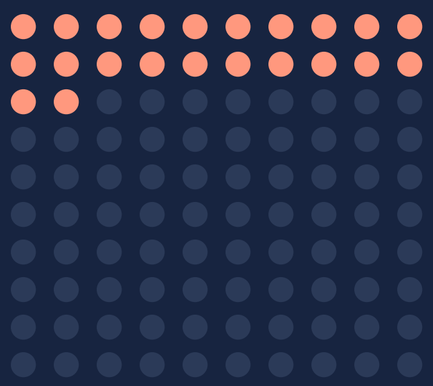
of PAD patients develop CLTI
Review estimate; no annual rate implied.

One-year outcome ranges reported in the review



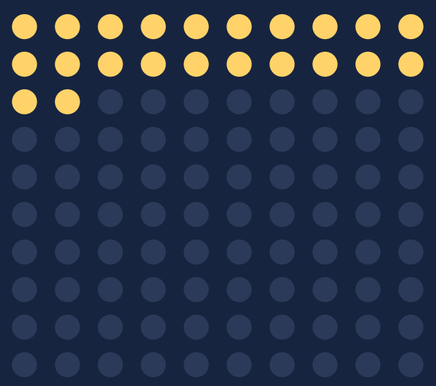
Ranges span differing CLTI definitions and clinical populations. Amputation definitions vary.
These are study ranges, not confidence intervals or predictions for a particular patient.

A separate population: severe / critical ischemia without revascularization



22%

All-cause mortality
95% CI: 12–33%



22%

Major amputation
95% CI: 2–42%

13 studies · 1,527 patients · median follow-up 12 months · low-quality evidence

Barnes JA, Eid MA, Creager MA, Goodney PP. ATVB 2020;40:1808–1817. doi:10.1161/ATVBAHA.120.314595
Abu Dabrh AM, et al. J Vasc Surg. 2015;62:1642–1651.e3. doi:10.1016/j.jvs.2015.07.065
Prevalence lower benchmark: Callegari et al. JAHA 2024;13:e034477. Outcomes may overlap; do not add them.

Treat infection. Keep the route back open.

A 40% infection prevalence does not establish a 40% permanent exclusion.

AT PRESENTATION

60%	40%
No infection at this assessment	Initially infected

Treat infection → Reassess wound, perfusion and indication

Planning scenario: 75% of the initially infected 40% returns to assessment.

AFTER REASSESSMENT · PROVISIONAL SCENARIO

60%	30%	10%
Retained	Returns	Non-return

90% retained at this step

This is arithmetic, not an observed CollateGene re-eligibility rate. Further clinical criteria still apply. Persistent ischemia, salvageability, survival and the assessment window determine the route back.

Clinical context: IWGDF/IDSA 2023 infection guideline; Global Vascular Guidelines 2019.
Assumptions: Armstrong population range review, 8 September 2026. dga-collategene.pages.dev/funnel.html

Healing begins remission. Keep following the patient.

Infection treatment, wound healing and recurrent disease belong in one longitudinal model.

Active CLTI episode

Assess the wound, perfusion and infection.
Apply indication-specific eligibility.

Treatment and reassessment

Control infection; deliver standard care.
Evaluate persistent ischemic tissue loss.

Healing and remission

Continue surveillance and prevention.
No active ulcer does not mean no future risk.

Recurrence

A new qualifying episode

Return the same person to assessment.
Deduplicate people, limbs and episodes.

At every state: model death, limb loss and other permanent exits once; retain eligible carryover.

DFU recurrence after healing

42%	58%	65%
1 year	3 years	5 years

Pooled recurrence estimates for diabetic foot ulcers

50.1% at 3 years

Reintervention after endovascular CLTI treatment.
A different endpoint from recurrent ulceration.

Source: Armstrong NS, Armstrong AA, et al. Int Wound J. 2025;22:e70724. doi:10.1111/iwj.70724.
Neither recurrence measure directly estimates eligibility for CollateGene or repeat treatment. | 6 September 2026