

# Bypass surgery and balloon angioplasty did not differ for amputation-free survival in severe limb ischemia

Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. *Lancet*. 2005;366:1925-34.

**Clinical impact ratings:** Hospitalists ★★★★★☆☆ Hematol/Thrombo ★★★★★☆☆

## QUESTION

In patients with severe limb ischemia (rest pain, ulceration, or gangrene of the leg), does a bypass surgery–first strategy improve amputation-free survival more than a balloon angioplasty–first strategy?

## METHODS

**Design:** Randomized controlled trial (Bypass versus angioplasty in severe ischaemia of the leg [BASIL] trial).

**Allocation:** Unclear allocation concealment.\*

**Blinding:** Unblinded.\*

**Follow-up period:** 5 years.

**Setting:** 27 hospitals in the United Kingdom.

**Patients:** 452 patients (67% patients  $\geq$  70 y, 60% men) with severe limb ischemia (defined as rest pain or tissue loss [ulcer or gangrene]) for  $>$  2 weeks who could be treated either by infrainguinal bypass surgery or balloon angioplasty based on their diagnostic images. Patients who required suprainguinal (aortoiliac) intervention were excluded.

**Intervention:** Bypass surgery–first strategy ( $n = 228$ ) or balloon angioplasty–first strategy ( $n = 224$ ).

**Outcomes:** Amputation-free survival (time to amputation of the trial leg above the ankle or all-cause mortality). Secondary outcomes were all-cause mortality, 30-day morbidity and mortality, re-intervention, health-related

quality of life (HRQL), and use of hospital resources.

**Patient follow-up:** 99% at 1 year and 98% at 5 years (intention-to-treat analysis).

## MAIN RESULTS

At 5 years, the bypass surgery–first group and the balloon angioplasty–first group did not differ for amputation-free survival (Table). Among the secondary outcomes, groups did not differ for all-cause mortality at 5 years (Table), 30-day mortality or morbidity (mainly infective wound and cardiovascular complications) (Table), or HRQL scores at 1 year. Patients in the bypass surgery–first group had lower re-intervention rates than did those in the balloon angioplasty–first group at 1 year (Table), but spent more mean days in hospital (46 vs 36 d,

$P < 0.001$ ), in the high-dependency unit (0.65 vs 0.18 d,  $P < 0.001$ ) and in the intensive therapy unit (0.13 vs 0.04 d,  $P = 0.012$ ).

## CONCLUSIONS

In patients with severe limb ischemia, initial strategies of bypass surgery or balloon angioplasty did not differ for amputation-free survival. Bypass surgery consumed more hospital resources.

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\*See Glossary.

## Bypass surgery vs balloon angioplasty for severe limb ischemia†

Outcomes	Follow-up	Surgery	Angioplasty	RRR (95% CI)	NNT (CI)
Amputation-free survival	5 y	43%	47%	8.9% (–11 to 27)	Not significant
All-cause mortality	5 y	35%	39%	3.9% (–21 to 26)	Not significant
Re-intervention	1 y	14%	26%	45% (20 to 63)	9 (6 to 23)
				RRI (CI)	NNH
Mortality	30 d	4.8%	3.1%	54% (–37 to 280)	Not significant
Morbidity	30 d	48%	40%	21% (–1.4 to 50)	Not significant

†Abbreviations defined in Glossary; RRR, RRI, NNT, NNH, and CI calculated from hazard ratios in article.

## COMMENTARY

The current trend in treatment of patients with critical leg ischemia is toward percutaneous procedures instead of surgery. This trend is a result of the fact that patients and physicians believe that, although less durable, percutaneous interventions lead to fewer complications than surgery, and surgery is still an option if the percutaneous procedure fails.

The well-designed BASIL trial provides evidence that in suitable patients, both treatments are equally effective. The trial had a pragmatic design: Patients were eligible for inclusion if both the vascular surgeon and the radiologist determined they could be treated either by surgery or angioplasty. In teams with extensive experience in percutaneous interventions, such opinions might differ from those of less-experienced teams. Furthermore, in the highly experienced units, only 29% of patients were potentially eligible for randomization. These results, therefore, might not apply to a local situation because the choice of treatment depends heavily on the radiologic and surgical experience of

the team and the extent of arterial obstruction in the patient.

Taking costs and quality of life into consideration, the study clearly supports percutaneous procedures despite the higher re-intervention rate. Patients with critical leg ischemia are frequently old and fragile, and both they and their doctors often prefer a less-invasive procedure (1). The results of the BASIL trial are in line with the developments in interventional cardiology—percutaneous interventions can compete with surgery (2).

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## References

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