



Bitesize Research: CHRONIC LIMB THREATENING ISCHAEMIA (CLTI)

References

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PAPER 1:

Benson et al. (2019) Comparison of Immediate and Long-term Outcomes in Men and Women Undergoing Revascularisation for Chronic Limb Threatening Ischaemia in the Bypass vs. Angioplasty in Severe Ischaemia of the Leg (BASIL-1) Trial. European Journal of Vascular and Endovascular Surgery, 2019; 58 (2); 224-228. DOI: 10.1016/j.ejvs.2019.03.001

SUMMARY

This reanalysis of the BASIL-1 study showed that, compared to men, women had similar short term but significantly better long-term outcomes after revascularisation. The outcomes measured were amputation free survival, overall survival, and freedom from major adverse limb events (MALE).

PROS

This was the first study to compare the outcomes for men and women in a randomised setting, where patients had similar anatomical and clinical disease severity and similar length of follow up. BASIL-1 had a well described selection criteria of patients with CLTI

requiring infra-inguinal treatment, allowing for other trends to be visible from the data.

CONS

CLTI patients will usually have an ankle pressure of <50mmHg, and this is often used in the selection criteria for CLTI studies. This was not a requirement for the BASIL-1 study; patients were only required to present with rest pain or tissue loss. Therefore, there may be more variation in the population recruited compared to other studies. Also, post-op differences in anatomical appearances post treatment were not assessed, so could not be included in the comparison.

IMPACT ON PRACTICE

It is important to consider the effect of sex when developing treatment pathways and revascularisation strategies for patients with CLTI.

PAPER 2:

Bradbury et al. (2023) A vein bypass first versus a best endovascular treatment first revascularisation strategy for patients with chronic limb threatening ischaemia (CLTI) who required an infra-popliteal, with or without an

additional more proximal infra-inguinal revascularisation procedure to restore limb perfusion (BASIL-2): an open-label, randomised, multicentre, phase 3 trial. The Lancet, 2023; 401(10390); 1798-1809. DOI: 10.1016/S0140-6736(23)00462-2

SUMMARY

CLTI patients often require multiple revascularisation procedures to maintain and restore limb perfusion and experience frequent readmissions for limb-related complications. In this study patients were assigned to either vein bypass or endovascular treatment. If no great saphenous vein (GSV) was suitable, then composite or prosthetic grafts were used at the surgeon's discretion.

BASIL-2 found that, for patients with CLTI who require infra-popliteal +/- infra-inguinal revascularisation, carrying out an endovascular intervention as the first line of treatment for CLTI is associated with better amputation-free survival compared to vein bypass as first line treatment. The primary outcome measured was the number of deaths, with a best endovascular treatment first revascularisation strategy resulting in fewer deaths. Limb-related outcomes were similar in both groups.

PROS

Data was collected from 41 vascular surgery centres.

CONS

Target number of participants not met due to challenges in recruitment (345 patients enrolled). To mitigate this, patients were followed up for longer.

IMPACT ON PRACTICE

Patients with CLTI should receive endovascular treatment first.

PAPER 3:

*Farber et al. (2022) **Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia (BEST-CLI)**. The New England Journal of Medicine, 2022; 387(25); 2305-2316. DOI: 10.1056/NEJMod2207899*

SUMMARY

In this study, patients needing infra-inguinal treatment who had a usable segment of GSV for bypass were assigned to 'cohort 1', whilst patients who would require an alternative conduit for bypass were assigned to 'cohort 2'. These two cohorts were then randomised to either vein bypass or endovascular treatment.

The primary outcome was MALE (defined as amputation above the ankle or a major limb reintervention) or death. BEST-CLI found that patients in 'cohort 1', with CLTI and a usable GSV conduit, the incidence of a MALE or death was significantly lower in the vein bypass group compared to the endovascular group. In patients in 'cohort 2' who lacked a

suitable GSV the outcomes were similar between bypass and endovascular.

PROS

A large sample size of 1830 patients were enrolled.

CONS

Target number of participants not met due to challenges in recruitment. Target percentage of women in the study (28%) was lower than the target. Lack of funds limited the follow up of 'cohort 2'.

IMPACT ON PRACTICE

Patients with CLTI should receive vein bypass first.

*1. Mills et al. (2014) **The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIFI)**. Journal of Vascular Surgery 59; (1); 220-234. DOI: 10.1016/j.jvs.2013.08.003*

PAPER 4:

*Teso et al. (2021) **Pedal Acceleration Time (PAT): A Novel Predictor of Limb Salvage**. Annals of Vascular Surgery, 2021; 75; 189-193. DOI: 10.1016/j.avsg.2021.02.038*

SUMMARY

For patients with CLTI and diabetes, non-invasive arterial tests such as ABPI and absolute toe pressures may not be viable due to tibial vessel calcification or extensive distal tissue loss (e.g. below ankle amputation).

Pedal acceleration time (PAT) involves assessment of the arcuate, first dorsal metatarsal and plantar arteries and measurement of time over slope from the onset of systole to the peak of systole (traditionally called systolic rise time).

A retrospective review of a prospectively kept database was carried out to identify limbs with CLTI planned for revascularisation with documented pedal acceleration time measurements. It was found that PAT could be used along with the current Wifi¹ (wound, ischaemia, and foot infection) scoring system to assess severity of ischaemia and could be associated with success of limb salvage. Primary outcome measured was limb loss higher than the ankle.

PROS

Four different PAT classifications were used: class 1 (20-120msec), class 2 (121-180msec), class 3 (181-224msec) and class 4 (>125msec). Class 1 suggests no ischaemia, class 2 is mild, class 3 moderate, class 4 severe. (msec=millisecond)

CONS

The data was obtained retrospectively from a single institution. The study was only performed on patients with infra-inguinal arterial occlusive diseases, so there is possibility of selection bias.

IMPACT ON PRACTICE

Pedal acceleration time can be used along with the current scoring system to evaluate severity of ischaemia as an alternative to ABPI or TBPI.

