Is the Open Surgery First or Endovascular First Approach Controversy Still Alive for CLTI

What Percentage Of An Interventionalist`s Patients Should be Treated By Open Surgery?

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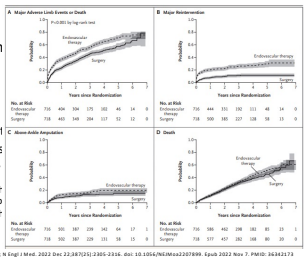
No Disclosures

Endo vs Open, do we have the answer?

The BEST-CLI With CLTI) an Patients chemia of the Leg-2)



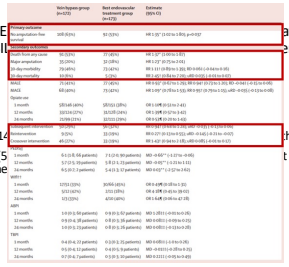
BEST-CLI

- August 2014 t
- 1830 patients Canada, Finland, Italy,
  - Patients wh
  - assigned to
  - Patients wh ery were

Farber A et al. N Engl J Med. 2022 Dec 22;387(25):2305-2316. doi: 10.1056/NEJMoa2207899. Epub 2022 Nov 7. PMID: 36342173

Endo vs Open, do we have the answer?

The BEST-CLI (Best E atients With CLTI) and BASI emia of the Leg-2)



BASIL- 2 Trial

- Between July 22, 2014 he trial
- Randomization 172 (5 t endovascular treatme

Bradbury AW et al; Lancet. 2023 May 27;401(10390):1798-1809. doi: 10.1016/S0140-6736(23)00462-2. Epub 2023 Apr 25. PMID: 37116524

Endo vs Open, do we have the answer?

Best-CLI

Several concerning aspects of the study that must be recognized

1. Trial defined technical failure for endovascular therapy as the inability to cross a stenosis or occlusion or a residual obstruction of >50% in the superficial femoral artery, popliteal artery, and/or all tibial arteries such that there is no in-line flow
   - The failure rate of Cohort 1 was 15.3%, which is a higher incidence than that reported in contemporary data and similar to the results of the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial conducted 17 years ago
2. BEST-CLI trial included patients undergoing infrainguinal revascularization intervention and the BASIL-2 trial included patients who were undergoing infrapopliteal revascularization
3. Reintervention in the endovascular group was the major driver of the composite endpoint
   - 42.5% of first reinterventions occurred within 30 days in the endovascular arm of Cohort 1
4. 73% of endovascular procedures were performed at sites with non high volume endoprocedures
5. Inclusion lasted years (before COVID!!!!) whereas there is a high number of CLTI patients

Endo vs Open, do we have the answer?

RealWorld in Contrast/Medicare Data

- 66,153 patients were included in this study (10,125 autologous grafts; 7867 nonautologous grafts; 48,161 endovascular)
- Compared with BEST-CLI cohort 1, patients in this study were older (mean age, 73.5 ± 5.7 vs 69.9 ± 9.9 years), more likely to be female (38.3% vs 28.5%), and presented with more comorbidities
- Endovascular operators for the study population vs BEST-CLI cohort 1 were less likely to be surgeons (55.9% vs 73.0%) and more likely to be cardiologists (25.5% vs 14.5%)

Secemsky E et al; J Soc Cardiovasc Angiogr Interv. 2023 ; 2(4) . doi:10.1016/j.jscai.2023.101036

Endo vs Open, do we have the answer?

RealWorld in Contrast/Medicare Data

- Long-term outcomes:
  - Crude risk of death or MALE in this cohort was higher with surgery
    - 56.6% autologous grafts vs 42.6% BEST-CLI cohort 1 at a median of follow-up 2.7 years
    - 51.6% nonautologous grafts vs 42.8% BEST-CLI cohort 2 at a median follow-up of 1.6 years)
    - but similar with the endovascular cohort (58.7% Medicare vs 57.4% cohort 1 at 2.7 years; 47.0% Medicare vs 47.7% cohort 2 at 1.6 years)
    - Of those who received endovascular treatment, the risk of incident major intervention was less than half in this cohort compared with the trial cohort (10.0% Medicare vs 23.5% cohort 1 at 2.7 years; 8.6% Medicare vs 25.6% cohort 2 at 1.6 years)

Secemsky E et al; J Soc Cardiovasc Angiogr Interv. 2023 ; 2(4) : . doi:10.1016/j.jcai.2023.101036

Endo vs Open, do we have the answer?

RealWorld in Contrast/Medicare Data

- Conclusions: These results suggest that the findings of the BEST-CLI trial may not be applicable to the entirety of the Medicare population of patients with CLTI undergoing revascularization.

Secemsky E et al; J Soc Cardiovasc Angiogr Interv. 2023 ; 2(4) : . doi:10.1016/j.jcai.2023.101036

Endo vs Open, do we have the answer?

An Endovascular- Versus a Surgery-First Revascularization Strategy for Chronic Limb-Threatening Ischemia: A Meta-Analysis of Randomized Controlled Trials

- A total of 3 RCTs with 2,627 patients (1,312 endovascular-first and 1,315 surgery-first) were included in the meta-analysis
- 1,864 patients (70.9%) were men and 347 (13.2%) were older than 80 years.
- Comparing the endovascular-first and surgery-first approaches, there was no significant difference in the overall (HR 0.92 [0.83 to 1.01], p = 0.09) or amputation-free survival (HR 0.98 [0.92 to 1.03], p = 0.42), reintervention (RR 1.24 [0.74 to 2.07], p = 0.41), major amputation, (RR 1.16 [0.87 to 1.54], p = 0.31), or therapeutic crossover (RR 0.92 [0.37 to 2.26], p = 0.85)
- In conclusion, data from available RCTs suggest that there is no difference in clinical outcomes between endovascular-first and surgery-first revascularization strategies for CLTI
- A planned patient-level meta-analysis may provide further insight

Aronow HD et al: Am J Cardiol; 2024 Mar 1:214:149-156. doi: 10.1016/j.amjcard.2024.01.007.

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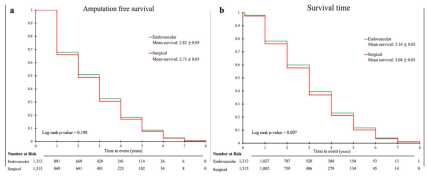

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Controversy Surgical/Endo CLI

ESC 2024 Recommandations/(CLTI)

Recommendations	Class	Level
In CLTI patients, it is recommended to perform revascularization as soon as possible.	I	B
In CLTI, it is recommended to use autologous veins as the preferred conduit for infra-inguinal bypass surgery.	I	B
In multilevel vascular disease, it is recommended to eliminate inflow obstructions when treating downstream lesions.	I	C
An individual risk assessment (weighing the patient's individual procedural risk of endovascular vs. surgical revascularization) by a multidisciplinary vascular team is recommended.	I	C
In CLTI patients with good autologous veins and low surgical risk (<5% peri-operative mortality, >50% 2-year survival), infra-inguinal bypass may be considered.	IIb	B
In CLTI patients, endovascular treatment may be considered as first-line therapy, especially in patients with increased surgical risk or inadequate autologous veins.	IIb	B

2024 ESC Guidelines for the management of PAD and Aortic diseases; Eur Heart J. 2024 Aug 30:ehae179. doi: 10.1093/eurheartj/ehae179. Online ahead of print

Controversy Surgical/Endo CLI

2024 How should we proceed?

- First of all stop fighting who can do it better
- It is not specialty which counts it is the patient who counts
- Patients are different especially CLI patients
- They need to be evaluated by multidisciplinary vascular team approach what kind of treatment should be applied

Thank you for your attention