




CLTI Nomenclature And Data End-Points Need Refurbishing: A Call To Action For The Next Decade Of Care

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Disclosures


- Abbott – consultant
- ASAHI – consultant
- BSCI – consultant
- COCK – consultant
- INARI – consultant
- AVEERA – stock options
- HENDOSYN – stock
- HENDOLAT – stock
- Euphrates Vascular – stock options
- Fastwave – stock
- Protexa – stock options
- Fastwave – stock
- Life Of Flow – stock
- ORCA research corp – stock
- Second Heart Assist – stock



Challenges in Researching CLTI


- Patient complexities due to severe comorbidities.
- Lack of standardized definitions for outcomes (e.g., MALE, patency).
- Variability in wound assessment and QOL measures.
- Limited patient-centric metrics in trials.

The "Global Vascular Guidelines on the Management of Chronic Lower Extremity Artery Disease" *Journal of Vascular Medicine and Biology* 2015




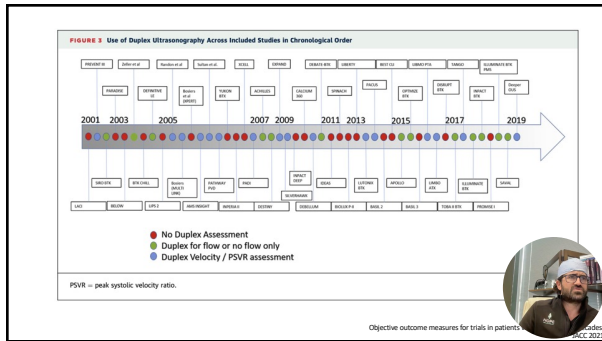
Trial Name	Device	Primary Endpoint	Outcome
IN.PACT DEEP Trial	IN.PACT Amphirion (DCB)	Late lumen loss at 6 months	Failed to show improvement, higher amputation rates
Lutonix BTK Trial	Lutonix 014 (DCB)	Primary patency at 6 months	Failed to meet primary efficacy endpoint
Biolux P-II BTK Study	Passeo-18 Lux (DCB)	Late lumen loss at 6 months	Did not achieve endpoint
SAVAL Trial	SAVAL DES (Boston Scientific)	12-month primary patency and major adverse event-free rates	Neither endpoint met; comparable patency and safety to PTA

Trial Name	Device	Primary Endpoint	Outcome
Tack BTK Study	Tack Endovascular System	Freedom from clinically-driven reintervention and procedural success	Successfully met endpoint
Esprit BTK Trial	Esprit BTK (Bioresorbable Stent)	Primary patency and freedom from target lesion revascularization (TLR) at 12 months	Successfully met endpoint



Trial Name	Device	Definition of Patency
IN.PACT DEEP Trial	IN.PACT Amphirion (DCB)	Freedom from >50% restenosis (PSVR >2.4) or need for TLR.
Lutonix BTK Trial	Lutonix 014 (DCB)	Freedom from target lesion occlusion or clinically-driven TLR.
Biolux P-II BTK Study	Passeo-18 Lux (DCB)	Absence of >50% restenosis or binary restenosis, no TLR.
Tack BTK Study	Tack Endovascular System	Absence of reintervention or restenosis >50% confirmed by imaging.
Esprit BTK Trial	Esprit BTK (Bioresorbable Stent)	Freedom from restenosis (binary >50%) or reintervention.
SAVAL Trial	SAVAL DES	Primary patency: Sustained vessel patency without reintervention or restenosis at 12 months.





Thoughts on how to advance this...

- Need to all speak the same language – WiFi
- Need to refurbish nomenclature (ie. Adapt from oncology)
- Need to advance patient-centric end-points
 - PROMs
 - WROs
- Hemodynamic assessment needs improvement

Oncology as a Model for CLTI

- Oncology uses terms like 'remission' and 'stable disease' to guide care.
- Proposed CLTI terms: 'Limb Remission' and 'Vascular Stability'
- Focus on perfusion improvements and sustained healing.

PROPOSAL

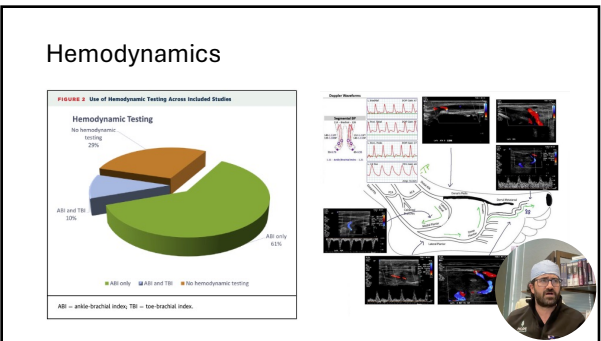
- Limb Remission: Resolution of ischemic wounds &/or pain
- Vascular Stability: Sustained improvement in perfusion metrics (achieving PAT = or <2).

Patient related outcomes (PROM)

- - QOL assessed in 55% of trials.
- - EQ-5D commonly used but lacks CLTI-specific validation.
- - Suggested tools:
 - * VascuQoL (vascular disease-specific tool).
 - * Functional status scales.
- [Source: Systematic Review of PROMs]

Standardizing Wound Assessment

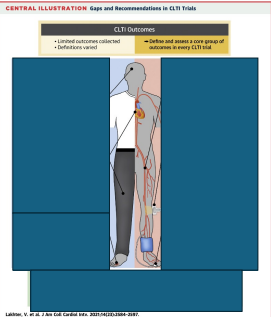
- Less than 20% quantitatively assess.
- Need for longitudinal tracking of wound healing.
- Weekly evaluations
- Determine the impact of any infectious hiccup




CENTRAL ILLUSTRATION: Gaps and Recommendations in CLTI Trials

CLTI Outcomes

- Limited outcome collection
- Definitions varied
- Standardized across study groups of outcomes among CLTI trials




LAMURA, M. ET AL. J GEN INTERN MED. 2021;46(12):1689-1695.




Suggested Core Outcomes for CLTI Trials

- QOL and functional outcomes. (e.g., pain, IDLs)
- Time to limb remission
- Time to 50% wound healing
- Time to 100% wound healing
- Time to surgical wound healing
- MACE and Mortality (all-cause, 30-day).
- MALE
- Patency, TLR and PATs



Conclusion

- Standardization and collaboration are key to advancing CLTI trials.
- Incorporate core outcomes and patient-centric metrics.
- Use validated tools for meaningful comparisons and improved care.
- Collaborative efforts across stakeholders




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