

The Concept of Venous Arterialization How do the Results Compare to Standard Revascularization Techniques?

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Disclosure

Speaker name:

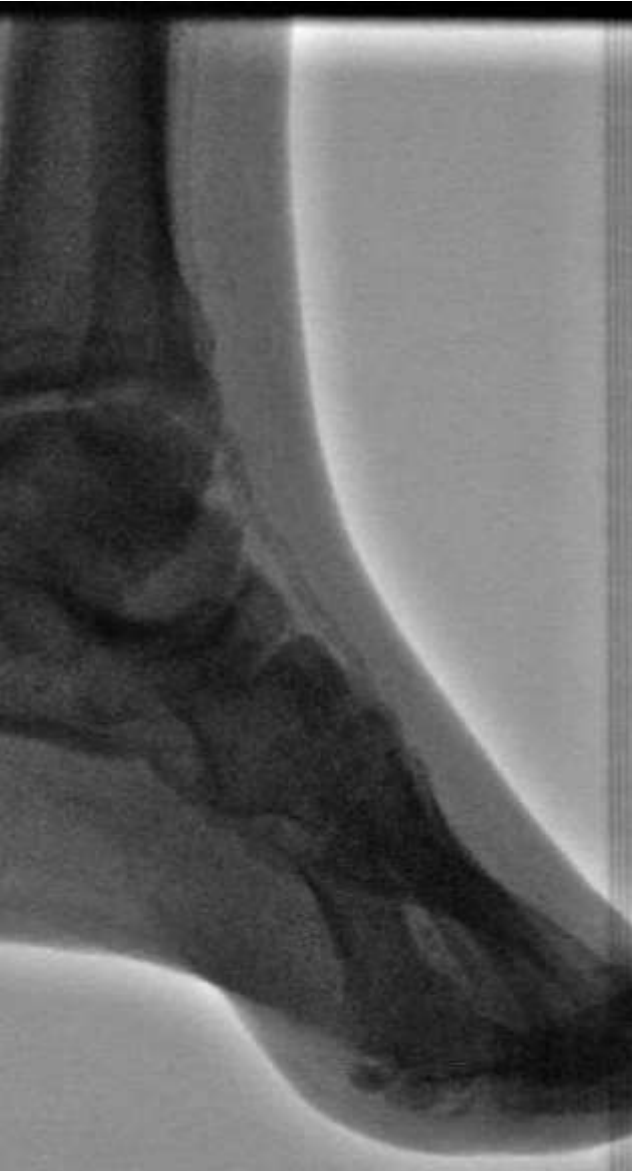
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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest





Traditional PAD therapies are not a blanket for all...

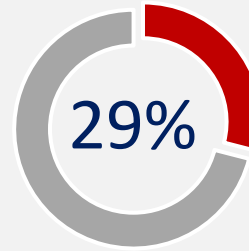
Clinical Investigation

JOURNAL OF
ENDOVASCULAR
THERAPY

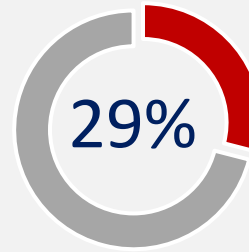
A Novel Scoring System for Small Artery Disease and Medial Arterial Calcification Is Strongly Associated With Major Adverse Limb Events in Patients With Chronic Limb-Threatening Ischemia

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**Wound Healing
At 12 Months**



**Freedom from
MALE At
12 Months**

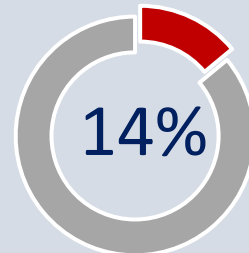
“Primary amputation, medical management or DVA should be the options considered for severe SAD/MAC patients”

Journal of
Clinical Medicine

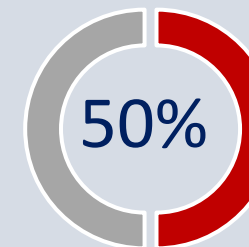
MD

Characteristics and Outcome for Persons with Diabetic Foot Ulcer and No-Option Critical Limb Ischemia

Marco Meloni ^{1,*}, Valentina Izzo ¹, Valerio Da Ros ², Daniele Morosetti ², Matteo Stefanini ³, Enrico Brocco ⁴, Laura Giurato ¹, Roberto Gandini ⁵ and Luigi Uccioli ¹



**Limb Salvage
At 12 months**



**Survival
At 12 months**

“Notwithstanding the fact that new extreme approaches for managing these patients are currently available, a substantial number of patients are not suitable for treatment, and the rate of major amputation is still high”

Efficacy of Revascularization for Critical Limb Ischemia in Patients with End-stage Renal Disease

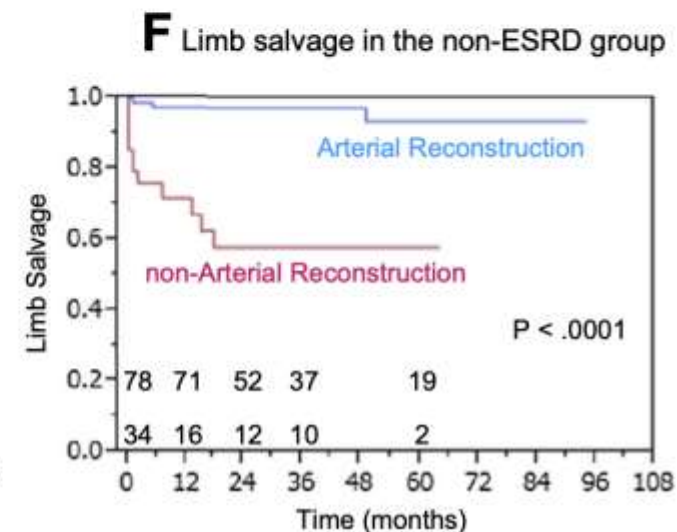
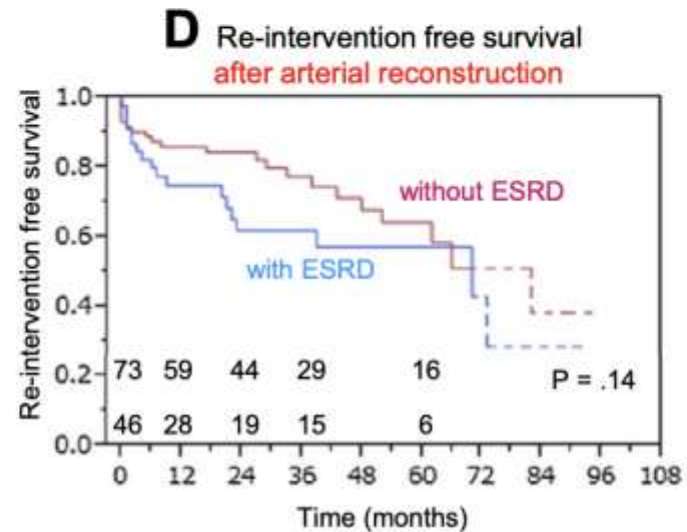
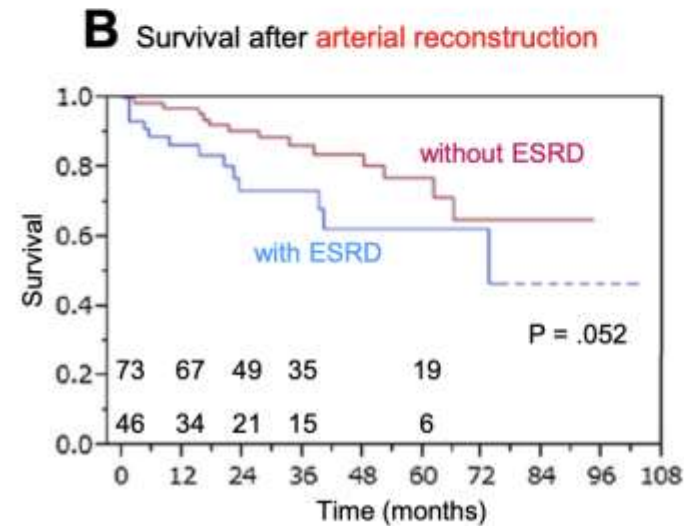
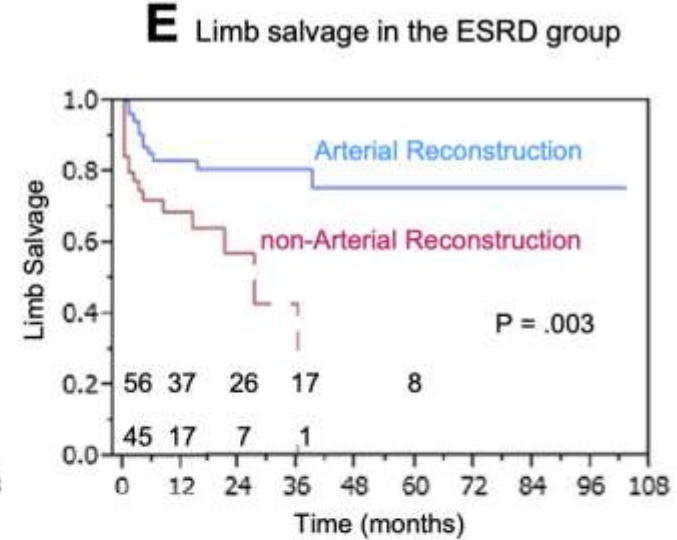
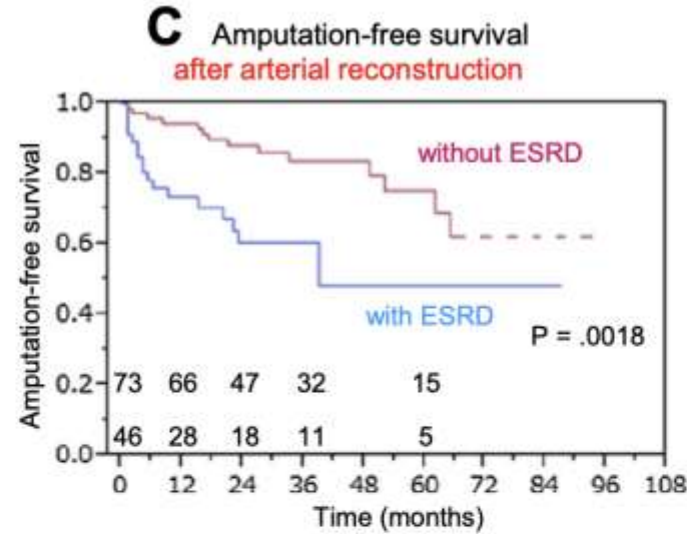
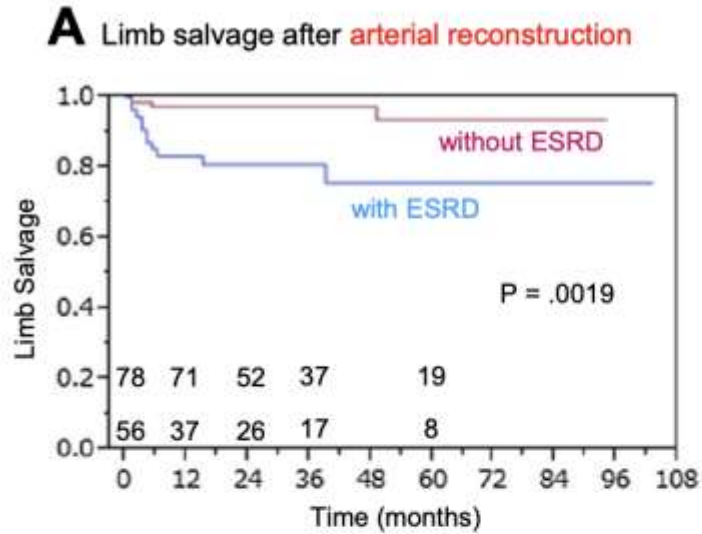
Yamamoto et al – EJEVS 2014, Vol.48 (3), p.316-324

S. Yamamoto, A. Hosaka*, H. Okamoto, K. Shigematsu, T. Miyata, T. Watanabe

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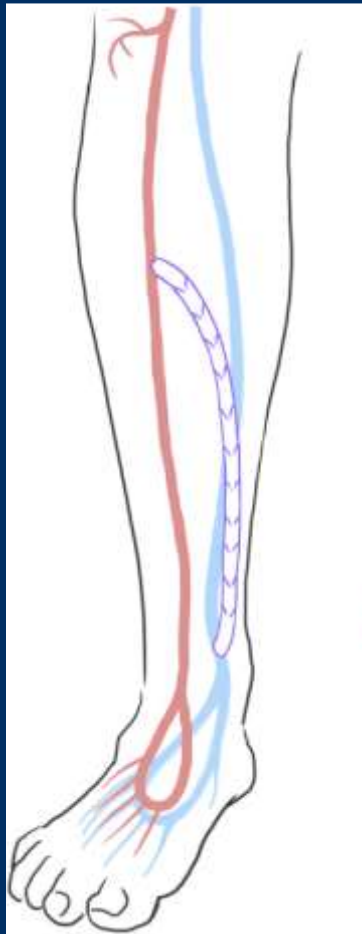
WHAT THIS PAPER ADDS

This paper presents the treatment of critical limb ischemia (CLI) in a series of patients with end-stage renal disease (ESRD) at a higher rate than the frequencies reported in the literature. CLI associated with ESRD facilitates development of a treatment strategy.



Venous Arterialization

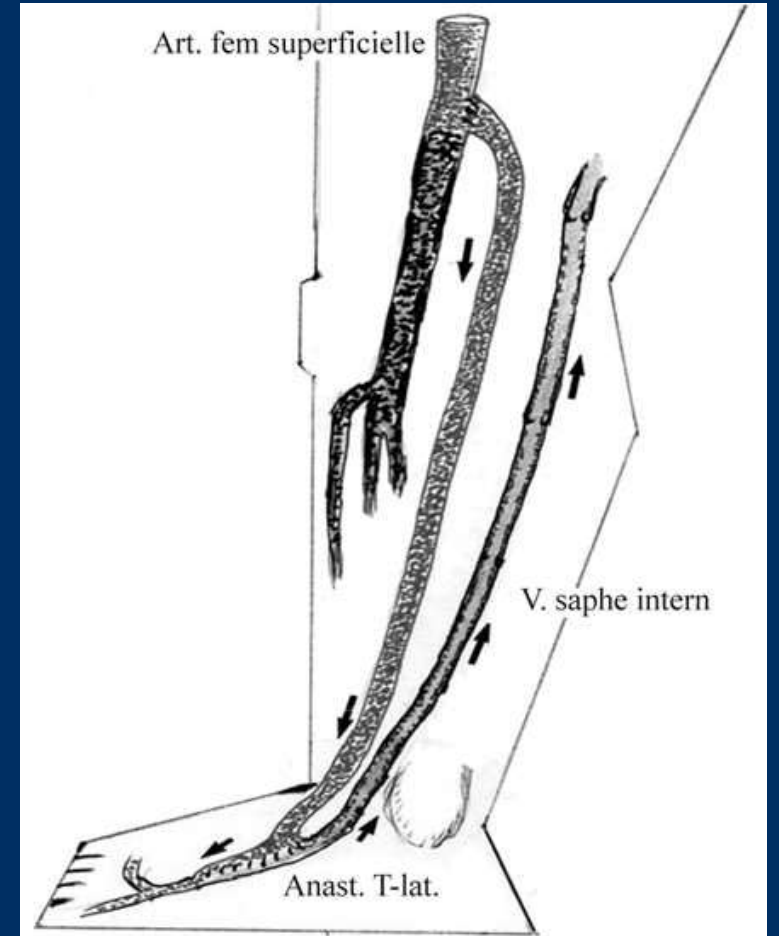
Open DVA



Percutaneous DVA



Hybrid Superficial VA (HYSA)



Open, percutaneous, and hybrid deep venous arterialization technique for no-option foot salvage



Vy T. Ho, MD,^a Rebecca Gologorsky, MD,^a Pavel Kibrik, DO,^b Venita Chandra, MD,^a Anna Prent, MD, MSc, FEBVS,^c Jisun Lee, MS, DPM,^d and Anahita Dua, MD, MS, MBA,^e *Palo Alto, Calif; Brooklyn, NY; London, United Kingdom; and Boston, Mass*

Open DVA

“...1-year primary patency for open DVA ranged from 44.4% to 87.5%; secondary patency was less reported but ranged from 55.6% at 1 year to 72% at 25-month follow-up. Limb salvage rates ranged from 25% to 100%, wound healing occurred in 28.6% to 100% of cases, and rest pain resolved in 11.9% to 100% across cohorts. Major amputation rates ranged from 0% to 70%.”

25-100%

Limb Salvage

28.6-100%

Wound Healing

Hybrid DVA

“...demonstrates <50% patency at 6-month follow-up across cohorts, with wound healing rates ranging from 44% to 46% and limb salvage rates ranging from 46% to 69%.”

46-69%

Limb Salvage

44-46%

Wound Healing

The determination is ultimately based on anatomy and presence of GSV

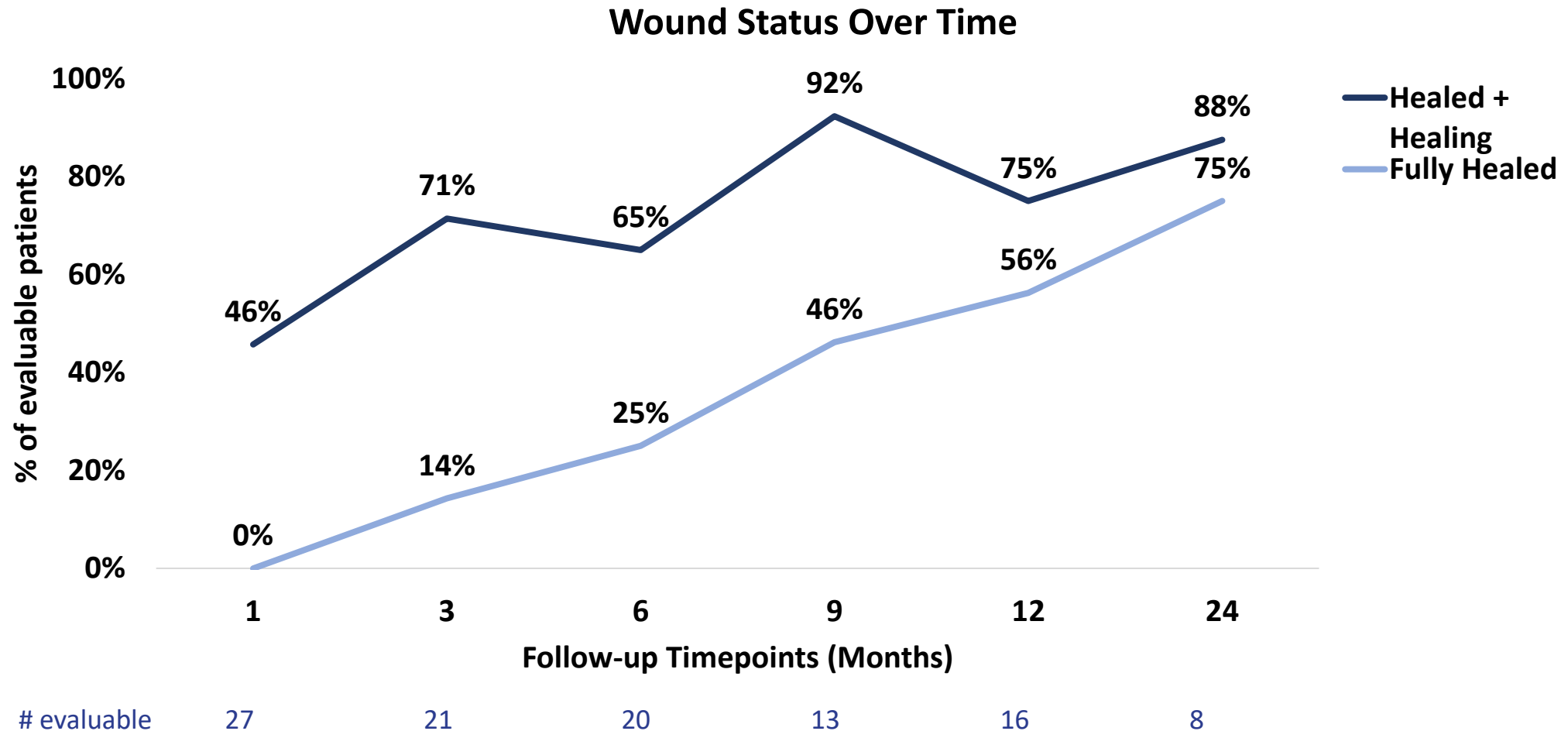


Best suited for HYSA



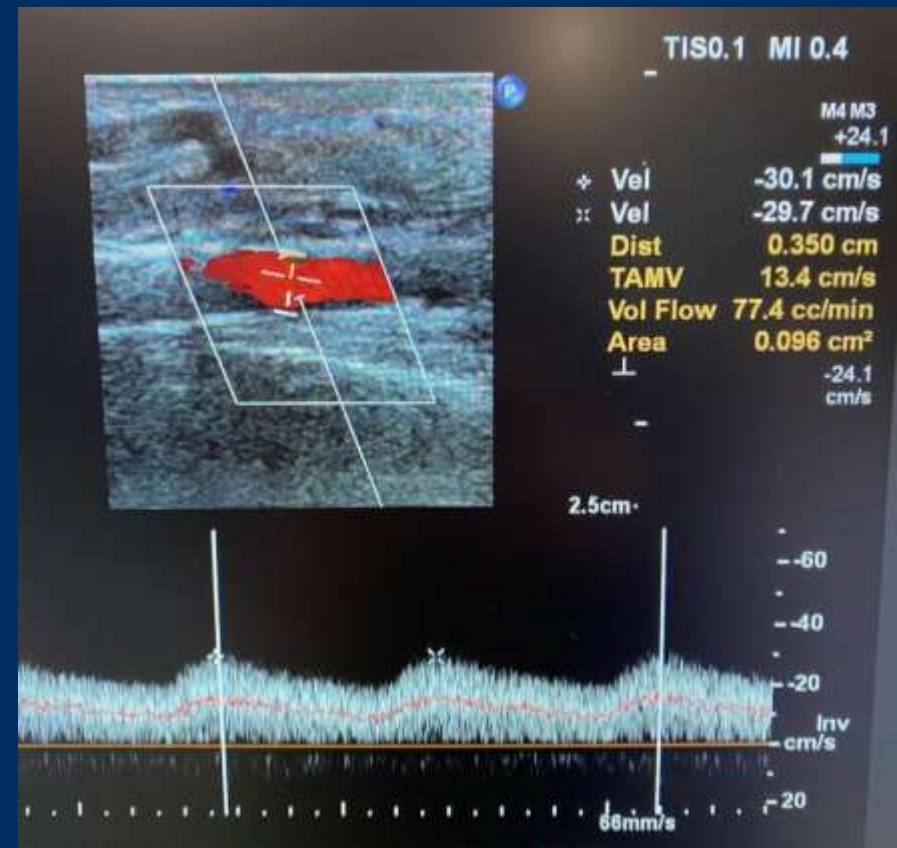
Best suited for endo

PROMISE I: US study



*At 9 months there were 12 patients healed or healing with 13 evaluable patients at 12 months there were 12 patients healed or healing with 16 evaluable patients

PROMISE II: April 3, 2020



Patient Follow-up

At Index: April 03



April 23



May 4



May 26



June 16



July 27



Sep 17



Dec 28



Conclusions

- Late stage CLTI and No-Option patients experience poor outcomes with traditional PAD therapies
- Primary amputation, medical management or DVA should be the options considered for these patients
- Surgical and Hybrid techniques are technically challenging and incomplete valve effacement may negatively impact reproducibility
- Percutaneous DVA is safe and technically feasible with limb salvage achievable in 77% of patients at 12 months (Limflo study data)



Please reach out for any questions!
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Pura Vida!