Commentary: Results of the EVRA Randomized Clinical Trial

Raghu Kolluri, MS, MD, PVT
Director – Syntropic Core Lab
Medical Director – Vascular Medicine and Laboratories
OhioHealth Heart & Vascular
Columbus, OH

I, Raghu Kolluri, have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

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  • Bard/BD, Boston Scientific, BTG, Inari, Innovein, Intervene, Janssen, Medtronic, Philips, Vascular Insights, Vesper Medical
• Board Member – VIVA Physicians Inc, 501c
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Disclosure Statement of Financial Interest

Results

Early Intervention Deferred Intervention HR
Median Time to Heal 56 days (95% CI, 49 to 66) 82 days (95% CI, 69 to 92)
1.42 (95% CI 1.16 – 1.73) p=0.001

Rate of Ulcer Healing at 24 weeks
85% 76.3%

Ulcer Free time in first year
306 278 1.54 (95% CI 1.07 – 2.21) p=0.02

VCSS, AVVQ, E5-QD Index, SF-36 body pain
• Improved from baseline to 6 months in both groups
• Early intervention group better than Deferred intervention group

ULCER RECURRENCE
• Before the end of the 1-year follow-up period
  • Early group 11.4% (24 of 210 patients)
  • Deferred group 16.5% (32 of 194 patients)

Overall Healing at 1 year ~ 90%

Interventional Therapies

Strictly EndoVenous Therapies
• No stripping
• No Phlebectomy

Endothermal and Foam Majority

But, any early therapy is better than deferred therapy

Concomitant deep venous disease

• Deep Venous occlusion – Excluded (6555 screened)
  • Ilio-caval obstruction not assessed. Treatment not reported
  • While deep venous reflux recorded, not an exclusion criteria
Reflux characteristics

Duration and size of the ulcer

Cost in USA – Added expense

Compression Rx

Some unanswered questions by EVRA

Summary Ramifications