One Month Duplex Ultrasound Evaluation of Vessel Recoil after Tibial Peripheral Vascular Intervention for Critical Limb Ischemia Predicts 12 Month Target Lesion Revascularization

Authors: Michael Sumners, DO; Osama Hallak, MS-4; Fadi Saab, MD; Larry Diaz-Sandoval, MD; Theresa McGoff, BSN, RN; Jihad Mustapha, MD

Introduction

The Peripheral Registry of Endovascular Clinical Outcomes (PRIME) Registry is the first registry of its kind that attempts to elucidate the best diagnostic and endovascular therapeutic modalities for advanced peripheral arterial disease (PAD) and critical limb ischemia (CLI). Currently, it represents the collaborative effort among five centers across the US with the goal of reaching 10 sites globally. PRIME explores aspects of advanced PAD and CLI care including the collection of comprehensive clinical, diagnostic, procedural, and follow-up data for three years following an index endovascular procedure. Data collection activities began in January of 2013 with the goal of collecting data on 5,000 subjects. Analysis of this multi-site registry will produce generalizable findings that describe the clinical epidemiology and management practices of advanced PAD and CLI patients.

Background

Late lumen loss by mechanical and biological recoil is a known mechanism of re-stenosis and late failure post peripheral endovascular intervention.

Methods

Tibial vessel recoil was determined by verifying the maximum inflation size of the treating balloon for the lesion site at index PVI compared to average luminal diameter at the same site (via 3 measurements) by 30 day DUS.

Methods, Cont’d

Pre Intervention

Results

• Recoil and vessel diameter were significant predictors of re-intervention within 12 months, for every 10% recoil, odds ratio 12.76 (95% CI: 11.51-14.22), p<0.001
• By multivariate analysis only recoil was a significant predictor of re-intervention within 12 months
• Freedom from re-intervention was 54% through 365 days
• Greater percentage of recoil was noted in distal vessels despite lower average inflation sizes:
  - 38% distal vessel
  - 31% mid vessel
  - 28% proximal vessel

Control Group:
• [60] lesions randomly selected with no TLR within 12 months – 51 evaluable via DUS

Conclusion

Vessel recoil after tibial PVI evaluated at one month duplex ultrasound may predict target lesion revascularization in advanced PAD and CLI patients over a 12 month follow-up. Multi-center analysis with a larger sample size is warranted to further validate findings.

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