# Reporting Characteristics of Randomized Controlled Trials of Endovascular Therapy for Peripheral Artery Disease: A Systematic Review

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## BACKGROUND

- Lower-extremity (LE) endovascular interventions have demonstrated clinical efficacy in treating peripheral artery disease (PAD).
- Examining the reporting characteristics of randomized controlled trials (RCTs) of LE endovascular interventions in patients with (PAD) is essential to ensure transparency and quality in the reporting of research findings.

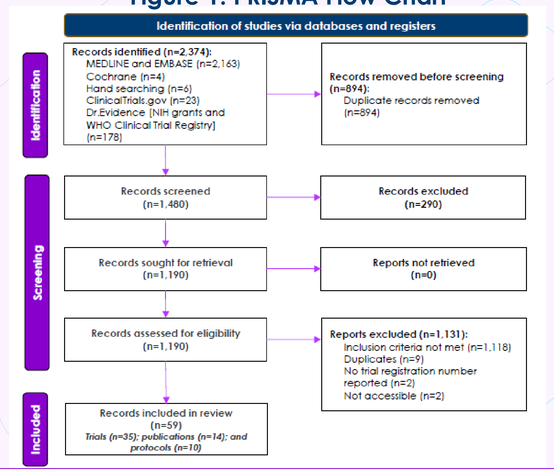
## OBJECTIVE

This systematic review examined the reporting characteristics of trial registries and protocols in LE endovascular RCTs involving PAD patients.

## METHODS

- This study followed the PRISMA guidelines and was registered in PROSPERO (CRD:42022378304).
- A validated search filter was applied across six databases to identify LE endovascular trials for PAD registered between 2012 and 2022 **(Fig. 1).**

**Figure 1. PRISMA Flow Chart**

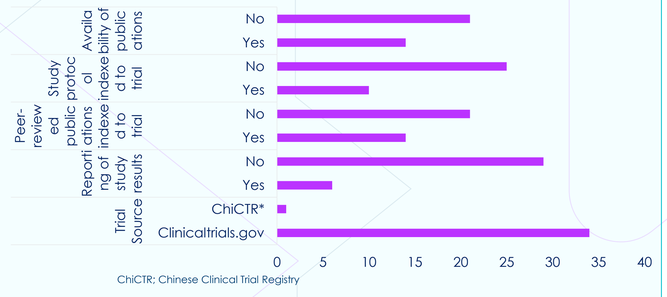



## RESULTS

- Fifty-nine records (35 RCTs, 14 publications, and 10 protocols) across 691 locations were identified. Of these, 19 (54.3%) were single- or double-blind, 5 (14.3%) were either phase III or IV, and 10 (28.6%) were 1:1 randomized RCTs **(Fig 2).**
- The median time from the trial start date to peer-reviewed publication was 5 years (range:3-8 years). The majority of the trials were conducted in the United States or Germany.
- Six of the 10 publications indexed in the registry had no study results posted. Eleven trials had completed recruitment (range:2014-2022), and five posted their study results in the registry **(Fig 3).**
- Information on enrollment strategies varied across protocols: recruitment (7), patient reimbursement (3), and withdrawal of patients (6) **(Fig 4).**
- Protocol reporting characteristics varied: cultural competency training for clinical research or principal investigators (0); reporting methods for withdrawing patients from RCTs (6); and providing participant-facing materials in other languages (2) **(Fig 4).**
- All publications reported age and sex; however, only four reported on race. Reporting of demographic characteristics by clinical outcomes was rarely performed, and no publication reported socio-economic status.

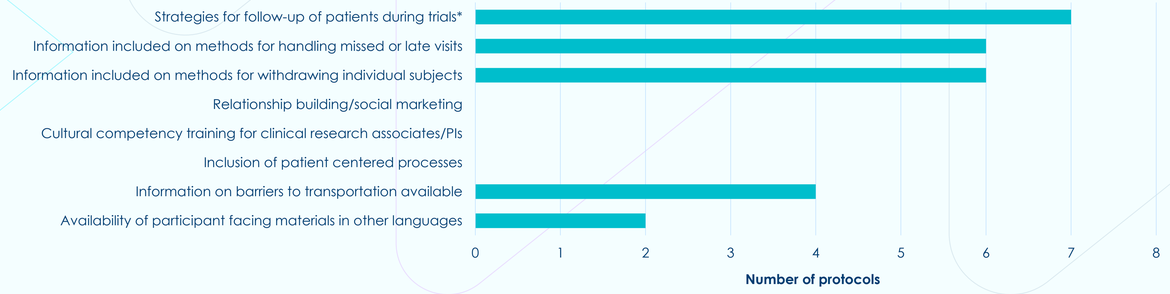
**Figure 2. Included RCTs, Protocols, and Publications**


**Figure 3. Trial Characteristics**




ChiCTR: Chinese Clinical Trial Registry

**Figure 4. Patient Recruitment and Follow-Up Strategies: Protocol Strategies**




## CONCLUSIONS

- This study highlights the need for improved transparency and standardized reporting practices in clinical trials.
- Addressing reporting issues could enhance the reliability of findings, ultimately advancing clinical decision-making and patient care in PAD.

## LIMITATIONS

- This research is susceptible to publication bias, where studies with statistically significant or positive results are more likely to be published than those with null or negative findings.
- The variability in global trials across included studies (heterogeneity) can make it challenging to statistically pool results (meta-analysis) and draw meaningful conclusions.

## DISCLOSURES

Chandler Long is a Physician and Assistant Professor of Surgery, Director of Vascular Surgery Fellowship Program Director of Vascular Surgery, and Integrated Residency Program Co-Director of Duke Center for Aortic Disease Duke Vascular and Endovascular Surgery Duke University Medical Center. Dr. Long was not compensated for his participation in this study.
Sue Duval is a contractor with Boston Scientific and a Professor at the University of Minnesota.
Abimbola O. Williams, Caroline M. Jacobsen, Alysha M. McGovern, Liesl M. Hargens, and Michael R. Jaff are employees of Boston Scientific.



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