

INVITED COMMENTARY

Outcome Differences in Critical Limb Ischaemia: Does Sex Matter?

Cornelis G. Vos^a, Jean-Paul P.M. de Vries^{b,*}^aDepartment of Surgery, Martini Hospital, Groningen, The Netherlands^bDepartment of Surgery, Division of Vascular Surgery, University Medical Centre Groningen, Groningen, The Netherlands

In this volume, Benson and colleagues¹ extrapolate data from the randomised BASIL-1 trial, where a bypass first strategy was compared with a percutaneous transluminal angioplasty (PTA) first strategy in patients with critical limb ischaemia (CLI).² They found that women had better overall survival (OS), amputation free survival (AFS), and fewer major adverse limb events (MALE) after three years follow up while re-intervention rates were similar.¹ Management of CLI is an important part of most vascular surgeons' practices and gender related differences in presentation and outcome for peripheral arterial disease (PAD) are well appreciated. While gender specific recommendations in guidelines exist for coronary artery³ and cerebrovascular disease,⁴ it is surprising that still no gender specific guidelines exist for CLI patients.

There are several limitations to the data delivered by the BASIL-1 trial that hamper the strength of its recommendations. First of all, the trial was published 15 years ago. Since the start of enrolment for this trial, much has changed in the endovascular treatment of CLI patients. Many new devices have been developed, such as atherectomy devices, drug coated balloons, and new stent designs. This means that more complex lesions are now amenable to endovascular therapy. In addition, several baseline characteristics in the BASIL-1 trial were significantly different between men and women. Women were older, more likely never to have smoked, less frequently presented with gangrene, and had lower creatinine levels. Therefore, one could question whether the scientific strength of the final outcomes is better than a recently published, large single centre experience, such as the report from Lejay and colleagues.⁵ They found higher rates of mortality, thrombosis, and limb loss in women undergoing bypass surgery for CLI.⁵ These conclusions conflict with the most important findings reported by Benson and colleagues.¹

Best medical treatment and primary and secondary prevention in cardiovascular disease have significantly changed over the years. This might be an area of particular interest where improvements in patient outcome can be obtained.

Patient specific best medical treatment, gender specific or not, should be further investigated and optimised. Also, patient and doctor adherence to guidelines on best medical treatment should be improved, since recent studies still report high proportions of PAD patients not taking and/or receiving best medical treatment.⁶

In conclusion, it is time for gender specific recommendations concerning the treatment of CLI patients that should be based on meaningful and proven trial data. A substantial number of these patients are frail, and major complications, including death, loom. Both men and women deserve our best pre-, per-, and post-procedural treatment to improve outcomes.

REFERENCES

- 1 Benson RA, Meecham L, Hewitt CA, Bradbury AW. Comparison of immediate and long-term outcomes in men and women undergoing revascularisation for chronic limb threatening ischaemia (CLTI) in the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL-1) trial. *Eur J Vasc Endovasc Surg* 2019;58:224–8.
- 2 Adam D, Beard J, Cleveland T, Bell J, Bradbury A, Forbes J, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomized controlled trial. *Lancet* 2005;366:1925–34.
- 3 Amsterdam EA, Wenger NK, Brindis RG, Casey Jr DE, Ganiats TG, Holmes Jr DR, et al. 2014 AHA/ACC guideline for the management of patients with non-ST-elevation acute coronary syndromes: a report of the American College of Cardiology/American heart association task force on practice guidelines. *J Am Coll Cardiol* 2014;64:e139–228.
- 4 Naylor AR, Ricco JB, de Borst GJ, Debus S, de Haro J, Halliday A, et al. Editor's choice – management of atherosclerotic carotid and vertebral artery disease: 2017 clinical practice guidelines of the European Society for vascular surgery (ESVS). *Eur J Vasc Endovasc Surg* 2018;55:3–81.
- 5 Lejay A, Schaeffer M, Georg Y, Lucereau B, Roussin M, Girsowicz E, et al. Gender related long-term differences after open infrainguinal surgery for critical limb ischemia. *Eur J Vasc Endovasc Surg* 2015;50:506–12.
- 6 Sigvant B, Kragsterman B, Falkenberg M, Hasvold P, Johansson S, Thuresson M, et al. Contemporary cardiovascular risk and secondary preventive drug treatment patterns in peripheral artery disease patients undergoing revascularization. *J Vasc Surg* 2016;64:1009–17.e3.

DOI of original article: <https://doi.org/10.1016/j.ejvs.2019.03.001>* Corresponding author. Department of Surgery, Division of Vascular Surgery, University Medical Centre Groningen, Groningen, The Netherlands
E-mail address: ncgvos@gmail.com (Cornelis G. Vos).

1078-5884/© 2019 European Society for Vascular Surgery. Published by Elsevier B.V. All rights reserved.

<https://doi.org/10.1016/j.ejvs.2019.03.035>