

EDITORIAL

## Intervention Should not be the Thermopylae to Avoid Amputation: Commentary on “Not All Patients with Critical Limb Ischaemia Require Revascularisation”

*Go tell the Spartans, stranger passing by,*

*That here obedient to their laws we lie*

Epitaph of Simonides

The Thermopylae gorge is famous for the battle that took place there between the Greek and the Persian forces. The pass of Thermopylae is the only land route large enough to bear any significant traffic between the north and the south of Greece along the east coast of the Balkan Peninsula. Not surprisingly, it was the site of several battles. Similarly, many colleagues think that winning the battle of the invasive approach to amputations is their Thermopylae and do not consider any other options.

In the paper by Santema et al. the most important and unique point is the direct comparison of outcomes after revascularisation and conservative therapy in patients who should undergo revascularisation for critical limb ischaemia (CLI) according to current guidelines.<sup>1</sup> The authors conclude that there are no differences between intervention and conservative therapy regarding amputation free survival and overall survival. The vast majority of publications show outcomes after ever increasingly sophisticated endovascular invasive procedures, but “forget” to report on those patients not amenable to interventions according to current guidelines, during the same time period. Apparently the same physicians, particularly interventionalists and surgeons, who are so proud of “saving” so many legs by being active, relegate conservative management to a minor enterprise.

Moreover, most papers dealing with revascularisation issues make no mention of patients’ quality of life (QoL) after the procedure. It is known that QoL is not always regained after successful invasive therapy. With only 53% of revascularised patients returning to work, a salvaged leg does not equate with return to pre-procedure ambulatory/occupational status. However, there might be some improvement in QoL for other reasons besides revascularisation. Kumar et al. advise us: “As surgeons, we need to look beyond leg salvage and graft patency and take on a more holistic approach”.<sup>2</sup>

The paper by Santema et al. arouses in me some interesting thoughts.<sup>1</sup>

### SHOULD WE RE-EVALUATE OUR CRITERIA FOR LIMB SALVAGE SUCCESS IN PATIENTS WITH DIABETES?

Diabetes mellitus is one of the major risk factors for peripheral arterial occlusive disease, its prevalence being particularly high in patients with chronic CLI. In the paper by Santema et al. 38.5% in the invasive group, 50% in the delayed and 45.5% in the conservative group were diabetic.<sup>1</sup> Although analysis of diabetic subgroups was not possible owing to the small numbers, note that diabetic patients have worse outcomes or are simply not suitable for revascularisation. Therefore, authors must have these observations in mind as diabetic patients behave differently, and revascularisation only reduces amputations when an adequate therapy is implemented equating to the invasive approach.

We must differentiate diabetic and non-diabetic patients with CLI, as for diabetic patients beyond ischaemia, wound and infection play a relevant role. In light of this, we should propose a different clinical classification for diabetic peripheral vascular disease with respect to the current classification, which basically concerns the population at large.

To date, papers mostly use the Rutherford grading to identify ischaemic patients, ignoring the fact that additional systems, such as Wound, Ischaemia and foot Infection (WIFI), are good predictors of outcome after revascularisation.<sup>3</sup>

Does limb salvage mean salvage of the functional foot? Despite the fact that many vascular specialists can successfully treat tibial vessels, foot ulcer prevention is a must in patients with diabetes and it should be a pre-emptive action. Functional foot salvage should be the primary endpoint by which the effectiveness of any proposed therapy should be measured in any clinical studies. In diabetic foot revascularisation, how much of the foot do we vascular surgeons/interventionalists save? The main aim of the majority of studies is limb salvage, while foot amputations are a collateral side effect which, in any case, obscures the primary goal.

Although revascularisation should be performed without delay in both non-diabetic and diabetic patients, clinical outcome regardless of endovascular first or surgical first approach, will improve if treatment is individually tailored to the patient, taking into account his/her medical and personal conditions.<sup>4</sup>

DOI of original article: <http://dx.doi.org/10.1016/j.ejvs.2016.10.018>.  
1078-5884/© 2016 European Society for Vascular Surgery. Published by Elsevier Ltd. All rights reserved.  
<http://dx.doi.org/10.1016/j.ejvs.2016.12.022>

### ENDOASCULAR FIRST LINE APPROACH MAY BE ADEQUATE AS LONG AS IT IS NOT CONSIDERED AS THE UNIQUE APPROACH

Many now use percutaneous transluminal angioplasty with or without stenting, as the first line approach for CLI because results are similar to reconstructive surgery, even in the infrapopliteal segment, and potentially offers advantages such as minimal aggression. However, surgeons and interventionalists must bear in mind that the procedure when it fails, is not innocuous.<sup>5</sup> Moreover, as happens on so many occasions, repeated endovascular procedures may condemn reconstructive surgery to failure.

### SOME YEARS AGO SUCCESSFUL INTERVENTIONS MEANT PATENCY OF THE OPEN VESSEL

Today, interventionalists do not consider patency as the main goal but limb salvage, and although this may be acceptable, functionality hardly comes into consideration. Functional outcome for patients undergoing intervention for CLI is determined not only by the traditional measures (patency/limb salvage), but also by the patient's comorbidity at the time of intervention. We should question the benefit of our current approach to CLI when patients are functionally impaired and chronically ill, and will certainly be more prevalent as the population gets older.<sup>6</sup>

### WHAT SHOULD WE DO WITH PATIENTS NOT AMENABLE TO REVASCULARISATION?

Some systematic reviews reported a 1 year amputation free survival of 55% in patients with CLI, without options for revascularisation for different reasons. The present paper hoped to create awareness about the lack of evidence that currently exists regarding outcome in these patients. In this sense, the paper by Santema et al. brings us the opportunity of alerting the scientific vascular world to the convenience of including outcomes of conservatively treated patients who are not suitable for revascularisation, according to current guidelines.<sup>1</sup> Are there any doubts that these patients deserve to be cared for, as many conservative measures are possible and useful, particularly in prevention?<sup>7,8</sup>

Outcomes research in CLI should enter a new phase where surgeon or lesion oriented outcomes be replaced by patient oriented ones. This will become increasingly important from a public health standpoint as the population of patients with CLI grows, and as treatment options for this disease continue to grow and aggressive options are not always appropriate for a particular patient.

According to Landry, "In selecting patients for endovascular or open revascularisation it must be realised that such

procedures are often accompanied by lengthy hospitalisation, complications, re-admissions and re-interventions, which will probably diminish the patient's quality of life".<sup>9</sup>

Coming back to the Thermopylae, the land is dominated by the coastal floodplain of the Spercheios River and is surrounded by sloping limestone forested mountains. There is continuous deposition of sediment from the river, which has substantially altered the landscape during the last few thousand years. The land surface on which the famous Battle of Thermopylae was fought in 480 BC is now buried under 20 m of soil. Do we have any doubts that the present aggressive approach will be buried by the next generation to give way to a new and more gentle approach to our sick and old people?

### REFERENCES

- 1 Santema TB, Stoekenbroek RM, van Loon J, Koelemay MJW, Ubbink DT. Not all patients with critical limb ischaemia require revascularisation. *Eur J Vasc Endovasc Surg* 2017;**53**:371–9.
- 2 Kumar BN, Ganbhir RP. Critical limb ischemia—need to look beyond limb salvage. *Ann Vasc Surg* 2011;**25**:873–7.
- 3 Vela-Orus MP. CLI in patients with diabetes: is the new Wifl classification a valuable tool for identifying benefits of revascularisation?. Available at: [www.oc.lm.ehu.es/Departamento/Investigacion/TesisPDF/Pilar%20Vela.pdf](http://www.oc.lm.ehu.es/Departamento/Investigacion/TesisPDF/Pilar%20Vela.pdf) [Accessed 22 December 2016] [in Spanish].
- 4 Dick F, Diehm N, Diehm N, Galimanis A, Husmann M, Schmidli J, et al. Surgical or endovascular revascularization in patients with critical limb ischemia: influence of diabetes mellitus on clinical outcome. *J Vasc Surg* 2007;**45**:751–61.
- 5 Conte MS. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) and the (hoped for) dawn of evidence-based treatment for advanced limb ischemia. *J Vasc Surg* 2010;**51**(Suppl.): 69S–75S.
- 6 Spence MT, Kalbaugh CA, Blackhurst DW, Cass AL, Trent EA, Eugene M, et al. Determinants of functional outcome after revascularization for critical limb ischemia: an analysis of 1000 consecutive vascular interventions. *J Vasc Surg* 2006;**44**:747–56.
- 7 Kavros SJ, Delis KT, Turner NS, Voll AE, Liedl DA, Gloviczki, et al. Improving limb salvage in critical ischemia with intermittent pneumatic compression: a controlled study with 18-month follow-up. *J Vasc Surg* 2008;**47**:543–9.
- 8 Elgzyri T, Larsson J, Thörne J, Eriksson KF, Apelqvist J. Outcome of ischemic foot ulcer in diabetic patients who had no invasive vascular intervention. *Eur J Vasc Endovasc Surg* 2013;**46**:110–7.
- 9 Landry GJ. Functional outcome of critical limb ischemia. *J Vasc Surg* 2007;**45**(Suppl. 336):A141–8.

M.A. Cairols  
Barcelona, Spain

Email-address: [cairols@hotmail.com](mailto:cairols@hotmail.com)