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### Regarding "Infrapopliteal balloon angioplasty for the treatment of chronic occlusive disease"

Critical limb ischemia (CLI) usually represents extensive multi-level arterial occlusive disease, often requiring infrapopliteal revascularization. Angioplasty also seems very promising in this segment. Previous studies on the effect of infrapopliteal angioplasty in CLI were often limited by a lack of description of patient and lesion characteristics. In a recent article in the *Journal of Vascular Surgery*, Conrad et al<sup>1</sup> described their results with infrapopliteal angioplasty in a large study with 144 patients and with well-described CLI and lesion characteristics. The limb salvage rate at 40 months of follow-up was 86%, despite inferior patency rates. The authors concluded that infrapopliteal angioplasty should be considered the initial therapy for these patients.

Important information is missing in their report, however. Almost 70% of their patients had diabetes mellitus, and claiming a success in limb salvage as a result of angioplasty in such patients seems somehow inappropriate. Tissue loss and healing of ulcers in diabetic patients is strongly related to diabetic neuropathy, infections, and microvascular diabetic complications, besides peripheral arterial occlusive disease.<sup>2</sup> Many of these patients often have an ankle-brachial index of about 50 mm Hg or higher (subcritical ischemia), and limb loss rates are relatively low whether they undergo revascularization or not.<sup>3,4</sup> Information on the presence of neuropathy and other microvascular complications, as well as the actual ankle-brachial index, are needed to adequately interpret the results reported by Conrad et al.

Furthermore, multilevel treatment was necessary in 74% of their patients. Dilatation of inflow lesions was performed in 40% to 88% of the patients in infrapopliteal angioplasty studies. Experience with combined multilevel occlusive disease indicates that treatment of the more proximal lesion alone was appropriate in >40% to 75% of the patients to relieve CLI.<sup>5</sup> The concurrent angioplasty of inflow lesions may explain the observed high gap between infrapopliteal lesion patency and limb salvage rates. What were the proximal lesions (ie, TransAtlantic InterSociety Consensus classification and level), what procedures were performed for these more proximal lesions (angioplasty or bypass surgery), and what were the patency rates of these procedures in the Conrad et al study? This information is needed to understand their success in treating these patients.

Finally, indicating angioplasty as the initial therapy in patients with CLI needs some caution after the results of the Bypass Versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial.<sup>6</sup> Approximately 75% of the BASIL cohort survived >2 years, and an angioplasty-first strategy in these patients did not fare as well as a bypass surgery-first strategy.

Improvements in endovascular therapy allow an increasing subset of patients to be treated with angioplasty. Angioplasty and open surgery are, however, complementary, and therapy must be individualized. More information is needed from Conrad et al to fully appreciate their study.

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### Reply

We respectfully disagree with Dr Meerwaldt and colleagues' assertion that diabetic patients with critical limb ischemia will heal ulcers without revascularization. Although it is true that diabetic wounds are often more difficult to manage due to factors such as neuropathy, infection, and microvascular disease, in the absence of macrovascular blood flow, these wounds simply do not heal. The current study did not intend to address the nuances of management of the diabetic foot and indeed, many of our diabetic patients (ie, those with intact macrovasculature) were not included in this series.

In our practice, we attempt to re-establish in-line flow to the foot in patients with tissue loss, and although improvement of inflow alone will often relieve rest pain, this approach is usually inadequate for ulcer healing. The disconnect between the primary patency and limb salvage in the current series is secondary to a strict definition of failure and an aggressive posture toward reintervention, as was stated in the article.

Although the Bypass Versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial has shown excellent results with its primary end points of survival and limb salvage, it is not applicable to the current series. Patients in BASIL were included only if there was agreement that they could be treated with angioplasty or bypass. In the current series, many of our patients were not bypass candidates due to comorbidities or a lack of an autogenous conduit. In addition, the difference between the two cohorts is accentuated by our 24-month survival of 68% (lower in those with critical limb ischemia) compared with a higher rate in the BASIL series.

Finally, we agree with Dr Meerwaldt and colleagues' statement that lower extremity revascularization needs to be tailored to the individual patient and stand by our results as written.

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