

which medicine is practiced today with the creation of accountable care organizations and increasing patient/payer scrutiny.

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## REPLY: 3-Year Outcomes of the OLIVE Registry, a Prospective Multicenter Study of Patients with Critical Limb Ischemia



We would like to thank Dr. Philip for his interest in the OLIVE (A Prospective, Multi-Center, Three-Year Follow-Up Study on Endovascular Treatment for Infra-Inguinal Vessel in Patients With Critical Limb Ischemia) registry (1) evaluating outcomes of endovascular treatment for infrainguinal vessels in patients with critical limb ischemia (CLI). One issue that was pointed out this time described problems in the current treatments for patients with CLI. We completely agree with Dr. Philip that the quality of baseline medical therapy is extremely important when assessing and comparing the overall quality and cost of vascular care. As noted, we have no evidence that the medical costs associated with revascularization with endovascular therapy actually prevent amputation, whereas the efficacy of optimal medical therapy (OMT) for amputation prevention and prognosis improvement has not been established, either (2). The current guidelines

recommend OMT for peripheral arterial disease (PAD) as follows: 1) antiplatelet therapy; 2) statins; and 3) angiotensin-converting enzyme inhibitors/angiotensin receptor blockers. There is a report that the administration of 2 or more of these agents reduces mortality. However, we should also note the lack of consistency in the provision and adherence of these recommended therapies in PAD patients (3). Some antiplatelet drugs and statins have been reported to improve limb prognosis (2). The OLIVE study demonstrated a low administration rate of statins in the real world. In this study, 52% of subjects were on dialysis, 41% had hyperlipidemia, and the mean body mass index was 22, but the administration rate of statins was as low as 26%. Inadequate drug treatment for PAD and poor adherence of patients have recently been reported (4,5), and it is meaningful that the OLIVE study also revealed that OMT is rarely provided for CLI in actual clinical practice. Among CLI patients in the clinical setting, some presented with hypotension or terminal status of arteriosclerosis with sarcopenia. For these patients facing such a prognosis, both OMT administration and revascularization are controversial. Either way, the evidence level for the role of OMT for CLI is insufficient, and such verification is urgently necessary.

The onset and progression of CLI are strongly correlated with diabetes mellitus and renal failure. Patients with these complications present with a higher prevalence of infrainguinal arterial lesions, which have a high rate of restenosis and reintervention after endovascular therapy. In the OLIVE study, the percentage of subjects with diabetes mellitus and those on dialysis was as high as 71% and 52%, respectively, and approximately 75% had the infra-popliteal arterial lesions, resulting in high rates of restenosis and reintervention (1). In patients with rest pain or ulcers/gangrene who developed a first episode or recurrence, reintervention seemed to be both inevitable and the only option: the medical intervention to prevent major amputations provides only class III guidance in the current guideline. On the other hand, repeated revascularization is an additional financial burden, despite providing only local treatment. A general treatment model, including systemic treatment and social aspects, should be considered in order to improve CLI prognosis as well as medical cost burdens. Even if revascularization is the first-line treatment for CLI, this does not necessarily justify repeated interventions performed within a short period of time.

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