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Chronic Limb-Threatening Ischemia, Which Way is the Best? Surgery or Endovascular; a Short Commentary

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Chronic limb-threatening ischemia (CLTI), is the most severe manifestation of peripheral artery disease, is defined by ischemic foot pain at rest, ischemic ulcerations, or gangrene [1]. More than 200 million people have peripheral artery disease worldwide; CLTI affects up to 11% of this population and if left untreated, it will cause permanent disability like amputation and even mortality [1,2]. Aside from the severe health outcomes associated with CLTI, the economic effect of the condition is substantial, with an estimated annual cost of approximately \$12 billion in the United States alone [3].

Treatment for CLTI includes medical therapy to reduce cardiovascular risk, revascularization to improve limb perfusion, and local care to control infection and improve wound healing [4]. Best medical therapy includes the use of antithrombotic, lipid-lowering, antihypertensive, and glycemic control agents, as well as counseling on smoking cessation, diet, exercise, and preventive foot care [5].

The effectiveness of nonrevascularization therapies (eg, spinal stimulation, pneumatic compression, prostanoids, and hyperbaric oxygen) has not been established. Regenerative medicine approaches (eg, cell, gene therapies) for CLTI should be restricted to rigorously conducted randomized clinical trials [5].

Without timely revascularization, the incidence of limb amputation is approximately 25% at 1 year after diagnosis [6,7]. Surgical bypass and endovascular therapy are the principal revascularization strategies used to treat CLTI. The choice of surgery or endovascular therapy as the initial treatment varies greatly among providers and is based on the patient's arterial disease pattern, surgical risk, availability of an autogenous conduit for vein bypass, and patient preference, along with such physician factors as training, skill set, and treatment bias [8-10].

The extent to which this variability affects clinical outcomes in patients with CLTI is unknown [8,9].

In this short commentary we will review some studies about choosing the best approach for treating CLTI.

The BASIL trial was the first study that provided level I evidence from RCTs in the field, firstly published in 2005. The aim of the BASIL trial was to determine whether, in patients with CLTI due to infra-inguinal arterial disease, a bypass first or an endovascular first revascularization strategy was associated with a better outcome in amputation free survival (AFS) and overall survival (OS) [11].

The overall recommendation from BASIL is that CLTI patients predicted to live >2 years, and with a useable vein, should usually have bypass first. This is because the long-term results of saphenous vein bypass are good, the rate of endovascular failure is high, and results of bypass after failed endovascular are significantly worse than for primary bypass. However, patients expected to live <2 years, and those without a useable vein, should usually have endovascular first because they will not survive to reap the longer-term benefits of surgery and the results of prosthetic bypass are poor [11].

BEST-CLI was an international, prospective, randomized, open-label, multicenter, superiority trial. Patients were enrolled at 150 sites in the United States, Canada, Finland, Italy, and New Zealand. The trial consisted of two parallel studies that were based on a preprocedural assessment of the availability of autogenous conduit for vein bypass: either a single segment of great saphenous vein (cohort 1) or the need for an alternative bypass conduit (cohort 2) [12].

According to this study, in patients with a good-quality great saphenous vein for conduit a surgery-first strategy was associated with a 32% lower risk of a composite of major adverse limb events or death than was the endovascular strategy. However, in patients without a great saphenous vein for conduit, overall efficacy and safety outcomes appeared to be similar in the two treatment groups, findings that emphasize the importance of individualized patient-level decision making in patients without an appropriate bypass conduit [12].

Overall, the findings from this large, international trial suggest that preprocedural planning of treatment in patients with CLTI should include a surgical risk assessment and a determination of

saphenous-vein availability [12].

Factors such as conduit availability for bypass, advanced age, and renal failure are key considerations in planning revascularization procedures. Our data also highlight the importance of a team approach that leverages experience with both strategies to most effectively treat patients with CLTI.

These two studies were about infrainguinal lesions, but the purpose of our study was to compare outcomes of bypass surgery and angioplasty in isolated below-the-knee lesions.

A total number of 88 patients who were undergone below-the-knee bypass surgery or angioplasty during the years of 2015–2017 because of foot ulcers or gangrene were enrolled in this study [13].

Amputation-free survival (AFS) in the bypass group was 43.5 (± 8.5) months and 39.8 (± 8.9) months in the angioplasty group. AFS was significantly higher in the bypass group compared to the angioplasty group ($P = 0.05$). In addition, the AFS survival survey showed that in the bypass group, the predicted survival rate was 45.1 ± 4.29 (42.87–47.95) months, and in the angioplasty group was 41.1 ± 7.27 (39.24–44.25) months, which showed a significant difference between the two groups ($P = 0.05$). Patients' overall survival (OS) was 49.6 ± 10.6 and 46.2 ± 11.7 months in the bypass and angioplasty groups, respectively. There was no significant difference between the groups ($P = 0.32$). The OS survey of patients indicated that the average predicted survival in the bypass group was 54.1 ± 6.7 months (51.13–58.09) and in the angioplasty group was 52.2 ± 2 months (48.3–56.1). Despite >4 months difference, it was not statistically significant ($P = 0.3$) [13].

The main finding of this study was that the surgical bypass procedure had a significantly higher AFS compared to angioplasty in the two examined groups during the follow-up period. Therefore, it is recommended for all patients with below-the-knee ischemic lesions to have surgical bypass procedures, except for patients with multiple underlying diseases, who have a high-risk condition for surgery, as well as for patients with veins not suitable for bypass [13].

The main goal was to answer the question of which method is better for below-the-knee lesions. Although the definition of “better” is not easy, we chose AFS as the main criterion, which is also the US Food and Drug Administration's criterion for such studies. The reason for not considering other criteria such as vascular patency and arterial pressure in the ankle (ankle pressure) was that we wanted to compare two therapeutic strategies, not just comparing bypass and angioplasty techniques. Morbidity was not evaluated in this study due to the controvert results reported in various studies pertaining to morbidity. For example, an article published by Siracuse et al. indicated endovascular procedures had been associated with lower 30-day mortality rate and 3-year worse survival compared to surgical bypass [14]. In another study by Tsai et al., no significant difference was reported between these two methods regarding the 30-day mortality. Moreover, studies often suggest that mortality and morbidity of the endovascular method are reduced within short-term periods. Thus, they are less indicative to determine the effectiveness of these methods, especially in long-term periods [14,15].

Although AFS was a clear and relevant measure in this study, it did not provide much information about the quality of life of patients after vascular reconstruction. It is quite acceptable that sometimes amputation in the early phase of the disease improves the patient's quality of life, but on the other hand, chronic pain, and

wound care reduce the quality of life of the patients. As a result, this issue should be taken into attention by vascular surgeons and intervention specialists, to not only consider vascular lesions in the treatment of these patients but also patients' needs and expectations.

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