

Treatment of No-Option CLI Patients

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Editorial

In the last 10-15 years, we have seen an increasing number of patients with critical limb ischemia (CLI), most due to an increase of population age and diabetes.

It is widely known that the most important factor to obtain wound healing in these patients is to increase distal vascularization, that is sufficient blood flow to the wound.

Unfortunately, in about 15%-20% of CLI patients, literature data showed that revascularization is not possible or not effective. For these patients the risk of major amputation is very high. This condition is defined as no-option CLI, it is most frequent in patients with diabetes and end-stage renal disease, who have below the knee and below the ankle heavily calcified arteries.

During the last decade, for these patients facing major amputation, new treatments have been proposed, like stem cell therapy, vasoactive therapy or spinal cord stimulation. However, reviews about these indirect revascularizations showed no effectiveness in major amputation reduction of vasoactive and stem cell therapy and only small benefit of spinal cord stimulation.

So, for these very complex patients, an alternative treatment can be considered the arterialization of the deep veins of the foot, in order to obtain distal direct arterial flow through an alternative, non stenotic and non-diseased, vessel, like a vein. The basic concept in this operation is to anastomize the artery with the vein in order to obtain direct arterial flow into the foot veins.

The idea and the history of deep foot vein arterialization is not new, because the first publications are from more than 100 years ago. Indeed, we find the first publication [1] in 1896 and in 1912 Halsted and Bernheim [2,3] published the first series of patients treated with this technique and showed in many patients a rapid relief of pain and improvement of wound healing.

Despite these beginning results, deep vein arterialization has not had a rapid and great success and has not spread, probably, because the operation is not easy to perform and there are a lot of technical issues, like: the right site to create

the arterial-venous (AV) fistula, how to treat distal competent valves, a high risk of distal anastomosis infection, etc.

However, in the literature, we find some meta-analyses and reviews [4,5] showing that open surgical arterialization of the deep foot veins can be considered a treatment for patients with no-option CLI. Particularly, in the last one by Schreve [6], published in 2016, the Author concludes: "the pooled proportion of limb salvage at 12 months was 75%. Venous arterialization could be a valuable treatment option in patients facing amputation of the affected limb".

Furthermore, some Authors [7,8] showed that deep foot vein arterialization can be performed with a totally percutaneous approach with acceptable results, being less invasive, reducing the risk of distal anastomosis infection and a better treatment of distal competent valves compared to open surgery.

Anyway, total percutaneous deep foot vein arterialization is at the beginning and so has a lot of controversial and unsolved issues. First of all, how and where to percutaneously create the AV fistula, that is the first step during arterialization. In the literature, there are different [7,8] techniques to create the AV fistula, with specific catheters, with re-entry systems or directly with catheters and guidewires.

Furthermore, we published [9] a novel technique using an IVUS-guided needle catheter, with indication as a re-entry system in case of sub-intimal revascularization at the femoro-popliteal level. The advantages of using this IVUS-guided needle catheter is to avoid the distal tibial vein puncture in an eventually infected and ischemic area and, also, to have a direct ultrasound view of the site where the AV fistula is to be created, and so making it possible to avoid heavily calcified areas in the tibial artery and finding the best tibial vein to arterialize.

However, if the issue of AV fistula creation is solved with the above described techniques, there are a lot of others issues not completely solved. First, what is the best vein to arterialize? In our experience, like in the literature, posterior tibial and peroneal veins seem to be the veins with better network in the foot. Second, where to create the AV fistula? proximally or distally? Lengua showed, in open surgery arterialization, that the fistula has to be created as distally as

possible, but in a totally endovascular technique it is not completely clear. Third, how to treat the competent distal valves and collaterals in the tibial and foot veins, to obtain direct and effective arterial flow in the deep venous plexus of the foot? We can use different methods: uncovered or covered stents, spot stents, avoiding stents and using a valvulotome and coil embolization; but also this issue remains unsolved.

Another important concept after deep foot vein arterialization is the “pressurization of the vein capillary bed” [10], arterialization allows to open and to increase capillary circulation. This is very important, because, when we perform deep foot vein arterialization, we do not have the presumption to say that this stays open for a long time, but with the neovasculogenesis due to “pressurization of the capillary bed”, after occlusion, we still have sufficient blood flow to avoid ischemia.

In conclusion, totally percutaneous deep foot vein arterialization is an exciting alternative technique to vascularize no-option CLI patients facing amputation. The first results are encouraging, but it’s mandatory not only to solve many open questions, but also to improve patient selection and to have new and more specific data.

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