Optimizing decision-making strategies in managing superficial femoral artery occlusive disease

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The peripheral artery disease (PAD) of the lower extremities, especially the superficial femoral artery (SFA) occlusive disease, is a common cause of impaired ambulation and is a leading cause of lower extremity wounds and amputations. Even though the life style and risk factors modification with antiplatelets and lipid lowering agents might attenuate the PAD symptoms and processes, endovascular and surgical interventions still remain the main strategies for revascularization of the occluded SFA lesions.

1. SURGERY

Surgical bypass surgery is indicated for critical limb ischemia salvage with the primary goal to relieve pain, to encourage ulcer healing, to prevent limb loss, and to improve life quality and survival of the patient. Although surgical procedures carry a higher early post-procedural complication rate, they improve medium to long-term outcomes compared to endovascular interventions. An aortobifemoral arterial bypass is usually recommended for diffuse aortoiliac disease with limb-based patency rates of around 90.0% and 84.3% at 5 and 10 years, respectively.[1,2] In extra-anatomical bypass modalities including femoro-femoral or axillo-femoral arterial conduits, the 5-year patency rates are between 51% and 75%. The infrainguinal arterial bypass requires uncompromised inflow at the proximal anastomosis, preferably to a native artery rather than graft. A satisfactory distal run-off vessel is the most important determinant of longer-term patency which ranges between 35% for prosthetic material to 60% for vein grafts over 5 years.[3]

2. ENDOVASCULAR

The endovascular strategy by percutaneous transluminal angioplasty and/or stenting is emerging new methodology and technology in the recent decade. The technical success rate for the iliac artery lesions exceeds 90%, and the 5-year primary patency rates range between 64% and 75%. Although the technique and clinical success rate for endovascular treatment of femoropopliteal lesions exceeds 95%, the longer-term 5-year patency rates are only between 42% and 55%. The unpersisted long-term benefits may be multifactorial, including the disease severity, the actual length of the diseased segments, the quality of the distal outflow (run-off) vessels, and the procedure techniques and production properties of the stents applied.[3]

The fracture rates for the bare-metal stent at 1, 2, and 3 years were reported to be 32.7%, 48.9%, and 50%, compared to 2.1%, 4.7%, and 2.6% for the Viabahn.[4] The stent fractures incidence increases as the follow-up period extends. Almost all the bare-metal stent fractures are correlated to the stented length longer than 15 cm.[4] Lin et al reviewed and reported their clinical experiences of covered stents vs bare-metal stents in managing chronic total long femoropopliteal lesions.[5] Although this study revealed the fracture rates between two groups were insignificant (9.5% for bare-metal stent, 3.6% for Viabahn; p 0.233), the longer lesions would theoretically carry higher fracture rate. Therefore, for those complicated and long (>15 cm) lesions, if the follow-up periods could be extended, the difference and the significance could be observed in this study.[5]

Besides, the distal SFA lesions in proximity to the popliteal artery has lower patency rate and higher fracture rates while stented with bare-metal stents. The Viabahn seemed to be more sustainable and fracture-resistant at the popliteal area. However, the Viabahn would also jeopardize some critical collateral branches from the upper stream SFA.

The luminal size of Viabahn also plays a role in long-term patency. From a 5-year-outcome study, the 7-mm supera Viabahn have superior performance than the other smaller size.[6] However, similar to the current study,[5] we found almost none femoral artery be suitable for 7 mm Viabahn in our daily practice. The demographic difference between the Asian and the western country-based studies would limit the choice of the stent size.

3. CHOSEN BETWEEN SURGERY AND ENDOVASCULAR

The SPINACH study compared the clinical outcomes between current optimal surgical reconstruction and endovascular treatment for critical limb ischemia patients in real-world clinical settings.[5] The 3-year amputation-free survivals were not different between the surgical and endovascular groups. The interaction analysis suggested that critical limb ischemia patients with

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severe wound status might be more suited for surgical reconstruction, whereas those with a poor general condition might benefit more from endovascular treatment in terms of amputation-free survival.[7]

4. STEM CELL, GENE THERAPY, AND NANOMEDICATION

Owing to excessive operative risk or unfavorable vascular involvement, up to 30% of patients are not candidates for surgical or endovascular revascularization. The cell therapy or gene therapy have been proposed as alternative strategies in the past two decades. The literature review confirmed the beneficial role of stem cell and gene therapy in reducing the rate of major amputations, improving distal perfusion, increasing ambulation capacities, reducing pain, improving ankle-brachial index and TcPO2, and overall ischemic symptoms and quality of life. However, the treatment induced improvements sustained only for 2-3 years. Intramuscular delivery is the only administration route for the cells. The stem cell and gene therapy are expensive treatments with undetermined cost-effectiveness. They are not indicated for standard therapy for chronic limb-threatening ischemia by ESC/ESVS guideline.[2] Constructed a magnetic Fe_3O_4-PLGA polymersome to carry the cilostazol into the ischemic area by magnetic attraction following remote-control drug release through low-energy ultrasound exposure is an interesting new topic for PAD treatment, but need further study for proving this concept.[8]

In conclusion, Lin et al have completed a relatively difficult and meaningful work, comparing Viabahn and bare-metal stents in long (>15 cm) TASC C and D femoropopliteal occlusive lesions.[3] Although the lesion is relatively complicated (long, >15 cm, occlusion, rather than stenosis), the technique success rate was 100% high. Their study discloses the real-world situation of endovascular treatment.[5] Although there is great evolution and progress of the endovascular treatment strategies, the surgical bypass still remains beneficial for some patients with high degree of critical limb ischemia. Those patients with high surgical risks and morbidities would benefit more from less invasive endovascular treatments.

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REFERENCES

1. Ali F, Pham ND, Bradford HJ, Khoshsirat N, Ostrikov K, Bell JM, et al. When are endovascular and open bypass treatments preferred for femoropopliteal occlusive disease? *Ann Vasc Dis* 2018;**11**:25–40.
2. Aboyans V, Ricco JB, Bartelink MEL, Björck M, Brodmann M, Cohnert T, et al.; ESC Scientific Document Group. 2017 ESC guidelines on the diagnosis and treatment of peripheral arterial diseases, in collaboration with the European society for vascular surgery (ESVS): document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteriesEndorsed by: the European stroke organization (ESO) the task force for the diagnosis and treatment of peripheral arterial diseases of the European society of cardiology (ESC) and of the European society for vascular surgery (ESVS). *Eur Heart J* 2018;**39**:763–16.
3. Azuma N, Kikuchi S, Okuda H, Miyake K, Koya A. Recent progress of bypass surgery to the dialysis-dependent patients with critical limb ischemia. *Ann Vasc Dis* 2017;**10**:178–84.
4. Geraghty PJ, Mewissen MW, Jaff MR, Ansel GM; VIBRANT Investigators. Three-year results of the VIBRANT trial of VIABAHN endoprosthesis versus bare nitinol stent implantation for complex superficial femoral artery occlusive disease. *J Vasc Surg* 2013;**58**:386–95.e4.
5. Lin TC, Chen PL, Lee CY, Shih CC, Chen IM. Covered stent versus bare-metal stents for chronic total occluded long complicated femoropopliteal lesions: a 2-year single center review. *J Chin Med Assoc* 2019;**82**:44–9.
6. Kruse RR, Poelmann FB, Doomernik D, Burgerhof HG, Fritschy WM, Moll FL, et al. Five-year outcome of self-expanding covered stents for superficial femoral artery occlusive disease and an analysis of factors predicting failure. *J Endovasc Ther* 2015;**22**:855–61.
7. Iida O, Takahara M, Soga Y, Kodama A, Terashi H, Azuma N; SPINACH Investigators. Three-year outcomes of surgical versus endovascular revascularization for critical limb ischemia: the SPINACH study (surgical reconstruction versus peripheral intervention in patients with critical limb ischemia). *Circ Cardiovasc Interv* 2017;**10**:e005531.
8. Kan CD, Wang JN, Li WP, Lin SH, Chen WL, Hsu YP, et al. Clinical ultrasound stimulating angiogenesis following drug-release from polymersomes on the ischemic zone for peripheral arterial occlusive disease. *Nanomedicine* 2018;**14**:2205–13.