Combined infrainguinal reconstruction and infrapopliteal intraluminal angioplasty for limb salvage in critical limb ischemia

Peter Balaz⁎, Slavomír Rokosný, Boris Koznar, Milos Adamec

⁎Department of Transplant Surgery, Institute of Clinical and Experimental Medicine, Vídeňská 1958/4, Prague 4, 140 21, Czech Republic

E-mail address: peter.balaz@ikem.cz (P. Balaz).

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2.4. Statistical analysis

Mean follow-up was 12.9 months (S.D. = 16.9). In all patients, infrainguinal reconstruction patency was assessed by clinical examination, palpation at two different sites and audio Doppler examination. In cases with an unclear clinical finding, puncture angiography or CT angiography was indicated. Limb salvage was defined as toe amputation or transmetatarsal amputation at most in the postoperative period.

2.4. Statistical analysis

Statistical methods used are descriptive (means, S.D. and relative frequencies). Survival curves were constructed by Kaplan–Meier method (product limit estimator). All calculations were done by statistical software SYSTAT™ 10.

3. Results

Postoperative complications in infrainguinal reconstructions were classified as early if occurring within three months and as late if developing after three months since surgery. Overall, there were 5 (17%) early and 8 (27%) late surgical complications.

3.1. Bleeding

Patients with femoropopliteal proximal venous bypass had four episodes of bleeding from the reconstruction (on postoperative days 0, 1, 10, and 30), requiring surgical revision.

3.2. Outflow tract stenosis

Five patients developed occlusion of the reconstruction secondary to outflow tract stenosis. Three patients had surgical thrombectomy with simultaneous intraluminal re-angioplasty of the infrapopliteal arteries (on postoperative day 6, and at postoperative 10 and 15 months). Two had femoropopliteal bypass reconstruction using an allogeneic venous graft combined with crural artery re-angioplasty (at postoperative 4 and 11 months).

3.3. Stenosis of the proximal anastomosis

We noted two cases of reconstruction occlusion because of proximal anastomosis stenosis (at 6 and 11 postoperative months); the condition was managed by surgical plasty of anastomosis.

3.4. Restenosis of plasty

The patient undergoing endarterectomy of the CFA and profundoplasty had femoropopliteal distal venous bypass (at 17 postoperative months) because of restenosis in the reconstruction and progression of the clinical finding.

3.5. Infection

In our group, infectious complications occurred only in one patient with crural bypass; the bypass was extracted (at 1 postoperative month).

3.6. Dissection

Transluminal infrapopliteal angioplasty was followed by non-occlusive crural artery dissection in seven cases, with self-expandable nitinol stent implantation in four cases, while the remaining three were left untreated because of their insignificance.

No other immediate complications of the procedure or early intra-operative death occurred in our group. During mean follow-up of 12.9 months, primary 1-year patency of vascular reconstruction was seen in 16 (52.6%) patients of our group (Fig. 1). Secondary 1-year patency over the same follow-up period was documented in 17 (56.2%) patients. In our retrospectively assessed group, 1-year limb salvage was obtained in 25 (82.6%) patients (Fig. 2).

4. Discussion

CLI characterized by rest pain, gangrene or ulceration of the leg or toes is a frequent problem encountered by the
vascular surgeon. According to the TASC, the term CLI should be used for all patients with chronic ischemic rest pain, ulcers or gangrene attributable to objectively proven arterial occlusive disease. The term CLI implies chronicity and is to be distinguished from acute limb ischemia. In CLI, multi-level disease is frequently encountered. Adequate inflow must be established prior to improvement in the outflow. Treatment of CLI for the limb salvage consists of endovascular therapy, vascular revascularization, or a combination of both. The first combined procedure was reported by Porter and Dotter in 1973, who were the first to undertake pelvic artery dilatation and femorofemoral bypass [8]. However, it was not until 1977, with the technical improvement of the balloon catheter by Gruntzig, that combined procedures came into widespread clinical use [9]. In general, the outcomes of revascularization depend upon the extent of the disease in the subjacent arterial tree (inflow, outflow and the size and length of the diseased segment), the degree of systemic disease and the type of procedure performed. According to TASC recommendation, in a situation where endovascular revascularization and open repair/bypass of a specific lesion causing symptoms of peripheral arterial disease give equivalent short-term and long-term symptomatic improvement, endovascular techniques should be used first.

The only valid study, the BASIL trial, was able to compare the outcomes of bypass surgery and angioplasty in individuals with severe limb-threatening ischemia who were suitable for either treatment. In this multicenter trial that involved 27 UK hospitals, 452 patients were recruited with CLI. The BASIL study showed no significant difference in 30-day mortality, and 1-year survival with intact leg was 68% and 71% after angioplasty or after surgery, respectively [5]. Experience with infrapopliteal artery PTA in salvaging limbs with CLI is encouraging. Preventional amputation and salvage of a functioning limb reported results for infrapopliteal PTA usually focus on these outcomes and report limb salvage rates of 59–91% [10, 11]. The salvage rate of limbs treated by infrapopliteal artery PTA is 83% over a mean follow-up of 12 months [12]. It should be noted that, should intraluminal angioplasty fail, the procedure can be repeated several times. Similarly, good experience has been reported with infrapopliteal PTA through infrainguinal reconstruction performed previously [13]. An important aspect in the treatment of CLI with infrainguinal and infrapopliteal vascular bed involvement is played by pedal bypass. In a study by Pomposeli with 10-year follow-up of 1032 pedal bypasses, primary patency was 56.8%, secondary patency 62.7%, and successful limb salvage rate 78.2% at 5 years; the respective figures at 10 years were 37.7%, 41.7%, and 57.7% [14]. In a study of 54 pedal bypasses for CLI, Staffa et al. reported a limb salvage rate of 81% over a follow-up period of 54 months [15]. Another alternative modality of treatment of patients with CLI manifesting as multilevel arterial involvement is a combined procedure.

The present retrospective study includes patients with CLI treated by a combination of infrainguinal reconstruction and infrapopliteal intraluminal angioplasty. After the mean follow-up of 12.9 (S.D. = 16.9) months, primary 1-year patency of vascular reconstructions amounted to 52.6% (16 patients). Secondary 1-year patency over the same follow-up period was 56.2% (17 patients) and 1-year limb salvage was achieved in 25 (82.6%) patients.

Based on this finding, we consider a combined surgical and endovascular procedure the method of choice in limb salvage in patients with CLI, not allowing for an isolated endovascular procedure. In cases where there is a choice, or where it is possible to perform pedal bypass or a combined procedure, our clear preference are combined procedures given the lower technical demands associated with infrainguinal reconstruction compared with pedal bypasses. Combined procedures are also our option in cases where lower limb defects make it impossible to perform pedal bypass. Last, but not least, infrapopliteal intraluminal angioplasty can be repeated through the vascular reconstitution in the postoperative period. The combined approach seems to be a valuable alternative to totally open or totally endovascular procedure. However, the final decision of the choice of the treatment of CLI depends on the size and length of the diseased segment, the degree of ischemia, status of systemic disease, quality of autologous

Fig. 1. Primary patency of combined vascular reconstruction in %.

Fig. 2. Limb salvage in % after combined vascular reconstruction.
conduit and on surgeon's own experience in treatment of CLI.

References


eComment: Femorocrural bypass surgery and intimal hyperplasia

Author: Narcis Hudorovic, University Clinic Sestre Milosrdnice, Vinogradaska 29, 10000 Zagreb, Croatia
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I read with great interest the article of Balaz et al. in which they described the primary and secondary patency rates of critical limb ischemia (CLI) patients undergoing combined infrainguinal bypass surgery and intra-luminal angioplasty of crural arteries [1]. In the infrapopliteal and crural region there are still unresolved problems (relapse rate around 50%), and stents should be implanted only in salvage situations, as the authors proposed. However, primary application of stents cannot be recommended even in the unproblematic regions, due to the possibility of stent-induced intimal hyperplasia and the high cost of the devices.

About experience in femoral arteries, less is published and the results are clearly inferior to those in the high-volume vessels. Based on the previously published results [2], and our own early results in which femoral occlusions around the length of 7 cm were stented primarily, no higher patency rate was achieved (70%) than with plain balloon PTA (69%), or with autologous conduit (75%) but with a significantly higher reintervention rate. Thus, in this region we regard the stent as an instrument to be kept in reserve for unsatisfactory results. In such situations a treatment failure or a result with poor prognosis may be reversed to a successful result with a secondary patency rate of 80%. In our experience, secondary interventions are often needed because of intimal hyperplasia, taking place in about 40% of cases. Moreover, the popliteal artery presents special difficulties because of the flexion limiting stent patency and the crural arteries because of their small caliber. Our series of patients shows that long-segment femoropopliteal stenoses (>7 cm) have a high-risk of early failure, with a 6-month patency of 26%. It is hoped that stents will improve these results. If stent placement in femoropopliteal arteries occlusions yields constantly good success and a low complication rate, it may become an attractive alternative to femorocrural bypass surgery. This, however, depends on the long-term results and, in particular, on the development, frequency, and progression of intimal hyperplasia compromising flow.

It remains to be seen whether this side effect can be managed percutaneously by means of balloon catheters with long-term success. Use of stents in the infrapopliteal segments currently does not seem advisable until the problem of intimal hyperplasia is solved. Moreover, stents should not be placed in arteries with poor peripheral flow because of the risk of early stent thrombosis. Altogether, the results reported by authors and those of the literature are promising, but long-term experience is required for definitive evaluation of this technique.

References