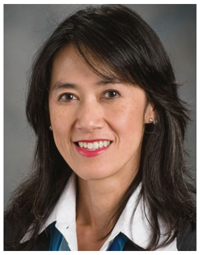

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HYBRID INTERVENTIONS IN LIMB SALVAGE

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Abstract

Hybrid interventions have become an integral part of our strategy for limb salvage in patients with multilevel arterial occlusive disease. In this article, we describe the commonly used hybrid interventions and review their indications and outcomes. Iliac stenting and femoral endarterectomy are the two most frequently performed procedures in hybrid cases. Short- and long-term outcomes of hybrid interventions are at least comparable to conventional endovascular and surgical revascularization procedures. Hybrid revascularization offers the efficiency and convenience of a single-stage revascularization.

Introduction

Hybrid interventions have emerged as a common method of revascularization in patients with critical lower extremity ischemia and multilevel arterial occlusive disease. The term "hybrid" denotes the use of combined open surgical and endovascular techniques simultaneously. In 1994, Marin et al. first reported the use of homemade stent grafts through an arterial cutdown remote from the site of occlusion for limb-salvage.[1] Soon after, open surgical femoral exposure for endovascular repair of abdominal aortic aneurysms became the prototype common hybrid procedure.[2] Hybrid interventions have since expanded to encompass simple and complex procedures for treating various types of vascular diseases.

Typically, the hybrid procedure is carried out by a single vascular surgeon skilled in both endovascular and operative techniques or a team that includes an experienced interventionalist and surgeon. Historically, vascular surgeons have performed hybrid interventions in the operating suite using a mobile fluoroscopy imaging unit with digital subtraction angiography. With the great rise in the number of hybrid procedures performed, a multitude of hybrid operating suites featuring high-quality fixed angiographic digital imaging units have been built nationwide. It is estimated that hybrid interventions make up 5% to 21% of current limb revascularization procedures.[3-5] Results of hybrid revascularization have been comparable to staged operative and percutaneous revascularization for multilevel arterial occlusive disease, although there has been no large-scale systematic direct comparison. The principal advantages of simultaneous hybrid treatment include prompt limb revascularization and patient convenience. In this article, we review the current use of hybrid revascularization procedures for lower extremity limb salvage.

Patient Selection and Procedure Planning

Critical limb-threatening ischemia is typically due to occlusive disease in more than one arterial segment in the lower extremity and less commonly due to severe diffuse tibial disease. The presence of a sole diseased arterial segment (aortoiliac or femoropopliteal) can cause disabling claudication but generally does not lead to limb-threatening ischemia. Patients with critical chronic limb ischemia are often elderly and have multiple other medical problems such as diabetes, hypertension, coronary artery disease, chronic obstructive pulmonary disease, and renal insufficiency. A lower-extremity arterial duplex examination can confirm the diagnosis of occlusive arterial disease. Computed tomography (CT) or magnetic resonance (MR) angiography is increasingly being used to help plan for an intervention.[6, 7] In patients with critical ischemia and multilevel arterial occlusive disease, the decision to reconstruct one or more segments is based on clinical judgment. It is estimated that approximately 25% of patients with multilevel arterial occlusive disease need both aortoiliac and infrainguinal revascularization.[8] In general, this is required for patients with extensive tissue loss in the distal leg or foot. Simultaneous aortofemoral bypass and infrainguinal bypass reconstructions are effective in achieving limb salvage.[9, 10] However, the mortality and morbidity for simultaneous inflow and outflow bypasses is not insignificant and is reported to be as high as 19% and 61%, respectively, with complex outflow procedures.[11] In contrast, Dougherty et al. reported much lower morbidity (11%) and 30-day mortality (1.4%) for concomitant lower extremity endovascular and open surgical revascularization with a comparable high limb salvage rate.[12] Hybrid intervention allows for simultaneous reconstruction of more than one segment and offers the efficiency and convenience of single-stage therapy without added risks.

Preprocedure planning is paramount to a successful hybrid intervention. First, the physician determines which segments will be treated based on duplex exam, CTA or MRA imaging, and physiologic data. Second, the physician forms a plan as to which arterial segment will be treated surgically versus endovascularly. In particular, preprocedure planning permits the selection of appropriate wires, sheaths, catheters, balloons, and stents as well as proper positioning of the patient on the table in relation to the angiographic unit. In general, endovascular treatment is preferred for TransAtlantic InterSociety Consensus (TASC) A and B lesions and surgery for TASC C and D lesions, although each case should be individualized.[13]

We perform hybrid interventions under general anesthesia because it is usually lengthier than a single bypass or percutaneous revascularization procedure. Alternatively, spinal or epidural anesthesia can be used. Loading with clopidogrel is not routinely done before the hybrid intervention due to the increased risk of bleeding related to the surgical part of the procedure. We give preoperative prophylactic cefazolin intravenously to all patients undergoing hybrid interventions. Prophylactic vancomycin is used for patients with a history of penicillin allergy or a history of (or at high risk for) methicillin-resistant staphylococcal infection. Typically, we begin the hybrid procedure with surgical exposure of the vessels. Unfractionated heparin is given intravenously (1 mg/kg) before vessel clamping or when the sheath is introduced into the vessel, whichever takes place first. An additional dose of heparin is administered (usually half of the first dose) at 90 minutes after the first dose if the revascularization takes longer. When an activated clotting time (ACT) test is available, we aim for the result to reach twice the ACT baseline level.

Common Hybrid Procedures

Ipsilateral Iliac Artery Stenting and Common Femoral Endarterectomy

The hybrid procedure is ideal for patients who have occlusive disease in the aortoiliac with extension to the common or bifurcation femoral arteries. We typically handle the surgical reconstruction first, exposing the common, superficial, and deep femoral arteries via a longitudinal incision in the groin while also trying to preserve the circumflex artery branches. The common femoral artery is opened via a longitudinal arteriotomy, and endarterectomy is performed to remove the occluding plaque. The arteriotomy can be extended distally into the proximal profunda or superficial femoral artery (SFA) to remove plaque from the proximal part of the respective vessel as indicated. The distal intima transition can be tacked down with polypropylene sutures to avoid an intimal flap that can cause postoperative vessel occlusion.

Reconstruction of the common femoral artery and bifurcation is typically completed using a patch (autogenous saphenous vein, synthetic or biologic material) or an interposition synthetic graft, depending on the length of the treated segment. Endarterectomy can be extended proximally into the distal part of the external iliac artery with mobilization of the vessel cephalad to the inguinal ligament. To accomplish this, the external iliac artery is separated posteriorly to the inguinal ligament by retracting the ligament superiorly, usually without having to divide it. After completion of the surgical reconstruction, arterial flow is restored to the native vessels.

We then proceed to the endovascular part of the procedure. Our preference is to obtain an aortogram via a contralateral retrograde approach, with placement of a multiside-hole catheter in the distal aorta. Once the ipsilateral common, external, and internal iliac arteries are assessed, the occluded segment is recanalized using a retrograde ipsilateral approach, with a sheath placed in the reconstructed femoral artery, or antegrade via the contralateral approach or the left brachial artery. The simplest method of recanalization is with a glide wire or catheter, although other devices have been used for recanalization of total iliac artery occlusion with variable success rates. After successful recanalization, re-entry into the true lumen is confirmed, and a stiff wire is placed to maintain access and for subsequent stenting. The native diameter of the reconstructed diseased vessel is estimated, and the appropriate size stent is selected; common stent sizes range from 7-12 mm for the common iliac artery and 6-10 mm for the external iliac artery. We favor primary stenting of diseased common and external iliac arteries using bare metal balloon-expandable stents for the common iliac segment and self-expandable stents for the external iliac segment. Balloon-expandable stents are more visible than self-expandable ones and allow more precise deployment. Stronger radial force afforded by the stainless steel balloon-expandable stent is preferred for orificial disease. Self-expandable stents can better conform to the vessel and are preferred for tortuous vessels. Figure 1 shows an example of combined open femoral endarterectomy/profundoplasty and retrograde stenting of the external iliac artery.

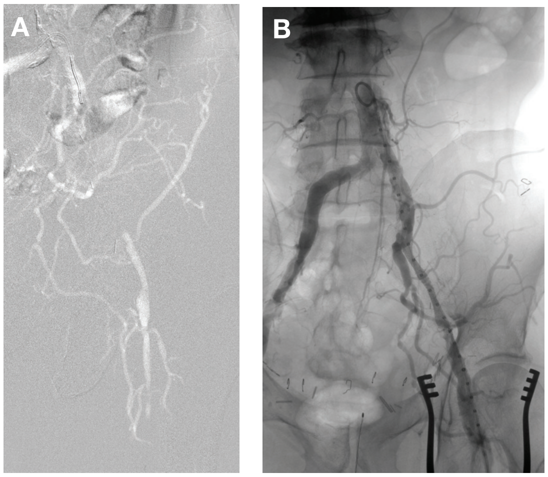

Figure 1. Common hybrid intervention. A 74-year-old man had severe ischemic rest pain in the left leg with multilevel arterial occlusive disease. (A) Total occlusion of external iliac and superficial femoral arteries. His leg rest pain completely resolved after combined open surgical common femoral endarterectomy and patch profundaplasty and external iliac artery stenting (8 x 80 mm self expandable). (B) Completion arteriogram. The patient's ABI increased to 0.49 from 0.3 in the affected leg after hybrid revascularization, and he remains asymptomatic 1 year postintervention.

Ipsilateral Iliac Artery Stenting and Infrainguinal Bypass

We start this hybrid procedure by exposing the femoral arteries in the groin through a longitudinal incision. A sheath is placed in the common femoral artery in a retrograde fashion, and iliac artery stenting is carried out as described above. After satisfactory stent placement, we harvest the ipsilateral great saphenous vein through skipped longitudinal incisions (or using an endoscopic harvesting technique). We take great care to avoid creating thin skin flaps that may leave the wound devascularized. The distal target vessel is then exposed. Our preference is to use the saphenous vein graft in a nonreversed fashion for a better size match. The proximal anastomosis is carried out first by sewing the proximal end of the conduit to the common femoral artery. Next, flow is restored to the native vessels. We then pass a valvulotome several times in a retrograde fashion inside the vein graft to cut all valves until unimpeded forward flow is seen. The vein graft can be tunneled subfascially or subcutaneously through the harvest wounds to the distal target. When the below-knee popliteal artery is the distal target vessel, we prefer tunneling the graft from above to below the knee in the deep anatomic space to avoid kinking of the graft. To reach the anterior tibial artery, we tunnel the graft either laterally via counterincisions or anatomically through the interosseous membrane. The distal end of the graft is then sewed end-to-side to the distal target artery, and flow is restored. When there is no autogenous conduit available, we use polytetrafluoroethylene (PTFE) conduit (size 6, 7, or 8 mm).

Femoral Endarterectomy and Distal Catheter-Based Intervention

For patients with critical ischemia and infrainguinal multi-level arterial disease, open femoral endarterectomy and distal intervention can be done simultaneously as a hybrid procedure by using catheter-directed techniques on the diseased femoropopliteal or tibial segment. First, open femoral endarterectomy is performed as described above. The sheath is then placed in an antegrade fashion to treat femoropopliteal or tibial lesions. This antegrade approach typically allows more "pushability" and "trackability" to treat distal lesions compared to the percutaneous up-and-over approach for infrainguinal catheter-based interventions.

Iliac Artery Stenting and Crossover Femoral-to-Femoral-Artery Bypass

In patients with complete occlusion of the ipsilateral common and external iliac arteries and contralateral iliac disease, stenting of the contralateral iliac artery and a crossover femoral-to-femoral-artery bypass is a good alternative to surgical aortobifemoral bypass, particularly in high-risk patients who may not be good candidates for aortobifemoral bypass. In this hybrid procedure, we begin by exposing the contralateral common femoral artery to be used as the inflow vessel. Retrograde access is obtained by puncturing the common femoral artery for iliac stenting. An angiographic catheter is advanced over the wire and positioned in the distal aorta to show the location and severity of the diseased iliac artery segment. A stiff wire is placed across the segment to be stented. The appropriately sized stent is then deployed across the diseased segment. After satisfactory stent placement, the surgical reconstruction takes place. First, the common femoral artery is mobilized and controlled. Next, an 8 or 10 mm PTFE or polyester synthetic graft is selected and the sheath removed. A longitudinal arteriotomy is made in the common femoral artery, to which the graft is sewn end-to-side. The recipient femoral artery is exposed through a longitudinal groin incision. Endarterectomy of the common femoral artery is often necessary. The graft is tunneled above the pubis in the subcutaneous plane, cut to length, and sewn end-to-side to the femoral arteriotomy. Frequently, the SFA is occluded and the profunda is the principal outflow vessel; in this scenario, the occlusive plaque in the profunda artery can be endarterectomized. When the endarterectomy is lengthy and extends across the common femoral into the profunda, a patch angioplasty can be used to close the arteriotomy, and the crossover graft is then sewn onto the patch. If necessary, a femoral-to-distal bypass procedure can be done in the same setting to restore in-line flow and heal distal leg or foot wounds.

Superficial Femoral Artery Intervention and Distal Bypass

In patients with multilevel infrainguinal arterial disease, a combined catheter-based intervention on the SFA and a distal bypass procedure, such as popliteal-to-pedal artery bypass, can be a good alternative to the traditional long bypass. This option is indicated when a long autogenous conduit is not available and percutaneous intervention of the infrapopliteal occlusive disease is not possible or has failed. Short focal stenosis of the SFA is the most suitable lesion for this scenario. However, the long-term patency of catheter-based intervention on long chronic segment occlusion of the SFA remains questionable, and such a treated vessel would be a suboptimal inflow source for a distal bypass. For these types of interventions, we prefer the contralateral up-and-over approach that can be done either prior to distal bypass or simultaneously in the same setting. Unlike the hybrid interventions described earlier, a simultaneous approach in this scenario does not often involve a common step between the catheter-based intervention and open surgical reconstruction, except when endarterectomy of the common femoral artery is indicated. The approach to SFA interventions can be done percutaneously or via the surgically exposed common femoral artery. Performing simultaneous SFA intervention and distal bypass allays the concern of leaving patients off clopidogrel during the revascularization period.

Miscellaneous Hybrid Interventions

Covered Stents

Emerging reports are demonstrating noninferiority and potential advantages of covered stents (also known as stent-grafts) compared to bare metal stents in the treatment of aortoiliac and femoropopliteal occlusive disease. The currently available covered stents still require relatively larger delivery catheters, particularly for the aorta and iliac arteries—ranging from 6 Fr for the smaller-profile balloon-expandable covered stents to between 7-18 Fr for the more commonly used self-expandable covered stents. Hence, open access is ideal for deployment of these larger profile covered stents during a planned hybrid intervention.
Not only can covered stents be used instead of bare metal in the hybrid procedures described above, but different permutations of hybrid revascularization also can be devised. For instance, the aortoiliac can be reconstructed using the modular aortoiliac system (originally designed for aneurysm exclusion) via an open femoral artery approach, and the sheath can be redirected downward to treat a mid-SFA lesion using simple balloon dilatation, bare metal stents, or covered stents. Recent reports have shown promising intermediate outcomes when covered stents are used to treat superficial femoral arteries, with patency similar to surgical femoral-to-popliteal artery bypass using synthetic grafts.[14, 15]

Hybrid Grafts

A variant hybrid technique has been described for the surgical femoral-to-popliteal artery bypass. This approach uses both a PTFE graft sewn to the proximal femoral artery and a covered stent deployed in the above-knee popliteal artery as a "sutureless" distal anastomosis.[16] The covered stent overlaps with the PTFE graft in the midthigh. The potential benefits of this approach are related to the minimal dissection and manipulation of the distal target vessel, which may hasten postoperative recovery and reduce the risk of hyperplastic response at the distal anastomosis. However, long-term results of this hybrid procedure remain to be determined. "Hybrid" vascular grafts are now available for use in arteriovenous access for hemodialysis. These hybrid grafts consist of PTFE material at one end and covered stent (nitinol and PTFE) at the other (central) end. Conceivably, similarly designed hybrid grafts can be used for arterial reconstruction in the future.

Adjunct Procedures

Although most planned hybrid procedures are performed for limb salvage in patients with chronic ischemia, hybrid techniques can be a useful adjunct in managing acute vascular emergencies. In particular, after open surgical thromboembolectomy due to embolic femoropopliteal artery occlusion, endovascular stenting can be performed to treat retained thrombus or residual arteriosclerotic disease in the aortoiliac segments. During open repair of injured distal aorta or iliac arteries, an aortogram is obtained to show the injured vessel, and vascular access is gained via the contralateral femoral artery or brachial artery. A wire is gently advanced into the aorta or iliac artery proximal to the injured site, and a balloon catheter is then inflated to stop or slow the bleeding. While retrograde bleeding may still occur from the distal injured end, this is usually at a slower rate. The injured segment is excised, and the vessel is reconstructed accordingly.

Posthybrid Revascularization Surveillance

Patients are maintained on clopidogrel 75 mg daily for at least 6 weeks after hybrid interventions that include balloon angioplasty or stenting. Thereafter, lifelong aspirin therapy can be substituted for clopidogrel. Statin therapy has been recommended for patients at risk for recurrent cardiovascular events. Close duplex surveillance is recommended to assess the catheter-based interventions and bypass grafts at 1, 3, 6, 9, 12, 18, and 24 months for the first 2 years after intervention. Reinterventions may be necessary to maintain long-term patency of both catheter-based interventions and surgical bypass grafts.

Hybrid Outcome

Surgical revascularization remains the gold standard treatment for patients with critical limb ischemia.[17] However, the advantages of catheter-based interventions are well recognized with reduced postop swelling, discomfort, and wound complications following surgical procedures. Most clinicians and authors agree that endovascular intervention is the preferred treatment for patients with symptomatic limb ischemia and TASC A and B aortoiliac and femoropopliteal lesions based on its excellent long-term patency and limb salvage rates that are comparable to surgical revascularization.[13] However, the primary therapy of choice for patients with TASC C and D aortoiliac and femoropopliteal lesions remains controversial. TASC II recommends surgical revascularization for the long occluded iliac and femoropopliteal segments.[13] In reality, endovascular revascularization of long iliac or femoropopliteal artery stenosis or occlusion is generally attempted first, with a relatively high technical success rate.[18, 19] Subsequent reinterventions provide primary-assisted and secondary patency rates comparable to surgical reconstructions.[18, 19] We usually reserve surgical bypass for patients with failed endovascular interventions. In our experience, failed endovascular iliac or infrainguinal interventions do not generally affect the outcome of subsequent surgical revascularization. Admittedly, reported long-term patency rates for infrainguinal and, particularly, infrapopliteal endovascular interventions are much lower than for iliac interventions.

Hybrid procedures allow simultaneous endovascular intervention and surgical reconstruction for patients with multi-level arterial disease. Early analysis of hybrid interventions has shown promising results. Of the reported hybrid procedures, iliac intervention is the most common, and femoral endarterectomy and infrainguinal bypass are the most common open surgical reconstructions. Dosluoglu et al. reported their retrospective series comparing results for hybrid interventions, open surgical reconstruction, and endovascular procedures in 654 patients.[5] The postintervention cardiac morbidity and mortality rates for the hybrid group (5.6% and 6.4%, respectively) were comparable to the open group (3.5% and 3.1%) but significantly higher than the endovascular group (1.1% and 1.1%), presumably because patients in the hybrid group had higher risk factors.[5] The 12- and 36-month limb salvage rates were excellent and comparable in all three groups (ranging from 80% to 100%).[5] Three-year primary and secondary patency rates and long-term survival were similar in all three groups.[5] Although the authors reported multilevel reconstructions in the open surgical and endovascular groups, it is not clear whether these were done in stages or simultaneously. Piazza et al. reported similar excellent results of their experience at the Mayo Clinic. The authors showed no differences with regard to 3-year patency and limb salvage rates, comparing open surgical reconstruction to hybrid concomitant iliac artery stenting (91% vs. 97%, respectively) and to common femoral endarterectomy (100% vs. 100%, respectively) in 92 patients.[20] Patients with TASC A through D lesions had comparable results whether they had hybrid interventions or open surgical procedures.[20] However, a significantly lower long-term survival rate was noted for hybrid patients compared to surgical patients (40% vs. 74%, respectively), which may be due in part to the older age and higher cardiac comorbidity risk scores in the hybrid group.[20]

Simultaneous infrainguinal endovascular interventions and surgical bypasses have been shown to produce highly acceptable results.[21] In particular, Lantis et al. reported 95% patency and limb salvage rates in 22 diabetic patients with critical leg ischemia after endovascular intervention on the SFA and popliteal-based distal bypass.[22] The authors excluded TASC D SFA lesions and used stents in the SFA in one-third of the cases. Hybrid interventions on infrainguinal segments are tedious and time-consuming, requiring a highly skilled operator with experience and patience. Emerging reports have shown favorable results regarding the short- and long-term outcomes of covered stents used to treat occlusive disease in the iliac and superficial femoral arteries. Chang et al. showed improved 5-year primary patency for covered iliac stents compared to bare metal stents (87% vs. 53%) when used in combination with common femoral endarterectomy.[14] In a randomized controlled trial, McQuade et al. compared outcomes for endovascular treatment with covered stents versus femoral above-knee bypass using synthetic grafts for SFA occlusive disease and showed comparable 4-year patency rates (59% vs. 71%, respectively).[15] This combined stent and graft technology will likely continue to improve and expand our endovascular options and may obviate the need for the open surgical component of hybrid interventions. Figure 2 shows an example of a hybrid

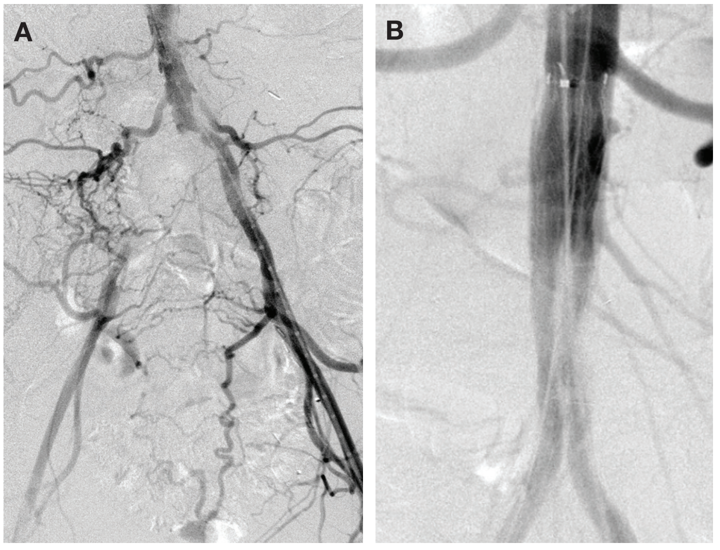

Figure 2. Hybrid intervention for acute or chronic ischemia. A 55-year-old woman with a history of bilateral hip claudication and ovarian cancer presented with acute right-leg ischemia 24 hours after bilateral mastectomy for breast cancer. (A) Preop evaluation showed severe aortoiliac occlusive disease, occluded right common and external iliac arteries, and embolus in the right popliteal artery (not shown). The patient had endovascular aortoiliac revascularization using the modular aortoiliac (aneurysm) stent-graft system and open femoral thromboembolectomy. (B) Completion arteriogram. Good revascularization was achieved and the patient remains asymptomatic with palpable pedal pulses 1 year after revascularization.

intervention with endovascular aortoiliac revascularization using the modular aortoiliac (aneurysm) stent-graft system and open femoral thromboembolectomy.

Summary

Hybrid interventions have become a well-accepted strategy for revascularization in patients with critical limb ischemia due to multilevel arterial occlusive disease. Technical success and short- and long-term limb salvage outcomes of hybrid interventions have been shown to be at least comparable to the conventional endovascular and surgical revascularization procedures. Hybrid revascularization offers the efficiency and convenience of a single-stage therapy without added risks for those with lower extremity ischemia.

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