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ORIGINAL ARTICLE

Efficacy of iliac inflow repair in patients with concomitant iliac and superficial femoral artery occlusive disease

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Summary *Background:* In multilevel arterial disease, whether complete revascularization or staged runoff repair should be performed remains controversial. The aim of this study was to evaluate the efficacy of iliac inflow repair and to identify clinical conditions that are associated with the need for runoff repair in concomitant iliac and superficial femoral artery (SFA) occlusive disease.
Methods: Patients undergoing inflow repair for complicated flow-limiting iliac lesions with diffuse SFA disease between 2007 and 2013 were retrospectively reviewed. Patients with poor response to inflow repair underwent infrainguinal revascularization (IIR).
Results: The 29 ischemic limbs examined in this study represent 26 different patients (22 males; mean age, 77 $\pm$ 8 years). Indications for inflow repair were Rutherford Classifications III (31%), IV (31%), V (31%), and VI (7%). Severity of the complicated SFA disease was either TASC (TransAtlantic Inter-Society Consensus) type C (14%) or type D (86%). Overall, freedom from IIR was 90% after 30 days and 83% after 1 year. Patients having claudication, rest pain, and shallow ischemic ulcers experienced the relief of symptoms, whereas patients with deep gangrene that needed minor amputation required IIR more frequently ($p < 0.01$). Anatomical risk factors for poor response to inflow repair were poor quality of the deep femoral artery ($p < 0.01$) and the flow-limiting popliteal artery ($p = 0.02$), and poor below-knee runoff ($\leq$ 1 vessel, $p < 0.01$).

Conflicts of interest: The authors do not have any financial relationships to disclose.

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Conclusion: Iliac inflow repair can reverse the symptoms in patients with multilevel arterial occlusive disease that are not associated with gangrenous toes.

1. Introduction

In cases of multilevel peripheral artery disease, such as complicated superficial femoral artery (SFA) with iliac disease, surgeons may be hesitant to perform complete revascularization because of operative stress or the prolonged operation time.[1,2] In the past decade, endovascular treatment (EVT) has become more widespread, and with advanced technology, improved skills, and potentially reduced invasiveness, complete revascularization has become more feasible. New devices have improved the initial success rate and patency during the early period; however, the treatment of long-segment SFA disease has scope for improvement, and its strategy has been a subject of controversy.[3–13] Traditionally, revascularization from an iliac artery to the deep femoral artery without repair of the SFA has been performed for iliac concomitant with SFA disease.[14–20] This "inflow repair" is a procedure that improves collateral flow, via the deep femoral artery (DFA), to the ischemic lower limb in cases of occlusion or severe diffuse stenosis of the SFA. Inflow repair significantly improves some clinical conditions and leads to safe revascularization of the SFA. SFA revascularization is not always justified in multifocal arterial disease, as some patients can achieve symptom relief and limb salvage solely by inflow repair.[14,19,20] Furthermore, symptoms sometimes worsen if stents placed in the SFA or the femoropopliteal bypass grafts fail.[21,22]

The aim of this study was to evaluate the efficacy of inflow repair and to identify clinical conditions that are associated with poor outcomes, specifically infrainguinal revascularization (IIR) in concomitant iliac and SFA occlusive disease.

2. Methods

Over a 6-year period (from February 2007 to December 2013), 56 limbs with concomitant iliac and SFA disease, suffering from claudication, ischemic rest pain or tissue loss, were referred to our hospital. Among these patients, 27 limbs required urgent minor amputation because of tissue loss or infection and were expected to tolerate complete revascularization; these patients underwent IIR, in addition to iliac revascularization, as the primary operation and were excluded from this analysis. Of the remaining 26 patients, 29 limbs that underwent inflow repair and considered staged runoff repair were included in this analysis.

High-resolution computed tomography (CT) and pre- or intraoperative digital subtraction angiography were performed on all patients. Image analyses were focused on the lesion characteristics of the iliac artery and the SFA, and on assessment of the quality of the DFA, popliteal artery, and below-knee runoff vessels. Inclusion criteria for this analysis of iliac disease included flow-limiting stenosis ($>$ 75%) or occlusion, regardless of its length. The percent stenosis was measured by comparing to the nearest normal diameter. Concomitant SFA disease included in this analysis was limited to TransAtlantic Inter-Society Consensus (TASC)[23] type C or type D lesions.

The quality of the DFA was classified as good, fair, or poor. The DFA was classified as poor when there was diffuse $>$ 50% stenosis or occlusion. The quality of the popliteal artery was classified as good, fair or poor. The popliteal artery was classified as poor when there was $>$ 75% stenosis or occlusion. The preoperative examination included ankle-brachial index (ABI) and duplex imaging in all cases, and skin perfusion pressure only in cases with critical limb ischemia (CLI).

2.1. Operative procedures

Iliac revascularizations were routinely performed by EVT in a hybrid operating room. An ipsilateral approach was used for stenotic lesions, and a bidirectional approach was used in cases with occlusive lesions. When the wire passed the lesion, intravascular ultrasonography was routinely used to check if the wire passed the true or false lumen, and to assess the diameter. Direct stenting was usually performed, but predilatation was used in cases that displayed an occlusion with moderate or severe calcification. Stents were placed in all iliac lesions. A common femoral artery (CFA) endarterectomy was also performed in the same session when there was a $>$ 75% stenosis or occlusion in the CFA to secure direct blood flow to the DFA, in addition to iliac stenting. The CFA endarterectomy routinely closed without patch. In a small number of cases, the CFA endarterectomy risked injuring the artery when a hard, bulky calcification reached near the adventitia. In such cases, bypass surgery was conducted on the DFA. The decision to perform bypass or CFA endarterectomy with iliac stent placement was at the discretion of the surgeon. Inflow repair was deemed technically successful if improved, direct blood flow to the DFA was documented by final angiography.

2.2. Postoperative management

In patients with claudication, clinical success was defined as the improved ability to walk, without disturbing daily life. In patients with CLI, rest pain relief and healing of the wound after debridement or minor amputation were considered clinical success. An additional IIR was considered when patients wanted to further improve their ability to walk or did not achieve relief of rest pain or wound healing. Particularly in cases of CLI, additional infrainguinal operations were performed without delay to prevent the progression of gangrene. Routinely, patients with tissue loss were hospitalized until granulation growth was acceptable and wound contraction was achieved. Postoperatively, dual antiplatelet therapy (100 mg aspirin plus 75 mg clopidogrel) was administered and continued if adverse effects did not develop. Postoperative assessment included clinical examinations with ABI and duplex imaging in all patients and skin perfusion pressure in cases of CLI within a week after the initial procedure. An enhanced CT was conducted when the ultrasonographic image was poor because of calcification. ABI tests and ultrasonography were repeated every 3 months at our outpatient clinic. Patients with worsening clinical symptoms underwent enhanced CT and/or arteriography.

2.3. Study outcome measure

The primary endpoint was freedom from IIR after the initial inflow repair; the secondary endpoints were primary patency of the revascularized inflow vessel and leg amputation. Freedom from major adverse limb events (MALEs), including amputation or any reintervention and amputation-free survival (AFS), were also analyzed.

2.4. Statistical analysis

Continuous variables were expressed as the mean ± standard deviation. Continuous variables were examined using of unpaired *t* tests. Categorical variables were examined using χ^2 tests. Survival curves were estimated using the Kaplan–Meier method and compared with the log-rank test. A *p* value < 0.05 was considered statistically significant. For statistical analysis, JMP pro 10 (SAS Institute Inc., Cary, NC, USA) was used.

The present study was carried out in accordance with the Declaration of Helsinki, and all participants provided written consent.

3. Results

3.1. Patients and procedures

The median patient age was 77 years (range, 57–89 years; Table 1). The common risk factors were history of hypertension (81%), smoking (79%), dyslipidemia (41%), cerebrovascular disease (31%), diabetes mellitus (27%), and coronary artery disease (CAD; 19%). Indications for inflow revascularization were claudication in nine procedures (31%) and limb salvage in 20 procedures [69%; ischemic rest pain in 9 (31%) and tissue loss in 11 (39%)]. According to the TASC classification of iliac lesions, two limbs (7%), nine limbs (31%), 11 limbs (38%), and seven limbs (24%) were in classes A, B, C, and D, respectively. For the SFA lesions, four limbs (14%) and 25 limbs (86%) were in classes C and D, respectively. The CFA lesions were complicated in 52% of limbs, and popliteal lesions were complicated in 52% of limbs. Forty-four percent of the limbs had poor below-knee runoff vessels (≤ 1 vessel). Regarding the quality of the DFA, 21% of the limbs were of poor quality, that is, they displayed diffuse stenosis or occlusion distal to the DFA.

Simple inflow repairs were performed by placing iliac stents in 13 limbs (45%; Table 2). Hybrid operations were performed in 10 limbs (34%). Eight limbs (28%) underwent

Table 1 Baseline characteristics.

Age, y	77 ± 8 (57–89)
Male sex	85 (22)
Risk factors	
Hypertension	81 (21)
Diabetes mellitus	27 (7)
Dyslipidemia	41 (12)
CAD	19 (5)
CVD	31 (8)
OPD	23 (6)
CKD	19 (5)
Albumin, g/dL	3.4 ± 0.5 (2.5–4.8)
BNP, pg/mL	105 ± 130 (5.8–460)
Smoking history	79 (23)
Lower limb clinical status	
Rutherford classification	
3/4/5/6	31 (9)/31 (9)/31 (9)/7 (2)
ABI	0.3 ± 0.3 (0–0.76)
CRP, mg/dL	2.27 ± 2.72 (0.1–12.4)
Iliac lesion TASC A/B/C/D	7 (2)/31 (9)/38 (11)/24 (7)
CFA lesion	52 (15)
SFA lesion TASC C/D	14 (4) 86 (25)
DFA quality; poor	21 (6)
Popliteal quality; poor	52 (15)
Below-knee runoff 0/1/2/3	10 (3)/34 (10)/21 (6)/34 (10)

Data are presented as % (*n*) or mean ± standard deviation (range).
ABI = ankle-brachial index; BNP = brain natriuretic peptide; CAD = coronary artery disease; CFA = common femoral artery; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; CVD = cerebrovascular disease; DFA = deep femoral artery; SFA, superficial femoral artery; TASC = TransAtlantic InterSociety Consensus.

Table 2 Initial procedures of inflow repair.

	% (*n*)
Iliac revascularization alone	52 (15)
Iliac stents	45 (13)
Bypass	7 (2)
Axillar–CFA	3 (1)
CFA–CFA crossover bypass	3 (1)
Iliac + CFA revascularization	48 (14)
Hybrid operation	34 (10)
Iliac stents + CFA endarterectomy	28 (8)
Contralateral iliac stents + CFA–DFA crossover bypass	7 (2)
Bypass	14 (4)
Axillar–DFA bypass	14 (4)

CFA = common femoral artery; DFA = deep femoral artery.

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CFA endarterectomy, in addition to having iliac stents placed at the ipsilateral iliac lesion; two cases had stents placed in the contralateral iliac lesion and a femorofemoral crossover bypass with an ePTFE (expanded polytetrafluoroethylene) graft. Bypass surgery was conducted in six limbs (21%), originating from the axillar artery in five limbs (17%) and from the contralateral CFA in one limb (3%). In four limbs (14%), out of those undergoing bypass surgeries, the distal anastomosis sites were the DFA, bypassing the CFA or the DFA orifice occlusion.

Surgical complications occurred in three cases. Complications included thrombus embolization in the DFA in two patients and iliac perforation in one patient. There were no perioperative deaths (< 30 days after surgery). The median preoperative ABI for all patients was 0.3 ± 0.3 [0.4 ± 0.2 (0–0.8) in claudication patients and 0.2 ± 0.2 (0–0.6) in CLI patients] and improved to 0.6 ± 0.1 [0.7 ± 0.1 (0.6–0.8) in claudication patients and 0.6 ± 0.2 (0.4–0.8) in CLI patients].

3.2. Freedom from additional IIR

Within 6 months of the initial procedures, five limbs (17%) required IIR. The median time between the initial procedure and additional procedures was 28 ± 38 days (range, 1–93 days). Two limbs underwent an above-knee femoropopliteal bypass with an ePTFE graft, one limb underwent a DFA-peroneal bypass with an autologous vein, and one limb underwent EVT for an SFA occlusion. All limbs that required IIR had gangrenous toes that needed minor amputation, and inflow repair resulted in insufficient flow improvement. Symptoms such as severe claudication, rest pain, and shallow ischemic ulcers improved after inflow repair and did not require IIR. Upon examining all patients, freedom from IIR was 90% after 30 days and 83% after 1 year; freedom from IIR in patients with claudication/rest pain was 100% after 30 days and 100% after 1 year; freedom from IIR in patients with tissue loss was 73% after 30 days and 53% after 1 year (Rutherford III plus IV vs. Rutherford V plus VI, $p < 0.01$).

In a subanalysis of patients with tissue loss (Rutherford V plus VI, $n = 11$), limbs with deep gangrene that reached the bone and required minor amputation ($n = 6$) required additional IIR more frequently than those with a shallow ulcer ($p = 0.01$).

Regarding other clinical backgrounds, patients with a history of CAD ($p < 0.01$), a history of chronic kidney disease (CKD; $p = 0.03$), C-reactive protein (CRP) > 2.7 mg/dL ($p = 0.04$), poor quality of the DFA ($p < 0.01$), poor quality of the popliteal artery ($p = 0.02$), and poor below-knee runoff vessels ($p < 0.01$) were significantly more likely to require additional IIR (Table 3, Figure 1).

3.3. Secondary endpoints

The overall primary patency rates for revascularized inflow vessels at 1-, 3-, and 5-years were 100%, 95%, and 72%, respectively. The mean follow-up period was 878 ± 686 days (median, 630 days). At the 1-, 3-, and 5-year follow-up visits, patency rates tended to be lower ($p = 0.34$) in patients with CLI (100%, 93%, and 65%, respectively) than in patients with claudication (100%, 100%, and 100%, respectively). Three failures occurred 13 months, 29 months, and 38 months after inflow repair; in all of these, the initial symptom was rest pain, and none required additional IIR. One limb had recurrent severe rest pain and underwent an emergency thrombectomy of the iliac stents and femoral revascularization with a prosthetic graft to treat a common femoral lesion. One limb was amputated because the patient became bedridden with dementia and the limb was contractual during the follow-up period. One limb was observed without revascularization because the patient had minor ischemic symptoms.

Table 3 Univariate analysis: associations between freedom from IIR, freedom from MALEs, AFS, and risk factors.

Variables	Univariate analysis (log-rank test, p value)		
	Freedom from IIR	Freedom from MALEs	AFS
Risk factors			
Hypertension	0.48	0.79	0.32
Diabetes mellitus	0.59	0.45	0.57
CAD	<0.01*	<0.01*	0.01*
CVD	0.65	0.75	0.13
COPD	0.86	0.86	0.41
CKD	0.03*	0.03*	0.14
Albumin < 3 (g/dL)	0.19	0.44	0.2
BNP > 162 (pg/mL)	0.23	0.23	0.02*
Lower limb clinical status			
Tissue loss	<0.01*	<0.01*	<0.01*
ABI = 0	0.28	0.27	0.27
CRP > 2.7 (mg/dL)	0.04*	<0.01*	0.05
Arterial lesion characteristics			
CFA lesion	0.18	0.18	0.88
DFA quality; poor	<0.01*	<0.01*	0.01*
Popliteal quality; poor	0.02*	0.1	0.6
Below-knee runoff ≤ 1	<0.01*	<0.01*	0.16

* $p < 0.05$.
ABI = ankle-brachial index; AFS = amputation-free survival; BNP = brain natriuretic peptide; CAD = coronary artery disease; CFA = common femoral artery; CKD, chronic kidney disease; COPD = chronic obstructive pulmonary disease; CVD = cerebrovascular disease; CRP = C-reactive protein; DFA = deep femoral artery; IIR = Infrainguinal revascularization; MALEs = major adverse limb events.

The limb salvage rates at 1-, 3-, and 5-years after surgery were 92%, 92%, and 79%, respectively, for all patients; 100%, 100%, and 100%, respectively, in patients with claudication; and 89%, 89%, and 74%, respectively, in patients with CLI ($p = 0.21$). Four limbs were amputated during follow-up; three were attributable to tissue loss and underwent additional IIR. The limbs needing IIR were lower in limb salvage ($p = 0.01$).

MALEs, including major amputation and any type of revascularization, were analyzed (Table 3). The freedom from MALEs at the 1-, 3-, and 5-year follow-ups were 83%,

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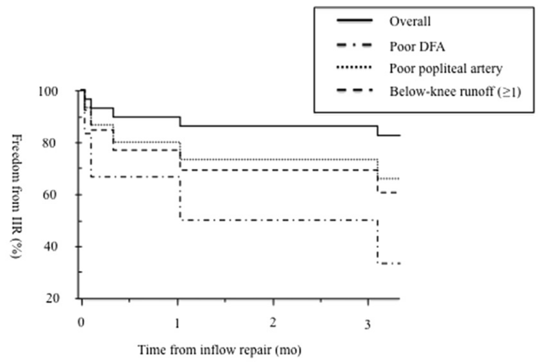

Patients at risk

Overall	29	26	25	24
Poor DFA	6	4	4	3
Poor popliteal artery	15	12	11	10
Below-knee runoff (≥1)	13	10	9	8

Figure 1 Freedom from infrainguinal revascularization (IIR) after the initial inflow repair.

83%, and 66%, respectively, for all patients; 100%, 100%, and 100%, respectively, in patients with claudication; and 75%, 75%, and 56%, respectively, in patients with CLI ($p = 0.09$). History of CAD ($p < 0.01$), history of CKD ($p = 0.03$), CRP > 2.7 mg/dL ($p < 0.01$), tissue loss ($p < 0.01$), poor below-knee runoff (≤1 vessel) ($p < 0.01$), and poor DFA quality ($p < 0.01$) were associated with the incidence of MALEs. Survival rates at the 1-, 3-, and 5-year follow-up, were 88%, 77%, and 64%, respectively, in all patients; 100%, 100%, and 100%, respectively, in patients with claudication; and 83%, 68%, and 54%, respectively, in patients with CLI ($p = 0.11$). The frequency rates of AFS at 1-, 3-, and 5-years after the initial procedure were 86%, 76%, and 54%, respectively. History of CAD ($p = 0.01$), brain natriuretic peptide (BNP) > 162 pg/mL ($p = 0.02$), tissue loss ($p < 0.01$), and poor quality of the DFA ($p = 0.01$) were associated with lower AFS rates (Table 3).

4. Discussion

The results of our study indicate the clinical conditions that affect poor outcomes after inflow repair in concomitant iliac and SFA occlusive disease. Although simultaneous inflow and outflow repair is clinically effective,[2] by the 1990s, inflow repair was widely used because of the high mortality and morbidity associated with complete revascularization using bypass surgery.[1] Since then, advanced endovascular techniques and technology have made multilevel revascularization more feasible. Although EVT and perioperative management have improved, complete revascularization is not always justified because there is always the possibility of nonessential runoff repair. In 1961, Morris et al[14] showed that it is generally sufficient to reconstruct the iliofemoral segment with adequate results in more than two-thirds of cases of multilevel arterial disease. Thereafter, the indications for and the efficacy of inflow repair were discussed throughout the next two decades.[15–17] However, these issues have rarely been addressed during the current endovascular era.

Despite the small number of participants in our study, inflow repair in patients with severe claudication resulted in improved ABI and walking ability, enhancing the patients' daily lives. As others have previously discussed,[16–19] the important issues are patient selection and planning treatment strategies in patients with CLI. In our early results, patients with rest pain or shallow foot ulcers experienced pain relief, experienced the healing of ulcers, and averted major amputation without runoff repair. Although some of these patients had a complicated DFA or more distal runoff lesions, inflow repair reestablished blood flow enough to achieve symptomatic relief. Patients with gangrene that required minor amputation showed significantly poor response to solo inflow repair. This probably reflected the considerably higher perfusion needs for wound healing and worsened distal runoff vessels in such clinical situations. It would be better to perform outflow revascularization along with inflow repair in those who require minor amputation, if the patients' conditions permit, and staged outflow revascularization should be considered in patients with rest pain or with a shallow foot ulcer.

When considering the clinical success of inflow repair, complicated arterial disease at sites other than the iliac or the SFA is an essential point, especially in cases with CLI requiring minor amputation. First, the quality of the DFA is very important because it is the sole collateral source for the lower extremity when the SFA is occluded.

In cases with complicated CFA disease, the best way to treat the lesion is unclear. The percutaneous approach for lesions in the CFA may be an alternative; however a hybrid method combining iliac stents with open endarterectomy would be better in terms of patency rate and feasibility.[24–27] In a few cases with CFA obstruction and bulky calcification, bypass surgery anastomosing to the patent DFA is an option because of the risks associated with endarterectomy, specifically, irreparable arterial injury.

The anatomy of more distal runoff arteries was also associated with clinical outcome after inflow repair; although some previous reports supported this finding,[16,18] others did not.[19] A patent popliteal artery was an important factor, probably because collateral vessels from the DFA, such as the genicular arteries, merge at this point and supply blood flow distally. Poor below-knee runoff was also associated with the need for additional IIR. In the current analysis, one or more patent crural arteries had a significant predictive value for clinical outcome.

Higher levels of CRP, which reflect the extent of tissue necrosis or infection, were associated with poor response to inflow repair. Risk factors such as CAD or CKD were also associated with poor response, probably because patients with tissue loss were more afflicted with these disorders.

Although the current study included both endovascular and a small number of bypass revascularizations, patency in the current analysis was comparable to that of previous studies[25] that performed inflow repair in poor SFAs or runoff vessels.[20] In the present study, a nonsignificant tendency toward a lower patency rate for inflow repair was observed in patients with CLI compared to those with claudication.

There were several limitations in our study. First, the present study is a retrospective observational study, with potential, inherent biases associated with this method.

Second, patients were selected and treated on biases according to their presentation, ambulatory status, and medical condition. In addition, the number of cases was small; thus, we could not perform multivariate analyses to determine the factors that had the strongest effects on the clinical success of inflow repairs.

In conclusion, we have identified the clinical conditions affecting the success of inflow repair in patients with multilevel arterial disease. IIR can be avoided even in cases of CLI when those are not associated with gangrenous toes. The appropriate use of inflow repair can limit nonessential revascularizations.

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