Simultaneous Hybrid Operation Common Femoral Endarterectomy and Endovascular Treatment in Multilevel Peripheral Arterial Disease with Critical Limb Ischemia

Hyuk Jae Jung¹ · Soon Chon Lee¹ · Kyung Yun Kim¹ · Sang Su Lee¹

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Abstract The purpose of revascularization in lower extremity arterial occlusive disease is to prevent amputation and improve walking ability. Many surgical techniques for peripheral vascular disease (PAD) have been reported. The hybrid operation composed of open surgery and endovascular procedure has been increasingly used for multilevel revascularization. The goal of this study is to evaluate feasibility of simultaneous hybrid femoral endarterectomy and endovascular treatment in patients who need multilevel revascularization with critical limb ischemia. Between March 2011 and July 2014, 38 consecutive patients (43 limbs) with multilevel peripheral arterial disease in critical limb ischemia were treated by simultaneous hybrid operation by single surgeon. The hybrid operation which combines common femoral artery endarterectomy and additive interventional procedure was simultaneously performed for multilevel revascularization. The measurements of primary outcome were primary patency rates, secondary patency rates, and limb salvage rates. Patients who underwent single procedure of surgery or intervention were excluded. The mean age was 72.48 years old and 92.1% were male. The primary and secondary patency rates at 24 months were

67.3 and 72.1%, respectively. The preoperative mean ABI of 0.51 ± 0.27 increased to postoperative mean ABI of 0.88 ± 0.35 . The limb salvage rate was 95.3%. Major amputation was performed in 2 out of 43 limbs. There was no early postoperative mortality. The simultaneous hybrid operation for multilevel revascularization may be feasible to treat in multilevel PAD with high technical success and limb salvage rates, thus providing an attractive alternative to larger open surgery or endovascular procedures.

Keywords Simultaneous hybrid operation · Peripheral arterial disease · Critical limb ischemia · Open surgery · Endovascular procedure

Introduction

The peripheral arterial disease (PAD) with multilevel involvement has been rapidly increasing [1], and its condition with critical limb ischemia (CLI) has a potential risk of limb loss with amputation [2]. Although postoperative intensive care and anesthetic technique have been improved, extensive revascularization in patients with CLI has risk of high morbidity and mortality rates [2]. As atherosclerosis usually involves multiple level lesions, it usually requires wide and multilevel revascularization procedures [3, 4]. The successful management of patients with CLI has always been a challenge for vascular surgeons. The indications for endovascular treatment in patients with PAD have rapidly increased since introduction of percutaneous transluminal angioplasty (PTA) and stenting [2].

The endovascular procedure has advantages of low perioperative morbidity and mortality [5]. Adam et al. [5] reported similar clinical outcomes between surgical and endovascular procedures. However, PAD involved common femoral artery

✉ Sang Su Lee
phoenixdr@naver.com

Hyuk Jae Jung
goodsight@empas.com

Soon Chon Lee
drsclee@hanmail.net

Kyung Yun Kim
abbit@hanmail.net

¹ Division of Vascular and EndoVascular Division, Department of Surgery, Pusan National University Yangsan Hospital, Beomeo-ri, Mulgeum-eup, Yangsan-si, Gyeongnam 626-770, South Korea

has limit to treat with endovascular approach alone due to its anatomic location. Endovascular procedure is poorly suited to treat in the femoral bifurcation atherosclerotic disease, because it is bulky and eccentric. In addition, the anatomic location of femoral bifurcation makes ipsilateral access difficult and stent placement impossible. As multilevel PAD with CLI has been frequently observed, the hybrid operation, which is the combination of open surgery and endovascular procedure, has been emerged as a new strategy. It has advantages of eliminating the need of major surgery and avoiding separate staged interventions [6].

Adjunctive use of the balloon dilatation catheter during vascular reconstructive procedure results in decreased morbidity and expense compared to separate procedure and expands scope of arterial reconstruction without expansion of the operation [7].

The goal of this study is to evaluate feasibility of simultaneous hybrid femoral endarterectomy and endovascular treatment in patients with CLI who need multilevel revascularization.

Material and Methods

Between March 2011 and July 2014, 38 consecutive patients (43 limbs) of multilevel peripheral arterial disease with critical limb ischemia were treated by simultaneous hybrid operation by single surgeon. We performed retrospective review of prospectively collected data from these patients. Lesions were categorized according to the TASC II classification [Fig. 1a, b]. Preoperative evaluations for PAD were physical examination, measurement of ankle brachial index (ABI), and computed tomography (CT) angiography.

All patients underwent common femoral artery (CFA) endarterectomy in combination with endovascular procedure or bypass surgery. For specifically technical description, the CFA was dissected; seven Fr sheath was inserted retrogradely to treat proximal iliac lesions and contralateral lesions amenable to contralateral approach. If ipsilateral distal disease was present, antegrade puncture was performed through the CFA. Following the interventional procedure, CFA endarterectomy and bovine pericardial patch angioplasty were done. For the CFA endarterectomy, the common femoral artery, deep femoral artery, and superficial femoral artery are exposed via an incision in the groin with information from CT angiogram and also by palpating the artery. Clamps or loops are placed around proximal common, superficial, and deep femoral arteries to block blood flow and protect migration of atheroma during endarterectomy. After arteriotomy above atheroma, the atheromatous plaque can be removed by dissector. The opening in the artery is closed by sewing in a bovine pericardial patch. The conduit for bypass was expanded polytetrafluoroethylene (ePTFE) graft (Bard Peripheral

Vascular Inc., Temple, AZ), stents were Lifestents (Bard Peripheral Vascular Inc., Temple, AZ) for superficial femoral artery, and E-luminex (Bard Peripheral Vascular Inc., Temple, AZ) for iliac artery. All procedures were done with mobile C-arm in the operating room.

Patients who underwent combined CFA endarterectomy and interventional procedure were included in this study. Follow-up study was done with clinical evaluation, continuous wave Doppler exam, ABI, and CT angiography. Postoperative adverse events such as myocardial ischemia, renal impairment, wound infection, and major amputation were recorded. Primary patency was defined according to TASC II classification which stands for means patent vessel that do not have restenosis or need of reintervention. Assisted patency was defined as patent vessel that required at least one intervention to treat the recurrent stenosis. Secondary patency was defined as an occluded artery that required at least one intervention to restore patency. Technical success was defined as residual stenosis <30% in the postprocedural image.

Hemodynamic success was defined as an increase in the ABI of at least 0.15. Statistical analysis was performed using the SPSS software v18.0. Patency analysis was performed using Kaplan–Meier survival graph.

Results

Thirty-eight consecutive patients (43 limbs) of multilevel peripheral arterial disease with critical limb ischemia were treated by hybrid operation during the study period.

Patient characteristics are shown in Table 1. The study group (mean age 72.48) consisted of 35 males, and 5 patients had both leg symptoms. Twenty-five patients had diabetes, 31 had hypertension, 9 had history of cerebrovascular accidents, 10 had history of coronary arterial disease, 20 had current smoker, and 5 had end-stage renal disease (ESRD) (Table 1).

According to the Rutherford classification, 16 (37.2%) patients were treated for resting pain, and 27 (62.8%) were treated for tissue loss. A total of 70 lesions consisted of 18 iliac, 39 superficial femoral artery (SFA), and 13 infrapopliteal. Table 2 shows anatomic features of treated lesions which is classified according to the TASC II classification, and iliac lesions consist of five TASC II A, two TASC II B, four TASC II C, and seven TASC II D lesions. Femoropopliteal lesions consist of 6 TASC II A, 7 TASC II B, 10 TASC II C, and 16 TASC II D lesions (Table 2).

CFA endarterectomy was combined with iliac endoluminal procedures proximally in 17 iliac lesions, SFA endoluminal procedure distally in 29 SFA lesions, and infrapopliteal PTA distally in 13 infrapopliteal lesions. One femorofemoral bypass and 10 femoropopliteal bypass were combined (Table 3).

Fig. 1 **a** Classification of iliac lesion (TASC II). **b** Classification of femoropopliteal lesion (TASC II)

Cumulative primary and secondary patency rates at 24 months were 67.3 and 72.1%, respectively (Fig. 2a, b). There was no postoperative 30 day mortality.

Technical success was achieved in 43 of 43 limbs including end. Medical record data about ABI was available in 29 limbs, and hemodynamic success was achieved in 24 of 29 limbs (82.8%). The mean preoperative ABI of 0.51 ± 0.27 increased to 0.88 ± 0.35 after procedure.

Table 1 Patient characteristics

	Number (%)	
Age	72.48 (47–87)	
Sex		
Male	35/38	92.1%
Famale	3/38	7.9%
Lesion location		
Right	16/38	42.1%
Left	17/38	44.7%
Both	5/38	13.2%
Diabetes mellitus	28/38	73.7%
Hypertension	31/38	81.6%
Cerebrovascular disease	9/38	23.7%
Cardiovascular disease	10/38	26.3%
Smoking	20/38	52.6%
End-stage renal disease	5/38	13.2%

Limb salvage rate was 95.3% (Table 4). There were 2 major amputations, which were below the knee amputation, and 13 minor amputations including 2 patients of ESRD patients. There was one wound complication of lymphocele.

Discussions

CLI patients usually have multilevel PAD and significant combined disease, and its management is a challenge to vascular specialist. Endovascular technique is an attractive alternative to open surgery in the treatment of multilevel PAD, especially in high-risk patients. Endovascular treatment for TASC II A and B iliac lesions provides good patency rates and has become the standard treatment [1]. However, endovascular treatment of CFA often fails and may show suboptimal results because the atherosclerotic

Table 2 Lesion characteristics

TASC II	Iliac	Femoropopliteal
A	5/70 (7.1%)	6/70 (8.5%)
B	2/70 (2.9%)	7/70 (10%)
C	4/70 (5.7%)	10/70 (14.3%)
D	7/70 (10%)	16/70 (22.9%)
Total	18	39

Table 3 Type of surgery

Treatments	Number (%)
CFA Endarterectomy	
+ Iliac PTA	2/70 (2.86)
+ Iliac stent	15/70 (21.4)
+ SFA PTA	10/70 (14.3)
+ SFA stent	19/70 (27.1)
+ Infrapopliteal PTA	13/70 (18.6)
+ femoropopliteal bypass	10/70 (14.3)
+ femorofemoral bypass	1/70 (1.43)

CFA common femoral artery, PTA percutaneous transluminal angioplasty, SFA superficial femoral artery

lesion in this area tends to be heavily calcified and bulky [8]. Many interventionalists avoid CFA stenting because deployment across a high mobility joint area may result in a more extensive neointimal hyperplasia. Therefore, CFA endarterectomy and patch angioplasty appears to be the standard treatment for CFA occlusive disease [9].

Hybrid open and endovascular procedure can be performed on the same setting or as a staged procedure. Staged approach, compared to simultaneous hybrid procedure, is associated with longer hospital stay, high cost, groin wound problems, and additive cardiac risk with multiple procedures [10–12]. Ebaugh et al. [11] concluded in their study about hybrid operation which was composed of femoral endarterectomy, bypass, and angioplasty that simultaneous hybrid surgery greatly reduces hospital charges and length of stay, emphasizing preadmission

Table 4 Clinical outcomes

	Number	(%)
Hemodynamic success	24/29	82.8
Technical success	43/43	100
Limb salvage	41/43	95.3
Complications	5/43	11.6
Wound complications	1/43	2.3
Minor amputation	13/43	30.2

planning. These aspects make hybrid procedure a good option to patients with CLI. Other merit of hybrid procedure is that minimally invasive procedure can be performed with small groin incision in high-risk patients, and compared to percutaneous endovascular treatment, endovascular intervention can be performed proximally and distally (bidirectionally) with one incision.

Simultaneous hybrid procedure does not need use of access closure devices which may be used in percutaneous intervention and can complete the treatment of multi-level atherosclerotic disease in single treatment session [13]. Laminar flow in closed operating theater may provide more aseptic environment than angiographic suite opened to external environment [14]. However, there was several drawback of simultaneous procedure such as longer operation time, blood loss, and postoperative complication. Shin et al. [15] reported 75% in 3 year primary patency rates of staged hybrid treatment for 11 patients in whom proximal inflow iliac and SFA intervention and distal outflow femorodistal or femorofemoral bypass was

Fig. 2 **a** Primary patency rates. **b** Secondary patency rates

performed. They concluded that hybrid procedure provides greater options for revascularization in complex anatomy with less invasive procedure and quote other authors' remark that simultaneous hybrid procedure may provide more variable decisions in combining the endovascular procedure with open surgery.

Zhou et al. [16] reported that the result of simultaneous hybrid procedure composed of iliac artery stenting and open femoral endarterectomy in the treatment of multilevel iliac and common femoral occlusive disease with claudication. The mean follow-up duration was 24.2 months, and the primary patency rates, primary assisted patency rates, and secondary patency rates were 72.2, 83.3, and 94.4%, respectively.

In our study, all patients presented critical limb ischemia and many patients had infrageniculate arterial occlusion, and cumulative primary and secondary patency rates at 2 years were 67.3 and 72.1%, respectively.

Joh et al. [17] compared treatment result of open revascularization group ($n = 55$) and hybrid surgery group ($n = 21$); mean follow-up duration was 10.4 ± 9.4 months, and all revascularized arteries in hybrid group were patent during the follow-up period. The overall limb salvage rate was 97.4%, and ipsilateral ABI increased from 0.53 ± 0.21 to 0.75 ± 0.16 in the hybrid group. Six of 21 limbs (28%) in hybrid group had tissue loss in their study, and 27 of 43 limbs (62.7%) had tissue loss in our study.

Piazza et al. [18] described in their study that hybrid treatment that consisted of open femoral endarterectomy and iliac stenting (hybrid repair) is as effective as surgical reconstruction for severe iliac and common femoral occlusive disease (operative repair). Most patients in both groups presented with disabling claudication (74.4 OR vs 60% HR). Hybrid repair (HR) patients experienced shorter ICU and hospital stay than operative repair (OR) patients. Primary patency at 3 years was similar (91 vs 97%, $p = 0.29$). Their conclusion was that HR should be considered for all patients with iliofemoral occlusive disease regardless the severity of TASC II classification, particularly in those with high surgical risk, and major tissue loss at presentation is a negative predictor of long term patency in patients undergoing HR.

Primary patency is higher than that of our study. But, most of their patients were claudicants (60% HR) and all of our patients presented with critical limb ischemia.

Because simultaneous hybrid procedure is performed under fluoroscopy, results of the treatment can be improved by immediately verifying the procedural success. CLI patients are frequently elderly and frail with high mortality. Taking this into account, we believe that simultaneous hybrid procedure is a feasible and efficacious treatment for CLI patients with multilevel high-risk atherosclerotic disease.

Conclusions

The simultaneous hybrid CFA endarterectomy and endovascular therapy can provide an immediate satisfactory results, durable midterm patency, and also less invasive therapeutic option in high-risk patients. Compared to staged hybrid procedure, simultaneous hybrid treatment may be associated with shorter hospital stay and lower cost and may provide more variable decisions in combining the endovascular procedure with open surgery. This study shows that simultaneous hybrid surgery combining CFA endarterectomy with inflow or outflow endovascular procedures can improve limb salvage and provide a more rapid recovery in this group of high-risk multilevel PAD patients while minimizing the overall risk for the patient.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

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