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Okadome, Jun

Department of Surgery and Science, Graduate school of Medical Sciences, Kyushu University

Matsumoto, Takuya

Department of Surgery and Science, Graduate school of Medical Sciences, Kyushu University

Aoyagi, Yukihiro

Department of Surgery and Science, Graduate school of Medical Sciences, Kyushu University

Matsuda, Daisuke

Department of Surgery and Science, Graduate school of Medical Sciences, Kyushu University

他

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Original Article

Long Term Results of a Hybrid Revascularization Procedure for Peripheral Arterial Disease

Jun OKADOME¹⁾, Takuya MATSUMOTO¹⁾, Yukihiro AOYAGI¹⁾, Daisuke MATSUDA¹⁾,
Shinichi TANAKA¹⁾, Eisuke KAWAKUBO²⁾, Ryoichi KYURAGI³⁾, Kouichi MORISAKI¹⁾,
Kenichi HOMMA⁴⁾, Kazuomi IWASA⁵⁾, Takahiro OHMINE⁵⁾, Atsushi GUNTANI⁶⁾,
Ryota FUKUNAGA¹⁾ and Yoshihiko MAEHARA¹⁾

¹⁾Department of Surgery and Science, Graduate school of Medical Sciences, Kyushu University

²⁾Department of Surgery, Saiseikai Karatsu Hospital

³⁾Department of Vascular Surgery, Steel Memorial Yawata Hospital

⁴⁾Department of Surgery, Saiseikai Yahata General Hospital

⁵⁾Department of Vascular Surgery, Matsuyama Red Cross Hospital

⁶⁾Department of Surgery, Hiroshima Red Cross Hospital & Atomic-bomb Survivors Hospital

Abstract

Objective : To evaluate the efficacy of hybrid procedure for peripheral arterial disease (PAD), we compared the cases treated using the hybrid procedure with those treated using open revascularization (bypass alone) in our facilities.

Materials and Methods : We retrospectively reviewed 204 patients who underwent revascularization for PAD between 2007 and 2013. We divided the patients into two groups based on the type of procedure. Group 1 included patients who underwent the hybrid procedure, that is, doing endovascular therapy (EVT) either femoral or iliac resection and added the bypass procedure (infragenicular vein bypass) to the below knee artery, and group 2 included patients who underwent only bypass procedure (used autovein), that is, central anastomotic region was femoral artery region and peripheral anastomotic region was below knee artery. We evaluated various factors between the two groups, including the primary patency rate, secondary patency rate, amputation-free survival rate, and determined the efficacy of the hybrid procedure for PAD.

Results : In the patient's characteristics, there was significant difference between the two groups in the cases with cerebrovascular disease, only ($p=0.03$). There were no significant differences in the primary or secondary patency rates, and the amputation-free survival rate.

Conclusions : Primary patency rate, secondary patency rate, and amputation-free survival rate of the hybrid procedure were comparable to those of bypass (alone) procedure. The hybrid procedure is therefore an acceptable strategy for patients with PAD.

Key words : hybrid procedure, open revascularization, Peripheral Arterial Disease (PAD)

Introduction

In the hybrid procedure for lower extremity peripheral arterial disease (PAD), patients are treated with both endovascular therapy and open revascularization simultaneously.

In the past, the indications for the treatment strategy for PAD were determined by the Trans-Atlantic InterSociety Consensus (TASC) II classifications, where endovascular therapy is preferred to open surgery in the presence of TASC A and B iliac lesions, and surgical

Corresponding Author : Jun OKADOME

Department of Surgery and Science, Graduate school of Medical Sciences, Kyushu University, 3-1-1 Maidasi, Higashi-ku, Fukuoka-shi, Fukuoka

TEL : + 81-92-642-5466 FAX : + 81-92-642-5482

E-mail : ojun@surg2.med.kyushu-u.ac.jp

reconstruction is the recommended treatment for TASC C and D lesions¹.

However, in many cases, PAD is associated with a multilevel pattern of occlusive disease, and open revascularization is associated with a long operation, high level of invasion, and a high incidence of much postoperative complications in difficult cases and high-risk surgical patients. Thus, improved treatment strategies are needed to improve the outcomes of such patients. As vascular surgeons have developed their endovascular techniques and the devices used for endovascular therapy (EVT) have improved, more complex lesions, such as like multilevel occlusive lesions, have been able to be treated without open surgery^{2,3}. Therefore, the potential treatment strategies for difficult cases, including patients with critical limb ischemia (CLI), have expanded. The goal of this study is to define the efficacy of simple and complex hybrid procedures in patients who need multilevel revascularization for their symptomatic PAD.

Patients and Methods

Group 1 (hybrid procedure group) included 13 procedures in 12 patients (mean age, 73.1 years), whereas group 2 (only for bypass procedure group) included 29 procedures in 27 patients (mean age, 72.6 years). Both types of procedures were performed between January 2007 and July 2013 in patients with peripheral arterial disease in the Department of Surgery and Science, Graduate School of Medical Sciences, Kyushu University Hospital. Both procedures were performed on the patients who presented with symptomatic lower extremity peripheral arterial disease as severe claudication or CLI, defined by the "recommended standards for reports dealing with lower extremity ischemia"⁴. The Rutherford classification was used to determine the clinical category of the patients⁴. The patients in group 1 comprised 8 (67 %) males and 4 (33 %) females, and their underlying risk factors were hypertension in 9 patients (75 %), diabetes mellitus in 9 patients (75

%), dyslipidemia in 5 patients (42 %), coronary artery disease in 5 patients (42 %), a history of cerebrovascular disease in 7 patients (58 %), and kidney disease requiring dialysis in 5 patients (42 %). The indications for arterial reconstruction were severe claudication in 1 case (8 %) and CLI in 12 cases (92 %). The target lesion of the endovascular therapy (EVT) in group 1 was an iliac artery lesions in 5 cases (38 %), femoral artery lesions in 8 cases (62 %). In group 1, the breakdown of open revascularizations was follows : an infragenicular vein bypass was performed in 13 cases (100 %), an extra-anatomic bypass was performed in 1 case (8 %), and femoral endarterectomy (FEA) and patch arterioplasty were performed in 3 cases (23 %). The patients in group 2 comprised 17 (63 %) males and 10 (37 %) females, and their underlying risk factors were hypertension in 20 patients (74 %), diabetes mellitus in 17 patients (63 %), dyslipidemia in 5 patients (19 %), coronary artery disease in 10 patients (37 %), a history of cerebrovascular disease in 6 patients (22 %), and kidney disease requiring dialysis in 11 patients (41 %). The indications for arterial reconstruction were severe claudication in 0 patients (0 %) and CLI in 29 patients (100 %). In group 2, the breakdown of open revascularizations is as follows : an infrainguinal bypass (used autovein) was performed in 29 patients (100 %). Primary or secondary patency, 2 years after procedure, was confirmed by feeling the pulsatile blood flow or by Doppler blood flow measurement at the most recent examination. The amputation-free survival was defined as limbs that were free of the excision proximal to the metatarsal. Preoperative and follow-up data were retrospectively collected from a computerized database, the surgical records and directly from telephone interviews with the patients directly. A Kaplan-Meier survival analysis was used to compare the amputation-free survival rate of the procedures. All comparisons of the various factors in each group were made using the Wilcoxon-Mann-Whitney test.

Table 1 Patient characteristics

Characteristics	Group 1 (n=12) hybrid procedure	Group 2 (n=27) only for bypass procedure	p-value
Number of procedures	13	29	-
Mean age (years)	73.1	72.6	N. S
Gender			N. S
Male	8 (67%)	17 (63%)	
Female	4 (33%)	10 (37%)	
Complications			
Hypertention	9 (75%)	20 (74%)	N. S
Diabetes	9 (75%)	17 (63%)	N. S
Dyslipidemia	5 (42%)	5 (19%)	N. S
Coronary disease	5 (42%)	10 (37%)	N. S
Cerebrovascular disease	7 (58%)	6 (22%)	0.03
Dialysis	5 (42%)	11 (41%)	N. S
Operative indication			
Severe claudication	1 (8%)	0 (0%)	N. S
Critical limb ischemia	12 (92%)	29 (100%)	N. S
EVT target lesions		-	-
Iliac artery	5 (38%)		
Femoral artery	8 (62%)		
Reconstructive procedures			
Infrainguinal bypass	13 (100%)	29 (100%)	-
Extra anatomic bypass	1 (8%)	-	-
FEA · patch arterioplasty	3 (23%)	-	-
Occlusion	3 (23%)	6 (22%)	N. S
Additional treatment	1/3 (33%)	1/6 (17%)	N. S
Amputation	1/3 (33%)	2/6 (33%)	N. S
Conservative	1/3 (33%)	3/6 (50%)	N. S

EVT : endovascular therapy ; FEA : femoral endarterectomy

Results

We divided the patients with PAD into two groups (Group 1 and Group 2), as noted above. Group 1 (hybrid procedure), included 13 procedures in 12 patients (mean age, 73.1 years ; 67 % male). Group 2 (only for bypass procedure), included 29 procedures in 27 patients (mean age, 72.6 years ; 63 % male). The demographic data for these two groups are shown in Table 1. There were no significant differences in the mean age or gender. In the atherosclerotic risk factors, there was significant difference in terms of cerebrovascular disease (58 % and, 22 %, respectively, $p=0.03$), but there were no significant differences in another complications, including hypertension (75 % and, 74 %, respectively), diabetes mellitus (75 % and, 63 %, respectively) , dyslipidemia (42 %

and, 19 %, respectively), coronary disease (42 % and, 37 %, respectively), dialysis (42 % and, 41 %, respectively) between the two groups. According to the Rutherford grading, 1 case (8 %) and 0 case (0 %) were treated for severe intermittent claudication (Rutherford grade I, category 3), 12 cases (92 %) and 29 cases (100 %) had persistent ischemic rest pain or either minor or major tissue loss (Rutherford grade II or III, category 4, 5 or 6), respectively, and there were no significant differences between the groups in terms of the grading. The breakdown of the EVT target lesions in group 1 included the iliac artery in 38 % of cases and the femoral artery in 62 % of the cases. The frequency of reconstructive procedures in both groups were followed, and an infrainguinal bypass was performed in 13 cases (100 %) and 29 cases (100 %) respectively. An

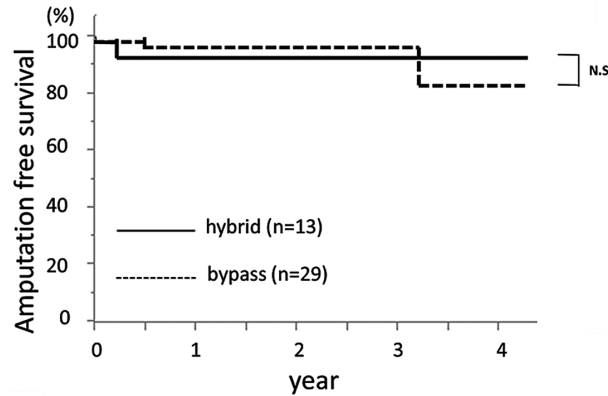


Fig. 1 The cumulative amputation free survival rates of all cases. There were no statistically significant differences between the two groups. The solid line indicates the hybrid procedure group (group 1), and the dotted line indicates the bypass procedure group (group 2). (Kaplan–Meier analysis, log–rank test)

Table 2 The amputation free survival rate and freedom from secondary intervention rate

Characteristics	Group 1 (n=12) hybrid procedure	Group 2 (n=27) open revascularization	p-value
Patency (2 years after procedure)			
Primary patency	77% (10/13)	79% (23/29)	N. S
Secondary patency	85% (11/13)	83% (24/29)	N. S
Amputation free survival rate	96% (12/13)	93% (27/29)	N. S
Freedom from secondary intervention rate (above-mentioned : 2 years after procedure)	96% (12/13)	90% (26/29)	N. S

extra anatomic bypass was performed in 1 case (8 %), and a FEA and patch arterioplasty was performed in 3 cases (23 %), in the group 1. The primary and secondary patency rates, 2 years after procedure, of the groups were 77 % and 85 % and, 79 % and 83 % respectively, which were not significantly different (Table 2). The amputation-free survival rates and the freedom from secondary intervention rates, 2 years after procedure, of the groups were 96 % and 96 %, and, 93 % and 90 %, respectively, which were not significantly different (Fig. 1, Table 2). During the follow-up period in group 1, 3 of 13 procedures (23 %) were occluded of primary angioplasty. 1 patient of those 3 (33 %) underwent a major amputation, defined as a limb amputated above the ankle, 1 of those 3 (33 %) added bypass

procedure, and 1 of those 3 (33 %) got a follow-up examination. The needed additional procedure case of group 1 was patent up to the present time. In group 2, 6 of 29 procedures (22 %) were occluded of bypass graft. 2 patient of those 6 (33 %) underwent a major amputation, defined as a limb amputated above the ankle, 1 of those 6 (17 %) had a thrombus removed from the bypass graft, and 3 of those 6 (50 %) got a follow-up examination. The needed additional procedure case of group 2 was patent up to the present time.

Discussion

The concept of combining endovascular and open procedures was first reported in the 1970's with iliac angioplasty and femorofemoral bypass⁵. The use of hybrid procedures has been reported

to comprise constitute approximately 5 % to 21 % of all revascularizations performed today⁶⁾⁻⁸⁾.

Ebaugh et al. reported a 7 % increase in hybrid procedures in a Nationwide Inpatient Sample (NIS) database between 2001 and 2004. In our study, hybrid procedures constituted approximately 19 % of all revascularizations, with increased use of complex hybrid procedures occurring over time⁷⁾. The recent developments in imaging techniques, angioplasty devices, and EVT techniques has led to an increase in the use of EVT procedures for CLI patients⁹⁾¹⁰⁾ because of the lower morbidity, invasiveness, cost, hospital stay and reported technical and clinical results comparable to those of bypass surgery¹¹⁾. Although it remains controversial, the EVT procedure for PAD is useful not only for femoropopliteal occlusive disease, but also for infrapopliteal occlusive disease. According to the TASCII guidelines, the EVT procedure is recommended for TASCII A and/or B lesions, but the indications have recently been extended to more diffuse or multilevel atherosclerotic arterial disease, categorized as TASC type C and D lesions¹²⁾. Park et al. reported that the one, three and five year primary patencies of the iliac arterial stents used for TASC A were 96 %, 84 %, and 81 %, for TASC B were 95 %, 85 %, and 85 %, for TASC C were 94 %, 94 %, and 78 %, and for TASC D were 93 %, 74 %, and 74 %, respectively. The outcomes in the four TASC groups were not significantly different with regard to primary patency rates¹³⁾. Pomposelli et al. reported that the primary patency, secondary patency, limb salvage and patient survival rates were 56.8 %, 62.7 %, 78.2 %, and 48.6 %, respectively, at five years¹⁴⁾. In contrast, Dorros et al. reported that the EVT procedure for the infrapopliteal tibioperoneal vessel was comparable to the bypass procedure, with a technical successful rate of 92 % and a limb salvage rate of 91 % at five years¹⁵⁾.

However, in many patients treated with EVT only procedures cases, repetitive additional EVT procedures were required for the development of

restenosis. As many studies have reported that the primary patency rate of the EVT procedure is lower than that of bypass surgery, it is not reasonable to treat every case using only an EVT procedure¹⁶⁾⁻¹⁸⁾. There are several advantages to using a hybrid procedure. For the high arteriosclerotic risk and elderly patients, a hybrid procedure can shorten the length of the operation, reduce the hospital charges and decrease the length of the hospital stay⁷⁾. When we perform an infrapopliteal bypass, it is necessary to secure a sufficient length of vein grafts. The hybrid procedure permits vascular surgeons to use shorter bypass grafts when there is an insufficient length grafts due to various causes, such as patients who are post coronary artery bypass grafting (CABG). In our study, there was a significant difference in the portion of infrainguinal bypasses between the patients treated using the hybrid procedure and open revascularization. We thought the reason for this was that, during the hybrid procedures, other procedures are unnecessary because of the increased inflow and/or outflow. The hybrid procedure allowed us to obtain a primary patency rate of 89 %, a secondary patency rate of 100 %, an amputation-free survival rate of 96 % and a freedom from secondary intervention rate of 91 % during the follow-up period. The follow-up period was limited, but we obtained results comparable to or better than those reported in several previous studies, and these results justify our hybrid treatment of PAD, because the primary patency rate has improved since 2001, when we started using the procedure. Using self-expanding nitinol stents for the treatment of femoropopliteal obstructive disease beginning in 2001 further improved the primary patency rate¹⁹⁾²⁰⁾.

Several recent studies reported that the efficacy and long-term patency of the drug-eluting stents in patients with femoropopliteal occlusions. Dako et al. reported that paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in patients with femoropopliteal

disease, where the event-free survival rate was 90.4 % versus 82.6 % and, the primary patency rate was 83.1 % versus 32.8 %, in the paclitaxel-eluting stents group and the balloon angioplasty and bare metal stents group, respectively²¹). There are a few limitations to our study that might have affected the outcomes, including the relatively small number of hybrid procedures, various procedures used for the revascularization, and our facilities. Our operating room was not equipped with an angiographic unit until 2009, but the hybrid procedure in our study has performed in a staged fashion since this was introduced.

Conclusion

The long-term primary patency rate, secondary patency rate, amputation-free survival rate and freedom from secondary intervention rate of the hybrid procedure for PAD were satisfactory, and were comparable to the outcomes of open revascularization. When vascular surgeons do not have sufficient length grafts (for example, after CABG), the hybrid procedure can be used to treat severe lower extremity arterial disease with shorter grafts, which may result in a less invasive procedure and a reduced cost for high-risk patients. In the current era, the devices used for endovascular procedures have continued to improve, so performing the hybrid procedure using a combination of these improved devices with open revascularization may be even more successful that it was in the past.

Disclosure Statement

The authors have no conflict of interest to declare.

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PAD 患者に対するハイブリッド血行再建術の長期成績

¹⁾九州大学大学院 消化器・総合外科

²⁾済生会唐津病院

³⁾製鉄記念八幡病院

⁴⁾済生会八幡総合病院

⁵⁾松山赤十字病院

⁶⁾広島赤十字・原爆病院

岡留 淳¹⁾, 松本拓也¹⁾, 青柳幸彦¹⁾, 松田大介¹⁾, 田中慎一¹⁾,
川久保英介²⁾, 久良木亮一³⁾, 森崎浩一¹⁾, 本間健一⁴⁾, 岩佐憲臣⁵⁾,
大峰高広⁵⁾, 郡谷篤史⁶⁾, 福永亮大¹⁾, 前原喜彦¹⁾

【背景】末梢動脈疾患 (peripheral arterial disease: PAD) 患者に対しての血行再建術の治療戦略は主に TASC II (Trans-Atlantic Inter-Society Consensus II) 分類によって決定される。かつては、大動脈腸骨動脈領域・大腿膝窩動脈領域を含め、TASC A/B 病変は血管内治療が、TASC C/D 病変は外科的血行再建術が一般的には適応とされていた。しかし、病変・患者背景の多様性や血管内治療 (EVT) の適応拡大に伴い、腸骨動脈領域病変に対して行う血管内治療と、大腿膝窩動脈以下の領域の病変に対して行う外科的血行再建術とを同時に行うハイブリッド治療が血行再建術の適用とされる症例が増加している。

【目的】PAD 患者に対しての、血行再建術におけるハイブリッド治療の有効性、外科的血行再建術と比較しての非劣性を示し、ハイブリッド治療の妥当性を検討する。

【対象・方法】2007年1月から2013年7月までの間に、当科における PAD 症例の中で腸骨・大腿動脈領域に対して EVT を行い、下腿動脈に bypass を加えた症例をハイブリッド治療症例 (12 症例 13 肢) とし、一方で、同時期に施行した、大腿動脈領域を中枢吻合部とし、下腿 3 分枝を末梢吻合部とした 27 症例 29 肢を比較対象の bypass 症例として患者背景、施行術内容、開存率、救肢率、非追加治療率を比較し、その成績を retrospective に検討した。

【結果】ハイブリッド症例において、施行した EVT の内訳は、腸骨動脈に対してが 8 例 (71%)、浅大腿動脈に対してが 5 例 (29%) であった。加えた外科的血行再建術の内訳は、大動脈-大動脈交叉バイパス (F-F bypass) が 2 例、末梢吻合部に前脛骨動脈を選択した症例が 7 例 (中枢吻合部は大腿動脈領域が 3 例、膝窩動脈領域が 4 例)、後脛骨動脈を選択した症例が 4 例 (中枢吻合部は大腿動脈領域が 1 例、膝窩動脈領域が 3 例) であった。3 例 (全て Fontaine IV 度) において、ステントまたはグラフトに閉塞を認め、その内 1 例で下肢切断を要した。ハイブリッド症例の 2 年一次開存率は 77% で、比較対象とした bypass 手術群における 2 年一次開存率は 79% であり、両群間に有意な差は認めなかった。また、救肢率においても両群間に有意な差は認めなかった。

【結語】ハイブリッド症例においては、腸骨・大腿動脈病変に EVT を施行し、下腿動脈に bypass 術を行った症例の開存率・救肢率と比較すると、遜色のないものであった。高齢者数の増加、糖尿病患者数・透析症例数の増加が見込まれる今後において、複雑な術式の単純化・低侵襲化が可能であるハイブリッド治療は、有用で妥当な血行再建術となることが示唆された。現在、薬剤溶出性バルーンやステントの開発が進んでおり、今後ハイブリッド治療の更なる適用の拡大が想定される。