Evaluation of the Paramalleolar Bypass for Critical Limb Ischemia Patients on Hemodialysis with Diabetes Mellitus and Chronic Renal Failure

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Objective: To assess the influence of diabetes mellitus (DM) and end-stage renal failure on hemodialysis (HD) on the healing time of tissue lesions and blood flow to the foot following a paramalleolar bypass in patients with critical limb ischemia (CLI).

Methods: Consecutive patients with CLI and tissue loss (24 limbs) were followed up retrospectively after paramalleolar bypass, and the healing time of tissue lesions, graft patency, limb salvage and survival rates were analyzed. The blood flow to the foot was assessed by skin perfusion pressure (SPP) pre- and postoperatively. The delta SPP was calculated as the difference between the SPP before and after bypass. The patients were divided into 3 groups: diabetic (DM, n = 9); diabetic and end-stage renal failure on hemodialysis (HD, n = 10); or neither (n = 5).

Results: A total of 15 dorsal and 9 plantar artery bypasses were performed. The median follow-up was 7.3 months (range, 1–18 months). No patients required major amputations, and all tissue lesions healed. The mean duration to complete tissue healing of the DM, HD and neither groups was 2.2, 2.5 and 1.2 months, respectively, and these were not statistically significant. A significant improvement in the delta SPP after paramalleolar bypass was observed in the neither group compared with both the DM and HD groups.

Conclusion: Blood flow to the foot was not sufficiently improved in CLI patients with DM and HD, despite paramalleolar bypass. This may be the cause of the prolonged tissue healing duration of CLI patients with DM and HD. (*English Translation of Jpn J Vasc Surg 2012; 21: 91-95)

Keywords: paramalleolar bypass, critical limb ischemia, diabetes mellitus, hemodialysis, skin perfusion pressure

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INTRODUCTION

Critical limb ischemia (CLI) with tissue loss complicated by diabetes mellitus (DM) or end-stage renal disease on hemodialysis (HD) often requires dorsalis pedis or plantar artery bypass to secure the blood supply to the foot. However, as patients with DM or HD are considered to have lesions in the vascular bed at the arteriole level, sufficient blood flow to the entire foot cannot be restored even after bypass surgery, and tissue healing is delayed. Unfortunately, some patients must undergo lower limb amputation due to foot necrosis and infection even though the bypass remains patent.¹⁾

The skin perfusion pressure (SPP), which is relatively immune from the effects of vascular calcification, is considered to be useful for the evaluation of peripheral microcirculation, and has been used recently as an index of improvement in the blood flow after paramalleolar bypass surgery.²⁻⁴⁾ In this study, we evaluated the effects of DM and HD on the improvement in the foot blood flow in CLI patients with tissue loss after bypass surgery by comparing changes in the SPP between before and after surgery among those with DM, HD, and no DM or HD. Regarding endovascular treatment, which has recently begun to be performed frequently for CLI, Iida, et al. compared direct (revascularization of the ulcerated area) and indirect (revascularization out of the ulcerated area) groups, and reported that the SPP increased significantly with a higher limb salvage rate in the direct than in the indirect group (82% vs. 64%, respectively).⁵⁾ However, revascularization is often performed regardless of the ulcerated area in bypass surgery, and there is no literature on the evaluation of the degree of improvement in the SPP in the entire foot by comparing revascularized and non-revascularized areas.

We, therefore, attempted to clarify the effects of DM and HD on improvement in the blood flow of the entire foot after bypass surgery by evaluating the degree of postoperative improvement in the SPP in not only the revascularized area but also non-revascularized areas (plantar artery region after dorsalis pedis artery bypass and dorsalis pedis artery region after plantar artery bypass) of the affected limb in patients who underwent paramalleolar bypass for CLI complicated by DM or HD.

SUBJECTS AND METHODS

The subjects were 24 patients (24 limbs) with CLI accompanied by ulcer who underwent paramalleolar bypass grafting after November 2007, when the SPP was introduced. The patients were divided into those with DM, those with diabetes and undergoing HD for end-stage renal disease, and those with no DM or HD, and the time until ulcer or wound healing, bypass patency rate, limb salvage rate, and SPP were compared. Revascularization for Burger's disease was excluded.

All patients received an autogenous venous bypass graft, and revascularization involved dorsalis pedis artery grafting in 15 limbs and plantar artery bypass grafting in 9 limbs. Saphenous vein grafts (SVGs) were prepared primarily as non-reversed grafts using an expandable LeMaitre® valvulotome (LeMaitre Vascular,

Inc., Burlington, Massachusetts, USA) in consideration of the compatibility of the vascular orifice, and non-reversed, reversed, and spliced SVGs were grafted to 12, 8, and 4 limbs, respectively.

The pre- and postoperative SPP were measured in the dorsalis pedis and plantar artery regions in each patient. The measurement of the SPP was performed by the Laboratory Department, which was not directly involved in surgery. The values 1 week after surgery were used as the postoperative values, in principle, but, if measurement was impossible due to the location of the ulcer, those 2–4 weeks after bypass, when partial healing was observed, were used.

Changes in the SPP were evaluated in not only the revascularized area (direct area) but also a non-revascularized area of the affected limb (indirect area: plantar artery region after dorsalis pedis artery bypass or dorsalis pedis artery region after plantar artery bypass).

The change in the SPP from before to after bypass surgery was defined as the post- minus preoperative SPP (mmHg), and its difference between the groups was evaluated with the non-paired t-test using the statistical software JMP (ver.8) at the $p < 0.05$ level of significance.

RESULTS

The mean observation period was 7.3 months (1–18 months), and the bypasses were patent in 23 limbs. Graft stenosis was noted in 2 and 1 patient at 2 and 4 months, respectively, after ulcer healing, but the patency of these grafts was maintained by graft repair procedures. One graft was occluded after 3 months, and is currently being observed without ulcer. Ulcers healed in all patients, and the limbs could be preserved without major amputation. Death due to myocardial infarction was observed in 1 patient each after 3 and 4 months. Death due to metastatic liver cancer was observed in 1 patient after 4 months.

The ulcers were treated following bypass surgery by debridement in 4, toe amputation in 17 (amputation of 1 toe in 12, 2 toes in 3, and 3 toes in 2), and metatarsal amputation in 3, and treatment was continued with open wounds.

Of the 24 patients, 9 were diabetic (DM group), 10 were diabetic and undergoing hemodialysis for end-stage renal disease (HD group), and 5 had no DM or HD (no-comorbidity group). Ten patients (52.6%) in the DM and HD groups were receiving insulin therapy (**Table 1**).

The time until ulcer healing was 2.2 months in the DM group, 2.5 months in the HD group, and 1.2 months

Table 1 Patient characteristics and performed operation

Factors	CLI 24 limbs	
Comorbidities	DM	9
	DM and HD	10
	Neither	5
Bypass	Dorsal pedal artery	15
	Plantar artery	9
Treatment for tissue loss	Debridement	4
	Toe amputation	17
	Metatarsal amputation	3
Patency	Yes (revision operation 3)	23
	No	1

DM: diabetes mellitus; HD: hemodialysis; CLI: critical limb ischemia

Table 2 SPP at the direct and indirect area

Factors	Limbs	SPP (mmHg) pre		SPP (mmHg) post		Months to wound healing
		Direct	Indirect	Direct	Indirect	
DM	9	21.1	28.4	55.7	59.3	2.2
DM and HD	10	23.3	29.2	48.6	51.0	2.5
Niether	5	20.4	13.0	74.0	66.4	1.2

The direct area means the plantar area when the plantar artery bypass was performed, and the indirect area is the dorsal area at that condition. DM: diabetes mellitus; HD: hemodialysis; SPP: skin perfusion pressure

in the no-comorbidity group, with no significant difference ($p = \text{NS}$), but healing was delayed in the DM and HD groups.

In the direct area, the change in the SPP between before and after paramalleolar bypass was +34.6 mmHg (mean SPP: 21.1 mmHg before and 55.7 mmHg after surgery) in the DM group, +25.3 mmHg (23.3 and 48.6 mmHg) in the HD group, and +53.6 mmHg (20.4 mmHg and 74.0 mmHg) in the no-comorbidity group.

In the indirect area, it was +30.9 mmHg (28.4 mmHg and 59.3 mmHg) in the DM group, +21.8 mmHg (29.2 mmHg and 51.0 mmHg) in the HD group, and +53.4 mmHg (13.0 mmHg and 66.4 mmHg) in the no-comorbidity group (**Table 2**).

The increase in the SPP was smaller in the direct ($p = 0.09$) and indirect ($p = 0.17$) areas in the DM group and significantly smaller in the direct ($p = 0.01$) and indirect ($p = 0.05$) areas in the HD group, compared with the no-comorbidity group (**Fig. 1**).

DISCUSSION

No large-scale, prospective study on CLI has been reported. However, according to guidelines for the diag-

Fig. 1 CLI with Diabetes and hemodialysis had tendency not to improve the SPP after paramalleolar bypass at direct area as well as indirect area. The direct area means the plantar area when the plantar artery bypass was performed, and the indirect area is the dorsal area at that condition. CLI: critical limb ischemia; SPP: skin perfusion pressure

nosis and treatment of peripheral arterial disease (PAD) (Trans-Atlantic Inter-Society Consensus: TASC), the prognosis of CLI patients without treatment is poor; limb amputation was necessitated in 40% of the patients within 6 months, and the life prognosis was exacerbated

by vascular complications such as ischemic heart disease and cerebrovascular disorders, with the 1-year mortality rate being about 20%. Also, as the perioperative mortality rate due to leg amputation is high, and as the life prognosis and recovery of motor functions after thigh amputation are particularly unfavorable, efforts for aggressive revascularization are necessary.⁶⁾

Regarding the SPP, the skin blood flow can be measured by analyzing laser Doppler data of the blood cell volume and velocity. Since the laser beam penetrates to only about 1–2 mm from the skin surface, blood flow at the capillary level can be evaluated with relatively little effect due to arteriosclerosis or calcification. The patient must be rested in bed for measurement of the SPP, so it is often impossible to measure in those with pain on rest, but it has been sporadically reported to be useful for the evaluation of revascularization in CLI. Castronuovo, et al. defined an SPP of 30 mmHg as a borderline for the diagnosis of ischemic ulcer, and reported that wound healing can be expected in about 80% of patients with an SPP of 30 mmHg and 95% or more of patients with an SPP of 40 mmHg.^{2–4)}

In our patients, also, the SPP improved to 30 mmHg or higher in 23 limbs with the exception of 1 limb after paramalleolar bypass, and ulcers and wounds healed in all patients, with no major amputation.

Azuma, et al. evaluated 190 limbs of CLI patients after bypass surgery by dividing them into dialysis and non-dialysis groups, and reported that the 4-year cumulative primary and secondary graft patency rates, limb salvage rate, and survival rate were 67.6%, 94.2%, 99.0%, and 80.2%, respectively, in the non-dialysis group (106 limbs of 104 patients) and 65.9%, 89.1%, 86.3%, and 38.2%, respectively, in the dialysis group (84 limbs of 78 patients) ($p = 0.916, 0.514, 0.0124$, and <0.001 , respectively; log rank test). They suggested that the life prognosis after limb salvage is favorable even in CLI patients if they are not on hemodialysis, and concluded that bypass surgery using a venous graft, which can provide adequate blood flow over a long period, is the first choice.⁷⁾

According to other reports, also, the survival rate was low in patients on hemodialysis, but the graft patency rate was not inferior, and the results of bypass surgery for limb salvage were reasonable, encouraging aggressive revascularization.^{8–12)}

In patients with DM and those undergoing HD, the obstructive lesion is often located in a lower leg artery and is accompanied by marked calcification. Therefore, a sufficient blood supply to the foot by dorsalis pedis,

posterior tibial, or plantar artery bypass surgery using a venous graft, which is obtained primarily from the greater saphenous vein, is necessary. In HD patients, in particular, the host artery of the foot may be severely calcified, and tissue healing after bypass surgery may be delayed, so limb amputation may become necessary even though the bypass remains patent. Inaba, et al. reported that arterial perfusion to the foot was often insufficient with bypass surgery to the dorsalis pedis or plantar artery alone, and that simultaneous bypassing of the anterior and posterior tibial arteries in the ankle region was effective in patients with extensive necrosis of the foot or infection.¹⁾

Iida, et al. evaluated 203 patients with CLI who underwent endovascular treatments by dividing them into direct (revascularization of the ulcerated region) and indirect (revascularization out of the ulcerated region) groups on the basis of the angiosome concept.

They reported: The SPP increased significantly, and the limb salvage rate was higher, in the direct group, in which the ulcerated region could be revascularized, compared with the indirect group (82% vs. 64%, respectively).⁵⁾

We, therefore, studied changes in the SPP in not only the revascularized area (direct area) but also non-revascularized area of the affected limb (indirect area), and evaluated the improvement in blood flow in the entire foot to demonstrate that it remains insufficient, and tissue healing is delayed, after bypass surgery in CLI patients with DM or HD. As a result, the improvement in the SPP was significantly smaller in the direct area in the DM and HD groups compared with the no-comorbidity group. In the indirect area, also, the improvement in the SPP after bypass surgery was smaller in the DM and HD groups. Moreover, while the SPP showed similar improvements after paramalleolar bypass in the direct and indirect areas in the no-comorbidity group, the improvement in the SPP was smaller in the indirect than direct area in the DM and HD groups. Although no significance was noted, the time until ulcer or wound healing was 2.2, 2.5, and 1.2 months, in the DM, HD, and no-comorbidity groups, respectively, showing a delay of wound healing in the DM and HD groups even after bypass surgery.

These results suggest that, in patients with CLI complicated by DM or HD, the improvement in the SPP is insufficient, causing a delay in tissue healing, in not only the direct but also indirect area. In patients with DM or HD, the arterial network is considered to be disrupted in distal parts of the foot, and revascularization with the ulcerated area in mind is considered to be more

important in bypass surgery.

CONCLUSION

Ulcers healed in all patients, the limbs could be saved without major amputation, and the survival rate was satisfactory. Paramalleolar bypass is considered to be a reasonable treatment, and aggressive revascularization using this procedure is recommended, in CLI complicated by DM or HD with tissue loss.

In CLI complicated by DM or HD with tissue loss, the improvement in the SPP may be insufficient in the entire foot, and tissue healing may be delayed, even after bypass.

DISCLOSURE STATEMENT

Atsushi Guntani and other co-authors have no conflict of interest.

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