Bypass vs. Endovascular Therapy of Infrapopliteal Lesions for Critical Limb Ischemia

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Objective: This study was conducted to determine whether to perform endovascular intervention or bypass surgery as a treatment option for critical limb ischemia (CLI) with lesions in the popliteal artery or below.

Subjects and Methods: A total of 150 patients (164 limbs) with CLI underwent endovascular intervention or bypass surgery for lesions in the popliteal artery or below at our department between May 1995 and June 2011. Therapeutic outcomes were examined by surgical technique. An indication for endovascular intervention was established with the combination of (1) poor general condition, and (2) a stenotic or occlusive lesion ≤5 cm.

Results: The bypass group (group B) comprised 119 patients (99 males, 20 females) with 131 affected limbs at 46 to 89 years of age (mean: 70 years). The endovascular intervention group (group E) comprised 31 patients (25 males, 6 females) with 33 affected limbs at 47 to 89 years of age (mean: 72 years). There was no significant difference in patient demography between the two groups. Regarding preoperative complications, hypertension was observed in 54% and 61% of the subjects in groups B and E, respectively, diabetes in 36% and 55%, renal dysfunction in 29% and 58%, ischemic heart disease in 27% and 32%, and cerebrovascular disorder in 18% and 23%; renal dysfunction accounted for a significantly higher percentage in group E. As for early postoperative complications, subjects in group B experienced wound infections (6 patients), hemorrhage (2), thrombosis (2), pneumonia (1), and another complication (1), and those in group E experienced wound infections (1) and another complication (1). The hospital mortality rate was 0.8% (1 patient) for group B and 0% for group E. The 3-year cumulative primary patency rate was 72% for group B and 54% for group E; the rate was significantly higher for group B. The 3-year secondary patency rate was 82% for group B and 60% for group E. The 3-year limb salvage rate was 86% for group B and 82% for group E; there was no significant difference between the two groups. The 5-year survival rate was 57% for group B and 42% for group E; the survival rate was significantly lower for group E.

Conclusion: For the study population of CLI patients with lesions in the popliteal artery or below, the patency rate was higher for the bypass group than for the endovascular intervention group, whereas there was no difference in the limb salvage rate. Based on the findings in prognosis for survival, the indication for endovascular intervention at our department is believed to be appropriate. (*English translation of Jpn J Vasc Surg 2013; 22: 715-718)

Keywords: critical limb ischemia, endovascular therapy, bypass
However, for the aortoiliac area, endovascular treatment has recently become the first-line treatment with the improvement of devices. For the femoropopliteal area, endovascular treatment is selected for TASC types A and B and bypass for types C and D. For lesions in the popliteal artery or below, it is controversial whether endovascular treatment or bypass should be indicated. Thus, we investigated the outcomes of patients with critical limb ischemia in the popliteal artery or below treated with endovascular therapy and bypass.

**Subjects and Methods**

The subjects were 150 patients with critical limb ischemia in the popliteal artery or below (164 legs) who underwent endovascular treatment or bypass at our department between May 1995 and June 2011. The therapeutic outcomes were investigated in terms of the procedures. Endovascular treatment was indicated for patients with: (1) poor general condition and (2) a stenotic or occlusive lesion extending 5 cm or less, and percutaneous old balloon angioplasty (POBA) was employed in all. Patients judged as in poor general condition were subjected to the risk assessment reported by Goodney, et al.² For statistical analysis, the t-test was employed for between-group comparison, and \( p < 0.05 \) was regarded as significant. The patency, limb salvage, and survival rates were analyzed using the Kaplan-Meier method.

**Results**

The bypass group (B) was comprised of 119 patients (131 legs) aged 46–89 years (mean: 70 years old, 99 males and 20 females), and the endovascular treatment group (E) was comprised of 31 patients (33 legs) aged 47–89 years (mean: 72 years old, 25 males and 6 females), showing no significant differences in the background between the 2 groups. Ankle brechial pressure index (ABI) was \( 0.24 \pm 0.21 \) in group B and \( 0.38 \pm 0.25 \) in group E, showing a significantly lower value in group A (Table 1).

In terms of the treatment in group B, femoro below knee popliteal bypass was applied in 68 (blood vessel prosthesis: 4, autologous vein: 64), femoro-posterior tibial bypass in 33 (autologous vein in all), popliteal to posterior tibial bypass in 4 (autologous vein in all), femoro-anterior tibial bypass in 15 (including the dorsal artery of the foot, all used an autologous vein), popliteal to dorsal artery of the foot bypass in 5 (autologous vein in all), and femoro-peroneal bypass in 6 (autologous vein in all). In group E, the technical success rate was 87%, and treatment of 4 and 2 of 6 unsuccessfully treated legs was switched to bypass and drug therapy, respectively. Lesions in group E were located in the popliteal artery in 10, tibio-peroneal trunk in 10, anterior tibial artery in 7, posterior tibial artery in 7, and peroneal artery in 6. As combined surgery for lesions on the central side in group B, aorto-femoral bypass was applied in 4, axillo-femoral bypass in 1, femoro-femoral crossover bypass in 6, endovascular treatment (iliac artery) in 7, and thromboendarterectomy (common femoral artery) in 4. In group E, femoro-above knee popliteal bypass was performed in 1, endovascular treatment (superficial femoral artery) in 7, and thromboendarterectomy (common femoral artery) in 6.

Regarding preoperative complications, hypertension was present in 54% and 61% in groups B and E, diabetes in 36% and 58%, chronic dialysis in 29% and 58%, ischemic heart disease in 27% and 32%, cerebrovascular disorder in 18% and 23%, hyperlipidemia in 14% and 26%, and pulmonary complications including pulmonary dysfunction in 14% and 23%, respectively. The frequency of dialysis was significantly higher in group E (\( p < 0.008 \)).

Regarding early postoperative complications, wound infection, hemorrhage, thrombosis, pneumonia, and another complication developed in 6, 2, 2, 1, and 1 patient in group B, respectively. In group E, dissection and another complication developed in 3 and 1 patients, respectively. The hospital mortality rates were 0.8% and 0% in groups B and E, respectively (Table 2).

In the risk assessment using the method reported by Goodney, et al., in group B, 8 patients were scored as 1 and one of them (13%) died within 2 years, 52 were scored as 2 and 10 (19%) of them died, 45 were scored as 3 and 12 (27%) of them died, 13 were scored as 4 and 7 (54%) of them died, and one was scored as 5 and died (100%). In group E, none of the patients who were scored as 1 or 2 died. However, two (25%) of 8 patients who were scored as 3, 4 (67%) of 6 patients who were scored as 4, 5 (83%) of 5 patients who were scored as 5, and 2 (100%) of 2 patients who were scored as 6 died (Table 3). Treatment of localized stenosis extending 5 cm or less was
prioritized in patients who were scored as 1 or 2 in group E.

The primary cumulative patency rates at 3 years were 72% and 54% in groups B and E, respectively, which were significantly different (p < 0.009) (Fig. 1); the secondary patency rates at 3 years were 82% and 60%, respectively. The limb salvage rates at 3 years were 86% and 82%, respectively, showing no significant difference (Fig. 2). The survival rates at 5 years were 57% and 42%, respectively, with a significant difference between them.

### Table 1 Patients characteristics

|                | BY 119 cases 131 limbs | EV 31 cases 33 limbs | P value |
|----------------|------------------------|----------------------|---------|
| Age (mean)     | 46–89 (70)             | 47–89 (72)           | 0.093   |
| Sex            |                        |                      |         |
| Male/Female    | 99/20                  | 25/6                 | 1.000   |
| Fontaine       |                        |                      |         |
| III            | 63                     | 16                   | 0.888   |
| IV             | 68                     | 17                   | 0.888   |
| ABI            | 0.24 ± 0.21            | 0.38 ± 0.25          | 0.042   |

May, 1995–June, 2011, Kawasaki Medical School. ABI: ankle brachial pressure index; BY: bypass group; EV: endovascular therapy

### Table 2 Postoperative early complications and Hospital deaths

|                | BY          | EV          | P value |
|----------------|-------------|-------------|---------|
| Wound infection| 6 (5%)      | 0           | 0.446   |
| Bleeding       | 2 (1.6%)    | 0           | 1.000   |
| Cardiac failure| 1 (0.8%)    | 0           | 1.000   |
| G-I bleeding   | 1 (0.8%)    | 0           | 1.000   |
| Dissection     | 0 (0%)      | 3 (10%)     | 0.007   |
| Thrombosis     | 2 (1.6%)    | 1 (3%)      | 0.467   |
| Pneumonia      | 1 (1.6%)    | 0           | 1.000   |
| Prosthetic infection| 1 (1.6%) | 0           | 1.000   |
| Hospital death (rate) | 1 (0.8%) | 0 (%)      | 1.000   |

BY: bypass group; EV: endovascular therapy

### Table 3 Relationship between Goodney’s score and death at 2 years following bypass or EV

| Goodney’ score | BY | EV |
|----------------|----|----|
| 7              | 0  | 0  |
| 6              | 0  | 2 (2) (100%) |
| 5              | 1 (1) (100%) | 6 (5) (83%) |
| 4              | 13 (7) (54%) | 6 (4) (67%) |
| 3              | 45 (12) (27%) | 8 (2) (25%) |
| 2              | 52 (10) (19%) | 5 |
| 1              | 8 (1) (13%) | 4 |
| 0              | 0  | 0  |

BY: bypass group; EV: endovascular therapy; (): number of deaths; (%): death rates

### Discussion

In the treatment policy for critical limb ischemia, the first-line treatment is revascularization, such as endovascular treatment and bypass, as specified in TASC II, and the selection of endovascular treatment or bypass should be comprehensively decided based on the location and range of lesions, general condition, limb salvage rate, and prognosis of life.

In the 2011 American Heart Association (AHA) guidelines update, bypass is specified as the first-line treatment for lesions in the inguinal region or below for patients with a prognosis of life of 2 years or longer and a favorable autologous vein, based on the BASIL trial, and endovascular treatment is specified as the first-line treatment for patients for whom survival of 2 years or longer cannot be expected and no favorable autologous vein is available.

There are various evaluation methods for general condition. We used Goodney’s score because of its simplicity. Goodney, et al. investigated risk factors for death within one year after lower limb bypass in about 2000 patients, and identified that the most influential factor was emergency surgery, followed by dialysis, an age of 80 years old or older, the absence of the saphenous vein, critical limb ischemia, diabetes,
The limb salvage rates after 3 years were 86% and 82% in the bypass and endovascular treatment groups, respectively. Although the difference was not significant, the rate was higher in the bypass group. Pomposelli, et al.\(^5\) reported that the limb salvage rate at 5 years after bypass was 78%, and those reported by Shah, et al.\(^6\) and Higashi\(^7\) were 94%, whereas Iida, et al.\(^8\) reported that the rate at 3 years after endovascular treatment was 80%, Donas, et al.\(^9\) reported it to be 88.7% after 2 years, and Ferraresi, et al.\(^10\) reported it to be 93% after 3 years.

In the sub-analysis of the BASIL trial,\(^11\) the groups treated with bypass in the first treatment and after failure of endovascular treatment were compared, and the limb salvage rate was higher in the group treated with bypass in the first treatment, showing that endovascular treatment should be performed after fully investigating the indication, and it should not be easily selected.

Goodney, et al.\(^2\) prepared the prevent III risk score for critical limb ischemia treated with bypass in the inguinal region or below, and presented the limb salvage rate after one year based on the score. Dialysis, ulcerative necrosis, an age of 75 years old or older, and coronary arterial disease are scored as 4, 3, 2, and 1, respectively. The limb salvage rates of patients with low (3 or lower), medium (4–7), and high (8 or higher) scores were 86%, 74%, and 56%, respectively, showing that the score is useful to predict the limb salvage rate.

In our patients, the limb salvage rates at one year based on the prevent III score were 96%, 88%, and 66% in the low, medium, and high groups, respectively, showing a similar tendency. Thus, this evaluation method may be useful, and it was suggested that not only the treatment procedure but also background factors have a marked influence.

**Conclusion**

For critical limb ischemia with a lesion in the popliteal artery or below, the patency rate was higher in the bypass than in the endovascular treatment group, but no significant difference was noted in the limb salvage rate. Considering the vital prognosis, the indication of endovascular treatment at our department may be appropriate.
Disclosure Statement

Masaki and the other co-authors have no conflict of interest to declare.

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