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Original Article

Preoperative Non-ambulatory Status Predicts Poor Outcome after Below Knee Bypass Surgery

Kota Yamamoto, MD, PhD, Tadashi Kitaoka, MD, Harunobu Matsumoto, MD, Juno Deguchi, MD, PhD, and Osamu Sato, MD, PhD

Objective: **To identify the outcome of below knee bypass that focuses on the functional status and to investigate whether preoperative functional status can predict these outcomes.**
Materials and Methods: **One hundred and fifty one limbs in one hundred and thirty two patients that underwent below knee bypass between 2004 and 2008 were retrospectively reviewed. The patients were grouped as "ambulatory," "non-ambulatory transfer" and "non-ambulatory bedridden," according to their functional status. Clinical success was defined as the achievement of all of following end points; graft patency to wound healing, limb salvage for 1 year or until death, maintenance of ambulatory status for 1 year, and survival for 6 months. The effect of preoperative ambulatory status was analyzed.**
Results: **The overall primary and secondary graft patency, limb salvage and survival at 1 year were 76.3%, 81.8%, 89.1% and 84.1%, respectively. The overall success rate was 62.0%. Clinical success rates for the ambulatory and non-ambulatory groups were 75.6% and 34.9% (P = 0.0009, OR: 4.4; 95% CI: 1.8–10.6).**
Conclusions: **Bypass surgery is justified for maintaining the independent status of ambulatory patients. On the other hand, the high likelihood of poor outcomes for non-ambulatory patients must be considered before performing bypass surgery.**

Key words: below knee bypass, ambulatory status, clinical success rate, risk factors

Introduction

Due to an upward trend in the prevalence of risk factors for atherosclerosis, especially diabetes,[1] the prevalence of peripheral arterial disease (PAD) is estimated to be increasing in Japan over the last decade. This has led to an increase in the number of patients undergoing bypass surgery and radiological intervention. Despite these therapies, the main outcomes, such as patency and limb salvage, remain as described by Rutherford in 1997.[2]

Department of Vascular Surgery, Saitama Medical Center, Saitama Medical University, Kawagoe, Saitama, Japan

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Corresponding author: Kota Yamamoto, MD, PhD. Department of Vascular Surgery, Saitama Medical Center, Saitama Medical University, 1981 Kamoda, Kawagoe, Saitama 350-0844, Japan
Tel: +81-49-228-3462, Fax: +81-49-228-3462
E-mail: k-yamamo@tc4.so-net.ne.jp

Cardiovascular disease in patients with critical limb ischemia imposes obvious limitations on life expectancy. Thus, preserving functional status and minimizing complications after intervention for peripheral arterial occlusive disease are equally important to limb salvage and graft patency.

In this study, we examined the results of below-knee bypass based on various factors including ambulatory status and survival. And because we have focused on ambulatory status as one of the main outcome, this study also investigated whether preoperative ambulatory status affects the outcome of bypass surgery.

Materials and Methods

This study proceeded following the guidelines of the research ethics committee of our institution between January 2004 and December 2008. We obtained written, informed consent from patients with limb ischemia to

perform below-knee bypasses. As a basic rule, we performed bypass surgery on all patients visiting our hospital with ischemic symptoms due to peripheral arterial disease. If bypass surgeries were possible to perform, we would offer bypass surgeries regardless of the patients' mental status. We did not perform bypass surgery on patients who were regarded to be unable to tolerate the operation due to their medical comorbidities, had no recipient artery to perform a bypass, had infection or gangrene invading the site of anastomosis, had no vein usable as a graft, or refused to undergo the operation. Due to our policy, we did not perform any endovascular interventions on infrainguinal lesions.

The recorded preoperative characteristics were age, sex, hypertension, diabetes, renal failure, smoking status, serum albumin values, ejection fraction measured by transthoracic echocardiography as means of heart failure, sites of distal anastomosis and ambulatory status at 1 month before the onset of their ischemic symptoms. Patients were regarded as ambulatory if they could walk with or without a cane. As reported by Taylor, non-ambulatory patients were further classified as "non-ambulatory-transfer" if they could move into a wheelchair unassisted and the remaining patients were regarded as "non-ambulatory-bedridden."[3] For patients undergoing surgeries for bilateral limbs, data regarding the first surgery was used. When the surgery was performed simultaneously for both limbs, the more critical limb was analyzed.

A vein graft (reversed, non-reversed transposed or in-situ) was applied in all surgeries under total limb ischemia accomplished with a pneumatic tourniquet (non-dissection method).[4–6] Postoperative computed tomography (CT) or angiography was performed 1–2 weeks after surgery, and a second operation was performed when necessary. The patients were asked to attend the hospital at 1- to 2-month intervals after discharge so that the status of the operated limb could be recorded. The patency of the graft was assessed by pulsation and Duplex sonography.

The results of the bypass surgery were analyzed using traditional graft patency, limb salvage, survival rate and the factors introduced by Taylor.[3] A successful outcome was defined as the achievement of all of the following end points; graft patency to wound healing, limb salvage for 1 year or until death, maintenance of ambulatory status for 1 year and survival for 6 months. Transmetatarsal and toe amputations were regarded as limb salvage. Therefore, patients that were nonambulatory transfer preoperatively but nonambulatory bedridden postoperatively were regarded as a failure. Limb salvage was defined as the absence of lower limb shortening.

All data were analyzed using JMP 5.0 software (SAS Institute Inc.), and a P value of < 0.05 was considered significant in each analysis.

Results

Between January 2004 and December 2008, two hundred and two patients visited our hospital for critical limb ischemia. Below knee bypass was performed on 151 limbs in 132 patients, primary amputation was performed in 13 patients, and 57 patients were regarded as non-operable. As a result, the bypass surgery was performed in 65.3% of patients. Nineteen patients required bypass surgery for the contralateral limb simultaneously or later.

Of 132 patients, 85 (64.4%) were ambulatory, and 47 (35.6%) were non-ambulatory. **Table 1** shows the baseline characteristics of the 132 patients. As in Table 1, all patients were operated for symptoms of critical limb ischemia, but 20 of the 85 ambulatory patients were severe claudicants one month before the operation. These claudicants had at least rest pain by the time of operation, which may seem a rapid change in ischemic condition. This was probably possible because we were able to perform most of the operation, especially patients whose symptoms changed rapidly, within one to two weeks after the first visit. The median follow up period was 14.5 months. The overall rates of primary and secondary graft patency, limb salvage and survival at 1 year were 76.8%, 81.1%, 89.2% and 83.8%, respectively. The overall clinical success rate was 62.3%.

First, we performed univariate risk analysis on 132 patients regarding clinical success rate. As shown in **Table 2**, statistically significant factors were; age > 80, non-ambulatory status and gangrenous symptoms. Although not significant, smoking status tended to have some effect on clinical success rate. We then underwent multivariate analysis limited to these four factors. As in **Table 3**, the only significant factor was non-ambulatory status (P = 0.0005, OR: 5.6; 95% CI: 2.2–15.3).

Discussion

Due to the increasing prevalence of risk factors for cardiovascular disease,[1] it can be deduced that the prevalence of PAD is increasing in Japan, as in other countries. Infrainguinal bypass has been established as a treatment for PAD over the past few decades, and although the

Table 1 Baseline characteristics of 132 patients

Age (mean ± SD)		68.5 ± 12.1
Sex (Male : Female)		102 : 30
Diabetes		86 (65.2%)
Hypertension		45 (34.1%)
End stage renal disease		45 (34.1%)
Smoking		66 (50.0%)
Albumin (mean ± SD)		3.5 ± 0.6
Indication for operation	Rest pain	47 (35.7%)
	Ulcer	20 (15.2%)
	Gangrene ± infection	65 (49.2%)
Ambulatory status	Ambulatory	85 (64.4%)
	Non-ambulatory	47 (35.6%)
Low cardiac function (Ejection fraction < 50%)		19 (24.6%) (n = 77)
Distal anastomosis	Below knee popliteal	30 (22.7%)
	Posterior tibial	41 (31.1%)
	Anterior tibial	15 (11.4%)
	Tibiopereneal trunk	7 (5.3%)
	Peroneal	17 (12.9%)
	Dorsalis pedis	16 (12.1%)

Table 2 Univariate analysis for clinical success rate (n = 132)

Risk Factors		Clinical success rate		P value
		Factor present	Factor absent	
Age > 80		37.5%	66.3%	0.03
Male		66.3%	50.0%	0.12
Diabetes		60.0%	66.7%	0.48
Hypertension		52.6%	67.1%	0.14
End stage renal disease		55.0%	66.2%	0.24
Smoking		70.7%	53.6%	0.06
Albumin < 2.5		33.3%	63.9%	0.14
Non-ambulatory		32.4%	76.6%	< 0.0001
Gangrene ± infection		51.7%	73.2%	0.02
Low cardiac function		38.5%	45.7%	0.65
Distal anastomosis	Below knee popliteal		80.8%	0.14
	Posterior tibial		51.4%	
	Anterior tibial		53.8%	
	Tibiopereneal trunk		83.3%	
	Peroneal		53.3%	
	Dorsalis pedis		53.9%	
	Plantar		83.3%	

Table 3 Multivariate risk factor analysis for clinical success rate

	Odds ratio (95% CI)	P value
Age > 80	2.2 (0.6–7.9)	0.23
Smoking	1.7 (0.7–4.2)	0.23
Non-ambulatory	5.6 (2.2–15.3)	0.0005
Gangrene	1.3 (0.5–3.3)	0.61

status of endovascular treatment has increased, bypass surgery remains the treatment of first choice for lesions below the knee.

The outcomes of lower extremity bypass surgery are traditionally assessed as graft patency, limb salvage and patient survival. Many factors including anatomical disease extent, clinical presentation, and resource availability can influence these outcomes.[7] Despite the repeatedly documented ability of bypass surgery to achieve graft patency and limb salvage, legitimate concerns persist regarding the appropriate roles of these procedures.

One of the main concerns about bypass surgery is limited life expectancy, especially for patients with critical limb ischemia.[8] Given the evident limitations on life expectancy imposed by critical limb ischemia,[7] preserving functional status and minimizing complications after intervention for PAD are of equal importance to limb salvage and graft patency. Therefore, in addition to the traditional factors recommended by Rutherford,[2] we used Taylor's clinical success rate that included ambulatory status as a functional factor.[3] Using these tools, we showed that the outcome after 1 year is worse in functionally dependent patients. The clinical success rate was considerably poorer in the non-ambulatory than ambulatory patients (32.4% vs. 76.6%). We are convinced that this is not due to technical problems because our overall success rate of 62.2% was comparable with that reported by Taylor (44.4%).[3]

We were quite surprised that end-stage renal disease (ESRD) did not turn out to be a risk factor in our study. Due to the limited number of patients especially those with ESRD, this study can only say that the preoperative ambulatory status is more powerful risk factor compared with ESRD.

These findings indicate that ambulatory status is not only an outcome measure in bypass surgery, but also a preoperative risk factor that closely correlates with success rates. Crawford has also shown that preoperative functional status can predict perioperative outcomes (30-day morbidity and mortality) after infrainguinal bypass.[9]

Abou-Zamzam has reported that 99% of survivors who lived independently before surgery continued to do so after surgery, whereas only 4% of survivors who did not live independently before the surgery achieved independence thereafter.[10] Their study also concluded that preoperative non-ambulatory status and renal insufficiency or failure were independent predictors of death within 6 months. This report, together with our findings of better life expectancy for ambulatory patients (88.0% at 1 year) justifies performing bypass surgery on ambulatory patients to maintain their independence and ambulatory status.

On the other hand, these results also indicate a need for awareness of the poor outcomes of bypass surgery for non-ambulatory patients; however, this does not mean that primary amputation should be the first consideration for such patients. The potential effects of these strategies should be carefully compared before reaching a conclusion.

For example, the length of hospital stay and cost effectiveness should be considered. Chung found that wounds had not healed after 1 year in 25% of patients who had undergone infrainguinal bypass to treat critical limb ischemia.[11] These patients might remain in hospital longer and thus miss the opportunity to be fitted with an appropriate prosthesis.

Primary amputation is by no means a safe remedy. Although not a randomized control trial, Sottiurai found that 30-day mortality rates of patients after femorodistal revascularization, below-knee amputations and above-knee (primary) amputations were 2.1%, 6.3% and 13.3%, respectively.[12]

Lastly, primary amputation does not improve the outcomes of non-ambulatory patients. Taylor identified non-ambulatory status as a preoperative risk factor for an unsuccessful outcome after major lower limb amputation.[13]

Conclusion

Due to relatively high success and survival rates, bypass surgery is justified for maintaining the independent status of ambulatory patients. On the other hand, for the non- ambulatory patients, in addition to the low probability of regaining ambulatory status, the high likelihood of poor general outcomes must be considered. Further studies should compare bypass surgery and primary amputation to determine a better strategy for treating PAD.

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