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The effect of peripheral vascular interventions on future infrainguinal bypass

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ABSTRACT

Objectives: This study aims to investigate the effect of peripheral vascular interventions (PVIs) on future infrainguinal bypass (IIB).

Patients and methods: Between January 2008 and January 2018, a total of 152 patients (110 males, 42 females; mean age 60.1±8.7 years; range, 38 to 81 years) who underwent lower extremity bypass surgery in our clinic with complete pre- and postoperative follow-up data were retrospectively analyzed using the hospital records. A successful percutaneous intervention was defined as the symptomatic improvement for one month after the procedure and these patients included in the study group (PVI group, n=53). Control group included patients who underwent open bypass without any prior endovascular intervention (IIB group, n=98). Pre-, intra-, and postoperative data were recorded.

Results: Although critical leg ischemia was more common in the PVI group (p=0.03), the difference was not statistically significant compared to the preoperative data. The below-knee bypass was performed more frequently in the PVI group (41.5% vs. 19.2%, p<0.01). During the follow-up period, the rate of restenosis of the bypass graft was similar between the two groups, although the rate of minor amputations was significantly higher in the PVI group (p=0.04). There was a 1.6-fold increase in the relative risk of restenosis with previous PVI.

Conclusion: Our study results suggest that PVIs result in a decrease in lower limb vascular reserve, particularly at the distal arteriolar level. In our study, the presence of more critical leg ischemia and high minor amputation rate in the PVI group support this proposal. In addition, reduced vascular reserve has the potential to adversely affect the future bypass.

Keywords: Arterial bypass; endovascular procedures; infrainguinal bypass; peripheral vascular disease.

Despite well-known morbidity and mortality outcomes of infrainguinal bypass (IIB) in lower limb arterial stenosis or occlusion,[1-3] open surgery has become a less popular choice in most centers worldwide. Peripheral vascular intervention (PVI) with more favorable initial results has been used as the first-line treatment. One of the primary endpoints of the two treatment options is amputation-free survival which does not significantly differ between the procedures, as shown in the Bypass versus Angioplasty in Severe Ischemia of the Leg (BASIL) trial.[4]

Although the expected initial benefit of PVI is mostly appreciated, its potential impact on limb salvage in the long-term still remains unclear. To date, several reports have suggested that uncomplicated and failed endovascular interventions of the femoral artery do not compromise subsequent surgery and long-term outcomes, some others have demonstrated that a prior failed ipsilateral infrainguinal ipsilateral PVI has a negative prognostic effect on subsequent lower extremity bypass.[5-7] Considering PVI in favor of vascular trauma and alteration in the vascular reserve, it may be reasonable to examine the simultaneous results of prior ipsilateral successful, eventually failed, PVI and index IIB procedures. In the present study, we aimed to investigate the effect of PVIs on future IIB procedures.

PATIENTS AND METHODS

We retrospectively screened the surgery records of Cardiovascular Surgery Department of Gaziantep University, Faculty of Medicine between January 2008 and January 2018. Amongst 209 patients who

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underwent IIB, a total of 152 patients (110 males, 42 females; mean age 60.1±8.7 years; range, 38 to 81 years) who underwent lower extremity bypass surgery in our clinic with complete pre- and postoperative follow-up data were retrospectively analyzed. The study group consisted of the patients with a prior successful and eventually failed PVI (PVI group, n=53), while the control group consisted of the patients who had surgery without prior PVI (IIB group, n=98). Using medical files of the patients, we meticulously analyzed the past medical history section to identify previous PVI and its results. The successful prior PVI was defined as the relief of symptoms for at least one month following PVI and medical records indicating optimal recanalization with or without stenting. The patients referred to surgery within the following 30 days after PVI were excluded. A written informed consent was obtained from each patient. The study protocol was approved by the Gaziantep University, Faculty of Medicine Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Since the patients included in both groups had peripheral arterial disease which has a progressive nature, our null hypothesis was that both groups would have similar restenosis rates. We tested this probability in the present study. Although the design of the study was retrospective in nature, we used the patients' files of the tertiary health center, which has been a referral center for decades in this region. This factor increased the probability of covering largest patient population with peripheral arterial disease in this territory with a more powerful analysis.

Comorbidities were as follows: diabetes mellitus (DM, on maintenance treatment with oral antidiabetics or with insulin), coronary artery disease (CAD, electrocardiographic changes consistent with previous myocardial infarction, history of angina, myocardial infarction, or prior coronary intervention), hypertension (HT, on oral antihypertensive treatment), hyperlipidemia (HL, low-density lipoprotein ≥100 mg/dL, or on oral medication) and chronic renal disease (CRF, serum creatinine ≥2 mg/dL and/or on maintenance dialysis). Graft preference and distal target vessels (below-knee versus above-knee) were recorded as the surgical data. Postoperative follow-up records were scanned to evaluate graft patency, secondary interventions, level of amputation, and mortality rates. Below-ankle amputation was defined as minor amputation and above this level as major amputation.

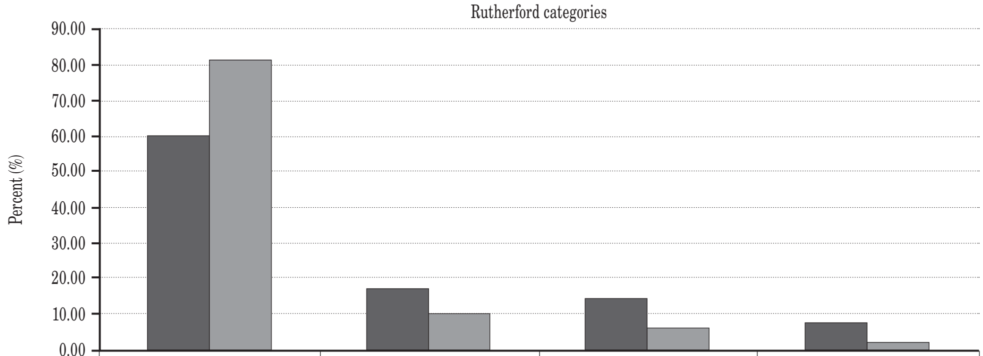
Statistical analysis

Statistical analyses were performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean ± standard deviation (SD) and in number and frequency. The univariate analyses to identify variables associated with patient outcomes was performed using the chi-square (for comparison of the presence of HT, DM, HL, CAD, cardiac insufficiency, chronic obstructive

Table 1. Preoperative demographic characteristics and risk factors

	PVI group (n=53)			IIB group (n=98)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Age (year)			59.4±10.2			60.5±7.9	0.45
Gender							0.81
Male	39	73.6		71	71.7		
Female	14	26.4		28	28.3		
Hypertension	17	32.1		32	32.3		0.97
Diabetes mellitus	11	20.8		24	24.2		0.63
Hyperlipidemia	19	35.8		35	35.4		0.95
Coronary artery disease	19	38.8		39	39.4		0.67
Cardiac insufficiency	9	17		15	15.2		0.77
Chronic obtructive pulmonary disease	8	15.1		12	12.1		0.60
Chronic renal failure	7	13.2		9	9.1		0.43
Rutherford category							0.03
III	32	60.4		81	81.8		
IV	9	17		10	10.1		
V	8	15.1		8	6.1		
VI	4	7.5		2	2		

PVI: Peripheral vascular interventions; IIB: Infrainguinal bypass; SD: Standard deviation.



	Category III	Category IV	Category V	Category VI
PVI	60.40%	17.00%	15.10%	7.50%
IIB	81.80%	10.10%	6.10%	2.00%

Figure 1. Distribution of patients according to the Rutherford classification.

pulmonary disease (COPD), CRF, Rutherford category, statin use, beta-blocker use, graft preference, distal target vessel, need for fibrinolytics, need for angiography, minor amputation, major amputation, mortality rate, and prescribed drugs) and Student's t-tests (for comparison of age and follow-up time), where applicable. In the multivariate analysis, possible factors identified with univariate analyses were further included in the binary logistic regression analysis to examine independent predictors of patient outcomes. The Kaplan-Meier survival estimates were used to calculate the graft patency and mortality rates. A p value of less than 0.05 was considered statistically significant.

RESULTS

Demographic factors were almost similar in both two groups (Table 1). However, there was a significant

Table 2. Operative and follow-up data

	PVI group (n=53)			IIB group (n=98)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Graft							0.96
Saphenous vein	35	66		68	68.7		
Polytetrafluoroethylene	16	30.2		28	28.3		
Dacron	1	1.9		2	2		
Biologic	1	1.9		1	1		
Distal target vessel							<0.01
Below-knee	22	41.5		19	19.2		
Above-knee	31	58.5		80	80.8		
Fibrinolytic treatment	9	17		14	14.1		0.64
Peripheral angiography	30	56.6		37	37.4		0.02
Restenosis	20	37.7		23	23.2		0.06
Minor amputation	14	26.4		13	13.1		0.04
Major amputation	5	9.4		6	6.1		0.44
Drugs							
Statin	20	37.7		46	46.5		0.30
Beta-blocker	15	28.3		35	35.4		0.38
Acetyl salicylic acid	37	68.8		65	65.7		0.60
Clopidogrel	42	79.2		78	78.8		0.95
Mortality	14	26.4		22	22.2		0.56
Follow-up (month)			52.6±26.1			61.8±24.5	0.03

PVI: Peripheral vascular interventions; IIB: Infrainguinal bypass; SD: Standard deviation.

Table 3. Logistic regression analysis			
Risk factors	*p*	Relative risk	95%CI
Prior peripheral vascular intervention	0.04	1.602	1.105-4.214
Critical leg ischemia	<0.01	4.165	1.461-11.875
Chronic renal failure	0.04	4.949	1.075-22.778

CI: Confidence interval.

difference in the Rutherford categories (p=0.027). This difference was tested via transforming those four variables into four-chamber chi-square test and it was found that a higher number of patients in the IIB group was in the Rutherford Category III than the study group, indicating that a higher number of patients in the IPV group had critical leg ischemia (CLI) (Figure 1).

The operative and follow-up outcomes are listed in Table 2. Although the types of grafts used during bypass surgery were similar in both groups, below-knee arteries were preferred more frequently in the PVI group than the IIB group as distal target vessels (22 legs, 41.5% and 19 legs, 19.2% respectively, p=0.003). Considering follow-up data, both groups had similar rates of restenosis, need for fibrinolytic treatment, and major amputation. However, the PVI group significantly more frequently needed for angiography (56.6% vs. 37.4%, p=0.023) with a higher minor amputation rate (p=0.041) in the following >5 years. In addition, prescriptions for the maintenance of the graft patency were similar. Although the PVI group had higher major amputation and mortality rates, it did not significantly differ between the groups.

Two covariates which were found to be significant in the univariate analysis (p<0.2) were included in the multivariate model with previous PVI. Diabetes mellitus and CRF, which are well-known potential risk factors for atherosclerotic peripheral arterial disease, were also attached to the model. In the multivariate analysis, five independent predictors of clinical outcome stenosis were identified. The previous PCI was associated with the 1.6-fold increase in the odds of stenosis compared to those without previous PVI. The presence of CLI (Rutherford Category ≥IV) and CRF were also associated with stenosis (Table 3).

Survival analysis was made using the Kaplan-Meier plots to estimate the graft patency and mortality rates. Accordingly, the graft patency rate was significantly higher in the IIB group than the IPV group (76.8% vs. 62.3%, p=0.014). However, both groups had similar survival rates at the end of the follow-up period (73.6% vs. 77.8%, p=0.275).

DISCUSSION

The present study demonstrated that initially successful PVI was an important predictor of poor outcomes for a future ipsilateral IIB for atherosclerotic stenosis or occlusion of the lower extremity. In our patient population, failed prior PVI was associated with a 1.6-fold increase in the risk of restenosis for future bypass. In addition, the patients with previous PVI had more CLI following restenosis and they needed longer grafts. These results suggest that PVI itself prepares the leg for a poor pre- and postoperative status in the long-term. Considering a higher minor amputation rate in the PVI group rather than major amputations, we suggest that preconditioning have a higher effect on small arteries than large ones.

There are some reports supporting our results and indicating that previous PVI has a negative impact on future bypass. Varu et al.[8] suggested that the degree of peripheral ischemia became worsened after stent failure, and there were more complications, bypass failures, and amputations after bypass grafting for stent failure compared to the patients undergoing primary bypass surgery for CLI. Some others also reported that biology of percutaneous interventions of long lesions (greater length of arterial injury and inflammation) and significant residual stenosis (less tolerance of late lumen loss) were critical for restenosis.[9] In the present study, we observed that the failure of previous intravascular recanalization was associated with sudden-onset of CLI, thereby leading to poor preoperative status of the leg. In the multivariate analysis, we consistently showed that preoperative CLI increased the risk of restenosis by 4.1 fold.

The extent of local arterial injury and inflammation of distal segments on the femoral artery with percutaneous interventions possibly cause to target more distal arterial bed in subsequent bypass procedures and, eventually longer grafts. This can be attributed to the fact that atherosclerosis is a progressive disease and long lesions are suggestive of more disseminated atherosclerosis.[10] It is also well-known that insidious onset of main artery stenosis prepares the distal limb to protect from ischemia by flow redirection and dilatation of collateral arteries.[11] In their study, Desai et al.[12] reported that graft implanted to the blind distal arterial bed with only collateral circulation could achieve long-term patency. Therefore, we believe that distal collateral artery durability together with distal main artery integrity contributes to the graft patency.

It is not uncommon to see disappearing collaterals nearby the total occlusion on the femoral artery during balloon dilatation or stenting procedure; however, there is lack of information in the literature about the impact of those collaterals on leg ischemia. The issue about collaterals may be due to the redirection of blood to decreased resistance in the main arterial lumen after recanalization and maybe partly due to the spread of the crashed plaque to the origin of a collateral artery. Also, crushing the plaque can produce small particles which are prone to move to the distal arteriolar bed. Do those changes in collateral and distal arterioles have no effect on the limb salvage?

In addition to local intrinsic vascular alterations induced by endovascular trauma and disease progression, there may be other factors having an influence on poor outcomes. Before routine use of embolism protection devices during carotid artery stenting, it was reported that neurological events associated with the embolization of particulate materials in the cerebral circulation occurred in about 5% of cases.[13] Later on, proactive use of embolism protection devices has become a well-established procedure to avoid highly symptomatic neurological consequences and to preserve arterial reserve of the cerebral circulation.[14] Although lower limb PVI has been more frequently applied than carotid stenting, embolism protection during PVI for lower extremity arteries has gained not much interest, probably due to high compliance of the leg to microembolism in the short- and mid-term.[11,15]

Although well-established proposals have been presented for embolism protection for carotid stenting, we believe that there is a limited number of data in the literature to elucidate potential harms of microembolism to the limited arterial reserve during lower extremity PVI. Fortunately, Kudo et al.[16] reported detection of microembolization with ultrasonography during percutaneous intervention. Since atherosclerosis narrows distal arteries as well, such a microembolism together with compromised collaterals may affect the distal runoff and eventually future graft patency. Nonetheless, a controversy still remains regarding the magnitude of the effect of such microembolism. We believe that indirect evaluation of the results of PVI with further studies would be valuable. Considering the outcomes of a percutaneous intervention to the lower extremity arteries, it is reasonable to propose that the arterial bed reservoir can decrease to an unknown level following PVI. Clamping the artery during open bypass may cause the same particles; however, at least, we hope that retrograde bleeding removes embolic debris. Of note, the pedal arteries with small diameters seem to be more susceptible to such a decrease in collateral reserve and microembolism. It would be rational to explain major discrepancies in minor amputation rates in our PVI group.

Patients characteristics, adherence to medication, and risk factors obviously have an effect on the severity of the disease process. Neglecting the potential harm of PVI to distal arterioles and collaterals may suggest that all these risk factors have an unfavorable effect on the patency of treated arterial segment with distal arterial structures. Contrary to these hypotheses, there are some reports suggesting that, in contrast to the impact of prior ipsilateral PVI or bypass, contralateral PVI or bypass does not affect the risk of either amputation or graft occlusion.[7]

The infrainguinal revascularization of failed PVI group needed more distal target vessel anastomoses and longer grafts than the primary bypass. However, the saphenous vein preference, as the best graft in lower limb bypass, did not differ between PVI and IIB groups. Therefore, considering graft length rather than graft quality seems to be another reasonable cause for subsequent failure. It is needed to clearly demonstrate that, whether the below-knee grafts are affected by mechanical high mobility of knee joint or intrinsic pathophysiological factors of long graft have more influence on failure.

Our study has several limitations. Most notably, our patients in the PVI group underwent prior percutaneous interventions which resulted in recanalization; however, we have no data on the type of procedure, such as atherectomy, balloon angioplasty, stenting, or combination of these. The reason for these shortcomings occurred due to referral of most patients from other centers for surgery after a failed PVI. These patients account for 60.4% of the PVI group. Additionally, the lack of detailed surgical information is another limitation. Although we cautiously evaluated the surgery notes, we found scant information about criteria to standardize distal target selection and graft preference.

In conclusion, PVI to lower limb arteries has favorable short-term results with low mortality and morbidity rates. However, affected collaterals and distal arterioles during PVI procedures may decrease the arterial reserve in a long period of time, and those with a progressive nature of atherosclerosis have a negative impact on the future bypass.

Declaration of conflicting interests

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