FACTORS AFFECTING QUALITY OF LIFE AFTER BYPASS GRAFTING IN CRITICAL LEG ISCHEMIA

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ABSTRACT

Objective: *The aim of the study was to investigate health-related quality of life (QOL) an the impact of demographic factors after bypass grafting (BG) in patients with critical limb ischemia (CLI).*

Material and Method: *A total of 33 patients with CLI underwent BG over a period of 18 months. Quality of life data were collected before and three months after BG with the Short-Form 36 (SF-36) questionnaire. Demographic data and information about the disease presentation were evaluated with another form.*

Results: *There were 32 male patients and one female patient. The SF-36 questionnaire was completed by all patients before and after BG. There was an improvement in all categories of QOL, and statistically significant changes were observed in the pain and physical role restriction subdomains after the operation (p=0.020 and p=0.012, respectively). Education level was found to be associated with post-operative pain. The attitude of the patient after diagnosis (quitting smoking, obeying diet and regularly taking medicine) affected post-operative physical function, energy, general health and emotional role restriction. Proximal artery interventions (aorto-femoral, ilio-femoraland cross-femoral) resulted in more improvements in pain and mental health subdomains than distal interventions (femoropopliteal and crural) (p=0.027 and p=0.017, respectively).*

Conclusion: *Most patients with CLI smoked and had low or intermediate income. Pain and physical role restriction, which are subdomains of QOL, were improved by BG, and post-operative pain was affected by the education level of the patient. Proximal interventions were related with better QOL.*

Keywords: *Peripheral arterial disease, SF-36, quality of life, bypass grafting.* **Nobel Med 2017; 13(2): 52-56**

KRİTİK BACAK İSKEMİSİNDE BYPASS GREFT UYGULANMASI SONRASI YAŞAM KALİTESİNİ ETKİLEYEN FAKTÖRLER

ÖZET

Amaç: Kritik bacak iskemisi (KBİ) olan hastaların bypass greft uygulanması (BG) sonrası yaşam kalitelerinin ve bunu etkileyen demografik faktörlerin incelenmesi amaçlandı.

Materyal ve Metot: KBI nedeni ile alt ekstremite BG uygulanan 33 hasta 18 aylık süre içerisinde operasyon öncesi ve 3 ay sonrası uygulanan SF-36 yaşam kalitesi ölçeği ile değerlendirildi. Demografik veriler ve hastalığın süreci ile ilgili bilgiler ayrı bir soru formu ile araştırıldı.

Bulgular: Hastaların 32'si erkek, biri kadındı. Bypass greft öncesi ve sonrası olguların tamamına SF-36 uygulandı. Yaşam kalitesi ölçeğinin tüm alt gruplarında operasyon sonrası iyileşme görülürken, ağrı ve fiziksel rol kısıtlaması alt gruplarında bu iyileşme anlamlıydı (p=0,020, p=0,012). Eğitim düzeyi post-operatif ağrı ile ilişkili bulundu. Hastanın tanı aldıktan sonra tutumu (sigarayı bırakma, düzenli ilaç kullanma, diyete uyma) operasyon sonrası fiziksel fonksiyon, enerji, genel sağlık ve duygusal rol kısıtlılığını etkiliyordu. Proksimal girişimlerin (aorto-femoral, cross-femoral, ilio-femoral) ağrı ve mental durum üzerine etkisi distal girişimlerden (femoro-popliteal, krural) daha fazlaydı (p=0,027, p=0,017).

Sonuç: Kritik bacak iskemisi olan hastaların çoğunda sigara kullanımı, orta veya düşük gelir düzeyi görülüyordu. Yaşam kalitesi ölçeğinin alt grupları olan ağrı ve fiziksel rol kısıtlılığı bypass greft sonrası iyileşiyor ve ağrı alt grubu hastanın eğitim düzeyinden etkileniyordu. Proksimal bypass operasyonlarının ağrı ve mental sağlık skorlarını düzeltmede distal girişimlere göre daha etkili olduğu saptandı.

Anahtar kelimeler: Periferik arter hastalığı, SF-36, yaşam kalitesi, bypass greft. **Nobel Med 2017; 13(2): 52-56**

INTRODUCTION

Peripheral arterial disease may be asymptomatic or may have clinical manifestations associated with a significant reduction in quality of life.[1]

Chronic critical limb ischemia (CLI), defined as rest pain longer than two weeks, ulcers or tissue loss attributed to arterial occlusive disease is associated with loss of both limb and life. Therapeutic goals in treating patients with CLI include reducing cardiovascular risk factors, relieving ischemic pain, healing ulcers, preventing major amputation, improving quality of life (QOL) and increasing survival.[2]

Intermittent claudication is uncommon in patients younger than 55 years old, affecting less than 1% of the population, but its prevalence increases sharply to 5% in the age group of 55-74 years old.[2,3] From the patient's perspective, the QOL of claudicants centers on their discomfort during walking, whereas patients with CLI are concerned with rest pain and the risk of limb amputation.[4]

Revascularization using the bypass grafting technique is the optimal treatment for CLI. Traditional measures of the outcome of intervention are as follows: graft patency, limb salvage rates, and patient survival rates. Leg-specific symptoms cause morbidity by affecting pain-free mobility, functional performance, and quality of life.[5,6]

The term 'quality of life' refers to the physical, psychological and social domains of health, which are considered distinct areas that are influenced by a person's experiences, beliefs, expectations, and perceptions. The SF-36 questionnaire is a generic QOL tool that contains 36 questions, producing a health profile in eight different domains, namely physical function, role limitation due to physical state, bodily pain, general health, vitality, social function and role limitation due to emotional state, which are rated on a scale from 0 (worst possible health) to 100 (best possible health). The quality of life assessment measures changes in physical, functional, mental and social health to evaluate the human and financial costs and benefits of new programs and interventions.[5-7]

There are several studies reporting improvements in QOL scores after successful bypass grafting for CLI at a maximum of 2 years of follow-up.[8,9]

The objective of this prospective study was to assess short-term changes in QOL in patients with CLI after bypass grafting.

MATERIAL AND METHOD

Patients with CLI who were admitted to a single academic vascular surgery unit of a university hospital were recruited to this study during 18 months between May 2013 and December 2014.

The exclusion criterion was inability to complete the questionnaire due to impairment of function (i.e.: confusion or dementia). Patients were considered confused if they were disoriented in person, place and time or if during the informed consent process,

Table 1. Mean overall SF-36 QOL questionnaire scores for all health domains before and 3 months after bypass grafting

SF-36	Pre-op	3 months post-op	*p*
Pain	14.17±24.29	36.67±40.86	0.012*
PRR	37.83±31.23	58.08±31.28	0.020*
Physical Function	43.47±23.70	50.02±25.97	0.254
ERR	32.32±33.83	40.17±41.27	0.517
Energy	43.27±22.91	48.33±23.32	0.596
Mental Health	59.15±20.90	64.00±24.16	0.198
SRR	54.70±33.38	59.92±31.83	0.665
General Health	51.36±19.09	56.33±21.23	0.373

***:** Significance level $p<0.05$, **PRR:** physical role restriction, **ERR:** emotional role restriction, and **SRR:** social role restriction.
Wilcoxon rank test

Table 2. Demographic features of the patients

	n	%
Gender		
Female	1	3
Male	32	97
Education		
≤Primary	24	72.7
≥Highschool	9	27.3
Smoking		
Yes	4	12.1
No	3	9.1
Quit	26	78.8
Work Status		
Retired	15	45.5
Working	10	30.3
Not work	13	24.2
Income		
Intermediate	25	75.8
Low	8	24.2

they were not able to understand the nature of the study.[6] Patients with other self-limiting conditions (such as active cancer) and severe mobility problems (such as major limb amputations, wheel-chair use and hemiplegia) were also excluded.[10] The inclusion criteria included speaking Turkish and being able to comply with simple study protocol instructions.

There were 33 patients and only one of them was female. All the patients were physically examined, and their ankle-brachial indexes (ABIs) were measured. They were administered the SF-36 questionnaire with the face-to-face interview technique before surgery. Another questionnaire was completed regarding demographic data and information on the presentation of the disease, including onset symptoms, rest pain, current symptoms, other sites of atherosclerotic disease, medications, history of amputation and previous admittance. A second interview was carried out three months after the first one either personally, via posting the questionnaire to the participants or via a telephone call.

Distal bypass (crural and femoropopliteal) was performed on 51% of the patients (n=17), and proximal bypass (aorto-femoral, cross-femoral and ilio-femoral) was performed on 49% of the patients (n=16).

The ethical approval for the study was obtained from the Istanbul University Ethics Committee (No:1, protocol No:83045809/913). Informed consent was received from all the patients before involvement in the study.

Statistical Analysis

All analyses were carried out with SPSS 20 for Windows. The Wilcoxon test was used to compare the SF-36 questionnaire scores before and after the operation. For the dichotomic comparison of subgroups (symptoms, comorbid diseases, etc.), the Mann-Whitney U test was used; for comparisons of three or more groups (education level, number of hospitalizations, etc.) the Kruskal-Wallis test was used. Statistical significance was considered at the level of $p<0.05$.

RESULT

The age of the patients was between 40-79 years old (mean: 59.06±9.94). There were 32 male patients and one female patient. Their body mass index (BMI) was between 17 and 38 (mean: 26.24±4.50) (Table 1). The mean time interval since diagnosis was 2 months at the time of hospitalization.

The mean ABI of the patients before surgery was 0.55±0.07, and it was 0.67±0.08 after surgery. The increase in ABI was 22%, and the difference was statistically significant ($p<0.05$).

All of the domains in the SF-36 questionnaire were improved while the pain and physical role restriction scores were significantly improved after BG ($p=0.020$ and $p=0.012$, respectively) (Table 2).

Proximal artery interventions were more effective at improving the pain and mental health subgroups of the SF-36 questionnaire than interventions of the distal arteries ($p=0.027$ and $p=0.017$, respectively).

Pre-operative pain and energy level were affected by BMI ($p=0.038$ and $p=0.054$, respectively). Post-operative pain was associated with low education level

(p=0.036). Becoming educated about the disease and the source of education affected general preoperative health (p=0.032 and p=0.030, respectively).

The previous number of hospitalizations was related to preoperative mental health (p<0.001) and social role restriction (p=0.044).

Pain with walking was related to preoperative social role restriction (p=0.044) and post-operative physical function (p=0.01). Tingling of the feet was associated with preoperative emotional and social role restriction (p<0.001 and p=0.01, respectively); physical function (p=0.031); mental health (p=0.017); post-operative physical function and general health (p<0.001 and p=0.003, respectively). Foot ulcer was associated with preoperative and post-operative emotional role restriction (p=0.024 and p=0.05, respectively). Leg or foot cramps were associated with preoperative emotional role restriction (p=0.034). Night pain was associated with preoperative social role restriction (p=0.007) (Table 3).

The attitude of the patient after diagnosis (obeying diet, quitting smoking and making regular visits to doctor) affected post-operative physical function (p=0.003), emotional role restriction (p=0.007), energy (p=0.035) and general health (p=0.008).

Hypertension as a comorbid disease was associated with preoperative impaired physical function (p=0.004) and post-operative mental health (p=0.025). Coronary artery disease was related to preoperative impaired physical function (p=0.001), social role restriction (p=0.119) and post-operative physical function (p=0.006). Diabetes as a comorbid disease was associated with preoperative emotional role restriction (p=0.04). Hyperlipidemia was associated with post-operative physical function (p=0.028), emotional role restriction (p=0.022) and mental health (p=0.031) (Table 3).

Table 3. The frequency of complaints and co-morbidities

Comorbidity	**Frequency (%)**
Diabetes	48.5
Hypertension	42.4
Hyperlipidemia	39.4
Coronary artery disease	48.5
Disease Complaints	**Frequency (%)**
Pain with walking	75.8
Night pain	45.5
Tingling of the feet	60.6
Foot Ulcer	30.3
Leg cramps	78.8

DISCUSSION

The patient profile of CLI included being retired, smoking (90%), with low or intermediate income and with primary or lower education. Approximately 50% of the patients had at least one concomitant chronic atherosclerotic disease.

The results of our study show a positive influence of bypass grafting on the QOL of patients with CLI. All 8 domains of the SF-36 questionnaire were improved. The highest impact of bypass treatment on QOL scores was observed for the physical components of the SF-36 questionnaire physical role restriction and bodily pain, and the difference was statistically significant. Patients with high-school or higher education complained of pain less than the patients with lower levels of education.

This observation is in concordance with the results of Landy *et al*., Klevsgard *et al*., Wann-Hansson *et al*. and Engelhard *et al*.[11-14]

In Landry's study assessing quality of life after revascularization, 18 patients (aged 65±11 years) were observed for four months after lower extremity bypass for CLI, and the study revealed a significant improvement in bodily pain (p=0.011). Another study conducted in Sweden reported that in 80 patients, 40 with CLI and 40 with claudication, the SF-36 questionnaire scores revealed decreased bodily pain and improvements in physical functioning for patients with CLI, whereas the Nottingham Health Profile (NHP) demonstrated a significant abatement of pain and an improvement in physical mobility and isolation. This study concluded that the NHP better discriminated among levels of ischemia and was more responsive in detecting quality of life changes than the SF-36 questionnaire. A different study by the same group also confirmed this finding.

Another study by Wann-Hansson *et al*. reported that in 62 patients with CLI, an improvement in pain and sleep was observed with NHP 6 months, 12 months and 4 years after bypass grafting. This study concluded that CLI patients were older, had more co-morbidities and had a lower quality of life than patients with claudication.[11-13]

In a German study by Engelhardt *et al*., 86 patients (72% male) were assessed by the SF-36 questionnaire before and 6 months after infrageniculate bypass, and they found that health-related QOL (HRQOL) was significantly improved in all eight dimensions of the SF-36 questionnaire, but the improvement was significantly less in the diabetes group.[14]

Tretinyak *et al*. measured QOL with the SF-36 questionnaire in 46 patients with CLI who were undergoing revascularization with bypass grafting. The patients reported a mild improvement in functional status and overall HRQuOL.[15]

Deutschmann *et al*. stated that a possible explanation for the improvement in pain may be that the main effect of the bypass grafting is the reduction of pain and a subsequent increase in the pain-free walking distance. In this study, it was also observed that emotional components are highly influenced by significant comorbidities, such as hypertension, hyperlipidemia and diabetes mellitus, which is in concordance with our findings.[1]

In Keeling's study, there was no significant difference in the improvement of QOL scores for the two lesion sites (aorto-iliac and femoropopliteal) in any of the nine health domains despite stating that they expected more improvements after bypass operations at proximal lesions than at distal lesions since the former limits QOL more severely.[16] Deutschmann *et al*. also did not observe significant differences in the SF-36 questionnaire scores between interventions of the crural arteries and interventions of the femoropopliteal or iliac arteries. In our current study, proximal interventions were associated with better SF-36 questionnaire outcomes in the pain and mental health domains than distal interventions.

In this study, patients with CLI benefited from bypass grafting regarding the pain and physical role restriction subgroups of the SF-36 questionnaire. This is in agreement with the literature. The new dimension added by the findings of our study to this result may be that post-operative pain was associated with the level of education. Higher education resulted in fewer complaints of pain. Another significant finding was that proximal artery interventions lead to more improvements in the pain and mental health domains than distal artery interventions.

There are limitations of the study regarding gender and the number of patients. It was not possible to evaluate gender differences in the presentation of the disease and in QOL since there was only one female patient.

Many patients with CLI are older and many are frail with limited mobility; therefore, optimizing the efficacy of arterial intervention and keeping these patients ambulatory are important factors in retaining an independent life style and QOL.[17]

Larger studies with larger patient cohorts are necessary to investigate the effect of arterial bypass operations on QOL and related factors; additionally, the studies should be performed with patients of both genders with different assessment methods.

*The authors declare that there are no conflicts of interest.

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REFERENCES

1. Deutschmann HA, Schoellnast H, Temmel W, et al. Endoluminal therapy in patients with peripheral arterial disease: Prospective assessment of quality of life in 190 patients. AJR 2007; 188: 169-175.
2. Slovut DP, Sullivan TM. Critical limb ischemia: medical and surgical management. Vasc Med 2008; 13: 281-291.
3. Wann-Hansson C, Hallberg IR, Risberg B, Lundell A, Klevsgard R. Health related quality of life after revascularization for peripheral arterial occlusive disease: long term follow-up. J Adv Nurs 2005; 51: 227-235.
4. Serrano H, Martin C. Peripheral artery disease, pathophysiology, diagnosis and treatment. Rev Esp Cardiol 2007; 60: 969-982.
5. Kinlay S.Outcomes for clinical studies assessing drug and revascularization therapies for claudication and critical limb ischemia in peripheral artery disease. Circulation 2013;127:1241-1250. doi:10.1161/CIRCULATIONAHA.112.001232.
6. Kumar BN, Gambhir RP. Critical limb ischemia-need to look beyond limb salvage. Ann Vasc Surg 2011; 25: 873-877.
7. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). Conceptual framework and item selection. Med Care 1992; 30: 473-483
8. Moneta GL, Landry GJ, Nguyen LL. Does lower-extremity bypass improve quality of life? Is it cost effective? Semin Vasc Surg 2009; 22: 275-280.
9. Donker J, de Vries J, Ho GH, et al. Review: Quality of life in lower limb perpheral vascular surgery. Vascular 2016; 24: 88-95. doi: 10.1177/1708538115578961
10. Gohil RA, Mockford KA, Mazari FA, et al. Percutaneous transluminal angioplasty results in improved physical function but not balance in patients with intermittent claudication. J Vasc Surg 2013; 58: 1533-1539.
11. Landry GJ, NO Esmonde, Lewis JR, et al. Objective measurement of lower extremity function and quality of life after surgical revascularization for critical lower extremity ischemia. J Vasc Surg 2014; 60:136-142.
12. Engelhardt M, Bruijnen H, Scharmer C, Jezdinsky N, Wolfle K. Improvement of quality of life six months after infrageniculate bypass surgery: Diabetic patients benefit less than non-diabetic patients Eur J Vasc Endovasc Surg 2006; 32: 182–187.
13. Wann-Hansson C, Hallberg IR, Risberg B, Klevsgard R. A comparison of the Nottingham Health Profile and Short Form 36 Health survey in patients with chronic lower limb ischaemia in a longitudinal perspective. Health qual life outcomes 2004; 2: 9. doi: 10.1186/1477-7525-2-9
14. Klevsgard R, Froberg BL, Risberg B, Hallberg IR. Nottingham Health Profile and Short-Form 36 Health Survey questionnaires in patients with chronic lower limb ischemia: before and after revascularization. J Vasc Surg 2002; 36: 310-317.
15. Vartanian SM. Conte MS. Surgical intervention for peripheral arterial disease. Circ Res 2015; 116: 1614-1628.
16. Keeling AN, Naughton PA, O'Connell A, Lee MJ. Does percutaneous transluminal angioplasty improve quality of life? J Vasc Interv Radiol 2008; 19: 169-176.
17. Barleben A, Bandyk DF. Surveillance and follow-up after revascularization for critical limb ischemia. Semin Vasc Surg 2014; 27: 75-81.doi: 10.1053/j.semvascsurg.2014.11.002.