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Quality of life for patients with in-stent restenosis after interventional therapy of peripheral artery disease

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SUMMARY

OBJECTIVE: The aim of this study was to investigate the quality of life for patients with in-stent restenosis after interventional therapy of peripheral artery disease and the influencing factors.

METHODS: A total of 72 in-stent restenosis patients after interventional therapy of peripheral artery disease were enrolled, whose general data were obtained. SF-12 scale was used to evaluate the quality of life. Tilburg Frailty Scale was used to assess senile debilitation. Pittsburgh Quality Index Scale was used to evaluate sleep quality. Activity of Daily Living Scale was used to evaluate the self-care ability. The general data and in-stent restenosis-related indicators were compared between patients with low and high quality of life, respectively. Multivariate regression analysis was made on the factors affecting quality of life.

RESULTS: The average total quality of life score of 72 patients was 74.06±19.26 points. The gender, Fontaine stage and smoking, Activity of Daily Living Scale score, painless walking distance, senile debilitation score, sleep quality score, white blood cells, and C-reactive protein had significant differences between the two groups, respectively ($p<0.05$). Multivariate regression analysis showed that the female gender, low Fontaine stage (OR=0.186), low senile debilitation score (OR=0.492), and high sleep quality score (OR=0.633) were the protective factors for high quality of life (all $p<0.05$), and the low Activity of Daily Living score (OR=1.282) was the risk factor for high quality of life ($p<0.05$).

CONCLUSION: Quality of life of in-stent restenosis patients after interventional therapy of peripheral artery disease is low. Gender, Fontaine stage, senile debilitation, sleep quality, and Activity of Daily Living score are the influencing factors of quality of life for in-stent restenosis patients.

KEYWORDS: Quality of life. Constriction. Peripheral artery disease.

INTRODUCTION

Peripheral artery disease (PAD) is a form of arteriosclerosis that occurs in the extremities and involves Ischemia. It is a common disease in vascular surgery. Due to chronic occlusion of peripheral artery, the clinical manifestations of PAD are the pain in lower limb, intermittent claudication, severe limb ulcer, and gangrene, leading to a serious decline in the daily quality of life (QOL)[1]. The incidence of PAD increases exponentially with the increase in age[2]. Interventional treatment has become the preferred surgical treatment method for PAD due to the low incidence of complications, fast postoperative recovery, and short hospitalization time. However, in-stent restenosis (ISR) is a common complication after the lumen stent implantation, which will lead to the recurrence of arterial occlusion symptoms. According to statistics, the rate of ISR within 1 year is as high as 20–50%[3,4], and within 2 years, it is as high as at 60%[5]. As PAD is an incurable chronic progressive disease, mitigating the symptoms of patients and improving the QOL have become the common understanding of more scholars[6]. A previous study has shown that improving the quality of executing functional tasks, such as bathing, stair climbing, and walking, can enhance the QOL of PAD patients[7]. At present, the research on ISR focuses more on risk predictors, prevention, and medical methods through medication and surgery. There is less research on the current QOL, daily living ability, or related influencing factors of ISR patients. Does the QOL of PAD patients decrease or remain unchanged after interventional therapy? This study aimed to investigate the QOL for patients with ISR after interventional therapy of PAD and the influencing factors, for providing a basis for further developing personalized nursing interventions to improve the QOL of PAD patients.

METHODS

Patients

A total of 106 patients with ISR after interventional therapy of PAD in Third Hospital in Hangzhou from January 2016

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to August 2021 were consecutively recruited in this study. The inclusion criteria were as follows: (i) patients who were over 55 years old, (ii) those who met the diagnostic criteria of ISR—vascular restenosis of the lesion segment (stenosis>50% of the target vessel) in PAD patients determined by color ultrasound or occlusion, and (iii) those who required target lesion blood flow reconstruction of target lesions. target lesion blood flow reconstruction was defined as restenosis or occlusion of target blood vessels and repeated symptoms such as affected limb chills, pain, intermittent claudication, and resting pain. Conservative treatment was ineffective, and re-surgical intervention was required. The exclusion criteria were as follows: (i) conservative treatment was effective; (ii) restenosis<50%; (iii) patients with severe cognitive dysfunction or other reasons who cannot communicate; and (iv) other diseases seriously affecting the quality of life, such as intractable heart failure, chronic kidney disease, and respiratory failure. Finally, 34 patients (32.08%, 34/106) were excluded, and 72 patients (67.92%, 72/106) were included. This study was approved by the ethics committee of Hangzhou Third Hospital. Written informed consent was obtained from all participants.

Study methods

The general data of patients were obtained from the medical records within 24 h after they were admitted. The Fontaine classification system was used for staging PAD as follows[8]: Stage I:asymptomatic; Stage II: intermittent claudication; Stage III: rest pain; and Stage IV: necrosis and/or gangrene of the limb. The fasting blood samples were taken in the morning of the first day after admission, and the biochemical indexes were determined using a fully automatic blood analyzer. In addition, within 24 h after admission, SF-12 scale[9] was used to evaluate the QOL of patients, including Physical Component Summary (PCS) Scale and Mental Component Summary (MCS) Scale. Tilburg Frailty Scale was used to assess the senile debilitation of patients[10]. Pittsburgh Quality Index Scale (PSQI)[11] was used to evaluate the sleep quality of patients. Activity of Daily Living Scale (ADL) was used to evaluate the self-care ability of patients[12]. The data of the questionnaire survey were collected by a senior nurse who was familiar with the contents.

Statistical analysis

Data were statistically analyzed using the SPSS 22.0 software. Measurement data of normal distribution were described by mean±standard deviation and were compared using the independent-sample t-test. Non-normal distributed measurement data were described by M (P_{25}–P_{75}), and the groups were compared by the Mann-Whitney test. Classification data were described by frequency (percentage), and the Pearson χ^2 test was used for comparison between groups. Multivariate logistic regression was used to study independent factors affecting patient QOL. $p<0.05$ was considered significantly different.

RESULTS

Quality of life scores of patients

The questionnaire with SF-12 scale showed that the lowest, highest, and average PCS scores of 72 ISR patients were 20.24, 54.84, and 35.97±10.14 points, respectively, and the lowest, highest, and average MCS scores were 19.37, 59.78, and 38.09±10.53 points, respectively. The lowest, highest, and average total QOL scores (PCS+MCS) were 46.95, 114.61, and 74.06±19.26 points, respectively.

Comparison of general data between patients with low and high quality of life

Based on the median of total QOL scores, 72 ISR patients were divided into low QOL group (n=36) and high QOL group (n=36). The gender, Fontaine stage, and smoking status had significant difference between the two groups, respectively ($p<0.05$). There was no significant difference in other general data between the two groups ($p>0.05$) (Table 1).

Comparison of in-stent restenosis-related indicators between patients with low and high quality of life

As shown in Table 2, the ADL score, painless walking distance, senile debilitation score, sleep quality score, white blood cells, and C-reactive protein had significant difference between the low and high QOL groups, respectively ($p<0.05$). There was no significant difference in ISR-related indicators between the two groups ($p>0.05$).

Multivariate regression analysis results of factors influencing quality of life

Using QOL as the dependent variable and gender, Fontaine stage, smoking, ADL score, painless walking distance, senile debilitation score, sleep quality score, white blood cells, and C-reactive protein as regression variables, the multivariate regression analysis was performed. Results showed that the female gender, low Fontaine stage, low senile debilitation score, and high sleep quality score were the protective factors for high QOL. The low ADL score was the risk factor for high QOL (Table 3).

Table 1. Comparison of general data between in-stent restenosis patients with low and high quality of life after interventional therapy of peripheral artery disease.

Index	Low QOL	High QOL	t/χ^2	p
n	36	36		
Age (age)	77.06±7.18	73.86±7.51	1.844	0.069
BMI (kg/m^2)	22.11±3.59	22.53±3.26	0.516	0.608
Gender, n (%)			6.923	0.009
Male	31 (86.1)	21 (58.3)		
Female	5 (13.9)	15 (41.7)		
Education, n (%)			0.441	0.932
Illiterate	12 (33.3)	10 (27.8)		
Primary school	14 (38.9)	14 (38.9)		
Junior high school	8 (22.2)	9 (25.0)		
Senior high schools and above	2 (5.6)	3 (8.3)		
Smoking status, n (%)	28 (77.8)	14 (38.9)	11.200	0.001
Disease history, n (%)				
Hypertension	30 (83.3)	25 (69.4)	1.925	0.165
Diabetes	19 (52.8)	13 (36.1)	2.025	0.155
Cerebral infarction	15 (41.7)	8 (22.2)	3.130	0.077
Coronary heart disease	7 (19.4)	5 (13.9)	0.400	0.527
Affected limb, n (%)			0.229	0.633
Left lower limb	14 (38.9)	16 (44.4)		
Right lower limb	22 (61.1)	20 (55.6)		
Fontaine stage, n (%)			9.864	0.007
II	5 (13.9)	15 (41.7)		
III	7 (19.4)	1 (2.8)		
IV	24 (66.7)	20 (55.6)		
Use of antiplatelet or vasodilator drugs, n(%)	27 (75.0)	27 (75.0)	0.000	1.000

ISR: in-stent restenosis; QOL: quality of life; PAD: peripheral artery disease; BMI: body mass index.

DISCUSSION

This study has investigated the QOL for patients with ISR after interventional therapy of PAD and the influencing factors. It is indicated that the QOL of ISR patients after interventional therapy of PAD is low. Gender, Fontaine stage, senile debilitation, sleep quality, and ADL score are the influencing factors of QOL for ISR patients.

In this study, the average total QOL score of patients with ISR was at a lower middle level. This is similar to the study results by Wu et al.[13] The vascular occlusion symptoms occur after intervention treatment of PAD, including intermittent lameness, resting pain, and foot gangrene symptoms, leading to different degrees of lower limb pain and difficult-to-heal foot ulcer. The patients cannot walk, climb stairs, dress, go toilet, or even complete other daily activities. In addition, the occurrence of ISR not only makes the patient feel physical pain but also increases the negative psychological mood and reduces happiness. Depression is a common negative psychological mood in patients with arterial disease[14]. Resting pain leads to poor sleep at night, causing anxiety, fear, and other bad emotions[15]. These can cause the low QOL of ISR patients.

Fontaine stage is based on the clinical symptoms of PAD patients. It is reported that the lower QOL is related to the higher Fontaine stage[16]. This is consistent with the findings of our study in which the low Fontaine stage is a protective factor for high QOL. A previous study[17] has shown that decreased ADL score severely affects the QOL of the elderly. This is consistent with the findings of our study in which the

Table 2. Comparison of in-stent restenosis-related indicators between patients with low and high quality of life after interventional therapy of peripheral artery disease.

ISR-related indicator	Low QOL	High QOL	t/z	p
n	36	36		
Time before reoccurrence (months)	18.94±17.05	14.14±10.50	1.440	0.155
Time before visiting (days)	30 (15–90)	20 (14–50)	1.663	0.096
NRS pain score (points)	3.08±2.06	2.39±1.27	1.720	0.090
ADL score (points)	68.75±12.89	95.00±6.09	3.487	0.000
Painless walking distance (m)	45 (10–100)	100 (50–300)	3.159	0.003
Senile debilitation score (points)	8.19±1.83	4.89±2.29	6.761	0.000
Sleep quality score (points)	12.39±4.08	7.75±3.83	4.971	0.000
Type of drugs (n)	4.78±2.84	3.92±2.44	1.379	0.172
Biochemical indexes				
Triglyceride (mmol/L)	1.46±1.54	1.33±1.04	0.430	0.669
LDL (mmol/L)	2.30±1.11	2.74±1.21	1.608	0.112
HDL (mmol/L)	1.18±0.38	1.20±0.39	0.306	0.761
Albumin (g/L)	33.67±4.28	34.93±3.44	1.380	0.172
Apolipoprotein A1 (g/L)	1.27±0.30	1.30±0.31	0.293	0.771
Apolipoprotein B (g/L)	0.75±0.34	0.88±0.39	1.475	0.145
Total protein (g/L)	62.78±5.07	60.79±6.32	1.471	0.146
Total cholesterol (mmol/L)	3.88±1.27	4.66±3.22	1.340	0.185
White blood cells (10^9/L)	6.9 (5.7–9.43)	5.95 (5.3–6.8)	2.091	0.037
Blood platelet (10^9/L)	227.36±105.93	229.92±81.72	0.115	0.909
C-reactive protein (mg/L)	3.95 (1.2–33.18)	1.45 (0.63–5.78)	2.198	0.028
Mean platelet volume (fL)	10.70±1.09	10.27±1.04	1.736	0.087

ISR: in-stent restenosis; QOL: quality of life; PAD: peripheral artery disease; NRS: Numerical Rating Scale; ADL: Activity of Daily Living Scale; LDL: low-density lipoprotein; HDL: high-density lipoprotein.

Table 3. Multivariate regression analysis results of factors influencing quality of life of in-stent restenosis patients after interventional therapy of peripheral artery disease.

Factor	B	SE	Wald	p	OR	95%CI
Gender	-4.064	2.075	3.835	0.048	0.017	0.001–0.903
Fontaine stage	-1.682	0.865	3.981	0.042	0.186	0.034–0.914
Senile debilitation score	-0.709	0.360	3.871	0.049	0.492	0.243–0.997
Sleep quality score	-0.458	0.197	5.375	0.020	0.633	0.430–0.932
ADL score	0.248	0.086	8.234	0.004	1.282	1.082–1.518

QOL: quality of life; ISR: in-stent restenosis; PAD: peripheral artery disease; ADL: Activity of Daily Living Scale; B: regression coefficient; SE: standard error; Wald: corresponding to χ^2 value; p: difference; OR: odds ratio; CI: confidence interval.

ADL score is low in the low QOL group. In addition, the logistic regression analysis showed that patients with ADL scores had poor QOL. These indicate that patients with low QOL are in a state of slight dependence and need care from others in their daily life.

Senile debilitation is an elderly syndrome affecting multiple functional domains in humans and shares the same pathogenesis and risk factors as PAD[18]. Our study showed that senile debilitation is a risk factor for decreased QOL in ISR patients. Exercise is an effective way to prevent and

treat weakness. Therefore, we can improve the QOL of ISR patients by guiding them to adhere to exercise. It is believed that the elderly themselves are prone to various sleep disorder symptoms, which seriously affects the QOL[19]. Our study finds that a high sleep quality score is one of the protective factors for high QOL. Therefore, the nurses should assess the cause of poor sleep of ISR patients and take targeted care measures. In addition, our study shows that female gender is one of the protective factors for high QOL, which is different from a foreign study[20], which may be related to the race of research objects.

Our study still has some limitations. First, this study conducted a single-center research, with a small sample size. The next multi-center and large-sample size investigation should be performed for obtaining more persuasive findings. Second, there were obviously more male patients than female patients in this study. If more female patients participate in the study, we may rule out different results. In the future study, more female patients should be enrolled to make the findings more convincing.

CONCLUSION

QOL of ISR patients after interventional therapy of PAD is low. Gender, Fontaine stage, senile debilitation, sleep quality, and ADL score are the influencing factors of QOL for ISR patients. Therefore, delaying the recurrence of ischemic symptoms, mitigating the debilitation, improving the activities, and ensuring good sleep quality are the keys to improve the QOL of ISR patients.

AUTHORS' CONTRIBUTIONS

JT: Conceptualization, Formal Analysis, Investigation, Project administration, Resources, Supervision, Writing – review & editing. **ZZ:** Data curation, Funding acquisition, Software, Writing – original draft. **FX:** Validation, Visualization. **LL:** Methodology, Validation, Visualization.

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