Crosstalk Between Medication Adherence and Quality of Life Among Patients with Peripheral Arterial Disease

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SUMMARY

Peripheral arterial disease (PAD) has a pronounced negative impact on an individual's health-related quality of life (HRQoL). The pharmacotherapy of PAD involves long-term therapy. Improving the quality of life and achieving optimal adherence are important goals of PAD treatment. The aim was to examine the impact of therapeutic modalities and adherence on HRQoL in patients with PAD. This prospective study included 82 PAD patients treated on an outpatient basis. HRQoL was assessed using the Short Form 36 Health Survey (SF-36). After 6-month treatment, HRQoL was reassessed and adherence was assessed using the Adherence in Chronic Diseases Scale. Six months after therapy initiation, the SF-36 survey scores indicated improvement of HRQoL in study subjects. HRQoL improvement was observed in the group of respondents with a high degree of adherence ($p<0.001$). The results obtained showed that there was no statistically significant correlation between the choice of therapeutic modality and HRQoL, but indicated a statistically significant correlation between adherence and quality of life improvement in all domains ($p<0.001$). In conclusion, there was a significant correlation between the degree of adherence and HRQoL in patients with PAD.

KEYWORDS

Medication adherence; *Quality of life*; *Peripheral arterial disease*

Introduction

Quality of life is a concept that monitors the influence of various aspects of life on an individual's general well-being and functioning[1]. Unlike general quality of life, the concept of health-related quality of life (HRQoL) is a more specific term and refers to the part of life that is clearly affected by health, with all its variables[2].

Most chronic diseases that restrict an individual's ability to live a normal life can lead to decreased general health of patients, restricted performance, reduced HRQoL, and increased healthcare costs[3]. Peripheral arterial disease (PAD) is a chronic progressive atherosclerotic disease that leads to partial or complete peripheral vascular occlusion with a pronounced negative impact on an individual's quality of life[4,5]. Patients diagnosed with PAD require a comprehensive approach to treatment grounded on all the existing risk factors, the severity of the disease, and the patient's functioning status. As the treatment of PAD requires a multi-year application of medical therapy, a high degree of adherence to the proposed therapy is essential in achieving optimal therapeutic goals, preventing disease progression, and improving the quality of life[6]. Adherence is extremely important for the efficiency and safety of pharmacotherapy, significantly affecting its clinical, economic, and humanistic outcomes, which can be monitored from both the individual aspect of the patient and the aspect of the entire health system[7].

The main goal of this research was to examine the impact of therapeutic modalities and adherence on the quality of life in patients with PAD.

Material and methods

The cross-sectional study included for the first time diagnosed PAD patients treated on an outpatient basis at the Clinic of Vascular Surgery, Niš Clinical Center in Niš, Serbia, during the period from January 2020 to December 2020. The diagnosis was established on the basis of medical history data, clinical examination, Doppler echosonography and/or computed tomography (CT) angiography of the main arteries of lower extremities.

The criteria for inclusion in the research involved patients with stage IIa and IIb disease according to Fontaine, who had PAD of lower extremities verified by Doppler sonography or CT angiography[8]. The criteria for exclusion from the study involved patients with PAD stage I, III and IV according to Fontaine, amputation of lower extremities, ejection fraction <40%, chronic peritoneal dialysis or hemodialysis, malignancies and associated diseases that lead to impaired general condition and physical condition.

The research protocol was approved by the Ethics Committee of the Niš School of Medicine (12-15637-2/5 dated 12/24/2019). The research was fully adapted to the Declaration of Helsinki on ethical behavior and conducted according to the principles of Good Clinical Practice (GCP). All patients were informed about the purpose of the study and voluntarily signed the consent form.

Classification of the respondent disease stage was determined according to Fontaine: stage I (asymptomatic); stage IIa (moderate claudication distance (CD) >200 m); stage IIb (moderate to severe CD <200 m); stage III (ischemic pain at rest, CD up to 50 m); and stage IV (presence of ulceration and gangrene). Patients with Fontaine stage IIa and IIb disease were included in the study.

For proper data analysis, study subjects were divided into groups according to gender, age (<65 years and ≥65 years), medical therapy applied (pentoxifylline 1200 mg/day + acetylsalicylic acid 100 mg/day (PTX+ASA) or cilostazol 200 mg/day + acetylsalicylic acid 100 mg/day (CIL+ASA)), presence of risk factors (smoking, obesity, diabetes, dyslipidemia and hypertension), and level of average daily physical activity (up to 500 m; 500-1000 m, and over 1000 m).

Assessment of adherence

Estimation of adherence was performed using a validated scale for assessing adherence in patients with chronic diseases (Adherence in Chronic Diseases Scale, ACDS)[9]. The ACDS is a survey designed to assess adherence in adults suffering from chronic diseases. It consists of 7 questions with predefined answers. The survey was designed to enable assessment of adherence and factors influencing it. The ACDS survey includes seven questions with five possible answers. The answers are scored according to the following principle: a=4; b=3; c=2; d=1; and e=0. The ACDS survey results assesses the patient level of adherence to the medicaments they use. Total number of points that could be obtained for all questions is 28. The degree of adherence resulting from the sum of answers is assessed according to the predetermined scoring criteria: <20 points low level of adherence, 21-26 points medium adherent, and 27 points high adherent.

Assessment of HRQoL

The conducted research comprised assessment of the quality of life using the Short Form 36 Health Survey version 2 (SF-36v2), a well-known and widely used instrument for assessing patient quality of life. It is used internationally and is standardized and validated for use in Serbian language. The questions in the survey have multiple answers, scoring of answers ranges from 0 to 100 and is calculated for each area, with a higher score indicating better HRQoL. A higher score indicates better state of health, i.e., fewer limitations in everyday life, better functional status of the patient, or less physical pain. In this way, it is possible to quantitatively compare various manifestations of health measured by the survey[10,11].

Statistical analysis

Statistical analysis was performed using the SPSS 16.0 software package for Windows. The methods of descriptive and analytical statistics were used. Continuous variables were described as the mean value ($\bar{X}$) and standard deviation (SD), while the proportions (percentages) were used for categorical variables. The normality of distribution was assessed by the Kolmogorov-Smirnov test, while the homogeneity of distribution was assessed by the Levin test. The significance of difference for continuous variables with normal distribution was assessed by parametric methods. The t-test for independent samples was used to compare two groups of respondents, and one-way ANOVA was used for three or more groups, while the χ^2-test was used for nonparametric variables. The difference was considered significant if $p<0.05$. Tukey's HSD test was used in the case of a statistically significant difference. Spearman's correlation was used to assess correlation.

Results

The study included 82 patients, 59.76% of male and 40.24% of female. Table 1 presents basic patient demographics and clinical data.

The mean age of the respondents was 67.62 (SD 8.22) years. Smoking was the most prevalent risk factor (76.82%), while dyslipidemia was the least prevalent (63.71%). In the conducted research, 48.78% of study subjects were treated with PTX+ASA, whereas 51.22% of subjects were treated with CIL+ASA.

In the conducted research, the quality of life was assessed using the SF-36v2 quality of life survey. The SF-36v2 results are presented as difference in the mean values for each individual domain ±

Table 1. Patient characteristics

		n	%
Gender	Male	49	59.76
	Female	33	40.24
Age (yrs)	<65	29	35.37
	≥ 65	53	64.63
Comorbidity/risk factor	Obesity	59	71.95
	Smoking	63	76.82
	Diabetes mellitus	57	69.51
	Dyslipidemia	52	63.71
	Hypertension	62	75.60
Therapy	PTX+ASA	40	48.78
	CIL+ASA	42	51.22
Level of adherence	Low level	23	28.05
	Medium level	40	48.78
	High level	19	23.17

PTX+ASA = pentoxifylline 1200 mg/day + acetylsalicylic acid 100 mg/day; CIL+ASA = cilostazol 200 mg/day + acetylsalicylic acid 100 mg/day

Table 2. Assessment of health-related quality of life at first examination and 6 months after therapy introduction

Domain	N	First visit		6-month follow-up	
		$\bar{X}$	SD	$\bar{X}$	SD
PF	82	58.12	14.73	65.37	15.51
RP	82	48.78	19.99	59.15	21.34
RE	82	65.85	26.18	69.58	27.65
V	82	49.42	15.35	57.93	16.87
MH	82	66.37	17.42	71.02	17.98
SF	82	43.20	13.92	57.01	16.50
P	82	44.36	10.66	55.46	13.24
GH	82	43.29	12.05	54.27	15.07
CH	82	26.52	18.15	57.32	29.52

$\bar{X}$ = mean; SD = standard deviation; PF = Physical function; RP = Role limitation due to physical problems; RE = Role limitation due to emotional problems; V = Vitality; MH = Mental health; SF = Social function; P = Bodily pain; GH = General health perception; CH = Change in reported health

Table 3. Comparison of subject quality of life 6 months after introduction of therapy according to particular characteristics

	N	PF	RP	RE	V	MH	SF	P	GH	CH
Gender										
Male	49	7.84±4.37	10.20±13.42	3.49±11.78	8.63±5.45	4.33±2.93	13.51±9.98	13.14±8.64†	10.82±7.17	**38.27±22.88†**
Female	33	6.36±3.37	10.61±12.55	4.00±13.75	8.33±4.79	5.15±2.96	13.64±9.75	7.64±8.62	11.21±6.96	**19.70±20.50**
Age (yrs)										
<65	29	8.41±4.52	7.76±13.53	5.69±12.69	9.14±6.69	3.93±3.40	16.10±11.11	11.72±10.37	10.00±6.81	**40.52±28.67†**
≥65	53	6.60±3.64	11.79±12.60	2.60±12.40	8.17±4.14	5.06±2.62	12.17±8.85	10.49±8.23	11.51±7.18	**25.47±18.66**
Risk factors										
≤3	33	6.97±3.94	9.85±12.40	5.00±14.58	8.12±5.53	5.21±3.24	12.52±9.09	12.36±9.77	11.21±7.81	36.36±26.58
>3	49	7.43±4.14	10.71±13.50	2.82±10.98	8.78±4.95	4.29±2.71	14.27±10.33	9.96±8.41	10.82±6.56	27.04±20.94
Physical activity										
≤500 m	28	6.56±3.97	9.38±15.48	4.13±11.27	8.13±5.44	4.63±3.98	**9.69±6.65***	13.13±9.74	9.06±7.79	31.25±28.14
500-1000 m	38	6.71±3.14	9.21±12.22	3.63±12.38	8.37±5.91	4.53±2.49	**12.61±11.01**	9.37±8.79	10.00±6.15	28.95±23.63
≥ 1000 m	16	8.36±4.98	12.50±12.73	3.54±13.74	8.93±3.93	4.86±2.95	**17.07±8.73**	11.79±8.80	13.39±7.34	33.04±21.57
Therapy										
PTX+ASA	40	6.38±3.75	8.13±13.14	3.30±10.03	8.00±5.97	4.20±3.00	12.50±11.07	9.85±9.80	9.63±7.20	30.63±26.85
CIL+ASA	42	8.07±4.18	12.50±12.65	4.07±14.60	9.00±4.28	5.10±2.87	14.57±8.49	11.95±8.15	12.26±6.74	30.95±20.52

*p<0.05; †p<0.01; PF = Physical function; RP = Role limitation due to physical problems; RE = Role limitation due to emotional problems; V = Vitality; MH = Mental health; SF = Social function; P = Bodily pain; GH = General health perception; CH = Change in reported health; PTX+ASA = pentoxifylline 1200 mg/day + acetylsalicylic acid 100 mg/day; CIL+ASA = cilostazol 200 mg/day + acetylsalicylic acid 100 mg/day

SD. Table 2 presents comparison of HRQoL at first examination and 6 months after therapy initiation.

Regarding scores of the SF-36v2 before therapy initiation, it can be observed that patients with PAD had a reduced quality of life (49.54±16.49). The lowest values within individual scores were observed in the domains of social functioning (SF: 43.20±13.92), perception of general health (GH: 43.29±12.05) and pain (P: 44.36±10.66), noting that there was a pronounced deterioration of health in the last year (CH: 26.52±18.15). Six months after medicamentous therapy initiation, the SF-36v2 scores indicated that the subject quality of life improved. More significant changes were recorded in the domains of social functioning (SF:13.81), pain (P:11.1) and general health (GH:10.98) with pronounced positive health changes compared to the previous year (CH:30.8).

Table 3 shows comparison of the HRQoL at the first examination and 6 months after therapy initiation according to the subject individual characteristics. The SF-36v2 results are presented as difference of mean values for each individual domain ± SD.

Analysis of the results revealed no statistically significant relationship between gender and individual quality of life domains, except for health improvement in the last year (CH: 38.27±22.88 *vs.* 19.70±20.50; p<0.01).

By comparing HRQoL at the first examination and 6 months after therapy initiation according to subject age, statistical significance was only recorded for health improvement in the last year (CH: 40.52±28.67 *vs.* 25.47±18.66; p<0.01), noting that the respondents under the age of 65 achieved greater improvement in their health status.

By comparing HRQoL at the first examination and 6 months after therapy initiation according to the subject physical activity, statistical significance was only recorded for improvement in

Table 4. Comparison of quality of life at first examination and 6 months after therapy introduction according to degree of subject adherence

Domain	Low level			Medium level			High level			F	p	η^2
	N	$\bar{X}$	SD	N	$\bar{X}$	SD	N	$\bar{X}$	SD			
PF	23	50.65	10.37	40	66.88	12.49	19	80.00	10.27	34.88	**<0.001**	0.47
RP	23	42.39	21.89	40	62.50	17.90	19	72.37	14.18	15.15	**<0.001**	0.28
RE	23	49.28	22.18	40	69.31	26.21	19	94.74	12.49	21.02	**<0.001**	0.35
E	23	40.00	11.48	40	60.38	12.32	19	74.47	8.80	49.63	**<0.001**	0.56
MH	23	51.04	16.36	40	75.75	11.74	19	85.26	7.43	44.88	**<0.001**	0.53
SF	23	42.39	13.97	40	57.88	13.03	19	72.89	8.79	31.27	**<0.001**	0.44
P	23	43.91	10.02	40	56.44	10.64	19	67.37	9.95	27.26	**<0.001**	0.41
GH	23	37.39	12.24	40	58.00	9.66	19	66.84	8.69	48.16	**<0.001**	0.55
CH	23	27.17	22.50	40	62.50	23.34	19	82.89	14.56	37.53	**<0.001**	0.49

PF = Physical function; RP = Role limitation due to physical problems; RE = Role limitation due to emotional problems; V = Vitality; MH = Mental health; SF = Social function; P = Bodily pain; GH = General health perception; CH = Change in reported health

social functioning (SF: 17.07±8.73 *vs*. 12.61±11.01 *vs*. 9.69±6.65, p<0.05). Subsequent comparisons using Tukey's test confirmed a statistically significant difference between the subjects who walked ≤500 m and those who walked ≥1000 m. Analysis of the results recorded no statistically significant relationship between the choice of therapeutic modalities and individual quality of life domains at the first examination and 6 months after therapy initiation, with improvement of the quality of life at the level of all examined domains being more pronounced in the group of respondents who used CIL+ASA.

In the conducted research, the largest number of respondents showed a medium level of adherence (48.78%), a high level of adherence was recorded in 23.17% of respondents, while a low level of adherence was recorded in almost one third of respondents (28.05%) (Table 1). Table 4 illustrates comparison of the HRQoL at the first examination and 6 months after therapy initiation according to the subject degree of adherence. Results of the SF-36v2 survey are presented as difference in mean values for each individual domain ± SD.

The impact of adherence on the quality of life was investigated using one-factor analysis of variance. The results obtained indicated a statistically significant relationship between adherence and improvement in the quality of life in all domains (p<0.001), noting that the greatest improvement in the quality of life was recorded in the group of respondents with a high degree of adherence (p<0.001).

Discussion

Peripheral arterial disease is a chronic disorder characterized by the presence of intermittent claudication, which, at long term, leads to significant functional limitations and reduced quality of life[12]. A large number of studies have analyzed the impact of PAD on the patient quality of life; however, most studies were limited by a small number of subjects or selection of the study population with a specific cardiovascular profile[13-15]. In this regard, the impact of PAD on the quality of life of patients in the general population has yet to be investigated in detail.

According to available sources, this is the first research to examine and analyze the quality of life in patients with PAD in the Republic of Serbia. Results of the research showed that patients with PAD had a reduced quality of life before medicamentous therapy initiation (Table 2). The lowest values within individual scores were recorded in the SF, GH and P domains. It is important to note that there was pronounced deterioration of the respondent health status in the last year of the analyzed period. According to a research conducted by Wu *et al*., the lowest values were achieved in the PF domain and highest in the MH domain[16]. Low values in the PH domain in respondents with PAD recorded in the conducted research were also found in the research conducted by Regensteiner *et al*.[17]. Six months after medicamentous therapy initiation, the SF-36v2 scores indicated that the subject quality of life improved. More significant changes were recorded in the SF, P and GH domains with distinct positive changes in health status compared to the previous year. The results of the conducted research are consistent with the results of the only available study that compared quality of life of subjects with PAD before and after medicamentous therapy initiation[18].

The results obtained showed that there was no statistically significant correlation between the choice of therapeutic modality and individual domains of the quality of life at the first examination and 6 months after therapy initiation, with improvement of the quality of life at the level of all examined domains being more pronounced in the group of subjects who used CIL+ASA. Although pentoxifylline and cilostazol have been the drugs of choice for many years to improve the symptoms in patients with PAD, it is important to point out that there have been no comparative studies that would

simultaneously monitor the effectiveness of these medicaments and HRQoL in patients with PAD.

The examination of HRQoL was performed at the first examination and 6 months after therapy initiation according to individual characteristics of the subjects (Table 3). Analysis of the results revealed that there was no statistically significant correlation between gender and individual domains of the quality of life, except for the improvement of health in the last year in male patients ($p<0.01$). The results obtained were consistent with the research by Collins *et al.*[19]. Statistical significance related to health improvement in male patients in the last year can be explained by the general opinion that women with PAD have a worse health status and HRQoL compared to men[20,21]. Comparison of HRQoL at the first examination and 6 months after therapy initiation according to subject age showed statistical significance only in terms of health improvement in the last year ($p<0.01$), noting that the subjects under the age of 65 achieved greater health state improvement. The results of the conducted research were consistent with the research conducted in the Egyptian and Dutch populations of patients with PAD[12,22].

The beneficial effects of physical activity in patients with intermittent claudication are supported by a large body of evidence collected from studies conducted over the last 30 years. Comparing HRQoL at the first examination and 6 months after therapy initiation according to physical activity of the subjects yielded statistical significance only in terms of improvement in social functioning ($p<0.05$). The results obtained suggest that physical activity, including walking beyond the pain limit, is important for improving the quality of life in patients with PAD, assuming that even better results would be achieved if, in addition to medicamentous therapy, appropriate exercise programs and/or supervised physical activity were included[23,24].

In patients with chronic diseases, the management of their health condition is essential for improving health outcomes, preventing further disease progression, occurrence and development of complications. Therefore, a high level of adherence is extremely important for achieving effective and safe pharmacotherapy, as well as desired therapeutic outcomes, especially in patients suffering from chronic diseases. However, a large number of studies indicate that only 50% of patients with chronic diseases are adherent[25].

Peripheral arterial disease is a chronic disease that requires many years of medicamentous therapy. In the conducted research, the largest number of respondents showed a medium level of adherence (48.78%), high level of adherence was recorded in 23.17% of respondents, while low level of adherence was recorded in almost one third of respondents (28.05%) (Table 1). A study conducted by Hiatt *et al.* indicated a generally low degree of adherence in patients who used cilostazol in therapy. Namely, the results of the mentioned research indicate that more than 60% of respondents stopped using the medicine 36 months after therapy initiation, which can be significantly associated with difficulty in achieving long-term therapeutic goals[26].

The results obtained indicated a statistically significant correlation between adherence and improvement in all quality of life domains ($p<0.001$), noting that the greatest improvement in the quality of life was recorded in the group of respondents with a high degree of adherence ($p<0.001$) (Table 4). Timely initiation of medicamentous therapy with a medium and high degree of adherence in two thirds of patients resulted in improvement in the quality of life in all domains. In the conducted research, patients with a medium and high degree of adherence (71.95%) had significantly higher scores in all examined domains of HRQoL compared to the group of respondents with a low degree of adherence. According to the obtained results, it can be concluded that there is a significant relationship between the degree of adherence and quality of life of patients with PAD. Until today, there have been no available studies to compare the obtained results. However, the relationship between the degree of adherence and quality of life has been

examined in other chronic diseases, and the available results indicate that a higher level of adherence leads to the increased values of the quality of life parameters, which consequently results in a reduction of symptoms, progression, frequency and severity of the disease[27].

Conclusion

The results of the conducted research indicated that patients with PAD had a reduced quality of life before initiation of medicamentous therapy, while during medicamentous therapy use, the SF-36v2 scores indicated that the subject quality of life improved. There was a significant correlation between the degree of adherence and HRQoL in patients with PAD. The patients with a medium and high degree of adherence (71.95%) had significantly higher scores in all investigated domains of HRQoL compared to the group of respondents with a low degree of adherence. Concerning the fact that the prevalence of PAD is increasing from year to year, raising the patient awareness of the importance of improving lifestyle habits, HRQoL and adherence to prescribed therapy can significantly contribute to achieving the desired therapeutic outcomes. ■

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SAŽETAK

Međudjelovanje između pridržavanja terapije i kvalitete života kod bolesnika s perifernom arterijskom bolešću

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Periferna arterijska bolest (PAB) ima izražen negativan utjecaj na kvalitetu života povezanu sa zdravljem (*Health Related Quality of Life*) pojedinca. Farmakoterapija PAB-a uključuje dugotrajno liječenje. Poboljšanje kvalitete života i postizanje optimalnog pridržavanja terapije važni su ciljevi liječenja PAB-a. Cilj ovog istraživanja bio je ispitati utjecaj terapijskih modaliteta i pridržavanja terapije na kvalitetu života povezanu sa zdravljem kod bolesnika s PAB-om. Ova prospektivna studija obuhvatila je 82 bolesnika s PAB-om koji su liječeni ambulantno. Kvaliteta života povezana sa zdravljem procijenjena je pomoću upitnika *Short Form 36 Health Survey* (SF-36). Nakon šest mjeseci liječenja ponovno je procijenjena kvaliteta života, a pridržavanje terapije ocijenjeno je pomoću Ljestvice pridržavanja terapije kod kroničnih bolesti (*Adherence in Chronic Diseases Scale*). Šest mjeseci nakon početka terapije rezultati upitnika SF-36 pokazali su poboljšanje kvalitete života ispitanika. Poboljšanje kvalitete života zabilježeno je u skupini ispitanika s visokim stupnjem pridržavanja terapije ($p<0,001$). Dobiveni rezultati pokazali su da ne postoji statistički značajna povezanost između odabira terapijskog modaliteta i kvalitete života povezane sa zdravljem, ali su ukazali na statistički značajnu povezanost između pridržavanja terapije i poboljšanja kvalitete života u svim domenama ($p<0,001$). Zaključno, utvrđena je značajna povezanost između stupnja pridržavanja terapije i kvalitete života povezane sa zdravljem kod bolesnika s perifernom arterijskom bolešću.

KLJUČNE RIJEČI

Pridržavanje terapije; *Kvaliteta života*; *Periferna arterijska bolest*