Quality of life and objective disease criteria in patients with intermittent claudication in general practice

Uwe Müller-Bühl, Peter Engeser, Hans-Dieter Klimm and Armin Wiesemann

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Background. The quality of life (QoL) of patients with chronic diseases is an important decision criterion for medical treatment, especially in primary care settings. It is known that subjective sickness feelings often cannot be correlated with objective disease criteria.

Objective. The aim of the study was to determine the QoL of patients with intermittent claudication with the arterial morphology, haemodynamic parameters and functional disability of peripheral arterial occlusive disease (PAOD).

Methods. In 150 patients with stable intermittent claudication, the health-related QoL was compared with the angiogram score, the resting Doppler pressure values, and the initial claudication distance (ICD) and absolute claudication distance (ACD) with treadmill exercise.

Results. The QoL did not correlate significantly with either the angiogram score or the ankle systolic blood pressure and ankle brachial index. ICD and ACD correlated significantly with the QoL activity subscales of pain, complaints and functional status ($P < 0.001$). In a multiple regression analysis, ACD and body mass index were the most predictive variables for the QoL.

Conclusion. The QoL of PAOD patients is independent of the peripheral Doppler pressure and the angiographic severity of the disease. The most important criterion for the QoL is the patient's functional disability.

Keywords. General practice, intermittent claudication, peripheral arterial occlusive disease, quality of life.

Introduction

About 50% of doctor–patient contacts in primary care settings concern patients with chronic diseases.[1] Determination of the quality of life (QoL) for such patients has been assigned increasing scientific attention in recent years for two reasons. First, the population age pyramid in industrial nations leads to an increase in the frequency of patients with chronic diseases, together with long-term symptom-oriented treatment.[2] In particular, however, the rapid further development of medical treatment methods requires criteria for differentiating modern diagnostic and therapeutic measures from the question of their direct benefit to the patient—not least because of economical considerations.[3]

Patients suffering from peripheral arterial occlusive disease (PAOD) seem to be particularly suitable for such QoL studies, because this chronic disease has *quoad vitam* a good outcome, but intermittent claudication restricts patients' activity and mobility and considerably reduces their QoL.[4]

The aim of this study amongst PAOD patients in primary care settings was to compare the health-related QoL with the degree of functional disability and the haemodynamic and morphological disease parameters.

Department of General Medicine, University of Heidelberg, Germany. Correspondence to Dr Uwe Müller-Bühl, Universitätsklinikum Heidelberg, Sektion Allgemeinmedizin und Versorgungsforschung, Im Neuenheimer Feld 347, D-69115 Heidelberg, Germany; E-mail: office_allmed@med.uni-heidelberg.de

Methods

Patient selection

The study consisted of a cross-sectional survey of 150 patients (103 males, 47 females) with stable intermittent claudication. Patients were selected by and referred

from GPs for participation in PAOD training groups, which have been organized and monitored for >10 years at the community level. Patients who were suffering from intermittent claudication for at least 6 months were included consecutively in the trial. They were recruited and examined over a period of 12 months. Exclusion criteria were the presence of rest pain, symptoms of gangrene or ulceration, or medical problems permanently impairing patients' mobility and known to affect QoL. Before entering the exercise programme, the localization and severity of the PAOD were determined by recording the patient's history, physical examination, Doppler measurement and treadmill test in a practice specialized in the treatment of vascular diseases. Angiography was performed to assess if an interventional procedure or reconstructive surgery was indicated in each subject.

Measurement of haemodynamic and functional parameters

The Dopplersonographic ankle/brachial pressure index (ABI) of the more diseased leg was used for statistical analysis. Measurement of the walking distance was performed as a constant load test using a treadmill at 3 km/h and 12% inclination. Both the initial claudication distance (ICD, i.e. the distance in metres walked until the onset of pain) and the absolute claudication distance (ACD, i.e. the maximum distance in metres walked by patients) were assessed. The actual body weight was determined before entering the treadmill.

Angiographic scoring

Angiographic assessment of the atherosclerotic vascular lesions of the lower extremities was carried out according to the method described by Bollinger et al.[5] The system consists of an additive score describing the severity of the lesions. In a modified manner in this study, only the haemodynamically relevant vascular segments of common and external iliac arteries, common and superficial femoral arteries and popliteal arteries were assessed.

Quality of life measurement

QoL was measured with PAVK-86, a disease-specific questionnaire. It has been shown to be a sensitive, reliable and valid instrument for describing health-related QoL in patients with intermittent claudication.[6] The questionnaire consists of 86 items assigned to seven subscales of the QoL: pain, general complaints, functional status, anxiety, mood, social life, and patients outcome expectation of treatment. For disease-specific QoL, a numerical rating scale ranging from 1 to 4 was used. General health status and global QoL were assessed using a numerical rating scale ranging from 0 to 10. High scores on the QoL scales inversely indicate low physical and emotional functioning. The questionnaire was filled in by the patient with interviewer supervision before measurement of the objective disease parameters.

Statistical analysis

Data analysis was performed using the SAS software package (Release 6.12). Differences between groups were tested using the non-parametric Mann–Whitney U-test for data classified in two levels or the Kruskal–Wallis test for more than two samples. Correlation was determined by calculation of Pearson's correlation coefficient (r). Multiple linear regression models used the method of stepwise regression with backward elimination. The subscales of pain, general complaints and functional status were selected as criteria variables for the multiple regressions. In addition to the ICD and the ACD, the variables of age, gender, duration of the disease, ABI, cigarette pack years, body mass index (BMI) and laterality were included in the regression model as being the most important components in the QoL of patients with PAOD.

Results

Eighteen GPs asked a total of 198 patients with intermittent claudication to participate in the PAOD training groups. According to the exclusion criteria, these patients were assessed to see if they were eligible to participate in an exercise programme and referred for angiological examination. Forty-six subjects could not be enrolled in the study because they did not attend the arranged examination. The reasons for their non-compliance were not registered. In the case of two patients, no angiography could be performed.

The baseline characteristics and disease-relevant parameters of the study sample are shown in Tables 1 and 2. All data were obtained before study patients started the exercise programme. The subscales of QoL did not differ significantly between males and females (Fig. 1).

Quality of life, and morphological and haemodynamic parameters

The angiogram scores failed to correlate with the QoL subscales. The correlation between QoL subscale pain

TABLE 1 *Baseline characteristics of the study population*

	All subjects (n = 150)	Females (n = 47)	Males (n = 103)
Mean age (years)	62 ± 9	66 ± 9	60 ± 9
Body mass index (kg/m²)	25.8 ± 3.6	26.5 ± 4.4	25.5 ± 3.2
Current smoker (n)	92	22	70
Pack-years (mean ± SD)	39.8 ± 23.5	27.2 ± 25.1	45.2 ± 20.4
Diabetes (%)	16.7	22.0	14.8
Hypertension (%)	58	63.9	57.2
Hyperlipoproteinaemia (%)	67.3	66.3	68.1

TABLE 2   *Vascular disease status of PAOD patients*

	All subjects (n = 150)	Females (n = 47)	Males (n = 103)
Median duration of claudication (months)	12	9	14
IQR duration of claudication (months)	8–36	7–30	6–40
Former angioplasty/operation (n)	31	9	22
Median ABI[a]	0.58	0.58	0.58
IQR ABI[a]	0.5–0.67	0.5–0.67	0.47–0.67
Median initial claudication distance (m)	65.5	65	67
IQR ICD (m)	43; 104	35–96	45–105
Median ACD (m)	149.5	122	162
IQR ACD (m)	88–249	75–223	94–276
Median angiogram score	22.5	19	26
IQR angiogram score	18–33	16–26	20–34

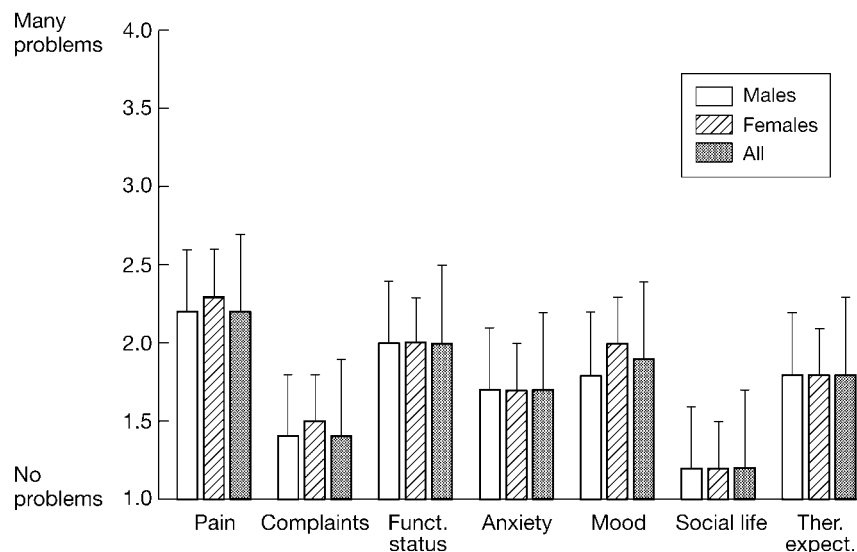[a] Of the more diseased lower limb.

FIGURE 1   *Quality of life in patients with intermittent claudication (mean ± SD)*

and ABI reached statistical significance; the Pearson correlation coefficient was low ($r = -0.17$; $P < 0.05$). The remaining subscales of QoL did not correlate with ABI or peripheral Doppler pressures at all. Even when the Doppler pressure indices were divided into three groups representing different degrees of haemodynamic impairment, no statistical correlation was found. There was a significant correlation between Doppler pressure indices and angiogram scores ($r = -0.34$; $P > 0.001$).

Quality of life and functional indicators

The correlation between the ICD and ACD and the subscales of the QoL yielded negative coefficients, indicating an improved QoL (lower scale ratings), combined with longer walking distances (Table 3). Functional QoL

domains, as represented by the subscales of pain, complaints and functional status, demonstrated statistically significant correlation with the ICD and ACD ($P < 0.001$). The correlations with the dimensions representing the mental/psychological well-being of the patients (anxiety, mood) are only significant in the case of ACD ($r = -0.19$; $P > 0.05$). There was a significant correlation between increasing BMI and the QoL activity subscales ($P < 0.001$). Classification of patients into groups with different walking capacities showed a tendency but not a significant correlation between QoL subscales and claudication distance.

According to the linear regression models after elimination of those predictors with the least usefulness, the ACD and the BMI remained as significant predictors

TABLE 3 *Pearson correlation coefficients between QoL subscales and functional indicators*

	Pain	Complaints	Funtional status	Anxiety	Mood	Social life	Therapy expectation
ICD	−0.41***	−0.20**	−0.34***	−0.11	−0.16	−0.10	−0.03
ACD	−0.47***	−0.31***	−0.42***	−0.19*	−0.19*	−0.16	−0.02
BMI	0.25**	0.25**	0.25**	−0.12	0.08	0.09	0.03

ACD, absolute claudication index; BMI, body mass index; ICD, initial claudication distance.
$*P < 0.05$, $**P < 0.01$, $***P < 0.001$.

in all three models; in addition, the patients' ages were found to be predictors of functional status. The variance of the criteria variables was explained by the significant predictors between 13.6 and 24.1%.

Discussion

In a series of patients with intermittent claudication intended for an exercise programme, QoL is correlated with walking capacity, expressed by the ICD and ACD. The physical QoL domains of pain, complaints and functional status of the disease-specific PAVK-86 questionnaire indicate a close correlation with the walking capacity. Also, the emotional QoL factors of anxiety and mood are related to the maximum walking distance, but the low correlation coefficients emphasize only a tenuous association.

These results are consistent with those reported in other trials using disease-specific and generic QoL instruments.[7–9] In a study by Barletta *et al.*,[8] treadmill performance did not correlate with the social or emotional function scores of the McMaster Health Index, whereas there was a significant relationship between maximal walking capacity and physical function scores. However, the latter correlation was slight, probably because many of the global QoL items assessing physical function concern areas such as self-care activities and communication, which are not affected by peripheral arterial disease. Chetter *et al.*[9] analysed the impact of increasing lower limb ischaemia upon QoL in 235 PAOD patients using the generic EuroQol questionnaire. They could suggest that the correlation between clinical indicators and QoL was significant but not sufficiently close. As in our study, the maximum walking distance on treadmill testing was the clinical indicator which most closely reflected QoL. A significant deterioration in overall QoL occurred with increasing lower limb ischaemia. In those patients suffering from critical ischaemia, scoring was even close to the lowest possible scores. Also, the importance of sufficient physical mobility for QoL of PAOD patients could be demonstrated in a study in patients who had undergone lower limb amputation.[10] Evaluated with the generic Nottingham Health Profile, the impaired mobility of amputees was the most important factor for their QoL. Differences in social isolation and emotional distress of the amputees lost their significance after statistical adjustment for mobility. Obviously, compared with the physical function, the psychosocial distress plays a more secondary role in the QoL of PAOD patients. Perhaps this is due to the high average age of the PAOD population, where a certain degree of acceptance of the physical disability may be attributed to a different attitude towards life. Moreover, the importance of physical limitations for the QoL of patients with intermittent claudication emphasizes the fact that besides the maximal walking distance, BMI and higher age in our study were shown to be relevant predictors of patient-reported QoL.

In the present study, no correlation could be found between the angiographic severity of disease and the QoL domains. This proves that the QoL does not depend on the atherosclerotic vascular damage but on the level of functional disability. It should be considered that only single plane angiograpic views were available, which are known to underestimate disease,[11] but the angiographic findings were confirmed by the poor relationship between QoL and Doppler measures. Only the QoL subscale of pain was correlated with lower ABI, suggesting the weak relationship between the QoL of PAOD patients and limb perfusion.

As may be expected, a significant correlation between the ABI and angiogram scores could be demonstrated. The peripheral Doppler pressure as a reliable marker of the morphological severity and prognosis of PAOD is evident.[12,13]

In conclusion, the results of this study emphasize the close relationship between physical disability and QoL of patients with intermittent claudication. Thus, the assessment of QoL is an important criterion in primary care, in particular because objective disease indicators do not reflect the subjective state of the disease adequately.

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