

QUALITY OF LIFE IN PATIENTS WITH PERIPHERAL ARTERIAL DISEASE BEFORE AND AFTER SURGICAL TREATMENT

Lucian S. Falnita¹, Mioara Cocora¹, Dan Nechifor¹, Ion Socoteanu¹, Doru Bordos²

REZUMAT

Introducere: Calitatea vieții, în sens medical, măsoară efectul bolii și al tratamentului asupra confortului pacientului, depășind indicatorii clinici măsurați de medic. Ea poate fi măsurată utilizând chestionare generale sau specifice pentru o anumită boală. **Material și metodă:** Am utilizat un chestionar specific pentru arteriopatia cronică obliterantă, King's College VascQOL, pe care l-am adresat spre completare unui număr de 120 de pacienți, înainte și după operația de revascularizare. **Rezultate:** Scorurile de calitate a vieții scad odată cu: vârsta pacientului, stadiul ischemiei cronice, distalitatea leziunilor arteriale, numărul bolilor asociate și vechimea bolii. După intervenția de revascularizare chirurgicală se înregistrează creșterea semnificativă a scorurilor de calitate a vieții. Scoruri relativ mai scăzute s-au înregistrat la pacienții în stadii anterioare avansate de ischemie, la cei cu leziuni distale și la pacienții care au suferit complicații postoperator. **Concluzii:** Chestionarul de calitate a vieții este un instrument util, specific și cost-eficient, atât pentru a selecta pacienții pentru operație și a stabili momentul operator, cât și pentru a cuantifica rezultatele operatorii (poate fi utilizat în compararea diverselor metode de tratament).

Cuvinte cheie: calitatea vieții, boala arterială periferică, chirurgie

ABSTRACT

Background: Quality of life (QOL) measurements have only seldom been used in Romanian medicine. Quality of life can be assessed using questionnaires, generic or disease-specific. **Material and methods:** The King's College VascQOL questionnaire is specific for the peripheral arterial disease and has been used in 120 patients, before and after surgical revascularization. **Results:** The scores of QOL are decreasing proportionally with: patients' age, the stage of chronic ischemia, the distal nature of vascular lesions, the number of concomitant diseases and the disease duration. After surgical revascularization the QOL scores are significantly increased. The patients with advanced chronic ischemia, distal lesions and postoperative complications had relatively lower scores. **Conclusions:** The QOL questionnaire is a specific, useful and cost-effective tool for selecting patients for surgery and choosing the time for operation, as well as for quantifying the results of surgery and comparison of various treatment methods.

Keywords: quality of life, peripheral arterial disease, surgery

INTRODUCTION

The effects of a disease and its treatment on patients are studied usually through clinical outcomes, such as survival, recurrence-free survival, length and number of hospitalizations. These results, as well as some socio-economic factors (the cost and the time spent for the treatment) are used in clinical studies to determine the efficiency of a treatment. Nevertheless, the disease and its treatment have an impact not only on the quantity of life (survival), but also on the well-

being of the patient, the binomial comfort-discomfort: the quality of life (QOL). Quality of life, as a medical concept, measures the effect of a disease and its treatment on the patient's comfort.¹

Quality of life can be measured using questionnaires. The qualitative information is transformed into quantitative data through the scores given to every domain of the questionnaire. The questionnaire can be completed either by the physician, acting as an interviewer, or directly by the patient. The first method has the advantage of minimizing the misunderstandings of questions, but the results may be not be accurate because not all patients "open their hearts" so easily to another person.

The QOL questionnaires are classified into generic (health profiles) and disease/condition specific.

Almost all questionnaires collect data about 4 domains:

¹Institute of Cardiovascular Medicine, ²Second Surgical Clinic, Victor Babes University of Medicine and Pharmacy, Timisoara

Correspondence to:
Lucian Falnita, Institute of Cardiovascular Medicine, G. Adam Str. 13A,
Timisoara, Romania, Tel: +40-256-207355, Email: lfalnita@cardiologie.ro

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1 - functional status: determines how well the patient can perform basic physical tasks, such as the ability to climb stairs, read a newspaper, or hold a pen.

2 - perceived health: determines how healthy the patient thinks he is and how much he worries about his health

3 - psychological well-being: determines how much the patient is distressed, anxious or depressed about his illness and its treatment

4 - role function (social function): determines how much impact the illness and the treatment have on the capacity of the patient to work and to perform his obligatory duties (taking care of himself and his family).²

Generic questionnaires examples:

- SF-36 (The Medical Outcomes Study Short Form36): contains 36 questions grouped into 8 categories.³

- RAND 36: similar with SF36.³

- SIP (Sickness Impact Profile): utilized in the USA in a study that compares the surgical treatment with the endovascular treatment of peripheral arterial disease.⁴

- NHP (Nottingham Health Profile): utilized in the UK in a study that compares the surgical treatment with the pharmacological treatment.¹

Examples of questionnaires specific for peripheral arterial disease (PAD):

- WIQ (Walking Impairment Questionnaire): one of the earliest questionnaires, which, although not very sensitive, was utilized to identify the claudicants and to grade the claudication.¹

- PAD-PAR (Physical Activity Recall)²

- Spitzer QL index²

- ARTEMIS²

- CLAU-S²

King's College VasuQOL, the questionnaire utilized in this study, is specific for the peripheral arterial disease and contains 25 questions (minimum of questions necessary to maintain its validity), each one with 7 possible answers, scored from 1 to 7. The questions are grouped into 5 domains: activity items (physical activity), symptom items, pain items, emotional items (psychological well-being) and social items (social activity). This questionnaire was compared with the SF-36 and its reliability, internal consistency, responsiveness and validity demonstrated. Also, the authors demonstrated the high correlation between the changes of the scores and the stage of the disease, the treadmill walking distance and the patient's global

estimate of change in the symptoms. However, the ankle-brachial index does not correlate with the VasuQOL score, as it does not correlate with other QOL questionnaires, used in other studies.⁵

King's College VasuQOL has some advantages: it is disease specific (SF-36 is generic), it covers all the stages of peripheral ischemia (other specific questionnaires, like CLAU-S, are oriented only on some stages), it is relatively easy to complete (in average 9.6 minutes). In addition to that, it was translated into French, German, Italian, Swedish and it is utilized in a multicenter UK trial of bypass graft versus angioplasty in severe limb ischemia.⁶

The purpose of this study is to test the possibility of utilizing a QOL specific questionnaire on vascular patients, as an indicator for the severity of disease (useful for the therapeutic management) and for the postoperative results.

The King's College VasuQOL questionnaire

The following questions are about how you have been affected by the poor circulation in your legs in the past two weeks. You will be asked about the symptoms you have had, the way that your activities have been affected, and how you have been feeling. For each question please read all of the answers and then check the one that applies best to you. If you are not sure about how to answer a question then please give the best answer you can. There are no right or wrong answers. Please answer every question. Thank you!

1. During the past two weeks, I have had pain in my leg (or foot) when walking:

- All of the time;
- Most of the time;
- Much of the time;
- Some of the time;
- A little of the time;
- Hardly any of the time;
- None of the time.

2. During the past two weeks, I have been worried that I might injure my leg:

- All of the time;
- Most of the time;
- Much of the time;
- Some of the time;
- A little of the time;
- Hardly any of the time;
- None of the time.

3. During the past two weeks, cold feet have given me:

- A very great deal of discomfort or distress;
- A great deal of discomfort or distress;
- A good deal of discomfort or distress;
- A moderate amount of discomfort or distress;
- Some discomfort or distress;
- Very little discomfort or distress;
- No discomfort or distress.

4. During the past two weeks, because of the poor circulation to my legs, my ability to exercise or to play sports has been:

- Totally limited, couldn't exercise at all;
- Extremely limited;
- Very limited;
- Moderately limited;
- A little limited;
- Only very slightly limited;
- Not at all limited.

5. During the past two weeks, my legs felt tired or weak:

- All of the time;
- Most of the time;
- Much of the time;
- Some of the time;
- A little of the time;
- Hardly any of the time;
- None of the time.

6. During the past two weeks, because of the poor circulation in my legs I have been restricted in spending time with my friends or relatives:

- All of the time;
- Most of the time;
- Much of the time;
- Some of the time;
- A little of the time;
- Hardly any of the time;
- None of the time.

7. During the past two weeks, I have had pain in the foot (or leg) after going to bed at night:

- All of the time;
- Most of the time;
- Much of the time;
- Some of the time;
- A little of the time;
- Hardly any of the time;
- None of the time.

8. During the past two weeks, pins and needles or numbness in my leg (or foot) have caused me:

- A very great deal of discomfort or distress;
- A great deal of discomfort or distress;
- A good deal of discomfort or distress;
- A moderate amount of discomfort or distress;
- Some discomfort or distress;
- Very little discomfort or distress;
- No discomfort or distress.

9. During the past two weeks, the distance I can walk has improved:

- Not at all-check this if the distance is unchanged or has decreased;
- A little;
- Somewhat;
- Moderately;
- A good deal;
- A great deal;
- A very great deal.

10. During the past two weeks, because of the poor circulation in my legs, my ability to walk has been:

- Totally limited, couldn't walk at all;
- Extremely limited;
- Very limited;
- Moderately limited;
- A little limited;
- Only very slightly limited;
- Not at all limited.

11. During the past two weeks, being (or becoming) housebound has concerned me:

- A very great deal;
- A great deal;
- A good deal;
- Moderately;
- Somewhat;
- A little;
- Not at all.

12. During the past two weeks, I have been concerned about having poor circulation in my legs:

- All of the time;
- Most of the time;
- Much of the time;
- Some of the time;
- A little of the time;
- Hardly any of the time;
- None of the time.

13. During the past two weeks, I have had pain in the foot (or leg) when I am resting:

- All of the time;
- Most of the time;
- Much of the time;
- Some of the time;
- A little of the time;
- Hardly any of the time;
- None of the time.

14. During the past two weeks, because of the poor circulation in my legs, my ability to climb stairs has been:

- Totally limited, couldn't climb stairs at all;
- Extremely limited;
- Very limited;
- Moderately limited;
- A little limited;
- Only very slightly limited;
- Not at all limited.

15. During the past two weeks, because of the poor circulation in my legs, my ability to participate in social activities has been:

- Totally limited, couldn't socialize at all;
- Extremely limited;
- Very limited;
- Moderately limited;
- A little limited;
- Only very slightly limited;
- Not at all limited.

16. During the past two weeks, because of the poor circulation in my legs my ability to do routine household work has been:

- Totally limited, couldn't perform housework at all;
- Extremely limited;
- Very limited;
- Moderately limited;
- A little limited;
- Only very slightly limited;
- Not at all limited.

17. During the past two weeks, ulcers or sores on my leg (or foot) have caused me pain or distress:

- All of the time;
- Most of the time;
- Much of the time;
- Some of the time;
- A little of the time;
- Hardly any of the time;
- None of the time - (pick this one if you do not have leg ulcers).

18. Because of the poor circulation in my legs, the range of activities that I would have liked to do in the past two weeks has been:

- Severely limited - most activities not done;
- Very limited;
- Moderately limited- several activities not done;
- Slightly limited;
- Very slightly limited - very few activities not done;
- Hardly limited at all;
- Not limited at all - have done all activities that I wanted to.

19. During the past two weeks, problems caused by poor circulation in my legs has made me feel frustrated:

- All of the time;
- Most of the time;
- Much of the time;
- Some of the time;
- A little of the time;
- Hardly any of the time;
- None of the time.

20. During the past two weeks, when I have had pain in the leg (or foot) it has given me:

- A very great deal of discomfort or distress;
- A great deal of discomfort or distress;
- A good deal of discomfort or distress;
- A moderate amount of discomfort or distress;
- Some discomfort or distress;
- Very little discomfort or distress;
- No discomfort or distress.

21. During the past two weeks, I have felt guilty about relying on friends or relatives:

- All of the time;
- Most of the time;
- Much of the time;
- Some of the time;
- A little of the time;
- Hardly any of the time;
- None of the time.

22. During the past two weeks, because of the poor circulation in my legs, my ability to go shopping or carry bags has been:

- Totally limited, couldn't go shopping at all;
- Extremely limited;
- Very limited;
- Moderately limited;
- A little limited;
- Only very slightly limited;
- Not at all limited.

23. During the past two weeks, I have worried I might be in danger of losing a part of my leg or foot:

- All of the time;
- Most of the time;
- Much of the time;
- Some of the time;
- A little of the time;
- Hardly any of the time;
- None of the time.

24. During the past two weeks, the distance I can walk became less:
 - A very great deal;
 - A great deal;
 - A good deal;
 - Moderately;
 - Somewhat;
 - A little;
 - Not at all - check this if the distance is unchanged or has increased.

25. During the past two weeks, I have been depressed about the poor circulation in my legs:
 - All of the time;
 - Most of the time;
 - Much of the time;
 - Some of the time;
 - A little of the time;
 - Hardly any of the time;
 - None of the time.

Domains:

- Activity items - 4,9,10,14,16,18,22,24
- Symptom items - 3,5,8,17
- Pain items - 1,7,13,20
- Emotional items - 2,11,12,19,21,23,25
- Social items - 6,15

Each domain is scored 1-7 = the total of domain item scores divided by the number of questions in the domain. The total score is scored 1-7 = the total of all the item scores divided by 25.

MATERIAL AND METHODS

A total of 120 patients, 111 men (92.5%) and 9 women (7.5%), who underwent revascularization for peripheral arterial disease, were assessed for quality of life, before the operation and 1 month after. Their mean age was 58.3 years (range 35-82 years). The risk factors included diabetes mellitus – 21.17%, hypertension – 38.82%, diabetes and hypertension – 15.3%, smoking – 75.45%

The patients were staged (Fontaine) before the operation as follows: stage IIB – 49.16%, stage III – 26.66%, stage IV – 24.16%.

The surgical procedures for revascularization were: aorto-femoral or -bifemoral bypasses – 33.33%, ilio-femoral bypasses or iliac endarterectomies – 9.16%, femuro-popliteal bypasses – 49.16%, femuro-distal bypasses – 8.33%.

The statistical instruments we used are the Student test, the chi square test, the correlation coefficient.

The VasuQol questionnaire conceived and validated by Mark B.F. Morgan at King’s College Hospital from London in 2000-2001 was used for the assessment of quality of life.⁶ The questionnaire was translated and adapted by us.

RESULTS

1. BEFORE REVASCLARIZATION

A. Total

The total score was between 1.2 and 5.96, with a mean of 3,56 and a standard deviation of 1.52 .

The score by domains (means):

- 1. Physical activity: 2.87

- 2. Pain: 4
- 3. Psychological well-being: 4.7
- 4. Symptoms: 3.75
- 5. Social activity: 3.6 (Fig.1)

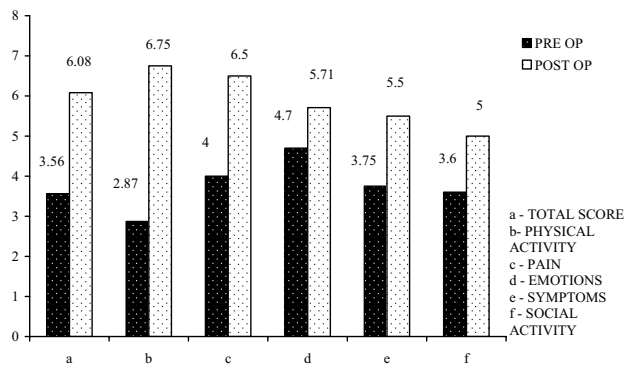


Figure 1. Increase of scores after operation

B. Distribution of scores depending on:

1. Age:

The correlation between the age of patients and their QOL scores was -0.77: the score diminishes with ageing, older patients have lower scores. Also, there is a negative correlation with age as it concerns the physical activity and psychological scores (-0.75 and -0.72).

2. Gender

The score was lower in women than in men: 3.32 and 3.58, but the difference was not statistically significant.

3. Risk factors

The patients suffering from diabetes had an average score of 3.24, those with hypertension 3.32, and those with both diseases 3.16.

4. Stage of ischemia (means)(Table 1):

- stage IIB: 4.76
- stage III: 3.36
- stage IV: 1.96

The stage IV score is significantly (p<0.001) lower than the scores of other stages. The stage III score is significantly (p<0.05) lower than the score of stage IIB.

5. Domains and ischemia stages:

In the case of the patients with stage IIB ischemia the lower score appears at physical activity and the higher at pain and symptoms. (Fig. 2)

In the case of the patients with stage III ischemia the lower score appears at pain and symptoms and the higher at psychological well-being. (Fig.3)

In the case of the patients with stage IV ischemia the lower score appears at physical activity and social activity and the higher at psychological well-being and symptoms. (Fig.4)

Table 1. The score by domains and ischemia stages, pre- and postoperative

LEVEL / DOMAIN	PHYSICAL ACTIVITY		PAIN		PSYCHOLOGICAL WELL-BEING		SYMPTOMS		SOCIAL ACTIVITY	
	preop	postop	preop	postop	preop	postop	preop	postop	preop	postop
II B	3.62	6.87	5.25	6.75	4.85	6.14	5.25	5.62	4.5	5.5
III	2.75	6.75	3.25	6.25	4.28	5.57	2.66	5.5	3.5	5.75
IV	1.37	6.5	2	6	2.25	5	2.25	5.25	1.5	4.5

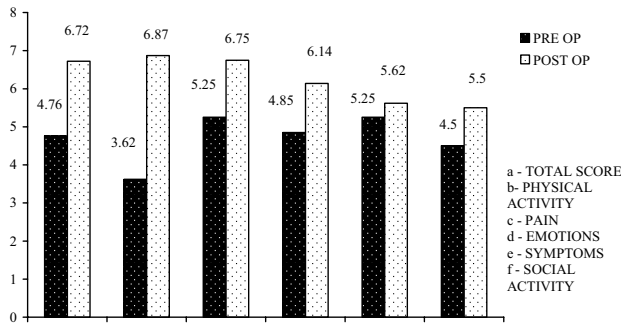


Figure 2. Increase of scores after operation, at patients in stage IIB

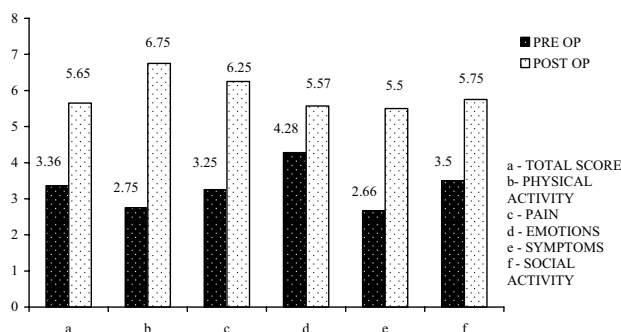


Figure 3. Increase of scores after operation, at patients in stage III

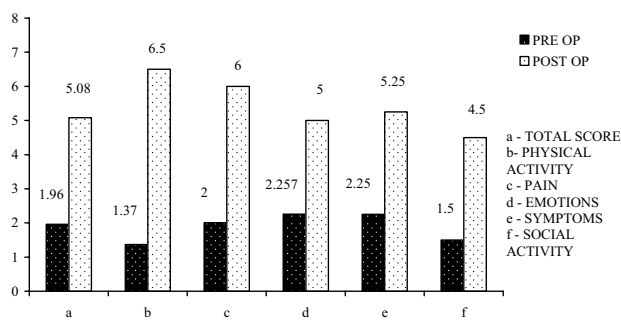


Figure 4. Increase of scores after operation, at patients in stage IV

6. Level of arterial lesion (means):

- aortic - 3.48
- iliac - 3.28
- femuro-popliteal - 3.84
- distal - 2.68

The score of patients with distal lesions is significantly lower than the others' score ($p < 0.005$).

Although the tendency is that the score diminishes as the lesion becomes more distal, those with femuro-popliteal lesions had the highest score (significantly higher than the score of those with aortic lesions, $p < 0.05$), probably because of the higher percentage of stage IIB ischemia between those with femuro-popliteal lesions. (Table 2)

As in the case of the general score, the domains scores are significantly lower at those with distal lesions and higher at those with femuro-popliteal lesions.

7. Duration of disease

Between the duration of disease (how old the history of disease is in a specific patient) and the QOL score was a not very significant (-0.63) negative correlation, probably because of the advances in the stage of ischemia and the accentuation of the psychical component of discomfort.

II. AFTER REVASCULARIZATION

A. Total score

The total score was between 4.08 and 6.88, with a mean of 6.08 and a standard deviation of 1.24.

The increase of the total score was 70% and of the scores by domains between 21% and 135%. (Fig.5) The biggest improvement was in the case of physical activity, and the lowest in the case of psychological well-being.

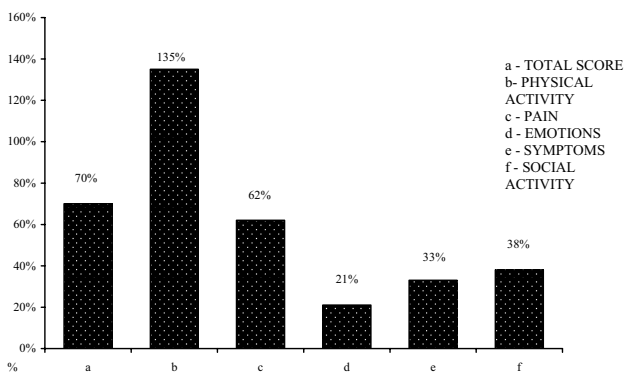


Figure 5. Increase of scores by domains and operations

Table 2. The score by domains and lesional level, pre- and postoperative

LEVEL/ DOMAIN	PHYSICAL ACTIVITY		PAIN		PSYCHOLOGICAL WELL-BEING		SYMPTOMS		SOCIAL ACTIVITY	
	preop	postop	preop	postop	preop	postop	preop	postop	preop	postop
AORTIC	2.87	6.87	3.75	6.5	4.57	6	4	5.5	3.5	5.5
ILIAC	2.75	6.62	3.5	6.75	4.7	5.85	4.25	5.75	4.5	5
FEMORAL	3.12	6.75	4.5	6.5	5.14	5.71	3.75	5.75	4	5
DISTAL	1.5	6.25	2.5	5.75	2.85	4.42	2.25	4.5	1.5	3.5

B. The scores by categories:

1. Scores by the stage of ischemia (means)

- stage IIB: 6.72 increased from 4.76
- stage III: 5.65 increased from 3.36
- stage IV: 5.08 increased from 1.96

The stage IV score is significantly lower than the others, but has the biggest increase (159%)

2. Scores by domains and ischemia stages (Table 1)

All the scores increase significantly, but scores close to the maximum (higher than 6) appeared only in the case of physical activity, pain and psychological well-being in the former stage IIB.

In case of the patients that were before operation in stage IIB ischemia, the highest increase (90%) was in the domain of physical activity, and the lowest (7%) at symptoms (because that score was high before revascularization).

The patients in the stage III of ischemia benefited from higher increases of the scores at physical activity (145%) and symptoms (107%); the lowest increases were at psychological well-being.

In the stage IV of chronic ischemia the highest rise was at physical activity (374%), pain and social activity (200%), and the lowest at psychological well-being. (Fig. 6)

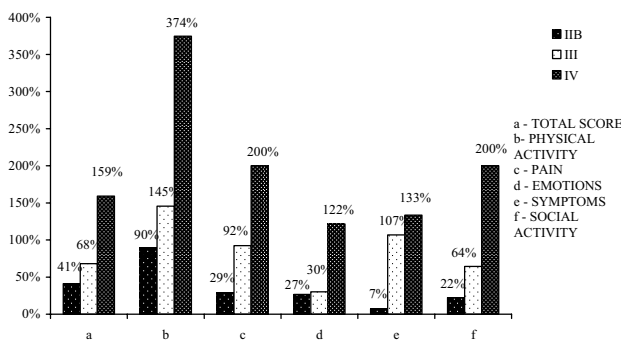


Figure 6. Percent increase of scores by domains and ischemia stages

3. Scores by domains and revascularization type (Table 2)

Those operated at the following levels had the highest scores:

- aortic - for physical activity, psychological well-being and social activity
- iliac - for pain
- femoro-popliteal - for symptoms

The increase of the score was between 11% and 316%, the highest increase being for physical activity after distal revascularization. (Fig. 7)

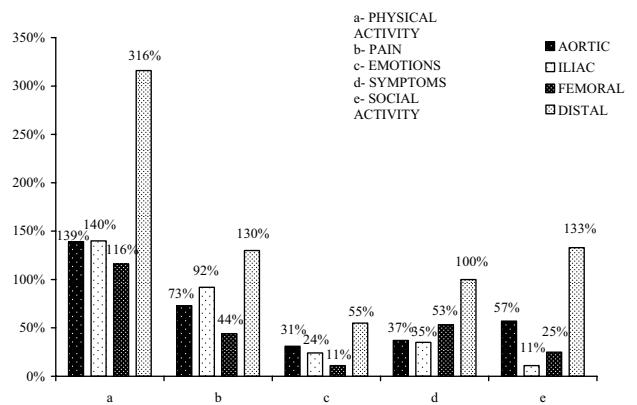


Figure 7. Percent increase of scores by domains and type of surgery

3. COMPLICATIONS

The cases that had postoperative complications had an average total score of 5.72 (those without complications scored 6.12, $p < 0,05$), the symptoms and emotion domains having the lowest scores.

DISCUSSIONS

The patients did not meet with any significant problems in answering the questionnaire, and the average completing time was 11 minutes.

Table 3. Results from literature

Author	Questionnaire	Results, conclusions
Schechter M 2003 ⁷	SF-36	The quality of life of old age patients is low. The surgical treatment increase their score, but it remains lower than the score of general population.
Marquis P 1998 ⁸	ARTEMIS	There is no close correlation between the walking distance at claudicants and the QOL score - those with a walking distance under 500m may have all kinds of scores.
Muller- Buhl 2003 ⁹	SF-36	There is good correlation between the QOL scores and the corporeal mass index and the walking distance, but there is no correlation with the angiographic severity of the disease.
Holtzman J 1999 ¹⁰	SF-36	The elderly patients and those with diabetes have lower functional scores, even after revascularization.
Bloemenkamp DG 2003 ¹¹	RAND 36	The scores are higher at patients with more proximal lesions. Efficient therapy does not significantly increase the quality of life at young women (under 50 years)
De Graaff JC 2002 ¹²	SF-36	The patients with PAD had lower QOL scores than those with coronary ischemic disease.
Treat Jacobson D 2002 ¹³	HRQoL	Generic questionnaires do not cover all the specific aspects for peripheral arterial disease.
Wohlgemuth WA 2003 ¹⁴	CLAU-S, PAVK-86, WIQ	The conservatory treatment does not prevent the decrease of QOL in the social and psycho-emotional domains. Angioplasty and surgical treatment produce similar increases in all the domains of QOL.
Hallin A 2002 ¹⁵	SF-36, LiSat-11	Generic questionnaires do not cover all the specific aspects for peripheral arterial disease.
Ponte E 1996 ¹⁶	NHIQ, GHIQ	Patients with stage II chronic ischemia: lower scores at physical and social activity, but higher at psychological well-being.
Cassar K 2003 ¹⁷	NHP, SF-36, EuroQol	The angioplasty improves somehow the QOL, but further studies with specific questionnaires are necessities.
Gherman I 2003 ¹⁸	NHP	Significant decrease of all the QOL parameters at claudicants

For the assessment of QOL in PAD patients other authors used various questionnaires, generic or PAD-specific. (Table 3)

In some aspects, our results are similar to those revealed in studies with generic QOL questionnaires:

- a decrease in all the scores by domains in the patients with PAD;^{12,18}
- an increase of scores after revascularisation;^{7,17}
- low QOL scores at older patients, even after revascularisation;^{7,10}

or some divergent results: the scores are not higher at patients with more proximal lesions,¹¹ but at those with femuro-popliteal lesions.

Also, the studies with disease-specific QOL questionnaires showed results that matched ours,^{8,14,16} but only as it concerns the claudicants; they are not covering the whole aria of PAD, including the critical ischemia, as King's College VasuQOL does.

CONCLUSIONS

To summarize, the most important results of the present study are:

Before operation, the patients with PAD have lower QOL scores. The scores decrease proportionally with: patient's age (especially those for physical activity and psychological well-being), the stage of chronic ischemia, the distal nature of the vascular lesion (excepting the femuro-popliteal lesions, with the higher

scores), disease duration. After surgical revascularization the QOL scores are significantly increased. The patients with advanced chronic ischemia, distal lesions and postoperative complications had relatively lower scores, although the percentual increase from the preoperative scores are obviously the highest in these categories.

The results obtained using this questionnaire are similar with those from other studies, confirming its validity and applicability in our country.

These results can be used to select the claudicants for revascularisation: a total score that is lower than the average for chronic ischemia stage II,^{4,76} especially when it is approaching the score for stage III,^{3,36} indicates the need for surgery or endovascular treatment.

Also, even if in the stages III or IV the criteria for critical ischemia are not attempted (rapid evolution leading to major amputation in 6-12 months), a very low total score (or the majority of scores by domains reduced) may indicate the urgency of revascularisation.

Even after successful revascularisation the score do not increase to the maximum, and the patient may be a little disappointed. The results from this study may aid us to know better what to expect from revascularisation in different categories of patients and to let them know from the beginning.

The King's College VasuQOL can be used to asses the results of a specific treatment or to compare two treatments, for example, the surgical and the

endovascular revascularisation. Furthermore, the QOL assessment is mandatory in every clinical study about the treatment of PAD.

*Recommendation 44 (TransAtlantic Inter-Society Consensus on PAD): "Quality-of-life instruments should be used in all trials, and ultimately this may become a primary end point."*¹⁹

In conclusion, although the aspect of quality of life was only seldom or empirically considered in the Romanian medicine, the QOL questionnaire is a specific, useful and cost-effective tool for selecting the patients for surgery and choosing the time for operation, and also for quantifying the results of operations or comparing various treatments.

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