Walking distance and quality of life in patients selected for endovascular treatment

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Abstract

Aims: To investigate the association between walking distance and health-related quality of life (HRQoL), and to explore the possible relation between HRQoL and walking distance, classified by the Fontaine stage, in patients with peripheral arterial disease (PAD) selected for endovascular treatment. Method: A cross-sectional study of 50 PAD patients (49–83 years) selected for endovascular treatment. Walking distance (Six Minute Walk Test and treadmill test), patient-reported walking distance and HRQoL [Medical Outcome Study Short Form Health Survey (SF-36) and Claudication Scale (CLAU-S)] were assessed. Results: The associations between measures of walking distance and domains of HRQoL were small to medium in strength. The measured walking distance was markedly longer than the patient-reported walking distance and correlated only with medium strength. There was a significant reduction in the SF-36 domains physical function, physical role and bodily pain, and the CLAU-S domain daily life between patients who had a walking distance below 200 m, compared with patients with a walking distance above that. Conclusions: The results demonstrate the usefulness of assessing HRQoL in addition to performance-based measurements of walking distance in PAD patients. Its utilization may increase awareness of patients’ actual condition and will be a better guide for identifying the best treatment relative to risks.

Key words: Intermittent claudication, patient-reported measurements, performance-based measurement
performance, whereas endovascular treatment was better than SET for the endpoint HRQoL.

Regardless of the lack of evidence of its superiority, the frequency of using endovascular treatment to treat intermittent claudication is increasing as an alternative to both surgery and conservative treatments (1,7). Specific criteria for the selection of endovascular treatment have not been commonly agreed upon, and selection criteria differ between vascular centres (1,12,13). Impaired HRQoL due to reduced walking ability is usually the main selection criteria for endovascular treatment after a conservative treatment has failed. However, HRQoL and walking distance are often based on patient history, with emphasis on the patient’s subjective statement of walking distance and functional status rather than on performance-based validated clinical measurements.

Considering this background, several questions may be raised. What are the consequences of the potential discrepancy between patient-reported and measured walking distance when making a decision regarding possible treatment options? Likewise, what is the consequence of HRQoL not being registered by validated assessments? Are there differences in HRQoL related to the severity of PAD? What is the association between walking distance and HRQoL? It is important to evaluate HRQoL and walking distance in patients with PAD; previous research indicated that these patients are at risk of inactivity, functional decline and further decreased HRQoL (14). As far as we know, information regarding the association between walking distance and HRQoL, as well as knowledge about possible differences in HRQoL regarding the Fontaine stage classification, is sparse. Thus, the aim of this study was to investigate the association between walking distance and HRQoL in PAD patients. In addition, we aimed to explore the possible differences in HRQoL regarding the Fontaine stage. Our hypothesis is that there is a statistically significant association between HRQoL and walking distance in PAD patients.

Material and methods

Design and sample

This study used a cross-sectional design. The data were collected as part of a project at the Oslo University Hospital, Norway, in which eligible patients who were selected to undergo endovascular treatment for PAD due to intermittent claudication (Fontaine stage II) between March 2010 and June 2012 were consecutively invited to participate. The inclusion criterion for the trial was indication for endovascular treatment due to intermittent claudication after the best available medical treatment had failed. The exclusion criteria were previous endovascular treatment in the past 2 years in the same leg, a history of unsuccessful endovascular treatment attempts, critical limb ischaemia and reduced walking ability due to factors other than PAD (i.e. orthopaedic problems, spinal stenosis, angina pectoris or dyspnoea).

Measurements

All measurements were taken during the same visit, which occurred 1–14 days prior to the planned endovascular treatment.

Walking distance. The patients’ walking distance was assessed with the standardized Six Minute Walk Test (6MWT) (15). The 6MWT was performed in a 30-m pre-marked hospital corridor, and instructions and encouragement were given according to the test guidelines. The treadmill protocol was graded (3.2 km/h constant speed, starting with 0% incline, increasing by 2% every 2 min until 10% incline was reached) (16). In addition, the patient-reported walking distance was obtained from the record of the patients’ last clinical visit prior to endovascular treatment.

HRQoL. The Medical Outcome Study Short Form Health Survey (SF-36) (17) is one of the most commonly used HRQoL measures in PAD and was used in this study with the Claudication Scale (CLAU-S) (18). Considerable controversy exists regarding which HRQoL measures are most appropriate. According to Liles et al. (3), a general agreement exists that generic in conjunction with disease-specific HRQoL can be useful for examining the extent to which patients with PAD are compromised by the illness in carrying out activities of daily living, and for examining the impact of treatment in sustaining or improving functional status as well as its effects on emotional and social well-being.

The SF-36 items are grouped into eight subscales: physical functioning, role limitation due to physical problems (physical role), role limitation due to emotional problems (emotional role), bodily pain, social functioning, mental health, vitality and general health perception. CLAU-S is a disease-specific HRQoL instrument with five subscales: daily life, pain, social life, disease-specific anxiety and psychological well-being.

The raw SF-36 scores were coded and recalibrated following standard guidelines, and the items were then summed and transformed into the eight scales ranging from 0 to 100 (higher scores indicate better quality of life) (17). The CLAU-S raw scores...
were also coded, recalibrated, summed and transformed into the five scales ranging from 0 to 100 (higher scores indicate better quality of life). To investigate the differences related to HRQoL, patients were analysed with regard to their walking distance, both pain-free and maximum distance shorter or longer than 200 m.

**Demographics.** Information regarding age, gender, blood status, smoking status, medication, previous cardiovascular events and comorbidity was collected. Patient limb haemodynamics were assessed by the ankle–brachial index (ABI) and pulse volume recordings (PVR) of the leg (19).

**Statistics**

The data are presented as the median with the minimum and maximum values or as exact numbers and percentages. Comparisons between groups were analysed using the Mann–Whitney Wilcoxon test because not all variables were normally distributed. For the correlation analysis, Spearman correlation coefficients were calculated. The strength of the correlations was interpreted according to Cohen’s criteria: 0.10–0.29 as small, 0.3–0.49 as medium and 0.5–1 as large (20). All statistical analyses were performed with SPSS Software 20.0 (SPSS Inc., Chicago, IL); \( p \)-values < 0.05 were considered statistically significant, and all tests were two-sided.

**Ethical considerations**

All work related to this study was conducted in accordance with the Declaration of Helsinki. The study is registered with ClinicalTrials.gov (NCT01109732), and was approved by the Regional Ethics Committee for Medical Research of the Eastern Health Region (2009/2192-1), Norway. All the participants provided written informed consent prior to participation.

**Results**

A total of 50 patients with intermittent claudication for whom endovascular treatment was planned were analysed in this study. Descriptive characteristics for the patients are listed in Table I. Concerning gender, there were no statistically significant differences regarding the variables connected to the outcome.

Measured (via the 6MWT, maximum walking distance treadmill and PFWD treadmill) and patient-reported walking distances are described in Table II. Patient-reported walking distance was significantly correlated with the 6MWT (rho = 0.47). Patient-reported walking distance was not significantly correlated with the maximum or pain-free walking distance on a treadmill (Table III).

HRQoL as measured by the SF-36 was analysed according to walking distance and demonstrated that

| Table I. Descriptive characteristics of all patients (n = 50). |
|-------------------------------------------------------------|
| **Median** (min-max) |
| **Demographics** |
| Age (years) | 67 (49–83) |
| Body mass index (kg/m²) | 27.3 (17.9–38.7) |
| Gender (% men) | 24 (48) |
| Marital status | 28 (56) |
| Years of school (> 9 years) | 38 (76) |
| **Limb-hemodynamic status** |
| ABI | 0.57 (0.25–0.83) |
| PVR (mm) | 4 (1–10) |
| **Blood status** |
| Total cholesterol (mmol/l) | 4.7 (3.0–7.1) |
| HDL (mmol/l) | 1.5 (0.9–3.3) |
| LDL (mmol/l) | 2.4 (1.3–4.5) |
| Triglycerides (mmol/l) | 1.3 (0.4–4.8) |
| Glucose (mmol/l) | 5.7 (3.1–10.9) |
| HbA1c (%) | 6.0 (4.0–8.1) |
| **Smoking status** |
| Have never smoked | 1 (2) |
| Used to smoke | 29 (98) |
| Currently smoke | 20 (40) |
| **Medication** |
| Statins | 47 (94) |
| Platelet inhibitors | 45 (90) |
| Anticoagulants | 2 (4) |
| Hypertension | 28 (56) |
| **Comorbidity** |
| Diabetes | 7 (14) |
| COPD | 3 (6) |
| **Previous cardiovascular events** |
| Myocardial infarction | 16 (32) |
| Stroke/TIA | 1 (2) |
| Previous peripheral arterial surgery or endovascular treatment | 9 (18) |

| Table II. Walking distance – measured and patient-reported. |
|-----------------------------------------------------------|
| **Metres** |
| **Median** (min-max) |
| 6MWD | 431 (224–561) |
| MWD treadmill | 332 (58–1175) |
| PFWD treadmill | 101 (36–534) |
| Patient-reported walking distance | 100 (10–500) |

6MWD, 6-minute walking distance; MWD, maximum walking distance; PFWD, pain-free walking distance.
those who were able to walk more than 200 m (maximum) had significantly better results than those who walked less than 200 m (maximum) in three of the SF-36 domains – physical function, physical role and bodily pain – and in one CLAU-S domain – daily life (Table IV). A statistically significant difference was observed between those who had a pain-free walking distance of 200 m or more and those who walked less than 200 m for the CLAU-S domain of daily life (Table IV). For the other domains, no statistically significant differences were observed between patients regarding neither pain-free walking distance nor maximum walking distance.

The measured walking distance on the 6MWT was significantly correlated with the SF-36 domains bodily pain (rho = 0.38) and emotional role (rho = 0.29). Maximum walking distance on a treadmill was significantly correlated with physical role (rho = 0.35) and bodily pain (rho = 0.35). Pain-free walking distance on the treadmill was correlated with the physical function (rho = 0.37), bodily pain (rho = 0.35) and vitality (rho = 0.35) domains (Table V). Each correlation was considered of medium strength.

The daily life domain of the CLAU-S was significantly correlated with the 6MWT (rho = 0.36), treadmill maximum (rho = 0.47) and pain-free walking distances (rho = 0.58). The other CLAU-S domains (pain, social life, disease-specific anxiety and psychological well-being) were not significantly correlated with any of the measured walking distances (Table IV). The patient-reported walking distance was not significantly correlated with any of the SF-36 or CLAU-S domains.

**Discussion**

The main finding of the present study was that the correlations between measures of walking distance and various HRQoL domains were of small to medium strength (20) and, for most domains, were not statistically significant. Additionally, patients’ measured walking distance was markedly longer than their self-reported walking distance and was correlated to HRQoL with only medium strength.

A significant difference was found in the SF-36 domains physical function, physical role and bodily pain, and in the CLAU-S domain daily life, between those patients who were able to maximally walk less than 200 m and those who walked 200 m or more. The latter obtained higher HRQoL scores. Based on a thorough literature search, no studies showing this significant difference were found. Differences were greater than 5–10 points, which has been shown to be clinically relevant (21). Previous research has shown that high levels of physical fitness are important for good HRQoL, especially in older people (22,23).

Table IV. Medical Outcome Study Short Form Health Survey (SF-36) and Claudication Scale (CLAU-S) scores regarding pain-free and maximum walking distances.

|                      | Pain-free walking distance, median (min-max) | Maximum walking distance, median (min-max) |
|----------------------|---------------------------------------------|------------------------------------------|
|                      | < 200 m, n = 34                             | ≥ 200 m, n = 12                           | < 200 m, n = 21 | ≥ 200 m, n = 26 |
| SF-36                |                                             |                                         | | |
| Physical functioning (PF) | 45 (10–70)                              | 52.5 (35–70)                              | 40 (10–70) | 50 (20–70)* |
| Physical role (RP)   | 59.4 (6.3–100)                            | 68.8 (6.3–93.8)                           | 43.8 (6.3–81.3) | 68.8 (6.3–100)* |
| Bodily pain (BP)     | 41 (12–62)                                | 51 (0–62)                                | 32 (12–62) | 51 (0–62)* |
| General health (GH)  | 52 (20–97)                                | 67 (10–92)                               | 48.5 (27–97) | 62 (10–92) |
| Vitality (VT)        | 45 (10–75)                                | 50 (40–73.3)                             | 50 (10–75) | 45 (25–75) |
| Social functioning (SF) | 75 (0–100)                             | 93.7 (50–100)                            | 75 (0–100) | 93.8 (37.5–100) |
| Emotional role (RE)  | 60 (6.7–80)                               | 60 (40–80)                               | 53.3 (6.7–80) | 60 (20–80) |
| Mental health (MH)   | 76 (12–88)                                | 76 (40–88)                               | 74 (12–88) | 76 (40–88) |
| CLAU-S               |                                             |                                         | | |
| Daily life (DL)      | 61.1 (16.7–97.2)                          | 75 (53.1–94.4)*                          | 58.3 (16.7–91.7) | 66.7 (52.8–97.2)* |
| Pain (P)             | 46.7 (5.6–76.2)                           | 55 (29–68.3)                             | 45.4 (20.4–75.3) | 52.3 (5.6–76.2) |
| Social life (SL)     | 93.8 (18.8–100)                           | 100 (62.5–100)                           | 87.5 (18.8–100) | 100 (56.3–100) |
| Disease-specific anxiety (DSA) | 86.5 (18.2–100)                  | 86.5 (73.1–94.2)                         | 88.5 (18.2–100) | 86.5 (65.4–98.1) |
| Psychological well-being (PWB) | 86.4 (0–100)                    | 84.1 (47.7–100)                          | 86.4 (0–100) | 84.1 (47.7–100) |

*Statistically significant (p < 0.05) difference compared with the group whose walking distance was less than 200 m (Mann–Whitney U-test).
Assessing both walking distance and HRQoL (by performance-based measurements and validated HRQoL instruments, respectively) is important; the results of the present study revealed that there are only small to medium strength correlations between the few statistically significant results of the walking distance and HRQoL measures. Additionally, the vitality domain and pain-free walking distance demonstrated a large correlation. The small to medium-strength correlations may be explained by the complexities within HRQoL and by the complex and multifaceted relationship between physical activity and HRQoL (24).

As mentioned, the assessment of HRQoL and walking distance are often based on patient history and emphasize the patient’s subjective statement of walking distance and functional status rather than performance-based clinically valid measurements. These types of data are conceptually different. Self-report data are related to the concept of disability because they reflect subjective performance within a socio-cultural context; assessment by an external observer is closer to objective functional limitations (25). Thus, tests based on self-reported functioning and actual performance are assumed to complement each other (26–28). Furthermore, it is stated that performance-based tests are more robust than self-reported measures in terms of validity, reliability and sensitivity to change (29,30). The results of the present study revealed that patient-reported walking distance is an underestimation of actual patient performance. This tendency is also previously reported (31,32). Concerning gender, there were no statistically significant differences regarding the variables connected to the outcomes presented. However, in a recent review from 2012 by Brenner et al. (33), it was elucidated that the symptom presentation of PAD in men and women might differentiate, though mainly for micro-circulatory outcomes and cardiovascular comorbidity. Reasons for the discrepancy between patient-reported and actual performed walking distance may be that many patients with PAD have low self-efficacy, which may disturb the self-evaluation of their own walking distance (34). In addition, a cardinal symptom of PAD is pain when walking in this phase; thus, there may be some who underestimate their walking distance to increase their chances of receiving attention at the doctor’s office, and, potentially, surgical intervention.

Differences in some HRQoL domains were observed, in both the generic and the disease-specific instruments, which depended on walking distance. These differences may be expected because longer walking distances could mirror less severely affected physical function and pain. Studies have found positive associations between various aspects of HRQoL and physical activity (22,24,35). Thus, it might be more interesting that other domains exhibited no statistically significant differences with regard to shorter or longer walking distances. These domains included the SF-36 domains general health, vitality, social functioning, emotional role, and mental health and the CLAU-S domains social life, disease-specific anxiety and psychological well-being. This result emphasizes the importance of considering more than walking distance in treatment and more than the most physical aspects of HRQoL, which are those most frequently explored in the literature (36).

| Table V. Correlations between health-related quality of life (HRQoL) and walking distance. |
| sf-36 | 6MWD, MWD, PFWD, Patient-reported walking distance, rho |
| 6MWD, MWD, PFWD, Patient-reported walking distance, rho |
| SF-36 | rho | rho | rho | rho |
| Physical functioning (PF) | 0.220 | 0.283 | 0.365* | (-) 0.043 |
| Physical role (RP) | 0.195 | 0.349* | 0.175 | 0.159 |
| Bodily pain (BP) | 0.382* | 0.348* | 0.349* | (-) 0.023 |
| General health (GH) | 0.127 | 0.202 | 0.145 | 0.014 |
| Vitality (VT) | 0.069 | 0.214 | 0.352* | (-) 0.149 |
| Social functioning (SF) | 0.168 | 0.163 | 0.261 | 0.044 |
| Emotional role (RE) | 0.288* | 0.152 | 0.227 | 0.097 |
| Mental health (MH) | (-) 0.050 | (-) 0.065 | 0.026 | (-) 0.243 |

6MWD, 6-minute walking distance; MWD, maximum walking distance; PFWD, pain-free walking distance; SF-36, the Medical Outcome Study Short Form Health Survey; CLAU-S, the Claudication Scale; rho, Spearman’s correlation coefficient. *Correlation is significant at the 0.05 level (two-tailed).
Differences related to walking distance were all mainly related to the maximum distance walked in contrast to pain-free walking distance. This result was also expected and reasonable; many patients may, in daily activities, be able to continue walking even with some amount of pain, yet stop before they reach their maximum distance. This matter was also raised by Kruidenier et al. (37) in their study of functional walking distance. Regarding HRQoL instruments, disease-specific instruments are usually found to be more sensitive to change than generic instruments (38). The use of HRQoL instruments as an end-point in studies was recommended in TASC II (the Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease) (1); however, no consensus exists regarding the assessment of QoL in PAD beyond using one generic and one disease-specific instrument (9).

There is no explicit limit on walking distance in the choice between the best available medical treatment and endovascular treatment for PAD. How the disease affects HRQoL is also different for each patient and may be hard to categorize. However, with performance-based assessments, it is possible to increase awareness of both the actual walking distance and the ways in which HRQoL is affected to reach a decision about the best treatment relative to the possible risks involved, especially regarding endovascular treatment. Better assessments and utilizing the advantages of existing validated instruments have already been mentioned in a study published in 1996 (39) and have been emphasized repeatedly (1,3,38). It still appears that some patients have a longer walking distance and possibly better HRQoL than they report. Endovascular treatments have recently increased in frequency (1,7), which may be due to technical improvements and an increase in the number of treatment sites; however, less severely affected patients may be treated to a greater extent. Although complications are few, it is known that invasive treatments are associated with risks, and re-occlusions may require open surgery at earlier stages. This should be taken into account when making treatment decisions (9). Patients are aware of their own quality of life, although they may not have the same appreciation of treatment risks. Clinical experience shows that some patients may change their minds regarding treatment when given more information. It is possible that with time, patients will accept and consequently adapt to the consequences of the disease.

A limitation of the present study is that the cross-sectional design does not allow us to make conclusions regarding causality. Although the sample size is quite small, the measured outcomes of the sample and its general characteristics are representative of the patient population, with the exception of the percentage of men, and the percentage of current smokers, which were slightly lower in the present study. Several studies on patients with intermittent claudication (Fontaine stage II) who were selected for endovascular treatment have measured their HRQoL using the SF-36 (8,40–42). The patient characteristics in these intervention studies were quite similar to the present study’s participants’ characteristics and findings, also here with the same exceptions with regard to gender and smoking. Very few studies have used the CLAU-S as a disease-specific HRQoL instrument, so comparisons are difficult. Patients in the Egberg et al. (43) study were all selected for endovascular treatment and had lower scores in all the domains of the CLAU-S; lower scores reflect worse perceived health than in the present study. However, 15% of the patients in the Egberg et al. study had symptoms classified as critical limb ischaemia (Fontaine stage III or IV), which may be a reason for the lower observed scores. Due to different treadmill protocols and inconsistent reporting in prior studies, it was not possible to make clear comparisons with all of the clinical trials regarding walking distance. Izquierdo-Porrera et al. (44), Nicolai et al. (45) and Kruidenier et al. (40) all used the same treadmill protocol as in the present study. Kruidenier et al. and Izquierdo-Porrera et al. obtained quite similar walking distance test results. The latter study also included a 6MWT, which showed quite similar results to those obtained in the present study. Nicolai et al. found shorter distances on the treadmill test; however, this study excluded patients who had walked more than 500 m, which may conceivably underlie the difference.

As a consequence of the relatively small sample size in the present study, precautions need to be taken in the interpretation of the results and its importance. The different clinics and treatment sites have procedures fitting their patient population and internal resources that might not be amendable to a certain fixed procedure. However, it is important that the patients with PAD receive a thorough assessment of their condition. Performance-based assessments for walking distance and HRQoL instruments could be useful tools in this respect.

For further research, we would recommend, in line with earlier recommendations, additional focus on HRQoL and possibly also health economic analyses for selection to and planning of appropriate treatments and evaluation of treatment. This is better done in clinical randomized controlled trials, possibly also with a multicentre design that gives the possibility of a larger sample size.
Conclusion
This study of patients with PAD, who were specifically selected for endovascular treatment after best available medical treatment had failed, showed that the patients’ measured walking distance was markedly longer than the patient-reported walking distance. The associations between measures of walking distance and the different HRQoL domains were small to medium in strength and, for most domains, were not statistically significant. There was a significant difference in some HRQoL domains between those patients who were able to walk less than 200 m and those who walked more than 200 m. The use of performance-based assessments for walking distance and HRQoL instruments in clinical practice may increase awareness of patients’ actual condition and serve as a better guide for identifying the best treatment for PAD relative to risks.

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