Outcome Assessment of Intermittent Claudication in Clinical Practice

global impact on the patient. Patients so afflicted experience broad limitations in their level of daily functioning that extend beyond the ambulatory disability. Using a variety of quality-of-life assessment instruments, such as the SF-36 and the Nottingham Health Profile, investigators have documented increased bodily pain and decreased physical, emotional, social functions, and worse perceived health as well as a variety of other disturbances in patients with claudication compared with age-matched controls.\(^1\)\(^2\)\(^3\)\(^4\)\(^5\)

Appropriate therapeutic goals for the treatment of the claudicant must address both the specific lower-extremity disability and the systemic impact of the disease. Ideally, treatment will result in an improvement in both the vascular status of the lower extremity and the patient’s general health status, indicated by at least four attributes on the SF-36 or RAND-36, and level of functioning, indicated by at least two attributes on the WIQ. The complete assessment of the outcomes of treatment of the claudicant, therefore, requires the use of both clinical and patient-based parameters. It is impossible to define “relevant” improvement.

Recommendation 19: Success of treatment for intermittent claudication

Ideally, success of treatment for intermittent claudication should take into account an improvement in the following:

- **Objective outcome:** relevant improvement in walking distance as measured by a standardised exercise test
- **Symptomatic outcome:** improvement on a validated disease-specific health status questionnaire
- **General quality of life:** improvement on a validated generic health status questionnaire
- **Postrevascularisation:** objective proof of patency of any revascularised segment (ideally with imaging)

B 3.1.1

Relationship Between Clinical and Quality-of-Life Outcomes Parameters

Despite the performance of a complete clinical evaluation, physicians cannot accurately assess the overall impact of IC on the patient. Pell\(^2\) compared quality-of-life assessments of 201 claudicants before their first visit to their vascular surgeon with the surgeon’s impression of the patient’s symptoms and examination. The correlation between these two assessments was poor.

Studies evaluating patients with IC by walking distance, ABPI, and quality of life have also demonstrated a poor or limited correlation between the clinical parameters and quality-of-life index. Assessing 157 claudicant patients with treadmill walking distance, ABPI, and the EuroQol generic quality-of-life survey, Chetter et al\(^6\) noted a poor correlation between the clinical parameters of treadmill walking distance and ABPI and the measured quality of life. Barletta et al\(^7\) evaluated treadmill performance and the quality of life with the McMaster Health Index Questionnaire in 251 patients and 89 age-matched controls. These investigators documented a reduction in physical, emotional, and social function in patients with IC compared with controls, but the reduction in these quality-of-life parameters did not correlate well with treadmill performance.

Similarly, the clinical outcome of treatment does not directly correlate with quality-of-life outcomes. An optimal interventional result represents a step toward the achievement of an improved functional status, but it is not indicative of an overall improvement in the patient’s quality of life. Currie et al\(^8\) studied 186 patients undergoing treatment for claudication by unsupervised exercise, angioplasty, or surgery and documented that angioplasty and surgery improved quality-of-life scores, but the improvement did not correlate with changes in the ABPI. Gibbons et al\(^9\) found that the only independent predictor of improved function and well-being in 156 patients after infrainguinal revascularisation was the patients’ perception of their status at baseline: those patients who functioned better before operation reported improved function and well-being at 6 months.

Schneider et al\(^10\) evaluated the functional status and well-being of 60 patients who had undergone successful aortobifemoral bypass grafting at least 6 months earlier. They found that physical function, role function, and perceived health were worse and bodily pain greater than in those without symptomatic arterial occlusive disease, despite a patent bypass. These findings indicate that clinical measures, such as ABPI, patency, and limb salvage, effectively assess the physiological impact of vascular intervention but do not adequately describe overall patient benefit or adverse effect. This lack of correlation underscores the need to use both clinical and quality-of-life parameters to adequately determine the impact of vascular disease and its treatment on the claudicant (see Critical Issue 1, p S33).
Critical Issue 5: Outcome measures of intermittent claudication therapy in clinical practice

Several validated and established methods assess outcome of claudication therapy in clinical trials (eg, treadmill walking distance, functional status, and quality-of-life questionnaires). Future studies are needed to develop practical methods to assess outcome measures of intermittent claudication therapy that can be used in everyday clinical practice.

Clinical Measures: Walking Distance

Because the major clinical manifestation of IC is walking impairment, walking distance is the primary objective parameter for the assessment of treatment. This is best evaluated through the use of a standardised exercise protocol. The general details regarding the performance of a treadmill exercise test are provided in Basic Treatment (p S68). Either the distance to the onset of claudication (initial claudication distance [ICD]) or the absolute (maximal) claudication distance (ACD) achieved on a treadmill at a constant speed and percent incline can be used to evaluate the success of treatment over time. The same value must be used for each subsequent evaluation.

Walking distance may change in a manner independent of the ABPI. Therefore, though the ABPI is of value in determining the severity of impairment of arterial flow (see B 2.2.1, Routine Tests, p S54) and patency of the revascularised and distal arterial segments within the lower extremity (see also A 3.2.9, Patency, p S37), walking distance is the most appropriate objective measure of success of treatment of IC.

B 3.1.2

Patient-Based Outcomes Parameters

Symptomatic outcome

The severity of PAD can be judged by classifying patients' symptoms on a scale of six categories (see Table 9, p S34). Three categories are pertinent to claudication: category 1 indicates mild, category 2 moderate, and 3 severe claudication. Symptomatic improvement of claudication requires an upward shift of at least one category on this scale. These three levels of severity, of help to the clinician in planning therapy, are based largely on walking ability. The Walking Impairment Questionnaire assesses the cause and degree of walking discomfort, the patient's estimate of walking distance, walking speed, and stair-climbing ability (see A 3.2.6, Disease-Specific Health Status Questionnaires, p S34). This questionnaire provides a simple measure of symptomatic improvement beyond that indicated by treadmill testing. It is widely used for evaluation of the claudicant, increasing its value as an outcomes measure.

General quality of life

The SF-36 has been broadly applied to patients with IC before and after intervention. Though scores do not correlate directly with clinical parameters, such as ABPI or graft patency, they show the impact of treatment on the patient. As with other generic health status questionnaires, the SF-36 scores may be affected by patient age. A younger patient, for example, may experience a greater overall negative impact from claudication than an older patient because of differing needs for walking. Therefore, appropriate interpretation of scores may require stratification of the patient sample by age. The timing of patient assessment through use of a generic health status instrument is also important, especially in the posttreatment period. Because of the numerous comorbid conditions experienced by those with IC, patients may show changes in their health status scores despite continued patency of the treated arterial segment. Using the SF-36, Currie et al noted a significant improvement in physical function and pain scores shortly after either balloon angioplasty or surgical intervention in the claudicant.

Pell and Lee found that improvements in these scores on the SF-36 persisted at 6 months after treatment but continued to deteriorate in those managed without intervention in a review of 195 patients. At 1 year after balloon angioplasty, Cook and Galland documented with the EuroQol questionnaire a decrease in perceived health scores despite maintained improvement in walking distance in 24 patients with IC. By 2 years after intervention with balloon angioplasty, Whyman et al reported no differences in quality-of-life scores between two groups of patients with IC—those treated by angioplasty and those treated medically. These data confirm the global impact of claudication on the patient and underscore the systemic nature of the disease. The assessment of the success of an intervention performed for the treatment of IC by a generic health status questionnaire requires documentation of the date of intervention.

Postrevascularisation

The clinical result of any intervention for IC should be documented through postprocedural ABPI and imag-
ing studies that detail the area of intervention. A reduction in ABPI should be correlated with the images of the treated segment to determine whether a reduction in index has been caused by problems within the treated segment or by progressive disease proximal or distal to the treated segment.

Recommendation 20: Reporting intermittent claudication outcomes separately from critical limb ischaemia

Results of treatment in patients with intermittent claudication should be analysed separately from those of patients with critical limb ischaemia.

B 3.1.3 Impact of Outcomes Assessment on Management of Intermittent Claudication

Only through an understanding of the specific and overall effects of vascular disease on the patient can physicians develop appropriate therapeutic plans. Management guidelines for treatment and definitions of success of treatment should consider all types of outcomes. For example, a patient with mild claudication according to the walking distance categories should be considered for treatment if his or her quality of life is severely impacted by the disease as measured by the health-related quality-of-life measures. Conversely, a patient with severe claudication would not require treatment if his or her quality of life is not affected by the disease. Success of an intervention is defined as improvement of at least one category and function after infrainguinal revascularization. J Vasc Med 1996; 1: 1-3.


References


