Estimation of walking distance in intermittent claudication: need for standardization

Intermittent claudication is the most striking symptom of peripheral arterial occlusive disease, a disease mostly confined to the lower limb arteries and characterized by ischaemic processes in one or both legs and important reductions of the patients’ walking distance. In a large number of patients significant reduction of symptoms can be achieved by correction of associated risk factors, particularly smoking, and by (supervised) training programmes (walking)\cite{1-3}. The treadmill is generally accepted as the reference method for evaluating severity of intermittent claudication and effects of treatment options.

However, as yet there are no sound literature data to sustain these widely accepted indications. Ideally any standardization of a treadmill test should fulfil several criteria: simplicity and cheapness, no complications, a good reproducibility and predictive value and accuracy against a gold standard. Whether arteriography of the lower limb arteries constitutes the gold standard to assess severeness of arterial lesions remains a matter of debate. A recent review of all methodology used in the literature to measure claudication distance revealed that at present it is measured spuriously and inappropriately, is inaccurately reported and usually misinterpreted\cite{4}. We will limit ourselves to critical discussion of the evaluation of the walking distance by treadmill tests or alternatives.

The following parameters can be derived from a treadmill test: (1) the claudication-free walking time or distance; (2) the maximal walking time or distance. We prefer to use the distance parameters, because this is more meaningful than considering walking time. The claudication-free distance is the distance that a claudicant can walk on the treadmill without pain in the limb(s). The pain-free walking or the initial claudication distance is another method of measuring the claudication-free walking distance. The maximal walking distance is the maximal distance that a claudicant can walk on a treadmill. Other terms for the maximal walking distance are the claudication-limited or absolute claudication distance. It should be recommended that in study protocols and drug testing only one term should be used.

A variety of treadmill tests in patients with intermittent claudication have been performed. The constant-load (single-stage) type of treadmill tests\cite{5} consists of a motorized treadmill with a constant speed of 1·5 or 2 mph (miles per hour) or 2·5–3 km . h\(^{-1}\) with a fixed grade between 8 and 12·5%. This type of treadmill test is easy to perform; however, it has a limited reproducibility and sensitivity\cite{6,7}. Coefficients of variation are between 30 and 40%. In constant-load exercise it is not uncommon for patients never to reach claudication pain because of the low workload. As a result it might not be possible to differentiate the claudication symptoms at low degrees of claudication.

Graded treadmill protocols have been developed by Bruce and colleagues\cite{8} to perform functional assessments of patients with cardiac disease. These protocols are characterized by an initially low work demand that can be sustained by even the most impaired patient. The workload is then increased until each patient reaches a definable, reproducible peak workload during a test of moderate duration. The success of this protocol is, in part, due to its ability to define peak exercise performance reproducibly across the full spectrum of cardiac impairment. This graded testing concept developed for patients with cardiac disease has been extended to patients with peripheral arterial obstructive disease. The speed of the treadmill is normally 2 m . h\(^{-1}\) or 3 km . h\(^{-1}\). Some protocols increase the grade every 3 min by either 3·5% or 5%, while other protocols increase the grade every 2 min by 2%. Using graded treadmill protocols coefficients of variation are approximately 8 to 13%\cite{6,9}. The graded exercise test has been shown to accommodate claudicants with various disease severity without modification of the rate of increase in workload. Previous experience has demonstrated that the graded treadmill test is well accepted by nearly all peripheral arterial disease patients, including patients over the age of 70 years\cite{10}. The reproducibility and
sensitivity of a graded treadmill protocol is better for diagnosing peripheral arterial occlusive disease than a constant-load protocol. Therefore, we recommend a graded treadmill protocol with a speed of 2 mph or 3 km h\(^{-1}\) and a grade increase of 5% every 3 min until a maximum of 15%. It has been stated that a graded load treadmill test abolishes the placebo effect that has been reported with the constant-load test\(^2\). However, both tests have not always been carried out in the same patient group and there has often been a variation in speed and grade between the protocols.

ECG monitoring can be useful during the treadmill test. It should be mandatory if the vascular patient has symptoms of myocardial ischaemia or rhythm disturbance, or if future vascular surgery is scheduled, because diagnostic exercise testing in such patients is sometimes impossible\(^1\). For routine treadmill testing in other patients ECG monitoring is not mandatory, if careful clinical examination is used as surveillance during the test. Measuring oxygen consumption during graded treadmill testing provides an additional objective physiological marker of peak exercise and cardiovascular function.

There has been considerable criticism of the use of the handrail support during treadmill testing in peripheral arterial occlusive disease\(^7\). An alternate stress test has been formulated using the following protocol: walking in an adjacent corridor until claudication develops and then recording ankle pressure. However, this method is limited because of the variable walking speed and the time delay in measuring the ankle pressure. Another stress test involves inflating the thigh cuff above systolic pressure for 3 to 5 min in order to produce a similar degree of reactive hyperaemia, as during a maximal walking test, and then measuring ankle pressure 30 s after cuff deflation. However, it is evident that this test is not convenient in daily practice.

For 25 years the treadmill test has been the cornerstone for assessing walking distances in peripheral vascular disease. Its imperfections are due to the size of the treadmill, the expense and the need for a trained technician to perform the test and the need for cardiac intensive care equipment, including a defibrillator, next to the treadmill. Therefore new devices have been developed as alternatives to the treadmill test.

The ‘Stresst’er’ is a new exercise device which can be clamped on the end of an examination couch and allows the calf muscle to be exercised against a standardized resistance\(^1\). This new device was found comparable to treadmill testing in a two-hospital study\(^1\). The patient has to lie semi-recumbent and to exercise the limb by depressing a pedal against a resistance of 49·2 Joule min\(^{-1}\) (with a standardized frequency of 60 pumps min\(^{-1}\) to an audible signal). The total number of pumps is counted. The main difference between the new device and treadmill exercise is that with the Stresst’er device legs are independently assessed, which leads to a significant but only moderate correlation between the number of pumps and meters walked. In our opinion, this is not the best test with which to estimate walking distance because the test is in recumbent position (with no gravity-induced perfusion pressure). Any system needs to have a well-defined audible signal at 60 min\(^{-1}\) and this device is more a model of rhythmic exercise than of walking. Therefore the authors doubt that the Stresst’er ergometer is a valid alternative to treadmill testing in patients with claudication.

The PADHOC (Peripheral Arterial Disease Holter Control) system is a portable walking Holter monitor, which allows the patient to self-administer the test outside the hospital environment. The device consists of a main unit worn by the patient on a belt containing a removable computer card that records the data\(^1\). It is connected to two ultrasound sensors, each fixed to the inside of the patient’s ankles by a strap, and to a control module held in the patient’s hand. This module enables the various stages of the test to be recorded; the patient presses a green button at the start of the walking test, a yellow button at the onset of discomfort and a red button when the pain prevents further walking. The belt pack receives and processes the signal and displays the global results on the screen. It stores the content of the display and the primary measurements for subsequent processing of the data. This device has several advantages: (a) the test need not be performed in a hospital setting, (b) it measures the actual incapacity experienced by the patient under normal conditions of everyday life, (c) it is not subject to interference from arm support, (d) it provides a shorter recovery time than the treadmill test\(^1\). In contrast to the Stresst’er test there is no preset constant workload against which the patient has to exercise during the walking test. Each patient can walk following his/her own physical capacity and rhythm. This is a limitation for standardization but avoids the negative points of the Stresst’er. The product of speed multiplied by maximum distance calculated with PADHOC correlated with the pain-free and maximum walking distance on a treadmill\(^1\). Compared to the Stresst’er, the PADHOC system seems to have several advantages in assessing walking capacity in daily life conditions, although standardization is not yet optimal. Therefore we recommend clinical studies for critical validation of the system, where the patients walk on a flat road at a fixed speed.
In previous studies, the use of either self-reported claudication distance or questionnaires have been the methods used to estimate the functional severity of peripheral vascular disease[16,17]. Self-reported distances are inaccurate, as they correlate poorly with actually measured distances. An alternative to the self-report or questionnaire methods is to use the multiple regression technique to predict claudication distances from a battery of objective, resting non-invasive measurements and medical history data routinely obtained from peripheral arterial occlusive disease patients. Gardner et al.[18] found that regression equations, for predicting the distances to onset and to maximal claudication pain, including ankle/brachial index, body mass index, gender and current smoking status were successfully cross-validated on an independent group of similar peripheral arterial occlusive disease patients. Regression equations to predict initial and maximal claudication distances were more accurate when compared to the self-report method. However, these equations are not useful for the evaluation of therapeutic interventions.

In peripheral arterial occlusive disease patients, limitation of exercise capacity will reduce the level of everyday physical activities. It is much less clear what the effects of claudication are in terms of quality of life. The McMaster Health Index Questionnaire has been widely used to evaluate quality of life and to describe specific dysfunction profiles in a variety of chronic diseases[19]. The McMaster Health Index Questionnaire which covers three dimensions of life (physical, social and emotional function) has been correlated with the treadmill performance in a large group of claudicants[20]. Treadmill performance did not correlate with social or emotional function, whereas there was a limited but significant relationship between maximal walking capacity and physical function scores. This study suggested that impairment in quality of life experienced by patients with intermittent claudication poorly correlates with the reduced exercise capacity assessed by the treadmill test. Next to insufficient standardization of the treadmill test, another reason for the poor correlation might be that the claudicant suffers from many other associated cardiovascular and other diseases that can influence as well their quality of life.

In conclusion, claudication is one of the most important handicaps in peripheral arterial occlusive disease. Therefore in evaluating new therapeutic regimens on functional capacity in claudicants, a standardized graded treadmill test should be included in therapeutic trials as well as quality of life assessment by questionnaire. We recommend a graded treadmill test standardized as following: a constant speed of 3 km.h⁻¹ starting at zero degrees for 3 min, followed by a 5% increase every 3 min, and registration of the pain-free and maximal walking distance. Taking this into consideration will ultimately lead to better evidence-based medicine in peripheral arterial disease concerning the aspect of walking distance.

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References