Outcome Assessment for Intermittent Claudication

J. Golledge, C. Askew, A. Leicht and B. Oldenburg

Peripheral vascular disease (PVD) defined by imaging or reduced ankle blood pressure affects around 20% of the elderly population; however, only around 6% report symptoms of intermittent claudication. Thus, while the results of imaging may give information relevant to the risk of cardiovascular events and the technical success of an invasive intervention on patients with peripheral vascular disease, it will not provide a measure of symptomatic outcome. Two types of outcome measures have been suggested in patients with intermittent claudication, namely objective measures of walking distance and subjective symptomatic assessments.

The need for patient-assessed health outcomes of intermittent claudication has been appreciated for some time and has led to the increasing use of both generic and more specific health-related quality of life questionnaires. The most frequently utilised and relevant generic quality of life questionnaire is the Short Form-36 (SF-36). Such generic instruments have the advantage of being well validated for the overall assessment of quality of life but may not provide information specific to intermittent claudication and thereby, not be responsive to changes after therapeutic interventions. In order to improve outcome assessments of intermittent claudication, a number of disease-specific questionnaires have been developed. In this issue of The European Journal of Vascular and Endovascular Surgery, Mehta and colleagues report a study in which various disease-specific and generic questionnaires are compared as outcome measures for 70 patients undergoing treatment of intermittent claudication. The authors correlate the questionnaire scores with each other and also with treadmill assessments of intermittent claudication distance (ICD) and maximal walking distance (MWD). Mehta et al. also analyse how these assessments change in response to treatment.

Assessment of the validity and responsiveness of such questionnaires is not straightforward. Since there is no current gold standard for outcome assessment in intermittent claudication it is contentious as to what measures should be compared with the quality of life (QOL) scores. As in previous validation studies, the authors have used the ICD and MWD determined during a treadmill-walking test as the criterion measures. This is reasonable given that improving functional capacity is a primary goal of therapy in patients with intermittent claudication. However, this also assumes that QOL in PVD patients is determined only by their walking tolerance, which is not likely to be the case; moreover, there will also be natural variance between QOL and functional capacity. The methods used to determine ICD and MWD also impact upon their usefulness as criterion measures. Constant load walking tests, such as that used by Mehta et al., have been shown by some to be more variable than incremental walking tests. Furthermore, the magnitude and variability of MWD and ICD changes with test familiarisation or training and can be influenced by subtle test protocol variations. For this reason, it is recommended that a stable baseline for treadmill walking distances be achieved prior to clinical trials, and the same should be done when these measures are being used as a criterion measure to validate QOL assessment tools.

While the authors tested validity against MWD, they assessed the responsiveness of the QOL measures with the International Society of Cardiovascular Surgery criteria, which were designed to
assess the outcomes of revascularisation procedures and include ankle pressure criteria. Using this approach Mehta and colleagues conclude that the VASCUQOL is the most responsive disease-specific questionnaire and, therefore, recommend its use in clinical practice. Support for this recommendation is provided in a recent study by de Vries and colleagues, in which they compared the SF-36, the EUROQUOL and the VASCUQOL in over 400 patients with intermittent claudication. Using different analysis methods, de Vries et al. reported the VASCUQOL to be more responsive to changes in intermittent claudication symptoms than the generic instruments.

The VASCUQOL was originally developed as a disease-specific quality of life measure for lower limb ischaemia. Around half of the patients used in the development and validation of this instrument had rest pain, ischaemic ulceration or gangrene and, therefore, the resultant 25 item questionnaire includes some questions related to pain at rest, ulceration and limb loss. Since, these questions are not very relevant to patients with intermittent claudication, and were not associated with disease deterioration in Mehta and colleagues study, it could be argued that a more specific questionnaire is warranted. Chong and colleagues developed a quality of life instrument specific for intermittent claudication in 124 patients and reported good validity and responsiveness by comparison to symptoms and generic instruments. The resultant questionnaire has the advantage of being time efficient and relevant to intermittent claudication as it includes only 16 items related to the effect of leg pain on activity. A study comparing the VASCUQOL and intermittent claudication questionnaire is required.

Mehta and colleagues should be commended for attempting to bring about standardisation in the use of patient-focused assessment techniques. To reach this end, a better understanding of the determinants of QOL in patients with PVD of varying severity is required. Studies adopting reliable criterion measures and assessments of other validated measures of disease specific QOL, such as the intermittent claudication questionnaire, would be advisable prior to making firm conclusions on the most appropriate disease-specific quality of life instrument to assess intermittent claudication.

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References