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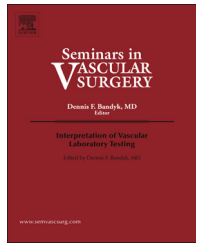

Patient-reported outcome measures in vascular surgery

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ABSTRACT

Patient-reported outcomes (PROs) after vascular surgery are becoming increasingly important in the current era of health care reform. Although a number of general quality of life instruments exist, vascular disease–specific instruments may provide more targeted data on how patients feel after specific interventions. Here we provide a review of both generic and disease-specific instruments focused on arterial conditions, including peripheral arterial disease, carotid arterial disease, and aortic disease, which have been described in the literature. While many different tools currently exist, there is a paucity of well-validated, specific instruments that accurately reflect functional and objective measures of patients' arterial disease burden. A full understanding of the existing tools available to assess patients' perceived lifestyle impact of their disease and its treatments is essential for both research and clinical purposes, and to highlight the need for additional work on this topic.

1. Introduction

The passage of the Patient Protection and Affordable Care Act in 2010 has contributed to the emerging importance of comparative effectiveness research. Health care specialists treating vascular disease are often challenged in choosing therapies from a gamut of advancing technologies, many of which are associated with higher costs. Nevertheless, the majority of such technological advancements in the field of vascular surgery frequently focus on less-invasive modalities of treatment. These less-invasive treatments can have a more profound impact on a patients perceived quality of life and health status. Although surgical outcomes have traditionally focused on morbidity and mortality, an emphasis on health-related quality of life (HRQOL) and patient-reported outcomes (PROs) in measuring treatment effectiveness has gained momentum in recent years. The domains of outcomes that are measured in such QOL instruments include assessing social functioning, emotional health, and physical impairment. Simply put, PROs come directly from the patient and assess how patients feel or function in relation to their health condition without any interpretation from a health care provider or anyone else.

In general, there are two different approaches to assess a patient's health status. Quality of life may be analyzed using either generic or disease-specific instruments. Generic questionnaires tend to cover, as the name implies, generalized situations/conditions. Such questionnaires are used in a variety of disease conditions and scores from each can actually be compared against each other and the general population. The disadvantage to these generic tools is that the questions may not focus on or cover specific details

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related to the disease condition being studied. Disease-specific measures, on the other hand, are more likely to be more sensitive and specific to the studied condition. They can better demonstrate efficacy for treatment of a specific disease condition with more targeted questionnaires. However, disease-specific instruments can be more costly and time consuming because a new disease-specific questionnaire has to undergo a series of tests across different population and get validated before universal acceptance. Furthermore, while disease-specific instruments related to venous disease have been rather well developed [1], it can be argued that disease-specific instruments have been less developed and are not uniformly accepted in several arterial disease conditions. This article will focus on a review of both generic and disease-specific instruments focused on arterial conditions that have been described in the literature.

2. PROs in peripheral arterial disease

PROs among patients with peripheral arterial disease (PAD) are relatively more common than PROs among patients with other forms of arterial disease. There are a number of validated QOL instruments used for this purpose, ranging from generic scales geared toward assessing overall QOL perceptions, to more disease-specific tools that focus specifically on PAD-related QOL (Table 1). Within the latter group, there is also a wide range of tools available, from those that are designed to assess PAD-related functionality to those that are more comprehensive and assess an individual's perception of his or her overall health status, as well as the effect of PAD on daily activities, treatment, mood, and social functionality.

We briefly describe the most commonly encountered PRO tools available in the PAD literature, as well as the advantages and disadvantages of each.

2.1. *Generic QOL tools*

2.1.1. *Medical Outcomes Study Short-Form 36 Health Survey*

The Medical Outcomes Study Short-Form 36 Health Survey (MOS SF-36, or SF-36 as it is most commonly referred to) was first developed by Ware et al in 1992 [2]. It has garnered widespread use throughout the United States since its development, and is available in a number of languages for use in countries across the world [3].

The SF-36 is a patient-based questionnaire that consists of 35 items assessing eight different QOL domains, including physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, pain, mental health, vitality, and general health perceptions. Each dimension is scored on a scale of 0 (worst) to 100 (best), and summary scores can be analyzed overall or divided into mental and physical component summary scores. In general, the SF-36 can be completed in approximately 10 minutes, although some difficulties completing the questionnaire have been reported among elderly patients [4].

The SF-36 has been validated in both the general US population and within populations with specific chronic disease processes [5]. It has been used extensively as a PRO tool among patients with PAD, including for studies evaluating QOL effects of exercise regimens, medical management, and open and endovascular interventions for patients with claudication [5], and was actually considered the gold standard for assessing QOL within the PAD population before the development of the Vascular Quality of Life (VascuQoL) tool [3,5,6] (see section on VascuQoL). It should be noted that the SF-36 is a generic QOL tool, and although PAD patients report lower scores in the pain and physical domains compared with healthy controls [7,8], there is no correlation with ankle brachial indexes [9].

2.1.2. *SF-12*

The Medical Outcomes Study Short-Form12 Health Survey (SF-12) is an abbreviated version of SF-36 that was developed by Ware et al in 1996 [10]. It consists of 12 items assessing the same eight QOL domains as the SF-36 and was designed to capture the highest-impact data from the longer version of the tool. Just like the SF-36, it is also scored on a scale of 0 (worst) to 100 (best) and includes the same physical and mental component summary scores [10].

Within the PAD population, the physical component of the SF-12 is more affected by disease status than the mental component [11,12]. Improvements in the physical component have been reported after open and endovascular intervention for PAD [12], although QOL outcomes using the SF-12 have not been nearly as extensively studied as other QOL instruments [5].

2.1.3. *European Quality of Life Questionnaire*

The European Quality of Life Questionnaire (EQ-5D) was first developed by EuroQOL Group in 1990 [13]. It is a generic patient-based tool designed to assess an individual's perceived current health status in terms of both functional status and QOL. The EQ-5D consists of five items assessing five different domains, including mobility, self-care, usual activities, pain and discomfort, and anxiety and depression. Each dimension is scored on three levels, ranging from no problems to moderate problems to extreme problems, although reported scores are frequently dichotomized. The overall score is reported on a scale of 0 (worst) to 1 (best). The tool also contains a visual analog scale designed to assess individuals' overall perception of their health; each participant is to draw a line on a thermometer rating their health from worst imaginable health (score 0) to best imaginable health (score 1).

The ED-5D is a generic QOL tool that is used frequently in Europe [14], and is most commonly reported on in studies assessing PROs after endovascular interventions for PAD [12,15–20]. It is relatively brief and simple to use, although its application has not taken off in US studies of PAD [5].

2.1.4. *Nottingham Health Profile*

The Nottingham Health Profile (NHP) is a generic QOL instrument developed in 1980 by Hunt et al [21,22]. It consists of 45 items assessing seven QOL domains, including energy, pain, emotional reactions, sleep, physical mobility, social isolation, and daily activities. It is scored on a scale of 0 (best) to 100 (worst) and is considered to be one of the most comprehensive generic QOL instruments available to assess an