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Title: Exercise therapy in routine management of peripheral arterial disease and intermittent claudication: a scoping review.

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Abstract

Background

Little is known about the extent to which routine care management of peripheral arterial disease and intermittent claudication align with best practice recommendation on exercise therapy. We conducted a scoping review to examine the published literature on availability and workings of exercise therapy in routine management of patients with peripheral arterial disease and intermittent claudication, and health professional and patients' attitude and practice.

Data sources

The Cumulative Index of Nursing and Allied Health Literature, Ovid MEDLINE, Allied and Complementary Medicine Database, ScienceDirect, Web of Science and the Directory of Open Access Repositories were searched. Hand searching of reference lists of identified studies was also performed.

Methods

A systematic search was conducted in February 2018. Inclusion criteria were based on study aim, and included studies that reported on perceptions, practices, and workings of routine exercise programs for patients with intermittent claudication, their availability, access and perceived barriers.

Results

Eight studies met the eligibility criteria and were included in the review. Included studies were studies conducted within Europe. Findings indicate that vascular surgeons in parts of Europe generally recognize supervised exercise therapy as a best practice treatment for intermittent claudication, but do not often refer their patients for supervised exercise therapy due to the unavailability of, or lack of access to supervised exercise therapy programs. Available supervised exercise therapy programs do not implement best practice recommendations, and in the majority, patients only undergo one session per week. Some challenges were cited as the cause of the sub-optimal program implementation. These included issues related to patients' engagement and adherence as well as resource constraints.

Conclusion

There is dearth of published research on exercise therapy in routine management of peripheral arterial disease and intermittent claudication. Available data from few countries within the Europe indicate that supervised exercise is an underutilized despite health professionals recognizing the benefits. Research is needed to understand how to improve the availability, access, uptake and adherence to the best exercise recommendations in routine management of people with peripheral arterial disease and intermittent claudication.

INTRODUCTION

The most common symptom of peripheral arterial disease (PAD) is intermittent claudication (IC)[1] defined as exertional pain in the lower limb(s) which is relieved by rest. Intermittent claudication limits individuals' exercise capacity, decreases functional ability and leads to poorer quality of life. [2–4] Individuals with PAD and IC have lower levels of physical activity compared with their age-matched healthy controls.[5,6] Exercise therapy is the most effective conservative therapy for improving walking capacity in people with IC.[7,89–11] Exercise therapy is an important area of research in PAD and IC care internationally, and is recommended by several professional guidelines.[7,12–14] Although both supervised and unsupervised exercise programs improve pain-free and maximal walking distances in IC,[15–17] best evidence recommendations support the use of supervised exercise program (SEP).[18,19] A recent Cochrane review update provided high-quality evidence that SEPs is more beneficial compared to placebo or usual care in improving both pain-free and maximum walking distance in people with symptomatic IC.[20]

Despite the level of evidence for the use of exercise therapy for the management of PAD and IC, and the professional bodies' guidelines and endorsements, there are concerns that this is yet to be given a priority in the management of IC. [21,22] Access to, and uptake of health care is determined by factors within and outside the health care system.[23,24] Some of the important stakeholders within this system are the patients, the healthcare professionals and the hospital management. To maximize patient outcomes related to exercise treatments for IC, the patients, health care professionals and facilities involved in IC treatment should align their management with best-evidence recommendations. However, little is known about the extent to which routine care treatments for IC align with best practice recommendation on exercise therapy.

There is a close association between individuals' attitudes and beliefs and their practices.[25] It has been suggested that health care professionals' self-interest and wider health system factors, but not lack of evidence, are among the main challenges in adopting and implementing exercise recommendations for IC.[21,26] This underscores the importance of understanding perceptions and practices related to routine provision of exercise for IC. No systematic review has examined the attitudes, beliefs or practices of health care professionals, facilities or patients regarding exercise provision in routine care of IC.

METHODS

Design and Rationale

We performed a scoping review using five stages of the Arksey and O'Malley scoping review methodology[27] as revised by Levac et al.[28] The completed review is reported according to the preferred reporting items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews [29]. A scoping review design was justified given that no prior systematic review evidence exists regarding the type and extent of available literature; and the need to systematically summarize primary research in an effective and timely manner. Findings will provide direction to reflect on ways to enhancing delivery of best practice exercise recommendations in the routine care of people with IC.

Step 1: Identifying the research question

The aim of this review is to scope literature on perceptions, practices, and workings of routine exercise programs for patients with IC, their availability, access and perceived barriers.

Stage 2: Identifying relevant studies

Search strategy:
The search strategy was deliberately narrow and intended to retrieve only peer review published articles with a mention of exercise or exercise programs or walking or supervised exercise or homebased exercise or exercise therapy and peripheral vascular disease or intermittent claudication (and their synonymous terms) in their title, keywords, or abstracts. The search aimed to find only peer review published studies.

Identification of primary research studies:
A search was implemented in five databases (CINAHL via EBSCO, MEDLINE via ProQuest, AMED via Ovid, ScienceDirect, Social citation index/Science citation index /Emerging sources citation index via Web of Science (WOS)) and the Directory of Open Access Repositories website until February 2018 with no date parameters. The reference lists of included articles were checked for relevant studies. Search terms were identified by exploring the National Library of Medicine Subject Headings (MESH), in addition to exploring the keywords of relevant articles, and the search strategy was developed by the primary author (AU), with support of a co-author (DD). The following keywords were used: provision OR availability OR attitude OR perceptions OR perspective OR access OR accessibility AND exercise OR physical activity OR exercise training OR supervised exercise OR supervised exercise programs OR walking exercise OR walking program OR walking OR homebased exercise OR unsupervised exercise AND peripheral arterial disease OR peripheral vascular disease OR intermittent claudication OR intermittent claudication treatment. Abstract searches were performed for those words using Boolean operators, searching related terms and limited only to English language literature. An example of a detailed search strategy is shown in Appendix 1.

Stage 3: Study Selection

Data management, screening and extraction:
The identified studies were imported to Refworks™ and duplicates removed. Studies were then exported to Microsoft Excel 2010 where the screening were undertaken. Specific eligibility criteria were developed through iteration and piloting, and included the removal of studies that did not investigate exercise in routine care. Initially, titles and abstracts of identified studies were independently screened by two authors (UA, DD) and the overtly irrelevant studies were excluded. Next, the full text of selected studies after abstract and title screening were then read independently to determine studies inclusion in the review. Differences of opinion regarding inclusion or exclusion were resolved by discussion and reaching consensus between the two authors (UA, DD), or in consultation with a third author (CS) when consensus could not be reached. The process of identifying, screening, and inclusion of studies is summarized in Figure 1. All articles had sufficient information enabling a decision on eligibility and inclusion; no study author was contacted to request missing information.

Inclusion and exclusion criteria

Articles meeting the following criteria were included in the review:
Studies that focused on health care workforce directly or indirectly involved in exercise therapy for patients with IC (e.g. GPs, Surgeons, Physiotherapists, Nurses, Exercise physiologists) or focused on the description of routine delivery of exercise for individuals with PAD and IC (description could be reported by either health care professionals or patients). Studies that reported on provision, attitude, access, availability or other factors regarding routine exercise for IC. Studies of any design published in English and reported primary data whether they were published as full length article or only as abstract. No restriction was placed regarding publication date

Stage 4: charting the data

Critical appraisal:

Given the review objective to scope the extent and type of literature, a quality appraisal was not implemented for this scoping review. This is consistent with current guideline for conducting systematic scoping reviews. [30]

Data collection and synthesis:
Study characteristics were recorded in a data extraction form specifically developed and piloted for this review (Table 1). Data elements included authors' details (author, year, and country), study aim, participant characteristics, study design, findings, and authors' main conclusions. Studies meeting inclusion criteria were summarized in a narrative synthesis, including the overall number of studies, geographical location, design, population, and summary of results (Table 1).

Stage 5: collating, summarising and reporting the results

A total of 102 records were identified through the searches. Following the screening process, 8 records met the study inclusion criteria. The screening process and reasons for excluding studies is presented in Figure 1. Included studies are summarized in table 1.

Characteristics of included studies

The included studies were published between 2004 and 2017. All studies were from European countries. The Netherlands contributed the largest volume of literature (n=4), followed by the United Kingdom (n=2), and one study was from Germany (n=1). There was also one international study which surveyed respondents from 43 European countries (although it reported collected data from only 9 countries due to response variability)[31].

Populations

Some studies had more than one population of interest. However, populations included vascular surgeons/vascular residents (n=4), patients and/or service user/delivery (n=3), and GPs and physiotherapists (n=1).

Study design:

According to the Littlewood and May classification[32] all studies were primary research and were mostly of cross-sectional observational survey (n=5), followed by cohort studies (n=2), and a mixed-method study.

Focus/theme of the studies:

The included studies fell broadly into three categories:

1) Determining access, availability, practice, provision, and opinion regarding exercise for IC. This include survey among vascular surgeons, vascular residents, physiotherapists, or patients (n=5).

2) Investigating the role of GPs and physiotherapists in non-invasive therapy, including exercise therapy programs for people with IC (n=1)

3) Documenting the functioning of routine exercise therapy programs s for IC and/or patients' participation in the program (n=2)

Outcomes in included studies

Availability, Access and Practices related to Supervised exercise programs (SEPs):

Three studies reported on the availability of SEPs and access to them, and scoped responses from vascular surgeons.[31,33,34] Results showed that across Europe, less than 1 in 3 vascular surgeons reported having access to SEPs to refer patients.[31] Country specific data indicated that all vascular surgeons in the Netherlands, most (67%) of those in France, and about 10% in Spain and Greece have access to SEPs to refer their patients.[31] Data from the UK suggest improvements in the access of vascular surgeons to SEPs over the past decade (24% in 2009, 36% in 2012, and 41.6% in 2017), however the majority still did not have access to a SEP.

[31,33,34] When examined in terms of facility access, just about one in three (38.9%) vascular units in the UK reported having access to SEP for UK NHS patients.[34]

Between 2011 and 2012 about 45% of vascular surgeons within Europe who have access to SEP would refer less than 50% of their eligible patients, with only 18% saying they would refer all their patients.[31] Almost half (46%) of UK vascular surgeons in 2009 reported referring less than 50% of their eligible patients for SEP, with only 14% referring 100% of their patients.[33] In a 2004 survey, although most (86%) GPs in the Netherlands indicated that they advised their patients with IC to exercise, 38% said they did not provide supervision or follow up as part of exercise therapy.[35] Only a minority (15%) referred their patients to a physiotherapist for supervised exercise.[35] Expectedly in this survey, only 8% of physiotherapists occasionally treated patients with IC.[35] In a survey among patients a year later (Between 2005-2006), Dutch patients with IC reported that they received advice to walk mainly from their vascular surgeons and GPs, with only 11% reporting being referred to a physiotherapist for supervised exercise.[36] A survey in 2012, however, showed that almost all (about 97%) of vascular surgeons in the Netherlands reported referring more than 75% of their eligible patients for SEPs.[37]

Only one study investigated if follow-up visits are schedule for patients who undergo SEP. [31] In this survey, 70.4% of vascular surgeons said they will bring back patients for follow up. Similarly, one study reported that the majority of vascular surgeons would judge the success of SEP based on patients' satisfaction, while improvement in walking distance were used by only 27% of the vascular surgeon.[37]

Attitude to supervised exercise programs (SEPs) therapy: A study in Netherlands reported that all vascular surgeons surveyed agreed that SEP should be part of rehabilitation for IC, and that it is more effective than one-off unsupervised advice to walk (usual care).[37] Also, a large majority of them (about 97%) agreed that SEP is the primary treatment for IC, believed that community-based and hospital-based SEPs are equally effective (about 93%), and 60% will consider continuing their patients in SEP beyond 3 months if patients do not show improvement.[37]

Patient engagement and adherence to exercise therapy:
A 2009-2010 investigation of routine exercise therapy for IC in a German outpatient clinic reported that 69% of the patients either declined invitation or did not eventually turn up for any of the training sessions.[38] This study also indicated that only 22% of patients attended regularly.[38] Similarly, a 2009 survey of vascular surgeons in the UK NHS showed that, where SEPs are available, majority of patients do not comply with recommendations: only 39% of them reported up to 50% patients of their patient taking SEP or adhering to their SEP recommendations.[33] Although patients adherence to SEP had risen in 2017 (5 in 6 vascular units recorded >90% completion), patients engagement was still a great challenge (only 1 in 6 of the vascular units had up to 80% of referred patients starting a SEP).[34] These units did not generally document information related to commencement and completion rates for home-based exercise therapy.[34]

A survey of Dutch patients with IC indicated that only 32% underwent SEP[36]. The majority (52%) walked for exercise mostly in the neighborhood, and not reaching optimum walking intensity (only 44% walked through pain) or frequency (only 25% walked 3x/week).[36]

Personnel who delivers exercise program: Vascular surgeons in the UK reported that exercise therapy for IC in the UK whether home or hospital based were run by physiotherapists and specialist nurses with a few run by exercise and non-healthcare professionals.[33,34] Also vascular surgeons across Europe indicated that the majority (48%) of SEPs in their countries were run by physiotherapists while 37% were run by doctors.[31]

Program types (Hospital versus Home based), and features of exercise programs: Regarding the site of exercise, one of the studies indicated that the majority of SEPs in the United Kingdom were delivered in hospital facilities.[34] In contrast, the majority (70%) of Dutch patients with IC reported they received advice to walk at home.[36] Hospital based SEPs in the UK generally consisted of either a combination of aerobic and resistance exercises or aerobic exercise alone.[33,34]. Whilst 55-90% of the programs lasted for 30-60 minute per session for 3 months, 65-80% ran as one session per week (65-80%).[33,34] Across Europe the majority of SEP programs were run as 1-2 hour/session (53%), and lasted between 3-6 months, but the number of sessions undertaken in a week was not investigated.[31]

Common indications, contra-indications and obstacles to exercise:

Vascular Surgeons' attitude towards indications and contra-indications for people with IC for participation in SEPS was reported by two studies from Netherlands. The following comorbidities were cited as contraindications: mobility problems, hypertension, angina/IHD/ACS/MI, rest pain/tissue loss/CLI, musculoskeletal/arthritis,[33] COPD/respiratory compromise,[33,37] significant iliac stenosis,[37] In contrast, maximal walking distance <100m or age >80 years were not considered contraindications. Also the majority of vascular surgeons would consider SEP as adjunct therapy pre- or post-surgery.[37] Factors cited as obstacles to making SEP available to patients included resource challenge, and patient compliance.[33] Similarly reasons for not attending SEP in a German clinic included deficient patient motivation, travel distance, and the perception that exercise is physically demanding.[38]

Alternative services in place when a SEP is not available or feasible

The majority (75%) of patients in one study reported that they had received nonspecific advice to walk.[36] Other reported alternatives included receiving specific instruction on how much walk that can be done (43%),[31] and receiving verbal advice or leaflets (30%).[31,33]

DISCUSSION

The key aims of this systematic scoping review were to identify and map the body of literature related to routine provision of exercise for the treatment IC. Findings provide an essential contribution for reflections and research on access, utilization and stakeholders' perspectives on the guideline-recommended, non-invasive therapy for this patient population. It was deliberate to include only studies that reported on exercise in routine care, and excluded the vast majority of studies because they reported on trials and/or experimental studies of exercise interventions. The inclusion of only eight eligible studies underscores the paucity of literature on this topic. The overall trend showed that literature related to provision of exercise in routine care for persons with PAD and IC is relatively new (<14years old), and nonexistent in majority of countries in Europe and around the world.

Similarly, the overall volume of literature remained small despite the overwhelming evidence of the benefits and effectiveness of exercise therapy in experimental literature. Furthermore, the geographical location of studies highlights that larger area of the global health systems is not yet represented. For instance, the majority of the publications were from the Netherlands and United Kingdom, and no data was found originating from outside Europe. This may indicate that despite the fact that much research evidence supporting exercise as a treatment for IC is relatively old, research into practices related to routine provision of exercises in health care systems is yet to be made a research priority. Paucity of research into provision of exercise in the management of IC may also reflect the absence of this service in most public health systems around the world. For instance the Centers for Medicare and Medicaid Services (CMS) in the US only gave a national coverage decision (NCD) of supervised exercise therapy for PAD and IC in mid-2017.[39] Until this decision, there was no national coverage reimbursement for supervised exercise therapy treatment for patients with PAD and IC.

Although vascular surgeons in parts of Europe generally recognize SEPs to be beneficial to patients with PAD and IC, they do not often refer their patients for SEPs due to the unavailability of programs or lack of access. Where programs are available and accessible, challenges related to patients’ engagement and adherence were significant causes of sub-optimal implementation, and may be some of the reasons why about 45% of surgeons within Europe refer less than 50% of their eligible patients to SEP.[31] Another important concern is that routine SEPs may not be complying with the best practice recommendations in terms of frequency. For instance, the frequency of the sessions for the greater majority of SEPs in the UK is once a week,[33,34] and this arguably raises a question about the efficacy of the programs. The included studies in this review did not research on why the hospitals are only putting on the sessions once per week. However, there is an opinion that the commissioners in the UK NHS are reluctant to fund SEPs and best medical therapy in majority of patients with IC. Certainly, this highlights the need to adequately incentivize and reward hospitals to prioritise supervised exercise and best medical therapy as a first option prior to surgical intervention.[21] Similarly, barriers to exercise in patients with PAD and IC are multidimensional including individual level factors (e.g. poor health literacy and comorbid health concerns), disease specific factors (e.g. claudication pain), and availability or otherwise of environmental and social enablers,[40,41] and worth considering when planning exercise for patients.

Despite seeing no improvement in the walking distances of patients at 12 weeks, 60% of providers considered continuing SEPs. Some patients specific factors may require a longer duration than 12 weeks for important benefits to be accrued. In addition, there is evidence of benefits to overall cardiovascular health and quality of life of exercise in patients with PAD and IC, separate from any improvement in walking ability measures.[42] Indeed, it is the potential improvement in cardiovascular health and the overall potential secondary prevention benefits that is central to exercise therapy recommendations in patients with PAD and IC.[42,43] Therefore, considering continuing SEPs in absence of improvement in walking distances is recommended.[39]

Some limitation regarding the review findings need to be considered. First, although our search string aimed to include data from all regions of the world, it was limited to peer review published English language literature. Literature in other languages may not have been retrieved, and retrieved data were limited to a few countries within Europe. Second, poor response rates in the surveys of vascular surgeon in the UK (24.6%), and in Europe (23%) meant that caution should be applied when generalizing finding to all the UK or Europe.

Conclusion

A number of conclusions can be drawn. SEPs are not always utilized by referring healthcare providers. Although health professionals recognize that SEPs are useful and should be available and accessible to patients with IC, available evidence indicates that SEPs are not always available or accessible to patients. When available, the sustainability of continual provision of SEPs in the continuum of chronic disease pathway of IC may not be feasible due to the resource and time cost to both the patient and the health system. Key areas of focus for integrating and implementing exercise recommendations to routine clinical practice in people with IC are needed. It may be important to understand factors such as barriers and enablers to exercise in individuals with PAD and IC. Although some may be similar across health systems, many may be specific to each health system and need to be investigated individually. It will be beneficial to understand why health systems do not fund SEPs for PAD and IC despite the overwhelming evidence for the clinical and cost effectiveness. This may be important to further understanding of patient, environmental and behavioral constructs worth considering in developing relevant and patient-focused intervention to increase the availability of and access to exercise programs, as well as to encourage the uptake and adherence to exercise in people with PAD and IC.

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