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Supervised exercise training in patients with lower extremity peripheral artery disease

A European overview

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Summary: The optimal first line management of patients with symptomatic chronic lower extremity peripheral artery disease (PAD) includes secondary prevention of cardiovascular risk factors, pharmacological treatment, and supervised exercise therapy (SET). SET programs have shown to be effective in improving walking performance, functional performance, and quality of life. However, despite a large body of evidence, and despite national and international guidelines recommending SET as first line therapy, SET remains largely underused in patients with chronic PAD. This position paper aims to describe how SET is perceived, its accessibility and structure through Europe. An anonymous web-based survey was used. It comprised 21 questions developed in conjunction with an angiologist and a clinical exercise physiologist specialist in vascular rehabilitation. We had 131 responders from 17 countries. For patients with PAD, SET programs exist only in 59% of European countries. SET reimbursement is available in 41% of countries. SET programs showed to be heterogeneous across countries. Thirty-four percent of the SET programs are PAD-dedicated, while 23% are part of a cardiac rehabilitation program. In addition, among existing SET programs, 65% are dedicated to symptomatic patients with PAD only, 9% to both asymptomatic and symptomatic, 8% to post-revascularized patients only, and 1% to asymptomatic patients with PAD only. Finally, 17% reported not knowing which patients are eligible for enrolment in a SET program. Duration, frequency, and modality of SET also varied from country to country. Overall, these data indicate that a large variability of SET availability and characteristics exists across Europe. Therefore, there is an urgent need to provide detailed guidance to deliver optimal exercise therapeutic care in patients with PAD.

Keywords: Rehabilitation, intermittent claudication, vascular medicine

Introduction

Atherosclerotic lower extremity peripheral artery disease (PAD) is characterized by narrowing or occlusion of arteries supplying the legs [1, 2, 3]. It is estimated that a total of 236 million men and women are living with PAD [3]. Although patients with PAD have a known high risk of cardiovascular morbidity and mortality [1, 4], PAD remains understudied and undertreated as compared to myocardial infarction and stroke [1]. Intermittent claudication (IC) – exertional leg pain resolving with rest – is a typical symptom in patients with PAD [1, 2, 3], even though a proportion of them presents with atypical claudication or no exertional leg symptoms [1]. The presence of PAD

affects walking performance, functional performance, balance, muscle strength, gait pattern, and quality of life [5, 6, 7, 8, 9, 10].

Initial optimal management of patients with chronic PAD includes secondary prevention of cardiovascular risk factors, pharmacological treatment, and supervised exercise therapy (SET) [1, 2, 10, 11]. Lower limb revascularization is considered in symptomatic chronic patients with PAD refractory to well-managed conservative treatment [2, 12, 13]. SET programs have shown to be effective in PAD in improving treadmill and functional over-ground (i.e. six-minute walk) walking performance [14, 15, 16, 17], quality of life [18, 19], gait pattern [20, 21, 22, 23], and patency after revascularization [13]. Notably, although less investigated,

positive long-term effects of SET on walking performance have also been documented [24, 25, 26, 27].

In spite of the large body of evidences highlighting the clinical benefits of SET programs in patients with chronic PAD, SET is underused and its availability and adherence is low [28, 29, 30, 31, 32, 33, 34]. Recent surveys showed that only 48% [32] or 46% [30] of responders reported having access to SET for patients with PAD in the United Kingdom. Interestingly, similar results were reported in the United States, where 54% of responders stated that SET facilities are not available [28]. Half of the clinician responders reported they had never referred a patient for SET, and one quarter were not aware that the Centers for Medicare & Medicaid Services added coverage for payment for SET in the United States since 2017 [28]. Recently, data from the Patient-Centered Outcomes Related to Treatment Practice in Peripheral Arterial Disease: Investigating Trajectories (PORTRAIT) registry reported that among patients referred to SET the most reported reasons for not participating were the preference to walk by oneself, lack of facilities, feeling worse, costs, and time [29]. In addition, previous studies reported travel time, lack of motivation, and comorbidities as a barrier to SET [28, 32].

To date, a general European overview of SET availability and access for patients with chronic PAD is lacking. This position paper aims to describe how SET is perceived, accessible, and structured in different European countries.

Materials and methods

We developed an anonymous web-based survey with Web Survey Creator (Dipolar Pty Limited, Australia). The survey was in English and designed to be completed in less than 10 min. It comprised 21 questions developed in conjunction with an angiologist and a clinical exercise physiologist specialist in vascular rehabilitation (see supplement material for full survey text). The link to the survey was published on the web pages of the European Society for Vascular Medicine (ESVM) and sent to ESVM board members, representing national vascular societies, who in turn send it to vascular medicine national societies for widespread participation. A reminder was sent to all contacts.

All the responses were exported to a Microsoft Excel document and were analysed using descriptive statistics.

Results

We had 131 responders from 17 countries: 52% (68/131) of responders were from France, 13% (17/131) from Switzerland, 11% (14/131) from Italy, 7% (9/131) from Spain, 5% (7/131) from Germany, 2% (2/131) from Ireland, 2% (2/131) from Slovak Republic, 2% (3/131) from United Kingdom, and 1% (1/131) from Austria, Belgium, Czech Republic, Greece, Poland, Serbia, Slovenia, Sweden, and

Ukraine. The survey was mainly completed by angiologists (80%; 105/131), internal medicine doctors (9%; 12/131), vascular surgeons (4%; 5/131), cardiologists (2%; 3/131), sport scientists (2%; 2/131), and nurses, physiotherapists, researchers, and pneumologists (1%; 1/131). Overall, 59% (77/130) of responders practiced in Hospitals and University Hospitals, 29% (38/130) in private practice, and 12% (15/130) in private Hospitals.

Awareness of SET

Of the responders, 95% (125/131) were aware that SET is a first-line therapeutic option in patients with symptomatic chronic PAD. In addition, 96% (126/131) were aware that SET increases walking performance, functional performance, and quality of life in these individuals. Of responders, 95% (123/130) reported that, if available, they would refer a patient with PAD to a SET program.

Access to SET

When data were analysed by country, responders from Austria, Belgium, France, Germany, Sweden, and Switzerland reported that SET is reimbursed by the health insurance (Figure 1A). In the United Kingdom, SET programs are funded by the National Health Service (Figure 1A). On the contrary, responders from Czech Republic, Greece, Ireland, Italy, Poland, Serbia, Slovak Republic, Slovenia, Spain, and Ukraine reported that SET is not reimbursed by health insurance in their countries (Figure 1A). Overall, 17% (22/131) of responders reported that they do not know if SET was reimbursed by health insurance.

Responders from Austria, Belgium, Czech Republic, France, Germany, Italy, Spain, Sweden, Switzerland, and United Kingdom reported that SET exists for patients with PAD in their country (Figure 1B). On the contrary, responders from Greece, Ireland, Poland, Serbia, Slovak Republic, Slovenia, Ukraine reported that SET does not exist for patients with PAD in their countries (Figure 1B). Overall, 7% (9/130) of responders reported that they do not know if SET existed in their country.

SET characteristics

The majority of responders reported that SET programs are specifically dedicated for patients with PAD (34%; 45/131) or are part of a cardiac rehabilitation program (23%; 30/131). In addition, 26% (34/131) of responders reported that each hospital/community has its own program (i.e., individual practice). Overall, 17% (22/131) reported that they do not know, or that there was no program in their country.

The responders reported that patients enrolled in SET programs are those who are symptomatic only (65%; 85/131), can be both asymptomatic and symptomatic (9%; 12/131), are post-revascularized patients only

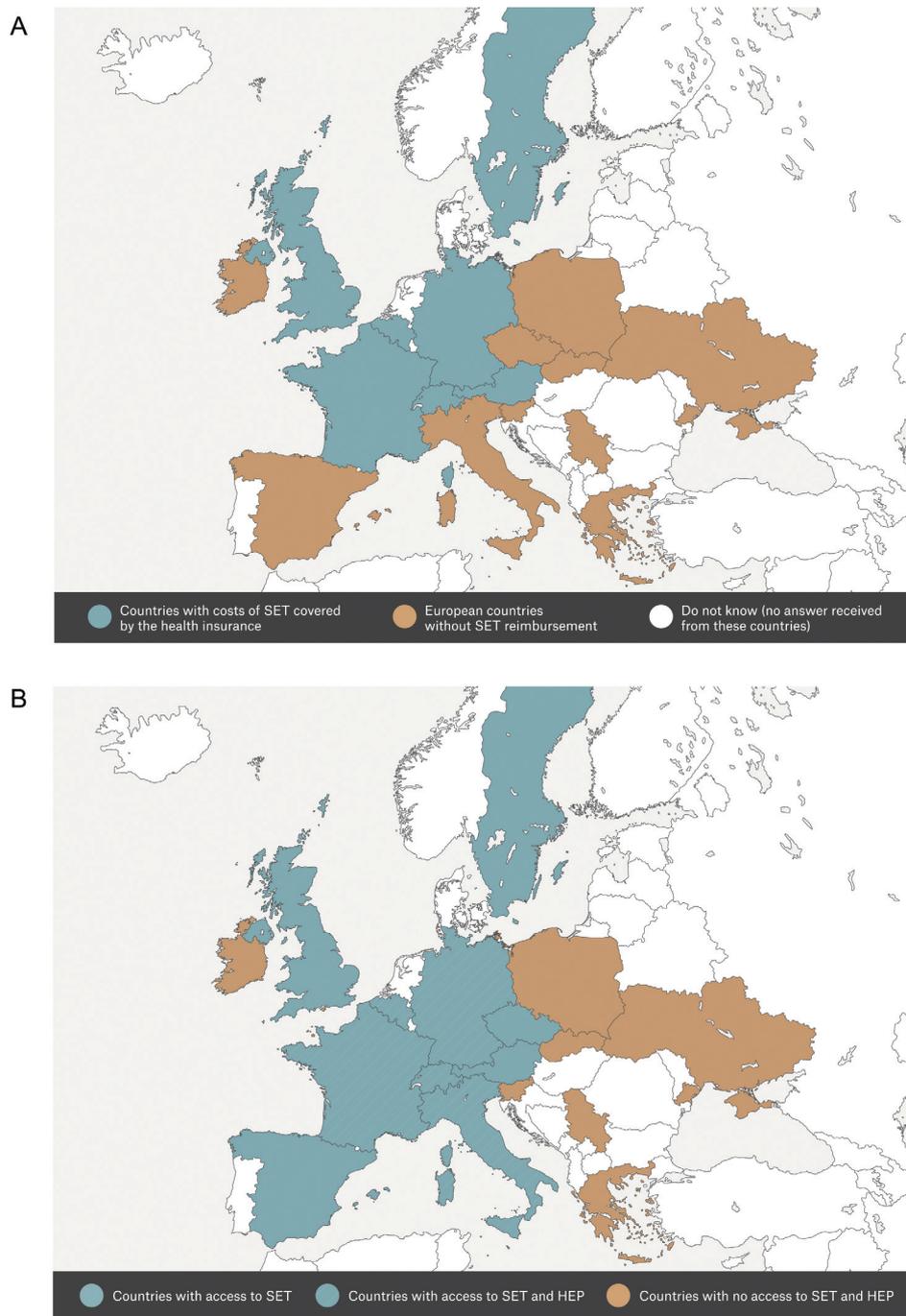


Figure 1. A: Reimbursement of supervised exercise therapy (SET) by the health insurance in patients with peripheral artery disease in different European countries. Note that in the United Kingdom, SET programs are NHS (National Health Service) funded. B: Access to supervised exercise therapy (SET) and home-based exercise program (HEP) in patients with peripheral artery disease in different European countries.

(8%; 11/131), or asymptomatic only (1%; 1/131). Overall, 17% (22/131) reported not knowing which patients are eligible for enrolment in a SET program.

Responders reported that programs are mainly coordinated by angiologist/vascular physicians (Table I). The training frequency mostly reported is 2-3x weekly, with a duration of less or equal to 12 weeks (Table I). The training session duration mostly reported was 30-60 min (Table I). Walking only and combined walking and resistance training are the most reported training modalities (Table I).

A large heterogeneity in the observed outcomes was reported (Table I). To note, for unknown reasons, not all the 131 respondents answered these questions (Table I).

Home-based exercise programs

Overall, 24% (32/131) of responders reported that home-based exercise programs (HEP) exist in their country or hospital/community, whereas 42% (55/131) reported that

Table I. Characteristics of the supervised exercise training program

Program coordinator	
Angiologist/Vascular physician	48% (62/129)
Cardiologist	26% (33/129)
Vascular surgeon	7% (9/129)
Nurses	6% (8/129)
Sport scientists	5% (7/129)
Physiotherapist	29% (38/129)
Researchers	0% (0/129)
Other (Physical medicine specialists or N/A)	3% (4/129)
I don't know	17% (22/129)
Training sessions supervision	
Angiologist/Vascular physician	29% (37/128)
Cardiologist	17% (22/128)
Vascular surgeon	2% (3/128)
Nurses	17% (22/128)
Sport scientists	9% (11/128)
Physiotherapist	46% (59/128)
Researchers	1% (1/128)
Other (Sport educators, Rehabilitation medicine or N/A)	3% (4/128)
I don't know	18% (23/128)
Training program duration	
Less than 12 weeks	35% (46/130)
12 weeks	32% (41/130)
More than 12 weeks	5% (7/130)
I don't know	28% (36/130)
Training program frequency	
1–2×per week	18% (23/130)
2–3×per week	37% (48/130)
More than 3×per week	19% (25/130)
I don't know	26% (34/130)
Training sessions duration	
Less than 30 min	2% (3/129)
30–60 min	57% (73/129)
More than 60 min	7% (9/129)
I don't know	34% (44/129)
Training modalities	
Walking only	26% (32/125)
Resistance training only (with dumbbells or elastic bands)	1% (1/125)
Combined walking and resistance training	47% (59/125)
Other forms of aerobic exercise (arm/leg ergometer, etc.)	18% (23/125)
I don't know	24% (30/125)
Endpoints/outcomes	
Symptoms questionnaires	37% (45/121)
Quality of life questionnaires	34% (41/121)
Walking capacity questionnaires	29% (35/121)
Satisfaction questionnaires	14% (17/121)
Walking distance(s) on 6 min walk test or on treadmill	57% (69/121)
Physical function assessment (SPPB, stair climbing test, etc.)	12% (15/121)
Change in hemodynamic parameters	29% (35/121)
Podometer and/or other device	15% (18/121)
Morbidity and/or mortality	7% (9/121)
None	16% (19/121)
% of referred patients complete the program	
<40%	18% (23/130)
40–60%	11% (14/130)
60–80%	16% (21/130)
80–100%	12% (16/130)
I don't know	43% (56/130)

HEP does not exist, and 34% (44/131) reported not knowing. When data were analysed by country, responders from Belgium, France, Germany, Italy, Switzerland reported that HEP exists for patients with PAD in their country (Figure 1B). However, a large variability of responses was found within each country: 29% of responders from France reported that HEP does not exist for patients with PAD in their country and 37% reported not knowing if HEP was available; 57% of responders from Germany reported that HEP does not exist for patients with PAD in their country and 29% reported not knowing; 43% of responders from Italy reported that HEP does not exist for patients with PAD in their country and 21% reported not knowing; 65% of responders from Switzerland reported that HEP does not exist for patients with PAD in their country and 24% reported not knowing.

Responders from Austria, Czech Republic, Greece, Ireland, Poland, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Ukraine, United Kingdom, reported that HEP does not exist for patients with PAD in their country or that they do not know (Figure 1B).

Written advice

Overall, 74% (97/131) of responders reported giving written advice to patients with PAD about benefits of walking and/or regular exercise.

Discussion

The principal finding of this survey is that a large variability of SET availability and characteristics exists across countries throughout Europe. Despite the fact that responders seemed aware that SET is the first-line therapeutic option for symptomatic patients with chronic PAD, in a fairly large part of Europe SET is yet underused. In addition, SET is reimbursed by the health insurance (or by the NHS in the United Kingdom) only in 41% of the countries represented in this survey.

It is well known that SET is effective in improving treadmill performance in patients with symptomatic PAD. A recent meta-analysis showed improvements in pain-free (PFWD: 82 m; 95% IC: 72–92) and maximal (MWD: 120 m; 95% IC 51–190) walking distance following SET [15]. It is interesting to note that improvements in treadmill performance are similar to those observed following endovascular revascularization [35, 36, 37]. SET also improved functional over-ground walking performance (i.e., six-minute walking distance) in patients with PAD. A meta-analysis showed a mean between-group difference of 35 m (95% IC 26–44 m) in the six-minute walking distance following SET [16]. Notably, it has previously been shown that lower functional walking performance during the six-minute walk test may predict further mobility loss, all-cause and cardiovascular mortality [38, 39]. From a clinical standpoint, the improvements in functional walking performance achieved following

SET are therefore of great importance. This may also lead to improved quality of life (usually assessed by questionnaire) [15, 19]. In this context, a recent study showed that larger increases in six-minute walking distance following SET are predictive of larger improvements physical and mental self-reported health-related quality of life in patients with PAD [40]. Taken together, these findings highlight the importance of exercise training to deliver optimal therapeutic care in patients with PAD. The limited access to SET observed in the present survey indicates a suboptimal care in these individuals.

The results of the present survey also showed a large variability in SET characteristics. Notably, the training duration (session and program) and frequency varied among responders. In addition, 20–35% of the responders reported not knowing how SET is prescribed and delivered to patients with PAD (Table I). International guidelines all recommend (Class 1A recommendation) SET in patients with chronic PAD. However, training modality, parameters, duration (session and program), frequency, and claudication pain intensity to be reached [10, 11, 12, 41, 42, 43] are inconsistently and heterogeneously addressed in guidelines [44]. In general, SET programs consist of at least three weekly training sessions with a duration between 30 and 60 min over a 12–24 weeks period. Walking is the most investigated and used training modality. Patients are instructed to walk at a speed that induces the onset of claudication pain within 3–5 min and moderate-to-severe claudication pain within 8–10 min [10, 11, 12, 41, 42, 43]. Then, patients are instructed to rest until pain resolution (or almost complete resolution) before resuming walking. Alternative training modalities such as arm ergometer, resistance training, and cycling also induce improvements in walking performance, and should be proposed when walking is not an option [10, 44]. In general, there is no clear distinction between claudication pain intensity (the intensity of symptoms during exertion) and common exercise training intensity measures such as heart rate (HR), oxygen uptake ($\dot{V}O_2$), or rate of perceived exertion (RPE) to monitor exercise therapy. Indeed, in the majority of PAD trials, monitoring of exercise therapy is mainly symptoms-based. A recent meta-analysis conducted by Fassora et al. [45] showed that walking at vigorous exercise intensity induced the greatest improvement in maximal walking distance, while cycling and other non-walking training modalities performed at vigorous intensity elicited the greatest improvements in cardiorespiratory fitness (i.e. $\dot{V}O_{2peak}$) [45]. These findings suggest that (1) both exercise training modality and intensity should be considered when looking for the best results, and (2) future studies are needed to optimize the training guidance in patients with PAD [45, 46].

Structured HEP has been shown to be effective in improving walking performance, physical, and vascular function in patients with PAD [47, 48]. However, improvements in walking distance appear inferior to those observed following SET [49]. HEP reduces the numbers of visits and the number of medical staff involved in care. Therefore, HEP has the potential to overcome the commonly

mentioned barriers of SET [28, 29, 32]. It is interesting to note that when monitored by pedometer or activity monitors and when the FITT principles of exercise prescription (frequency, intensity, time and type) are considered, HEP elicits similar results than SET programs, or at least reduces its inferiority for improvements in walking distance in patients with PAD [49]. A recent systematic review reported that HEP is safe in patients with PAD, with findings indicating an all-cause complication rate of one event per 36,953 patient-hours [50]. Given the lack of availability and common barriers in participating in SET programs, home-based programs are a valuable alternative to improve walking capacities in patients with PAD. The findings of the present survey have shown that HEP is also underused in Europe. Indeed, only 24% of the responders reported that HEP exists in their country. Notably, a large variability of responses exists within the countries.

Limitations

Despite we published the link to the survey on the web pages of the ESVM and we sent it to all the ESVM board members, we obtained responses from only 17 European countries. In addition, it should be noted that the responder rate is heterogeneous among countries. Therefore, only a rough European overview of SET can be given from this survey.

Perspectives

To move forward, it is essential to provide detailed guidance to deliver optimal exercise therapeutic care in patients with PAD. To achieve this goal, following steps include: (1) a more widespread availability of SET programs and standardized outcomes (such as treadmill performance, quality of life, and functional performance) to check their effectiveness in both asymptomatic and symptomatic patients with PAD; (2) a more defined harmonization of SET characteristics (duration, claudication pain intensity, exercise intensity, type of exercise, monitoring, etc.); (3) a strong argument for health insurance reimbursement of costs, possibly with the collaboration of scientific societies which should vocalise the need for SET in many countries; and (4) action to improve the public knowledge about SET benefits. To achieve these goals it would be desirable that European societies (ESVM, ESC, ESVS) join forces to develop research collaborations and guidelines in the field of exercise and PAD.

Conclusions

SET is highly recommended to improve walking abilities and quality of life in patients with PAD. However, SET is usually underused in the therapeutic care management.

The results of the present survey showed that a large variability of SET availability and characteristics exists across Europe. These data indicate that there is an urgent need to provide detailed guidance to deliver optimal exercise therapeutic care in patients with PAD.

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