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Title: “Intermittent claudication a real pain in the calf” – patient experience of diagnosis and treatment with a supervised exercise programme.

Abstract

Objectives: Intermittent claudication is a common condition which has severe impacts on quality of life, physical function, mental health and quality of life. Supervised exercise is the recommended first line treatment for patients with this condition; however these are not always feasible or accessible to patients. As the proportion of patients who have this treatment remains suboptimal it is important to better understand the perception of exercise in this population. A gap in the literature exists about the barriers and facilitators to exercise in patients completing, dropping out of or declining an exercise programme.

Methods: A qualitative analysis was undertaken to understand this further. 25 patients were interviewed face-to-face, 10 who had completed exercise, 10 who had declined and 5 who had dropped out of an exercise programme.

Results: Three major themes emerged from the data, intermittent claudication, and perception to exercise and experience or beliefs of the exercise programme.

Conclusions: Addressing the barriers and facilitators to exercise in patients with intermittent claudication is crucial in optimising the delivery and uptake of exercise programmes. More education or time investment is needed with these patients during initial diagnostic to help overcome perceived barriers and emphasis healthy behavioural changes.

Introduction

Peripheral arterial disease (PAD) is a common condition that may cause exertional lower extremity muscle pain classically known as intermittent claudication (IC). The impact of IC on quality of life has been well demonstrated ¹, with IC not only affecting walking distance, walking ability and physical activity levels but also social function, mental health and emotional well-being ².

The current first line therapy in the UK, as recommended by the National Institute of Health and Clinical Excellence (NICE), is a supervised exercise programme (SEP). Studies have shown that these are not always feasible, acceptable or accessible for patients ^{3,4} and that many patients who commence on a SEP fail to complete the programme. It is evident that the clinical and cost effectiveness of a SEP for the management of IC may be significantly affected by poor recruitment and adherence to programmes.

As the proportion of patients who are referred for treatment and who go on to participate remains suboptimal ³, it is important to examine the barriers and facilitators to exercise in this population.

One method of better understanding the patient experience is to conduct in depth interviews, as this is a powerful method for generating both descriptive, explorative and opinion based data. To date there have been few studies specifically engaging with patient perceptions of a SEP. Therefore the aim of this study was to conduct face to face in-depth interviews with three subsets of patients with IC; those that participate and complete a SEP,

those that decline treatment and those who initially agree to participate but subsequently withdraw from the SEP.

Methods

This was a qualitative study, using semi-structured interviews, conducted in a single vascular surgery unit of a tertiary teaching hospital. Ethical approval was granted by the Research Ethics Committee and the study was conducted in accordance with the ethical standards of the Declaration of Helsinki 1975. All participants provided informed written consent.

Participants and SEP

All patients had been reviewed by a consultant vascular surgeon and were documented to have stable yet persisting IC. Inclusion criteria included adults over the age of 45, and an ankle-brachial pressure (ABPI) < 0.9. Exclusion criteria included; severe cardiovascular or musculo-skeletal illness precluding participation in SEP, critical limb ischemia or active cancer treatments. All patients suitable for inclusion were offered the SEP provided in secondary care. The SEP was performed three times a week for twelve weeks under the supervision of an exercise physiologist. The SEP is based on the recommendations of a previous meta-analysis⁵ and has been validated for clinical and cost-effectiveness⁶. The SEP:

- A warm up period of five minutes, including passive stretches.
- A six station circuit, with each station lasting two minutes with two minutes of walking in between. Patients completed one full circuit during the first six weeks and then one station per week was added during the final two weeks⁷.
- A cool down period of five minutes concluded the session including passive stretches

Interviews

Interviews were conducted using a topic guide to ensure consistency across participants, however a flexible format was used to allow participants to generate naturalistic data. All interviews were conducted on a face to face basis at a place convenient for the patient, either in the home or a comfortable, accessible hospital setting. All interviews were audio recorded and transcribed verbatim.

Interviews were split into three groups:

- Group A – Exercise decliners
- Group B – Exercise completers
- Group C – Exercise withdrawers

Interviews took place over a 1 year period. A minimum of 5 patients were required per group, and groups were filled to maximum of 10. These numbers have proved sufficient for thematic saturation and allows for separate analysis of patients who are atypical^{8,9}

Data analysis

Data was analysed using thematic analysis. This approach is inductive (themes emerge from the data and are not imposed upon it by the researcher) and iterative (data collection and analysis occur simultaneously)⁹. Participants were also compared for commonality and differences.

Atypical cases were actively sought throughout the analysis and emerging ideas and themes modified in response. Data analysis involved a process of organising the data, descriptive

coding, thematic coding, writing and theorising. Data was managed using a qualitative computer software package (NVIVO, QSR International).

Results

Recruitment Between May 2015 and January 2017 a total of 547 patients were screened for the supervised exercise programme. 125 patients were excluded based on the exclusion criteria, leaving a total of 422 eligible patients invited to participate. 92 patients (22%) agreed to take part in the exercise programme. Of the 92 patients who commenced on exercise only 38 fully completed (41%), 38 patients actively withdrew from the exercise programme and two patients died.

Drop out interval

Seven patients did not attend the exercise class despite agreeing at the baseline appointment and a further three withdrew from exercise after 1 session, with some patients phoning after their baseline clinic visit to say that they did not want to attend the exercise class. Nine patients withdrew from exercise within the first week. Eight patients withdrew between week's two to four, nine patients withdrew from week's four to eight and two patients withdrew from exercise between 8 and 12 weeks.

Interview Recruitment

The first ten patients who completed the supervised exercise programme were approached and consented to be interviewed. 20 patients who declined participation in the exercise programme were approached for interview with 10 patients consenting to interview. All patients who dropped out of the exercise programme were invited to interview, with only five patients from this sub-set agreeing.

Of the cohort of 25 interviewees, 14 were men (56 %) and age of the participants ranged from 44 – 79 with a mean of 71 years (SD =9). Fifteen patients (60%) chose to be interviewed at home and 10 patients (40%) to be interviewed in the hospital setting. Three major themes emerged during the analysis of interviews and several sub-themes were identified for each theme. A summary of these themes and characteristics are presented in table I.

Intermittent Claudication

Understanding of the disease and risk factors

Many patients did not have a clear understanding of the disease process with only seven patients giving a clear description of a “blockage” or “furring” up of the arteries in their legs. Patients often used the terms “veins” and “arteries” interchangeably during the discussion. More men than woman responded with pathophysiological descriptions of the disease. Additionally, a minority of patients discussed the potentially progressive nature of intermittent claudication. “It is getting worse and I needed to do something because my leg could be in danger”. 16 of 25 patients mentioned risk factors with the majority referencing smoking. “I was on 20-30 a day, but I regret it now, it’s the worst thing I ever did.”

Therapeutic advice and best medical therapy

Twenty-two patients were able to discuss medication. Of these, some were fully aware of their prescriptions “He prescribed me Praxaline to help widen my arteries and let the blood flow” in contrast with some patients “I just take those capsules he gave me”. In addition to this, many patients felt that their disease was not adequately described to them by the

consultant during their clinical visit. “He didn’t really explain anything; I think he could have given me more information at the time”.

Effects of IC on lifestyle and daily activity levels Most patients described an effect of their claudication symptoms on their daily activities, such as a reduction in shopping, walking or going out with friends. “[...] last year we went on three holidays and I didn’t enjoy any of them because I couldn’t walk, we won’t be going again”. The majority of patients also described feeling “upset”, “fed-up” or “frustrated” with their reduction in activity levels, with a number of patients becoming visibly emotional during the interview. Some patients coped with symptoms by attributing it to “old age” and stating that it “just comes with life”.

Perception of Exercise

Previous exercise experience and current activity levels

Twenty-two patients had some level of exercise experience with most of them ending participation in sport at a school level. “I played netball at school but I didn’t do anything after I left”. A minority (14) of patients continued with exercise in their adult life, mainly with activities such as walking. Only nine patients out of the 25 interviewees were currently engaging in some form of physical activity which was mainly walking. “I try to walk every day; it’s the only little bit of exercise I get”, with one patient swimming three times a week.

Benefits to exercise

Less than half the patients were able to discuss the benefits of engaging in regular physical activities and most gave descriptions such as “you have to do something don’t you” or “I just like walking.” Some patients described it as “getting the blood flowing” and “working the muscles.”

Experience of the exercise programme

Of the 14 patients who attended the class and were interviewed (four drop outs), 13 described it as “social” with the “instructors and other people who went making the class”. Only one patient (who had additional problems) said she “felt embarrassed because of her stomach”. Many patients described the class as “friendly, “relaxing” and a “feeling of all being in it together”. Whilst the ten that completed the programme did discuss the “commitment to coming three times a week”, they all said that they would be happy to come back if the consultant deemed it necessary. “At first I felt like a fish out of water but as time went on my energy and fitness improved so yes I would definitely come and do it again [repeat the exercise programme].” Most of the patients described how they found the first few weeks challenging but noticed an improvement in their walking ability after approximately three weeks. “I noticed after about two weeks that my walking was getting better, I realised how beneficial it actually was.”

Barriers to exercise

Most patients discussed the burden of attending a hospital based SEP three times a week for 12 weeks. In general, the biggest factor for restriction was the timing of the exercise programme, which ran from 4pm to 5pm. “It’s just around rush hour and you could spend more time sat in your car than at the exercise programme.” Some patients also highlighted the implications of having elderly relatives or grandchildren to care for so couldn’t afford the time to come. “I have the grandchildren you see and it wouldn’t be fair to my wife to leave her alone with them three days a week.” Transport was another issue that was identified. “I would have to get two buses just to make it there and then I would have to walk from one bus to another and then walk from the bus stop to the class, I just couldn’t do it.” In

comparison those that attended and completed the exercise programme; “The time wasn’t an issue for me but I had a car, maybe it is more difficult for those getting a bus”, “I wouldn’t have changed anything about the class except the time but that didn’t stop me from coming, I wanted to get my legs better”.

Cost was also highlighted as an implication, “If I didn’t have my car I wouldn’t have been able to afford the bus” however in comparison some patients were happy to pay the cost for the perceived health benefits of attending exercise “It cost me £12 in a taxi but it didn’t matter to matter, once I was coming I was in it 100%”. “Money could be a factor for some people but for me it wouldn’t stop”

In relation to the four patients who dropped out of the exercise programme, two dropped out for medical reasons (one for revascularisation and one with ulcerative colitis), one patient dropped out due to the stress of travelling to the exercise class and the fourth could not afford the bus fare.

Discussion

This study aimed to examine the barriers and facilitators to exercise programmes in patients with IC. Throughout the interviews patients living with IC described significant symptoms with major functional reduction and impairment of daily activity levels. There were no discernible differences in symptoms or experiences between men and women and no difference between patients during the winter and summer months.

There were three major themes that emerged from the data including intermittent claudication, perception to exercise and experience of the exercise programme (facilitators

& barriers). Within each individual theme there were several emerging sub-themes (table one).

Intermittent Claudication

In general, patients did not have a clear understanding of intermittent claudication, with only seven out of the 25 patients interviewed giving a clear and reasonable description of the disease process, which is consistent with previous research ¹⁰. It is difficult to draw an accurate conclusion as to whether this is a nationwide issue, given that these interviews took place in a single tertiary vascular unit in England but does highlight potential communication barriers and breakdown between consultant and patient during the initial diagnostic phase of treatment. It may also highlight a level of social deprivation and lower education levels as patients in a less deprived area may have greater understanding of their disease. Within our tertiary vascular unit patients are seen by the consultant in clinic for 10 minutes, which leaves little room for thorough explanations and “time-investment” in the patient. Some patients expressed this during interview “I felt like I had lots more questions after my appointment”. For those patients suitable for engagement in an exercise programme nurse-led claudication clinics may be more appropriate where more time could be spent with the patient, explaining their condition and educating them about their disease. Multi-centre nationwide interviews would be needed to understand this further. Surprisingly, more patients were able to discuss the actions of medications prescribed to them such as “widening the artery” and “improving blood flow”, although again some patients felt that more information could have been given to them about medication and the reasons for taking it. Often patients felt “let down” with information providing at the time of consultation and advice given to them was not specific enough ¹¹.

Lifestyle and daily activities

It is well known that intermittent claudication has a severe impact on physical function, daily activity and walking abilities ². Many patients in this study felt that their symptoms had a significant impact on their ability to function on a day to day basis and even simple tasks such as food shopping had become a struggle. This struggle often led patients to describe feeling “upset” and “frustrated.” The emotional feelings that come with peripheral arterial disease can often be overlooked as clinicians treat the disease rather than the whole patient ¹². Undoubtedly when patients begin to experience a reduction in walking ability a cycle of disability leading to a reduction in physical activity levels and a worsening of the condition may be triggered. This is highlighted further by only 36% of interviewees engaging in some form of regular physical activity prior to screening for SEP. Many patients felt that they were unable to “walk to the shops in the morning for the paper,” highlighting the level of their perceived disability. Additionally, only half of the patients interviewed were able to discuss the benefits of engaging in physical activity, with many assuming that surgical intervention was the only course of action. Knowledge of, and belief in, the health benefits of exercise can be highly motivational for a patient to begin exercise and can influence programme adherence. Patients who are looking for a “quick-fix” treatment are much less likely to engage in an exercise programme or subsequently drop out ¹³. This further feeds into the need for more education in this clinically population such as the SEDRIC study ¹⁴

Exercise Programmes

Supervised exercise programmes are the recommended first-line treatment for IC patients ¹⁵ and can lead to improvements in walking distance, quality of life and functional capacity ¹⁶. In the general population approximately 60% of adults do not engage with physical activity

and this value is even higher in the PAD population³. Acknowledgement of the facilitators and barriers to any exercise programme is crucial in augmenting exercise programmes to suit the patient population that is being served. Time was one of the biggest reasons patients did not attend the exercise therapy, both the time of the exercise class and the time in travelling, either by bus, car or on foot. Travel burden is an important factor as the perceived distance to an exercise programme is a good predictor of a patient's likelihood of participation. The findings also highlighted a difference between those who attend the exercise programme and those who did not. In both groups time, travel and cost were highlighted but for those who attended the exercise programme they were willing to overlook or overcome this potential barrier to improve their overall health and wellbeing. Indeed those that completed exercise were the most likely to have engaged or still be engaging in physical activity. As already highlighted more education and awareness is needed in these patients to help patients overcome perceived barriers and attend exercise.

By hospitals and trusts engaging with patient's perceived barriers, health care providers can address the delivery of exercise programmes to promote higher uptake and adherence. More recently areas such as cardiac rehabilitation are engaging with the concept of "patient preference" for treatment and although hospital SEP is still the most commonly delivered form of exercise some patients discuss the desire for home, community and even online web based activities^{17, 18}.

Conclusion

This is the first study to assess the opinions of exercise programmes in patients with IC using in depth semi structured interviews. The first line treatment for patients with IC is a supervised exercise programme; however a majority of patients either fail to engage or

complete this treatment. The findings of this study identified four major themes including intermittent claudication, perception to exercise, experience of exercise programmes and barriers to SEP participation. Whilst data suggests that SEP is still the most clinical and cost effective intervention to improve outcomes in IC patients low rates of uptake and adherence are a real problem. Potential solutions e.g. patient preferences merit further investigation.

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