Impact of twelve weeks march field training on intermittent claudication in patients with peripheral artery disease after endovascular procedures

A – preparing concepts
B – formulating methods
C – conducting research
D – processing results
E – interpretation and conclusions
F – editing the final version

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Abstract

Introduction: March Training (MT) is one of the ways to improve the results of treatment in patients with peripheral artery disease (PAD). The aim of this study was to investigate the effect of 12 weeks of march training on the claudication distance in patients with PAD who underwent endovascular surgery.

Material and methods: The study included 30 patients with peripheral arterial disease (PAD) and evaluated the claudication distance on a treadmill: before endovascular surgery, 3 days and 3 months after the surgery. The maximum claudication distance (MCD) was measured during each test on a treadmill. Patients were randomly divided into 2 groups of 15: group A consisted of patients who were not recommended to march after endovascular surgery and group B consisted of patients to whom training was recommended. Patients in group B were recommended march training at home for 3 months according to the following schedule: walking at a regular walking pace of 60-120 feet's per minute for at least 30 minutes, 3 times a day, 3 days a week, supervised by a physiotherapist.

Results: Group A - MCD before surgery: 103,23m , MCD 3 days after surgery: 179m, MCD 3 months after treatment: 136,67m , $p < 0.001$. Group B - MCD before surgery: 97,07m, MCD 3 days after surgery: 192,62m, MCD 3 months after treatment: 270,53m, $p < 0.001$.

Conclusions: MCD carried out for 3 months after endovascular treatment of patients with PAD is better in group of patient systematically doing march training compared to patients without such training.

Key words: **peripheral artery disease, intermittent claudication, march training, Endovascular Procedures**

Introduction

Peripheral artery disease (PAD) is a serious clinical condition with significant social issues. In 98% of cases, the cause of PAD is atherosclerosis, which leads to aortic coarctation and can further lead to occlusion of the abdominal aorta, iliac arteries and arteries of the lower extremities. The remaining 2% of cases maybe associated with arteritis and/or fibromuscular dysplasia [1-3].

Lower limb atherosclerosis is a multi-tiered disease. 70% of the atherosclerotic changes are found in the femoral or popliteal arteries, 15-20% in iliac arteries and 10-20% in arteries of the calf**.** In most of the cases, atherosclerotic changes in these arteries lead to lower limb ischemia [4, 5]. It is rare for the disease to affect a single isolated area.

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The most frequently used scale to assess chronic lower limb ischemia is the Fontaine classification consisting of four grades: (Table 1) [6].

Tab. 1. Clinical classification of the limb ischemia [7]

Fontaine's stages	Clinical symptoms
I	asymptomatic
IIa	intermittent claudication after walking a distance>200 m
IIb	intermittent claudication after walking a distance<200 m
III	rest pain
IV	ulcers and gangrene of the limb

According to the European Society of Cardiology, one of the effective treatments for intermittent claudication in patients with chronic limb ischemia is March Training (MT). Revascularization surgical therapy is typically used if MT combined with pharmacological treatment does not lead to improvements. However, patients often expect immediate results of therapy and lack the needed patience for MT which lasts several months. Therefore, the surgical alternative is more attractive for those patients and is chosen more often as the prime therapy [8].

Lately, complex rehabilitation in the form of MT has been discussed as an adjunctive treatment, not only to pharmacological treatment, but also to surgical revascularization for patients with intermittent claudication.

In clinical practice, supervised MT programs are rare due to the limited options and most importantly due to lack of funding from public healthcare. It is also a matter of contention that patients are not educated properly on how to perform this form of exercise training, which compounds the problem. Doctors often advise patients suffering from intermittent claudication to "walk a lot" without further descriptions. According to Rutkowska's observations [9], 2/3 of patients with intermittent claudication, are not given appropriate instructions on MT and are not aware of the meaning of this treatment.

As reported in Gardner's meta-analysis [10], an effective form of MT is the march training performed on a treadmill three times a week for 3-6 months [10]. According to the TASC II (*TransAtlantic Inter-Society Consensus*), MT may not only by advised as the prime therapy for patients with intermittent claudication, but also as an ancillary treatment after operations performed on the lower limbs' vessels, leading to improvement of walking quality and extending the distance of intermittent claudication [11].

A similar topic was discussed by Fakhry et al. [12,13], who evaluated the effectiveness of revascularization supported by MT in patients who suffered from intermittent claudication. The study group consisted of patients in whom surgical revascularization was performed, and a control group of patients who had not undergone a surgical revascularization procedure. Patients in both groups participated in MT. After one year, the distance walked prior to the onset of intermittent claudication was found to be longer in both groups. Nevertheless, patients who underwent combination therapy reported "painless walking" much faster than patients from control group. This study shows that among people who experienced intermittent claudication, after 1 year of observation, combination therapy brought significant elongation of marching distance and improvement of health quality compared to patients who underwent only supervised MT. According to studies carried on by Fakhry et al. revascularization in patients with intermittent claudication improves the blood supply of the lower limbs to a considerable degree, and facilitates subsequent training program, which influences further life quality of people who were operated [12,13].

The CLEVER study studied the outcomes of three treatment approaches: simple pharmacological treatment, physical training combined with pharmacological treatment and surgical stenting combined with pharmacological treatment [14]. The results showed that stenting and pharmacological treatment, were the most effective in patients with chronic lower limbs ischemia. Simple pharmacological treatment was found to be the least effective method [14-16].

Furthermore, the study led by Tomoyuki et al. supports the predefined thesis [17]. This study shows that even very short 2-weeks-long intensive MT has a positive effect on intermittent claudication after endovascular procedure.

The analysis of available existing literature shows that the effect of long-term unassisted MT outside the clinical setting, supervised pro term, on the intermittent claudication distance by patients afflicted by PAD has not been assessed. Therefore, the purpose of this study was to demonstrate the effects of a 12-weeks MT unsupervised program, on the intermittent claudication distance in patients who underwent endovascular treatment of PAD.

Material and methods

Study group

The participant group consisted of 30 patients with symptomatic peripheral artery disease. These patients suffered over 70% stenosis of the femoral arteries, common iliac arteries and external iliac arteries demonstrated by diagnostic ultrasonography. Patients with intermittent claudication were qualified for endovascular treatment in the General and Vascular Surgery Department in the Specialist Hospital in Międzylesie, Warsaw**,** between July and December 2015. Average age of people who underwent this study was 67. Among the research group were 9 women and 21 men. All people qualified to study were diagnosed with IIb grade according to the Faontaine's scale. The majority of the patients smoked a minimum of one package of cigarettes per day, and all of them were diagnosed with hypertension. Those with diabetes were excluded from the study. Two different endovascular procedures were performed: stenting and balloon angioplasty. Patients were randomly divided into two groups: group A – patients who underwent only the endovascular procedure and group B – patients underwent combination therapy consisting of endovascular procedure and MT.

Equipment

For the assessment of the intermittent claudication distance by inpatients treadmill ERT-200 was used (figure 1).

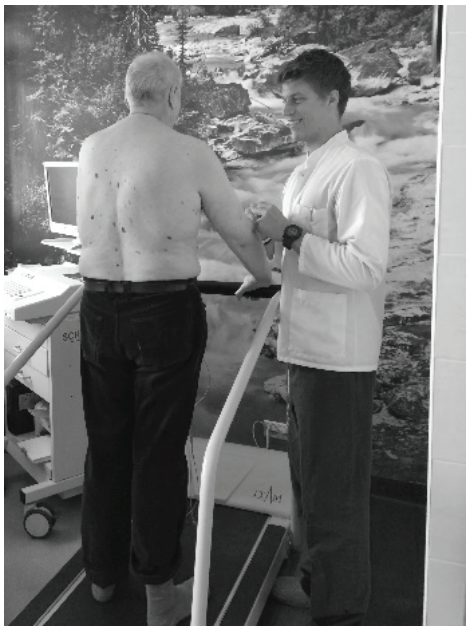

Fig.1. March training. (personal source)

Study design

Before the investigation, ECG electrodes were affixed to every patient's chest in order to assess heart activity. If any type of arrhythmia occurred, investigation was immediately stopped. The treadmill was started when the patient stood with both legs on the tape of the treadmill and held on to the railing. After that the treadmill was raised at an angle of 12 degrees against the floor. Velocity of the treadmill was 2.7 km/h during first 3 minutes (1. Level), during next 3 minutes the velocity of the treadmill was 4.0 km/h (2. Level), during the last 3 minutes the velocity of the treadmill was 5.4 km/h.

During each investigation on the treadmill maximal claudication distance (MCD) was measured [18, 19].

Endovascular procedures were performed by the interventional radiologist or the vascular surgeon according to the current standards. Stents were implanted into the iliac and femoral arteries only when the initial balloon angioplasty failed (selective stenting). Endovascular procedures – balloon angioplasty with stent's implantation were performed in 16 patients, whereas 14 patients underwent only balloon angioplasty.

Investigation begun from the MCD measurement in every patient with intermittent claudication on the treadmill one or two days before the endovascular procedure. Marching time of each patient was converted into meters according to the formula given in figure 2.

$$V = \frac{\Delta s}{\Delta t} \longrightarrow s = v \cdot t$$

Fig. 2. Speed and distance formula (personal source)

The time taken by every patient during the assessment was converted to distance using this equation, with simultaneous control of which level was achieved. If the patient could not reach the second stage (i.e. the time of his march was less than 3 minutes), then t = 3*60 s = 180 s or the time shorter than 3 min and the speed of the treadmill during the first level (v = 2,7 km/h) was added to the equation. The result given in km/h had to be converted into m/s, therefore the distance travelled was calculated in meters. A different approach had to be taken if the patients reached level 2 or 3. In this case, the performance in the first level was

measured as above, but in the second level, the time that the patient spent in this level alone was considered, along with the speed as it was increased compared to level 1. An analogous approach was taken to the third level.

Two days after the initial assessment on the treadmill, the endovascular procedure was performed. Subsequently, one week after the procedure, a second assessment was performed on the treadmill in order to measure the MCD distance according to the same protocol. Patients who were in group B underwent the MT in the open ground. Every patient was given a notebook in which marching distance, time of marching and number of stops should be written down. This notebook was the basis of the pro term supervision. At the end of each notebook, a pattern of the MT prepared by the physiotherapist was included, according to which patient should perform the training. The description of that pattern is shown below:

1. Supervised physical training should be performed in 3 sessions, 3 times a week for at least 3 months.
2. Each training session should last at least 20-50 minutes. Initially 20 minutes, later increasing in order to achieve 50 minutes.
3. Marching ground should not be solid and shoes worn for the marching should be comfortable. The patient should walk 2-3 times per day at 60-120 steps per minute (until achieving submaximum pain)
4. Greatest effects are gained while marching until ischemic submaximal pain , according to the 5-grade-scale of pain of the American College of Sports Medicine (ACSM) it is 4th level – moderate intensity of pain. It was advised to march using Nordic Walking poles.
5. Marching should be rhythmic and dynamic at a normal-walking pace, around 3-5 km/h, without sparing the affected lower limb and if possible not using crutches. If pain appears during the training, marching should stop and begin again 2-5 minutes after the pain goes away.
6. Marching until maximal pain is not advised because it carries a risk of cardiovascular sequel.

Patients from group A undertook everyday activities without marching training. every patient had their distance on the treadmill assessed again after 3 months, and outcomes were compared.

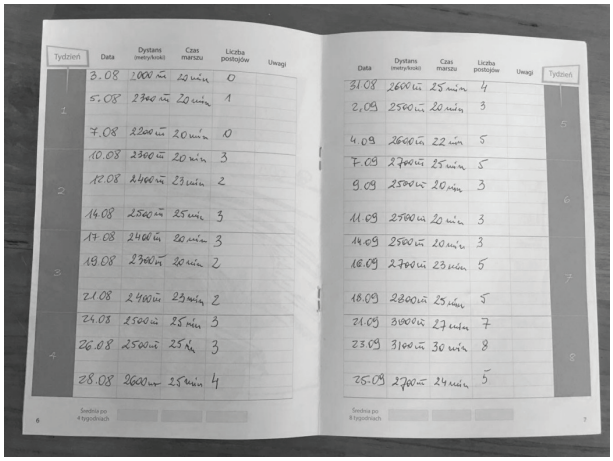

Fig. 3. One of the patient's marching notebooks (personal source)

Before the endovascular procedure patients were asked to fill a form assessing life quality, created specifically for this study. 3 months after the surgical procedure, march training (group B) patients filled the same forms. Patients from group A who did not undergo march training at home were also asked to fill the forms. Forms describing life quality before and after the procedure were compared in both groups.

Statistical Analysis

Statistical analysis was performs using STATISTICA software. The mean and the standard deviation were calculated. T-tests were used to evaluate if the data were significant. Statistical significance level of p=0.001 was assumed.

Results

Figure 4 shows mean values of the MCD evaluated before the procedure, 3 days after the procedure and 3 months after the procedure in both groups A and B.

Fig. 4. Mean MCD values for groups A and B (personal source).

Discussion

March training is an important method of treatment in lower limb ischemia. It has a positive effect on MCD, possibly due to development of collateral circulation. Few studies have been carried out to assess if MT performed after endovascular

procedures affects the intermittent claudication distance.

One of the studies conducted by Morisawa et al. showed a positive effect of very short, 2-weeks-long, intensive MT on extension of the intermittent claudication distance [17]. Author's own research demonstrates that a, 12-week, MT appears to be even more effective. It should be pointed out that patients investigated by the Japanese group performed their MT at the hospital. In the study presented in this work, patients after endovascular procedure trained on their own in the open ground for 12 weeks.

Patients performed the MT on their own, according to the given training plan in the open ground, so they did not have to spend additional time on hospital visits. It must be pointed out that patients who trained were controlled pro term by the physiotherapist. Each one of the patients was given a notebook with exact instructions on how to perform the training and were asked to write down their results in this notebook. It was a way in which the physiotherapist could control the patients and assess if the patient performed the marching training in an appropriate manner. However, this method of control is not fully reliable as the patients could write down untrue results. On the other hand, this is one of the best methods of patient control, justifying the author decided to use it.

Patients from group A, who did not undergo the MT, were asked to do their everyday work as usual. Based on that it was possible to compare both groups and assess the influence of the MT on the MCD distance by patients after endovascular procedures.

The gathered data implies that only four patients began 3rd level, and only one patient finished 3rd level, however this one patient did not begin the 4th level. This achievement was possible only after 3 months of the self-reliant marching training, performed in the open ground.

Moreover, 14 patients underwent only arterial balloon angioplasty and 16 of them underwent both - arterial balloon angioplasty and arterial stenting. Studies conducted after endovascular procedures showed that both surgical procedures improved MCD index 3 days after the procedure in patients from group B, whereas in group A the evaluated index was lower. The type of procedure had no influence on the index.

The present study shows that mean MCD value before the procedure was similar for patients from both groups. On the other hand, mean MCD value of patients in group A increased by 74% and then, 3 months after the procedure decrease by 24%, whereas in group B after the procedure mean MCD values increased by 98% and 3 months after the procedure increased by additional 36%.

After 3 months each patient from both groups had MCD values assessed using the treadmill. The results show that patients who were asked to perform the MT in the open ground had higher index compared to the patients who did not train. This provides evidence that the MT in the open ground has a positive impact on the MCD distance and improves general function of patients.

These results are comparable to Fakhry et al. based on the implication of the combination therapy by patients who suffered intermittent claudication [12].

It is worth noticing that patients with intermittent claudication who were asked to undergo the march trainings initially had problems understanding how to perform the training. A similar problem was discussed by Makris et al. who emphasized lack of proper education from the general practitioner, surgeon, angiologist and physiotherapist [20].

Observations show that patients are usually simply asked to "walk a lot". Unfortunately, it is not an appropriate instruction and it should be further evaluated. Therefore, special notebook with very precise instructions, including days and length of the training, are a very good option. Another point is that the marching training should be controlled by the physiotherapist or general practitioner in order to achieve long-term satisfactory results.

According to the studies conducted by Micker et al., there are several key risk factors contributing to critical lower limbs ischemia [21], including the following:

- Age of the patient – the older the person the higher the risk,
- Family interview – genetics, other members who suffered ischemia
- Smoking cigarettes – 4 times higher risk of ischemia comparing to non-smoking
- Hypertension.

In this study, main risk factors found in patients were smoking cigarettes, hypertension and old age. All the risk factors found in this work correspond with the factors described in the work published by Micker et al. [21].

Currently there is no pharmacological treatment that has been found to increase the MCD distance.

Marching treatment may improve the effects of pharmacological treatment.

At this point, it seems relevant to quote Wojciech Oczko, Doctor of Medicine and Philosophy, aulic doctor of polish kings: Zygmunt August, Stefan Batory and Zygmunt III Waza – "*Movement may replace almost every drug, whereas no drug can replace movement*". This should be borne in mind by the physiotherapists and doctors. Each patient suffering from ischemia of lower limbs should be encouraged to undergo marching training, regardless of other methods of treatment.

Conclusions

1. March training, controlled pro term, performed 3 months after the endovascular procedure by patients with PAD, has an influence on MCD elongation.
2. In patients with PAD 3 months after the endovascular procedures MCD is significantly longer in the group of patients who underwent the march training comparing to those who did not train.
3. Patients should continue the trainings under the control of physiotherapist using the notebook in which they can write down achieved results.

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