

Remission of Walking Parameters in Peripheral Arterial Disease through Association of Galvanic Baths and Kinesytherapy

SIMONA PĂTRU¹, A. C. BIGHEA¹, ROXANA POPESCU¹

¹Department of Medical Rehabilitation, University of Medicine and Pharmacy of Craiova, Romania

ABSTRACT: Chronic peripheral obstructive arteriopathies (CPOA), together with their determinations, play an important role in the elderly pathology and represent one of the most frequent causes of disability, thus having a negative impact on the patient's quality of life. Therefore, in this clinical randomized trial we proposed to study the efficiency of several treatment methods based on physical exercise together with other therapeutical approaches specific to physical medicine such as galvanic baths. We formed a group of 111 patients diagnosed with peripheral arterial disease in inferior limbs randomized into three groups: the control group (drug treatment and hygiene-dietary), the exercise group (12 weeks supervised exercises program, followed by another 12 weeks home unsupervised exercises) and the exercise and procedure group (kinesitherapy and galvanic baths). All the subjects performed the exercise treadmill test, according to the Gardner protocol, at the beginning of the study, after 12 weeks and after 24 weeks, at the end of the study and were measured: the time to pain onset (TDC) and the time to maximum pain onset (maximum walking time=TDD). We observed quite high TDC differences in the two groups that performed physical exercises compared to the control group, while the amelioration of walking periods was recorded after the first 12 weeks, and after 24 weeks they reached walking periods 2.5 times higher than at the beginning of the study. Adding hydrotherapy to the physical exercise led to even higher TDC values. After 12 weeks, we obtained a 54% TDD remission in the exercise group ($p<0.005$) and a 65% remission in the exercise and hydrotherapy group ($p<0.005$) and at the end of period, the TDD remission was 90% in the exercise group ($p<0.005$) and 100% in the exercise and hydrotherapy group ($p<0.05$). The kinetic-physical modalities show its efficiency in ameliorating the walking parameters in the patients with claudication and may offer low risks compared to the revascularization methods, high addressability, diminished costs.

KEYWORDS: peripheral arteriopathy, exercises, galvanic baths

Introduction

Chronic peripheral obstructive arteriopathies (CPOA), together with their determinations, play an important role in the elderly pathology, a worldwide population segment in continuous growth.

Chronic peripheral vascular lesions, usually with a long evolution in time, represent one of the most frequent causes of disability, thus having a negative impact on the patient's quality of life. Despite any appropriate caution measures imposed for cardiovascular diseases, peripheral arteriopathy still remains a poorly diagnosed affection. Only 20% of the patients with arteriopathies are informed by their doctors about their suffering, numerous studies indicating that these patients do not even benefit from an appropriate treatment at all. We have established that one of the neuralgic points of the medical journey an arteriopathy patient covers is the one represented by the collaboration between the medical staff he addresses most frequently and the rehabilitation specialist. Therefore, we proposed to find an answer to the question "what is the best approach a medical team may have when dealing with a CPOA patient" so that we could

minimize to the maximum the evolution of possible cardiovascular complications or reaching stage IV, which requires revascularization procedures.

Material and Methods

For demonstrating the efficiency of several treatment methods based on physical exercise together with other therapeutical approaches specific to physical medicine, we formed a group of 111 patients diagnosed with chronic obstructive peripheral arteriopathy in the inferior limbs. The patients in the group have been treated in the Emergency County Clinical Hospital of Craiova, either hospitalized in the Clinic of Physical Medicine and Rehabilitation, or in the specialty ambulatory.

Inclusion criteria:

- being diagnosed with CPOA in the inferior limbs, the Fontaine II stage
- having the ankle-brachial index (ABI) lower than or equal to 0.90

The following categories of patients were not included in the studied group:

- Locomotion disorders caused by other affections than CPOA

-New York Heart Association (NYHA) Type II heart block or pectoral angina after repose or a minimum effort

-Revascularization or other major surgeries planned for the next 12 months.

-Revascularization in the inferior limbs, major orthopedic or surgical interventions three months before the inclusion in the study

-Other major medical affections that may impede the patient from completing the study

-Difficult to control values of blood pressure (repose BP values > 140/90 mmHg)

-CPOA secondary to Buerger disease, autoimmune arthritis, fibromuscular dysplasia, recurrent chronic occupational injuries, venous stasis, hypercoagulation or arterial embolism

-Unbalanced Diabetes Mellitus (a jeun glycemic values > 110 mg/dl)

After confirming the diagnosis of peripheral arteriopathy in the inferior limbs and after the analysis of the inclusion and exclusion criteria, the patients gave the informed consent and were included in the study. The randomization was performed in three groups according to the inclusion order:

-the control group, which benefited only from drug treatment together with hygiene-dietary approaches during the whole study period (51 patients)

-the exercise group, which benefited from a well-established, supervised, 12 weeks kinesitherapy program, followed by the practice of the learnt program at home for another 12 weeks (24 patients)

-the exercise and procedure group, which also benefited from a 12 weeks preestablished set of hydrotherapy procedures, besides the supervised kinesitherapy program, continuing the learnt program at home for another 12 weeks (36 patients).

The patients in the control group benefited from the common medical care, which consisted in: hygiene-dietary treatment and drug treatment according to the prescriptions of the cardiologist or the nutritionist, previously to study inclusion, both during the first stage (the first 12 weeks) and during the final stage (the following 12 weeks). The second group starts with a period of 10 minutes warm-up, consisting in mobility and respiration exercises, followed by analytical gymnastics exercises, Buerger exercises, cardiac flow increase exercises and interval training (15-60 minutes daily), finalizing the training with relaxation exercises (5-10 minutes). The number of exercise repetitions was established individually, according to the patient's physical

state, and they practiced until the onset of moderate pain, followed by a repose period, in orthostatism or sitting, until the symptoms improved. At first, the sessions lasted for approximately 30 minutes, followed by a step by step increase of training time until approximately 60 minutes. Kinesitherapy sessions were performed 3 times a week.

During the first stage, besides the supervised kinesitherapy program, the patients in the exercise and procedure group also benefited from 4-cellular galvanic baths, the effect of partial hydrotherapy at 36-37° being added to the galvanic flow effect. Galvanic baths use recipients with water at a prescribed temperature, with embedded continuous electricity electrodes in their walls. The patient may introduce two, three or all four limbs in these recipients. In our study, we used the procedure of 4-cellular galvanic baths, with a negative pole on the affected inferior limb. The intensity of the galvanic flow was set at 40 mA, the water temperature at 36°C and the duration of 20 minutes.

During the final stage, the following 12 weeks, the patients in the exercise and procedure group practiced the learnt kinesitherapy program at home, unsupervised.

All the subjects performed the exercise treadmill test, at the beginning of the study, after 12 weeks and after 24 weeks, at the end of the study. Using this test, we measured two important parameters for functional evaluation: the time to pain onset (TDC) and the time to maximum pain onset (maximum walking time=TDD), according to the Gardner protocol. This protocol involved symptom-limited effort test, performed at a constant speed of 3.2 km/h and an inclination raise of 2% every 2 minutes, starting from 0% (1-2 METs/stage) until a maximum intensity of claudication. The intensity of claudicative pain felt by the patients during the test was recorded on a scale from 0 up to 4, where: 0 = no pain, 1 = claudication onset, 2 = mild claudication, 3 = moderate claudication and 4 = severe pain. For every patient there were measured: the time to claudication onset (value 1) and the time to severe, intolerable pain onset (value 4). During the exercise treadmill test, every patient was connected at an ECG with 12 derivations, monitoring the ventricular allure, the electrocardiographic line, as well as other manifestations of effort intolerance.

Results

Baseline characteristics: The studied group was made up of 88 male patients (79.27%) and 23 female patients (20.73%), males predominating in all the other subgroups. Also, the groups were homogenous as far as age was concerned, having a similar age mean (67.7 years old in the control group, 68 years old in the exercise group) and a little higher in the exercise and procedure group (70.8 years old).

From the medical history performed at study inclusion there resulted a mean 4 years time period since the claudication onset. The mean values of this period in the three groups were quite close to that value.

In the study, there were included 68 smoking patients, out of which 93% men, and 43 non-smoking patients, out of which 58% men. The mean age of smoking subjects was over 2 years old lower than the mean age of non-smokers.

During the initial TDC testing, we obtained a mean value of the whole group of 3.07 minutes (SD=1.64), with a minimum value of 1 minute

and a maximum value of 7 minutes (Fig.1). We observed quite high TDC differences in the two groups that performed physical exercises compared to the control group, while the amelioration of walking periods was recorded after the first 12 weeks, and after 24 weeks they reached walking periods 2.5 times higher than at the beginning of the study. Adding hydrotherapy to the physical exercise led to even higher TDC values, as seen in Table 1. In the control group, the results show no statistically significant TDC modifications after 12 and 24 weeks compared to the initial stage.

At study inclusion, the maximum walking time (TDD) had a mean value of 7.68 minutes (SD=2.86), with a minimum value of 3 minutes and a maximum one of 12 minutes (Fig.2). After 12 weeks, we obtained a 54% TDD remission in the exercise group (p<0.005) and a 65% remission in the exercise and hydrotherapy group (p<0.005). At the end of period, after 24 weeks, the TDD remission was 90% in the exercise group (p<0.005) and 100% in the exercise and hydrotherapy group (p<0.05).

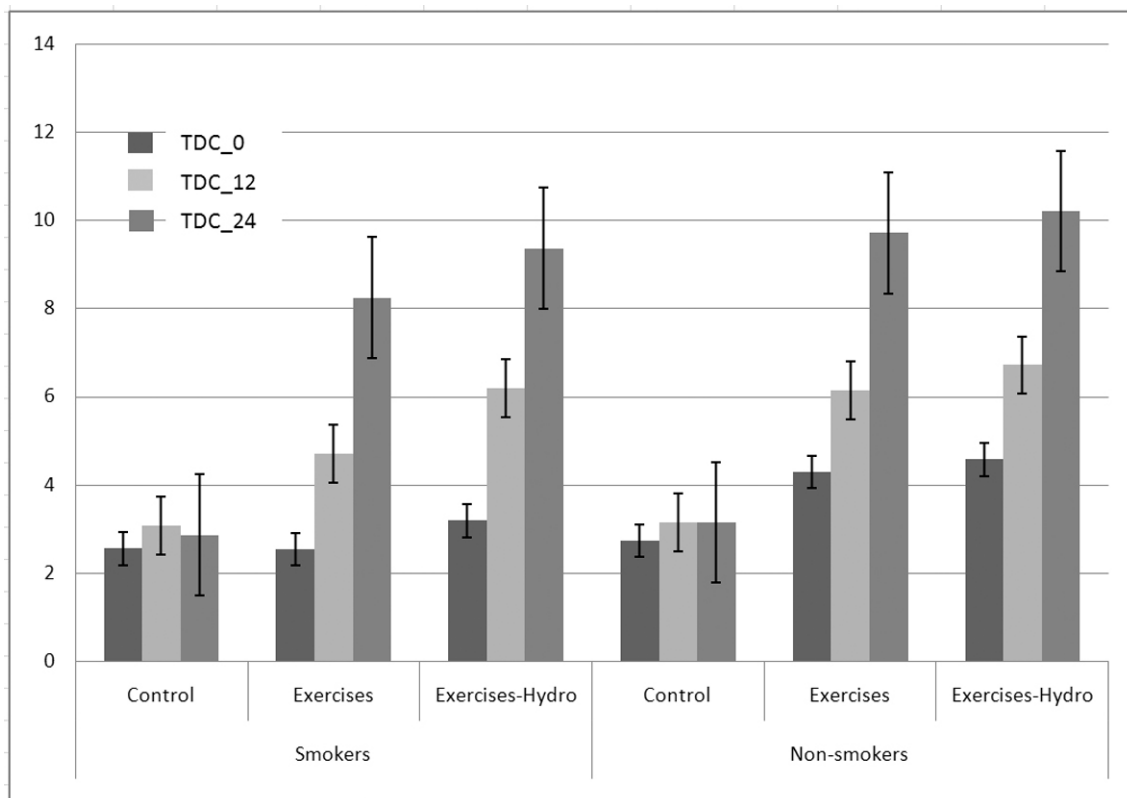


Fig.1. Comparison between mean values of TDC for smoker and nonsmoker patients

We observed a significant difference of TDC values at study inclusion between women and men in favor of women (3.87±1 vs 2.94±0.45), and, at the end of the study, we observed that in

the exercise and hydrotherapy group the values for men exceeded the TDC mean found in women (9.86 vs 9.01)

Table 1. Mean values (\pm SD) of TDD and TDC at baseline, at 12 weeks and at 24 weeks

		Mean \pm SD					
Lot	Parameter	TDC_0	TDC_12	TDC_24	TDD_0	TDD_12	TDD_24
	Control	2.63 \pm 1.3	3.1 \pm 1.4	2.98 \pm 1.4	7.75 \pm 2.8	7.96 \pm 2.6	7.67 \pm 2.7
	Exercises	3.04 \pm 1.4	5.12 \pm 1.6	8.67 \pm 1.5	7.42 \pm 2.6	11.46 \pm 2.5	14.12 \pm 2.9
	Exercises-Hydro	3.72 \pm 1.9	6.39 \pm 1.6	9.69 \pm 1.8	7.78 \pm 3.1	12.8 \pm 2.6	15.86 \pm 2.6

In the sex comparative analysis of the TDD parameter there were no significant differences between men and women.

Although lower at first in smokers, the TDC values also increased during the therapy based on physical means, without reaching the values of the non-smoker group.

As far as TDD is concerned, there may be observed that, besides the fact that in non-smokers the values were higher at study inclusion, the response to physical exercise based therapy was significantly better in non-smokers than in smokers.

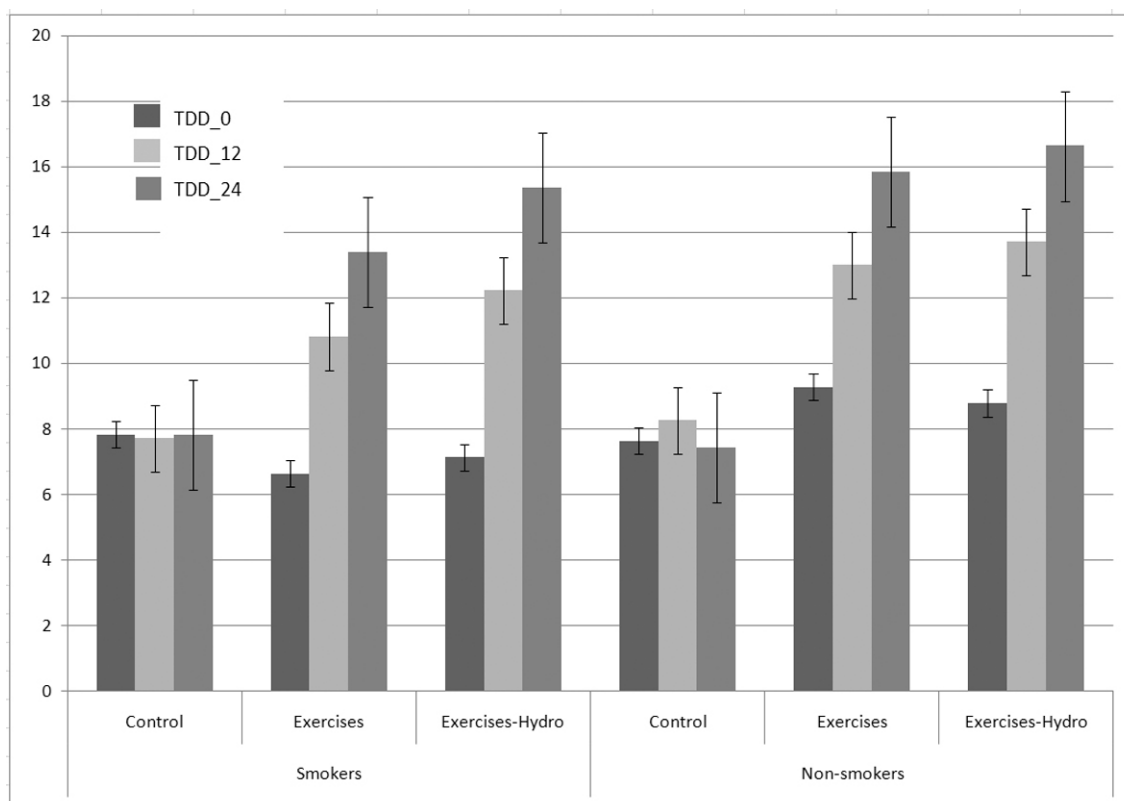


Fig.2. Comparison between mean values of TDD for smoker and nonsmoker patients

Discussions

Over time, there have been experienced various techniques leading to the amelioration of collateral blood flow in the affected areas, the most used being the following: the Buerger posture gymnastics, intermediary analytical contractions of muscle groups in the lower limbs [1], exercises of increasing the blood flow and pressure, and of peripheral perfusion pressure, implicitly, and the most physiological development method of peripheral blood flow,

the interval training [2]. Out of various authors' multiple variants, we chose those exercises that were easily understood by the patients, easy to learn and, especially, easy to perform at home, without requiring any special equipment. The patients in the exercise group benefited from a supervised kinesitherapy program during the first 12 weeks, and in the following 12 weeks, they continued this training program at home, without any supervision. The exercises were chosen according to the location of obliterations. In upper obliterations, there were chosen exercises that involved the thigh and pelvis

muscles, in middle obliterations, of femoral and popliteal arteries, there were performed exercises involving the calf muscles, while in distal obliterations, exercises for leg short muscles were preferred.

Other therapeutically factors that may ameliorate the peripheral blood flow come from the physical therapy specialty. Damp heat easily enters the organism, less activating the skin receptors, having no vasoconstriction paradoxal effects. Also, the galvanic flow triggers the activation of the vascularization by hyperemia, arising after a short vasoconstriction period. The vascular reaction is maintained for a while after the procedure has been performed, being more intense at the negative pole. Vasodilatation does not manifest only at surface, in the skin vessels, but also in depth, in the muscular vessels. Measurements showed an increase up to 500% in the skin blood flow and up to 300% in the muscular blood flow at galvanic flow, these values persisting up to 15-30 minutes after the application was ended [3]. The hypermiatic effect of the galvanic flow leads to the improvement of tissular nutrition, the amelioration of local catabolites release and the facilitation of local exudate or oedema resorbtion. As far as we know, there are no other studies analyzing the effect of galvanic baths in the peripheral arteriopathy patients, but the results we obtained show that in this way there may be obtained a better amelioration of walking parameters.

The TDC and TDD values we obtained for patients at study inclusion are close to those previously obtained by other authors. From a study performed by Tsai JC [4] there arises the fact that a 12 week training in the peripheral arteriopathy patients increases the time to claudication pain onset by 88% and the maximal walking time by 70%. The meta-analysis of 21 studies evaluating the benefits of physical training in the claudication patients showed that, in the subjects following an exercise program, the mean distance to the onset of pain increased by 179%, while the distance to the maximal claudication pain increased by 122%, compared to the distances in the control group ($p < 0.001$) [5].

Although the medical literature stipulates that the prevalence of peripheral arterial disease is similar in women and men [6], in our study most of the patients were men over 67 years old (men-women rate approx. 4:1). A plausible explanation may be that given by McDermott [7]: men suffering from symptomatic peripheral

arteriopathy are more likely to obtain medical attention than women are.

Even though significant, the amelioration of walking parameters through physical treatment is lower in peripheral arteriopathy smokers than in non-smokers. As seen by Gardner [8] this fact exposes the smokers to a higher risk of disability.

The measurement protocol of the TDD parameter, as important as it is, is only a chronophagous one and also quite difficult to tolerate by patients, who have to make effort on the treadmill to maximum pain onset. For this reason, we tried to see if there are any significant differences between the clinical relevance of TDD and TDC, the latter being shorter and more easily to tolerate by the patient. By using the bivariate correlation, we established that there is a strong positive correlation between the two parameters.

Indeed, at a Pearson correlation index value of 0.857 there may be stated that TDD has almost the same clinical signification as TDC and, at least for the studied groups, there are enlisted relatively many patients where a TDC measurement is not required, as we can obtain enough information by measuring the first parameter, namely TDC.

Due to a very strong Pearson correlation, there may be proposed the use of a remission equation that allows estimating the time to maximum pain onset.

$$TDD = 1.49 \times TDC + 3.1$$

Starting from the obtained results, we may state that a physical exercise program of 12-24 weeks shows its efficiency in ameliorating the walking parameters in the patients with claudication, supporting the recommendations found in the guidebooks concerning this affection, as well [9, 10, 11].

Conclusions

World widely, in the last years there have been made prospects for the best physical, drug, revascularization treatment methods in order to lower or impede the CPOA progress. The present treatment, as well as the selection criteria of patients, is clearly standardized by treatment guides made up based on the results of various clinical trials. Currently, the indication for physical exercises in the CPOA patients resumes to walking, without having the patients oriented to any parameters of intensity, duration, frequency or being called back for check-up. This fact leads to a very low compliance of this type of treatment.

The various kinetic-physical treatments represent the object of recent or older research due to the great advantages they may offer: increased efficiency, low risks compared to the revascularization methods, high addressability, diminished costs. By identifying the optimum exercise program for functional capacity amelioration, the obtained results will have substantial clinical implications on the public healthcare for millions of CPOA patients, as well.

Abbreviations:

CPOA - Chronic peripheral obstructive arteriopathies

ABI - Ankle-brachial index

NYHA - New York Heart Association

BP - Blood pressure

TDC - Time to pain onset

TDD - Maximum walking time

MET - Metabolic Equivalent of Task

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*Corresponding Author: Simona Pătru, Str. Imparatul Traian nr. 138, Craiova, Romania;
email: s_patru@yahoo.com*