

**Investigation of the Influence of the Infrasound on the tissue
microcirculation in Patients with Arteriosclerosis of lower Extremities**

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Summary

A number of biological effects of the infrasound were recently published in the medical literature. An analgesic and procirculatory effect could be resulted in case of direct exposition to an infrasound of given intensity and frequency in certain patients. These observations, in part, may be in connection with the possible therapeutic efficacy of the infrasound therapy in arteriosclerosis. In our present work, the microcirculatory effect of the infrasound therapy synchronized with the heart cycles as been studied on the impaired circulatory conditions of lower limbs in patients with Fontaine II. stage obliterative arteriopathy in a placebo controlled, double blind trial. The efficiency of the treatment was monitored by measuring the pain-free walking distance and the changes of the Doppler-index and by a lower limb radioisotope perfusion scanning performed before and after the treatment. We could reliably perform the study in 73 patients. After 8 weeks of the therapy the pain-free walking, distance increased significantly in both the treated and the placebo groups but the increase proved to be significantly higher in the treated group in comparison with the placebo one ($p < 0.05$). The values of the Doppler-index increased also significantly in both of the investigated groups but a significantly higher increase could be found in the treated group ($p < 0.05$). The changes of the perfusion index did not show a significant difference in the two groups ($p > 0.05$). The improvement of the finger/palm ratio was significantly higher in the treated group ($p < 0.05$). According to our results the local infrasound therapy can effectively be used in reducing of the increasing complaints of patients suffering from lower limb arteriosclerosis, as supportive treatment being suitable to complete our therapeutic armature in case of adequate indication.

Keywords: infrasound, lower limb atherosclerosis, Doppler-index, perfusion scan.

Introduction

Obliterative arteriosclerosis is a widespread disease: in our country the mortality rate is 700 deaths/100 000 inhabitants per year as an outcome of the diseases of the vascular system. In patients with obliterative arterial disease of the distal extremities the operative resolution may result in a significant improvement in their state of health leading to the increase of walking distance and diminishing of the rest pain and to the healing of the gangrenous process. However, this successful outcome may be accomplished merely in 3 to 22% in the literature and in 2000 in our country since in a significant number of the patients being in an early or late stage of the disease cannot be underwent to the operation because of the highly damaged blood vessels or of poor health state (2). Applying of the different conservative treatments (medicament, physiotherapy, balneo-physiotherapy, hemodilution etc.) may be the management of choice in these patients reaching just the 70 to 800 of the total cases. The advantages of the operative or other invasive interventions in comparison those with the conservative treatment are ambiguous as for the chronic arterial disease of the lower limbs in Fontaine II. stage (1, 7, 9, 10, 14, 15, 16, 19, 23). These data make easily clear the interest in the different conservative therapeutic measures namely in the different medicinal treatments, hemodilution, effervescent bath etc.

By reason of different studies the infrasounds are capable to exercise an influence upon the rate of anaphylactoid reaction and the activity and regenerative ability of the liver cell membrane, and on the permeability of the erythrocyte membrane. In addition to, they may cause an alteration of the vascular membrane of the eye resulting in a reduction of the progression of the myopia in childhood and can diminish the erectile dysfunction of atherosclerotic origin (4, 6, 8, 11, 12, 18, 20, 21, 24, 26, 28) . A non-invasive therapeutic method was developed in the SOs in the Netherlands by making use the international scientific results related to the infrasound.

Applying locally an infrasound of well-defined frequency and wavelength in a certain phase of the heart function a benefit reduction in the progression of the peripheral arterial stenosis could be observed. The adoption of this treatment was already authorized in a number of countries in Europe (the Netherlands, Germany) and it is in progress in the US as well, as an alternative physiotherapy.

According to preliminary, uncontrolled studies in Hungary the infrasound treatment produces a benefit effect on the complaints and walking ability of patients suffering from the stenotizing arterial disease of the lower limbs. The purpose of our present study was to investigate by objective methods and under well-controlled circumstances and in contrast with a placebo group the suspected benefit influence of the infrasound wave therapy synchronized with the heart frequency on the circulation of the lower limb arteries of patients with arterial diseases being in Fontaine ha, Jib stages.

Patients and Methods

Patients suffering from an arterial disease of lower limbs of Fontaine ha and ilb stages were included into the study groups. In patients with Fontain II the walking distance was above 300 meters and with Fontaine Lib stage was under one. The age and sex of patients were not taken into consideration at their listing into groups.

The patients with lower limb arterial diseases of Fontain II stage complicated by an acute arterial occlusion requiring an urgent surgical intervention have been excluded. The presence of rest pain and ulcus cruris and/or malignant disease, or an active inflammatory process in the limb or in any other organs, and of unsatisfactory medical or neurological status and also the necessity of a vascular surgery intervention all have formed the criteria of the exclusion.

The study was begun in 80 patients. In the course of the study 3 patients of them because of personal reasons, 2 patients of respiratory infection, 1 patient of obstructive ictenis and 1 patient of a leg fracture were not be able to continue the investigation.

The study could be carried out in 73 patients and 45 was the men and 28 the women of them. The mean age was 59 years \pm 24 SD (39-65) years. The investigation and treatment were based on the voluntary principle proved by the written consent of patients and were made after a sufficient information of them, and with the permission of the Ethical Committee of the University.

The study was randomized, placebo controlled and double blind. The course of the therapy of the control group was the same in every respect as those in the group with the active treatment. A computer programmed guaranteed the accidental randomization of the patients. In the time of the study we have solely treated the patients of placebo and active groups with the „SONOMAT 4000” apparatus used. The patients included have got aserial number and had also an identifying by their monogram.

At the beginning of the actual treatment the serial number of the patients was given by the assistant to the

computer and the listing of the patients into a placebo or actively treated group was made automatically on

the bases of the computer programmed. Consequently, the classification of the patients remained

obscure for both the physician and the patients and for the assistant performing otherwise the therapeutic

procedure by the "Sonomat 4000". The infrasound applied in the treatment had 20 to 60 dB volumes and

so may be audible in certain cases. To eliminate the possibility of identifying the active or placebo

characters of the infrasound treatment by means of the audible sound an another permanent sound was

produced by a loudspeaker placed at the treating head of the "Sonomat 400".

The ~pulsating infrasound" treatment was made by a "Sonomat 400" (Innomed Ltd.Co., Hungary)

(Fig. 1). The apparatus contains a treating head supplied with a signal device of an x s a l e generator being in contact with the central unit and the latter, by means of an adapter, with two parameter-detectors (the heart rate and the skin temperature). One of the parameters for detecting is the heart rate of patients before the treatment, and another one are the data given before, during and after the treatment, supplied by skin thermometers placed on the skin surface surrounded the treated skin area.

The central unit of the apparatus consists of four parts, namely an impulse generator, a joining adapter, a signal processing part and a timer. The *impulse generator* can be adjusted from 1 to 20 kHz range of frequency. The *joining adapter* serves for the suitable input impedance, adjusts the inner voltage necessary to the central unit and it has a life-saving role on the basis of the relevant directions and standards since the sensors are in direct contact with the patients. The *signal processor* emits control signs for the impulse generator by correlating the signs coming from the impulse generator and the own internal functional relations. The *timing piece* consists of a starter switch and an adjusting unit and it is connected with the impulse generator and it determines the treating time, that is the time during which the produced and

Result

Walking distance

Before beginning the treatment the mean walking distance was 294 ± 470 (S.D.) meter (15-1240) in the subsequently placebo group and 261 ± 574 (S.D.) meter (12-1477) in the treated group thus no significant difference could be found in the starting values of the two groups. The values of the dysbasic distance after the treatment proved to be 358 ± 641 (S.D.) meter (281-1172) in the placebo group and 396 ± 944 (S.D.) meter (249-1507) in the really treated group.

Thus a considerable increase in the claudication distances could be observed in both of the placebo and the actively treated groups but the increase was mathematically significant in the

really treated group ($p < 0,05$) (Fig. 3)

Doppler—index

The Doppler-indexes of patients before and after the treatment measured on the arteria dorsalis pedis and tibialis posterior of both lower limbs are documented in the Table 1. As for the Doppler-index measured on the arteria dorsalis pedis the next conclusion can be made:

- before the treatment no significant differences of the measured values between the two (placebo and treated) groups could be detected.
- the Doppler-index significantly increased in both of groups ($p < 0,05$).
- the increase of the measured values proved to be significantly higher in the treated group (20.000 average increase) in comparison with the placebo group (8.9% average increase).

In the respect of changes of the Doppler-indexes measured above the arteria tibialis posterior we could establish the next:

- there was no significant difference between the two (placebo and treated) groups before the treatment.
- the Doppler-index significantly elevated in both of groups ($p < 0,05$).
- the increase of the measured values was significantly ($p < 0,05$) higher in the treated group (15.10o increase) than in the placebo one (10.40o increase) (Fig. 4).

Sural tissue perfusion index

The sural tissue perfusion index did not differ significantly in the two groups before the treatment. It was $940 \pm 17\%$ (S.D.) in the treated group and 890 ± 160 (S.D.) in the placebo one. After the treatment there was also not a significant alteration of the perfusion index in the two groups. 940 ± 150 (S.D.) was calculated in the treated group and $890 \pm 16\%$ (S.D.) in the untreated one being practically unchanged after the therapy.

The toe/sole rate

Before the treatment the toe/sole ratio showed a significantly lower level in the treated group (0.45 ± 0.13) comparing it with the untreated one (0.54 ± 0.19). After the treatment the change of the toe/sole ratio was significantly higher (0.48 ± 0.15 , 6.6% increase, $p < 0.05$) in contrast with the placebo group (0.50 ± 0.16 , 8% increase) where a certain worsening could be found at the end of the treatment. (Fig. 5.)

Discussion

According to our results the complaints of patients triggered by a moderately serious arterial stenosis of the lower limb can be mitigated by the infrasound therapy applying it by the method mentioned in detail above. Analyzing our data is conspicuous the considerable improvement in the peripheral circulatory parameters (dysbasic distance, Doppler-index) in the patients with placebo group. This result can be explained with the placebo effect of the therapy. However, the sural tissue perfusion index showed not a significant alteration in the two groups of patients. It is just possible, that the infrasound therapy may take an effect not only on the microcirculation of the tissue as it can be documented by the increase of the Doppler-index. Otherwise, the isotopic method can reflect the microcirculation of the tissue mainly in the case of a given larger arterial perfusion. Further investigations made on larger number of patients will be necessary for clearing this problem. The efficiency of the infrasound treatment seems to be proved by the significantly *larger improvement* of the parameters showing the increase of the microcirculation of limbs in the really treated group of the patients. Moreover, the toe/sole ratio characterizing mostly the distal microcirculation showed a moderate worsening in the untreated group during some months of the study. The obliterative arterial disease is an endemic disease and the mortality caused by it is not negligible in our country as well. The operative resolution can only be performed in a small part of the patients suffering from an obliterative arterial disease of the lower limbs because of either anatomic or anaesthesiologic or internal medical considerations (5, 22, 27). One or more of the conservative procedures have to be the treatment of choice in these inoperable or not operated patients and the number of these patients is approaching the three-quarters of the total case with such disease.

The direct infrasound treatment used by us in this study can be successfully applied for the treatment of the obliterative arterial disease of lower limbs with the purpose of reducing the complaints of patients as it was proved by objective methods in our study. This therapy serves as a supplementary procedure for the internal medical treatment and as an alternative therapy on the basis of an adequate indication. According to our data and knowledge the infrasound treatment has no contra-indication and can be used widely in patients and besides is noninvasive and unpainful. In addition to, this therapy does not require hospitalization but the necessity of a hospital background for performing it is yet to be decided.

In summary, our work may be considered the first study of scholarly character in the correct judgement of the usefulness of the infrasound treatment in patients with obliterative arterial disease of lower limbs. But our results have to be supported by further studies made on a larger number of patients. On the other hand, the influences of the infrasound on the tissue microcirculation have to be specified precisely and the improvement of the health state in infrasound treated patients has also to be explained exactly by the basic researches.

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