

# EFFECTS OF ELECTROACUPUNCTURE IN RECENTLY OPERATED PERIPHERAL ARTERIAL DISEASE PATIENTS, EXPRESSED BY ANKLE-BRACHIAL INDEX. PILOT STUDY.

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## REZUMAT

**Obiectivul** studiului a fost de a studia în ce măsură se modifică indexul gleznă-braț (IGB) la pacienții cu boală arterială periferică cronică obstructivă, în prima săptămână post operator, printr-un tratament de electro-acupunctură (EA). S-a pornit de la premiza că EA ar putea avea efecte similare cu cele obținute de anestezia loco-regională: diminuarea durerii și, în speță, prelungirea efectelor benefice ale simpatectomiei asupra circulației periferice. **Material și metodă:** În studiu au fost cuprinși 40 de pacienți cu boală vasculară periferică (37 bărbați și 3 femei), operați consecutiv în Institutul de Boli Cardiovasculare Timișoara, care au acceptat introducerea în studiu. În lot au fost cuprinși 8 pacienți cu bypass aorto-bi-femural, doi cu ilio-femural și 30 de pacienți cu bypass femuro-popliteal. Tratamentul de acupunctură a constituit în electrostimularea unor puncte de acupunctură (P9, Pc6, St36 și Sp9), considerate a avea efecte hemodinamice în medicina tradițională chineză. Tensiunile arteriale au fost măsurate și IGB calculate înainte de EA, la 5 minute și după 30 minute de la procedură. Creșterea IGB-ului a fost variabilă, fiind cuprinsă între 0,03 și 0,05 față de valorile inițiale. **Rezultate:** IGB crește la 5 min. post EA ( $p < 0,05$ ) și se menține parțial și după 30 min. în lotul cu bypass femuro-popliteal la piciorul neoperat ( $p < 0,05$ ). **Concluzii:** EA are efecte benefice și asupra perfuziei vasculare postoperator, la pacienții vasculari periferici, revascularizați chirurgical prin bypass-vascular

**Cuvinte cheie:** electroacupunctură, boală vasculară periferică, indice gleznă-braț

## ABSTRACT

**Objective:** The aim of the study was to observe the changes of the ankle-brachial index (ABI) in patients with peripheral artery disease (PAD), in the first week post-operatively, after having been submitted to electroacupuncture (EA). We started from the premises that EA could have similar effects to regional anesthesia, diminishing post-operative pain and improving peripheral circulation. **Material and methods:** 40 patients with PAD (37 male and 3 female) were enrolled in the study. They were consecutively operated at The Institute of Cardiovascular Diseases, Timisoara and accepted to participate to this study. The lot includes 8 patients with aorto-femoral by-pass, 2 patients with ilio-femoral by-pass, and 30 patients with femoro-popliteal by-pass. EA treatment consisted in electrical stimulation of acupuncture points (P9, Pc6, St36, and Sp9) considered in the Traditional Chinese Medicine (TCM) to influence the blood circulation in the human body. The blood pressure (BP) was measured and ABI calculated before EA and after the procedure at 5 and 30 minutes (min) respectively. **Results:** ABI increased at 5 min post EA ( $p > 0.05$ ), and this increase was partially maintained after 30 min in the lot of the femoro-popliteal by-pass surgery patients at the non operated limb ( $p > 0.05$ ). The degree of the ABI increase varied between 0.03 and 0.05 from baseline. **Conclusion:** EA has benefic effects on post-operative vascular perfusion, expressed by ABI, in the PAD patients who were subjects to revascularization surgery.

**Key Words:** electroacupuncture, peripheral vascular disease, ankle brachial index

## INTRODUCTION

The lower extremity peripheral arterial disease (PAD) is a prevalent manifestation of atherosclerosis, and it is associated with significant risk of mortality,

morbidity and reduction of functional abilities. Intermittent claudication is the most classic symptom of PAD. The prevalence of intermittent claudication is estimated between 1-5% in males and 1-2% in females, and it is increasing with age. The ankle brachial index (ABI) is a sensitive tool for PAD.<sup>1-4</sup> The management of PAD is complex and facilitates the penetration of other treatment methods like palliative and alternative medicine, which are increasing in popularity and usage. For example there are studies that show positive results in claudication with ginkgo-biloba, and also promising results were found for acupuncture.<sup>5-8</sup>

According to TCM, acupuncture aims to reset the harmony in the Yin/Yang balance, and into energy ("Qi") and blood flow through the body by

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stimulating so called “acupuncture points” (there are 365 points organized in 14 canals or meridians of acupuncture). It is known that acupuncture is successfully used in the treatment of some chronic pain conditions, including post operative pain and nausea. EA uses electrical energy to stimulate the acupuncture needles inserted into the skin.

In this study EA is used and the effects of electrostimulation upon certain points of acupuncture are observed. The points chosen are considered, according to TCM, to be important in the harmonious circulation of the blood and Qi through vessels. (Table 1) The effects of EA were determined and quantified by measuring the BP and ABI to the operated PAD patients, in the first week after surgery.

## MATERIALS AND METHODS

In this pilot study were included 40 patients with PAD, Fontaine class IIB, III and IV, who underwent by-pass surgery for peripheral revascularization: 8 operations of aorto-bi-femoral by-pass, 2 operations of ilio-femoral by-pass, and 30 operations of femuro-popliteal by-pass. The selection criteria was the consecutive enrolment of 40 patients with vascular by-pass surgery at Timisoara Institute of Cardiovascular Medicine, during the period of Oct. 2005- Nov. 2007, who accepted to be enrolled in the study. (Table 2)

Our institution’s ethical committee approved this study and all patients have signed the informed consent.

Exclusion criteria: diabetes mellitus (DM) with glycemia > 150mg/dl during hospital stay or DM type I or DM requiring insulin; chronic renal failure with creatinine > 2mg/dl; severe COPD requiring steroid treatment and hospital admittance in the past; hepatic insufficiency: elevated liver function tests > 2 normal; coagulopathies; vasculites and autoimmune diseases; acute arterial occlusions (traumatic) and arterio-venose malformations. In total were enrolled 42 patients, but one was excluded because his BP values could not be measured, and the second patient because of independent (administrative) reasons concerning the study protocol, the test could not be completed.

In our clinic, vascular surgery for PAD patients is done routinely by using regional anesthesia, mostly epidural catheters. The operated patients, in the second or the third post-operative day, at minimum of 12 hours after removal of epidural catheter, received an EA procedure. EA consisted in electrostimulation of the following acupuncture points: Pc6, P9, St36 and Sp6; also on the operated lower limb we used Sp4, for the placement of the neutral electrode of the neuro-stimulator apparatus. The needle used was “Natural, 0.30 x 40 mm”. The needles were inserted through the skin between 5-10 mm deep looking to obtain “De Qi” sensation at the moment of insertion. After the needles were inserted in the acupoints, as mentioned above, each needle was stimulated with the neurostimulating device Braun Stimuplex HNS 11 in the following order: first the least painful lower limb at St36 and then Sp6, then in the same sequence the

**Table 1.** Acupuncture points (TCM).

Acupoint	Code	Traditional application	Therapeutic indications
Taiyaun	P 9	Influential point for vessels	Disorders of vessels and lungs
Neiguan	Pc 6	Regulates the flow of the heart Qi and blood	Analgesic, heart problems, nausea
Zusanli	St 36	Tonify the blood/Qi and the Yang	Analgesic, regulates the gastrointestinal tract, metabolic/ endocrine homeostasis
Sanyinjiao	Sp 6	Tonifies Qi, kidney yin and blood	Urogenital disorders, pelvic analgesia, hypotension, edema,

**Table 2.** Demographic data.

Age (mean) years:		Gender		PAD - Fontaine			Other medical conditions				
M	F	M	F	IIB	III	IV	HBP	CAD	CVA	COPD	DM
60.83	70	37	3	18	19	3	23	8	3	5	6
std 7.86	std 7.9										

M = male, F = female; HBP = high blood pressure, CAD = coronary artery disease, CVA = cerebral vascular accidents, COPD = chronic obstructive pulmonary disease, DM = diabetes mellitus.

painful lower limb; next we stimulated P9 and then Pc6 at the right arm and then to the left.

EA was performed with the Braun 11 neurostimplex set as: frequency 2 Hz, time 0.03 ms, with variable amplitude between 0 and 5 Am determined for each patient by his level of comfort at each point of acupuncture.

We studied a potential hemodynamic benefit of EA by observing at each patient the modification of ABI in relation with EA. The BP was measured before and after EA, at 5 and 30 min. The ABI is the ratio of the systolic BP in the lower and the upper extremities. The BP is more difficult to be measured in the case of calcified vessels (like in DM) when it is recommended to determined at the first or second toe, or at any distal level where is measurable. An ABI of 1.0 and 1.29 is considered to be normal.<sup>9</sup> Monitor Spacelab Medical Ultraview™ 1030 was used to measure BP by sfigmomanometric method.

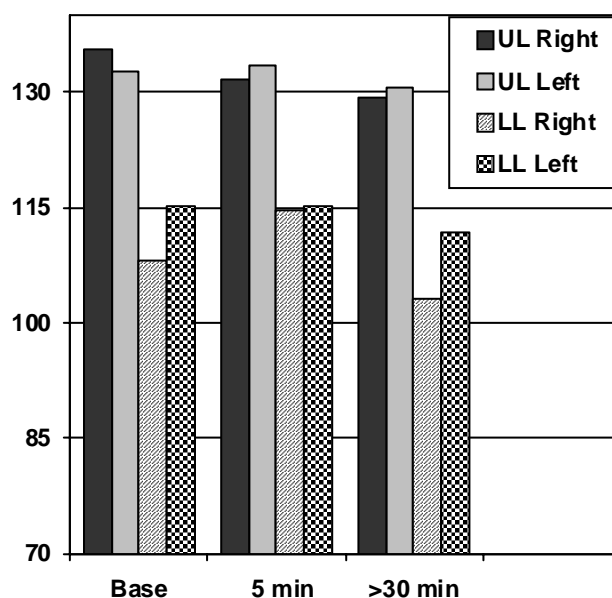
## RESULTS

The values of the BP measured in the group of 40 patients with vascular by-pass surgery and treated with EA, are presented in Table 3. In this table there are shown the systolic arterial pressures - the mean value and the standard deviation at each limb, for the entire group of 40 patients, at three moments in time: base line and after 5 and 30 min post EA treatment.

**Table 3.** The systolic BP measured at 40 PAD operated patients and postoperative EA treatment.

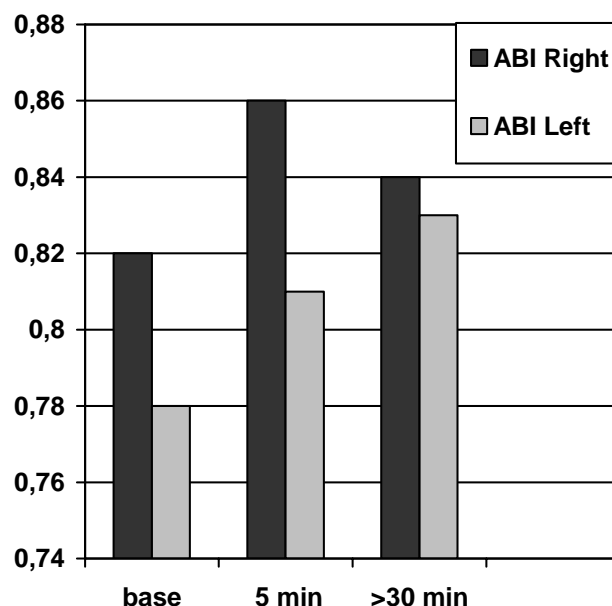
Time	Data	Base	5 min	30 min
<b>Upper Limb Right</b>	BP	134.58	134.1	130.55
	stdev	22.67	23.28	18.22
<b>Upper Limb Left</b>	BP	135.42	135.58	133
	stdev	22.41	22.18	20.02
<b>Lower Limb Right</b>	BP	116.35	118.58	112.28
	stdev	33.05	32.4	26.43
<b>Lower Limb Left</b>	BP	111.05	112.1	108.71
	stdev	29.04	31.2	23.8

As it is shown in Figure 1, if the BP values at the base line are compared with those measured at 5 and 30 min, a discrete decrease of the BP values at all limbs can be observed; at half hour measured BPs are the lowest, but these changes are not significant. A larger variability of the BP can be noticed at the lower limbs.



**Figure 1.** Systolic BP measured in 40 operated PAD patients and with EA treatment.

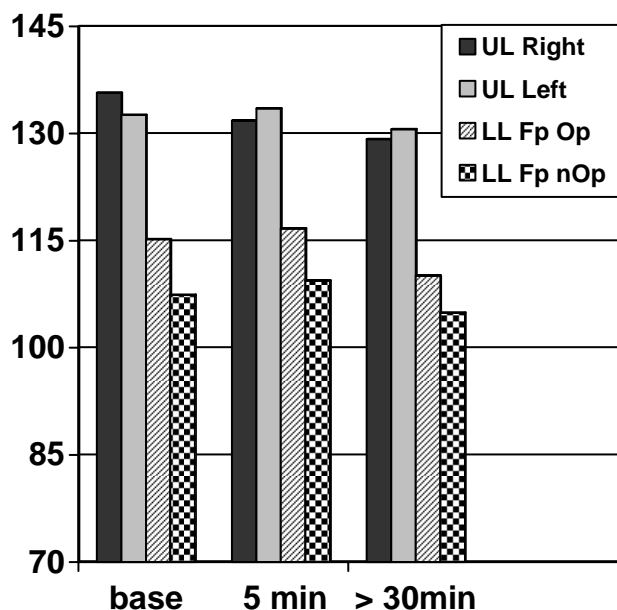
If we analyze the pressure values by the means of ABI, we can see that ABI is increased at 5 min for both lower limbs ( $p < 0.05$ ) and that at 30 min this significant increase is maintained at the left leg. (Fig. 2) This raised the question if the surgery influenced somehow the outcome of the EA treatment, reflected in ABI changes. In 10 cases the surgery was performed by using synthetic grafts.



**Figure 2.** ABI values in 40 PAD operated patients with EA treatment.

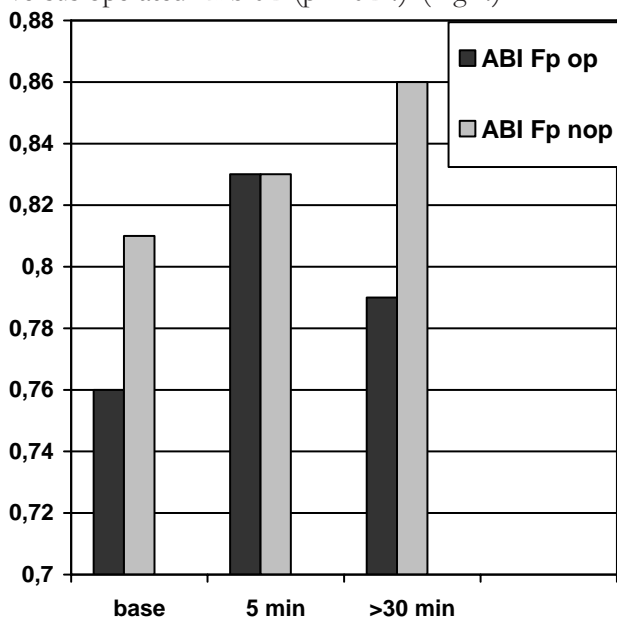
A lot of 30 patients operated with femuro-popliteal bypass was selected from the larger group of 40 PAD patients by excluding the aorto-bifemoral surgery (eight patients) and ilio-femoral surgery (two patients) where synthetic material prosthesis (Dacron), were used.

The following graphic of the 30 patients with femuro-popliteal bypass shows that the BP of the four limbs is not that different than the BP values of the 40 PAD group. (Fig. 3) This lot of patients included 16 patients who had surgery on the left lower limb and 14 on the right side.



**Figure 3.** BP measured at 30 femoro-politeal by-pass patients with EA treatment.

The ABI data was grouped and compared differently, the ABI values of the operated limb versus the ABI of non-operated limb. In this case the ABI increase was 0.05 at 5 min post EA ( $p < 0.5$ ) but it behaved differently at 30 min post EA: the increase of ABI is greater in the non-operated leg 0.4 ( $p < 0.05$ ) versus operated limb 0.2 ( $p < 0.24$ ). (Fig. 4)



**Figure 4.** ABI values in 30 femoro-politeal by-pass patients and EA treatment.

## DISCUSSION

The lower extremity peripheral arterial disease is associated with significant risk of mortality, morbidity, reduction of walking abilities and quality of life. Alternative medicine and acupuncture can be complementary to classical conservatory medical therapy and might improve the quality of life of PAD patients. Since 1970, when the interest of the western medicine in acupuncture began, more than 500 controlled, randomized trials and many meta-analyses evaluated the clinical efficacy of acupuncture. There is a favorable consensus that acupuncture and EA have a positive effect in pain syndromes (including post-operative pain), nausea and vomiting (post-operative, post-chemotherapy and pregnancy), some allergic respiratory disease.<sup>10-12</sup>

Acupuncture does not raise serious concerns regarding the adverse events. A prospective British survey of 32,000 consultations of acupuncturists (61% of them were doctors) found that serious events (e.g. sensory deficit persisting over a few weeks) were 1.2/10,000, while minor, transitory incidents were 14/10,000.<sup>13</sup> In our study the patients were receiving Clexane (low molecular weight heparin) two doses of 0.6 ml per day, and we did not have any incidents.

Electrostimulation has been used at different levels of the nervous system, mainly spinal, peripheral nerves, and points of TCM acupuncture. The most favorable results have been observed with spinal cord stimulators in patients with peripheral vascular disease, complex regional pain syndrome, and peripheral neuropathy (e.g., diabetic or causalgic origin). The proposed mechanism of analgesia is based on Melzack and Wall's Gate Control Theory (stimulation of the large-diameter A $\beta$  afferent fibers in the dorsal column of the spinal cord, are preventing the transmission of pain impulses via small-diameter C fibers). Alternative mechanisms that have been proposed for electro analgesia include activation of descending pain modulation pathways, inhibition of sympathetic efferents, antidromic conduction, alterations in the levels of endogenous analgesic substances, etc.<sup>14</sup> The electrical stimulation of the nervous system by the EA will be discussed in this section.

In our study we started from the hypothesis that by electrostimulation of acupuncture points through a neuromodulation phenomenon like in the gate theory, we will be able to induce sympathectomy and vasodilatation and also to increase the threshold for pain in the same area. It is known that somato-sensitive stimulation by EA induces vascular hemodynamic

responses. The arteries (large and medium size) have two types of innervations: 1) sensitive- afferent nerves and 2) autonomic- of sympathetic type. The nervous fibers, sensitive and sympathetic penetrate the artery adventice and give the adventiceal, medial and muscular plexus. The axonal reflex induced by EA vasodilates the arterioles, it is possible to be involved a release of nitric oxide (NO) from terminal axon.<sup>15,16</sup>

The interconnection of peripheral nervous system somato-sensitive and vegetative plexuses is probably the turning plate to electrostimulation interventions seen in neuropathic pain, tissular perfusion and trophic changes.

The effects of acupuncture on vascular hemodynamics at PAD patients were studied by selecting those acupoints that are considered by TCM to be active upon the circulatory system of blood and “Qi”. We selected a group of four points (P9, Pc6, St36, and Sp6). Regarding these points there is a consensus of their effects between the acupuncturists.<sup>11,17,18</sup> The objective of our study was to test a therapeutic protocol which is able to match the acupuncture concepts of TCM and a medical disease - PAD, as defined by western medicine. The result is a “personalized” and a standardized therapeutic plan (we used each time the four acupuncture points bilaterally). We did not intend to study the medical effects of stimulation of any particular acupoint or group of acupoints. We intended to establish a therapeutic protocol which addresses the operated vascular patient, that have the associated diseases found in many other PAD patients. The chosen acupoints are active in cardiovascular system and blood circulation. At the same time the points are useful in the management of surgical patients because of their effects analgesic, anti-inflammatory, reducing edema and digestive dysfunctions. The same points are believed to be active in the associated pathology of these patients, like pulmonary, cardiac or renal diseases, metabolic dysfunctions as diabetes.

The selected acupoints have a common feature from the western medicine point of view. All of them are in the close proximity with peripheral nerves, e.g., St36 close with peronier nerve, Sp6 with saphenous nerve, P9 with radial nerve, and Pc6 close with median nerve. It is possible that this proximity is an important factor in their physiologic effect. Wei Zhou et al, in a study on anesthetized rats (Sprague Dawley), observed that EA (2 Hz, 0.3-0.5 mA) at Pc5 - Pc6 and St36, St37 for 30 min. decrease the cardiovascular pressor reflex with 30-40%; similar values were obtained with manual acupuncture.<sup>19</sup> Another study shows that EA at Pc6, a feline model, situated near the median

nerve, diminished the regional myocardial ischemia by increasing cardiac oxygen demand by sympathetic mechanisms.<sup>20</sup> Also, EA at Zusanli resets the arterial baroreflex neural arc toward lower sympathetic nerve activity, and lowering blood pressure.<sup>21</sup> It was shown that EA has an inhibitory effect on the pressor response in exercise stress and interferes with fatigue and non-fatigue states.<sup>22,23</sup> We observed the changes in BP of all four limbs in response to EA, and when we determined the ABI we observed increased values. The ABI, because of its high specificity and sensitivity compared with angiography, was proposed by Rutherford to be used in monitoring the clinical status of these patients, operated or not.<sup>24</sup> A change of 0.1 of the ABI is considered significant.

The physiopathology of the PAD disease is determined by the blood flow deficit versus the energetic and metabolic needs of the perfused tissue. The adaptative mechanism at significative stenosis is mainly the dilatation of the resistance vessels from that territory and secondly the development of the collateral circulation (an adaptive and slow process induced by physical exercise). The resistance vessels of the runoff bed are composed especially from terminal arterioles and precapillary sphincters and are controlled by vegetative nervous system, circulating catecholamines, local metabolic products, nitric oxide, and myogenic influences. In case of multiple stenosis and ischemic rest pain, the blood flow and is diminished and after exercise the peak flow is lower and delayed. The reactive hyperemia is prolonged subsiding to normal levels in a logarithmic fashion over 4 to 30 min.<sup>15</sup> The blood pressure has the same pattern, it is decreased under resting conditions, it falls at exercise and begins to recover after peak flows begun to decline, and the BP recovery is prolonged 10 to 30 min.

Our results as shown by BP values are similar with the BP changes observed in the reactive hyperemia or in the regional anesthesia – the BP declines after EA. The decrease in BP can be explained by some mechanisms like vasodilatation caused by sympathetic block induced by nerve stimulation with EA, and patient relaxation by reducing the pain obtained by EA (release of endorphins and decline in the level of circulating catecholamine).<sup>11,14,25</sup> The decrease in BP is maximum at 5 min measurement and it recovers towards the 30 min BP measurement. We compared the mean values of BP, pre and post EA, at the four limbs, and we found that the changes in BP were not significant. But when we compared the BP values by looking at the ABI we found a significant increase of

ABI of 0.05 ( $p < 0.02$ ) at 5 min and they are partially maintained at 30 min, after one EA treatment. Noteworthy, the reactive hyperemia is usually subsided in half an hour. If we take in consideration that EA in general is decreasing the BP but in particular at PAD patients we observe an increase of ABI, then this it might raise the question that the stimulation of these acupuncture points (TCM), may offer a possibility to optimize the blood flow towards the deficitary areas of pour circulation, as claimed by TCM. Other benefits of EA at PAD patients beside decreasing the pain, are, on the same token, possible positive effects on the associated co morbidities, e.g. Zengyoung Li, et al, by stimulating Neiguan (P6) and (Li4), they observed that acupuncture increased vagal activity, reduced sympathetic activity and helped to recover from stress and fatigue.<sup>22</sup>

## **CONCLUSION**

EA interferes with tissular perfusion at PAD patients, at certain points of acupuncture (P9, Pc6, Sp6 and St36), considered by TCM to be active in blood flow (and “Qi”) homeostasis in the human body. This modulation of the arterial perfusion pressure can be demonstrated by measuring the ABI. EA treatment temporary improves ABI.

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