**EFFECT OF THE POSTURAL REPROGRAMMING INSOLES ON POSTURAL MISALIGNMENT IN HYPERTENSIVE INDIVIDUALS: an Exploratory Randomized Clinical Trial.**

Ana Lúcia Barbosa Góesa, Beatriz Guedes Ventura Araújob, Davi Mota de Jesusb, Felipe Araújo Campos de Oliveirab, Tiago Bastos Silvac, Vinícius Cardoso Lagoc, Vitor Pontes Soaresc, Luis Agnaldo Souzad, Ana Marice Teixeira Ladeiae

aMsc in Medicine and Human Health, Escola Bahiana de Medicina e Saúde Pública, Salvador-Ba, Brasil

bPhysical Therapy student, Escola Bahiana de Medicina e Saúde Pública, Salvador-Ba, Brasil

cPhysical Therapist, Escola Bahiana de Medicina e Saúde Pública, Salvador-Ba, Brasil

dMsc in Medicine, Escola Bahiana de Medicina e Saúde Pública, Salvador-Ba, Brasil

ePhD in Medicine, Escola Bahiana de Medicina e Saúde Pública, Salvador-Ba, Brasil

Escola Bahiana de Medicina e Saúde Pública, Fundação Bahiana para o Desenvolvimento das Ciências, FBDC, Salvador, Bahia 40.285-001, Brazil. **Insoles and Posture in Hypertensives.**

Contact:

Ana Lucia Barbosa Goes

albgoes@bahiana.edu.br

Telephone number: +55-71-3276-8200

Financial Statement: The authors declare that they have not received financial support of any nature to develop this paper.

Word count: words

**ABSTRACT**

**Introduction:** The excessive activation of the sympathetic nervous system (SNS) is related to blood pressure maintenance (BP). Postural misalignment may prompt muscle sympathetic nerve activity (MSNA) and raise BP. Postural Reprogramming Insole (PRI) may adjust posture and reduce MSNA. **Objective:** To test the hypothesis which supposes that PRI improves posture on hypertensive individuals. **Methods:** RCT (exploratory), registered at the *Clinical Trials* (NCT02401516), with 30 hypertensive individuals, in regular use of antihypertensive medication. All patients underwent ambulatory blood pressure monitoring (ABPM), in-office BP assessment and posture assessment (through a postural assessment software – PAS) at the beginning and at the end of six weeks. Intervention Group (IG) used PRI and Control Group (CG) used placebo, for at least 12 hours daily, that were supervised by a filled diary handed to the researchers. Wilcoxon test was applied to intragroup comparison and Mann-Whitney test to intergroup analysis.Categorical variables were analyzed through Chi-square test. **Results**: The basal values of the studied variables haven’t reported any difference between the groups (p>0,05). On intragroup (p>0,05) and intergroup comparisons, there was no difference on overall posture improvement, after six weeks (p>0,05). For specific postural angles, anterior body displacement revealed moderate positive correlation for SBP (p=0,03), 33% of SBP justified by the anterior displacement. For DBP, the knee angle showed positive moderate correlation (p< 0,01), the ankle angle with moderate negative correlation (p<0,01) with 46% and 55% of DBP, respectively defined by the angles. Conclusion: Even though PRI has not shown any improvement in overall posture, anterior body displacement and the knee and ankle angles would solely explain 33-55% of the highest BP.

Keywords: Insole, Posture, Hypertension.

**INTRODUCTION:**

**Referential**: Systemic Arterial Hypertension (SAH) is one of the main modifiable risk factors of cardiovascular diseases1,2, reaching, in 2011, $46,4 billion in direct and indirect2 costs. In a study held by this group, it was noted a possible altered posture pattern among the hypertensive individuals, namely, anterior trunk shift, posterior shift of the body, decreased³ hip, knee and ankle angles.

Misalignments on posture overload the neuromusculoskeletal4,5 system. Excessive muscular activity might stimulate muscle sympathetic nervous activity (MSNA) that consists in vasoconstricting impulses modulated by the central nervous system (CNS) and peripheral receptors, such as the arterial baroreceptor (AB)6. Studies that associate MSNA with hypertension revealed an increase in MSNA at muscle resting, a systemic increase of sympathetic activity, vascular tonus and peripheral vascular resistance (PVR) 7–9. It is understood that posture is the form achieved by the body at a certain moment in order to resisting the gravity action applied on every corporal segment, keeping the stable positioning of these segments10. Posturology deals with postural misalignments and it is based on the use of insoles for returning the adequate posture to an individual. Postural Reprogramming Insole (RPI) is composed of central relief in the midfoot, constituted by two crossed polarizing processes formed by ferromagnetic macromolecules, which are hot-rolled, generate electric current and cause vibration¹¹. This current permanently stimulates, through autonomous system, the Tonic Postural System (TPS), thus adjusting posture12-17.

Due to the hypothesis which states that postural misalignments might relate to pressure control, it is believed that PRI - once adjusting posture and reducing misalignments – might disclose some effect on AP regulation. Thus, it is important to analyze the possible influence of PRI on postural correction and, secondly, to ascertain if the postural correction may present any effect on BP control in hypertensive individuals.

**Objective:** To assess the effect of PRI on postural misalignment in hypertensive individuals.

**MATERIALS AND METHODS.**

**Study Design:** This is a controlled and randomized clinical trial, a double blind, pilot clinical trial, performed in hypertensive subjects who were accompanied in educational institution bound ambulatory and in a primary health care center, within a 20- month, from February 2016 to October 2017.

**Participants:** individuals who were diagnosed with SAH (SBP≥140mmHg and/or DBP≥90mmHg), at least 2 months ago, both genders, aged between 30-60, body mass index (BMI) up to 34,9 kg/m², in regular medicine use to reach pressure control and who were not using medicine for glycemic control. All participants were oriented to keep a dietary pattern and to use already prescribed medication.

Individuals with some history of sequelae from orthopedic diseases were not included in this study as well as those ones with some history of cerebrovascular diseases and previous cardiovascular occurrences (myocardial stroke, cardiac insufficiency, unstable angina), neurological and mental diseases, pregnancy, Diabetes Mellitus and the participants who did not undergo intervention assessment.

This project was approved by Comitê de Ética em Pesquisa da Bahiana, under CAAE 16952113.5.0000.5544 and registered under *clinical trials* registry number NCT02401516**.**

**Intervention and Randomization:** After identification of eligible participants for the study, participants were divided into two groups by lot: intervention group (IG) and control group (CG). The draw was made with two pieces of brown paper that had the number 0 on one and the number 1 on the other. After evaluations, the participants grabbed one of the pieces from closed hands of the responsible for allocation. Both groups used insoles, and in the IG, the PRI contained the resonator that emits the electromagnetic current, whereas the CG insole contained a relief with dimensions and size similar to the resonator but made of cork. The volunteer participants used the insole for at least 12 hours a day for 6 weeks and recorded their use on a daily diary.

After signing the informed consent form, participants attended the Laboratory of Cardiovascular Research-EBMSP for placement of ABPM, according to the V Brazilian Guideline for the use of ABPM18. ABPM was performed one day before PRI placement to define BP values, considered as baseline, and a new evaluation was performed six weeks after insole use.

An intention-to-treat analysis was performed. All participants in the project were accompanied. In case of loss to follow-up or withdrawal, the assessment data were filled with the initial values, at the end of six weeks, thus admitting that there was no improvement in posture.

**Postural Assessment:** Styrofoam hemispheres of 25mm diameter were glued on the main osseousaccidents with double sided tape (brand 3M), according with the protocol SAPO. Feet were positioned in 30° abduction for alignment and standardization of images. Subjects dressed in shorts and tops (women) and shorts (men) were positioned upon meter paper sheet measuring 1m² in area, near the plumb line attached to the ceiling and marked 10cm long for image calibration purposes in the software.Images were caught by Sony Cybershot digital still camera (DSC-W570, 16,1 Megapixels), supported on a tripod, placed three meters away from the individuals and on half their heights.

The software engenders report in the two side views and the Right Side View was raffled. The angles were described as : 1) Vertical Alignment of the Trunk (VAT), angle formed between the acromion, greater trochanter and vertical line; 2) Vertical Alignment of the Body (VAB), angle formed between the acromion, lateral malleolus and vertical line; 3) Hip Angle (HA), formed between the acromion, greater trochanter and lateral malleolus; 4) Knee Ankle (KA), formed between the major trochanter, lateral joint line of the knee and lateral malleolus and 5) Ankle Angle (AA), formed by the lateral joint line of the knee and the lateral and horizontal lines of the lateral malleolus **(Figure 1).**

**Main Outcome:** Improvement of posture – the following angles were assessed: Vertical Alignment of the Trunk (**VAT**) and Vertical Alignment of the Body (**VAB**), categorized as posterior shift (when angular values are negative) and anterior (positive values); Hip Angle (**HA**), categorized as increased (when angular values are negative, featuring extension) and decreased (positive values, featuring flexion); Knee angle (**KA**), categorized as increased (when angular values are negative, featuring hyperextension or geno recurvatum) and decreased (positive values featuring semiflexion). Ankle angle (**AA**), categorized as increased (angular values over 90°, featuring plantiflexion) and decreased (values under 90°, featuring dorsiflexion).

For analysis of the main outcome, the potential of posture improvement with the use of PRI was considered. Improvement was determined when the angle value decreased or reached zero (perfect alignment). It was considered worse when values increased or were reversed (changing between positive and negative).

**Secondary Outcome:** Posture angles solely examined.

After validation of ABPM exam, the participants answered a questionnaire containing sociodemographic data, life habits and health. Weight and height were evaluated on the manual scale Welmy® (Santa Bárbara D’Oeste, SP). Office BP was measured according to *VI Diretriz Brasileira de Hipertensão*¹, through an arm automatic digital device (model HEM-742 ), of Omron brand (*Omron Healthcare Inc., Lake Forest, IL, USA*). Three measures with a one minute break between them were held and the Arithmetic average was calculated. All assessments were performed by a blind researcher who was trained to achieve this end.

**Sample Calculation:** Considering a study that achieved improvement on posture around 20%, after an intervention with GPR19 it was decided to consider the proportion of postural changes: 60% for control group and 10% for intervention group, significance level of 5%, trial power of 80%, at two-tailed test with a total of 28 subjects, being 14 in each group. A *WinPepi* calculator was used and the data were organized and analyzed on SPSS 14.0 software for Windows.

**Blinding:** All ABPM exams were reported by a cardiologist with experience in the analysis of the method and who were blinded to the participants' allocation. Evaluations of outpatient BP were performed by a blinded and trained researcher for this purpose. Participants did not know in which group they were allocated. Only one person of the team was aware of PRI distribution and that person did not take part in the data collection.

**Statistical Analysis:**

**Inferential and descriptive analysis:** **Sociodemographic variable:** age (in years), skin color (black/brown/white/yellow/indigenous), education (up to 4 study years, from 5 to 8 years, 9-11 and 12 or over 12 study years), marital status (Married/Stable Union/Single/Widowed/Separated or Divorced); **anthropometric and life habits and health variables** : BMI (Kg/m²), smoking status (never smoked/smoker/ex-smoker), consumption of alcoholic beverage (dichotomous variable), regular use of medicine (dichotomous variable), kind of medicine (categoric variable). **Postural variables:** posture angles and **clinical variables:** practice measures of SBP and DBP. The posture variables were compared to the basal values and, at the end of the intervention, between CG and IG groups.

Mean and standard deviations were used for descriptive analysis of the quantitative variables. For categorical variables, absolute number and proportion. In order to identify the effects of PRI in posture, the Wilcoxon test was used in the intragroup analysis whereas the Chi-square test was used in the intergroup analysis. Pearson's Correlation test was used to associate posture angles with pressure variables. All with significance level of 5%, study power of 80%, in two-tailed hypothesis. The data were organized in SPSS 14.0 software for Windows, for later analysis.

**RESULTS**

During trials for eligibility assessment, 200 potential participants met the criteria. Among these, 150 were excluded: individuals aged over 60 (90) or with comorbidities such as diabetes mellitus, metabolic syndrome and target organ damage (60). Among the 50 participants assessed for eligibility, 20 were excluded: they did not meet the eligibility criteria, such as medical consultation for preoperative report (10) and refused to participate in the survey (10).

Among the 30 participants who agreed to participate in the study, 15 were allocated to each group and all received the proposed intervention. There was no loss of follow-up **(Figure 2)**.

Among the 30 participants assessed, the mean age was 48 ± 7.7 years, BMI 29.6 ± 4.7 kg /m², mean of systolic BP (SBP) was 151 ± 20.26 mmHg and of diastolic BP (DBP) was 92.8 ± 14.53 mmHg. Being female (80%), married (53.3%), with 12 or more years of study (70%) and of black or brown skin color (53.3% and 43.3%, respectively) were the most frequent characteristics. Most of them never smoked (80%), haven’t consumed alcoholic beverage (63.3%), were on regular antihypertensive medication (80%), being the receptor blocker of angiotensin II (56.7%) the most frequent medicine and hypertension was controlled (73.3%). The abovementioned data are described according to the groups, in which homogeneity can be observed at the basal values. **(Tables 1 and 2).**

For basal values ​​of posture parameters, the participants presented posterior trunk shift, anterior body shift , increased hip and knee angles and decreased ankle angle, with no difference between groups (p> 0.05). (Table 3). In both intragroup and intergroup comparisons, baseline parameters were maintained for CG and IG, with no statistical difference. After recategorization, similar improvement was observed between the two groups, with no statistical difference (p> 0.05) **(Table 4).**

For a secondary outcome, on posture angles and BP, considering the association between posture parameters and office BP, there was no difference in the correlations for the baseline parameters), both in the GC and in the IG (p> 0.05), as well as there was no difference in the association of these variables to GC after the intervention (p> 0.05). For IG, anterior body shift presented a moderate positive correlation for SBP (r = 0.57, p = 0.03), 33% of SBP explained by anterior displacement of the body. Knee angle with moderate positive correlation for DBP (r = 0.68, p <0.01), and ankle angle with moderate negative correlation for DBP (r = -0.75, p <0.01), with 46% and 55% of the DBP defined by the angles, respectively. **(Figure 3).** No correlations between specific posture parameters and BP were found, considering the initial values ​​in the two groups and the final GC values.

**DISCUSSION**

This study aimed to verify the effect of PRI on hypertensive individuals’ postures and after six weeks of PRI use, little change in posture was noted, with maintenance of initial postural patterns, for both groups.

Assessing associations between posture parameters and BP, as secondary outcome, this study observed that the anterior body shift revealed a moderate and positive association to SBP (the greater the projection of the body forward, the greater the BP value). Knee angle presented moderate and positive association (greater knee flexion, greater BP value) and ankle angle revealed moderate and negative association (decreased angle, higher BP value), both for DBP. In a previous study, postural misalignments showed association with ABPM elements: anterior trunk shift presented a lower wake /sleep variation for SBP (14.7%vs25.3%, p = 0.004), flexed hip presented higher pressure load (29.4%vs18.3% p = 0.016) and lower wake/sleep variation (13.4%vs22.3%, p = 0.056) for DBP³.

Although a difference was observed in the parameters that were associated with BP, the assumption that postural misalignments may modify BP regulation becomes more consistent. The decrease in the anterior displacement of the body and the consequent improvement of the distribution of the center of mass can impact the intensity of the muscular contraction of the whole posterior chain, that contracts so that people can keep themselves against gravity. Decrease of muscle contraction may decrease MSNA, with a potential decrease of systemic sympathetic activity and of release of circulating noradrenaline and glutamate, with a consequent decrease in BP 7-9.

The knee and ankle angles are proportional in the standing position: the smaller the knee angle (more flexion), the lower the ankle angle (more dorsiflexion). The decrease in angles caused an increase in DBP. The aforementioned angles generate eccentric stretching of the posterior muscles of the leg, mainly gastrocnemius and soleus, altering the state of muscle tension, with sustained mechanical vessel compressions and mechanoreceptor stimulus20.

This constant state of tension of the posterior muscles of the leg causes the loss of the calf pump mechanism. This pump has an important role on venous return and on the interaction of cardio-postural-musculoskeletal systems²¹. In a study developed with youngsters and elderly, correlating electromyographic activity (muscular performance) and non-invasive assessment with photoplethysmograph (blood pressure), ascertained that the calf pump plays a central role in increasing venous return while favoring the postural orientation and that, for the elderly, this mechanism was not so efficient, due to the muscular weakness inherent of the aging process²¹

It can be suggested that, just as the calf pump mechanism was not efficient in the elderly population, this mechanism presents flaws in the case of muscles in a constant state of tension, generating difficulty in venous return and compromising DBP.

PRI did not affect the posture correction, but it improved the anterior shift of the body, which favored an SBP decrease. The maintenance of knee flexion and ankle dorsiflexion impacted on DBP increase. It is important to stress that the artifact should not be the only correction to be performed on the insole for complete postural correction: shims are usually used to correct dysmetria of lower limbs, flat and valgus¹¹ feet, what could have impacted on improving posture. However, the main objective of this study was to verify the effect of the artifact, singly, on the posture of hypertensive individuals and to ascertain if the change on posture could affect BP.

The relief engendered by the artifact may have provided stimulus in the deep somatosensory system for the alterations found¹¹. Body shift determines the distance of the body line that is measured by the acromion and lateral malleolus, with vertical line that represents gravity. The decrease of this angle means tendency to reach the vertical line, with balance of the application of forces in the sagittal plane. The postural alignment improves the biomechanical positioning of the body segments and is one of the components that leads to postural control, minimizing neuromusculoskeletal overload 4,10,20,22.

Postural control is understood to be the complex ability of interaction of several sensorimotor processes10. Postural orientation is one of these processes and it regards to the active control of bone alignment, base of support and to the internal and environmental references. It can be suggested that the decrease of the anterior shift of the body promoted better bone alignment, with improvement of the postural orientation and better distribution of the center of mass.

The general limitation of the articles relates to not having reached the number estimated by the sample calculation. The reality of the local hypertensive population is to present, in an associated way, obesity, metabolic syndrome and diabetes mellitus, all of them as exclusion criteria of the study. Those conditions affect the neuroendocrine system and are considered, for those studies, potential modifiers and/or confounders of the outcome, since they interfere in the neurophysiological mechanisms that potentially explain the intervention. Even with uptake of 20 months and occurring at different times, the continuity of the study became unfeasible in view of the need to control the variables mentioned above.

Regarding the posture, it may be considered a limitation the lack of knowledge about BP behavior in the face of postural changes on healthy individuals with no arterial hypertension. Checking changes in posture and comparing them between similar groups of hypertensive and non-hypertensive individuals would be an important step for understanding the real impact of posture on BP modifications.

Another limitation concerns about outcomes potentially related to posture. The observed postural misalignments could disclose part of BP alterations, but the outcome variables that obtained correlation differed from the first study produced by the group: whereas in the transversal study the angles of posture affected the pressure loads, the clinical trial presented association of the angles with the peaks of blood pressure. It is important that other supporting studies are conducted to try to determine which posture parameters may impact the BP reduction.

From the findings, it is possible to consider that the improvement of specific posture angles, through PRI, may influence BP on hypertensive individuals.

**BIBLIOGRAPHIC REFERENCES:**