



Traditional Auriculotherapy for Hypertension: A Pilot Randomized Trial

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ABSTRACT

Patients who are on anti-hypertensive therapy may not consistently achieve the recommended blood pressure (BP) level. Given this limitation of pharmacologic therapy, the exploration of non-invasive complementary methods along with conventional medicine for BP control is warranted. The aim of the present study was to identify an optimal protocol for the administration of auriculotherapy (AT) integrated with Western medication for a better control of hypertension. This preliminary study adopted a two-arm experimental design. We enrolled patients with uncontrolled mild hypertension. The subjects in the experimental group (Group A) received an integrative approach (AT supplementing Western medication). The subjects in the comparison group (Group B) received the same kind of pellets as that in Group A, but were additionally asked to press the pellets against the acupoints thrice daily. Mean arterial BP was used as the main measure of outcome in this study. No significant difference in the therapeutic effect was observed between groups in which the pressure was applied on the magnetic pellets or not. This study demonstrates that AT with magnetic pellets together with western medication has a positive outcome for uncontrolled mild hypertension.

Keywords —Auriculotherapy, hypertension, mean arterial pressure

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I. INTRODUCTION

In many societies, hypertension-related diseases are the most common causes of morbidity and mortality.¹ Arterial hypertension is one of the top leading risk factors for global disease burden; and 16.5% of all mortality can be attributed to high blood pressure (BP).²

The World Health Organization defines hypertension as a systolic/diastolic pressure that is persistently greater than 140/90 mmHg.³

The standard treatment for hypertension, according to the guidelines stipulated in the “JNC 7 Report” released by the National Heart, Lung and Blood Institute (NHLBI), includes health-promoting lifestyle modifications and two or more anti-hypertensive medications to achieve the goal BP (140/90 mmHg).⁴ However, patients on anti-hypertensive therapy may not consistently achieve the recommended BP level. The prevalence of resistant hypertension has been reported to range 5 – 30% of the population with hypertension, and is associated with a high risk of cardiovascular and renal problems.⁵

Standing such pharmacologic limitation in hypertension control, the exploration of other non-invasive complementary methods, combined with conventional medicine for BP control, may be necessary. In line with this, auriculotherapy (AT), a method of traditional Chinese medicine (TCM), was thus proposed as a therapy to integrate Western medicine for a better hypertension control.

In particular, AT is a therapeutic method that utilizes specific points on the auricle, which in turn are punctured or stimulated to treat various disorders of the body.⁶ Hence, it is a specialized form of acupuncture in which the ear is viewed as the body’s microsystem.⁷ AT makes use of different materials, including acupuncture needles, press-tack needles, vaccaria seeds, and magnetic pellets, which are placed on acupoints located on the external ear for stimulation.

According to TCM in hypertension there is a hyperactivity of the Liver *Yang* due to the excess of *Yang Qi*, or, simply stated, the malnutrition of the Liver results from the deficiency of the Kidney *Yin*.⁸ Auriculo-acupoint pressing therapy has also demonstrated its effectiveness for the control of hypertension, with verified stability of the therapeutic effect.⁹

Auricular acupuncture employs needles as a source of stimulation.¹⁰ The effectiveness of magneto-therapy for acupoint stimulation is debatable¹¹⁻¹² while the additional effect of pressing on experimental objects has yet to be justified. Therefore, a minimally invasive measure and a standardized protocol using AT were proposed to determine the desirable treatment modality using this kind of therapy in the management of arterial hypertension.

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II. METHODS

The aim of this pilot study was to identify an optimal protocol as well as an appropriate method for AT administration integrated with Western medication for improved control of hypertension.

Research hypotheses

- (1) Auriculotherapy using magnetic pellets has a significant effect on hypertension control.
- (2) Auriculotherapy using magnetic pellets with or without additional pressing on the acupoints has no significant differences in hypertension control.

Settings and subjects

This pilot study implemented a two-arm experimental design. Borderline-controlled hypertension was defined as BP remaining above 140/90 mmHg even when the patient was on anti-hypertensive therapy in accordance with the JNC guidelines. Subjects were cases recruited from the out-patient cardiology clinic of a regional hospital in Hong Kong. The exclusion criteria involved patients with (i) secondary hypertension, (ii) upper limit of BP more than 160/99 mmHg, (iii) pacemakers/implanted electrical devices, (iv) pregnancy, (v) a history of coronary artery disease or stroke, or comorbid illnesses such as diabetes or chronic kidney disease (vi) regular maintenance medications (apart from anti-hypertensives) which may affect BP, and (vii) aural injuries or infections.

Group A (Experimental group): The subjects received an integrative approach (AT without magnetic pellet pressing plus Western medication). The magnetic pellets used in this study contained an average of ~200 gauss/pellet magnetic flux densities, with a diameter of ~0.13cm. No pellet pressing should take place.

Group B (Comparison group): The patients received an integrative approach (AT with magnetic pellet pressing, plus Western medication). Using the same kind of pellets as that in Group A, the subjects were additionally asked to press the pellets against the acupoints three times daily, with one minute for each point until a sensation of distension and warmth was felt. All the subjects were required to fill out a self-reported therapy compliance daily record to allow the researcher to monitor the degree of compliance in pellet pressing.

Interventions

Justification of acupoint selection for hypertension

The selection of auricular points is not only on the basis of traditional Chinese medical theory but on ideas borrowed from modern medicine as well. Seven auricular acupoints thought to have effects on achieving optimal BP and relieve associated

symptoms were then selected (Figure 1). These acupoints are as follows:

- **“Liver”**: suppresses the Liver Yang and abates the wind.
- **“Ear apex”**: dispels heat, tranquilizes the mind, and lowers BP.
- **“Sympathetic”**: links with the autonomic nervous system, thus regulates vasomotricity to alleviate blood vessel spasm.
- **“Groove of the Dorsal Surface”**: an empirical point in the treatment of hypertension.
- **“Heart”**: regulates BP, calms the state of mind, and clears away the heart-fire.¹² It also nourishes the yin and serves the blood.
- **“Kidney”**: nourishes the yin and serves blood.
- **“Superior Triangular Fossa”**: shown as clinically effective in the treatment of hypertension; also called “BP Lowering Point.”

The locations of these acupoints were identified using the Chinese Standard Ear Acupoints Chart. To ensure the accuracy of the identified acupoints, interrater reliability was tested, and an agreement of 95% between the TCM practitioner and the principal investigator was established.

Interventions and procedures

i) Treatment phase:

With the use of a computer-generated random table, the participants were then randomized, receiving either one of the two treatment modalities. Blocked randomization was employed to guarantee the presence of approximately the same sample size in each group at any time during the trial. The auricle of each subject was disinfected with 75% alcohol prior to the administration of the therapy, and only one ear received treatment at a time. Both ears were treated alternately. The experimental object was subsequently applied to the most reactive region of each selected auricular point. The objects were replaced once every week to avoid local irritation of the treated auricular points. The total treatment period was four weeks. In addition, no significant change was observed in the type and dosage of hypertensive drugs taken by the subjects in the current study.

ii) Follow-up phase

The subjects were invited to return for follow-up one month and two months after the four-week treatment course for monitoring of BP changes during these periods.

Ethical considerations



A written informed consent was obtained from every eligible subject after the risks and benefits of the study had been explained to them. Participation in the study was on a voluntary basis, and all potential subjects were informed and assured of their right to refuse or withdraw from the study at any time. Personal information and data remained confidential and anonymous. The study was approved by the Hong Kong East Cluster Ethics Committee (Ref: CRE-2006-398).

Main Outcome Measures

To achieve the effect of observer blinding, the treatment outcome was evaluated by another researcher unaware of the type of treatment modality received by the subjects. Mean Arterial Pressure (MAP) was used as the main outcome measure in this study owing to its clinical and physiological significance in both the representation of perfusion pressure and the effect on the calculation of hemodynamic variables. 13 BP readings were recorded using the Datascope Electronic Sphygmomanometer at baseline, at weekly visits to the clinic during the course of the treatment, and at 1 month and 2 months following the treatment course.

Data analyses

MAP was computed using the following standard formula: $\text{diastolic BP} + (\text{systolic} - \text{diastolic BP})/3$.¹⁴ Baseline background and clinical characteristics between the two groups were compared using t-test, Pearson Chi-square test or Fisher's exact test, as appropriate. Those background characteristics listed in Table 1 having p values <0.25 between the two groups were considered as potential confounding factors when making adjusted comparison between the two groups.

Generalized estimating equations (GEE) models were employed to assess differential change of the outcomes across the time points between the two groups. GEE model can account for intra-correlated repeated measures data and accommodate missing data due to incomplete visits or dropped-out, provided the data are missing at random. The PROC GENMOD (SAS Institute, Cary, NC, release 9.1) was used to fit GEE models. All other statistical analyses were done using SPSS 19.0. All statistical tests were two-sided and a p-value < 0.05 was considered statistically significant.

III. RESULTS

A total of 70 subjects of Chinese origin were recruited and 60 of them (30 per each arm) completed the study. Ten subjects did not complete the study (4 in Group A, and 6 in Group B). A detailed subject recruitment flowchart is illustrated in Figure 2.

Among the 70 subjects, 48.6% of them were female (n=34), and 51.4% were male (n=36). Their mean age was 56.4 (SD=11.4). There was no significant difference between the two groups at baseline on background and clinical characteristics (age, gender, BMI, number of years hypertensive, number of co-morbid illnesses, cholesterol and triglyceride levels, and BP), except smoking status, where group A had more regularly smokers (Table 1). The median duration of having hypertension of the subjects was 7.5 years, and the mean MAP (mmHg) at 107.6 (SD=10.6) at baseline.

The subjects in both groups succeeded in regaining better control of BP after incorporating AT into Western treatment. In most comparisons, the results illustrated that the MAP readings in both groups demonstrated significantly lower values across time as compared to the baseline in patients receiving magnetic pellets with or without pressing (Table 2). The subjects in Group B were asked to press the pellets against the acupoints three times daily, one minute to each point until a sensation of distension and warmth was felt. The overall compliance rate for regular pressing was 99.13%. We did not have significant evidence that pellet pressing was, in effect, better than without pressing in regulating BP.

Using GEE models, it was found that no significant differential change of systolic, diastolic and MAP in all the subsequent time points as compared to the baseline between the two groups after adjusting for potential confounding factors (Table 3).

IV. DISCUSSION

The effects of AT with magnetic pellets plus western medication on uncontrolled mild hypertension were observed in this small-scale study. However, such findings should be interpreted with caution because of the absence of a placebo-controlled group. The mechanisms for the interaction of magnetic fields with biological tissues resulting in functional changes may be explained by certain principles of physics. In particular, a principle known as Faraday's law states that a magnetic field exerts force on a moving ionic current, such as the electrically charged ions of blood.^{11, 15-16} AT with magnetic pellets may promote the circulation of Qi and blood in the meridians, and regulate the functions of the Zang Fu organs, thus improving the physiology of the body. This concept is also in accordance with the findings in previous studies wherein the magnetic pellets applied in AT were effective in treating various diseases of the body.¹⁷⁻²⁰ In a randomized trial of a 6-week acupuncture treatment on patients with essential arterial hypertension, it was found that the mean 24-hour ambulatory BP in the experimental group was significantly lowered when compared to the sham group.²¹

Decreased nitric oxide levels and increased endothelin-1 play both a functional regulatory role for arterial stiffness and endothelial dysfunction.²² Furthermore, the renin-angiotensin aldosterone system is central to the pathophysiology of cardiovascular disorders.²³ It has been reported that the influence of acupuncture on hypertension might be related to its regulatory effects on serum nitrogen monoxide level²⁴ or on renin secretion.²⁵ Cardiovascular depressant effects of electroacupuncture in an animal model have been reported and attributed to afferent nerves stimulation.²⁶ Apart from these findings, the mechanism by which acupuncture lowers BP still remains speculative. Therefore further studies need to be conducted for a clear understanding of the magnets' biological effects on the cardiovascular systems, as well as on the Qi, meridians, and the Zang Fu organs of the body.

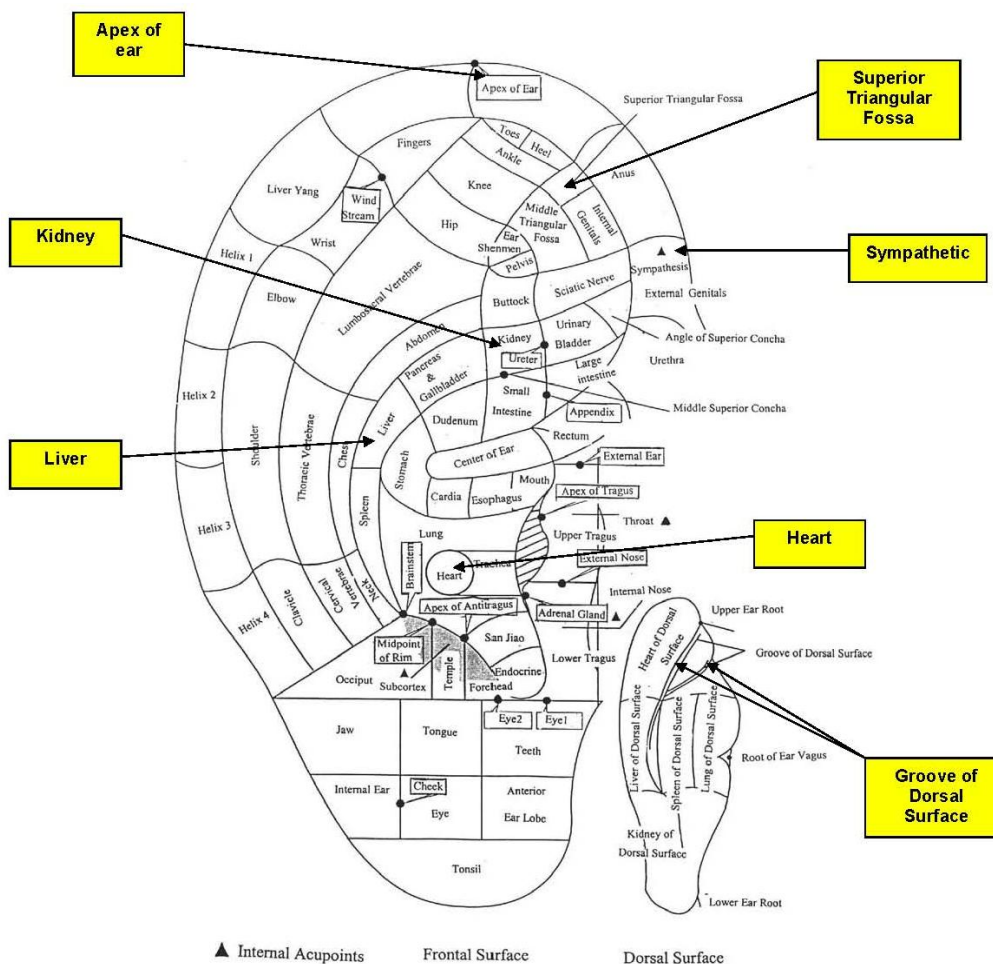


Figure 1. Anatomical location of selected acupoints for hypertension

The selection of the above points chosen in this study is based on traditional Chinese medical theory as well as modern medicine. For example, according to Western medicine, the sympathetic nervous system ("Sympathetic") is used in the regulation of BP as it is linked with the autonomic nervous system, and thus is able to control vascular tone that alleviates spasm of the blood vessels while the heart ("Heart") is a vital organ for BP control as cardiac output is a key determinant of arterial pressure.²⁷ On the other hand, from the point of view of Chinese medicine, hypertension is believed to be caused by the hyperactivity of the Liver Yang due to the excess of Yang Qi, or malnutrition of the Liver resulting from the deficiency of the Kidney Yin.⁸ Thus, the "Liver" suppresses the Liver Yang and abates the wind,⁸ the "Kidney" nourishes the yin and benefits the blood of the "Kidney,"²⁸ the "Ear apex" tranquilizes the mind and lowers BP,⁶ and the "Heart" calms the state of mind and clears away the heart-fire.²⁸ Apart from control of BP, it is possible that the simultaneous application of this holistic treatment approach may help a person achieve balance, as the selected acupoints regulate the functions of the body in a preferred direction. The traditional Chinese medical theory therefore appears to have a valid physiological basis in acupoint selection in this study. Auricular seed pressing therapy is a common therapeutic approach in Mainland China for treating hypertension through

additional stimulation of the acupoints. However, the results of this study indicate that pellet pressing may not be better than magnetic pellet application without pressing. It could be argued that most previous studies on the subject^{8, 29-30} utilized Semen Vaccariae as experimental objects instead of magnetic pellets, and that pressing is required to achieve a therapeutic effect. Semen Vaccariae [wang bu liu xing] is a small, round seed (~0.13 cm in diameter) frequently used for auricular taping. The effect of Semen Vaccariae, when taken orally, can stimulate blood circulation.²⁷ This was demonstrated by Suen et al.¹⁷ in an RCT study employing AT on subjects with insomnia, wherein the use of vaccaria seeds without pressing did not show any therapeutic effect. This thereby rejected the hypothesis that the skin could absorb the seeds' properties. Unlike vaccaria seeds, however, magneto-auriculotherapy is believed to accelerate blood circulation by dilating blood capillaries, treats diseases through application of a magnetic field to human Jing Luo (main and collateral channels), and produces sedative, analgesic, and anti-inflammatory effects.¹⁹ AT, coupled with other approaches for treating hypertension such as those using acupuncture needles^{10, 31-34} or electrotherapy³⁵ may not be easily accepted by patients. In this regard, the findings of this study indicate that magnetic pellets together with western medication have an



effect on regulating BP among the participants. It is to be noted that the use of magnetic pellets for AT is less traumatic, more convenient, and easily accepted by patients as compared to other invasive approaches of treatment for hypertension, such as ear acupuncture.

The therapeutic effects that were observed in the experimental group were thus solely due to magnetic effects plus western medication rather than the physical pressure induced by the pellets on the acupoints. Since the therapeutic effect is achieved even without pressing when magnetic pellets are used, this is then less troublesome, rendering increased treatment compliance rate and easy maintenance of consistency in future treatment protocols in clinical trials of this type.

The results also illustrated that the MAP readings at all the subsequent time points in both groups were significant lower than at the baseline. This suggests that AT with magnetic pellets together with western medication has a sustained effect, at least within a definite period of time, on hypertension control in participants. It was observed, however, that the mean MAP was slightly elevated at two-month follow-up. Perhaps a “top-up” treatment may be necessary by that time to sustain a longer therapeutic effect.

Since only one subject in Group A withdrew from the study due to the dissatisfaction with the treatment outcome, the tolerability of the subjects towards AT was generally high.

integration of Chinese and Western models of care. According to the scientific statement from the American Heart Association, it is reasonable for all individuals with BP >120/80 mmHg to consider trials of alternative approaches as adjuvant methods to help lower BP when clinically permissible.³⁶ The use of AT, if found effective in future clinical trials, can also be used as an adjunctive treatment approach for BP control that is holistic, convenient, hygienic, and safe.

The evaluation of TCM should be based on the best available empirical evidence that can be tested by scientific methods, for successful integration of Chinese and Western medicine into the existing health care system. It should be noted that the current study adopted an experimental approach in examining the therapeutic effects of AT as a forerunner for future studies in this area.

Limitations and Recommendations

Due to the small number of subjects enrolled in this pilot study, generalization of results is therefore limited. Moreover, a control group using placebo object for AT was lacking. It is recommended that further investigation by incorporating a control group should be performed for future studies.

The duration of the therapy in the present study was short (4 weeks) and no follow up measures were taken after the therapy was completed. Longer trials are necessary to test the durability of the BP lowering effect of AT. Also, no attempt was made to control for the physical activity level or salt intake of the subjects. Ambulatory BP monitoring could be considered for future trials so as to collect information on BP during daily activities and at night during sleep.

Although the therapeutic effects of AT using magnetic pellets were demonstrated in this study, no attempt has been made to understand clearly how the magnetic pathway works. Further studies from a biomedical perspective can be conducted to help us understand better what the biological effects magnets have on the cardiovascular systems as well as on the Qi, meridians, and Zang Fu organs of the body.

V. CONCLUSIONS

This pilot study has demonstrated positive effects of AT with magnetic pellets together with western medication in the management of uncontrolled mild hypertension. The subjects in the two groups under study both demonstrated significant improvement in BP regulation as evidenced by a decrease in mean MAP before and after the therapy. Therapeutic effect can also be achieved even without magnetic pellet pressing, resulting in an increase in treatment compliance rate and in easy maintenance in consistency of treatment protocol when employed in future clinical trials of this type.

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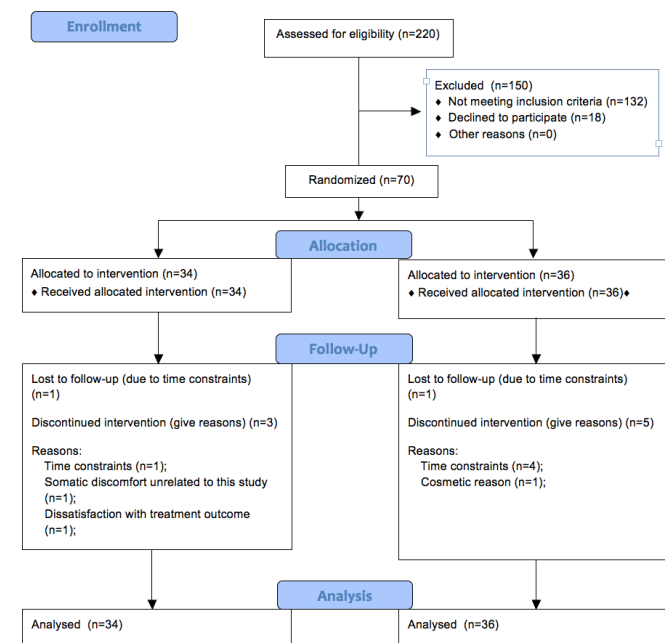


Figure 2: CONSORT Flow Diagram

Implications of the study

This study can advance our understanding of better hypertension management in subjects with regard to the



the volunteers for their participation and cooperation in this study.

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