Short-term effect of acupuncture on intraocular pressure in healthy subjects

Daniel Meira-Freitas,1 Angelino Julio Cariello,1,2 Ruth Cardoso Vita,1,2 Ângela Tabosa,2 Luiz Alberto S Melo Jr1

ABSTRACT

Purpose To evaluate the short-term effect of acupuncture on the intraocular pressure (IOP) in healthy subjects.

Methods A randomised controlled double-blinded trial was performed. 48 healthy volunteers (94 eyes) were randomly allocated to three groups: acupuncture group—19 subjects (38 eyes) were submitted to a 20 min session of acupuncture (GB1, GB14 and BL1); sham group—14 subjects (27 eyes) were submitted to a 20 min session of acupuncture with needles inserted in false points; and control group—15 subjects (29 eyes) who underwent no intervention. All subjects had the IOP measured by a masked investigator using Goldmann applanation tonometry immediately before intervention, as well as 20 min and 24 h after.

Results The mean (SD) IOP in the acupuncture group was 17.9 (3.3) mm Hg at baseline, 16.4 (3.9) mm Hg at 20 min and 16.3 (3.3) mm Hg at 24 h. The mean (SD) IOP in the sham group was 18.6 (3.3) mm Hg at baseline, 17.7 (2.6) mm Hg at 20 min and 15.9 (3.6) mm Hg at 24 h. The mean (SD) IOP in the control group was 16.9 (3.5) mm Hg at baseline, 16.5 (3.8) mm Hg at 20 min and 15.8 (3.3) mm Hg at 24 h. There was no statistically significant difference in the IOP variation (post-intervention minus baseline measurements) between groups after 20 min (p=0.13) and 24 h (p=0.21).

Conclusion Acupuncture in the studied points did not produce significant short-term effect on the IOP of healthy individuals in comparison with control groups.

Clinical Trials Registration Number: NCT00639977

INTRODUCTION

Acupuncture is an ancient Chinese technique of needle insertion through the skin with therapeutic purpose. It is used to treat many diseases although the evidence of its benefit is controversial.1 In recent decades, research has been conducted to study acupuncture’s effectiveness and mechanism of action.2 Experimental studies have demonstrated a hypotensor ocular effect of acupuncture in rabbits and dogs.3-5 Previous studies in humans have also described intraocular pressure (IOP) reduction.6,7 Chu and Potter (2002) hypothesised that acupuncture could reduce the aqueous humour flow rate through an endogenous mechanism, possibly by an induced decrease of catecholamine levels.4 However, these studies present controversial scientific methodology as absence of control group, no randomisation, reduced sample or inadequate blinding of the IOP measurement. The aim of this study was to evaluate the short-term effect of acupuncture on the IOP of healthy individuals.

MATERIALS AND METHODS

A randomised controlled double-blinded trial was performed. The study was carried out in keeping with the guidelines of the Declaration of Helsinki and the protocol was approved by the research ethics committee of the Federal University of São Paulo. Healthy subjects from both genders aged over 21 years were invited to participate. Individuals who had past history of glaucoma, intraocular surgery, corneal alterations and patients taking any kind of medicine that acts on the IOP, as well as those who did not give informed consent or were unwilling to follow the protocol, were excluded from the study.

All volunteers were evaluated by slit lamp to exclude anterior segment diseases of the eye and had the IOP measured through Goldmann applanation tonometry. The measurement of the pressure was accomplished in a masked fashion by two examiners, one to adjust the semicircles of the tonometer and other to write down the dial value, so that the first examiner did not have knowledge of the value of the measured pressure. This measurement was performed three times in each eye, in each session. There were three sessions in total: before the procedure of the acupuncture, after 20 min and 24 h later.

After this initial examination, all healthy volunteers were allocated into the three groups through simple randomisation method:

Acupuncture group: a 20 min session of acupuncture was performed with needles insertion in specific points (GB1, GB14 and BL1). These points are suitable for glaucoma treatment, accordingly to traditional Chinese medicine (TCM).8 The needles were inserted to reach the depth of the muscular tissue, with manual stimulation of the needle. Stimulation refers to manual rotation of the needle until a de qi sensation was elicited.

Sham group: a 20 min session was performed with needles inserted in non-acupuncture points that were at least 1.5 cm away from the real points mentioned above. The needle was inserted in the same depth of the acupuncture group, however the de qi sensation was not elicited in this group.

Control group: The subjects were maintained comfortably at a silent room with dim light in dor sal decubitus for 20 min, without any therapeutic intervention. Twenty minutes and 24 h after the procedures all individuals had the IOP measured as the baseline.

All acupuncture and sham procedures were performed by the same experienced physician who was blinded to the IOP measurements. All
procedures, including the IOP measurements and the acupuncture sessions, were performed between 9:00 and 11:00. There was no patient withdrawal or exclusion after the randomisation.

It was calculated that 28 eyes in each group were needed to have 80% power to detect a 3 mm Hg difference in IOP change from baseline between two groups, considering a SD of 3 mm Hg, an intraclass correlation between both eyes of the same individual of 0.6, a design effect of 1.6 and a significance level of 0.05. A 3 mm Hg difference in IOP change between groups was considered clinically significant. To take into account the correlation between both eyes of the same individual, generalised estimating equation was used to compare the IOP changes from baseline between the groups. A p value less than 0.05 was considered statistically significant.

RESULTS
Forty-eight healthy volunteers (94 eyes) were enrolled in this study. Ages ranged from 32 to 84 years with a mean of 61.3±11.3. Mean baseline IOP was 17.8±3.4. Acupuncture was performed in 19 subjects (38 eyes). Fourteen subjects (27 eyes) were enrolled in the sham group; and 15 subjects (29 eyes) underwent no intervention (control group). The characteristics of each group can be seen in table 1. The mean IOPs are shown in table 2 and the changes of the IOP (post-intervention minus baseline measurements) are shown in table 3.

There was no statistically significant difference in the change of the IOP (post-intervention minus baseline measurements) between groups after 20 min and 24 h (table 3).

Table 1 Demographic characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control</th>
<th>Sham</th>
<th>True</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>15</td>
<td>14</td>
<td>19</td>
</tr>
<tr>
<td>Age (Mean (SD), years)</td>
<td>61.1 (14.8)</td>
<td>62.3 (9.9)</td>
<td>60.3 (9.6)</td>
</tr>
<tr>
<td>Gender (male: female)</td>
<td>7:8</td>
<td>4:10</td>
<td>5:14</td>
</tr>
<tr>
<td>Baseline IOP (mm Hg – Mean (SD))</td>
<td>16.9 (3.5)</td>
<td>18.7 (3.2)</td>
<td>17.9 (3.3)</td>
</tr>
</tbody>
</table>

IOP, intraocular pressure.

Table 2 Intraocular pressure throughout the study

<table>
<thead>
<tr>
<th>Measurement session</th>
<th>True (mean (SD))</th>
<th>Sham (mean (SD))</th>
<th>Acupuncture (mean (SD))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>16.9 (3.5)</td>
<td>18.6 (3.3)</td>
<td>17.9 (3.3)</td>
</tr>
<tr>
<td>Post intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 min</td>
<td>16.5 (3.8)</td>
<td>17.7 (2.6)</td>
<td>16.4 (3.9)</td>
</tr>
<tr>
<td>24 h</td>
<td>15.8 (3.3)</td>
<td>15.9 (3.6)</td>
<td>16.3 (3.3)</td>
</tr>
</tbody>
</table>

Table 3 Comparison of intraocular pressure changes between groups

<table>
<thead>
<tr>
<th>Post intervention measurement</th>
<th>True (mean (95% CI))</th>
<th>Sham (mean (95% CI))</th>
<th>Acupuncture (mean (95% CI))</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 min</td>
<td>−0.4 (−1.1 to 0.3)</td>
<td>−0.3 (−1.6 to −0.2)</td>
<td>−1.5 (−2.3 to −0.6)</td>
<td>0.13</td>
</tr>
<tr>
<td>24 h</td>
<td>−1.2 (−2.3 to −0.0)</td>
<td>−2.7 (−4.0 to −1.3)</td>
<td>−1.6 (−2.6 to 0.5)</td>
<td>0.21</td>
</tr>
</tbody>
</table>

DISCUSSION
Glaucoma is a progressive optical neuropathy and one of the main causes of irreversible blindness. It is proven that the reduction of the IOP slows the progression of the glaucoma, and currently, it is the only treatment modality.1

Initial treatment of glaucoma is performed with eyedrops. The high costs, frequent need for polytherapy, increased drug regimens and side effects, such as arrhythmia, hypotension, bronchospasm, confusion, depression and sexual dysfunction, contribute for the low compliance.10–12 In the resistant cases for the clinical treatment, surgical procedures as trabeculectomy or artificial drainage implants may be indicated.13 However it carries a considerable risk of complications like bleb leaks, hypotonia, infections, cataract and others.13 A recent clinical trial comparing the trabeculectomy versus tube shunt surgery found a high incidence of postoperative complications: 34% in the tube group and 57% in the trabeculectomy group during the first year of follow-up.13 Therefore, the search for new therapy options for this disease is needed.

The increasing interest in complementary medicine has been leading patients with chronic diseases such as glaucoma to seek this kind of therapy.14 It was proposed that acupuncture may be potentially useful in treating a variety of ocular diseases.15 16 However, there is scarce evidence to support its efficacy in reducing IOP or in stopping the progression of glaucoma.17 Experimental studies demonstrated a hypotensor ocular effect of the acupuncture on rabbits and dogs.3 5 Uhrig et al reported a reduction in the IOP in a group of 18 patients with glaucoma or ocular hypertension after 15 min of the acupuncture (points LI3, LI4, GB37) as well as 24 h after the intervention. However, it had a small sample and was uncontrolled.18 In a recent report, Kurosu et al also found a reduction in the IOP at 15 min, 1 week, 2 weeks and 5 weeks after the therapy was initiated.19 The acupuncture was carried out twice a week in 11 patients with glaucoma, without control group and did not mention if there was a blinding method for the IOP verification. Our study is the first standardised, randomised, controlled, double-blind clinical trial about the intraocular effect of the acupuncture and did not show any significant alteration on the IOP in healthy volunteers.

Many substances are under investigation about their role on the glaucoma physiopathology by inducing the apoptosis of the ganglionic cells.19 Neufeld et al identified that the nitric oxide has an important role in this sense.20 Studies suggest that the acupuncture can acts through the inhibition of the production of nitric oxide, an apoptosis inductor.11 Thus, it is possible that the acupuncture may have a beneficial effect in glaucoma through a neuroprotection mechanism or increasing the blood flow in the optic nerve head as some studies previously hypothesised.21 22

Accordingly to TCM, the zang gan (liver) and shen (kidneys) and their coupled fu dan (gall bladder) and pangguang (bladder) have great influence in the preservation and energetic nutrition of the eye.23 Some previous studies suggested that local points act independently of the systemic acupuncture in some ocular dysfunctions.24–26 Based on this, it was decided that only local periorcular points of the gan-dan and shen-pangguang system were to be tested in this study. On the other hand, in acupuncture practice, local points are commonly associated with systemic points, therefore it is possible that if systemic points were used it could possibly have an additional effect on IOP reduction.

TCM states that the acupuncture’s aim is to bring balance to the body energy.27 The fact that the volunteers were already healthy could also be a reason for the absence of acupuncture IOP effect in our study. Prospective clinical trials involving
patients with the disease would be interesting to assess any benefit from acupuncture on the progression of glaucoma.

Acupuncture in specific points did not present significant IOP alteration in healthy subjects in comparison with control groups. However, needles inserted in the same neural segment as the intervention group may have a treatment effect and future studies should find another control method. Larger, prospective studies should be accomplished to analyse if glaucoma patients could benefit of acupuncture acting through IOP reduction or other mechanisms as neuroprotection or blood flow improvements.

Summary
► There is scarce evidence to support the efficacy of acupuncture to reduce the intraocular pressure or to stop the progression of glaucoma
► Acupuncture in specific points did not present significant short-term intraocular pressure alteration in healthy subjects in comparison with control groups

Acknowledgements The abstract of this paper was presented in the XXXIV Congresso Brasileiro de Oftalmologia, Brazilian Council of Ophthalmology, September 2007, Brasilia, Brazil.

Competing interests None.

Ethics approval This study was conducted with the approval of the research ethics committee of the Federal University of São Paulo.

Provenance and peer review Not commissioned; externally peer reviewed.

Patient consent Obtained.

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*Acupunct Med* 2010 28: 25-27
doi: 10.1136/aim.2009.001081

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