Sedative effect of acupuncture during cataract surgery

Prospective randomized double-blind study

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PURPOSE: To assess the effectiveness of acupuncture in reducing anxiety in patients having cataract surgery under topical anesthesia.

SETTING: Vita-Salute University of Milan and IRCCS H. San Raffaele, Milan, Italy.

METHODS: In a prospective randomized double-blind controlled trial, anxiety levels before and after cataract surgery in 3 groups (A = no acupuncture, B = true acupuncture starting 20 minutes before surgery, C = sham acupuncture starting 20 minutes before surgery) were compared using the Visual Analog Scale (VAS). Twenty-five patients scheduled for inpatient phacoemulsification were enrolled in each group. All surgeries were performed using topical anesthesia. Exclusion criteria were refusal to provide informed consent, use of drugs with sedative properties, psychiatric disease, pregnancy, knowledge of the principles of acupuncture, anatomic alterations, or cutaneous infections precluding acupuncture at the selected acupoints.

RESULTS: Preoperative anxiety levels were significantly lower only in Group B ($P = .001$). Anxiety in Group B was significantly lower than in Group A ($P = .001$) and Group C ($P = .037$). Regarding postoperative anxiety, the mean VAS score was 39 ± 5 in Group A, 19 ± 3 in Group B, and 31 ± 4 in Group C. The difference was significant only between Group A and Group B ($P = .003$).

CONCLUSION: Acupuncture was effective in reducing anxiety related to cataract surgery under topical anesthesia.

J Cataract Refract Surg 2006; 32:1951–1954 © 2006 ASCRS and ESCRS

Cataract extraction with phacoemulsification and intraocular lens implantation is one of the most frequently performed surgical procedures worldwide. It typically is a 15-minute outpatient procedure for which topical anesthesia can be administered. Although this type of anesthesia provides analgesia in most cases, many patients report pain during the procedure.[1] Moreover, patients can develop a high degree of anxiety during surgery under local anesthesia, possibly leading to cardiovascular stress. Analgesic and sedative intravenous drugs effectively control pain and anxiety and are often used with topical anesthesia by anesthetists and ophthalmologists.[2] However, this practice carries risks.[3]

A part of ancient Chinese medicine, acupuncture has gained acceptance in the modern Western world. The World Health Organization has recognized its benefit for some medical conditions.[4] Acupuncture has been frequently used for sedative and even hypnotic purposes.

The purpose of this prospective randomized controlled double-blind study was to assess the effectiveness of acupuncture in reducing anxiety in patients having cataract surgery under topical anesthesia.

Accepted for publication June 19, 2006.

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No author has a proprietary or financial interest in any material or method mentioned.

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0886-3350/06/$-see front matter
doi:10.1016/j.jcrs.2006.06.027

PATIENTS AND METHODS

After signing informed consent, 75 adults with an American Society of Anesthesiology score I to III scheduled for day-hospital phacoemulsification cataract surgery were enrolled. Exclusion criteria were refusal to provide informed consent, use of drugs with sedative properties, psychiatric disease, pregnancy, knowledge of the principles of acupuncture, anatomic alterations, or cutaneous infections precluding acupuncture at the selected acupoints. The study was approved by the hospital's Ethical Committee.

Surgical and Acupuncture Technique

On the day of surgery, patients were asked to score their baseline anxiety on a visual analog scale (VAS), with 0 being no anxiety and 100 being unbearable anxiety. The mean arterial pressure, heart rate, and pulse oximetry were recorded. Thereafter, topical eye anesthesia (lidocaine 4%) was applied, and patients were randomly assigned to 1 of 3 groups.

Group A patients were left alone in a quiet room for 20 minutes.

Group B, patients received true acupuncture and then were left alone in a quiet room for 20 minutes. The points selected for acupuncture were as follows:

- LI-4 (long intestine 4 [Hegu]): on the dorsum of the hand, between the first and second metacarpal bones, at the midpoint of the second metacarpal bone, and close to its radial border
- PC-6 (pericardium 6 [Neiguan]): on the volar aspect of the forearm, 3 cm above the wrist, between the tendons of the long palmar and of the radial carpal flexor muscles
- H-7 (heart 7 [Shenmen]): on the volar aspect of the wrist, between the ulna and the pisiform bone
- TE-5 (triple energizer 5 [Waiguan]): on the dorsal aspect of the forearm, between radium and ulna, 3 cm above the distal joint of radium and ulna
- LV-3 (liver 3 [Taichong]): on the dorsum of the foot distally to the joint between the first and second metatarsal bone
- Auricle Shenmen: at the apex of the triangular fossa of the ear.

Group C patients received sham acupuncture and then were left alone in a quiet room for 20 minutes. Sham acupuncture was performed in areas traditionally devoid of an acupuncture effect:

- on the volar aspect of the hand, in the interdigital membrane between the first and the second finger
- on the dorsal aspect of the hand, in the interdigital membrane between the first and the second finger
- on the medial aspect of the forearm, 6 cm above the wrist the elbow
- on the medial aspect of the forearm, 6 cm below the elbow
- in the scaphoid fossa of the ear ("elbow" point of the ear)
- on the dorsum of the foot distally to the joint between the third and fourth metatarsal bone.

After 20 minutes, a preoperative VAS evaluation of anxiety was performed and then surgery began. In Groups B and C, the needles were left in place throughout surgery. Manual stimulation was applied to the needles after insertion and immediately before surgery until the needling sensation (De Qi) was evoked.

Acupuncture was done by a single physician certified in acupuncture (G.L.) who did not perform the VAS anxiety evaluation. The physician (L.G.) who performed the VAS anxiety evaluation was masked to the randomization.

Noninvasive arterial pressure, heart rate, and pulse oximetry were recorded throughout surgery. Adverse events and drugs administered during the procedure were recorded. Hypotension was defined as a decrease in mean arterial pressure greater than 30 mm Hg from baseline, hypertension as an increase in mean arterial pressure greater than 30 mm Hg, bradycardia as a heart rate of fewer than 45 beats per minutes, tachycardia as a heart rate of more than 120 beats per minute, and desaturation as pulse oximetry less than 90%. A high level of care was maintained in recording possible acupuncture-related adverse events. The duration of surgery was recorded. Ten minutes after the end of surgery, patients were asked to complete a third VAS evaluation of anxiety.

Statistical Analysis

A VAS postoperative anxiety evaluation of 6 was considered the main endpoint of the study. With a standard deviation of 5/100, the plan was to enroll 75 patients (25 per group) to show a difference of at least 5/100 with a statistical power of 80% ($2\alpha = .05$). Continuous data, expressed as means $\pm$ SD, were compared with repeated-measures analysis of variance with Bonferroni post hoc analysis and paired and unpaired Student t tests with Bonferroni correction as appropriate. A P value less than 0.05 was considered statistically significant.

RESULTS

There was no significant difference between the 3 groups in age, body weight, duration of surgery, baseline anxiety, mean arterial pressure, heart rate, or pulse oximetry (Table 1). The mean preoperative anxiety VAS score significantly differed between groups. It was 50 $\pm$ 5 in Group A, 22 $\pm$ 3 in Group B, and 36 $\pm$ 4 in Group C ($P = .001$, A versus B; $P = .04$, A versus C; and $P = .037$, B versus C). Preoperative anxiety increased significantly from baseline in Group A ($P = .017$), decreased significantly from baseline in Group B ($P = .001$), and was similar to baseline in Group C ($P = .079$).

The postoperative anxiety VAS score differed significantly only between Group A and Group B. The mean was 39 $\pm$ 5 in Group A, 19 $\pm$ 3 in Group B, and 31 $\pm$ 4 in Group C ($P = .003$, A versus B; $P = .571$, A versus C; and $P = .127$, B versus C). Postoperative anxiety decreased significantly from preoperative values in Group A ($P = .06$) (when it was similar to that at baseline [$P = .313$]), but was unchanged in Group B ($P = .457$) (in which it remained different from that at baseline [$P = .001$]) and in Group C ($P = .385$) (Figure 1).

Preoperative mean arterial pressure was statistically higher than baseline in the 3 groups, although the differences were clinically negligible: 104 $\pm$ 4 versus 100 $\pm$ 3 in Group A ($P = .008$), 107 $\pm$ 3 versus 102 $\pm$ 3 in Group B ($P = .012$), and 109 $\pm$ 3 versus 103 $\pm$ 3 in Group C ($P = .001$).

Table 1. Baseline characteristics of the patients in the 3 groups.

Characteristic	Group A (No Acu)	Group B (Acu)	Group C (Sham Acu)
Patients (n)	25	25	25
Mean age (y)	72 ± 8	68 ± 12	74 ± 9
Mean body weight (kg)	65 ± 14	73 ± 13	68 ± 13
Mean duration of surgery (min)	16 ± 8	14 ± 5	15 ± 6
Mean baseline anxiety (VAS)	46 ± 24	52 ± 20	39 ± 19
Mean baseline MAP (mm Hg)	104 ± 18	107 ± 13	109 ± 16
Mean baseline HR (beats/min)	76 ± 13	71 ± 14	77 ± 13
Mean baseline SpO_2 (%)	98 ± 1	98 ± 1	98 ± 2

Means ± SD
ACU = acupuncture; HR = heart rate; MAP = mean arterial pressure; SpO_2 = pulse oximetry; VAS = visual analog scale

Intraoperative mean arterial pressure trends were similar between the 3 groups ($P = .955$). However, mean arterial pressure values in Group A were always lower than in Group B and Group C throughout surgery. These differences were statistically significant during the first 12 minutes of surgery (Figure 2). Heart rate and pulse oximetry trends were similar between the 3 groups throughout surgery.

Surgery was successfully completed in all cases with no adverse events. Analgesic and sedative drugs were not administered during surgery in any case.

DISCUSSION

Topical anesthesia for cataract surgery has gained great acceptance since its introduction to the clinical practice during the 1990s. Although it is a simple and safe method, 20% to 30% of patients report feeling pain during or after surgery.[1–5] Nausea[6] and anxiety[7] are also relatively common.

Patients having cataract surgery are often elderly with a high incidence of cardiovascular or cerebrovascular disease. Surgery-related anxiety combined with mydriatic eyedrops can cause dangerous, acute elevations in blood pressure and heart rate.

Patient comfort may be improved by several sedative and analgesic drugs. Fentanyl,[8–9] midazolam,[7,10] lorazepam,[11] propofol,[12,13] and various combinations[10,14] have been evaluated, but there is no agreement on their effectiveness and safety. The risks related to the administration of sedative drugs may be too high for the procedure because of the medical conditions of some elderly patients.[3] Moreover, the procedure is short and the effects of the sedatives may continue after surgery. Benzodiazepine and propofol, the most commonly used sedatives, may present paradoxical effects in the elderly, sometimes leading to the cessation of surgery because of patient agitation.[12] Pharmacologic sedation requires monitoring and dedicated personnel during surgery and recovery and usually prolongs the time to discharge.

Acupuncture has been used in different settings for analgesia or sedation.[15–19] It provides sedation and analgesia, allows the patient to collaborate with the surgeon, has almost no contraindications, requires few facilities, and does not prolong the time to discharge. A favorable effect of acupuncture on intraoperative and postoperative analgesia and sedation was observed 30 years ago in a series of 50 ophthalmic surgery patients.[20] This study used some

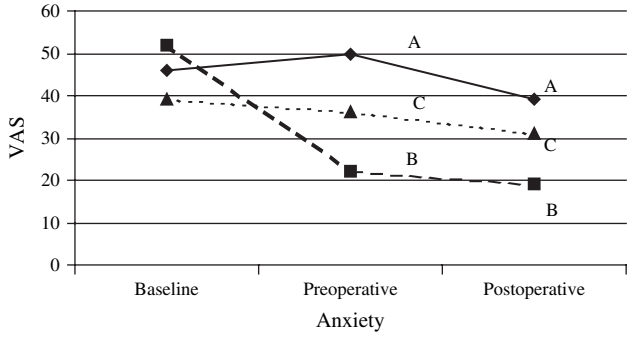

Figure 1. Anxiety trends assessed by the VAS.

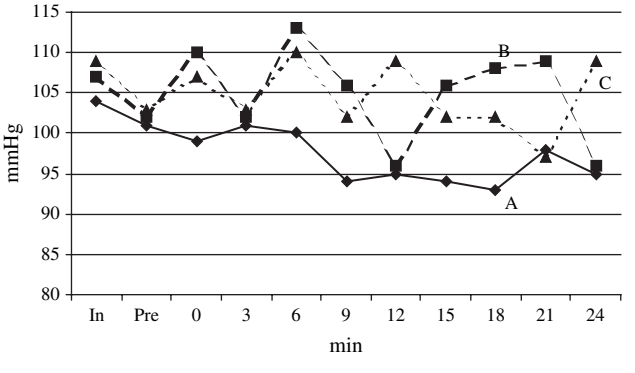

Figure 2. Mean arterial pressure trends during surgery.

acupoints we used (LI-4, TE-5, Auricle Shenmen). The uncontrolled study did not assess pain and sedation by validated means.

In our study, acupuncture reduced anxiety significantly during and at the end of cataract surgery. Preoperative relaxation cannot explain the results, since Group A and C (that experienced this relaxation as Group B) did not show an improvement in anxiety level. Placebo cannot explain the results, as Group C (with sham acupuncture acting as a placebo) did not show a reduction of anxiety. However, acupuncture caused no adverse events and did not prolong the duration of surgery. It did not require additional monitoring or dedicated personnel.

Patients having cataract surgery usually report a high level of satisfaction[7]; thus, a statistically significant improvement is difficult to achieve. However, refinement of anesthesia management is necessary because some studies show patients prefer peribulbar or retrobulbar anesthesia over topical anesthesia[21,22] and most take analgesics as soon as they can.[9,10,12]

Although we did not use patient selection, it is possible that selected cases could benefit from acupuncture. Further studies could address this topic.

We chose acupoints that are indicated in traditional Chinese medicine[23] as sedative and analgesic and distant from the ophthalmic operative field. Acupoints located on the back were not considered for the sake of convenience. Different acupoint sets may produce similar results.

In conclusion, in our study, acupuncture effectively reduced anxiety related to cataract surgery under topical anesthesia. Given the positive effect we observed, we think an acupuncture approach is worthy of study in different medical and surgical settings characterized by procedural anxiety in awake patients. Physicians can acquire sufficient knowledge in acupuncture, allowing them to administer it, which is particularly valuable in settings in which anesthesiologists only work on call.

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