



Comparative Effects of the Stimulation of BL10, BL11, and GB34 Acupuncture Points with P6 Point using a Low-Level Laser on the Prevention of Vomiting after Strabismus Surgery: A Randomized, Double-Blind, Controlled Clinical Trial

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Abstract

Background: Vomiting is a common act after strabismus surgery. Three points (BL10, BL11, GB34) belong to the eye's energy channels and may be more effective in vomiting after strabismus surgery compared to P6 point.

Objectives: The present study aimed to compare the effects of stimulation of BL10, BL11, and GB34 acupuncture points with point P6 via the use of a low-level laser in the prevention of vomiting after strabismus surgery.

Methods: The present study used a randomized, double-blind, clinical trial design. The participating samples of this study were 63 strabismus surgery candidates with ASA I physical status, aged from 3 to 35 years who admitted to a university-affiliated hospital in Ahvaz, Iran, and were. The patients were randomly divided into three groups (21 patients in each group): Group I (laser acupuncture P6), group II (laser acupuncture BL10, BL11, GB34), and group III (control). Laser stimulation was performed on acupuncture points (P6 & BL10, BL11, GB34) for 60 seconds and 15 minutes before anesthesia induction and 15 minutes after arrival in the PACU. Group III (control) received placebo (laser off) stimulation on sham point. The number of vomits occurred 2, 6, and 24 hours after the surgery was recorded.

Results: Significant statistical differences were not observed in the number of vomiting after 6 hours among the three groups ($P = 0.01$). On the other hand, significant statistical differences were found between P6 point and placebo groups in terms of the mean value of vomiting 2 and 24 hours after the surgery ($P = 0.03$). However, no significant statistical differences were observed between P6 and BL10 groups at any time of the study.

Conclusions: Based on the findings, laser acupuncture of P6 point reduced the incidence of vomiting after strabismus surgery. Also, laser acupuncture of BL10, BL11, and GB34 points showed no significant differences in terms of the incidence of PONV when compared to P6 point. P6 point was the most effective point in controlling the incidence of PONV.

Keywords: Acupuncture, BL10, BL11, GB34, Laser, Prevention, Strabismus, P6, Post Anesthesia Care Unit, Vomiting

1. Background

Strabismus surgery is among the surgical procedures associated with a high incidence of PONV. Despite the use of various drugs for prevention and treatment, the condition can still be seen after surgery (1). The most prevalent side effects following induction of anesthesia are nausea and vomiting which lead to prolonged recovery time, delayed patient discharge and occupation of hospital beds,

aspiration, dehydration, electrolyte disturbances, and the opening of the sutures, which are more debilitating and harassing than the surgery itself for some patients. Therefore, prevention and treatment of these complications are very important (2, 3). Based on previous surveys on children undergoing strabismus surgery, the size of nausea and vomiting has been reported to range from 48 to 85% (4). Problems caused by nausea are more prevalent in eye surgery than other surgeries (5). Nausea is the most un-

pleasant complication of eye surgery, especially strabismus surgery (5), since it can lead to increased pressure inside the eye and the associated injuries which may affect patient's eyesight with eyes rupture and surgical procedures (6). Increased rates of nausea after eye surgery, especially muscle surgery, raise ocular reactions - gastric hypothesis. In fact, the surgical repair may be endangered with a sudden increase in intraocular pressure, which leads to vomiting as a result of nausea. Thus, for these reasons, to keep balancing the intraocular pressure of the eye after surgery is one of the most important goals. Therefore, to prevent an increase in intraocular pressure, it is necessary to design nursing interventions to control nausea in patients undergoing eye surgery. So far, none of the pharmaceutical methods is accepted as a standard method for inhibiting nausea and vomiting after strabismus surgery (7). Drugs used to prevent and treat nausea and vomiting after surgery include anticholinergics, phenothiazines, antihistamines, butyrophenone, benzamides, etc. (7, 8). It should be noted that anti-nausea and vomiting prevention drugs are not good for patients undergoing surgery, since routine use of these drugs causes side effects that may cause more drug interactions and prolonged hospitalization (9). Restlessness, dry mouth, drowsiness, tachycardia, hypotension, and fatigue are among complications of drug treatment (8). So far, none of the medical methods is accepted as a standard and effective method for inhibiting nausea and vomiting after strabismus surgery. Many studies have demonstrated that stimulation of the P6 acupuncture point reduces nausea and vomiting after surgery (10-15). However, the results of some studies on children are different (16-18). Laser acupuncture is painless and is not associated with side effects of traditional acupuncture needle (burning, blistering, redness, & pain), and that is why it can be more easily accepted by children (10, 19). Children account for most of the patients undergoing strabismus surgery, and it seems that P6 point is more effective in hollow organs of children compared with adults. On the other side, BL10, BL11, and GB 34 points located on the eye meridians are related to eye energy channels, which can prevent eye stimulation and vomiting (20). On the one hand, three points of BL10, BL11, and GB34 are located on the eye meridians and may be effective in reducing vomiting. Also, strabismus surgery relates to the eye area and stimulation of these points may be more effective than the P6 point. Besides, acupuncture does not have any of the side effects of antiemetic drugs such as drowsiness, low blood pressure, and extra pyramidal symptom. The literature review showed that no similar study has been conducted in this respect.

2. Objectives

The present study aimed to compare the effect of stimulation of BL10, BL11, and GB34 acupuncture points with P6 point using a low-level laser on the prevention of vomiting after strabismus surgery.

3. Methods

The present study used a randomized and double-blind clinical trial design. This study was conducted at Imam Khomeini Hospital (governmental and referral hospital) of Ahvaz, Iran, in 2015. The study was preceded by the approval of the Research Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (AJUMS) (in compliance with the Declaration of Helsinki) and registered in the Iranian Registry of Clinical Trials (IRCT) with the registration code of IRCT2017011917268N2. Written informed consent was obtained from all patients and their parents. Sixty-three patients who were candidates for strabismus surgery were enrolled to compare the effect of stimulation of BL10, BL11, and GB34 acupuncture points with P6 point using a low-level laser on the prevention of vomiting after strabismus surgery. The amount of vomiting was recorded 2, 6, and 24 hours after the surgery.

The sample size was calculated in agreement with Schlager et al.'s study (21) using the following parameters: $\alpha = 0.05$, $d = 0.25$, $p_1 = \%25$ (incidence of vomiting in the laser stimulation group), $p_2 = \%85$ (incidence of vomiting in the placebo group). The sample size was calculated using the following formula:

$$n = \frac{Z_{1-\frac{\alpha}{2}}^2 [P_1 (1 - P_1) + P_2 (1 - P_2)]}{d^2}$$

We considered 21 samples in each group (sum 63).

3.1. Patients

Eligible patients who met inclusion criteria were considered as candidates for strabismus surgery. The inclusion criteria encompassed children and adults with ASA I (American Society of Anesthesiology) physical status, and the age range of 3-35 years. The exclusion criteria included: history of any diseases that could lead to nausea or vomiting like motion sickness, gastrointestinal disorder, and ear diseases, long surgeries (more than 2 hours), patients who received antihistaminic or antiemetic 24 hours before the surgery, history of nausea and vomiting after surgery (PONV) in the last week, and history of smoking (adult patients).

3.2. Randomization and Blinding

Using a computer-generated randomization list, participants were divided into three groups (21 patients in each group): Group I (laser acupuncture P6), group II (laser acupuncture BL10, BL11, GB34), and group III (control). Laser stimulation was implemented for acupuncture points (P6, BL10, BL11, and GB34) for 60 seconds, 15 minutes before anesthesia induction, and 15 minutes after their arrival in the PACU. Group III (control) received placebo (laser off) stimulation on the sham point.

The physicians who performed the intervention were different from the anesthetists who evaluated the patients for the number of nausea and vomiting in a recovery room. Also, the nurses of the ward had no information regarding the patients' grouping. Therefore, the trial was run using a double-blinded technique (Figure 1).

3.3. Study Protocol

At first, the purpose of the study was described to the patients and their parents before the surgery. Patients entered the study after completing the written consent from (by parents or adult patients). For all patients, we noted age, sex, and duration of surgery and anesthesia. The vital signs of inclusive blood pressure (systolic and diastolic), pulse rate, Oxygen saturation (SaO₂), End-tidal carbon dioxide (CO₂) were monitored before and during anesthesia.

The surgical operation was done for all patients by an eye specialist group and its assistants. All the patients were allowed to eat solid foods or transparent liquids 6 hours before the anesthesia. The premedication was performed using Midazolam (0.2 mg/kg IM) and Atropine (0.02 mg/kg) and one hour before transferring the patients to the operation room. EMLA Cream 5% (Astra, Austria) was used for painless IV line insertion. Necessary monitoring was connected to the patients. General anesthesia induction was performed using Thiopental (4-6 mg/kg), Atracurium (0.5 mg/kg), and Fentanyl (1 µg/kg). After intubation, anesthesia was maintained in oxygen and Isoflurane using 66.6% Nitrous oxide. Fluids shortage was offset using Ringer Lactate (4mL/kg). Residual neuromuscular block (reverse) was neutralized using Prostigmin (0.05 mg/kg) and Atropine (0.025 mg/kg). All patients were transferred to the PACU after complete recovery (score of 10 based on Post Anesthetic Recovery Scoring System (Aldrete) (22)).

Acupuncture points were stimulated using a stimulation device called L3728 Pointer Pulse II Dual Probe Laser & T.E.N.S (Figure 2) made in Hong Kong. (Stimulation-pulse frequency: 1-16 Hz x1 = X10 = 10-160 Hz (adjustable)/Width Stimulation pulse: x1 = X10 = 200 µ 300 µ (fixed)). It was used with a low power laser probes, the output of less than

5mw, and wave length of 650 nm for 60 seconds, 15 minutes before anesthesia induction and 15 min after their arrival in the PACU. Laser stimulation was done in groups I and II and respectively on the points of p6 and BL10 and BL11 and GB34. Group III (control) received placebo (laser off) stimulation on the sham point. Also, acupuncture points stimulation was performed by the same researcher. There were no side effects in the patients receiving acupuncture.

3.3.1. Acupuncture Point Location

P6: Nei Guan (P6) is located three fingerbreadths below the wrist on the inner forearm between the tendons of palmaris longus and flexor carpi radialis (Figure 3).

BL-10 (Tian Zhu): This acupoint is located in the depression on the lateral aspect of m. trapezius, 1.3 cun lateral to the midpoint of the posterior hairline, and about two fingers breadth to Yamen (GV 15) (Figure 4).

BL-11 (Da Zhu): It is located 1.5 cun lateral to Taodao (DU-13) at the level of the lower border of the spinous process of the first thoracic vertebra (Figure 5).

GB-34 (Yang Ling Quan): This is located in the depression anterior, inferior to the head of the fibula, and between the peroneus longus and extensor digitorum longus muscles (Figure 6).

All patients were found to be normal and had the same conditions. Patients who needed specific method or medication during anesthesia were excluded of the study.

3.4. Assessment

The number of vomiting occurred during the period that the patient stayed in the recovery room (2 hours after surgery) and ward (6 and 24 hours after surgery) was recorded by an anesthesia assistant (recovery room) and a trained nurse (ward) (who did not know the trial technique) through questions and clinical observations. The following definition of vomiting was formed: an act or instance of disgorging the contents of the stomach through the mouth.

3.5. Statistical Methods

Statistical analysis was conducted using IBM SPSS Statistics for Windows, version 19.0 (IBM Corp., Armonk, N.Y., USA) via descriptive statistics, mean and standard deviation of the demographic data (age, duration of surgery). The incidence of vomiting was mentioned in terms of frequencies (n) and percentages (%). In this study, in order to compare the incidence of vomiting between 2 or 3 groups, Chi-square tests were applied. P < 0.05 was considered as the significant level.

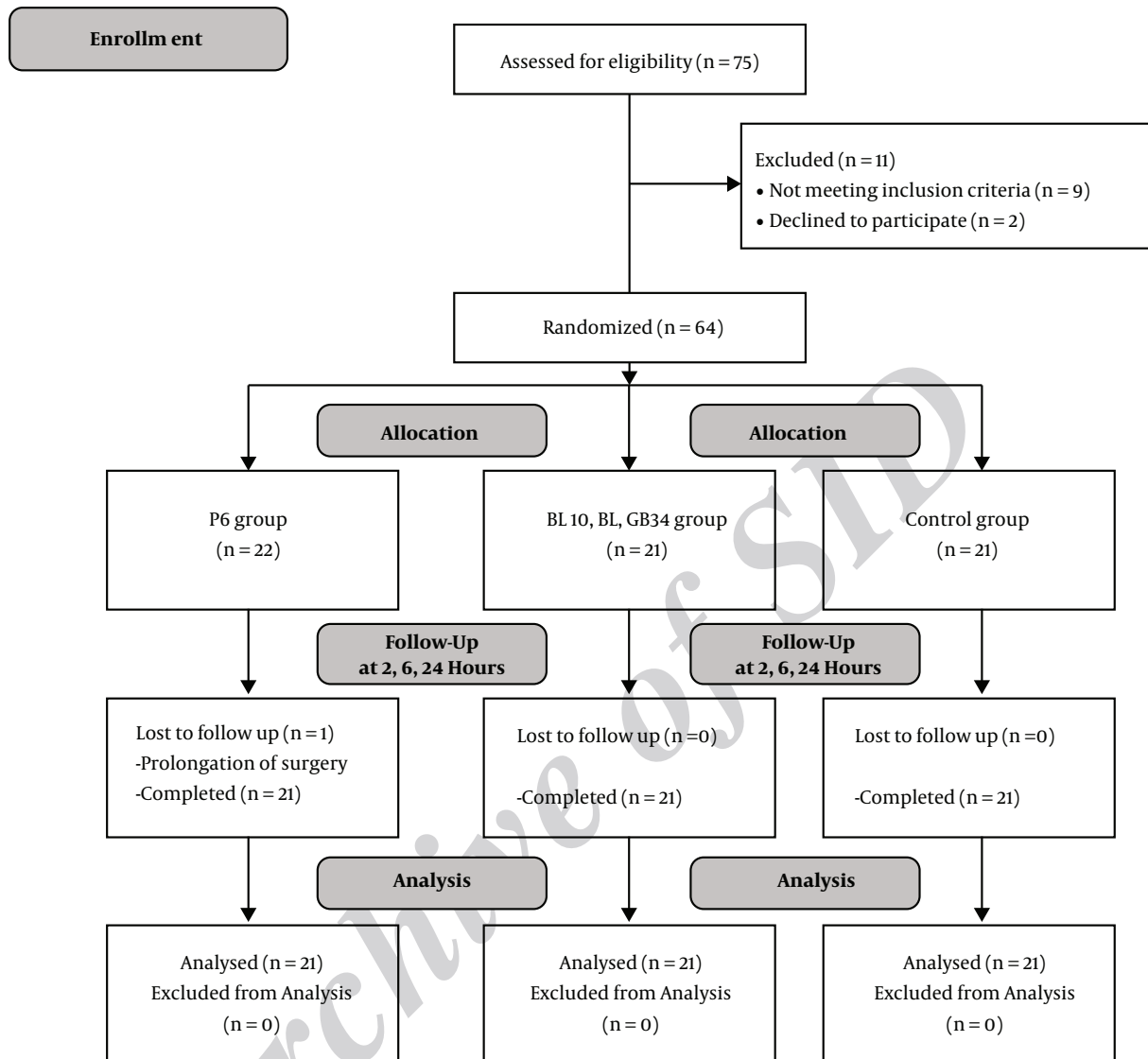


Figure 1. Flow chart of patients in trial

4. Results

The demographic data of the three groups (age, sex, duration of surgery) is shown in Table 1. There was no statistically significant difference between the 3 groups in terms of the demographic data ($P > 0.05$).

Table 2 shows the number of vomiting after 2 hours in the 3 groups. The number of vomiting after 2 hours was lower in P6 and BL10 groups than in the control group.

Table 3 shows the number of vomiting after 6 hours in all 3 groups. There was no significant difference among the groups in terms of number of vomiting after 6 hours ($P =$

0.01). The number of vomiting after 6 hours in P6 and BL10 groups was lower than it was in the control group.

Table 4 shows the number of vomiting after 24 hours in all 3 groups. The number of vomiting after 24 hours was lower in P6 and BL10 groups than in the control group.

Pairwise *t*-test comparison of the three groups showed that there was a significant difference between P6 and control groups in terms of the mean number of vomiting 2 hours after the surgery ($P = 0.03$). In contrast, there was no significant difference between P6 and BL10 as well as the control and BL10 groups in this respect. However, the mean number of vomiting two hours after the surgery in

Table 1. Demographic and Relevant Data^a

	P6 Point, (n = 21)	BL10 Point, (n = 21)	Control, (n = 21)	P Value
Age, y	15.11 ± 9.11	14.53 ± 9.29	13.64 ± 11.32	0.77
Sex, No. (male/female)	9/12	12/9	8/13	0.83
Duration of surgery, min	74 ± 13.53	73.30 ± 11.31	71.30 ± 12.2	0.65

^aValues are expressed as mean ± SD unless otherwise indicated.

Table 2. Numbers of Vomiting 2 Hour After Surgery in Study Groups^a

Numbers of Vomiting 2 Hour After Surgery	P6 Point, (n = 21)	BL10 Point, (n = 21)	Control, (n = 21)
0	17 (81)	16 (76.2)	13 (61.9)
1	2 (9.5)	2 (9.5)	3 (14.3)
2	2 (9.5)	4 (19)	2 (9.5)
3	0 (0)	0 (0)	1 (4.8)
4	0 (0)	0 (0)	1 (4.8)

^aValues are expressed as No. (%).

Table 3. Numbers of Vomiting 6 Hour After Surgery in Study Groups^a

Numbers of Vomiting 6 Hour After Surgery	P6 Point, (n = 21)	BL10 Point, (n = 21)	Control, (n = 21)
0	12 (57.1)	12 (57.1)	13 (61.9)
1	9 (42.9)	7 (33.3)	1 (4.8)
2	0 (0)	1 (4.8)	6 (28.6)
3	0 (0)	1 (4.8)	1 (4.8)
4	0 (0)	0 (0)	0 (0)

^aValues are expressed as No. (%).

Table 4. Numbers of Vomiting 24 Hour After Surgery in Study Groups^a

Numbers of Vomiting 24 Hour After Surgery	P6 Point, (n = 21)	BL10 Point, (n = 21)	Control, (n = 21)
0	20 (95.2)	19 (90.5)	15 (71.4)
1	1 (4.8)	1 (4.8)	4 (19)
2	0 (0)	1 (4.8)	1 (4.8)
3	0 (0)	0 (0)	0 (0)
4	0 (0)	0 (0)	1 (4.8)

^aValues are expressed as No. (%).

BL10 was lower than it was in the control group. There was no statistically significant difference between P6 and control and P6 and BL10 groups in terms of the mean number of vomiting 6 hours after the surgery. It was also found that there was a significant difference between P6 and control ($P = 0.04$) in terms of the mean number of vomiting 24 hours after the surgery. On the other hand, there was no significant difference between P6 and BL10 and BL10 and control groups. However, the mean number of vomiting 24 hours after the surgery in BL10 group was lower than it was the control group.

5. Discussion

The results of the present study showed that there were statistically significant differences among the groups in terms of the number of vomiting after 6 hours ($P = 0.01$). It was also found that laser stimulation of P6 point reduced the incidence of vomiting after strabismus surgery compared with the control group, which is consistent with the results obtained in previous studies. In a double-blind clinical trial, Schlager et al. studied the effectiveness of laser stimulation of acupuncture P6 point in the incidence



Figure 2. Stimulation device



Figure 3. P6 point

of vomiting after strabismus surgery in children. In this study, a total of 60 children aging 3 to 12 years with the physical status of ASA I and II were randomly assigned to two groups (laser acupuncture and placebo acupuncture). Laser stimulation of P6 point was performed 15 minutes before induction of anesthesia and 15 minutes after entering the recovery room. The incidence of vomiting in the laser acupuncture group was significantly less than the placebo acupuncture group ($P = 0.0001$) (21). Ozmert conducted a study to investigate the antiemetic effects of acupuncture on 70 children with ASA I-II and the age range of 2 to 14 years, who underwent tonsillectomy or adenoidectomy surgery. The results of the study showed that the incidence of postoperative vomiting (POV) in the acupuncture group was significantly lower than it was in the control group (23). In a clinical trial, Liodden et al. studied the effects of preoperative acupuncture and postoperative acupressure on PONV in children undergoing tonsillectomy and adenoidectomy surgery. In this study, 82 children aged 1 - 11 years with physical status of ASA I and II were randomly assigned into two groups (acupuncture/acupressure and standard treatment). In addition to standard treatments, point P6 acupuncture (before and during anesthesia) and postoperative wristband acupressure were performed in

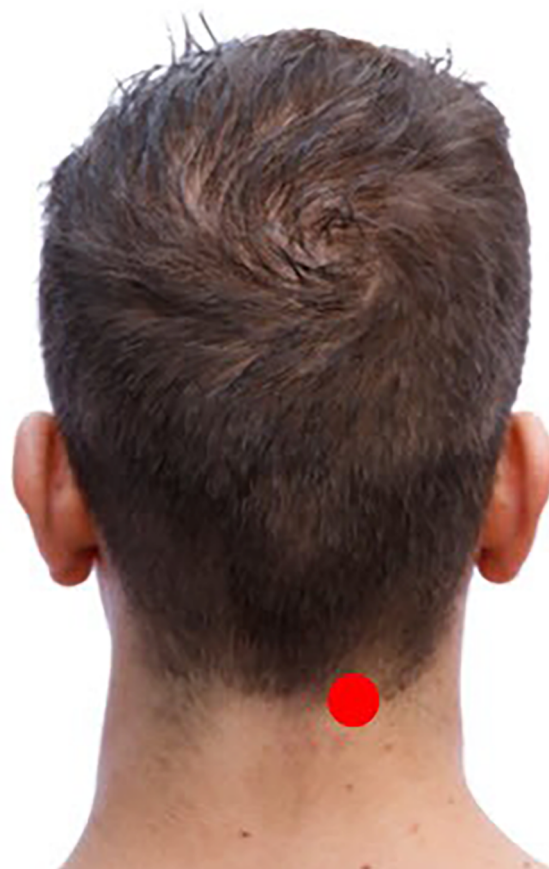


Figure 4. BL-10 point

the treatment group. The results of this study showed that the treatment group experienced (46.8%) less nausea and vomiting than the control group (66.2%) did ($P = 0.015$) (24). In a study, Saleh evaluated the effect of laser acupuncture on PONV in strabismus surgery. In this study, 60 children aged 3 - 12 years with physical status of ASA I, II were randomly divided into three groups (laser acupuncture/ondansetron /control). P6 point was stimulated using a laser for 30 seconds, 15 minutes before anesthesia induction, and 15 minutes after arrival in the recovery room. The incidence of PONV was evaluated in three stages of 0 - 1 hour, 1 - 6 hours, and 0 - 12 hours after the surgery. In the control group, the incidence of PONV was significantly ($P < 0.046$) higher than it was in the laser acupuncture and ondansetron groups (0.15 mg/kg IV). There was no statistically significant difference between laser acupuncture and ondansetron groups in terms of the incidence of PONV (25). Ebrahim Soltani et al. performed a study on 200 patients to compare the prophylactic effects of P6 point acu-

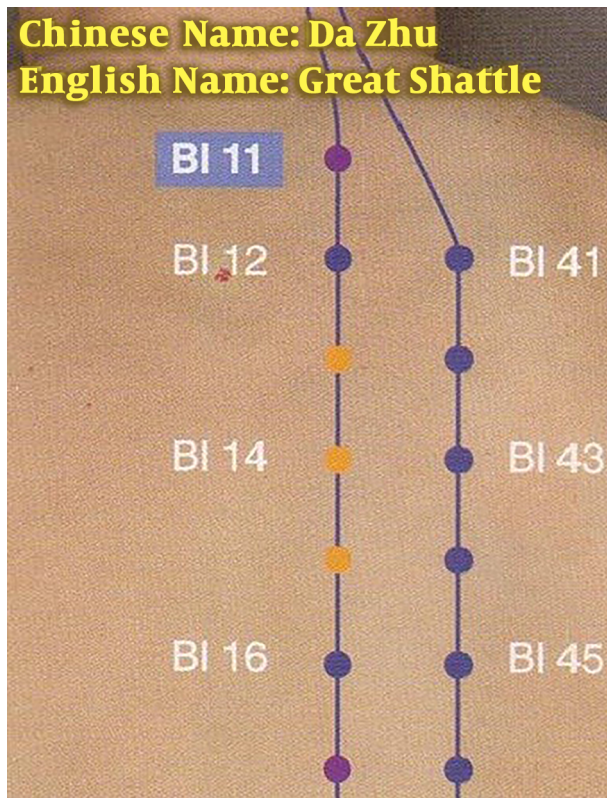


Figure 5. BL-11 point



Figure 6. GB-34 point

pressure with ondansetron and metoclopramide on the prevention of PONV in strabismus surgery. There was no statistically significant difference between acupressure using ondansetron versus metoclopramide in terms of the incidence of PONV. Acupressure using ondansetron (0.15 mg/kg) and metoclopramide (0.2 mg/kg) reduced the incidence of PONV 24 hours after strabismus surgery in the

patients aged 10 years and above (26).

The results of the present study showed that laser stimulation of BL10, BL11, and Gb34 points, compared to the control group, reduced the incidence of vomiting after strabismus surgery, which is consistent with the results obtained in the previous studies. The results of the present study also showed that the incidence of PONV in groups receiving laser stimulation of BL10, BL11, and Gb34 points was lower, compared to the control group; however, this difference was not statistically significant. Also, Laser stimulation of BL10, BL11, and Gb34 points made no significant changes in terms of the incidence of PONV in comparison with P6 point.

In fact, laser stimulation of P6 point, compared to BL10, BL11, and Gb34 points, was more effective in reducing the incidence PONV, although this difference was not statistically significant. After a systematic search, only one study on stimulation of BL10, BL11, and Gb34 was found. In the study, Chu et al. examined the effect of acuplaster stimulation of BL10, BL11, and GB34 on the prevention of vomiting after strabismus surgery in children. In this study, a total of 60 children aged 3-14 years with physical status of ASA I were randomly divided into two groups: placebo group (n = 31) and the acuplaster group (n = 34). The evaluation of the incidence of vomiting was carried out in two stages (PACU and ward). In the PACU, the incidence of vomiting was 35.5% and 14.7% in the placebo and acuplaster groups, respectively ($P < 0.05$). In the ward, the incidence of vomiting was 58.1% and 23.5% in the placebo and acuplaster groups, respectively ($P < 0.05$), which was a significant difference. Finally, it was concluded that acuplaster stimulation of BL10, BL11, and GB34 points significantly reduced the rate of vomiting after strabismus surgery (20), which is consistent with the results obtained in the present study. Acuplaster was used in the study conducted by Chu, while these points were stimulated using a laser in the current study. Moreover, in Chu's study, acuplaster stimulation of BL10, BL11, and GB34 points was performed the night before the surgery, while, in the present study, laser stimulation of these points was performed with an output of less than 5mw and wavelength of 650nm for 60 seconds, 15 minutes before anesthesia induction, and 15 minutes after entering the PACU. Of course, the differences mentioned in the final results are impressive.

5.1. Conclusions

Based on the findings, laser acupuncture of P6 point reduced the incidence of vomiting after strabismus surgery. Also, Laser acupuncture of BL10, BL11, and GB34 points depicted no significant difference, in comparison with P6 point, in the incidence of PONV. P6 point is still the most

effective point in controlling the incidence of PONV. In order to more clarify the matter, further studies are recommended in this area.

5.2. Limitation

Some patients did not undergo strabismus surgery at older ages due to the environmental conditions and cultural and financial problems.

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Footnotes

Clinical Trial Registration: The study was registered in the Iranian Registry of Clinical Trials (IRCT) with the ID: IRCT2017011917268N2.

Conflict of Interests: There was no conflict of interests.

Ethical Approval: The study was preceded by the approval of the Research Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (AJUMS) (in compliance with the Declaration of Helsinki).

Funding/Support: This research was financially supported by Ahvaz Jundishapur University of Medical Sciences (AJUMS).

Patient Consent: Written informed consent was obtained from all patients and their parents.

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