

Postoperative pain control of subtenon bupivacaine injection in adult strabismus surgery: a double-masked randomized trial

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Background: Pain from intraoperative retraction of extraocular muscles is the main cause of ocular discomfort after strabismus surgery. Injection of the long-acting local anesthetics can reduce ocular pain after strabismus surgery under general anesthesia.

Purpose: To evaluate the efficacy of subtenon bupivacaine injection on postoperative pain control

Methods: A prospective double-masked randomized trial was conducted in 18 eyes of 9 patients (age range 20-67 years) who underwent binocular strabismus surgery under general anesthesia at Thammasat hospital. Both eyes of each patient were randomized to receive subtenon injection with 0.5% bupivacaine 0.1 ml in one eye and sterile saline injection in the fellow eye at the end of surgery. Primary outcome measures were visual rating pain scores at 30 minutes, 1 hour, 4 hours and 6 hours postoperatively. Secondary outcome measures were adverse effects of bupivacaine injection. Oral acetaminophen was added as per patient pain requirement. The doses of this adjunctive analgesia were recorded.

Results: Average pain score between study group vs control group was 1.33 vs 2.66, 1.44 vs 2.77, 1 vs 1.66 and 0.3 vs 1.3 in the first 30 minutes, 1 hour, 4 hours and 6 hours, respectively. Pain scores at the first 6 hours postoperatively were significantly lower in the study group (P=0.001).

Discussion: Adjunctive subtenon bupivacaine injection had effects at the first 6 hours postoperatively in adults undergoing strabismus surgery with general anesthesia technique.

Conclusion: Subtenon injection of bupivacaine may reduce postoperative pain score in adult strabismus surgery.

Keywords: bupivacaine, subtenon injection, strabismus surgery

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Background:

In adult strabismus surgery, either regional anesthesia or general anesthesia can be used for providing anesthesia. Most steps in strabismus surgery are not painful procedures. The main cause of pain is produced by pulling on or against a restricted muscle or in cases with large angle of deviation which surgical exposure is difficult.¹ In cooperative patients, regional anesthesia is effective for control of the pain. In poor

cooperative adults or patients undergoing binocular surgery, the patient cannot remain still for long periods, general anesthesia may be the usual method for providing anesthesia. However, postoperative pain still causes patients to have ocular discomfort after surgery. Injection of long-acting local anesthetics can reduce ocular pain after strabismus surgery under general anesthesia.

Subtenon block was first described by Turnbull in 1884 and later by Swan in 1956.^{2,3} Then, in early 1990, sub-tenon's block was introduced into the clinical practice.^{4,5} The sub-tenon's block is used for cataract surgery, vitreoretinal surgery, trabeculectomy, strabismus surgery and postoperative pain control.^{6,7}

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Bupivacaine (Marcaine) has a slower onset of action (about 5-10 minutes after injection) but its effects last much longer, for about 4-8 hours. This injection is currently a procedure performed under regional anesthesia in cooperative adults, and has been used as an alternative procedure to decrease postoperative control.

In Thammasat hospital, when talking to the patients about the postoperative pain and choice of anesthesia, most patients are afraid of pain and would like to choose general anesthesia rather than local anesthesia. In the past, we performed adult strabismus surgery under general anesthesia in every case. The aim of the present study (primary outcome) was to compare the postoperative pain score in the first day after surgery. Secondary outcome was to compare adverse effects of subtenon bupivacaine injection.

Methods:

The study was approved by the Medical Ethics Committee of Thammasat University (MTU-EC-OP-1-167/60), Pathum thani, Thailand, and was conducted in accordance with the tenets of the Declaration of Helsinki. The study was conducted from 1st November, 2017 to 30th September 2018 in the Department of Ophthalmology, Thammasat Hospital. Subjects with comitant or incomitant strabismus were enrolled. The inclusion criteria included healthy subjects of either gender between the age of 20 to 70 years old, no previous strabismus surgery and no contraindication of general anesthesia. Subjects with a history of bupivacaine allergy, a history of drug use that have drug interaction with bupivacaine, female during pregnancy and lactation period, or subjects who do not communicate during pain score test were excluded.

Data collected consisted of age, gender, underlying disease, drug history, anesthetic history, best corrected visual acuity (BCVA) by Snellen chart, anterior segment, pupils, fundus examination, ocular motility, strabismus examination by alternate prism cover test, preoperative vital signs, dose of subtenon bupivacaine injection, postoperative vital signs, postoperative pain score at 30 minutes, 1 hour, 4 hours, 6 hours, 8 hours, 12 hours and 24 hours after surgery respectively. The study protocol was performed with

informed consent and the protocol was explained to all subjects before undergoing general anesthesia.

Study protocol:

Both eyes of each patient were randomized into two groups to receive either subtenon bupivacaine injection (study group; n=9 eyes) or sterile saline injection (control group; n=9 eyes). A single surgeon performed the fornix technique on all patients. Neither the patient nor surgeon knew which treatment the patient was randomized to. In the study group, an injection of 0.5% bupivacaine 0.5 ml was performed using a curved blunt 19-gauge cannula into the subtenon space through the fornix conjunctival incision at the end of the surgery. Pain assessment was performed by the co-author blinded as to the treatment group. The technique to be used for each eye was revealed by a surgical nurse thereafter. If the patient complained of pain postoperatively (pain score > 5), oral acetaminophen 500 tablet 2 tabs every 6 hours was given as adjunctive analgesia. The dose of oral acetaminophen can be added up to the satisfaction of the patient and the doses were recorded. Pain scores using the visual rating scale (score 0-10; 0 = very satisfied, 10 = very dissatisfied) in Thammasat Hospital. Bupivacaine-induced adverse effects were considered to present if the patients have central nervous system (CNS) or cardiovascular adverse effects such as convulsions, coma, arrhythmia, myocardial depression, and respiratory arrest postoperatively. Adverse effects and data as described above were collected by the co-author.

Statistical analysis:

We analyzed the data with excel tables (Microsoft windows XP professional version 2002 service pack3) and the statistical analysis was performed with SPSS software version 14.0 (IBM Inc, Chicago, IL). Demographic data are described in terms of mean and range. The data were analyzed statistically by using paired t-test to compare the result in both groups and the p-values were obtained. A p-value of less than 0.05 indicates statistical significance.

Results:

Nineteen cases of adult horizontal strabismus were enrolled in the study period. Ten cases of patients having monocular surgery (recess-resect procedure) or previous strabismus surgery was excluded. Nine healthy subjects (18 eyes) were included in the study. They had a mean age of 30 years (range 20 to 67 years). Six were female and three were male. All surgeries were performed in the operating room by an anesthesiologist experienced in the general anesthetic technique. Average pain score was 1.33, 1.44, 1, 0.3, 0.44, 0.22 and 0 in the first 30 minutes, 1 hour, 4 hours, 6 hours, 8 hours, 12 hours and 24 hours in the study group, respectively. Average pain score was 2.66, 2.77, 1.66, 1.3, 1.11, 0.33 and 0 in the first 30 minutes, 1 hour, 4 hours, 6 hours, 8 hours, 12 hours and 24 hours in the control group, respectively. There were significant differences in pain scores at 30 minutes ($p=0.002$) and at 6 hours postoperatively ($p=0.001$). There were no significant differences in postoperative pain score at the other time intervals (Figure 1). However, all patients are generally satisfied with subtenon bupivacaine injection. None of the patients manifested bupivacaine-induced adverse effects. Postoperative adjunctive analgesia was not given because no patient had complained of having a pain score greater than 5.

Discussion:

Although it is a randomized controlled trial, the authors compared fellow eyes of each patient to account for each individual's difference in pain tolerance and subjective pain threshold. Therefore, the authors would like to minimize the differences, then study the patient with unilateral surgery compared with sham injection. Moreover, the same patient will receive the same amount of general anesthetic drug. The authors included only horizontal muscle surgeries in this study because patients with strabismus surgery on vertical or oblique muscle surgery need to hook the muscle further and the intraoperative pain is often intolerable. This study excluded vertical or oblique muscle surgery.

In 2015, Bakr et al. studied a randomized controlled double blinded trial in children strabismus surgery. Sixty children (age range 2-6 years) were randomized to receive either subtenon bupivacaine 0.5% or a saline injection

before the beginning of surgery in a double-blind manner. He found that the pain scores were significantly lower in the subtenon bupivacaine group at 0 min ($p = 0.0056$) and at 30 min ($p = 0.013$). There was no significant difference between the two groups at the other time intervals. This study provided some evidence that a preoperative subtenon block with bupivacaine combined with general anesthesia allows efficient control of postoperative pain in young children undergoing strabismus surgery.⁸

In 2017, Talebnejad et al. studied a randomized controlled double blinded trial in children strabismus surgery. Fifty children (age range 8-17 years) were randomized to receive either subtenon bupivacaine 0.5% or a saline injection just prior to surgery in a double-blind manner. He found that the pain scores (using the Visual Analog Scale) were significantly lower in the subtenon bupivacaine group (mean score, 2.8 vs. 5.9 at 60 minutes after surgery; $P < 0.001$). This study provided some evidence that subtenon bupivacaine injection can also diminish postoperative pain in patients who underwent strabismus surgery.⁹

In the present study, we found that the average postoperative pain scores in patients in both groups were low and subtenon bupivacaine injection was associated with significant differences in pain score at 30 minutes and at 6 hours postoperatively. Similar results have been described in a previous study at 30 minutes.⁸ Our findings can be attributed to the duration of local bupivacaine action up to 4-8 hours. However, we did not find significant differences in postoperative pain score at 60 minutes as the previous study and the other time intervals. In fact, the control eye in the present study did not represent the good control group as previous studies.⁹ The limitations in the present study is a small amount of sample size due to a small number of adult patients, and some adult patients who have a history of previous strabismus surgery also had been excluded.

Conclusion:

In the present study, we evaluated the efficacy of subtenon bupivacaine injection on postoperative pain control and we found that this injection may reduce pain scores in adult strabismus surgery at early postoperative time intervals. Our results could help ophthalmologists

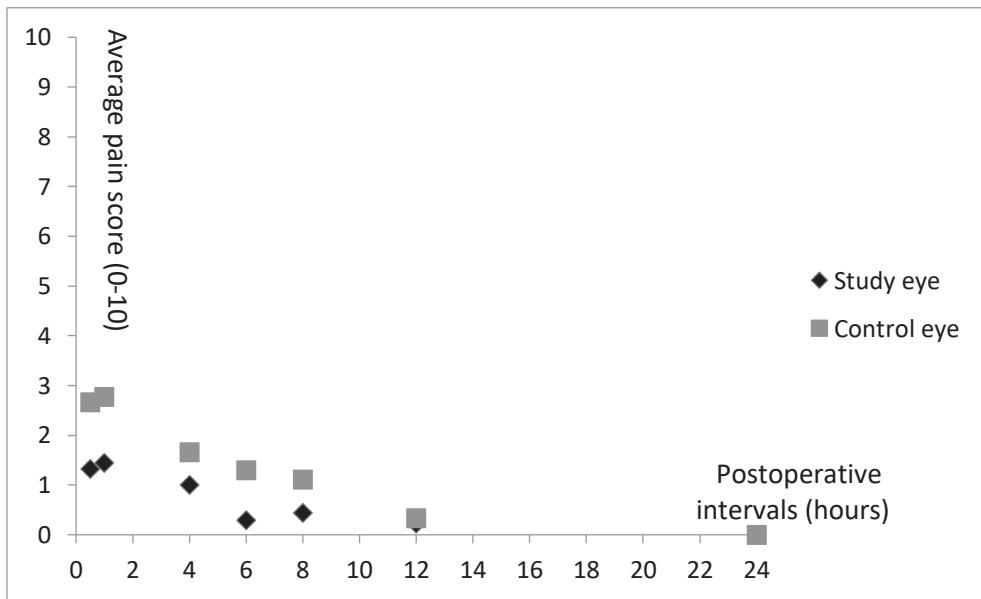


Figure 1 Average pain scores in the first day postoperatively

inform patients before making a decision regarding their choice of anesthesia.

Conflict of interest: no

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