

The efficacy of intravenous ketorolac for pain relief in single-stage adjustable strabismus surgery: a prospective, randomized, placebo-controlled trial

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Abstract

Purpose To determine the efficacy of preoperative intravenous ketorolac in reducing intraoperative and postoperative pain and improving patient satisfaction in patients undergoing single-stage adjustable strabismus surgery.

Methods A prospective, randomized, placebo-controlled clinical trial was performed with 67 patients who underwent horizontal recti muscle surgery with adjustable sutures. The test group received intravenous ketorolac (60 mg) before surgery, and the control group received intravenous normal saline. Topical 0.5% proparacaine was administered to both groups during surgery. Vital signs including heart rate and blood pressure were recorded every 10 min throughout the surgery. The patients were asked to rate their maximum intraoperative and postoperative pain scores using a numerical pain rating scale. Patient satisfaction was also assessed using a five-point analogue scale.

Results The ketorolac-premedicated patients had less pain both during and after surgery ($P = 0.033$ and $P = 0.024$, respectively). There were no differences in vital signs during surgery and patient satisfaction between the two groups.

Conclusions Intravenous ketorolac, when administered preoperatively for single-stage adjustable strabismus surgery under topical anaesthesia, was effective in reducing pain during and after surgery.

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Keywords: one-stage adjustable strabismus surgery; topical strabismus surgery; ketorolac; eye pain; prospective; randomized trial

Introduction

Strabismus surgery aims to achieve precise ocular alignment and can be performed either traditionally (non-adjustable) or with adjustable sutures. In traditional strabismus surgery, one cannot alter the results once the surgery is complete, often yielding unpredictable results. In an effort to reduce this problem, adjustable suture surgery was described and popularised by Jampolsky in 1965.¹

The use of adjustable sutures in strabismus surgery has decreased the re-operation rate to <10% (vs 20% with traditional strabismus surgery).² Adjustable suture surgery also reduces the systemic risk to the patient as it is done under local anaesthesia, making postoperative recovery shorter and easier.²

Adjustable suture surgery is usually carried out in two stages; in the first stage, surgery is performed under general or regional anaesthesia. Once the effects of the anaesthesia dissipate, the second stage adjustment can be performed.³ The adjustable procedure is tricky for both surgeons and patients, as it is usually performed outside the operating room, and

carries an increased risk of infection. Furthermore, the surgeon must wait for the anaesthetic effects to diminish, often causing patients to experience prolonged anxiety during this waiting stage. Single-stage adjustable suture surgery eliminates these problems. The ability to perform adjustments in the operating room during the surgery is more attractive with regard to patient monitoring, sterility, comfort, and timing.⁴ Additionally, the stability of one-stage adjustable sutures has been reported to be comparable to that of more widely used two-stage adjustable sutures.^{3,5,6}

One drawback of single-stage adjustable suture surgery under topical anaesthesia is that patients typically experience more pain and discomfort during surgery, which leads to increased stress for both the surgeon and the patient.³ Patient compliance is essential during adjustable suture surgery, thereby making effective pain control a top priority.

Ketorolac tromethamine is a non-narcotic analgesic that inhibits cyclooxygenase activity in the arachidonic acid cascade and interferes with prostaglandin production. Ketorolac is a non-steroidal anti-inflammatory drug (NSAID) with a 6 h half-life.⁷ It has been reported to have fewer side effects than narcotic analgesics, resulting in notably less sedation, nausea, and respiratory depression.⁸⁻¹⁰ These properties make ketorolac a potential solution for pain control in patients undergoing strabismus surgery. The effect of ketorolac has been evaluated in strabismus surgery; however, in these studies, the patients were under general or periocular anaesthesia.¹¹⁻¹³

We prospectively evaluated the efficacy of preoperative intravenous ketorolac in reducing intraoperative and postoperative pain and in improving patient satisfaction in patients undergoing one-stage adjustable strabismus surgery.

Materials and methods

This study was conducted prospectively from November 2008 to September 2009. A total of 67 cases (greater than 10 years of age) of horizontal strabismus were enrolled. Patients with restrictive strabismus, myasthenia gravis, paralytic strabismus, thyroid eye disease, or previous retinal detachment surgery were excluded. Basic haematology (haemoglobin, erythrocytes, white blood cells, and platelets), prothrombin time, activated partial thromboplastin time, biochemistry (total protein, urea, creatinine, glucose, electrolytes, aspartate transaminase, and alanine transaminase), urine analysis, chest X-ray, and electrocardiogram (EKG) was screened preoperatively in all patients and patients who showed any abnormal results were excluded. Patients with obvious contraindications to ketorolac such as asthma,

renal dysfunction, peptic ulceration, bleeding disorders, cardiovascular disease, mental retardation, or allergy to ketorolac or NSAIDs were also excluded.

The angle of deviation was measured using the alternate prism cover test or the Krimsky corneal reflex method. Manifest refraction and fundus examinations were also performed in all patients.

Patients were randomly divided into two groups with comparable ages, gender ratios, and types of surgery. Patients in group 1 received intravenous saline placebo and patients in group 2 received intravenous ketorolac (60 mg) 30 min before surgery. One examiner received the treatment group assignment at the time of surgery and administered the study doses. All other personnel involved in the surgeries were masked as to the identity of the treatment groups. All patients were monitored intraoperatively for heart rate, continuous EKG, non-invasive blood pressure (NIBP), and oxygen saturation by pulse-oximeter. Another blinded examiner (WKK) assessed the maximum intraoperative and postoperative pain scores. Patient satisfaction was assessed 10 min following the completion of surgery.

In all patients, topical 0.5% proparacaine (Alcaine, Alcon-Couvreur, Puurs, Belgium) was instilled 10 min before and at the beginning of surgery in each eye and was additionally administered during the incisions of the conjunctiva and Tenon's capsule and also if the patient complained of discomfort during the surgery. The surgical techniques used in all patients included unilateral or bilateral recession or resection of the horizontal recti muscles with a limbal conjunctival incision. When surgery was performed on two muscles, the first muscle was operated on according to a preoperative estimation using conventional techniques. When the first phase of the surgery was completed, the patient was asked to sit upright on the operative table for adjustment. For patients who required spectacles, the spectacles were gas-sterilised, and an assistant held the frame of the spectacles in front of the patient during the examination in order to maintain sterile conditions. If the ocular alignment was theoretically correct and diplopia was not noted, the strabismus surgery was considered complete. If strabismus persisted, surgery was performed on the second muscle with an adjustable suture. All adjustable suture operations were performed with 6-0 Vicryl using a single-loop bow tie (the 'bow tie' technique).¹⁴ This knot consisted of a single overhand knot followed by a second overhand knot which was left in a single loop. This single-loop bow tie could be untied in order to adjust the position of the muscle. Ocular alignment was measured with the alternate prism cover test using a suitable fixation target for near and distance, while the patient was

in the sitting position. The Krimsky prism reflex method was used in patients with sensory strabismus. The adjustment phase was repeated until the theoretical correct position was achieved and no diplopia was noted in the primary gaze position. After the muscle was appropriately adjusted, the bow was tied off by first cutting the loop and then carefully withdrawing the cut suture, leaving the knot in place. The square knot remained in place, joining the pole suture. Finally, the conjunctiva was closed with 6-0 black silk.

A good result was considered an angle of deviation of < eight prism dioptres with an absence of diplopia.

For data analysis, SPSS statistical software (version 15.0; SPSS Inc., Chicago, IL, USA) was used. The χ^2 -test was used for qualitative data including sex, diagnosis of strabismus (exodeviation vs esodeviation), and type of surgery (recession only vs resection included). Comparison of continuous data including age, angle of deviation, and total duration of surgery was performed using the independent two-sample *t*-test. Repeated measure ANOVA was used for analysing heart rate, systolic NIBP, and diastolic NIBP recorded every 10 min during surgery. Multiple regression analysis with adjustments for age, sex, and type of surgery was used for comparing maximum intraoperative and postoperative pain scores and patient satisfaction scores. In this study, *P*-value < 0.05 was considered statistically significant.

We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during this research.

Results

During an 11-month period, 67 patients who underwent one-stage adjustable strabismus surgery performed by the same surgeon (JBL) met the study inclusion criteria and were randomized into the study (31 into the placebo group and 36 into the ketorolac premedicated group). There were no differences in patient characteristics, preoperative angle of deviation, duration of surgery, and type of surgery between the two groups (Table 1).

There were no differences in systolic blood pressure, diastolic blood pressure, (Figure 1) or pulse rate (Figure 2) during surgery between and within the two groups (*P* = 1.00, 0.70, and 0.37, respectively).

The patients premedicated with ketorolac had significantly less pain both during and after surgery (*P* = 0.033 and 0.024, respectively). Patient satisfaction showed no difference between the two groups (Table 2).

None of the patients exhibited any undesirable side effects related to ketorolac.

Table 1 Basic clinical characteristics of the patients

	Placebo (n = 31)	Ketorolac (n = 36)	P-value
Age (years)	20.84 ± 11.09	21.28 ± 14.04	0.102 ^a
Sex			0.202 ^b
Male	16 (51.61%)	13 (36.11%)	
Female	15 (48.39%)	23 (63.89%)	
Duration of surgery (minutes)	31.71 ± 8.14	29.72 ± 9.71	0.372 ^a
Diagnosis			0.953 ^b
Exodeviation	26 (83.9%)	30 (83.3%)	
Esodeviation	5 (16.1%)	6 (16.7%)	
Preop deviation (PD)	31.0 ± 9.81	32.14 ± 16.31	0.683 ^a
Surgery performed			0.581 ^b
Recession only	25 (80.65%)	27 (75.00%)	
Resection included	6 (19.35%)	9 (25.00%)	

Abbreviations: Preop, preoperative; PD, prism dioptres.

^aAnalysed by independent two-sample *t*-test.

^bAnalysed by χ^2 -test.

Data presented as mean ± SD or absolute numbers (%).

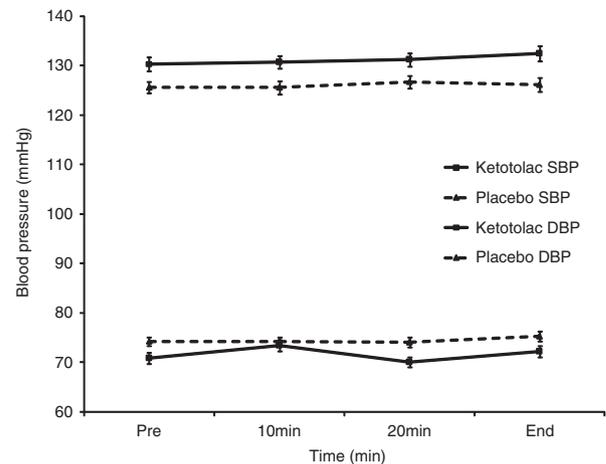


Figure 1 Comparison of blood pressures between the ketorolac and placebo groups. DBP, diastolic blood pressure; End, parameters measured at the conclusion of surgery; Pre, parameters measured at the beginning of surgery; SBP, systolic blood pressure; 10 min, parameters measured 10 min after initiation of surgery; 20 min, parameters measured 20 min after initiation of surgery.

Discussion

Adjustable suture strabismus surgery is thought to result in better ocular alignment and long-term stability compared with those of non-adjustable surgery.² Single-stage adjustable strabismus surgery involves adjustments during the operative period; in contrast, two-stage adjustable strabismus surgery involves

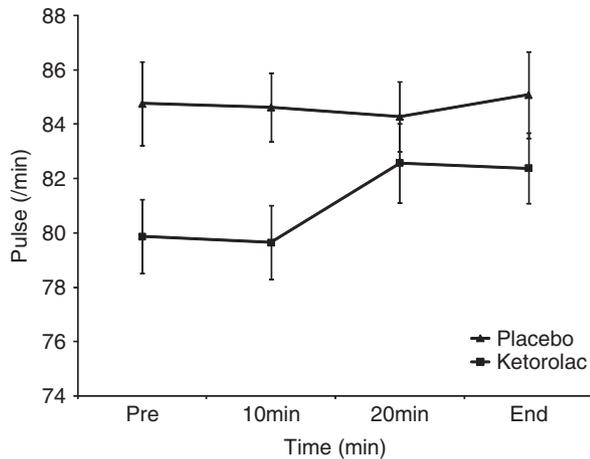


Figure 2 Comparison of pulse rates between the ketorolac and placebo groups. End, parameters measured at the conclusion of surgery; Pre, parameters measured at the beginning of surgery; 10 min, parameters measured 10 min after initiation of surgery; 20 min, parameters measured 20 min after initiation of surgery.

Table 2 Comparison of pain and patient satisfactions between the ketorolac and placebo groups

	Placebo (n = 31)	Ketorolac (n = 36)	P-value ^a
Maximal intraop pain	3.21 ± 1.29	2.76 ± 1.21	0.033
Postoperative pain	0.55 ± 0.96	0.13 ± 0.37	0.024
Patient satisfaction	4.06 ± 0.63	4.06 ± 0.53	0.640

Abbreviation: Intraop, intraoperative.

^aMultiple regression analysis with adjustments for age/sex/surgery type. Data presented as mean ± SD.

surgery performed under local or general anaesthesia followed by an adjustment 6–24 h later.¹⁵ The adjustable suture technique requires a fully awake and cooperative patient, recovery from anaesthesia, and return of muscle function.² A certain period of time is required for full recovery when peribulbar, retrobulbar, or general anaesthesia is used for strabismus surgery. This increases the time and cost of the hospital stay and increases the risk of complications including retrobulbar haemorrhage, eyeball perforation, optic nerve injury, and systemic complications that may occur following general anaesthesia. Despite these risks, single-stage adjustable surgery is known to be a safe procedure.^{6,15–19} The success rate of single-stage adjustable surgery is comparable to that observed in previous studies of two-stage adjustment surgery performed under general or retrobulbar anaesthesia.^{5,20,21} The primary disadvantages of single-stage adjustable surgery under topical anaesthesia include a longer procedure time and more intraoperative pain and discomfort of the patient.^{15,22}

In order to decrease pain and patient discomfort, we evaluated the effect of a single dose of intravenous ketorolac on intraoperative and postoperative pain during single-stage adjustable surgery in a prospective, randomized, placebo-controlled trial.

Ketorolac is a NSAID with an analgesic effect that becomes effective 30 min after dosing and reaches a maximum effect at 2 h.²³ The duration of strabismus surgeries is often short, and it would presumably be more effective to administer ketorolac before the surgical incision instead of at the completion of surgery. Ketorolac has proven to be effective in controlling perioperative pain and postoperative vomiting and nausea in strabismus and vitreoretinal surgeries.^{8–13,23–28} As narcotics can cause excessive sedation in patients, resulting in respiratory depression and delayed discharge, ketorolac is preferred in the prevention and treatment of postoperative pain in strabismus patients.

Mendel *et al*¹¹ reported that ketorolac was more effective in reducing postoperative vomiting in children undergoing strabismus surgery. Although postoperative pain scores did not differ significantly between the placebo and ketorolac groups, the scores in the ketorolac group tended to be lower. However, this study evaluated adjuvant ketorolac in childhood strabismus surgery performed under general anaesthesia. As such, it was impossible to accurately evaluate intraoperative and postoperative pain scores in preverbal children. Studies comparing the effects of intravenous ketorolac to those of pethidine²⁷ and morphine¹³ also showed that the efficacy of ketorolac was comparable to those of opioids; however, these studies had limitations similar to that of the study by Mendel *et al*.¹¹

Morrison *et al*¹² reported that intravenous ketorolac given at the conclusion of surgery was more effective than either oral acetaminophen or oral ibuprofen given 30–45 min after strabismus surgery in controlling postoperative pain. In their study, the patients were older than 12 years of age and surgery was performed under either general inhalational anaesthesia or local periocular lidocaine anaesthesia.

In the present study, we evaluated not only postoperative pain but also intraoperative pain during single-stage adjustable strabismus surgery under topical anaesthesia. Methods of local anaesthesia administration for strabismus surgery include retrobulbar, peribulbar, subtenons, and subconjunctival infiltration of local anaesthetic solution.²⁹ However, when these methods are used with an adjustable suture technique, a delay in adjustment of at least 6 h is required to make sure the effects of the local anaesthetics have adequately dissipated before the adjustment can be performed.^{30,31} As no other method of anaesthesia was used in our study, the effect of ketorolac was more clearly assessed.

The most frequently recorded pains began when the muscle was hooked for isolation and when the muscle was stretched during suturing before resecting the muscle. Ketorolac proved to be effective in decreasing the intraoperative pain with this procedure.

In a preliminary study, we injected intravenous ketorolac (30 mg) with no definite effect. We hypothesised that the amount given was not sufficient to reduce intra- and postoperative pain; therefore, 60 mg was administered in our follow-up study. The daily maximal intravenous administration dose for ketorolac tromethamine (Keromin; HanaPharm, Seoul, South Korea) recommended by the manufacturer was 90 mg. In cases for the elderly (over 65 years old), body weight under 50 kg, and patients with renal insufficiency, the maximum daily dose should not exceed 60 mg. The maximal daily dose administered intravenously recommended by the First DataBank,³² which provides guidelines for our hospital, is 4 mg/kg per day for children from age 180 days to under 16 years old and 120 mg/day for patients from 16 years old to under 65 years old. The mean age of ketorolac group was 26 years old (range, 11–61 years) and control group 20.1 years old (range, 11–54 years), and the mean body weight of ketorolac group was 59.97 kg (range, 45–100 kg) (mean dose, 1.0 mg/kg, range, 0.6–1.3 mg/kg) and control group 61.33 kg (range, 35–75), so no patient exceeded their recommended maximal daily dose.

The adverse effects of ketorolac are gastrointestinal disturbances and renal impairment; however, the reported incidence is low and clinically insignificant.^{33–35} However, Strom *et al*³⁵ reported that overall associations between ketorolac use and both gastrointestinal bleeding and operative site bleeding was small and the risk associated with the drug was larger and clinically important when ketorolac is used in larger doses (>105 mg/d), in older subjects (>65 years), and for more than 5 days. Although ketorolac is associated with a slightly higher incidence of postoperative bleeding (0.4%) than not receiving the drug (0.2%), it has not been reported to be a problem in strabismus surgery.^{11,12,28} Morrison *et al*¹² reported intravenous ketorolac 60 mg (mean dose 0.83 mg/kg, range 0.61–1.08 mg/kg) to be more effective than either oral acetaminophen (650 mg) or oral ibuprofen (600 mg) given 30–45 min after strabismus surgery in controlling postoperative pain without experiencing any episodes of remarkable bleeding or cutaneous bruising noted in the patients enrolled in their study. Also Mui *et al*³⁶ reported that no serious complication related to ketorolac was noted when 60 mg (mean dose, 0.95 mg/kg) was administered intravenously as premedication in colonoscopy.

In this study, there was no increase in perioperative bleeding in the ketorolac treatment group. In addition, no intraoperative complications such as the oculocardiac reflex, nausea, or vomiting occurred with the topical anaesthesia. The vital signs and consciousness level, skin tone, operation site bleeding, and any discomfort were checked and recorded by the nurses in the recovery room right after the surgery and before the patient was dismissed which was 3–5 h after surgery. Although all patients complained of fear and anxiety before surgery, none of the patients complained of gastrointestinal disturbances or oliguria or urinary retention after surgery nor was operation site bleeding recorded by the nurses. Also during the out-patient clinic follow-up, no operation site bleeding or periocular bruising was noted by the surgeon nor were gastrointestinal disturbances, renal complications, skin rashes, and allergic symptoms complained by the patient. Although we did no follow-up laboratory tests after using ketorolac, the monitoring recommended by the manufacturer is complete blood cell count, chemistry profile, blood pressure, fecal occult blood test, and liver function after initiation of NSAID therapy and every 6–12 months thereafter if prescribed for longer than the recommended 5 days. More frequent monitoring is recommended in patients at risk for hepatic, renal, cardiac, or gastrointestinal toxicity (eg, age greater than 60 years, high-dose NSAID therapy, concurrent corticosteroids or anticoagulants, history of cardiac, renal, or hepatic disease). Bleeding time monitoring is recommended in patients with coagulation disorders or on anticoagulants and renal function in patients with pre-existing renal dysfunction. As none of our patients fell into these categories nor complained of side effects, we felt no need to perform further postoperative laboratory tests. Despite the adverse effects of ketorolac, we believe that it is uncommon to experience clinically severe side effects after a single dose of intravenous ketorolac in healthy subjects before strabismus surgery.

The reasons we think that the patient satisfaction was similar in both groups were mainly because of the skill of the surgeon and patients anticipation. The surgeon had performed more than 10 000 cases of strabismus surgeries and 1000 cases under topical anaesthesia with adjustable sutures, so minimal suffering was experienced by the patients compared with being operated by an unskilful surgeon. Also, as we reviewed the medical records of the recovery room nurses, we found that the fear and anxiety the patients complained before the surgery was much more than we thought. Every patient was frightened that surgery would be done only under topical anaesthesia and was worried what would happen to them if their eyes would not be able to keep still during surgery. So we think that the thought of the

surgery being over itself might have made the patients to be satisfied in both groups regardless of the difference in pain.

In conclusion, ketorolac tromethamine appears to be an effective non-narcotic alternative for pain control in patients undergoing single-stage adjustable strabismus surgery. Ketorolac decreases eye pain intraoperatively and in the immediate postoperative period compared with those of the saline placebo. Expedient hospital discharge because of less pain and shorter adjustment time with single-stage adjustable strabismus surgery has advantages in terms of patient stress, satisfaction, and health-care cost efficacy. Finally, when patients experience less pain, cooperation can improve, allowing adjustable strabismus surgery to become a more attractive procedure for both patients and surgeons.

Summary

What was known before

- The effect of ketorolac has been evaluated in strabismus surgery; however, in these studies the patients were under general or periocular anaesthesia.

What this study adds

- We prospectively evaluated that intravenous ketorolac, when administered preoperatively for single-stage adjustable strabismus surgery under topical anaesthesia, was effective in reducing pain during and after surgery.

Conflict of interest

The authors declare no conflict of interest.

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