Comparison of Retrobulbar and Sub–Tenon's Capsule Injection of Local Anesthetic in Vitreoretinal Surgery

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Objective: To compare the efficacy and efficiency of retrobulbar versus sub–Tenon's capsule injection of local anesthetic in vitreoretinal surgery.

Design: Prospective, randomized, double-masked clinical trial.

Participants and Intervention: Sixty-four eyes from 61 patients undergoing vitreoretinal surgery were randomized to receive either retrobulbar or sub–Tenon's capsule injection of 5 ml of a 50:50 mixture of 4% lidocaine and 0.75% bupivacaine.

Main Outcome Measures: The primary outcome measured was intraoperative eye pain, which was rated by patients in both groups using an 11-point (0–10) numerical visual analogue scale immediately after surgery and again the next morning. The surgeons indicated whether they perceived patient discomfort during 4 different stages of the operation: opening of the conjunctiva, vitrectomy (if performed), placement of scleral buckle (if performed), and closing of the conjunctiva. The preincision time, need for supplemental local anesthesia, and use of IV sedation for additional pain control were compared between the two groups.

Results: Thirty-four eyes were randomized to retrobulbar injections, and 30 eyes were randomized to sub–Tenon's capsule injections. There was no significant difference in patient-reported intraoperative pain scores between the retrobulbar and sub–Tenon's capsule groups when assessed immediately after surgery (median, 2.0 vs. 2.0; $P = 0.52$) or the next day (median, 2.0 vs. 1.0; $P = 0.26$). The surgeons reported no difference between the two groups in terms of the percentages of patients with pain during opening of the conjunctiva (20.6% vs. 3.3%; $P = 0.058$), vitrectomy (31% vs. 32%; $P = 1.00$), placement of scleral buckle (33.3% vs. 40%; $P = 1.00$), and closing of the conjunctiva (26.5% vs. 26.7%; $P = 1.00$). There was a suggestion that preincision time was longer in the sub–Tenon's capsule group. Approximately equal percentages of patients in each group required supplemental local anesthesia (38% vs. 37%; $P = 0.90$) or IV medication (85% vs. 70%; $P = 0.14$) for pain control.

Conclusions: Sub–Tenon's capsule injection of local anesthetic seems as effective as retrobulbar injection at controlling intraoperative pain in vitreoretinal surgery. *Ophthalmology 2005;112:574–579 © 2005 by the American Academy of Ophthalmology.*

Local anesthesia in vitreoretinal surgery is traditionally achieved by a retrobulbar block, which involves the transcutaneous injection of anesthetic solution into the retrobulbar space using a sharp needle. Although effective, retrobulbar injection has been associated with rare but serious complications, including inadvertent globe penetration, optic nerve damage, injection into the subarachnoid space, retinal vascular occlusions, retrobulbar hemorrhage, and diplopia secondary to myotoxicity.[1–10] Using a blunt cannula to administer local anesthetic directly into the sub–Tenon's capsule space is potentially safer than a retrobulbar injection. Previous studies have demonstrated that sub–Tenon's capsule injection of local anesthesia is a safe and effective method to achieve local anesthesia for anterior segment surgery.[11–13] Several prospective studies have found that the anesthesia provided by sub–Tenon's capsule injection is as good as or better than that obtained from retrobulbar injection for cataract surgery.[14–17] The efficacy of sub–Tenon's capsule injection in posterior segment surgery is less well established. Although several investigators have demonstrated that sub–Tenon's capsule block can provide safe and effective local anesthesia for vitreoretinal

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procedures,[18–25] no study has compared the efficacy of sub–Tenon's capsule to that of retrobulbar injection for posterior segment surgery. We report here the results of a prospective, randomized, double-masked clinical trial that directly compared retrobulbar and sub–Tenon's capsule injection of local anesthetic in vitreoretinal surgery.

Patients and Methods

Patient Selection

The study protocol and informed consent form were approved by the institutional review board of the Johns Hopkins Hospital. Between August 2003 and April 2004, 64 eyes from 61 patients undergoing vitreoretinal surgery at the Wilmer Eye Institute were enrolled in the study. Patients 18 years and older were included if they had an indication for a primary vitreoretinal procedure, including scleral buckling, pars plana vitrectomy (PPV) alone, PPV with scleral buckling, and PPV with associated procedures. Patients were excluded from the study if they had previous posterior segment surgery; a known allergy to lidocaine or bupivacaine; active ocular infection; or a problem with communication, such as a language barrier, deafness, dementia, or psychiatric illness. Patients were also excluded from the study if they expressed a preference for general anesthesia or had a medical need to remain on anticoagulation perioperatively. Myopic eyes were enrolled in the study at the discretion of individual surgeons.

Treatment Assignment

A block randomization schedule was generated by one of the study coinvestigators (MM) and kept confidential from all of the physicians involved in the study. Eligible patients were randomized to receive either retrobulbar or sub–Tenon's capsule injections. When a patient whose other eye was already enrolled in the study presented, the second eye was automatically assigned to the opposite treatment. All of the injections were performed in a standardized fashion by vitreoretinal fellows (JJH, W-HL, SP, HSY).

After the patients were brought to the operating room and before preoperative preparations were performed, IV midazolam hydrochloride (0.5–3.0 mg), fentanyl citrate (20–100 μg), or propofol (0–100 mg) was given at a dose determined by the anesthesiologist. Once adequate sedation was obtained, either a retrobulbar or a sub–Tenon's capsule injection of local anesthetic was given. A retrobulbar injection was performed by inserting an Atkinson needle through the lower eyelid at the junction of the lateral and middle thirds of the inferior orbital rim parallel to the orbital floor, first to a depth of 25 mm, then angled up medially and advanced toward the apex to the hub of the needle. The needle was removed after a 5-ml anesthetic mixture (50:50, 4% lidocaine: 0.75% bupivacaine) was injected. A sub–Tenon's capsule injection was performed after placing a drop of 5% povidone–iodine, followed by lidocaine jelly on the cornea and conjunctiva. The surgeon then created a fornix-based incision through conjunctiva and Tenon's tissue inferonasally with Wescott scissors to expose the scleral surface before tunneling posteriorly with curved Stevens scissors. A 5-ml solution of the same anesthetic mixture was then injected with a blunt cannula. A videotape of the sub–Tenon's capsule injection as described above was given to the vitreoretinal fellows to facilitate standardization of the injections for this study.

Data Collection and Outcome Determination

Intraoperative pain was assessed by interviewing the patients and the surgeons. The level of intraoperative pain perceived by each patient was assessed twice, first at the conclusion of the operation and again the next morning. Assessing intraoperative pain twice allowed us to determine whether the effects of IV medications or recall bias could have influenced responses from patients. An 11-point (0–10) numerical visual analogue scale was used to assess patient-reported intraoperative pain. The scale consists of a linear line subdivided into 10 equal intervals, with the leftmost one marked 0, indicating no pain, and the rightmost one marked 10, representing the worst pain imaginable. This numerical scale has been shown to be sufficiently sensitive and reliable for pain assessment.[26,27] Its use also has been validated by previous studies of sub–Tenon's capsule anesthesia in vitreoretinal surgery.[19,22] In instances where the patient did not have sufficient vision in the nonoperated eye to use the visual analogue scale, a verbal description of the scale was given. Patients were masked to the type of anesthesia they received until after they provided their responses.

The surgeons also provided their assessments of intraoperative eye pain. At the conclusion of the operation, the attending surgeon, who was masked to the type of anesthesia, indicated whether he or she perceived patient discomfort during 4 different stages of the operation: opening of the conjunctiva, vitrectomy (if performed), placement of scleral buckle (if performed), and closing of the conjunctiva. A total of 9 attending surgeons participated in this study.

To determine whether the choice of injection influenced the time needed to achieve adequate anesthesia and begin surgery, the total preincision time, defined as the time between the patient's arrival in the operating room and the start of the operative incision, was determined by reviewing each patient's operative records.

Additional information collected for the study included patient age, gender, racial background, preoperative diagnoses, procedures performed, total operative time, type and volume of supplemental local anesthesia needed during the operation, and whether additional IV sedation medication was used for pain control after the initial block. No safety measures were included as outcomes because this study was not powered to detect these relatively rare occurences.

Statistical Analysis

Pretrial sample size calculations were performed based on the need to detect a difference of ≥ 2 on our numerical analogue scale between the two groups. A difference of <2 on the 11-point scale between the two groups was felt to be clinically insignificant. The calculations yielded a desired total sample size of 60 patients, based on an estimated standard deviation of 2.2, a probability of type I error (α) of 5%, and a power ($1-\beta$) of 90%.

The difference in the level of intraoperative pain as reported by patients was compared using the Wilcoxon rank sum test. The percentages of patients with pain at different stages of the operation as reported by surgeons were compared using the Fisher exact test. The need to use either supplemental local anesthesia or additional IV medication for pain control was compared between the two groups using the chi-square test. For continuous outcomes, such as pain score, an analysis using a linear, mixed, population-averaged model was performed to adjust for possible correlation in outcomes for the 3 patients with both eyes enrolled. For binary outcomes, such as use of supplemental anesthesia, a logistic regression analysis with generalized estimating equations was per-

Table 1. Baseline Patient Characteristics by Treatment Assignment

	Retrobulbar (n = 34)	Sub–Tenon's Capsule (n = 30)
Age (yrs)		
<30	3 (8.8%)	1 (3.3%)
30–49	5 (14.7%)	5 (16.7%)
50–69	21 (61.8%)	16 (53.3%)
≥70	5 (14.7%)	8 (26.7%)
Median	59.5	57.5
Gender		
Female	14 (41.2%)	16 (53.3%)
Male	20 (58.8%)	14 (46.7%)
Race		
African American	8 (23.5%)	8 (26.7%)
Asian American	1 (2.9%)	2 (6.7%)
Hispanic	1 (2.9%)	0 (0%)
Caucasian	24 (70.6%)	20 (66.7%)
Diagnoses		
Epiretinal membrane	13 (38.2%)	13 (43.3%)
Vitreous hemorrhage	13 (38.2%)	11 (36.7%)
Rhegmatogenous retinal detachment	6 (17.6%)	5 (16.7%)
Macular hole	5 (14.7%)	5 (16.7%)
Tractional retinal detachment	4 (11.8%)	6 (20%)
Other	2 (5.9%)	3 (10%)
Procedures		
PPV + associated procedures	26 (76.5%)	23 (76.7%)
PPV + lensectomy + associated procedures	2 (5.9%)	2 (6.7%)
PPV + scleral buckling	2 (5.9%)	3 (10%)
Scleral buckling	4 (11.8%)	2 (6.7%)
Total surgery time (min)		
Mean ± SD	96.6 ± 42.6	104.2 ± 54.8
Median (range)	90 (16–229)	88 (27–228)

PPV = pars plana vitrectomy; SD = standard deviation.

formed to adjust for possible correlation. It is noted in "Results" whenever the analysis adjusting for correlation gave results that differed in statistical significance or interpretation, as compared with analyses that did not adjust for correlation.

Results

Patient Characteristics

Of the 64 eyes from 61 patients enrolled in the study, 34 were randomized to retrobulbar injections, and 30 were randomized to sub–Tenon's capsule injections. Baseline characteristics of the eyes in the study were well balanced between the two groups with respect to age and race (Table 1). There was a chance imbalance with respect to gender, with more female patients randomized to sub–Tenon's capsule injections than to retrobulbar injections (53.3% vs. 41.2%); however, our posttrial analyses indicated that this imbalance did not alter the outcomes reported here. Distributions of preoperative diagnoses and procedures performed were similar in the two groups (Table 1). The studied eyes underwent a variety of posterior segment surgeries, including scleral buckling, PPV alone, PPV with scleral buckling, and PPV with other associated procedures (i.e., endolaser, cryotherapy, and injection of intravitreal medications). Because scleral buckle placement can potentially cause significant intraoperative eye pain, the randomization schedule was stratified to distribute approximately equal numbers of buckled eyes in each group. At the conclusion of the study, 6 (17.6%) eyes from the retrobulbar group and 5 (16.7%) eyes from the sub–Tenon's capsule group received scleral buckling. In addition, total surgery times were similar in the retrobulbar and sub–Tenon's capsule groups (median, 90 vs. 88 minutes; $P = 0.93$, Wilcoxon rank sum test), eliminating another potentially confounding variable.

Intraoperative Pain Control

The majority of patients in each group reported no or mild intraoperative eye pain (≤2 of 10) when asked immediately after surgery and again the next day (Fig 1). There was no statistically significant difference between the two groups with respect to intraoperative pain scores when patients were asked immediately after surgery (mean, 2.4 [retrobulbar] vs. 2.1 [sub–Tenon's capsule]; median, 2.0 [both groups]; $P = 0.52$) (Table 2). When asked to recall their levels of intraoperative pain the next day, patients from the sub–Tenon's capsule group reported lower mean (1.7 vs. 2.6) and median (1.0 vs. 2.0) pain scores than patients from the retrobulbar group; however, the difference was not statistically significant ($P = 0.26$) (Table 2).

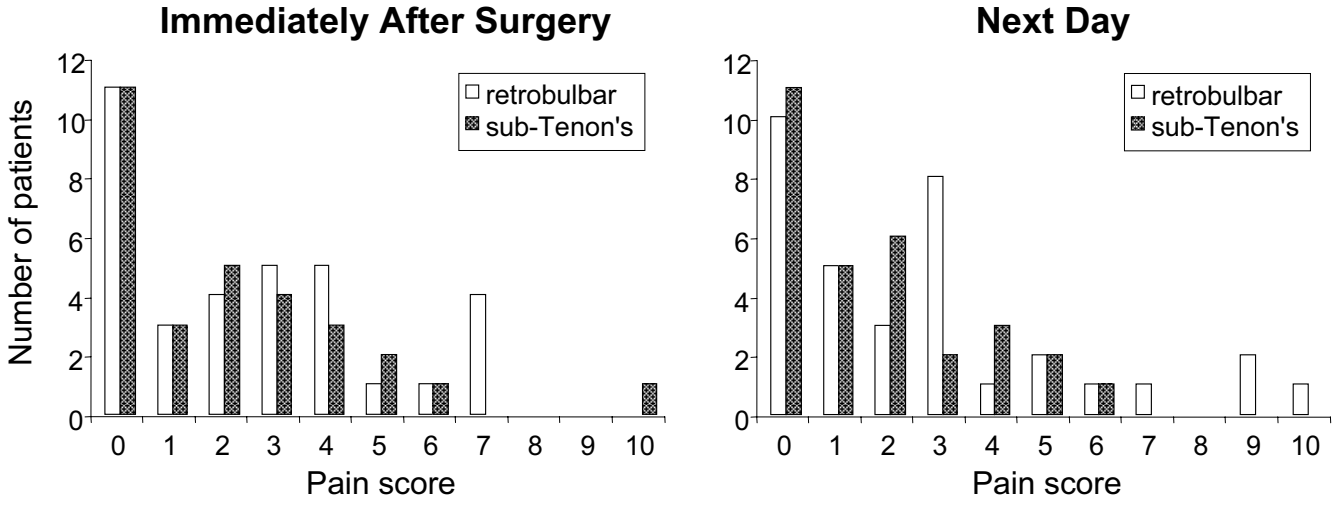

Figure 1. Intraoperative pain scores reported by patients.

The surgeons reported whether eye pain occurred during 4 different stages of the operation: opening of the conjunctiva, vitrectomy (if performed), placement of scleral buckle (if performed), and closing of the conjunctiva. The percentages of patients with pain as reported by the surgeon were equivalent in the retrobulbar and sub–Tenon's capsule groups during vitrectomy (31% vs. 32%; $P = 1.00$), placement of scleral buckle (33.3% vs. 40%; $P = 1.00$), and closing of the conjunctiva (26.5% vs. 26.7%; $P = 1.00$) (Table 3). There was a non–statistically significant trend towards a lower percentage of patients in the sub–Tenon's capsule group with pain during opening of the conjunctiva (3.3% vs. 20.6%; $P = 0.058$) (Table 3).

Table 3. Intraoperative Pain as Noted by Surgeons during Different Stages of the Operation

	Retrobulbar [n (%)]	Sub–Tenon's Capsule [n (%)]	*P* Value*
Opening of the conjunctiva			
Yes	7 (20.6)	1 (3.3)	0.058
No	27 (79.4)	29 (96.7)	
Vitrectomy			
Yes	9 (31.0)	9 (32.1)	1.00
No	20 (69.0)	19 (67.9)	
Not performed	5	2	
Placement of scleral buckle			
Yes	2 (33.3)	2 (40.0)	1.00
No	4 (66.7)	3 (60.0)	
Not performed	28	25	
Closing of the conjunctiva			
Yes	9 (26.5)	8 (26.7)	1.00
No	25 (73.5)	22 (73.3)	

*Fisher exact test.

Preincision Time

The preincision time was defined as the time between the patient's arrival in the operating room and the start of the operative incision. There was a suggestion that preincision time was longer in the sub–Tenon's capsule group. The median preincision time of 26 minutes (range, 7–41) in the sub–Tenon's capsule group was longer than the 22 minutes (range, 10–37) required in the retrobulbar group, and this difference was statistically significant ($P = 0.043$). However, the difference in mean preincision time (23.1 and 25.8 minutes in the retrobulbar and sub–Tenon's capsule groups, respectively) was only marginally statistically significant ($P = 0.080$) and was not statistically significant ($P = 0.17$) after adjustment for correlation in the 3 patients with both eyes enrolled (Table 4).

Supplemental Anesthesia and IV Sedation

Patients in both groups who experienced additional eye pain during the operation were given supplemental local anesthesia administered either topically or into the sub–Tenon's capsule space. Approximately equal percentages of patients in each group required supplemental anesthesia (38% of retrobulbar vs. 37% of sub–Tenon's capsule; $P = 0.90$) (Table 5). No difference was observed between the two groups with respect to the volumes of supplemental anesthesia used (mean, 1.9 ml [retrobulbar] vs. 1.6 ml [sub–Tenon's capsule]; median, 0 ml [both groups]; $P = 0.84$).

Additional IV sedation was given by the anesthesiologists for control of eye pain as needed. Statistically similar percentages of patients in both groups required additional IV sedation (85% of retrobulbar vs. 70% of sub–Tenon's capsule; $P = 0.14$) (Table 5).

Discussion

We have conducted the first prospective, randomized, double-masked clinical trial that directly compares the efficacy of retrobulbar and sub–Tenon's capsule injections of local anesthetic in vitreoretinal surgery. Previous studies have demonstrated that sub–Tenon's capsule anesthesia can be administered safely to patients undergoing posterior segment surgery[18–25]; however, its effectiveness had not been compared directly to that of retrobulbar injection, the current standard of practice. The primary outcome examined in this study was intraoperative pain control. This was assessed by interviewing the patients and the attending surgeons, who were both masked to the types of injections given. In designing the study, we postulated that the presence of residual IV medication could introduce unknown biases to pain assessments performed immediately after surgery. However, the assessment of intraoperative pain 1 day after surgery could be confounded by other variables such as recall bias. Therefore, every patient was interviewed twice, once immediately after surgery and again the next day, to determine whether the timing of this assessment would influence the outcome. In fact, we detected no statistical difference in the level of intraoperative pain between the two groups, regardless of when the patients were interviewed.

The surgeons rated the effectiveness of intraoperative pain control by noting whether patients experienced eye pain during 4 different stages of the operation. This was done to determine whether either injection provided better pain control during particular stages of the operation. The fact that both retrobulbar and sub–Tenon's capsule injec-

Table 2. Intraoperative Pain Scores as Reported by Patients

	Retrobulbar (n = 34)	Sub–Tenon's Capsule (n = 30)	*P* Value*
Assessed immediately after surgery			
Mean ± SD	2.4±2.3	2.1±2.4	
Median (range)	2.0 (0–7)	2.0 (0–10)	0.52
Assessed the next day			
Mean ± SD	2.6±2.8	1.7±1.8	
Median (range)	2.0 (0–10)	1.0 (0–6)	0.26

SD = standard deviation.
*Based on a comparison of treatments using the Wilcoxon rank sum test.

Table 4. Preincision Time (Minutes) by Treatment Assignment

	Retrobulbar (n = 34)	Sub–Tenon's Capsule (n = 30)	*P* Value*
Mean ± SD	23.1±5.6	25.8±6.5	0.17
Median (range)	22 (10–37)	26 (7–41)	0.043

SD = standard deviation.
*Based on a comparison of treatments using the Wilcoxon rank sum test.

Table 5. Use of Supplemental Anesthesia or Additional IV Sedation

	Retrobulbar (n = 34)	Sub–Tenon's Capsule (n = 30)	*P* Value
Supplemental anesthesia			
Yes	13 (38.2%)	11 (36.7%)	0.90*
No	21 (61.8%)	19 (63.3%)	
Volume of supplemental anesthesia (ml)			
Mean ± SD	1.9±3.5	1.6±3.0	
Median (range)	0 (0–15.0)	0 (0–10.0)	0.84†
IV sedation			
Yes	29 (85.3%)	21 (70.0%)	0.14*
No	5 (14.7%)	9 (30.0%)	

SD = standard deviation.
*Chi-square test.
†Wilcoxon rank sum test.

tions provided equivalent pain control during all stages of the operation served as an independent verification of the results obtained by interviewing patients.

The masking of the surgeons may have been less than 100%. Although not explicitly told of the anesthesia assignment, some surgeons could have identified the type of injection given because of the chemosis sometimes caused by sub–Tenon's capsule injection. The incidence of chemosis from sub–Tenon's capsule injection was not examined in our study, but has been previously reported in up to 40% of patients.[28] This is a potential weakness of our study. Fortunately, we reached the same conclusion regarding intraoperative pain control through both patient-reported pain scores and surgeon-reported pain assessments.

In this study, both retrobulbar and sub–Tenon's capsule injections were given before the formal preparation and draping of the eye so as not to introduce potentially confounding variables by performing the two injections at different times. Other investigators have performed sub–Tenon's capsule injections after the formal preparations and drapings.[10,18,24,25] It is possible that doing so may reduce the preincision time in the sub–Tenon's capsule group by negating the need to sterilize the ocular surface twice. However, the preincision time may lengthen if the surgeon has to wait for onset of adequate anesthesia.

Patients with inadequately controlled intraoperative pain received supplemental local anesthesia, additional IV medication, or both. Our study showed no difference in the percentages of patients who required these additional measures of pain control between the two treatment groups, further validating our conclusion that retrobulbar and sub–Tenon's capsule injections are equally efficacious.

We excluded patients who had previous posterior segment surgery from this study because extensive conjunctival and sub–Tenon's capsule scarring from these procedures could potentially make the sub–Tenon's capsule approach of delivering local anesthetic more difficult and less effective. In a case series of patients who received sub–Tenon's capsule anesthesia for posterior segment surgery, Li et al excluded patients with previous circumferential scleral buckle, previous trabeculectomy, or recent open-globe surgery from their study for similar reasons.[18] However, they noted that 16% of their patients had previous surgery with a conjunctival peritomy of ≤2 quadrants, suggesting that sub–Tenon's capsule injection can still be efficacious in patients who had limited conjunctival peritomy from previous vitreoretinal surgery.

Our finding that sub–Tenon's capsule injection is as effective as retrobulbar injection at controlling intraoperative pain complements a growing body of evidence that sub–Tenon's capsule injection represents a viable addition to our current standards of practice in providing local anesthesia in vitreoretinal surgery. Whether more widespread use of sub–Tenon's capsule injection in posterior segment surgeries reduces the incidence of complications associated with retrobulbar blocks remains to be determined.

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