

SCIENTIFIC REPORT

Prospective study comparing lidocaine 2% jelly versus sub-Tenon's anaesthesia for trabeculectomy surgery

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Aims: To compare the analgesic properties of lidocaine 2% jelly versus sub-Tenon's anaesthesia with lidocaine 2% without adrenaline (epinephrine) for trabeculectomy surgery.

Methods: A prospective randomised clinical trial. 59 consecutive patients scheduled for trabeculectomy at the Toronto Western Hospital were randomly assigned to topical unpreserved lidocaine 2% jelly or sub-Tenon's anaesthesia with 2% lidocaine. Both groups received a standardised sedative consisting of midazolam, fentanyl, and/or propofol. The visual analogue scale was utilised to measure intraoperative pain. Patient comfort, physician assessment of intraoperative patient compliance, volume of local anaesthetic used, need for supplemental anaesthesia, and any complications were recorded. The two groups were compared using the Student's *t* test.

Results: The sub-Tenon's anaesthesia group and the lidocaine 2% jelly group did not vary significantly in subjective pain score (18.3 (SD 16.2) v 19.8 (12.4) respectively, $p = 0.739$) and surgeons' satisfaction scale (3.6 (0.7) and 3.8 (0.6) respectively, $p = 0.328$). Four patients required additional anaesthesia, all of them in the sub-Tenon's group.

Conclusion: Topical lidocaine 2% jelly is as effective as sub-Tenon's anaesthesia for pain control in patients undergoing trabeculectomy. Lidocaine 2% jelly is similar to sub-Tenon's anaesthesia in patient comfort and surgeon satisfaction.

Topical anaesthesia for ophthalmological surgery has been successfully used by different authors for cataract surgery,^{1–5} trabeculectomy,^{6,7} vitrectomy,⁸ and phacotrabeculectomy surgery.^{9,10} Recent evidence suggests that topical anaesthesia with lidocaine 2% jelly is a safe and effective alternative for clear cornea cataract surgery¹¹ and phacotrabeculectomy, even without systemic sedation.¹⁰ The jelly provides a sustained effect during the surgical procedure. We designed this prospective randomised study to compare sub-Tenon's anaesthesia with unpreserved lidocaine 2% jelly for trabeculectomy surgery. This is the first study to do this.

PATIENTS AND METHODS

Ethical approval from the university health network research ethics board and informed consent from the patients were obtained. Consecutive eligible patients scheduled for trabeculectomy at the Toronto Western Hospital were enrolled in the study. Exclusion criteria were dementia or mental instability, deafness, movement disorders, hyperanxiety, and inability to complete the visual analogue scale (VAS) of pain line (for example, confusion, communication barriers, visual impairment). No patients received sedatives before entering the operating room. Patients were randomised to receive either lidocaine 2% jelly or sub-Tenon's anaesthesia by a coin toss. An intravenous line was established and a

standardised mild intravenous sedative consisting of midazolam hydrochloride 1 mg/ml, fentanyl citrate 0.05 mg/ml, and/or propofol 10 mg/ml was administered by the anaesthetist, who was not blinded to the results of randomisation (table 1). All surgery was performed with a mild intravenous sedation that included these three drugs. The dose of intravenous sedation was defined as low (a total intraoperative dose of midazolam <2 mg, fentanyl <75 mg, or propofol <50 mg) or moderate (midazolam >2 mg, fentanyl >75 mg, or propofol >50 mg). The patients assigned to lidocaine jelly received 0.2 ml of unpreserved lidocaine 2% jelly (Xylocaine, AstraZeneca, Mississauga, Canada) in the inferior conjunctival fornix 5 minutes before surgery. Additional lidocaine jelly was inserted into both fornices at the start of surgery and supplemented if required. Before final conjunctival closure a further application of jelly was administered. The total volume of jelly used was recorded. Patients in the sub-Tenon's group received topical 0.5% tetracaine before being prepared and draped. Following insertion of a lid speculum lidocaine 2% without adrenaline was injected under direct vision via a 30 gauge needle subconjunctivally 8 mm from the limbus in the surgical area.¹² The end point was to observe a continuous bleb of anaesthetic solution encompassing the operative area. The volume of anaesthetic solution administered was recorded. Patients were instructed to inform the surgeon if they experienced pain during surgery. During the surgery, the surgeon was in constant communication with the patients and frequently asked them if they wished to have additional anaesthesia. If breakthrough pain occurred in either group during surgery, supplemental sub-Tenon's or topical anaesthesia was administered. If this was not effective, additional midazolam, fentanyl, or propofol was given intravenously. Standard trabeculectomy, as described elsewhere by the authors,¹² was carried out in both groups using 6–0 polyglactin (Vicryl) traction suture placed mid-thickness through clear cornea 2 mm anterior to the limbus and secured to a surgical drape.¹² A fornix based or limbal based conjunctival flap was used. All surgeries were performed by two surgeons (YMB, GET) using the same technique. Patient comfort and pain were evaluated within 2 hours from the time of the surgery by an independent observer, without the presence of the surgeon, using a standard format, which describes comfort using the VAS.^{13–15}

Subjects were instructed to indicate the intensity of the pain by marking the point that best represents the intensity of his or her pain on a 100 mm line with terms describing the extremes of pain intensity. The VAS numeric value is the distance in millimetres from "no pain" to the point marked by the patient. Subsequently, the independent observer also collected surgeons' responses to complete a five point satisfaction scale immediately after each surgery rating the overall surgical experience. The surgeons were requested to consider not only a subjective impression of patient comfort and ease of surgery but also the presence of inadvertent eye

Table 1 Comparable characteristics between sub-Tenon’s and topical anaesthesia with lidocaine 2% jelly

	Sub-Tenon’s	Lidocaine 2% jelly	p Value
Mean quantity of midazolam (mg)	1.5	1.4	0.180
Mean quantity of fentanyl (µg)	52	45.8	0.564
Mean quantity of propofol (mg)	1.61	4.35	0.208
Mean intraoperative discomfort (VAS)	18.3	19.8	0.739
Mean surgeon satisfaction score	3.6	3.8	0.328

movements, patient reported painful sensations (including pain during the administration of the anaesthetic), lid squeezing, and intraoperative complications when providing an overall score. The final score was a general estimate considering all these variables. The scale used rated the surgical experience as follows: 0 = extremely poor; 1 = poor; 2 = fair, 3 = good, 4 = excellent. The need for supplemental anaesthesia was recorded. Further information recorded included: patient demographics, operative technique, quantity and type of sedative administered, and volume of anaesthetic used for supplemental anaesthesia. The power of this study was 96% using a sample size of 59 patients to find a difference in VAS score between groups of 15 with a standard deviation (SD) of 15 and a type 1 error of 0.05. For the surgeon satisfaction scale the power was 82% to find a difference between groups of 0.5 with SD of 0.65 and a sample size of 59 patients and a 0.05 type 1 error.

Primary outcome measures were patient comfort and physician assessment of intraoperative patient compliance. Volume of local anaesthetic used, need for supplemental anaesthesia, and any complications were recorded as secondary outcome measures.

The Student’s *t* test was used to compare the groups statistically. *p* Values less than 0.05 are considered statistically significant.

RESULTS

In all, 59 eyes of 57 patients were enrolled in this study. Twenty nine eyes were randomised to sub-Tenon’s anaesthesia and 30 to topical anaesthesia with lidocaine 2% jelly. The study population consisted of 38 patients (67%) with primary open angle glaucoma, eight patients (14%) with chronic angle closure glaucoma, five patients (9%) with pseudophakic glaucoma, two patients each (3%) with uveitic

and pseudoexfoliation glaucoma, and one patient each (2%) with pigmentary and mixed mechanism glaucoma.

There was no statistically significant difference between groups with respect to age, sex, use of mitomycin C, or conjunctival flap. A fornix based flap was done in three patients in each group and mitomycin C was not used in one patient in each group (table 2). There were no anaesthesia related complications. Two patients had both eyes included in our study. Bilateral trabeculectomies were performed as two separate operations to these two patients. Each eye was independently randomised before surgery.

Patients receiving sub-Tenon’s anaesthesia were more likely to require additional anaesthesia (n = 4/29) (p<0.001) compared with patients undergoing lidocaine 2% jelly anaesthesia (n = 0/30). A larger mean volume of topical anaesthetic was required in the lidocaine 2% jelly group than the sub-Tenon’s group (p<0.001) (table 3). The total mean quantity of sedatives (midazolam, fentanyl, and propofol) was rated low for both groups. There was no difference between groups with respect to quantity of intravenous sedative received (table 1) and complications. The sub-Tenon’s anaesthesia group and the lidocaine 2% jelly group did not vary significantly in subjective pain score (mean 18.3 (SD 16.2) v 19.8 (12.4) respectively, p = 0.739) and surgeon satisfaction scale (3.6 (0.7) and 3.8 (0.6) respectively, p = 0.328).

DISCUSSION

Several studies have demonstrated the ease and safety of sub-Tenon’s anaesthesia not only for trabeculectomy¹²⁻¹⁶⁻¹⁷ but also for cataract surgery.¹⁸⁻²¹ This technique, however, involves injection of anaesthetic with a sharp needle or blunt cannula which may result in complications such as subconjunctival haemorrhage, chemosis, conjunctival injection

Table 2 Patient characteristics and surgical technique

	Sub-Tenon’s	Lidocaine 2% jelly	p Value
Mean age (years)	65	63	0.547
Female (%)	16 (50)	16 (50)	0.890
Male (%)	13 (48)	14 (52)	0.890
Fornix based flap (%)	3 (11)	3 (10)	0.966
Limbal based flap (%)	26 (89)	27 (90)	0.966
Use of MMC (%)	28 (96)	29 (96)	0.981

Table 3 Significant differences between sub-Tenon’s versus topical anaesthesia with lidocaine 2% jelly

	Sub-Tenon’s	Lidocaine 2% jelly	p Value
Volume of local anaesthesia (ml)	0.45	0.99	<0.001*
Additional anaesthesia (%)	4 (13)	0	<0.001*

*Statistically significant.

holes, and even globe perforation. A potential advantage of sub-Tenon's anaesthesia is in cases of re-operation where the infiltration of anaesthetic fluid separates Tenon's capsule and conjunctiva from episclera, thus allowing the surgeon to check for conjunctival mobility when choosing a site for surgery.

Topical anaesthesia has been reported to be a safe and effective alternative to retrobulbar and peribulbar anaesthesia.¹⁻¹¹ Zabriskie *et al*⁷ found that patients on topical anaesthesia with bupivacaine hydrochloride 0.75% eye drops preoperatively and intraoperatively for trabeculectomy surgery reported equivalent pain scores as those patients who underwent retrobulbar anaesthesia. This finding was supported by a prospective clinical trial by Sauder and Jonas⁶ who used oxybuprocaine 0.4% and cocaine hydrochloride 10% eye drops in the topical anaesthesia group before penetrating trabeculectomy.

Topical anaesthesia has several advantages: early return of visual acuity without the potential complications of injection (subconjunctival and retrobulbar haemorrhage, chemosis, optic nerve injury, globe perforation, retinal detachment, diplopia, ptosis, periocular ecchymosis, increased orbital pressure, injection into the subarachnoid space, and respiratory arrest from brain stem anaesthesia).²²⁻²⁹ The disadvantages of local drops are the need for administration of several doses previous and during surgery, the short anaesthetic effect without elimination of ocular movement, and the potential for cumulative toxicity.

Lidocaine jelly is a widely used agent for topical anaesthesia in urogenital, laryngotracheal, and even skin anaesthesia and has recently been described in cataract surgery.^{11 30-33}

The gel formulation has the advantage of increased contact time with the ocular surface, providing prolonged release of lidocaine, thus creating a sustained effect. Five published clinical studies evaluated the clinical efficacy of lidocaine 2% jelly in ophthalmic surgery. All of them suggested that lidocaine 2% jelly provides adequate anaesthesia and patient comfort. Barequet *et al*¹¹ found that a single application of the jelly was similar to multiple topical tetracaine 0.5% eye drops for clear corneal cataract surgery in provision of corneal anaesthesia and patient comfort on a four grade pain scale. Lai *et al*¹⁰ using the VAS for intraoperative pain assessment reported topical 2% lidocaine hydrochloride jelly without systemic sedation to be a safe and effective anaesthetic method in phacotrabeculectomy for patients with primary open angle glaucoma with coexisting cataract. Similar findings were published by Assia *et al*³² using lidocaine 2% jelly as the sole anaesthetic agent in cataract surgery and the VAS to grade the intraoperative pain.

Koch³³ using oxybuprocaine (proparacaine) 1% eye drops plus lidocaine 2% jelly twice before cataract surgery as topical agents, reported pain scores equivalent to those obtained with oxybuprocaine 1% eye drops preoperatively plus intracameral 1% lidocaine on a five grade pain scale. Bardocci *et al*³⁰ recorded better analgesia and patient cooperation with lidocaine 2% jelly for cataract surgery than with lidocaine 4% unpreserved eye drops, using a three grade pain scale. We report no difference between jelly and sub-Tenon's injection in trabeculectomy patients. One of us (GET) has used topical lidocaine 2% jelly for many years in trabeculectomy surgery; however, to the best of our knowledge, this is the first prospective randomised study comparing topical lidocaine 2% jelly and sub-Tenon's anaesthesia with lidocaine 2% without adrenaline for trabeculectomy surgery. Specific factors evaluated during this study included patient comfort and surgeons' satisfaction considering eye movements and the surgeon's subjective impression of patient comfort and ease of surgery. Anticipating that

some of the sedatives used may produce anterograde amnesia, patients were asked to report any discomfort during surgery and any patient reported painful sensations were considered by the surgeons when scoring the surgical experience. Although systemic medications can affect patients' response, both groups were given systemic sedation of dosages that fall into the "low" category. No difference was observed between the two groups in both patients' self reporting of subjective pain and surgeons' satisfaction.

Neither of the anaesthetic methods was associated with significant complications. Although the volume of local anaesthetic used was significantly less in the sub-Tenon's group some of the patients in this group required additional anaesthesia while patients undergoing surgery with lidocaine 2% jelly did not. Although both fornix based and limbal based flaps were considered in this study, the same number of fornix based cases were included (n = 3) in each group. Therefore, we do not feel this influenced the outcome of our study as the same condition applied in both groups. The strengths of this study include its prospective randomised design. The pain scale used (VAS) has been used previously and has been found to be valid and reliable. The VAS has properties consistent with a linear scale, at least for patients with mild to moderate pain, and thus VAS scores can be treated as ratio data. This supports the notion that a change in the VAS score represents a relative change in the magnitude of pain sensation.^{13 14} Limitations of this study include the non-masked design. It would have been impossible to mask the surgeon, who according to our protocol, administered the local anaesthetic. The study protocol justified the administration of additional local or intravenous sedation only at the patients' request, the decision at the surgeon's or anaesthesiologist's discretion. The independent observer conducting the VAS was not blinded in our study; however, at no time was the patient prompted when grading the VAS.

One potential concern about the study is the use of sedation, which could affect patient recall when assessing intraoperative pain levels after surgery. As both groups were given systemic sedation of dosages that fall into the "low" category, patients were lightly sedated yet awake and cooperative.

A final concern is that no vital sign measurements were recorded during the surgery for the purpose of our study. Although these measurements add objective confirmation to the subjective reporting of pain intensity we consider that the use of other indirect measures of patient comfort recorded by the surgeon, such as patient cooperation and operative conditions, provide useful additional and accurate information of intraoperative pain levels.

In conclusion, we found topical anaesthesia with lidocaine 2% jelly to be as effective as sub-Tenon's anaesthesia for trabeculectomy surgery. In addition, it may be more advisable as it does not involve injections which may lead to complications such as subconjunctival haemorrhage, conjunctival button holes, and globe rupture.

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The authors have no proprietary interest in the materials mentioned here.

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