A Prospective Study Comparing Lidocaine 2% Jelly versus Retrobulbar Anesthesia in 23-G Suturless Vitrectomy for Macular-Based Disorders: Efficacy and Intraocular Pressure

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Abstract: Purpose: To compare Lidocaine 2% Jelly versus retrobulbar anesthesia on efficacy and IOP in 23-G suturless vitrectomy for macular-based disorders. **Materials and Methods**:A prospective clinical trial was conducted on 40 patients allocated into two equal groups; group 1 received topical lidocaine 2% Jelly and group 2 received retrobulbar anesthesia (6ml volume of bupivacaine 0.5% solution with 10 IU/ml hyaluronidase). Both groups received a standardized sedative consisting of midazolam, fentanyl and /or propofol intraoperatively. All patients underwent a 23 G-suturless vitrectomy for macular-based disorders. IOP was measured in both groups, immediately before and after anesthesia application, and at 5 and 10 minutes after application before start of surgery. Pain scores were assessed using a numerical visual analogue scale immediately after surgery. Patient comfort, physician assessment of intraoperative patient's compliance, need for supplemental anesthesia, volume of local anesthetic used and any complications were recorded. **Results**: There was a statistical significant variation in elevation in mean IOP in group 2 (retrobulbar group) compared to group 1 (lidocaine 2% Jelly) ($P< 0.01$). Mean IOP was elevated only in group 2 after injection and was reduced at all time-intervals. The two groups did not vary significantly in subjective pain score and surgeon's satisfaction scale. A statistical significant difference was noted regarding anesthetic supplement being more in group 1 (topical group) compared to group 2 (retrobulbar group).**Conclusion**: Topical Lidocaine 2% Jelly is as effective as retrobulbar anesthesia for pain control in patients undergoing 23G suturless vitrectomy for macular-based disorders. Lidocaine 2% Jelly is similar to retrobulbar anesthesia regarding patient's comfort and surgeon's satisfaction. Moreover, the Lidocaine 2% Jelly is found to have fewer effects on IOP prior to surgery. Lack of akinesia in this group (group 1) also did not prevent or hinder a successful surgical outcome.

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1. Introduction:

Topical anesthesia was first proposed by Fichman (**Feibel, 1985**) as an attractive alternative to the traditional method of injecting local anesthetic agents, resulting in faster visual recovery and high patient satisfaction[1]. The advantages of topical anesthesia include its ease of application, minimal to absent discomfort on administration, rapid onset of anesthesia and most important of all, elimination of the potential risks associated with other injections (retro, peri and subtenon) [2,3] .

Topical anesthesia has been successfully used by different authors for cataract surgery, trabeculectomy and phacotrabeculectomy surgeries [4-6] . **Yepez *et al.*** published a prospective study on 134 eyes operated with standard 20-gauge vitrectomy under topical anesthesia (4% Lidocaine drops)and preoperative or intraoperative sedation with various vitreoretinal diseases[7]. According to the authors, all patients experienced mild pain or discomfort during pars plana sclerotomies external bipolar cautery and conjunctival closure[4,7]. Now, with 23-G suturless vitrectomy technique becoming increasingly popular because of the decreased surgical trauma, faster wound healing and improved postoperative comfort, it was done under topical anesthesia with different authors [4,7-9].

In this study, we compared retrobulbar anesthesia to unpreserved lidocaine 2% Jelly in 23-G suturless vitrectomy, but specifically for macular based disorders regarding the efficacy and intraocular pressure changes.

2. Materials and Methods

Approval from the Ethical Committee in the Research Institute of Ophthalmology (RIO) and informed consent from the patients were obtained. Forty eligible patients scheduled for 23-G suturless vitrectomy for macular based disorders (namely idiopathic macular hole and epiretinal gliosis) at the RIO were enrolled in this study. Inclusion criteria were patients who were eligible to perform this procedure under local or topical anesthesia.

Exclusion criteria were patients with bleeding disorders, 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 theatre.

Patients were allocated into two groups; 20 patients in each group. Group 1 received lidocaine 2% Jelly and group 2 received retrobulbar anesthesia. On entrance to operating room (OR), patients were cannulated and a standardized mild intravenous sedation regimen was administered by one of the anesthetists of the study. Patients were instructed to be able to interpret the pain by the VAS scale. The sedation consisted of midazolam hydrochloride 1mg/ml, fentanyl citrate 0.05 mg/ml and propofol 10 mg/ml. This sedative mixture was used in all patients in the study. The dose of intravenous sedation was defined as low (a total intraoperative dose of midazolam < 3 mg, fentanyl < 85 µg and propofol < 70 mg) or high (a total intraoperative dose of midazolam > 3mg, fentanyl > 85 µg, propofol > 70 mg). The patients in both groups were monitored by an EGG, pulse oximetry and non-invasive blood pressure manometer. The patients in group 1 (Lidocaine 2% jelly; n = 20) received 0.2 ml of unpreserved lidocaine 2% jelly (xylocaine, Astra Zeneca, Mississauga, Canada) both in the superior and inferior conjunctival fornices 10 minutes before surgery. Additional lidocaine 2% jelly was inserted into both fornices at the start of surgery and supplemented if needed. The patients in group 2 (retrobulbar; n = 20) received local anesthetic mixture through the retrobulbar technique where a 27 G needle was introduced transcutaneously into the inferotemporal quadrant of the orbit at the junction of the lateral third and medial two-thirds of the inferior orbit rim and running tangentially to the globe. Passing initially close to the orbit floor and medially, the globe equator is passed, at this time the angle of direction was adjusted upwards and the needle advanced to enter within the muscle cone posterior to the globe. 6 ml of bupivacaine 0.5% with 10 IU/ml hyaluronidase was then injected after gentle aspiration was done[10].

Intraocular pressure (IOP) was measured in both groups, immediately before anesthesia application immediately after anesthesia application and at 5 and 10 minutes after application before start of surgery.

Patients were instructed to inform the surgeon with any pain or discomfort throughout the procedure.

All surgeries were performed by the three surgeons included in the study using the same technique for macular-based disorders namely macular hole and epiretinal gliosis.

Three 23-G- transconjunctival sclerotomy ports were created for infusion and illumination and introducing the vitrectomy probe (Alcon Laboratories Inc., Fort Worth, TX, USA). To create the 23-G-port, the conjunctiva was displaced by approximately 1-3 mm with 2 pressure plates.

A 23-G trocar cannula was first inserted through the conjunctiva and sclera, parallel and 3.5 mm posterior to the limbus and then at an angle of approximately 5° until it just passed the end of the bevel. At that point, the handle was slightly raised to an angle of approximately 30° and the cannula was then inserted into the hub.

The trocar was removed while the cannula was stabilized with a forceps. The same surgical technique was applied to introduce the illumination and the vitrectomy probe through the other two 23-G-ports. A complete vitrectomy was performed. Injection of a membrane blue dye (DORC, Inc, Holland) was performed to stain the ILM (internal limiting membrane) through the vitrectomy probe port via a cannula. Then, an ILM removal forceps was introduced through the same port to remove the ILM (macular rehexis). Air-fluid exchange, then injection of SF6 (sulfur hexaflouride) was done at the end of the operation.

During the procedure, the surgeons were in constant communication with the patients to assess their compliance and if additional anesthesia was needed. In cases of severe unbearable pain during the procedure, supplemental topical anesthesia was given in group 1, and a medial canthus injection was given in group 2. The total volume of anesthetic used was calculated.

If pain still persisted, additional sedative mixture was given I.V. and the total volume was calculated. Patient comfort and pain were evaluated immediately after surgery by an independent observer using the visual analogue score (VAS). The VAS scale was incorporated into the experimental design and pain score was illustrated on a 100 mm line with end values of “no pain” and “pain could not be worse” corresponding to the extremes of pain intensity.

Subsequently, the independent observer also collected surgeon’s responses to complete a five point satisfaction scale immediately after surgery rating the overall surgical experience. The surgeons were instructed to consider the patient’s comfort and the ease of the procedure (for example; eye movements, squeezing, any intraoperative complications regarding the surgical and/or the anesthetic technique). The final score was an estimate of all these findings. The scale used to assess the

surgical experience was as such: 0 = extremely poor, 1 = poor, 2 = fair, 3 = good and 4 = excellent. Further information included patient's demographic data.

Primary outcome measures were: patient comfort and physician assessment of intraoperative patient compliance. Secondary outcome measures were: intraocular pressure measurement, need for supplemental anesthesia, volume of local anesthetic used and any complications.

Statistical analysis:

The student's t-test was used to compare the group statistically. Numerical data were given as mean ± SD. P-values < 0.05 were considered statistically significant.

3. Results

Forty patients were enrolled in this study. 20 patients received topical anesthesia, 10 patients had epiretinal gliosis (50%) and 10 patients had idiopathic macular hole (50%) 20 patients received retrobulbar anesthesia, 10 patients had epiretinal gliosis (50%) and 10 patients had idiopathic macular hole (50%). There was no statistically significant difference between groups with respect to age, sex, weight and duration of surgery (Table 1)

Table (1): Patients' demographic data

	Group 1 (n = 20) (Topical lidocaine 2% jelly group)	Group 2 (n = 20) (retrobulbar group)	*P* value
Age (years)	45.3±11.4	46.8±12.1	0.51
Sex (M:F)	8:12	7:13	0.33
Weight (kg)	64.5±11.8	63.8±10.4	0.81
Duration of surgery (min)	34.5±13	36.1±12	0.47

Values are mean ± SD (Standard deviation).

There were no anesthesia related complications. 2 patients in the topical lidocaine group (group 1) had small retinal tears that were managed intra-operatively (one patient with epiretinal gliosis and one patient with idiopathic macular hole). Only one patient in the retrobulbar group (group 2) with epiretinal gliosis manifested with a retinal tear that was also managed intra-operatively.

Patients receiving topical lidocaine 2% jelly anesthesia were more likely to require additional anesthesia (n = 4/20) (p< 0.001) compared to patients receiving retrobulbar anesthesia (n = 0/20). A larger mean volume of topical anesthetic was required in the lidocaine 2% jelly group than the retrobulbar group (p < 0.001) (Table 2).

Table (2): Volume of total anesthetic solution & number of patients needing additional supplements in the 2 groups

	Group 1 (n = 20) (Topical lidocaine 2% jelly)	Group 2 (n = 20) (retrobulbar group)	*p* value
Volume of local anesthetic (ml)	0.83	0.37	< 0.001*
Additional anesthetic supplement (%)	4/20	0/20	< 0.001*

* p value statistically significant.

The total mean quantity of sedatives (midazolam, fentanyl and propofol) was rated low for both groups with no statistical significance. Both groups did not vary significantly regarding the pain score the lidocaine 2% jelly group (mean 17.4±11.1), the retrobulbar group (mean 16.1±14.3), p = 0.691 and the surgeon satisfaction scale; in lidocaine 2% jelly group (mean 3.2±0.4) and in the retrobulbar group (mean 2.9±0.5), p = 0.317 (Table 3).

Table (3): Comparable characteristics between lidocaine 2% jelly and retrobulbar groups

	Group 1 (n = 20) (Topical lidocaine 2% jelly group)	Group 2 (n = 20) (retrobulbar group)	*p* value
Mean quantity of midazolam (mg)	1.2	1.3	0.171
Mean quantity of fentanyl (μg)	41.2	45.7	0.473
Mean quantity of propofol (mg)	40.9	43.1	0.464
Mean intraoperative discomfort (VAS)	17.4±11.1	16.1±14.3	0.691
Mean surgeon satisfaction score	3.2±0.4	2.9±0.5	0.317

There was a statistical significant difference in IOP measurement immediately after anesthesia application being higher in retrobulbar group compared to lidocaine 2% jelly group (17.41±3.17, 13.12±3.13, respectively). But IOP levels were statistically insignificant in other time recordings

Table (4): Intraocular pressure measurements (mmHg) of both groups

	Group 1 (n = 20) (Topical lidocaine 2% jelly group)	Group 2 (n = 20) (retrobulbar group)	*p* value
IOP immediately before anesthesia application	13.07±2.7	13.19±2.13	0.31
IOP immediately after anesthesia application	13.12±3.13	17.41±3.17*	< 0.001*
5 minutes after anesthesia application	13.46±2.31	12.87±2.92	0.54
10 minutes after anesthesia application	13.31±2.2	12.91±2.83	0.73

*P-value statistically significant

4. Discussion

Topical anesthesia has been reported to be a safe and effective alternative to retro bulbar and peribulbar anesthesia. Conventional 20-G vitrectomies have been successfully performed under topical anesthesia with sedation[4]. Most of these reports have recorded grade 2 level of pain and discomfort during cauterization of scleral bed, during incision of sclerotomy, suturing of sclerotomy and conjunctiva. 25-gauge vitrectomies have been successfully done under topical anesthesia without sedation using anesthetic–soaked pledget at the site of sclerotomies[11]. The pledget delivery of anesthetic had the added advantage of prolonged delivery of the anesthetic to the areas where the sclerotomies are planned, thereby contributing to reduced pain and discomfort during the procedure[12].

Theocharis *et al.,* indicated that topical anesthesia could be considered an alternative to other anesthetic procedures in 25-G and 23-G vitrectomies. In our study, we used the 23-G vitrectomy system for macular based disorders mainly idiopathic macular hole and epiretinal gliosis. The 23-G technique relies on the trocar and cannula system for the sclerotomies. Conjunctival periotomy is not required and there is no contact of instruments with sclera or pars plana. Some studies suggested that 23- G vitrectomy was ideal for topical vitreoretinal surgeries in selected cases. Moreover, topical anesthesia has several advantages: early return of visual acuity without the potential complications of injection (for example; hemorrhage, chemosis, globe perforation, increased orbital pressure, ptosis, diplopia retinal detachment)[13-16]. Also the added advantage of topical anesthesia was that patients could be instructed to move the eye in the required direction intra-operatively whenever necessary as there was no akinesia[8]. Still yet, there are some disadvantages related to the local drops such as the need for administration of several doses prior to and during surgery, the short anesthetic effect and the potential for cummulative toxicity[17]. But, with lidocaine 2% jelly, there was the advantage of increased contact time with the ocular surface, providing prolonged release of lidocaine hence providing a sustained effect. Many published studies evaluated the clinical efficacy of lidocaine 2% jelly in ophthalmic surgery and suggested that it provided adequate anesthesia and patient comfort[17,18]. **Lai *et al.*** using the VAS for intraoperative pain assessment reported topical 2% lidocaine jelly without systemic sedation to be a safe and effective anesthetic method but in patients for phacotrabeculectomy[5].

Similar findings were published by **Assia *et al.*** using lidocaine 2% jelly as the sole anesthetic agent in cataract surgery and the VAS to grade the intraoperative pain[19]. But we had to correlate to other studies that compared the 2% lidocaine jelly to other local techniques in vitrectomy procedures.

Theocharis *et al.* concluded that lidocaine 2% jelly with or without per oral morphine and dixyrazine offered adequate analgesia to perform sutureless vitrectomy compared to peribulbar anesthesia, and the lack of akinesia did not prevent a successful surgical result[8]. These findings correlated with the results of this study, where there was no difference between the lidocaine jelly and retrobulbar group regarding the patient's comfort and surgeon's satisfaction. Despite the use of systemic sedatives that may affect patients' response and might cause anterograde amnesia, the patients in our study received low doses of these drugs, so there was no difference between both groups regarding the above mentioned parameters. Patients in both groups had favorable visual and surgical outcome with no anesthetic complications. Only 2 patients in the lidocaine 2% jelly group and one patient in the retrobulbar group manifested with intra-operative retinal tears and they were all successfully managed intraoperatively. Still yet, patients in the lidocaine 2% jelly group required a higher volume of local anesthetic and a higher need for additional anesthetic

supplement compared to the retrobulbar group with a significant statistical difference.

On the other hand, IOP was significantly higher in the retrobulbar group compared to the lidocaine 2% jelly group immediately after local anesthetic application. But IOP returned to baseline in the retrobulbar group in the rest of the time recordings. This was explained by the direct injection of local anesthetic inside the muscle cone.

The pain scale used (VAS) in our study, has been used previously and has been found to be valid and reliable[20,21]. The VAS has properties consistent with a linear scale, at least for patients with mild to moderate pain, and hence VAS score can be treated as ratio data, so a change in the VAS score could represent a relative change in the magnitude of pain sensation[20,21].

In conclusion, we found that topical lidocaine 2% jelly to be as effective as retrobulbar anesthesia for pain control in patients undergoing 23 G sutureless vitrectomy for selected cases of macular-based disorders (namely idiopathic macular hole and epiretinal gliosis). Lidocaine 2% jelly was found to be similar to retrobulbar anesthesia regarding patient's comfort and surgeon satisfaction. Moreover, it was found to have fewer effects on IOP prior to surgery compared to retrobulbar. In addition, it could be more advisable as it does not involve injections which may lead to complications seen with retrobulbar techniques such as hemorrhage, retinal tears or globe perforation. Finally, it was also found that the lack of akinesia in the lidocaine 2% jelly group did not prevent a successful, uneventful surgical outcome.

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