Original Article

Feasibility and safety of vitrectomy under topical anesthesia in an office-based setting

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Purpose: The purpose of this study was to evaluate the feasibility and safety of office-based vitreoretinal procedures. **Methods:** Patients undergoing primary elective pars plana vitrectomy were elected for surgery in an office-based setting (performed in a minor procedure room under topical anesthesia [TA] and oral anxiolysis). Rates of surgical objective achievement, surgical timing, and comfort were recorded to evaluate feasibility. Intraoperative and postoperative adverse events were assessed to evaluate safety. **Results:** Office-based vitrectomy surgery was performed in 34 eyes of 30 patients. The mean surgical time was 12.351 ± 8.21 min. Surgical objectives were achieved in 100% of cases. The mean best-corrected visual acuity improvement was 9.08 letters ($P < 0.0001$). During most parts of the procedure, no patient reported pain or discomfort. Neither intraoperative nor postoperative adverse events were reported until the final follow-up visit. **Conclusion:** Office-based vitreoretinal procedures under TA could be as feasible and as safe as vitreoretinal procedures under conventional anesthesia.

Key words: Office-based, topical anesthesia, vitrectomy, vitreoretinal procedures

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Ophthalmic regional anesthetic techniques have become the primary options for posterior vitrectomy procedures in recent years and include both akinetic (needle-/cannula-based technique) and nonakinetic (topical anesthesia [TA]) methods. The akinetic techniques are commonly used for posterior eye segment surgery and require the use of retrobulbar, parabulbar, subtenon, or peribulbar injection of anesthetic drugs.[1-3] However, TA has great advantages over regional anesthesia with needle-/cannula-based techniques. For example, TA is associated with quick visual recovery, easier administration, and lower cost with the benefit of avoiding the serious needle-related complications of akinetic anesthesia such as globe perforation.[3]

Yepez *et al*. demonstrated that TA combined with neuroleptic anesthesia was a safe and effective alternative to peribulbar or retrobulbar anesthesia in vitreoretinal procedures.[4,5] This anesthetic approximation has been replicated using 20G,[3] 23G,[2,6,7] and also 25G pars plana vitrectomies.[1,8] It is important to highlight that TA referred to in those reports is supported by the application of preoperative and intraoperative sedation of varying degrees using intravenous benzodiazepines and/or opioid agonists, in conjunction with lidocaine or tetracaine eye drops. Although this type of TA has been used successfully, concomitant intravenous medication with controlled drugs could reduce the vitreoretinal surgery safety and therefore, limit establishment of a standardized office-based procedure.

Office-based procedures in the US are done in an minor procedure room (MPR) with two advanced cardiac life support-certified registered nurses (one circulating and one monitoring) and a surgical technician assistant. An anesthesiologist is not present. Anesthetic protocol is reduced only to TA with oral anxiolysis.[9] To our knowledge, there are no reports in the literature of office-based vitreoretinal procedures. Hence, in this pilot study, we demonstrate the experience with office-based vitreoretinal surgeries under TA using tetracaine drops and an oral anxiolytic in single dose, emphasizing the clinical outcomes and safety.

Methods

Study design and patients

A pilot-study (prospective, interventional, and nonrandomized study) was performed to evaluate the feasibility and safety of office-based vitreoretinal procedures. The study participants were enrolled from August 2016 to March 2017 at a tertiary referral hospital in Zapopan, Jalisco, Mexico. Patients with vitreous haziness, floaters that affect quality of life (daily activities), epiretinal membrane, vitreomacular traction syndrome, and recent diabetic hemorrhage were selected for elective office-based pars plana vitrectomy under TA. Patients

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with previous vitreoretinal surgery, retinal detachment, speech disorder, orthopnea, severe cardiovascular disease, allergy to tetracaine or benzodiazepines, younger than 18 years old, or who had experienced pain prior to the procedure were excluded from the study. The study and informed consent were approved by the local ethics committee and adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all patients after explanation of the study's purpose.

Preoperative assessment

All patients underwent detailed preoperative workup, including best-corrected visual acuity (BCVA) evaluation with Early Treatment Diabetic Retinopathy Study (ETDRS) charts, intraocular pressure measurement, fundus photographs (color and red free), ultrasound B-scan, optical coherence tomography (OCT) scan (macular cube and High Definition (HD) scan) in a Spectral Domain OCT Cirrus (Carl Zeiss, Dublin, CA, USA), and anterior chamber photographs (four quadrants and retro-illumination) using a slit lamp. Besides, before the surgical procedure, patients were questioned about their visual quality rating from 0 (terrible sight) to 10 (excellent sight).

Topical anesthesia and surgical protocols

To achieve anxiolysis, each patient received oral diazepam (7.5 mg) (Valium; Roche, Toluca, Mexico) 30 min prior to the intervention. In addition, topical tropicamide 1% with phenylephrine 5% drops (TP-Ofteno; Sophia Laboratory, Jalisco, Mexico) and 0.5% tetracaine drops (PONTI-Ofteno; Sophia Laboratory, Jalisco, Mexico) were applied twice, every 10 min, before surgery. After achieving maximum pupillary dilation, the eye and the surrounding area were cleaned and given povidone-iodine 5%. After draping, the eye was kept open using a speculum. The surgical procedure was performed in an office-based setting, as previously described for cataract surgery.[9] Briefly, the procedures were done in an MPR, with two advanced cardiac life support-certified registered nurses (one circulating and one monitoring) and a surgical technician assistant. The MPR used in the study is located next to surgery facilities and is preserved under the same cleaning and disinfection protocols followed in an operating room (OR) (terminal cleaning and disinfection every 24 h and cleaning and disinfection between each surgical case with high-level disinfectants). Ventilation, temperature, and humidity of the MPR were regulated by a contamination-controlled airflow system (heating, ventilation, air-conditioning system). The programed room temperature was 21°C with a relative humidity of 40%–60%. Ventilation was preserved trough positive pressure with a minimum of 15 air exchanges per hour. Resuscitation facilities were available all time. This setting is of a clean room dedicated to intraocular injections or other sterile ophthalmic interventions.

During the surgical procedure, all patients were monitored (electrocardiography, O_2 saturation, and blood pressure) and continuous oxygen at 3 L/min was administered through nasal prongs to avoid drowning sensation. Intravenous saline solution was applied, maintaining permeable peripheral vein. Local block (sub-tenon anesthesia), additional anxiolytic, or any sedative medication application was available in case of emergency. One minute before trocar insertion, an additional drop of 0.5% tetracaine was given; after that, sterile swabs soaked in 0.5% tetracaine were placed for 30 s at the three sclerotomy port sites. Anesthetic status was ascertained by gently grasping the bulbar conjunctiva with toothed forceps. Surgeries were performed by two different surgeons using Zeiss OPMI Lumera 700 microscope (Carl Zeiss, Dublin, CA, USA) and a 27G trocar and self-sealing valved cannula system (Constellation Vitrectomy System, Alcon Laboratories, Fort Worth, TX, USA). Three transconjunctival sclerotomies were made in inferotemporal, superotemporal, and superonasal quadrants, after radial displacement of the conjunctiva. Infusion cannula was placed in the inferotemporal cannula. As per protocol, prophylactic ceftazidime (0.06%) in the balanced salt solution was used. Vitrectomy was performed using Alcon Constellation Vitrectomy System (Alcon Laboratories, Fort Worth, TX, USA).

Patients were asked to inform the surgeon if they felt pain or discomfort during the surgery in order to apply another drop of 0.5% tetracaine, this was also registered. When the surgery was completed, the cannulas were removed, and the sclerotomy sites were compressed with a sterile swab to allow self-sealing and to adjust the conjunctiva to its original position. Immediately, after surgery was completed, patients received tobramycin/dexamethasone ointment and were patched. Subsequently, they were kept in observation for 10–15 min and vital signs were obtained, during which, the same observer collected patient assessment responses to pain and experience questionnaires, as soon as possible.

Postoperative assessment

To describe pain experienced during the procedure and actual pain during recovery time, a video-assisted thoracoscopy (VAPS) was used with ratings grouped as follows; 0 (no pain), 1–3 (mild pain), 4–6 (moderate pain), 7–9 (severe pain), and 10 (unbearable pain).[3] Patients' experience was recorded with a second questionnaire, ranging from 0 to 10, grouped as follows; 0 (unpleasant), 1–3 (severe discomfort), 4–6 (moderate discomfort), 7–9 (mild discomfort), and 10 (extremely comfortable). In addition, they were also asked what they observe during the surgery. Furthermore, surgeons completed a questionnaire on the complexity of the procedure and were asked to describe their experience right after the surgery ranging from 0 to 10, grouped as follows; 0 (extremely comfortable), 1–3 (mild movements/squeezing), 4–6 (moderate discomfort significant ocular movements/squeezing/Bells phenomenon), 7–9 (severe discomfort hampering surgical maneuvering), and 10 (unable to perform surgery).[2] All questionnaires were presented to the patients and surgeons in a standardized written form.

Postoperative follow-up

Follow-ups were done at 6 h after surgery and at 2nd, 7th, and 30th postoperative days. In each evaluation, ophthalmic examination was done and questionnaires about ocular pain, visual quality, and visual quality improvement were applied. The visual quality improvement test ranging from 0 to 10, grouped as without improvement (0), mild improvement (1–3), moderate improvement (4–7), and accentuated improvement (8–10). On the 6-h visit, patch was removed and started on gatifloxacin/prednisolone drop every 4 h and oxymetazoline/sodium hyaluronate drop every 6 h.

Statistical analysis

Data were analyzed using the SPSS 22.0 software (SPSS Statistics for Macintosh, Version 22.0, IBM Corp., Armonk, NY, USA). Quantitative variables were described using mean and standard deviation. Difference between means was evaluated by the Wilcoxon signed-rank test. Qualitative variables were described using frequencies and percentages. Significance was defined as $P < 0.05$.

Results

The study included a total of 34 eyes of 30 patients with indication for vitrectomy in an office-based setting. The mean age of patients was 64.1 ± 12.2 years. Nearly 67.6% of patients who underwent surgical procedure were female. Ocular diagnosis and clinical characteristics of the group are detailed in Table 1.

Office-based vitrectomy surgery was performed successfully in all cases with a mean surgical time of 12.351 ± 8.21 min (range: 5.6–46 min). During the procedure, the patients experienced (according to VAPS)[3] no pain in 47.05% (n = 16) of the cases, mild pain in 26.47% (n = 9), moderate pain in 8.82% (n = 3), severe pain in 14.7% (n = 5), and unbearable pain in 2.94% (n = 1). Patients reported that surgical procedure was unpleasant in 0% (n = 0), severely discomfort in 5.88% (n = 2), moderately discomfort in 2.94% (n = 1), mildly discomfort in 14.7% (n = 5), and extremely comfortable in 76.47% (n = 26). In cases where pain was reported, the instillation of additional TA was enough to complete the surgical procedures. The average number of TA instillation was 2.18 ± 8.21 (range: 1–4 times). No regional anesthesia, additional intravenous anxiolytic, nor sedative medication application was required in any patient to complete the surgical procedures. According to procedure complexity reported by the surgeons,[2] 85.29% (n = 29) of cases were classified as extremely comfortable; mild movements in 11.76% (n = 4) and severe discomfort in 2.9% (n = 1). No endophthalmitis or other adverse ophthalmic or systemic events were reported (intraoperative or postoperative). Measures of variables evaluating feasibility and safety of vitrectomy under TA in an office-based setting are summarized in Table 2.

After surgery, BCVA improved from 61.05 ± 16.96 letters at baseline to 70.15 ± 14.94 letters at 30 days after surgery. On an average, the group improved 9.08 letters (range: 1–29) that was clinically and statistically significant ($P < 0.0001$). The same trend was observed in visual quality that improved the score from 5.61 ± 2.30 at baseline to 8.68 ± 1.61 at the 30th postoperative day ($P < 0.0001$). The visual quality improvement reported by the patients had a mild improvement in 2.9% (n = 1) of cases, moderate improvement in 14.7% (n = 5), and accentuated improvement in 82.3% (n = 28) at the end of the follow-up time. Results of visual acuity and visual quality of vitrectomy procedures under TA in an office-based setting are shown in Table 3.

Table 1: Clinical characteristics and ocular diagnosis of the group

	n (%)
Age (years)	
Mean±SD	64.1±12.2
Gender	
Male	11 (32.3)
Female	23 (67.6)
Reported systemic comorbidities	
Arterial hypertension	8 (20.51)
Diabetes mellitus	4 (10.25)
Hepatic insufficiency (posttransplantation)	4 (10.25)
Rheumatoid arthritis	1 (2.56)
Hypothyroidism	5 (12.82)
Other*	6 (15.38)
None	11 (28.2)
Ocular preoperative diagnosis	
Vitreous haziness†	30 (88.23)
Diabetic vitreous hemorrhage (recent)	1 (2.94)
Vitreomacular traction syndrome/macular pseudohole	2 (5.88)
Epiretinal membrane	1 (2.94)
Eye	
OD	22 (64.7)
OS	12 (35.29)

*Including; hepatitis C, breast cancer, migraine, fourth nerve palsy, heart rhythm disorder, Sjögren. †Accompanied or secondary to retinitis pigmentosa, posterior vitreous detachment, retinal tear, nonexudative macular degeneration. SD: Standard deviation, OD: Right eye, OS: Left eye

Table 2: Variables evaluating feasibility and safety of vitrectomy under topical anesthesia in an office-based setting

	n (%)
Reported visual quality improvement after surgery	
Without improvement	0
Mild improvement	1 (2.94)
Moderate improvement	5 (14.7)
Accentuated improvement	28 (82.35)
Pain*	
No pain	16 (47.05)
Mild pain	9 (26.47)
Moderate pain	3 (8.82)
Severe pain	5 (14.7)
Unbearable pain	1 (2.94)
Experience	
Unpleasant	0
Severe discomfort	2 (5.88)
Moderate discomfort	1 (2.94)
Mild discomfort	5 (14.7)
Extremely comfortable	26 (76.47)
Procedure complexity	
Extremely comfortable	29 (85.29)
Mild movements	4 (11.76)
Moderate discomfort	0
Severe discomfort	1 (2.94)
Unable to perform surgery	0
Adverse events related to anesthesia	0 (100)

*Pain reported by the patient during surgery

Table 3: Results of visual acuity and visual quality of vitrectomy procedures under topical anesthesia in an office-based setting

	Preoperative (baseline)	Postoperative (30th day)	*P*
BCVA (ETDRS visual acuity test)			
Mean±SD	61.05±16.69	70.15±14.94	<0.0001
Visual quality			
Mean±SD	5.61±2.30	8.68±1.61	<0.0001

BCVA: Best corrected visual acuity, ETDRS: early treatment diabetic retinopathy study, SD: Standard deviation

Discussion

Nowadays, sutureless vitreoretinal procedures are a common and safety practice with minimum risk and a good security profile. Traditionally, these kinds of procedures are commonly performed in an OR under regional akinetic (needle-/cannula-based) anesthesia and intravenous sedation monitored by an anesthesiologist. However various severe ocular and systemic complications have been reported with akinetic anesthesia. For example, retrobulbar anesthetic injection has been related to ptosis and diplopia,[10] globe perforation,[11,12] restrictive strabismus,[13] retinal vein and artery occlusion,[14,15] injury to the optic nerve,[16] cranial nerve palsies,[17] and seizures and cardiorespiratory arrest.[18,19] Furthermore, other less invasive forms of regional injected anesthesia can result in serious complications such as globe perforation or cardiovascular problems during peribulbar injections[20-22] and globe perforation during subtenon anesthesia.[23] Using intravenous controlled medication during vitreoretinal surgeries is a hurdle in the establishment of a standardized office-based procedure.

In an attempt to establish the bases for vitreoretinal procedures under TA in an office-based setting, we evaluated the feasibility and safety of posterior-segment eye surgeries, performed under TA and oral anxiolysis in an MPR. It was observed that vitreoretinal surgeries under these conditions are feasible, reaching the therapeutic objectives in 100% of the patients; in fact, visual acuity and visual quality were improved after the procedure. Although preoperative diagnoses varied, on an average, the group improved 9.08 letters ($P < 0.0001$) and reported moderate-to-accentuated visual quality improvement in the 97.05% of cases. This functional success was achieved with the patient perception of extremely comfortable experience in most cases (76.47%). In agreement with Raju *et al*.,[8] we reduced the initial discomfort by placing sterile swabs soaked in 0.5% tetracaine at the three sclerotomy port sites for 30 s. It is important to emphasize that all patients reporting their surgical experience with severe and moderate discomfort, or referred severe to unbearable pain, based their answer only in the moment of trocar insertion. Pain experienced by these patients was transient and related to trocar insertion. Like other authors have mentioned, we observed that the most painful moment or discomfort in vitreoretinal procedure is experienced during initial trocar insertion and no pain was reported during laser application and removal of cannulae.[1-3,6] In fact, the pain experienced by trocar insertion in TA is less frequent than the pain experienced by injection of anesthetic drugs in needle-/cannula-based regional anesthesia. For example, the injection in retrobulbar anesthesia is reported as the most painful step of the surgery in 46.9%[6] to 82%[3] of cases. It is important to mention that despite a few patients experienced pain, the instillation of additional TA was sufficient to complete the surgical procedures. In fact, no regional anesthesia was needed in any patient to reach the surgical objectives.

Depending on the experience of the surgeon, the vitreoretinal procedures under TA were extremely comfortable in most cases (85.29%). One case (2.94%) reported as severely discomforting and took longer time (46 min) than the mean time (12.351 ± 8.21 min); nonetheless, the patient cooperated adequately during the whole surgical time, and no additional anxiolytic or any sedative medication application was required. It is worth mentioning that none of the patients required application of intravenous medication or an extra dose of anxiolytic.

Regarding the safety of the procedures under TA, no adverse events, neither systemic nor ophthalmic related to anesthetic procedure, were reported. Although unexpected movement of the eye during macular procedures could be an issue with TA, this was neither an inconvenience nor an obstacle for the surgeon. The eye was stabilized through intraocular instruments and patients were explained in advance to avoid such movements. In fact, because TA was used, the position of the eyeball could easily be adjusted if necessary by a surgeon command. Furthermore, the patients were instructed to report any pain or discomfort throughout the process. There were no reported cases of iatrogenic complications due to sudden movement of the eyeball during the procedure, like others have referred.[3] This could be associated with the following: oral anxiolysis, use of small caliber trocars (27G), self-sealing (valved) cannulas, and the instruction of the patients previous to the procedure.

Finally, there was no need in this study to use sedatives or controlled drugs that required the continuous monitoring of an anesthesiologist, which are used exclusively in an OR. As Ianchulev *et al*. reported,[9] we did not use intravenous medication; reducing ophthalmic and systemic adverse events related to intravenous anesthesia. Therefore, the use of TA, the lack of need for an anesthesiologist during the procedure, and no use of controlled intravenous medication translate into a positive cost–benefit ratio of office-based vitreoretinal procedures. However, it should be considered that TA has its own limitations. It is highly dependent on patient co-operation as well as the skills of the surgeon. Therefore, a TA anesthesia protocol requires careful selection of patients.

Conclusion

We demonstrate that posterior eye surgeries performed under TA and oral anxiolysis in an MPR are feasible and can be as safe as those performed in an OR under regional blockage and intravenous sedation. However, large-scale, prospective multicenter studies are needed to further recommend this vitrectomy setting as a common practice.

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Conflicts of interest

There are no conflicts of interest.

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