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Ophthalmic Regional Anesthesia

Medial Canthus Episcleral (Sub-Tenon) Single Injection Block

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Background: **The purpose of this study was to evaluate the efficacy and safety of episcleral single-injection anesthesia in a large number of patients.**

Methods: **Over a period of 5 yr, in four institutions, anesthesiologists involved in this prospective study completed a standardized form to evaluate single-injection medial canthus high-volume episcleral anesthesia. The success rate of the block was rated according to an akinesia score. The study parameters included demographic data, surgical procedure, and anesthetic management. All patients were followed up at least until postoperative day 1, and all complications, pain, and discomfort were noted. Statistical analysis was done to assess the risk factors for complications.**

Results: **A total of 2,031 patients were included in the study. The most frequent surgical procedures performed were phacoemulsification and posterior chamber artificial lens implantation (91.0%). A total of 66 complications (3.3%) occurred in 60 patients. One patient had a retrobulbar hemorrhage, and 59 had one or two more minor incidents or pain/discomfort with the procedure. The complications consisted of subconjunctival hematoma (1.3%), ocular hypertonia (0.4%), and chemosis (0.30%). Statistical analysis revealed that inexperience in the technique represented a risk factor for complications.**

Conclusions: **This is the first survey of a large experience in episcleral single-injection anesthesia, a form of anesthesia that does not preclude sharp-needle complications and does require training. Only one complication occurred among 2,031 patients; however, a larger number of patients is needed to definitively evaluate the safety of episcleral single-injection anesthesia.**

REGIONAL anesthesia is commonly used during ophthalmic surgery. Previously, retrobulbar and peribulbar anesthesia were the techniques widely used for many years. Rare but dramatic complications (*e.g.*, globe perforation, brainstem anesthesia, postoperative strabismus, retrobulbar hemorrhage, optic nerve injury) have been described with these two techniques.[1] Sub-Tenon anesthesia is an alternative[2]; however, its safety is still debated.[3–5] We previously showed the efficacy of single-injection medial canthus high-volume episcleral (sub-Tenon) anesthesia (ESA).[6] The low incidence rate of complications with ophthalmic regional anesthesia dictates that a large sample be used to assess safety for ESA. Therefore, the aim of this prospective study is to report a large experience with ESA and to assess its efficacy and safety.

Materials and Methods

Inclusion Criteria

Following research committee approval from our four centers, patients scheduled for elective ophthalmic procedures with an expected duration of less than 60 min were eligible for this prospective observational study. Contraindications for regional anesthesia were clotting abnormalities, impaired mental status, uncontrolled glaucoma, recent surgical procedure on the same eye, and refusal to participate. During a period of 5 yr, anesthesiologists were asked to participate in this study. Participating anesthesiologists enrolled all eligible patients after the patient's verbal consent and anonymously completed a standardized evaluation form.

Anesthetic Management

Patients received oral premedication with 150 μg of clonidine 1 h before surgery. A peripheral intravenous catheter was inserted, and monitoring included continuous electrocardiography, pulse oxymetry, and automated noninvasive blood pressure measurement. Before induction of the blockade, oxybuprocaine or tetracaine drops were instilled on the eyeball and propofol was injected intravenously to obtain a brief period of sedation during eye puncture. Excessive sedation that could lead to apnea or loss of contact with the patient and result in possible movement during the puncture was avoided.

The technique used has been formally described.[6,7] A 25-gauge, short-bevel needle was inserted to contact the conjunctiva between the eyeball and the semilunaris fold, at a depth of less than 1 mm (fig. 1). The bevel was directed toward the globe. The needle was then shifted slightly, medially displacing the semilunaris fold and caruncle away from the eyeball (fig. 2). The needle was then advanced in an anteroposterior direction, with the globe directed slightly medially by the needle until a

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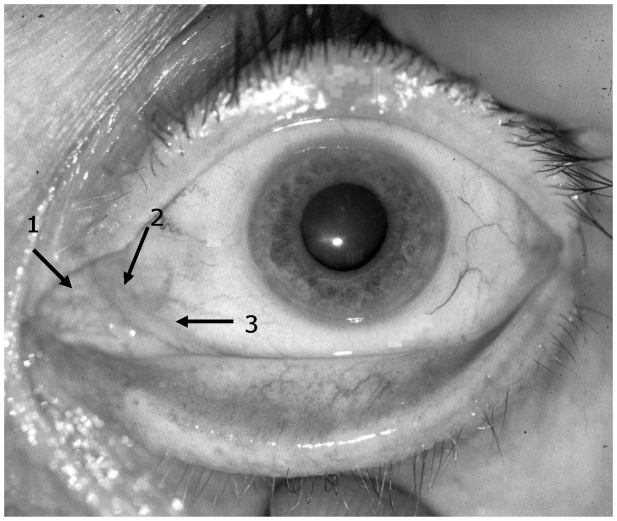

Fig. 1. Site of needle introduction in episcleral (sub-Tenon) anesthesia: *1* = caruncle, *2* = semilunaris fold of the conjunctiva, *3* = point of needle insertion.

"pop" was perceived, at a mean depth of 15–20 mm. At this point, the globe returned to the primary gaze position. This point is considered to be the depth marker, confirming the episcleral location of the needle tip. After an aspiration test, the local anesthetic mixture was slowly injected. A local anesthetic mixture, with hyaluronidase 25 U/ml, was chosen by the anesthesiologist as follows: lidocaine 2% in equal part with bupivacaine 0.5%, mepivacaine 2% alone, lidocaine 2% alone, or bupivacaine 0.5% alone. The injected volume was adjusted for each patient. The injection was continued until subconjunctival edema (chemosis), proptosis, and lid fullness appeared, which are considered predictive factors for success of the blockade. Ocular compression was then applied for 10–20 min using a Honan balloon set at 30 mmHg to lower intraocular pressure and resorb chemosis.

Study Parameters

Demographics, Surgical Procedures, and Anesthetic Management. All data were collected prospectively in the four centers using a standardized form. Demographic data included age, gender, weight, and height. Surgical description included side, axial length of the globe (as measured preoperatively using echography), type of procedure, and duration. Anesthesiologist's experience (inexperienced = resident and physicians having < 3 months' experience with the technique, or < 50 ESA performed; experienced = staff physicians), propofol dosage, depth of needle insertion (at 5-mm intervals), mixture of anesthetic, and volume injected were noted.

Primary Endpoint. All patients were followed at least until postoperative day 1. During the observation period, major complications (globe perforation, retrobulbar or peribulbar hemorrhage, brainstem or optic nerve injury, or strabismus) and minor incidents (persistent chemosis after compression, subconjunctival edema, ocular hypertonia) were recorded. Discomfort and pain were also noted during the procedure.

Secondary Endpoints. Efficacy of the block was evaluated according to the level of akinesia (immobility) of the globe and eyelids and was scored by the anesthesiologist at 5, 10, 15, and 20 min after the end of injection. An 18-point scale was used in which each of the four rectus muscles, levator palpebra, and orbicularis of the eyelids were scored between 0 and 3 (0 = no block, 1 = partial akinesia unsuitable for surgery, 2 = partial but sufficient akinesia, 3 = total akinesia). The final score added the six subscores and ranged from 0 (no block) to 18 (total akinesia). The best akinesia score was defined as the highest score obtained for each block without or before supplemental injection when necessary. Time of onset was defined as the time elapsed from the end of injection to the best akinesia score. If akinesia was judged to be insufficient, the anesthesiologist was free to perform an additional injection at the same site to provide total akinesia. Any need for supplemental injection was noted.

Anesthesia–related scores of satisfaction were determined postoperatively by the surgeon, patient, and anesthesiologist, using a subjective verbal scale from 0 (total dissatisfaction) to 10 (total satisfaction).

Statistical Analysis

Results are expressed as the median (minimum, maximum). To assess factors associated with complications, incidents, or pain, patients who reported one or more of these undesirable events were compared with those who did not. A Fisher exact test was used to compare categorical variables (gender, surgery side, type of surgical procedure, type of anesthetic mixture, supplemental injection, anesthesiologist's experience, inclusion

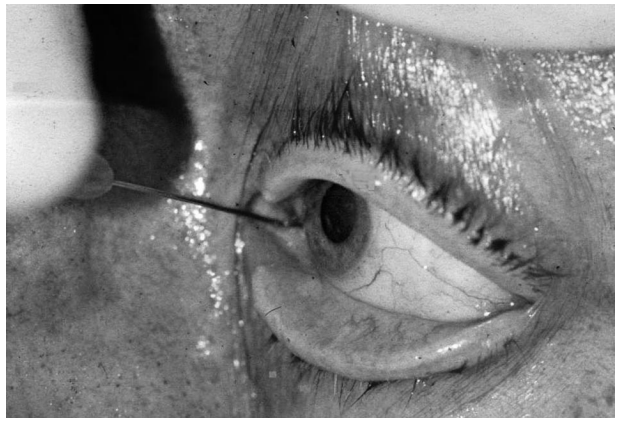

Fig. 2. Intraoperative view of episcleral (sub-Tenon) anesthesia. The bevel of the needle is inserted in the conjunctiva. The needle is shifted medially to point away from the globe and pull the Tenon capsule and the conjunctiva, which are joined at this level. The needle is advanced strictly posteriorly.

Table 1. Number, Percentage (± SD) of Complications, Minor Incidents, Pain, and Discomfort in 2,031 Patients Who Received ESA

	No.	%	±SD
Complication (retrobulbar hemorrhage)	1	0.05	±0.05
Minor incident	52	2.56	±0.35
Subconjunctival hemorrhage	26	1.28	±0.25
Ocular hypertonia	8	0.39	±0.14
Chemosis	6	0.30	±0.12
Corneal edema or ulceration	4	0.20	±0.10
Ocular–cardiac reflex	2	0.10	±0.07
Inexperienced anesthesiologist, puncture failure*	2	0.10	±0.07
Caroncular hematoma	1	0.05	±0.05
Conjunctival irritation	1	0.05	±0.05
Lacrymal puncture producing nasal anesthesia	1	0.05	±0.05
Bleeding during surgery (patient receiving aspirin)	1	0.05	±0.05
Pain and discomfort	13	0.64	±0.18
Pain during puncture	2	0.10	±0.07
Pain during surgery	3	0.15	±0.09
Pain during surgery with conversion to general anesthesia	1	0.05	±0.05
Pain during muscle traction	3	0.15	±0.09
Various pain or discomfort	4	0.20	±0.10
Total	66	3.25	±0.39

* Inexperienced anesthesiologist performed needle introduction but without injection; the block (puncture and injection) was completed by the experienced anesthesiologist.

ESA = episcleral (sub-Tenon) anesthesia.

center). Ordinal and continuous variables (age, weight, height, biometry, propofol dosage, injected volume of local anesthetic mixture, depth of needle insertion) were compared using the Kruskal-Wallis test. Univariate logistic regression analysis was used to measure the odds ratio between undesirable events and relevant risk factors. All risk factors that had a *P* value of less than 0.20 determined by univariate regression were entered into a multivariate logistic regression model. Using complications as the dependent variable, models were performed by the means of stepwise backward procedure. Odds ratios of complication occurrence are presented with 95% confidence intervals. All reported *P* values are two-tailed, and a *P* value of less than 0.05 was considered statistically significant. Statistical analyses were performed using SAS/STAT software, version 8.1 (SAS Institute, Cary, NC).

Results

Of the 2,031 forms collected, 94% were fully completed. A total of 1,557 patients were from Caremeau Hospital, University Hospital of Nîmes; 474 patients were from the three other institutions. There were 1,176 women (58.5%) and 835 men (41.5%); median age, weight, and height were, respectively, 75 (range, 19–96) yr, 65 (range, 30–125) kg, and 165 (range, 140–190) cm. Surgery was conducted in 996 right eyes (50.4%) and 979 left eyes (49.6%). The median axial length of the globe was 23.2 (range, 19.5–34.4) mm. Most (1,747; 91.0%) of the surgical procedures were phacoemulsifications and posterior chamber artificial lens implantations. Also performed were 48 (2.5%) open globe procedures for lens extraction, 69 (3.6%) procedures to treat glaucoma, 44 (2.3%) procedures in the posterior segment (retinal surgery, vitrectomy), and 12 (0.6%) miscellaneous procedures. The median duration of surgery was 20 (range, 5–180) min. Anesthesia was performed in 1,603 cases (79.0%) by an experienced anesthesiologist and in 426 cases (21.0%) by an inexperienced anesthesiologist. The dose of propofol given at the time of the puncture was 0.50 (0.0–3.5) mg/kg. The median depth of needle insertion and injected volume were, respectively, 15 (5–35) mm and 10 (2–14) ml. Only one patient received Xylocaine; 7 (0.3%) received bupivacaine, 194 (9.6%) received mepivacaine,

Table 2. Patients' Characteristics, Anesthetic, and Surgical Management According to Complication, Incident, or Pain Occurrence

	Complication, Incident, or Pain	
	No	Yes
Demographic data		
Gender		
Male	808 (41.4%)	27 (45.0%)
Female	1,143 (58.6%)	33 (55.0%)
Age (yr)	75.0	76.0
Weight (kg)	65.0	68.0
Height (cm)	164.0	165.0
Surgical characteristics		
Surgery side		
Right	972 (50.7%)	24 (41.4%)
Left	945 (49.3%)	34 (58.6%)
Surgical procedure		
Phacoemulsification	1,691 (90.8%)	56 (98.3%)
Open globe lens extraction	48 (2.5%)	0
Procedure for glaucoma	69 (3.7%)	0
Procedure on posterior segment	44 (2.4%)	0
Other	11 (0.6%)	1 (1.7%)
Biometry (mm)	23.2	23.3
Anesthetic characteristics		
Propofol (mg/kg)	0.5	0.4*
Injected volume (ml)	10.0	9.0*
Depth of needle injection (mm)	15.0	15.0
Local anesthetic mixture		
Xylocaine/bupivacaine	1,759 (90.0%)	53 (88.3%)
Mepivacaine	187 (9.6%)	7 (11.7%)
Bupivacaine or lidocaine alone	8 (0.4%)	0
Supplemental injection		
No	1,838 (93.8%)	54 (90.0%)
Yes	122 (6.2%)	6 (10.0%)
Anesthesiologist's experience		
Junior	400 (20.3%)	26 (43.3%)*
Senior	1,569 (79.7%)	34 (56.7%)*
Inclusion center		
CHU Nimes	1,515 (76.9%)	42 (70.0%)
Other	456 (23.1%)	18 (30.0%)

Values are median or number (percentage).

* $P < 0.05$.

Table 3. Univariate and Multivariate Logistic Regression Analysis to Assess Risk Factors for Complications, Incidents, or Pain with ESA

	Univariate Analysis		Multivariate Analysis			
			First Model		Final Model	
	OR	95% CI	OR	95% CI	OR	95% CI
Gender						
Female	1					
Male	1.2	0.7–1.9				
Age (yr)	1.0	0.9–1.1				
Weight (kg)	1.0	0.9–1.1				
Height (cm)	1.0	0.9–1.1				
Biometry (mm)	1.0	0.9–1.1				
Surgery side						
Right	1					
Left	1.5	0.9–2.5				
Surgical procedure						
Phacoemulsification	1					
Other surgical procedures	0.6	0.3–1.2				
Propofol dosage (mg/kg)	0.1*	0.1–0.5	0.1	0.1–0.5	0.1	0.1–0.4
Local anesthetic mixture						
Xylocaine + bupivacaine	1					
Other local anesthetic mixture	1.2	0.6–2.8				
Injected volume (ml)	0.8*	0.6–0.9	1.1	0.8–1.6		
Depth of needle insertion (mm)	1.0	0.9–1.1	1.1	0.9–1.2		
Additional injection						
No	1					
Yes	1.7	0.7–3.9				
Anesthesiologist's experience						
Experienced	1		1		1	
Inexperienced	3.0*	1.8–5.1	3.1	1.5–6.2	3.2*	1.7–6.3
Institution						
CHU Nimes	1					
Other institution	0.7	0.4–1.2				

* $P < 0.05$.

CI = confidence interval; ESA = episcleral (sub-Tenon) anesthesia; OR = odds ratio.

and 1,812 (90.0%) received a lidocaine-bupivacaine mixture. Hyaluronidase 25 U/ml was used in each case.

Primary Endpoint

A total of 66 complications occurred in 60 of the patients. One patient had a retrobulbar hemorrhage; 59 had one or two minor incidents or pain and discomfort (table 1). In the patient with a retrobulbar hemorrhage, a resident had performed the ESA for a phacoemulsification, and the needle insertion depth was 15 mm. After compression, the procedure was canceled; no morbidity related to this complication occurred. Only one patient required general anesthesia for pain, and no complications due to unsuitable anesthesia occurred.

A comparison between patients who presented with a complication and those who did not is presented in table 2. Results of the univariate and multivariate analyses revealed that inexperience in the technique represented a complication risk factor (table 3).

Secondary Endpoints

The best akinesia score was 18 (range, 0–18) and was reached after 5 min (range, 5–35 min). A full score (18 out of 18) was achieved after the first injection for 1,756 (86.5%) patients. The anesthesiologist determined that reinjection was needed in 128 cases (6.3%). The anesthesia-related satisfaction scores were, respectively, for the surgeon, patient, and anesthesiologist: 10 (4–10), 10 (5–10), and 10 (2–10).

Discussion

Based on this series of 2,031 cases, ESA provides relatively safe anesthesia. In regional ophthalmic anesthesia, the incidence of needlestick injuries is very low, but these injuries can be catastrophic. Incidence of and risk factors for complications have been reported in larger series[1,8–10] for retrobulbar and peribulbar anesthesia, but not for ESA. To our knowledge, this prospective study on the safety of ESA is the largest published to date.

We observed 52 minor incidents, which, as expected, consisted of subconjunctival hemorrhages and chemosis and are related to the space of injection. In a large study, using a similar space of injection, Guise observed a similar incidence of these events.[3] Transient and moderate spikes of ocular pressure are observed with ESA (J. Ripart, M.D., unpublished data, 1997). However, in this

study the surgeons noted persistent ocular hypertonia in seven patients, all of whom were scheduled for phacoemulsification. In one case, the anesthesiologist indicated that compression time had been too short; in another case hypertonia occurred after a supplemental injection (total injected volume, 14 ml). The use of a large volume of drug for sub-Tenon anesthesia is questionable, as it can induce retinal damage. Pianka *et al.* showed that sub-Tenon anesthesia causes a decrease in pulsatile ocular blood flow, even without a change in intraocular pressure.[5] However, in posterior segment surgery, Li *et al.* used a large volume of local anesthetic without complications.[11] Moreover, we observed no complications among the 69 patients scheduled for a procedure to treat glaucoma.

One patient had a retrobulbar hemorrhage, which has not previously been reported with ESA. Theoretically, ESA has many advantages, such as a point of puncture in an avascular zone, reduced depth of needle insertion, and rare occurrence of myopic staphyloma in the medial aspect of the globe.[12] Nevertheless, the complication we observed demonstrates that ESA does not avoid the sharp-needle complications previously described with retrobulbar or peribulbar block. Many other unpublished complications of ESA have been reported to our staff: three retrobulbar hemorrhages and one globe perforation. We are not aware of any other complications (brainstem, optic nerve injury, or retinal lesion), published or not. To avoid needle injuries, episcleral anesthesia may be performed using surgical blunt dissection and insertion of a cannula. Recently, Guise showed the excellent safety of this technique,[3] observing no hemorrhage or perforation in a larger number of patients than in the current study. Nevertheless, the use of a cannula does not entirely avoid major complications. Retrobulbar hemorrhage, globe perforation, and central nervous system spread have been reported.[4,13,14]

To our knowledge, all complications reported here occurred when an inexperienced operator performed the ESA. This is in agreement with the strong association observed (odds ratio, 3) between the operator's inexperience and the rate of complications in this survey. Performing ophthalmic regional anesthesia necessitates anatomical knowledge and technical skill. Lack of anatomical knowledge led one of our residents to puncture the lacrimal duct due to reluctance to insert the needle near the globe. However, blind needle insertion into the orbit carries its own hazards.

Secondary endpoints of this study were efficacy of the block based on akinesia and anesthesia-related satisfaction. Total akinesia was obtained in most of the patients (86.5%) after the first puncture and in more than 90% after a supplemental injection. These results are in agreement with other experiences with the use of episcleral anesthesia.[15,16] The choice of an akinesia scale may be criticized regarding efficacy of the block.[6] However, this scale is reproducible, and the efficacy of the anesthesia is in agreement with the good subjective anesthesia-related scores given by the surgeon or the patient.

Conclusion

This is the first survey of a large experience with ESA. ESA does not avoid sharp-needle complications and does require practice. Only one complication occurred among 2,031 patients; however, a larger patient group is needed to definitively evaluate the safety of ESA.

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