A Comparative Study of Topical Versus Peribulbar Anesthesia in Phacoemulsification and Implantation of Foldable Intraocular Lens in Cataract Surgery

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Citation

K Said, M Hassan, F Qahtani, F Mansoori. *A Comparative Study of Topical Versus Peribulbar Anesthesia in Phacoemulsification and Implantation of Foldable Intraocular Lens in Cataract Surgery*. The Internet Journal of Ophthalmology and Visual Science. 2002 Volume 2 Number 1.

Abstract

Objectives

To evaluate and compare levels of patient discomfort and complications during phacoemulsification and implantation of foldable intraocular lenses under topical and peribulbar anesthesia in senile cataract.

Methods

A prospective, randomized, controlled trial was carried out in our ophthalmology center, Doha, Qatar. The duration of the study was from August 4th, 1999 to August 4th, 2001.
A total of 730 eyes of 730 patients aged 48-100 years, females 41%., males, 59% . In 365 eyes phacoemulsification was done under peribulbar anesthesia, another 365 eyes received topical anesthesia. All patients underwent clear corneal incision in the steepest meridians, phacoemulsification and implantation of foldable intraocular lens. The group of peribulbar anesthesia received 2 injections (2-4 ml) of a combination of 0.5% bupivacaine hydrochloride, 2% lidocaine and hyaluronidase 150 iu into peribulbar space upper naselly and lower temporal, total (4-8ml). Patients in the topical group received drops (approximately 200 microl.) of oxybuprocaine hydrochloride 0.4%) and +/- murcaine 0.25% (bupivacaine drops)

Results

The overall intraoperative complication rate was 0.9 % for capsular tear, 3% for zonular tear, 1.5% for vitreous loss, and 0.5% for iris prolapse. Vitreous loss occurred in 5 cases in the peribulbar group and in 2 cases in topical group. Chemosis was found in 2.5% in the peribulbar group and zero % in the topical group. No difference in intraoperative and early postoperative complications was found. Subconjunctival hemorrhage, 1.7% and periorbital hematoma, 0.1% occurred in the peribulbar group. The pain scores was estimated to be 0 to 1 in 90% and 2 to 3 in 10% in the topical group, and 0 to-1 in 75% and 2 to-3 in 25% in the peribulbar group. Patient satisfaction was 90% for topical and 72% for peribulbar techniques. Surgeons found difficulties in 4% of the topical group.

Conclusion

Surgery-related complications and patients discomfort were similar for the two methods of anesthesia. Topical anesthesia is justified as a means of improving safety.

OVERVIEW

In our ophthalmology center in DOHA, QATAR (population of 500,000) approximately 6,626 ophthalmology-surgeries were performed under 60% local anesthesia and 40% under general anesthesia between 1995 and 2001. Cataract surgery (2,639 eyes) is performed almost exclusively as an outpatient procedure. 87.8% undergo local anesthesia and 12.2% general anesthesia. Local injections (retrobulbar, peribulbar, subconjunctival / sub-tenons) ([20]) and topical administration are performed according to accepted techniques as in any international ophthalmology center.([21])

Surgeons and anesthesiologists preferences, as well as patient characteristics, are believed to influence the choice of anesthetic management for cataract surgery ([22]). We investigated which would provide the best management of patient with fewer complications. ([23],[24])

BACKGROUND

Peribulbar injection of anesthetic agents has been used for more than a century in cataract surgery and various modifications have been devised over the last two decades to reduce the risks of injury of intraorbital structures during surgery.

The blind insertion of a needle into the retrobulbar space has never been completely free from sight and life threatening complications.([1])

Topical anesthesia was first used in 1884 by Koller who used cocaine.([2]) After one century, Fichman used an attractive alternative method of injecting local anesthetic agents resulting in faster visual recovery and high patient satisfaction 1995 ([3]) .

The advantages of topical anesthesia include its ease of application, minimal to absent discomfort on administration, rapid onset of anesthesia and more important reduction of risks associated with retrobulbar or peribulbar injection. The technique is also economical, avoids undesirable cosmetic adverse effects, and allows instant visual rehabilitation. Topical anesthesia blocks the trigeminal nerve ending, provides at least analgesia of the eye. The optic nerve and motor neurons are not affected, and the ocular motility is maintained. ([4])

Some reports indicate that topical anesthesia is safe and effective in most uncomplicated cataract procedures. Other studies ([5]) suggested that topical anesthesia should not be considered in eyeswith severe concomitant ocular pathological features. Manipulation of the iris or stretching of cilliary and zonular tissues which may be irritable during surgery in complicated cases, could irritate the unanesthetized ciliary nerve ending and result in patient discomfort and inadvertent eye movement, compromising the overall safety of the procedure. ([6])

METHODS AND PATIENTS SELECTION

To investigate the efficacy and safety of topical aesthesia, a prospective, randomized, controlled clinical trial was carried out, comparing peribulbar with topical anesthesia in patients with senile cataracts undergoing clear corneal pahcoemulsification and foldable intraocular lens (IOL) implantation.

Anesthesia related intraoperative and early postoperative complications were evaluated Patients pain score and intraoperative conditions judged by two surgeons, two anesthetists and the same group of nurses were recorded. Random cases were selected for either topical or peribulbar anesthesia. From the fourth of August 1999 to the fourth of August 2001 (two years duration) 2,639 cases (730 cases for phacoemulsification and foldable IOL implantation) were scheduled for either topical or peribulbar anesthesia.

Patients were prospectively assigned to a topical or peribulbar anesthesia group using a random number table. The patients included in the study had at least one of the following conditions: diabetes mellitus 75%, hypertension 40% , cardiac problems 13%, and chronic asthma 7%, (each of these diseases was controlled with one or two drugs two to three weeks before the operation prescribed by a specialist physician). The patients also had some ocular co-exciting diseases like glaucoma, axial myopia, axial hyperopia, sunken eyes, poor pupillary dilatation less than 3 mm (which happened in 6% of patients in our study), previous intraocular surgery, posterior synechia, phacodonesis or previous intraocular surgery (peripheral irredectomy, glaucoma).

Patients with allergy to lidocaine were excluded and also patients with complex anterior segment pathological features. During the patients visit to the clinic, they had been informed about details of the operation 2-3 weeks before the scheduled procedure. Consent was obtained before surgery from patients or relatives with possible topical or peribulbar anesthesia according to our ethics committee.

SURGICAL TECHNIQUE

All surgical procedures were performed in the ophthalmology center by the same two surgeons. They used standardized clear corneal phacoemulsification and implantation of IOL. A temporal clear corneal incision was made using a 3-step incision while the globe was immobilized by asking the patient to look to the light or to look down towards his feet.

Two side ports paracentesis, each 90 degrees from temporal miridian, were performed. Viscoelastic injection (Healon), continuous curvilinear capsular hexis, hydrodissection, hydrodelneation, phacoemulsification, bimanual aspiration of the remaining cortical lens material, and finally in the bag implantation of the foldable IOL was performed.([7]) The pupil was dilated with sphincterotomies (or iris retraction hooks in some difficult cases) followed by IOL implantation and removal of the viscoelastic substance. The pupil was constricted with intracameral application of 0.01% carbachol (Miochol) ([8]). The wound was tested for leaking of fluids by gentle compression with a sponge and in 98% of the patients there was no need to suture the wound.

Postoperative treatments were similar in both groups. In the peribulbar group we used subconjunctival injection of gentamycin and decadron via a tuberculin syringe. In the topical group, we used gentamycin and decadron ointment. Further drug administration was based on postoperative conditions.

ANESTHESIA ADMINISTRATION

No patients in either group received any oral sedation before operation or injection. The patients were fasting and used their routine drugs for treatment of hypertension, cardiac disease, or bronchial asthma (with sips of water early in the morning). All our patients were day care cases and were admitted at 7 am in the morning of the operation. Blood pressure, heart rate , temperature, chest auscultation, and blood sugar level were recorded in the anesthesia sheet .

On the table, the patients were connected to monitors for blood pressure, ECG, respiratory rate, pulse oximetry, and nasal or oral catheter for oxygen at a rate of 3-5 LPM. In addition, a venous cannula gauge 18 or 20 was inserted in the dorsum of one hand for emergency drug administration and for blood withdrawal.

Patients in the peribulbar anesthesia group received two injections each 2-3 ml of mixed solution of 0.5% bupivacaine hydrochloride (4ml), 2% lidocaine (4 ml), and 0.5 ml of hyaluronidase = 150 iu (wydase) into the peribulbar space (upper nasal and lower temporal) of the eye.([9])

The superior injection is performed below the supraocular notch and the inferior just above the infraocular notch in the anterior third of the eye globe. The volume and dose of the drugs were calculated according to size of the globe. Ocular compression for 5-10 minutes was achieved by manual compression. Prior to surgery, the surgeon assessed the effectiveness of the block. Minimal ocular motility of orbicularis function was observed.

PAIN ASSESSMENT

I Each patient was asked a direct question if he had pain and the answer was recorded as follows : No pain = 0 Mild pain=1 (tolerated pain) Moderate pain=2 (needs help or interference like more anesthetic or analgesic) Severe pain=3 (not tolerated and needs to stop the procedure) Time of pain record for each patient After lying down on the table and connecting with monitors just before any interfering After topical or peribulbar anesthesia application After phacoemulsification and removal of the content of lens . This is a very important stage due to pressure during phacoemulsification and fluid irrigation. After insertion of foldable lens.([10]) II Watching and recording the monitors data for vital signs, pulse, blood pressure, respiratory rate, pulse oxymeter, and ECG were recorded in each stage of patients pain record. III Any verbal expression or motor reflex of patient in every stage was recorded in anesthesia sheet by time. IV The surgeons comment during surgery was recorded as follows : No difficulty Slightly difficult Moderate difficult Difficult Extremely difficult V Blood samples were taken Just after lying down on table before any procedure after connecting the monitor Thirty minutes after topical or peribulbar injection (most of our surgery finished or about to finish). Sixty minutes after anesthesia in recovery room or day care rooms. ([11]) Random study for 10% of cases in topical or peribulbar anesthesia after 24 hours VI Direct questioning of the patient after 24 hours (if the patient likes to have the same procedures or type of anesthesia in the other eye in the future). The same question was posed to the surgeon and the results were recorded. ([12])

STATISTICAL ANALYSIS

Outcome measures were the number of complications and adverse events arising preoperative, intraoperative and

within 24 hours postoperatively. The surgeon judged patient pain score, and intraoperative condition after completion of the procedure. Outcome measures were compared by using an unpaired t test. Pain score for each patient in each group was compared using a 2 tailed Mann-Whitney test. Bivariate analysis was performed using the a X H2test

PAIN SCORE:

Pain scores were reported by patients after surgery. In 333 (91%) cases of the topical anesthesia group and 274 (75%) cases in the peribulbar anesthesia group, patients reported minimal pain (0-1). Outcome measures were compared using a t test / Mann-Whitney test. For parametric statistics a bivariate analysis x2 test was performed. (The mean +/- SD pain score in topical anesthesia group was 0.94+1.3 (range 0.-3) while the peribulbar anesthesia group revealed 0.86+1.5 (range 0-3)). The difference between the mean pain scores was not statistically significant. Anxiety before anesthesia administration was 4% in topical the group and while 9.5% in the peribulbar group.

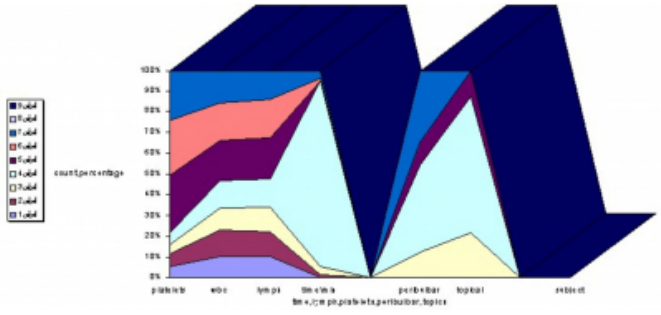
During anesthesia, approximately 53% in peribulbar group reported discomfort (pain score of 1-2) , while only 2% (pain score of 1-2) in the topical anesthesia group suffered pain. During intraoperative manipulation of the iris, distension of the anterior chamber, intracameral administration of acetylcholine chloride (Michole) and rotation of the IOL, 19% of the peribulbar group (score 1-2) and 1% in the topical anesthesia group (score 3) reported pain.

8% of the topical anesthesia group needed intracameral bupivacaine injections ($_{13}$,). Intraoperative conditions (judged by the surgeon) were unsatisfactory in 3% of the peribulbar and in 4% of topical anesthesia group due to movement of the eye, but there was no difficulty to slightly difficulty in the topical anesthesia group. Surgeon satisfaction was 90% in the topical group and 88% in the peribulbar group. Patients satisfaction was 90% in the topical and 72% in the peribulbar group.

After 24 hours, 18% of the patients in the peribulbar group asked for other types of anesthesia, while only 7% in topical anesthesia group wanted to change. In the peribulbar group, 9 cases needed intramuscular injection of voltaren (75 mg) to release back pain, while only one case in the topical anesthesia group suffered back pain. In the peribulbar group, 2 cases reported heart failure and pulmonary edema due to previous disease and stress, while nobody in topical anesthesia group had a similar complication . Figure1,2.

Figure 1

Figure 1



RESULTS

Three hundred sixty five cases (eyes) were randomized to the topical anesthesia group and the same number 365 eyes to peribulbar anesthesia group.

1. Differences between the two groups in age, sex, coexisting disease were not statistically significant (P=1)
2. Preoperative potential risk factors (Before) procedure showed no significant differences
3. Phacoemulsification and IOL implantation were shown to be more difficult in topical anesthesia group.
4. 14% of complications were sub grouped as anesthesia related and occurred intraoperative and within 24 hours postoperative.

Anesthesia related complications were significantly different between the two groups. Anesthesia-related chemosis, periorbital hematoma, subconjunctival hematoma occurred only in peribulbar group. Apart from vitreous loss which was significantly more frequent in peribulbar anesthesia group, other incidences of intraoperative complications did not differ significantly between the two groups.

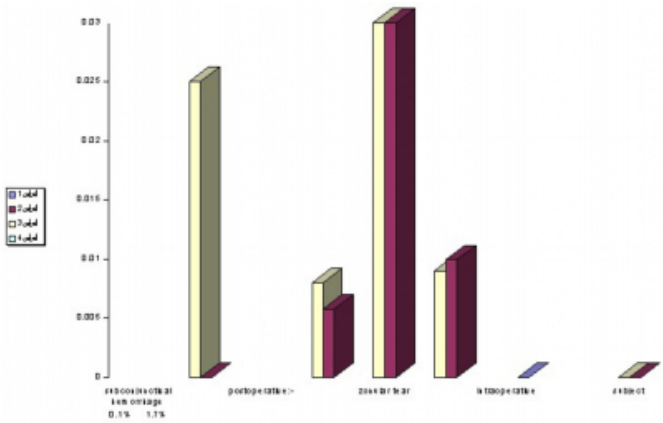
A zonular tear was the most common complication and was followed by capsular tear and vitreous loss. Sulcus implantation of the IOL was necessary in 4 patients, 1 in the topical anesthesia and 3 in the peribulbar anesthesia group. Capsular rupture with anterior vitrectomy occurred in 2 patients of the peribulbar group and 1 patient of topical group. Three cases of intraoperative iris prolapse into the tunnel incision occurred (two eyes in the topical anesthesia and one in the peribulbar group).

After 24 hours, no severe complications were observed in either of the 2 study groups .

A transient pressure increase of 30 mmHg occurred most frequently, but did not require surgical interfering. Figure2.

Figure 2

Figure 2



DISCUSSION

We started our assessment of both groups before the operation by speaking with the patients to evaluate their level of education, co-operation, hygiene, any back / spine pain and answered any question from the patients. We choose a verbal pain score of 4 levels: starting from 0 = no pain,1=mild pain,2= moderate discomfort, 3=pain which requires additional analgesia or increase the dose of local anesthesia, and finally level 4 in which severe pain obligated us to use another type of anesthesia. The verbal score had 4 levels (0 to 3). A visual analogue scale like the Steven Scale was difficult to apply for our patients for social reasons and poor vision in old patients and some difficulties to assess further steps in the procedures of surgery. We modified our verbal score in order to enable us to speak to the patient at any time, or to hear him ([15])

We concluded that the high score of 2 to 3 (25%) in the in peribulbar group was due to local injection and feeling of pressure sensation in theorbital area.

We faced some problems with asthmatic patients not related to pain and solved it by increasing the oxygen flow up to 12 LPM, with or without hydrocortisone 100mg IV as a bolus dose and holding the hand of the patient. We had 2 cases in each group of heart failure and one case of cardiac arrest (successful resuscitation). Generally, doctor satisfaction was the same in both groups and the patient satisfaction was better in the topical anesthesia group.

We studied also any change in CBC's, such as WBC, platelets, lymphocytes content, killing cells, and WBCs number related to patient stress before the operation, after30 minutes, 60 min, and 24 hours. We noticed an increase in all CBC contents starting on incision for 60 minutes and subsequently decreasing again to normal levels.

There is good relation between stress and number of Natural Killing cells and lymphocytes, which increase on start , then decrease after topical or peribulbar anesthesia. The second increase after 24 hours maybe due to the reaction of the wound and the IOL. We could correlate the score of pain and the amount of change in NK, or Platelets, or Lymphocytes.

Akinesia of the globe will not be achieved with topical anesthesia, which affects only the nerve endings of trigeminal nerve in cornea and conjunctiva . A 2000 survey of the practice styles and preferences of members of the American Society of Cataract and Refractive Surgery showed that the use of topical anesthesia increased from 8% in 1995 to 14% 1996 and to 49% in 2000 {[17]). We used bupivacaine hydrochloride as it is effective and has theoretical advantage of a longer half-life. Due to the lipid solubility, bupivacaine 0.5% has a greater potential to cause corneal endothelium damage if injected into anterior chamber. Therefore, we used bupivacaine hydrochloride 0.25% and it was diluted 1:1 with a balanced salt intraocular irrigating solution.

This study reflects our experience during the first two years after starting topical anesthesia in our center. Our study compared and evaluated the level of subjective pain, patient discomfort and perioperative complications under topical bupivacaine Hcl 0.5% or peribulbar anesthesia .([18])

Topical anesthesia administration was significantly less painful than the administration of peribulbar anesthesia (in the peribulbar group 53% reported some pain score (1-2) while only 2% in the topical anesthesia group felt burning sensation. Similar results have been reported in the literature ([19]). Our aim of peribulbar anesthesia is good akinesia, which had been considered essential to cataract surgery until few years ago. Now, most studies of topical anesthesia for cataract surgery report that eye movement is easily controlled and sometimes these movements are helpful.

In our study, eye movements are annoying for the surgeons but no case needed additional regional anesthesia. Anesthesia related chemosis, periorbital hematoma and subconjunctival hemorrhage occurred only in the peribulbar

group. Capsular tear was the most common complication and followed by vitreous loss, sulcus implantation of PMMA PCIOL was necessary in 5 patients. One case of peribulbar group we preferred AC IOL over scleral fixation PCIOL. In 6 cases, we added bupivacaine Hcl 0.5% intracameral due to patient discomfort. Apart from vitreous loss which was more common in the peribulbar group all other intraoperative complications did not differ significantly between the two groups.

We noticed in our study the most painful step for the patients is the injections of Miochol in the anterior chamber at the end of the surgery. Table1,2.

Figure 3

Table 1

Subject		Topical	Peribulbar
intraoperative			
capsular tear		1%	1%
zonular tear		3%	3%
vitreous loss		0.55%	1.37%
postoperative:-			
chemo sis		0	2.50%
subconjunctival hemorrhage :		0.1%	1.7%
pain score			
0		52 cases	26 cases
1		219 cases	248 cases
2		28 cases	88 cases
3		7 cases	3 cases
Surgeons opinion difficulties			
	slightly	14%	8%
	difficulty	4%	3%
Surgeons satisfaction		90%	88%
Patients opinion and satisfaction			
Anxiety before		4%	9.50%
Discomfort during application		2%	53%

Figure 4

Satisfaction:	90%	72%
Post operative Surgeons like same method to the same patient in future	95%	80%
Patients like same method by same doctors in future	79%	77%
Patients needing other method	7%	18%
Severe back pain	1 case	9 cases

Figure 5

Table 2: Monitoring of the patient

0 BP +/- Normal change pulse rate	+/- 10%
Blood pressure	+/-10%
1 Pulse rate	+/-15%
Systolic BP	+/-15%
2 Pulse rate change	>+/-10-20%
Systolic BP	>+/-15-30%
3 Pulse rate	>+/-20%
Systolic BP	30

Topical anesthesia avoids the risk of globe perforation, retrobulbar hemorrhage, damage to optic nerve, dural perforation and significant conjunctival chemosis. Possible disadvantages of topical anesthesia is adverse eye movement but it appear to provide acceptable analgesia during surgery, wears off rapidly after surgery, and does not interfere with the patients ability to blink, see or move the eye. Patients are able to follow commands, which is sometimes needed during surgery. In our study, movement of eyeball was rarely a problem

CONCLUSION

Our results demonstrate that topical anesthesia is a safe and an effective alternative to peribulbar anesthesia in cataract surgery using phacoemulsification and IOL folded lenses for experienced surgeons. Combined topical and intracameral anesthesia can further minimize intraoperative discomfort. However, surgical training and good patient preparation is required for safe use of topical anesthesia.

ACKNOWLEDGEMENT

We thank the authority of Hamad General Hospital specially the medical director Dr.SAAD ALKAABY, also Dr A .HAFIZ chairman of anesthesia, for their help and encouragement We appreciate the effort of operating theater staff , laboratory staff , and anesthesia technician specially Mr.Abdulnasser .

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