

*Research Article***Topical Versus Peribulbar Anesthesia During Cataract Extraction Under Propofol Sedation.****Ahmed Hassanein MD***, **Mohamed Farag MD**** and **Sahar Torky MD****.

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Abstract

Background: Topical anesthesia (TA) presents itself strongly as alternative to more invasive forms of ocular anesthesia, this progress augmented by reduction of the complications and increasing patient safety owing to improvements in monitored anesthesia care and use of short-acting anesthetic. This study aimed to compare the efficacy of topical anesthesia under sedation with peribulbar anesthesia (PBA) technique for cataract extraction regarding pain reduction, maintain low IOP, operative time affection and incidence of complications. **Methods:** 60 patients, (ASA) I-II, 26 female and 34 male with the ages between 65 to 75 years were scheduled for elective cataract surgery. Patients were randomly classified into two groups of 30 patients each: Peribulbar anesthesia group (PBA) and Topical anesthesia group (TA). Intraocular pressure (IOP), intra and postoperative sedation score and postoperative eye pain and pressure was measured using pain intensity scoring system. **Results:** IOP was significantly improved in both groups at the studied time points, with more reduction in PBA group. There were non-significant difference with slight increase in group of TA regarding postoperative pain score (p -value=0.29). There were no significant differences between both groups regarding intraoperative sedation score, with 96.7% of group PBA and 90% of group TA recording score 4 of sedation score. Also, the postoperative sedation score showed non-significant difference between both groups (3(1-3) in PBA versus (3(1-3)) p -value=0.09. **Conclusion:** Patient preference for TA is increasing at the expense of more invasive forms of anesthesia, making it a good alternative to PBA especially under controlled sedation.

Key words: Topical Anesthesia, peribulbar Anesthesia, Cataract surgery, Propofol Sedation.**Introduction**

Cataract surgery is one of the most commonly performed operations in our ageing world. This group of patients has concurrent disorders including hypertension, diabetes mellitus and coronary artery disease. Several anesthetic techniques were provided for cataract surgery^[1,2]. The use and advances in locoregional anesthesia is more prominent at the expense of general anesthesia on eye surgery. Peribulbar anesthesia (PBA) has been very successful over the retrobulbar anesthesia regarding its effectiveness and safety.^[3,4] Several studies have demonstrated that PBA provided optimal surgical conditions for cataract.^[5] However, the main drawback of peribulbar block is the use of long needles (1-1.2 inches), which may have the potential risk of retro-bulbar hemorrhage, optic nerve injury and globe perforation. In particular,

patients with shallow orbits are at a greater risk if long needles are used^[6,7]. Topical anesthesia of the eye, started with Karl Koller as early as 1883, as demonstrated by the anesthetic effect of cocaine on the cornea and its initiation of use in ophthalmic surgery, then popularity declined due to the addiction potential and side effects of cocaine^[8]. Without cocaine, topical anesthesia regained popularity, the complications was reduced from regional anesthesia, increasing confidence and patient safety owing to improvements in monitored anesthesia care and use of short-acting anesthetic.^[1,9] It can be performed using local anesthetic drops, gels or sponges applied to the conjunctival sac and gentle pressure applied to prevent loss from the nasolacrimal duct.^[10] Benoxinate, lignocaine, ametocaine, and bupivacaine are examples of commercially available local

anaesthetics. It has been demonstrated that intraocular pressure (IOP) can decrease after instillation.^[17] The aim of this study is to compare the efficacy of the PBA technique with that of TA under sedation for cataract extraction to produce optimal operating condition as maintaining low IOP, analgesia, lowering the incidence of complications, as well as increasing patient's and surgeon's satisfaction.

Methods

The study was conducted in Al-Minia university Hospital from December 2013 to July 2014. After the approval of university ethical committee and written consent from patients to be studied were obtained, (ASA) I-II, 60 patients, 26(43.3%) females, 34 (56.6%) males with the ages between 54 to 71 years (mean age 62.0 years) who were scheduled for elective cataract surgery were studied in a double-blind clinical trial. Patients were randomly allocated, using a computer-generated randomization schedule to one of two study groups of 30 patients each: peribulbar anesthesia group (PBA) and topical anesthesia group (TA). Patients with uncontrolled hypertension, morbid obesity, taking vasoactive drugs, suffering from glaucoma, having airway problem, patients with allergy to local anesthetics, poor pupillary dilatation (less than 3 mm), anterior segment pathology, dementia, deafness, anxiety, grade 4 nuclear sclerosis and abnormal ocular movements were excluded from the study. In the operative room the patient connected to continuous routine monitoring including ECG, pulse oximetry and noninvasive blood pressure using (Spacelabs; model 90364, USA). Intravenous (iv) cannula was inserted, and the patient given low flow oxygen (1/min) by nasal canula which was fixed in the face by adhesive tapes. All things made ready for general anesthesia including airway by different sizes for airway support at any time whenever needed. All patients were premedicated by iv fentanyl 1µg/kg, and sedation started by iv 4-6 mg propofol 2% with careful monitoring of conscious level to avoid deep sedation and respiratory obstruction, the anesthetist aimed to keep the level of sedation between 3 and 4 of Ramsay score.

Additional doses of propofol (1-2 mg) may be added when the patient moves his limbs or after needle injection during PBA. Once the patient became sedated, the non blinded surgeon gives PBA or instilling LA. All cases operated by the same surgeon to maintain uniformity of the technique. Standardized corneal incision was made by 2.6mm keratome, supero-temporal for right eye and supero-nasal for left eye with side port paracentesis, was done on left side of the main port. Viscoelastic injection, continuous curvilinear capsulorhexis, hydro-dissection, hydro delineation, phacoemulsification, aspiration of the residual lens matter, and finally implantation of foldable intra-ocular lens was performed. At the end of surgery viscoelastic substance was removed, the wound was secured by hydro-tamponade and tested for leakage of fluid by gentle compression with a sponge and sutured if needed.

- *Technique of topical anesthesia;* Benox (Benoxinate hydrochloride 0.4%, E.I.P.I.CO Pharmaceutical) eye drops were instilled on the ocular surface (two drops on the cornea, and one each in the superior and inferior conjunctival sac) 5 and then 10 min before surgery. 5 minutes before surgery two further drops were instilled on the cornea and the eye was padded, two other drops were instilled on the cornea just before corneal incision, intra-cameral injection of 0.5 ml lidocaine 1% was injected to block the sensation of the iris and ciliary bodies. Antibiotics and steroids eye drops were used at 1 hourly interval.

- *Technique of peribulbar anesthesia;* A 23-G, 20 mm long needle is inserted in the inferotemporal quadrant. Once it is under the globe, it is directed along the floor of the orbit, passing the equator of the eye until observing the needle/hub junction reaching the plane of the iris^[17]. After negative aspiration, with the eye in primary gaze, 5 cc of local anesthetic agent (5.0ml lidocaine 2% plus 2.0ml bupivacaine 0.5%) was injected. By this technique, all extraocular muscles including superior oblique can be paralyzed. The ocular digital compression is done gently by the middle three fingers placed over a sterile gauze pad

on the upper eyelid for about 10 minutes. Digital pressure is released for 10 sec. every 30 sec. to allow vascular pulsations to occur (intermittent digital pressure)^[14].

- Parameters assessed: the following time points were settled for measuring different parameters:

TB: Base line i.e. just before start of sedation, T0: Just before (PBA) or (TA), T1: three minutes after (PBA) or (TA), T2: Ten minutes after (PBA) or (TA) and before corneal incision, T3: Five minutes intraoperative, T4: Ten minutes postoperative, T5: twenty minute postoperative.

The following parameters were recorded:

Hemodynamics; HR and MAP, at TB, 0, 1, 2, 3

- *Intraocular pressure (IOP)*; at T0, B, 1, 2 by using hand held tonometer (tonopen)

- *Sedation scores*; at T3 and T4^[15]: 1=anxious, agitated, or restless; 2=cooperative, oriented, and tranquil; 3=responsive to commands; 4=a sleep, but with brisk response to light, glabellar tap, or loud auditory stimulus; 5=a sleep, sluggish response to glabellar tap, or auditory stimulus; and 6=a sleep, no response.

- *Postoperative pain score*; at T4 and T5 by using Pain intensity scoring system.

The pain scoring system was based on the Keele verbal pain chart^[16].

Intensity	Description	Score
0	None	0
1	(Mild); Momentary mild sensations of burning or piercing	1
2	(Moderate); Intermittent moderate sensations of burning, piercing, or fullness/ tightness in the eye lasting a few seconds	2
3	(Severe); Continuous sensations of piercing or swelling/stretching in the eye severe enough to require additional intervention	3
4	(Unbearable) Continuous sensations of piercing or swelling/stretching of the eye severe enough to make the patient want to stop the procedure.	4

- *Total analgesic and anesthetic requirements*

Statistical Analysis; for statistical analysis, Statistical Package for the Social Sciences (SPSS), version 16.0 (SPSS Inc., Chicago III) software was used. Continuous quantitative data were expressed as mean, standard deviation, median and range were

calculated. Non parameteric data were compared with Mann-Whitney test to compare independent groups and Wilcoxon test to compare related groups. $P \leq 0.05$ was considered to be significant.

The method of sample size calculation was based on the published data of previous studies by Smita et al.^[17] and Ahmad et al.^[18], who measured visual pain score in both techniques as in our study, and assumed a proportion of no pain ranged from 33% to 52% in group of TA, and 44% to 49% in group of PBA. When we assumed 80% power and 5% level of significance, the minimum required sample size ranged from 10 to 26 patients in each limb, to achieve a significant difference in the proportion of patients with post-operative no pain. Therefore, 30 patients in each group are sufficient to study this response in our trial.

Results

This study was conducted after obtaining an informed consent from each of 60 patients who were scheduled for cataract surgery. The patients were randomly assigned into 2 equal groups, to receive either PBA or TA under propofol sedation. Patient characteristics were comparable in both groups (Table 1). The groups were similar with regard to age, gender, ASA physical status, and operation time. Regarding hemodynamic parameters (Table 2), there were no significant changes in MAP in the 2 study groups, with increase in MAP in group of PBA at T1 compared to its base line value. Also, HR showed non-significant changes at all time points of the study. The IOP was significantly improved in both groups at the studied time points (Table 3). In group of PBA, the reduction in IOP was greater than that in group of surface anesthesia but it did not reach a statistically significant difference between both groups.

There were no significant differences between both groups regarding intraoperative sedation score, with 66.7% of group PBA and 40% of group TA recording score 4 of sedation score (Table 4). Also, the postoperative sedation score showed non-significant difference between both groups (2(1-3)

versus 2(1-2)), p -value=0.09. There was a slight non-significant increase in the group of TA compared to the PBA group regarding postoperative pain scores measured by pain intensity score at time points (T1, T2) with p -value(0.29 and 0.48) respectively.

Regarding total amount of analgesic and anesthetic requirement (table 6), there is no significant difference in between the two studied groups. There were no adverse events in both groups regarding occurrence of respiratory obstruction, marked bradycardia or hypotension or convulsions.

Table (1): Patient's characteristics

Characteristics	PBA (n=30)	TA (n=30)	P-value
Age (years)	64.7±8.3	61.37±7.92	0.12
Gender (male/female)	18/12	16/14	0.70
ASA (I/II/III)	19/11/0	21/8/1	0.10
Duration of surgery (min)	11.83±2.9	12.4±2.46	0.41

PBA: peribulbar anesthesia. TA: Aopical anesthesia.
Data expressed a mean±SD, or number of patients

Table (2): Haemodynamic parameters

Parameter	Time	PBA(n=30)	TA(n=30)	P-value
MAP	TB	91.11±8.18	91.77±7.42	0.77
	T0	90.17±0.33	91.78±0.88	0.22
	T1	92.33±7.67	90.77±7.10	0.08
	T2	92.33±7.67	91.78±0.92	0.14
	T3	91.11±8.18	91.77±7.42	0.77
HR	TB	79.87±10.21	79±12.91	0.77
	T0	77.97±8.76	77.1±11.02	0.74
	T1	82±11.92	78±13.70	0.23
	T2	79.3±7.9	78.93±10.73	0.88
	T3	78.87±10.21	78±11.91	0.76

PBA: peribulbar anesthesia. TA: Aopical anesthesia. MAP: Mean arterial pressure. HR: Heart rate.
Data are expressed as mean±SD.

Table (3): Intraocular pressure

Time	PBA (n=30)	TA (n=30)	P-value
TB	14.17±0.13	13.0±4.31	0.08
T0	10.47±3.39 ^Δ	11.17±2.48 ^Δ	0.30
T1	11.17±2.48 ^Δ	10.47±3.39 ^Δ	0.36
T2	7.47±2.91 ^Δ	8.17±2.21 ^Δ	0.27

PBA: peribulbar anesthesia. TA: Aopical anesthesia.
^Δ significant difference to baseline measurement within group.
Data expressed a mean±SD.

Table (4): Intraoperative sedation score

Parameters	PBA (n=30)	TA (n=30)	P-value
sedation score:T²			
4	23 (76.7%)	21 (70%)	0.00
3	6 (20%)	7 (23.3%)	0.70
2	1 (3.3%)	2 (6.7%)	0.00

PBA: peribulbar anesthesia. TA: Apical anesthesia.
Data are expressed as number (percentage).

Table (5): postoperative pain and sedation score

Parameter	PBA (n=30)	TA (n=30)	P-value
Pain score T⁴	0 (0-1)	0 (0-1)	0.29
Pain score T⁵	1 (0-2)	1 (0-3)	0.48
Sedation score T⁴	2 (1-3)	2 (1-3)	0.09

PBA: peribulbar anesthesia. TA: Topical anesthesia.
Data are expressed as median (range). Manny-Whitney test was used.

Table (6): Anesthetic and analgesic requirements

Parameter	PBA (n=30)	TA (n=30)	P-value
Propofol (mg)	09.0±11.0	71±12.7	0.62
Fentanyl (µg)	76±17.7	82.2±16.6	0.17

PBA: peribulbar anesthesia. TA: Topical anesthesia.
Data are expressed as mean ± SD. T-test was used.

Discussion

Great advances in cataract surgery have led to faster visual rehabilitation, improved comfort and safety. Peribulbar injection of anesthetic agent has been used for cataract surgery for more than a century, but it was associated with a high risk of injury to the orbital contents. Topical anesthesia is characterized by early recovery of sight and lack of injection related complications seen with peribulbar or retrobulbar anesthesia. With increasing use of topical anesthesia, different methods have been tried to improve the pain scores i.e. reduce pain during and after topical anesthesia. Lignocaine gel, instead of drops gives low pain score due to prolonged contact time and better penetration^[14]. Although many surgeons used intra-cameral anesthetic along with topical anesthesia, however no significant benefit is documented^[11]. The study of Zulfiqar et al.^[11], reveals that patients were more anxious, felt more pain and discomfort in the eye that operated under TA, however patients were more satisfied and calm during surgery with the other eye that had operated under PBA.

Also the study of Boezaart et al.^[15] reported that patients who have never experienced needle block may be satisfied with TA while those who have experienced both techniques preferred the PBA. Previous results are supported by Roman et al.^[17], as they reported that the level of satisfaction of patients undergoing cataract surgery with PBA is much higher than TA. In contrast to the previous studies, a study by Maclean and Burton^[14], revealed that most patients who received TA did not feel major pain, similar to patients who underwent cataract surgery with PBA or retrobulbar anesthesia.

In our study, feeling of pain, pressure and discomfort evaluated by pain intensity score which was measured 10 and 20 minute postoperatively showed non-significant differences between the studied groups with slight increase in group of TA (p-value=0.29), this improvement in pain scores, may be explained by iv analgesia, sedation and intracameral injection of local anesthetic. No significant differences existed in operative time or hemodynamics

between both groups in terms of changes in MAP and HR in all studied time points, which is consistent with study by Manuela Bezerril et al.,^[10]. They concluded that patients that received TA supplemented by intracameral lidocaine combined with sedation for cataract surgery reported adequate level of satisfaction, and the patients exhibited hemodynamic stability and pain control. In contrast to our study, Kallio et al.,^[11] demonstrated that IV sedation by propofol added to TA did not improve the operative conditions or surgical outcome, also during and after surgery, sedatives did not improve the pain score of patients receiving TA compared with patients receiving TA without sedation. This may be regarded to lighter sedation and absence of IV narcotic analgesia in their study.

The results of our study showed that (IOP) was significantly decreased in both groups at the studied time points. This caused by fentanyl and propofol sedation used in both groups and relaxing effect of local anesthetic can reduce extraocular muscle tone, improving aqueous humor drainage, reduce its production and arterial and venous blood pressure, and thereby can cause IOP reduction^[12]. In group of PBA, IOP was raised after needle injection but without significance, as the anesthetic solution is injected around the globe, the rise of IOP is related to factors such as orbital volume, size of globe, and tissue mass in the orbit. Rise of IOP for a given volume of injected anesthetic solution is likely to be less in older people, as compared to young individuals due to age related atrophy of orbital structures and orbital septum.

In conclusion; TA is a safe, simple, non traumatic technique. Its speed, ease of administration, and rapid visual recovery after surgery make this method a suitable and safe choice. Patient preference for TA is increasing in expense of more invasive forms of anesthesia, making it a good alternative to PBA especially under controlled sedation by anesthetist.

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