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Retrobulbar Versus Topical Anesthesia for Phacoemulsification

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Abstract: To evaluate and compare intraoperative pain, perioperative complications and hemodynamic changes during phacoemulsification under topical and retrobulbar anesthesia. A total of 564 patients were randomly allocated into topical and retrobulbar groups. All patients received 2 mcg kg^{-1} fentanyl 5 min before the start of their procedures. Patients in the topical group were treated with tetracaine 0.5% eye drops and given preservative free lidocaine 2% intracamerally during surgery. Patients in the retrobulbar group received a 4 mL lidocaine 2% into the retrobulbar space. The number of complications, hemodynamic changes, phaco time and pain severity on the base of a 10-point visual analog scale of pain were recorded immediately after surgery. Differences between the 2 study groups in age, sex, postoperative visual acuity and phaco time were not statistically significant. Blood oxygen saturation, heart rate, systolic and diastolic blood pressure had no difference before and after surgery in the two groups ($p>0.05$). Chemosis, periorbital hematoma and subconjunctival hemorrhage occurred only in the retrobulbar anesthesia group. Incidence of vitreous loss, corneal edema and zonular tear was not statistically significant in the two groups. Two hundred thirty five patients (83%) in the retrobulbar and 238 (84%) in the topical group reported minimal discomfort (0-2). The Mean±SD pain score in the topical group was 1.13±1.36 and in the retrobulbar group 1.14±1.47 ($p = 0.92$). Patients undergoing cataract surgery with topical anesthesia and those undergoing cataract surgery with retrobulbar block did not vary in terms of subjective pain score and other parameters measuring intraoperative pain, efficacy of anesthesia and feasibility of surgery. This suggests that cataract surgery can be performed with topical anesthesia without compromising the safety of the procedure.

Key words: Phacoemulsification, retrobulbar anesthesia, topical anesthesia, pain

INTRODUCTION

Cataract surgery is one of the most commonly performed surgical procedures in medicine (Lundström *et al*., 2002a, b). In the United States, with approximately 1.5 million surgeries performed on Medicare beneficiaries each year (Katz *et al*., 2000). Parallel to its increasing frequency, minimally invasive techniques have also been developed for routine cataract surgery, including small corneal or limbal incisions, phacoemulsification of the lens nucleus and implantation of foldable intraocular lenses (IOLs) (Lundström *et al*., 2001). These newer techniques have made it possible to switch from general to local anaesthesia, including retrobulbar or peribulbar injections of local anaesthetics. Retrobulbar injection of anesthetic agents has been used for more than a century in cataract surgery. Despite various modifications devised over the decades to reduce the potential risks of injuring intraorbital structures, the blind insertion of a needle into the retrobulbar space has never been completely free of several sight-and life-threatening complications such as inadvertent globe perforation, retinal vein occlusion and brain stem anesthesia, as well postoperative ptosis is an unexpected cosmetic effect (Gunja and Varshney, 2006; Torres *et al*., 2005; Wadood *et al*., 2002; Morgan and Clearkin, 2001; Edge and Navon, 1999; Duker *et al*., 1991). Recent studies have suggested that topical anesthesia, i.e., anesthetic eye drops may be used as an additional option for routine cataract surgery (Fichman, 1996; Patel *et al*., 1996; Zehetmayer *et al*., 1996; Tseng and Chen, 1998; Jacobi *et al*., 2000). 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. The advantages of topical anesthesia include its ease of application, minimal to absent discomfort on administration, rapid onset of anesthesia and, most

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important of all, elimination of the potential risks associated with retrobulbar injections (Fichman, 1996; Patel *et al*., 1996; Zehetmayer *et al*., 1996; Tseng and Chen, 1998; Koch, 1999). The purpose of the present study was to evaluate the efficacy and safety of topical anesthesia for cataract surgery and to prospectively compare it in a randomized manner with standard retrobulbar anesthesia as the conventional type of anesthesia.

MATERIALS AND METHODS

After approval by the Institutional Ethics Committee, written informed consent was obtained. Five hundred sixty four consecutive patients, with age related cataract, in a 14 month period from February, 2007 to March, 2008, admitted to Matini Hospital of Kashan University of Medical Sciences (KAUMS) enrolled the study. The patients were randomly assigned, via computer-generated random number table, into two groups of retrobulbar anesthesia (RBA) group including 282 patients (129 men and 153 women) and mean age of 71±8.9 years and topical anesthesia (TA) group including 282 patients (127 men, 155 women) and mean age of 70±8.3 years. Patients were excluded from the study if they had history of allergic response to tetracaine or other topical anesthetic agents, tremor, chronic cough, psychiatric disturbances, hearing impairment, dementia, uncontrolled diabetes or high blood pressure, any problem with lying on the back, the presence of any other ophthalmic disease apart from cataracts, eye movement disorder, excessive anxiety, poor fixation due to nystagmus or strabismus and previous surgery on the same eye. Other contraindications to participation in the study included complicated anterior segment pathological features that might preclude proper visualization of the chamber intraoperatively or might cause problems affecting clear corneal tunnel preparation, such as the extensive corneal pacification resulting from spheroid degeneration or the marginal thinning of the cornea produced by Terrien marginal degeneration. An anesthesiologist throughout the operation monitored electrocardiogram, arterial pressure, respiratory rate and oxygen saturation noninvasively. All the patients breathed oxygen-enriched air (10 L min^{-1} via a cannula near the mouth) and received 2 mic kg^{-1} fentanyl five minutes before the start of operation in TA group and five minutes before injection in RBA group. The patients in TA group were treated with tetracaine 0.5% eye drops, administered five times within 25 min prior to surgery. The final dose was administered after prep and drape and just prior to the initial corneal incision. They also received free preservative lidocaine 2% intracamerally during surgery. Patients in RBA group received 4 mL adrenaline free lidocaine 2% into their retrobulbar space via a 25-gauge sharp needle, inserted from lower temporal part of the orbit, for about 30 sec. A Honan balloon device was then placed on the eye for 10 min. If the patients needed additional anesthesia, intermittent conscious sedation dose of propofol (5 to 10 mg) was used. Cataract surgery was performed by one of two surgeons, each of whom had carried out over 5000 cataract surgeries and 500 phacoemulsification using TA before the start of this study. Disinfection procedure was performed using a Betadine solution contains 10% povidone-iodine. A 3.2-mm clear cut knife was used to make clear corneal incisions from temporal to upper part of the cornea. The procedure involved a continuous curvilinear capsulorrhexis, hydrodissection and phacoemulsification; this was followed by implantation of a foldable lens. The wound was then closed by hydration. The duration of phacoemulsification procedure and any intraoperative complications were documented. Immediately after surgery, the patients were asked to grade the pain felt during their operation, including the pain after delivery of TA or RBA. For that purpose, a 10-point scale was used as described by Steven (1992), where 0 equals with no pain and 10 with extreme pain.

Data were analyzed in the SPSS statistical program (SPSS Inc, Chicago). Pairwise comparisons were performed using Student's t-test for independent samples. The two-level data (e.g. patient gender) were compared using the chi-square test, $p<0.05$ was considered significant.

RESULTS AND DISCUSSION

Two hundred eighty-two patients were randomized to TA group and 282 to RBA group. Differences between the 2 study groups in age, sex, postoperative visual acuity and duration of surgery were not statistically significant. Blood oxygen saturation, heart rate, systolic and diastolic blood pressure had no difference before and after surgery (Table 1).

Chemosis, periorbital hematoma and subconjunctival hemorrhage was seen only in the RBA group and never led to cancellation or significant delay in the planned surgical intervention. Incidence of other intraoperative complications did not differ significantly between the 2 groups (Table 2).

Considering all 564 eyes, zonular tear was the most common complication, followed by vitreous loss. Corneal edema leading to a transient loss in best-corrected visual acuity occurred in 5 patients in RBA group and 7 in TA group ($p = 0.38$). Pain scores reported by the patients after surgery are shown in the Fig. 1.

Table 1: Comparative results in the two study groups

Variables	Rerobulbar anesthesia	Topical anesthesia	p-value
Age (years)	71.51±8.98	70.54±8.35	0.28
Sex (M/F)	129/153	127/155	0.46
Preoperative visual acuity	0.27±0.16	0.40±0.62	0.14
Bulbus length (mm)	23.17±1.48	23.34±1.2	0.13
Preoperative IOP (mmHg)	15.96±2.58	15.74±2.71	0.41
Duration of surgery (sec)	130.62±55.66	136.64±66.94	0.49
Postoperative visual acuity	0.43±0.21	0.52±0.64	0.94
Feasibility of surgery (1-4)	1.45±0.73	1.30±0.63	0.17
Patients' visual pain score (0-10)	1.14±1.47	1.13±1.36	0.92
SBP before of surgery (mmHg)	147.17±24.61	148.90±22.40	0.62
SBP after start of surgery (mmHg)	148.56±25.12	151.1±24.41	0.21
DBP before of surgery (mmHg)	87.49±14.64	88.89±15.00	0.51
DBP after start of surgery (mmHg)	88.49±16.39	90.71±13.59	0.33
HR before of surgery	77.66±16.37	75.62± 17.74	0.42
HR after start of surgery	77.11±15.73	73.84±18.88	0.47
Blood oxygen saturation	98.50±1.74%	98.85±1.60%	0.17

IOP = Intraocular pressure; SBP = Systolic Blood Pressure; DBP = Diastolic Blood Pressure; HR = Heart Rate, Results are presented as Mean± SD

Table 2: Intraoperative complication in the two study groups

Complication	Retrobulbar anesthesia	Topical anesthesia	p-value
Vitreous loss	2 (0.70)	3 (1.060)	0.500
Zonular tear	10 (3.54)	8 (2.830)	0.400
Chemosis	5 (1.76)	0.000	0.031
Periorbital hematoma	2 (0.70)	0.000	0.250
Subcojunctival hemorrhage	6 (2.10)	0.000	0.015
Corneal edema	5 (1.76)	7 (2.240)	0.380
Wound leak	2 (0.70)	1 (0.035)	0.500

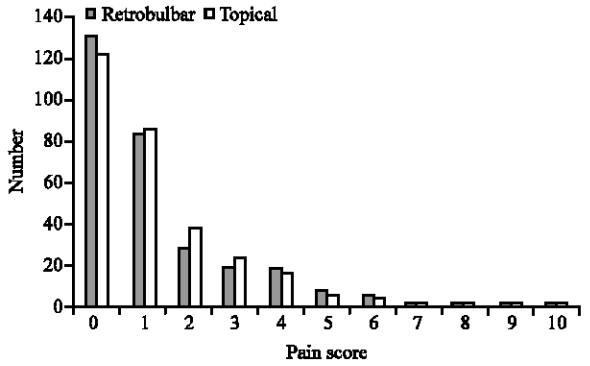

Fig. 1: Pain scores reported by the patients after surgery

Two hundred thirty five patients (83%) in RBA group and 238 (84%) in TA group reported minimal discomfort (a maximum score of 2) or no pain (score of 0). The Mean±SD pain score in TA group was 1.13±1.36 (range 0-6), while in RBA group it was 1.14±1.47 (range 0-6). The difference between the mean pain scores was not statistically significant (p = 0.92). Seventeen patients in retrobulbar and 14 in topical group needed propofol for additional sedation (12.33±5.93 mg vs. 10.62±6.78 mg Mean±SD). The difference was not statistically significant (p = 0.45).

In recent years, there has been considerable discussion in the literature about TA and RBA techniques for phacoemulsification anesthesia (Gombos *et al*., 2007). Choice of local anesthesia technique depends largely on the preferences of anesthesiologists and surgeons, but increasing attention is being paid to patient preferences and their perceptions of intraoperative pain (Katz *et al*., 2000; Boezaart *et al*., 2000). Approaches to anesthesia in uncomplicated cataract surgery vary from topical to retrobulbar and peribulbar anesthesia with or without oral or intravenous sedation in various combinations. As a result of improvements in surgical and anesthetic techniques, topical anesthesia has become more popular in recent years (Mönestam *et al*., 2001) . It is believed that topical anesthesia causes an increased risk of intraoperative complications from unrestricted eye movement and insufficient pain control (Fukaseku and Marron, 1994). Painless cataract surgery using only topical anesthesia is possible and desirable and topical anesthesia without sedation has been shown to be well tolerated (Mönestam *et al*., 2001). Patient preference for topical anesthesia appears to be significantly higher than for RBA and TA is justified as a means of improving safety without causing discomfort to the patient even in complicated cases of cataract surgery (Jacobi *et al*., 2000). Patients who had different types of anesthesia in each eye said they preferred the topical technique (Patel *et al*., 1996). Others have found that patient preference for retrobulbar anesthesia was higher than for topical anesthesia (Katz *et al*., 2000; Boezaart *et al*., 2000).There is also good evidence that retrobulbar block provides better pain control during surgery than topical anesthesia (Lundström *et al*., 2002; Friedman *et al*., 2001).

In the present study 83% of patients in RBA and 84% of patients in TA group had pain scores between 0 and 2. Jacobi *et al*. (2000) showed that even in complicated cataract surgery 85% of patients in TA group and 92% of patients in RBA had pain scores between 0 and 2 and mean pain scores reported by the patients immediately after surgery did not differ significantly between the groups. Balkan *et al*. (2004) used Patient-controlled sedation during surgery and found that pain score and sedation requirements were similar for cataract surgery under TA and RBA. Saunder and Jonas (2003) showed that patients undergoing cataract surgery with topical or peribulbar anaesthesia did not vary in terms of subjective pain score and other parameters measuring intraoperative pain, but this was not found in other studies, Katz *et al*. (2000) found that patients administered TA alone or with sedatives were more likely to report any pain perception

than those receiving anesthesia by injection. Katz *et al.* (2000) enrolled almost 20,000 surgeries over a 2-year period at nine centers in the United States and Canada. This patient population was not a random sample. A large number of anesthesiologists and surgeons participated in the study and surgical techniques, time taken to complete surgery and skill of the surgeons (from residents to high-volume cataract surgeons) varied enormously and very different types of sedation strategy, made it difficult to decided about the two methods. Our study was a randomized trial, with two well trained surgeons, fairly abundant number of patients and a fixed sedation strategy. In a randomized study on 115 patients, Gombos *et al.* (2007) showed that phacoemulsification with TA was more painful than RBA. In this study the sedative drug was oral alprazolanum, 0.25 mg 1 h before surgery, alone. The patients received oxybuprocain drops three times before surgery in TA group and didn't receive any kinds of opioid or hypnotic drugs. Appropriate intravenous sedation preoperatively seems to be an important determinant of relief of discomfort/pain during TA cataract surgery (Välimäki, 2007).

In this study fentanyl was used for sedation and tetracaine drop on five occasions with 5 minutes intervals before surgery and propofol for any supplementary anesthesia in two groups. VAS was our method for measuring pain. A possible explanation of higher scores of pain in TA group is that the ciliary ganglion and pain fibers from the iris or ciliary body are not blocked by the use of topical anesthesia. Therefore, intraocular manipulation, in particular, changes in depth of anterior chamber and the consequent stretching of the zonulae and ciliary bodies or iris manipulation might be expected to cause pain (Johnson, 1995). Intraoperative pain during cataract surgery under topical anesthetic can be reduced by intracameral lidocaine (Ezra *et al.*, 2007, 2008; Chuang *et al.*, 2007).

The effectiveness of anesthesia may be estimated by the frequency of any additional steps required to achieve pain-free surgery. Previous studies have showed that patients under topical anesthesia require additional anesthesia in comparison with RBA group (Tseng and Chen, 1998; Koch, 1999; Gombos *et al.*, 2007; Fukaseku and Marron, 1994). In this study authors did not observe any statistically significant difference for supplemental anesthesia between the groups, but in Saunderand Jonas (2003) study patients in TA group required additional anesthesia less frequently than those in the other group.

In the present study, before surgery, systolic (SBP) and diastolic (DBP) blood pressures were similar in both groups. After the start of surgery, SBP and DBP increased in both groups, but the difference between them was not significant. These data are compatible with earlier results in the literature (Saunder and Jonas, 2003) but Gombos *et al.* (2007) showed a significant increase in SBP in TA group after beginning of surgery. It can be related to lack of sedation use before surgery in TA group.

Preoperative complications such as chemosis, subconjunctival hemorrhage and periorbital hematoma were exclusively observed in the RBA group. However, these adverse events were of no substantial clinical concern, as they did not prevent or delay the planned surgical intervention in any patient. Our data showed no statistically significant difference in vitreous loss between the two groups (1.06% TA group vs. 0.7% in RBA group). In some other studies the incidence of vitreous loss was equal or significantly lower in the TA than RBA (Jacobi *et al.*, 2000; Unal *et al.*, 2006; Rengaraj *et al.*, 2004).

The results of the present prospective, randomized trial suggest that TA is as safe and effective as RBA for routine cataract surgery. Additionally, in our study, there was no statistically significant difference in the pain scores recorded by TA and RBA groups. This suggests that routine cataract surgery may be performed using TA. Further reasons for using TA include the fact that it eliminates the inherent risks of carrying out a retrobulbar injection, such as perforation of the globe, injection into the optic nerve meninges with indirect involvement of the brain stem, laceration of the optic nerve, retrobulbar hemorrhage, orbital infection and additional damage to the optic nerve in patients with advanced glaucomatous optic nerve atrophy. In a large case study Eke and Thompson (2007) showed potentially sight-threatening complications were mostly associated with retrobulbar and peribulbar techniques and potentially life-threatening complications with all techniques except topical/intracameral local anesthesia.

In conclusion, patients undergoing cataract surgery with either TA or RBA did not have differences in terms of subjective pain score, intraoperative pain, efficacy of anesthesia and feasibility of surgery. This suggests that cataract surgery can be performed with TA without compromising the safety of the procedure.

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