

Comparison of clinical outcomes, patient, and surgeon satisfaction following topical versus peribulbar anesthesia for phacoemulsification and intraocular lens implantation: A randomized, controlled trial

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Background: Both cataract surgery and anesthesia techniques are rapidly evolving to become more patient friendly. However, comparison of topical anesthesia (TA) and peribulbar anesthesia (PA) for phacoemulsification and cataract surgery is limited. We evaluated the clinical outcomes and patient and surgeon satisfaction between anesthetic techniques. **Materials and Methods:** This randomized clinical trial was conducted between January and June 2012. Patients were randomly assigned to TA and PA groups for surgery. Visual acuity at 4 weeks postoperatively, status of the cornea and the wound and intraoperative complications were compared between groups at day 1, and 1 and 4 weeks after surgery. Patients and the surgeon completed a close-ended questionnaire on satisfaction with analgesia and comfort. The relative risk (RR) with 95% confidence intervals (CI) was calculated. **Result:** There were 500 patients in each group. There were no significant differences between groups preoperatively. Complications at 1-day postoperatively were significantly greater in the TA group (RR = 1.36, 95% CI: 1.17–1.58). Satisfaction with the mitigation of pain was statistically significantly greater in the PA group compared to the TA group ($\chi^2 = 10.9$, $df = 3$, $P = 0.001$). Surgeons were more satisfied with PA compared to TA (RR = 1.4, 95% CI: 1.34–1.63). There were more anesthesia-related complications in the PA group compared to the TA group. **Conclusions:** Patients who underwent surgery with topical anesthetic experienced lower complications by more pain compared to patients who underwent PA. Topical anesthetic supplemented with analgesic medications could help the patient and surgeon during cataract surgery.

Key words: Anesthesia, cataract, phacoemulsification, randomized control trial

An ideal anesthetic should allow pain-free surgery with no systemic or local complications. It should be cost-effective and should facilitate a stress-free procedure for surgeon and patient. In the previous decade, peribulbar anesthesia (PA) for cataract surgery was the most popular technique. Advances in cataract surgery including the use of smaller and self-sealing incisions have shortened the duration of surgery resulting in the use of shorter acting anesthetics.^[1] In the United Kingdom, 21% of cataract surgeries in 2007 were performed with topical anesthesia (TA) and intra-cameral anesthesia and 3.5% of patients underwent surgery with PA.^[2] A retrospective study has reported the benefits of TA in reducing intraoperative complications.^[3] Pain is better controlled with Sub-Tenon's anesthesia compared to TA for cataract surgeries.^[4] To the best of our knowledge, no clinical trial has focused on patient satisfaction and surgeon comfort during cataract surgery using TA and PA. We compared patient satisfaction (qualitatively) after phacoemulsification and intraocular lens (IOL) implantation with TA versus PA.

Materials and Methods

This randomized clinical trial (RCT) was conducted between January and June 2012. The hospital Ethical and Research Board

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approved this study. Written informed consent was obtained from each participant. Adult patients who presented to our institute for cataract surgery and were selected for foldable IOL implantation comprised the study population. Patients were included if they were, between 40 years to 75 years old, with uncomplicated senile cataracts and without a history of previous ocular co-morbidities, injury, or surgery. Patients were excluded if they had an allergy to paracaine, history of convulsion/epilepsy, presence of other ocular co-morbidities such as exfoliation syndrome, uveitis, myopia with axial length >26 mm, hyperopia with axial length <21 mm, posterior synechia, phacodonesis, were hearing impaired, had dementia, strabismus or poor fixation due to nystagmus.

Four experienced cataract surgeons were the field staff. We assumed that a pain score of unacceptably high grade (needing an additional measure of analgesia during surgery) in TA and PA groups will be in 18% and 10%, respectively.^[5] To calculate the sample size for RCT with a two-sided significance of 95% and power of 90% with 1:1 ratio of two arms in our study, we used Open Epi (Rollin School of Public Health, http://www.openepi.com/Menu/OE_Menu.htm) software and found that 415 cases were required in each arm. To compensate for the loss of data and conversion due to inadequate anesthesia, we added an additional 20% to the required sample size. Thus, the minimum sample was 500 cataract surgeries with TA and 500 surgeries with PA. The randomization schedule for each surgeon was generated by an epi-table for 1000 surgeries. Patients were randomly assigned to a group using the sealed envelope method after the patient was in the preanesthesia room. PA

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was administered by an anesthetist/ophthalmologist and the TA was instilled by an assistant surgeon preoperatively. If needed, additional anesthesia was given and documented. The patients and the surgeon did not know the group assignment until 10 min preoperatively.

For the TA group, one drop of proparacaine hydrochloride 0.5% was instilled six times with an interval of 5 min. Topical anesthetic was instilled soon after dilating the pupil but before the start of the surgery. Patients were instructed to keep their eyes closed after instillation of topical anesthetic. The patients were in the supine position on the operating table with their eyes open and requested to minimize movement. For the PA group, 4 ml of 2% lignocaine with 1:10000 adrenaline was injected using a 24G needle. The needle was inserted at the junction of middle and outer third of the lower orbital margin and directed toward the floor of the orbit. The eyelids were closed, and pressure was applied on the eye for 5 min.

A 2.8 mm sized incision in the clear cornea was created for the phaco port, and two side ports were created of 0.8 mm each. Methylcellulose was inserted in the anterior chamber, and an anterior capsulorhexesis was performed with a cystotome. To separate the cortex from the capsule, hydro-dissection and hydro-delineation were performed. Minimum energy was used for the phacoemulsification procedure. Data were collected on total phacoemulsification and time to completion of surgery, complications and patient and surgeon satisfaction scores.

Patient was verbal questioned about pain during administration of the anesthetic, during surgery and 4 h postoperatively. After each surgery, the surgeon responded about his/her satisfaction based on positive intraocular pressure intraoperatively, chemosis, subconjunctival hemorrhage, and overall discomfort. All eyes underwent phacoemulsification with IOL implantation in the capsular bag. Any change in surgical technique and intraoperative complications were documented and managed.

The data were collected on a pretested form and transferred to an Excel® spreadsheet (Microsoft Corp., Redmond, WA, USA). Statistical package for social studies (SPSS 16) (IBM Corp., Chicago, USA) was used for univariate analysis with a parametric method. The mean, standard deviation, difference of mean, and the 95% confidence intervals (CI) were calculated. Quantitative variables such as age were compared between groups. For qualitative variables, the odd's ratio and a 95% CI were calculated. For variables from more than two subgroups, the Chi-square, degrees of freedom and *P* values were calculated.

Results

There were 500 eyes in each group. Between group comparison is presented in Table 1. There were no statistically significant differences in the patient profile between groups. Three patients in TA group received supplemental anesthesia.

During anesthesia, none of the patients in the TA group complained of pain and 444 (89%) experienced pain during needle insertion in the PA group. Intraoperatively, apart from one posterior capsular tear in TA group, there were no adverse events or complications. Table 2 presents the comparison between the first 24 after surgery and the status of the operated eye. In

Table 1: Profile of participants undergoing cataract surgery with phacoemulsification and intraocular lens implantation

	Topical anesthesia	Peribulbar anesthesia	Validation
Age			
Mean (years)	60	59.5	Difference of mean=0.47 (95% CI-0.32; 1.36), <i>P</i> =0.25
SD	6.2	6.6	
Number (%)			
Gender			
Male	273 (54.6)	251 (50.2)	OR=1.2 (95% CI-0.9-1.5)
Female	227 (45.4)	249 (49.8)	
Type of cataract			
NS ₂ grade 2	40 (8)	39 (7.8)	$\chi^2=0.41$ df=4
NS ₂ +cortical	202 (40.4)	213 (42.6)	
NS ₃	190 (38)	190 (38)	<i>P</i> =0.52
NS ₃ +cortical	64 (12.8)	48 (9.6)	
Sub-capsular	4 (0.8)	8 (1.6)	
Surgeon			
1	126 (25.2)	154 (30.8)	$\chi^2=1.01$ df=3
2	214 (42.8)	139 (27.8)	
3	84 (16.8)	118 (23.6)	<i>P</i> =0.31
4	76 (15.2)	89 (17.8)	
Preoperative vision			
<20/400	4 (0.8)	5 (1.0)	$\chi^2=0.88$ df=3
<20/200-20/400	67 (13.4)	84 (16.8)	
20/60-20/200	270 (54)	270 (54.0)	<i>P</i> =0.35
20/20-20/40	141 (28.2)	141 (28.2)	

SD: Standard deviation, CI: Confidence interval, DF: Degree of freedom, OR: Odds ratio, NS: Nuclear sclerosis

Table 2: Status of eye 24 h after phacoemulsification cataract surgery with lens implantation using topical and peribulbar anesthesia

Tissue involved	Signs	Number (%)	
		Topical anesthesia	Peribulbar anesthesia
Eyelid	Swelling	131 (26.2)	159 (31.8)
Conjunctiva	Congestion	147 (29.4)	75 (15)
Cornea	Haze/edema	94 (18.8)	76 (15.2)
No evidence of inflammation		128 (25.6)	190 (38)

PA group, 190 (38%) eyes did not have signs of inflammation. In TA group, 128 (25.6%) eyes had signs of inflammation.

Patient satisfaction for anesthesia mainly focused on pain scores between the TA and PA groups. Pain was not tolerable intraoperatively in 17 (3.4%) cases in the TA group and only one case in the PA. In 72 (14.4%) patients of the TA group, pain was moderate and only 15 (3%) patients in the PA group had moderate pain. Mild discomfort intraoperatively was noted in 411 (82.2%) and 484 (96.8%) patients of TA and PA groups,

respectively. For comparing pain analog score in the TA group and the PA group, we used a nonparametric method. The score was statistically significantly higher in the TA group compared to the PA group intraoperatively ($P = 0.003$, [95% CI: 0.002–0.004]).

The participants in both groups were further categorized based on age. In the TA group, 365 patients were 65 years and older and 135 patients were less than 65 years of age. In the PA group, 360 patients were 65 years and older age and 140 patients were less than 65 years of age. In the TA group, the difference in pain score was not statistically significant ($P = 0.06$ [0.59–0.68]).

During the 24 h following surgery, 6 (1.2%) and 85 (17%) patients in the TA group experienced mild discomfort and occasional pain, respectively. In the TA group, 408 (81.8%) patients did not feel any pain. In the PA group, 10 (2%) patients had mild discomfort and 144 (28.9%) had occasional pain. 345 (69.1%) patients of the PA group following surgery felt no pain.

The response to questions related to surgeon's comfort while performing surgery suggested that 46 (9.2%) and 23 (4.6%) cases in the TA and PA group, respectively, were not satisfactory. Surgeons were not satisfied with the level of anesthesia in the TA group compared to the PA group [Odd's ratio 2.1 (95% CI: 1.3–3.5)].

The visual acuity, 4–6 weeks following surgery was compared between groups [Fig. 1]. The difference in visual acuity was not statistically significant ($\chi^2 = 2.13$, $df = 4$, $P = 0.14$).

There were 254 and 238 patients with dense nuclear sclerosis (NS₃) type of cataract in the TA and PA groups, respectively. In the TA group, 94 patients with NS₃ and 73 patients without NS₃ experienced severe pain. In the PA group, 100 patients with NS₃ and 95 patients without NS₃ experienced severe pain. The pain score during and after cataract surgery between groups was not significantly influenced by the density of nuclear sclerosis (relative risk = 1.2 [95% CI: 0.9–1.6]).

Discussion

In this study, patients' feedback suggested that the severity of pain was high in cataract surgeries carried under topical anesthetic compared to peribulbar anesthetic. However, the postoperative period was painless in a larger proportion of cases in the TA group compared to the PA group. The surgeons were more comfortable operating PA compared to TA. The signs of inflammation were more prominent in the PA group compared to the TA group. However, visual status at 6 weeks postoperatively in both groups was not different.

Pain during peribulbar anesthetic has been documented to be higher compared to topical anesthetic and was the main reason for negative feedback from patients in previous studies.^[6-8] Our study confirmed this observation among Indian rural patients undergoing cataract surgery in a "cost sharing" eye hospital. This was in contrast to the observations of Pablo *et al.* and Sauder *et al.* that pain during and after surgery between groups was not significantly different.^[9,10]

The intraoperative complications in TA group and PA group were not significant in our study. However, in another study,

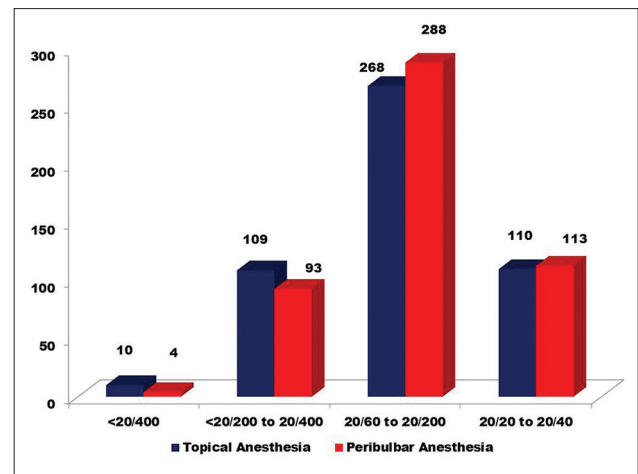


Figure 1: Visual status 4-6 weeks following phacoemulsification cataract surgery with intraocular lens implantation using topical and peribulbar anesthesia

it was greater among patients undergoing phacoemulsification with topical anesthetic compared to peribulbar anesthetic.^[11] Stupp *et al.* noted that the rate intraoperative complications were minimal in both groups, however, older age of the patient posed a higher risk of complications in the TA group.^[3] Chemosis and subconjunctival hemorrhage were the complications in PA group compared to TA group in the study for combined phaco-trabeculectomy surgeries and simple cataract surgeries.^[12,13]

In the current study, surgeon comfort was better when they were operating on a patient who had undergone PA compared to topic anesthetic. This confirmed observations from previous studies. Previous feedback of surgeons suggested that the surgery was more difficult with topical anesthetic compared to peribulbar anesthetic.^[14] In contrast, surgeons felt that phacoemulsification with topical anesthetic resulted in no difficulties or complications.^[15] Addition of intra-cameral lidocaine to topical anesthetic improved the patient and surgeon comfort.^[13] Addition of propofol sedation to topical anesthetic was useful for the surgeon to operate, but there were no differences in surgical outcomes and postoperative pain.^[8] The addition of melatonin was useful for improving the patient response and surgeon comfort for cataract cases under topical anesthetic.^[16] With the advent of Femtosecond laser-assisted cataract surgeries, a greater number of patients undergo surgery with topical anesthetic without any untoward effects.^[17]

There are some limitations to our study. Three cases initially in the TA group required additional PA. This conversion could influence the study outcome by 0.6% change in TA and PA group proportions. In some cases, sulcus fixated IOLs were implanted instead of IOLs insertion within the capsular bag. This could have affected the surgery time and pain score. However, these cases were rare in both groups. Hence, this factor is unlikely to influence the study outcomes.

Topical anesthesia compared to PA is more common now in cataract surgery. It gives more discomfort to the patients and the operating surgeons but reduces the risk of injectable anesthetist-related complications. Measures for further reduction of pain in patients who undergo topical anesthetic instillation by supplementary medication could be

an alternative for better anesthesia and analgesia for cataract surgery.

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