Original Article

# Comparison between ropivacaine and bupivacaine in deep topical fornix nerve block anesthesia in patients undergoing cataract surgery by phacoemulsification

*Anshika Kashyap, Rahul Varshney[1], Govind Singh Titiyal[2], Ajay Kumar Sinha[3]*

**Purpose:** In this study, we intend to analyze ropivacaine and bupivacaine in various parameters during phacoemulsification under deep topical fornix nerve block (DTFNB), a known form of nerve block for phacoemulsification. **Methods:** This prospective randomized study was conducted on 100 patients undergoing elective cataract surgery by phacoemulsification under DTFNB. Patients were divided into two equal groups of fifty patients each, Groups B (bupivacaine) and Group R (ropivacaine). Two sponges, approximately 2 mm × 3 mm dimensions, saturated with either 0.5% bupivacaine or 0.75% ropivacaine were placed deep in the conjunctival fornices to perform the deep topical block. Both groups were evaluated for magnitude of pain and discomfort at various stages of phacoemulsification using a simple pain scoring system. The level of surgeon satisfaction, requirement for supplementary anesthesia, and surgical complications were also evaluated. Quantitative variables between the two groups were compared using unpaired *t*-test. Qualitative variables were correlated using Chi-square test. **Results:** Overall demographic parameters of patients were similar in both groups. Similar mean pain scores were found in the ropivacaine and bupivacaine groups, with no statistical significance. Surgical satisfaction and the need for supplemental anesthesia were also statistically insignificant. **Conclusion:** Ropivacaine is a good alternative for deep topical anesthesia as it has a better safety margin and lesser toxic effect than other comparable local anesthetic agents.

**Key words:** Anesthetics, bupivacaine, cataract extraction, deep topical fornix nerve block anesthesia, local, eye surgery blocks, phacoemulsification, ropivacaine

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Anesthesia for ophthalmic surgery requires a careful approach. Majority of the patients presenting belong to the geriatric age group and invariably suffer from coexisting medical diseases including hypertension, cardiac disease, and diabetes. Surgery in this population group is always challenging and is associated with various risks, whether it is performed under general anesthesia or regional anesthesia.[1]

As general anesthesia can be hazardous in the elderly population and not advisable in view of a short procedure (15–20 min), needle blocks are the most preferred for anesthesia in ocular surgeries. However, the introduction of needle around the eye has its own set of complications. In view of these complications, there has been a shift toward topical anesthesia. It was first performed by Koller in 1884 for cataract surgery.[2] The most common method of applying topical anesthesia is by eye drops or gels.[3,4] Lidocaine 4%, bupivacaine 0.5%, benoxinate 0.4%, and proparacaine 0.5% have been evaluated as topical anesthetic agents during cataract surgery. However, frequent instillation of these drops preoperatively can lead to corneal clouding intraoperatively.[5]

Deep topical fornix nerve block (DTFNB) anesthesia combines the safety, comfort, ease of administration, and rapid onset of topical anesthesia with the deep, extensive anatomical distribution of retrobulbar anesthesia. It is performed by introducing small sponges saturated with anesthetic solution deep in the conjunctival fornices. The technique has advantages over injection and topical methods of anesthesia and is applicable to a variety of surgical procedures.[2]

Ropivacaine, a newer amide local anesthetic available in our setup, is gaining popularity on account of its favorable cardiovascular and neurologic pharmacological profile.[6-8]

Department of Ophthalmology, Doon Government Medical College, [1]Department of Anaesthesia and Critical Care, Synergy Institute of Medical Sciences, Dehradun, Departments of [2]Ophthalmology and [3]Anaesthesiology, Government Medical College, Haldwani, Uttarakhand, India

Correspondence to: Dr. Rahul Varshney, Department of Anaesthesia and Critical Care, Synergy Institute of Medical Sciences, Canal Road, Ballupur, Dehradun - 248 001, Uttarakhand, India. E-mail: drrahulvarshney@gmail.com

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Although the efficacy and safety of ropivacaine for peribulbar and retrobulbar anesthesia during cataract surgery have been extensively studied, data on the use of topical ropivacaine in cataract surgery are limited.[9-13]

In this study, we intend to analyze and compare ropivacaine with bupivacaine in terms of efficacy, patient satisfaction, surgeon satisfaction, and complications during phacoemulsification under DTFNB.

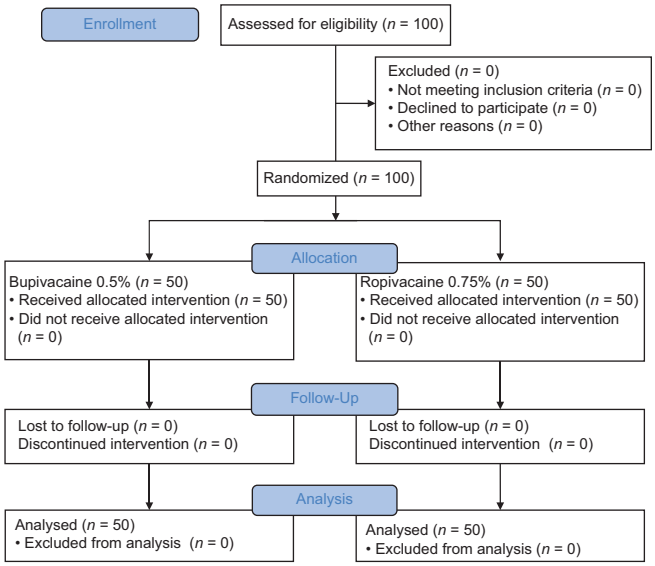
## Methods

After approval from the Institutional Ethical Committee, 100 patients were enrolled. A randomized prospective study was designed to compare bupivacaine and ropivacaine in DTFNB in patients undergoing elective cataract surgery by phacoemulsification. This study was conducted according to good clinical practice standards and the Helsinki Declaration. The protocol was registered at ClinicalTrial.gov (clinical trial identifier NCT02925832) and clinical registry of India (CTRI Reg No: CTRI/2016/11/007445). Our study followed the CONSORT recommendation [Flow Chart 1].

Following preliminary examination and informed written consent, 100 patients fulfilling the required criteria were selected. Patients were equally randomized by block randomization to two groups, namely Groups B (bupivacaine: $n$ = 50) and Group R (ropivacaine: $n$ = 50), using computer-generated randomization program by an ophthalmologist who was not involved in the operating room procedure. Operating room nurse in-charge assigned the participants to respective groups.

The American Society of Anesthesiologists Class I and II patients planned to undergo cataract surgery by phacoemulsification were included in the study. Among those excluded from the study were patients younger than 50 years, presence of very hard cataracts (nuclear sclerosis Grade 4 and 5), history of psychiatric disorders, allergic to anesthetic agent, insufficient pupil dilatation, presence of nystagmus, language barrier, or patient refusal.

To perform DTFNB, the conjunctiva was anesthetized with proparacaine 0.5% local anesthetic drops. Two sponges, approximately 2 mm × 3 mm dimensions, saturated with either 0.5% bupivacaine or 0.75% ropivacaine were placed deep in the conjunctival fornices. After 15–20 min, these sponges were removed. The anesthetic effect and adequacy were verified by holding the limbus with Castroviejo 0.12 tissue forceps.[2] No sedative premedications were given to the patient perioperatively. Preoperative pupillary dilatation was achieved with topical phenylephrine 5% and tropicamide 0.8% in all patients.




**Flow Chart 1:** CONSORT 2010 flow diagram

A common surgeon performed all the surgeries. A 2.8 mm scleral tunnel incision and two side ports were made. After filling the anterior chamber with viscoelastic, capsulorhexis was performed using cystotome. Following this cortical cleaving, hydrodissection and hydrodilineation were done. Phacoemulsification was performed by stop and chop technique followed up by irrigation/aspiration of cortex. A foldable posterior chamber intra-ocular lens was implanted in the bag, with subsequent washing of viscoelastic and hydration of side port. The duration of surgery was recorded from putting incision to stromal hydration.

The primary outcome of the study was to evaluate the magnitude of pain and discomfort at various stages of phacoemulsification. A verbal assessment of pain was made during surgery using a simple pain intensity scale (0: No pain; 1: Discomfort; and 2: Pain).[14] Assessment included scoring predefined step of the surgery, i.e. scleral tunnel incision, capsulorhexis, hydrodissection, phacoemulsification, irrigation and aspiration, intra-ocular lens implantation, and stromal hydration for pain.[15] In case of score being 0 or 1, no intervention was done. But in cases of score being 2 during any step of the surgery, supplemental anesthesia was administered through intracameral route with 1% preservative free lignocaine. The level of surgeon satisfaction was assessed by the surgeon as 0: Poor, 1: Adequate, and 2: Good. Surgical complications, if any, which occurred during the entire procedure, were noted.

### Statistical analysis

The data were documented in a Microsoft Excel spreadsheet and analyzed using SPSS statistics software version 24 (IBM SPSS Inc., Chicago, IL, USA).

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± standard deviation and median. Statistical tests were applied as follows:

1. Quantitative variables between the two groups were compared using unpaired *t*-test/Mann–Whitney Test (when the data sets were not normally distributed)
2. Qualitative variables were correlated using Chi-square test/Fisher's exact test
3. $P < 0.05$ was considered statistically significant.

## Results

The study took place over a period of 3 months and proper record was maintained regarding demographic data and measured parameters at various steps. There was no statistical difference in demographic data between the two groups [Table 1].

The pain assessment scores at various stages of surgery are shown in Table 2. The pain scores during scleral tunnel incision,

capsulorhexis, hydrodissection, and stromal hydration were 0, i.e. at no point did patient complain of any discomfort or pain during these steps. Whereas during phacoemulsification, maximum number of patients complained of discomfort (R: 5, B: 7) and pain (R: 1, B: 2), though statistically, the results were insignificant ($P$ = 0.680). There were also some patients who gave complains of discomfort but required no need for supplemental anesthesia during irrigation and aspiration and intraocular lens (IOL) implantation.

The need for supplemental anesthesia was seen in two cases in bupivacaine group (pain score 2) and one case in ropivacaine group only during phacoemulsification step, which was statistically insignificant.

Surgeon satisfaction between both the groups did not show any statistical significance ($P$ = 0.453) [Table 3]. The rate and severity of intraoperative complication in both the groups were similar. Miosis was seen in one patient of Group R and two patients from group B. Furthermore, one patient from Group B had iris prolapse and one in Group R had posterior capsular tear.

**Table 1: Demographic data, American Society of Anesthesiologists status, and surgical duration comparison**

| Demographic parameters | Group R ($n$=50) | Group B ($n$=50) |
|---|---|---|
| Mean age (years, mean±SD) | 65.84±9.21 | 67.64±8.29 |
| Sex (male/female) | 24/26 | 24/26 |
| ASA Status (I/II) | 16/34 | 13/37 |
| Duration of surgery (min) | 14.67±2.75 | 15.22±2.54 |

Data are presented as mean±SD or number of patients. There were no significant differences between groups. Group R: Ropivacaine, Group B: Bupivacaine, ASA: American Society of Anesthesiologists, SD: Standard deviation

**Table 2: Comparison of pain score during various steps of surgery**

| Pain scores at various Steps | Ropivacaine (0/1/2) | Bupivacaine (0/1/2) | $P$ |
|---|---|---|---|
| Scleral tunnel incision | 50/0/0 | 50/0/0 | 0.9999 |
| Capsulorhexis | 50/0/0 | 50/0/0 | 0.9999 |
| Hydrodissection | 50/0/0 | 50/0/0 | 0.9999 |
| Phacoemulsification | 44/5/1 | 41/7/2 | 0.680 |
| Irrigation aspiration | 48/2/0 | 48/2/0 | 0.984 |
| IOL implantation | 47/3/0 | 46/4/0 | 0.717 |
| Stromal hydration | 50/0/0 | 50/0/0 | 0.9999 |

There is no statistical significance between groups. Data are presented as number of patients. $P$<0.05 was considered statistically significant. IOL: Intraocular lens

**Table 3: Surgeon satisfaction between both the groups**

| Surgeon satisfaction | 0: Poor | 1: Adequate | 2: Good |
|---|---|---|---|
| Ropivacaine | 2 | 6 | 42 |
| Bupivacaine | 4 | 9 | 37 |

Data are presented as number of patients. 0, 1, and 2 being the levels of surgeon satisfaction

## Discussion

Technological developments in cataract surgery such as phacoemulsification, microincision cataract surgery, and Femto laser-assisted cataract surgery have reduced the need of ocular akinesia and patient immobilization. These developments also led to changes in anesthesia techniques.

Over the last few years, topical anesthesia has gained popularity over peribulbar and sub-Tenon's block, as it is safer and has a higher patient satisfaction with immediate visual rehabilitation in comparison to needle approach.[16] Patients receiving peribulbar anesthesia reported more pain during anesthetic solution infiltration and throughout the procedure than those receiving topical anesthesia.[17]

The use of topical anesthesia in eye surgery dates back to the 19th century, when an aqueous solution of 5% cocaine was used for cataract removal; however, it was not widely accepted due to the toxic effects of the drug. It was only in 1991 that 0.5% tetracaine eye drops were used. In 1993, topical 0.5% proparacaine was used instead of tetracaine for the same purposes. Nowadays, topical anesthesia can be achieved using anesthetic agents as drops, gel, or associated or not with intracameral anesthetics or sedation.[18]

In 1995, Rosenthal proposed an alternative to needle procedures, as deep topical nerve block anesthesia. He believed that placement of the sponges soaked with anesthetic solution in the fornices allows absorption by the nerve trunks subserving the conjunctiva, as they radiate across it. At the same time, by being absorbed posteriorly into the peribulbar space, the posterior ciliary nerves, which supply the anterior sclera, anterior conjunctiva, and limbus as well as the iris and ciliary body, are anesthetized at their nerve roots. As with traditional topical anesthesia techniques, deep topical nerve block anesthesia has less motor neuron effect than retrobulbar anesthesia; however, some globe and lid "hypokinesia" was seen.[2]

The ocular anesthetics belong to one of two groups, either ester or amide. The ester group includes oxybuprocaine 0.4% (benoxinate), which is the most commonly used due to its high degree of safety. Tetracaine 0.5 or 1.0% and proparacaine also belong to the same group with a short duration of action (20 min) and are least toxic to the epithelium.[19] Lidocaine 4% (lignocaine) and bupivacaine 0.5% and 0.75% both belong to the amide group. These, in turn, have a longer duration of action.

Ropivacaine, a newer amide local anesthetic agent, is nearly identical to bupivacaine in quality and duration of sensory block, but it produces faster onset and lesser duration of motor blockade. It also has a better safety profile. This is very helpful for short-duration surgeries as well as for early ambulation.[20]

Mostly, lignocaine and bupivacaine or its combination is used as anesthetic agents of choice for phacoemulsification.[21] Although used extensively, bupivacaine has occasionally displayed serious dose-related adverse drug reactions and even death as a result of its cardio and neurotoxicity.[22,23] Topical and intracameral bupivacaine also has toxic effects over corneal endothelium causing thickening and opacification.[24] Perfusion with 0.5% bupivacaine decreased endothelial cells viability too.[25] Toxic effect of lignocaine on ganglion cells have also been documented in recent *in vitro* and *in vivo* studies.[26,27]

Besides, the short duration of action of lignocaine necessitates repeated administration of drug, especially during topical cataract surgery. This further increases the risk of toxicity.

In this scenario, ropivacaine presents a valid alternative to traditional bupivacaine and lidocaine. In fact, ropivacaine presents the advantages of its long duration of action and vasoconstrictive effect.[28] It is this vasoconstrictive property, which helps in lowering intraocular pressure by reducing intraocular blood flow without causing any degenerative effects on endothelial cells.[6,29] Martini *et al*. in his study showed that topical ropivacaine is nontoxic to endothelial cells and can be presented as a good alternative to Lignocaine.[13]

Pain or discomfort during various steps throughout surgery correlates well with the study by O'Brein, where phacoemulsification was the most painful stage, followed by IOL insertion and irrigation and aspiration.[15]

## Conclusion

Ropivacaine was effective in providing anesthesia with sufficient quality for cataract surgery as with bupivacaine. It also provided adequate and long-lasting analgesia without the frequent need of supplementation during surgery. It can be clearly stated that both the anesthetic agents are equivalent in their efficacy and comfort scores. Ropivacaine can be a good alternative for deep topical anesthesia, as it has a better safety margin and lesser toxic effect than other comparable local anesthetic agents.

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### Conflicts of interest

There are no conflicts of interest.

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