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Intracameral Phenocaine Plusr as a Supplement to Conventional Topical Anesthesia for Relieving Ocular Pain in Cataract Surgery

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ABSTRACT

Purpose: To evaluate safety and efficacy of intracameral Phenocaine plus as a supplement to conventional topical proparacaine anesthetic drops in cataract surgery.
Methods: A prospective and controlled study including 100 patients suffering with bilateral cataract were assigned to 2 different groups for the type of anesthesia received, 0.5% proparacaine hydrochloride drops in the first eye, and 0.5% proparacaine drops augmented with intracameral Phenocaine plus in the fellow eye for phacoemulsification surgery . At the end of surgery questionnaire were assigned to patient in both groups indicating the degree of pain (0-3) felt during the surgery.
Results: Thirty-six percent of patients in group 1 declared to have not felt any pain against the 84% of patients in group 2. Fifty-six percent of patients in group 1 complained about only a slight discomfort against 16% of group 2 patients. Only a small percentage of patients in group 1 (8%) admitted severe pain, while no patient in group 2 admitted severe pain. Postoperative day 1 unaided visual acuity was in the range of 6/18–6/9 for most of the patients. No adverse event like corneal decompensation or TASS were noted. Two patients in group 2 reported an episode of transient IOP spike, lasting several hours after surgery and 1 patient in group 2 had corneal edema resolving at end of 1 week after surgery
Conclusion: Intracameral administration of Phenocaine plus is a safe, simple and readily available method to increase the analgesia and in addition mydriasis during the cataract surgery, eliminating the discomfort and increasing the cooperation of the patients during surgery.

Key Words: *Phacoemulsification ,intracameral analgesia mydriatic, proparacaine*

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INTRODUCTION

Cataract is the leading cause of preventable visual impairment with an estimated 63% of all cases of blindness worldwide [1, 2]. Phacoemulsification with intraocular lens (IOL) implantation under topical anaesthesia has become the most common surgical procedure to remove cataracts [3]. Recent ophthalmic methods of local anesthesia have been developed to improve preference, comfort, and adherence of patients [4]. Intracameral anesthesia involves the injection of anesthetics directly into the anterior chamber of the eye at the start of the surgery. Supplemental topical anaesthesia with intracameral mydriatic anesthetic agents may further reduce intraoperative pain, particularly during surgical stages involving manipulation of intraocular structures and rapid changes in fluid dynamics [5-10]. Phenocaine plus [(Tropicamide 0.02% + Phenylephrine HCl 0.31% + Lidocaine HCl 1%) Entod pharmaceuticals, India] is the first fixed-dose mydriatic/anaesthetic combination approved for intracameral use in India in adults undergoing cataract surgery and is readily available in the market. It can be used to augment the topical anesthesia obtained with proparacaine HCl 0.5 % USP [PARACAIN drops Sunways India Ltd.] However Proparacaine drops when used excessively in the eye can cause irritation, hypersensitivity and corneal damage like any other topical anesthetics [11-12]. Intracameral anesthesia allows for reducing the dose of topical drugs and makes handling easier decreasing the discomfort of patient and increasing, therefore, cooperation during the surgery. Thus, tropicamide/phenylephrine/lidocaine fixed dose injectable solution is an option for mydriasis/anaesthesia in adults undergoing cataract surgery. Accordingly, the objective of our study was to evaluate patient preference, satisfaction, and acceptability of intracameral anaesthetic supplemental to topical drugs during cataract surgery.

SUBJECTS AND METHODS

From January 2022 to December 2022 the eyes of 100 patients undergoing sequential cataract surgery were enrolled in our study (n=200) at Vedant Eye Hospital Bhavnagar. The study protocol was approved by the Local Ethics

Committees and, in accordance with Helsinki Declaration, written consent was obtained from all the patients. Participants with measurable visual acuity, normal intraocular pressure (IOP), no signs of inflammation (uveitis), normal macular function and retinal nerve fibre layers by spectral domain-optical coherence tomography were included in the study. Patients with hypermature cataract, senile miosis, pseudoexfoliation, glaucoma, optic atrophy, signs of exudative or atrophic age related macular degeneration, or other ocular disorders were excluded. Patients with problems that would make it difficult to fixate the microscope light, like movement disorders, nystagmus, hearing problems, high degree of anxiety, etc. were also excluded from the study. Complicated cataract surgery with posterior capsule rupture or nucleus drop was removed from the study.

The individuals were divided into 2 groups according to the type of anesthesia to which the eye being examined was subjected. In the first group the first eye requiring cataract (i.e with lesser visual acuity) was anesthetized using thrice instillation of Proparacaine HCl drops [Paracain 0.5% USP, Sunways India Ltd] at 5 minute intervals prior to surgery. The second group was composed of the other eye of the same patients operated at 1-2 month interval after the first surgery. These eyes were anesthetized using first thrice instillation of Paracain drops at five minute intervals and a supplementation of intracameral Phenocaine plus [(Tropicamide 0.02% + Phenylephrine 0.3% + Lidocaine 1%) Entod pharmaceuticals, India] introduced in the anterior chamber immediately after the side port incisions. During the surgery the contents of the syringe (0.2 ml) was injected by irrigation into the anterior chamber in the patients of group 2 and was left in the eye for two minutes. After this, viscoelastic was injected to fill the anterior chamber and the surgeon proceeded with the remainder of the surgery similarly in both groups. Phacoemulsification with aspiration of cortical material and insertion of an IOL was performed in all cases by the same surgeon [SM]. The wounds were hydrated at the end of the surgery. Immediately after the surgery, each patient was asked to fill a numeric table descriptive from 0 to 3, which would indicate the pain experienced during surgery. Zero indicated complete absence of pain, 1-mild discomfort, 2-pain tolerable, and 3-pain very strong. Assessments were performed before surgery and immediately postsurgery, at 12 to 36 hours postsurgery (day 1), and 7 days postsurgery upto end of 1 month consisting of unaided and best corrected visual acuity, evaluation of the anterior segment using the slit-lamp biomicroscopy and IOP with Non contact tonometer.

Statistical Analysis

Results were entered in an Excel spreadsheet and analyzed using SPSS Statistics 20.0. The results were expressed in rates, ratios, and percentages. Significant values were calculated using ANOVA test.

RESULTS

The mean age of the 100 individuals included was 69.0y (range 54-84y). Forty nine % were male and 51% were female. All subjects underwent phacoemulsification with IOL implantation as a day-case surgery. None of our patients needed peribulbar or retrobulbar anesthesia or sedation with intravenous benzodiazepines or conversion into small incision cataract surgery. The pain scores reported by patients were lower in group 2 at all time points as shown in the Table 1. Thirty-six percent of patients in group 1 reported no pain (score=0) against the 84% of the group 2. Fifty six % of the patients in group 1 complained of mild discomfort (score=1) and 16% in group 2. Six % reported of moderate pain (score=2) and 2% of severe pain (score =3) in group 1 while none in group 2 reported of moderate to severe pain during the same procedures (Table 1). Postoperative day 1 unaided visual acuity was in the range of 6/18–6/9 for most of the patients. Two patients in group 2 showed a brief IOP spike that returned to normal by within few days after surgery and 1 patient developed moderate corneal edema that resolved with intensive topical treatment by end of 1 week.

Table 1: Distribution of pain scores in both groups in percentage

Group	Score =0	Score =1	Score=2	Score=3
Group 1	36	56	6	2
Group 2	84	16	0	0
Pain	No Pain	Mild	Moderate	Severe

Figure 1: IOP recordings of patient in both groups on postoperative day 1

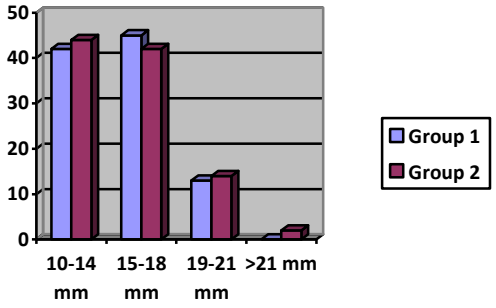

Figure 1 IOP recordings in mm of Hg on postop day 1

Table 2: Distribution of postoperative parameters i.e. Uncorrected Distance visual acuity (UDVA) and corneal edema

Postoperative status
Postoperative Day 1
UDVA: 6/9-6/6 (N =63)
6/12-6/9 (N=18)
6/18 or less (n=6)
6/60-6/18(n=3)
Corneal edema
None(n=73)
Mild (n=26)
Moderate(n=1)

DISCUSSION

Adequate pupillary analgesia and mydriasis is essential for an uncomplicated cataract surgery. Perioperative analgesia can be obtained with topical drops instilled prior to and during surgery and can be supplanted with intracameral agents that are now available.

Fixed dose analgesic mydriatic agents were approved for intracameral use to improve patient compliance during cataract surgery [13]. Lignocaine alone [7-10], Phenylephrine-ketorolac [14-16], and tropicamide + phenylephrine + lidocaine [17-22] combination all were made commercially available for use during cataract surgery. Phenocaine plus^{R} [(Tropicamide 0.02% + Phenylephrine 0.3% + Lidocaine 1%) Entod pharmaceuticals, India] is one such agent that has been introduced and available in Indian market.

Many researchers have used and compared additional use of intracameral agents with conventional topical anesthesia during cataract surgery for sustained mydriasis and analgesia [7-10, 14-22].

The objective of our research consisted of evaluating the compliance and adherence of the patients using combined IC injection of fixed dose combination of Phenocaine plus [(Tropicamide 0.02% + Phenylephrine 0.3% + Lidocaine 1%) Entod pharmaceuticals, India as supplement to classic topical anesthesia in 100 patients undergoing sequential cataract surgery. As inferred from the table the percentage of patients experiencing pain decreases considerably from the first to the second group, with the addition of IC solution, the perception of pain disappears or at least it is widely reduced. Fifty six % of the patients of the group 1 declared discomfort during several times of the surgery: manipulation of iris, sudden distension of the anterior chamber by irrigating fluid and or viscoelastic, after introduction of the phacoemulsification tip, or hydrodissection, or rotation of the nucleus. A smaller proportion of patients in group 2 (16%) reported ocular discomfort during such manipulations. Generally, such discomfort lasted for only few seconds and only reassurance was enough to comfort the patient. The difference in mean pain scores for the two groups was statistically significant. Similar findings have been recorded by other authors [9, 10 & 14-21].

Many researchers have compared the safety and efficacy of intracameral mydriatic analgesic with conventional topical anesthesia [14-21]. We in our study found similar results with respect to pain scores that were statistically significant. Also no significant adverse effects like corneal decompensation or sustained IOP rise was noted upto 1 month of follow up of our patients.

Thus we from our study from a regional individual practice setup from a semi urban town in Gujarat would emphasize to use Phenocaine plus in the Indian context for cataract surgery as it is safe and readily available and does not increase the overall cost of surgery substantially [22-24].

Overall, the preparation was generally well tolerated, with no serious adverse events leading to hospitalization or permanent vision loss. Thus, tropicamide/phenylephrine/lidocaine injectable solution is an emerging cost effective option for anaesthesia/ mydriasis in adults undergoing cataract surgery.

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