Comparison of Topical Anesthesia, Intracameral 1% Lignocaine and Topical Anesthesia and Intravenous Acetaminophen and Topical Anesthesia for Phacoemulsification in Cataract Surgery


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ABSTRACT

Objective: To compare the effectiveness of topical Proparacaine 0.5%, topical Proparacaine 0.5% and topical Proparacaine 0.5% for intraoperative analgesia and surgeon’s score undergoing simple cataract surgery.

Study Design: Quasi-experimental study.

Place and Duration of Study: Department of Anaesthesia, Armed Forces Institute of Ophthalmology, Rawalpindi Pakistan, from Sep 2022 to Mar 2023.

Methodology: Sixty patients aged 40 years and more, ASA-I and II, undergoing elective simple cataract surgeries were observed by taking 20 patients in all three groups (n=20). Group-T: Topical Anesthesia group, 0.5% Proparacaine Group-I: Topical Anesthesia & Intracameral 1% Lignocaine Group-A: Topical Anesthesia and IV Acetaminophen groups were randomly allocated for pretreatment to either receive the 0.5% Proparacaine Eye drops (Group-T) or 0.5% Proparacaine eye drops with Intracameral 1ml 1% Lignocaine (I group) or 0.5% Proparacaine Eye drops with intravenous Acetaminophen 15ml/kg (A group). Incidence of pain by Visual analogue scale/wong-baker faces scale was noted. The surgeon’s comfort was assessed by using Gupta’s surgeon score questionnaire.

Results: The results showed Group-I had better analgesic score than Group-T with only 1(5%) patient had a score of 4 but even more significant efficacy of intravenous aceterminophen plus topical anesthesia (Group-A) was shown as compared to rest of the groups with none (0%) patient had a VAS score of 4 (p-value=0.002). The results also showed Group-I had better surgeon comfort score than both Group-T and Group-A, with only 1(5%) patient had a score of 7 or above as compared to Group-T, 9(45%) patients and Group-A 7(35%) patients. (p-value=0.005).

Conclusion: Intravenous acetaminophen plus topical anesthesia is better at reducing perioperative pain scores as compared to topical anesthesia alone or augmented intracameral Lidoacine plus topical anesthesia. And intracameral 1% Lidocaine injection plus topical is better combination for surgeon comfort perioperative as compared to topical anesthesia and intravenous acetaminophen plus topical anesthesia.

Keywords: Acetaminophen, Cataract, Intracameral, Pain, Surgeon score, Topical.


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INTRODUCTION

Cataracts are the commonest basis of treatable visual loss worldwide, amounting for 62% of blindness.1 The single most important treatment for cataract is surgery. From ancient times to today, there is a remarkable evolution in cataract surgery. Phacoemulsification is leading surgery carried out as day care procedure both in developing & developed world. Cataract surgery was performed under local anesthesia in past which included retrobulbar, peribulbar & subtenon’s block. But these blocks had their own set of complications and were much painful.2 However, in recent times, topical anesthesia has gained much popularity for phacoemulsification which involves instilling anesthetic drops on ocular surface preoperative and intraoperatively. It is safe and highly acceptable worldwide. Short duration of surgery and topical anesthesia allow for quick turn over & accomplishment of long surgical. It has limited bioavailability and hence poor efficacy. It requires patient’s cooperation for immobilization. Upto 38% of patient population reports pain and poor satisfaction with topical anesthesia alone leading to squeezing of eye and movement, creating difficulty for patients.

Most ophtalmologists now perform cataract surgical procedure in topical Anesthesia supplemented with Intracameral Lidocaine along with Adrenaline.3
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It helps to augment analgesia especially during stage of intraocular structures manipulation & changes in fluid dynamics. It also provides mydriasis. This regime leads to reduced intraoperative pain, improved surgical field & enhanced surgeon’s satisfaction. According to meta-analysis, odds of experiencing pain are 40-60% less as compared to topical anesthesia alone but when measured on visual analogue scale, this reduction in pain doesn’t seem clinically significant overall. There is no evidence of improvement in Postoperative pain & patient satisfaction. Incidence of adverse intraoperative events is also similar to topical anesthesia population. Concerns of ocular toxicity are raised with Intracameral drugs but so far no conclusive evidence is available and further research is needed to rule out loss of endothelial cells and risk of ocular toxicity. Some patients may get cardiovascular side effects as well.

To provide intraoperative & postoperative analgesia, multiple agents are used to date including opioids, NSAIDs, Dexmedetomidine. Opioids are associated with respiratory depression, sedation, nausea, vomiting, constipation and pruritus. NSAIDs cause dyspepsia, increased risk of bleeding and deranged renal profile. Dexmedetomidine is very effective analgesic but causes sedation or respiratory depression. A perfect combination is improved surgical field and surgeon’s satisfaction, low risk of corneal toxicity along with intraoperative & post-operative analgesia.

So far globally no study is conducted comparing three groups studying surgical field, patient cooperation, surgeon’s satisfaction and pain scores measured together for visual rehabilitation.

**METHODOLOGY**

This study was prospective, single centered, double blind, quasi experimental study. The study was conducted in Operation Theater, Armed Forces Institute of Ophthalmology (AFIO), Rawalpindi Pakistan, from Sep 2022 to Feb 2023. The study went underway after receipt of sanction from hospital ethical committee certificate (IERB Ltr no: 9-9-22). A printed educated consent was taken from parents or their lawful guardians. Sample size of 20 for each group was estimated by using 5% level of significance, 80% power of test with probable incidence of 56 emergency agitation (EA) in both groups with Open Epi sample size calculator. So the number of participants included were increased to 30 in each group to enhance the power of study. Sampling technique was non-probability, consecutive sampling. Inclusion Criteria: Patients with American society of anesthesiologists (ASA) functional Grade-I, II & III, aged >40 years, the patients with quantifiable visual acuity, normal intraocular pressure (IOP) and without coexisting eye pathology were included in the study.

Exclusion Criteria: Patients with contraindication to paracetamol, local anesthetic allergies, blood clotting difficulties, changed GCS, severe lung or heart disease and aged >80 years were not involved. The patients needing change of plans regarding surgery or anesthesia departing from decided were also excluded.

Patients were indiscriminately assigned into one of three study groups using simulated random number; distribution disguise was completed using closed non see through envelopes. The first group (Group-T) was topical anesthesia group (n=20), in which patients expected of topical Lidocaine drops for anesthesia. The second group (Group-I) is intracameral (IC) group (n=20) in which patients received 1% Lidocaine intracameral injection in addition to Lidocaine drops. The third group (Group-A) is Acetaminophen Group (n=20) in which patients received intravenous acetaminophen injection 15mg/kg in addition to Lidocaine drops. Drugs in all the studied groups were given before start of the surgery. The drops bottles and drugs holding IV. solutions were set by anesthesia operators not incorporated in the follow-up of the patients during recovery in all matching non-labeled syringes as per subject groups. The perioperative data was gathered by the working anesthesiologist who didn’t know about subject groups.

The patients were made Nil Per Oral (NPO) for 6 hours for solid and 2 hours for clear fluids. No premedication was used for any patient; the elderly was booked first in the operating theater list. On entrance to the OR, standard AAGBI monitoring was used for all patients. All patients’ eyes of Group-T were anesthetized using 4 drops of 0.5% proparacaine hydrochloride drops. The Group-I (second group) was made numb using 4 drops of 0.5% proparacaine hydrochloride drops and augmented with intracameral 1% Lidocaine. The Group-A (third group) patients’ eyes were anesthetized using 4 drops of 0.5% proparacaine hydrochloride drops and also received acetaminophen at a dose of 15 mg/kg with in 15 minutes of start of operation.

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Straightaway after the procedure, individually patient was enquired to score their pain using visual analogue pain score (VAS) while patients who were unable to understand the language were provided with modified WONG-BAKER faces scale which indicated the pain experienced during surgery. The patients were asked to score between 0-10 with 10 being the worst pain. If any patient showed a score of 3 or more on VAS scale, meperidine 0.5mg/kg was used as rescue analgesic. The VAS is a valid and trustworthy instrument for quantifying acute pain. The surgeon was asked to share their experience concerning the patient cooperation and comfort of surgery as per the inquiry form designated by Gupta et al. (Table-I)

Table-I: Surgeon’s score questionnaire for phacoemulsification

<table>
<thead>
<tr>
<th>Per-Op Parameter</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Cooperation</td>
<td>Excellent</td>
<td>Good</td>
<td>Poor</td>
</tr>
<tr>
<td>Difficulty due to ocular movement</td>
<td>None</td>
<td>Some</td>
<td>Great</td>
</tr>
<tr>
<td>Anterior Chamber Stability</td>
<td>Excellent</td>
<td>Good</td>
<td>Poor</td>
</tr>
<tr>
<td>Complications</td>
<td>None</td>
<td>Yes (Mention)</td>
<td></td>
</tr>
<tr>
<td>Pupillary Size (in mm)</td>
<td>Peroperative</td>
<td>After intracameral</td>
<td></td>
</tr>
</tbody>
</table>

Furthermore, the presence of any complications like nausea or vomiting were documented. Severe nausea and vomiting were managed with 0.05mg/kg of intravenous ondansetron dosage. The period for the initial sedatives request was documented for all patients.

Statistical Package for Social Sciences (SPSS) version 23.0 was used for the data analysis. Kolmogorov-Smirnov test and the Shapiro-Wilk test were applied to check the normality of the data. As the data found deviated from the normal distribution. Baseline variables were analyzed descriptively using frequencies and percentages for qualitative variables and median with IQR for non-normal continuous variables i.e age, weight. The Kruskal-Wallis test was used to determine the difference between groups. Frequencies were matched using chi-square test. The p-value lower than or up to 0.05 was considered as significant.

RESULTS

A total of 60 patients were enrolled in the study, 39(65%) patients were male and 21(35%) were females. The median age and weight of the patients was 54.50 (64.75-43.00) years (Range: 25-85) and 65(71.75-55.25) kg (range: 41-98kg) respectively. Furthermore, 15(25%) patients had ASA Class-I, 40(66.7%) patients had Class-II and 5(8.3%) patients had Class-III. There was insignificant difference was found age (p-value=0.155), weight (p-value=0.130) and ASA status (p-value=0.517) among three groups. The detail of Demographic Characteristics in each groups shown in Table-II. Of the total, 7(35.0%) patients in Group-T had no pain intraoperatively (score=0), 9(45.0%) patients had a score of 2 while only 4(20%) patients had score of 4 requiring rescue analgesic. However, 14(70%) patients in Group-I had no pain intraoperatively (score=0), 5(25%) patients had a score of 2 while only 1(5%) patient had score of 4 requiring rescue analgesic. This is in wide contrast to Group-A where 19(95%) patients had no pain intraoperatively (score=0) and just 1(5%) patient had score of 2. There was significant efficacy of intravenous acetaminophen plus topical anesthesia as compared to rest of the groups as p-value=0.002 shown in Table-III.

Table-II: Demographic Characteristics of the Patients (n=60)

| Age (years) | 59.50 (69.50-48.50) | 53.50 (64.75-37.25) | 53.00 (58.00-43.00) |
| Weight (kg) | 66.50 (74.50-62.50) | 65.00 (73.50-57.25) | 60.00 (69.75-51.50) |

Table-III: Comparison of Pain Score with respect to Study groups (n=60)

<table>
<thead>
<tr>
<th>Pain Score</th>
<th>Group-T (n=20)</th>
<th>Group-I (n=20)</th>
<th>Group-A (n=20)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>7(35%)</td>
<td>14(70%)</td>
<td>19(95%)</td>
<td>0.002</td>
</tr>
<tr>
<td>2</td>
<td>9(45%)</td>
<td>5(25%)</td>
<td>1(5%)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>4(20%)</td>
<td>1(5%)</td>
<td>0(0%)</td>
<td></td>
</tr>
</tbody>
</table>

The outcome of surgeon’s comfort was assessed by utilizing Gupta’s surgeon questionnaire at the end of surgery and it showed the following results as depicted in Table-IV. This Table depicts that Group-T had score of >5 in all patients with 11(55.0%) falling in score of 6 and 6(30.0%) patients had a score of 7. While Group-A had a slight better profile with 3(15.0%) patients had a score of 5, 10(50.0%) patients had score of 6 and 2(10.0%) patients even had score of 2. The best surgeon scores were shown by Group-I which had majority of patients (95.0%) under score of 6, and had only 1(5.0%) patient with a score of 7. The p-value for surgeon score questionnaire was calculated to be 0.005 which is significant.
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Table IV: Comparison of Surgeon Score with respect to Study groups (n=60)

<table>
<thead>
<tr>
<th>Surgeon Score</th>
<th>Group T (n=20)</th>
<th>Group I (n=20)</th>
<th>Group A (n=20)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>0(0%)</td>
<td>10(50%)</td>
<td>3(15%)</td>
<td>0.005</td>
</tr>
<tr>
<td>6</td>
<td>11(55%)</td>
<td>9(45%)</td>
<td>10(50%)</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>6(30%)</td>
<td>1(5%)</td>
<td>5(25%)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>3(15%)</td>
<td>0(0%)</td>
<td>2(10%)</td>
<td></td>
</tr>
</tbody>
</table>

**DISCUSSION**

The objective of our investigation entailed of assessing the incidence of pain in patients undergoing phacoemulsification by and also measure the outcomes of surgeon satisfaction scores by comparing the trading topical anesthesia & intracameral injection with use of intravenous acetaminophen. Moreover, we sought to define whether or not the use of Lidocaine could improve the safety and effectiveness of the clinical yields of monitored eyes.

Pain is one of the significant prognosticators of return to normal activity after procedure. Although the pain intensity after cataract surgery is trivial in most patients, results displayed that there was some pain in 34% of the subjects and 9% had greater than moderate pain (VAS >4) in the initial hours after cataract surgery. Pain control has to be taken seriously because ignorance of patient comfort and pain can have adverse outcomes not only on eye but also psychologically and socially. Surgeon's contentment was evaluated by various surveys in similar studies on the foundation of patient uneasiness and surgeon anxiety.

Our results indicate that intraoperative pain score of patients undergoing phacoemulsification is much better in Group-A suggesting that intravenous acetaminophen is better in analgesic profile than traditional topical and intracamaeraal augmented analgesia. A Polish study conducted by Kaluzny et al. compared the acetaminophen addition to analgesic regime along with topical anesthesia and showed that acetaminophen group had better pain control. These results have also been concluded in a study conducted in Iran by Moradi et al. They showed that acetaminophen intravenous injection was as efficacious as dexametomidine in pain control without bearing its adverse effects.

The second observation in our study reflected that Intracameral 1% Lidocaine injection was better in pain control as compared to traditional topical local anesthesi. These results are endorsed by Cochrane meta-analysis review by Manikaran et al. which showed 1% Lidocaine intracameral injections as better in pain control than topical anesthesia. Similar studies have been conducted by Reddy et al. showing intracameral local anesthetics being superior to only topical anesthesia.

Surgeon score questionnaire was the measure for surgeon satisfaction (our second outcome variable) in patients undergoing phacoemulsification. The results showed that intracameral 1% Lidocaine had less score compared to both other groups. These results have been reflected in Chandravanshi et al. in a study. They concluded that intracameral Lidocaine and ropivaicane had similar efficacy and were better than topical anesthesia. Similar study results were shown by Donnenfeld et al. and multiple other studies.

Therefore, the choice of anesthesia for cataract surgery is a compromise between patient pain scores and surgeon satisfaction score. Our study reflects that it is best achieved by using augmented intracameral 1% Lidocaine anesthesia in addition to topical anesthesia to get the better outcomes for both.

This study has numerous strong points. It is well designed, single-centered, randomized, double blinded trial with a good sample size. To our knowledge, this is the earliest study anesthesia setup in Pakistan to compare these three modes of anesthesia in eye surgery. This study has helped in consolidating the knowledge about this relatively easily available drugs and hence made it easier for limited resource countries like ours to go for cheaper option with equal efficacy and better patient outcomes.

**ACKNOWLEDGEMENTS**

The authors are highly obliged to Advisor in Anesthesia, Anesthesia colleagues, surgeons, contemporaries, OR Staff and patients for their kind & effective assistance in conducting the study.

**LIMITATIONS OF STUDY**

This study has some limitations like only patients entitled in military setup were included. Further studies are crucial to overcome these confines.

**CONCLUSION**

Intravenous acetaminophen plus topical anesthesia is better at reducing perioperative pain scores as compared to topical anesthesia alone. And intracameral 1% Lidocaine injection plus topical is better combination for surgeon comfort perioperative as compared to topical anesthesia. It’s the augmented Intracameral 1% Lidocaine injection plus topical anesthesia which provides the best scores for pain and surgeon comfort.

**Conflict of Interest:** None.

**Author’s Contribution**
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Following authors have made significant contribution to the document as under:

AAM & SR: Critical review and Drafting of manuscript to be published, reviewing the final version to be published
SN & MS: Conception, Data Acquisition, Enlisting the manuscript, reviewing the final version to be published
AH & SH: Data interpretation & analysis, Critical review reviewing the final version to be published.

Authors approve to be answerable for all facets of the work in certifying that queries linked to the truthfulness or veracity of any part of the work are suitably examined and decided.

REFERENCES