

A prospective study on the effect of topical lidocaine gel versus drops on ocular pain in manual small incision cataract surgeryPrakash Krishnan¹, Sanitha Kuriachan^{1*}, Nirmala Sethuraman²¹Department of Pharmacology, Al Azhar Medical College and Super Speciality Hospital, Thodupuzha, Kerala, India²Department of Pharmacology, Vinayaka Mission's Kirupananda Variyar Medical College, Salem, Tamilnadu, India**Received:** 19 May 2018**Accepted:** 05 June 2018***Correspondence to:**Dr. Sanitha Kuriachan,
Email: sanithacyril@gmail.com**Copyright:** © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.**ABSTRACT****Background:** Cataract is globally acknowledged leading cause of blindness. This study was undertaken to compare the effects of Lidocaine 4% drops with 2% gel on intra operative and post-operative pain in patients who underwent manual small incision cataract surgery.**Methods:** It was a single Centre, one-surgeon, prospective, comparison study. Patients enrolled for surgeries were divided into Group A: Lidocaine 4% drops 1 ml was instilled in the conjunctival sac 5 minutes before surgery and Group B: Lidocaine 2% gel 2ml was applied. Endpoints evaluated were ocular pain of patient during and after surgery.**Results:** A total of 60 patients underwent MSICS, out of which 30 each received drops and gel. Mean intraoperative pain VAS score was 2.26 ± 0.69 for gel group and 5.13 ± 1.13 for drops group ($p < 0.001$) Mean post-operative pain VAS score was 0.26 ± 0.69 in gel group and 1.13 ± 1.13 in drops group ($p = 0.002$).**Conclusions:** Compared to drops, Lidocaine gel has reduced intraoperative and post-operative pain.**Keywords:** Lidocaine gel, Lidocaine drops, MSICS, Topical anaesthesia**INTRODUCTION**Cataract is globally acknowledged leading cause of blindness. According to a statistical survey by WHO 90% blind people live in developing countries and in about 65% cataract is the cause.^{1,2} The only treatment for cataract is surgical removal.³

The state-of-the-art technique is phacoemulsification with the insertion of a foldable intraocular lens through a self-sealing incision. The cost considerations and the steep

learning curve associated with the phacoemulsification procedure make it an unsuitable procedure for high-volume surgery needed in developing countries. However, the manual small incision cataract surgery (MSICS) is the surgery of choice in such circumstances as it is cheaper yet equally effective.^{4,5}

Since painless surgery is the aim from the patient's and the surgeon's view, an attempt was made here to compare the efficacy of two topical preparations of Lidocaine 4% drops with 2% gel on intra operative and post-operative pain in patients who underwent manual small incision cataract surgery.

METHODS

It was single centre, one-surgeon, prospective, comparison study. Period of the study was from November 2012 to May 2013.

Study population

Patients posted for manual small incision cataract surgery in ophthalmology department of Vinayaka Mission's Kirupananda Variyar Medical College, Salem.

Study was started after the protocol was approved by the institutional ethical committee of Vinayaka Mission's Kirupananda Variyar Medical College, Salem. All patients who were diagnosed to have cataract and then posted for manual small incision cataract surgery from November 2012 to May 2013 were screened and selected based on the following criteria

Inclusion criteria

Patients of both sexes aged 50 and above were included in the study.

Exclusion criteria

Patients meeting anyone of the following criteria at baseline were not considered for the study

- Hypersensitivity to Lidocaine
- Other eye was blind
- Below 50 years
- Pregnant woman
- Lactating mother
- Shock
- Epilepsy
- Complete heart block
- Impaired cardiac conduction
- Congestive heart failure
- Impaired respiratory function
- Renal failure
- Hepatic impairment
- Porphyria

The day before surgery a written informed consent form was given and explained to each patient and their bystander. All consenting patients were included in the study. They received a test dose of lidocaine subcutaneously in the forearm. They also received Ofloxacin eye drops every two hours on both eyes. One hour prior to surgery the patients were instilled with eye drops containing Tropicamide and Phenylephrine till complete dilatation of pupil. The selected patients were divided into two groups systematically. It was done in 1:1 ratio by administering alternate patients as per their inpatient register number with drops and gel. Type of sample: Systematic sample. A total of 60 patients

underwent MSICS, out of which 30 each received drops and gel.

Group A

Lidocaine 4% drops [LOX 4%, NEON] 1ml was instilled in the conjunctival sac 5 minutes before the surgery.

Group B

Lidocaine 2% gel [LOX 2%, NEON] 2ml was applied over the palpebral conjunctiva 5 minutes before the surgery.

Both groups then underwent manual small incision cataract surgery by the same surgeon. At the end of surgery Gentamicin and Dexamethasone was injected subconjunctival and the eye was covered.

After surgery, intra operative pain as felt by the patient was quantified by recall using a 0 to 10cm long visual analog scale (VAS). Post-operative pain was also quantified 30 minutes later using the same scale.

Statistical analysis

The data obtained was analyzed using the SPSS software version 16. Descriptive statistics including the mean and standard deviation were calculated for quantitative variables. Quantitative variables were compared with paired sample Student's t-test. Charts were generated using MS-EXCEL and MS -WORD.

RESULTS

The mean age of patients who received Lidocaine drops was 69 ± 7 years and that of Lidocaine gel was 55 ± 5 years. Of the 30 patients who received gel 28 were males and 2 were females. Of the 30 patients who received drops 19 were females and 11 were males. The main endpoints evaluated during the study were ocular pain experienced by the patient during and after surgery.

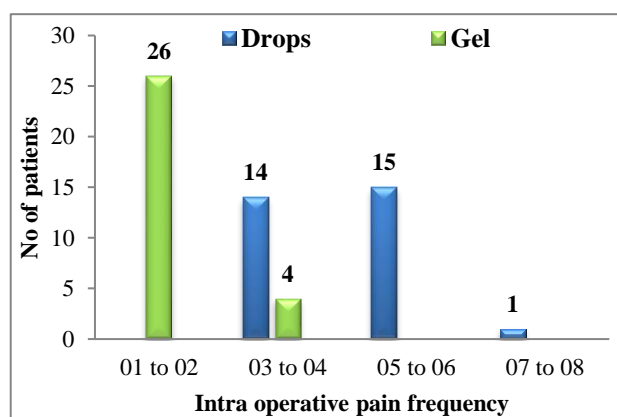


Figure 1: Distribution of patient based on Intra Operative Pain Score and local anaesthetic formulation used in eye.

As shown in Figure 1, a low intraoperative pain VAS score of <2 was seen in 26 (87%) patients in gel group as compared to 0 in drops group. A low intraoperative pain VAS score of 3-4 was seen in 4(13%) patients in gel group as compared to 14 (47%) in drops group. More pain with a VAS score of >4 was seen in 16 (53%) patients in drops group as compared to 0 in gel group. The difference was statistically significant, ($p^* < 0.001$).

As shown in Figure 2, the mean intraoperative pain VAS score was 2.26 ± 0.69 for gel group as compared to 5.13 ± 1.13 for drops group. The difference was statistically significant, ($p^* < 0.001$).

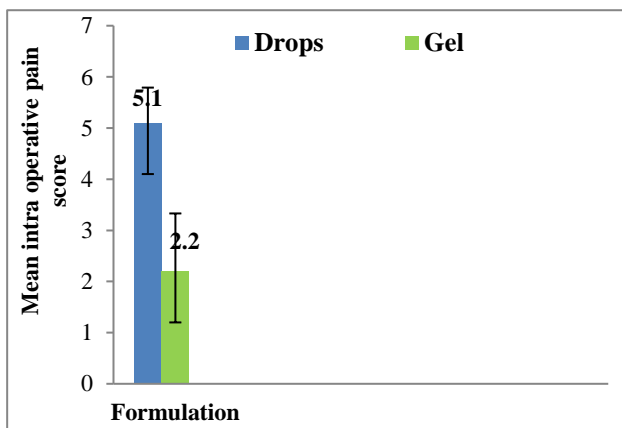


Figure 2: Comparison of Intra Operative Pain Score for local anesthetic drops and gel used in eye.

As shown in Figure 3, a minimal post-operative pain VAS score of “0” was seen in 22 (74%) patients in gel group as compared to 9 (30%) in drops group. A higher score of “1” was seen in 5 (17%) patients in drops group as compared to 4 (13%) patients in gel group. A higher score of > 1 was seen in as compared to 4 (13%) patients in gel group. The difference was statistically significant, ($p^* < 0.001$).

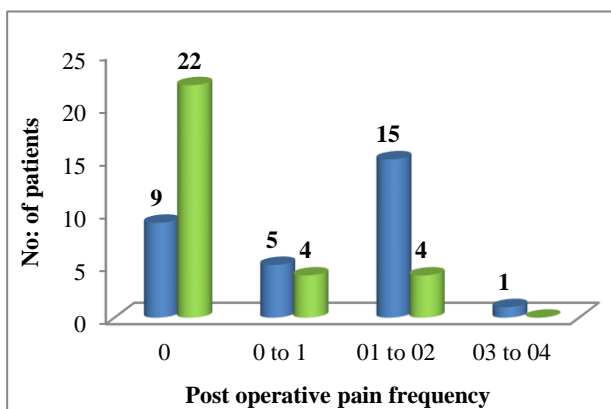


Figure 3: Distribution of patient based on Post-Operative Pain Score and local anesthetic formulation used in eye.

As shown in Figure 4, the mean post-operative pain VAS score was only 0.26 ± 0.69 in gel group as compared to a

higher score of 1.13 ± 1.13 in drops group. The difference was statistically significant, ($p^* - \text{value} = 0.002$).

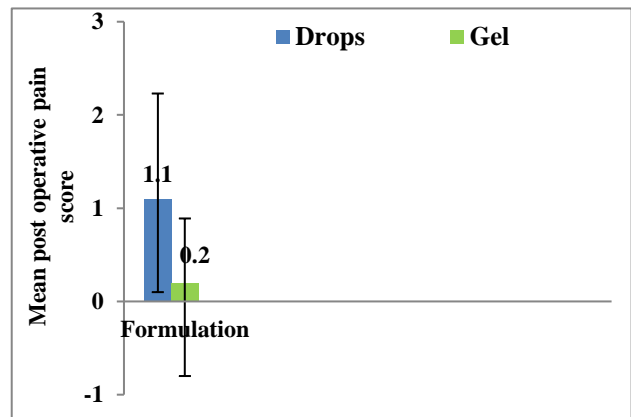


Figure 4: Comparison of post operative Pain Score for local anesthetic drops and gel used in eye.

DISCUSSION

A total of 60 patients underwent MSICS under topical anesthesia, out of which 30 patients (50%) each received drops and gel formulations of Lidocaine. Elderly patients received drops, while the gel group had comparatively younger patients. However, we could not control this difference as patients were allotted systematically into alternate group as per their inpatient register number. Majority of gel group were males and that of drops were females which also happened randomly.

Authors have observed that, Lidocaine gel has produced better analgesia during and after the surgery than Lidocaine drops as reflected by the lower intraoperative and post-operative pain VAS scores. The present study has analyzed the effects of Lidocaine 4% drops and 2% gel in patients who underwent manual small incision cataract surgery from their point of view. The patients were happier with the gel formulation as per the study.

The advantage of topical application is that there is no preoperative pain due to injection which is at times very severe triggering an autonomic response. In topical, this stimulation of sympathetic system due to pain is avoided and the patient remains relaxed.⁶ Considering the elimination of preoperative pain as well as the mild to very severe complications of injection technique, application of topical gel seems to be better.⁷⁻¹¹ This could be attributed to the increased contact time of the gel and prolonged duration of action of 20-25 minutes as compared to 15-20 minutes for drops.^{12,13} These findings are supported by the randomized controlled trial done by Bardocci A, et al.¹⁴ They compared Lidocaine 2% gel versus lidocaine 4% unpreserved drops for topical anesthesia in cataract surgery. They concluded that, if administered by means of gel, the same amount of Lidocaine gives significantly higher intracameral levels of Lidocaine, better analgesia,

better patient cooperation, and less need for intraoperative supplemental anesthesia.

Hence the conclusion from this study is, with proper selection and good motivation of patients, painless cataract surgery with topical Lidocaine gel is a good alternative.

But the drawbacks in this study are small sample size and unequal distribution of age and sex of patients. More aged and female fell in the drops group. Since both groups have low threshold for pain, it may explain the high pain scores with drops group. At the same time, it cannot be assumed that gel will be effective in this group. This requires further study.

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