Special Focus, Cataract Surgery, Original Article

Can lubrication of the eyelid speculum reduce overall pain perception associated with cataract surgery by phacoemulsification performed under topical anesthesia?

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Purpose: This study aimed to evaluate the effect of using the lubricated eyelid speculum on the overall pain perception by the subject patients who underwent cataract surgery by phacoemulsification technique under topical anesthesia. **Methods:** A prospective interventional randomized comparative study was conducted at the tertiary eye care center, wherein adult patients scheduled for bilateral cataract surgery with phacoemulsification techniques under topical anesthesia were randomized to undergo surgery with two different modes of eyelid speculum insertion, either with or without lubrication of the eyelid speculum. Fifty percent of the patients underwent surgery with eyelid speculum without lubrication, and 50% with lubrication of the eyelid speculum. The primary outcome was to compare the level of overall pain perception among the subject patients of the two groups by using the Visual Analogue Scale (VAS) in the immediate postoperative period. **Results:** The study included 130 patients who underwent bilateral cataract surgery (n = 260 eyes) under topical anesthesia, wherein n = 130 eyes underwent surgery using lubricated eyelid speculum and n = 130 eyes underwent surgery with dry eyelid speculum. Pain perception score assessed on the VAS (0–10 cm) ranged from 0.5 to 6, with a mean ± standard deviation of 2.06 ± 1.12. A significant correlation was found with two different methods of eyelid speculum insertion with reduced overall pain perception in patients with the use of lubricated eyelid speculum compared to the dry eyelid speculum ($P = 0.0001$). **Conclusion:** The overall pain perception associated with cataract surgery performed by phacoemulsification technique under topical anesthesia can be further minimized by lubricating the eyelid speculum prior to insertion for exposing the globe.

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Cataract surgery using only topical anesthesia has become the standard practice among most ophthalmologists worldwide.[1] Being more acceptable to patients, this form of anesthesia has several advantages over infiltrative anesthesia, the foremost of which is the abolition of the risk of inadvertent injury to the globe or intra-orbital contents.[2]

Topical anesthesia results in adequate analgesia for cataract surgery using phacoemulsification technique; however, the patient still perceives a substantial amount of pain intraoperatively[3] and in some circumstances, may involve the administration of supplemental anesthesia.[4,5] Any breakthrough discomfort or pain perceived by the patient intraoperatively may lead to undesirable movement of the globe, which in turn may lead to complications in the form of running out of capsulorhexis and rupture of the posterior capsule.

For minimizing the pain associated with cataract surgery under topical anesthesia, studies have been focused on modifying the anesthetic technique[6-8] using different types of preoperative medications,[9-12] intraoperative medications,[13] postoperative medications,[14] modifying intraoperative surgical techniques such as using persistent cycloplegia and[1] lowering the bottle height;[15] however, the source of pain for the patients is not only due to the surgery itself but rather the eyelid speculum exerting a constant force on the eyelids to keep globe exposed.[16]

Presently, there is a paucity of clinical data and studies for the eyelid speculum-related pain associated with cataract surgery performed under topical anesthesia. Commonly, the eyelid speculum is inserted into the patient's eye in the dry form with non-available associated clinical guidelines or research data for the prior lubrication of the eyelid speculum. Thus, this study was designed to evaluate if overall pain perception associated with cataract surgery under topical anesthesia is further reduced by the use of lubricated eye speculum, based on patient feedback.

Methods

This prospective interventional randomized single-blinded comparative study was conducted at a tertiary care center

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between September 2020 and August 2021 after obtaining institutional ethical clearance and written informed consent from all subject patients. The study was performed in accordance with the tenets of the Declaration of Helsinki.

Study design

Two methods of eyelid speculum insertion were assigned to expose the globe for the subject patients: (1) the "lubricated eyelid speculum (LES)" method, wherein the speculum was prior lubricated by dipping the blade part of the speculum into a container filled with 2% hydroxy-propyl-methyl cellulose (HPMC) [Fig. 1]; and (2) the "dry eyelid speculum (DES)" method, wherein speculum was inserted in the conventional dry form without any prior lubrication. Additionally, each patient was planned to undergo surgery with both methods in their sequential surgeries of two eyes.

Patients were randomly allocated into two groups by assigning the successive patient bearing odd serial number to group 1 and those bearing the even serial number to group 2. In group 1 patients, cataract surgery was performed first using LES followed by the use of DES in the subsequent second cataract surgery, while in group 2, cataract surgery was performed first with DES followed by second eye surgery by using the LES.

Subsequently, the LES subgroup was made, which included data of patients' eyes from both groups wherein the LES was used. Similarly, the DES subgroup was made, which included data of patients' eyes from both groups wherein the DES was used. The primary outcome was to compare overall pain scores between these LES and DES subgroups.

A single right-handed ophthalmologist who was blinded for the allocation of patients groups performed surgeries on all participant patients using a standardized protocol that was identical for each participant. Self-retaining Barraquer wire eyelid speculum of adult size (overall length: 40 mm, blades: 14 mm) made of stainless steel with spring style (weight: 0.05 kg) was used to expose the globe in both groups.[17]

Sample size

Assuming a standard deviation of 2.75[18] on the Visual Analog Scale (VAS) pain scoring (0–10 cm) and clinically significant difference in pain perception of at least 1 unit (out of 10)[19,20] between the two test groups, a sample size of 238 with 119 in each arm with 1:1 allocation ratio using a one-sided test was calculated to achieve a power of 80% with a level of significance of 5% for this study.

To cater for approximately 15% of dropouts, a total of 280 eyes of 140 patients were initially enrolled. Both eyes of each enrolled patient were analyzed for the subject study.

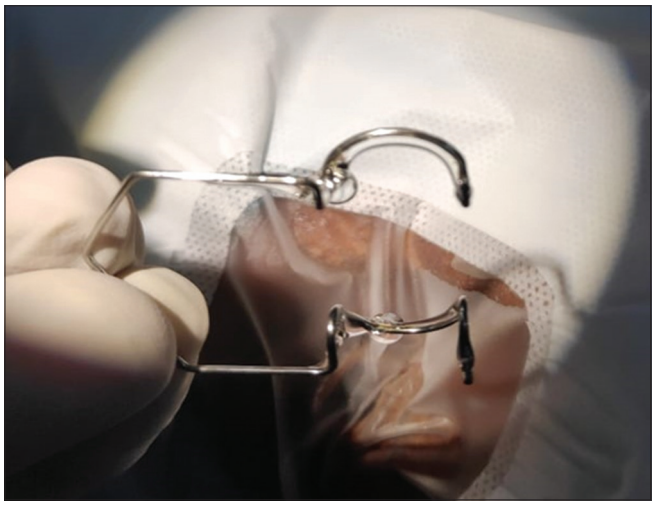

Figure 1: Lubricated eyelid speculum

Inclusion and exclusion criteria

Patients included in the study were those with bilateral senile uncomplicated cataract with nucleus sclerosis (NS) of grade I–III planned for sequential elective cataract surgery by phacoemulsification technique under topical anesthesia.

Patients excluded from the study were those with a past history of cataract surgery except operated for subject study, unwillingness to undergo surgery under topical anesthesia, any ocular condition that may affect pain perception (such as previous ocular surgery involving manipulation of adnexal conjunctiva and sclera), inflammatory conditions of eye and adnexa, insufficient pupillary dilation, pseudo-exfoliation syndrome, past cryo-therapy procedures, herpetic eye diseases, and systemic conditions involving the use of systemic analgesic or sedatives. The patients having a barrier to communication were also excluded.

Patient preparation and anesthesia

The pain scoring system was based on the VAS, which was explained along with the method of marking preoperatively. All patients received one drop of 0.5% moxifloxacin at 20 and 10 min before surgery. Mydriasis was achieved by instilling one drop of eye drop tropicamide 0.5% with 10% phenylephrine at 60, 45, 30, and 15 min before surgery. Topical anesthesia with two drops of 0.5% proparacaine (Sunways India Pvt. Ltd.) was given to patients at 5 min before surgery and immediately before creating the first corneal incision. No non-steroidal anti-inflammatory drugs were used preoperatively. No patients received preoperative or intraoperative sedation.

Surgical technique

After cleaning lid and periorbital skin with 5% povidone-iodine solution and draping, the eyelid speculum was inserted as per the study design in the respective groups. Povidone-iodine (5%) was applied for 2 min over the exposed area followed by flushing out with BSS. A side port clear corneal incision was created at 10 o'clock through which continuous curvilinear capsule-rhexis of approximately 5.5 mm in diameter was created using a bent 26-G needle. Subsequently, the main clear corneal incision of 2.6 mm at 12 o'clock and second side port at 2 o'clock was created. Following hydro-dissection with a 27-G cannula, phacoemulsification of the nucleus was carried out using the stop and chop technique. Parameters were vacuum: 450 cc, flow rate: 30 cc, and power: (10–40) based on the grade of the nucleus in the burst mode using the Infinity System (Alcon Laboratories) with a 30° straight micro-tip. After performing cortical clean-up with bimanual irrigation/aspiration probe, a single-piece hydrophobic intraocular lens based on the patient's choice was implanted in the bag using the wound-assisted delivery method. The incision was sealed by creating incisional edema with BSS. No sutures were required in any case. The eye was cleaned with BSS to remove the

adnexal residual viscoelastic substance from the exposed area followed by instillation of one drop of 0.5% moxifloxacin with 0.1% dexamethasone followed by the removal of the speculum.

No patients received intraoperative intra-cameral Miotics or subconjunctival injection completion of the surgery. All surgeries were performed by a single right-handed surgeon in the same operative room. Time of surgery was noted from making the first corneal incision to the removal of the speculum.

Patients who had intraoperative complications such as posterior capsular tear, intraoperative miosis requiring manipulation of the iris or intra-cameral mydriatics, zonular dialysis, or IOL breaks were excluded from the study; the patients who had breakthrough pain requiring additional supplementation of topical anesthetic drops were also excluded.

Second eye surgery was performed on dates as desired by the patient electively after a minimum duration of 3 weeks.

Pain measurement

After completion of the procedure, the patient was taken to the recovery room and asked to rate their overall perceived pain on a VAS of 0 (no pain) to 10 (unbearable/worst pain)[21] along with placement of line perpendicular to VAS line at the point corresponding to overall perceived pain during the surgery with a standard set of questionnaire pertaining to pain levels by a trained paramedical staff in the absence of surgeon within 10 min of completion of surgery. The distance of the marked line on the VAS was measured in millimeters and transformed into a score between 0 and 10.

Additionally, the patients who underwent second-eye surgery were asked to compare the severity of overall pain perceived during their first-eye and second-eye surgery, with the following possible responses: "I had more pain during the first surgery," "I had more pain during the second surgery," "I experienced the same pain during both surgeries," or "I cannot remember."

Statistical analysis

The data were compiled in a Microsoft Excel worksheet and analyzed using statistical software: Statistical Package for Social Sciences (SPSS) version 24.0 (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, version 24.0 Armonk, NY: IBM Corp.) Data were expressed as mean ± standard deviation. Independent *t* test was used for comparison of the two groups. Chi-square test was used for comparison of nominal variables of subject groups. Pearson's correlation test was used to evaluate the relationship between quantitative variables and pain scores. *P* values smaller than 0.05 were considered as statistically significant.

Results

Baseline subject characteristics

Initially, 280 eyes of 140 study patients were included for the study, with 70 patients each in group 1 and group 2; however, 10 study patients (4 patients in group 1 and 6 patients in group 2) were excluded from the study because of "lost to follow-up."

Out of the remaining 130 study patients (66 and 64 patients in group 1 and group 2, respectively) with surgery on their 260 eyes, a total of 130 eyes underwent surgery with the LES technique and 130 eyes underwent surgery with the DES technique.

Subject characteristics of study patients of both groups as depicted in [Table 1] included 77 (59.23%) men and 53 (40.77%) women, with a mean age of 67.45 ± 7.25 years (range: 55–82 years).

No difference in demographic parameters such as age and sex between the LES and DES subgroups was recordable as each patient participated in both subgroups with either eye. The mean time elapsed between the first and the second eye procedure was 29 days (SD: 6). The mean surgical duration was 15.47 (SD: 2.83) min for the first eye procedure and 15.54 (SD: 2.55) min for the second eye procedure, and the difference was not statistically significant ($P = 0.57$, Mann–Whitney test). The mean surgical duration was 15.35 (SD: 2.77) min for the LES subgroup and 15.66 (SD: 2.60) min for the DES subgroup, and the difference was again not statistically significant ($P = 0.33$, Mann–Whitney test).

Comparative pain perception scores

Pain scores of subject patients on the VAS (0–10 cm) ranged from 0.5 to 6, with a mean ± SD of 2.06 ± 1.12. The mean VAS pain scores in the LES subgroup was 1.52 ± 0.84, which was lower than the mean VAS pain score of 2.60 ± 1.10 in the DES subgroup, and the difference was statistically significant ($P < 0.0001$) as depicted in Table 2 and Fig. 2.

In group 1, 78.79% of the patients experienced second surgery to be more painful than first surgery, while in group 2, this experience was limited to a mere 12.5% of patients, as summarized in Table 3. VAS pain scores as per grades of cataract in the LES and DES subgroups are summarized in Table 4, with significant differences between the LES and DES subgroups in all grades.

Discussion

While performing cataract surgery under topical anesthesia, a sustained amount of force for a substantial period is exerted

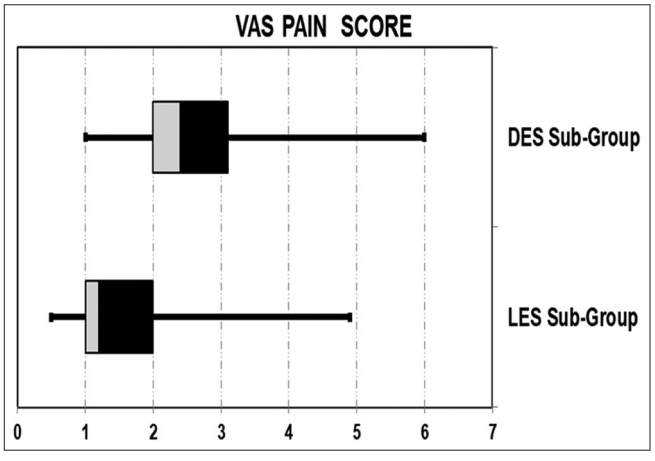

Figure 2: Mean Visual Analog Scale (VAS) pain scores reported in two groups plotted in Box and whisker chart. The patient's pain level was evaluated by using a VAS (0–10 cm), where 0 = no pain/no distress and 10 = agonizing pain/unbearable distress DES = Dry eyelid speculum, LES = Lubricated eyelid speculum

Table 1: Subject demographics and baseline parameter

	LES Subgroup (*n*=130)		DES Subgroup (*n*=130)		Cumulative (*n*=260)		
	Parametric value	VAS score	Parametric value	VAS score	Parametric value	VAS score	*P*
Age (years)	67.45±7.25 (*r*=0.30)[ł]		67.45±7.25 (*r*=0.25)[ł]		67.45±7.2 (*r*=0.28)[ł]	2.06±1.12	<0.0001*
Gender (eyes/numbers)	M=77/77 F=53/53	1.61±0.92 1.40±0.71	M=77/77 F=53/53	2.58±1.19 2.63±0.97	M=154/77 F=106/53	2.10±0.96 2.01±0.73	0.42*
Surgical time (minutes)	15.35±2.77		15.66±2.66			15.51±2.69	0.33*
Surgical sequence interval (days)					29±6		
Sequence of surgery (numbers)	FST=66 SND=64	1.52±0.83 1.53±0.87	FST=64 SND=66	2.50±1.19 2.69±1.02	FST=130 SND=130	2.00±1.13 2.12±1.11	0.39*

Legends: M=Male, F=Female, FST=First, SND=Second, VAS=Visual Analog Scale (0-10 cm) Data are as Mean±Standard deviation * Determined by *t* test
[ł]Determined by χ^2 test

Table 2: Mean VAS pain scores reported in two study groups

	LES Sub-group (*n*=130)	DES Sub-group (*n*=130)	Cumulative (*n*=260)	*P*
10-cm VAS score	1.52±0.84	2.60±1.10	2.06±1.12	<0.0001*

Legends: LES=Lubricated eye speculum. DES=Dry eye speculum Data are presented as mean±standard deviation *Determined by *t* test

Table 3: Subject characteristics to pain questionnaires of two study groups (130 patients)

Pain questionnaire	Group 1 (Lubricated eyelid speculum in first surgery)		Group 2 (Dry eyelid speculum in first surgery)	
	n	%	*n*	%
I had more pain during the first surgery	11/66	16.67	46/64	71.88
I had more pain during the second surgery	52/66	78.79	8/64	12.5
I experienced the same pain during both surgeries	3/66	4.55	10/64	15.63
I cannot remember	0/66	0	0/64	0
Total: 130	66/66	100	64/64	100

Table 4: VAS score of different grades of cataract between the two study subgroups

Grade of cataract	LES subgroup		DES subgroup		Clinical Difference	*P**
	n	VAS	*n*	VAS Score		
NS 1	30	0.90±0.36	32	2.61±0.61	1.71	*P*<0.0001
NS 2	56	1.25±0.40	62	2.32±1.23	1.07	*P*<0.0001
NS 3	44	2.30±0.93	36	3.06±1.09	0.76	*P*=0.0012
Total: (*n*=260)	130	1.52±0.84	130	2.60±1.10	1.08	*P*<0.0001

Legends: NS=Nucleus Sclerosis, VAS=Visual Analog Scale, LES=Lubricated eyelid speculum DES=Dry eyelid speculum. Data are presented as mean±standard deviation * Determined by t test

by the blades of speculum against the constricting force of the orbicularis oculi, thereby creating a constant pressure build-up on the sensitive palpebral conjunctiva, which is inadvertently felt as ocular discomfort and consequent pain by the patient despite adequate analgesia with topical anesthetics. This leads to increased blinking effort and more forceful closure of eyelids against speculum with a resultant chain of increased pressure build-ups and secondary ocular discomfort. If the level of ocular discomfort crosses the limit of the patient's tolerance, it might lead to forceful closure of eyelids and contraction of extraocular movements along with the movement of eyeballs, which may, in turn, lead to intraoperative complications. In addition, associated contraction of the extra-ocular muscles leads to an increase in intraocular pressure (IOP). An increase in IOP by 10 mm in regular blinking and up to 50 mm during forceful contraction of the orbicularis oculi has been shown in a previous study.[22] These episodic spikes of IOP may also lead to intraocular complications during surgery with overall increased ocular discomfort and pain perception by the patient.

Another likely biological explanation that may contribute to ocular discomfort may be attributed to the inadvertent microscopic corneal erosions sustained with dry speculum insertion and removal from the globe.

We thought that putting an interface of lubricant between the blades of the speculum and the palpebral conjunctiva might

reduce the friction along with distribution of the speculum force into a larger contact area on the palpebral conjunctiva with consequent minimized pressure build-up with resultant overall decreased ocular pain and discomfort.

Ocular Viscoelastic Devices (OVDs) are indispensable items for the performance of cataract surgery and are readily available to surgeons. We choose HPMC 2% as a lubricating agent for the subject study as it has moderate viscoelasticity characteristics with substantive retentive and tissue coating abilities besides being inexpensive.

We choose the Barraquer eyelid wire speculum for the subject study as it exerts a uniform level of force to retract eyelids, thereby avoiding measurement error due to variable force created consequent to the variable extent of manual adjustments in cases of manually adjustable eyelid speculums. Besides, it is light in weight and has been found to create the least IOP rise.[23]

We used VAS for the assessment of pain perceived by the subject patient as it has been found to be valid, reliable,[24,25] and been used successfully in ophthalmological research evaluating pain experience associated with cataract surgery under topical anesthesia.[18-20,24-26]

We chose a 1.0-cm mean difference in the VAS score as clinically significant as previous research indicated a difference of 9–13 mm in VAS scores to assign it as clinically significant.[19,20,25]

The overall mean VAS pain score in our study was 2.06 ± 1.12; however, the mean VAS pain score in similar surgery has been reported from as low as 0.70 to the extent of 4.19 as each study has been different in their choice of anesthetic drugs and surgical techniques. Tsoumani *et al*.[26] reported a VAS pain score of 4.19 ± 2.32 in patients who underwent cataract surgery with 0.5% tetracaine, while Chalam *et al*.[27] reported 0.70 ± 0.31 by using 0.5% tetracaine hydrochloride using five doses of anesthetic drops preoperatively. Similarly, Pandey *et al*.[28] and Joshi *et al*.[29] obtained a mean VAS pain score of 1.44 ± 1.04 using 4% xylocaine and 1.17 ± 1.50 using 0.5% proparacaine, respectively. The VAS pain score in our study was equivalent to a score of 1.17 ± 1.50 obtained by Joshi *et al*.,[29] who used a similar single application of topical proparacaine in their study.

The mean VAS pain scores of patients using LES was 1.52 ± 0.84, which was lower than the mean VAS pain score of 2.60 ± 1.10 in the patients wherein DES was used, and the difference was statistically significant ($P < 0.0001$). Besides, the mean difference of 1.08 cm between the VAS pain scores of the two study subgroups appeared to be clinically significant. Additionally, one-third of the total patients in the LES subgroup reported a zero score on the VAS compared with a mere 2% of patients in the DES" subgroup, leading to the conclusion that lubricating the eyelid speculum can be a valuable technique for minimizing the overall pain perception.

In our series, a striking consistency was observed regarding the overall pain experience of first versus second eye surgery. When asked to specify which eye surgery was more painful, 52 out of 66 patients in group 1 answered that they experienced more pain in second eye surgery, while 46 out of 64 patients in group 2 answered that they received more pain in first eye surgery instead [Table 3]. Moreover, subjective experience answered was consistent with their corresponding VAS measurements in up to 95% in group 1 and 88% in group 2, which confirms that the patients consistently experienced less pain in both groups wherein the lubricated speculum was used.

Although not a primary aim of this study, we found that there was a significant difference in the VAS pain scores of different grades of cataract between the LES and DES subgroups with consistently lesser pain scores among the LES subgroup. Interestingly, the difference in mean pain score was higher with lower grades of cataract [Table 4], with a clinically significant difference in lower grades of cataract (NS I and NS II).

In this study, bias related to an inter-individual variation on pain perception was minimized by designing the study as the intra-individual study by including each patient to report his pain perception on two occasions for his two consecutive surgeries. Besides this, no sedation was used in the peri-operative period, which could have affected pain perception.

To limit operative variability factor on pain perception, the study was conducted using a standard surgical protocol in a similar setup by a single right-handed surgeon.

Interestingly, we found no significant difference ($P = 0.39$) in pain perception level between the first (2.00 ± 1.13) and second-eye surgery (2.12 ± 1.11), which appeared to be against the common observation of patients experiencing more pain during the second-eye surgery as indicated in recent studies.[30,31] We presume that certainty of whether the second-eye cataract surgery is more painful under topical anesthesia remains a vexed issue even today as others have shown no such difference.[6,32,33]

Limitation of the study

A limitation of this study was the inability to perform a double-blinded study as it was not possible to blind the surgeon regarding the preparation and use of the lubricated speculum, which might have introduced surgeon bias; however, standardized surgical protocol and assessment technique was designed to limit this bias.

Besides this, our data of pain might have been affected by the use of standard size and design of the speculum for all patients as there are physiological variations of eyeball and eyelid from patient to patient, which may be attributed to differential pressure build-ups and consequent differential pain perception scores.[16]

Conclusion

Topical anesthesia provides adequate analgesia for cataract surgery using the phacoemulsification technique; however, the patient still perceives a substantial amount of overall ocular pain. The study results indicate that placement of lubricated viscoelastic material between the metallic blades of the speculum and the palpebral conjunctiva of lids can decrease friction and pressure build-ups, which we theorized would lead to lesser pain associated with this surgery compared to using it in plain dry form. Thus, lubricating the eyelid speculum prior to insertion for exposing the globe for performing cataract surgery by phacoemulsification technique under topical

anesthesia can be a simple, safe, and inexpensive technique for further reducing the overall associated pain perception and ocular discomfort.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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