

Comparative Assessment of Pain in Sequential Cataract Surgery with Topical Phacoemulsification - A Prospective Observational Study from a Tertiary Care Hospital in Uttar Pradesh

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ABSTRACT

BACKGROUND

With the advancement in anaesthetic measures, a safe and effective alternative to peribulbar and retrobulbar anaesthesia for phacoemulsification is provided by topical anaesthesia.¹ (Fichman, 1996). Studies highlighting varied pain experiences have been published with some reporting higher pain in second eye surgery,^{2,3} (Ursea et al. 2011; Tan et al. 2011) while others did not.^{4,5} (Bardocci, 2011; Hari-Kovacs, 2012). So, we conducted this study to assess and compare pain experienced by patients subjectively as well as objectively in first and subsequent eye following topical phacoemulsification cataract surgery.

METHODS

A prospective observational clinical study was done for a duration of two years at Institute of Ophthalmology, Jawaharlal Nehru Medical College, AMU Aligarh. Study groups consisted of patients having bilateral cataract, to be operated in both eyes undergoing topical phacoemulsification and placement of an intraocular lens within one-year interval. Subjective as well as objective assessment of postoperative pain was done in the recovery room.

RESULTS

A total of 60 patients were included in the study with 51 (85 %) patients having higher pain score for second eye surgery as compared to first eye surgery, which was also significant while comparing their mean pain score (0.73 ± 0.86 vs 2.17 ± 0.91). Systolic and diastolic blood pressure as well as mean arterial pressure (MAP) were higher in first eye surgery as compared to second eye surgery.

CONCLUSIONS

In our comparative study, we observed higher pain in second eye surgery. As this subjective assessment of higher pain was not supplemented by objective assessment, we concluded that it may be due to more apprehension and uneasiness because of previous surgery. Patients going for second eye surgery should be prior consulted as well as managed properly.

KEYWORDS

Cataract, Pain, Topical Phacoemulsification

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BACKGROUND

Cataract is the main cause of curable blindness in India and worldwide. It can be easily cured by phacoemulsification, which is the method of choice for most ophthalmologists. With the advancement in anaesthetic measures, a safe and effective alternative to peribulbar and retrobulbar anaesthesia for phacoemulsification, is provided by topical anaesthesia.¹ (Fichman, 1996) It is also likely to be more acceptable to the patients, a large proportion of people who are afraid of needles.

While after-surgery pain is nothing new in majority of surgeries, it is less commonly experienced in ocular surgeries. Studies have reported patients complaining of after-surgery pain in ocular surgeries too in the past, but with the use of topical anaesthesia, there reports and intensity, both have declined. Even if these after-surgery eye pain has been reported in literature, they never go beyond annoying or uncomfortable,^{2,3} (Ursea et al. 2011; Tan et al. 2011) unless associated with any complication. Our goal of making every cataract surgery a day-care surgery cannot be fulfilled unless we work hard and prevent even these mild intensity pain.

As cataract develops due to senile degeneration of lenticular fibres, opacity in one eye is often followed by opacity in other eye. Surgeons do not advice cataract removal of different eyes in same go, thus two surgeries are often done. Apart from various planning, management and complication in two surgeries, there are studies highlighting varied pain experiences in them with some reporting higher pain in second eye surgery,^{2,3} (Ursea et al. 2011; Tan et al. 2011) while others did not.^{4,5} (Bardocci, 2011; Hari-Kovacs, 2012) However, these studies mainly focused on the patient's subjectively evaluated pain, results may be influenced by bias due to individual differences in pain threshold and comprehension of the questionnaires used. It has been established that if someone experienced any pain, his/her blood pressure and pulse also rises along as one becomes anxious.⁶ (Chawla, 1999) So we conducted this study to assess and compare pain experienced by patients subjectively as well as objectively in first and subsequent eye following topical phacoemulsification cataract surgery.

METHODS

We conducted a prospective observational clinical study at Institute of Ophthalmology, Jawaharlal Nehru Medical College, AMU Aligarh. The duration of study was two years, from October 2016 to September 2018. Study population included all the patients having bilateral cataract, willing to get operated by phacoemulsification under topical anaesthesia. The first surgery was performed in the eye with a higher-grade cataract or otherwise poor vision. The other eye was operated within one year, based on the patient's choice and or progression of cataract. The inclusion criteria were: 1. Patients with bilateral cataract undergoing phacoemulsification cataract surgery. 2. Age 50 years or

above, 3. Uncomplicated senile cataract, 4. No previous history of ocular co-morbidities, ocular injury or intraocular surgery. The exclusion criteria were 1. Second cataract surgery after one year, 2. Any history of allergy to proparacaine hydrochloride, 3. Any contraindication or expected poor compliance to cataract surgery due to communication problem (impaired hearing, dementia), fixating instability (strabismus), 4 Patients having any complication during phacoemulsification of first eye were excluded from the study.

Written, informed consent was taken from all the participants, which included an explanation of the study design, goals and methodology. We selected the patents following these criteria and agreeing for second eye cataract surgery by phacoemulsification. Assuming to find out a difference of at least 1 in 10 in visual analogue scale (VAS) score of pain between both the surgeries, with a significance level of 0.05 and assumed standard deviation of 2.78, based on a similar study,⁴ (Bardocci et al. 2011) the sample size was calculated as follows:

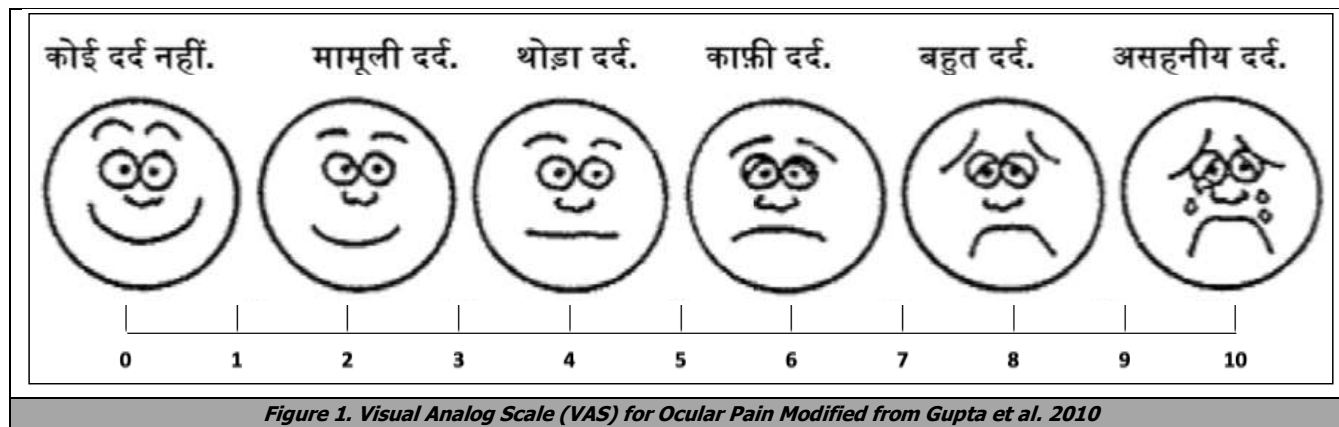
$$n = Z_{\alpha/2}^2 (2\sigma^2) / (d)^2$$

$$= (1.96)^2 (2 * 2.78^2) / (1)^2$$

$$= 59.38 \sim 60$$

Our main study outcome, experiencing postoperative pain, was assessed both subjectively as well as objectively. Subjectively postoperative pain was evaluated using a visual analog scale for pain which has been validated in Indian settings. (Gupta, 2010) The VAS is a psychometric scale used for subjective characteristics or attitudes that cannot be directly measured. In this, the subjects specify their level of agreement to a statement by indicating a position along a continuous line between two end-points. The VAS instrument we used in our study numbered line ranging from 0 (no pain) to 10 (unbearable pain) along with faces depicting pain (Figure 1). The postoperative pain assessment was completed when the patient was transferred to the recovery room postoperatively. Patients who were unable to read the VAS for pain by themselves were asked to verbally report the perceived pain using the same scale.

To decrease interviewer bias, the questionnaires were administered by the same investigator after both the surgeries. Patients undergoing first eye surgery were also asked for overall comfort and satisfaction with anaesthetic and surgical technique and if they would prefer the same for their other eye cataract surgery. Similarly, patients undergoing second-eye surgery were asked in addition to their overall comfort and satisfaction with anaesthetic and surgical technique, to compare the severity of pain during their first-eye and second-eye surgery. They were also asked if they would recommend the anaesthetic and surgical technique to other patients or relatives for their cataract surgery.



Objective measurement of pain was assessed by measuring mean arterial pressure (MAP) as well as by systolic blood pressure (SBP), diastolic blood pressure (DBP) and pulse rate. MAP, SBP and DBP were measured using an electric monitor (multipara) preoperatively, during phacoemulsification, as well as post operatively in the recovery room, and calculated by the formula, $MAP = SBP \times 1 / 3 + DBP \times 2 / 3$.

Study Procedure

After the selection of patients, a preoperative assessment was done by ophthalmologist to exclude those having any contraindication of phacoemulsification. A detailed eye examination included visual acuity, refraction under dilation with Tropicamide 1 %, slit lamp examination including anterior segment evaluation and grading of cataract as per LOCS classification, intraocular pressure (IOP) measurement by non-Contact tonometry, fundus examination by 90D condensing lens and biometry (IOL master Carl Zeiss meditec). A total of 60 patents were finally included in the study.

Anaesthesia Technique

Two drops of topical Proparacaine hydrochloride 0.5 % eye drops were instilled 10 minutes pre-op after dilating the pupil, further two drops were instilled immediately after entering the operating room, prior to cleaning and draping and finally two drops prior to insertion of eye speculum. Patients were instructed to keep their eyes closed after instillation of topical anaesthetic. The patients were asked to remain in the supine position on the operating table and were requested to minimize ocular movement.

Surgical Technique

The surgical technique was clear corneal stop and chop phacoemulsification through a 2.8 mm incision. In all cases, foldable intraocular lenses were implanted using the dedicated injector system. Insertion of eye speculum was marked as the start of surgery and once hydration of incision sites with balanced salt solution was done, it marked the end of the surgery and duration between both was the total operation time. Actual phacoemulsification time was also recorded from the machine data. To minimize the bias, all

surgical procedures were performed in the same operating room with the same equipment, by the same surgeon.

Statistical Analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) Version 20 ("IBM SPSS Statistics for Windows," 2011). The descriptive variables were described in numbers and percentages for categorical variables and mean and SD for continuous variables. The statistical significance was tested by independent t test, paired t test and chi square test, whenever applicable. All tests were two tailed, and a P - value of ≤ 0.05 was considered significant.

Ethics

The study was approved by the board of studies and Institutional Ethics and Research Advisory Committee, JN Medical College, AMU, Aligarh. An informed consent was obtained from each participant prior to study. The participants were ensured about the privacy and confidentiality of the exercise. Before preceding the study, each patient was informed briefly about the study and given free will to participate and appropriate health education, counselling and referral were provided to all the patients.

RESULTS

As per the inclusion and exclusion criteria, 60 patients were included in the study during the study period. None of the patient developed any allergic complication to anaesthetic drug, none required any supplementation of anaesthesia or conversion to regional nerve block. All surgeries were successfully completed with no incidence of PCR or vitreous loss. Minimum gap between surgery of the two eyes was 1 week and maximum gap was 60 weeks (mean 24.31 weeks, median 24 weeks). As per response to questionnaires, all patients were comfortable and satisfied with anaesthetic and surgical technique during their first eye surgery and they preferred the same technique for second eye surgery. During the second eye surgery patients were comfortable and satisfied with similar technique and they also recommended same for other patients and their relatives.

Characteristic	Frequency/ Mean	Percentage/ SD
Age	50 - 59	31 51.7
	60 - 69	25 41.7
	70 and above	4 6.7
Gender	Male	39 65.0
	Female	21 35.0

Table 1. Distribution of Study Population

As shown in the Table 1, majority (51.7 %) of cases were from age group 50 - 60 years of age having mean age of study population was 59.4 ± 6.9 years. Males outnumbered females as 39 (65 %) were males and 21 (35 %) were females.

Variable	First Eye Freq (%) or Mean \pm SD	Second Eye Freq (%) or Mean \pm SD	Test Value	Sig. (P Value)
Cataract Grading			chi square = 3.4	0.183
Grade 0	22 (45.8 %)	26 (54.2 %)		
Grade 1	29 (48.3 %)	31 (51.7 %)		
Grade 2 or more	9 (75.0 %)	3 (25.0 %)		
Phaco time (in sec)	18.38 ± 5.961	17.35 ± 5.859	T = 0.958	0.340
Surgery time (in min)	15.07 ± 1.765	14.52 ± 2.228	T = 1.499	0.137
Pain score	0.73 ± 0.861	2.17 ± 0.905	T = -8.89	< 0.001

Table 2. Comparison of Surgery Time and Pain Score between First and Second Eye Surgery

Table 2 show comparison of two study groups. As show in Table 2, the study groups were similar in grading of cataract at the time of operation. The comparison of phaco time and surgery time between first eye and second eye surgery, which too was found to be similar and was not statistically significant. Thus, we can easily say that the study population was comparable in their characteristics.

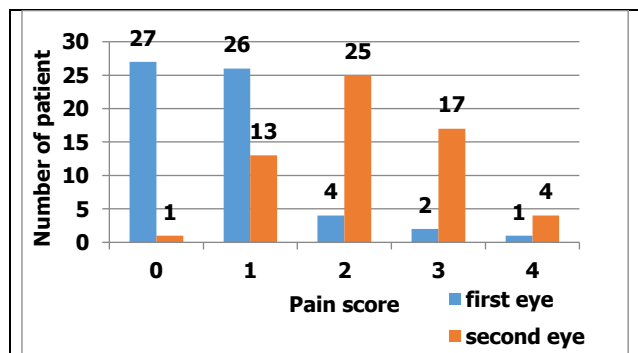


Figure 2. Pain Score (VAS) Comparison between First and Second Eye Surgery

	Pre-operative		Peri-operative		Post-operative	
	First eye Mean \pm SD	Second Eye Mean \pm SD	First eye Mean \pm SD	Second Eye Mean \pm SD	First eye Mean \pm SD	Second Eye Mean \pm SD
Systolic BP	139.50	137.37	139.00	137.63	132.70	132.10
	\pm 13.68	\pm 12.87	\pm 13.69	\pm 17.02	\pm 11.57	\pm 13.29
	P = 0.38		P = 0.62		P = 0.79	
Diastolic BP	85.87	84.57	85.37	84.23	82.47	82.30
	\pm 6.39	\pm 6.86	\pm 5.38	\pm 7.73	\pm 5.09	\pm 6.72
	P = 0.28		P = 0.35		P = 0.14	
MAP	103.74	102.17	103.20	102.09	99.38	98.87
	\pm 8.19	\pm 8.15	\pm 7.72	\pm 10.08	\pm 6.86	\pm 8.45
	P = 0.29		P = 0.50		P = 0.72	
Pulse	84.15	81.23	83.77	80.73	79.78	78.57
	\pm 9.61	\pm 10.74	\pm 10.17	\pm 10.67	\pm 7.00	\pm 8.79
	P = 0.12		P = 0.11		P = 0.41	

Table 3. Objective Measurement of Pain in First and Second Eye Surgery

Table 2 and 3 and figure 2 show the pattern of pain experienced by the study population, subjectively and objectively following cataract surgery. The mean pain score was 0.73 ± 0.861 (median: 1 and range: 0 to 4) in first eye surgery as compared to 2.17 ± 0.905 (median: 2, range: 0 to 4) in second eye surgery. Fifty-one (85 %) patients gave more pain score to second eye surgery as compared to first eye surgery. There was statistically significantly higher pain score given by the patients during their second eye surgery as compared to first eye surgery (P < 0.001).

Objective analysis of pain was done by measuring SBP, DBP, MAP and pulse rate. We observed all these parameters to be slightly higher in first eye pre-operatively, peri-operatively as well as post operatively in comparison to second eye but this relationship was not found to be statistically significant on independent t test analysis. (Table 3).

DISCUSSION

In our study total 60 patients were enrolled who were scheduled to undergo bilateral phacoemulsification cataract surgery. We did this study to find any pattern of pain experience by patient following phacoemulsification and its association with first or second eye surgery. We observed that patients reported significantly higher pain following second eye phacoemulsification in comparison to first eye surgery, although this was not observed in objective assessment by SBP, DBP, MAP and pulse rate.

As this was prospective observational clinical study involving same group of patients, thus patient's characteristic was not of question. We also found that patient's eye which was going to be operated, were also similar in characteristics including similar cataract grading. Similarly, these two groups performed very similar in terms of phaco-time as well as surgery time which was observed to be not significant. Thus, we could easily say that the two groups we studied, were comparable and there was no selection bias in our study.

In regard to overall experience following phacoemulsification of first eye surgery, all patients were comfortable and satisfied and they preferred the same technique for second eye surgery. Similarly, after the second eye surgery, patients were comfortable and satisfied with similar technique and they also recommended same for other patients and their relatives. This shows a good acceptance and overall satisfaction of phacoemulsification under local anaesthesia.

The pattern of pain experienced by patients following first and second eye surgery was assessed subjectively as well as objectively. While most of the patients following first eye surgery reported no pain following phacoemulsification, a few were annoyed while one patient described his pain as uncomfortable. In contrast to pain following second eye surgery, majority were annoyed by the pain with few also reported uncomfortable, while only one patient had no pain. This distribution of differences in pain experiences in first and second surgeries was found to be statistically significant. Thus, pain experienced by the patients was more in

subsequent second eye cataract surgery as reported by the patients. This is similar to the reports from various studies from India as well as Internationally.^{2,7,8} (Ursea et al. 2011; Jiang, 2015; Nijkamp, 2004)

Ursea et al. in their study found patients after second cataract extraction have higher visual analog scale pain scores in comparison to first. (Ursea et al. 2011) Tan et al. in their large, multiracial and multicentric study observed that those who had previously undergone cataract surgery in other eye experienced significantly more pain compared to those undergoing for the first time. (Tan et al. 2011)

In contrast to this study as well as by others which used intracameral lignocaine or oral/intravenous sedatives during surgery^(2,3,4,5), (Ursea et al. 2011; Tan et al. 2011; Bardocci et al. 2011; Hari-Kovacs et al. 2012;) we used only topical anaesthesia (0.5 % proparacaine eye drops) which is preferred choice in most of the cases. In 2014, Deschaumes C et al. in their study found that objective measures, including blood pressure and heart rate in the perioperative period, may be correlated with subjective perceptions and might be influenced by the patient's anxiety and nervousness.⁹ (Deschaumes, 2015) The inclusion of objective measures should reduce the possible bias associated with subjective measure. In 2016 Ji-guo Yu et al. compared pain and anxiety in 127 patients undergoing consecutive bilateral phacoemulsification surgery. They found 26 % patients reported more pain in first, 41.7 % reported more pain in second eye and 27.6 % reported same pain in both eyes.¹⁰ (Yu, 2016)

Our results differ from the study done by Sharma et al. Bardocci et al. Andras Hari-Kovacs et al. and Khezri MB 2013.^{4,5,11,12} (Bardocci et al. 2011; Hari-Kovacs et al. 2012; Khezri, 2013 ; Sharma, 2008) In 2008 Sharma et al. in their study of eye phacoemulsification cataract surgery under ATA (iv midazolam / propofol / fentanyl + topical 1 % amethocaine and 1 % ropivacaine) found no significant difference in pain (P = 0.47) between the first and second eye surgery.¹² (Sharma et al. 2008) In 2011 Bardocci et al. compared pain experience in 73 consecutive patients undergoing bilateral non simultaneous cataract surgery under topical (xylocaine 2 % jelly) anaesthesia, found no significant difference in pain (2.35 vs 2.89) between first and second eye surgery (P = 0.17). (Bardocci et al. 2011) In 2012 Andras Hari-Kovacs et al. compared the pain perceived in first and second eye cataract surgery among 187 patients undergoing consecutive bilateral phacoemulsification surgery under ATA (0.5 % proxymetacaine drops + 10 mg/os oral temazepam) and found no significant difference in the pain.⁵ (Hari-Kovacs et al. 2012) These differences could be due to different population, methodology, multiple surgeons, as well as use of i.v sedative during surgery. In first eye cataract extraction, patients have higher expectations of success, and with return of vision to sufficient level, his/her coexisting pain feeling might become submissive to excitement and positive influence after first surgery.¹³ (Adatia, 2015) All these fades with second surgery and patients are more attentive to the level of pain/comfort, better aware of the procedure and may be higher sensitivity to pain during second eye cataract surgery.⁸ One study has

also found expression of MCP-1, inflammatory chemokine associated with pain, increased significantly in the aqueous humour of other eye following the first surgery.¹⁴ (Zhu, 2015)

Objective assessment parameters were found to be higher before cataract surgery as compared to perioperative and postoperative period in both eye surgeries except SBP in second eye which was slightly higher in perioperative period although these relationships were not found to be statistically significant. Researcher from China have also observed similar findings.⁷ (Jiang et al. 2015) In 2015 Lin Jiang et al. found that the perioperative blood pressure and heart rate were not significantly different between the two groups of patients. However, SBP, DBP, and MAP were significantly lower after cataract surgery than before surgery but there was no significant difference between first and second eye surgery. They also found that patient felt more pain in second eye (P = 0.047) and more anxiety in first eye (P = 0.003).⁷ (Jiang et al. 2015) As its been reported that experiencing acute pain by any patient often transiently increases their blood pressure,⁶ (Chawla et al. 1999) we were in opinion that this will hold true in cataract surgeries too. It is well known that psychological factors, such as mental stress and anxiety, are often present before any surgery and they influence patient responses to local anaesthesia as well as his/her cardiovascular measure including MAP.^{11,10} (Khezri et al. 2013; Yu et al. 2016). Further studies are needed to assess the relations.

In spite of our study being done in a way to minimize bias including intra-individual and inter-observer bias, strong methodology, exclusive topical anaesthesia, we had some limitation. It was a single centric study done on limited sample, restricting its generality, though sample size was calculated in accordance with statistical principles. Furthermore, by excluding patients who have gap of more than one year between their cataract surgeries, we may exclude a lot of patients, although it may cause bias as patients tend to lose memory of painful events over time and are more likely to grade surgical event as less painful.

CONCLUSIONS

Patients reported experiencing higher pain while undergoing their cataract surgery of second eye by phacoemulsification under topical anaesthesia, in comparison to first eye surgery. While we observed strong relation in subjective assessment of pain by visual analogue score, it was not supplemented by objective assessment. This variation may be due to more apprehension, uneasiness, and memory of traumatic experience, from the previous surgery. We suggest that patients going for second eye surgery should be prior consulted as well as managed properly.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.

Financial or other competing interests: None.

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