Dexmedetomidine premedication in cataract surgery under topical anaesthesia: to assess patient and surgeon satisfaction

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Background: Dexmedetomidine is a potent non-opioid analgesic that may enhance analgesia for cataract surgery under topical anaesthesia. This study was undertaken to assess sedation and analgesia provided by dexmedetomidine and evaluating patients' satisfaction. Secondary aims were: (1) To study the effect of dexmedetomidine in decreasing the intraocular pressure. (2) The impact on surgeons' satisfaction. (3) Hemodynamic effects.

Methods: We conducted a prospective randomized study on ASA I/II patients presenting for cataract surgery under topical anesthesia. Patients were randomly assigned to two groups: group D received dexmedetomidine premedication 1 mcg/kg over 10 minutes and group C received saline at the same rate. Sedation and pain score, intraocular pressure, patient and surgeon satisfaction score and hemodynamics were monitored and compared.

Results: There was a significant increase in sedation assessed by the Ramsay sedation score at all times in group D after receiving dexmedetomidine ($p < 0.0001$). However, pain scores (numeric rating scale) were similar in both groups ($p > 0.05$). Dexmedetomidine decreased the intraocular pressure and the difference was statistically highly significant ($p < 0.0001$). Group D had better patient and surgeon satisfaction score as against group C ($p = 0.0001$). Noticeably, the incidence of dry mouth was higher in group D. Hemodynamic parameters were well maintained in both groups with no adverse events in either group.

Conclusions: Dexmedetomidine can be used safely for cataract surgery under topical anesthesia surgery. Administration of dexmedetomidine was associated with better patient and surgeon satisfaction.

Keywords: cataract surgery, dexmedetomidine, intraocular pressure, patient and surgeon satisfaction, topical anesthesia

Introduction

Traditionally, cataract surgeries are performed under regional anaesthesia with either a peribulbar or retrobulbar block. With the evolution of phacoemulsification surgery for cataract, the anaesthesia has also evolved from painful regional blocks to painless topical anaesthesia.[1] However, with topical anaesthesia the patient has to cooperate for an akinetic eye as compared with a regional block. The requirement for cooperation may lead to increased anxiety in patients. Moreover, the fall in intraocular pressure (IOP) seen with regional block, which is desirable for a good operative field, is not achieved with topical anaesthesia. Yet, topical anaesthesia is preferred as the patient is not required to undergo the painful injections for blocks and avoids the complications of blocks, including globe perforation and optic nerve injury.[1,2] Nevertheless, all cataract surgeries whether under regional blocks or topical anesthesia are performed under monitored anesthesia care (MAC) requiring the presence of an anaesthetist.[3]

Several agents such as propofol, midazolam and opioids have been used to allay anxiety and provide sedation for cataract surgery.[4–6] However, each of these drugs has limitations including over-sedation leading to impairment of patient's cooperation and respiratory depression. Dexmedetomidine is an alpha2 agonist that provides sedation and analgesia without respiratory depression.[7,8] Dexmedetomidine, through its central action, has been shown to decrease IOP.[9]

Previous studies on dexmedetomidine have been conducted either in cataract surgeries under regional blocks or have not included IOP in the studied parameter.[10,11] The aim of our study was to evaluate the effects of dexmedetomidine premedication on patient's satisfaction by assessing sedation and pain scores as well as surgeon's satisfaction by assessing the operating conditions and IOP during phacoemulsification cataract surgery under topical anaesthesia.

Material and methods

After institutional ethics committee approval, the study was conducted on 60 patients as a placebo controlled, randomized double blind study. Patients were fully informed about the study protocol and provided written informed consent. Inclusion criteria were patients aged 50-75 years belonging to ASA physical status I/II scheduled for phacoemulsification cataract surgery under topical anaesthesia. Exclusion criteria were any contraindication to the use of dexmedetomidine (cardiac disorders, hypertensive patients on beta blockers, liver and kidney diseases). Using a computer generated randomisation schedule, patients were assigned to either of the following two groups:

- Group D: Received dexmedetomidine premedication ($n = 30$)
- Group C: Received saline ($n = 30$)

During the preanaesthesia check-up, numeric rating scale (NRS) from 0 to 10 was explained to the patient for pain (0 = no pain, 10 = worst possible pain) and satisfaction (0 = complete dissatisfaction, 10 = most satisfaction).[3] On arrival in the operating theatre, basic monitors were attached and the baseline values of heart rate (HR), mean arterial pressure (MAP), respiratory rate (RR), oxygen saturation (spO$_2$), end tidal carbon dioxide using a side stream port (etCO$_2$) and electrocardiogram (ECG) were recorded.

Group D received intravenous infusion of dexmedetomidine 1 mcg/kg for 10 minutes, while group C received normal saline at the same rate. The infusion was started by anesthesiologist who was unaware of the study drug. Supplemental oxygen at 4 l/min was delivered to all patients using a nasal cannula. Intraoperative sedation was monitored using Ramsay sedation score (RSS)[12] (1 = agitated and restless, 2 = cooperative and tranquil, 3 = responds to verbal commands while sleeping, 4 = brisk response to gabellar tap or loud voice while sleeping, 5 = sluggish response to gabellar tap or loud voice, 6 = no response to gabellar tap or loud voice). The target endpoint was to achieve RSS 3. If the target end point was reached before completing the infusion, the infusion was stopped and noted. All the parameters to be studied i.e. HR, MAP, spO_2, RR, $etCO_2$, NRS (pain and patient satisfaction) and RSS were monitored and recorded for each patient before premedication (T1), after premedication (T2), intra operatively (T3) and post operatively (T4). The ophthalmologist, blinded to the study group, measured the IOP using a Schioetz tonometer under topical analgesia in the non-operated eye. The IOP was recorded before the premedication and at the end of the surgery. Surgery was performed under topical anaesthesia using instillation of few drops of 0.5% paracaine.

Any episode of bradycardia or hypotension (both defined as fall in values below 20% of baseline) was recorded and treated with intravenous atropine or ephedrine respectively. All adverse events including but not limited to respiratory depression, nausea, vomiting, dry mouth and oversedation were also noted. Pain, defined as a NRS score above 4, was treated with intravenous fentanyl 1 mcg/kg. The number of patients who needed fentanyl was recorded.

At the end of surgery, patients were asked about average level of pain and the surgeon satisfaction was assessed by the adequacy of operating conditions using the following scale: excellent (completely calm and cooperative patient), good (cooperative patient but slight undesirable movements of eyes) and poor (highly uncooperative patient with severe undesirable movements of eyes).[3] Patients were monitored in the recovery room, their Aldrete score observed and then discharged to the ward. All the study data was recorded by a blinded observer.

Based upon previously published data,[10,11] we assumed that the placebo could have an effect in causing sedation in 5% patients, whereas with dexmedetomidine, sedation would be obvious in at least 40% of patients and this provided an 80% power with an error equal to 0.05, therefore a sample size of 22 patients per group appeared sufficient. To compensate for drop out cases and cases with violation of study protocol, a total of 30 cases were studied in each group.

Statistical analysis was conducted with SPSS (version 10) for Windows statistical package using paired and unpaired Student's *t*-test. Parametric variables such as age, duration of surgery, HR, MAP, spO_2, RR, $etCO_2$ and IOP were analysed using a *t*-test, while for non-parametric data (NRS and RSS), Mann–Whitney test was employed. A *p*-value < 0.05 was considered significant.

Results

The groups were comparable in terms of demographic data, ASA grading and duration of surgery (Table 1).

The mean dexmedetomidine dose in group D was 65.4(3.6) mcg (1.08 mcg/kg)

The baseline values of HR and MAP were similar in both study groups. However, a gradual fall in both HR and MAP was recorded in group D after completion of infusion which continued throughout the intra and postoperative period (p). One patient in group D needed atropine for bradycardia, but the study drug was not stopped after atropine administration. There was a fall in MAP, but none of the patients needed ephedrine treatment. (Table 2)

Table 1: Demographic profile and surgical time

	Group D	Group C	*p*-value
Age (years)	62.6 (6.5)	61.4 (6.9)	NS
Weight (kgs)	60.4 (10.2)	58.6 (11.2)	NS
Male/Female	11:19	10:20	NS
ASA I/II	20:10	21:9	NS
Duration of surgery (minutes)	23.4 (4.4)	22.7 (5.2)	NS

Note: Values expressed as Mean (SD). NS: *p*-value > 0.05, not significant.

Table 2: Heart rate (HR) and Mean arterial pressure (MAP) changes

	T1	T2	T3	T4
HR (per min)				
Group D	74.5(8.18)	72.42(13.25)	76.00(14.21)	68.50(11.54)
Group C	73.52(7.82)	81.4(7.36)	89.75(9.21)	79.50(15.68)
p-value	0.74	0.005	0.000	0.009
MAP (mm of Hg)				
Group D	92.46(8.32)	86.88(10.75)	88.26(11.03)	81.02(11.10)
Group C	95.70(9.42)	99.10(12.36)	107.20(7.90)	90.03(9.24)
p-value	0.28	0.005	0.000	0.008

Notes: (T1): Premedication, (T2): After premedication, (T3): Intraoperatively and (T4): Postoperatively.
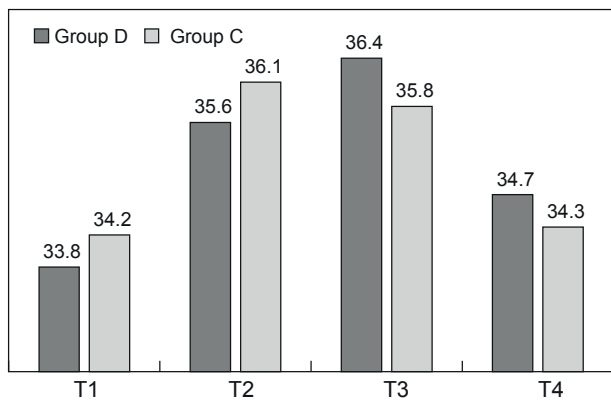
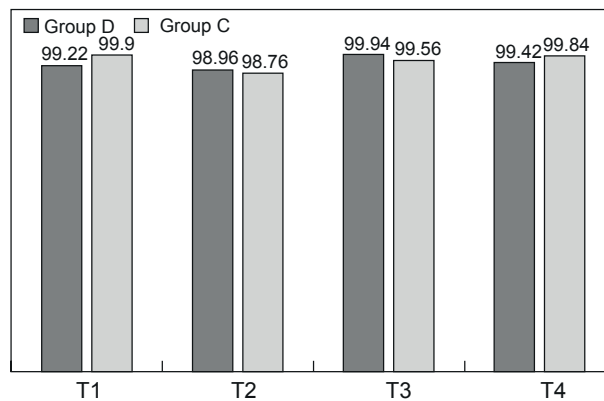**Figure 1:** Changes in end tidal carbon dioxide ($etCO_2$) (mm of Hg)

Figure 2: Changes in oxygen saturation (spO_2), (%)

The $etCO_2$ monitored from the side stream capnometer, albeit a rough indication of ventilation, was maintained in both the groups (Figure 1). Despite an apparently normal $etCO_2$ on monitor, any occurrence of hypoventilation could not be precisely ruled out.

All patients received oxygen by nasal prongs, the saturation was maintained and respiratory rate was never below 10/min in both the groups (Figures 2 and 3).

The preoperative IOP values were similar in both the groups. Strikingly, in group D there was a significant fall in IOP postoperatively as compared to group C (from mean 17.10 ± 1.92 mm of Hg to postoperative 13.81 ± 1.63 mm of Hg. The difference was highly statistically significant. (Table 3)

While comparing the sedation, we observed that the overall RSS was higher at all times after completion of premedication in group D ($p < 0.0001$). On the contrary, and as evident from Table 3, the patients had a lower RSS in group C.

The patients' NRS for studying overall satisfaction was higher in group D compared to group C, indicating a statistically significant improvement in patient's satisfaction with dexmedetomidine premedication. In group D, a maximum score of 10 was given by patients, while in group C, the maximum score given was 8 (Table 3).

Neither the intraoperative ($p = 0.182$) nor the postoperative ($p = 0.081$) NRS for pain were different between the groups (Table 3). However two patients in group C demanded rescue analgesia and were given fentanyl boluses. None of the patients in group D
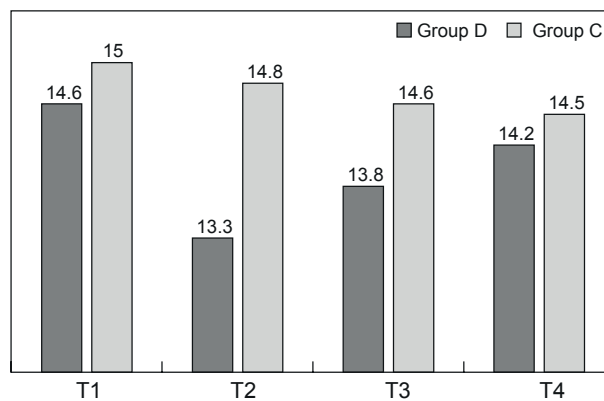

Figure 3: Changes in Respiratory rate (per min)

needed a fentanyl bolus and the difference in fentanyl requirement was not statistically significant (Table 3)

In group D, the quality of operating conditions as assessed by ophthalmologist (surgeon satisfaction score) was rated excellent in 26 patients and good in rest 4, while in group C, only 13 patients had excellent conditions and other 17 had good operating conditions. None of the patients exhibited poor operating conditions. This difference was statistically significant ($p = 0.001$) (Table 3)

Twelve patients in group D suffered from dry mouth compared with none in group C ($p < 0.005$) but this was not clinically significant as the patient satisfaction score was higher in group D.

Table 3: Other parametric and nonparametric data

	Group D	Group C	*p*-value
IOP (mm of Hg)			
Baseline	17.10(1.92)	16.90(4.11)	NS
End of surgery	13.81(1.63)	15.41(3.93)	<0.0001
RSS (average score)	2.67(0.48)	1.56(0.44)	<0.0001
VAS for pain (per op)	3(0–4)	3(2–4)	0.182
(post op)	1(0–1)	1(1–2)	0.081
Requirement of fentanyl (no. of patients)	0	2	–
Patient satisfaction score	9(8–10)	7(5–8)	0.0001
Surgeon satisfaction score (excellent/good)	26/4	13/17	0.0001

Notes: IOP: intraocular pressure, RSS: Ramsay sedation score, VAS: visual analogue score.

Other adverse events like nausea, vomiting or over sedation were not recorded in either groups.

Both the groups achieved Aldrete scores of 10 by the end of 30th minute and the difference in recovery time was not statistically significant.

Discussion

We conducted this randomised double-blind study in an attempt to examine the efficacy of dexmedetomidine in improving patient's and surgeon's satisfaction in patients undergoing phacoemulsification cataract surgery under topical anaesthesia. We observed that dexmedetomidine provides conscious sedation with better patient cooperation and satisfaction, decreases the IOP leading to improved operating conditions and better surgeon satisfaction.

Cataract surgery using phacoemulsification under topical anaesthesia is the preferred method for lens replacement.[1,2] However, motor activity remains spared in topical anaesthesia and hence akinesis of eye is not achieved, causing discomfort to both the patient and surgeon.[1]

Central stimulation of parasympathetic outflow and inhibition of sympathetic outflow from locus coeruleus in the brain stem is responsible for sedation and anxiolysis produced by dexmedetomidine.[7] Patients premedicated with dexmedetomidine typically stay tranquil and cooperative while sleeping when unstimulated.[13–15] This characteristic of dexmedetomidine has prompted its use in patients undergoing day case surgery without any adverse effect.[14]

On the other hand, use of propofol and opioids more commonly leads to over-sedation and respiratory depression and may also delay the recovery of patients when used for a day case operations like cataract surgery.[4,16]

Alhashemi et al. compared midazolam with dexmedetomidine sedation for cataract surgery under topical anesthesia and found dexmedetomidine was inferior to midazolam due to a higher incidence of cardiovascular depression and delayed recovery.[10] These results are in contradiction with our study results. This may be explained by the fact that in the study by Alhashemi et al., the loading dose of dexmedetomidine was followed by a maintenance infusion, which was not done in our study using a loading dose alone. Dexmedetomidine when given as a loading dose has an onset of action of less than 5 minutes and the peak effect is reached at 15 minutes. Elimination half-life of dexmedetomidine is 2 hours.[8,9] Thus, a loading dose appears sufficient for a short duration surgery like phacoemulsification. The results of our study are in agreement with the study by Ayoglu et al. finding a single dose of dexmedetomidine to be sufficient. Dexmedetomidine has been shown to be devoid of respiratory depressant effects.[11] The quality of sedation offered by dexmedetomidine is better and the need for rescue sedation is reduced as compared to midazolam with no significant effect on haemodynamics or the respiratory system.[14,15]

The HR and MAP were found to be low with premedication in our study. This is attributed to the central sympatholysis after dexmedetomidine administration.[7,8,17] Similar results have been obtained in previous studies.[10,18]

None of the patients developed bradypnoea in our study. Dexmedetomidine is unique in that it does not cause respiratory depression because its effects are not mediated by gamma aminobutyric system,[7] contrary to the situation with the benzodiazepines.[18,19] These findings agree with the results of prior studies.[10,11,18]

Patients were more comfortable with better sedation scores in group D. This could be explained, at least in part, by the additional analgesic property of dexmedetomidine that improves patient's perception of sedation.[8,15] However, we could not demonstrate better pain scores in group D, as topical anesthesia itself provided adequate sensory anaesthesia.

Dexmedetomidine, by its central action leads to a fall in IOP.[7,20] This finding was shown in this study. The decrease in IOP improves surgical field by optimizing the operating conditions. A well-sedated but cooperative patient would provide better operating conditions providing a reason for better surgeon satisfaction in group D. The reduced IOP found in this study is in agreement with the study results of Ayoglu et al.[11]

The single dose of dexmedetomidine, used in this study is not associated with any major adverse cardiovascular effects. The occurrence of dry mouth is an established fact with the use of alpha 2 agonists[7] but did not reduce patient satisfaction.

There are limitations to this study. Firstly, only ASA status I and II patients were included in the study and to prove its benefit in ASA status III/IV, further studies recruiting high-risk patients need to be carried out. A second limitation was in monitoring respiration – although saturation and respiratory rate were accurately monitored, we used a side stream capnometer to monitor etCO$_2$, which requires airway instrumentation for accurate measurement and is inherently less accurate in sedated patients without airway devices. This limitation affected both the study groups equally. The capnometer has been used previously to measure etCO$_2$ in sedated patients.[10] Another possible limitation is the use of RSS to monitor sedation as opposed to the use of bispectral index or entropy. The RSS is more appropriate for sedated patients while monitoring depth of anaesthesia is more appropriate for general anaesthesia and monitors may not be readily available in all institutions.

Conclusion

We conclude that dexmedetomidine can be used safely for MAC in cataract surgery as the drug is associated with better patient and surgeon satisfaction. However, patients need to be closely monitored, following minimum monitoring standards.

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