A Prospective, Randomized, Double-blinded Control study on evaluation of low dose dexmedetomidine infusion in patients undergoing cataract surgery under peribulbar block

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Abstract

Background: The cataract surgeries are usually done in elderly patients under monitored anaesthesia care with or without sedation. Dexmedetomidine is a non-opioid sedative and analgesic and is devoid of respiratory depression. The objective of this present study is to evaluate the sedative effects of low dose dexmedetomidine infusion for unilateral cataract surgery. The patient and surgeon satisfaction scores were also recorded.

Methods: Sixty patients scheduled for unilateral cataract surgery were randomly assigned to two groups: Group 1 receiving dexmedetomidine 0.5mcg/kg diluted in 100ml normal saline infusion over 15min while group 2 received normal saline. The patients in both the groups received premedication with alprazolam 0.5mg two hours prior to surgery. The hemodynamics, sedation score, patient and surgeon satisfaction scores and any adverse effects were recorded. Ramsay sedation score (RSS) of 3 was kept as a satisfactory sedation for the patient.

Results: All the patients in group 1 achieved RSS of 3 while in group 2 only 47% of patients reached the target score. The patient and surgeon satisfaction scores were better with group 1. There was a significant fall in heart rate and blood pressure between 15 and 25 min after dexmedetomidine infusion. In group 1, two patients had bradycardia and four patients developed hypotension which was easily manageable.

Conclusion: Dexmedetomidine, when administered as a low dose infusion provides reliable sedation and is a useful anaesthetic adjuvant for monitored anaesthesia care in cataract surgery. The patient and surgeon satisfaction scores were also better with dexmedetomidine infusion.

Keywords: Cataract, Dexmedetomidine, Monitored anaesthesia care, Patient and Surgeon satisfaction scores, Sedation.

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Introduction

Cataract surgery is the most frequently performed ophthalmic procedure that is usually done under peribulbar block or topical anaesthesia[1]. Patients need monitored anaesthesia care (MAC) and might require sedation to reduce anxiety as it may raise heart rate, blood pressure as well as intraocular pressure. Most of these patients are elderly and have concurrent medical illness like hypertension, diabetes, ischemic heart disease for which tachycardia and hypertension are not desirable.

Good sedation to these patients will allay their anxiety and stress making it comfortable not only to the patients but also to the surgeons. The most commonly used drugs for sedation in cataract surgery are benzodiazepenes, propofol and opioids[2]. Benzodiazepene may cause confusion in elderly patients[3], opioids may cause respiratory depression and propofol may cause respiratory depression and hypotension[4]. In order to avoid these side effects, α_2 agonists are nowadays being utilized in cataract surgeries.

Dexmedetomidine is a α_2 agonist which has sedative and analgesic actions without causing respiratory depression[5]. Dexmedetomidine is frequently used for sedation in day care procedures. It has a short elimination half-life of two hours making the patient fit for earlier discharge from the hospital. Dexmedetomidine has been shown to reduce intraocular pressure. Patients sedated with dexmedetomidine respond to verbal commands during surgery and has easy awakening from sleep[6]. Dexmedetomidine is used for sedation in intensive care unit, radiological imaging of paediatric and uncooperative patients, awake intubation, stress attenuation to intubation, extra corporeal shock wave lithotripsy, endoscopy and as an adjuvant to anaeshetic agents[7-14].

The objective of this prospective, randomized, double-blinded control study is to compare the sedative and hemodynamic effects of dexmedetomidine with placebo in patients undergoing unilateral cataract surgery. The patient and surgeon satisfaction, hemodynamics, use of rescue sedative and adverse effects were observed.

Materials and Methods

The study was performed in a tertiary medical college hospital after obtaining institutional ethical committee approval and written, informed consent from patients. Patients in the age group of 50 to 75, American Society of Anesthesiologists (ASA) physical status 1 and 2 patients and scheduled to undergo elective unilateral cataract surgery under peribulbar block were included in the study. Patients with ASA physical status 3 and above, cardiac, liver and renal diseases, allergic to any of the study drugs and patient refusal were excluded from the study. The patients were randomized to receive either dexmedetomidine (Group 1) or normal saline (Group 2) during cataract surgery performed under peribulbar block. The Group allotment was decided by the computer generated random envelope method. The first anesthesiologist opens the envelope and adds either dexmedetomidine (Group 1) or normal saline (Group 2) in a 100ml normal saline and hands it to the second anesthesiologist who is blinded to the study drug. He administers the drug over 15 minutes and monitors the patient.

All the patients got alprazolam 0.5mg orally two hours before surgery. Intravenous access was established with 18G intravenous (IV) canula. Standard monitoring like pulse oximetry, noninvasive blood pressure (BP) and electrocardiogram were done intraoperatively. All patients were preloaded with 500ml of Ringer lactate. Oxygen 2 L/min was administered via nasal canula to all patients. Patients in Group 1 received Dexmedetomidine 0.5mcg/kg diluted in 100ml normal saline (NS) infusion over 15min. Similarly patients in Group 2 received Normal Saline in 100ml NS infusion over 15min. Peribulbar block was performed after the infusion. The study groups were compared with respect to hemodynamic variables, sedation score, recovery criteria, and patient and surgeon satisfaction using Numeric Rating Scale. It was recorded as hypotension and bradycardia when blood pressure and heart rate were reduced by 20% of baseline values. Ramsay sedation score (RSS) was followed to assess the sedation of patients and is given in Appendix 1[15]. The recovery criteria was assessed using Modified Aldtrete score and given in Table 2. The patient and surgeon satisfaction score from 1 to 7 was followed for the study and is given in Fig. 1[21]. RSS of 3 was kept as a target to achieve after study drug administration. If it was not reached then rescue sedation with midazolam 1mg IV was given and recorded. The duration of surgery and time to achieve Ramsay sedation score 3 were also noted and compared. The side effects like bradycardia were treated with glycopyrrolate 0.2mg IV and hypotension with ephedrine 6mg IV.

The sample size estimation was done based on previous studies[17,19] and we assumed that obvious sedation could be achieved with dexmedetomidine in 40% of patients. We calculated that 22 patients per group would be required for the study incorporating two equal sized groups, using α=0.05 and β=0.2. We elected to recruit 30 patients in each group into the study to minimize any effect of data loss[15].

Statistical analysis was performed using a standard statistical program, The Statistical Package for Social Sciences version 17.0 software (IBM Corporation, Armonk, NY, USA). Student's *t*-test was utilized to analyze parametric variables like demographic profile, heart rate and blood pressure. All the values are expressed as Mean±Standard deviation and the level for all analyses was set at p=0.05 and a p-value less than 0.05 were considered statistically significant and less than 0.01 were considered extremely significant.

Table 1: Ramsay Sedation Scale[16]

1.	Patient is anxious and agitated or restless, or both.
2.	Patient is cooperative, oriented, and tranquil.
3.	Patient responds to command only.
4.	A brisk response to a light glabella tap or a loud auditory stimulus.
5.	A sluggish response to a light glabella tap or a loud auditory stimulus.
6.	No response to a light glabella tap or a loud auditory stimulus.

Table 2: The Modified Aldrete Scoring System for Determining when Patients Are Ready for Discharge from the Postanesthesia Care Unit[17]

Activity: able to move voluntarily or on command	
4 extremities	2
2 extremities	1
0 extremities	0
Respiration	
Able to deep breathe and cough freely	2
Dyspnea, shallow or limited breathing	1
Apneic	0
Circulation	
BP±20 mm of preanesthetic level	2
BP±20–50 mm of preanesthesia level	1
BP±50 mm of preanesthesia level	0
Consciousness	
Fully awake	2
Arousable on calling	1
Not responding	0
O2 saturation	
Able to maintain O2 saturation 92% on room air	2
Needs O2 inhalation to maintain O2 saturation 90%	1
O2 saturation 90% even with O2 supplementation	0

A score ≥ 9 was required for discharge.
Abbreviations BP: blood pressure

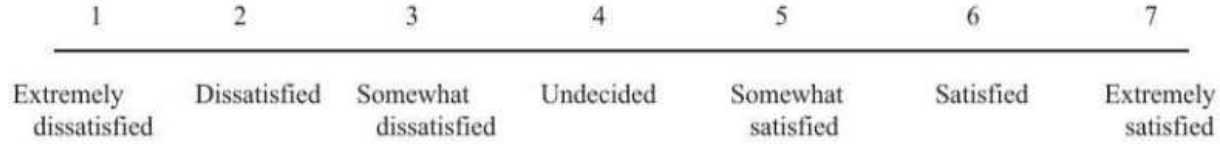

Fig. 1: 7 point patient and surgeon satisfaction score[18]

Observation and Results

Both the groups were comparable in terms of demographic data. The mean age in Group 1 was 57.76±5.39 and Group 2 was 56.23±5.21 and was found to be statistically insignificant. The gender distribution in both groups was identical (17 males and 13 females). Regarding patient distribution according to ASA physical status, both the groups were comparable. The demographic data are given in table 3. All the patients in Group 1 achieved desired sedation (RSS ≥ 3). 21 patients achieved sedation score of 4, seven patients achieved RSS of 3 and two patients achieved RSS of 5. On the other hand, in Group 2, only 14 patients achieved desired sedation (RSS ≥ 3) and 16 patients did not achieve desired sedation and is given in Fig. 2.

Patients in both the groups were hemodynamically stable throughout the intraoperative period. There was a statistically significant fall in heart rate and systolic blood pressure between 15 to 25 minutes after dexmedetomidine administration. There was a significant fall in diastolic blood pressure after 15 minutes. Two patients in group 1 had bradycardia (incidence rate- 6.66%) and hypotension was observed in four patients in group 1 (incidence rate – 13.33%) whereas no complications were observed in group 2. The hemodynamic parameters are given in Tables 4-6 and Fig. 3-5.

Both the groups were comparable in terms of satisfaction score by patients as well as to surgeons. Regarding patient satisfaction, all the patients in group 1 gave score ≥ 5/7 whereas in group 2, only two patients had score of 4/7 while rest (87%) gave score ≥ 5/7 and is given in Fig. 6. Regarding surgeon satisfaction, satisfaction score of ≥ 5/7 is achieved in all patients in both groups. The quality of satisfaction rate by surgeons is more in group 1 and given in Fig. 7. Six patients in group 2 required rescue sedation (Inj. Midazolam 1mg IV) whereas rescue sedation is not required for any patient in group 1. There was no difference in achieving an Aldrete score of ≥ 9 between both the groups and they are fit for discharge from post anaesthesia care unit within five minutes after being shifted there.

Table 3: Demographic profile

Patient characteristics	Group 1	Group 2	p value
Age	57.76±5.39	56.23±5.21	0.268
Sex (M/F)	17/13	17/13	0.461
ASA grade (I/II)	12/18	13/17	0.346
Duration of surgery (min)	23.9±1.41	23.1±2.82	0.169
Weight (kg)	58.3±9.34	60.1±10.31	0.481

All values are in Mean±SD or number of patients

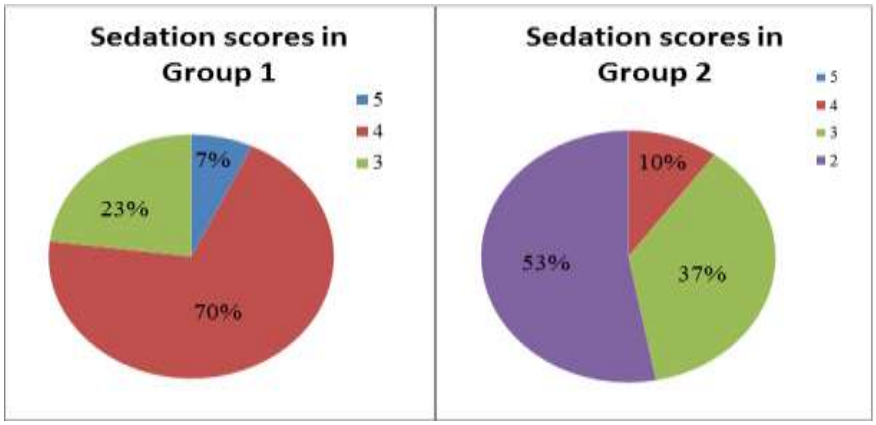

Fig. 2: Sedation score

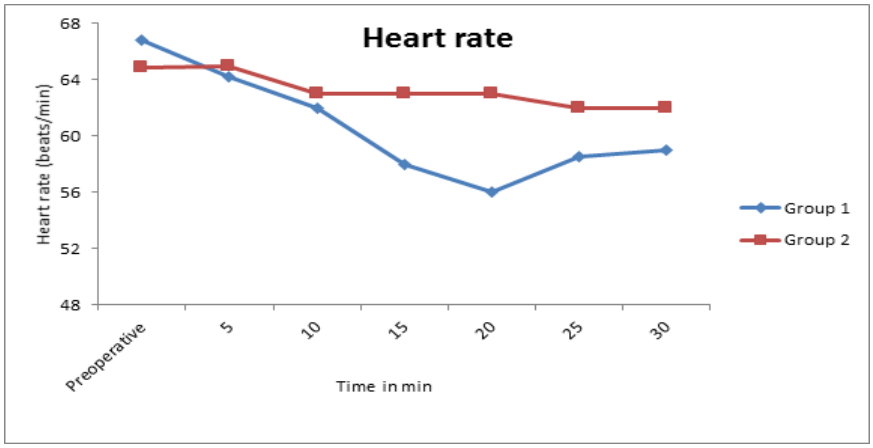

Fig. 3: Variations in heart rate after study drug administration

Table 4: Variations in heart rate after study drug administration

Time in min	Group 1 beats/min	Group 2 beats/min	p value
Preoperative	66.82±6.43	64.92±7.89	0.318
5	64.22±9.82	65.14±8.29	0.685
10	62.91±7.48	63.83±6.83	0.620
15	58.88±7.84	63.65±9.93	0.043*
20	56.87±5.72	63.86±6.81	0.001**
25	58.59±8.21	62.62±6.28	0.037*
30	59.46±5.76	62.76±7.42	0.058

All values are in Mean ± SD.

p value * means significant, ** means highly significant

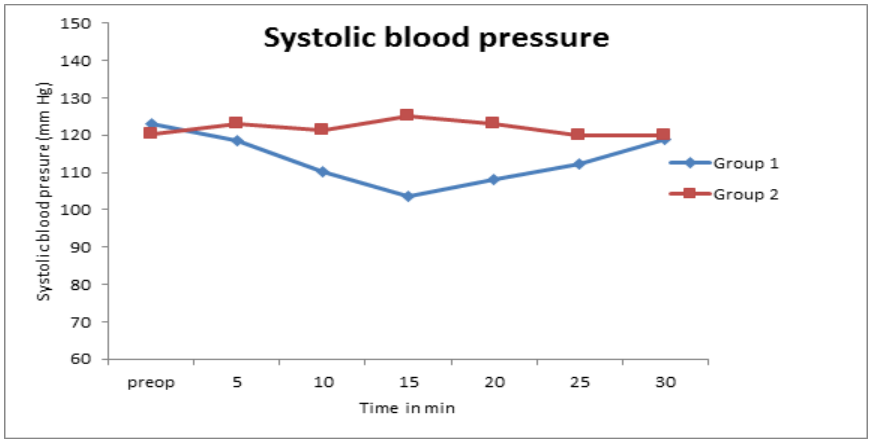

Fig. 4: Variations in systolic blood pressure after study drug administration

Table 5: Variations in systolic blood pressure after study drug administration

Time in min	Group 1 mm Hg	Group 2 mm Hg	p value
Preoperative	123.06±12.48	120.45±15.93	0.478
5	118.67±18.54	123.11±14.37	0.304
10	110.11±16.73	121.21±17.38	0.014*
15	103.78±14.26	125.25±12.41	0.001**
20	108.23±17.81	122.98±13. 26	0.001**
25	112.32±13.56	120.01±14.92	0.041*
30	118.73±16.39	119.9±17.28	0.788

All values are in Mean±SD.
p value * means significant, ** means highly significant

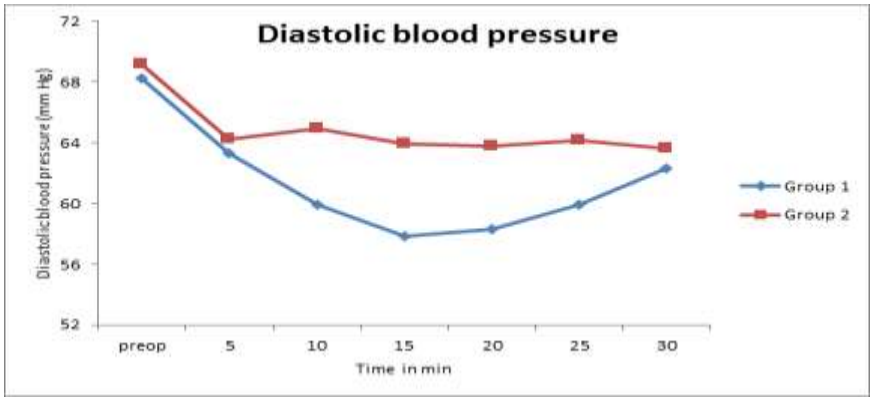

Fig. 5: Variations in diastolic blood pressure after study drug administration

Table 6: Variations in diastolic blood pressure after study drug administration

Time in min	Group 1 mm Hg	Group 2 mm Hg	p value
Preoperative	68.24±10.63	69.21±8.58	0.698
5	63.29±7.42	64.26±11.74	0.703
10	59.94±10.72	64.9±9.04	0.057
15	57.83±12.84	63.91±8.47	0.034*
20	58.28±10.26	63.74±12.81	0.073
25	59.89±8.25	64.15±10.20	0.080
30	62.30±12.31	63.66±10.52	0.647

All values are in Mean±SD.
p value * means significant.

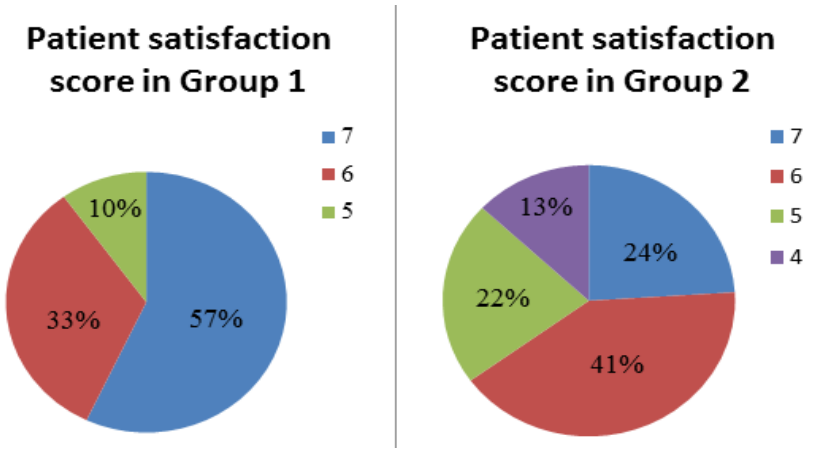

Fig. 6: Patient satisfaction score

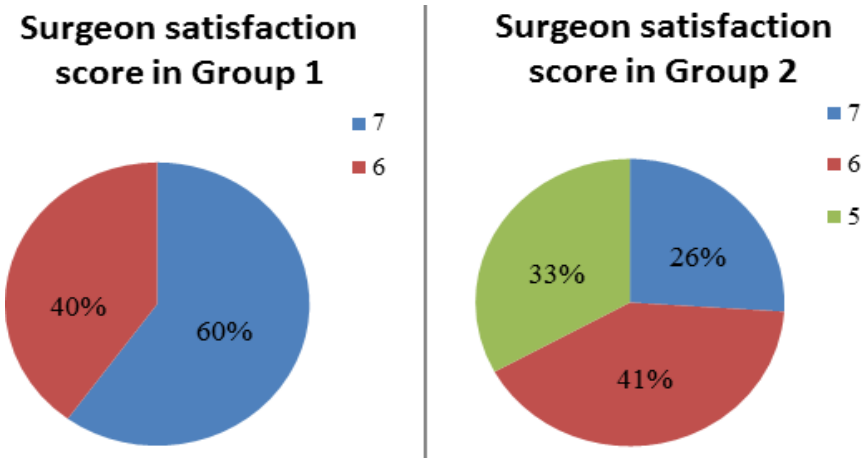

Fig. 7: Surgeon satisfaction score

Discussion

Cataract surgery is most frequently performed under topical anaesthesia or nerve blocks with or without sedation. The essential requirement during cataract surgery under regional anaesthesia includes an immobile surgical field, an uncongested eye, reduced intraocular pressure and most importantly good cooperation between the surgeon and the patient[19]. A good sedative agent in a cataract surgery should provide a calm and cooperative patient without causing confusion, agitation or hemodynamic disturbances. Since most of the cataract surgeries are done as a day care procedure, the sedation provided should not last long in to the postoperative period. Dexmedetomidine, α_2 agonist, has been widely used in anaesthesia practice for sedation and analgesia in intensive care unit, endoscopy procedures, radiological imaging procedures, lithotripsy, awake fibreoptic intubation and as an additive in central and peripheral and neuraxial blockade. This randomized, double blinded, clinical study demonstrated that dexmedetomidine is effective in sedating patients undergoing cataract surgery under peribulbar block.

In our study, all the patients who received dexmedetomidine achieved desired sedation score (RSS≥3) with no patients requiring additional rescue sedation. About 70% of the patients achieved a RSS of 4 and 23% patients reached a stage of 3 with 7% of patients having score of 5. However none of the patients developed respiratory depression and there was no delay in the recovery period. The sedation achieved in group 2 was due to premedication with alprazolam. Ayoglu et al[20] demonstrated that satisfactory sedation and analgesia were achieved by loading dose infusion of 1 µg/kg administered for 10 min preoperatively. Decrease in intraocular pressure was also observed in their study. In our study we administered 0.5 µg/kg of dexmedetomidine over 15 min to avoid sudden hypotension and bradycardia. Hyo-Seok Na et al[21] also demonstrated that dexmedetomidine could be used for MAC in cataract surgery with better patient satisfaction and better cardiovascular stability with an infusion dose of 0.6 µg/kg/hr. In study by Alhashemi et al[18] loading dose of 1µg/kg over 10 min followed by 0.1-0.7µg/kg/hr infusion was used to achieve a target RSS of 3. He found better subjective patient satisfaction with dexmedetomidine compared to midazolam in spite of relative cardiovascular depression and delayed recovery room discharge. Virkkila et al[22] concluded that single intramuscular loading dose of dexmedetomidine administered 45 min before surgery provides sedation

comparable with that produced by midazolam. Eskandr AM et al[23] used dexmedetomidine 0.5 µ/kg as adjuvant to local anaesthetic mixture in subtenon block for cataract surgeries and demonstrated desired sedation and prolonged analgesia.

Patients in dexmedetomidine group were hemodynamically stable throughout the intraoperative period though there was a statistically significant decrease in heart rate and blood pressure between 15 and 25 min after administration of dexmedetomidine. The lower heart rate and blood pressure could be explained by decreased sympathetic outflow and circulatory levels of catecholamines that are caused by dexmedetomidine[24]. Alhashemi[18] performed their study on cataract surgery with dexmedetomidine by using a loading dose of 1 µg/kg over 10 min and followed by 0.1-0.7 µg/kg to achieve a prefixed target RSS of 3. He concluded though there was better patient satisfaction, the incidence of cardiovascular depression was relatively higher with delay in discharge from recovery room. But we utilized only a low loading dose of dexmedetomidine of 0.5 µg/kg over 15 min without any maintenance dose as the average duration of cataract surgery was less than 30 min. Hyo-Seok Na et al[21] reported hypotension in 3.2% and bradycardia in 3.2% of patients with only maintenance infusion of 0.6 µg/kg/hr without any loading dose of dexmedetomidine. Similar hemodynamic changes have been reported by Arain and Ebert[25], Irwin Gratz et al[26], Gonciarz et al[27], Ghodki et al[28] and Bokesch et al[29].

The patient sedation satisfaction and surgeon satisfaction in patients treated with dexmedetomidine were better than the placebo group which correlates with the study of Ghodki et al[28]. In study by Irwin Gratz et al[26], patient and surgeon satisfaction scores were similar between the propofol and dexmedetomidine groups. Alhashemi et al[18] demonstrated better patient satisfaction with dexmedetomidine compared to midazolam. No adverse effects other than hypotension and bradycardia were encountered in patients treated with dexmedetomidine in our study. Dry mouth was encountered in some patients treated with dexmedetomidine in study by Ghodki et al[28] which was not statistically significant and Alhashemi et al[18] demonstrated delayed recovery room discharge in patients of dexmedetomidine group compared to midazolam because of higher dosage.

The limitations of the study include not monitoring intraocular pressure (IOP) and end tidal carbon dioxide monitoring to prove hypoventilation. Dexmedetomidine is shown to reduce IOP in many studies[23,28]. Monitoring IOP intraoperatively is not favoured by our surgeons due to increased risk of infection. End tidal monitoring will be not accurate in these patients as oxygen is administered via nasal cannula to all patients and potential of rebreathing due to surgical draping over face.

In conclusion, this study demonstrated that low dose dexmedetomidine infusion provides safe and effective sedation for patients undergoing cataract surgery under regional anaesthesia. In spite of drop in heart rate and blood pressure, it was easily treatable. The patient and surgeon satisfaction scores were also better with dexmedetomidine infusion.

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