

## A comparison of dexmedetomidine versus midazolam for sedation, hemodynamic and intraocular pressure response during cataract surgery under conscious sedation: A randomized, double-blind trial

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### Abstract

**Objectives** To investigate the efficacy and safety of sedation and hemodynamic changes with dexmedetomidine and midazolam in cataract surgery.

**Methods** Patients with ASA physical status I–II undergoing elective cataract surgery were randomly allocated in two groups to receive dexmedetomidine or midazolam for conscious sedation. Intraocular pressure (IOP), continuous peripheral oxygen saturation (SpO<sub>2</sub>), heart rate, mean arterial pressure (MAP), Ramsay Sedation Scale (RSS), during and after the procedure.

**Results** Patients in the dexmedetomidine group ( $n = 30$ ) had lower heart rate, MAP, higher SpO<sub>2</sub> and lower RSS scores during sedation than those in the midazolam group. There was decreased in intraocular pressure after sedation and statistically was not significant. However satisfaction was higher in the dexmedetomidine group than the midazolam group. There were no any kind of complication reported in either group.

**Conclusion** Dexmedetomidine is a good safety profile as compared to midazolam group and an effective sedative agent for use in cataract surgery.

**Keywords:** Cataract surgery, Dexmedetomidine, Hemodynamics changes, Intraocular pressure, Midazolam

### Introduction

The goal of conscious sedation to provide good control of intraocular pressure (IOP), and to prevent intraoperative hypertension, anxiety, panic disorder, tachycardia and CAD with an adequate level of sedation. Sudden significant rise of IOP can produce permanent loss of vision perioperatively, so success in ophthalmic surgery mainly depends on meticulous control of IOP<sup>1</sup>. Therefore, many drugs and methods have been proposed to prevent IOP, as rise in ophthalmic surgery. Dexmedetomidine a centrally acting alpha 2 adrenoceptor agonist and antihypertensive agent, reduces anaesthetic requirements, improves perioperative haemodynamic and adrenergic stability and reduces IOP.<sup>2-5</sup>

The aim of this study is to investigate the use of dexmedetomidine compared with midazolam in conscious sedation for cataract Surgery, and examine its effects on perioperative haemodynamics and sedation.

### Materials and Methods

After approval from ethical committee sixty patients aged 40-70 yr, selected using a computer generated randomized table, patients were assigned in two group to undergo conscious sedation with either dexmedetomidine (D) 29 patients or midazolam (M) 31 patients and were taken into the operating room without any premedication. Patients in the dexmedetomidine group received 0.4 µg/kg dexmedetomidine bolus over 10 min before cataract surgery, followed by 0.2–

0.3 µg/kg/hr dexmedetomidine continuous infusion until an appropriate level of sedation was achieved<sup>6</sup>.

Midazolam group patients received 0.05 mg/kg midazolam bolus injection and 1 µg/kg fentanyl citrate intravenous infusion 10 min before cataract surgery, followed by 0.01 mg/kg midazolam at intervals of approximately 2–5 min until a satisfactory level of sedation was achieved<sup>1</sup>. Additional 0.01 mg/kg midazolam boluses were available for rescue sedation, if required. In both groups, additional 1 µg/kg fentanyl boluses were available for rescue analgesia. Before surgery peribulbar block were given with 2% lignocaine.

In this randomized double blind clinical study, we compared the effects of dexmedetomidine and midazolam as pre-medications to control IOP and hemodynamics in conscious sedation.

**Statistical analyses:** Data was entered and analyzed with SPSS software. Mean of all numeric data were compared with Students *t*-test. Continuous data were presented as mean ± SD and range. Between-group comparisons were made using Student's *t*-test for normally distributed data. *P*-values <0.05 were defined as statistically significant.

### Results

Demographic and clinical data on the patients are shown in **Table 1** were no statically difference.

**Table 1: Demographic Profile**

Groups	Number	Age in year	Weight in KG	Gender (M:F)
D	29	61±8.1	64±12.2	14:15
M	31	60±11.17	66±10.41	16:15

Data on clinical parameters at each time-point are shown in **Table 2**. RSS, Heart rate and blood pressure were lower after sedation with dexmedetomidine and significantly lower than midazolam group at point number 2 and 3 ( $P < 0.05$  for all comparisons). There was not much change at SpO<sub>2</sub> in either group. Intraocular pressure were lower in dexmedetomidine as compared to midazolam and statistically insignificant. No patient experienced rebound hypertension, tachycardia or acute reversal of sedative and analgesic effects in either group. **Table 2**

Parameters	Group D		
	1	2	3
HR (bpm)	80±6.16	70.97±7.05*	90.43±8.08
MAP	94.20±3.01	78.93±5.29*	93.00±4.63
Spo2	97.83±1.17	97.47±1.53	98.14±1.90
RSS	NR	3.2±0.5	2.2±0.7
IOP	14.8±1.2	14.2±0.5	NR
Group M			
HR	76.53±6.47	70.13±9.14	84.60±8.37
MAP	85.33±7.46	84.57±7.11	91.20±7.39
Spo2	98.23±1.50	95.50±1.02	97.63±3.87
RSS	NR	4.2±0.1	2.0±0.5
IOP	14.2±0.8	15.8±0.2	NR

\*p value < 0.05 is statistically significant as compared to base line value in both group.

1-Before procedure, 2- Sedation before surgery, 3- After surgery and discontinuation of Drug, RSS: Ramsay Sedation Scale, IOP: Intraocular Pressure, NR- Not recorded.

## Discussion

The main goal of sedation for cataract surgery is to prepare the patient to stay calm during peribulbar injection and cataract surgery. Under local anesthesia for cataract surgery provides clear immobile field with good patient and surgeon cooperation. Therefore, most cataract surgeries in recent years are performed by phacoemulsification under topical anesthesia. Dexmedetomidine is known sedative agent in critically ill patients in the intensive care unit, and during surgery, cardiac catheterization and radiology. In the present study Dexmedetomidine and midazolam were used because these drugs have distinctive pharmacological properties and their respective adverse effects require different management strategies.<sup>7</sup> Our data showed that patients in the dexmedetomidine group experienced better peripheral oxygen saturation and RSS scores, decreased mean arterial pressure, heart rate and intraocular pressure than those in the midazolam group. Jakolla et al also shown same effects

as our present study<sup>8</sup>. Anxiety before surgery can stimulate catecholamine secretion and result there is possibility of tachycardia, hypertension and myocardial infarction. Proper using of sedative agents as premedication can reduce this anxiety and prepare patient for surgery. In elderly, hypertension is the most common, and nearly half of the cataract patients have co morbid condition like hypertension/ diabetes/ coronary artery disease especially in Indian scenario and this kind of patients more prone for ischemic heart disease.

Limitations of this study are small number of sample size which is concerned with safety profile, this study included only low-risk patients (ASA I or II), and single-centre study.

In conclusion, our results suggest that dexmedetomidine has a good safety profile and is an effective sedative agent to control anxiety or hypertension perioperatively in cataract surgery elderly patients.

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