

Conscious sedation for cataract surgery done under retrobulbar block – a comparative study evaluating the effects of midazolam and dexmedetomidine

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Abstract

Background: A comfortable co-operative stationary patient is essential for cataract surgery especially under retrobulbar block. This can be achieved by placing the patient under 'conscious sedation' in which the patient will be arousable but at the same time can tolerate pain.

Aim: To compare the efficacy of midazolam with dexmedetomidine for conscious sedation in cataract surgery with regard to anxiolysis, patient's cooperation, haemodynamic stability, surgeon's satisfaction, recovery profile and incidence of complications.

Materials and Methods: 90 adult patients undergoing cataract surgery were randomized to three groups. Group M (n=30) patients received midazolam in loading dose of 0.03mg/kg over 10 minutes and a maintenance dose of 0.05mg/kg/hr. Group D (n=30) patients received dexmedetomidine in loading dose of 0.3mcg/kg over 10 minutes and a maintenance dose of 0.3µg/kg/hr. Group C (n=30) are control group receiving normal saline infusion as loading and maintenance doses. Statistical analysis was done using Chi-square test and ANOVA test with p value <0.05 taken as statistically significant.

Results: Anxiolysis, patient comfort and surgeon's satisfaction were better in midazolam and dexmedetomidine groups when compared to the control group. In dexmedetomidine group there were significant incidences of hypotension and bradycardia when compared to midazolam group. Time to achieve sedation was faster in the dexmedetomidine group than in the midazolam group.

Conclusion: Midazolam and dexmedetomidine are effective in the aspects of patient co-operation, surgeon's comfort, sedation and recovery profiles, and is safe to administer in cataract surgeries.

Keywords: Conscious sedation, Retrobulbar block, Dexmedetomidine, Midazolam, Cataract surgery

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Introduction

Retro bulbar block is a regional nerve block where local anesthetic is injected in the retro bulbar space behind the globe of eye. This blocks cranial nerves II, III, VI, IV and ciliary nerves causing motor block to extraocular muscles and sensory loss to conjunctiva, cornea and uvea. This is most frequently used in cataract surgery and other intraocular surgeries¹. A comfortable co-operative stationary patient is a key to achieve good result with these patients².

Recently cataract surgeries are performed under conscious sedation which is defined as a state in which the patient will be in a depressed level of consciousness and tolerate unpleasant procedures while maintaining oxygenation, airway control and cardiovascular function².

Nowadays it is preferred in many of the day care surgeries like cataract surgeries, cholangiopancreatography, dental procedures, and

minor procedures during trauma care. This procedure has led to lesser duration of hospital stay with lesser incidence of post-operative complications.³

Current drugs used in conscious sedation include benzodiazepines⁴ most commonly midazolam⁵, opioids, ketamine with or without propofol.^{6,7,8} Newer agents such as dexmedetomidine and fospropofol are also being used nowadays.^{9,10}

Midazolam has all five properties of a benzodiazepine such as anxiolysis, sedation, anticonvulsant action, skeletal muscle relaxation and anterograde amnesia.¹¹ The adverse effects of midazolam are hypotension, respiratory depression and hypoxemia if given in larger doses and particularly when it is combined with an opioid.¹²

Dexmedetomidine is a α_2 agonist. Dexmedetomidine acts by enhancing the endogenous sleep producing pathways.³ Dexmedetomidine decreases the central sympathetic outflow and this is responsible for reducing B.P and pulse rate. It produces a unique form of 'conscious sedation' with good analgesic effect and without significant respiratory depression.¹³

Aim

The aim of the study is to compare the efficacy of midazolam with dexmedetomidine for conscious sedation in cataract surgery with a control group. The efficacy regarding

1. Anxiolysis of the patient
2. Patient's cooperation
 - a. In the placement of retro bulbar block and
 - b. During the procedure
3. Hemodynamic stability
4. Satisfaction of the surgeon
5. Recovery profile of the patients and
6. Incidence of complications
 - were noted and compared

Materials and Methods

After getting approval from the institutional ethical committee, 90 adult patients of either sex belonging to the age group 50-70 years weighing between 45-75kg, undergoing elective cataract surgery were identified. These 90 patients were chosen based on a power analysis done on a pilot study on 15 patients to detect a difference in patient movement scale of 1 with a significant p value of 0.05 between the control and other groups. To obtain power of 80%, 30 patients in each group sufficed.

All patients are kept nil per oral for six hours. Every patient's age and weight were noted. Thorough examination of all systems and airway assessment was done in all patients.

Inclusion Criteria	Exclusion Criteria
Patients posted for cataract surgery.	Hypertensive patients
Age 50-70 years.	Renal disorders
ASA I and II.	CNS disorders, autonomic neuropathy patients
Weight 45-75kgs	Coronary artery disease, heart block patients
Duration of surgery less than 30 min	ASA III and IV
	Anticipated difficult airway patients
	Patients receiving analgesics and anxiolytics

Informed written consent was obtained from the patients who were included in the study.

Patients were randomly divided into 3 groups by draw of lots.

Group M-Patients receiving midazolam

Loading dose-0.03mg/kg over 10 min^{14,15}

Maintenance dose-0.05mg/kg/hr¹⁶

Group D-Patients receiving dexmedetomidine

Loading dose-0.3mcg/kg over 10 min¹⁷

Maintenance dose-0.3mcg/kg/hr^{5,15,18}

Group C-control

Loading and maintenance dose is given as plain N.S infusion

In the operating room, monitors like pulse-oximeter, N.I.B.P and E.C.G were connected. Baseline parameters like mean arterial blood pressure, pulse rate and oxygen saturation were noted. All the drug preparation was made by another anaesthetist who was not involved in this study and both the observer and the patient didn't know the content of the preparation.

For group M loading dose was given as 0.03mg/kg iv bolus followed by plain N.S infusion for 10 min and for group D loading dose was given as iv bolus of 0.3 mcg/kg over 10 min through normal saline. Group C patients received plain normal saline bolus and infusion.

Loading dose was followed by retro bulbar block which was a mixture of inj .bupivacine 0.5% 2.5cc and inj.lignocaine 2% 2.5 cc.

Surgery started 10 min after the retrobulbar block was administered. Intraoperatively music was played after the start of surgery which continued till the end of the procedure. Maintenance dose was given as infusion as per each patients group till the end of the procedure irrespective of the RSS achieved by the patient.

Oxygen desaturation was considered when SpO₂ <95%.¹⁹ A heart rate less than 50 beats/min was considered as bradycardia. Inj.atropine 0.6 mg iv was given to counteract the bradycardia. Hypotension was considered when there was a drop in MAP below 30% from the baseline. Intravenous fluids were rushed and the drug infusion was stopped briefly till the MAP recovered to come within 30% of the baseline.

Parameters Monitored^{20,21,22}

- ❖ Mean arterial blood pressure (MAP), Pulse rate, SpO₂ were noted during these periods
 - Baseline
 - after loading dose administration
 - intra-operatively (every 5 min till end of surgery)
 - post-operatively (every 30 min till 2 hours)
- ❖ Wong Baker Facial pain rating scale.⁸
- ❖ Ramsay sedation score.²³
- ❖ Patient movement scale during surgery.²⁴
- ❖ Aldrete Recovery score.²⁵
- ❖ Likert like verbal rating of surgeon's satisfaction^{12,26}
- ❖ Patients were observed in the post-operative ward for minimum 12 hours and were asked about awareness of intraoperative events.
- ❖ Post-operative period vitals and complications were noted

Facial pain rating scale⁸



This parameter was measured at the time of retro bulbar block which was given after the loading dose. Patient’s pain scale was numbered based on their facial expression at the time of giving the block.

Recall of intra operative events

Patients were enquired about whether

1. They were able to hear the conversation of nurses and surgeon while operating
2. They were aware of movements to body or head
3. They were able to recollect the music which was played intra operatively

Patients who were able to recall any one of the above was considered to say as ‘YES’ and if not as ‘NO’.

Ramsay sedation scoring was done every 1 min from the time of loading dose till they attain the Ramsay sedation score of 3. The time to achieve RSS 2 and RSS 3 were noted. After attaining RSS 3, scoring was done every 5 min till end of surgery and every 10 min in the post-operative period for two hours.

Ramsay sedation score²³

Score	Response
1	Anxious, restless or both
2	Co-operative, oriented and tranquilised
3	Responds to commands but arousable
4	Brisk response to light glabellar tap
5	Sluggish response to light glabellar tap
6	No response to stimulus

Patient’s movement scale during surgery²⁴

- 1-No movement
- 2-Movement with slight effect on surgical field (less than ½ of eye outside the microscope)
- 3-Movement with moderate effect (more than ½ of eye outside the microscope)
- 4-Movement with major effect (whole eye outside the microscope)

This parameter was noted by the observer in the television which showed the events which was recorded in the operative microscope. This was observed till the end of the procedure.

Aldrete recovery scale²⁵

Parameter	2	1	0
Respiration	Able to take deep breath and cough	Dyspnoea/Shallow breathing	Apnoea
O ₂ Saturation	Maintains >92% on room air	Needs O ₂ inhalation to maintain O ₂ saturation >90%	Saturation <90% even with supplemental O ₂
Consciousness	Fully awake	Arousable on calling	Not responding
Circulation	BP ± 20mmHg preoperatively	BP ± 20-50mmHg preoperatively	BP ± 50mmHg preoperatively
Activity	Able to move 4 extremities voluntarily or on command	Able to move 2 extremities voluntarily or on command	Able to move 0 extremities voluntarily or on command

Time to attain the Aldrete recovery score of 10 from the end of surgery was recorded. Patients were shifted to recovery after they achieved an Aldrete recovery scoring of 10.

Likert-like verbal rating scale^{12, 26}

- 1- Extremely dissatisfied
- 2- Dissatisfied
- 3- Somewhat dissatisfied
- 4- Undecided
- 5- Somewhat Satisfied
- 6- Satisfied
- 7- Extremely satisfied

This parameter was measured by asking the surgeon to rate the level of his satisfaction as a numerical from 1 to 7.

Statistical analysis

Statistical analysis was done using SPSS version 17. Mean and standard deviation was calculated. Chi square test and ANOVA test was applied and p value <0.05 was considered as statistically significant and p value >0.05 was considered not significant.

Results

Table 1: Demographic data and ASA grading of patients

Variables		Control(n=30)	Group M(n=30)	Group D(n=30)
Age (Years)(Mean±SD)		60.83±4.54	61.56±4.86	60.13±4.89
Weight (KG)(Mean±SD)		61.23±5.55	61.66±5.39	61.30±6.17
Sex	Male	14 (46.7%)	16 (53.3%)	14 (46.7%)
	Female	16 (53.3%)	14 (46.7%)	16 (53.3%)
ASA	Grade 1	12 (40.0%)	15 (50.0%)	13 (43.3%)
	Grade 2	18 (60.0%)	15 (50.0%)	17 (56.7%)

Of the 50 patients in ASA 2 grading, all the patients were known cases of type 2 diabetes mellitus under control (Table 1). All these patients had diabetes for less than 1 year duration. Autonomic neuropathy was ruled out in all these patients.

Table 2: Mean arterial blood pressure

MAP (Mean±SD)	Control (mmHg)	Group M (mmHg)	Group D (mmHg)
Baseline	89.58±3.49	89.3±4.33	89.39±3.95
After loading dose	89.5±3.49	83.9±3.55	73.19±1.86
Intra-operative	90.72±3.18	81.6±3.21	71.85±1.52
Post-operative	91.5±2.88	90.87±2.91	91.32±3.00

The intraoperative reading is the mean value across all the time periods for all the patients in that particular group (Table 2). The drug infusion was stopped briefly in case of hypotension and started again after the MAP recovered to come within 30% from baseline.

'p' value was significant (<0.0001) only after loading dose administration and intraoperatively between

- Control and Group M
- Control and Group D
- Group M and Group D
- and all 3 groups

'p' value was insignificant in all other periods between the groups.

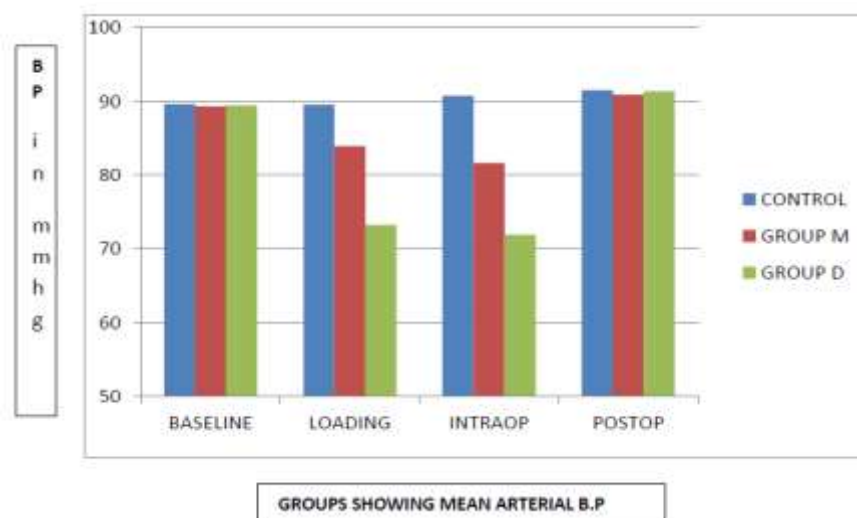


Fig. 1: Mean arterial blood pressure between groups

Table 3: Pulse rate

Pulse rate (Mean±SD)	Control (beats per min)	Group M (beats per min)	Group D (beats per min)
Baseline	85.6±12.65	80.6±6.605	81.06±5.63
After loading dose	91.0±7.51	72.63±5.92	68.2±4.37
Intra Op	95.7±7.27	72.23±5.91	64.79±5.88
Post Op	78.1±2.71	77.02±3.22	76.1±6.28

'p' value was significant (<0.0001) only after loading dose administration and intraoperatively between

- Control and Group M
- Control and Group D
- Group M and Group D
- and all 3 groups

'p' value was insignificant in all other periods between the groups. (Table 3)

The infusion dose of the drugs was not stopped intraoperatively as no patient had any incidence of bradycardia.

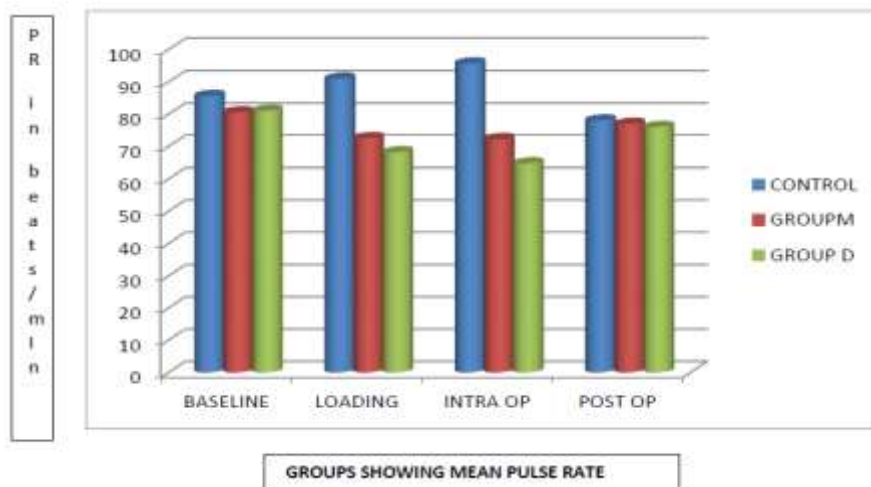


Fig. 2: Mean pulse rate between groups

Table 4: Maximum Ramsay sedation scale (RSS) score achieved

Maximum RSS Achieved	Control (N=30)	Group M (N=30)	Group D (N=30)
RSS 1	30 (100%)	0	0
RSS 2	0	0	0
RSS 3	0	30 (100%)	30 (100%)

The entire loading dose was given for the 10 minutes duration even if the patients attained RSS 2 or 3. The maintenance infusion was continued throughout the intra-operative period.

'p' value was highly significant (<0.0001) between

- between all the 3 groups
- between Control and Group M
- between Control and Group D

There was no significance between Group M and Group D as all their patients achieved a maximum RSS of 3. (Table 4)

Table 5: Time taken to attain RSS 2 and RSS 3

	Comparison between	Mean±S.D (min)	'p' Value
Time to RSS 2 (min)	Group M	5.88±1.14	<0.0001
	Group D	3.55±0.99	
Time to RSS 3 (min)	Group M	8.37±0.90	<0.0001
	Group D	6.33±0.84	

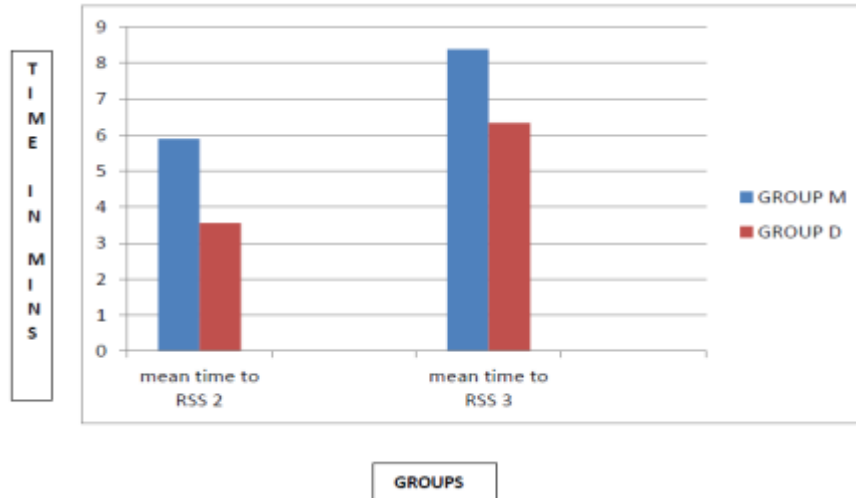


Fig. 3: Mean time to acheive RSS 2 and RSS 3 in two groups

Control group was not taken into consideration as there was no sedation. Time was noted when the patient achieved RSS 2 and without stopping the drug infusion, the time taken to achieve RSS 3 was noted from the start of loading dose.

'p' value was <0.0001 in both the periods, which is statistically significant. (Table 5)

Table 6: Wong baker facial pain scale

Facial pain scale	Control		Group M		Group D	
	N	%	N	%	N	%
1-Mild hurt	2	6.7%	23	76.7%	25	83.3%
2-Little hurt	8	26.7%	5	16.7%	4	13.3%
3-Moderate hurt	17	56.7%	2	6.7%	1	3.3%
4-Severe hurt	3	10.0%	0	0%	0	0%

'p' value was highly significant (<0.0001)

- between Control group and Group M.
- between Control group and Group D.
- Between all the 3 groups.

'p' value between Group M and Group D was 0.651 and was insignificant. (Table 6)

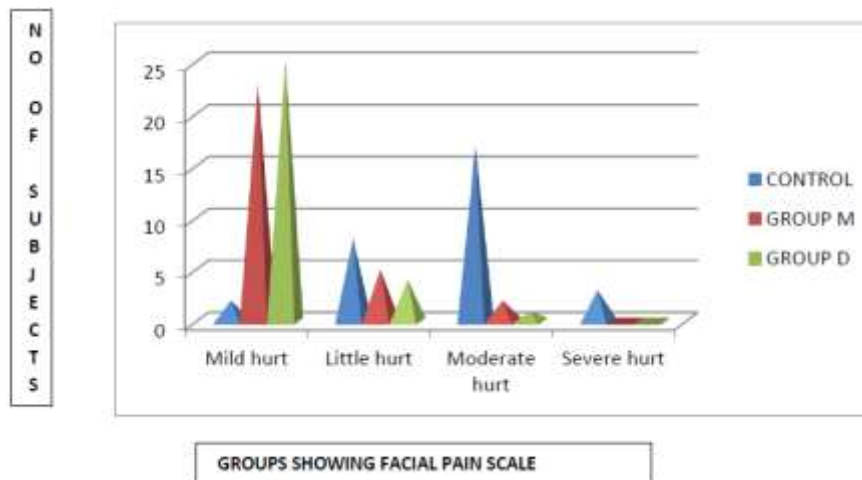


Fig. 4: Wong baker facial pain scale

Table 7: Patient movement scale

Patient movement scale	Control		Group M		Group D	
	N	%	N	%	N	%
1-No movement	10	33.4%	22	73.4%	27	90.0%
2-Mild movement	12	40.0%	7	23.3%	2	6.7%
3-Moderate movement	8	26.6%	1	3.3%	1	3.3%

‘p’ value

- between Control group and Group M was **0.003** which was statistically significant.
- between Group M and Group D was **0.17** which was insignificant.
- between Control group and Group D was **0.0003** which was statistically significant.
- between all 3 groups was **<0.0001** which was statistically highly significant. (Table 7)

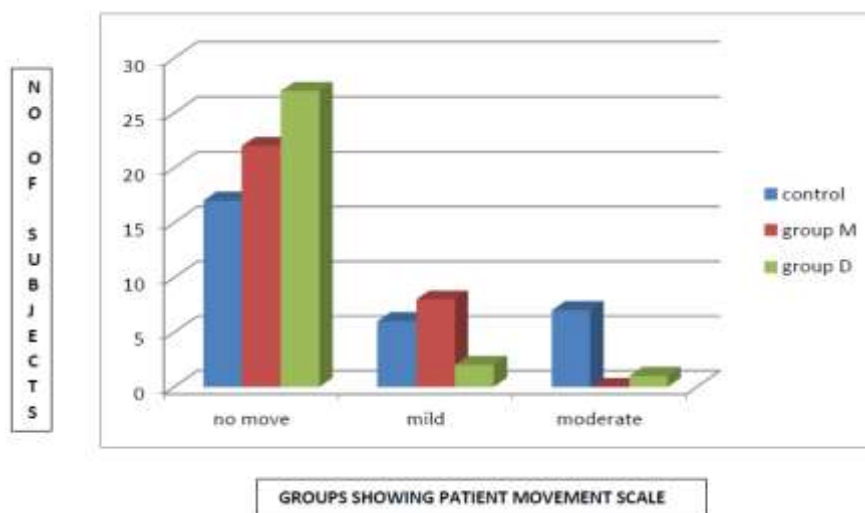


Fig. 5: Patient movement scale

Table 8: Duration of surgery and total drug dose given

	Control	Group M	Group D
Duration of surgery	25.83±2.32 (min)	26.00±2.58 (min)	25.46±2.58 (min)
Total drug dose given	-	3.18±0.33 (mg)	26.19±2.72 (µg)

The **p value** between all the groups for duration of surgery group was **>0.05** and **p value** within the groups for the drug dosage was **>0.05** for both the groups and considered statistically insignificant. (Table 8)

Table 9: Mean time to achieve aldrete recovery score (ARS) 10

Comparison between groups	Time to achieve aldrete recovery score 10 Mean±Standard Deviation (min)	p-value
Group M	4.07±0.97	<0.0001
Group D	8.09±1.03	

‘p’ values between Group M and Group D was **< 0.0001** which was statistically significant. (Table 9)

Table 10: Likert-like verbal rating scale by surgeon

L.V.R.S	Control (N=30)		Group M (N=30)		Group D (N=30)	
	N	%	N	%	N	%
3-Somewhat dissatisfied	9	30.0%	4	13.3%	3	10.0%
4-Undecided	13	43.4%	6	20.0%	4	13.3%
5-Somewhat satisfied	4	13.3%	8	26.7%	9	30.0%
6-Satisfied	4	13.3%	12	40.0%	14	46.7%

‘p’ value

- between group M and group D was **0.20** which was not significant
- between control and group M was **0.02** which was statistically significant

- between control and group D was **0.0016** which was statistically significant
- between all 3 groups was **0.0082** which was statistically significant (Table 10)

Table 11: Recall of intra operative events by patients

Recall of intra operative events	Control (N=30)		Group M (N=30)		Group D (N=30)	
	N	%	N	%	N	%
No	6	20%	27	50.9%	26	49.1%
Yes	24	80%	3	8.1%	4	10.8%

‘p’ value

- between group M and group D was **0.6** which was not significant
- between control and group M was **<0.05** which was statistically significant
- between control and group D was **<0.05** which was statistically significant
- between all 3 groups was **<0.0001** which was statistically highly significant (Table 11)

Table 12: Post-operative complications

Post-operative complications	Control (N=30)		Group M(N=30)		Group D (N=30)	
	N	%	N	%	N	%
Hypotension	0	0%	1	3.3%	2	6.6%
Bradycardia	0	0%	0	0%	2	6.6%
Vomiting	2	6.6%	2	6.6%	2	6.6%

‘p’ value was insignificant (>0.05)

- between all 3 groups
- between control and Group M
- between control and Group D
- between Group M and Group D (Table 12)

Each incidence of hypotension lasted only 5-7 min within which was countered by rushing normal saline intravenously. Bradycardia was treated with inj.atropine 0.6mg i.v bolus, with each incidence lasting only about 2-3 min. Inj.ondansetron 4mg i.v was given in case of vomiting. There was no incidence of respiratory depression in any patient.

Discussion

The maintenance dose of dexmedetomidine was decided on the basis of the studies done by Dere K et al, Sethi P et al and Al Taher WM et al.^{5,15,18} There were significant incidences of bradycardia in the study conducted by Riker RR et al who used dexmedetomidine in a loading dose of 1 µg/kg.²⁷ Moreover according to Tan JA et al dexmedetomidine increases the risk of bradycardia when both loading and maintenance doses were used.²⁸ So it was decided to reduce the loading dose in our study to 0.3µg/kg based on a study by Dawes J et al.¹⁷ The loading dose of midazolam was decided based on the studies done by Rolo R et al and Sethi P et al.^{14,15} The maintenance dose of midazolam was decided based on the study by Michalk S et al.¹⁶ In our study we used maintenance doses in addition to bolus doses because of the lower loading dose of dexmedetomidine and since there were lesser surgeon satisfaction while using only loading dose of midazolam.²⁹ But the equipotent doses of midazolam and dexmedetomidine to be used in our study could not be arrived at, which was a limitation to our study.

The results of MAP in our study were similar to the studies conducted by Rolo et al¹⁴ (where they administered midazolam in a loading dose of 0.05mg/kg for Fibre optic bronchoscope insertion) and Al Taher et al who administered inj. dexmedetomidine in a loading dose of 2µg/kg for dental procedures followed by 0.4 µg/kg/hr as maintenance dose for one group and other group received midazolam 0.05mg/kg followed by propofol 1mg/kg over 5 min.¹⁸ The reduction in systolic blood pressure and MAP was due to reduction in systolic vascular resistance produced by the drugs. The fall in the mean arterial pressure and the pulse rate intra-operatively was comparatively lower in the midazolam group when compared to dexmedetomidine group thereby providing better haemodynamic stability.

There was no significant difference in SPO₂ between the groups throughout the procedure. No patients in any group had a SPO₂ below 95% and supplemental O₂ was not given in any patient.

In our study heart rate was slightly lower in group D when compared to midazolam group. In the study conducted by Sethi P et al one group received dexmedetomidine in a loading dose of 1µg/kg iv followed by a maintenance dose of 0.5µg/kg/hr and other group received midazolam in loading dose of 0.04mg/kg followed by additional 0.5mg till RSS 3-4 was achieved.¹⁵ There was lower heart rates following initiation of sedation in the dexmedetomidine group in Sethi P et al and also in the study by Hasanina et al who compared dexmedetomidine loading (2.5µg/kg) and maintenance doses (2µg/kg/hr) with propofol bolus (2mg/kg) and maintenance dose (100µg/kg/min) in paediatric patients gastrointestinal endoscopy.³⁰ In the study conducted by Riker RR et al²⁷ there was significant incidence of bradycardia in dexmedetomidine group when compared to that of midazolam group where the

patient received dexmedetomidine in the maintenance dose of 1mcg/kg/hr which was higher when compared to our study (0.3 mcg/kg/hr). Hence in our study we had only 2 patients having bradycardia in the postoperative period. No patients in our study had a heart rate below 50/min in the intraoperative period. Dexmedetomidine decreases the central sympathetic outflow and this was responsible for reducing the heart rate.

In our study mean time to reach RSS of 3 was shorter in dexmedetomidine group than midazolam group but in Sethi P et al¹⁵ study it was shorter for midazolam group than dexmedetomidine group as the patients received midazolam loading dose of 0.03mg/kg which was supplemented by 0.5mg incremental doses. But in our study no supplemental dosing was given during loading dose. Hence this shows that the onset of effect of midazolam can be made rapid by administering additional incremental doses following loading dose.

In our study there was no statistically significant difference between the group M and group D in Wong Baker facial pain scale (FPS). Our study with a loading dose of 0.05 mg/kg midazolam was found to be equally effective with that of dexmedetomidine in attaining the patient's cooperation during block which was not present in the studies which used lesser loading doses of midazolam.⁴

In our study there was no significant difference in the patient movement between group M and group D. In Alhashemi et al⁴ study, patient movement was higher in midazolam group. But they administered only loading dose of midazolam with supplemental doses 0.5 mg of midazolam which is in contrast to continuous infusion of midazolam in our study. This made patient movement scale of group M to be similar to that of dexmedetomidine group in our study because of deeper plane of sedation.

Mean time to achieve Aldrete Recovery Score of 10 in our study was prolonged in group D when compared to group M. Similar results were observed in a study conducted by Alhashemi et al.⁴ But in the studies by Sethi P et al, Al Taher WM et al and Hasanina et al there was faster recovery in the dexmedetomidine group.^{15,18,30}

In our study there was statistical significance in Likert like verbal response scale (LVRS) when all the three groups were compared. In the study conducted by Vyas DA et al²⁹ Surgeon's satisfaction scale was higher in group D than group M but in that study loading dose of dexmedetomidine was given at a higher dose (1 µg/kg) when compared to our study (0.3µg/kg) and lower loading dose of midazolam (0.01 mg/kg) than our study. Moreover maintenance infusion of midazolam was not given in the above study. Hence in our study by increasing the loading dose of midazolam deeper plane of sedation was possible which was maintained throughout the procedure with the help of maintenance infusion. Study by Sethi P et al also had better patient and surgeon satisfaction scores in the dexmedetomidine

group where both loading and maintenance doses were used.¹⁵

Like our study, in the study conducted by Vyas DA et al, group D had lesser recall of events when compared to group M, despite using a lesser infusion dose of midazolam which was 0.01 mg/kg when compared to our study (0.05 mg/kg).²⁹

In our study there were fewer incidences of complications like vomiting, hypotension, respiratory depression and bradycardia in the post-operative period. In the studies by Al Taher WM et al and Hasanina et al there was no complications except for unwanted movements in a few patients in dexmedetomidine group.^{18,30} In the study by Sethi P et al 23% patients in midazolam group had incidences of vomiting, cough and hiccup whereas no patient had any complication in the dexmedetomidine group.¹⁵

Limitation of the study

Our study had limitation pertaining to the equipotency of the midazolam and dexmedetomidine doses used. The equipotent doses of midazolam and dexmedetomidine to be used in our study could not be determined. Though the doses used in our study were effective in all aspects (like patient and surgeon comfort, sedation and recovery profiles) they cannot be compared.

Conclusion

We conclude that conscious sedation is safe and effective to practise in the case of cataract surgeries and is associated with better patient co-operation and surgeon comfort when compared to the surgeries which are done with retro bulbar block alone. Midazolam and dexmedetomidine are effective in the aspects of patient co-operation, surgeon's comfort, sedation and recovery profiles, and safe to administer during cataract surgeries.

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