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 can be arousal 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

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 surgeries. A comfortable co-operative stationary patient is a key to achieve good result with these patients.

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 function.

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.

Current drugs used in conscious sedation include benzodiazepines most commonly midazolam, opioids, ketamine with or without propofol. Newer agents such as dexmedetomidine and fospropofol are also being used nowadays.

Midazolam has all five properties of a benzodiazepine such as anxiolysis, sedation, anticonvulsant action, skeletal muscle relaxation and anterograde amnesia. 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.

Dexmedetomidine is a α² agonist. Dexmedetomidine acts by enhancing the endogenous sleep producing pathways. 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.

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.

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

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
   Maintenance dose-0.05mg/kg/hr

**Group D** - Patients receiving dexmedetomidine
   Loading dose-0.3mcg/kg over 10 min
   Maintenance dose-0.3mcg/kg/hr

**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 .bupivacaine 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%. 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**

- 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.
- Ramsay sedation score.
- Patient movement scale during surgery.
- Aldrete Recovery score.
- Likert like verbal rating of surgeon’s satisfaction
- 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 scale

![Facial Pain Rating Scale](image)

This parameter was measured at the time of retrobulbar 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 intraoperative 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 intraoperatively

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

Ramsay sedation score

<table>
<thead>
<tr>
<th>Score</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Anxious, restless or both</td>
</tr>
<tr>
<td>2</td>
<td>Co-operative, oriented and tranquilised</td>
</tr>
<tr>
<td>3</td>
<td>Responds to commands but arousable</td>
</tr>
<tr>
<td>4</td>
<td>Brisk response to light glabellar tap</td>
</tr>
<tr>
<td>5</td>
<td>Sluggish response to light glabellar tap</td>
</tr>
<tr>
<td>6</td>
<td>No response to stimulus</td>
</tr>
</tbody>
</table>

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.

Patient’s movement scale during surgery

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 scale

<table>
<thead>
<tr>
<th>Parameter</th>
<th>2</th>
<th>1</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiration</td>
<td>Able to take deep breath and cough</td>
<td>Dyspnoea/Shallow breathing</td>
<td>Apnoea</td>
</tr>
<tr>
<td>O₂ Saturation</td>
<td>Maintains &gt;92% on room air</td>
<td>Needs O₂ inhalation to maintain O₂ saturation &gt;90%</td>
<td>Saturation &lt;90% even with supplemental O₂</td>
</tr>
<tr>
<td>Consciousness</td>
<td>Fully awake</td>
<td>Arousable on calling</td>
<td>Not responding</td>
</tr>
<tr>
<td>Circulation</td>
<td>BP ± 20mmHg preoperatively</td>
<td>BP ± 20-50mmHg preoperatively</td>
<td>BP ± 50mmHg preoperatively</td>
</tr>
<tr>
<td>Activity</td>
<td>Able to move 4 extremities voluntarily or on command</td>
<td>Able to move 2 extremities voluntarily or on command</td>
<td>Able to move 0 extremities voluntarily or on command</td>
</tr>
</tbody>
</table>

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

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

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

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

<table>
<thead>
<tr>
<th>MAP (Mean±SD)</th>
<th>Control (mmHg)</th>
<th>Group M (mmHg)</th>
<th>Group D (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>89.58±3.49</td>
<td>89.3±4.33</td>
<td>89.39±3.95</td>
</tr>
<tr>
<td>After loading dose</td>
<td>88.5±3.49</td>
<td>83.9±3.55</td>
<td>73.19±1.86</td>
</tr>
<tr>
<td>Intra-operative</td>
<td>90.7±3.18</td>
<td>81.6±3.21</td>
<td>71.85±1.52</td>
</tr>
<tr>
<td>Post-operative</td>
<td>91.5±2.88</td>
<td>90.87±2.91</td>
<td>91.32±3.00</td>
</tr>
</tbody>
</table>

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
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Table 3: Pulse rate

<table>
<thead>
<tr>
<th></th>
<th>Control (beats per min)</th>
<th>Group M (beats per min)</th>
<th>Group D (beats per min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>85.6±12.65</td>
<td>80.6±6.605</td>
<td>81.06±5.63</td>
</tr>
<tr>
<td>After loading dose</td>
<td>91.0±7.51</td>
<td>72.63±5.92</td>
<td>68.2±4.37</td>
</tr>
<tr>
<td>Intra Op</td>
<td>95.7±7.27</td>
<td>72.23±5.91</td>
<td>64.79±5.88</td>
</tr>
<tr>
<td>Post Op</td>
<td>78.1±2.71</td>
<td>77.02±3.22</td>
<td>76.1±6.28</td>
</tr>
</tbody>
</table>

‘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

<table>
<thead>
<tr>
<th>Maximum RSS Achieved</th>
<th>Control (N=30)</th>
<th>Group M (N=30)</th>
<th>Group D (N=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSS 1</td>
<td>30 (100%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>RSS 2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>RSS 3</td>
<td>0</td>
<td>30 (100%)</td>
<td>30 (100%)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Comparison between</th>
<th>Mean±S.D (min)</th>
<th>‘p’ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to RSS 2 (min)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group M</td>
<td>5.88±1.14</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Group D</td>
<td>3.55±0.99</td>
<td></td>
</tr>
<tr>
<td>Time to RSS 3 (min)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group M</td>
<td>8.37±0.90</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Group D</td>
<td>6.33±0.84</td>
<td></td>
</tr>
</tbody>
</table>
Fig. 3: Mean time to achieve 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

<table>
<thead>
<tr>
<th>Facial pain scale</th>
<th>Control</th>
<th>Group M</th>
<th>Group D</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Mild hurt</td>
<td>N=2</td>
<td>%6.7</td>
<td>N=23</td>
</tr>
<tr>
<td>2-Little hurt</td>
<td>N=8</td>
<td>%26.7</td>
<td>N=5</td>
</tr>
<tr>
<td>3-Moderate hurt</td>
<td>N=17</td>
<td>%56.7</td>
<td>N=2</td>
</tr>
<tr>
<td>4-Severe hurt</td>
<td>N=3</td>
<td>%10.0</td>
<td>N=0</td>
</tr>
</tbody>
</table>

‘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

<table>
<thead>
<tr>
<th>Patient movement scale</th>
<th>Control</th>
<th>Group M</th>
<th>Group D</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>1-No movement</td>
<td>10</td>
<td>33.4%</td>
<td>22</td>
</tr>
<tr>
<td>2-Mild movement</td>
<td>12</td>
<td>40.0%</td>
<td>7</td>
</tr>
<tr>
<td>3-Moderate movement</td>
<td>8</td>
<td>26.6%</td>
<td>1</td>
</tr>
</tbody>
</table>

‘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 **0.003** which was statistically significant.
- between all 3 groups was **<0.0001** which was statistically highly significant. (Table 7)

![Groups showing patient movement scale](image)

Fig. 5: Patient movement scale

Table 8: Duration of surgery and total drug dose given

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Group M</th>
<th>Group D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of surgery</td>
<td>25.8±2.32 (min)</td>
<td>26.0±2.58 (min)</td>
<td>25.4±2.58 (min)</td>
</tr>
<tr>
<td>Total drug dose given</td>
<td>-</td>
<td>3.18±0.33 (mg)</td>
<td>26.19±2.72 (µg)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Comparison between groups</th>
<th>Time to achieve aldrete recovery score 10</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group M</td>
<td>Mean±Standard Deviation (min)</td>
<td></td>
</tr>
<tr>
<td>Group D</td>
<td>4.07±0.97</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

‘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

<table>
<thead>
<tr>
<th>L.V.R.S</th>
<th>Control (N=30)</th>
<th>Group M (N=30)</th>
<th>Group D (N=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>3-Somewhat dissatisfied</td>
<td>9</td>
<td>30.0%</td>
<td>4</td>
</tr>
<tr>
<td>4-Undecided</td>
<td>13</td>
<td>43.4%</td>
<td>6</td>
</tr>
<tr>
<td>5-Somewhat satisfied</td>
<td>4</td>
<td>13.3%</td>
<td>8</td>
</tr>
<tr>
<td>6-Satisfied</td>
<td>4</td>
<td>13.3%</td>
<td>12</td>
</tr>
</tbody>
</table>

‘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

<table>
<thead>
<tr>
<th>Recall of intra operative events</th>
<th>Control (N=30)</th>
<th>Group M (N=30)</th>
<th>Group D (N=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>No</td>
<td>6</td>
<td>20%</td>
<td>27</td>
</tr>
<tr>
<td>Yes</td>
<td>24</td>
<td>80%</td>
<td>3</td>
</tr>
</tbody>
</table>

‘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

<table>
<thead>
<tr>
<th>Post-operative complications</th>
<th>Control (N=30)</th>
<th>Group M (N=30)</th>
<th>Group D (N=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Hypotension</td>
<td>0</td>
<td>0%</td>
<td>1</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>0</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2</td>
<td>6.6%</td>
<td>2</td>
</tr>
</tbody>
</table>

‘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. 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. Moreover according to Tan JA et al dexmedetomidine increases the risk of bradycardia when both loading and maintenance doses were used. 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. The loading dose of midazolam was decided based on the studies done by Rolo R et al and Sethi P et al. The maintenance dose of midazolam was decided based on the study by Michalk S et al. 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. 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 al (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. 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 intraoperatively 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. 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. In the study conducted by Riker RR et al 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 1mg/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 administrating 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 al 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.5 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.15,18,20

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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