Anaesthesiologists grade I and II, undergoing tympanoplasty and modified radical mastoidectomy under monitored anaesthesia care. This prospective randomized comparative study was conducted after obtaining approval from local ethical committee including eighty adult patients of either sex, aged 18-60 years with American Society of Anaesthesiologists grade I and II, undergoing tympanoplasty and modified radical mastoidectomy under monitored anaesthesia care.

**METHODS**

Mostly adult patients of either sex aged 18-60 years with ASA grade I and II undergoing tympanoplasty and modified radical mastoidectomy under MAC were randomly allocated into two groups. Group D (n = 40) received intravenous dexmedetomidine 1 μg/kg diluted up to 30 ml by normal saline given over 15 min followed by a continuous infusion of 0.5 μg/kg/h and Group M (n = 40) received intravenous midazolam 0.05 μg/kg diluted up to 30 ml normal saline given over 15 min followed by continuous infusion of 0.01 mg/kg/h. Ramsay sedation score (RSS), Visual analogue score (VAS), rescue sedative and analgesic requirement, patient and surgeon satisfaction scores, haemodynamic parameters and side effects were recorded and compared in both groups. The data were analysed using different statistical tests.

**RESULTS**

The mean RSS was significantly more in Group D (3.0±0.0) as compared to Group M (2.85±0.362), (P<0.05). The mean VAS was significantly lower in Group D (12.30%(30.0.3.3.0.4.641)) as compared to Group M (36.90%,1.3.0.6.48),(P<0.05). Similarly, the total number of patients and number of doses of rescue analgesic were significantly lesser in Group D (4.10%,0.10±0.308) as compared to Group M (14.35%,0.38±0.540),(P<0.05). The patient and surgeon satisfaction scores were significantly better in Group D, (P<0.05). The HR was reduced significantly in Group D,D<0.05, while SBP and DBP remained comparable to their respective baseline values in both groups, (P>0.05). In Group D, four patients had experienced bradycardia.

**Conclusion:** Dexmedetomidine could be a safer and effective alternative to midazolam for tympanoplasty and modified radical mastoidectomy done under monitored anaesthesia care.

**KEYWORDS:**

Dexmedetomidine, Midazolam, Monitored Anaesthesia Care, Fentanyl, Tympanoplasty, Sedation Score

**INTRODUCTION**

Middle ear surgeries like tympanoplasty and modified radical mastoidectomy are usually done under local anaesthesia or local anaesthesia with sedation under monitored anaesthesia care (MAC) in adult patients. This technique of local anaesthesia with sedation have various advantages including less bleeding, better postoperative analgesia, rapid recovery, increased cost effectiveness with the ability to test hearing during the procedure or surgery.

Various drugs have been used for sedation along with local anaesthesia for MAC including benzodiazepines, propofol, opioids and α2 agonists either alone or in combination. Midazolam, a short acting benzodiazepine, has become the most frequently used drug for procedural sedation, as it has hypnotic, amnestic and anxiolytic properties which are desirable for procedures under MAC. However, it can cause prolonged sedation and respiratory depression after repeated administration of bolus doses. The newer drugs, like dexmedetomidine, a highly selective α2 adrenoceptor agonist, has emerged as an alternative drug for intravenous sedation and gained popularity nowadays, as it has both sedative and analgesic properties. It provides conscious sedation without significant respiratory depression along with shorter half life and wider margin of safety which makes it a suitable agent to be used for procedures under MAC.

Dexmedetomidine also attenuates the stress response to surgery due to its sympatholytic effect and has opioid sparing effect which provides stable haemodynamics both during and after surgery.

So based on above hypothesis, this prospective, randomized, clinical study was undertaken to compare efficacy of dexmedetomidine and midazolam for sedation and analgesia along with various haemodynamic changes during tympanoplasty and modified radical mastoidectomy under monitored anaesthesia care.

**METHODS**

This prospective randomized comparative study was conducted after obtaining approval from local ethical committee including eighty adult patients of either sex, aged 18-60 years with American Society of Anaesthesiologists grade I and II, undergoing tympanoplasty and modified radical mastoidectomy under monitored anaesthesia care.
The visual analogue scale (VAS) was used to evaluate pain both during intraoperative and postoperative periods. VAS (0-10, where 0 indicated no pain while 10 corresponded to maximum pain), was explained to the patient during the preoperative period and the target was to achieve a score of 3 or less. If VAS >3, then fentanyl 1 μg/kg was given intravenously as rescue analgesia in both the groups. The number of rescue doses along with total number of patients who required rescue midazolam and fentanyl were recorded. The standard protocol was followed for rescue sedation and analgesics which included to give maximum three rescue doses each of midazolam and fentanyl in both groups. At any time during the study if the amount of rescue drugs had reached their specified limits, this sedation technique was abolished along with discontinuation of the study drug. RSS and VAS were assessed during the loading infusion of the study drugs and thereafter at 10-min intervals till 65 min, the maintenance infusions were discontinued towards the completion of surgery. Intraoperative haemodynamic parameters i.e. HR, SBP, DBP and SpO2 were recorded every 5 min during loading infusion of the study drugs and thereafter at 10-min intervals till 65 min.

Any of the adverse haemodynamic variations including bradycardia (HR < 60 beats per minute), hypotension (fall in SBP or DBP >20% of baseline value or MAP < 60 mmHg), hypertension (an increase in SBP or MAP > 20% of baseline value), respiratory depression (respiratory rate < 10 breaths/min), desaturation (SpO2 <90%) and other side effects like nausea, vomiting and dry mouth during or within immediate postoperative period of the procedure were observed. Bradycardia was treated with atropine (0.01 mg/kg) given intravenously whereas if required either by fluid replacement or if required mephentermine 6 mg given intravenously in incremental doses. Desaturation was treated either by increasing the oxygen flow or if required, using 100% O2 with bag mask (bain’s circuit) ventilation. Both, the surgeons and patients were asked to rate their satisfaction using seven point scale, the Likert scale13 [1- Extremely dissatisfied; 2- Dissatisfied; 3- Dissatisfied somewhat; 4- Undecided; 5- Somewhat satisfied; 6- Satisfied; 7- Extremely satisfied].

All the patients remained in the Post Anaesthesia Care Unit (PACU) for a minimum of 1 hour after discontinuation of the study drug. In PACU the RSS, VAS and haemodynamic parameters (HR,SBP,DBP,SpO2) were recorded at arrival, 30 min and 60 min.

Statistical analysis: The sample size was calculated based on the results of a previous study and to demonstrate a power of 0.8 and type 1 error of 0.05. The above sample size was calculated to be 40 patients in each group. The primary objective of our study was to compare the level of sedation using RSS between the two groups. In our study all the patients in Group D achieved RSS≤3 at the end of loading drug infusion whereas only 34 patients achieved RSS≤3 in Group M, as the target end point of RSS was at 3 and at the end of 15 min we observed that RSS was significantly higher at almost all time intervals in Group D. This implies that the level of sedation was found to be significantly lower in group D than Group M at various time intervals. Similarly, at arrival in the recovery room the RSS was significantly lower in Group D as compared to Group M (P <0.05), however it remained comparable throughout in both the groups till the end point of 60 min (Table 2) The number of patients required rescue dose of midazolam in Group M was more (14, 35%) as compared to Group D (4, 10%) and rest of the time HR was comparable to baseline values till 60 min. However, in Group M, the HR did not show any statistical difference from their baseline values at any time interval, (P>0.05). The intra group comparison of SBP and DBP at different time intervals from their respective baseline values was found to be statistically not significant till 65 min,(P>0.05) in both groups. Similarly, no statistically significant difference was observed till 60 min in the recovery room,(P>0.05) in both groups. The mean VAS was found to be significantly lower in group D than Group M (4.75±0.5430 in Group D and Group M respectively) while patient satisfaction scores were 6.5±0.679 and 4.8±0.686 in Group D and Group M respectively and both were significantly higher in Group D, (P=0.001). (Table 4)

DISCUSSION
MAC is one of the methods of outpatient anaesthesia which usually combines a local anaesthetic agent with parenteral drugs for sedation, anxiolysis and analgesia. It requires proper selection of drugs with adequate titration of doses so that there would be minimal physiological alterations and adverse effects associated with rapid recovery. It has become increasingly used for middle ear surgeries like tympanoplasty and modified radical mastoidectomy. Dexmedetomidine, a highly selective α2 adrenoceptor agonist, can be used effectively for the procedures or surgeries to be done under conscious sedation and monitored anaesthesia care. The primary objective of our study was to compare the level of sedation using RSS between the two groups. In our study all the patients in Group D achieved RSS≤3 at the end of loading drug infusion whereas only 34 patients achieved RSS≤3 in Group M, as the target end point of RSS was at 3 and at the end of 15 min we observed that RSS was significantly higher at almost all time intervals in Group D. This implies that the level of sedation was found to be significantly better with dexmedetomidine and the patients remained calmer and co-operative during surgery, which is desirable for the surgeries to be done under sedation and MAC. In recovery room, the mean RSS was also found to be significantly higher in Group D which showed that the recovery of patients in dexmedetomidine group was somewhat delayed but clinically patients remained calm and arousable as sedation scores were in acceptable range. This may be attributed to sustained therapeutic plasma concentration of dexmedetomidine as it has elimination half life of 2 hours. Our results concur with the study done by Parikh DA et al who found better sedation with dexmedetomidine when compared to midazolam fentanyl combination in patients for tympanoplasty under MAC. Similarly Mohamed MH et al also showed higher sedation scores in dexmedetomidine group than midazolam group in ear surgeries under...
monitored anaesthesia care. Nallam SR et al also found significantly higher sedation scores in dexmedetomidine group as compared to propofol group, *P* < 0.01 in middle ear surgeries under MAC. However, they have used nalbuphine as a common drug in both groups.

The total number of rescue doses and number of patients required rescue doses of midazolam to achieve RSS 3 was significantly lesser in dexmedetomidine group which was consistent with the findings of Parikh DA et al.7 and Gupta P et al.10, and also with some other studies too.1,6,11 This could be explained by the fact that dexmedetomidine has both sedative and analgesic properties by acting on spinal cord and locus ceruleus and thereby reduced the requirement of rescue midazolam and the target level of sedation had achieved with dexmedetomidine alone.8,17

The mean VAS values were found to be lower in dexmedetomidine group when compared to midazolam group as the target VAS was lower than 3. Mohamed MH et al.11 and Nallam SR et al.1 were found significantly higher VAS in midazolam group and propofol group respectively while comparing it with dexmedetomidine and these results were in concordance with our study too.

The lesser number of rescue doses of fentanyl were required in dexmedetomidine group. Similarly the number of patients who required rescue doses of analgesic were significantly lesser in Group D as compared to Group M. P < 0.05. Turan et al. found that total dioclofenac consumption as rescue alagesic was significantly higher in propofol group in comparison to dexmedetomidine group in septoplasty and endoscopic sinus surgeries, which was similar to results of our study. Similarly, Karaaslan K et al. also found that rescue tramadol required was significantly higher with midazolam as compared to dexmedetomidine in endoscopic nasal surgeries. Mohamed et al. also showed in their study that use of rescue analgesic was significantly more in midazolam group in comparison to dexmedetomidine group. Similar results were also found in other studies.3,4,10 The reduced requirement of rescue analgesic with dexmedetomidine may be attributed to its additional analgesic property which provides better control of pain along with reduced level of anxiety. Similarly the mean VAS values were lesser with dexmedetomidine because of this property of dexmedetomidine only.4,11,26

In our study, both patient and surgeon satisfaction scores were found to be better with dexmedetomidine. Delmade MA et al demonstrated significantly better patient and surgeon satisfaction scores in dexmedetomidine group while comparing with midazolam group in ENT surgeries under MAC. Our results are also consistent with the findings of Nallam SR et al., Vyas DA et al., Alhashemi JA et al., and Gupta P et al.10 who found better patient and surgeon satisfaction scores in their studies too. The patient’s satisfaction score was better with dexmedetomidine as it provides better sedation which allyays anxiety along with adequate analgesia which makes the patient more comfortable and pain free during the surgery. Similarly surgeon’s satisfaction score was found to be higher with dexmedetomidine as it provides bloodless field along with calm and co-operative patient which is desirable for the surgeries to be done under sedation with MAC.3,4,10,11,26

Our study demonstrated a significantly lower mean HR in Group D when compared to their baseline values both during intraoperative and postoperative period. However, both SBP and DBP were found to be comparable to their baseline values in individual groups respectively. Although dexmedetomidine affected both HR and MAP in various studies by significantly decreasing both parameters but in our study the SBP and DBP remained stable throughout both intraoperative and postoperative period, which is somewhat contrary to these studies.15,16,20,21,22

The decreased sympathetic activity might be responsible for lower HR in dexmedetomidine group.15,20,21 Parikh DA et al.7 found significantly lower mean HR in dexmedetomidine group from their baseline values and corresponding values in midazolam-fentanyl group. P < 0.05. MAP was also found to be significantly lower in their study but our results regarding SBP and DBP were found to be not in concordance to study done by Parikh DA et al. Similar results were found by Alhashemi et al. Kazim Karaaslan et al.11 while comparing mean HR between dexmedetomidine and midazolam group. Delmade MA et al also found similar decrease in mean HR from their baseline values in dexmedetomidine group when comparing midazolam in ENT surgeries under MAC.

The bradycardia was observed in four patients in dexmedetomidine group while no patient had any episode of bradycardia in midazolam group. However this was reversed with atropine in titrated doses. No other side effect like hypotension, hypertension, dryness of mouth and PONV were reported in any of the patients in both groups.

**Conclusion:** Dexmedetomidine could be a better alternative to midazolam for providing sedation in various middle ear surgeries done under monitored anaesthesia care as it provides better level of sedation with adequate intraoperative and postoperative analgesia along with reduced rescue sedative and analgesic requirements which makes the patient more calm and co-operative leading to better patient and surgeon satisfaction which is desirable for the surgeries to be done under MAC. Dexmedetomidine was also associated with no significant haemodynamic changes and any other adverse events except for bradycardia which could be managed effectively.

**Table 1: Demographic data and duration of surgery**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group D (n=40)</th>
<th>Group M (n=40)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (years)</td>
<td>25.73±1.309</td>
<td>25.55±1.461</td>
<td>0.921</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M</td>
<td>22/18</td>
<td>21/19</td>
<td>0.8226</td>
</tr>
<tr>
<td>Mean Weight (kg)</td>
<td>55.05±8.87</td>
<td>53.38±1.129</td>
<td>0.245</td>
</tr>
<tr>
<td>ASA (I/II)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>30/10</td>
<td>30/10</td>
<td>0.616</td>
</tr>
<tr>
<td>Mean Duration of surgery(min)</td>
<td>91.43±15.07</td>
<td>95.29±15.29</td>
<td>0.236</td>
</tr>
</tbody>
</table>

**Table 2: Comparison of Ramsay sedation score (RSS), visual analogue score (VAS) at various time intervals**

<table>
<thead>
<tr>
<th>Time</th>
<th>Group D (n=40)</th>
<th>Group M (n=40)</th>
<th>P value</th>
<th>Group D (n=40)</th>
<th>Group M (n=40)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1±0.0</td>
<td>1±0.0</td>
<td>0.9999</td>
<td>0.0±0.0</td>
<td>0.0±0.0</td>
<td>0.9999</td>
</tr>
<tr>
<td>5 min</td>
<td>2.70±0.3</td>
<td>1.85±0.35</td>
<td>0.002*</td>
<td>0.0±0.0</td>
<td>0.0±0.0</td>
<td>0.9999</td>
</tr>
<tr>
<td>10 min</td>
<td>2.60±0.4</td>
<td>2.40±0.50</td>
<td>0.2629</td>
<td>0.0±0.0</td>
<td>0.0±0.0</td>
<td>0.9999</td>
</tr>
<tr>
<td>15 min</td>
<td>3.00±0.4</td>
<td>2.85±0.36</td>
<td>0.0255*</td>
<td>0.30±0.5</td>
<td>2</td>
<td>1.2±1.34</td>
</tr>
<tr>
<td>25 min</td>
<td>2.80±0.4</td>
<td>2.80±0.40</td>
<td>0.9999</td>
<td>1.10±1.1</td>
<td>0.5±0.0</td>
<td>0.001</td>
</tr>
<tr>
<td>35 min</td>
<td>3.00±0.0</td>
<td>2.70±0.43</td>
<td>0.0010*</td>
<td>1.08±0.9</td>
<td>4</td>
<td>1.47±1.11</td>
</tr>
<tr>
<td>45 min</td>
<td>2.90±0.3</td>
<td>2.70±0.07</td>
<td>0.0482*</td>
<td>1.13±0.1</td>
<td>3</td>
<td>1.3±0.18</td>
</tr>
<tr>
<td>55 min</td>
<td>3.00±0.0</td>
<td>2.70±0.46</td>
<td>0.0002*</td>
<td>0.70±0.7</td>
<td>2</td>
<td>1.98±1.09</td>
</tr>
<tr>
<td>65 min</td>
<td>3.00±0.0</td>
<td>3.00±0.0</td>
<td>0.9999</td>
<td>0.20±0.4</td>
<td>6</td>
<td>2.10±1.43</td>
</tr>
<tr>
<td>At post arrival</td>
<td>3.00±0.0</td>
<td>2.80±0.36</td>
<td>0.0255*</td>
<td>0.50±0.8</td>
<td>2</td>
<td>1.20±1.11</td>
</tr>
<tr>
<td>30 min</td>
<td>2.41±0.4</td>
<td>2.02±0.71</td>
<td>0.0025*</td>
<td>0.28±0.5</td>
<td>5</td>
<td>0.48±0.64</td>
</tr>
<tr>
<td>60 min</td>
<td>2.29±0.4</td>
<td>1.91±0.78</td>
<td>0.0018*</td>
<td>0.13±0.3</td>
<td>3</td>
<td>0.43±0.84</td>
</tr>
</tbody>
</table>

*P value > 0.05, not significant.

* Data expressed as Mean ± SD or number.

**Table 3: Requirement of rescue Midazolam and Fentanyl in both groups**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group D (n=40)</th>
<th>Group M (n=40)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients required rescue dose of midazolam</td>
<td>12 (30%)</td>
<td>36 (90%)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*I* Value: Data are represented as Mean ± SD.

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Table 4: Patient and surgeon satisfaction scores in both groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group D (n=40)</th>
<th>Group M (n=40)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon satisfaction score</td>
<td>6.65±0.749</td>
<td>6.5±0.679</td>
<td>0.001</td>
</tr>
<tr>
<td>Patient satisfaction score</td>
<td>4.5±0.679</td>
<td>4.9±0.687</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*Data are represented as Mean ± SD

Figure 1: Comparison of mean heart rate (HR) at various time intervals in both groups

*Data expressed as Mean ± S

Figure 2: Comparison of mean systolic blood pressure (SBP) at various time intervals in both Groups

*Data expressed as Mean ± SD

Figure 3: Comparison of mean diastolic blood pressure (DBP) at various time intervals in both groups

*Data expressed as Mean ± S

Figure 4: Comparison of mean arterial oxygen saturation (SpO2) in both groups

*Data expressed as Mean ±

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