Original Article - Evaluative Study

Comparision of Vital Surgical Parameters, after Administration of Midazolam and Dexmedetomidine for Conscious Sedation in Minor Oral Surgery

Suryahanthmihiran Sivasubramani, Deepak Abraham Pandyan, C. Ravindran

Department of Oral and Maxillofacial Surgery, Sri Ramachandra Institute of Higher Education and Research, Chennai, Tamil Nadu, India

Abstract

Aim: The aim of this study is to compare the efficacy between midazolam and dexmedetomidine in relation to vital parameters, sedation score, pain score, cognitive judgment, and postoperative amnesia to the event in conscious sedation for minor oral surgical procedure. **Materials and Methods:** A sample size of 30 patients were selected in each group: Group M (midazolam) and Group D (dexmedetomidine). **Results:** The mean heart rate (HR) and systolic and diastolic blood pressure measurements were significantly higher in Group M after the 20th min when compared to Group D. The visual analog scale (VAS) scores of pain were not statistically significant between the two groups during the procedure, but at the time of discharge, statistically significant VAS scores were found between the two groups. Nine (30%) patients in Group D and 21 (70%) patients in Group M showed cognitive judgment impairment with the Stroop Color and Word Test at the 30th min. **Conclusion:** The dexmedetomidine group of patients had reduced blood pressure and HR. No significant differences were noted in oxygen saturation or in respiratory rate between the two drugs. Patients had better sedation, analgesia, lesser cognitive impairment, and amnesia in the dexmedetomidine group.

Keywords: Conscious sedation, dexmedetomidine, midazolam, minor oral surgery

Introduction

Anxiety and pain are the most common complaints of patients undergoing minor oral surgical procedures. Conscious sedation using intravenous (IV) drugs is an effective, safe, and reliable method for the patients requiring minor oral surgical procedures.

IV drug-induced conscious sedation uses various drugs such as barbiturates, benzodiazepines, ketamine, and dexmedetomidine. Midazolam is one of the most extensively used benzodiazepines for conscious sedation.[1,2] Dexmedetomidine was approved by the Food and Drug Administration at the end of 1999.[3] Dexmedetomidine is a highly selective α-2 adrenoceptor agonist.

Aim

The aim of this study is to compare the efficacy between midazolam and dexmedetomidine in relation to vital parameters, sedation score, pain score, cognitive judgment, and postoperative amnesia to the event in conscious sedation for minor oral surgical procedure.

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Materials and Methods

A sample size of 30 patients were selected and were divided into two groups. The groups were Group M (midazolam) and Group D (dexmedetomidine). The selection criteria were done according to a confidence interval of 95% with a level of significance of 5% using the mean value of previous investigations. This study was designed as a double-blinded study.

Address for correspondence: Dr. Suryahanthmihiran Sivasubramani, 208, Pothigai Nagar, Ponnagaram, Dindigul - 624 003, Tamil Nadu, India.
E-mail: suriyasm9@gmail.com

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Inclusion criteria

Patients whose age group ranged between 18 and 40 years and who belong to the American Society of Anesthesiologists physical status I and II were included in the study.

Exclusion criteria

Patients below 18 years and above 40 years; patients with a history of neurologic, cardiac, pulmonary, hepatic, renal disease, mental disorders, drug addiction, bleeding disorders, patients on anticoagulants, antiplatelet drugs, and patients who are allergic to midazolam or dexmedetomidine were excluded from the study.

Patients were nil per oral for a minimum of 6 h before surgery. After obtaining informed consent, dexmedetomidine (Group D) or midazolam (Group M) sedation was administered randomly.

Preoperatively, patients were monitored in a semi-supine position. Baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), electrocardiogram, arterial oxygen saturation (SpO_2), and respiratory rate (RR) were recorded.

Confirming the patient was hemodynamically stable, a suitable vein was identified, and IV cannula was inserted in the forearm. Midazolam 0.05 mg/kg[2,4] or dexmedetomidine 1 μg/kg/h as a loading dose was administered using a micro-infusion syringe pump for 10 min before the procedure, and the maintenance level was achieved by additional infusion of 0.5 μg/h.[4] The drug administration and recording were done by an anesthetist who was blind to the study.

Before starting the procedure, the operator scored the Ramsay sedation score. The procedures were done under local anesthesia using lignocaine with 1:200,000 epinephrine. Intraoperative evaluations of HR, RR, blood pressure, and arterial SpO_2 by pulse oximetry were monitored continuously and were recorded at 5–30-min interval by the anesthetist at the time of procedure.

The patients were asked to give pain score using the 10-unit visual analog scale (VAS) (0: no pain and 10: excessive pain) at the same 5–30-min interval [Figure 1].

The Stroop Color and Word Test (SCWT) was used to assess the cognitive judgment function preoperatively and after 30 min.[5-7] For SCWT, the number of correct answers was evaluated. Fifteen differently colored words were shown on a liquid crystal display screen for a duration of 3 s, placed at a distance of 100 cm from the patients. The patients were asked to identify the color of the words without reading them [Figure 2].

Once the procedure was completed, the patients were shifted to the postoperative anesthetic care unit, and the vitals were monitored.

The review at discharge was assessed by the principal investigator 2 h after the procedure. Parameters evaluated include the ambulatory status of the patients, vital signs, surgical wound, pain score, output, amnesia to the event, and the SCWT. Ambulatory status was assessed by evaluating their eye opening, motor response, and movement of limbs, followed with a brief evaluation of the patients' gait and ability to walk a distance of 15 feet comfortably. Event of amnesia was assessed by asking objectively the specific details of the procedure, such as administration of local anesthesia at the surgical site, whether the procedure was carried out in the left or right quadrant. The SCWT was used to access the cognitive judgment. Patients were discharged when their vitals reached the preoperative baseline values.

Statistical Package for the Social Sciences version 16 (SPSS Inc., Chicago) was used for statistical analysis.

Results

The following results were obtained from our study. The Student's *t*-test was used for the independent samples of HR, SBP, DBP, RR, SpO_2, VAS score, sedation score, SCWT, and event of amnesia and also used for intergroup comparisons for paired samples. The statistical normality was confirmed before parametric analyses.

Mean heart rate [Table 1 and Graph 1]

After the 20th min, $P < 0.05$. It denotes that the dexmedetomidine group has a statistically significant reduction in the HR by 14% and only 5% in midazolam at the 20th min interval.

Mean oxygen saturation [Table 2 and Graph 2]

Even though $P < 0.05$ at the 20th min and was statistically significant, there was no clinical significance observed.

Mean systolic blood pressure (mmHg) [Table 3 and Graph 3]

After the 20th min, SBP reduced by 10% in dexmedetomidine and 5% in midazolam.

Mean diastolic blood pressure (mmHg) [Table 4 and Graph 3]

During the 30th min, DBP reduced by 13.5% in dexmedetomidine and 5.5% in midazolam.

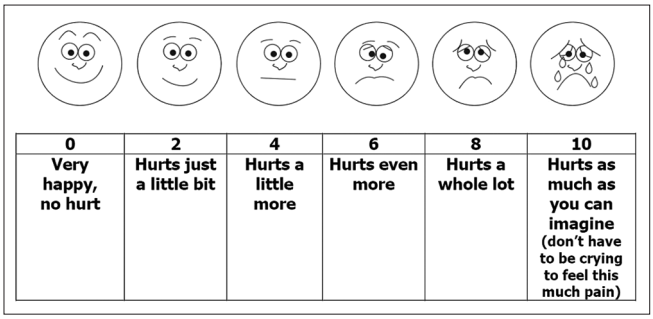


Figure 1: Visual analog scale

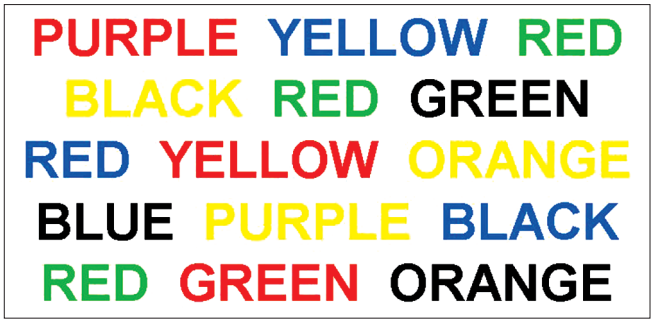


Figure 2: The Stroop Color and Word Test

Mean respiratory rate alteration [Table 5 and Graph 4]

RR decreased after administration of either drug, but there was no statistically significant difference between the two drugs.

Mean sedation score [Table 6 and Graph 5]

After the 10th min, $P < 0.05$. Sedation score increased by 73% in dexmedetomidine and 58% in midazolam at the time interval of maximum significance (20th min interval).

Event of amnesia [Table 7]

Statistically significant amnesia for the event was present in the midazolam group compared to the dexmedetomidine group ($P = 0.05$).

Table 1: Mean heart rate

Drug	Preoperative	5th min	10th min	20th min	30th min
Dexmedetomidine	82.60	75.5	72.90	71.10	71.50
Midazolam	83.33	77.6	80.30	81.50	78.33
*P**	0.83	0.66	0.09	0.008	0.05

*Significant (*P* value) difference between Midazolam and Dexamedetomidine

Table 2: Mean oxygen saturation

Drug	Preoperative	5th min	10th min	20th min	30th min
Dexmedetomidine	99.66	99.8	99.8	99.9	99.86
Midazolam	99.56	99.73	99.7	99.6	99.80
*P**	0.56	0.54	0.22	0.009	0.49

*Significant (*P* value) difference between Midazolam and Dexamedetomidine

Table 3: Mean systolic blood pressure (MMHg)

Drug	Preoperative	5th min	10th min	20th min	30th min
Dexmedetomidine	120.33	115.93	113.83	109.5	109.46
Midazolam	124.23	118.56	119.06	118.3	116.83
*P**	0.25	0.40	0.135	0.011	0.048

*Significant (*P* value) difference between Midazolam and Dexamedetomidine

Table 4: Mean diastolic blood pressure (mmHg)

Drug	Preoperative	5th min	10th min	20th min	30th min
Dexmedetomidine	71.96	69.10	66.13	64.33	62.30
Midazolam	71.96	68.50	68.46	67.60	67.86
*P**	0.25	0.82	0.37	0.263	0.059

*Significant (*P* value) difference between Midazolam and Dexamedetomidine

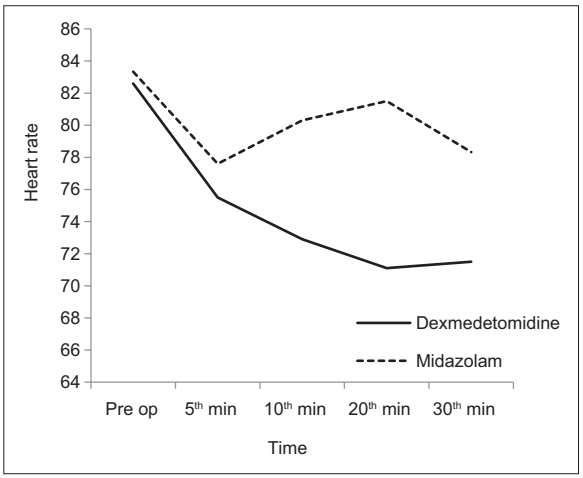
Table 5: Mean respiratory rate alteration

Drug	Preoperative	5th min	10th min	20th min	30th min
Dexmedetomidine	17.96	15.96	16.93	15.56	15.8
Midazolam	17.93	16.06	15.80	16.20	16.0
*P**	0.96	0.86	0.84	0.402	0.719

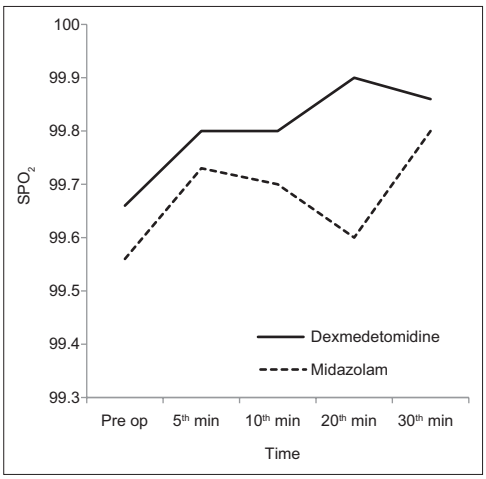
*Significant (*P* value) difference between Midazolam and Dexamedetomidine

Stroop Color and Word Test at the 30th min [Table 8]

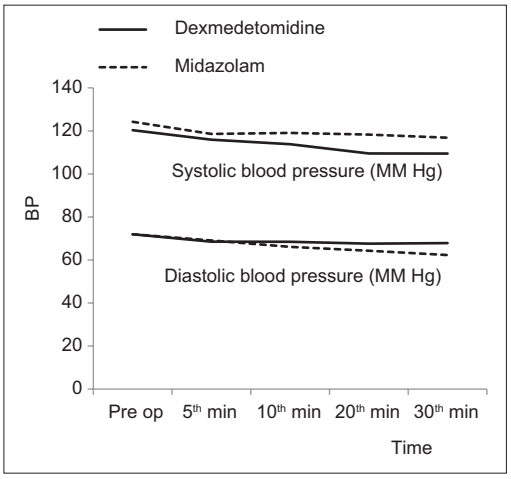
Statistically significant cognitive impairment was present in the midazolam group compared to the dexmedetomidine group ($P = 0.05$)



Graph 1: Mean heart rate alteration



Graph 2: Oxygen saturation alterations



Graph 3: Mean blood pressure alterations

Visual analog scale score at discharge [Table 9 and Graph 6]

Statistically significant VAS score below 4 was obtained in the dexmedetomidine group compared to the midazolam group ($P = 0.059$).

The mean SBP and DBP and HR measurements were significantly higher in Group M after the 20th min. There was no significant difference in RR and mean SpO_2 values between the two groups at all recorded time intervals.

The differences in Ramsay sedation scores were statistically significant between the two groups after 10 min. VAS scores of pain were not statistically significant between the two groups during the procedure, but at the time of discharge, statistically significant VAS scores between the two groups were found. At the time of discharge, in Group D, 21 patients had a pain score below 4 and 9 patients had a pain score 4, and in Group M, 14 patients had pain score below 4 and 16 patients had a pain score 4 and above.

Nine (30%) patients in Group D and 21 (70%) patients in Group M showed cognitive judgment impairment with the SCWT at the 30th min, which was statistically significant. The difference in the number of patients recalling the administration of local anesthesia and the first site of procedure was statistically significant between the two groups. Seventeen (63%) patients in Group M and 10 (33%) patients in Group D were not able to recall the first site of procedure.

Table 6: Mean sedation score

Drug	Preoperative	5th min	10th min	20th min	30th min
Dexmedetomidine	1	1.90	2.4	2.9	2.86
Midazolam	1	1.96	1.9	2.4	2.56

Table 7: Event of amnesia

	Amnesia present	Amnesia absent
Dexmedetomidine	10	20
Midazolam	17	13

Table 8: Stroop Color and Word Test at 30th min

	Cognitive impairment present	Cognitive impairment absent
Dexmedetomidine	9	21
Midazolam	21	9

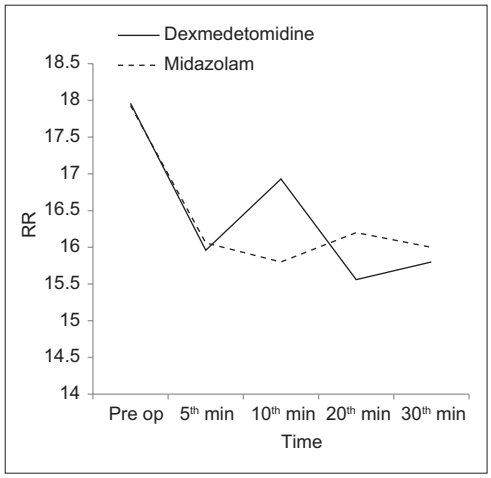
Table 9: Visual analog scale score at discharge

	VAS score below 4	VAS score 4 and above
Dexmedetomidine	21	9
Midazolam	14	16

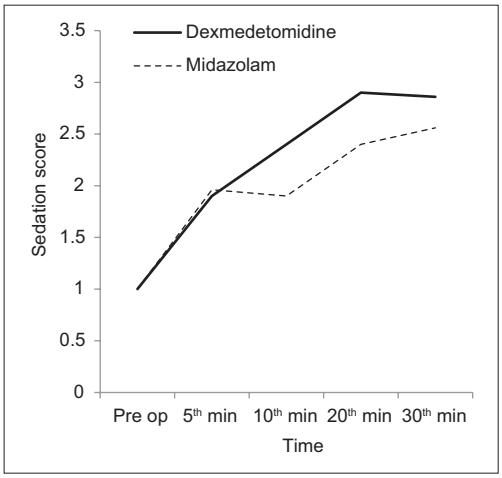
VAS=Visual analog scale

Discussion

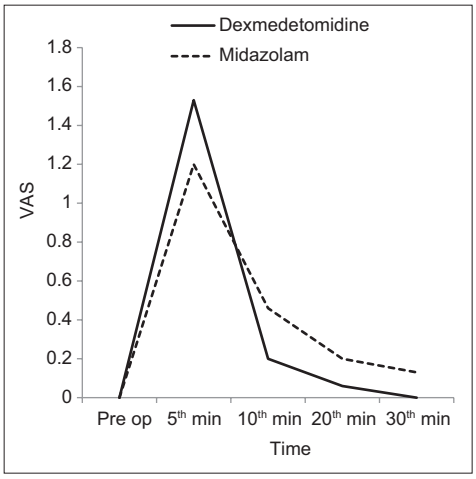
Patients have higher anxiety levels for "jaw becoming tired" and "collection of fluid in the mouth" than "feeling



Graph 4: Mean respiratory rate alterations



Graph 5: Mean sedation alterations



Graph 6: Mean visual analog scale score alterations

pain during the operation" during the procedure under local anesthesia.[8]

The most common IV conscious sedation medications used are midazolam and diazepam.[2] Midazolam is a potent imidazobenzodiazepine. Midazolam has become commonly used for conscious sedation.[2] However, midazolam produces cognitive impairment, delayed recovery of psychomotor function, adverse respiratory effects, and impairment of memory, and in previous studies, pain reactions were seen significantly in a higher number of patients.[9-11]

Dexmedetomidine activates the α_2-adrenoceptor.[12] This provides sympathetic inhibition in the central nervous system, which leads to a reduction in blood pressure, HR, sedation, decreased arousal, analgesic effect, and anxiolysis.[4,12,13]

Dexmedetomidine is a better sedative drug for sedation for minor oral surgery than midazolam because of its shorter recovery profile, analgesic property, minimal respiratory depression, minimal cognitive impairment,[11,14] and antisialogogue effect.[15]

The most commonly reported adverse effects of dexmedetomidine are vasoconstriction leading to bradycardia and hypertension. Caution should be taken in patients with low ventricular ejection fraction (≤30%) and heart block, as an episode of sinus arrest associated with dexmedetomidine use has been reported.[16]

This study compares the efficacy between midazolam and dexmedetomidine in relation to vital parameters, sedation score, pain score, cognitive judgment, and postoperative amnesia to the event.

Intraoperative mean arterial blood pressure and HR in dexmedetomidine were lower than their baseline values and the corresponding values in midazolam.[4,13]

Patients treated with dexmedetomidine had a lower systolic and diastolic pressure and slower HR than midazolam.[14]

In our study, the results showed that the average HR of the patients in the dexmedetomidine group was significantly reduced compared to the midazolam group. The mean reduction in HR was 14% for dexmedetomidine and 5% for midazolam [Table 1 and Graph 1].

The results for the mean SBP and DBP showed a significant reduction in both the groups. SBP showed a reduction after the 20th min of dexmedetomidine administration as compared to midazolam to the baseline value [Table 3 and Graph 3]. There was no significant difference in DBP till the 20th min [Table 4 and Graph 3]. However, the reduction was considerable after the 30th min in dexmedetomidine when compared to midazolam. This can be due to the delayed hypotension effect in dexmedetomidine.[16]

No significant oxygen desaturation is attributable to midazolam sedation.[6]

Dexmedetomidine was more effective in attenuating airway reflex responses and maintaining hemodynamic stability without prolonging recovery.[17]

In this study, the mean SpO_2 for both midazolam and dexmedetomidine showed no clinically significant changes either from the baseline values or in comparison between the two drugs [Table 2 and Graph 2].

The RR decreased from the baseline after administration of the two drugs, but there was no statistical or clinical significant difference in RR between the two drugs [Table 5 and Graph 4].

In our study, the cognitive impairment was measured using the SCWT. 70% of patients with midazolam and 30% with dexmedetomidine showed sign of cognitive impairment [Table 8]. Dexmedetomidine has a lower influence on cognitive impairment compared to midazolam. This further testifies the drawback of the increased effect on the cognitive ability by midazolam as an IV conscious sedation drug.[5] The comparative low incidence of cognitive impairment with dexmedetomidine overcomes this drawback of the midazolam in conscious sedation.[18]

Dexmedetomidine reduces postoperative rise of the pro-inflammatory cytokine and interleukin-6 and results in lower levels of markers of stress response to surgery such as cortisol and blood glucose. Dexmedetomidine also reduces the postoperative pain without altering recovery from anesthesia.[18]

In our study, the VAS was used to assess pain intraoperatively and at the time of discharge in both the drug groups. VAS pain scores below 3, 3–6.9, and above 7 were categorized as mild, moderate, and severe pain, respectively.[19]

In our study, no statistical or clinically significant difference was found intraoperatively between the two drugs. This finding can be attributed to the standardized local anesthesia technique and anesthetic drugs used in both the groups. The VAS values showed a peak in the pain at the time of administration of local anesthesia using syringe for the surgical procedure, which corresponded to the 5th min recorded values [Table 7 and Graph 6]. Postoperatively, at the time of discharge, the VAS score of dexmedetomidine group was significantly lower than the midazolam group [Table 9]. This can be attributed to the better analgesic property of dexmedetomidine as reported in the literature.[4,11,16] Other confounding factors such as the difficulty of the procedures, time, and the level of experience of the clinician can affect the VAS postoperatively.

Dexmedetomidine achieved a faster sedation score <3 in a 4-point sedation scale at the time of 10 min.[14] Dexmedetomidine required fewer adjustments in dosing compared with midazolam to maintain adequate sedation. They assessed the patients for Ramsay sedation score for the sedation level intraoperatively.[14]

In our study, the sedation score showed a definite increase after administration of both the drugs at the 5th min as well as the 30th min with an average score of 1.93–2.67, respectively. The comparison showed a statistically significant increased sedation score for the dexmedetomidine group from the

10th min onward [Table 6 and Graph 5]. This validates the previous studies, showing the good sedation property of dexmedetomidine.[4]

The VAS pain score can be used to assess the impairment of memory due to the effects of IV sedation on the central nervous system.[18]

In this study, the event of amnesia was evaluated by asking the objective and specific details of the procedures, such as administration of local anesthesia at the surgical site and the first site of surgical procedure done.

The present study showed that the event of amnesia was present in 10 patients in the dexmedetomidine group and 17 in the midazolam group. The comparison showed a statistically significant higher event of amnesia with midazolam [Table 7]. This is due to the anterograde amnesic property of midazolam, which has been already reported in the previous studies. Dexmedetomidine produces a relatively weaker event of amnesia in conscious sedation, and the results of this study validate this finding.

Conclusion

We found that the dexmedetomidine group of patients had reduced blood pressure and HR. No significant differences were noted in SpO_2 or in RR between the two drugs. Patients had better sedation, analgesia, lesser cognitive impairment, and amnesia in the dexmedetomidine group.

In our study, dexmedetomidine may be a better alternative to midazolam for IV sedation because of its higher sedation level and increased analgesic effect with lesser cognitive impairment and amnesia.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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