Original Article

Sedation in oral and maxillofacial day care surgery: A comparative study between intravenous dexmedetomidine and midazolam

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ABSTRACT

Introduction: Sedation is an important component of day care oral and maxillofacial surgical procedures under local anesthesia. Although various sedative drugs in different regimens have been used for sedation, an ideal agent and regimen are yet to be established. **Aim:** The aim of this study is to compare the efficacy of intravenous (IV) dexmedetomidine and midazolam as a sedative agent for day care oral and maxillofacial surgical procedures. **Settings:** The study was conducted in the Department of Oral and Maxillofacial Surgery, SCB Dental College and Hospital, Cuttack, Odisha, India. **Materials and Methods:** A total of sixty adult patients of age group 18–65 years, of either sex were randomly selected equally in two groups for the study. One group named Group D received dexmedetomidine and the other named Group M received midazolam. Patients were evaluated for oxygen saturation (SPO_2), respiration rate (RR), systolic blood pressure (SBP), diastolic blood pressure (DBP), Ramsay sedation score, bispectral index (BIS) score, amnesia, Aldrete score, relaxation during the surgery, and drug preference. **Results:** Midazolam was associated with greater amnesia. Dexmedetomidine was associated with lower heart rate, SBP, and DBP. There was no significant difference in SPO_2, RR, Aldrete score, Ramsay sedation score, and BIS score between the two drugs. Patient preference and relaxation were more in dexmedetomidine group. **Conclusion:** IV dexmedetomidine is a comparable alternative to midazolam for sedation in day care oral and maxillofacial surgery under local anesthesia. It is the preferred drug when a lower heart rate and blood pressure or less amnesia is needed without any serious side effects.

Key words: Aldrete score, bispectral index, Ramsay sedation score

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INTRODUCTION

In the last few years, there has been a dramatic increase in day care oral and maxillofacial surgical procedures.[1] Compared to hospital-based surgery, day care surgery has the advantages of compliance for patients and surgeons as well as decrease in financial costs and nosocomial infections. These surgical procedures are often associated with fear of pain, preoperative anxiety, and treatment-related stress. Anxiety toward surgical

procedures varies from a suppressed fear of pain to a phobia which may make treatment impossible.[2] These patients not only find these procedures unpleasant but they may also exhibit peripheral manifestations such as, sympathetic over-activity such as xerostomia, tachycardia, sweating, and tremors which in some instance may lead to anxiety-induced arrhythmias and vasovagal reactions. Sedation plays a vital role in managing these patients by attenuating the stress and anxiety. Although the ideal sedation agent used in day care practices should provide a rapid onset of action, provides stable operating conditions, easily reversible, with fewer side effects with fast, and predictable recovery, there has always been potential risks associated with sedation such as airway obstruction, laryngospasm, and aspiration.[3] These risk factors have always stimulated the enthusiastic researcher for the safest sedative agent and technique.

Although there are various routes of sedative administrations such as inhalational, oral, and intramuscular, the intravenous (IV) technique has attained the greatest popularity due to the ability to titrate the dose of sedative drug according to the response of the patient and quick onset of action. One of the popular drugs for day care IV sedation is midazolam, a derivative of benzodiazepine. It has a rapid onset, a short duration of action, and favorable pharmacologic properties such as anxiolytic, hypnotic, and anterograde amnesic effects.[4] In low-dose midazolam has little influence on circulatory dynamics. The midazolam hydroxymetabolite has a relatively long half-life, and after repeated administration, there may be delayed recovery and hangover effects, such as excessive sleepiness and psychomotor impairment.[5] Moreover, it also depresses the ventilator response to carbon dioxide and results in respiratory depression.[6]

Recently, dexmedetomidine a newly developed drug being used clinically for sedation in intensive care units has shown exciting prospects. It is an alpha-2 agonist acting on adrenoceptors in many tissues including the nervous, cardiovascular, and respiratory systems.[7,8] It acts in the central nervous system (CNS) at the locus coeruleus, where it induces electroencephalographic activity similar to natural sleep.[9] It also reduces catecholamine secretion, thereby reducing stress and leading to a modest decrease in heart rate and blood pressure (BP).[10] Unlike midazolam, dexmedetomidine does not affect the ventilatory response to carbon dioxide.[11,12] Such a pharmacodynamic profile may have an advantage over midazolam for day care oral and maxillofacial surgery.

The aim of this study was to assess the efficacy of IV midazolam and dexmedetomidine as a sedative agent for day care oral and maxillofacial surgical procedures under local anesthesia. The objectives were to compare and assess the clinical efficiency of IV midazolam bolus with continuously maintained infusion of IV midazolam and IV dexmedetomidine bolus with continuously maintained infusion of IV dexmedetomidine.

MATERIALS AND METHODS

The study was conducted in the Department of Oral and Maxillofacial Surgery, SCB Dental College and Hospital, Cuttack, Odisha, India, from January 2013 to December 2014.

The trial protocol was approved by the Institutional Ethical Committee vide letter no Institutional Ethics Committee/Institutional Review Board No: 97 dated 22.11.2014 (Reg No: ECR/84Inst/OR/2013).

Our hospital data reveals that an average of 120 patients was operated annually as day care oral and maxillofacial surgical procedures under local anesthesia. Out of these subjects, sixty were selected ranging in age 18–65 years, of both the sexes and were grouped into Group M and Group D, randomly using lottery method for the study.

- Group M ($n = 30$): Subjects in this group received bolus and continuously maintenance dose of midazolam
    Bolus/loading dose: 0.08 mg/kg weight for 10 min
    Maintenance dose: 0.05 mg/kg/h, given after the bolus dose, till the end of the procedure.
- Group D ($n = 30$): Subjects in this group received bolus and continuously maintenance dose of dexmedetomidine
    Bolus/loading dose: 1 µg/kg weight for 10 min
    Maintenance dose: 0.5 µg/kg/h, given after the bolus dose, till the end of procedure.

The drugs were prepared by a pharmacist, who did not participate in subject management or data collection. Either dexmedetomidine (Group D) or midazolam (Group M) was mixed with normal saline to a total volume of 50 ml solution. Both preparations were clear solutions and patients, operator and nursing staff, and data collectors were blind to the allocated drug.

Inclusion criteria were healthy hemodynamically stable subjects, with all routine investigation within normal limits, the American Society of Anesthesiologist (ASA) Class l and ll, and duration of surgery up to 60 min. Subjects having history of adverse reaction or allergy to any drug used during anesthesia, clinical history or ECG evidence of heart block, asthma, sleep apnea syndrome, impaired liver, renal or mental function, pregnancy, known alcoholic, recent administration of sedative, or other CNS depressant drugs were excluded from the study.

An information sheet explaining the aim of our study in simple nonscientific terms was given to each patient who was then asked to sign a consent form before surgery.

Armamentarium

Infusion pump, noninvasive BP monitor, oximetry monitor, stethoscope, 100% oxygen source and administration supplies, airways and positive pressure breathing device, bispectral index (BIS) sensor and monitor, IV supplies, and emergency kit.

Procedure

The patients were instructed to fast 6 h before their surgical appointment and to bring a responsible adult to accompany them home after the procedure. No preoperative opioids were given before the surgery. It was explained to the patient that sedation was given to help them tolerate the surgery. They were instructed that although sedated they should be able to respond to the surgeons command. In the preoperative room, baseline vitals, oxygen saturation (SPO_2) systolic BP (SBP), diastolic BP (DBP), pulse rate (PR) and respiration rate (RR) were recorded, along with body weight. They were then shifted to operation theater.

On arrival at the operating room, an 18-gauge IV cannula was inserted over the forearm. Once again, the baseline vitals were recorded and monitored with pulse oximeter, noninvasive BP measuring device, and by observation of RR. The sedative drug was prepared in 50 ml solution of saline. BIS electrodes were applied on the frontotemporal region after cleansing the skin with alcohol [Figure 1]. Infusion of sedative drug in bolus dose is given for 10 min using the infusion pump, and surgery was started. From the commencement of surgery to the end of surgery, continuous infusion of the drug as a maintenance dose is given using infusion pump.

During the infusion of bolus dose, the vitals were recorded every 2 min, and thereafter every 5 min

Figure 1: Vital and bispectral index monitoring of subjects

intervals during the maintenance dose. Similarly, the level of sedation was assessed every 2 min during the bolus dose and 5 min during maintenance dose using the Ramsay sedation scale (RSS) score and BIS score. Following the bolus drug infusion and before surgery, two pictures were shown to the patients, and they were asked to remember their contents.

Ten minutes after the infusion of sedative agents, the local anesthetic was injected (comprising 2% lignocaine hydrochloride with 1:200,000 adrenaline) at the surgical site by nerve block or regional anesthesia. The adequacy of analgesia was confirmed before the surgical procedure subjectively and objectively.

Minor elective surgical procedures, performed on subjects, were surgical extraction of impacted teeth, cystic enucleation, endodontic surgery, facial fracture reduction and fixation, and intraoral biopsy.

The drug administration was stopped when the surgeon completes the surgical procedure. After surgery, the patient was sent to the recovery room and monitored for 2 h and the vitals (PR, SBP, DBP, RR, and SPO_2) were recorded at frequent intervals (every 5 min interval for the first 30 min than at 1 and 2 h). The patient was discharged after satisfying the Standard Aldrete Discharge Criteria.[13] Apart from baseline vitals, others parameters such as incidence of side effect, degree of amnesia, discharge score, patient's relaxation, and patients satisfaction were also recorded. Degree of amnesia was assessed by asking the subject about remembrance of bur or any other surgical instrument, shifting to the ward, or suturing along with the picture shown.

Statistical method

The observations collected were processed for statistical analysis using (SPSS Inc., Chicago, IL, USA) software. Preoperative and postoperative parameters between the two study group were compared using independent sample *t*-test. Categorical and nominal variables were compared using nonparametric Chi-square test. Ordinal variables such as Aldrete score, etc., were compared using nonparametric tests such as Mann–Whitney U-test. Descriptive statistics such as mean and standard deviation was computed using descriptive statistics procedure. A $P < 0.05$ was considered significant for all statistical inferences in this study.

RESULTS

The mean age of study participants was 33.53 ± 10.92 years. The demographic characteristics including age, sex, and weight are presented in Table 1. The preoperative vital parameters showed no significant difference [Table 2].

Table 1: Comparison of demographic characteristics and American Society of Anesthesiologist grade between study groups

	Dexmedetomidine, *n* (%)	Midazolam, *n* (%)	χ^2 and *t*	P
Age				
<35	17 (56.7)	20 (66.7)	$\chi^2=0.634$	0.425
≥35	13 (43.3)	10 (33.3)		
Total	30 (100)	30 (100)		
Mean±SD	33.1±10.4	33.97±11.5	$t=-0.305$	0.762
Sex				
Male	22 (73.3)	24 (80)	$\chi^2=0.577$	0.448
Female	8 (26.6)	6 (20)		
Weight	54.73±7.9	56.27±11.6	$t=-0.595$	0.554
ASA grade				
Grade I	27 (90)	25 (83.3)	$\chi^2=0.577$	0.448
Grade II	3 (10)	5 (16.7)		

ASA: American Society of Anesthesiologist, SD: Standard deviation. (*P*<0.05)

Table 2: Comparison of baseline vital parameters between study groups

Vital rates	Mean±SD		*t*	P
	Dexmedtomidene	Midazolam		
Preoperative				
SpO_2	99.77±0.56	99.83±0.37	−0.535	0.595
PR	79.43±6.08	80.5±6.55	−0.653	0.516
SBP	125.8±13.41	125.3±9.85	0.165	0.87
DBP	80.33±8.07	77.3±7.84	1.476	0.145
RR	14.33±1.26	14.53±1	−0.676	0.502

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, RR: Respiration rate, SpO_2: Oxygen saturation, SD: Standard deviation, PR: Pulse rate. (*P*<0.05)

Comparison of mean scores of vital parameters along with Ramsay sedation scale, bispectral index score during loading dose, intraoperative, and recovery period and of Aldrete score, amnesia scores, patient satisfaction, and relaxation between study groups are shown in [Tables 3 and 4] respectively.

DISCUSSION

Daycare surgical procedures under local anesthesia comprise a major part of oral and maxillofacial surgery. Although local anesthesia usually provides adequate analgesia for surgery, patients usually suffer from the discomfort associated with surgical procedures and the pain during the initial administration of local anesthetics. Effective use of sedative-hypnotic and analgesic agents is an integral part of providing patient comfort and safety in day care surgery.

To circumvent variables of age at the extreme of life, patients above 65 years and below 18 years were excluded from this study. Age, sex, weight, and ASA grading distribution among the two groups were comparable to each other. Preoperative vitals such as PR, SBP, DBP, RR, and SPO_2 were also found similar among the two groups in this study.

SPO_2 during the loading/bolus dosing and recovery period were comparable between the two groups, but during the intraoperating maintenance dose period, SPO_2 was less in Group D from 15 to 60 min (at 5 min intervals), which was significant. Although the SPO_2 was lower in Group D, it never reached below 95% saturation level, to cause any concern throughout the study in any subjects. In a similar study conducted by Cheung *et al*.,[14] SPO_2 was lower in Group M during drug infusion, lower in Group D during surgery, and similar in both the group during the recovery period.

PR, during loading/bolus dose, was comparable in both the groups except at 6th to 10th min, during which, PR was lesser in Group D, which was found to be statistically significant. The PR during intraoperative maintenance dose infusion in Group D was lesser than that of Group M, throughout, right from local anesthetic application to 60 min of intraoperative maintenance dose period when measured every 5 min of intervals, which was also statistically significant. During recovery period, PR was lesser in Group D than in Group M, which was statistically significant, except during 120 min of recovery period. In a similar study by Ustün *et al*.[1] and Cheung *et al*.,[14] the mean PR was significantly lower in dexmedetomidine group than midazolam group during surgery, recovery periods, which was comparable to this study.

SBP and DBP were comparable between the two groups during the bolus dose period. During intraoperative maintenance dose period and recovery period (60 min), they were lesser in Group D than in Group M and were statistically significant. They were comparable at 120 min of recovery period. Ustün *et al*.,[1] Cheung *et al*.,[14] Fan *et al*.,[15] and Jaakola *et al*.[16] have found the similar result, where BP was significantly lower in Group D than in Group M.

Contrary to our findings, Dyck *et al*.[17] have found IV use of dexmedetomidine making biphasic changes in BP. There was an initial increase in mean arterial pressure and decrease in heart rate followed by a decrease in both. This initial increase may be due to the direct effects of α_2-adrenoceptor stimulation of vascular smooth muscle. After the transient increase in BP, the following decrease may be presumably due by an inhibition of sympathetic outflow that overrides the direct effects

of dexmedetomidine on the vasculature. In our study, such a biphasic change was not observed, and it may be related to the use of a relatively lower dose and a slow rate of infusion of bolus dose (over 10 min) in our study.

RR respiratory depression is a common side effect of benzodiazepines. Various levels of respiratory depression are reported depending on the dosage and the type of the sedative drugs. Midazolam is accepted to be safe sedative agent with minimal incidence of adverse effects among benzodiazepines. In our study, it was found that neither drug significantly depresses the RR. The RR was comparable between the two groups during all the three phases, i.e., during the loading phase, intraoperative maintenance phase, and recovery phase. Hall *et al*.[18] and Ustün *et al*.[1] showed that sedation with dexmedetomidine preserves the RR and oxygen concentration during operation and recovery, similar to this study. Taniyama *et al*.[19] found that dexmedetomidine-related respiratory depression was not significantly lower than that caused by propofol. They suggested that changes in tidal volume and arterial blood carbon dioxide tension should be investigated.

The BIS provides a quantitative measure of sedation and does not require stimulation of the patients. In our study, there was no significant difference in the recorded bispectral analysis values, of the two groups during the loading and intraoperative maintenance dose period. Taniyama *et al*.[19] found that the BIS gradually decreased during initial loading and ranged between 80 and 85 at the time of optimal sedation, which is similar to our finding. According to Chernik *et al*.,[20] "Adequate sedation was defined as the achievement of an observer's assessment of alertness and sedation (OOA/S) score of 4". According to Fan *et al*.,[15] OOA/S score of 4 corresponds to BIS score of 80. In this study, BIS score was around 80 (78–85) in the two group intraoperatively. Hence, we can conclude that the patient in the both group achieved optimal amount of sedation and both the drugs had optimum sedative effect at the dose used by us. Our finding in this study contradicts that of Morse *et al*.[21] Morse *et al*., in their study of BIS monitoring on the patients undergoing oral surgery under conscious sedation using IV midazolam, had found that the BIS value did not alter significantly from baseline level for the majority of time and remained around 90. They also had suggested that BIS monitoring was not deemed to be useful and would not provide any benefit to the currently established methods of monitoring patient consciousness.

In both the groups, Ramsay sedation score was comparable, during loading as well as intraoperative maintenance dose periods. There was a persistent

Table 3: Comparison of mean scores of vital parameters along with Ramsay sedation scale and bispectral index score during loading dose, intraoperative, and recovery period between study groups

	SpO$_2$		PR		SBP	
	Dexmedetomidine	Midazolam	Dexmedetomidine	Midazolam	Dexmedetomidine	Midazolam
Loading dose (m)						
SOI	99.73 ± 0.74	99.87 ± 0.35	85.43 ± 14.50	83.83 ± 6.56	129.23 ± 14.30	130.47 ± 11.10
2	99.70 ± 0.65	99.90 ± 0.31	83.07 ± 12.54	87.40 ± 6.79	125.77 ± 16.61	125.17 ± 10.34
4	99.70 ± 0.79	99.60 ± 1.38	80.57 ± 15.24	85.27 ± 7.70	126 ± 14.94	121.03 ± 10.41
6	99.60 ± 0.81	99.67 ± 0.61	76.80 ± 13.74	83.63 ± 6.87*	122.33 ± 14.98	117.13 ± 9.66
8	99.80 ± 0.48	99.60 ± 0.77	75.07 ± 13.68	81.20 ± 8.36*	119.77 ± 13.78	115.43 ± 8.08
10	99.37 ± 0.93	99.70 ± 0.65	74.77 ± 16.22	81.73 ± 8.60*	116.5 ± 12.58	112.6 ± 7.26
Intraoperative (min)						
La	99.63 ± 0.77	99.93 ± 0.25	77.33 ± 14.87	85.13 ± 10.26*	116.43 ± 14.65	126.83 ± 10.61*
SOS	99.80 ± 0.811	100 ± 0.00	82.37 ± 14.61	91.40 ± 9.45*	115.63 ± 14.38	125.17 ± 11.85*
5	99.43 ± 0.90	99.60 ± 0.89	82.23 ± 14.74	89.47 ± 8.55*	115.33 ± 15.73	125.57 ± 11.15*
10	99.60 ± 0.81	99.87 ± 0.51	78.27 ± 16.86	88.00 ± 6.47*	115.40 ± 11.84	125.57 ± 10.75*
15	99.37 ± 1.03	100 ± 0.00*	77.53 ± 14.18	85.53 ± 7.10*	114.80 ± 14.65	129.50 ± 9.18*
20	99.53 ± 0.82	99.97 ± 0.18*	78.80 ± 17.88	87.60 ± 6.11*	117.57 ± 15.23	132.13 ± 11.79*
25	99.60 ± 0.68	99.93 ± 0.25*	78.17 ± 11.94	85.57 ± 6.25*	115.80 ± 16.08	133.67 ± 9.20*
30	99.21 ± 0.98	99.89 ± 0.32*	77.48 ± 12.12	87.44 ± 5.96*	115.38 ± 16.42	132.22 ± 9.54*
35	99.52 ± 0.68	99.92 ± 0.40*	76.3011.08	88.60 ± 6.27*	116.52 ± 15.38	132.36 ± 8.19*
40	99.52 ± 0.98	99.96 ± 0.20*	74.09 ± 10.44	85.76 ± 6.65*	119.81 ± 20.62	132.62 ± 8.22*
45	99.42 ± 0.79	99.86 ± 0.40*	74.25 ± 10.88	86.18 ± 12.07*	116.50 ± 19.80	135.18 ± 10.47*
50	99.21 ± 0.98	99.83 ± 0.38*	74.42 ± 12.40	86.06 ± 9.74*	116.18 ± 19.44	134.00 ± 12.71*
55	99.52 ± 0.68	100 ± 0.00*	75.36 ± 15.10	89.94 ± 13.32*	119.73 ± 21.85	135.50 ± 10.85*
60	99.52 ± 0.98	99.92 ± 0.28*	73.67 ± 15.05	88.75 ± 12.55*	119.08 ± 24.04	139.00 ± 11.46*
Recovery (min)						
0	99.43 ± 1.01	99.70 ± 0.60	73.30 ± 10.63	83.97 ± 7.50*	113.03 ± 14.151	132.23 ± 17.176*
5	99.63 ± 0.81	99.77 ± 0.50	73.37 ± 9.27	84.17 ± 7.55*	110.47 ± 17.122	130.37 ± 18.557*
10	99.60 ± 1.00	99.93 ± 0.37	71.13 ± 9.30	81.83 ± 6.74*	108.07 ± 16.152	128.27 ± 18.697*
15	99.43 ± 1.33	99.80 ± 0.41	70.70 ± 9.68	82.07 ± 7.92*	107.43 ± 16.196	124.63 ± 17.949*
20	99.47 ± 1.31	99.83 ± 0.38	69.90 ± 10.24	80.20 ± 8.35*	108.27 ± 17.249	123.17 ± 17.396*
25	99.63 ± 1.03	99.93 ± 0.25	71.13 ± 9.29	81.37 ± 8.41*	111.4 ± 18.72	124.7 ± 18.683*
30	99.77 ± 0.57	99.87 ± 0.35	75.03 ± 9.28	85.13 ± 9.83*	112.9 ± 16.715	125.93 ± 18.149*
60	99.67 ± 1.03	99.97 ± 0.18	74.97 ± 7.36	81.83 ± 6.93*	118.73 ± 15.752	126.47 ± 15.272*
120	99.83 ± 0.53	99.97 ± 0.18	77.13 ± 6.67	80.37 ± 7.36	124.3 ± 11.222	124.87 ± 15.294

Contd...

Table 3: Contd…

	DBP		RR		BIS		RSS	
	Dexmedetomidine	Midazolam	Dexmedetomidine	Midazolam	Dexmedetomidine	Midazolam	Dexmedetomidine	Midazolam
Loading dose (m)								
SOI	84.40 ± 9.04	80.37 ± 7.66	14.87 ± 1.28	14.37 ± 0.96	97.67 ± 1.30	97.73 ± 1.23	1.60 ± 0.50	1.77 ± 0.43
2	80.50 ± 11.35	81.0 ± 7.78	15.10 ± 0.92	14.70 ± 1.15	94.10 ± 3.24	93.07 ± 4.79	2.27 ± 0.64	2.17 ± 0.38
4	78.87 ± 10.93	76.9 ± 6.95	14.87 ± 1.04	14.47 ± 1.11	90.30 ± 3.35	89.53 ± 4.08	2.43 ± 0.56	2.47 ± 0.63
6	76.63 ± 11.65	74.2 ± 7.08	15.00 ± 1.41	15.13 ± 1.25	83.47 ± 5.34	83.07 ± 4.50	2.87 ± 0.97	3.10 ± 0.55
8	75.47 ± 11.89	73.9 ± 8.44	14.20 ± 0.55	14.23 ± 0.50	79.33 ± 6.43	77.40 ± 6.09	3.13 ± 0.94	3.43 ± 0.68
10	74.47 ± 12.08	71.53 ± 8.46	14.53 ± 1.07	14.47 ± 0.94	75.90 ± 6.52	75.83 ± 5.16	3.73 ± 0.45	3.67 ± 0.66
Intraoperative (min)								
La	75.00 ± 11.76	77.07 ± 10.30	14.97 ± 1.16	14.63 ± 1.19	82.20 ± 9.13	78.60 ± 6.46	3.17 ± 1.09	3.33 ± 0.66
SOS	69.57 ± 11.25	75.73 ± 10.08*	14.77 ± 1.19	14.57 ± 1.22	80.40 ± 7.58	80.23 ± 4.70	3.33 ± 1.06	3.30 ± 0.70
5	69.00 ± 10.84	76.07 ± 9.47*	14.77 ± 1.17	14.87 ± 1.11	82.67 ± 7.30	81.17 ± 4.56	3.47 ± 0.94	3.13 ± 0.82
10	71.23 ± 10.56	75.47 ± 8.55*	14.00 ± 1.31	14.47 ± 1.57	83.40 ± 6.64	83.33 ± 4.69	3.23 ± 0.77	3.20 ± 0.93
15	72.27 ± 12.87	81.07 ± 11.44*	13.97 ± 1.22	14.33 ± 1.37	83.57 ± 7.84	82.13 ± 7.07	3.00 ± 1.11	3.03 ± 0.96
20	73.07 ± 10.52	80.80 ± 9.50*	14.37 ± 1.16	14.07 ± 1.41	80.90 ± 7.18	80.10 ± 8.35	3.00 ± 0.91	3.17 ± 0.83
25	71.37 ± 12.19	81.30 ± 10.15*	14.37 ± 1.16	14.67 ± 1.16	83.60 ± 6.83	79.73 ± 7.43	3.20 ± 0.81	3.27 ± 0.87
30	70.41 ± 10.53	79.33 ± 9.32*	14.45 ± 1.53	14.22 ± 1.55	83.41 ± 7.20	82.745.28	3.27 ± 0.87	3.22 ± 0.93
35	72.81 ± 11.93	81.52 ± 8.26*	15.00 ± 1.04	14.68 ± 0.95	84.15 ± 4.52	82.684.85	3.28 ± 0.79	3.20 ± 0.87
40	73.00 ± 12.79	83.38 ± 7.72*	15.24 ± 1.14	14.79 ± 1.56	84.24 ± 6.69	81.835.15	3.00 ± 0.91	3.35 ± 0.89
45	71.44 ± 13.84	87.00 ± 15.59*	15.00 ± 1.37	15.67 ± 1.24	84.33 ± 8.15	82.553.33	2.85 ± 0.88	2.82 ± 1.10
50	72.59 ± 13.98	85.82 ± 6.41*	14.24 ± 1.75	14.76 ± 1.35	83.94 ± 6.51	81.715.29	2.79 ± 1.26	2.82 ± 0.75
55	74.87 ± 14.75	84.50 ± 8.07*	14.47 ± 1.41	15.07 ± 1.07	84.85 ± 7.54	85.065.85	2.87 ± 0.83	3.44 ± 0.73
60	77.15 ± 15.32	90.10 ± 10.99*	14.54 ± 0.97	15.20 ± 1.23	82.18 ± 8.70	85.673.11	3.54 ± 0.66	3.00 ± 1.21
Recovery (min)								
0	75.77 ± 11.66	84.73 ± 11.05*	14.53 ± 1.25	13.90 ± 1.27				
5	73.47 ± 12.95	83.30 ± 9.83*	14.60 ± 1.13	14.57 ± 1.46				
10	73.07 ± 11.99	83.17 ± 8.62*	14.57 ± 1.33	14.57 ± 1.10				
15	73.17 ± 13.67	83.43 ± 8.78*	15.00 ± 1.17	15.03 ± 1.00				
20	74.33 ± 14.39	82.00 ± 7.22*	14.50 ± 1.25	14.53 ± 1.22				
25	73.67 ± 13.61	80.97 ± 9.02*	14.33 ± 1.24	14.53 ± 1.31				
30	73.97 ± 12.78	82.40 ± 11.32*	14.53 ± 1.33	14.30 ± 1.26				
60	74.63 ± 11.55	81.63 ± 9.28*	13.40 ± 1.45	13.67 ± 1.47				
120	79.90 ± 7.12	77.62 ± 7.59	14.27 ± 0.91	14.27 ± 0.87				

*Corresponds to statically significant value. SOI: Start of drug infusion, La: Application of local anesthesia, SOS: Start of surgery, Zero: Recovery room reading just after patient shifted, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, RR: Respiration rate, RSS: Ramsay sedation scale, BIS: Bispectral index, SpO$_2$: Oxygen saturation, PR: Pulse rate. ($P<0.05$)

Table 4: Comparison of Aldrete score, amnesia scores, patient satisfaction, and relaxation between study groups

	Dexmedetomidine	Midazolam	χ^2 and *P*
Aldrete score			
After end of surgery	9.83	9.70	*P*=0.226
1 h	9.90	9.97	*P*=0.305
2 h	10	10	*P*=1.000
Amnesia score			
Picture shown remembered			
Yes	24 (80)	6 (20)	χ^2=21.6,
No	6 (20)	24 (80)	*P*=0.001*
Use of bur or surgical instrument, remembered			
Yes	13 (43.30)	13 (43.30)	χ^2=0.0, *P*=1.00
No	17 (56.70)	17 (56.70)	
Suturing remembered or shifting to the ward			
Yes	25 (83.30)	25 (83.30)	χ^2=0.0, *P*=1.00
No	5 (16.70)	5 (83.30)	
Subjects preferring the same sedation and subjects relax during the surgery			
Yes	25 (83.3)	16 (53.3)	χ^2=6.239,
No	5 (16.7)	14 (46.7)	*P*=0.012*

*($P<0.05$)

increase in RSS score in both the group from start of loading dose to 10 min during loading dose. The mean RSS score during intraoperative maintenance dose infusion has minimum value of 2.79 for Group D and 2.82 for Group M while the maximum value was 3.54 and 3.35, respectively. Ustün *et al.*[1] found the similar result, where the RSS score between the two group was comparable. The mean RSS score in their study after the drug infusion was 2.9 ± 1.21 for Group M and 2.90 ± 1.19 for the Group D.

Although we had used both BIS score and RSS score in our study, Ramsay sedation score has certain disadvantages. It is difficult to use for patients having oral surgical operations. The patient is usually draped, and this makes it difficult for the surgeon to observe the patients eyes. It is also inconvenient to get patients to speak during operation, and it is difficult to do a glabellar tap; a loud auditory stimulus would be inappropriate. In contrast, the BIS is easy to use and can be monitored continuously.

In both the group, the incidence of side effects (bradycardia, nausea/vomiting, cough, desaturation, head reeling, and disoriented body movements) was comparable. There were two cases of bradycardia in Group D (PR below 50), while none in Group M. Two patients complained of head reeling in Group M. There was no incidence of any desaturation (SPO$_2$ <92), nausea/vomiting, and cough in any group. Midazolam is well known to cause restlessness and disinhibition (paradoxial reaction) in some patients, causing extreme difficulty in performing surgery, and patients may require flumazenil for reversal. Two of the subjects showed agitated behavior in our study. The drug infusion was stopped, and surgery was started after gap of sometime in these subjects although they could not recall the incident in recovery room when asked.

We have used modified Aldrete score as a criterion for discharging the patient. It involves assessment of respiration pattern, consciousness status, and level of SPO$_2$, BP, and physical activities (motor). A score of 8 or more than 8 out of 10 is sufficient to discharge the patient. We measured the Aldrete score at hourly interval for three times of all the subjects three times, after the surgery. There was no statistically significant difference recorded in the Aldrete score between the two groups. None of the patients in our study required any intervention after the end of surgery. This suggests that all the patients involved in our study were fit to discharge after the end of surgery, without any intervention, this may due to lower dose of sedation and slow rate of infusion used by us, in our study.

Amnesia may or may not be an advantage to patients. Some may wish to avoid the recall of unpleasant experience in surgery, but others dislike having memory loss. It is well known that midazolam has a potent anterograde amnesic effect. On the other hand, dexmedetomidine infusion also results in impairment of memory and psychomotor performance, according to Hall *et al*.[18] In our study, 20% of patients of Group D had amnesia of pictures shown at the end of drug infusion, whereas 80% of Group M had the same. However, the amnesic effect of midazolam rapidly diminished with time, and

a comparable number of patients in both groups could remember the surgical procedures, such as sound of bur used, and suturing done intraoperative. Hall *et al*.[18] reported amnesic effect of dexmedetomidine in half of their patients when administered at a dose of 6 µg/k/h for 10 min continued by 0.2 or 0.6 µg/kg/h infusion for 50 min. In our study, lesser amnesic score of Group D may be due to lower dose used by us (1 µg/kg for 10 min and 0.5 µg/kg for maintenance). Cheung *et al*.[14] had similar findings to our study.

In this study, when patients were asked about the choice of anesthetic drug in case of a similar surgery in future, majority 83.3% voted in favor of dexmedetomidine as compared to 53.3% for midazolam, and the data were statistically significant. Similar result was obtained by Fan *et al*.[15] and Cheung *et al*.[14] in their study. Ustün *et al*.[15] had found a comparable visual analog scale score of satisfaction for Group D (9.70) and Group M (9.05) in their study.

In the recovery room, just before discharging, when the subjects were asked, whether they were relaxed during the surgery (yes/no), more number of subjects were replied positively in Group D (83.3%) than in Group M (53.3%), and the result was statistically significant also. Cheung *et al*.[14] and Fan *et al*.[1] had a comparable result in their study.

CONCLUSION

Dexmedetomidine is a comparable alternative to midazolam for IV sedation in day care oral and maxillofacial surgery under local anesthesia. It is the preferred drug when a lower heart rate and BP or less amnesia is needed. It seems to be a reliable and safe drug providing a sedation level without any serious side effects.

Declaration of patient consent
The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest
There are no conflicts of interest.

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