Original Article

DOI: 10.7860/JCDR/2021/49206.15294

Anaesthesia Section

Comparison of Dexmedetomidine vs Midazolam for Sedation during Awake Fiberoptic Intubation in Oral Cancer Surgeries- A Randomised Clinical Study

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ABSTRACT

Introduction: Fiberoptic nasotracheal intubation is a prime method for managing difficult airway in patients. Besides local blocks, some sedation is required during the procedure to make it more tolerable to the patients. Dexmedetomidine (DEX) and Midazolam (MDZ) can be used for this purpose.

Aim: To compare dexmedetomidine versus midazolam for sedation and intubating condition during Awake Fiberoptic Intubation (AFOI) in patients undergoing oral cancer surgeries.

Materials and Methods: This was a prospective randomised double blind study on total of 60 patients randomly allocated into group 1(MDZ) and group 2(DEX). Group 1 received intravenous (i.v.) Midazolam 0.05 mg/kg bolus in 10 mL normal saline over 10 minutes followed by 0.1 mg/kg/hr infusion titrated upto 0.2 mg/kg/hr to achieve a Ramsay Sedation Score (RSS) ≥2. Group 2 (DEX) received i.v. Dexmedetomidine 1 µg/kg bolus in 10 mL normal saline over 10 minutes followed by infusion at the rate of 0.2 µg/kg/hr titrated upto 0.7 µg/kg/hr to achieve a RSS ≥2. Comfort Scale values, haemodynamic parameters, patient's tolerance score and patient's satisfaction score (24 hours after the surgery) were assessed. Significance was calculated using Student t-test. The number of patients with adverse effects was compared using Chi-square test.

Results: In the total sample of 60 patients (30 subjects in MDZ group and 30 subjects in DEX group). The demographic data, blood pressure and Oxygen(O_2) saturation were comparable. Significant change in Heart Rate (HR) was observed in group MDZ while HR was stable in DEX group ($p<0.001$). Group DEX patients were more comfortable and had greater endurance with tolerance score <2.5 compared to MDZ group >2.5 ($p<0.001$) and had an acceptable level of RSS. After 24 hours, DEX group patients judged their sedation more positively than MDZ group with a score of 6.16 vs. 3.6 ($p<0.001$).

Conclusion: Both Midazolam and Dexmedetomidine are effective for AFOI. But Dexmedetomidine provided better patient comfort and satisfaction along with stable haemodynamics.

Keywords: Comfort score, Consious sedation, Difficult airway, Patient satisfaction score, Tolerance score

INTRODUCTION

The Awake Fiberoptic Intubation (AFOI) is the recomended technique for securing airway in recognized difficult cases while keeping the patient conscious but sedated with intact respiratory drive. In oral cancer surgeries, there is potential for difficult airway due to restricted mouth opening, distorted upper airway anatomy by tumor expansion or previous surgery, surgical scar, radiation fibrosis [1]. Though general anesthesia can be given to such patients for intubation through the nasal route but the safest plan for most cases is to keep the patient conscious and perform tracheal intubation under topical anesthesia.

Sedation can be used during such procedure for better patient cooperation and the ideal sedative for AFOI would be the one which provide patient comfort and good intubating conditions and at the same time maintain a patent airway and ventilation. It should have analgesic, anxiolytic, amnesic properties, should suppress the cough and gag reflex with minimal side effects [2].

Many medications, such as fentanyl, and remifentanil are used for AFOI. However, they have many undesirable effects like loss of airway control, respiratory and cardiovascular depression, especially when these are used at high doses [3-5]. Dexmedetomidine is a selective alpha-2-adrenoceptor agonist that can cause sedation, anxiolysis, sparing with minimal respiratory depression and reduced salivary secretion; which might be advantageous for patients undergoing awake fiberoptic [6].

Singh P et al., found that DEX group patient had lower total comfort score and five point Fiberoptic Intubation (FOI) score than in midazolam group [7]. It was also observed in another study that patients in DEX-MDZ group were significantly calmer and more co-operative during AFOI than in patients with MDZ alone [3].

As not much literature has been found on use of DEX vs MDZ for AFOI in oral cancer surgery, so this study was planned to compare the effects of DEX vs MDZ for use in AFOI with the primary objective to assess the patient comfort score, patient tolerance and satisfaction score and secondary objective to compare the haemodynamic variables and evaluate the side-effects, if any, during AFOI.

MATERIALS AND METHODS

This randomised, double-blind, prospective study was conducted in patients undergoing awake fibreoptic intubation for oral cancer surgeries under sedation between October 2019 to February 2020. The study protocol was approved by the Institutional Ethics Committee (172/MC/EC/2019) and written informed consent was taken from each patient. (CTRI number 2019/08/020698 registered on 13/08/2019).

Sample size calculation: A sample size of 15 cases in each group was required at 95% confidence interval and 80% power to verify the expected difference of 0.7±0.63 in mean tolerance score in both groups as per the seed article [7]. Hence, for study purpose the sample size was increased to 30 in each group. This sample size was adequate to cover patient comfort score, satisfaction score and haemodynamic variables.

Inclusion criteria: American Society of Anaesthesiologists (ASA) grade II and III patients, age between 18 to 60 years and weight 40 to 70 kg, undergoing oral cancer surgeries were included.

Exclusion criteria: Patients having allergy to the drugs involved in the study, with bleeding disorders, cardiovascular diseases and alcohol abuse were excluded from the study.

Patients were randomly assigned to group 1 (MDZ) and group 2 (DEX) (each containing 30 patients). Random allocation into these groups was done by computer generated random numbers and group allocation was placed in sealed, opaque envelope on initial randomisation. Patients as well as researcher were blinded to the study drug [Table/Fig-1].

On arrival of patient in the operation theatre patient was identified, overnight fasting status was confirmed, pre-anaesthetic checkup was done and written informed consent was taken from each participant. All routine monitors were attached and baseline parameters like Heart Rate (HR), Systolic blood Pressure (SBP), Diastolic Blood Pressure (DBP), Oxygen (O_2) saturation were noted. Peripheral i.v. line secured and i.v. Fluid infusion ringer lactate started join both groups.

Premedication was done with inj. ranitidine 50 mg i.v. inj. metoclopramide 10 mg i.v, inj. Glycopyrrolate (0.005 mg/kg) i.v. Xylometazoline nasal drops were put in both nasal passages. Patients were pre-oxygenated for three minutes. Glossopharyngeal nerve was blocked topically with 10% lidocaine spray. The long spray nozzle was inserted into both the nostrils and the mouth and 2-3 puffs were given to anaesthetise the nasopharynx and oropharynx respectively.

For superior laryngeal nerve block, patient was asked to extend his/her neck. Then after identifying the greater cornua of hyoid bone, a 25 gauge needle attached to a 5 mL syringe with 2% lignocaine was inserted inferior to the cornua. The needle was retracted marginally after contacting the greater cornua and 1 mL of Local Anaesthetic (LA) was deposited. Same was repeated on the opposite side.

Translaryngeal block was given for recurrent laryngeal nerve. Cricothyroid membrane was identified. A 5 mL syringe with LA with a 22-gauge needle was advanced until air was aspirated into the syringe. A 2 mL of LA (4% Lidocaine) was then injected; inducing coughing that disperses the LA.

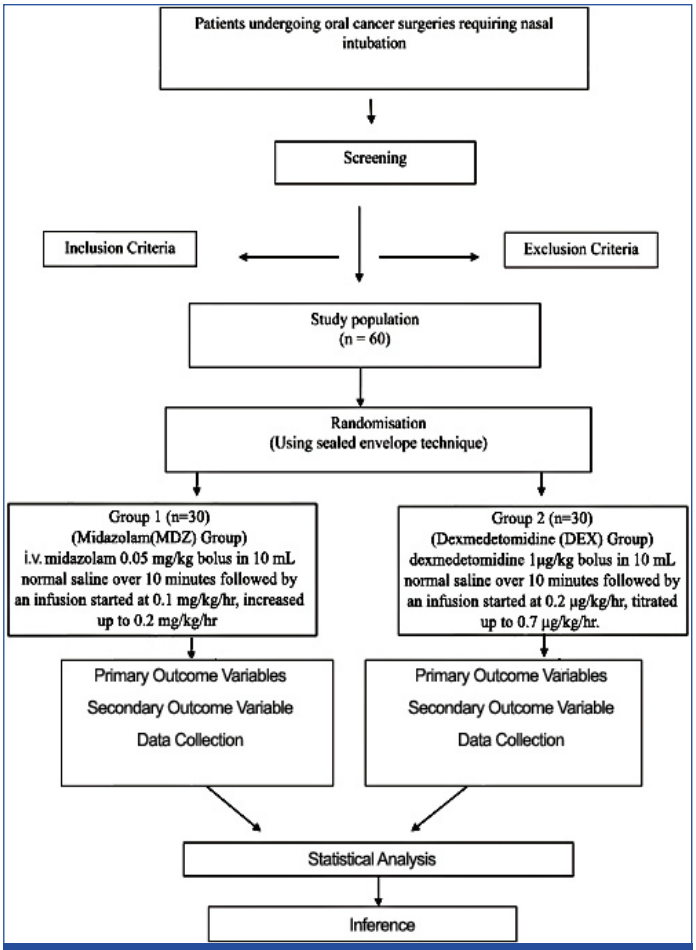
Group 1 (MDZ): Subjects received i.v. midazolam 0.05 mg/kg bolus in 10 mL normal saline over 10 minutes followed by an infusion started at 0.1 mg/kg/hr, increased upto 0.2 mg/kg/hr until they were adequately sedated as defined by a Respiratory Severity Score (RSS) ≥2 [Table/Fig-1].

Group 2 (DEX): Subjects were given dexmedetomidine 1 µg/kg bolus in 10 mL normal saline over 10 minutes followed by an infusion started at 0.2 µg/kg/hr, titrated upto 0.7 µg/kg/hr until they were adequately sedated i.e., (RSS ≥2) [Table/Fig-1].

A lubricated flexometallic (armored) Endotracheal Tube (ETT) of appropriate size was mounted over the fiberscope and introduced. After visualisation of the glottis and vocal cords, the fiberoptic was maneuvered into the trachea through the vocal cords. Flexometallic ETT was passed over into the trachea and positioned 2-3 cm above the carina. The cuff inflated, and the fiberscope withdrawn. After intubation, study drugs were discontinued.

Comfort Scale [7] values [Appendix-1] were recorded during pre-oxygenation, at introduction of fiberoptic scope (time point designated as FOS), and at introduction of the ETT (time point designated as ET). The maximum value of total comfort score is 35. A maximum of five points were given to seven parameters- Alertness, Calmness, Respiratory response, Crying, Physical movement, Muscle tone and Facial tension. Higher scores denote lesser comfort.

A person who was blinded to the study group assessed patient's reaction (Tolerance score) [7] to placement of the fiberoptic scope and the ETT on a scale of 1 to 5 [Appendix-2]. Haemodynamic parameters, including HR, SBP, and DBP, as well as oxygen saturation, were recorded as baseline then at the end of loading dose of study drug and then every minute until the placement of ETT and than one minute and three minute after intubation.



[Table/Fig-1]: CONSORT flow diagram.

Anaesthesia was induced with Inj. propofol 2mg/kg intravenously slowly and Inj. Atracurium loading 0.5 mg/kg. Anaesthesia was maintained with 40% O_2 +60% N_2O, Inj. Atracurium 0.1 mg/kg and Sevoflurane 1-2 Minimum Alveolar Concentration (MAC) and the surgical procedure proceeded as planned. At the end of surgery, neuromuscular blockade was reversed with Inj. Neostigmine 0.05 mg/kg i.v. and Inj. Glycopyrrolate 0.01 mg/kg i.v. and extubation was individualised as per the type of surgery and patient was shifted to recovery room. After the surgery, each patient was questioned (within 24 hrs) to assess his/her experience and recall of the procedure with the help of seven questions (Patient's satisfaction) [Appendix-3] [7].

STATISTICAL ANALYSIS

Statistical analysis was performed with Statistical Package for Social Sciences (SPSS) version 21.0. Data was presented in Microsoft (MS) Excel spreadsheet. Sex and ASA grade of patients were presented as numbers and were compared among groups using Chi-square test. Age, weight, HR, SBP, DBP, SpO_2 was summarised in form of mean±SD. The difference in mean was analysed using the student t-test. Total comfort score, tolerance score and satisfaction score were summarised in form of mean±SD. Significance was calculated using Student t-test. The number of subjects with adverse effects was compared using Chi-square test. Significance level was taken as p-value <0.05.

RESULTS

In the present study total 60 subjects were included, 30 subjects in each group: group 1 (midazolam group) and group 2 (dexmedetomidine group), comparative analysis was done and the results were tabulated.

There was no statistically significant difference between the groups with regards to age, sex, weight and ASA status (p-value >0.05) [Table/Fig-2].

Variables	Group 1	Group 2	p-value
Age (years)	44.6±10	42.27±10.52	0.382 (Student t-test)
Weight (kg)	57.4±9.38	58.87±8.98	0.539 (Student t-test)
Sex (M/F)	23/7	25/5	0.747(Chi-square test)
ASA status (II:III)	24/6	25/5	0.716 (Chi-square test)

[Table/Fig-2]: Demographic data of both groups.
ASA: American society of anaesthesiologists

The mean total comfort scores were significantly higher in MDZ group (group 1) during fiberoscopy (22±4.857 vs. 15.7±2.322), p-value <0.001 and during introduction of ET tube (27.17±4.793 vs. 20.67±2.617), p-value <0.001 showing lesser comfort in MDZ Group [Table/Fig-3].

Variables studied	Mean total comfort score			Mean tolerance score		
Timing of measurement	Group 1	Group 2	p-value (Student t-test)	Group 1	Group 2	p-value (Student t-test)
During pre-oxygenation	15±2.477	14.1±1.9	0.120			
During insertion of FOS#	22±4.857	15.7±2.322	**<0.001**	2.567±0.85	1.467±0.50	**<0.001**
During ET##	27.17±4.793	20.67±2.617	**<0.001**	3.533±1.00	2.167±0.46	**<0.001**

[Table/Fig-3]: Mean Total Comfort Score and Tolerance Score in both groups.
#Fiberoptic scope; ##Endotracheal intubation, MDZ: Midazolam; DEX: Dexmedetomidine
p-value <0.05 considered statistically significant

The tolerance score was also significantly higher in MDZ Group during fiberscopy (2.567±0.8584 vs. 1.467±0.5074), p-value <0.001 and ET tube introduction (3.533±1.008 vs 2.167±0.4611), p-value <0.001 denoting lesser tolerance in Group 1 [Table/Fig-3].

Within 24 hours of surgery, patients judged their own AFOI experience. Patients in DEX group were more positive regarding their sedation. Also, the DEX group patients reported less pain and discomfort during the procedure. The overall satisfaction score was more (6.167±1.416) with the DEX group patients, compared with the MDZ patients' satisfaction score (3.6±1.886). Patients were more satisfied in DEX Group and the difference was significant, p-value <0.001 [Table/Fig-4].

Questions	Group 1	Group 2	p-value
Q1	3.1±0.4807	2.333±0.4795	**<0.001**
Q2	2.633±0.4901	2.133±0.4342	**<0.001**
Q3	1.633±0.4901	1.7±0.4661	0.591
Q4	2±0	1.967±0.1826	0.321
Q5	1.833±0.379	1.3±0.4661	**<0.001**
Q6	3.034±0.6805	2.069±0.5299	**<0.001**
Q7	3.6±1.886	6.167±1.416	**<0.001**

[Table/Fig-4]: Mean Patient satisfaction score (questionnaire) in both groups.

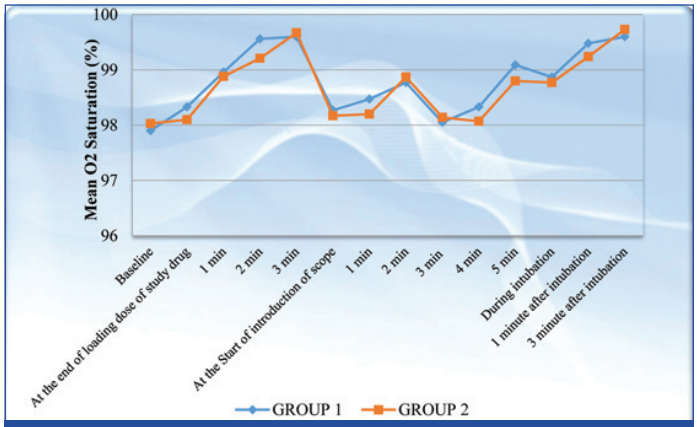
From the start of introduction of scope, MDZ Group subjects showed a >10% rise in mean HR from the baseline till three minute after intubation while DEX Group patients were more stable and this difference was statistically significant, p-value <0.05 [Table/Fig-5]. Mean arterial pressure of both the groups was comparable. There was a transient fall in mean arterial BP after the administration of study drug in both the groups which was slightly more in DEX Group but was not statistically significant throughout the study duration, p-value >0.05 [Table/Fig-6]. Both the groups were comparable in terms of baseline O_2 saturation (97.9±1.125% vs 98.03±1.377%), p-value >0.05. There was no significant difference in mean O_2 saturation between the groups throughout the procedure and till three minute after intubation, p-value >0.05 (Student t-test). Both the groups maintained their SpO_2 throughout the procedure [Table/Fig-7].

Time interval	Group 1 Mean±SD (beats/minute)	Group 2 Mean±SD (beats/minute)	p-value (Student t-test)
Baseline	98.37±14.28	95.07±15.6	0.396
At the end of loading dose of study drug	99.27±15.34	96.07±14.05	0.403
1 min	96.44±13.67	94.08±12.41	0.531
2 min	99±15.5	95.86±13.87	0.556
3 min	95±11.05	100.3±16.37	0.552
At the start of introduction of scope	114±20.38	95.07±15.6	**<0.001**
1 min	112±20.85	92.77±15.7	**<0.001**
2 min	111.2±20.66	94.93±16.41	0.001
3 min	109.3±15.63	97.09±16.2	0.019
4 min	116.5±7.891	95.33±16.58	**<0.001**
5 min	103±16.22	91±12.22	0.073
During intubation	115±21.08	95.53±14.56	**<0.001**
1 min after intubation	112.7±19.65	94.83±14.89	**<0.001**
3 min after intubation	112.3±16.37	94.93±15.55	**<0.001**

[Table/Fig-5]: Mean HR between both the groups.
HR: Heart rate

Time interval	Group 1 Mean±SD (MDZ, mmHg)	Group 2 Mean±SD (DEX, mmHg)	p-value (Student t-test)
Baseline	103.8±8.054	103.5±9.895	0.890
At the end of loading dose of study drug	102.7±9.188	102.1±10.64	0.816
1 min	102.2±7.192	101.1±8.597	0.627
2 min	101.6±7.555	101.1±10.27	0.879
3 min	104.2±7.396	95.5±11.9	0.190
At the Start of introduction of scope	98.7±7.043	97.93±10.6	0.743
1 min	94.83±7.437	94.2±9.894	0.780
2 min	93.83±9.311	91.13±12.04	0.335
3 min	89.32±10.03	83.57±22	0.300
4 min	90.62±5.059	92.6±7.89	0.444
5 min	91.09±7.049	89.1±8.647	0.568
During intubation	93.13±11.68	91.03±12.76	0.509
1 min after intubation	90.31±12.59	87.8±15.77	0.498
3 min after intubation	82.9±13.95	81.16±15.35	0.647

[Table/Fig-6]: Mean arterial pressure (mmHg).



[Table/Fig-7]: Trends of SpO_2, (partial pressure of oxygen).

DISCUSSION

Fibreoptic nasotracheal intubation is an important and safe method for securing the airway in anticipated difficult airway cases. It is always preferable to keep patients in a state called 'conscious sedation'. Available conventional sedatives can cause respiratory depression, especially when used in higher doses. Also, there is

risk of cardiovascular depression and loss of airway control [3-5]. Dexmedetomidine has gained confidence for use during fibreoptic intubation as it does not cause respiratory depression and at the same time produces sedation and analgesia. It also helps in keeping haemodynamic parameters stable [8]. So, this study was planned with the aim to compare the effects of Dexmedetomidine versus midazolam for sedation and intubating condition during awake fiberoptic intubation.

The present study demonstrated that Dexmedetomidine i.v. 1 µg/kg bolus over 10 minutes, followed by infusion of 0.2-0.7 µg/kg/hr provided better patient comfort and tolerance, higher patient satisfaction, and reduced haemodynamic responses than Midazolam. However fibreoptic intubation could be performed in both groups of patients without any complications. The present study mainly focused on comparing the drugs for their ability to provide patient comfort, making the procedure tolerable, and to provide an acceptable level of satisfaction to the patients.

During fibroscopy and intubation, a rise in the comfort score was recorded in both the groups which was significantly more in MDZ group (more than 20), showing lesser comfort in MDZ Group i.e., DEX group patients were more calm (comfort score 20 or less). The findings of this study correlate with Singh P et al., who used the same comfort scale and reported that the DEX group had lesser comfort score than MDZ group [7]. In a study done by Bergese SD et al., also, the comfort score was well above 20 in MDZ group, similar to the present study [3]. The greater comfort with dexmedetomidine could be because of its additional analgesic property which Midazolam lacks.

Mean tolerance score showed a statistically significant difference between the groups in the present study. During fiberoscopy and intubation, DEX group showed lesser scores (1.46 and 2.16) than MDZ group (2.56 and 3.53) denoting better tolerance with dexmedetomidine. Similar finding was seen in the study by Singh P et al., in which tolerance score during fiberscopy and intubation was less in DEX group (3.40 and 1.40) in comparison to MDZ group (4.40 and 2.10) showing better tolerance with dexmedetomidine [7]. The findings with respect to tolerance score were in agreement with Chu KS et al., [9]. They noted that post-intubation score in the DEX group was between (1-3) similar to DEX group in the present study (2.1) [9].

These studies emphasise that sedation with dexmedetomidine is unique from other conventional drugs that it characteristically resembles natural sleep. Hence, the patients were easily arousable with verbal or mild tactile stimulation, and once aroused, they were well cooperative and communicative. This was reflected in our tolerance score which assessed the patient's reaction during the procedure.

The questions referring to the level of sedation, recall of the procedure and any discomfort during the procedure all came out to be in favour for Dexmedetomidine, and when the patients were asked to grade their overall experience of the procedure on a scale of 0-10 where 0=complete dissatisfaction and 10=complete satisfaction, the DEX group patients reported their sedation more satisfying (score of 6.1) than MDZ group (score of 3.6). The satisfaction score in DEX group in study of Singh P et al., was even more than 8 [7]. Similar to the index study Sayeed T et al., recorded that when patients were asked to evaluate the discomfort experienced during fibrescopy and intubation process on a scale of 10 (1 is minimum and 10 is maximum discomfort)in DEX group, only 5 patients showed discomfort more than satisfaction score of 4 [10].

Present findings were also strengthened by Chopra P et al., [11]. They observed that 8% (DEX) vs 0% (placebo) and 84% (DEX) vs 14% (placebo) had excellent and good grades respectively in the satisfaction score which is in conformity with the index study [11].

The greater satisfaction in group DEX in this study could be explained, atleast in part, by the additional analgesic property of dexmedetomidine that could have contributed to improved patient's perception of this form of sedation. Although the prime focus was on patient comfort and satisfaction in haemodynamic variables were also given due importance in this study.

From the start of introduction of scope, there was a rise (>10% from baseline) in HR in MDZ Group which was not observed in DEX Group which persisted till three minutes after intubation. This difference was statistically significant between the groups at all the time points from the start of introduction of scope, p-value >0.05. Bradycardia which is common with dexmedetomidine was not observed. Similar results were obtained by Singh P et al., during Fiberoscopy and intubation, the mean heart rate was lower in DEX group than midazolam [7]. They observed that during fibroscopy and intubation, HR gradually increased to 97.7±2.830 at three minutes after intubation in MDZ group while it decreased to 65.60±2.633, p-value <0.01 in DEX group. The present study results were in accordance with Fadel N et al., [12]. They reported that heart rate significantly decreased in dexmedetomidine group before intubation, with p-value less than 0.05 with higher mean among midazolam group [12].

Similar reaction to Dexmedetomidine has been reported by Niyogi S et al., [8]. They reported that HR significantly increased (92.67±11.47/min) from baseline (74±14.54/min) in the control group during FOB (p-value <0.001), whereas in Group DEX, HR was significantly decreased (64.25±8.92/min) during FOB from baseline (72+12.54/min) (p-value <0.001). Intergroup comparison of changes in HR during AFOB was also statistically significant (p-value <0.001) [8]. Dexmedetomidine causes a decrease in HR by an inhibition of central sympathetic outflow that overrides the direct effect on the vasculature could have contributed to stable HR during Fibroscopy and Endotracheal intubation with the DEX group of patients in the present study could be a reflection of less sympathetic discharge. Bradycardia from DEX may not have occured in the present study by the use of glycopyrrolate.

In the present study, mean blood pressure showed no significant difference between both the groups throughout the procedure. The results are same as found by Singh P et al., They found that no significant difference in mean blood pressure was noted between the two groups. Though a fall in blood pressure in both the groups (MDZ and DEX) as compared with the baseline was noted during fiberoscopy [7].

Bloor BC et al., stated that dexmedetomidine bolus causes a transient rise in blood pressure and a decrease in HR followed by a fall in blood pressure. A slow loading bolus of 1 µg/kg administered during 10-20 minutes followed by an infusion of 0.2-0.6 µg/kg/hr are recommended for less haemodynamic alterations [13]. Ebert T and Maze M; reported that a low dose of dexmedetomidine inhibits release of nor-epinephrine from sympathetic terminal resulting in hypotension but a high doses causes hypertension due to vasoconstriction caused by direct stimulation of α-2 receptors on blood vessels [14]. This biphasic response was not seen in the present study, which may be because of reduction of dexmedetomidine bolus dose to 1 µg/kg bolus given slowly over 10 minutes.

No significant difference in SpO_2 was noted between the groups throughout the study procedure, p-value >0.05. There was no desaturation in both the groups. Even though the difference of mean SpO_2 was insignificant and none had SpO_2 <90% three patients in Group MDZ had a slight fall in saturation (91%-93%) which was not there in DEX group showing the slight propensity to respiratory depression with Midazolam and the respiratory sparing effect of dexmedetomidine. The results with regard to SpO_2 are similar to with Singh P et al., [7]. They observed that SpO_2 values were well maintained in both the patients groups, (midazolam and dexmedetomidine) [7]. Niyogi S et al., reported that all the patients

of both groups (DEX vs control) maintained SpO_2 level (98%-99%) during the study period and the changes were not significant (p-value=0.321) [8].

But Fadel N et al., observed that there was a statistically significant difference between two study groups (MDZ+Fentanyl) vs (DEX+Fentanyl) at three minutes and six minutes after starting study drugs with higher mean in dexmedetomidine group [12]. This difference in findings from this study could be attributed to the use of fentanyl in the above studies which is known for its respiratory depression which could be accentuated by Midazolam [4]. Dexmedetomedine is acknowledged for its unique respiratory sparing sedation.

The benefits of prompt pre-oxygenation were well reflected in the present study. Desaturation was not observed in any of the patients. None of the patients encountered bradycardia (HR <50 bpm) or hypoxia (SpO_2 <90%) during the study period. Two patients in both the groups had hypotension (SBP <80 mmHg) during the study period. We were able to manage hypotension in all the patients with a bolus of i.v. fluid. Nine patients in Group MDZ and four patients in Group DEX had hypertension (DBP >100 mmHg) during the study period. This difference was not statistically significant, p-value >0.05. The hypertension resolved in all the cases after induction with Inj propofol.

Limitation(s)

Invasive blood pressure monitoring could have been done to be more accurate. The comfort, tolerance and satisfaction scores were assessed by the researcher on the subjective response of the subjects, there may be variability of responses elicited, and it is difficult to standardise the variables. Some patients may tolerate intubation better than others at same levels of sedation and may add to bias in the study.

CONCLUSION(S)

Dexmedetomidine i.v. at 1 µg/kg bolus over 10 minutes, with maintenance rates of 0.2-0.7 µg/kg/hr provided better patient comfort, higher patient satisfaction, with greater tolerance and reduced hemodynamic responses than midazolam to the Awake Fiberoptic Intubation (AFOI) procedure.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Mar 15, 2021
- Manual Googling: Jun 17, 2021
- iThenticate Software: Jul 31, 2021 (16%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Mar 14, 2021**
Date of Peer Review: **May 15, 2021**
Date of Acceptance: **Jun 19, 2021**
Date of Publishing: **Aug 01, 2021**

Appendix 1: Comfort scale

Parameter	Score	Assessment
Alertness	1	Deeply asleep
	2	Lightly asleep
	3	Drowsy
	4	Fully awake and alert
	5	Hyper alert
Calmness	1	Calm
	2	Slightly anxious
	3	Anxious
	4	Very anxious
	5	Panicky
Respiratory response	1	No coughing
	2	Occasional cough
	3	Frequent coughing
	4	Coughing regularly
	5	Choking
Crying	1	Quiet breathing, no crying
	2	Sobbing or gasping
	3	Moaning
	4	Crying
	5	Screaming
Physical movement	1	No movement
	2	Occasional light movements
	3	Frequent slight movements
	4	Vigorous movements limited to extremities
	5	Vigorous movements including torso and head
Muscle tone	1	Muscles totally relaxed
	2	Reduced muscle tone
	3	Normal muscle tone
	4	Increased muscle tone and flexing of fingers and toes
	5	Extreme muscle rigidity
Facial tension	1	Facial muscle totally relaxed
	2	Facial muscle tone normal
	3	Tension evident in some facial muscles
	4	Tension evident throughout facial muscles
	5	Facial muscles contorted and grimacing
Total score	35	

Appendix 2: Patient tolerance score

Score	Assessment
1	No reaction
2	Slight grimacing
3	Severe grimacing
4	Verbal objection
5	Defensive movements of head hands or feet

Appendix 3: Questionnaire assessment at 24 hours after surgery for patient satisfaction

Question	Possible answers
1.How did you find the sedation for your procedure?	1=Excellent
	2=Good
	3=Fair
	4=Poor
2. Do you consider any adjustment was needed in the amount of sedation you received?	1=Needed less
	2=Right amount
	3=Needed more
3. Do you remember the starting when the scope was introduced?	1=No
	2=Yes
4. Do you remember being awake at any time during the procedure?	1=No
	2=Yes
5. Do you remember the end when the scope was removed?	1=No
	2=Yes
6. Any discomfort you experienced during the procedure?	1=None
	2=Mild
	3=Moderate
	4=Severe
7. Overall on a scale of 10 where one end is complete dissatisfaction and the other end is complete satisfaction how would you rate your satisfaction with your intubation?	0=Complete dissatisfaction
	10=Complete satisfaction