

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

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Abstract

Background and Aims: Fiberoptic nasotracheal intubation is an effective method for the management of patients with difficult airways. Optimal intubating conditions and patient comfort are important while preparing the patient for fiberoptic intubation. The aim of this study is to compare Dexmedetomidine and Midazolam for sedation during awake fiberoptic intubation in oral cancer surgeries. **Methods:** Patients were randomly allocated into two groups. Each consisted of 30 patients. Group 1 (MDZ) Subjects received IV Midazolam 0.05mg/kg bolus in 10ml normal saline over 10 minutes followed by infusion at the rate of 0.1mg/kg/hr titrated upto 0.2mg/kg/hr to achieve a RSS \geq 2. Group 2(DEX) Subjects received IV Dexmedetomidine 1 μ g/kg bolus in 10ml normal saline over 10 minutes followed by infusion at the rate of 0.2 μ g/kg/hr titrated upto 0.7 μ g/kg/hr to achieve a RSS \geq 2. Comfort Scale values, hemodynamic parameters and patient's tolerance was observed. 24 hours after the surgery patient's satisfaction was assessed with a questionnaire. **Results:** The demographic data, systolic and diastolic blood pressures and O₂ saturation were comparable. Significant change in heart rate was observed in group MDZ while heart rate was stable in DEX group (p<0.01). Group DEX patients were more comfortable with comfort score <20 and had greater endurance with tolerance score <2.5 compared to MDZ group (>20/>2.5, p<0.01) and had an acceptable level of sedation. After 24 hours DEX group patients judged their sedation more positively than MDZ group with a score (6.16 vs. 3.6). **Conclusions:** Both Midazolam and Dexmedetomidine are effective for awake fiberoptic intubation. But Dexmedetomidine provided better patient comfort and satisfaction along with stable hemodynamics.

Keywords: Awake Fiberoptic Intubation, Dexmedetomidine, Midazolam

1. Introduction

General anesthesia involves administration of the anesthetic agents to render the patient unconscious, control of the airway and then instrumentation of airway to provide artificial ventilation. When a difficult airway is present, safe option is to achieve tracheal intubation while the patient's consciousness and respiratory drive are

still intact. This is generally referred to as Awake Fibre-Optic Intubation (AFOI) and it has become the accepted gold standard technique for management of a recognized difficult airway.

In oral cancer surgeries there is potential for difficult airway due to limited head and neck mobility, mouth opening, upper airway open space resulting from distorted airway anatomy by tumor expansion or previous

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surgery and fixation of the tissues by tumors, surgical scar or radiation fibrosis¹. Airway management in such patients can be mostly done with general anesthesia induction with or without a muscle relaxant through the nasal route. While the safest plan for most cases is to perform tracheal intubation in conscious patients under topical anesthesia.

Sedation is frequently used to make the process more tolerable to patients. But very often it is not easy to strike a balance between patient comfort and good intubating conditions on the one hand and maintaining ventilation and a patent airway on the other. The ideal sedative for AFOI would provide anxiolysis and a degree of amnesia with a low incidence of recall of the procedure. It should have analgesic properties, suppress the cough and gag reflex, and be safe and easy to titrate with minimal respiratory and cardiovascular side effects².

Many medications, such as fentanyl, remifentanyl, midazolam and propofol, have been reported to be used for AFOI. However, they have many undesirable effects like respiratory depression, loss of airway control and cardiovascular depression, especially when these are used at high doses³⁻⁵. Dexmedetomidine is a selective alpha-2-adrenoceptor agonist that can cause sedation, anxiolysis, analgesic sparing, reduced salivary secretion and minimal respiratory depression; this might be beneficial for patients with a difficult or unstable airway undergoing AFOI⁶.

With this background this study was conducted to compare the effects of Dexmedetomidine and Midazolam on patient comfort, satisfaction and hemodynamic variables during AFOI and to evaluate the side effects if any.

2. Methods

The study protocol was approved by the institutional ethics committee and written informed consent was taken from each patient. The confidentiality of the participants was ensured and the names, initials or hospital numbers are not mentioned anywhere in the manuscript.

A sample size of 15 cases in each group was required at 95% confidence and 80% power to verify the expected difference of 0.7 ± 0.63 in mean tolerance score in both groups as per the seed article⁷. Hence for study purpose

the sample size was increased to 30 in each group to compensate for possible drop outs. This sample size was adequate to cover patient comfort score, satisfaction score and hemodynamic variables.

This study was a prospective, randomized, double blind, interventional study. The study was conducted in patients undergoing oral cancer surgeries with AFOI under sedation between October 2019 to February 2020. Sixty ASA Class II and III patients, aged 18–60 years and weighing 40 to 70 kg, undergoing oral cancer surgeries were randomly assigned (each containing 30 patients) into two groups, Group 1 (Midazolam group) and Group 2 (Dexmedetomidine group). Random allocation into these groups was done by computer generated random numbers. Group allocation was placed in sealed, opaque envelope on initial randomization. Patients were also blinded to the study drug.

Patients with known or admitted alcohol or drug abuse, allergy to the drugs involved in the study, bleeding disorders and existing cardiovascular diseases were excluded from the study.

On arrival of patient in the operation theatre patient was identified, overnight fasting status confirmed, pre-anesthetic checkup checked, consent checked. All routine monitors were attached and baseline parameters like heart rate, systolic blood pressure, diastolic blood pressure, peripheral oxygen saturation were noted. Peripheral Intra-Venous (IV) line secured and IV Fluid infusion ringer lactate started.

Patients were pre medicated with inj. ranitidine 50 mg i.v. inj. metoclopramide 10mg i.v, inj. Glycopyrrolate (0.005mg/kg) iv. Xylometazoline nasal drops were put in both nasal passages. Patients were preoxygenated for 3 min.

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 anaesthetize 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 G needle attached to a 5ml 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 anesthetic

(LA) was deposited. Same was repeated on the opposite side.

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

Group 1 (MDZ) subjects received IV midazolam 0.05 mg/kg bolus in 10 ml normal saline over 10 minutes followed by an infusion of 0.1 mg/kg/hr which was then titrated up to 0.2 mg/kg/hr until they were adequately sedated as defined by a Ramsay Sedation Score (RSS \geq 2).

Group 2 (DEX) patients were given dexmedetomidine 1 μ g/kg bolus in 10 ml normal saline over 10 minutes followed by an infusion of dexmedetomidine 0.2 μ g/kg/hr infusion, which was then titrated up to 0.7 μ g/kg/hr until they were adequately sedated i.e. (RSS \geq 2).

A lubricated flexometallic (armored) Endo-Tracheal Tube (ETT) of appropriate size was mounted over the fiberscope and introduced. After visualization of the glottis and vocal cords the fiberoptic was maneuvered across the vocal cord into the trachea. 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 Scale⁸ values were recorded during Pre-Oxygenation (Pre-Ox), at introduction of fiberoptic scope (time point designated as FOS), and at introduction of the endotracheal tube (time point designated as ET). The maximum value of total comfort score is 35. A maximum of 5 points were given to 7 parameters- Alertness, Calmness, Respiratory response, Crying, Physical movement, Muscle tone and Facial tension. Higher scores denote lesser comfort.

One of the independent, study-blinded observers assessed patient's reaction (Tolerance score)⁷ to placement of the fiberoptic scope and the endotracheal tube on a scale of 1 to 5 (1 = no reaction; 2 = slight grimacing; 3 = severe grimacing; 4 = verbal objection; and 5 = defensive movement of head, hands, or feet). Haemodynamic parameters, including Heart Rate (HR), Systolic Blood Pressure (SBP), and Diastolic Blood Pressure (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 endotracheal tube and 1 minute and 3 minute after intubation.

Anesthesia was induced with Inj propofol 2mg/kg intravenously slowly and Inj Atracurium loading 0.5 mg/kg. Anesthesia was maintained with 40% O₂+60% N₂O, Inj Atracurium 0.1 mg/kg and Sevoflurane 1-2 MAC and the surgical procedure proceeded as planned. At the end of surgery neuromuscular blockade was reversed with Inj Neostigmine 0.05 mg/kg iv and Inj Glycopyrrolate 0.01 mg/kg iv and extubation was individualized as per the type of surgery and patient was shifted to recovery room.

Twenty-four hours after the surgical procedure, each patient was questioned to assess his/her experience and recall of the procedure with the help of 7 questions (Patients satisfaction)⁷ Appendix 1.

Statistical analysis was performed with SPSS-21 statistical software package. Data was presented in MS Excel spreadsheet. Qualitative parameters are presented as numbers and were compared among groups using chi square test. Continuous variables are represented as Mean \pm SD. The difference in mean within the group was analyzed using the paired t test and intergroup comparison using independent sample t-test. Significance level was taken as *P* value < 0.05.

3. Results

A total of 60 patients were enrolled and all patients completed the study. There were no drop outs following recruitment and the patients were included in statistical analysis (Figure 1). In our study there was no statistically significant difference between the groups with regards to age, sex, weight and ASA status (*P*>0.05) (Table 1).

There was no significant difference between mean baseline heart rate between the groups and also heart rates were comparable till the start of introduction of scope. From the start of introduction of scope Group 1 subjects showed a >10% rise in mean heart rate from the baseline till 3 minute after intubation while Group 2 patients were more stable and this difference was statistically significant, *P*<0.05 (Table 2).

Baseline 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 Group 2 but was

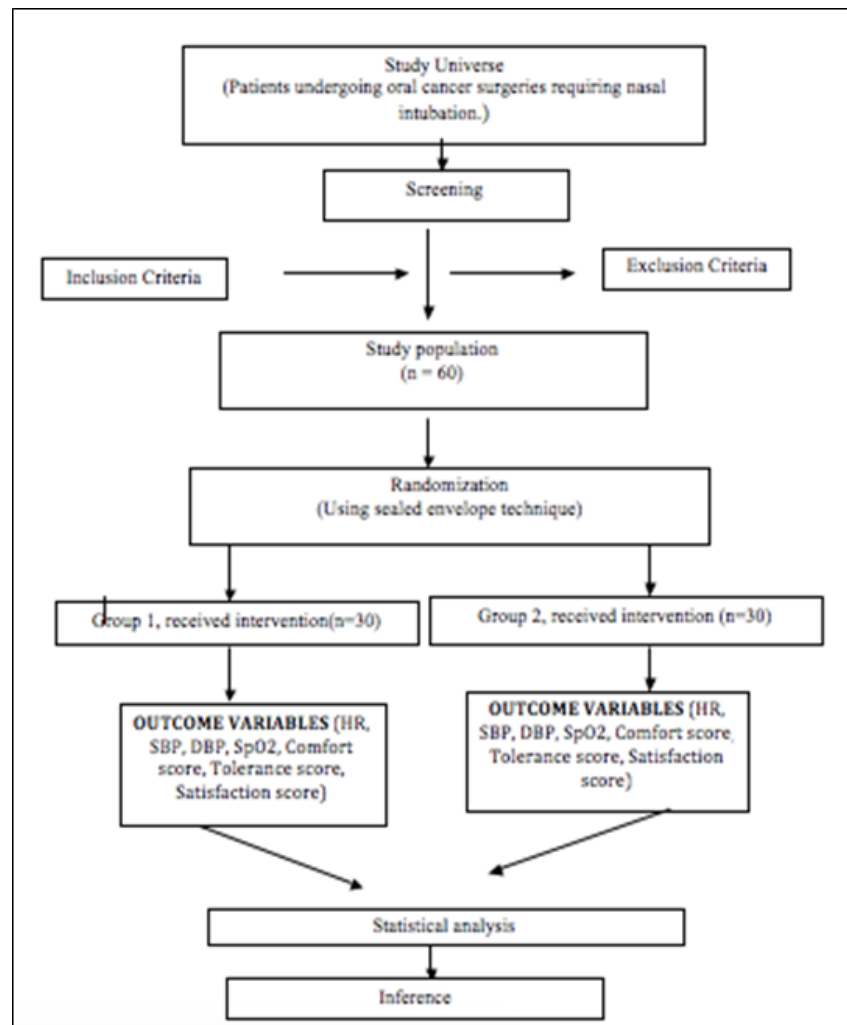


Figure 1. Consort diagram.

Table 1. Demographic parameters

Variable	Group 1	Group 2	P Value
Age (years)	44.6±10	42.27±10.52	0.382
Weight (kg)	57.4±9.38	58.87±8.98	0.539
Sex (M/F)	23/7	25/5	0.747
ASA status (II:III)	24/6	25/5	0.716

Table 2. Comparison of mean Heart Rate between the groups

Time Interval	Group 1		Group 2		P Value
	Mean	SD	Mean	SD	
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 (S)
1 min	112	20.85	92.77	15.7	<0.001 (S)
2 min	111.2	20.66	94.93	16.41	0.001 (S)
3 min	109.3	15.63	97.09	16.2	.019 (S)
4 min	116.5	7.891	95.33	16.58	<0.001 (S)
5 min	103	16.22	91	12.22	.073
During intubation	115	21.08	95.53	14.56	<0.001 (S)
1 minute after intubation	112.7	19.65	94.83	14.89	<0.001 (S)
3 minute after intubation	112.3	16.37	94.93	15.55	<0.001 (S)

not statistically significant throughout the study duration, p value >0.05 (Table 3).

Before the starting of introduction of fiberoptic score the total comfort score was comparable in both the groups. However, the mean total comfort scores were significantly higher in group 1 during fiberoptic (22±2.477 vs. 15.7±2.322), $P<0.001$ and during introduction of ET tube (27.17±4.793 vs. 20.67±2.617), $P<0.001$ showing lesser comfort in Group 1. The tolerance score was significantly higher in Group 1 during fiberoptic (2.567±0.8584 vs. 1.467±0.5074), $P<0.001$ and ET tube introduction (3.533±1.008 vs. 2.167±0.4611), $P<0.001$ denoting lesser

tolerance in Group 1. (Table 4). Patients were more satisfied in Group 2 and the difference was significant, $P<0.05$ (Table 5). Nine patients in group 1 and four patients in group 2 had hypertension (DBP > 100 mm of Hg) during the study period. This difference was not statistically significant, $P> 0.05$.

4. Discussion

Fiberoptic nasotracheal intubation is considered as the gold standard for the management of patients with recognized or anticipated difficult airway. The safety of this

Table 3. Comparison of mean arterial pressure between the groups (mm of Hg)

Time Interval	Group 1		Group 2		P Value
	Mean	SD	Mean	SD	
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 minute after intubation	90.31	12.59	87.8	15.77	0.498
3 minute after intubation	82.9	13.95	81.16	15.35	0.647

Table 4. Mean total comfort score and Mean tolerance score in both groups

Mean total comfort score in both groups			
Time Interval	Group 1	Group 2	P Value
During preoxygenation	15±2.477	14.1±1.9	0.120
During FOS	22±4.857	15.7±2.322	<0.001
During ET	27.17±4.793	20.67±2.617	<0.001
Mean tolerance score in both groups			
FOS	2.567±0.8584	1.467±0.5074	<0.001
ET	3.533±1.008	2.167±0.4611	<0.001

Table 5. Mean Patient satisfaction score (questionnaire) in both groups*

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

procedure is enhanced many fold by keeping the patients awake. Although good topical anaesthesia to the airway can help suppress airway responses to awake fiberoptic intubation, an anxious patient can create considerable difficulty in performing fibroscopy and intubation.

Hence it is always preferable to keep patients in a state called 'conscious sedation'. An ideal sedation regimen should provide patient comfort, abolishing airway reflexes, patient cooperation, hemodynamic stability, amnesia and the maintenance of a patent airway with spontaneous respiration⁷. Available conventional sedatives such as benzodiazepines, opioids and propofol cause respiratory depression, especially when used in higher doses. Also there is risk of cardiovascular depression and loss of airway control³⁻⁵.

Meanwhile Dexmedetomidine has gained confidence worldwide as being a wondrous drug for use during fiberoptic intubation as it produces sedation and analgesia without concomitant depressing respiratory function. It was also gaining popularity for its hemodynamic stability during procedural sedation⁹.

Our 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 and dexmedetomidine infusion resulted in favourable outcomes compared to midazolam.

Our findings correlate with Bergese *et al.* (2010)³, who used the same comfort scale and reported lower comfort scores with combination of midazolam and dexmedetomidine compared to midazolam alone³. On the contrary, addition of fentanyl to midazolam resulted in similar comfort scores as that of dexmedetomidine during fiberoptic intubation as demonstrated by Sayeed *et al.* (2013)¹⁰ the additional analgesic property of fentanyl would have resulted in better comfort scores. The greater comfort with Dexmedetomidine in our study could be because of its additional analgesic property which Midazolam lacks.

Mean tolerance score revealed better tolerance with dexmedetomidine compared to midazolam with is in agreement with findings of Chu *et al.* (2010)¹¹. They noted that Post intubation score representing tolerance to intubation showed more favourable results with dexmedetomidine compared to fentanyl.

Fentanyl and propofol resulted in similar sedation scores for fiberoptic intubation¹².

But when dexmedetomidine was compared with Propofol and Fentanyl, Masoud *et al.* (2013)¹³ concluded that all the scores that quantified patient tolerability and the fiberoptic intubating conditions were significantly better in group D (dexmedetomidine) than both groups.

These studies emphasize 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 which is in concurrence with other studies^{9,10,14}.

The greater satisfaction in group DEX in our study could be explained, at least in part, by the additional analgesic property of dexmedetomidine that could have contributed to improved patients' perception of this form of sedation.

Although our prime focus was on patient comfort and satisfaction hemodynamic variables were also given due importance in our study.

From the start of introduction of scope there was a rise (>10% from baseline) in heart rate in Group 1 which was not observed in Group 2 which persisted till 3 min after intubation. This difference was statistically significant between the groups at all the time points from the start of introduction of scope, $P > 0.05$. Bradycardia which is common with Dexmedetomidine was not observed with midazolam^{7,15-17}. Dexmedetomidine causes a decrease in HR by an inhibition of central sympathetic outflow that overrides the direct effects of DEX on the vasculature. The stable HR during Fibroscopy and Endotracheal intubation with the DEX group of patients in our study could be a reflection of less sympathetic discharge. Bradycardia from dexmedetomidine may have been mitigated 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. Our results are supported by Singh *et al.* (2015)⁷ and Hassani *et al.* (2018)¹⁶ who found no significant difference in the above parameters between Dexmedetomidine vs Midazolam and Dexmedetomidine vs Midazolam-Fentanyl respectively.

Bloor *et al.* (1992)¹⁸ described the cardiovascular response to Dexmedetomidine bolus to be a transient rise in blood pressure and a decrease in heart rate followed

by a fall in blood pressure. A slow loading bolus of 1µg/kg administered during 10-20 minutes and maintenance doses ranging from 0.2-0.6µg/kg/hr are recommended for less hemodynamic alterations.

Ebert *et al.* (2004)¹⁹ reported that high doses of Dexmedetomidine cause hypertension due to vasoconstriction caused by direct stimulation of α-2 receptors on blood vessels and low dose inhibits release of nor-epinephrine from sympathetic terminal resulting in hypotension.

This biphasic response was not noted in our study, which may have been abolished by reduction of dexmedetomidine bolus to 1µg/kg bolus and an increase of the duration of bolus to 10 minutes²⁰.

Fadel *et al.* (2017)¹⁵ observed that decrease in saturation with midazolam and fentanyl compared to dexmedetomidine fentanyl combination. Dexmedetomidine is acknowledged for its unique respiratory sparing sedation. The benefits of prompt preoxygenation were well reflected in our study. Desaturation was not observed in any of the patients.

None of the patients encountered bradycardia (HR < 50 bpm) or hypoxia (SpO₂ < 90%) during the study period. 2 patients in both the groups had hypotension (SBP < 80 mm of Hg) during the study period. We were able to manage hypotension in all the patients with a bolus of IV fluid.

The study has some limitations. The patient population was small. We suggest large randomized controlled trials have to be carried out on a larger population. 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 standardize the variables. Some patients may tolerate intubation better than others at same levels of sedation and may add to bias in the study.

5. Conclusion

Dexmedetomidine iv at 1µg/kg bolus over 10 minutes, with maintenance rates of 0.2-0.7µg/kg/hr provided better patient comfort, higher patient satisfaction, and reduced hemodynamic responses than Midazolam.

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Appendix

Comfort Scale (Table 4)⁸

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	

Patient Tolerance Score (Table 5)⁷

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

Questionnaire Assesment at 24 Hours After Surgery for Patient Satisfaction (Table 6)⁷

Questions	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

Ramsay Sedation Scale²¹

Level	Response
1	Anxious, agitated, restless
2	Oriented, tranquil
3	Responds to commands
4	Asleep, but brisk response to light glabella tap or loud noise
5	Asleep, sluggish response to light glabella tap or loud noise
6	Asleep, no response