Original Article

A comparison of dexmedetomidine plus ketamine combination with dexmedetomidine alone for awake fiberoptic nasotracheal intubation: A randomized controlled study

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Abstract

Background and Aims : We designed a study to compare the effectiveness of dexmedetomidine plus ketamine combination with dexmedetomidine alone in search of an ideal sedation regime, which would achieve better intubating conditions, hemodynamic stability, and sedation for awake fiberoptic nasotracheal intubation.

Materials and Methods: A total of 60 adult patients of age group 18-60 years with American Society of Anesthesiologists I and II posted for elective surgery under general anesthesia were randomly divided into two groups of 30 each in this prospective randomized controlled double-blinded study. Groups I and II patients received a bolus dose of dexmedetomidine at 1 mcg/kg over 10 min followed by a continuous infusion of dexmedetomidine at 0.5 mcg/kg/h. Upon completion of the dexmedetomidine bolus, Group I patients received 15 mg of ketamine and an infusion of ketamine at 20 mg/h followed by awake fiberoptic nasotracheal intubation, while Group II patients upon completion of dexmedetomidine bolus received plain normal saline instead of ketamine. Hemodynamic variables like heart rate (HR) and mean arterial pressure (MAP), oxygen saturation, electrocardiogram changes, sedation score (modified Observer assessment of alertness/sedation score), intubation score (vocal cord movement and coughing), grimace score, time taken for intubation, amount of lignocaine used were noted during the course of study. Patient satisfaction score and level of recall were assessed during the postoperative visit the next day.

Results: Group I patients maintained a stable HR and MAP (<10% fall when compared with the baseline value). Sedation score (3.47 vs. 3.93) and patient satisfaction score were better in Group I patients. There was no significant difference in intubation scores, grimace scores, oxygen saturation and level of recall when compared between the two groups ($P > 0.05$).

Conclusion: The use of dexmedetomidine plus ketamine combination in awake fiberoptic nasotracheal intubation provided better hemodynamic stability and sedation than dexmedetomidine alone.

Key words: Awake, bronchoscopy, dexmedetomidine, fiberoptic, ketamine, sedation

Introduction

Fiberoptic intubation is a valuable technique in securing the airway in predicted difficult intubation scenario, compromised airway, lower airway pathology and when neck extension is to be avoided.[1] In awake fiberoptic intubation under intravenous (IV) sedation patient should remain calm, fall asleep if undisturbed and follow verbal commands. An ideal sedation regime should provide patient comfort, cooperation, amnesia, hemodynamic stability, blunt airway reflexes, and maintain a patent airway with spontaneous ventilation.

Available conventional sedatives such as benzodiazepines, opioids and propofol cause respiratory depression, especially when used in higher doses. Dexmedetomidine, an α_2-adrenoreceptor agonist, is a valuable drug for fiberoptic intubation as it induces sedation and analgesia without depressing respiratory function.[2] In addition, xerostomia is commonly reported by patients. These two effects make dexmedetomidine highly desirable for awake fiberoptic nasotracheal intubation.[3] Unlike patients sedated with propofol, patients receiving dexmedetomidine are easily arousable without expressing irritation.[4] The relative sympatholysis achieved during dexmedetomidine infusions is an additional benefit in a procedure that may lead to elevations of heart rate (HR) and blood pressure.[5]

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It has been suggested that low-dose ketamine infusion (4 mcg/kg/min), effectively lowers postoperative narcotic requirements and has minimal impact on ventilatory drive and analgesic properties. The undesirable increase in airway secretions with ketamine administration is attenuated by the xerostomia induced by dexmedetomidine, while concurrent ketamine bolus injection prevents bradycardia and hypotension reported with dexmedetomidine. In addition, dexmedetomidine attenuates ketamine induced cardio stimulatory effects and drug induced delirium.[6] Scher and Gitlin used ketamine combined with dexmedetomidine for awake fiberoptic intubation in a case of 52 years male with failed previous fiberoptic intubations and found this combination to provide excellent intubating conditions.[6]

However, there are no randomized control trials comparing the effectiveness of dexmedetomidine plus ketamine combination with dexmedetomidine alone for awake fiberoptic nasotracheal intubation. Hence, this study was undertaken to compare the effectiveness of dexmedetomidine plus ketamine combination with dexmedetomidine alone in achieving better intubating conditions during awake fiberoptic nasotracheal intubation.

Materials and Methods

After approved by Local Institutional Ethics Committee and obtaining written informed consent, 60 adult patients of age group 18-60 years of either sex, American Society of Anesthesiologists Grades I and II posted for elective surgery under general anesthesia and were randomly allocated using computer generated randomization list into two groups of 30 each. A sample size of 30 patients in each group was calculated to have at least 80% power and an alpha of 0.05 to detect the expected differences between the two groups with respect to the primary goal of mean sedation score. Finding a difference of at least 15% change in mean sedation scores was regarded as a clinically significant difference. Exclusion criteria included uncooperative patients, any type of A-V block on electrocardiogram (ECG), heart failure, liver cirrhosis, thrombocytopenia and coagulopathies, severe bradycardia, current psychiatric disorder or any respiratory disorders.

To achieve blinding three anesthesiologists were required to conduct the study case. One anesthesiologist prepared and controlled the drug infusions; the second one performed fiberoptic intubation and the third anesthesiologist documented the data and made postoperative visits the next day.

All patients were premeditated with tablet ranitidine 150 mg HS and then at 6 a.m. on the day of surgery along with injection metoclopramide 10 mg as an institutional protocol for awake fiberoptic. In the operating theater, routine monitoring devices were placed and baseline ECG, HR, mean blood pressure, mean arterial pressure (MAP) and oxygen saturation (SpO_2) were recorded. O_2 at 2 L/min was given through a nasal catheter. Injection glycopyrrolate 0.2 mg IV was given 5 min prior to administering the study drugs. Groups I and II patients received a bolus dose of dexmedetomidine at 1 mcg/kg over 10 min in 100 mL normal saline followed by a continuous infusion of dexmedetomidine at 0.5 mcg/kg/h using B-Braun (Software PFAE) infusion pump. Upon completion of dexmedetomidine bolus, Group I patients received ketamine 15 mg as a bolus of 5 mL, followed by continuous infusion of ketamine at 20 mg/h, while Group II patients received normal saline 5 mL bolus, followed by plain normal saline infusion until the end of intubation. Hence, both groups had two infusion pumps. Following the bolus doses, sedation score was assessed by anesthesiologist unaware of regime used by modified observer assessment of alertness/sedation (OAA/S) scale (5 = respond readily to name spoken in normal tone, 4 = lethargic response to name spoken in normal tone, 3 = respond only after name spoken loudly or repeatedly, 2 = respond after mild prodding or shaking, and 1 = does not respond to mild prodding or shaking).[7]

Nasal fiberoscopy is easier for tracheal intubation than oral technique for anatomic reasons. Hence, we chose nasal approach. Xylometazoline nasal drops 0.1% (2 drops in each nostril), followed by 2 mL of 4% of lignocaine were administered. Two puffs of 15% lignocaine were instilled in the same nostril immediately before starting nasal fiberscopy. An endotracheal tube (ETT) of appropriate size (softened in warm water) was mounted over the fiberscope (Karl Storz, working length 65 cm, distal tip diameter 3.7 mm) and introduced through the selected nostril after 10 min of the start of study drugs. After visualization of the glottis and vocal cords, 2 mL of 4% lignocaine was injected through epidural catheter passed through the working channel. Further aliquots were given if vocal cords moved vigorously. The fiberoptic was maneuvered across the vocal cord into the trachea. Again 2 mL of 4% lignocaine was given. A lubricated ETT was passed over it into the trachea and positioned 2-3 cm above the carina. The cuff was inflated, and the FOL withdrawn. General anesthesia was administered and the study drugs were discontinued.

The primary outcome measurements were: (i) Intubation scores as assessed by vocal cord movement (1 = open, 2 = moving, 3 = closing, 4 = closed), coughing (1 = none, 2 = one gag or cough only, 3 = >1 gag or cough, but acceptable conditions, 4 = unacceptable conditions) and (ii) patient tolerance as assessed by facial grimace score (1 = no grimace, 2 = minimal grimace, 3 = mild grimace, 4 = moderate grimace, 5 = severe

grimace, 6 = very severe grimace).[8] Hemodynamic variables (HR, MAP, SpO_2, and ECG) which were assessed at five different time intervals (baseline, 2 min after sedation, at the beginning of fiberscopy as it passes through the nostril, after advancing the ETT through the nasopharynx and 2 min after endotracheal intubation). Other parameters included time taken for intubation, total dose of lignocaine used (for ensuring safe therapeutic levels) and the amount of study drugs used.

A postoperative visit was undertaken the day after operation during, which the level of recall (memory of preanesthetic preparations, topical anesthesia, endoscopy, and intubation), adverse events (sore throat, hoarseness) and satisfaction score (1 = excellent, 2 = good, 3 = fair, and 4 = poor) were noted [Appendix 1].

Statistical analysis of the data collected was done using SPSS 17 (SSPS Inc., Chicago, IL, USA). Intubation score, sedation score, grimace, time taken for intubation were analyzed by Mann-Whitney test. Hemodynamic variables, SpO_2 and amount of lignocaine used were analyzed by Student's *t*-test. Degree of patient satisfaction, level of recall, and adverse events were analyzed using the Chi-square test.

Results

All patients underwent successful fiberoptic intubation. There was no statistically significant difference in the baseline data between the two groups [Table 1].

The mean HR and MAP decreased persistently in both groups. The mean HR decreased significantly at all points of measurements (2 min after sedation, start of fiberscopy, after passage of ETT, 2 min after ETT) compared to baseline in Group II patients (P = 0.019, 0.02, 0.028, and 0.03, respectively), while in Group I the fall in HR was insignificant at all measurement points (P = 0.059, 0.271, 0.4, and 0.163, respectively). The maximum percentage fall in mean HR was 5.33% in Group I and 9.2% in Group II patients and there were no episodes of bradycardia (<40 beats/min).

Appendix 1: Scoring systems

Vocal cord movement	**(1 = Open, 2 = Moving, 3 = Closing, 4 = Closed)**
Coughing	(1=None, 2=One gag or cough only, 3=More than one gag or cough but acceptable conditions, 4=Unacceptable conditions)
Facial grimace score	(1=No grimace, 2=Minimal grimace, 3=Mild grimace, 4=Moderate grimace, 5=Severe grimace, 6=Very severe grimace)
Satisfaction score	(1=Excellent, 2=Good, 3=Fair, 4=Poor)

Mean HR when compared between the two groups was not significant at all the points of measurement [Figure 1].

The MAP decreased significantly at all intervals (2 min after sedation, start of fiberscopy, after passage of ETT, 2 min after ETT) compared to baseline in Group II patients (P = 0.038, 0.003, 0.000, and 0.000), and at 2 min after passage of ETT in Group I patients (P = 0.000). The maximum percentage fall in MAP was 8.17% in Group I and 14.81% in Group II patients. The fall in MAP, when compared between the two groups was significant from the start of fiberoscopy toward the end of the procedure [Figure 1] (P = 0.014, 0.003 and 0.005 at start of fiberscopy, after passage of ETT, 2 min after ETT, respectively). There was no statistically significant difference in saturation in between the two groups, and there was no episode of desaturation in either group [Figure 1].

Group I patients were sedated deeper at the end of 10 min after the start of the study drugs and none of the patients were sedated to a score of <2 (modified OAA/S score) in either of the groups. The mean sedation score in Group I patients

Table 1: Distribution of subjects according to baseline demographic profile and baseline hemodynamic parameters

Parameter	Group I	Group II	*P* value	Significance
Age (years)	44±10.55	43.95±10.62	0.983	NS
Sex (male/female)	2/28	2/28	1	NS
Weight (kg)	60.66±13.46	58.48±9.98		NS
ASA Grade (I/II)	28/12	30/10	0.617	NS
HR (beats/min)	93.17±18.40	97.77±22.52	0.849	NS
Mean arterial pressure (mm Hg)	100.77±8.99	97.47±7.84	0.185	NS
SpO_2	98.23±1.43	97.73±0.90	0.730	NS

Parametric data expressed as mean ± SD and categorical data expressed as frequency, P < 0.05 is statistically significant, SD = Standard deviation, HR = Heart rate, ASA = American Society of Anesthesiologists, NS = Not significant, SpO_2 = Oxygen saturation, MAP = Mean arterial pressure

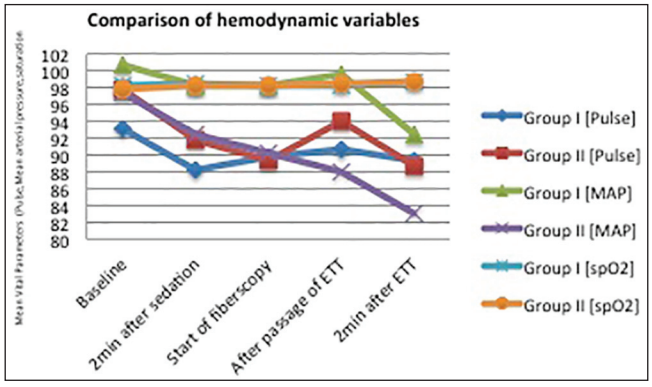

Figure 1: Comparison of vitals (pulse, mean arterial pressure, oxygen saturation) in between the groups

was 3.47, while in Group II the score was 3.93, which was statistically significant ($P = 0.015$) [Table 2].

There was no statistically significant difference in the intubation scores, grimace score and time taken for intubation in between the two groups ($P > 0.05$). Only 1 patient in Group I developed severe coughing while advancing the fiberoscope past the vocal cords, which was considered unacceptable for further guiding the fiberscope into the trachea and excluded from study group. Tracheal intubation was done immediately after giving induction dose of thiopentone.

The dose of lignocaine used was significantly lower in Group I patients ($P = 0.043$). However, there was no significant difference in the dose of dexmedetomidine used ($P = 0.45$) [Table 2].

The recall of administering preanesthetic preparations, topical anesthesia, and intubation were higher in Group I patients (100%, 90%, and 86.7%, respectively) when compared with Group II patients (93.3%, 90%, and 70%, respectively), but this difference was statistically insignificant ($P > 0.05$). Increased recall was not associated with increased grimace score or poor patient satisfaction score. Satisfaction score was rated excellent in more number of patients in Group I (53.3%) versus 20% in Group II, incidence of adverse events like hoarseness and sore throat were higher in Group II patients, but were statistically insignificant [Table 3].

Table 2: Parameters measured during fiberoptic intubation

Parameter	Group I ($n = 30$)	Group II ($n = 30$)	*P* value
Sedation score (modified OAA/S scale)	3.47±0.776	3.93±0.785	0.015*
Intubation score			
Vocal cord movement	1.43	1.43	>0.05
Coughing	1.4	1.5	>0.05
Facial grimace score	1.57	1.73	>0.05
Intubation time (min)	7.07	6.93	>0.05
Lignocaine used (mg)	251.00±33.35	270.93±40.801	0.043*
Dexmedetomidine (mcg)	66.87±10.90	64.60±12.00	>0.05

*Data expressed as mean ± SD or numbers, *P < 0.05 is statistically significant, OAA/S = Observer assessment of alertness/sedation, SD = Standard deviation*

Table 3: Satisfaction score, level of recall and adverse events expressed as frequency (%)

Parameter	Group I ($n = 30$)	Group II ($n = 30$)	*P* value
Satisfaction score (1/2/3/4)	16 (53.3)/14 (46.7)/0 (0)/0 (0)	6 (20)/24 (80)/0 (0)/0 (0)	0.007
Level of recall			
Preanesthetic preparations	30 (100)	28 (93.3)/2 (6.7)	>0.05
Topical anesthesia	27 (90)	27 (90)	>0.05
Endoscopy and intubation	26 (86.7)	21 (70.0)	>0.05
Hoarseness	1 (3.3)	3 (10)	>0.05
Sore throat	2 (6.7)	8 (26.7)	>0.05

Satisfaction score (1 = Excellent, 2 = Good, 3 = Fair, 4 = Poor)

Discussion

The primary outcomes of the study show that both dexmedetomidine with ketamine combination and dexmedetomidine alone provide satisfactory intubating conditions for awake fiberoptic nasotracheal intubation with minimal adverse effects and better patient satisfaction score. Dexmedetomidine provides appropriate sedation in which the patient is calm and easily arousable from sleep to wakefulness to allow cooperation, excellent communication and task performance while being ventilated and intubated and then quickly back to sleep when not stimulated.[9] The primary site of action of alpha2 agonists is the locus ceruleous and not the cerebral cortex, unlike gamma-amino butyric acid-mimetic drugs.[10] Locus ceruleous (nucleus in the pons) that is involved in physiological response to stress and anxiety is the principal site in the brain for norepinephrine synthesis.

The present randomized controlled study comparing the effectiveness of dexmedetomdine plus ketamine combination against dexmedetomidine alone is unique as a thorough literature search could not elucidate similar studies, though a case report of the same is available.[6]

Sedation score was higher (lower sedation level) in Group II (dexmedetomidine alone) when compared to Group I (dexmedetomidine and ketamine) which was statistically significant ($P = 0.015$). The sedative effects of the combination of ketamine and dexmedetomidine were found to be additive at the endpoints of hypnosis and anesthesia.[6] Shimabukuro and Satoh[7] used Ramsay sedation scale in their study and their patients were sedated in the scale of 2-4 and were very cooperative during the procedure, which is similar to the sedation levels achieved by our study subjects.

Satisfactory intubating conditions were found in either group in our study. Chu *et al.*[8] have reported better intubating conditions and patient comfort in patients who received dexmedetomidine. Dexmedetomidine combined with topical anesthesia provided better patient tolerance and amnesia and satisfaction.[11-13] Vocal cord movement and coughing were comparable similar to our study. Patient comfort is quintessential during awake fiberoptic intubation, which helps in confirming the position of tracheal tube and perform general anesthesia under controlled conditions. In our study, majority of patients in Group I had no grimace (56.6%) or had minimal grimace (30%). This is because dexmedetomidine blocks the sympathetic supply of the upper airway, while lignocaine

provided airway anesthesia. The amount of lignocaine used in Group I patients was significantly lower than that of Group II patients probably due to better sedation level, hence better intubation scores and better cooperation of the patient to the procedure of fiberscopy and intubation.

Group I patients had better hemodynamic stability because of the attenuation of bradycardia and hypotension by ketamine. It is noteworthy to mention that at all levels of intervention, there was no increase, rather decrease in the mean HR. Scheinin *et al*.[14] Yildiz *et al*.[11] noted an increase in mean HR during laryngoscopy and intubation; however, we never encountered any increase in the HR, which could probably be related to the use of lignocaine through "spray as you go" technique in anesthetizing the upper airway. There was a significant fall in the MAP when compared with the baseline at 2 min after intubation in Group I patients that can be attributed to the use of inhalational agents and induction agents combined. However, in Group II patients there was a fall in MAP at all points of measurements due to the action of dexmedetomidine alone. None of the patients in either group had a fall in the mean HR and MAP more than 20% of the baseline value. The opposing action of ketamine and dexmedetomidine on cardiac and sympathetic system probably resulted in a more stable hemodynamic response.[6] Dexmedetomidine has been reported to prevent the hemodynamic response to tracheal intubation more effectively than esmolol.[12] The use of dexmedetomidine was associated with a decrease in MAP and HR, which might result from decrease in noradrenaline release, a decrease in centrally mediated sympathetic tone and an increase in vagal activity.[13,15] Dexmedetomidine is reported to produce severe bradycardia, hypotension, hypertension and arrhythmias as side-effects. We never encountered severe bradycardia, hypertension or arrhythmias in our study. Moderate hypotension was managed by IV fluid administration.

Recall of the procedures performed on the patient were more in Group I patients (86.7%) than Group II (70%), but it was insignificant. This could probably be due to central nervous system stimulation effect of ketamine that is associated with hallucinations. Tsai *et al*.[16] have reported a higher incidence of recall of endoscopy (50%) and intubation (5%) than the propofol group. This was in concordant with the significantly lower state of entropy values in the propofol group, indicating higher sedation levels. Amnesia induced by dexmedetomidine has also been reported.[2] There was increased the hoarseness (10% vs. 3.3%) and sore throat (26.7% vs. 6.9%) in Group II, but it was insignificant. This could probably be because ketamine produces intense analgesia and additive sedation effect with dexmedetomidine leading to less coughing and hence lesser incidence of hoarseness and sore throat.

One of the limitations of the study was small sample size. We suggests large randomized controlled trials have to be carried out on a larger population. Another limitation of the study is a high incidence of recall in both groups.

Conclusion

From our study, we conclude that the dexmedetomidine is a useful sedative agent for awake fiberoptic intubation when used with "spray as you go technique" for anesthetizing the upper airway. The drug allows good sedation, unusually cooperative patient who maintains the responsiveness with the task performance then going back to sleep without any respiratory depression or clinically significant hemodynamic compromise. The addition of low-dose ketamine further enhances the hemodynamic stability because of the opposing action on the cardiovascular system when compared with dexmedetomidine. Low-dose ketamine confers additive sedation when used in conjugation with dexmedetomidine. Thus, we recommend the use of low-dose ketamine plus dexmedetomidine combination for hemodynamic stability and better sedation during awake fiberoptic nasotracheal intubation.

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