

Dexmedetomidine versus remifentanil sedation during awake fiberoptic nasotracheal intubation: a double-blinded randomized controlled trial

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Abstract

Background Awake fiberoptic nasotracheal intubation is usually performed in patients with an anticipated difficult airway. This study compares dexmedetomidine and remifentanil for conscious sedation during fiberoptic intubation.

Methods Forty patients undergoing elective awake fiberoptic nasotracheal intubation were allocated randomly to receive either dexmedetomidine ($n = 20$) or remifentanil ($n = 20$). Primary outcome measures were endoscopy, intubation, and post-intubation conditions as scored by the attending anesthesiologist. Other parameters included the time taken to achieve the desired level of sedation, endoscopy time, intubation time, and hemodynamic changes during the procedure. An interview was conducted 24 h after surgery to evaluate patients' recall of and satisfaction with the procedure.

Results The median [interquartile range] endoscopy score (graded 0–5) in the dexmedetomidine group (2 [1–2]) was significantly better than in patients who received remifentanil (3 [2–3]; $p < 0.01$). Recall of intubation was significantly lower in the dexmedetomidine group ($p = 0.027$). Dexmedetomidine provided better patient satisfaction than remifentanil (2 [1–2] and 2 [2–3], respectively; $p = 0.022$). Patients in the dexmedetomidine group had fewer heart rate responses during endoscopy and intubation as compared to the remifentanil group ($p < 0.001$ and $p = 0.004$, respectively). Peripheral oxygen saturation was less in the remifentanil group during endoscopy ($p = 0.003$). There were

no significant differences in intubation and post-intubation conditions.

Conclusions Both dexmedetomidine and remifentanil were effective as sedatives in patients undergoing awake fiberoptic nasotracheal intubation. Compared with remifentanil, dexmedetomidine offered better endoscopy scores, lower recall of intubation, and greater patient satisfaction, with minor hemodynamic side effects.

Keywords Awake fiberoptic intubation · Conscious sedation · Dexmedetomidine · Remifentanil

Introduction

Awake fiberoptic nasotracheal intubation is used in patients with an anticipated difficult airway. Adequate sedation during the procedure is important to maintain a patent airway and minimize discomfort.

Many agents are used for sedation during awake fiberoptic intubation, including benzodiazepines, opioids, ketamine, propofol, and dexmedetomidine [1–4]. Remifentanil is of interest because it has analgesic and antitussive properties during awake intubation, while allowing communication with the patient to be maintained [5]. Dexmedetomidine is an attractive alternative as a sedative for managing a difficult airway because of its anxiolytic and analgesic properties [6–10]. It has been used to achieve conscious sedation in patients undergoing awake fiberoptic nasal intubation [11–13].

Previous studies have demonstrated that both dexmedetomidine and remifentanil are better than propofol target-controlled infusion (TCI) in conscious fiberoptic intubation [14–16]. However, to our knowledge, no previous studies have compared dexmedetomidine to remifentanil.

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The purpose of this study was to compare the effectiveness of dexmedetomidine and remifentanyl in providing conscious sedation during awake fiberoptic nasotracheal intubation in patients undergoing oromaxillofacial surgery.

Methods

This study was approved by the Institutional Review Board of the Ethics Committee of Shanghai Ninth People's Hospital affiliated with Shanghai Jiao Tong University School of Medicine, and written informed consent was obtained from each patient. It was also registered as a clinical trial (<http://www.clinicaltrials.gov>, identifier: NCT01474213).

Forty-two adult patients with American Society of Anesthesiologists (ASA) classifications of I–III were recruited for elective awake fiberoptic nasotracheal intubation following diagnosis of maxillofacial cancer or fracture with limited mouth opening. Exclusion criteria were pregnant or lactating women, heart rate (HR) <50 beats per min, systolic blood pressure <90 mmHg, atrioventricular block on ECG, high-dose opiate medication, use of an α 2-adrenoceptor agonist or antagonist within the previous 14 days, liver cirrhosis, contraindications to nasal intubation, and refusal to be involved in the study. One patient declined consent, and one operation was cancelled. Forty patients were randomized 1:1 to receive dexmedetomidine or remifentanyl using a covariate adaptive randomization algorithm. The randomization schedule was stratified based on both the ASA classification (I–II vs. III) and Mallampati classification (III vs. IV).

Two consultant anesthetists were present during all procedures. One was responsible for performing the awake nasal fiberoptic intubation and scoring sedation, endoscopy, intubation, and post-intubation conditions; the other administered the study drugs. An anesthetist nurse collected anesthetic data and postoperative records. The intubating anesthetist, the patients, and the nurse anesthetist were all blinded to the study drugs used.

In the operating room, intravenous access was established, and standard monitoring parameters were recorded every minute (electrocardiogram, non-invasive blood pressure, pulse oximetry, and respiratory rate). Nasal oxygen (3 l/min) was administered, and no premedication was given to patients. The study drugs were administered with a 50-ml syringe as 200 μ g (2 ml) of dexmedetomidine in 48 ml of 0.9 % saline or 1 mg remifentanyl in 50 ml of 0.9 % saline. Patients in the dexmedetomidine group received a loading dose (1.5 μ g/kg) infused over 10 min followed by a continuous infusion of 0.7 μ g/kg/h. Patients in the remifentanyl group received remifentanyl via an Orchestra Base Primea (Fresenius Vial) infusion system using a Minto pharmacokinetic model. The initial target

was 3.0 ng/ml, and the TCI was adjusted by 0.5 ng/ml after the target concentration at the effect site had equilibrated with the plasma concentration until the desired level of sedation was achieved. During drug infusion, two drops of ephedrine hydrochloride and nitrofurazone (containing approximately 1 mg of ephedrine) were instilled into both nasal cavities, and the tongue and hypopharynx were sprayed with 7 % lidocaine (45 mg). The level of patient sedation was assessed using the Ramsay Sedation Scale (RSS; Table 1) once per minute. After 15 min, any patient with a RSS = 1 was given an infusion of rescue midazolam in 0.5-mg bolus doses until a RSS of 2 was achieved.

Fiberoptic intubation was started once the RSS reached 2. A fiberoptic scope (Pentax FI-7BS, 6.0 mm; Japan) was loaded with a 7.0-mm tracheal tube for male patients or a 6.5-mm tube for females [17]. Two milliliters of 2 % lidocaine was sprayed onto the glottis and below the vocal cords via the channel of the fiberoptic scope.

Our primary outcome measures were endoscopy score, intubation score, and post-intubation scores, which were obtained using Rai's standard scoring system [14]. Endoscopy and intubation were graded from 0 to 5 according to the positive data encountered during the procedure (Appendix 1), with lower scores indicating better conditions. Similarly, post-intubation was scored from 1 to 3, with higher scores indicating worse conditions. The times taken to achieve sedation (RSS = 2), endoscopy (from inserting the fiberoptic scope to visualizing the carina), and tracheal intubation (from inserting the tracheal tube into the nostril to ensuring intubation with capnography) were recorded.

Blood pressure, HR, and peripheral oxygen saturation (SpO₂) were recorded before starting drug infusion and every minute until tracheal intubation. Atropine (0.5 mg) was injected if the HR was <40 beats/min, and 10 mg ephedrine was given when the blood pressure was <90 mmHg. Hemodynamic data (mean arterial pressure, HR, and SpO₂) were compared between the two groups at

Table 1 Ramsay sedation scale

Clinical score	Level of sedation
1	Patient is anxious and agitated or restless or both
2	Patient is cooperative, oriented, and tranquil
3	Patient responds to commands only
4	Patient exhibits a brisk response to a light glabellar (between the eyebrows) tap or loud auditory stimulus
5	Patient exhibits a sluggish response to a light glabellar tap or loud auditory stimulus
6	Patient exhibits no response to stimuli

three time points: baseline (during pre-anesthetic preparation), endoscopy (immediately after fiberoptic endoscopy), and intubation (immediately after intubation). Hypoxic episodes ($SpO_2 < 90\%$) and the use of ephedrine or atropine for hemodynamic support were also recorded.

A postoperative interview was conducted 24 h after the procedure to evaluate patients' recall (memory of endoscopy and intubation), side effects (sore throat and hoarseness), and satisfaction score (1, excellent; 2, good; 3, acceptable; 4, poor).

The sample size calculation was based on a pilot study. Sixteen patients in each group were required to detect a difference of "1 over 5" in the endoscopy or intubation scores with a power of 0.8 and a type I error of 0.05. To compensate for dropped cases and deviation from normality, 42 patients were studied. After assessing normality, continuous data were compared using unpaired *t* tests, and the Mann-Whitney test was used to compare non-continuous data and non-normally distributed data. Chi-squared (χ^2) tests or Fisher's exact test were used to compare categorical data between the two groups. A *p* value of < 0.05 was considered significant. SPSS 17.0 statistical software was used for all analyses.

Results

Forty patients completed this study. The demographic data were comparable between groups (Table 2). Data acquired during the fiberoptic procedures are shown in Tables 3 and 4. Different distributions of endoscopy, intubation, and post-intubation scores in the two groups are illustrated in Table 5.

All patients had successful fiberoptic intubation at the first trial. No patients needed a rescue infusion of midazolam to achieve adequate sedation. The patients in the dexmedetomidine group had better endoscopy scores than

those in the remifentanil group. During endoscopy insertion, equivalent numbers of patients in the two groups appeared to cough upon lidocaine treatment via scope, while fewer patients seemed to have limb movements in the dexmedetomidine group. There were no significant differences in intubation or post-intubation scores between the two groups. During tracheal intubation, no patients in either group exhibited localization of two limbs under the management of two sedatives. Fewer patients in the remifentanil group coughed on entering the trachea compared to those in the dexmedetomidine group ($p = 0.018$). Only one patient in the remifentanil group exhibited obvious discomfort after nasotracheal intubation. The time to achieve sedation was shorter in the remifentanil group than in the dexmedetomidine group.

As shown in Figs. 1, 2 and 3, the HR was less in the dexmedetomidine group at the end of endoscopy and intubation ($p < 0.001$ and $p = 0.004$, respectively). On the contrary, peripheral oxygen saturation at the end of endoscopy was less in the remifentanil group ($p = 0.003$). There were no differences in mean arterial pressure between the two groups.

Two patients in the remifentanil group exhibited desaturation; their SpO_2 values decreased to 85 and 88 %, respectively, and their respiratory rates decreased to seven and eight times per min, respectively. Loud auditory stimuli and high-flow nasal oxygen (5 l/min) were required to resolve transient hypoxia. Two patients in the dexmedetomidine group who developed bradycardia received temporary support with atropine (Table 4).

Post-anesthetic interview parameters are shown in Table 4. Recall of intubation was higher in the remifentanil group (65 %) than in the dexmedetomidine group (30 %) ($p = 0.027$). Patient satisfaction (median [interquartile range]) was greater in the dexmedetomidine group than in the remifentanil group (2 [1–2] and 2 [2–3], respectively, $p = 0.022$). Although there was no statistically significant difference for recall of endoscopy between the two groups (70 vs. 40 % with $p = 0.057$), the result appears to be clinically worthwhile. Other post-anesthetic parameters did not differ between the two groups.

Discussion

This study showed that both dexmedetomidine and remifentanil were effective in patients undergoing conscious fiberoptic nasotracheal intubation. Although endoscopy was better tolerated with dexmedetomidine, the intubation scores were similar in both groups. The ability of both drugs to achieve the desired level of sedation and the absence of differences in sedation scores in both groups during the procedure may suggest that the difference in

Table 2 Patient characteristics

	Dexmedetomidine group	Remifentanil group
Number	20	20
Gender (M:F)	11:9	10:10
Age (years)	39.4 (15.2)	37.8 (14.9)
Weight (kg)	66.5 (11.8)	60.2 (10.5)
Height (cm)	167.2 (6.9)	165.0 (5.8)
BMI (kg/m ²)	23.7 (2.8)	22.0 (3.0)
ASA status (1/2/3)	12/7/1	10/8/2
Mallampati classification	9/11 (3/4)	9/11

Data are expressed as mean (standard deviation) or numbers

Table 3 Measurements made during fiberoptic intubation

	Dexmedetomidine group	Remifentanil group	<i>p</i> value
Data are expressed as mean (standard deviation), median (interquartile range [range]) or mean (range)			
Endoscopy time, time from inserting the fiberoptic scope to visualizing the carina; intubation time, time from inserting the tracheal tube into the nostril to ensuring intubation with capnography			
Ramsay sedation score	3 (3–4 [2–4])	3 (3–4 [2–4])	0.36
Endoscopy score (1–5)	2 (1–2 [0–3])	3 (2–3 [1–3])	0.01
Intubation score (1–5)	1 (1–2 [0–3])	1 (1–2 [1–3])	0.85
Post-intubation score (1–3)	1 (1–2 [1–2])	1 (1–2 [1–3])	0.66
Time taken to achieve sedation (s)	668.9 (78.6)	610.4 (92.3)	0.04
Endoscopy time (s)	69.9 (35.4)	82.2 (37.9)	0.30
Intubation time (s)	30.9 (8.8)	33.3 (6.5)	0.31
Target concentration at effect site (ng/ml)	NA	3.9 (3.5–4.1)	–
Drug requirement (μg)	131.2 (40.0)	231.6 (58.1)	–

Table 4 Adverse events and satisfaction data during awake intubation

	Dexmedetomidine group	Remifentanil group	<i>p</i> value
Hypoxia	0	2 (10 %)	0.147
Temporary hemodynamic support			
Atropine	2 (10 %)	0	0.147
Ephedrine	0	0	1
Cough during intubation	10 (50 %)	3 (15 %)	0.018
Sore throat	5 (25 %)	5 (25 %)	1
Hoarseness	2 (10 %)	3 (15 %)	0.633
Recall of endoscopy	8 (40 %)	14 (70 %)	0.057
Recall of intubation	6 (30 %)	13 (65 %)	0.027
Satisfaction score	2 (1–2 [1–3])	2 (2–3 [1–3])	0.022

endoscopy scores reflects inherent properties of dexmedetomidine other than sedation.

Dexmedetomidine induces conscious sedation by activating the endogenous sleep-promoting pathway. Compared with midazolam, patients sedated with dexmedetomidine are aroused more easily when stimulated; in addition, they experience little respiratory depression [18, 19]. Xerostomia has been reported as an effect of dexmedetomidine. Therefore, this drug may provide a better field for fiberoptic endoscopy [20, 21]. Moreover, the analgesic effects may play a role in improving patient comfort during fiberoptic intubation, giving better endoscopy scores. On the other hand, the antitussive action of remifentanil lowered the incidence of coughing during tracheal intubation. This property may have made intubation scores comparable between the two groups, despite higher endoscopy scores in the remifentanil group. During awake intubation, it is crucial that the patient is relaxed and cooperative. Most patients in both groups could obey commands immediately after nasotracheal intubation at the doses used in our study.

Some trials have investigated the dose of dexmedetomidine required for conscious sedation. Bergese [10] found that a loading dose of 1 μg/kg followed by a 0.7 μg/kg/h maintenance infusion of dexmedetomidine achieved adequate sedation in patients undergoing awake fiberoptic

intubation with or without small supplemental doses of midazolam. Chu [11] reported that a loading dose of dexmedetomidine (1 μg/kg) provided conscious sedation with spontaneous ventilation for fiberoptic intubation. In our pilot study, a loading dose of dexmedetomidine (1.5 μg/kg) infused over 10 min followed by a continuous infusion of 0.7 μg/kg/h enabled a smooth intubation procedure with no predisposition to airway obstruction or respiratory depression.

Use of remifentanil has been reported to be useful for awake intubation with or without the application of local anesthetic to the larynx and trachea [22–25]. Few studies have reported the effective target concentration of remifentanil required for sedation by TCI in awake intubation. Rai and colleagues [14] found that an effect-site concentration of remifentanil of 3.2 (2.8–3.5) ng/ml achieved adequate sedation for awake fiberoptic intubation. In their study, the median endoscopy score was better than ours with a similar concentration of remifentanil [1 (0–3) vs. 3 (1–3)]. This discrepancy may be due to the use of midazolam as a premedication in their patients and the application of more local anesthetic during fiberoptic insertion. Moreover, Vennila and colleagues [26] reported that intubation was achieved with a mean (standard deviation) effect-site concentration of 8.06 (3.52) ng/ml during

Table 5 Number of patients exhibiting different levels of endoscopy, intubation, and post-intubation scores in the two groups

	Dexmedetomidine group	Remifentanil group
Endoscopy score		
0	1	0
1	7	3
2	9	6
3	3	11
4	0	0
5	0	0
Intubation score		
0	1	0
1	11	12
2	7	7
3	1	1
4	0	0
5	0	0
Post-intubation score		
1	15	14
2	5	5
3	0	1

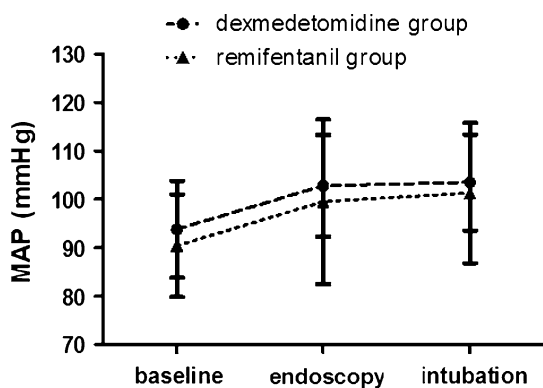


Fig. 1 Changes in mean arterial blood pressure (MAP) in patients receiving dexmedetomidine (closed circle) or remifentanil (closed triangle) during intubation. Hemodynamic parameters at three time points were analyzed: (1) baseline: pre-anesthetic preparation; (2) endoscopy: immediately after fiberoptic endoscopy; (3) intubation: immediately after tracheal intubation. There were no significant differences in MAP between the two groups at any time point

tracheal intubation in the absence of local anesthesia and benzodiazepine. In our study, the mean (range) remifentanil TCI dose was 3.9 (3.5–4.1) ng/ml, which provided adequate comfort relief of pain and anxiety with smaller doses of local anesthetics.

Dexmedetomidine has been reported to prevent hemodynamic responses by decreasing noradrenaline release and centrally mediated sympathetic tone [27]. However, it may cause side effects including hypotension, bradycardia,

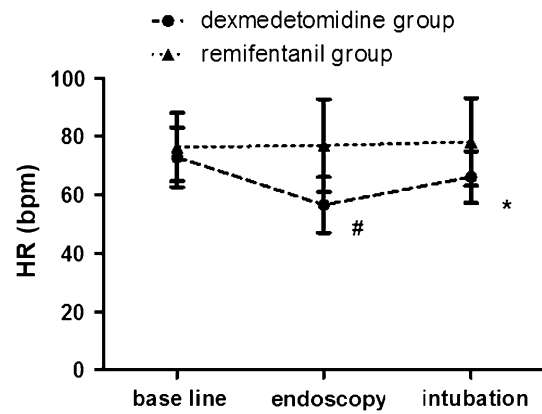


Fig. 2 Changes in heart rate (HR) in patients receiving dexmedetomidine (closed circle) or remifentanil (closed triangle) during intubation. Hemodynamic parameters at three time points were analyzed: (1) baseline: pre-anesthetic preparation; (2) endoscopy: immediately after fiberoptic endoscopy; (3) intubation: immediately after tracheal intubation. There were significant differences in HR at the end of endoscopy and intubation ($p < 0.001$ and $p = 0.004$, respectively) between the two groups. [#] $p < 0.001$; ^{*} $p < 0.05$

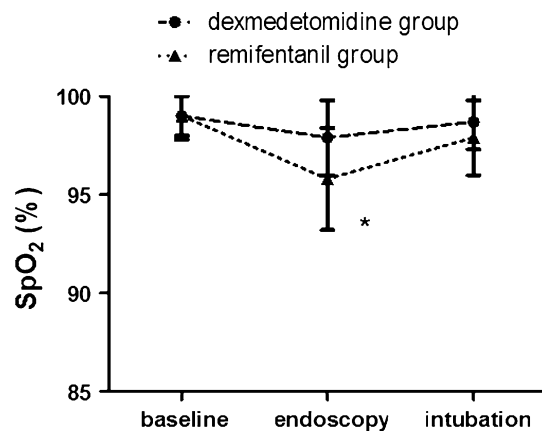


Fig. 3 Changes in peripheral oxygen saturation (SpO₂) in patients receiving dexmedetomidine (closed circle) or remifentanil (closed triangle) during intubation. Hemodynamic parameters at three time points were analyzed: (1) baseline: pre-anesthetic preparation; (2) endoscopy: immediately after fiberoptic endoscopy; (3) intubation: immediately after tracheal intubation. There were significant differences in SpO₂ at the end of endoscopy ($p = 0.003$) between the two groups. ^{*} $p < 0.05$

atrial arrhythmia, and hypoxia [18]. In our study, two patients developed bradycardia, which was easily managed with atropine. In contrast, previous studies indicate that doses of remifentanil as low as 0.25 µg/kg/min can lead to significant dose-dependent respiratory depression. In this study, two patients experienced transient hypoxia. Although loud auditory stimuli and high-flow nasal oxygen (5 l/min) rapidly resolved the situation, caution is needed when using remifentanil in patients with anticipated mask ventilation.

Without midazolam premedication, greater recall of intubation in the remifentanyl group may indicate that remifentanyl has less of an amnesic effect than dexmedetomidine at the same level of sedation. The pharmacokinetic properties of remifentanyl and the mode of administration in the study may be the reasons for faster achievement of the desired level of sedation. Amnesia and lower endoscopy scores, on the other hand, may explain the greater patient satisfaction with dexmedetomidine sedation.

Conclusion

Both dexmedetomidine and remifentanyl were effective in patients undergoing awake fiberoptic nasotracheal intubation. Compared with remifentanyl, dexmedetomidine offers better endoscopy scores, lower recall of intubation, and greater patient satisfaction, with minor hemodynamic side effects.

Conflict of interest None.

Appendix 1

Endoscopy score 0, 1, 2, 3, 4, 5

Grimacing

Localizing

Coughing on lidocaine via scope

Coughing on entering infraglottic space

Prolonged coughing

Intubation score 0, 1, 2, 3, 4, 5

Grimacing when tube in nares

Localizing with one limb at any stage

Localizing with two limbs at any stage

Coughing on entering trachea

Prolonged coughing

Post-intubation score 1, 2, 3

1 Cooperative, obeying commands

2 Uncomfortable, GA imminent

3 Other (specify)

Postoperative interview

Amnesia

Recall of endoscopy: Yes, No

Recall of intubation: Yes, No

Adverse events

Sore throat: Yes, No

Hoarseness: Yes, No

Satisfaction score: 1, 2, 3, 4

Excellent

Good

Acceptable

Poor

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