A randomized double-blind controlled trial comparing three sedation regimens during flexible bronchoscopy: Dexmedetomidine, alfentanil and lidocaine

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Funding information
‘Conseil de la Recherche—Faculty of Medicine, Saint Joseph University, Grant/Award Number: FM 235

Abstract

Introduction: No standardized sedation protocol is available for flexible bronchoscopy (FB).

Objectives: The aim of this study was to evaluate the efficacy and safety of three regimens used for sedation during FB.

Methods: This randomized double-blind controlled trial assessed patients undergoing bronchoscopy and receiving lidocaine alone (C) or combined with dexmedetomidine (D) or alfentanil (A). Tolerance was assessed using the bronchoscopy score, and level of sedation was assessed using the Nursing Instrument for the Communication of Sedation. Safety was evaluated in terms of pulmonary function and vital signs.

Results: A total of 162 patients were enrolled. The bronchoscopy score was identical in all groups. Group D subjects were the most sedated ($P = .013$), whereas group A subjects were the least agitated. Linear regression showed a negative association between bronchoscopy score and age in A ($\beta = -0.06; P = .001$). Positive predictors of bronchoscopy score were female gender ($\beta = 1.96; P = .003$) in D and obesity ($\beta = 2.41; P = .012$), longer procedures ($\beta = 0.08; P = .009$) and female gender ($\beta = 1.15; P = .038$) in C. Longer procedures ($\beta = -0.12; P = .010$) was a negative predictor of bronchoscopy score in D. Desaturation, hypoxia and heart rate changes were most prevalent in group A. Hypotension was mostly observed in D.

Conclusions: No consistent differences were present between the three regimens; however, each was more appropriate in certain patient profiles. We consequently proposed a protocol as a first step towards standardizing sedation practice in FB in a patient-tailored manner. A more comprehensive and detailed protocol including other sedative agents with their corresponding doses should be developed.

KEYWORDS
alfentanil, bronchoscopy, conscious sedation, dexmedetomidine, lidocaine

The results of this study have been presented at the European Respiratory Society 2015 International Congress, Amsterdam, Netherlands (Abstract Number: 850487).

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Flexible bronchoscopy (FB) is the most frequently performed procedure in clinical practice for the diagnosis and treatment of pulmonary disease. Patients undergoing FB often experience sore nose and throat, cough, shortness of breath and other chest discomforts.\(^1\)

FB is usually performed under monitored anesthesia care to attenuate the stress, reduce the complications and simplify the procedure.\(^2\) The British Thoracic Society has published guidelines that recommend offering sedation to all patients undergoing FB when there is no contraindication.\(^3\) Sedatives are usually selected based on the best pharmacokinetic characteristics including fast onset, short action and rapid recovery.

Alfentanil is a fast onset and short-acting opioid with analgesic and cough suppression properties.

Dexmedetomidine is a highly selective adrenergic α-2 agonist with sedative and analgesic properties resulting from reduced endogenous norepinephrine release in the brain and spinal cord. Unlike other sedatives, dexmedetomidine does not cause any respiratory depression\(^4\) and it has been used as a sedative in different procedures, including cataract surgery.\(^5\)–\(^7\) Several studies have reported the efficacy and safety of dexmedetomidine for FB during awake fibreoptic intubation.\(^8\)–\(^11\)

Since there is no standardized sedation protocol during FB,\(^12\)\(^,\)\(^13\) we conducted this study to compare dexmedetomidine with two other agents, alfentanil and lidocaine alone.

2 | MATERIALS AND METHODS

2.1 | Study subjects

This was a randomized, double-blind, controlled study, conducted in Hotel Dieu de France University Hospital in Lebanon in accordance with the amended Declaration of Helsinki. The study protocol was approved by the hospital institutional review board (approval number: CEHDF 438), and a written informed consent was obtained from all enrolled patients.

Patients aged 18–70 years, undergoing elective FB for diagnostic purposes in the endoscopy unit, were evaluated for eligibility between December 2012 and December 2014. Patients who met any of the following criteria were not eligible for the study: case of tracheal stenosis, baseline hypoxia with measured peripheral capillary oxygen saturation (SpO\(_2\)) <90% in room air, known history of bradycardia (pulse <55 beats per minute), atrioventricular block, heart failure with ejection fraction (EF) <40% and consumption of more than five alcoholic drinks per week. Eligible patients were randomized in a 1:1:1 ratio through an electronic randomization software using simple randomization to receive either dexmedetomidine or alfentanil or local anesthesia alone.

2.2 | Procedure and sedation

An unblinded study nurse not involved in the bronchoscopy procedure was responsible of collecting demographic data on patients, getting their written informed consent and preparing the study drugs in labelled syringes.

The blinded team consisted of the bronchoscopist, a fellow resident, a nurse and a nurse assistant.

Five millilitres of lidocaine jelly 2% were applied by nasal swaps in each nose for all patients.

In all groups, the infused lidocaine 1% was given in five sets of 5 ml each (2 above and 3 beneath vocal cords level).

The bronchoscopy was performed 5 minutes after the administration of the following protocols:

- **Group C (lidocaine alone):** 25 ml of lidocaine 1% by bronchoscopy 1 slow intravenous infusion of saline serum 0.9% with electronic pump over 10 minutes + slow intravenous infusion of 2 ml saline serum 0.9% over 5 seconds.

- **Group A (lidocaine combined with alfentanil):** 25 ml of lidocaine 1% by bronchoscopy + slow intravenous infusion of saline serum 0.9% with electronic pump over 10 minutes + slow intravenous infusion of alfentanil 10 mcg/kg over 5 seconds.

- **Group D (lidocaine combined with dexmedetomidine):** 25 ml of lidocaine 1% by bronchoscopy + slow intravenous infusion with electronic pump of dexmedetomidine 0.5 mcg/kg over 10 minutes + slow intravenous infusion of 2 ml saline serum 0.9% over 5 seconds.

During the procedure, the bronchoscopist had the possibility to add a bolus of 1 mg of midazolam for a maximum dose of 5 mg in order to attenuate agitations. Moreover, 5 ml of lidocaine could be delivered through the bronchoscope in the case of cough or not optimally open vocal cords. The final cumulative dose was calculated. Whenever oxygen saturation dropped less than 88%, subjects received supplemental oxygen titrated by nasal cannula to maintain an oxygen saturation above 90%.

2.3 | Patient assessment

The bronchoscopy feasibility was assessed using the bronchoscopy score which was computed by combining three variables graded 1–4: movement of the vocal cords, cough occurrence and limb movement. The final bronchoscopy score varied between 3 and 12 where 3 represented the optimal score and 12 represented the worst score (Appendix).
The level of sedation was assessed using the Nursing Instrument for the Communication of Sedation (NICS) score\textsuperscript{14} and varied between −3 and +3, with −3 representing a state of deep sedation, +3 representing a state of dangerous agitation and 0 representing the optimal clinical level of awakening, cooperation and calmness. The level of sedation was also assessed by the doses of added midazolam and lidocaine.

The tolerance to the bronchoscopy procedure was evaluated during the procedure and the recovery period, through the monitoring of vital signs, supplemented oxygen (O\textsubscript{2}), exhaled carbon dioxide (CO\textsubscript{2}) and pulmonary functions [vital capacity (VC), forced expiratory volume 1 (FEV\textsubscript{1}), Tiffeneau-Pinelli index and Peak Expiratory Flow (PEF)]. Systolic and diastolic blood pressures (SBP and DBP) were measured using an automated pressure device (Omron M6 Blood Pressure Monitor\textsuperscript{®}) and heart rate and rhythm were monitored using standard three-lead electrocardiography. Sp\textsubscript{O}\textsubscript{2}, exhaled CO\textsubscript{2} and respiratory rate were measured using a portable spirometer (Reliant I for Windows. Version 2.11 CB\textsuperscript{®}). Patients were also monitored for any complication encountered during the procedure such as hypoxia, cough, shortness of breath, heart rate changes and thoraco-abdominal motion changes. Patients were monitored at baseline, before the administration of the sedatives (T0), five minutes before the start of the procedure (T1), during the procedure, 3 minutes after the end of the procedure (T2) and 1 hour after the end of the procedure (T3).

2.4 | Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 20.0 (IBM Corporation, Armonk, NY). Comparisons of the bronchoscopy score, the NICS score, pulmonary functions and vital signs between the three arms were performed using analysis of variance (ANOVA); pair-wise comparisons were computed based on Bonferroni’s method. Categorical variables were compared using chi square tests. The association of the bronchoscopy score with different demographic and cardiovascular variables was tested using Student’s \(t\)-tests. Pearson correlation coefficients were computed for exploring the association between the bronchoscopy score and continuous variables. Subsequently, a multiple linear regression model was used to identify the predictors of the dependent variable ‘Bronchoscopy Score’ in each of the three groups.

In order to optimize correlations with clinical outcomes, we manually investigated and optimized cutoff points for the continuous variables that were found to be significant predictors of the bronchoscopy score. A sedation protocol for different patient profiles, based on the score predictors was proposed.

All tests were two-tailed and a \(P\) value of <.05 was considered as statistically significant. None of the missing values were replaced.

3 | RESULTS

3.1 | Study population and baseline characteristics

A total of 342 patients were screened for eligibility, of whom 162 were enrolled in the study and randomized to receive alfentanil (group A, \(n = 55\)), dexmedetomidine (group D, \(n = 53\)) or local anesthesia alone (group C, \(n = 54\)) (Figure 1). In these patients, the indication for FB was either to investigate endobronchial signs and symptoms or to diagnose lung cancer. At baseline, the three groups were comparable in terms of demographic characteristics (Table 1).

3.2 | Procedure feasibility and level of sedation

No statistically significant differences in the mean bronchoscopy score were found between the groups (Table 2). Further pairwise analyses showed no statistically significant differences either. However, taken alone, the limb agitation score was significantly higher in group D than in group A (2.13 vs 1.60, \(P = .004\)).

A statistically significant difference in the NICS score was found between the three groups at T1 (\(P = .013\)); it was the highest in group D (0.81 ± 1.12) followed by group C (0.46 ± 0.91) and group A (0.24 ± 0.94). Nevertheless, all scores showed that the patients were clinically awake, cooperative and calm at T1. After the procedure, the NICS scores were identical in the three groups at T3 (\(P > .05\)), though they were similarly the highest in groups C and D.

With regards to the added doses of anesthetics, one third of all patients needed additional doses of midazolam but no statistically significant differences in the proportion of patients requiring supplementary midazolam doses >2 mg were found between the three groups (\(P = .062\)). Pairwise testing showed that group C included a higher proportion of patients on midazolam doses >2 mg as compared to group D (13.6% vs 42.9% \(P = .033\)).

In addition, more than 90% of all patients needed additional doses of lidocaine. Total mean doses of lidocaine were also similar across the three groups, however, the highest mean dose was reported in group C (9.58 mg/kg) followed by group D (8.60 mg/kg) and group A (9.36 mg/kg). Similarly, the maximum dose was reached in group C (19.23 mg/kg), followed by group A (16.67 mg/kg) and group D (14.19 mg/kg).
3.3 | Tolerance of procedure

The analysis of the vital signs at different time points showed statistically significant differences in mean DBP and SBP between the three groups at T1, during the procedure and at T3 (\( P < .05 \)). Mean values were the lowest in group D, followed by group A and then group C.

Mean pulse values and respiratory rates were identical in all three groups and within the normal range at the different time points.

Statistically significant differences in mean SpO2 were found between the three groups before and after the procedure. At T1, mean SpO2 was the lowest in group A (94.13) (\( P = .021 \)), while at T3, it was lowest in group D (94.31) (\( P = .047 \)). SpO2 dropped below the normal range (\(<95\%\)) after the beginning of the procedure, and it was normalized after the end of the procedure in group A patients only. Supplementary O2 at T1 and during the procedure was highest in group A (\( P < .05 \)), with flow increasing mostly during the procedure.

There were no statistically significant differences in mean exhaled CO2 between the three groups at any of the time points (\( P > .05 \)), and values were within the normal range at the different time points in the three groups (45 mm Hg).

At all time points, mean FEV1 was the highest in group C (\( P < .05 \)). Of note, FEV1 was below the normal range (\(<75\%\)) at T1 in groups A and D and at T2 and T3 in all three groups. Mean VC, mean Tiffeneau-Pinelli index (FEV1/FVC ratio) and mean PEF were identical in the three

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**FIGURE 1** Patients flow diagram. Group C: standard/control: local anesthesia; group A: alfentanil + local anesthesia; and group D: dexmedetomidine + local anesthesia.
groups at all time points, and all values fluctuated around the normal ranges.

Complications experienced during the procedure included hypoxia in 104 patients (64.2%), need for oxygen supply in 85 patients (52.5%) and cough in 138 patients (85.2%). Hypoxia occurrence was most prevalent in group A, followed by group D and group C (78.2% vs 62.3% vs 51.9%, \( P < .008 \)). Heart rate changes also significantly differed between the three groups \( (P = .001) \) and were most common in group A (Table 3).

### 3.4 Predictors of bronchoscopy score

Results of the bivariate analysis are reported in Tables 4 and 5. Only significant variables at the bivariate level were entered in the regression models. In group C, bronchoscopy score increased in obese patients \( (\beta = 2.41; P = .012) \), with longer procedures \( (\beta = 0.08; P = .009) \), and in females \( (\beta = 1.15; P = .038) \).

In group A, age was the only independent predictor of bronchoscopy score, which decreased with older age \( (\beta = -0.06; P = .001) \). In group D, bronchoscopy score increased in females \( (\beta = 1.96; P = .003) \) and decreased in longer procedures \( (\beta = -0.12; P = .010) \). Multivariate regression analyses in each group are shown in Table 6.

Multiple cutoff points for the continuous predictors of the bronchoscopy score were investigated in subsequent analyses. The selected cutoff points for age and duration of the procedure coincided closely with the corresponding data medians and fitted the three final models that were described above. The cutoff point for age and bronchoscopy duration were 63 years and 16 minutes, respectively.

### 4 Discussion

This study is the first to compare the feasibility and tolerability of three different sedation regimens in FB and to determine the most appropriate one in selected patient profiles.

Though there were no differences between the three groups with regards to the procedure feasibility, however, limbs movements were significantly more observed in group D, keeping the patient agitated and uncomfortable specifically at the start of the procedure, which is attributable to the drug’s late onset of sedation activity.\(^7\)
Group C patients needed multiple interventions to control agitation, attenuate the cough, adjust the opening of the vocal cords and increase sedation level during a relatively short procedure duration. The mean and maximum doses of lidocaine required in this group, were higher than those reported in some studies, but dose ranges were consistent with other studies reporting doses as high as 19 mg/kg with no incidence of adverse events. Likewise, no adverse events were reported in our study, though the British Thoracic Society recommends ‘the use of the lowest dose of lidocaine possible, while ensuring good bronchoscopic conditions and patient comfort’. Therefore, the use of a combination therapy with lidocaine would be more favourable than the use of lidocaine alone for sedation during FB.

Oxygen desaturation is a common complication during FB, manifesting in hypoventilation secondary to sedation and partial airway obstruction by the bronchoscope. Our comparisons showed the highest rate of oxygen desaturation in patients receiving alfentanil; this may be partly explained by the effects of morphinics on the respiratory centre in the brainstem, leading to an increase in the apneic threshold and thus to a reduced hypoxic drive especially when associated with benzodiazepine. A randomized controlled study compared dexmedetomidine to remifentanil in addition to

### TABLE 4

| Gender       | Group C | P value | Group A | P value | Group D | P value |
|--------------|---------|---------|---------|---------|---------|---------|
| Male         | 6.17 ± 2.02 | .030    | 5.46 ± 1.69 | .028    | 6.10 ± 2.26 | .004    |
| Female       | 7.50 ± 2.38 |         | 6.71 ± 2.40 |         | 8.05 ± 2.27 |         |

| Smoking      | Group C | P value | Group A | P value | Group D | P value |
|--------------|---------|---------|---------|---------|---------|---------|
| Yes          | 6.28 ± 2.14 | .178    | 6.75 ± 2.22 | .395    | 7.22 ± 2.95 | .789    |
| No           | 7.19 ± 2.32 |         | 6.21 ± 2.14 |         | 6.97 ± 2.38 |         |

| Alcohol consumption | Group C | P value | Group A | P value | Group D | P value |
|---------------------|---------|---------|---------|---------|---------|---------|
| Yes                 | 5.33 ± 1.21 | .022    | 4.50 ± 0.71 | .244    | 7.71 ± 2.22 | .338    |
| No                  | 6.94 ± 2.31 |         | 6.33 ± 2.18 |         | 6.76 ± 2.47 |         |

| Diabetes mellitus  | Group C | P value | Group A | P value | Group D | P value |
|--------------------|---------|---------|---------|---------|---------|---------|
| Yes                | 7.67 ± 2.12 | .191    | 5.58 ± 2.35 | .304    | 6.18 ± 2.27 | .286    |
| No                 | 6.58 ± 2.27 |         | 6.33 ± 2.15 |         | 7.07 ± 2.47 |         |

| Arterial hypertension | Group C | P value | Group A | P value | Group D | P value |
|-----------------------|---------|---------|---------|---------|---------|---------|
| Yes                   | 6.30 ± 2.00 | .096    | 5.67 ± 1.88 | .245    | 7.00 ± 2.12 | .782    |
| No                    | 7.33 ± 2.48 |         | 6.41 ± 2.32 |         | 6.81 ± 2.66 |         |

| Dyslipidemia         | Group C | P value | Group A | P value | Group D | P value |
|----------------------|---------|---------|---------|---------|---------|---------|
| Yes                  | 6.76 ± 2.17 | .991    | 6.14 ± 2.48 | .968    | 6.50 ± 2.78 | .539    |
| No                   | 6.76 ± 2.34 |         | 6.17 ± 2.12 |         | 7.00 ± 2.35 |         |

| Obesity              | Group C | P value | Group A | P value | Group D | P value |
|----------------------|---------|---------|---------|---------|---------|---------|
| Yes                  | 9.00 ± 1.41 | .012    | 6.10 ± 1.86 | .920    | 6.89 ± 1.90 | .995    |
| No                   | 6.53 ± 2.22 |         | 6.18 ± 2.28 |         | 6.88 ± 2.56 |         |

A P value <.05 was considered significant. Group C: standard/control: local anesthesia; group A: alfentanil + local anesthesia; and group D: dexmedetomidine + local anesthesia.

### TABLE 5

| Bronchoscopy Score | Group C | Group A | Group D |
|--------------------|---------|---------|---------|
| Age                | −0.165  | −0.474**| 0.003   |
| Bronchoscopy duration | **0.348** | 0.123 | **−0.331** |

Group C: standard/control: local anesthesia; group A: alfentanil + local anesthesia; and group D: dexmedetomidine + local anesthesia.

*Significant at the .05 level.
**Significant at the .01 level.
propofol in patients undergoing bronchoscopy and showed a more pronounced desaturation in the remifentanyl arm.\textsuperscript{26} Dreher et al.\textsuperscript{23} compared midazolam to midazolam combined with alfentanil in respiratory failure patients during FB and found that combined sedation produced a comparable degree of desaturation and hypoventilation though it was better tolerated with only 50\% consumption of midazolam. This combination could be responsible of a significantly greater drop in oxygen saturation when larger total doses of sedative drugs were used.\textsuperscript{24} An open-label randomized trial compared

| TABLE 6 | Group-specific multiple linear regression for the prediction of the bronchoscopy score |
|---------|-----------------------------------------------------------------------------------------------------------------|
| Predictors | Group C Regression, parameter $\beta$ | $P$ value | Group A Regression, parameter $\beta$ | $P$ value | Group D Regression, parameter $\beta$ | $P$ value |
| Gender | 1.151 | .038 | 1.019 | .064 | 1.956 | .003 |
| Age | $-0.023$ | .369 | $-0.063$ | .001 | $-0.011$ | .707 |
| Obesity | 2.410 | .012 | $-0.038$ | .958 | $-0.202$ | .802 |
| Bronchoscopy duration | 0.083 | .009 | 0.030 | .453 | $-0.120$ | .010 |

Group C: standard/control: local anesthesia; group A: alfentanil + local anesthesia; and group D: dexmedetomidine + local anesthesia. $R^2$ for group C: .308, $P$ value .001; $R^2$ for group A: .289, $P$ value 0.002; and $R^2$ for group D: .269, $P$ value 0.000.

FIGURE 2 Proposed algorithm for sedation during Bronchoscopy
dexmedetomidine to midazolam in patients receiving vasopressors in an intensive care setting after cardiac surgery and showed the mean lowest oxygenation in the midazolam arm despite the use of a high loading dose of 1 μg/kg dexmedetomidine.27

Our results showed the lowest O2 supplementation in dexmedetomidine group, which is a determinant advantage for its use, particularly in patients with obstructive airway diseases.26–28

Our data did not suggest any difference in the respiratory rate between the three groups; additionally, there was no excessive reduction in the respiratory rate in group A, though morphinics are known to be notorious depressors of the respiratory system.29,30

There were no episodes of clinically relevant bradycardia at any time point in any of three groups. Alfentanil and lidocaine alone were associated with an elevation in systolic and diastolic blood pressures throughout the procedure, whereas dexmedetomidine relatively maintained the blood pressure within the normal range. This was consistent with other recent findings,26,28 although it has been extensively shown that dexmedetomidine may induce hypotension or in some cases hypertension and bradycardia.15–17 Loading dose reduction and its slow infusion might have reduced hemodynamic side effects.

We relied on the multiple regression analyses to select the determinant factors related to the patients and to the procedure and to propose the appropriate decision rule of sedation in each scenario. We based our proposition on the following factors: age, gender; obesity and anticipated procedure duration (based on the procedure indication). The proposed algorithm shown in Figure 2 needs to be validated in future studies before its use in clinical practice.

We may also consider the presence of respiratory diseases as another determinant for the use of dexmedetomidine since they are known for their clinical impact, although they did not show any statistically significant effect on the bronchoscopy score in this study.

This study compared three different sedation regimens during FB, using lidocaine alone, dexmedetomidine- and alfentanil-based regimens. The three regimens were found suitable but each was more appropriate in certain patient profiles. The proposed protocol is a first step towards standardizing sedation practice in FB in a patient-tailored manner. A more comprehensive and detailed protocol including other sedative agents with their corresponding doses should be developed.

ACKNOWLEDGMENTS
None.

CONFLICT OF INTEREST
The authors declare that they have no competing interests.

AUTHOR CONTRIBUTIONS
All authors critically revised the manuscript and approved the final version.

Study conception and design: Riachy, Khayat, Ibrahim, Aoun, Dabar, Habr
Data acquisition: Riachy, Khayat, Ibrahim, Aoun, Dabar, Habr
Data analysis and interpretation and manuscript drafting: Riachy, Habr

ETHICS
The study protocol was approved by the hospital (Hotel Dieu de France) Institutional Review Board (approval number: CEHDF 438), and a written informed consent was obtained from all enrolled patients. Clinical trial registration: Saint-Joseph University, NCT01805726, ClinicalTrials.gov.

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APPENDIX

Bronchoscopy score computation,

Movement of the vocal cords,
- Open (1), in movement (2), closing (3), closed (4).

Cough occurrence,
- No occurrence (1), minimal occurrence (2), moderate occurrence (3), severe occurrence (4).

Limb movement,
- No movement (1), minimal movement (2), moderate movement (3), severe movement (4).

The final bronchoscopy score is the summation of the 3 sub-divisions score.

The final score can vary between 3 and 12 where 3 represents the optimal score and 12 represents the worst score.

How to cite this article: Riachy M, Khayat G, Ibrahim I, et al. A randomized double-blind controlled trial comparing three sedation regimens during flexible bronchoscopy: Dexmedetomidine, alfentanil and lidocaine. *Clin Respir J*. 2018;12:1407–1415. [https://doi.org/10.1111/crj.12669](https://doi.org/10.1111/crj.12669)