Nurse administered propofol sedation for pulmonary endoscopies requires a specific protocol

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ABSTRACT

INTRODUCTION: This study provides an evaluation and risk analysis of propofol sedation for endoscopic pulmonary procedures according to our unit's "gastroenterologic nurse-administered propofol sedation (NAPS) guideline".

MATERIALS AND METHODS: The present study is a prospective descriptive study performed at the Endoscopy Unit, Gentofte Hospital, Copenhagen, from May to July 2009. The study comprised at total of 51 consecutive patients who underwent 77 endoscopic procedures. Only patients above the age of 16 years were eligible for treatment. The exclusion criteria were as follows: American Society of Anesthesiologists (ASA) class > 3, history of sedation-related complications, severe chronic obstructive pulmonary disease. Excluded were patients with a potentially difficult airway and ventricular retention. Data on the number and type of procedure, baseline characteristics, sedation time, propofol dose administered and adverse events were obtained from medical histories.

RESULTS: A total of 23 cases of adverse events were recorded, including one event of hypotension and 22 events of hypoxaemia. Five patients needed assisted ventilation. The frequency of hypoxaemia in sessions involving bronchoscopy was 17 of 26 (65%) compared with trans-oesophageal endoscopic ultrasound (EUS) (17 of 45, 35%) and endoscopic bronchial ultrasound (EBUS) (three of six, 50%). Endoscopist assessment of working conditions was good and patient assessment of discomfort was low. No patients required endotracheal intubation and there was no mortality.

CONCLUSION: This study supports the conclusion that propofol administered by nurses provides for good working conditions and satisfied patients. But our "NAPS for endoscopic gastroenterologic procedures" guideline was unsuited for endoscopic pulmonary procedures including EUS.

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TRIAL REGISTRATION: not relevant.

Nurse administered propofol sedation (NAPS) without anaesthesiologic assistance has gained increasing popularity for gastrointestinal endoscopic procedures, and it was demonstrated that the method is safe provided proper training in airway management is given [1-5]. Propofol administered by anaesthesiologists has been used for sedation during endoscopic pulmonary procedures for some time [6-8], predominantly in cases where midazolam and opiate sedation (conventional regimens) have proven insufficient. Some studies have documented that for flexible bronchoscopy NAPS has the same rate of adverse events as midazolam/opiate sedation [9, 10]. Other studies conclude that propofol has superior characteristics including faster induction (30-60 sec.), faster recovery and return of psychomotor control and equal or superior patient and endoscopist satisfaction [11-13]. At Gentofte Hospital, Copenhagen, Denmark, diagnostic evaluation in patients either diagnosed with or suspected of lung cancer implies one to three of the following procedures: flexible bronchoscopy, trans-oesophageal endoscopic ultrasound (EUS) or endoscopic bronchial ultrasound (EBUS). The need for repeated procedures, the demand for fast-track evaluations and the high level of discomfort during these procedures have led to an increased demand for sedation [14-16]. The appealing characteristics of propofol meet this demand [17]. The feasibility and safety of conscious sedation with propofol for flexible bronchoscopy has been emphasised in some of the above-mentioned studies, but the data are still limited. The aim of this case series was to report the satisfaction and safety of propofol sedation in a cohort of patients undergoing diagnostic and therapeutic pulmonary endoscopy in a tertiary care hospital, and to investigate whether or not our NAPS guidelines, which are routinely used for gastrointestinal endoscopy, were feasible for pulmonary endoscopy.

MATERIAL AND METHODS

The pilot was terminated after 51 patients due to an unacceptably high rate of hypoxia as evaluated by the team together. All of the 51 consecutive patients in the pilot were included in this case series.

Propofol was administered by experienced "NAPS" nurses in an anaesthesiology set-up where the anaesthesiology personnel served as observers with responsibility for the sedation. The dosing regimen was given according to the already implemented "NAPS for endoscopic gastroenterologic procedures guidelines". The selection of patients for NAPS in the pilot was based on the following: Inclusion criteria: age ≥ 16 years; exclu-

ORIGINAL ARTICLE

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sion criteria: American Society of Anesthesiologists (ASA) classification > 3, history of sedation-related complications, sleep apnoea, pregnancy, allergy against soy/egg/peanuts, body mass index (BMI) > 35 kg/m^2, previously diagnosed with severe chronic obstructive lung disease, potentially difficult airway and ventricular retention. Patient eligibility was evaluated by an anaesthesiologist, a pulmonary physician and the NAPS-certified nurse. Prior to inclusion, all patients provided informed consent.

All patients were continuously monitored with single-axis electrocardiography, oxygen saturation (SAT), heart rate and blood pressure every 5 min. and on demand. Patients were treated with continuous intravenous administration of saline infusion 250-500 ml. Preoxygenation and supplemental oxygen 3 l/min. via a nasal cannula was initiated 2 min. before induction and continuously through the procedure, as is standard in the unit. 2 ml aliquots of 1% lidocaine were administered topically over the vocal cords, trachea and main bronchi during flexible bronchoscopy.

TABLE 1

Baseline characteristics.

	Hypoxaemia			
	group I (n = 22)	group II (n = 29)	total (n = 51)	p value
Age, years, mean ± SD	67.1 ± 11.2	58.3 ± 14.0	61.8[a]	0.020[b]
BMI, kg/m^2, mean ± SD	23.9 ± 4.2	26.2 ± 4.7	25.2	0.074[b]
ASA, n (%)				0.201[c]
I	3 (14)	9 (31)	12 (23)	
II	18 (82)	20 (69)	38 (75)	
III	1 (5)	0	1 (2)	
Smoker, n (%)	14 (64)	11 (38)	25 (49)	0.164[c]
Previously a smoker, n (%)	5 (23)	9 (39)	12 (24)	
FEV1%, mean ± SD	71.5 ± 14.4	78.6 ± 14.7	75.9[a]	0.135[b]
Procedure, n (%)				
Bronchoscopy	17 (65)	7 (27)	26 (33.8)	
EUS	17 (38)	28 (62)	45 (58.4)	
EBUS	3 (50)	3 (50)	6 (7.8)	

ASA = American Society of Anesthesiologists; BMI = body mass index; EBUS = endoscopic bronchial ultrasound; EUS = trans-oesophageal endoscopic ultrasound; FEV1%, mean = forced expiratory volume in the first sec.,% of age mean; SD = standard deviation.
a) Ten values missing; b) Independent samples t-test; c) Pearson's chi-square.

TABLE 2

Sedation time, quantity of propofol and adverse events.

	Hypoxaemia (n = 22)	Control (n = 29)	p value
Sedation time, min., mean ± SD	33.2 ± 14.7	29.5 ± 12.9	0.344[a]
Propofol dose total, mg, mean ± SD	581.9 ± 413.3	495.4 ± 233.1	0.357[a]
Time to discharge, min., mean ± SD	82 ± 65.4	62 ± 19.3	0.131[a]

SD = standard deviation. a) Independent samples t-test

Propofol administration

Propofol was administered as monotherapy. The initial propofol loading dose was 100 mg minus the patient's age, but not exceeding 60 mg. If needed, a second loading bolus was administered after a minimum 40 sec. as the initial dose, but with a 50% reduction, hence not exceeding 30 mg. The depth of sedation was assessed after every dose through verbal and tactile stimulation similar to the Modified Observer's Assessment of Alertness/Sedation (MOAA/S) [18] score and through monitoring of hearth rate, blood pressure and respiratory movements. If deeper sedation was needed after the first two doses, refract doses of 5 mg to 20 mg could be administered with a 20-sec. observation interval. There was no predefined cumulative maximum loading dose. Maintenance of sedation was achieved through careful, intermittent 10-20 mg bolus administration. Movement of the eyes, extremities, sounds or other signs of pain or discomfort were considered signs of superficial sedation leading to administration. Furthermore, if the patient was adequately sedated with sufficient respiration, doses of 10-20 mg could be administered every 1-2 min. The level of sedation aimed for was moderate sedation with spontaneous respiration, no circulatory depression and possible tactile stimulation of the patient. The nurse administrating propofol had no other tasks except to sedate and monitor the patient and was competent in airway manipulation and assisted ventilation with a face-mask. The anaesthesiologist and the endoscopist were responsible for the patient's safety and could intervene if needed.

Data collection

Data for this case series were obtained from patient sedation records. Variables included were: Patient demographics, sedation time, quantity of propofol and adverse events. Furthermore, The endoscopist had been asked to fill in a satisfaction questionnaire and the patient an experience of discomfort questionnaire. This was obtained from the patient's medical records and included in this study.

Adverse events

Adverse events were pre-defined as peri-procedural hypoxaemia (SAT ≤ 90%, or the starting value minus five in case of starting values below 95%) measured with pulse oxymetry. Also, duration of hypoxaemia was recorded in a checklist box on the sedation record as < 30 sec., 30-60 sec. or > 60 sec. Furthermore, a decline in systolic blood pressure of more than 30% was regarded an adverse event along with arrhythmias occurring during sedation.

Ethics

This study was considered a quality-control study by the

Local Ethics Committee, so no approval was needed J. no. H-1-2012-FSP-13. Danish Data Protection Agency J. no. 2011-41-6849.

Statistics

In addition to descriptive statistics, a risk analysis was performed comparing baseline characteristics, intervention and quantity of propofol in patients who experienced sedation-related hypoxaemia (group I) with those who did not (group II).

Statistics and calculations on the data were done using the Statistical Package for the Social Sciences (SPSS) 17.0 (SPSS Inc. Chicago, IL). For continuous variables, values were presented as means ± standard deviations with corresponding 95% confidence intervals as relevant. Differences between group means were evaluated using Student's t-test adjusted for equal or non-equal variance as calculated by Levene's test. Group differences for categorical values were evaluated using Fisher's exact test. p values below 0.05 were considered statistically significant.

Trial registration: not relevant.

RESULTS

All treated patients, i.e. a total of 51 patients undergoing 77 procedures, were included for analysis. The mean age was 61.8 year and the mean BMI was 25.2 kg/m^2. Furthermore, the forced expiratory volume in the first sec.,% of age mean, (mean FEV1%) was 75.9, and the mean SAT prior to procedure without supplemental oxygen 96.5%. Twenty-three cases of adverse events were recorded. One adverse event was due to hypotension. The remaining 22 were due to hypoxaemia. Five patients needed assisted ventilation. There was no need for the anaesthesiologist to intervene and no patients required endotracheal intubation. There was no mortality. The endoscopist level of satisfaction with sedation was good, ranging from VAS 6-10 (mean 9.1), ten being very satisfied. The patients' experience of discomfort was low, ranging from VAS 0-4 (mean 1.1,), zero being no discomfort.

Hypotension

One patient experienced hypotension due to sedation. The patient was stabilized with a high saline flow and Trendelenburg. The procedure was completed. No cases of arrhythmias were noted.

Hypoxaemia

Hypoxaemia was seen in 22 cases (43%). There was no significant difference in baseline characteristics in terms of age, BMI, mean FEV1%, ASA class and use of tobacco between the group of patients with hypoxaemia (group I) and the group with no hypoxaemia (group II) (**Table 1**). Nor did the two groups differ with regard to, propofol dose administered, sedation time or time to discharge (**Table 2**). The only single factor that differed significantly was age (p = 0.02), but according to Levene's test, this could be natural variance (Sig. 0.170). The highest frequency of hypoxaemia occurred in sessions involving bronchoscopy (17 of 26, 65%) compared with EBUS (3 of 6, 50%) and EUS (17 of 45, 35%) as shown in Table 1. The data were widely spread according to the degree of hypoxaemia and its duration as shown in **Table 3**.

TABLE 3

Degree and duration of hypoxaemia. Number of cases.

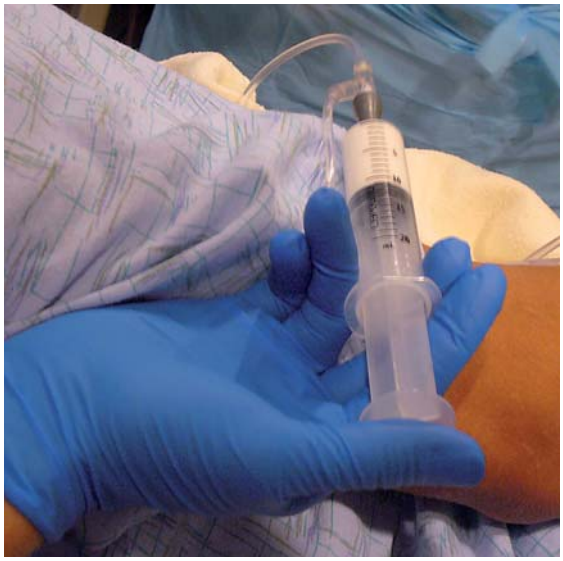
	Duration, sec.			
	< 30	30-60	> 60	Total
Oxygen saturation,%				
< 90	6	5	4	15[a]
< 85		1	5	6
Total	6	6	9	

a) One dataset was incomplete.

Five of the 22 procedures (23%) with hypoxaemia were terminated (9.8% of total) in order to initiate assisted ventilation with a face-mask, and two procedures were resumed after patients had been stabilized. Three procedures were terminated simply because the patients could not be sufficiently sedated without a need for assisted ventilation. There were no cases of intervention from the anaesthesiologist present.

Endoscopist and patient assessment

Endoscopist satisfaction with sedation and working conditions was scored on five items according to a visual



Propofol administration.

analogue score (VAS) from zero to ten, ten being very satisfied. The general impression was: EUS VAS = 10, flexible bronchoscopy VAS = 9.1, EBUS VAS = 7.6 and the overall average score was 9.1 (**Figure 1**).

Patients' expectations and their experience were also scored according to a VAS on seven items, ten being very unpleasant. The overall average score was 1.1 (Figure 1).

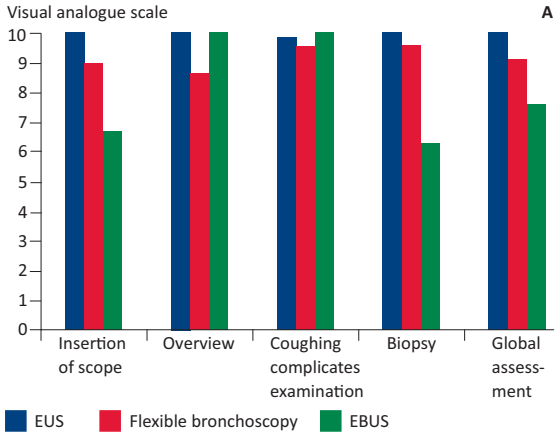
DISCUSSION

In 2009, two prospective randomised controlled studies, one by Clark et al [10] and one by Stolz et al [9] compared sedation with midazolam versus propofol and midazolam/hydrocodone versus propofol for flexible bronchoscopy. A total of 82 and 200, consecutive patients, respectively, were randomised to receive NAPS for flexible bronchoscopy.

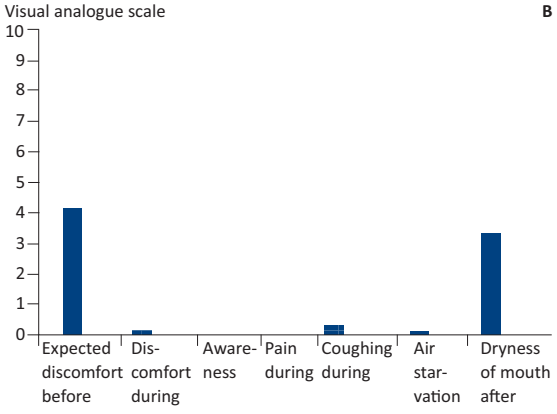
In the study by Clark et al, hypoxaemia events with a SAT < 90% were transient, treated with oxygen and occurred with the same frequency in both groups

FIGURE 1

A. Endoscopist assessment of sedation. **B.** Patient assessment of discomfort.



EBUS = endoscopic bronchial ultrasound.
EUS = trans-oesophageal endoscopic ultrasound.



(35.9%/34.9%). Two patients in the propofol group had hypotension (4.7%). The mean propofol dose was 135.1 ± 71.7 mg.

In the work by Stolz et al, no significant difference in frequency of hypoxaemia with a SAT < 90% was observed between those receiving midazolam/hydrocodone and those receiving propofol (25%/32%). Nor was the difference in need for chin support significant (34% total). The mean propofol dose required was 217 ± 131 mg.

A randomised study by Oztürk et al [19] reported on 100 patients among whom hypoxaemia with a SAT < 90% occurred in 16 (32%) who were receiving midazolam and in five (10%) who were receiving propofol. The mean dose of propofol used was 81.8 ± 20.1 mg.

One retrospective single-centre study by Bosslet et al [20] summarized 498 endoscopic pulmonary procedures performed in a variety of patients. The adverse event rate reported was 6.6% minor adverse events and 1.2% major adverse events. Hypoxaemia was rated as a minor adverse event occurring with a frequency of 3.8%. Three patients required intubation. The average propofol dose was 242 mg (range 10-1,320 mg).

The frequency of hypoxaemia in the present study is higher than the frequencies reported by the above-mentioned trials. According to these trials [9, 10], propofol can be titrated to a similar or lower incidence of hypoxaemia as that of midazolam sedation [19]. The mean propofol dose administered in this study was 582 mg in the hypoxaemia group I and 495 mg in group II compared with 81.8-242 mg in the above-mentioned studies even if the lengths of examination of the studies were comparable.

This study has limitations. Firstly, the population is small; and secondly, it is not randomised. It seems unlikely, however, that the frequency of hypoxia is underreported due to the large number of personnel in the room. The frequency of hypotension could be underestimated. Furthermore, the aim of the pilot was not to document a certain frequency of adverse events, which could theoretically affect the administration, but to routinely provide for sufficient sedation as assessed by the team and to observe the feasibility of this approach.

It is likely that the hypoxaemia frequency would drop if titration of propofol was administered according to a more restrictive regimen. This would result in a more superficial sedation, likely affecting the working conditions and the acceptance of the procedure. With this regimen, patient and endoscopist satisfaction assessment scores were high; hence, the working conditions and patient satisfaction achieved with this regimen met our expectations, and the feasibility as measured by the frequency of hypoxia and airway handling did not. The amount of airway handling needed was too

extensive to be considered feasible and practical. There was no need for anaesthesiologist assistance, but the size of the study does not allow for further conclusions on safety.

CONCLUSION

This study supports the conclusion that propofol administered by NAPS-nurses provides for good working conditions and satisfied patients. But our "NAPS for endoscopic gastroenterologic procedures" guideline was unsuited for endoscopic pulmonary procedures including EUS.

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