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Titrated Sedation with Propofol for Medical Thoracoscopy: A Feasibility and Safety Study

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Key Words
Propofol sedation · Bispectral analysis · Anesthesia · Pneumothorax · Thoracoscopy

Abstract
Background: Bispectral index (BIS) is a valuable tool for assessing the depth of sedation and guiding the administration of sedative drugs. We previously demonstrated the benefits of BIS-guided propofol sedation in patients undergoing flexible bronchoscopy. ***Objective:*** To examine the feasibility and safety profile of propofol sedation in patients undergoing medical thoracoscopy (MT). ***Methods:*** Patients undergoing MT for diagnostic evaluation or treatment of pleuropulmonary diseases were enrolled over a 2-year period. Nurses and chest physicians were trained by anesthetists to provide analgosedation, to detect and correct cardiopulmonary disturbances. The level of sedation was optimized individually by titrating the propofol infusion according to the BIS and clinical evaluation. Patients' clinical data, procedure time, medications and any adverse events were recorded. ***Results:*** Fifty-three patients (60% male) with a median age of 62 years (range 19–84 years) underwent MT. The operative procedure lasted a median time of 28 min (range 9–112 min). The median doses of anesthetic drugs were 145 mg of propofol (range 20–410 mg) and 84 μg of fentanyl (range 0–225 μg). Hemodynamic disturbances occurred in 39 patients (bradycardia n = 4, tachycardia n = 12, hypotension n = 34) and required drug administration in only 4 cases. Hypoxemic events (n = 4) resolved upon gentle patient stimulation (verbal command, chin lift, oral cannula). All patients could be discharged from the recovery unit within 105 min after the procedure. ***Conclusions:*** BIS-guided propofol sedation is a safe method that might replace midazolam sedation in MT and can be managed by well-trained nonanesthesiologist personnel.

Introduction

Over the last decade, video-assisted thoracoscopic surgery (VATS) and medical thoracoscopy (MT) have emerged as diagnostic and therapeutic procedures for patients with pleural or pulmonary diseases [1–3]. Although the British Thoracic Society has issued recommendations emphasizing the need for preoperative risk assessment and routine monitoring of cardiopulmonary function, evidence-based guidelines are still lacking regarding the most appropriate approach for anesthesia and sedation in patients undergoing minimally invasive pulmonary procedures [3, 4]. To date, VATS is always performed under

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general anesthetic with endotracheal intubation and selective one-lung ventilation by surgical and anesthesia teams (thoracic surgeon, scrub nurse, anesthesiologist and residents or assistants), in a fully equipped operating theater. In contrast, MT is routinely performed by chest physicians under light sedation (or so-called 'conscious sedation') in spontaneously breathing patients in facilities outside the costly environment of operating rooms [5–8]. Among nonanesthesiologists, midazolam remains the preferred sedative drug, although gastrointestinal endoscopists have gained much experience with the administration of propofol [9–13]. In patients undergoing flexible bronchoscopy, preliminary results also support the feasibility, safety and potential advantages of propofol sedation compared with midazolam [14–17]. Therefore, in 2007 we elected to modify our sedation protocol, switching from the classic midazolam/pethidine regimen to the combination of propofol/fentanyl for all pulmonary interventional procedures. In collaboration with anesthesiologists, we set up a standardized approach for the safe management of propofol sedation using a clinical scale and bispectral analysis of the electroencephalogram.

The aim of this study was to describe our sedation technique and to evaluate its safety among patients undergoing MT over a 2-year period.

Methods

Patient Selection

Between January 2008 and December 2009, 69 adult patients (>18 years) were referred to our chest hospital for diagnostic evaluation of pleuropulmonary disease or treatment of persistent or recurrent spontaneous pneumothorax. Preintervention evaluation included clinical history, ECG, standard laboratory tests, chest radiography and computed tomography of the chest. Flexible bronchoscopy was performed in all cases of suspected primary lung cancer. The study and database were approved by the Institutional Review Board and informed consent was waived, given the retrospective nature of this study and the fact that all data in the electronic registry were anonymous.

Exclusion criteria for MT included the anticipated need for decortication or mediastinal dissection, hemodynamic instability requiring cardiovascular drug support, respiratory failure requiring intubation or noninvasive ventilatory support, psychological disorders and allergy or hypersensitivity to soybeans or propofol.

Education and Training

To qualify the nonanesthesiologist health care professionals (1 nurse, 1 medical officer and 2 staff physicians), a training program in sedation and analgesia was set up by anesthesiologists that included didactic lectures (pharmacology of sedatives, analgesics and cardiovascular drugs) and workshops focused on airway management, monitoring the depth of sedation/anesthesia and advanced life support. Each participant took part in supervised clinical sessions (2 cases) followed by discussions.

Management of Analgosedation

In the operating room, a peripheral intravenous cannula was inserted for fluid and drug administration. The standard anesthetic monitoring included noninvasive blood pressure, ECG, pulse oximetry (Sp_{O_2}) and end-tidal carbon dioxide. Processed EEG parameters were acquired with a bispectral index (BIS) monitor, using Zipprep surface electrodes, with impedance maintained at less than 5 kΩ to ensure adequate signal quality (A-2000 monitor, 3.11 version software; Aspect Medical Systems, Newton, Mass., USA). Raw EEG data from two channels (F_7-C_Z and F_8-C_Z) were processed by company proprietary software and the BIS values (calculated for each 4-second epoch) were continuously displayed along with the trend line. Oxygen was given via a facial mask at a flow of 2–6 liters/min.

The depth of sedation was assessed by the BIS monitor and the Observer's Assessment of Alertness/Sedation (OAAS) scale (5 = awake and responds readily to name spoken in normal tone, 4 = lethargic response to name in normal tone, 3 = response only after name is called loudly and/or repeatedly, 2 = response only after name is called loudly and after mild shaking, 1 = does not respond when name is called and after mild shaking). Sedation was titrated with small i.v. doses of propofol (10–20 mg) to achieve an OAAS score of 2–3 before local anesthetic infiltration and to target BIS values between 60 and 80 throughout the procedure. Complementary doses of opiates (fentanyl 50 μg) were given if a patient felt uncomfortable as indicated by an increasing respiratory rate (>20/min) or a withdrawal response to incision or intrathoracic manipulation.

Other drugs and dedicated equipment for cardiopulmonary support were readily available. Management of sedation and the treatment of potential adverse events were standardized and described thoroughly in a formal protocol (table 1). Contingency plans in case of hypoxemia, hypoventilation and hemodynamic disturbances included definition criteria and specific correcting interventions.

Thoracoscopy was carried out in the lateral position as previously described [16]. A local anesthetic (lidocaine 1%, 10–15 ml) were infiltrated subcutaneously prior to incision and thereafter under direct vision into the intercostal muscles and pleura.

After the procedure, patients were transferred to the recovery unit and were discharged when they had fulfilled the safety criteria of the modified Aldrete score (table 2) [18].

Data Collection and Analysis

Besides a patient's clinical data, specific time periods were recorded: the induction time (from the start of propofol infusion to skin incision), the operating time (from skin incision to closure) and the time up until discharge after the MT (from closure to discharge from the recovery unit).

The cardiopulmonary safety profile was the primary clinical endpoint as determined by the following adverse events: hypotension [systolic arterial pressure (SAP) <100 mm Hg or mean arterial blood pressure (MAP) <60 mm Hg], tachycardia [heart rate (HR) >90/min and/or a variation of >20% from baseline value], bradycardia (HR <50/min), hypoxemia (Sp_{O_2} <90% for >30 s), the need for noninvasive ventilation or for tracheal intubation.

Table 1. Protocol for BIS-guided sedation for pneumological interventions

1 Preintervention assessment Medical history and examination ASA score Routine laboratory tests Informed consent	Exclusion criteria ASA 4–5 High bleeding risk (e.g. antiplatelet, anticoagulant) Unstable hemodynamics (need for drug support) Difficult upper airway anatomy Respiratory failure requiring ventilatory support Allergy to soybeans or profol
2 Patient preparation and installation i.v. line with 500 ml NaCl 0.9% or Ringer lactate Monitoring ECG, noninvasive blood pressu Pulsed oxygen oxymetry, end-tidal carbon dioxide BIS analyzer and OAAS scale* Lateral positioning Facial mask with oxygen 2–4 liters/min	Available equipment (to be checked) Gas supply (oxygen, air), suction tube and device Oral cannula, facial masks, laryngeal masks Endotracheal tube (No. 7–8), laryngoscope Ventilator Automated external defibrillator
3 Sedation and analgesia Propofol (200 mg/20 ml) repeated 10–20 mg bolus or continuous infusion Start 5 min before skin incision, local anesthesia Target BIS 60–80, OAAS 2–3 Fentanyl (100 μg/2 ml) 50 μg 5 min before skin incision 25–50 μg before talc insufflation or as deemed necessary	Available drugs Prepared Atropine (0.5 mg/2 ml) Ephedrine (50 mg/5 ml) Not prepared but checked Ondansetron (4 mg/2 ml) Epinephrine (1 mg/10 ml) Nitroglycerine (1 mg/10 ml) Metoprolol (5 mg/5 ml) Salbutamol (inhaled) Naloxone (0.4 mg/1 ml)
4 Hemodynamic management Keep MAP 60–95 mm Hg or within 80–110% basal values Keep HR 50–90 best/min or within 80–120% basal values	Adverse hemodynamic events Hypotension = MAP <60 mm Hg or SAP <100 mm Hg Ephedrine 5–10 mg, infuse 250 ml cristalloids over 5–10 min, exclude bleeding Hypertension = increase in MAP/SAP ≥20% Check analgesia; exclude hypoxia and myocardial ischemia Consider metoprolol 2 mg, nitroglycerine 100 μg i.v. Bradycardia = HR <50/min 0.5 mg atropine Tachycardia = HR >90/min Check analgesia; exclude hypoxia and myocardial ischemia Metoprolol 2 mg i.v.
5 Respiratory management Keep respiratory rate >8/min ($_{\text{end-tidal}}CO_2$) Observe chest movements Keep SpO_2 90%	Adverse respiratory events Hypoxemia = SpO_2 <90% for >60 s (1) Check for upper airway obstruction, chin lift, insert an oral cannula, increase FIO_2 (4–8 liters/min) (2) Check anesthesia depth, reduce propofol infusion (3) Assist spontaneous ventilation with mask (4) If unresolved hypoxemia: interrupt thoracoscopy, return into supine position, administer noninvasive ventilation and consider tracheal intubation with placement of a chest tube Bradypnea (1) Check anesthesia depth, reduce propofol infusion, consider opiate overdosage and naloxone administration (2) Assist spontaneous ventilation with mask
6 Discharge criteria from the operating room MAP and HR within 80–120% of preintervention values SpO_2 ≥94% or recovery of preintervention values BIS >90 and OAAS ≥4 Adequate analgesia (VAS ≤3/10)	OAAS sedation scale 5 = Awake, responds readily to name spoken in normal tone 4 = Lethargic response to name in normal tone 3 = Response only after name is called loudly and/or repeatedly 2 = Response only after name is called loudly and after mild shaking 1 = Does not respond when name is called and after mild shaking

ASA = Physical status classification of the American Society of Anesthesiologists; VAS = visual analog scale.

Table 2. Safety criteria for patient discharge from the ambulatory unit

	Score
Level of consciousness	
Awake and oriented	2
Arousable with minimal stimulation	1
Responsive only to tactile stimulation	0
Physical activity	
Able to move all extremities on command	2
Some weakness in movement of extremities	1
Unable to voluntarily move extremities	0
Hemodynamic stability	
Blood pressure <15% of baseline MAP value	2
Blood pressure 15–30% of baseline MAP value	1
Blood pressure >30% below baseline MAP value	0
Respiratory stability	
Able to breathe deeply	2
Tachypnea with good cough	1
Dyspneic with weak cough	0
Oxygen saturation status	
Maintains value >90% on room air	2
Requires supplemental oxygen (nasal prongs)	1
Saturation <90% with supplemental oxygen	0
Postoperative pain assessment	
None or mild discomfort	2
Moderate to severe pain controlled with i.v. analgesics	1
Persistent severe pain	0
Postoperative emetic symptoms	
None or mild nausea with no active vomiting	2
Transient vomiting or retching	1
Persistent moderate to severe nausea and vomiting	0
Total score	14

Table 3. Baseline patient characteristics

Demographic and clinical data	
Age, years	62 (19–84)
BMI	1.76 (1.61–2.09)
ASA class 3	7 (13)
Female	22 (41.5)
Indications for medical thoracoscopy	
Malignant pleural effusion	27 (50.9)
Lung cancer	11 (20.8)
Mesothelioma	4 (11.3)
Breast cancer	6 (11.3)
Colonic cancer	2 (3.8)
Ovarian cancer	1 (1.9)
Unknown origin	1 (1.9)
Benign pleural effusion	2 (3.8)
Biopsy (lung, pleura)	12 (15.1)
Complicated pneumothorax	16 (30.2)

Data are expressed as median (range) or number (%). ASA = Physical status classification of the American Society of Anesthesiologists: 1 = a normal healthy patient; 2 = a patient with mild systemic disease; 3 = a patient with severe systemic disease; 4 = a patient with severe systemic disease that is a constant threat; 5 = a patient who is not expected to survive without the operation.

Continuous data were expressed as means [±standard deviation (SD)] or median and range, depending on data distribution. Categorical data were expressed as numbers and percentages.

Results

As shown in figure 1, of the 69 patients referred to our hospital, 53 underwent MT either for talc pleurodesis with thoracic drainage (n = 43) or for diagnostic purposes (n = 10). Patients' clinical data and medical diagnosis are listed in table 3.

All planned procedures were successfully completed under sedation, with no interruption. The median induction time was 3 min (range 2–5 min) and the median operating time was 28 min (range 9–112 min). Throughout the procedure, patients received a median cumulative dose of 130 mg propofol (range 20–410 mg) with fentanyl being administered to all except 2 patients (median dose 75 μg, range 0–225 μg). Adverse events are reported in table 4. All four hypoxemic events resolved upon gentle patient stimulation (verbal command, chin lift, insertion of an oral cannula) and did not require ventilatory support. Hemodynamic disturbances occurred in 39 patients (bradycardia n = 4, tachycardia n = 12, hypotension n = 34) that resolved upon fluid infusion, optimization of analgesia or the administration of vasopressive drugs (n = 4). The time up to discharge did not exceed 85 min, except for 1 patient, due to delayed neurological recovery (105 min). Before discharge, all patients fulfilled the Aldrete safety criteria and none of them expressed any complaints.

Discussion

In this study, we demonstrated that BIS-guided propofol sedation for MT can be safely conducted by well-trained nonanesthesiologist personnel. Indeed, the operating conditions were satisfactory and there were no major adverse cardiopulmonary events. Hypoxemia, hypotension and bradytachycardia either resolved spontaneously or were rapidly corrected by simple interventions.

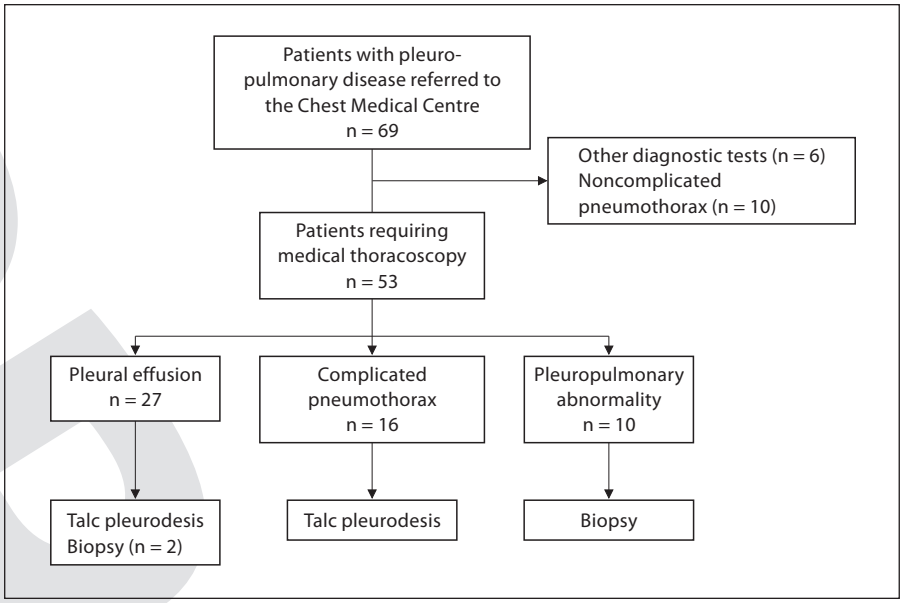

Fig. 1. Participant flow diagram, based on their clinical history and chest imaging, patients underwent further diagnostic testing and/or medical thoracoscopy involving talc pleurodesis and/or biopsy.

Table 4. Sedation-associated adverse events during medical thoracoscopy

Hypoxemia (SpO_2 <90% lasting at least 120 s)	4 (7.6%)
Need for ventilatory support	0
Hypotension	34 (64.1%)
Need for ephedrine	3 (5.7%)
Tachycardia	12 (22.6%)
Need for metoprolol	0
Bradycardia	4 (7.6%)
Need for atropine	1 (1.9%)
Nausea requiring domperidone	4 (7.6%)

Currently, no consensus exists regarding the choice of sedative and analgesic agents, the mandatory monitoring equipment and the minimal training and qualifications required for health care professionals providing analgosedation [3]. Drug-induced cardiopulmonary disturbances and difficulties in managing the upper airways are the most-feared complications that might justify the presence of an anesthesiologist, particularly in high-risk patients and for complex or prolonged interventions [19].

In 2002, guidelines from the American Society of Anesthesiologists (ASA) suggested that nonanesthesiologist personnel might be trained and qualified to perform moderate levels of sedation in low-to-intermediate risk patients undergoing minimally invasive procedures [20]. Since that time, propofol has emerged as a drug of choice for managing sedation, given its excellent safety profile and ease of titration to the desired level of sedation even by nonanesthesiologists [12, 13]. In contrast to gastroenterologists or cardiologists, chest physicians are well qualified to control ventilation and manage the upper airways in case of sudden respiratory depression. Strong supportive data on the optimal sedation regimen for mini-invasive procedures such as MT are still lacking, although concerns have been raised regarding the risk of drug-induced cardiac depression, vasodilatory hypotension, tachy-/bradyarrhythmias or hypoventilation [19, 21].

In this study, we implemented a propofol sedation protocol that had been previously validated in patients undergoing flexible bronchoscopy. This observational study involving patients undergoing MT lends further support for the use of propofol under BIS monitoring and in collaboration with anesthesiologists. First, propofol is a 'near-ideal' sedative drug with a short onset of action, dose-dependent hypnotic effects with minimal cardiopulmonary depression at low doses and rapid clearance allowing fast neurological recovery. Second, the BIS correlates closely with the clinical signs of propofol-induced sedation [22]. In contrast to the intermittent evaluation on the OAAS scale, bispectral analysis provides a continuous assessment of the cortical EEG activity that renders the management of sedation safer when BIS values between 60 and 80 are targeted [23]. The small costs incurred by the routine implementation of BIS monitoring

(EUR 11 per case) are largely compensated by the reduction of resource utilization associated with the shorter length of stay in the ambulatory unit. Finally, the close interactions with the anesthesia team helped us to strengthen our skills and expertise regarding safe and appropriate periprocedural medical management. We implemented a standardized approach for analgosedation that included patient selection criteria, a checklist for drugs and equipment as well as guidelines for anesthetic-drug titration and management of hemodynamic and respiratory disturbances (table 1). Besides standard measurements of MAP, HR and Sp_{O_2}, monitoring of BIS and end-tidal CO_2 were key components to achieve adequate levels of sedation while preventing major adverse events and facilitating a speedy recovery [19, 23].

Management of sedation for endoscopic procedures has been the focus of increased interest over the last decade since sedation may not only optimize patient comfort and facilitate the intervention but also reduce health care costs when performed by nonanesthetists.

There is an ongoing debate between thoracic surgeons and pulmonologists regarding lung interventions under MT or VATS. Local anesthesia supplemented with sedatives and analgesics is widely practiced by pulmonologists [8], whereas most thoracic surgeons prefer to perform VATS with general anesthesia with selective lung ventilation [7]. Obviously, the 'VATS surgical option' offers the best operating conditions and a safe control of the cardiopulmonary status, which is deemed necessary for handling complex cases (e.g. bulla resection, severe respiratory disease), but with the additional costs associated with the utilization of an operating room, the implication of an anesthesia team and the need for postoperative hospitalization. In contrast, MT under monitored sedation seems ideally suited in the majority of patients with complicated pneumothorax or lung effusion, providing shorter occupation of the operating room (or endoscopy suite), faster patient recovery, reduced utilization of hospital resources and hence reduced health care costs [24–26].

As in many other countries, Switzerland has adopted the Diagnosis-Related Group codes to estimate medical fees and hospital reimbursement. For a standard case requiring talc pleurodesis and lung biopsy (e.g. a 55-year-old man, ASA class 2, with no complications), the burden of costs is markedly greater for VATS than for MT (ratio 2.1); accordingly, performing MT (instead of VATS) may save up to EUR 2,900 per case.

We are mindful of several limitations. First, the observational prospective design of this study precludes any conclusion regarding the superiority (or equivalence) of propofol compared with other hypnotics (e.g. nitrous oxide, ketamine, midazolam) in the specific setting of MT. In a previous randomized controlled trial involving patients undergoing bronchoscopy, we gained expertise with BIS-guided sedation and we clearly demonstrated the advantages of propofol compared to midazolam, particularly in terms of neuropsychometric recovery [14]. Second, this study included a relatively small number of patients and it was conducted in a single referral thoracic center. As most of these cases presented with a low-to-intermediate risk profile (13% of the patients had ASA class 3), our findings need to be replicated in other settings using a similar sedation protocol and including larger population samples with higher-risk profiles. Third, given our local expertise in performing MT, there was a selection bias. If referred to other institutions, some patients would have undergone VATS instead of MT. Accordingly, future studies should question whether spontaneous ventilation under sedation or mechanical ventilation under general anesthesia is the best approach in patients undergoing a therapeutic thoracoscopic procedure.

In conclusion, MT for various diagnostic and therapeutic purposes can be safely performed if a standardized sedation protocol is implemented by well-trained nonanesthetists. Guidelines for sedation for pulmonary interventions should be updated by taking into account the recent pharmacological advances and progress in anesthesia monitoring while emphasizing the importance of interdisciplinary collaborations.

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