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Feasibility and safety of propofol sedation in flexible bronchoscopy

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Summary

BACKGROUND: Propofol is a sedative-hypnotic with a rapid onset of action. There are only limited data evaluating propofol for flexible bronchoscopy. We analysed the feasibility and safety of propofol for bronchoscopy in a high output tertiary care centre.

METHODS: Prospective data on patients undergoing flexible bronchoscopy at the University Hospital Basel, Switzerland, were analysed. Patient demographics, ASA class, Mallampati class, indication for bronchoscopy, bronchoscopic procedures, duration of examination, medication requirements, minor and major adverse events, haemodynamic parameters, as well as cough scores during the procedure were documented. Patients were followed up to discharge from the bronchoscopy suite.

RESULTS: Data from 440 patients with a mean age 60 years (±15.5, 260 male) were analysed. The main indication for bronchoscopy was a suspicion of malignancy. The most common diagnostic procedures were bronchoalveolar lavage in 253 cases (31.5%) and bronchial washing in 174 cases (21.7%). The mean duration of the procedure was 19.6 min (±12.08). The mean propofol dose was 200 mg (±107.5) corresponding to 2.89 mg/kg (±1.70). Minor adverse events included oxygen desaturation in 72 (16.4%), hypotension in 68 (15.4%) and minor bleeding in 11 (2.5%) patients. No major adverse events were recorded. The median decline in systolic blood pressure after initiation of sedation was 14 mm Hg (3–28). A drop in systolic blood pressure greater than 20 mm Hg was observed in 166 of the 440 patients (37%).

CONCLUSION: Propofol sedation for flexible bronchoscopy is feasible and safe.

Key words: *endoscopy; medication; risk, procedure; respiratory*

Introduction

The British Thoracic Society states that sedation for flexible bronchoscopy should be offered to patients where there is no contraindication [1]. The aim of sedation is to facilitate patient comfort and satisfaction, and to alleviate patient anxiety, coughing and dyspnoea, while reducing the complications of the procedure [2–4]. According to a European survey, more than 95% of centres routinely perform sedated bronchoscopies [5].

Optimal sedation for flexible bronchoscopy has been assessed in a number of studies evaluating different sedative drug regimens using single agents or combinations thereof [6–9]. Furthermore, particular drug requirements in specific sub-groups of patients have been studied. Combined sedation using an opiate and a benzodiazepine was shown to be effective and safe even in high risk patients suffering from chronic obstructive pulmonary disease (COPD) [10].

Propofol (2.6 di-isopropylphenol), a sedative-hypnotic frequently used in the induction and maintenance of anaesthesia, has recently proved to be an attractive option to combined sedation with midazolam and hydrocodone, particularly if a timely discharge is a priority due to its rapid onset of action and fast recovery time [11–16]. Additionally, propofol seems to provide a higher quality of sedation in terms of neuropsychometric recovery and patient tolerance [17]. Propofol for conscious sedation during gastrointestinal endoscopies has proved to be safe in a number of studies [18, 19]. There is mounting evidence suggesting that this sedation technique can also be safely performed by a non-anaesthesiologist during bronchoscopy [11, 14, 17]. Finally, fospropofol was shown to provide effective and safe sedation during flexible bronchoscopy in a recent randomised, double-blind trial [20].

Due to its rapid onset of action and amnesic properties and coupled with a smooth and rapid recovery, propofol is an appealing agent for procedural sedation [11, 21, 22]. The significant advantage of a faster recovery time compared to other sedative-hypnotic agents has been emphasised in several studies examining a series of procedures, including upper- and lower gastrointestinal endoscopy [15, 23–25]. However, as yet, there are only limited data evaluating the safety of propofol sedation for flexible bronchoscopy. In this study, we report the feasibility and safety of propofol sedation for flexible bronchoscopy in a cohort of patients undergoing diagnostic and therapeutic bronchoscopy in a high output, tertiary care hospital.

Methods

Prospective data of patients undergoing elective diagnostic and therapeutic flexible bronchoscopy over a period of six months at the University Hospital Basel, Switzerland, were analysed. Intubated patients and those with a known allergy or intolerance to propofol were not included in the study. A total of 440 patients were included in this case series. Before inclusion, all patients provided informed consent, which has been previously approved by the Law Department of the Institution for the assessment of bronchoscopy-related outcomes. Due to its quality-control character, the study was withdrawn from approval by the Institutional Review Board.

After obtaining informed consent, physicians performing bronchoscopy classified the patient as either low (ASA I–II), medium (ASA III), or high risk (ASA IV–V) for the procedure according to the American Society of Anaesthesiologists (ASA) criteria. The Mallampati class was assessed by the bronchoscopy team. Bronchoscopies were performed transnasally or transorally with the patients in the semi-recumbent position, by a total of five pulmonary fellows under close supervision of four pulmonary attendings. Pulse oximetry was recorded continuously during the procedure and automated non-invasive blood pressure was monitored every 5 minutes. Supplemental oxygen was given at 4 l/min via nasal cannula to all patients. In case of desaturation ≤90%, oxygen delivery was increased to 6 l/min [26]. Nasal anaesthesia was achieved by applying 2% lidocaine gel locally. 3 ml aliquots of 1% lidocaine were instilled over the vocal cords, onto the trachea and to both the right and left main bronchi. Supplemental local anaesthesia was given as judged by the bronchoscopist. No inhaled lidocaine was given prior to the procedure [7].

Loading doses of propofol were titrated to achieve adequate conscious sedation (onset of ptosis for bronchoscopy). Thereafter, conscious sedation was achieved with an intravenous (i.v.) infusion using an intermittent bolus technique, as follows. After an initial 10–20 mg i.v. propofol, the dose was then carefully titrated according to the American Society of Anaesthesiologists (ASA) physical status classification: for ASA I and II, i.v. propofol boluses of 10–20 mg i.v. were applied, whereas for ASA III and IV, precisely 10 mg propofol i.v. were administered based on the clinical response, as previously described [18]. Between each bolus, a pause lasting at least 20 seconds had to be observed. If the effect disappeared during the examination, additional intravenous boluses of 10 mg propofol were given, depending on the clinical effect to maintain the required level of sedation. Signs of pain or discomfort, agitation, a persistent cough and inadequate motor or verbal response to manipulation were considered indicators for insufficient sedation, leading to administration of an additional dose of propofol (10–20 mg). Propofol administration was performed by a nurse and was based on the judgement of the bronchoscopist.

Diagnostic procedures (e.g. brushing, bronchoalveolar lavage, endobronchial and transbronchial biopsies) were performed depending on the clinical indication. The following data were collected: patient age, sex, weight, height, body mass index, co-morbidities, procedure indication, procedure(s) performed, procedure duration (time from scope insertion to scope removal), propofol dose, baseline and lowest blood pressure, heart rate and oxygen saturation, adverse events and rescue procedures required, as well a coughing score between a minimum of zero points and a maximum of 100 points based on a visual analogue scale (VAS) as judged by the bronchoscopy team during the procedure.

Adverse events were pre-defined and classified as minor or major, depending upon the interventions required. Minor adverse events were defined as peri-procedural hypoxia (oxygen saturation ≤90%), insertion of a nasopharyngeal or an oropharyngeal airway, need to abort bronchoscopy, minor bleeding and hypotension (systolic blood pressure <90 mmHg). Additionally, a drop of systolic blood pressure greater than 20 mm Hg was assessed as a minor complication. Major complications were those that resulted in death, unplanned endotracheal intubation, admission to the hospital or need for transfer to the ICU/intermediate care.

Data analysis

In addition to the descriptive statistics, the incidence of minor and major adverse events were assessed in the whole population and stratified according to the ASA classification. Given the severity of background co-morbidities and the significant number of patients presenting a systolic blood pressure of less than 90 mm Hg before the initiation of sedation, we assessed not only crude systolic blood pressure but also the incidence of a drop of systolic blood pressure greater than 20 mm Hg during the procedure as a measure of clinically significant hypotension related bronchoscopy.

Differences in dichotomous variables were evaluated using the Chi-square test or Fischer's Exact test, as appropriate. Normally distributed parameters were analysed using the Student's t-test for equality of means. All other continuously non-normally distributed parameters were evaluated using the non-parametric Mann-Whitney U test or Kruskal-Wallis test, as appropriate.

The Statistical Package for Social Sciences (SSPS Inc, version 18 for Windows) programme was used. All tests were two-tailed; a p value of <0.05 was considered significant. Results are expressed as mean (standard deviation) or median [interquartile range] unless otherwise stated.

Results

A total of 442 patients were screened for study inclusion. Sedation with propofol was administered to 440 patients (99.5%). In the remaining 2 cases, sedation with midazolam was used and therefore these patients were excluded from the analysis. Demographic data including co-morbidities of the study population are depicted in table 1 and table 2, respectively.

The mean age was 60 years (±15.5). Most patients were male (59.1%). The majority of patients were considered to be of intermediate or high risk for undergoing a procedure according to the ASA classification (ASA class greater or equal to III).

The indications for bronchoscopy and the diagnostic procedures performed are shown in table 3. The main in-

dications for bronchoscopy were suspicion of malignancy followed by pulmonary infection. Accordingly, the most common diagnostic procedures were bronchoalveolar lavage (31.5%) and bronchial washing (21.7%). Transbronchial needle aspiration, both from mediastinal lymph nodes and/or from the periphery of the lung, was performed in 113 cases (14.1). A total of 36 patients (8.2%) underwent inspection only. One bronchoscopic procedure was performed in 164 patients (37.2%), two procedures were done in 120 patients (27.3%), and more than two procedures were required in the remaining 120 patients (27.3%). Overall, 802 procedures were performed in 440 patients, corresponding to an average of 1.82 procedures per patient. The mean duration of all bronchoscopies was 19.6 minutes (±12.08).

The mean required propofol dose was 200 mg (±107.5). The required propofol doses adjusted for body weight and adjusted for body weight and duration of the procedure were 2.89 mg/kg (±1.70) and 0.18 mg/kg/min (±0.14), respectively.

Table 4 presents the haemodynamic findings before, during and after bronchoscopy. The median drop in systolic blood pressure after initiation of sedation with propofol was 14 mm Hg (3–28). A drop in systolic blood pressure greater than 20 mm Hg was observed in 166 of the 440 patients (37%). The median cough score as assessed by the bronchoscopy team was 30 (30–60) out of 100.

Minor and major adverse events are shown in table 5 and in figure 1. The most common complications were oxygen desaturation ≤90% (16.4%) and hypotension, as defined by a systolic blood pressure of <90 mm Hg (15.4%). Importantly, from those patients presenting a significant desaturation, a total of 13 (18%) were already hypoxemic at arrival in our bronchoscopy suite. From those, two remained hypoxemic despite oxygen administration before administration of sedation. Similarly, 5 patients (7.4%) of the patients developing hypotension presented a systolic blood pressure <90 mm Hg before receiving propofol. Interestingly, the incidence of desaturation was higher in patients of ASA classes III and IV compared to the patients of ASA classes I and II (18.7% versus 12.1%), although the difference did not reach statistical significance ($p = 0.098$). ASA class did not influence the incidence of hypotension (16.3% versus 15.3 %; $p = 0.7791$).

Additional less common complications included minor bleeding (2.5%) and airway instability leading to a requirement for insertion of a nasopharyngeal or an oropharyngeal airway (1.6%). There was no need for tracheal intubation, ICU transfer or death.

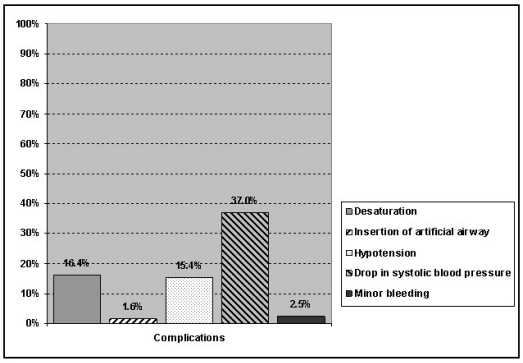

Figure 1

Minor adverse events in 440 patients receiving propofol sedation.

Discussion

This prospective analysis suggests that propofol sedation is feasible in flexible bronchoscopy, even for those examinations including several bronchoscopic procedures. The mean required propofol doses were 200 mg per examination or 2.89 mg/kg (±1.70 mg/kg). We observed an acceptable rate of side effects such as oxygen desaturation and arterial hypotension. Thus, propofol sedation seems to represent a viable alternative in bronchoscopic procedures.

Recently, propofol was shown to be an attractive option to combined sedation with midazolam and hydrocodone, with propofol presenting significantly faster recovery times and improved patient satisfaction scores [11]. Although sedation with propofol has been evaluated in a few studies [11, 14], data on the feasibility and safety of propofol sedation for flexible bronchoscopy is scarce [11, 14, 17]. There is only one large cohort study reporting the performance

Table 1: Demographic data of 440 patients undergoing bronchoscopy.

Characteristics	**n = 440**
Mean age in years (SD)	60 (± 15.5)
Male gender, %	260 (59.1)
Mean weight, kg	71.5 (± 15.6)
Mean BMI, kg/m^2	24.9 (± 4.8)
ASA class I or II III IV or V	 141 (32.4%) 287 (65.8%) 8 (1.8%)
Mallampati class* 1 2 3 4	 59 (19.3%) 133 (43.4%) 91 (29.7%) 23 (7.6%)
Mean prothrombin time, % (SD)	93% (± 27.6)
Mean platelet count, g/L (SD)	313 (± 319)

Abbreviations: BMI stands for body mass index; ASA stands for American Society of Anaesthesiologists. ASA class was not documented in 4 cases. Mallampati score was not available for 134 patients.

of propofol in flexible bronchoscopy. However, this previous study reported to rely on nurse-administered propofol sedation only [14]. Importantly, propofol sedation requires an anaesthesiologist in many countries. In our study, decisions on propofol administration were primarily based on the judgment of bronchoscopists. Propofol was given intravenously by a nurse. Thus, our findings suggest that propofol sedation can also successfully be administered on a physician guided basis.

In our study, the mean required propofol dose was 200 mg per examination. Adjusted for body weight and adjusted for body weight and duration of the procedure the mean values were 2.89 mg/kg (±1.70) and 0.18 mg/kg/min (±0.14), respectively. The mean duration of the examination was 19.6 minutes (±12.08). The total propofol dose and mean duration of the procedure are similar to the values reported in the study by Stolz et al. [11]. In contrast, in the study by Bosslet et al. [14] the total amount of propofol applied was 242 mg and therefore higher than in our cohort. However, the mean procedure duration in that study was longer (25 minutes compared to 19 minutes in our current report), despite a smaller number of broncoscopic procedures per-

Table 2: Co-morbidities of 440 patients undergoing bronchoscopy.

Characteristics, %	**n = 440**
Chronic obstructive pulmonary disease	79 (18)
Coronary artery disease	52 (11.8)
Congestive heart failure	30 (6.8)
Arterial hypertension	169 (38.4)
Renal failure	63 (14.3)
Diabetes mellitus	54 (12.3)
Drug abuse	10 (2.3)
Immunocompromised patients	116 (26.4)

Table 3: Indications for flexible bronchoscopy and bronchoscopic procedures performed.

Characteristics	**n = 440**
Indication for bronchoscopy	**n (%)**
Infection	133 (30.2%)
Suspicion of malignancy	158 (35.9%)
Haemoptysis	35 (8%)
Interstitial lung disease	25 (5.7%)
Interventional	10 (2.3%)
Miscellaneous	79 (18%)
Diagnostic procedures	**n (%)**
Bronchial washings	174 (21.7%)
Bronchial brushing	52 (6.5%)
Bronchoalveolar lavage	253 (31.5%)
Endobronchial biopsy	105 (13.1%)
Transbronchial biopsy	92 (11.5%)
TBNA mediastinum or periphery	113 (14.1%)
EBUS	13 (1.7%)

Abbreviations: TBNA: transbronchial needle aspiration; EBUS: endobronchial ultrasound.

Table 4: Haemodynamic findings before, during and after sedation with propofol.

Characteristics	**Mean (SD)**
Initial systolic blood pressure, mm Hg (SD)	127 (± 25.8)
Initial diastolic blood pressure, mm Hg (SD)	76 (± 17.4)
Initial heart rate, bpm (SD)	81 (± 14.6)
Initial oxygen saturation, % (SD)	96.0 (± 3.4)
Lowest systolic blood pressure, mm Hg (SD)	108 (± 19.6)
Lowest diastolic blood pressure, mm Hg (SD)	63 (± 12.3)
Highest heart rate, bpm (SD)	90 (± 15.3)
Mean lowest oxygen saturation, % (SD)	93.0 (± 4.3)
Maximum oxygen requirement, lpm (SD)	5.2 (± 2.1)
Final systolic blood pressure, mm Hg (SD)	124 (± 27.3)
Final diastolic blood pressure, mm Hg (SD)	74 (± 20.4)
Final heart rate, bpm (SD)	84 (± 15.5)
Final oxygen saturation, % (SD)	96.8 (± 3.3)
Systolic blood pressure at discharge from BS, mm Hg (SD)	121 (± 22.5)
Blood pressure at discharge from BS, mm Hg (SD)	71 (± 15.2)
Heart rate at discharge from BS, bpm (SD)	84 (± 15.5)
Oxygen saturation at discharge from BS, % (SD)	95.0 (± 2.7)

Values are expressed as means (SD = standard deviation); mm Hg: millimetre mercury; bpm: beats per minute; lpm: litres per minute. Initial parameters refer to before sedation, and final parameters refer to after sedation.

formed per examination (54.3% underwent 2 or more procedures in the current study versus 35% in the previous report by Bosslet et al.).

Although haemodynamic and respiratory adverse events are relatively common with propofol sedation, the majority of them are minor and self-limiting. In the 440 patients described in the current study, the most common complication was oxygen saturation ≤90% and was recorded in 72 patients (16.4%). Hypotension defined as a systolic blood pressure of <90 mm Hg on at least one occasion was seen in 68 patients (15.4%). A drop in systolic blood pressure >20 mm Hg could even be found in more than one third of all patients. We believe it is fair to assume that a drop of 20 mm Hg in systolic pressure is to be considered clinically significant and might therefore indicate relevant hypotension in the group of patients undergoing bronchoscopy. In the study by Stolz et al. comparing propofol versus combined sedation with a benzodiazepine and hydrocodone, the number of patients who recorded a saturation of ≤90% on at least one occasion was 32% [11]. A similar incidence of hypoxemia was found in one of the first comparative evaluations of propofol versus midazolam for sedation in bronchoscopy (10 out of 21 patients) [15] and in another previous study [17]. Interestingly, the incidence of hypoxemia did not differ significantly between the two groups sedated with propofol or midazolam, respectively [11, 15, 17]. However, blood pressure at the end of the procedure was significantly higher in the midazolam group [11].

However, in the recent study by Bosslet et al. using a nurse administered protocol, hypoxemia (defined as an oxygen saturation of <90%) was observed in only 3.8% and hypotension (defined as a systolic blood pressure of <90 mm Hg) was observed in only 1% (5) of all patients [14]. Interestingly, the amount of propofol given per minute was comparable to the amount used in the current study. Similarly, the amount of initial propofol bolus given did not differ in both studies. Therefore, there is no obvious explanation for the higher incidence of desaturation and hypotension in our patients. Nevertheless, only roughly one third of the patients in our series were ASA classes I or II and therefore considered low risk for procedural complications, while 84% of the patients included in the study by Bosslet et al. belonged to those two low risk classes. More than one fourth of our patients were immunocompromised and 10 out of the 440 patients were active drug users. It is well known that patients with advanced oncologic and haematologic disease, as well as solid organ and bone marrow transplantation patients have a higher incidence of complications with bronchoscopy [27], and that patients with HIV and drug abuse show a tendency for higher sedative requirements and significantly higher doses of midazolam are needed in patients with stem cell transplantation compared with controls [6]. Furthermore, the definition of 'hypoxemia' varied in both studies (<90% versus ≤90%) and might at least partly explain the differences observed. In this context, given the high frequency of oxygen desaturation and hypotension the importance of standard pulse oximetry, oxygen supplementation and recording of blood pressure at regular intervals has to be emphasised, as stated in the British Thoracic Society guidelines [1]. It is worth mentioning that no minor adverse event led to the abortion of the bronchoscopy. Hypoxemia could be managed by chin-lift, the insertion of a nasopharyngeal or oropharyngeal tube and by increasing the amount of oxygen applied via a nasal cannula. The management of hypoxemia during flexible bronchoscopy has been described in detail elsewhere [26].

No major adverse events were noted in our series. The incidence of major adverse events described by other authors is low, representing less than 3% of all bronchoscopies [11, 14, 17].

The use of hydrocodone was shown to significantly reduce coughing in flexible bronchoscopy when combined with midazolam in a randomised, double blind, placebo controlled trial. The use of this opioid was not associated with an increase in significant desaturation [8]. At the time of the current investigation no data existed about the combination of propofol and opioid in flexible bronchoscopy. Furthermore, the use of the combination of a narcotic drug with sedation was not recommended routinely by the British Thoracic Society [1]. We therefore opted to demonstrate the safety and feasibility of propofol sedation first, before combining it with a narcotic.

This study has some limitations. Firstly, the patients were not randomised. Even though the data were recorded prospectively, the possibility of under-reporting adverse events has to be considered. The higher incidence of hypoxemia compared to a previous study suggests, however, that most complications have been documented. Finally, our study did not address recovery time or patient satisfaction.

In conclusion, our data suggest that propofol is a feasible and safe method for sedation in patients undergoing flexible bronchoscopy if properly trained personnel are involved. Therefore, propofol seems to represent a valid al-

Table 5: Minor and major adverse events in 440 patients receiving propofol sedation.

Characteristics	**n (%)**
Oxygen desaturation (≤90%)	72 (16.4)
Insertion of nasopharyngeal / oropharyngeal airway	7 (1.6)
Hypotension (<90 mm Hg)	68 (15.4)
Drop in systolic blood pressure >20 mm Hg	166 (37)
Minor bleeding	11 (2.5)
Major bleeding	0 (0)
Termination of the examination	0 (0)
Intubation	0 (0)
Transfer to Intensive care unit	0 (0)
Death	0 (0)

Values are expressed as absolute numbers (percentage).

ternative to sedation regimens including a benzodiazepine such as midazolam.

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Figures (large format)

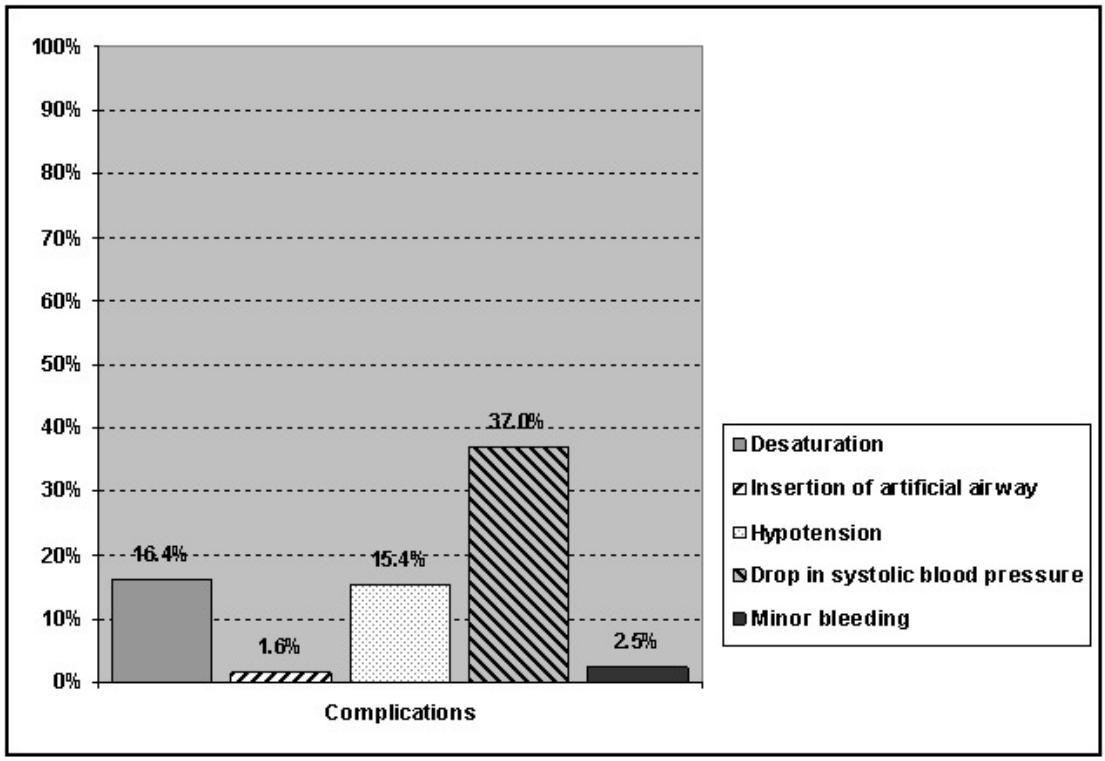

Figure 1

Minor adverse events in 440 patients receiving propofol sedation.