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# The Evaluation of 1-Physician Versus 2-Physician Deep Sedation with Propofol

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## Abstract

**Background:** Emergency physicians routinely perform emergency department procedural sedation (EDPS) with propofol and its safety is well established. However, in 2009 the Centers for Medicare and Medicaid Services (CMS) enacted guidelines defining propofol as deep sedation and requiring administration by a physician. Common EDPS practice had been one-physician performing both the sedation and procedure. EDPS has proven safe under this 1-physician practice. However, the 2009 guidelines mandated separate physicians perform each.

**Objective:** The study hypothesis was that 1-physician propofol sedation complication rates are similar to 2-physician.

**Methods:** We performed an observational study of an a priori defined specific aims via secondary analysis of a prospectively collected database. Patients included were >17 years of age consenting to EDPS with propofol. EDPS completed with one physician were compared to those completed with two (separate physicians performing the sedation and the procedure). All data was prospectively collected. The study was completed at an urban Level 1 trauma center. Standard monitoring and procedures for EDPS were followed with physicians blind to the objectives of this research. The frequency and incremental dosing of medication was left to the discretion of the treating physicians. The study protocol required an ED nurse trained in data collection to be present to record vital signs and assess for any prospectively defined complications. We used Chi-square tests to compare the binary outcomes and ASA score across the time periods and two-sample T-tests to test for differences in age between the two time periods.

**Results:** During the 2-year study period we enrolled 481 patients, 252 1-physician EDPS sedations and 229 2-physician. All patients meeting inclusion criteria were included in the study. Total adverse event rates were 4.4%, and 3.1%, respectively ($p = 0.450$). The most common complications were hypotension and $O_2$ desaturation and they respectively showed a 1-physcian rate of 2.0% and 0.8% and 2-physician rate of 1.8% and 0.9% ($p = 0.848$ and 0.923.) The unsuccessful procedural rates were 4.0% vs 3.9% ($p = 0.983$).

**Conclusions:** This study demonstrated no significant difference in complication rate for propofol EDPS completed by one physician as compared to two.

## Introduction

Emergency physicians routinely perform emergency department procedural sedation (EDPS) with propofol and its safety is well established [1-7]. However, in 2009 the Centers for Medicare and Medicaid Services (CMS) enacted guidelines defining propofol as deep sedation and requiring administration by a physician [8]. This is similar to the anesthesia model for procedural sedation consisting of two physicians, one to perform sedation and monitor the patient and the other to perform the procedure. In theory, if one physician is dedicated to administer procedural sedation and analgesia (PSA) it should be possible to monitor the level of sedation and titrate medication carefully, and identify adverse effects earlier. However, despite such potential benefits, clinical observation indicates that one emergency physician-providing both the PSA and performing the procedure-may achieve safe sedation with a low risk of adverse events [9,10]. Such a practice of one-physician performing both the sedation and procedure had been a common emergency department approach to procedural sedation. The aforementioned 2009 guidelines mandated separate physicians perform each.

To our knowledge, there has not been a previously published evaluation of EDPS administered by one physician as compared to that carried out by two physicians. The study hypothesis was that 1-physician propofol sedation complication rates are similar to 2-physician.

## Methods

### Study design

This was an observational study of an a priori defined specific aims via secondary analysis of a prospectively collected database. The study was of the before and after nature to evaluate EDPS with propofol administered with one-physician versus two-physicians. The Indiana University School of Medicine Institutional Review Board (IRB) approved the study prior to data collection.

### Study population and setting

The study population included all ED patients who received procedural sedation with propofol between January 2010 and December 2011. The "before" group included all sedations completed with one physician prior to the CMS guideline introduction (January, 2010-December, 2010) and the "after" group encompassed those propofol sedations performed with two-physicians after guideline introduction (January 2011-December, 2011). This study was conducted in the ED of an urban, academic, Level I trauma center with a volume of approximately 105,000 annual visits.

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### Procedures and measurements

Standard monitoring and procedures, as required by the hospital's EDPS protocol, were followed. In addition to an emergency physician(s), the EDPS protocol requires an emergency nurse assistant to be in the room to monitor the vital signs, pulse oximetry, possible complications, and administer the ordered medications. Data for this research were collected by the emergency nurses. Prior to data collection, we defined each data point and trained the nurses collecting the data. The trained emergency nurses assessed and recorded vital signs, ventilation, airway evaluation (e.g. snoring, partial obstruction, obstruction, signs of aspiration), pulse oximetry, and complications every 5 minutes and nadir. The nurses also documented all administered medications and doses.

Inclusion criteria for the study were all patients receiving propofol for procedural sedation in the emergency department between the dates of January 2010 and December 2011. No patients receiving such treatment during this time period were excluded.

All emergency physicians, other than the investigators, were blind to the objectives of this research. The emergency medicine attending physician or the emergency medicine resident (under the direct supervision of the attending physician) conducted the procedural sedation in their usual fashion. The emergency physician was responsible for the pre-procedure assessment, sedation plan, dosing of medication, completion of the procedure, and standard monitoring of the patient. The frequency and incremental dosing of medication was left to the discretion of the individual treating physician. Only attending physicians qualified as the "physician administering the sedation". In the before period with 1-physician sedation, one attending physician was carrying out the EDPS (with or without a resident) and in the after period with 2-physician sedation, two attending physicians were in the room participating in the EDPS.

Complications were prospectively defined as apnea, post procedure nausea/vomiting, laryngospasm, hypotension, heart rate less than 50 beats per minute or rhythm disturbance, rescue maneuver (i.e., head repositioning, jaw thrust, use of oral airway, increase in oxygen administration, increase in stimulation, unplanned use of reversal agents), hypoxemia, aspiration, bag-valve-mask ventilation, intubation, any blood pressure or heart rate interventions, hospital admission, and death. Apnea was defined as no ventilation effort with no obvious airway obstruction. Systolic blood pressure < 90 mmHg was considered hypotension. Bradycardia was defined as a heart rate less than 50 unless the patient had pre-existing bradycardia. Any patient with an oxygen saturation < 90% for > 10 seconds was considered to be hypoxemic. Aspiration was defined as emesis or reflux from mouth or nose during sedation, coughing or gagging during sedation and subsequent prolonged decrease in oxygen saturation by 5% from baseline, chest X-ray evidence of aspiration, or evidence of aspiration including respiratory complaints, prolonged unexplained cough, or dyspnea.

We utilized the American Society of Anesthesiologists (ASA) physical status classification for systemic disease [11] evaluate and account for the comorbidities of patients when comparing complications. We enrolled patients in Classes I (normal healthy patient), II (mild systemic disease), III (severe systemic disease), and IV (severe systemic disease that is a constant threat to life), but none in Class V (moribund patient not expected to live another 24 hours) or VI (brain-dead patient whose organs are being removed for donor purposes).

### Data analysis

We used Chi-square tests to compare the binary outcomes, procedure type and ASA score across the time periods and two-sample T-tests to test for differences in age between the two time periods. All analyses were performed using SAS v. 9.3.

## Results

During the 2-year study period we enrolled 481 patients, 252 1-physician EDPS sedations and 229 2-physician sedations. All patients meeting inclusion criteria were included in the study. Table 1 represents the demographic and clinical characteristics of the study group. The ASA score is included in the clinical characteristics representation and there was no significant difference between the pre- and post-periods (p = 0.200).

**Table 1:** Demographics and clinical characteristics of the study population.

| | 1-physician | 2-physician | P value |
|---|---|---|---|
| Mean Age (SD) | 40.2 (14.8) | 42.3 (16.0) | 0.146 |
| %Male | 61.8 | 52.0 | 0.031 |
| | | | |
| **ASA Score** | | | 0.200 |
| % 1 | 61.2 | 68.1 | |
| % 2 | 31.5 | 27.8 | |
| % 3 | 6.9 | 3.2 | |
| % 4 | 0.4 | 0.9 | |
| | | | |
| **Procedure** | | | 0.052 |
| % Fracture/Dislocation Reduction | 81.0 | 90.5 | |
| % Other | 2.8 | 2.2 | |
| % Bronchoscopy | 0.8 | 0.4 | |
| % Cardioversion | 1.6 | 1.8 | |
| % Chest Tube | 1.2 | 1.8 | |
| % Endoscopy | 3.2 | 0.9 | |
| % I &D | 6.8 | 1.8 | |
| % Laceration Repair | 1.6 | 0.0 | |
| % Lumbar Puncture | 0.8 | 0.5 | |

**Table 2:** Main study results.

| | N = 481 | | |
|---|---|---|---|
| | Pre (n = 252) | Post (n = 229) | P-value |
| % Any complication | 4.4 (11) | 3.1 (7) | 0.450 |
| % SBP* complication | 2.0 (5) | 1.8 (4) | 0.848 |
| % Oxygen Saturation | 0.8 (2) | 0.9 (2) | 0.923 |
| | | | |
| % Unsuccessful procedure | 4.0 (10) | 3.9 (9) | 0.983 |
| | | | |
| % Adverse event or unsuccessful procedure | 7.9 (20) | 7.0 (16) | 0.693 |

*SBP = systolic blood pressure complication for systolic blood pressure < 90.

As represented in Table 2, the primary study outcome demonstrated no significant difference in total adverse event rates in the 1-physician sedation group as compared to the 2-physician group (4.4% to 3.1%; p = 0.450). The most common complications were hypotension and $O_2$ desaturation. 2.0% of the 1-physician group experience hypotension compared to 1.8% of the 2-physician group (p = 0.848). Hypoxemia occurred in 0.8% of the 1-physician cohort and 0.9% of the 2-physician (p = 0.923.) The unsuccessful procedural rates were 4.0% vs 3.9% (p = 0.983).

## Limitations

The interpretation of this study is subject to several limitations. Although this is the only study to our knowledge directly evaluating one versus two physician sedation, it is possible that the size of the study precluded us from detecting a statistically significant difference among groups and demonstrates the need for further study. This was an observational study and patients were not randomly allocated to the two treatment groups. This lack of randomization could have affected the results and is a limitation of the study. Multiple nurses participated in monitoring patients and it is possible that a recording error or omission occurred, despite thorough training and standardization of the data collection instrument. Patients were observed in the study only until they appeared to be recovered from sedation. No follow-up data were obtained. The study was completed at a teaching institution with residents often involved in patient care. We're unable to quantify the effect of residents being present in 1-physician or 2-physician sedations as compared to what would occur in community practice without a resident presence.

## Discussion

We performed an observational study of an a priori defined specific aims via secondary analysis of a prospectively collected database. The study was of the before and after nature to evaluate EDPS with propofol administered with one-physician versus two-physicians and found no significant difference in total adverse event rates between the groups. Previous literature does not provide clear evidence on the number of personnel necessary to safely provide EDPS as this is the first study directly evaluating such personnel requirements.

Godwin et al. indicate a Level C recommendation that "during moderate and deep sedation, a qualified support person should be present for continuous monitoring of the patient [9]". It is also logical that the presence of a support person assumes increased importance when the physician is involved in a procedure that precludes the ability to continually assess the patient's clinical status. However, there is no evidence that this support person need be another physician versus a qualified nurse. Our findings would suggest that a nurse-physician team may achieve safe EDPS as demonstrated in the 1-physician sedation group in our study. The nurse served as the additional patient status monitor while the physician both administered the sedation and performed the procedure.

In the only other study identified that reported outcomes related to personnel involved in EDPS, Procedural Sedation in the Community Emergency Department: Initial Results of the ProSCED Registry reported the safety of EDPS in the community hospital setting [10]. The registry is an observational database comprised of sedation cases from a variety of hospitals. While it's a report of a registry database and not a study designed to compare 1-physician to 2-physician sedation, in the majority of cases (82.9%) the emergency physician both directed the sedation and performed the procedure on the patient. Those in which the EDPS was performed in this fashion experienced a 4.1% complication rate as compared to 4.0% in whom the emergency physician only directed the sedation ($p > 0.9$). As an analysis of a registry, Sacchetti et al. [10] only observed how individual emergency physicians managed cases in their EDs, it did not compare the number of personnel performing sedations. However, the complication numbers reported in their registry study are very similar to ours results of 4.4% for 1-physician to 3.1% for 2-physician ($p = 0.450$).

In an effort to account for any possible unidentified changes in practice that could have affected sedation performance in the after period as compared to the before period, we also analyzed all other EDPS performed at the institution and not included in the study (not sedated with propofol). All other sedations sustained an overall complication rate of 11.3% in the before period and 9.9% after ($p = 0.789$). There was also no significant difference in any specific complication nor procedural success rate. It does not appear that any change in practice occurred that resulted in a significantly worse complication rate in the "2-physician sedation time period" that would have affected the outcome measures in the study population during this time period.

The 2009 CMS guideline specifically listed sedation with propofol as deep sedation and mandated it a two-physician procedure because of its potential to inadvertent progression to general anesthesia in certain procedures [8]. In 2011, CMS updated its policy to acknowledge that anesthesia exists along a continuum. The update stated that "for some medications there is no bright line that distinguishes when their pharmacological properties bring about the physiologic transition from the analgesic to the anesthetic effects. Furthermore, each individual patient may respond differently to different types of medications [12]". Though CMS seemed to soften their stance regarding specific drugs equaling definite sedation levels and the proper manpower to perform deep sedation, there remains controversy around the necessity of having a separate physician administer and monitor the sedation aside from the provider performing the procedure. To our knowledge, this is the first paper to directly assess the manpower needs to safely and successfully perform procedural sedation and we found no significant difference between 1- and 2-physician sedations.

## Conclusion

This study demonstrated no significant difference in complication rate for propofol EDPS completed by one physician as compared to two physicians. There was no significant difference between the time periods in any type of complication and the procedural success rates were similar.

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