



## Original Contribution

## Feasibility of single- vs two-physician procedural sedation in a small community emergency department☆☆☆☆

Clayton P. Josephy<sup>a,\*</sup>, David R. Vinson<sup>b,c</sup><sup>a</sup> Barton Health System and the Department of Emergency Medicine Barton Memorial Hospital, South Lake Tahoe, CA, United States<sup>b</sup> The Permanente Medical Group, the Kaiser Permanente Division of Research, and the KP CREST Network, Oakland, CA, United States<sup>c</sup> Kaiser Permanente Sacramento Medical Center, Sacramento, CA, United States

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## ABSTRACT

**Objective:** Sedation is commonly required for painful procedures in the emergency department (ED). Some facilities mandate two physicians be present for deep sedation cases. Evidence is lacking, however, that a two-physician approach improves safety outcomes. We report our experience on the feasibility of replacing a two-physician ED procedural sedation policy with a single-physician policy in a small, single-coverage community ED.

**Methods:** This is a retrospective, before/after, single-center observational study of prospectively collected data from January 2013 through December 2016. In September 2014, our medical center implemented a single-physician policy requiring only one emergency physician, accompanied by a sedation-trained ED registered nurse. The primary outcome was a sedation-related escalation of care that resulted in one of the following adverse events or interventions: dysrhythmia (symptomatic bradycardia or ventricular arrhythmias), cardiac arrest, endotracheal intubation, or unanticipated hospitalization. Secondary outcomes included hypoxemia (peripheral oxygen saturation less than 90% for greater than 1 min), the use of bag-valve mask ventilation (BVM), use of a reversal agent, laryngospasm or pulmonary aspiration.

**Results:** We performed 381 sedations during the study period: 135 patients in the two-physician group (before) and 246 patients in the single-physician group (after). The two groups were comparable in age and gender. There was no occurrence of the primary outcome. Secondary outcomes were uncommon, and were similar in the two groups.

**Conclusions:** In this small, single-coverage community ED, replacement of a two-physician policy with a single-physician policy for deep sedation in the ED was feasible and was not associated with an increase in adverse events.

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## 1. Introduction

Emergency department (ED) procedural sedation and analgesia is a fundamental and essential aspect of daily practice and is a core competency in emergency medicine (EM) training and board certification and maintenance [1,2,3]. As of 2011, following the revision of Center for Medicare Services (CMS) Interpretive Guidelines for Anesthesia Services, emergency physicians (EPs) are nationally regarded as skilled professionals in sedation, and are considered “uniquely qualified to provide all levels of analgesia/sedation and anesthesia (moderate to deep to

general)” [4]. The American College of Emergency Physicians (ACEP) has provided clinical practice guidelines [5], while additional recommendations for practicing EPs to create individual departmental procedural sedation policies have also been published [6,7,8].

The optimal number of providers necessary to perform safe procedural sedation in the ED, however, is not known. Most ED sedation studies fail to mention the number of personnel involved, because this critical component of the procedure was not under investigation. One might assume that studies undertaken in academic settings that fail to report this variable operated with a two-physician model. Limited attention has been directed to evaluating the number of physicians as a variable in itself that might influence clinical outcomes.

Based on consensus guidelines published by the American Society of Anesthesiology and the American Association of Nurse Anesthetists, it has become standard in some facilities to require that two physicians be present for deep sedation cases in the ED [9,10]. In our facility, the policy and procedure for deep sedation required one EP to perform and monitor the sedation uninterrupted, while an additional physician,

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\* Corresponding author at: 2170 South Avenue, South Lake Tahoe, CA 96150, United States.

E-mail address: [cjosephy@gmail.com](mailto:cjosephy@gmail.com) (C.P. Josephy).

either another EP or a consultant, perform the procedure. A single EP and ED registered nurse (ED RN) team could, however, provide moderate sedation with an opioid and midazolam.

In most smaller EDs it is impractical, and at times impossible, to have two physicians available for deep sedation cases in a timely and reliable manner to provide care on an unscheduled urgent, and often emergent, basis. A two-physician mandate leads to a multitude of barriers to providing patients with modern sedation services in the ED, which can result in delays in care, or worse, the use of strategies such as suboptimal analgesia and sedation when performing painful procedures.

In September 2014, we implemented a single-physician ED procedural sedation clinical policy that included all depths of sedation for both pediatric and adult patients. This study is a systematic report of our experience with implementation of a single-physician policy compared with the two-physician policy it replaced.

## 2. Methods

### 2.1. Study design and setting

This is a retrospective before and after observational analysis of data collected prospectively as part of an institutional quality assurance and process improvement (QAPI) program. The study took place between January 1, 2013 and December 31, 2016, and was approved by the Barton Health System Institutional Review Board with a waiver of informed consent owing to the nature of the study design.

The study was conducted in a small, semi-rural, geographically isolated community hospital. The ED is single-coverage with an on-call backup EP between 1000 and 2200 daily, and has an annual census of approximately 22,000 visits per year. It is staffed exclusively by board-certified (or board-eligible) EPs. At night, the EP is the only continuously in-house physician. In order to perform two-physician deep sedation in this setting, the attending on duty would either have to call in the

backup EP or request a consultant come to the ED to assist with the sedation or procedure.

### 2.2. The quality assurance and process improvement program

In January 2013, we implemented a QAPI program for procedural sedation performed throughout the medical center. The multi-specialty program was designed by clinical leadership at the facility to standardize and monitor sedation services, and to include representation from individual departments utilizing procedural sedation in their clinical environments (i.e., interventional radiology, gastroenterology, surgery and emergency medicine). The program required data reporting and safety audits for all procedural sedation cases performed in the facility. Sedation data was recorded on a standardized sedation record (on paper) that was scanned into the electronic medical record. Data collected on the standardized sedation record are listed in Fig. 1.

Monthly, all procedural sedation cases performed in the ED were identified by the hospital's clinical pharmacists. Initial reports were generated from pharmacy records of sedative utilization by searching for propofol, ketamine, etomidate, midazolam or fentanyl. All cases were then verified within the electronic medical record by trained data abstractors from the facility's Quality Department and the physician Director of ED Sedation and Analgesia (physician abstractor). Cases in which sedatives were used for analgesia and/or anxiolysis, rapid sequence intubation, sedation for the purpose of mechanical ventilation, management of seizure, or for the management of acute agitated delirium were excluded. Verified procedural sedation cases were then reviewed by the physician abstractor who performed a standardized structured chart audit of each case for pre-defined sedation outcomes and documentation compliance.

Each quarter the abstracted data were reported at the multi-disciplinary anesthesia services committee meeting and were stored in the facility's secure network within the Quality Department. Any deviations

<b>Pre-sedation data</b>
Patient demographics
Indication for procedural sedation
Vital signs, pain level and sedation scores
American Society of Anesthesiologists physical status classification
Airway characteristics (Mallampati and Cormacke-Lehane classifications)
NPO status
Anesthesia history
Medication history and allergies
Written consent
Updated history and physical examination
<b>Intra-procedural data</b>
Vital signs, pain level and sedation scores at 5-minute intervals
End-tidal waveform capnographic data
Doses, timing and route of medications administered
<b>Post-sedation data</b>
Procedural success and disposition
Vital signs, pain level and sedation scores
Oral tolerance
Standardized sedation recovery score (modified Aldrete)
<b>Sedation-related therapeutic interventions</b>
Administration of reversal agents
Use of positive pressure ventilation or advance airway interventions
Volume of intravenous fluid administered
Dose and route of supplemental oxygen delivered

Fig. 1. Data collected on the standardized sedation record for all procedural sedation cases.

from the policy and procedure were communicated directly with the relevant sedation providers to ensure continuing process improvement.

### 2.3. The change in ED procedural sedation policy

Prior to 2012, facility EPs were not credentialed to provide deep sedation. That year a hospital-based Procedural Sedation Policy was implemented that allowed EP privileging for deep sedation, provided they pass an initial competency exam, attend simulation training and have two cases formally proctored by a privileged medical staff member. This policy required the presence of two physicians for deep or dissociative sedation, defined by the administration of propofol, ketamine or etomidate. Either an EP or a consultant anesthesiologist was required to administer the deep sedation with no additional clinical responsibilities, while a separate physician independently performed the procedure.

In September 2014, this policy was replaced by an ED-specific departmental policy (authored by the principal investigator) that required the presence of the following personnel for deep sedation: a single EP, a sedation-trained ED RN, and a respiratory therapist whenever possible. ED RNs were required to undergo annual competency training, which included attendance at a didactic course, an online exam and a skills maintenance lab with simulation cases, in order to be qualified to monitor patients undergoing procedural sedation in the ED. In our facility, we required continuous end-tidal capnography for all sedations in the ED, regardless of targeted depth or sedative administered. The sedation policy included all depths of sedation in both pediatric and adult patients. The choice of sedative agent employed, targeted depth of sedation and the use of supplemental analgesia or co-administered adjuvants was left to the physician's discretion. Moderate sedation was defined as a drug-induced depression of consciousness in which patients purposefully respond to verbal or tactile stimuli, while deep sedation was defined as purposeful response to repeated or painful stimulation. All deep sedations in our ED were performed with propofol, ketamine or etomidate or some combination of propofol and ketamine. Only physicians were permitted to administer these medications. Documentation in the standardized sedation record continued and the QAPI program was unchanged.

### 2.4. Case ascertainment and data collection

The study population included a consecutive series of ED patients of any age who received procedural sedation for any indication in our department during the study period. We utilized all cases abstracted for the QAPI program in our analysis. There were no cases excluded for missing data. For each case, we undertook a pre-defined structured manual chart review of the ED provider, nursing, respiratory therapy and any consultant notes, as well as the standardized sedation record. In addition to the data abstracted from the standardized sedation record, we also collected additional descriptive information from the procedure notes regarding procedural success, rationale for sedation strategy, details regarding rescue or therapeutic interventions and peri-procedural patient condition.

The cases were first abstracted by a Quality Specialist in the hospital and then reported to the ED physician abstractor, who was responsible for the QAPI program chart audits. All data abstractors received standardized training on data collection methods. All personnel responsible for data abstraction and review were blinded to the study hypothesis with the exception of the ED physician abstractor (principal investigator). We entered our findings directly into a standardized electronic data collection instrument, modified to its final form after pilot testing.

To evaluate inter-rater reliability among the QAPI program chart reviewers, a random sample of ED procedural sedation cases (10%) was intermittently selected for independent review by the director of anesthesia services (an anesthesiologist), who was blinded to the study hypothesis, along with any cases involving the following adverse events:

pulmonary aspiration, unplanned intubation, the use of reversal agents or vasopressors, an emergent anesthesia consultation, cardiac arrest or death. Any discrepancies in case audits were arbitrated by the multi-disciplinary Anesthesia Services Committee.

### 2.5. Outcome measures

Our primary outcome measure was any unanticipated clinically-important escalation of care attributable to the sedation. This was defined as unplanned intubation and mechanical ventilation, cardiac arrest, dysrhythmia (symptomatic bradycardia [pulse < 50 beats/min] or ventricular arrhythmias), or an unplanned hospitalization attributable to the sedation. Our secondary outcomes included use of bag-valve mask ventilation with or without apnea (> 30 s), hypoxemia (SpO<sub>2</sub> < 90% for greater than 1 min), reversal agent utilization, laryngospasm, pulmonary aspiration and termination of the procedure because of a sedation-related complication.

### 2.6. Analysis

We present continuous variables as means with standard deviations and categorical data as the number and proportion of occurrence. Bivariate comparisons between the before and after group with respect to baseline characteristics, sedation indication, depth and sedative agents used, as well as the relative frequency of adverse events, were undertaken using Fisher's exact test for categorical data and the *t*-test for continuous variables (GraphPad Software 2015 [La Jolla, CA]). Differences in observed proportions between groups were reported with 95% confidence intervals. A two-tailed *P* value of < 0.05 was considered to indicate statistical significance.

## 3. Results

During the study period, we performed 381 sedations in our ED, 321 (84%) of which were deep or dissociative sedations. One hundred thirty-five patients received sedation during the two-physician policy (before), and 246 received sedation following the implementation of the single-physician policy (after). Baseline characteristics were similar between the two groups and are shown in Table 1.

The procedures for which sedation was indicated are listed in Table 2. Joint or fracture reductions were the most common in both groups. Deep and dissociative sedations were more frequently administered in the single-physician group. Propofol and ketamine were the most commonly used agents for deep and dissociative sedations, followed by etomidate and some combination of ketamine and propofol (Table 3).

There were no cases of our primary outcome measure of unanticipated escalation of care observed in our study. Secondary outcomes were uncommon and similar in the two groups (Table 4).

## 4. Discussion

Procedural sedation and analgesia, and specifically deep sedation, is critical to the delivery of high-quality, modern EM. In this single-center observational study there was no difference in adverse event rates between cases under the two-physician and single-physician ED

**Table 1**  
Demographics of emergency department patients who received procedural sedation during the study period.

n = 381	Two-physician policy n = 135	Single-physician policy n = 246	P-value
Age, mean (SD), years	32.1 (23.9)	35.1 (23.5)	0.25
Range	1.6–83	1–93	0.25
	<b>No. (%)</b>	<b>No. (%)</b>	<b>P-value</b>
Gender (male)	90 (67)	162 (66)	0.91
Pediatric (< 13 years)	43 (32)	64 (26)	0.28

**Table 2**  
Comparison of indications for procedural sedation under the two-physician and single-physician policies.

n = 381	Two-physician policy	Single-physician policy	Difference (95% CI)	P-value
	n = 135	n = 246		
	No. (%)	No. (%)		
Procedure				
Joint or fracture reduction	88 (65.2)	142 (57.7)	0.07 (−0.03–0.17)	0.27
Laceration repair	12 (8.9)	29 (11.8)	0.03 (−0.05–0.09)	0.48
Thoracostomy	12 (8.9)	11 (4.5)	0.04 (−0.01–0.11)	0.11
Cardioversion	7 (5.2)	47 (19.1)	0.14 (0.07–0.20)	<0.001
Incision and drainage	5 (3.7)	5 (2.0)	0.02 (−0.02–0.07)	0.33
Lumbar puncture	3 (2.2)	3 (1.2)	0.01 (−0.02–0.06)	0.67
Foreign body removal	3 (2.2)	1 (0.4)	0.02 (−0.01–0.06)	0.13
Imaging	2 (1.5)	3 (1.2)	0.003 (−0.02–0.05)	1.0
Central line placement	1 (0.7)	0	0.01 (−0.01–0.05)	0.35
Hernia reduction	1 (0.7)	0	0.01 (−0.01–0.05)	0.35
Wound debridement/burn	1 (0.7)	0	0.01 (−0.01–0.05)	0.35
Fecal disimpaction	0	3 (1.2)	0.01 (−0.02–0.04)	0.55
Other <sup>a</sup>	0	2 (0.8)	0.01 (−0.03–0.03)	0.54

<sup>a</sup> One sedation was performed to abort vocal cord dysfunction and another was performed to remove ski boots from and splint a patient with a tibial plateau fracture.

procedural sedation policies. These results suggest that a single-physician practice may be as safe as a two-physician model in the setting of a small, single-coverage community ED staffed by board certified EPs.

While there were no statistically significant differences in sedation outcomes between the study groups, in the single-physician group there was a trend toward increased BVM utilization, but with a concomitant decrease in the rate of hypoxemia. Simultaneously, after the implementation of the single-physician policy, there was a significant increase in targeted deep and dissociative sedations and the use of general anesthetics, such as propofol and ketamine. One possible explanation of this observation is that a requirement for two physicians to be present at deep sedations may have led EPs to defer to moderate sedation (allowing for a single physician) when personnel were not immediately available. This is supported by the relatively uncommon use of moderate sedation following the removal of the two-physician mandate. On the other hand, this may also simply represent a changing trend in EM practice toward deep sedation, as the specialty gained more familiarity with, and access to, general anesthetics.

This statistical increase in the use of deep sedation and general anesthetics may be responsible for the increase use of BVM, owing to deeper levels of sedation. However, we observed during our QAPI reviews that the behavior of different providers regarding when to apply positive pressure ventilation during procedural sedation varied significantly, as there were no known strict criteria for when BVM should be applied during apnea associated with procedural sedation. Because there is a lack of standardization of BVM utilization, it is difficult to meaningfully compare rates of BVM as an endpoint. In our sample, BVM was initiated in most cases at the discretion of the respiratory therapist, and often only a few breaths were given before the EP discontinued positive

pressure ventilation. It is possible that having a respiratory therapist at the bedside during the procedure increased the rate of BVM. We also observed variation among EPs as to when to apply BVM, particularly in patients who were receiving supplemental oxygen. Additionally, in our sample, all patients undergoing procedural sedation were receiving supplemental oxygen, which may have influenced hypoxemia rates. Recognizing that “hypoxemia” is defined variably in the ED sedation literature, we chose to use an oxygen saturation of <90% for 60 s or more to capture only those cases in which decreased oxygen saturation was both an accurate variable and clinically relevant. Among the 10 patients in our sample (2.6% overall) who received BVM, only 3 had documented apnea that lasted >30 s.

We observed a low incidence of sedation-related adverse events under both policies, a finding corroborated by much larger EM sedation studies. For example, in a study from the Pediatric Sedation Research Consortium (PSRC), which included 131,751 cases of pediatric procedural sedations, the incidence of major complication for EPs was 0.08%. There were no deaths and 1 cardiac arrest in nearly 40,000 sedations performed by EPs. Incidentally, 60% of these cases were performed using propofol, and there was no difference in adverse event rates between EPs and anesthesiologists [11]. In another important epidemiologic study of over 30,000 pediatric procedural sedations performed outside the operating room, patient-oriented adverse events were rare, with only 1 pulmonary aspiration and 1 cardiac arrest [12]. The PSRC, like most ED sedation studies, did not report the number of physicians involved in the procedural sedations performed by EPs. Similarly, ketamine is the most commonly used agent for ED procedural sedation in children, and its efficacy and safety has been widely reported [13,14].

**Table 3**  
Comparison of sedative agents and targeted depth of sedation between cases under the two-physician and single-physician policies.

n = 381	Two-physician policy	Single-physician policy	Difference (95% CI)	P-value
	n = 135	n = 246		
	No. (%)	No. (%)		
Sedative agent				
Propofol	49 (36.3)	117 (47.6)	0.11 (0.01–0.21)	0.04
Midazolam	42 (31.1)	9 (3.7)	0.27 (0.19–0.36)	<0.001
Ketamine	34 (31.9)	106 (43.1)	0.18 (0.08–0.27)	<0.001
Ketamine/propofol	10 (7.4)	6 (2.4)	0.05 (0.01–0.11)	0.03
Etomidate	0	8 (3.3)	0.03 (−0.01–0.06)	0.05
Depth of sedation				
Deep/dissociative	92 (68.2)	229 (93.1)	0.25 (0.16–0.34)	<0.001
Moderate	43 (31.9)	17 (6.9)	0.25 (0.16–0.34)	<0.001

**Table 4**  
Comparison of adverse outcomes during emergency department procedural sedation between cases under the two-physician and the single-physician policies.

n = 381	Two-physician policy	Single-physician policy	Difference (95% CI)	P-value
	n = 135	n = 246		
	No. (%)	No. (%)		
Primary outcome				
Unanticipated escalation of care <sup>a</sup>	0	0	NA	NA
Secondary outcomes				
Bag-valve mask ventilation	2 (1.5)	8 (3.3)	0.02 (−0.03–0.05)	0.51
Hypoxemia	2 (1.5)	1 (0.4)	0.01 (−0.03–0.05)	0.28
Dysrhythmia	0	0	NA	NA
Reversal agent used	0	0	NA	NA
Oral airway or intubation	0	0	NA	NA
Procedure aborted due to sedation-related event	0	1 (0.4)	0.01 (−0.03–0.03)	1.0
Laryngospasm	0	0	NA	NA
Pulmonary aspiration	0	0	NA	NA

NA = Not applicable.

<sup>a</sup> Tracheal intubation and mechanical ventilation, cardiac arrest, dysrhythmia, unanticipated admission attributable to sedation.

In adults, no such registry exists comparable to the PSRC. However, multiple studies of varying methodologies have reported similarly low adverse event rates during procedural sedation in the ED. These studies demonstrate, independently and collectively, that adverse events leading to patient-oriented outcomes, such as intubation, unexpected hospital admission or morbidity and mortality, are exquisitely rare. This body of literature is large and consistent and includes thousands of cases where the sedation and procedure were simultaneously performed by a single EP, accompanied by an ED RN monitoring the patient [15–29].

Because patients arrive to the ED at all times of the day and night with urgent conditions requiring deep sedation, it can be challenging or impossible to have two physicians immediately available to provide deep sedation in a timely and reliable fashion. The question of the appropriate number of personnel necessary to provide safe deep sedation is therefore an important aspect of policy development, ED resource utilization and staffing.

There have been studies that specifically evaluated the safety and effectiveness of a single EP simultaneously administering procedural sedation while performing the procedure, with an ED RN monitoring the patient. In a registry-based observational study of 1028 ED sedations performed in 14 study sites (Procedural Sedation in the Community Emergency Department Registry), there were no detectable differences in adverse event rates between patients monitored by an ED RN versus those monitored by a second physician [30]. In a retrospective study by Vinson and Hoehn, the safety, procedural success and adverse event rates of single-physician ED sedations were reported. Of 435 sedations performed by a single physician and ED RN team, there was a 2.8% incidence of intervention-requiring adverse events, which is similar to our study. There were no adverse events that resulted in alteration of the patient's disposition [31]. Miner and Burton provided an evidence-based clinical practice advisory for the administration of propofol in the ED in which they concluded that "...there is no current evidence to suggest that propofol is unsafe without a second physician present" [32]. These results support the conclusion that a policy requiring that two physicians be present at deep sedations in the ED does not appear to influence adverse event rates, nor does it appear to confer a safety advantage. It has also been demonstrated, both within and outside the ED, that RNs are able to safely and effectively both administer sedative medications and monitor the patient, while a physician both performs the procedure and any interventions or rescue related to the sedation [33, 34, 35]. The low rates of adverse outcomes reported in these single-physician sedation studies is comparable to those reported in studies with two physicians, as well as studies that fail to mention the number of physicians involved.

Finally, as ED procedural sedation policies must be based on recognized national guidelines per CMS requirements, it is important to

quote at length the ACEP recommendations for physician credentialing, privileging, and practice that state the following:

"Deep sedation may be accomplished with the emergency physician monitoring the patient and a separate practitioner performing the procedure, or by the same emergency physician both administering sedation and performing the procedure. Given that ED procedures are typically brief and can be readily interrupted, there will be occurrences when the benefits outweigh the risks for performing deep sedation using a single emergency physician and an ED nurse. In these circumstances, the emergency physician will initiate effective sedation and, once stable sedation is established, the physician will perform the procedure while the nurse monitors the patient. The caveat is that the supervising practitioner performing sedation may also perform the procedure only if the procedure is of such a nature that it can be immediately halted should the patient suffer an adverse reaction that requires urgent attention or resuscitation [7]."

As it is neither practical nor possible for most EDs to staff unplanned urgent and emergent sedations with two physicians, many EDs need to implement single-physician deep sedation policies. There is a growing body of evidence to support this practice. Most published literature on ED procedural sedation comes from academic facilities, where there is commonly more than one physician available at the bedside during procedural sedation. It is, therefore, important to monitor and report data on the use of single-physician sedation protocols in small, single-coverage community EDs. The results of our study add to the growing body of evidence demonstrating that deep procedural sedation can safely be performed by a team of one emergency physician and one emergency nurse.

## 5. Limitations

The results of our study need to be cautiously applied outside their clinical context. This is a single-center study, all the physicians are board-certified EPs, and it took place in the context of a high-fidelity sedation process improvement program. Nevertheless, we believe our study is generalizable to most, if not all, EDs that are staffed by board-certified EPs.

Additionally, the reliance on data collection from the electronic medical record can result in missing data and under-reporting of adverse events. This was mitigated by standardizing documentation on a sedation record. In addition, structured chart review of the EP, nursing, consultant and respiratory therapist notes were performed to minimize the risk of missing data. It is also possible that sedation cases performed in the ED were not captured using our search methods for tracking sedation cases. While we believe that potential error resulting from these phenomena was limited by our study design, and institutional protocols for data recording, missing data remains a potential source of error.

The most important limitation of this study is the small sample size. Because adverse events in ED procedural sedation are so uncommon, it would take a much larger study to capture rare adverse events, much less analyze them to make predictive conclusions or guide policy decisions. A study of this magnitude would be infeasible to perform in a small community hospital. Also, because group assignment was not randomized, this study is unable to directly answer the question: "Is deep sedation safer with two physicians compared with one physician?" This study, instead, adds to an existing body of observational data that suggests that single-physician policies are safe and effective, and given the preponderance and consistency of the available literature, it is unlikely that a two-physician presence results in a safety advantage.

## 6. Conclusion

In this single-center observational study, we found no difference in ED sedation outcomes following implementation of a policy that allowed a single physician to simultaneously administer deep sedation while performing the procedure, with an ED RN monitoring the patient. Single-physician sedation policies can be feasibly implemented in a small, single-coverage community ED.

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