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Randomized clinical trial of propofol versus alfentanil for moderate procedural sedation in the emergency department

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ABSTRACT

Study objective: To compare the frequency of airway and respiratory adverse events leading to an intervention between moderate sedation using alfentanil or propofol.
Methods: We performed a randomized clinical trial in which adults undergoing moderate sedation in the ED received either alfentanil or propofol. Our primary outcome was the frequency of airway and respiratory adverse events leading to an intervention. Other outcomes included sedation depth, efficacy, sedation time, patient satisfaction, pain, and satisfaction.
Results: 108 subjects completed the trial: 52 receiving alfentanil and 56 receiving propofol. Airway or respiratory adverse events leading to an intervention were similar between the two groups: 23% for alfentanil and 20% for propofol ($p = 0.657$). There were no serious adverse events in any group. Secondary outcomes were notably different in the rate of reported pain (48% for alfentanil, 13% for propofol) and recall (75% for alfentanil, 23% for propofol) and similar in the rate of satisfaction with the procedure (87% for alfentanil, 84% for propofol).
Conclusion: We found a similar frequency of airway and respiratory adverse events leading to intervention between alfentanil and propofol used for moderate procedural sedation. Both agents appear safe for moderate procedural sedation.

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1. Introduction

Moderate procedural sedation refers to the use of an analgesic and/or amnestic sedative/hypnotic agent to produce a sedated state for a procedure from which a patient can be aroused with voice or light touch. Deep sedation refers to patients that have been sedated to a level in which they respond to painful stimulus, but not voice or light touch. Both levels have been described frequently for procedural sedation with a variety of agents [1-8].

Previous research has shown that using a target of moderate rather than deep sedation can lead to a lower rate of sub clinical respiratory depression [1]. However, it has also been shown that targeting moderate sedation frequently results in deep sedation [1,4,9]. It has not been shown whether using an agent typically associated with moderate sedation, such as an opioid, would result in less frequent adverse events than using an agent more typically associated with deep sedation, such as propofol, when they were both used with a target of moderate sedation.

Propofol is frequently used for both moderate and deep procedural sedation in the ED, although it is most frequently described for deep sedation. Propofol produces sedation, hypnosis, and dense amnesia. It has an adverse effect rate of 5% in ED patients, with transient hypoxia occurring in 5%–30% of sedations [8-12]. Amnesia from propofol has been described as lasting 15.7 min in patients who have received 1 mg/kg IV bolus followed by 0.5 mg/kg until sedation is achieved [13]. Patients sedated with these doses often demonstrate responses to pain during the procedure they do not later recall. Such a response is in fact the defining characteristic of deep sedation relative to general anesthesia. Patients sedated at this dose of propofol have also been described to continue to respond to voice and answer questions, consistent with the description of moderate sedation and indicating that this dose of propofol likely achieves amnesia with when either moderate or deep sedation is achieved [13] [7-9,11,14-17].

Alfentanil is an ultra-short acting opioid and an effective analgesic that is also described for the induction of moderate sedation [18]. It induces 7 to 9 min of analgesia after a bolus of 10 μg/kg, which is a similar duration as that of propofol [18]. Studies of alfentanil sedation have shown that use of the agent alone results in lower rates of hypoxia that those reported for alfentanil combined with other sedative agents [18-21]. Both alfentanil and propofol are used for moderate procedural sedation frequently and have been shown to be safe [7,9,10,18-21].

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Most of the studies of propofol have used both moderate and deep sedation or deep sedation alone, while alfentanil is typically used for moderate sedation.

We have studied the combination of alfentanil and propofol given together to induce deep sedation and have found it to induce a higher rate of respiratory depression than propofol alone, with no improvement in patient perceived pain or measured stress over propofol alone [4,7]. It appears possible that the risk of sedation is more related to the depth of sedation achieved than the agent selected, and that an agent's risk for inducing an adverse event would be related to the level of sedation achieved rather than the agent itself [22].

Propofol is most often described when used for deep sedation, and its use is sometimes limited to providers who typically perform deep sedation [9]. This has been based on the assumption that agents more typically used to target moderate sedation, such as opioids or benzodiazepines, are safer than agents typically used to target deep sedation. Given that previous research has shown that moderate sedation is associated with less adverse events than deep sedation, and is associated with similar procedural amnesia, and that both moderate and deep sedation have been described with a variety of agents, we hypothesize that using different agents to induce the same level of sedation would result in similar frequencies of adverse events. This would imply that the safety of procedural sedation is based on the level of sedation achieved, rather than the agent, and that the use of propofol for moderate sedation is similarly safe to using more typical moderate sedation medications. Since the occurrence of adverse events is also related to the duration of the procedure [9], we choose to compare alfentanil to propofol due to the agent's similar duration of action.

The goal of this investigation is to determine if moderate procedural sedation using alfentanil results in a 20% or more decrease in adverse airway or respiratory adverse events leading to an intervention compared to propofol. We also contrasted sedation efficacy, sedation duration, other adverse events, and patient reported pain, recall, and satisfaction.

2. Methods

2.1. Study design and setting

We performed a randomized clinical trial at (blinded for peer-review), an urban county medical center with approximately 108,000 ED patient visits per year (Clinicaltrials.gov NCT00997126). Our institutional review board approved the study and subjects provided written informed consent. The study was initially intended to compare alfentanil to propofol to nitrous oxide moderate sedation, but due to technical difficulties initiating the nitrous oxide arm of the study, it was conducted as a two-arm trial.

2.2. Selection of participants

We enrolled adult (age ≥ 18 years) ED patients chosen to receive moderate procedural sedation, as identified by emergency physicians and trained research associates 24 h a day 7 days a week. We excluded subjects who were unable to give consent, had an American Society of Anesthesiologists physical status > 2 [23], had a known hypersensitivity to either study medication, were pregnant, were prisoners, or showed evidence of intoxication. Moderate sedation is performed much less frequently in our ED than deep sedation, and the majority of sedation during the enrollment period used deep sedation as the target.

2.3. Interventions

At least 20 min following the last dose of any opioid, subjects received either a 10 μg/kg dose of alfentanil or a 1 mg/kg dose of propofol followed by additional doses of ½ the initial bolus every 3 to 5 min at the discretion of the treating physician in order to achieve and maintain moderate sedation. Trained research assistants recorded monitoring data, vital signs, and depth of sedation (OAA/S: observer's assessment of alertness/sedation score Appendix A) starting 1 min prior to the initial medication, every minute thereafter, immediately after any repeat dosing, and after any changes in the OAA/S. Recording continued until the subject recovered to their baseline OAA/S. Data collection was performed on data sheets separate from the clinical record.

2.4. Standard moderate sedation care

As per department standard practice, patients with pain prior to procedural sedation received an opioid: morphine 0.1 mg/kg IV followed by 0.05 mg/kg IV q 10 min as needed/tolerated for pain relief, or hydromorphone 0.015 mg/kg IV followed by 0.0075 mg/kg IV as needed. All patients had cardiac, blood pressure, pulse oximeter and nasal sample end-tidal CO2 (ETCO2) monitor, the latter with continuous waveform display (Oridion Capnostream 20, Oridion Capnography Inc.) [24]. For most patients we administered supplemental oxygen by face mask (8–10 l) prior to the start of the procedure [25]. Each sedation was attended by a respiratory therapist, a registered nurse, and 2 physicians (1 for the procedure, 1 for administering study medication). These are our departmental standards for sedation, regardless of whether or not moderate or deep sedation is targeted.

2.5. Randomization and blinding

A computer-generated randomization schedule was maintained. Randomization was achieved by selecting a sequentially numbered sealed envelope containing the group assignment determined using the randomization schedule. Patients were blinded to the randomization assignment.

2.6. Outcomes

Our primary outcome was the relative number and proportion of subjects experiencing airway or respiratory adverse events leading to an intervention, defined as the composite of one or more predefined

Airway or Respiratory Adverse Events	
Hypoxia	An oxygen saturation of <92% at any time during the procedure
Central Apnea	A pause in respiratory effort, defined as an absent end tidal CO2 waveform >6 seconds during the procedure
Sub-clinical respiratory depression	Hypopneic hypoventilation, defined as a decrease in end tidal CO2 >10mmHg recorded during the procedure or by physician report of partial upper airway obstruction
Complete Upper Airway Obstruction	Ventilatory effort without air exchange, defined by an absent end tidal CO2 waveform with physician report of ventilatory effort
Laryngospasm	Partial or complete airway obstruction caused by involuntary closure of the vocal cords not relieved by routine airway repositioning or insertion of a nasal or oral airway, by physician report
Aspiration	Clinically apparent aspiration after vomiting, by physician report
Clinical Interventions	
Increased supplemental oxygen	Any addition or increase in supplemental oxygen provided to the patient
Airway adjunct use	The use of an oral airway or nasal trumpet to improve the patients ventilations
Repositioning	Any repositioning of the patient's airway in order to improve ventilation
Stimulus for respiration	Any verbal or physical stimulus used to induce ventilation
Assisted Ventilation	The use of a bag valve mask device to positive pressure ventilate a patient

Fig. 1. Definition of the airway and respiratory adverse events and associated clinical interventions used to define the composite primary study outcome.

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