

Moderate vs. Deep Procedural Sedation with Propofol in the Emergency Department

Background:

Providing appropriate analgesia and sedation for the management of pain and anxiety to a diverse group of patients has become a commonplace procedure in the ED. Adequate pain control and alleviation of anxiety improves quality of care and patient satisfaction. Numerous studies have found that PS in the ED is safe, and when properly administered, the incidence of reported complications, including clinically significant respiratory depression, is rare.

Propofol is an anesthetic agent frequently used for PS in the ED and produces sedation, hypnosis, and amnesia, but lacks analgesic properties. In studies conducted at HCMC, we have found that patients are unable to recall whether or not they experienced pain during the procedure when sedated with propofol. There is the possibility that certain parts of the procedure can be later recalled by the patient. If extensive parts of the procedure can be recalled, then this is not an effective sedation.

Previous studies on memory have utilized both images and words as prompts.[1] Research has shown that many people can recall pictures more easily than words.[2] Therefore, using images as prompts could be a more sensitive way to detect whether patients are forming a memory during sedation. A previous study on sedation at HCMC used verbal prompts, and so the feasibility of using images during sedations needs to be assessed.[3] For the pilot portion of this study, a verbal memory assessment will also be performed to ensure that the visual memory assessment is an effective way to assess memory during procedural sedation. If this method of assessing memory is feasible and efficacious, then the randomized phase of the study will commence with using the visual memory assessment alone.

It is unknown whether moderate sedation can decrease respiratory distress while maintaining adequate amnesia. This question was previously asked in another study at HCMC where pre-sedation targets of moderate or deep sedation were assigned. However, there was not adequate separation of the two arms of the study and the sedation target was achieved for only 69.4% of the deep sedation group and 53.8% of the moderate sedation group.[4] Given the lack of separation of the two subject groups, further investigation is required. This study will randomize 150 patients to moderate or deep sedation. The physician will continuously monitor the patient's level of responsiveness to reach the appropriate level of sedation, and will report the achieved depth of sedation following the procedure.

Methods:

The pilot phase will be a prospective, observational study of the feasibility of the use of a visual memory assessment test during PS in the ED. The second phase will be a prospective, randomized study of the relative amnesia and respiratory distress in patients receiving either moderate or deep sedation with propofol. Patients who present to the ED requiring PS who are 18 years of age or older, are able to provide informed consent, and meet criteria for ASA class I or II are eligible for enrollment into the study. Patients will be excluded if they have a known hypersensitivity or contraindication to propofol, are pregnant, are a prisoner, or are unable to give informed consent for any reason, including having clinical evidence of intoxication. During the randomization phase of the study, the patient will be

randomized to moderate or deep sedation after informed consent is obtained. During the pilot study, a baseline memory assessment will be performed by showing the patient one image every 30 seconds for 10 minutes. The patient will be asked to verbalize what the image shows at the time of presentation. During the pilot phase, the patient will also be read a word every 30 seconds and asked to repeat it. Then, the researcher ask the patient which images and words they can recall after 10 minutes; after this, the patient will be shown images in groups of three and asked to pick which image they were shown.

Prior to the procedure, patients will be placed on monitors, per standard of care for ED PS. During the randomized phase, visual prompts will be shown every 30 seconds during the 5 minutes before propofol is given. Baseline measurements will then be obtained. Every 30 seconds during the procedure, data will be recorded and an image will be shown. The patients will be asked to verbalize what the image shows. For the pilot phase, a word will be read every minute and the patient will be asked to repeat it. The patient will be monitored during the procedure by a physician. After the procedure, the physician will record whether moderate or deep sedation was achieved. The patient's recollection after the procedure will be tested with both free recall and recognition in the same manner as the baseline memory test. Also, patients will be asked to score three separate 100 mm visual analog scales in relation to perceived pain during the procedure, recall of the procedure, and overall satisfaction with the procedure.

In addition, during the procedure, all events including drug dosing, interventions, procedures, and adverse events, will be time stamped in the end tidal CO₂ monitor.

Inclusion criteria:

All patients 18 years and older who will undergo procedural sedation in the ED with propofol; procedures requiring sedation include, but are not limited to: fracture reduction, dislocation reduction, cardioversion, incision and drainage, or chest tube placement.

Exclusion criteria:

Known contraindication or allergy to propofol

Unable to give informed consent for any reason, including having clinical evidence of intoxication

Have a chronic medical condition that is currently unstable, or are currently critically ill (ASA Class III or IV)

Are pregnant

Data collection will be performed by trained RAs and will include:

Indication for procedural sedation

Presumed ED diagnosis

Patient demographic information

ED vital signs including pulse, blood pressure, respiratory rate, oxygen saturation, end tidal carbon dioxide

Objective Assessment of Alertness Scale (OAAS) score during the procedure

Interventions during procedure (i.e. bag valve mask use, airway repositioning).

Answers to visual and verbal memory assessment pre-test and post-procedure test

Ability of a patient to verbalize image content during the procedures

Ability of a patient to repeat a word during the procedure

Medications administered or prescribed

Total time of procedure

Procedure outcome (successful or unsuccessful)

Physician rating of procedure difficulty

Patient perception of perceived pain during the procedure, memory of the procedure, and overall satisfaction with the procedure

Data Analysis

The primary outcome of the study is procedural recall. There is currently insufficient data to determine the accuracy or precision of the primary outcome measure, procedural recall as measured by the memory assessment. The first phase of this study will determine the distribution of this measure in the groups and will be used to perform a power analysis for a subsequent trial.

Secondary outcomes will include: adverse respiratory events, defined as any intervention during the procedure in the setting or apnea as measured by end tidal CO₂ or an oxygen saturation of <93%, time of the procedure, success of the procedure, defined as complete procedure in the absence of recall or an adverse respiratory event, patient pain with the procedure, and patient satisfaction.

Data from the end tidal CO₂ monitor will be downloaded in 20 us increments. This deidentified data will be pooled with investigators at three other institutions in order to study waveform changes at the time of events during the procedure.

References:

- [1]: Kawaii H et al. Intravenous sedation for implant surgery: Midazolam, butorphanol and dexmedetomidine versus midazolam, butorphanol and propofol. *J Oral Implantol*. 2011 Dec 29. Epub.
- [2]: Paivio A et al. Free and serial recall of pictures, sounds, and words. *Memory & Cognition*. 1975; 2(6):586-590.
- [3]: Miner JR et al. Assessment of the onset and persistence of amnesia during procedural sedation with propofol. *Acad Emerg Med*. 2005 Jun; 12(6):491-6.
- [4]: Miner JR, Huber D, Nichols S, Biros M. The effect of the assignment of a pre-sedation target level on procedural sedation using propofol. *J Emerg Med*. 2007 Apr; 32(3):249-255.