Procedural Sedation

- Clinical policy: procedural sedation and analgesia in the emergency department.
- Update from last revision in 2005 asking 4 critical questions and presenting recommendations and the literature to support those recommendations.

Questions

- Does pre-procedural fasting reduce the risk of emesis and/or aspiration?
- Does the routine use of capnography reduce the incidence of adverse respiratory events?
- What is the minimal number of staff necessary to manage complications of procedural sedation?
- Can ketamine, propofol, etomidate, dexmedetomidine, alfentanil, and remifentanil be safely administered?

What is the Importance of this Article?

- Procedural sedation has attracted the attention of policymakers and regulatory agencies not necessarily understanding emergency medicine.
- Nursing organizations have promulgated opinions not based in any literature or understanding of procedural sedation.
- CMS has acknowledged that there is "no bright line" in medication induced transition from analgesia to anesthesia and that the "ED is a unique environment where patients present on an unscheduled basis . . . that may require emergency or urgent interventions".

Definitions

- The old system of minimal, moderate, and deep sedation is clearly outdated and clinically irrelevant as the divisions between moderate and deep are near impossible and irrelevant in terms of approach in the ED and the division of drugs into the deep or moderate agents was utter nonsense.
- Procedural sedation is the process of providing analgesics and/or sedatives to allow patients to tolerate painful procedures without compromise of cardiorespiratory status.
- The newest term of monitored anesthesia care acknowledges the continuum of administering these agents from being awake to general anesthesia without dividing the level into arbitrary divisions.

Methodology

- The usual evidence/recommendation levels for ACEP reviews:
  - Level A – high degree of clinical certainty, based to studies of Class I and Class II studies.
  - Level B – moderate clinical certainty, predominantly Class II studies.
  - Level C – Class III studies or no adequate studies so based on expert opinion and/or consensus.
**Question 1 - NPO**

- In patients undergoing procedural sedation does pre-procedure fasting demonstrate a reduction in risk for emesis or aspiration?
- Level B recommendation – do not delay procedural sedation in adults or children based on fasting time.
- NPO status has not demonstrated a reduction in risk for emesis or aspiration when administering the agents used for procedural sedation that does not induce the depth of sedation to impair airway reflexes to the extent that general anesthesia does.

**The History of NPO Guidelines**

- NPO guidelines came out of the experience of providing anesthesia during deliveries.
- Pain management during birth had significant religious barriers to overcome in Western medicine given the biblical admonition of Eve’s sin in the Garden of Eden condemning women to suffer pain in childbirth.
- It took Queen Victoria who insisted that Edward Snow provide chloroform anesthesia for the birth of her 4th child, Prince Leopold, in 4/7/1853 (poor Dr. Snow was either going to be known as the Father of obstetrical anesthesia or the doctor who killed the Queen).

**The History of NPO Guidelines**

- This broke the dam and very rapidly women were insisting on having the option of some pain management during labor.
- Rather quickly cases of vomiting with aspiration during the administration of the common anesthetics, chloroform or ether, started to be seen with a very high mortality in those pre-antibiotic days.
- It became evident that women who had not eaten for several hours vomited less often and if they did aspirate their course was less fulminant.
- Rather quickly the NPO guidelines for general anesthesia were codified and applied to every situation where sedation was performed.

**NPO and Procedural Sedation**

- Initially it was assumed that the NPO guidelines for general anesthesia should apply to procedural sedation without critical thought or any study of the matter (DOGMA).
- Studies of the issue have failed to demonstrate any significant association of emesis and/or aspiration with NPO status for procedural sedation.
- This included Class II studies for both adults and children including a study by Roback with 1555 pediatric patients and 3 other studies with a total of 946 children and one by Bell with 400 adult patients – all had the same conclusion that fasting prior to procedural sedation did not reduce the risk of emesis or aspiration.

**Question 2 - Capnography**

- The second question asked if routine capnography during procedural sedation reduce the incidence of adverse respiratory events?
- Level B recommendation – capnography may be used as an adjunct to pulse oximetry and clinical assessment to detect hypoventilation and apnea earlier.
- ETCO2 reacts far faster than PO2 to a patients respiratory status.
- Its use during procedural sedation adds a measure of safety in that it will detect when a patient’s breathing rate starts to fall to the extent that they are not moving sufficient air or if they stop breathing altogether.
In a systematic Class II meta-analysis by Waugh capnography was 17.6 times more likely to detect respiratory depression than standard monitoring.

In a Class III study of ED patients all episodes of respiratory depression were detected by ETCO2 vs. 33% by Pox alone.

In another Class III ED study looking at physician assessment vs. capnography ETCO2 was particularly good at detecting patients with respiratory depression but not to the point of hypoxia.

Studies do show that ETCO2 monitoring is better than just physician assessment of respiratory status.

The third question asks what is the minimum number of personnel necessary to manage complications during procedural sedation?

There was no Level A or B recommendations – only a Level C recommendation that during procedural sedation a nurse or other qualified person should be present to monitor the patient outside of the person performing the procedure.

This mirrors a 2011 ACEP statement that also expressed strong support for nurses to be able to administer propofol, ketamine, and other sedatives under the supervision of a qualified emergency physician.

The literature is sparse on this matter.

Two Class III studies comprising some 1,000 patients undergoing procedural sedation found the rate of complications was similar if 1 physician administered the sedation and did the procedure versus 2 physicians.

However, in both scenarios there was a nurse present to monitor the patient with all adverse events resolved successfully.

It makes common sense that the person doing the procedure be able to concentrate on that while someone else watches over the status of the patient.

Like everything in emergency medicine procedural sedation is a team effort – not diluting the team is a commonsense approach.

Level A recommendations – ketamine and propofol are safe medications for use in procedural sedation for both adults and children.

Level B recommendations – etomidate offers a safe option in adults for sedation/analgesia in the ED for procedural sedation and a combination of ketamine and propofol (Ketofol) can be safely administered to both adults and children for procedural sedation.

Level C recommendations – ketamine is safe in adults for procedural sedation. Alfentanil is a safe option for procedural sedation in adults. Etomidate can be used in children for procedural sedation in the ED.

Level A recommendations – ketamine and propofol are safe medications for use in procedural sedation for both adults and children.

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Level C recommendations – ketamine is safe in adults for procedural sedation. Alfentanil is a safe option for procedural sedation in adults. Etomidate can be used in children for procedural sedation in the ED.

Multiple Class I, II, and III studies support the use of ketamine and propofol in the ED as safe and effective agents for procedural sedation.

They have become standard and accepted for use.

The use of Ketofol – the combination of ketamine and propofol typically in the 1:1 with a dose between 0.5 – 75 mg/kg of each drug with the idea being ketamine would reduce the hypotension associated with propofol and propofol with reduce the emergence and emesis issues seen with ketamine.

In studies with children the combination was found to be effective but respiratory depression was similar compared to the single agents.
Medications

- While multiple studies clearly support the use of ketamine in children there is less literature on the use in adults but there are reports on the use in adults without the dreaded problems of recovery agitation precluding its use.
- Etomidate has been shown to be safe in both adults and children but there is a disadvantage with myoclonus reported in 20-40% of patients (way more common than the presenter's experience with the drug).
- Its adrenal suppression effect has not shown to be clinically significant and its short duration of action and cardiovascular stability makes it quite useful (my go-to agent for cardioversion – 2.5-5 mg).

Summary

- The fasting/NPO guidelines for general anesthesia have not been shown to reduce the risks of emesis or aspiration for procedural sedation – the impairment of airway reflexes is sufficiently less than general anesthesia and the procedure trumps NPO status.
- Capnography adds additional safety to monitor patients during procedural sedation for hypoxia and apnea.
- While there is no literature to clearly delineate the number of personnel necessary for procedural sedation common sense would suggest at least 2 persons are needed – one to do the procedure and one to monitor the patient and administer medications.

Medications

- Alfentanil is an ultra-short analogue of fentanyl and it was surmised that its even faster onset and offset compared to fentanyl might be advantageous with procedural sedation.
- In a Class II study when added to propofol sedation it worked well but there was an increase in patients who needed some simulation for hyperventilation and recovery rates were longer – it was not felt to add anything over current agents used.
- Remifentanil is another ultra-short acting synthetic opioid and dexmedetomidine is a sedative similar in action to a benzodiazepine with both agents only addressed for procedural sedation in brief case reports – not quite ready for prime time.

Summary

- Propofol is well established as a safe agent for procedural sedation in both adults and children.
- Ketamine also has ample support in the literature and practice as a safe agent for children and a number of good reports on its use in adults as well.
- Ketofol is an effective and safe combination of ketamine and propofol but has not shown a clear advantage over either agent alone.
- Etomidate is also a safe agent for procedural sedation in adults but can have issues with myoclonus, its use in children has also been shown to be safe.
- Alfentanil, remifentanil, and dexmedetomidine have not shown to add much to the above the agents and cannot be recommended at this time.