

Contact Information

Lois Pizzi BSN, RN-BC
Inpatient Pain Management Clinician
UPMC Presbyterian Shadyside
pizzili@upmc.edu 412-623-3814

Colleen J. Dunwoody MS, RN-BC
Pain Management Educator and Clinical Consultant
dunwoody140@comcast.net 412-310-0485

Objectives

- Identify the limitations for the administration of ketamine (Ketalar®) according to Pennsylvania State Board of Nursing; and identify appropriate guidelines for comparison when using ketamine off-label as an analgesic agent.
- Identify elements of the hospital culture and administrative processes that must be considered for successful implementation of a ketamine protocol.
- List the major elements of a self-learning module for nurses implementing a ketamine protocol.

Ketamine Indications

FDA-approved

- Sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation
- Induction of anesthesia prior to the administration of other general anesthetic agents
- Supplement low-potency agents, such as nitrous oxide.

Off-label indications

- Prevention/reversal of central sensitization and wind-up
- Treatment of poorly opioid-responsive pain
- Management of neuropathic pain
- Management of acute pain in opioid-tolerant patients

Where we started.....

Physicians requested off-label use of ketamine for analgesia
Risk Management reviewed use; subsequently asked for input from corporate legal department
Ketamine for analgesia discussed at P&T meetings
Administration via PCA pump discussed due to safety and security
eRecord discussions were included due to the need for electronic order sets

State Board of Nursing (SBON)

- Defines ketamine as an anesthetic agent, per FDA classification
 - Most SBON do not define ketamine as an analgesic
- Specific uses of this drug are defined for FDA-approved used
 - OR by CRNA
 - Controlled settings for conscious sedation

New York SBON



The Role of the Registered Professional Nurse in the Administration of IV Anesthetic Drugs in the Treatment of Intractable Pain

A Registered Professional Nurse may administer intravenous anesthetic drugs such as Ketamine to patients experiencing documented intractable pain in critical care, hospice, or palliative care areas under the following circumstances:

- The facility has specific policies and procedures related to the administration of IV anesthetic drugs for this purpose.
- The RN has successfully completed didactic coursework in the pharmacology, administration, side effects, and complications of these drugs; including contraindications and signs and symptoms of unwanted effects of their use.
- The RN has successfully completed and has current training in basic airway management, such as that provided within Basic Life Support for Healthcare Providers. Verification of the date of this training should be conducted by the facility in which care is delivered annually.
- Competency evaluation must be documented annually in the personnel file of the RN providing this care.
- There is a patient specific order from an authorized provider for the administration of these drugs for this purpose.

October 2006

UPMC

- Ketamine off-label use as an analgesic
 - Approved through the Pharmacy and Therapeutics Committees
 - Recommendations and oversight by the Risk Management Department
 - Recommendations and oversight by the Corporate Legal Department

UPMC Guidelines for Low-Dose Ketamine for Analgesia

- Ketamine will be prescribed only by the following pain management services:
 - Acute Interventional Postoperative Pain Service (AIPPS) or Anesthesiology Service for the management of postoperative pain in opioid tolerant patients.
 - Palliative Care Service in the management of opioid refractory pain
 - Chronic Pain Service in the outpatient management of refractory complex regional pain syndrome

Evidence Level

- I An opioid-sparing effect in postoperative pain
- I NMDA receptor antagonist drugs may show preventive analgesic effects
- II Improves analgesia in patients with severe pain that is poorly responsive to opioids
- IV May reduce opioid requirements in opioid-tolerant patients

Acute Pain Management: Scientific Evidence ANZCA and FPM (2005)

Ketamine Analgesic Dosing Summary

Indication	Initial Dose	Maximum Dose	Route	Notes
Opioid Refractory Pain (Palliative care)	0.1mg/kg/hr	0.5mg/kg/hr (Max 42mg/hr)	IV/SC	Continuous Infusion
Postoperative Pain (AIPPS)	≤ 50kg: 0.1-0.2mg/kg/hr	0.2mg/kg/hr	IV	Continuous Infusion
	> 50kg: 4mg/hr	10mg/hr		
Refractory Complex Regional Pain Syndrome (Chronic pain)	10mg/hr	30mg/hr	IV	Continuous Infusion (usually over 4 hours)

General anesthesia doses: 1 to 2 mg/kg IV bolus dose

Application Measures to Meet the PA SBON Criteria

PA SBON* Criteria for "Conscious Sedation"	UPMC Legal Statement	UPMC P&T/Formulary Guideline Actions
1. A licensed physician is present and has written the order that specifies the dosage and manner in which the drug is to be given.	Must include	Prescribers limited to AIPPS, Chronic Pain and Palliative Care Services; licensed physician available 24/7; initial orders cannot be verbal orders; CPOE care set/order set will be developed and required for all orders.
2. There are written guidelines specifying which medications the registered nurse may administer.	Must include	Ketamine is the only medication that is included in this guideline. Dosing recommendations are delineated.
3. Monitoring and emergency resuscitation equipment is available for the patient.	Must include	Crash carts are available on every inpatient unit where patients will be receiving ketamine.

* State Board of Nursing

Application Measures to Meet the PA SBON Criteria		
PA SBON* Criteria for "Conscious Sedation"	UPMC Legal Statement	UPMC P&T/Formulary Guideline Actions
4. The patient has IV access.	Must include	Ketamine will be administered to patients via a dedicated infusion pump. IV access may not be available for patients at the end of life.
5. The registered nurse is certified in advanced cardiac life support (ACLS).	Must include	Non-ICU nurses are Basic Life Support (BLS) certified. Guidelines will denote specific patient assessment criteria and when to call the physician.
6. The registered nurse has been tested on his or her competence for administering anesthesia on a regular basis.	Must include	A ketamine-specific nursing competency has been developed. Nurses must pass this with a score of 100%. The Unit Director is responsible for ensuring nursing competency at the bedside.

Application Measures to Meet the PA SBON Criteria		
PA SBON* Criteria for "Conscious Sedation"	UPMC Legal Statement	UPMC P&T/Formulary Guideline Actions
7. The registered nurse has no other tasks or responsibilities during the administration of anesthesia.	Must include	Analgesic doses of ketamine are below the doses required for anesthesia or conscious sedation. Nurses will have regular patient assignments. Specific assessment criteria are identical to routine patient-controlled analgesia (PCA) parameters for patients on general units.
8. The registered nurse continuously monitors the patient.	Must include	Monitoring will be as per current PCA guidelines, which is an existing nursing-driven standing order protocol. Monitoring is q 30 minutes after dose change, q 2hrs x 4hrs; then q 4hrs while ketamine is infusing. When comfort measure orders have been instituted; assessment criteria do not apply.

Application Measures to Meet the PA SBON Criteria		
PA SBON* Criteria for "Conscious Sedation"	UPMC Legal Statement	UPMC P&T/Formulary Guideline Actions
9. The patient retains the ability to independently and continuously maintain an airway and to respond appropriately to physical stimulation and verbal commands.	Must include	Patient will not be intubated on a med/surg unit. Analgesic ketamine should not be doses to produce significant sedation. Patients will maintain ability to respond to physical stimulation and verbal commands.

Ketamine Administration



Hospira PCA Pump:
http://www.hospira.com/media/catalog/product/each/111img/5p60311be1608070e435848c230972d110c_HOSPIRA_111384_ca.jpg

- Nurses will complete a ketamine (Ketalar®) education: ongoing annual competency training.
- Ketamine should be administered through the Hospira® pump ONLY
 - On ALL units, including ICU
 - Via the continuous mode
 - This pump has a locked control panel and a locked drug reservoir.

Any patient receiving a ketamine infusion exceeding 42 mg/hr is to be transferred to ICU, where higher doses may be used (maximum of 60 mg/hr)

Nursing Education Module for the Administration of ketamine

- Objectives:
 - Identify the indications for the administration of ketamine for analgesia.
 - Describe the mechanism of action of ketamine for analgesia.
 - List the adverse effects related to the administration of ketamine for analgesia.
 - Explain the nursing assessment required for the patient receiving ketamine for analgesia.
 - Identify appropriate dosing parameters for the use of ketamine as an analgesic agent.

Compliance

- 100% completion by nurses is required to administer ketamine for analgesic use.
- Initially, the module was completed by nurses on the pilot units, the PACU and the Surgical ICU (surgical patients were our target patient population).
- Subsequent units to do the education were those indicated by the AIPPS service.
- Palliative care use would require all nursing units to complete the module (no designated palliative care unit on either campus).

Patient Assessment

- Assessment of the patient will follow the standard routine for a patient on PCA.
- Perform standard assessments of pain score, sedation score, and quality descriptors:
 - Assess within 30 minutes of initiation and after a rate/dose change
 - Assess every 2 hours x 4 (total of 8 hours)
 - Then assess every 4 hours for the duration of the infusion

Opioid Tapering Recommendations

- Ketamine administration for analgesic use may have an opioid-sparing effect
- Reduce opioid doses 25-50%
- Excessive patient sedation may indicate the need for a decrease in opioid dose
 - Follow naloxone (Narcan®) administration guidelines for excessive opioid-induced sedation
 - Notify MD

Naloxone (Narcan®) Administration

GOAL : Avoid causing pain or withdrawal symptoms

- | | |
|---|---|
| <ul style="list-style-type: none"> ■ Dilute 0.4 mg Naloxone {1 ampoule} in 9 ml. saline then 1 ml. = 0.04 mg ■ Naloxone 0.04 mg q1min until a change in alertness is observed - watch eyelids | <p>Minimal Monitoring Requirements</p> <ul style="list-style-type: none"> ■ Respiratory rate, blood pressure, heart rate, oxygen saturation, and pain score <ul style="list-style-type: none"> ■ q15 minutes x 2 hours ■ q 30 minutes x 4 hours |
|---|---|

Naloxone (Narcan®) Administration

And ...

- Consider other causes of sedation and respiratory depression if no response after full ampoule given
- If symptoms return, consider continuous infusion (3 mcg/kg/hr)
- If sustained release opioid necessitated naloxone, start continuous infusion

When pain returns

- restart opioid at 50% dose and titrate up if necessary

Outcome Data

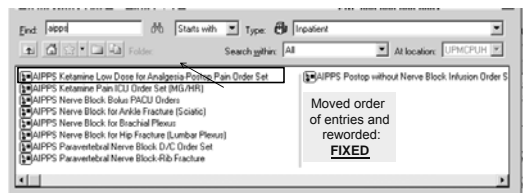
- Special thanks to the UPMC Presbyterian/Shadyside Pharmacy Department
- Extra Special thanks for the following data slides to:

Colleen M. Culley, Pharm.D., BCPS
 Clinical Pharmacy Specialist, Drug Use and Disease State Management Program, UPMC Presbyterian
 Associate Professor, University of Pittsburgh School of Pharmacy

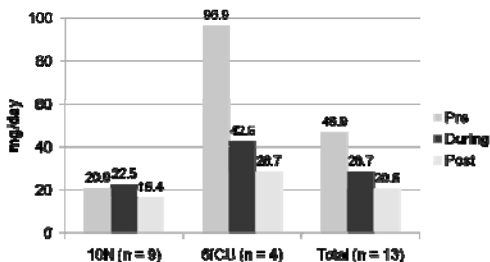
Project Timeline

	2009								2010										
	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Initial MD discussion	X																		
Evidence-review by Rx		X	X																
1 st draft of guideline to MDs					X														
Safe Medication Practices Committee						X													
Patient Safety Committee							X												
Legal counsel meeting								X											
2 nd draft w/legal recommendations									X										
Final legal statement										X									
Final guideline ready										X									
Formulary Subcommittee approval											X	PUH							
P&T Committee approval											X	SHY	X	PUH					
Hospira pump decision													X						
Nursing U Learn draft											X								
Error order set build												X	X	X	X				
Finalize Hospira pump settings														X	X	X	X	X	X (pump upgrade)
Nursing U Learn training																X			
Pharmacy education																X			
Go-live PILOT																		X	PUH X SHY 24

Order Entry Confusion

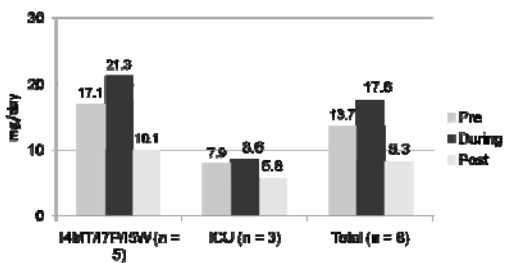


Hydromorphone PCA Use Before, During and After Ketamine Infusion: Presbyterian Pilot



One patient on 10N received hydromorphone IV intermittently, not PCA

Hydromorphone PCA Use Before, During and After Ketamine Infusion: Shadyside Pilot



One patient on 15W received fentanyl due to hydromorphone allergy; fentanyl doses converted to mg.

Where we are now...

- Complete pilot of 10 patients on each campus; on a selected units (surgical/oncology).
 - Competed at Presbyterian and Shadyside
- Audits will be done to assess outcomes.
- Approved at July 2010 P&T Presbyterian and Shadyside
 - Expand to other units after nursing training complete, Self-Learning module added to the yearly competency list
 - Expand use by other pain services

Moral of the story...

- The devil is in the details.....



Barriers and Lessons Learned

Barriers

- Time was needed to gain input and approval from Legal Counsel to meet PA State Board of Nursing Requirements
- Clinicians wanted to start protocol, as other states allowed this practice – PA adherence was essential
- Needed secure pump for drug administration – ketamine is a controlled substance
 - Pump update is manual process that took over one month
- Needed to ensure RN training was completed prior to go-live
- Go-live date chosen before order set final proofing was complete and CPOE listing was prescriber-friendly
- Order entry confusion related to CPOE listing of new sets

Lessons Learned

- Constant communication is essential on development steps
- Diligence with prescriber order entry is essential to ensure safety parameters are met for the patient
- E-MAR build for nurses is critical piece of planning
- Use non-weight based dosing if administering via the Hospira pump
- Individual patient monitoring is critical
- Pilot approach was successful in identifying improvements:
 - EMAR enhancement for clarity
 - Standardization to one concentration
 - RN competency was effective
 - CPOE orderable must be listed so prescribers can easily find the correct care set

Few things we do for patients are more fundamental to the quality of life than relieving pain.

Dunwoody, C.J. Patient-Controlled Analgesia: Rationale, Attributes, and Essential Factors. *ONJ*. 1987, 6(5), 31-36.
