Opioids in Post-Acute & Long-Term Care: A Delicate Balance

Karl Steinberg, MD, CMD, HMDC
karlsteinberg@MAIL.com
Twitter: @karlsteinberg

Disclosures

- Karl Steinberg, MD, CMD, HMDC has no relevant disclosures

Objectives

- Discern the reasons for the current "opioid crisis" in the U.S. in the context of historical factors and medical practice
- Appreciate the specific factors that pertain to pain control and opioids in nursing facilities
- Implement strategies to balance resident safety, symptom relief, and regulatory concerns
- Emphasize the importance of treating pain in SNF residents, keeping residents' rights and person-centered care in the forefront when weighing treatment options

Introduction to Pain

- Pain is common in the PALTC setting
- Physicians have generally done a poor job of adequately treating chronic pain
- Substantial literature documents chronic pain underdetected and undertreated with advancing age
- Pain may be associated with mood disturbances (for example, depression, anxiety, and sleep disorders)
- Enormous consequences of unrelieved pain—especially functional impairment→bad prognosis

Pain in the Nursing Facility

- 49-84% prevalence of persistent pain in various populations
- 66% with intermittent pain, 34% with constant pain
- 55% with intermittent pain have daily pain
- Pain is inconsistently and often inadequately managed, typically just with prn acetaminophen
- Only 15% have had medication in last 24 hours
- 6.4% and 32% untreated and undertreated
- Some evidence of improvement in recent years

Pain in the Nursing Facility

- Largest category of pain: musculoskeletal
- Low back (40%), arthritis (24%), previous fracture site (14%), foot (8%), neck (6%)
- Other sources: neuropathies (11%), leg cramps (9%), claudication (8%), headache (6%), pressure ulcers
- Cancer only 3% but source of some of most severe pain encountered in PALTC

Brief Opioid History

- Derived from opium poppy (*Papaver somniferum*)
- Natural components include morphine and codeine
- Recognized for their analgesic and euphorigenic properties from ancient times
- Tolerance, dependence, addiction potential also identified centuries ago
- Very useful in the field of medicine
  - Excellent for treatment of dyspnea and unlikely to cause respiratory depression in therapeutic doses
    - More dangerous when combined with benzodiazepines
  - Also useful and often prescribed for cough, diarrhea
  - Side effects include constipation, nausea, somnolence, pruritus
    - Saunders: "The hand that writes the opiate prescription should also write the laxative"

Brief Opioid History

- Perennial search for safer, less addictive modified or synthetic alternatives (e.g., heroin, pentazocine, methadone)
  - Has not really been a success, but some very potent agents have been developed (e.g., fentanyl)
- Controlled Substances Act of 1970
  - The most potent legal opioids (fentanyl, morphine, oxycodone, others) are C-II, cannot be phoned in and cannot be refilled
  - Only codeine combinations, tramadol, mixed agonist/antagonists, antidiarrheals not C-II
    - Note that buprenorphine (including Subutex/Suboxone), nalbuphine, others are C-III
  - Heroin and illicit fentanyl derivatives are Schedule I (no legally recognized use in U.S.)

Brief Opioid History

Pendulum of prescribing

- 1980s: Standard practice: generally reserve use for severe post-op or trauma pain, terminal cancer
- 1990s: More relaxed prescribing, pain as the Fifth Vital Sign, advent of pain specialists
- 2000s: Even more relaxed, many new opioid formulations became available
- 2010s: Recognition of opioid epidemic has rapidly returned us to highly restricted use
  - Some facilities are refusing to admit residents who are on opioids, especially with a history of addiction—or those on maintenance therapy (e.g., buprenorphine or methadone).
  - But in 2014, over 200 million opioid prescriptions were filled by US pharmacies
  - Mostly for acute pain (<3 weeks) but 10 million patients were receiving chronic opioid Rx's
  - Many are being diverted
  - New opioid formulations with deterrents (not a new concept)
  - Numerous recent laws and regulations passed with respect to opioid prescribing, including limits on duration (e.g., 1 week), dosages (e.g., 90 mg morphine equivalents [MME])
  - Also limits on opioid production—has resulted in shortages in hospitals and local pharmacies

The Opioid Crisis

- With wider availability of prescription opioids in the last 20 years, use increased
  - Patients were kept on opioids long-term for chronic pain [note: not very effective or evidence-based]
  - Abuse/misuse/addiction also increased
- But they are killing more people than auto accidents, AIDS at peak: >50,000 in 2018
- "Traditional" opioid addiction was heroin, historically very expensive (>$100/day) and associated with criminal activity to support habit
  - Methadone clinics
  - Heroin maintenance used in England
- Combination of factors drove opioid crisis
  - Largesse in prescribing by pain specialists and others
  - Larger supply of illicit opioids, also less expensive and more accessible to "average" and younger users
  - Different kinds of "marketing" also de-stigmatized opioid use and abuse—both traditional pharmaceutical companies and illegal drug traffickers
  - Now laced with super-potent fentanyl derivatives—some are 100x stronger than morphine
    - Much higher risk of overdose
  - Excellent article in lay press: http://nymag.com/daily/intelligencer/2018/02/americas-opioid-epidemic.html

Opioids in Skilled Nursing Facilities

- **With wider availability of prescription opioids in the last 20 years, use increased substantially**
- **Chronic pain is very common in nursing home residents due to arthritis, many other conditions**
  - **Acetaminophen is a good first choice, should be given routinely up to 3 grams daily**
  - **Relative contraindications to other types of agents (e.g., nonsteroidal anti-inflammatories)**
  - **2012 data: 1 in 7 nursing home residents on chronic opioid therapy—but most of them continue to report moderate to severe pain (MDS data)**
  - **No good data to support the efficacy of opioids for chronic nonmalignant pain**
- **Many residents come to us from hospital with opioid prescriptions—some never go off them**
  - **Patients who take prescription opioids for more than a few weeks often wind up on them long-term**
  - **May be worthwhile to request a stop date for opioids when treating short-term pain**

Opioids in Skilled Nursing Facilities

- **Most guidelines recommend routine, around-the-clock dosing of opioids for patients who will predictably have pain**
  - **Preferably long-acting agents without a rapid rise in serum levels, which can be reinforcing**
  - **Helps keep pain levels lower, because it takes higher dosages to treat breakthrough pain than to prevent severe pain from occurring.**
  - **In postoperative or post-trauma pain, routine opioids should be tapered rather than dc'ed "cold turkey" as the painful condition improves**
- **Adjuvant medications can be very helpful to potentiate analgesic effects of opioids (or replace them)**
  - **Specific medications for neuropathic pain**
  - **Psychostimulants**
  - **Antidepressants**
  - **Corticosteroids (e.g., dexamethasone, prednisone)**
  - **Topical meds (capsaicin, diclofenac, lidocaine)**
  - **Many others including some compounded medications**
- **Nonpharmacologic measures: Cognitive Behavioral Therapy, modalities, massage, acupuncture, manipulation, many others—with varying evidence base. Physical activity generally improves pain**

Opioids in Skilled Nursing Facilities

- DEA, nurse-as-agent controversy, tightened requirements for dispensing pharmacies to fill CS Rx's
  - 2012: large settlement for improper dispensing of meds "without valid prescription"
  - Since then, controlled substance Rx's have required written Rx or verbal OK from prescriber to pharmacist for emergency fills—SNF nurse no longer able to authorize (without explicit "contract" between prescriber and nurse)
  - Some states have even more restrictive laws/regulations
  - This has caused delays in residents receiving needed pain medication
  - Even applies to dispensing from E-kits
- Facsimile Rx's for C-II OK in LTCF, "original" does not have to be sent
- E-prescribing will probably become more prevalent in next few years; state laws vary
- Acceptable to order up to a 60-day supply of C-II medication in LTCF pharmacy (under federal law)
  - LTCF Pharmacy can do partial fills
- Acceptable to order up to 120 days' supply (including refills) valid up to 6 months of C-III to C-V
  - Oral Rx is OK, no written Rx is required
- Pharmacies are tending to dispense shorter durations
  - Important to get reordered before resident runs out of opioid on med cart

Opioids in Skilled Nursing Facilities

- Controlled substances cannot be returned to pharmacy or transferred to any other patient, must be destroyed
  - Instances of diversion related to non-destruction of SNF controlled substances have been identified
  - Robust processes for counting/inventory and destruction of unused meds are a best practice
- Hydrocodone products became C-II in 2014, making codeine combinations, mixed agonist-antagonists (e.g., buprenorphine) and tramadol available without written Rx required
- In proposed rule for 2016 revision of 42CFR§483 (Requirements of Participation), opioids were to be considered a psychotropic medication
  - This was removed in the Final Rule at the urging of AMDA, AHCA, LeadingAge, others
  - But opioid prevalence may become a quality metric for prescribers and/or facilities in the future

Opioids in Skilled Nursing Facilities

Relevant F Tags

- F757 (old F329), Unnecessary Drugs (and F 756, "irregularities") 483.45(c)(d)(e)
  - Excessive dose, including duplicative drugs—if multiple opioids or analgesics used, document why
  - Excessive duration
  - Without adequate monitoring
  - Without adequate indications for use
  - In the presence of adverse consequences "which indicate the dose should be reduced or discontinued"
- F697 (Quality of Care: Pain Management) 483.25(k)
  - Based on the comprehensive assessment of a resident, the facility must ensure that residents receive the treatment and care in accordance with professional standards of practice, the comprehensive care plan, and the resident's choices, related to pain management.

- *Best practice*: Specific care plan for opioid use, including realistic goals (not usually pain level = 0)
  - Obviously, need care plan for pain
  - Monitoring pre-and post-dose pain levels for effectiveness (don't just document "improved")
  - Use pain scales appropriate to the individual resident
  - Note controversy about using pain as "Fifth Vital Sign"

CDC Guideline for Prescribing Opioids for Chronic Pain (2016)

- Not intended for patients in active cancer treatment, palliative care, or end-of-life care
- "Don't use opioids routinely for chronic pain"
- Regularly monitor patients to make sure opioids are improving pain and function without causing harm
- Management of chronic pain is an art and a science

BUT: Many governmental agencies took these as absolute requirements, which has been harmful

- See recent NEJM piece from CDC guideline authors:

www.nejm.org/doi/full/10.1056/NEJMp1904190

Evidence Basis for CDC Guidelines

- Very little research on long-term benefits of opioids for chronic pain
- No studies comparing opioid outcomes related to pain, function or QOL
- Question if opioids have continued effectiveness or may even increase pain after several months of use

Key Principles of CDC Guidelines

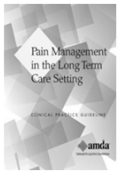
- Non-opioid management preferred, use opioids only when expected benefits (pain, function) likely to outweigh substantial risks—encouraged non-pharmacologic therapies
- Use opioid at lowest possible effective dose
- Monitor closely, avoid concurrent use of benzodiazepines
- 3 days or less often sufficient; more than 7 days rarely required

CDC Guideline Content

- Determining when to initiate or continue opioids for chronic pain
- Opioid selection, dosage, duration, follow-up and discontinuation
- Assessing risk and addressing harms of opioid use
- Dosing Recommendations, Assessing Risks and Harms, Monitoring and Discontinuing
- Checklist decision aid, patient poster, fact sheets for non-opioid therapies
- Have seen greater decline in opioid prescribing since release (Ann Int Med 169(6);18 Sept 2018 367-375)
- http://www.cdc.gov/drugoverdose/prescribing/resources.html

Pain Guidelines

- AMDA released its first guidelines on managing chronic pain in the nursing home setting in 1999, and they were subsequently revised in 2003, 2009, and 2012
  - -- slides for CNAs, RNs and MD/NPPs
- AGS published its first clinical practice guidelines in 1998 with revisions in 2002 and 2009



Key Points/Summary

- **Opioids are still the most effective pain reliever available, as they have been for millennia (and good for other symptoms too)**
- **Opioid crisis is real and must be addressed by our society**
- **Opioid "crisis" probably doesn't exist in nursing homes, but we can do better with our processes**
- **When appropriate: taper, use adjuvants, consider other analgesics, non-pharmacologic measures**
- **Constraints on opioid prescribing do not apply to hospice enrollees**
  - **There is no ceiling for pure opioid agonists; patients may require 1000+ mg of morphine daily because of tolerance**
- **Order ongoing opioids in plenty of time before resident runs out**
- **Have naloxone on hand for potential overdose situations**
- **Use caution when prescribing/administering opioids with benzodiazepines, respiratory depression**

Key Points/Summary

- For residents with potential addiction issues, consider usual measures (check PDMP, urine drug screens, contracts, observed administration, use of abuse-deterrent formulations, long-acting rather than short-acting formulations, use of buprenorphine and/or methadone to treat pain, specialty [addiction medicine/pain medicine] consultation)
- Treat addiction like any other disease, not a character defect
- Have strict policies about destruction of unused medications
- Be vigilant for diversion of opioids and unusual behavior by nursing staff
- Be realistic in goals of pain management, and create realistic expectations for residents/families – always demonstrate concern and a therapeutic alliance
- Always consider pain as a cause of behavioral disturbances in residents with cognitive deficits

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