Opiate Therapy and Treatment of Chronic Non-cancer Pain

A Clinical Perspective
Objectives

– Review evidence and guidelines surrounding opiate treatment of CNCP
– Share resources to help improve clinical outcomes and adherence to these guidelines
– Convey my perspective regarding the use of opiates in real-life practice over the past 10 years
– Allow time to discuss how we move forward to improve our systems of care for patients with CNMP, gather audience perspectives, obtain feedback and answer questions
Lecture Outline

• My Background
• Evidence Base Surrounding Opiates and CNCP
• Guidelines Along With Practical Suggestions
• Conclusions
• Q&A/Discussion
My Story

Why I’m interested in the management of CNCP
A Day At The Office

• [http://www.youtube.com/watch?v=b6jKkFJkLrl](http://www.youtube.com/watch?v=b6jKkFJkLrl)
A UCD-IM Patient

- Between 1996-2011, a middle aged female with a history of Crohn’s disease and polysubstance abuse presented to our resident clinic over 90 times with varied pain complaints.
- There was ample evidence that her pain was not from Crohn’s.
- More than 26 residents and 29 attending physicians saw her.
- Her pain was managed with escalating doses of opiates.
A UCD-IM Patient (Cont)

- Extensive documentation of both aberrant opiate seeking behavior and major opiate side effects
  - 26 calls for early renewals between visits
  - 4 reports of opiate theft leading to early refill requests
  - 7 reports of falls as an outpatient during clinic visits
- No documentation that providers discussed stopping opiates or referring the patient to a treatment program until 2011
<table>
<thead>
<tr>
<th>Date of Service</th>
<th>Representative Behavior</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/00</td>
<td>Attending notes <strong>suspicion for psychogenic component to pain and drug seeking behavior</strong>. Plan documents continue narcotics.</td>
</tr>
<tr>
<td>12/02</td>
<td>Patient reports <strong>letter she asked for at prior visit was for DA office regarding a prior conviction related to narcotic abuse</strong>. Plan, “Continue (narcotics) and certainly any further break of narcotic policy should warrant immediate dismissal from clinic.”</td>
</tr>
<tr>
<td>08/07</td>
<td>Patient reports <strong>stolen opiates</strong>. Note indicates “Pt has been compliant in the past without clear e/o abusing the refill policy.”</td>
</tr>
<tr>
<td>09/08</td>
<td>During visit, patient noted to be “Sleeping while standing up.” “She reports falling asleep while standing at least 3 times. Husband states that he has seen her walking and nearly falling asleep while walking. Pt states she almost walked out into traffic.” Pain meds are suspected and pt advised to cut down oxycodone to 7.5 mg q 6 hrs.</td>
</tr>
</tbody>
</table>
Patients on Chronic Opiates Comprise a Disproportionate Share of Office Visits

**Clinic Population Garfield 2007 (By Percentage)**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Faculty Clinic</th>
<th>Resident Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetics</td>
<td>9</td>
<td>84</td>
</tr>
<tr>
<td>Chronic Pain</td>
<td>16</td>
<td>22</td>
</tr>
<tr>
<td>Office Population without chronic pain</td>
<td>12</td>
<td>26</td>
</tr>
</tbody>
</table>

**% of Total Office Visits/Group (2007)**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Faculty Clinic</th>
<th>Resident Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetics</td>
<td>15</td>
<td>28</td>
</tr>
<tr>
<td>Chronic Pain</td>
<td>88</td>
<td>74</td>
</tr>
</tbody>
</table>

Chronic Pain=3 or more scheduled opiate rxs during 12 month period
Mean # of Office Visits/Patient 2007

Chronic Pain=3 or more scheduled opiate rx's during 12 month period
Mean # of Phone Notes/Patient (2007)

Chronic Pain=3 or more scheduled opiate rx's during 12 month period
Rates of opioid pain reliever (OPR) overdose death, OPR treatment admissions, and kilograms of OPR sold --- United States, 1999—2010 (1)

Today

• 15.1 million Americans reported abuse of prescription drugs in 2003
• 15,000 Americans died from prescription drug abuse in 2008
• ED visits rise 177% for narcotic abuse (1994-2002)

“Opium gives and takes away.”
--Dequincy 1901, Confessions of an English Opium Eater

Matthew Hollon ACP Lecture Handout (April 8, 2006)
Radio personality Rush Limbaugh for

OxyContin®

“OxyContin® helped me
deal with the pain of
living in a world that
just didn’t resemble
my perceptions
or my claims.”

WARNING: This drug has been shown to
cause sudden death in long-time abusers.
Chronic Non-Cancer Pain

• State of pain which persists beyond the usual course of an acute disease or healing process
• Complex condition with myriad of causes and perpetuating factors including psychiatric co-morbidity
• A condition often with poor correlation between pain complaints and results of physical findings or diagnostic tests
How Does Non-Cancer Pain Differ From Terminal Cancer Pain?

• Treatment horizon much longer in general
• Treatment goals should differ (function vs. comfort)
Ideal Goals of Treatment

- Decrease pain
- Improve function
- Decrease reliance on health care system
- Increase physical activity
- Enhance relationships and psychological integrity
- Return to work
We Should Own This Condition: Why?

• A complex condition which falls squarely into the bio**PSYCHOSOCIAL** rubric

• Treatment requires
  – A multidisciplinary approach (ie care coordination)
  – A therapeutic relationship with a caring provider who understands complexity
  – A clinician with good communication skills
How Can We Improve
(Lower Our Pain Levels 2-3 Points)

Revised Pain Scale, From Hyperbole And A Half
Portenoy’s Complaint

- 1986 retrospective case series
- 38 cases non-malignant pain
  - All had failed more conservative measures for many years
  - About half received disability payments
  - 19/38 received opioids for > 4 years
  - 0 adverse events reported
  - 29% adequate pain relief
  - 34% partial pain relief
  - 37% continued to have severe pain intermittently
  - Only 2/38 posed “management problems”

- “Suggests that opioid maintenance therapy initiated for the treatment of chronic non-malignant pain can be safely and often effectively continued for long periods of time.”
  - “Few” patients had dramatic improvement in functional status or psych status
  - 100% feared worsening pain if opioids withdrawn
  - Only 4/38 took more than 40 mg maintenance morphine/day

Portenoy, 1986
# Trials of Opioids for Chronic Pain

## Supplementary Appendix 1. Trials of Opioids for Chronic Pain Not Associated with Terminal Disease.

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of Study</th>
<th>Type of Pain</th>
<th>No. of Patients</th>
<th>Drugs Compared</th>
<th>Daily Dose of Opioid</th>
<th>Follow-up</th>
<th>Pain Relief</th>
<th>Level of Functioning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kjaersgaard-Andersen et al.</td>
<td>RCT</td>
<td>Osteoarthritis of the hip, in elderly patients</td>
<td>83/75</td>
<td>Codeine with acetaminophen vs. acetaminophen</td>
<td>180</td>
<td>4 wk</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Moran et al.</td>
<td>RCT, crossover</td>
<td>Rheumatoid arthritis</td>
<td>20</td>
<td>CR morphine vs. placebo</td>
<td>Up to 120</td>
<td>10 wk</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Arkingall et al.</td>
<td>RCT, crossover</td>
<td>Musculoskeletal in most patients</td>
<td>46</td>
<td>CR codeine vs. placebo</td>
<td>200–400</td>
<td>1 wk</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Haythornthwaite et al.</td>
<td>Non-RCT</td>
<td>Mixed nociceptive and neuropathic; back pain in 68% of patients</td>
<td>19/10</td>
<td>Methadone or CR morphine vs. “usual care,” which may include short-acting opioid</td>
<td>Mean, 111 (morphine equivalent), range not stated</td>
<td>Up to 8 wk</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Jamison et al.</td>
<td>RCT</td>
<td>Back pain</td>
<td>24/12</td>
<td>Oxycodone or CR morphine plus oxycodone vs. naproxen</td>
<td>Up to 130 (morphine equivalent)</td>
<td>16–32 wk</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Sheather-Reid and Cohen</td>
<td>RCT, crossover</td>
<td>Cervicobrachial syndrome, fibromyalgia</td>
<td>6</td>
<td>Codeine vs. ibuprofen or placebo</td>
<td>120</td>
<td>12 wk</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Watson and Babul</td>
<td>RCT, crossover</td>
<td>Postherpetic neuralgia</td>
<td>38</td>
<td>CR oxycodone vs. placebo</td>
<td>28–62</td>
<td>8 wk</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Caldwell et al.</td>
<td>RCT</td>
<td>Osteoarthritis</td>
<td>71/36</td>
<td>CR oxycodone or oxycodone with acetaminophen vs. placebo</td>
<td>Up to 60</td>
<td>8 wk</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Schofferman</td>
<td>Non-RCT</td>
<td>Refractory low back pain</td>
<td>21/12</td>
<td>CR opioids (various) vs. treatment failed (dropouts)</td>
<td>Not recorded</td>
<td>Up to 60 mo</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Moulin et al.</td>
<td>RCT, crossover</td>
<td>Musculoskeletal or soft tissue</td>
<td>46</td>
<td>CR morphine vs. active placebo (bentzpotine)</td>
<td>Up to 120</td>
<td>11 wk</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Peloso et al.</td>
<td>RCT</td>
<td>Osteoarthritis of the hip and knee</td>
<td>31/35</td>
<td>CR codeine vs. placebo</td>
<td>Up to 400</td>
<td>4 wk</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Roth et al.</td>
<td>RCT</td>
<td>Osteoarthritis</td>
<td>44/44/45</td>
<td>CR oxycodone, high dose (or low dose) vs. placebo</td>
<td>Up to 40</td>
<td>14 wk</td>
<td>+ (0)</td>
<td>+ (0)</td>
</tr>
<tr>
<td>Caldwell et al.</td>
<td>RCT</td>
<td>Osteoarthritis</td>
<td>73/73/76/73</td>
<td>CR morphine (24-hr, a.m. or p.m.) or CR morphine (12-hr) vs. placebo</td>
<td>30</td>
<td>4 wk</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Maier et al.</td>
<td>RCT, crossover</td>
<td>Mixed</td>
<td>49</td>
<td>CR morphine vs. placebo</td>
<td>Up to 180</td>
<td>2 wk</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Raja et al.</td>
<td>RCT, crossover</td>
<td>Postherpetic neuralgia</td>
<td>76/44</td>
<td>CR morphine or methadone vs. placebo (or tricyclic antidepressant)</td>
<td>15–225 (morphine), 40–140 (methadone)</td>
<td>8–24 wk</td>
<td>+ (0)</td>
<td>0</td>
</tr>
<tr>
<td>Rowbotham et al.</td>
<td>RCT</td>
<td>Peripheral and central neuropathic pain</td>
<td>43/38</td>
<td>High-dose levorphanol vs. low-dose levorphanol</td>
<td>Up to 11.8 (approximately 60, morphine equivalent)</td>
<td>8 wk</td>
<td>+</td>
<td>0</td>
</tr>
</tbody>
</table>

* RCT denotes randomized, controlled trial, and CR controlled release or sustained release. Study drugs not labeled CR were immediate-release preparations. A plus sign denotes a statistically significant positive difference, and 0 no statistically significant difference.

† Where two numbers are given, the first is the number of patients in the experimental group and the second is the number in the control group.

§ There were more than two treatment groups in the study.

¶ Parentheses link treatment with outcome when more than two treatment groups are included in the study.

---

Ballantyne, NEJM 2003
Known Knowns (The RCTs)

- 14 RCTs, 1201 patients, approx 85/study
- Short follow-up
  - Most less than 14 weeks
- Most compared opiate vs. placebo
- Substance abusers excluded
- Usually well defined pain causes (OA, RA)
- 13/14 showed benefit vs. placebo for pain (Analgesia)
- 7/13 showed no benefit for function (ADLs)

Ballantyne, NEJM 2003
Known Knowns (RCT results)

- Patients report approx 30% pain relief on opioids
- Side effects are more common with opioids (constipation, somnolence, dry mouth, n/v)
- Cognitive skills do not decline with steady dose

Ballantyne, NEJM 2003
Known Unknowns

- Hardly any evidence on patients with history of substance abuse
- No good evidence on long term treatment
- Limited evidence for poorly defined pain syndromes
Guideline Based Care

• Last week’s Annals
  – Evaluated quality and content of guidelines for opioids for CNCP
  – Found 13 guidelines met selection criteria
  – 2 received high AGREE II and AMSTAR scores
  – Most recommendations based on observational data/expert consensus
Guideline Risk Mitigation Consensus

• Upper dosing thresholds (90-200 mg MED)
• Caution with certain medications (methadone)
• Use risk assessment tools
• Use treatment agreements
• Use urine drug testing
• Be especially careful of opioids with other sedative drugs (benzos)
Opioid Treatment Guidelines

• 25 recommendations
  – 21 supported by weak evidence
  – 4 supported by moderate evidence

• Unanimous consensus on “almost all” recommendations

• All recs we discuss are “strong”
Rec 1: Patient Selection and Risk Stratification

• “Before initiating opioids, clinicians should conduct a history... including an assessment of risk of substance abuse, misuse or addiction.”

• SOAPP, ORT, DIRE
  – All published screening tools that can be used in office
## Opioid Risk Tool

**Date**

**Patient Name**

### 1. Family History of Substance Abuse

<table>
<thead>
<tr>
<th>Substance</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Illegal Drugs</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Prescription Drugs</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

### 2. Personal History of Substance Abuse

<table>
<thead>
<tr>
<th>Substance</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Illegal Drugs</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Prescription Drugs</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

### 3. Age (Mark box if 16 – 45)

- [ ] 1

### 4. History of Preadolescent Sexual Abuse

- [ ] 3

### 5. Psychological Disease

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Disorder</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Obsessive Compulsive Disorder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schizophrenia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Total Score Risk Category**

- **Low Risk** 0 – 3
- **Moderate Risk** 4 – 7
- **High Risk** ≥ 8

Reprinted by Permission: Lynn Webster, MD
Rec 2: High-Risk Patients

• Clinicians may consider COT for patients with CNCP and history of drug abuse, psychiatric issues or serious aberrant drug-related behaviors only if they are able to implement more frequent and stringent monitoring parameters. In such situations, clinicians should strongly consider consultation with a mental health or addiction specialist.
Where to find help for patients


Substance Abuse Programs
Mental Health Programs
Buprenorphine providers
Rec 3: Informed Consent and Opioid Management Plans

• When starting chronic opioid therapy (COT), informed consent should be obtained. A continuing discussion... should include goals, expectations, potential risks and alternatives to COT
  – Relief of pain completely is not realistic
  – Specific, realistic functional goals should be documented

• Examples of appropriate, short-term functional goals
  – Decrease pain so that I can get out of the house to visit the grandkids
  – Decrease pain so that I can walk for 5 minutes most days during the week
  – Decrease pain so that I can do the cooking for myself
Rec 4: Monitoring

• Monitoring should include documentation of pain intensity, level of functioning, assessments of progress toward achieving goals, presence of adverse events and adherence to therapy

• The 4 As
  – Analgesia
  – Activities of Daily Living
  – Aberrant Behaviors
  – Adverse Side Effects
# Pain Assessment Documentation Tool

<table>
<thead>
<tr>
<th>Progress Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Assessment and Documentation Tool (PADT™)</td>
</tr>
</tbody>
</table>

Patient Stamp Here
Rec 5: Indications for Discontinuation of Therapy

- Clinicians should wean patients off of COT who engage in repeated aberrant drug-related behaviors or drug abuse/diversion, experience no progress toward meeting goals or experience intolerable adverse effects.

- Weaning by 10% week should be tolerable
  - Can reduce wean to 5%/week when down to 1/3 of initial dose

- Clonidine can be used to help with withdrawal
  - 0.1 mg po bid for 2 days
  - 0.2 mg patch q 7 days
  - Repeat if symptoms persist
Rec 6: Use of Psychotherapeutic Cointerventions

- As CNCP is often a complex biopsychosocial condition, clinicians who prescribe COT should routinely integrate psychotherapeutic interventions, functional restoration, interdisciplinary therapy and other adjunctive nonopioid therapies (mod quality)
Psychotherapeutic Options

• Integrative Medicine
• PT
• SAMHSA website for counseling
• [John Otis: Managing Chronic Pain: A CBT Approach](#)
• This should be easier for us and our patients
Rec 7: Identifying a Medical Home

- Patients on COT should identify a clinician who accepts primary responsibility for their overall medical care. This clinician may or may not prescribe COT, but should coordinate consultation and communication among all clinicians involved in the patient’s care.

- Given the nature of this disease, is this an appropriate role for our residents or should attendings co-manage???
2013 FSMB Controlled Substance Model Policy Statement

• “Since 2004... evidence for risk associated with opiates has surged, while evidence for benefits has remained controversial and insufficient.”

• Will consider inappropriate management of pain, particularly chronic pain, to be a departure from best clinical practices including:
  – Inattention attention to initial assessment
  – Inadequate monitoring during use of medication
  – Inadequate attention to education and informed consent
  – Unjustified dose escalation w/o attention to risks/other options
  – Excessive reliance on opioids particularly in high doses
  – Not making use of available tools for risk mitigation (CPDMP)
FMSB Controlled Substance Policy (Cont)

• “Criteria when evaluating the physician’s treatment of pain”
  – Medical records should contain
    • Medical history and physical exam
    • Diagnostic test results
    • Evaluations and consultations
    • Steps taken in response to aberrant behavior
    • Results of risk assessment including screening instruments if used
    • Informed Consent and Treatment Agreement copies
    • Treatments
    • Medications
    • Patient instructions
    • Results of ongoing monitoring of progress on pain and function
My Soapbox
Perspective and Practical Advice
At Lowry: We Can Do Better

• How:
  – Consistent documentation of the 4As
  – Take ownership of patient
  – Mandating regular follow-up with a specific provider.
  – Recognizing and treating psychiatric issues including addiction
  – Referring more patients to addiction treatment
  – Avoiding large quantities of short acting opiates for chronic pain problems
  – Stopping opiates according to guideline-based recs
  – Creating and advocating for better systems to help us
Final Practical Suggestions
1. The initial few visits are key

- Take your time (60 min)
- Validate patient
- Assess function
- Review records
- Review pain intensity
  - Take your time, chronic pain is never an emergency
  - You should feel no obligation to prescribe medication at the first visit
Other Practical Suggestions

2. It is OK to say “No”

- Offer alternative treatment for poor candidates
- Remember it is your job to do no harm and do what you feel is best, not do only what the patient wants
- Listen to your inner voice. If you are uncomfortable there is probably a reason for it.
- Frame decision as risk:benefit analysis
3: Require Patients to Take Some Ownership of Illness

• At the very least patients on opiates need to:
  – Make the vast majority of clinic appointments
  – Define and agree to appropriate goals of care
  – Participate in some non-pharmacologic therapy for their pain
  – Submit to random urine tox screens
Final Practical Suggestions:

4. Web-based and library resources are available to help clinicians and patients

Provider Training

https://www.scopeofpain.com/

Patient Resources

http://www.fmaware.org/
http://www.med.umich.edu/painresearch/


Conclusions

• CNCP is a biopsychosocial illness that we manage as frequently as diabetes at Lowry clinic
• Guidelines and consensus statements are available and should guide our care
• A multidisciplinary approach should be utilized when treating this illness
• Documentation is key and should include pain history, psychosocial history, functional goals, risk assessment initially and 4As upon follow-up
• Patients on opiates with numerous red flags who fail to meet functional goals should not continue to receive opiates indefinitely
Conclusions (cont)

• Underlying psychiatric illness should be identified and treated

• As PCPs, we should take the lead managing these patients

• Pain management requires art as well as knowledge and from time to time, we are likely to make the wrong decisions

Portenoy, 1996