Approach to Use of Opioids in Patients with Low Back Pain

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Conflict of Interest Disclosure

- Research funding from the American Pain Society and the Agency for Healthcare Research and Quality
- Consultant with Wellpoint Inc, Blue Cross Blue Shield, Palladian Health
- Author royalties from UpToDate
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Target Audience

- The overarching goal of PCSS-O is to offer evidence-based trainings on the safe and effective prescribing of opioid medications in the treatment of pain and/or opioid addiction.

- Our focus is to reach providers and/or providers-in-training from diverse healthcare professions including physicians, nurses, dentists, physician assistants, pharmacists, and program administrators.
Educational Objectives

At the conclusion of this activity participants should be able to:

• List the benefits and harms of opioids in patients with low back pain.

• Summarize an evidence-based approach in the use of opioids for low back pain.
Mr. S. is a 57 year old with LBP x 2 years, no specific inciting event

- No associated leg pain or other neurological symptoms
- Pain slowly worsening, to the point of not being able to walk more than 2 to 3 blocks, rated 7/10 most days
- Continues to golf most weekends, but riding cart now
- Working as an engineer
- X-rays show lumbar disc degeneration and facet joint arthropathy
- Tried acetaminophen and NSAIDs and has undergone PT
- “What do you think about trying an opioid doc?”
Background

• Low back pain is the 5\textsuperscript{th} most common reason for U.S. office visits, and the 2\textsuperscript{nd} most common symptomatic reason
  - Lifetime prevalence for any LBP episode: 49% to 70%
  - Point prevalence: 12% to 30%

• Estimated >$100 billion dollars in total health care expenditures for LBP in U.S.
  - Pharmacy costs >20% of total health care expenditures

• Large indirect costs
  - Low back pain is the most common cause for activity limitations in persons under the age of 45

Prevalence of Chronic LBP is Rising

- Percentage of North Carolina adults with chronic low back pain
Opioid Prescribing Patterns

- Increased use of opioids in patients with LBP
  - Prescribing rates more than doubled (108% increase) from 1997 through 2004
  - Increased prescribing resulted in 423% inflation-adjusted increase in expenditures
  - >50% of regular prescription opioid users have LBP

- High proportions of patients with LBP prescribed opioids
  - 42% in a prospective study of patients with work-related LBP
  - 61% in large health maintenance organization with LBP received opioids, 19% chronic use

- Marked practice variations in opioid prescribing rates for LBP
Increasing Rates of Opioid Use

b. Opioid analgesic prescriptions for spine problems

Millions of Prescriptions

<table>
<thead>
<tr>
<th>Year</th>
<th>1997</th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
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</thead>
<tbody>
<tr>
<td>Value</td>
<td>9.42</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>19.56</td>
</tr>
</tbody>
</table>

Which Patients with LBP are Treated with Opioids?

• Variations not explained by differences in pain severity

• Factors associated with increased likelihood of opioid prescribing:
  - Greater psychologic distress
  - Poorer health and unhealthy lifestyles
  - Use of sedative-hypnotics
  - Similar factors associated with use of high-dose opioids

• Data indicate use of opioids related in part to presence of psychosocial factors that put patients at increased use for adverse opioid-related drug events

Benefits of Opioid Therapy for LBP

• Benefits for chronic LBP appear moderate at best
  o Few randomized trials of patients specifically with chronic LBP; results mixed, with some studies showing no clear benefits
  o For chronic pain in general, more evidence, with benefits in randomized trials averaging 20-30% for short-term (<12 weeks) pain relief; can we extrapolate to LBP?
  o No studies on long-term benefits of opioid therapy vs. no opioid
  o Effects on function not consistently demonstrated in randomized trials
  o Some observational studies suggest opioid use associated with poorer functional outcomes

• No trials of opioids for acute LBP
  o Opioid generally accepted as effective for various types of acute pain

Abuse Potential of Opioids

Estimates of abuse/misuse vary from 4% to 26%, or higher

- Definitions inconsistent across studies and behaviors evaluated vary in seriousness
- Poorly standardized methods to detect these outcomes
- Data from efficacy trials underestimate risks due to patient selection methods
- One study (n=801) based on standardized, detailed interviews of patients on chronic opioids
  - 26% purposeful oversedation
  - 39% increased dose without prescription
  - 8% obtained extra opioids from other doctors
  - 18% used for purposes other than pain
  - 12% hoarded pain medications

Prescription Drug Overdoses

- Large increases in prescription opioid overdoses nationally
- Overdose trends parallel opioid prescribing trends
  - 15,000 cases/year
  - In some states, opioid-related overdose deaths exceed MVA’s as most common cause of accidental death
  - Exceed deaths from heroin and cocaine combined
  - High proportion of deaths occur in patients prescribed opioids for chronic pain, but also observed in patients treated for opioid dependence

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm
Opioid Pain Reliever (OPR) Overdose Deaths, Treatment Admissions, and Kilograms Sold

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm
Risk Factors for Overdose

- Higher-dose opioid therapy
- Concomitant use of CNS depressants (especially benzodiazepines)
- Recent initiation of opioids
- Multiple opioid prescribers
- Significant mental health disorders
- Aberrant drug related behaviors
- Use of methadone
- Presence of significant medical comorbidities
- Active or history of substance abuse

Other Harms Associated with Opioids

• High rates of adverse events
  o Constipation, nausea, sedation, and others

• Hyperalgesia
  o Paradoxical increased sensitivity to pain
  o Prevalence, risk factors and clinical significance not well understood
  o Generally associated with higher doses

• Hypogonadism
  o Primarily based on cross-sectional studies
  o Clinical significance not well understood

• Falls/fracture risk

Chou R et al. J Pain 2009;10:113
Use Opioids Only in the Context of an Overall LBP Management Plan

• Understand chronic LBP as a complex biopsychosocial condition
  o Opioids alone do not address psychosocial contributors to pain
  o Benefits of opioids unlikely to exceed an average 20-30% reduction in pain (may be smaller)
  o Be clear with patients that opioids generally do not eliminate pain, and are just part of a comprehensive management plan
  o Use opioids in conjunction with therapies that address psychosocial factors

• For acute LBP, the natural history is very favorable
  o ~85% of patients improve substantially in the first month
  o Opioid use in acute LBP associated with poorer functional outcomes and subsequent long-term use
  o Selective opioid use for acute severe pain on a time-limited basis, for short-term symptomatic relief

Management Approach to LBP

• First-line medications: acetaminophen and NSAIDs
  o Recent RCT showed no benefits of acetaminophen for acute LBP
  o Second-line options: skeletal muscle relaxants (acute LBP) and antidepressants (chronic LBP)

• Emphasis on self-care and improving function
  o Advise patients to remain active
  o Exercise therapy, interdisciplinary rehabilitation

• Identify and address psychosocial contributors to pain
  o Depression, anxiety, maladaptive coping behaviors (fear avoidance, catastrophizing)
  o Cognitive behavioral therapy, functional restoration, interdisciplinary rehabilitation

• Consider other non-pharmacological therapies
  o Spinal manipulation, acupuncture, massage

• Reserve opioids for patients who don’t respond to first-line therapies, or selected cases with very severe symptoms

**Will this Patient Develop Persistent Disabling LBP?**

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Positive likelihood ratio for persistent disabling LBP at 1 year: median (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonorganic signs</td>
<td>3.0 (1.7-4.6)</td>
</tr>
<tr>
<td>Maladaptive pain coping behaviors</td>
<td>2.5 (2.2-2.8)</td>
</tr>
<tr>
<td>Baseline functional impairment</td>
<td>2.1 (1.2-2.7)</td>
</tr>
<tr>
<td>Psychiatric comorbidities</td>
<td>2.2 (1.9-2.3)</td>
</tr>
<tr>
<td>Low general health status</td>
<td>1.8 (1.1-2.0)</td>
</tr>
<tr>
<td>Variables related to work environment, baseline pain, presence of radiculopathy</td>
<td>Around 1.5</td>
</tr>
<tr>
<td>History of prior LBP episodes, demographic variables (age, sex, overweight, smoking, education)</td>
<td>Not predictive</td>
</tr>
</tbody>
</table>

Chou R and Shekelle P. JAMA 2010;303:1295-1302
Targeting Patients at Risk for Chronicity

STarT Back Trial

- 1573 UK patients with LBP (+/- radiculopathy)
- Randomized to stratified care based on prognosis (low, medium, or high-risk) or usual care
  - Low-risk intervention: educational video and booklet
  - Medium and high-risk interventions: referred for psychologically informed physiotherapy (3 vs. 9 days of additional training)
- Stratified care more effective than usual care for function (1.8 points at 4 months and 1.1 pts at 12 months); also cost effective
- STarT Back approach being tested in the U.S.

The Keele STarT Back Screening Tool

Patient name: _____________________________  Date: ____________

Thinking about the last 2 weeks tick your response to the following questions:

<table>
<thead>
<tr>
<th>Question</th>
<th>Disagree</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. My back pain has spread down my leg(s) at some time in the last 2 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I have had pain in the shoulder or neck at some time in the last 2 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I have only walked short distances because of my back pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. In the last 2 weeks, I have dressed more slowly than usual because of back pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. It's not really safe for a person with a condition like mine to be physically active</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Worrying thoughts have been going through my mind a lot of the time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. I feel that my back pain is terrible and it's never going to get any better</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. In general I have not enjoyed all the things I used to enjoy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Overall, how bothersome has your back pain been in the last 2 weeks?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Very much</th>
<th>Extremely</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Total score (all 9): ___________________  Sub Score (Q5-9): ____________
Scoring the STarT Back Screening Tool

Note: Psych score based on items 5-9 of STarT Back Screening Tool
Selecting Patients for Opioid Therapy

- Risk assessment is critical before using opioids
  - Helps inform the decision of whether to initiate opioids
  - Helps determine the intensity of follow-up and monitoring
- Assessment of abuse potential required in all patients considered for opioids
  - Strongest predictor is personal or family history of substance abuse
  - The Opioid Risk Tool allows clinicians to categorize patients as low, medium, or high risk for aberrant drug-related behaviors based on a simple point system
  - Additional validation needed for risk assessment instruments
  - Avoid opioids in patients at high risk; consider alternatives in patients at medium risk; address identified risk factors
- Also consider potential benefits, and other potential harms (i.e. respiratory depression in patients with sleep apnea) when making decision to start opioids

Opioid Risk Tool (ORT)

Administration
• On initial visit
• Prior to opioid therapy

Scoring
• 0-3: low risk (6%)
• 4-7: moderate risk (28%)
• > 8: high risk (> 90%)

Mark each box that applies

<table>
<thead>
<tr>
<th>Mark each box that applies</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
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<td>1. Family history of substance abuse</td>
<td></td>
<td></td>
</tr>
<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>
<tr>
<td>2. Personal history of substance abuse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>□ 3</td>
<td>□ 3</td>
</tr>
<tr>
<td>Illegal drugs</td>
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</tr>
<tr>
<td>Prescription drugs</td>
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<td>□ 5</td>
</tr>
<tr>
<td>3. Age (mark if between 16-45 yrs)</td>
<td>□ 1</td>
<td>□ 1</td>
</tr>
<tr>
<td>4. History of preadolescent sexual abuse</td>
<td>□ 3</td>
<td>□ 0</td>
</tr>
<tr>
<td>5. Psychological disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADO, OCD, bipolar, schizophrenia</td>
<td>□ 2</td>
<td>□ 2</td>
</tr>
<tr>
<td>Depression</td>
<td>□ 1</td>
<td>□ 1</td>
</tr>
</tbody>
</table>

Scoring totals _______ _______
Initiation and Titration of Opioids

• Initial course of treatment should be viewed as a short-term, therapeutic trial
  o The decision to proceed (or continue) with COT should be a conscious one
  o Determine achievable functional goals in order to assess benefits
  o Do not continue COT in patients who are not benefitting

• Start at low doses and titrate cautiously, to reduce risk of accidental overdose
  o Particular caution with methadone (long and unpredictable half-life)

Set Functional Treatment Goals

Goals should be actionable, measurable, and achievable

- Regular assessments of whether patients are achieving treatment goals, in order to guide treatment decisions
  - Consider discontinuation in patients not making progress towards meeting goals

- Not achievable: “I want to be pain-free.”

- Actionable, measurable, and achievable: “I want to be able to walk my dog 20 minutes a day, 4-5 times a week.”

Dose Escalations

- Opioids for chronic pain often prescribed with no ceiling dose
- Risk of overdose begins to increase at <50 mg morphine equivalents/day, and continues to rise in dose-dependent fashion
- Very limited data on effectiveness of opioids at higher doses
  - Patients who do not respond often do not appear to respond at higher doses
- Only prescribe higher doses in patients with clear improvements in pain and function and with close monitoring
  - Caution with use of >100-120 mg morphine equivalents/day
- Slow dose increases, with follow-up after changes

Dose-response relationship for opioids and overdose

1. Cohort study (n=9940, 51 opioid overdoses, 6 fatal)
   • Risk of opioid overdose (vs. 1 to <20 mg/day)
     o \( \geq 100 \text{ mg/d} \): HR 8.9 (4.0-20)
     o \( 50 \text{ -}<100 \text{ mg/d} \): HR 3.7 (1.5-9.5)
     o \( 20\text{ -}<50 \text{ mg/d} \): HR 1.4 (0.57-3.6)

2. Case-control study (VA, 750 cases)
   • Risk of opioid overdose-related death (vs. 1 to <20 mg/day)
     o \( \geq 100 \text{ mg/d} \): HR 7.2 (4.8-11)
     o \( 50\text{ -}<100 \text{ mg/d} \): HR 4.6 (3.2-6.7)
     o \( 20\text{ -}<50 \text{ mg/d} \): HR 1.9 (1.3-2.7)

3. Nested case-control study (Ontario, 498 cases)
   • Risk of opioid-related mortality (vs. 1 to <20 mg/day)
     o \( \geq 200 \text{ mg/d} \): OR 2.9 (1.8-4.6)
     o \( 100\text{ -}199 \text{ mg/d} \): OR 2.0 (1.3-3.2)
     o \( 50\text{ -}99 \text{ mg/d} \): OR 1.9 (1.3-2.8)
     o \( 20\text{ -}49 \text{ mg/d} \): OR 1.3 (0.94-1.8)

Effects of Dose Limitation Strategies

In 2007, WA state implemented dosing policy of <120 mg/day morphine equivalents in workers’ compensation

- After 2007, proportion prescribed >120 mg/day decreased by 35%
- 50% decrease from 2009 to 2010 in number of opioid-related deaths
- Data observational, subject to confounding and attribution bias
- Overdose trend based on a single year in published study, though trend maintained for additional year (personal communication with author)

Selection of Opioids

• No evidence that long-acting opioids are safer or less prone to abuse than short-acting opioids
  o Long-acting opioids may result in fewer drug peaks associated with euphoria, but decreased risk of addiction or abuse has not been demonstrated

• No evidence that round-the-clock, scheduled dosing safer or less prone to abuse than PRN dosing
  o Use of round-the-clock, scheduled dosing may contribute to development of tolerance and dose escalations

• Recommend initiation with short-acting opioids
  o Safer in opioid-naïve patients, easier to titrate doses
  o Can transition to long-acting opioids, but no compelling reason to do so in patients without aberrant behaviors and good response on short-acting meds

Risk Mitigation Strategies

- Informed consent required in all patients

- Long-term opioid therapy management plan recommended by guidelines
  - Components include: Follow-up expectations, single prescriber and pharmacy, no early or off-hour fill requests, expectations for monitoring, use of non-opioid therapies, functional goals, indications for tapering or discontinuation
  - Helps define expectations as well as assist other providers who see patient

- Follow-up generally recommended q3-6 months, may be more frequent in high risk patients

- Consider dispensing weekly or biweekly rather than monthly in higher risk patients
  - Some data suggesting shorter duration between prescription refills (smaller amounts dispensed) associated with shorter time off work

Prescription Drug Monitoring Programs

- Available now in almost all states
- Studies show that use of PDMPs can identify cases of diversion, doctor shopping and flag unsafe prescribing practices
  - Recent study found decreased inappropriate drug prescribing with use of a centralized prescribing system in Canada
  - Effects on clinical outcomes (e.g., overdose) not known
- Use variable and generally suboptimal
- PDMPs vary in who can access, information not available across states, functionality variable

Gugelman HM. JAMA 2011;306:2258; Dormuth CR et al. CMAJ 2012;184:E852
Status of State Prescription Drug Monitoring Programs (PDMPs)

- States with operational PDMPs
- States with enacted PDMP legislation, but program not yet operational
- States with legislation pending

*The operation of Nebraska’s Prescription Monitoring Program is currently being facilitated through the state’s Health Information Initiative. Participation by patients, physicians, and other health care providers is voluntary.

This information was compiled using legal databases, state agency websites and direct communications with state PDMP representatives.
Urine Drug Tests

• Diagnostic accuracy for presence or absence of a drug at a defined concentration in the urine is well-established
  - Very useful for identifying use of non-opioid illicit drugs

• Must consider differential diagnosis when evaluating urine drug test results
  - False-positives or -negatives can occur based on dose, differences in rates of metabolism, cross-reaction, presence of uncommon metabolites
  - Must understand metabolic pathways of opioids

• Diagnostic accuracy for abuse/addiction not well studied
  - Always evaluate suspected aberrant behaviors, consider dose adjustments or discontinuation for serious and recurrent behaviors

Opioid-deterrent Formulations

Opioid-deterrent formulations recently approved by FDA or undergoing FDA approval process

- Designed to be tamper-resistant or co-formulated with medications that reverse opioid effects or produce noxious side effects when tampered with.
- Effectiveness for reducing misuse/substance abuse and improving clinical outcomes yet to be established.
- Likely to be primarily effective in patients who crush or inject oral opioids.
  - May not improve safety related to accidental overdose from oral ingestion.
  - Does not remove the need to perform appropriate risk assessment and monitoring when using opioids.

Webster L. J Opioid Manage 2011;7:235
BAYER Pharmaceutical Products

HEROIN—HYDROCHLORIDE

is pre-eminently adapted for the manufacture of cough elixirs, cough balsams, cough drops, cough lozenges, and cough medicines of any kind. Price in 1 oz. packages, $4.85 per ounce; less in larger quantities. The efficient dose being very small (1-48 to 1-24 gr.), it is

The Cheapest Specific for the Relief of Coughs
(In bronchitis, phthisis, whooping cough, etc., etc.)

WRITE FOR LITERATURE TO

FARBENFABRIKEN OF ELBERFELD COMPANY
SELLING AGENTS

P. O. Box 2160
40 Stone Street, NEW YORK
Discontinuing Opioids or Restructuring Therapy

Have an “exit strategy” when starting opioids for LBP
- Clear understanding of circumstances that will lead to discontinuation
  - Patients not benefitting from opioids in terms of reduced pain AND improved function
  - Patients experiencing harms or unable to safely manage opioids
- Plan for tapering opioids and managing withdrawal

Patients may require restructuring of therapy to safely continue opioids
- Lowering dose
- Intensified monitoring
- Specialty consultation

Continue to manage patients for pain with non-opioid therapies
- Interventions to address psychological comorbidities and maladaptive coping
- Focus on improving function

Opioids and Low Back Pain

• Consider opioids only in the context of an overall pain management plan
  o Opioids do not address the psychosocial contributors to pain
• Not recommended as first-line treatment
  o Evidence on effectiveness for LBP limited
    ▪ Average 20-30% improvement in pain at best, limited data on improvement in function
      o Potential harms include addiction, abuse potential, overdose
      o Consider only after performing risk assessment and with appropriate monitoring
        ▪ Duration-limited trial of therapy
          o Dose-dependent overdose risks
            ▪ Unclear benefits of higher doses
            ▪ Caution with doses >80-120 mg morphine equivalents/day
Case—Risk Assessment

- Mr. S. has no personal or family history of substance abuse
- No history of depression or other psychological disorders
- No serious comorbid conditions that are contraindications to opioid therapy
- Opioid Risk Tool score: 0
- Urine drug test negative
- Assessed risk: Low
Case—Management Plan

- Set goal of walking 30 minutes 4 times a week
- Longer term goal walking 9 holes of golf
- Low-dose opioid therapy (oxycodone 5 mg twice daily) initiated
- At 4 week follow-up, pain decreased from 7/10 to 4/10
- Able to walk 20-30 minutes 4 times a week
- No signs of aberrant behaviors
- Plan: Continue opioid therapy at the same, low dose, follow-up in 2 months
References

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• Webster L. J Opioid Manage 2011; 7: 235.
• Williams CM et al. Lancet (e-published 23 July 2014)
PCSS-O Colleague Support Program and Listserv

- PCSS-O Colleague Support Program is designed to offer general information to health professionals seeking guidance in their clinical practice in prescribing opioid medications.
- PCSS-O Mentors comprise a national network of trained providers with expertise in addiction medicine/psychiatry and pain management.
- Our mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.
- The mentoring program is available at no cost to providers.

For more information on requesting or becoming a mentor visit: pcss-o.org/ask-colleague

- Listserv: A resource that provides an “Expert of the Month” who will answer questions about educational content that has been presented through PCSS-O project. To join email: pcss-o@aaap.org.
PCSS-O is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: American Dental Association (ADA), American Medical Association (AMA), American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society for Pain Management Nursing (ASPMN), and International Nurses Society on Addictions (IntNSA).

For more information visit: www.pcss-o.org
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