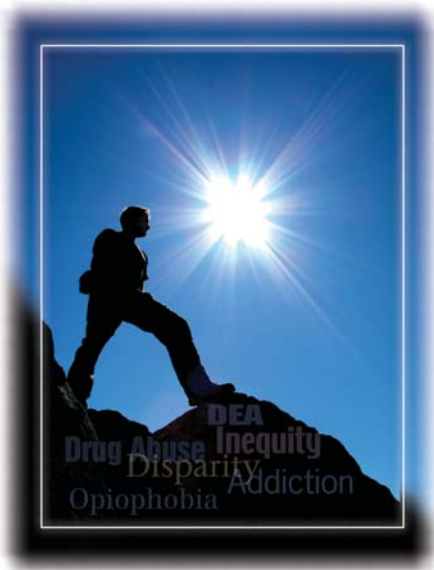




Using Opioids for Patients With Moderate to Severe Pain

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In the United States, many visits to physician offices are for complaints of pain. Patients who have moderate to severe pain can be effectively treated with different modalities, including opioids. Proper management requires that physicians be open-minded and thorough. Physicians should take a complete history and perform a complete physical evaluation including an osteopathic structural examination to develop a comprehensive treatment plan. This strategy should include follow-up visits for continued assessment of therapy. Continued reassessment of treatment and patient responsiveness have been shown to be most beneficial to both physician and patient. Using the osteopathic medical model of treatment, physicians should identify psychosocial as well as somatic dysfunctions and appropriately treat patients for them. They should not avoid prescribing opioids because of fear of a patient's becoming addicted, but instead, integrate the use of such important analgesics in a multidisciplinary treatment plan. However, it must be recognized that opioids are powerful medications that require monitoring and dosing according to patient response.

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Annually, more than 80 million Americans have serious pain, with approximately 86% having such discomfort on a chronic basis¹; most common disorders are headache, lower back pain, arthritis, and other joint pain²; 25 million experience this condition acutely. Pain accounts for an estimated \$61.2 billion in lost productive time annually; 76.6% of that cost is attributed to poor health-related performance while at work.³

Pain is the second leading cause to be absent from work with the common cold being the first, and pain is the second leading cause for a person to

seek medical care.⁴ Common pain complaints such as back pain, headache, arthritis, joint pain, and other musculoskeletal pains were found to account for 13% of the total workforce's losing productive time within a 2-week period.³

Adequate treatment is necessary to allow patients to have a meaningful and productive life. Opioid use for pain management allows successful restoration of this ability. Thus, this article examines opioid use for effective analgesic therapy in patients with moderate to severe pain.

Use of Opioids for Pain Control

Opioids can be traced back 8000 years to a Sumerian ideogram of *hul gil*, the "plant of joy." Throughout history, opioids have been found useful in the treatment of multiple ailments. In the early 1900s, opioids became a controlled substance to be prescribed for medicinal reasons only; it could not be prescribed to addicts. Throughout the 20th century, control became tighter with the 1970 Federal Controlled Substance Act,⁵ which increased the monitoring of opioids and other controlled substances, and required registration of all prescribers. In certain contexts, this social move regulating medical practice and criminalizing the prescribing of these controlled substances created problems. Legal ramifications led to undertreatment of patients with pain, illegal opioid trafficking, and addiction.

With continued education of health-care providers, modifications in health-care policy, consistency in management, and assessment in patient care, the emphasis on opioids as a legal issue shifted to a focus on medical management approaches.⁶

Clinical Evaluation With Pain Assessment

To understand and effectively treat patients in pain, physicians must do a comprehensive evaluation that includes history, severity of pain, quality of life, and physical examination. Physicians should obtain and record a comprehensive medical, surgical, and family history, as well as information relative to prior pain treatment modalities and their

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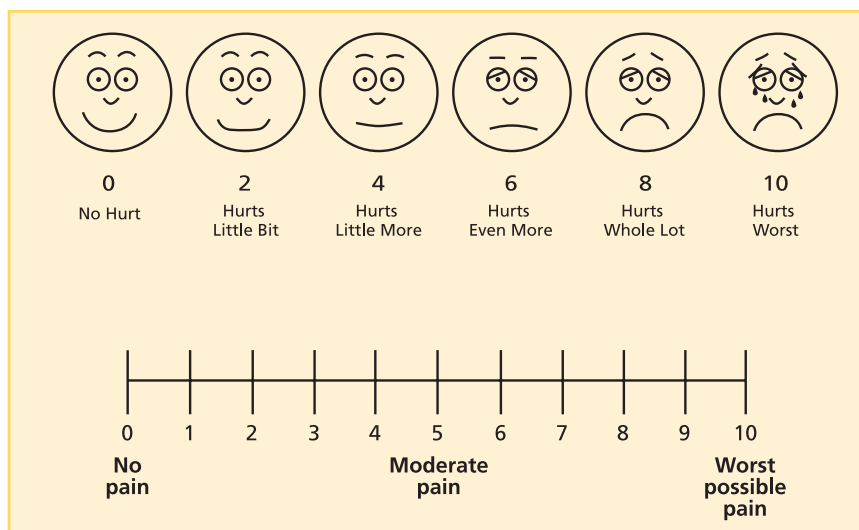


Figure 1. Faces and visual analog scale for patient's self-assessment of pain.

Treatment Paradigm

■ History

- ☐ Medical history
- ☐ Surgical history
- ☐ Family history
- ☐ Previous pain treatment modalities
- ☐ Medication use—current and history
- ☐ Substance use
 - alcohol
 - tobacco
 - over-the-counter drugs
 - illicit drugs
- ☐ Understanding of illness

■ Severity of Pain

- ☐ Description
- ☐ Location
- ☐ Onset and pattern
- ☐ Visual analog scale
- ☐ Associated factors that relieve pain
- ☐ Associated factors that exacerbate pain

■ Quality of Life

- ☐ Physical well-being
- ☐ Psychological well-being
- ☐ Social well-being
- ☐ Role functioning
- ☐ Spiritual and religious status
- ☐ Financial status

■ Osteopathic Assessment

- ☐ Physical examination
- ☐ Active and passive range of motion
- ☐ Strength testing
- ☐ Neurologic testing
- ☐ Structural and postural assessment

■ Osteopathic Diagnosis of Somatic Dysfunction

■ Treatment

- ☐ Coordinated multidisciplinary team of healthcare professionals
- ☐ Opioid use
 - selection
 - dosing
 - monitoring
- ☐ Osteopathic manipulative treatment

■ Follow-up Visits and Continued Monitoring

Figure 2. Components of paradigm for treatment of patients with pain.

effectiveness. Necessary documentation includes a complete list of current and past medications, including over-the-counter medications and supplements, as well as a history of alcohol, tobacco, and illicit drug consumptions. Physicians should also query patients to ascertain if they understand their dysfunction and their prognosis.⁶

When patients are viewed as part of the treatment plan, they develop a greater understanding of their pain. They then are able to discriminate and characterize their pain at a more knowledgeable level, thus assisting physicians to obtain increased understanding of how the designed therapy benefits their patients. Patients should describe pain in their words and designate the location by use of a diagram or illustration. They should describe the onset, history, and pattern of pain over time. Use of a visual analog scale (Figure 1) allows documentation of the patient's pain at each visit for future comparisons. Patients should describe associated factors that relieve or exacerbate this discomfort.⁶

Physicians must identify the impairment and how pain is adversely affecting various aspects of a patient's quality of life. Patients should evaluate their physical and psychosocial well-being, and also develop an understanding of how pain is adversely affecting their roles as an employee, spouse, parent, and human being. Physicians should take into account a patient's spiritual/religious beliefs so they can be aware of how the disease process relates to these important factors. Physicians should help patients understand how their ailment can affect their financial status (eg, cost of medicines, visits for medical care and lost wages).⁵ These characteristics are strongly tied to the success of a program and give subjective and objective measures by which physicians can document progress.⁷

Physicians must establish the treatment goal for each patient with pain and know what the patient expects. It is important for physicians to relate realistic goals to their patients, thus offering opportunity to them for patient education on treatment and improved chance of success, as well as increased patient compliance and ownership of their problem.

Definitions

- **Tolerance**—The need to increase dosage to maintain a therapeutic drug effect
- **Physical Dependence**—Biological adaptation whereby a dose reduction or cessation will result in withdrawal reactions
- **Addiction**—Behavioral response where a person, despite adverse consequences, seeks and develops compulsive behaviors to obtain and consume drugs

Figure 3. Definitions denoting differences between physical dependence, tolerance, and addiction.

A physical examination evaluating all systems, active and passive range of motion, strength testing, neurologic testing, and structural and postural assessment should be included in the initial assessment.⁸ Documenting objective findings allows comparison at follow-up visits to assess improvement or failure with the treatment plan. Applying the osteopathic model addresses the entire physical and spiritual being as a whole, allowing for the diagnosis of a somatic dysfunction.⁹ Figure 2 outlines the paradigm of treatment of patients with pain.

Treatment With Opioids

When using opioids in the treatment of patients in pain, the treatment plan should be comprehensive, including:

- ☐ selection and use of the appropriate opioid,
- ☐ involvement of other healthcare providers, as warranted,
- ☐ osteopathic manipulative treatment (OMT), as appropriate, and
- ☐ patient education.

Administration of opioids for pain control has been shown to be effective for improving pain control and quality of life. They are powerful analgesics that can produce life-threatening toxicities; therefore, both physician and patient should carefully evaluate the risk-to-benefit profile of opioids.¹⁰

It is well documented that clear differences exist between physical dependence, tolerance, and addiction (Figure 3). *Tolerance* occurs when the body adapts to

the daily dose of the drug such that the pharmacologic effect is reduced; consequently, the patient requires an increased dose of the drug to achieve the desired therapeutic action. *Physical dependence* is a more significant clinical adaptation such that withdrawal reactions would occur on decreasing the dose. *Addiction* is a behavioral response whereby a person, despite adverse consequences, acts on compulsion to obtain and consume a drug. Undertreatment for pain may lead to a patient's drug-seeking behaviors to self-medicate.^{11,12}

Physicians are concerned about their patients' becoming addicted when using opioids for pain management. It was found that when physicians prescribe opioid therapy for patients with chronic cancer pain, with no drug abuse history, they have confidence that 75% of these patients will not become addicted. In contrast, when these same physicians are prescribing opioid therapy for patients with noncancer pain, with a history of drug abuse, they have a confidence level that 3% of these patients will not become addicted.¹¹ The fact is that only between 3.2% and 18.9% of patients with a prior history of addictive behavior become psychologically dependent, a prevalence rate approximating that of the general population without a history of addiction. Furthermore, for patients with no history of drug abuse for whom opioid medication was prescribed for pain, the prevalence of drug addiction drops to less than 1%.¹²

An understanding should be made between patient and physician that the patient's powerful pain medication is for his or her use only, and it is to be taken as agreed on by these two parties. Such an understanding should be written as a contract or an agreement and signed by both persons (Figure 4). It is essential that there be one prescribing physician and one pharmacy to avoid the potential for error or diversion, or both.

Initial therapy should be with the lowest effective dose possible to minimize pain and medication side effects and to maximize the quality of life. The only limiting factor is patient response. Therefore, it is necessary to titrate dosage.

Selection of the proper opioid (Figure 5) is crucial. Opioid dosing and conversion are complex procedures, as indicated by three Web sites.¹³⁻¹⁵ The greater the affinity of the opioid at the μ receptor, the greater the analgesic effect or potency.¹⁰ Opioids have pharmacokinetic differences in bioavailability, such as morphine, which is the standard, compared with fentanyl, which is 50 times as potent. Scheduled dosing is more effective at pain control and improving quality of life.¹⁶

Combining sustained-release and immediate-release dosage forms has been shown to be effective.¹⁶ Additionally, having "rescue" or "breakthrough" medication (ie, immediate-release) allows the patient in periods of aggravated pain to increase the dose in minor steps to provide adequate analgesia.^{17,18} For example, a typical patient would have scheduled sustained-release dosing every 12 hours and scheduled immediate-release dosing every 6 hours, with breakthrough medication as needed with a previously discussed total number per day.

Follow-up visits and continued monitoring are crucial for success and proper management of pain. These interactions ensure constant communication, patient coordination, patient support, and opportunities for education and proper adjustments to medication. Visits should be scheduled every 2 weeks for the first 2 to 4 months, then once a month.⁶ Pain medication should be prescribed at each office visit, with the dosage adjusted as needed based on patient reports of pain, use of rescue

AGREEMENT FOR CHRONIC USE OF CONTROLLED SUBSTANCES

Controlled substance medications such as opioids, sedatives, hypnotics, and stimulants are very useful in treating medical conditions, but have a high potential for misuse. Therefore, the state and federal government closely control the prescribing and dispensing of such medications.

I understand that the main goal of treatment with chronic controlled substances is to improve my ability to function and/or work and/or reduce pain.

- In consideration of that goal, and the fact that I am being given potent medication to help me to reach that goal, I agree to help myself by following better health habits, including exercise, weight control, safe sex, avoiding the use of tobacco, alcohol, and illegal drugs/substances.
- Chronic controlled substance medications are intended to improve function and quality of life.
- I must comply with the treatment plan as prescribed by my provider.

I understand that only through following a healthier lifestyle can I hope to have the most successful outcome to my treatment. Because my provider is prescribing such medication for me to help manage my _____ (diagnosis), I agree to the following conditions:

1. I am responsible for my controlled substance medications.

If the medication(s) are lost, misplaced, or stolen, or if I use it up sooner than prescribed, I understand that it may not be replaced. I will not increase or decrease my dosage without talking with my provider.

2. I will not request or accept controlled substance medication from any other provider or facility without notifying my (clinic name) or provider or their designee, except in emergency or urgent healthcare situations.

I acknowledge that receiving duplicate medications may endanger my health. The only exception is in an emergency or urgent healthcare situation.

I will not allow anyone else to use my medications and will keep them secure.

3. Refills of chronic controlled substance medications.

A. Will be made during regular clinic hours. Refills will not be made at night, on holidays, or weekends.

B. Any exceptions such as "I ran out early" or "I lost my prescription" or "I spilled or misplaced my medicine" must be addressed by the provider or designee.

I am responsible for taking the medication in the dose prescribed and for keeping track of the amount remaining.

C. If I need assistance with a chronic controlled substance medication prescription, I will call to discuss this with my provider or his or her designee.

4. My provider may require me to see a specialist at any time while I am receiving controlled substance medications.

- If I am unable to meet the requirements of this agreement, there may be medical and safety risks of continuing my controlled substance medication. I understand that my medications may not be continued or refilled.

5. I agree to comply with random laboratory testing documenting the proper use of my medications and confirming compliance. I understand the importance of avoiding alcohol or other substances of abuse when taking a controlled substance medication. A positive test for any substance besides my prescribed medications will be grounds for action and/or discontinuation of my medications.

(continued)

Figure 4. *Typographically enhanced physician and patient pain contract. (Adapted from contract used at the Phoenix [Arizona] Indian Medical Center.)*

6. I understand that controlled substances can cause marked drowsiness (sleepiness). I will not drive a motor vehicle or operate dangerous equipment while I am sleepy. I understand that I will need to talk with my provider about my ability to drive or operate dangerous equipment.

It is my responsibility to comply with the laws of the State of _____ while taking the medications prescribed.

7. I understand that if I violate any of the above conditions, my controlled substance prescriptions may be tapered and not refilled, or ended immediately and alternative treatments for pain offered.

If the violation involves obtaining controlled substances from any other individual, as described above, or the use of street (illegal) drugs, I may be reported to my provider, medical facilities, and other agencies as appropriate.

8. I understand that the long-term advantages and disadvantages of chronic opiate usage have yet to be scientifically determined.

- I understand that my treatment may change throughout my time as a patient.
- I understand, accept, and agree that there may be unknown risks associated with the long-term use of controlled substances, and that my provider will advise me of medical advances and will discuss treatment changes with me as appropriate.

I have been fully informed by my provider, _____, and staff regarding the probability of addiction to a controlled substance, which I understand is low.

I know that some persons may develop a tolerance, which is the need to increase the dose of the medication to achieve the desired effect. In addition, I know that by increasing the medication, a physical dependence of medication use will be created. This will occur if I am on the medication for several weeks. When I stop the medication, I must do so slowly under a plan developed with my provider, or I may have withdrawal symptoms.

I have read this agreement. By signing this agreement I hereby grant my provider the right to contact any other professional involved in my care concerning my use of opioid medications.

The same has been explained to me by my provider, _____, and staff.

I fully understand the consequences of violating this agreement.

Name of Patient

Medical Record Number

Patient Signature

Date

Provider Signature

Date

Pharmacist Signature

Date

Patient Advocate/Witness Signature

Date

Figure 4. (continued) *Typographically enhanced physician and patient pain contract. (Adapted from contract used at the Phoenix [Arizona] Indian Medical Center.)*

dosing, and quality of life. Education should consist of goal setting and helping patients understand different measures in pain relief through reduction in pain, improvements in quality of life, and decreases in the need for rescue drugs.¹⁹

Having a multidisciplinary team of healthcare professionals who coordinate their efforts has proven to be effective in the management of pain. Depending on the identified specific needs of the patient, the team approach could consist of physical and/or occupational therapy, psychologists, sclerotherapy, physiatrics, interventional anesthesia, and/or invasive procedures (singly or in combination).⁸ Compared with single treatment, multidisciplinary approaches have been shown to reduce pain by an additional 20% to 40%; such effects are maintained up to 2 years.⁷ Applying osteopathic medicine skills during office visits can aid in pain reduction. Improving postural and mechanical alignments, fascial strains, and tissue texture changes can be highly effective for pain management and the body's innate ability to heal, which is at the very foundation of osteopathic medicine.²⁰

When patients have improved significantly, it is vital that opioid medication not be discontinued abruptly to avoid their having withdrawal reactions. Their dosage must be tapered slowly, reducing the amount every 2 to 3 days.¹¹ The following case vignette illustrates a multidisciplinary and opioid-tapering approach in a patient with severe pain.

Case Presentation

Marcie, a 26-year-old Native American woman, is recovering from a trimaleolar fracture and subsequent open reduction with internal fixation (ORIF) on the right side. She has had a slow recovery, hampered by her obesity (BMI 42) and marginal muscle strength from lack of conditioning. Her ambulation is limited as she is continuing to use crutches for locomotion. Marcie has requested short-acting opioids during the past 2 months since her ORIF. She is now taking oxycodone hydrochloride, 10 mg, with acetaminophen, 650 mg, every 3 hours. Her osteopathic physician is concerned with the rising opioid load and lack of improvement in mobility and muscle strength. Her osteopathic physical examination reveals asymmetric thoracic and

lumbar range of motion (ROM) with increased somatic dysfunction and pain perceptions. She has reported pain levels in her back at 8 on a scale of 0 to 10 (8/10) with some improvements with the opioids.

When should the provider consider prescribing long-acting opioids?

What other modalities should be incorporated in Marcie's care?

The physician has good reason to be worried about Marcie's severe pain. Her discomfort is validated with the somatic dysfunctions and diminished ROM found on osteopathic physical examination. Acute pain treatment with opioids has moved Marcie's pain into a chronic state, and she has now developed opioid tolerance and physical dependency; she currently requires oxycodone hydrochloride, 10 mg every 3 hours with minimal relief from severe (8/10) pain. With proper history, education, and the controlled substance agreement between Marcie and her physician, she was given a long-acting opioid analgesic to be taken twice a day; oxycodone hydrochloride 10 mg, was used for breakthrough pain. After a few weeks with close follow-up, Marcie reported adequate pain control (2/10). She stated that her worst pain was 5/10, which responded to her breakthrough opioid analgesic.

Marcie was referred to physical therapy with evaluation, education, gait training, body mechanics, stretching, and exercise prescribed. She was also evaluated by dietary services for nutritional counseling. Marcie has continued to improve, decreasing her use of 10-mg oxycodone hydrochloride, to 5 to 6 tablets per week. This taper was over 12 weeks. It is expected that as Marcie improves her physical and somatic dysfunctions, she will continue to be titrated off short-acting opioid analgesics and later from long-acting opioid analgesics, and ultimately transitioned to nonopioid modalities with continuation of physical medicine.

Comment

Comprehensive history, assessment—including an osteopathic structural examination—management, and education assure success in reducing pain. These key elements decrease the known small

OPIOIDS

PHENANTHRENES

■ Agonists

- ☐ Naturally-occurring opium alkaloids
 - Codeine
 - Morphine
- ☐ Semisynthetic derivatives of morphine
 - Hydromorphone
 - Oxymorphone
- ☐ Semisynthetic derivatives of codeine
 - Hydrocodone
 - Oxycodone

■ Partial Agonist

- ☐ Buprenorphine

■ Agonist-Antagonist

- ☐ Nalbuphine

PHENYLHEPTANES

- ☐ Levomethadyl
- ☐ Methadone
- ☐ Propoxyphene

MORPHINANS

■ Agonist

- ☐ Levorphanol

■ Agonist-Antagonist

- ☐ Butorphanol

PHENYLPIPERIDINES

- ☐ Alfentanil
- ☐ Fentanyl
- ☐ Meperidine
- ☐ Sufentanil

BENZOMORPHAN

■ Agonist-Antagonist

- ☐ Pentazocine

AMINOTETRALIN

■ Agonist-Antagonist

- ☐ Dezocine

Figure 5.

risk of opioid abuse. Understanding the need for titration and opioid tolerance and awareness of the possible need to increase dosage over time are important concepts. Combined physician-patient effort, frequent reassessment, and patient understanding substantially reduce opioid abuse and enhance the ability to improve quality of life and pain reduction. Understanding differences between addiction (psychological and deviant behavioral condition) and physical dependence (related to compensatory changes at receptor level [quantity and/or affinity]) will improve physician comfort in prescribing opioid therapy.

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PROFESSIONAL ADDICTION-RELATED ASSOCIATION WEB SITES

- **American Academy of Addiction Psychiatry (AAAP)**
www.aaap.org
- **American Osteopathic Association (AOA), American Osteopathic Academy of Addiction Medicine (AOAAM)**
www.osteopathic.org
- **American Psychiatric Association (APA)**
www.psych.org
- **American Psychological Association (APA), College of Professional Psychology**
www.apa.org/college
- **American Society of Addiction Medicine**
www.asam.org
- **Federation of State Medical Boards**
www.fsmb.org
- **Institute for Professional Development in the Addictions (PDA)**
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- **National Association of Alcoholism and Drug Abuse Counselors (NAADAC), The Association for Addiction Professionals**
www.naadac.org
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