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NIPC
NATIONAL INITIATIVE ON PAIN CONTROL™

Documenting Opioid Usage

MICHAEL H. MOSKOWITZ, MD, MPH
DIANE MOSKOWITZ KEANEY, RN, BSN
Bay Area Pain Medical Associates
Dr Moskowitz is a research consultant for Endo Pharmaceuticals and a member of the speakers bureau for Cephalon, Forrest Laboratories, and Pfizer Inc.

There is a need to provide effective treatment for patients with pain disorders while shielding the patient and the public from inappropriate prescribing and the prescribing physician from suspicion, investigation, or sanction. Bulletproof documentation is necessary for any mode of treatment, but it is absolutely critical when using long-term opioid treatment for patients with chronic pain. This article focuses on the evolution of our established documentation process, which encompasses the goals of quality care and effective risk reduction and also serves as a paradigm for all other documentation in pain treatment.

Overview of Documentation

Our first step was to examine our then-current documentation, which had been brought into compliance with Medicare guidelines for evaluation and management codes.[1] Next we explored government laws,[2-4] Federation of State Medical Board guidelines,[5] and pain medicine specialty organizations' recommendations.[6,7] We also evaluated Joint Commission on Accreditation of Healthcare Organization hospital standards[8] and other clinical guidelines,[9,10] pharmaceutical industry recommendations, local medical board communications,[11] available literature, and policies of

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Guidelines for the Treatment of Neuropathic Pain

ROBERT H. DWORKIN, PhD
University of Rochester School of Medicine and Dentistry
Dr Dworkin is a consultant or member of the speakers bureau for Abbott Laboratories, Allergan, AstraZeneca, Bristol-Myers Squibb, Elan Pharmaceuticals, Eli Lilly & Co, Endo Pharmaceuticals, EpiCept Corporation, GlaxoSmithKline, Johnson & Johnson, Merck KGaA, NeurogesX, Novartis Pharmaceuticals, Ortho-McNeil Pharmaceutical, Pfizer Inc, Reliant Pharmaceuticals, and UCB Pharma.

Neuropathic pain is common, and patients with conditions as diverse as diabetic polyneuropathy, HIV sensory neuropathy, and multiple sclerosis frequently suffer from daily pain that interferes with their quality of life. Although precise estimates of the prevalence of chronic neuropathic pain are not available, it is more common than has been generally appreciated, probably affecting 6 million or more people in the United States.

This article discusses recently published evidence-based treatment guidelines for the pharmacologic management of chronic neuropathic pain that take into account clinical effectiveness, adverse effects, impact on quality of life, and costs of treatment.[1] These recommendations were co-authored by 21 members of the faculty of the Fourth International Conference on the Mechanisms and Treatment of Neuropathic Pain, who participated in a consensus meeting supported by an unrestricted educational grant to the University of Rochester Office of Professional Education from Endo Pharmaceuticals. Specialties represented included anesthesiology, basic neuroscience, epidemiology, geriatrics, internal medicine, neurology, neurosurgery, outcomes research, pharmacoeconomics, and psychology.

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LETTER FROM THE CHAIRMAN

Dear Colleague,

Pain management is among the most challenging issues facing primary care physicians today. Nearly 80 million Americans suffer from chronic pain. Daily, physicians are faced with finding safe and effective methods and treatments to provide optimal pain relief for their patients.

To maintain state-of-the-art knowledge and skills in this rapidly changing discipline, continuing education is key. Many renowned pain professionals and educators are involved in the National Initiative for Pain Control™ (NIPC™), and this year we welcome nearly 15 new faculty members.

The NIPC offers, through numerous educational venues, innovative, interactive, and practical tools and activities that support the Initiative's goals. A new slide module on low back pain has been developed by the NIPC to provide an overview of mechanisms for chronic back pain, assessment and diagnostic techniques for evaluation, and a review of comprehensive management strategies. A task force of back pain specialists has prepared a dynamic compendium of slides. We expect that this important new program, requested by previous program participants, will be a valuable education aid for your practice.

The NIPC newsletter offers clinically practical information on novel approaches to assessing and managing pain that you can use in your day-to-day practice. In this issue, articles address such clinical topics as the assessment of low back pain, the newly released guidelines on the treatment of neuropathic pain, and models for a balanced approach and proper documentation of opioids in clinical practice.

Our new collaborative Web site alliance with PainEDU (www.painedu.org) was launched this year to communicate timely information on pain-related issues and facilitate registration for NIPC programs. We at the NIPC encourage you to enroll in our upcoming CME-certified education activities, such as the Audioconference Series, DINNER DIALOGUES® Series, and Saturday Seminars in New York City and Los Angeles scheduled for May. You will see more detailed information on pages 6 and 11-12.

All of us at the NIPC encourage you to take advantage of the educational opportunities offered during 2004 and to share your insights and comments with us throughout the year.

Sincerely,

Perry G. Fine, MD
NIPC Chairman

Complete the evaluation form in the next issue and send to PPS for CME credit.

Volume 4, Number 1, released April 2004, is the first part of a two-part CME activity. The second issue, scheduled for publication in August 2004, will include a posttest and evaluation form that will cover the contents of both issues. Physicians who wish to receive credit should do the following: (1) read each newsletter, (2) review all the articles in their entirety, (3) complete the posttest and mail the evaluation form to Thomson Professional Postgraduate Services®, CME Dept. #B294, 150 Meadowlands Parkway, PO Box 1505, Secaucus, NJ 07096-1505. Within 8 weeks of receipt of the registration evaluation form, applicants will be sent a letter of completion from Thomson Professional Postgraduate Services®. To receive CME credit, the evaluation form must be returned by December 1, 2004. This is valid for CME credit through December 1, 2004.

CME INFORMATION

This CME activity is sponsored by Thomson Professional Postgraduate Services®, Secaucus, NJ.

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The National Initiative on Pain Control™ (NIPC™) and its educational components are supported by an unrestricted educational grant from Endo Pharmaceuticals.

After reading the two-part newsletter series for 2004, participants should be able to:

- Identify a balanced approach to the use of opioid analgesia in the treatment of chronic pain.
- Discuss evidence-based treatment recommendations for the pharmacologic management of chronic neuropathic pain.
- Assess the patient with low back pain and select appropriate diagnostic tests.
- Describe the role of a comprehensive treatment plan for patients with chronic pain that includes biopsychosocial approaches.
- Differentiate between the distinctive biochemical properties and potential mechanisms of major classes of pain medications in the treatment of neuropathic pain.
- Understand how to transition a patient through continuation/maintenance therapy and discontinuation of opioids.
- Document opioid usage and monitor progress and treatment outcomes in patient management.

This educational activity is a component of the NIPC™ and is designed to heighten the knowledge of physicians and other healthcare providers about the serious impact of unresolved pain on patient care. Some of the agents included in this newsletter are discussed in the context of uses for which they have not been approved by the FDA.

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ABOUT THE NIPC

The National Initiative on Pain Control™ (NIPC™) is an integrated CME education initiative that was established in 2001 to help physicians improve outcomes for their patients who have pain. Living with chronic pain has deleterious effects on many aspects of the patient's life including deterioration of physical functioning, the development of psychological distress and psychiatric disorders, and impairment of interpersonal functioning. In fact, approximately 40% of patients with chronic pain also experience major depression. The program heightens physician awareness of the impact of pain on patient's daily living in terms of quality of life, lost workdays, and societal/familial consequences.

Of special concern, more than 1 million cases of neuropathic pain are reported each year, which accounts for between 25% and 50% of all visits to pain clinics. Unfortunately, less than optimal training of physicians in pain disorders has led to the underassessment and undertreatment of patients who are living with pain.

NIPC addresses the barriers to achieving pain control by providing potential pathways for action and expected amelioration of their patients' pain. By providing physicians with the latest advances and strategies in pain management, they will be better able to translate clinical data into clinical practice.

All NIPC programs are developed and continuously evaluated by the NIPC Education Council, an expert, multidisciplinary team of specialists, researchers, and practicing physicians in pain management.

You have received this mail because we believe it may be of interest to you. If you would like your name to be removed from our mailing list, please follow these instructions:

Call 1 (800) 873-1362 and leave a message with your name and address indicating that you would like to be removed.

When to Consider Diagnostic Tests for Back Pain

DANIEL A. BRZUSEK, DO
University of Washington
Dr Brzusek has reported no significant financial interests or affiliations.

Evaluating patients in pain who look to you for consultation, diagnosis, and treatment can certainly be a challenge, given the current constraints on balancing appropriate assessment vs cost containment. A plethora of diagnostic tests is available for the patient presenting with pain—some of which pass scrutiny as being scientific while others certainly are not supported by any meta-analysis. With exploding technology, exposure of patients via various sources of media (including the Internet) to the most "up-to-date" tests can prove to be a delicate juggling act. The primary care physician's role in acting as the appropriate advocate and source of information for patients is crucial.

Several years ago, for example, thermography was being presented as the "ultimate picture of pain." Thermography was even accepted by several courts as being the ultimate arbiter and determinant of patients who really were in pain. Putting thermography through the rigors of scientific method, however, resulted in totally discrediting this falsely hopeful and somewhat expensive test for pain. When dealing with pain in a patient, the most appropriate scientifically tested and cost-effective method is, first, a careful clinical assessment, including pain history and physical examination. The ultimate challenge is to then choose the appropriate tests while balancing cost vs appropriateness issues.

"Of all the symptoms for which physicians are consulted, pain in one form or another is the most common and often the most urgent. Properly assessed, it stands preeminent amongst sensory phenomena of disease as a guide to diagnosis."

—Charles H. Mayo[1]

The intent of this short article is to answer the questions of when and why to pursue further diagnostic tests for pain within the context of emerging technology. It is not the ultimate resource for such decision making, but it is meant to introduce and review just a few points for consideration in evaluating patients with either acute or chronic pain.

Functional Index

As an extension of a physical examination, the functional rating index for patients who experience pain should be a mainstay of primary care physicians assessing patients with acute and chronic pain. Visual pain analog scales may be helpful, but it is the functional status of the patient that is the best determination of treatment effectiveness.

By obtaining a functional rating on a scale of 0 to 10 at the inception of the assessment, the physician can quantify the effectiveness of any subsequent treatment and also determine over the course of time whether the patient is stable, improving, or deteriorating despite intervention. Although there are many functional rating indexes available, we prefer a modification in compendium of several functional scales (see Figure). Practical and useful functional assessment is often done between the patient and the physician and determines what existing limitations are meaningful to the patient. Return to work, for example, may be meaningful to the employer and society but unrealistic and unwanted by the patient. A short discussion with the patient about what functional improvements are desired allows the physician to track improvement as an outcome for pain treatment. Seeing a movie, cheering for the kids playing soccer, and working in the garden are examples of functional outcomes that can be followed with treatment and have meaning to the patient.

Clinical assessment of the patient in either acute or chronic pain should include the following:

1. Intensity (at rest, movement, and provocation), description, distribution and pattern of pain, and modifiers
2. Results of careful palpation, localization of pain, and its segmental dysfunction
3. Distribution of numbness, including a meticulous sensory examination
4. Weakness and its appropriate distribution associated with atrophy
5. Reflex changes
6. Results of provocative testing (described below)
7. Asymmetry in temperature distribution

Provocative Tests

A number of provocative tests for chronic lower back pain are available and can be used to establish physical findings that can subsequently lead to the appropriate choice of more sophisticated, technologically based diagnostic studies. Examples of provocative tests that I find helpful include:

Pinch test.[2] The skin and subcutaneous tissue on both sides of the lumbar spine are pinched lightly but firmly. If back pain is reproduced or increased by the maneuver, response is considered positive for nonorganic disease, since fat tissue has a meager nerve supply. If the patient has allodynia or hyperalgesia from a neuropathic component of the pain, the pinch test would be positive and organic. Pain would be expected on skin pinching with a recent history of fracture or superficial abscess. This may be combined with Waddell's test.[3]

Ely's test. The patient is examined in the prone position with either leg flexed back on the buttock. In the presence of lumbar disease, extending the spine causes pain when the maneuver stretches the femoral nerve, indicating irritation of the L2, L3, and L4 lumbar roots.

Ober's test. The patient lies on his or her side, with the under leg kept flexed on the abdomen while clasping with both hands the leg below the knee. The upper leg is extended back with the knee flexed. This extended position would indicate a tight iliotibial band and would indicate that further diagnostic testing, such as x-rays, magnetic resonance imaging (MRI), or computed tomography (CT) scan would produce a very low yield.

Gaenslen's sign. One leg is flexed forcibly on the abdomen while the other leg is maximally extended over the side of the examining table. If stress placed on either one of the sacroiliac joints causes pain in the lower back, sacroiliac disease is present. This is a controversial test; some physicians believe that the only appropriate sacroiliac test would be a sacroiliac joint injection.

Stoop test. This test is for diagnosing pseudoclaudication caused by nerve root irritation. The patient walks briskly for 1 to 2 minutes. The patient experiences back and leg pain, sits on a chair, and leans forward. If the pain is relieved in forward flexion, the test is positive for nerve root irritation and possible spinal stenosis.

Kernig-Brudzinski test. The patient is asked to pull his or her head forward and rest it on his or her chest. The examiner then raises the symptomatic leg with the knee extended. This position will cause pain if nerve root irritation is present. Pain will be relieved when the knee is bent. The maneuver first tenses the lumbar nerve roots and meninges and then relaxes them when the knee is flexed.

Flip test. The patient sits on the side of the examining table with legs dangling. The examiner holds the thigh down with one hand and straightens the knee into extension with the other hand. If sciatica is present, the patient may flip backward on the examining table.

Bragard's sign. This test consists of flexing the hip and raising the legs straight until pain is experienced, then the foot is dorsiflexed. Increased pain is experienced in the presence of

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When to Consider Diagnostic Tests for Back Pain

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nerve stretching and nerve root irritation.

Adding these tests to the pain control armamentarium should provide some guidance as to the appropriateness and specificity of further diagnostic studies.[4-6] If, on the basis of accumulated data, the pain reported is nonspecific and nonorganic pain,[3] then no additional diagnostic studies should be considered. If an inflammatory disease is being considered, then some simple laboratory studies (eg, sedimentation rate, cross-reactive protein, acetylneuraminic acid) would be sufficient.

If a specific peripheral nerve root distribution or proximal lesion (herniated disc or spinal stenosis) in a specific distribution is identified, the most appropriate test may be an MRI; the more traditional method of obtaining plain x-rays before obtaining an MRI should be abandoned. Cost-effectiveness should determine more specificity. For confirmation purposes, performance of electrodiagnostic testing may also be considered if muscle weakness and atrophy in a fairly specific nerve root distribution can be identified.

Repeat MRI studies, myelograms, CTs, positron emission tomography scans, etc, should not be considered for the patient with nonspecific back pain unless the patient reports a changing pattern of symptoms or the physical exam indicates significant alterations. Additional diagnostic tests may even lead to further confusion regarding the appropriateness of treatment.

Unfortunately, even with all of the technology available, there are no specific tests for either acute or chronic pain. Even with the exact mechanism of pain remaining unproved, this article reinforces the role of provocative tests in the diagnosis and treatment of low back pain.

In the absence of specific findings, the functional status of the patient should be the determining factor for which tests are appropriate and possibly helpful in elucidating the patient's reports of pain and other symptoms.

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Functional Rating Index For use with Neck and/or Back Problems only.

In order to properly assess your condition, we must understand how much your neck and/or back problems have affected your ability to manage everyday activities. For each item below, **please circle the number that most closely describes your condition right now.**

1. Pain Intensity

0	1	2	3	4
No pain	Mild pain	Moderate pain	Severe pain	Worst possible pain

2. Sleeping

0	1	2	3	4
Perfect sleep	Mildly disturbed sleep	Moderately disturbed sleep	Greatly disturbed sleep	Totally disturbed sleep

3. Personal care (washing, dressing, etc)

0	1	2	3	4
No pain; no restrictions	Mild pain; no restrictions	Moderate pain; need to go slowly	Moderate pain; need some assistance	Severe pain; need 100% assistance

4. Travel (driving, etc)

0	1	2	3	4
No pain on long trips	Mild pain on long trips	Moderate pain on long trips	Moderate pain on short trips	Severe pain on short trips

5. Work

0	1	2	3	4
Can do usual work plus unlimited extra work	Can do usual work; no extra work	Can do 50% of usual work	Can do 25% of usual work	Cannot work

6. Recreation

0	1	2	3	4
Can do all activities	Can do most activities	Can do some activities	Can do a few activities	Cannot do any activities

7. Frequency of pain

0	1	2	3	4
No pain	Occasional pain; 25% of the day	Intermittent pain; 50% of the day	Frequent pain; 75% of the day	Constant pain; 100% of the day

8. Lifting

0	1	2	3	4
No pain with heavy weight	Increased pain with heavy weight	Increased pain with moderate weight	Increased pain with light weight	Increased pain with any weight

9. Walking

0	1	2	3	4
No pain at any distance	Increased pain after 1 mile	Increased pain after ½ mile	Increased pain after ¼ mile	Increased pain with all walking

10. Standing

0	1	2	3	4
No pain after several hours	Increased pain after several hours	Increased pain after 1 hour	Increased pain after ½ hour	Increased pain with any standing

Patient's Signature _____ Date _____

Adapted with permission from the author.

Documenting Opioid Usage

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other practitioners in our area. Finally we reviewed recent lawsuits[12] and criminal prosecution of physicians,[13] met with local pharmacists, spoke with national law enforcement experts, and talked with our malpractice carrier about their recommendations. To our surprise, good clinical guidelines for treating chronic nonmalignant pain with opioids and documenting this use were sorely lacking. Ultimately we felt that the best source of information for compliance were the guidelines from the Federation of State Medical Boards.[5]

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Establishing Documentation for Physician Practice

When prescribing long-term opioid analgesics, the challenge is to include documentation in the chart that incorporates the elements of both risk management and patient care for the health and safety of the patient and protection of the practice. Prior to the initial patient evaluation, medical records from the referring physician and a complete set of prior medical records from others treating the pain disorder should be acquired and reviewed. It is essential to integrate appropriate self-report questionnaires, standardized clinical scales, medical and psychosocial history, drug or alcohol abuse history, physical examination, treatment planning, goal setting, and medication updates into the documentation (see Table).

Evaluation of patient. Standardized clinical scales can be used to document patient improvement in a number of areas, including psychosocial function, physical function, pain intensity, and pain relief. This can range from simple analog numeric scales for pain (0 = no pain and 10 = the worst possible pain) to more detailed pain scales of best and worst pain in a day and the degree of interference of pain with life activities (Pain Disability Index, Brief Pain Inventory, Multidimensional Pain Inventory, Oswestry Disability Index). Depression and anxiety inventories are also helpful.

Treatment plan. Goal setting is an important aspect of initial evaluations and follow-up visits. There should be documentation of success or failure in achieving those goals, which should be specific and measurable (eg, 30% reduction in pain, increased sitting tolerance by a particular amount from baseline). Such documentation should be reflected in both treatment planning and updating.

Medication updates. Medications should be reviewed for efficacy, safety, side effects, and drug interactions. Prior history of drug or alcohol abuse should be documented. High-risk indi-

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Federation of State Medical Board Guidelines

Guidelines for Controlled Substances	Key Factors
Evaluation of the patient	• Complete medical history and physical • Description of pain location, quality, duration, intensity, provocation, and amelioration • History of current and past treatment • Pain effects of physical and psychological function • Comorbid disease(s) • Substance abuse history • Medical indication for use of controlled substance
Treatment plan	• Objectives for treatment success • Correlation between medication adjustments and clinical changes • Documentation of other treatment modalities • Documentation of referrals to other resources
Informed consent	• Review of risks and benefits • Outline of patient responsibilities • Discussion of office policy and possible signed controlled substance agreement
Periodic review	• Review etiology • Review treatment course • Continue or modify therapy regarding treatment objectives • Monitor compliance
Consultation	• Refer for specialty treatment as indicated 1. Patients at high risk for misuse or diversion need closer monitoring 2. High-risk patients may require referral to substance abuse specialists
Medical records	• Documentation of the above
Compliance with controlled substance laws and regulations	• Refer to state and federal laws for specific rules

Adapted from Model guidelines for the use of controlled substances for the treatment of pain. Federation of State Medical Boards of the United States, Inc. May 1998.[5]

Documenting Opioid Usage

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viduals should be identified and followed more closely. Controlled substance agreements[7] delineating patient responsibilities and practice expectations can be developed using the American Academy of Pain Medicine recommendations as a template that can be modified for individual practice needs [Available at: www.painmed.org/productpub/pdfs/order_form.pdf]. Periodic review of opioid efficacy in pain reduction and functional improvements not only should be documented, but also should be discussed with patients to clarify treatment goals and involve patients as active partners in their own care. Use of the Federation of State Medical Board Guidelines to ensure that important points are covered is a good start, but it is both possible and desirable to individualize documentation to fit the focus of the physician's practice.

Informed consent. Informed consent is not the same as the controlled substance agreement. Informed consent should document risks and benefits, side-effect profile, clinical controversies, and abstinence syndrome. A broad spectrum of patient education aids can be implemented, including self-developed handouts or professionally prepared brochures. These patient responsibility materials can involve medication or procedure information sheets, informed consent forms, informational Web sites, medication titration schedules, and self-help support group brochures.

Periodic review. Medication misuse should be recorded. Urine and blood screens for opioid analgesics and nonprescribed substances may be useful in certain cases, although their limitations should be understood. Consider consulting an addiction expert for help in interpretation of positive results of urine drug screens, which may be complicated. Referral to an addiction specialist of a patient exhibiting aberrant behavior can be helpful if the specialist understands the use of opioids in pain treatment. It may also be necessary for the physician to document additional consultations for other modalities of treatment, including physical therapy, invasive treatment, and treatment of comorbid conditions, to demonstrate balanced treatment of pain beyond long-term opioid therapy.

Management of chronic pain with long-term opioid therapy is challenging and requires that the practitioner devote adequate time to the process. Meticulous attention to record keeping is essential. Careful opioid documentation can satisfy risk management needs while serving as the foundation for excellent patient care.

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Management of chronic pain with long-term opioid therapy is challenging and requires that the practitioner devote adequate time to the process.

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Guidelines for the Treatment of Neuropathic Pain

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Before discussing these treatment guidelines, two important caveats are required. First, the majority of the randomized controlled trials of chronic neuropathic pain have examined only two pain syndromes: painful diabetic neuropathy (PDN) and postherpetic neuralgia (PHN). Moreover, the US Food and Drug Administration (FDA) has approved medications for the treatment of only two specific neuropathic pain syndromes: carbamazepine (trigeminal neuralgia) and gabapentin and the lidocaine patch 5% (PHN). The applicability of the results of clinical trials on one chronic neuropathic syndrome to other such syndromes is unknown, but most first-line therapies identified in the guidelines were tested on several types of neuropathic pain with generally similar results. Because pharmacologic management rarely provides a cure, it should be considered an integral component of a more comprehensive approach to treatment that includes nonpharmacologic approaches.

First-line Treatments

All treatments recommended as first-line have demonstrated statistically significant and clinically meaningful benefits compared with placebo in multiple randomized controlled trials. The results of these published trials (safety, side effects, drug interactions, and clinical experiences of the authors) provided the basis for the specific recommendations for using these medications.

Many different medications are used in the treatment of neuropathic pain, but until recently only tricyclic antidepressants (TCAs) had been evaluated in multiple randomized, double-blind, placebo-controlled clinical trials. However, the efficacy of each of five pharmacologic treatments in patients with neuropathic pain has now been demonstrated by the results of multiple consistent, randomized, controlled trials. These five medications—gabapentin, lidocaine patch 5%, opioid analgesics, tramadol, and TCAs—provide the clinician with an evidence-based approach for the first-line treatment of neuropathic pain. These five medications were considered first-line because clinical circumstances exist in which each one can be used in the initial treatment of patients with neuropathic pain, although opioid analgesics and TCAs generally require greater caution than the other options. Specific treatment recommendations for the five medications are summarized in the Table.

Gabapentin. Eight double-blind, placebo-controlled, randomized clinical trials of gabapentin have been published for treatment of PHN, PDN, mixed neuropathic pain syndromes, phantom limb pain, Guillain-Barré syndrome, and acute and chronic spinal cord injury pain.[2-9] Gabapentin (at daily dosages up to 3600 mg; FDA-approved dosage for PHN = 1800 mg daily) significantly reduced pain compared with placebo, and improvements in sleep, mood, and quality of life were also demonstrated in some trials.

The side effects of gabapentin are somnolence and dizziness, and, less often, gastrointestinal symptoms and mild peripheral edema, all of which require monitoring and dosage adjustment but usually not drug discontinuation. Gabapentin may cause or exacerbate gait and balance problems and cognitive impairment in the elderly, and dosage adjustment is necessary in patients with renal insufficiency. However, its generally excellent tolerability, safety, and lack of drug interactions dis-

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First-line Medications for Neuropathic Pain[1]

Medication	Beginning Dosage	Titration	Maximum Dosage	Duration of Adequate Trial
Gabapentin	100-300 mg qhs or 100-300 mg tid	Increase by 100-300 mg tid every 1-7 days as tolerated	3600 mg daily (1200 mg tid); reduce if low creatinine clearance	3-8 weeks for titration plus 1-2 weeks at maximum tolerated dosage
Lidocaine patch 5%	Maximum of 3 patches daily for a maximum of 12 hours	None needed	Maximum of 3 patches daily for a maximum of 12 hours	2 weeks
Opioid analgesics (dosages given are for morphine)	5-15 mg every 4 hours as needed	After 1-2 weeks, convert total daily dosage to long-acting opioid analgesic and continue short-acting medication as needed	No maximum with careful titration; consider evaluation by pain specialist at dosages exceeding 120-180 mg daily	4-6 weeks
Tramadol	50 mg once or twice daily	Increase by 50-100 mg daily in divided doses every 3-7 days as tolerated	400 mg daily (100 mg qid); in patients over 75 years of age, 300 mg daily in divided doses	4 weeks
Tricyclic antidepressants (especially nortriptyline or desipramine)	10-25 mg qhs	Increase by 10-25 mg daily every 3-7 days as tolerated	75-150 mg daily; if blood level of active drug and its metabolite is below 100 ng/mL, continue titration with caution	6-8 weeks with at least 1-2 weeks at maximum tolerated dosage

Reprinted with permission from Dworkin RH et al.[1]

Guidelines for the Treatment of Neuropathic Pain

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tinguish gabapentin from most other oral medications used in the treatment of chronic neuropathic pain.

Lidocaine patch 5%. There are two published, double-blind, vehicle-controlled, randomized clinical trials of lidocaine patch 5% that demonstrated statistically significantly greater pain relief with lidocaine patch 5% compared with vehicle-control patches in patients with PHN.[10,11] Lidocaine patch 5% is a topical preparation; hence, there is little risk of systemic side effects or drug interactions. Blood levels are minimal and accumulation does not occur with the 12 hours on/12 hours off dosage schedule in patients with normal hepatic function. Lidocaine patch 5% has excellent safety and tolerability, and the only side effects involve mild skin reactions (ie, erythema, rash). Systemic absorption from lidocaine patch 5% must be considered in patients receiving oral Class I antiarrhythmic drugs (eg, mexiletine).

Opioid analgesics. Five double-blind, randomized trials of oral opioid analgesics have been published since 1998 in patients with PHN, PDN, and phantom limb pain, as well as a variety of peripheral and central neuropathic pain syndromes.[12-16] Results of these five studies taken together provide the basis for considering opioid analgesics as first-line treatment for neuropathic pain. The most common side effects of opioid analgesics are constipation, sedation, and nausea. In older patients treated with opioid analgesics, cognitive impairment and problems with mobility can occur. Opioid analgesics must be used very cautiously in patients with a history of substance abuse or attempted suicide, because accidental death or suicide can occur with overdose. Patients treated with opioid analgesics may develop analgesic tolerance (ie, a reduction in analgesic benefit over time), although a stable dosage can usually be achieved. All patients treated with opioids will develop physical dependence (ie, withdrawal symptoms develop with abrupt discontinuation or rapid dose reduction), and they must be advised not to abruptly discontinue the medication.

Tramadol. There are two published, double-blind, placebo-controlled, randomized clinical trials of tramadol in neuropathic pain, one in patients with PDN and one in patients with painful polyneuropathy of different etiologies, including PDN.[17,18] In both trials, tramadol titrated to a maximum dosage of 400 mg daily significantly relieved pain compared with placebo, and beneficial effects of treatment on allodynia and quality of life also were reported.

The side effects of tramadol include dizziness, nausea, constipation, somnolence, and orthostatic hypotension, which occur more frequently when the dosage is escalated rapidly. There is an increased risk of seizures in patients treated with tramadol who have a history of seizures or who are also receiving antidepressants, opioids, or other drugs that can reduce the seizure threshold. Serotonin syndrome may occur if tramadol is used concurrently with other serotonergic medications. Tramadol may cause or exacerbate cognitive impairment in the elderly, and dosage adjustment is necessary in patients with renal or hepatic disease. Abuse of tramadol is thought to be rare, but has been observed.

Tricyclic antidepressants. TCAs were the first medication category proved effective for neuropathic pain in placebo-controlled trials.[19-22] Although clinical trials of patients with HIV sensory neuropathy, spinal cord injury pain, and *cis*-platinum neuropathy found little benefit for amitriptyline compared with placebo, an apt summary of the overall efficacy of TCAs in neuropathic pain was provided in the review "Thirteen Consecutive Randomized Trials Show That Antidepressants Relieve Neuropathic Pain."[23] TCAs must be used very cautiously in patients with a history of cardiovascular disease, glaucoma, urinary retention, and autonomic neuropathy. Almost 20% of patients treated with a TCA after a myocardial infarction developed adverse cardiac events in a recent study. A screening EKG to check for cardiac conduction abnormalities is recommended before beginning treatment with TCAs, especially in patients over 40 years of age. As with opioid analgesics, TCAs must be used cautiously when there is a risk of suicide or accidental death from overdose.

TCAs may block the effects of certain antihypertensive drugs, and they interact with drugs metabolized by P450 2D6. All selective serotonin reuptake inhibitors (SSRIs) inhibit P450 2D6, and caution must be exercised in the concomitant administration of TCAs and SSRIs and in switching from one drug class to the other. In the elderly, TCAs may cause balance problems and cognitive impairment. Milder side effects of TCAs include sedation, anticholinergic effects, postural hypotension, and weight gain.

Most clinical trials of TCAs in neuropathic pain have examined amitriptyline, but amitriptyline is not recommended in elderly patients because of the risk of significant adverse events. Nortriptyline and desipramine have fewer side effects and are generally better tolerated than

amitriptyline. In a recent randomized double-blind trial, nortriptyline was found to provide equivalent analgesic benefits in patients with PHN when directly compared with amitriptyline and was better tolerated. Regardless of which TCA is used, patients must be informed that TCAs have an analgesic effect independent of their antidepressant effect.

Sequential and Combination Treatment With First-line Medications

Current understanding of the pathophysiology of neuropathic pain is consistent with the existence of multiple pain mechanisms, which may each respond differently to medications with different mechanisms of action. It is recommended that patients who do not respond to one of these five first-line medications be treated with one or more of the others. Despite the lack of controlled data, combinations of two or more of these first-line medications can be recommended when patients have a partial response to one alone and at the beginning of treatment as well—either to increase the likelihood of a beneficial response or when one medication requires titration to reach an effective dosage. Disadvantages of combination therapy include an increased risk of side effects as the number of medications is increased.

Second-line Medications

When patients do not have a satisfactory response to treatment with the five first-line medications alone or in combination, there are several medications that can be recommended as second-line based on positive results from a single randomized controlled trial or inconsistent results from multiple randomized controlled trials (with one exception). Lamotrigine and carbamazepine are recommended for patients who have not responded to an adequate trial of gabapentin when treatment with an anticonvulsant is sought. Lamotrigine is the one second-line pharmacologic treatment for which there is evidence of efficacy based on the results of multiple, consistent randomized controlled trials in several neuropathic pain syndromes. It was not considered first-line, however, because it requires slow and careful titration and is associated with a risk of severe rash and Stevens-Johnson syndrome.

Clinical trials of bupropion, citalopram, paroxetine, and venlafaxine in a variety of neuropathic pain syndromes provided the basis for recommending these four antidepressants for patients who have not responded to an adequate trial of nortriptyline (or another TCA) when additional treatment with an antidepressant is being considered.

Future Needs

Development of new treatments for neuropathic pain is continuing at a rapid pace, but few clinical trials have directly compared medication options. Such trials would make it possible to determine how treatments vary in their efficacy, safety, and tolerability. Likewise, although a large percentage of patients with neuropathic pain currently are treated with two or more of the first- and second-line medications, little is known about which patients are most likely to benefit from combination treatment; systematic evaluations of combination treatments are, therefore, also needed.

Progress in basic neuroscience is leading to a greater understanding of the pathophysiologic mechanisms of neuropathic pain. Interest in these mechanisms and the treatment of chronic neuropathic pain has greatly increased during the past several years and likely will result in significant treatment advances in the future. These advances will make it possible to go beyond determination of whether treatment is efficacious to identification of which treatments are most effective for particular patients.

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Opioids for Chronic Pain: A Question of Balance

NATHANIEL P. KATZ, MD, MS
Massachusetts General Hospital
Dr Katz is a research consultant for Elan Pharmaceuticals, Endo Pharmaceuticals, and Janssen Pharmaceutica, and also a retained consultant for Merck & Co., Inc., Pfizer Inc, and Schwartz Pharma.

A number of studies and anecdotal accounts suggest that many individuals with significant chronic pain conditions, including extreme examples of elderly patients with advanced cancer, are underprescribed reasonable doses of opioid analgesics and suffer unnecessarily.[1,2]

Because of a heightened awareness of undertreated pain, providers with little understanding of the risks of this treatment may overprescribe for chronic pain. Patients with scant documentation of painful illnesses and obvious risk factors for drug addiction or diversion may be prescribed high doses of opioids on an ongoing basis, despite "aberrant drug-taking behaviors" and without evidence of any meaningful functional benefit. Patient addiction may be nourished, along with the inevitable morbidity or mortality associated with that disease. Prescription opioids may be sold to teenagers in schoolyards, and drugs may be diverted.

Regulators, including members of the US Congress, are greatly concerned about prescription opioid abuse, as well as about undertreatment of pain. In response to the public pressures of the day, regulations have been proposed to curtail prescription opioid abuse, but, if not designed carefully, stand little chance of accomplishing that worthwhile goal and, even worse, may diminish access to appropriate pain treatment.

Choosing Between Two Extremes

Historically, the debate surrounding the use of opioids for chronic pain has been mired in a narrow dimension of "more liberal" vs "less liberal." The choice has been viewed as between two polar extremes. The extreme liberal view is: defeat all regulations so that patients in pain can receive unbridled access to opioids for their pain; if bad people get addicted, that is their problem—our only interest should be our patients. The other extreme is: diversion and addiction are terrible public health problems that devastate many lives; many patients do not benefit from opioids anyway, so these medications should be severely restricted to only those patients treated by specialists for the most severe pain problems.

The extreme liberal view of pseudoaddiction is that any aberrant behavior always means undertreated pain. When difficult behavior develops around opioid use, undertreatment is the cause that has led to high opioid doses. Instead of stopping aberrant behavior, these doses may be associated with more behavior that is difficult for the primary care physician to understand. As a result, many physicians will just stop prescribing, which defeats our purpose. Our goal is overcoming the forces that lead to both underprescription and overprescription of opioids.

Sources of information on the use of opioids for chronic pain consist of about a dozen randomized controlled trials, several of which include open-label extension studies; a number of studies that focus on opioid side effects (cognitive and somatic symptoms, and outcomes related to addiction); survey studies of patients who have succeeded with long-term opioid therapy, but also survey studies of chronic pain patients who have done better after detoxification from opioids; and epidemiologic studies showing the increasing problem of prescription opioid abuse. Key issues, such as the phenomenon of tolerance, the incidence of iatrogenic addiction (a new case of addiction in a previously addiction-free patient), appropriate criteria for successful or failed opioid trials, and the proportion of patients who enjoy long-term benefit, have never been directly addressed.

Current Evidence

A few reasonable conclusions, however, can be drawn from the existing evidence base:

- Opioids can potentially benefit any type of pain.
- Most patients on opioids do not cause problems for themselves or their physicians, but a highly visible minority does.
- Only a minority of patients experience long-term benefit, but this benefit is vital for those patients and thus mandates liberal interpretation of opioid *trials*.
- Physicians have to judge, partly with patient input, whether an opioid trial is successful. In any opioid trial, an exit strategy is vital so that both provider and patient should agree (before treatment begins) as to when and how the trial is to terminate.
- Most side effects can be proactively and successfully managed.
- Iatrogenic addiction is uncommon, but does occur.
- Relapse or exacerbation of an addiction that may or may not be known to the physician may be more common than previously thought.
- Relying on the patient on opioid therapy as the only source of information on the patient's well-being is an inadequate and potentially harmful approach.
- Despite the complexity of monitoring, physicians must get used to incorporating outside information (eg, urine toxicology screens, prescription monitoring program data) in assessing complications related to addiction. The monitoring can be learned and implemented by the primary care provider.
- High-risk patients (eg, psychiatric comorbidity, addiction risks, confusing pain syndrome) should be managed in a sophisticated setting.
- It is imperative that the benefits of a less conventional management program (eg, high-dose opioids in a high-risk patient with a poorly documented pain problem) be clear and well documented.
- Basic documentation is the best protection for a well-meaning physician against almost all regulatory scrutiny—help the regulators!
- There is insufficient information available on prescription opioid abuse to create rational regulatory approaches. The first goal of any such regulations, therefore, should be *primum non nocere* (first, do no harm) to our patients with chronic pain.

Conclusions

By keeping the above principles in mind, physicians can learn to prescribe opioids *more often* when they *should* be prescribed and *less often* when they *should not* be prescribed. Opioids are like all other medications: they provide meaningful benefit to a subgroup. The physician's tasks are to use whatever methods are available to distinguish responders from nonresponders and to maximize the number of responders in his or her practice while minimizing the nonresponders. By doing these things, therapeutic goals can be achieved more successfully.

Regulators should adhere to David Joranson's "principle of balance" (available at: http://www.medsch.wisc.edu/painpolicy/). Until more information is available to direct policy to limit prescription opioid abuse, policy approaches should ensure that access of pain patients to opioids is maintained. However, physicians must recognize and share responsibility for the potentially devastating problems of prescription opioid abuse and engage in a partnership with regulators to address this issue.

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B276-002	Thursday, May 6	6:00 PM	7:00 PM	8:00 PM	9:00 PM	Michael H. Moskowitz, MD, MPH
B276-003	Monday, May 10	6:00 PM	7:00 PM	8:00 PM	9:00 PM	Veronica D. Mitchell, MD, PhD
B276-004	Tuesday, May 11	9:00 AM	10:00 AM	11:00 AM	12 :00 PM	Bruce D. Nicholson, MD
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B276-006	Monday, May 24	9:00 AM	10:00 AM	11:00 AM	12:00 PM	Michael H. Moskowitz, MD, MPH
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