The Journal of Pain, Vol 10, No 10 (October), 2009: pp 1051-1057
Available online at www.sciencedirect.com

Opioid Prescribing Practices in Chronic Pain Management: Guidelines Do Not Sufficiently Influence Clinical Practice

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Abstract: **To examine the use of extended-release (ER) opioids relative to immediate-release (IR) opioids in chronic opioid prescription episodes, pharmacy claim data from a national health plan database were analyzed. Enrollees having at least 1 pharmacy claim for an opioid formulation between June 2003 and May 2006, and at least 1 year of continuous enrollment after their first observed pharmacy claim were included. Opioid prescription episodes were created by combining contiguous days of therapy, allowing for a maximum of 7 days between refills (≥8 d = new episode). Outcomes are reported in the form of probabilities and odds ratios (ORs). A total of 3,993,011 opioid prescription episodes were derived from 1,967,898 enrollees. Overall, prescription episodes involving IR preparations (97.7%) were more prevalent than episodes using ER preparations (2.3%). The odds of an ER preparation being prescribed chronically (≥60 d) were approximately 11 times that of an IR preparation (OR = 10.7); however, the majority of chronic prescription episodes used IR formulations (84.8%). When stratified by prescriber type (specialist vs nonspecialists), the probability of a specialist prescribing ER opioids in these chronic prescription episodes was 19.1% versus 13.7% for nonspecialists. Specialists were about 50% more likely to prescribe ER opioids relative to nonspecialists (OR = 1.49).**
Perspective: ***This analysis suggests that the availability of pain-treatment guidelines, recommendations, and education alone may not be enough to influence opioid-prescribing practices in the treatment of chronic pain.***

Key words: *Pain-management specialists, nonspecialists, treatment guidelines, opioids.*

Chronic pain affects approximately 48 million Americans (24% of the population).[1] Chronic pain remains poorly managed in the entire population and in subpopulations, including patients with lower back pain, osteoarthritis, cancer, and pain at the end of life.[1,10,17,19] A 2005 insurance-claims analysis found that patients with painful conditions had 3-fold higher total healthcare costs compared with other patients, although medication costs accounted for <20% of total costs.[24]

Effective pain management remains challenging because pain pathophysiology is complex and because pain may continue, owing to multiple underlying mechanisms, beyond the expected time of healing. Furthering the complexity, there is also an affective component of pain because patients with chronic pain may become depressed, anxious, or need to deal with alterations in daily life or with the approach of death.[3,26] Multifaceted pain management incorporates nonpharmacologic approaches (ie, physical or cognitive-behavioral therapy) and pharmacotherapy for both the pain and psychological sequelae.[5] Opioids have become a cornerstone of pharmacotherapy for chronic cancer pain and are increasingly accepted for use in chronic noncancer pain because of data demonstrating their efficacy, general tolerability,[11] and low cost vs other interventions.

Incorporation of evidence-based medicine into pain-management guidelines aids the decision-making process in patient care. The available guidelines focus on patient-specific factors and generally recommend the least-intensive therapy, which provides effective analgesia with acceptable tolerability. Nonopioid medications (eg, nonsteroidal anti-inflammatory drugs [NSAIDs]) are often considered first for patients with mild to moderate pain without significant risk for cardiovascular, gastric, or hepatic adverse events. For many patients with chronic pain, an opioid trial, dosed to achieve a balance between adequate analgesia and acceptable tolerability, is recommended as either an add-on to current nonopioid medication when additional analgesia is required or alone when use of an NSAID is contraindicated. In

Received September 10, 2008; Revised March 24, 2009; Accepted March 25, 2009.
Supported by Endo Pharmaceuticals Inc., Chadds Ford, PA.
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1526-5900/$36.00

doi:10.1016/j.jpain.2009.03.019

patients treated chronically, extended-release (ER) opioids that allow for twice-daily, or even once-daily, dosing are proposed to present advantages over immediate-release (IR) opioids that must be administered 4 or more times daily. Over the past decade, guidelines have indicated that fewer daily doses likely promote improved patient adherence and may produce more consistent plasma concentrations and better tolerability.[3,6,9,18,22] Moreover, ER opioids can provide consistent around-the-clock analgesia with fewer interruptions of sleep compared with IR formulations that may require nighttime administration to maintain adequate pain relief.[22] The most recent guidelines (2009) of the American Pain Society and American Academy of Pain Medicine state that there is insufficient evidence to recommend a preference of ER over IR opioids for chronic noncancer pain.[8] One distinction of these new guidelines is that they are limited to chronic noncancer pain, and cite a lack of evidence concerning the use of IR vs ER opioids for the management of noncancer pain. However, there has been little documentation of the extent to which clinicians adhered to the earlier guidelines in the pain-specialty literature which recommend ER opioids for the treatment of chronic pain.

Previous analyses conducted with patient data, primarily derived from the late 1990s, suggested that clinicians were routinely prescribing IR opioids for extended periods for patients with chronic pain.[15,21,25] For example, for more than 10,000 nursing home residents with persistent noncancer pain who were receiving analgesics, IR opioids were prescribed to 18.9% and ER opioids to 3.3% of the residents, despite the observation that patients treated with ER opioids reported improved functional and psychosocial status vs patients receiving IR formulations.[25]

As noted, available studies of prescribing practices were largely based on decade-old data. Historically, a variety of factors have limited ER opioid use, such as few available ER opioids and the absence of guidelines recommending their use beyond cancer pain. Currently, it is not clear whether prescribing practices have been influenced by the introduction of additional ER formulations or by guidelines and increased education on opioid use for chronic pain. The current analysis examines recent prescribing of ER and IR opioids to patients for either <60 days or ≥60 days (ie, those without or with chronic pain) and compares the prescribing practices of specialists vs nonspecialists. Portions of this work were presented at the 2008 Annual Meeting of the American Pain Society.[4]

Methods

Data for this analysis were derived from a national health plan database comprising data on more than 39 million insured lives. The study population included health plan enrollees with at least 1 pharmacy prescription for an IR opioid, ER opioid, or combination opioid analgesic between June 2003 and May 2006. To be eligible for the analysis, enrollees had to have at least 1 year of continuous enrollment since their initial opioid pharmacy claim.

Patients who received an opioid prescription during the analysis period were included, and an opioid-prescription episode was calculated for each patient. The length of each opioid prescription was defined as beginning on the prescription date and extending to the imputed end of the prescription based on the number of tablets dispensed and the dosing instructions. Opioid-prescription episodes were created by combining consecutive prescriptions for the same opioid formulation (ER or IR) with ≤7 days between prescriptions. If another prescription for the same opioid formulation was filled for a patient ≤7 days after the imputed end of the preceding prescription, the 2 prescriptions were combined as 1 opioid-prescription episode. If ≥8 days passed from the imputed end of the prescription and the date of the next prescription, a new prescription episode was defined. If a patient switched between an IR and an ER drug, a new prescription episode was defined. If a patient switched between 2 ER opioid drugs (eg, Kadian to OPANA® ER) within the 7-day window, the data were analyzed as a single prescription episode (in this case, as an ER episode).

Patient prescription episodes were defined only by the physician speciality (specialist or nonspecialist) of the physician who prescribed the opioid without regard to any specialized training or certificates (eg, a primary-care doctor who acted as a pain specialist was categorized as a nonspecialist). If a patient consulted with a physician but was not prescribed an opioid, no data would be present to determine an opioid-prescription episode.

Chronic-prescription episodes were defined as any opioid-prescription episode lasting ≥60 days. During the development of our analytical methodology, we compared data with the definition of chronic at ≥60 vs ≥90 days and found no difference except for the last decile. Because there was no difference in the overall inference, ≥60 days was chosen to increase the sample size and thus, the precision of the analysis. Only the results derived from defining chronic as ≥60 days are presented. We acknowledge that ≥90 days may be a more frequently cited definition of chronic pain.[2]

Opioids were classified as ER or IR, with combination therapies that contain both an opioid and nonopioid included in the IR category. Methadone was also included in the IR category based on formulation and not based on duration of action, which is acknowledged as being of greater duration. Prescribing patterns for ER and IR opioids for all prescription episodes and for the subset of episodes lasting ≥60 days were quantified.

The prescribing behavior of specialists vs nonspecialists was compared with respect to all prescription episodes and the subset of episodes lasting ≥60 days. Specialists were defined as physicians specializing in areas that frequently involve pain management, including neurologists, anesthesiologists, rheumatologists, nurse anesthetists, orthopedists, and other specialists in physical medicine and rehabilitation. The data did not indicate whether the prescribers defined as specialists by our criteria were in fact practicing as pain specialists or had fellowship training in pain management. Odds ratios (OR) for prescribing an ER opioid rather than an IR opioid were calculated using logistic regression models.