American Pain Society
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PUBLISHED BY ELSEVIER

The Journal of Pain, Vol 12, No 6 (June), 2011: pp 652-666
Available online at www.sciencedirect.com

Trajectories of Pain and Analgesics in Oncology Outpatients With Metastatic Bone Pain During Participation in a Psychoeducational Intervention Study to Improve Pain Management

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Abstract: A large number of oncology patients with bone metastasis report significant and often unrelieved pain that is associated with reduced quality of life and impaired functional status. Our research team previously assessed the efficacy of a tailored self-care psychoeducational intervention to improve pain management in these patients. Samplewide analyses demonstrated improvements in pain intensity and analgesic prescriptions. However, substantial interindividual variability was observed within the intervention group. In the current paper, hierarchical linear modeling (HLM) was used to determine factors that contributed to variability in pain intensity and analgesic prescription and intake in the sample of patients who participated in the intervention. Specifically, HLM analyses identified demographic, clinical, and psychological characteristics that predicted variation in pain intensity and analgesic prescription and intake at baseline (intercepts) and over the course of the 6-week study (trajectories). Awareness of these predictors may be particularly useful for the identification of patients who would benefit most from this type of intervention. Furthermore, these findings highlight specific aspects of the intervention that may be modified in order to further improve pain management in these patients.

***Perspective:** This paper describes the application of HLM to explain interindividual variability in pain and analgesic outcomes among oncology outpatients with metastatic bone pain who participated in a psychoeducational intervention to improve pain management. Findings identify particularly responsive subgroups, areas for improvement to the intervention, and targets for future intervention.*

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***Key words:** Oncology, pain management, psychoeducational intervention, hierarchical linear modeling, interindividual variability.*

Although pain can arise from a number of etiologies, bone metastasis is the most common cause of cancer pain.[5,21] The majority of these patients report moderate-to-severe pain that has deleterious effects on quality of life (QOL) and functional status.[5,9,29,35] This pain is particularly distressing and a biopsychosocial approach to pain management that incorporates both pharmacologic and nonpharmacologic treatments is the foundation of clinical practice guidelines.[9,22] International guidelines advise that effective pharmacologic management of cancer pain generally requires administration of around-the-clock analgesics in combination with more potent analgesics for breakthrough pain.[11,22,34] Despite evidence that adherence to published guidelines typically results in significant pain relief,[30] oncology patients frequently report persistent, unrelieved pain.[36] This undertreatment of pain may exist for several reasons. At the provider level, deficiencies

Received August 20, 2010; Revised November 27, 2010; Accepted December 8, 2010.
Supported by a grant (CA 64734) from the National Cancer Institute. Additional support for the corresponding author's program of research was provided through unrestricted grants from Janssen Pharmaceutica and Purdue Pharma LP.
The authors declare no potential conflicts of interest.
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1526-5900/$36.00
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doi:10.1016/j.jpain.2010.12.003

may exist in comprehensive pain assessment, collaborative design and implementation of individualized multidimensional treatment plans, as well as adequate follow-up. At the patient level, difficulties may exist with the communication of pain severity and its impact on function. Moreover, attitudinal barriers, such as fear of addiction, stoicism, or lack of knowledge about how to use and titrate different types of analgesic medications, may impede communication and interfere with adherence to analgesic regimens.

In an effort to improve pain management in these patients, our research group tested a self-care psychoeducational intervention, called the PRO-SELF© Pain Control Program,[33] which aimed to improve patients' communication with their providers as well as their knowledge of pain management and analgesic use. The program was tailored to address individual knowledge deficits, and outcome measures such as pain intensity ratings and analgesic prescriptions were assessed. Results of this randomized clinical trial (RCT) indicated a significant increase in pain and analgesic knowledge,[14] a reduction in average and worst pain ratings, as well as a significant increase in the appropriate analgesic prescription in the intervention group, relative to the standard care group.[24] However, substantial individual variability was observed in this sample, which prompted the use of a responder analysis to identify differences in QOL and functional status[23] among patients in the intervention arm of the study. Of note, only half of the patients in the intervention group were classified as responders, using the criterion of a $\geq$30% reduction in pain intensity ratings, which suggests that the intervention was successful in improving pain management for only a particular subgroup of patients. Although efforts were made to identify demographic and clinical characteristics associated with subgroup membership (none were found), these analyses did not assess how such characteristics predicted individual trajectories in pain and analgesic outcomes over the course of the 6-week intervention.

Thus, the primary goal of this analysis was to use a more sophisticated statistical approach (ie, hierarchical linear modeling [HLM]) in an effort to explain the interindividual variability observed among the patients who participated in the PRO-SELF© intervention for pain management. Specifically, HLM was used to determine how pain intensity ratings (average and worst), as well as analgesic prescription and intake (ie, Medication Quantification Scale scores; MQS prescribed and MQS taken,[19] respectively) changed over the course of the intervention. Importantly, HLM allows for the identification of variables (eg, demographic and clinical characteristics) that predict variability in baseline values (intercepts) and trajectories of pain intensity and analgesic prescription and intake. Such findings may provide insight into which subgroups of patients may benefit most from such an intervention, and importantly, may highlight weaknesses in the intervention that can be addressed in future studies and/or clinical practice in order to yield clinically meaningful improvements in pain management for a greater proportion of oncology patients.

Methods

Sample and Settings

This descriptive, longitudinal study was part of a RCT that evaluated the effects of a psychoeducational intervention for cancer pain management.[24] For the purposes of this paper, the analyses were limited to patients in the intervention arm of the study, in an effort to identify individual characteristics that uniquely predicted the trajectories of pain and analgesic outcomes in these patients. All 97 oncology outpatients were experiencing pain from bone metastasis. Patients were recruited from 7 outpatient settings in Northern California: a university-based cancer center, 2 community based oncology practices, 1 health maintenance organization, 1 outpatient radiation therapy center, 1 veteran's affairs facility, and 1 military hospital. All participants were adult oncology outpatients (>18years) who were able to read, write, and understand English. All had Karnofsky Performance Status (KPS) scores[13] of $\geq$50, average pain intensity scores of $\geq$2.5, and radiographic evidence of bone metastasis. The study was approved by the Human Subjects Committee at the University of California San Francisco, and at each of the study sites. All patients signed a written informed consent.

Procedure

Detailed study procedures are described elsewhere.[33] Briefly, patients were approached in the outpatient setting by a recruitment nurse who explained the study and obtained written informed consent. Patients were randomly assigned to either the standard care or intervention group. At the time of enrollment, patients completed a demographic questionnaire, the KPS, as well as the Brief Pain Inventory (BPI),[6] the Profile of Mood States (POMS[2,20]), the Medical Outcomes Study Short-Form (SF-36[31,32]) and a disease specific measure of QOL.[7] In addition, 1 week prior to the first study visit, patients rated their level of pain intensity on a daily basis.

As a measure of the adequacy of pharmacologic pain management at baseline, Pain Management Index (PMI) scores were calculated at the beginning of the study. The PMI is a method of quantifying and evaluating the adequacy of pharmacologic pain treatment. It is used to calculate a score between -2 and $+2$ based on a patient's worst pain rating and the most potent analgesic prescribed. In general, negative scores denote inadequate treatment, while positive scores conservatively indicate adequate pain treatment.[4]

At the beginning and end of the study, the patients' medical records were reviewed for disease and treatment information. Also, at these time points, patients completed the Pain Experience Scale (PES)[8] that consists of 9 (10 mm) visual analog scales that evaluated knowledge about pain and its management (ie, addiction, physical dependence, frequency and scheduling of analgesic intake, and side effects of opioid analgesics) and 4 scales that evaluated various aspects of pain perception. Items that assessed pain perception included current pain, satisfaction with pain relief, and 2 items that assessed pain-related distress (ie, how upsetting the pain was to

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