Individualized Patient Education and Coaching to Improve Pain Control Among Cancer Outpatients

By Jennifer Wright Oliver, Richard L. Kravitz, Sherrie H. Kaplan, and Frederick J. Meyers

Purpose: **An estimated 42% of cancer patients suffer from poorly controlled pain, in part because of patient-related barriers to pain control. The objective of this study was to evaluate the effect of an individualized education and coaching intervention on pain outcomes and pain-related knowledge among outpatients with cancer-related pain.**

Patients and Methods: **English-speaking cancer patients (18 to 75 years old) with moderate pain over the past 2 weeks were randomly assigned to the experimental (n = 34) or control group (n = 33). Experimental patients received a 20-minute individualized education and coaching session to increase knowledge of pain self-management, to redress personal misconceptions about pain treatment, and to rehearse an individually scripted patient-physician dialog about pain control. The control group received standardized instruction on controlling pain. Data on average pain, functional impairment as a result of pain, pain frequency, and pain-related knowledge were collected at enrollment and 2-week follow-up.**

Results: **At baseline, there were no significant differences between experimental and control groups in terms of average pain, functional impairment as a result of pain, pain frequency, or pain-related knowledge. At follow-up, average pain severity improved significantly more among experimental group patients than among control patients (*P* = .014). The intervention had no statistically significant impact on functional impairment as a result of pain, pain frequency, or pain-related knowledge.**

Conclusion: **Compared with provision of standard educational materials and counseling, a brief individualized education and coaching intervention for outpatients with cancer-related pain was associated with improvement in average pain levels. Larger studies are needed to validate these effects and elucidate their mechanisms.**

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DESPITE THE availability of highly effective therapies for pain, recent research suggests that uncontrolled cancer pain remains highly prevalent. An estimated 90% of patients with cancer experience at least moderate pain at some point in their illness, and 42% of patients do not receive adequate palliation.[1] Aside from its deleterious effects on quality of life, uncontrolled pain can contribute to depression, increase the likelihood of suicide, and decrease patient acceptance of potentially beneficial cytoreductive therapy.[2] Fear of unrelieved pain is so strong that 69% of cancer patients reported that they would consider suicide if their pain reached unacceptable levels.[3] In one pain clinic, physicians noted that many patients who were considering suicide changed their minds once pain control was achieved.[4]

Barriers to effective pain control have been identified at the level of the health care system, the physician, and the patient.[5,6] Health care systems and organizations may discourage effective pain control by over-regulating analgesic use and giving low priority to palliative care. Health care professionals may lack training or confidence in cancer pain assessment and management.[7] Patients themselves, although presumably highly motivated to obtain adequate pain relief, are sometimes reluctant to discuss their pain with their physicians and may have misconceptions about addiction and tolerance.[8]

Efforts to improve the current state of cancer pain treatment have attempted to address barriers at all three levels. Legislative efforts to legalize certain scheduled narcotics and the evolving hospice movement are examples of interventions targeted at the system level. At the provider level, conventional continuing medical education in the form of conferences, symposia, single notices, and one-time practice audits seem to offer little.[9] Tutorials by pharmacists and consultations by pain management teams both seem promising, but these interventions are cumbersome, expensive, and best suited to the inpatient setting within large cancer centers.[10] Patients are an attractive target for interventions because they stand to gain the most from effective

From the Department of Medicine and Center for Health Services Research in Primary Care, University of California, Davis, CA; and Primary Care Outcomes Research Institute, New England Medical Center, Boston, MA.

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Address reprint requests to Richard L. Kravitz, MD, MSPH, Professor and Director, University of California Davis Center for Health Services Research in Primary Care, 4150 V St, PSSB Suite 2500, Sacramento, CA 95817; email: rlkravitz@ucdavis.edu.

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pain management and because they may be effective change agents in altering physician behavior.

In studies of patients with a variety of chronic illnesses, randomized trials of interventions designed to expand the patient's role in treatment decisions have been shown to improve both physiologic and functional outcomes.[11,12,13] In addition, physicians with a naturally more participatory style (ie, those who involve patients in treatment decisions) have been shown to provide better interpersonal care and greater patient loyalty and continuity.[14] The mechanism through which these interventions affect health status is not known. In the field of pain management, multiple empirical studies have shown that a sense of control over the pain management process itself (eg, administration of medications) has been associated with lessened experience of pain, less utilization of health care services, and faster recovery after surgical procedures.[15,16,17] It is at least plausible that an increased sense of control over the process of medical care reduces anxiety and allows patients to plan, prepare, and adopt a sensible course of action for pain management. This explanation is consistent with social learning theory[18] and its more recent derivative, mastery theory.[19 20] In addition, perceived self-efficacy to reduce pain may itself have an analgesic effect, which is mediated by both opioid and nonopioid mechanisms.[21]

Based on this conceptual understanding, we developed an intervention aimed at cancer-related pain and designed a randomized controlled trial to test its effectiveness. The intervention was designed both to teach patients practical pain management techniques and to empower patients to participate actively in their own care.

PATIENTS AND METHODS

Overview

The study was designed as a randomized controlled trial. Patients at two oncology clinics were screened for cancer-related pain. Eligible patients completed baseline telephone assessments, were randomly assigned to the experimental or control group, and received individualized education and coaching (experimental intervention) or a standard educational session (control intervention) right before their scheduled oncology visit. Outcomes were assessed with a telephone interview 2 weeks later. The project was approved by the University of California, Davis (UCD) Institutional Review Board and the Northern California Kaiser Institutional Review Board.

Patients and Settings

The study was conducted at the UCD Cancer Center, a university-based tertiary care center, and at Kaiser Permanente, Sacramento, CA, a group model health maintenance organization. A total of eight oncologists participated, four at each site. Participating physicians were aware of study and its general aims but had no knowledge of which specific patients were enrolled, nor to which study arm they were assigned.

English-speaking patients between 18 and 75 who had a diagnosis of cancer, experienced at least a moderate level of pain (as indicated by a baseline Verbal Analog Scale average pain score of 30 (of 100) or greater over the previous 2 weeks), and had no scheduled major surgical procedures during the follow-up interval were eligible for the study. We excluded patients enrolled in hospice as well as those under the care of the Pain Management Service because such patients would already have access to aggressive pain management services and would, therefore, be less likely to benefit from the intervention.

Patient Enrollment and Follow-Up

Both participating clinics provided study staff with patient appointment lists each week. From these lists, potential study patients were selected if they were between 18 and 75 and had been seen at the clinic within the previous 2 months (indicating active disease). These potential subjects received an informational letter describing the study about a week before their appointment. One to 2 days before the appointment, a student assistant phoned the patients to recruit them for the study. During this baseline phone call, eligible patients who consented to participate completed the baseline questionnaire. The process of screening and baseline telephone assessment took approximately 45 minutes. Two weeks after the index visit, a student assistant blinded to group assignment phoned participants to administer the follow-up questionnaire, which took about 25 minutes to complete.

Intervention

Patients in the experimental group participated in an individualized education and coaching session designed to redress misconceptions about pain treatment and to encourage dialog about pain control with their oncologist. The session lasted approximately 20 minutes and consisted of five components: review of the patient's baseline questionnaire, education about misconceptions identified in the questionnaire, explanation of the World Health Organization pain control guidelines, identification of treatment goals, and development of strategies to meet these goals.

Before the appointment, one of two Health Educators (HEs) (a masters level psychology student and a fourth-year medical student) reviewed the pain-related knowledge section of the patient's baseline questionnaire to identify important misconceptions. Six potential misconceptions were addressed, including concerns about addiction, beliefs that pain medications simply cannot control pain, fears of being viewed as a bad patient, concerns that treating pain could distract the physician from treating the cancer, incorrect knowledge of how to take analgesics, and the assumption that analgesic side effects cannot be controlled and are worse than the pain. After greeting the patient in the waiting room, the HE led him or her to a private area and discussed pertinent misconceptions, explained why the statements were not true, and presented the correct information. Instruction was supplemented by reference to a specially prepared 11-page booklet. The booklet refuted common pain management misconceptions and provided information on cancer pain treatments, guidelines for discussing pain with the physician, space to write down pain control goals and questions, and a set of pain control algorithms. The algorithms were based on World Health Organization guidelines for cancer pain treatment[22] and emphasized: (1) identification of the type of pain; (2) quantification of pain severity; and (3) application of appropriate self-management strategies (including use of analgesic medications).

The coaching aspect of the intervention involved having the patient first identify treatment goals, such as "I want to be able to sleep through the night without being awakened by pain." The HE asked the patient

Table 1. Description of Study Instruments

Scale	No. of Items	Purpose	Cronbach's Alpha	Source
Average pain	1	Measure effect of intervention	–	Jensen et al[24] DeLoach et al[25]
Impairment due to pain	6	Measure effect of intervention	0.80	Sherbourne[26]
Pain frequency	1	Measure effect of intervention	–	Sherbourne[26]
Pain-related knowledge	6	Measure effect of intervention and gather information for intervention	0.70	Ward[6] American Pain Society[27]

to formulate questions to ask the doctor that would help the patient achieve the goal, such as "What pain medication can I take that will last through the night?" Finally, the HE discussed techniques on how to talk to the doctor about pain and negotiate a satisfactory pain treatment plan; she also provided supervised practice in question-asking.

Control patients received standardized instruction from the HE. They met with the HE for approximately the same length of time as intervention patients. However, instead of individualized education and coaching, patients in the control group received standard education on controlling cancer pain, following the outline of a pamphlet produced by the Agency for Healthcare Policy and Research (now the Agency for Healthcare Research and Quality).[23]

Measures

At baseline and again at follow-up, we collected information on patients' average pain, impairment due to pain, pain frequency, and pain-related knowledge. Baseline data were used to establish a standard against which pain-related outcomes at follow-up could be assessed. In addition, for patients randomized to the intervention group, baseline data were used to individualize the content of the education and coaching intervention. A summary of key measures is provided in Table 1.

Average pain was assessed with a previously validated single-item scale.[24,25] "On a scale of 0-10, with 0 being no pain and 10 being the worst pain imaginable, how would you rate your average level of pain over the past 2 weeks?" Impairment caused by pain was measured using the six-item pain effects subscale of the Medical Outcomes Study Patient Assessment Questionnaire (MOS-PAQ).[26] This scale had high internal consistency (alpha = 0.80). Pain frequency was measured with a single item drawn from the MOS-PAQ ("During the past 2 weeks, how often have you had pain or discomfort: 1 = once or twice—5 = every day or almost every day.") All pain measures were converted to a 0 to 100 scale, with higher scores representing greater pain. Pain-related knowledge was assessed using a six-item scale adapted from the American Pain Society Guidelines for the Treatment of Pain Patient Outcome questionnaire (alpha in the current study, 0.70).[27]

To assess the success of randomization and to facilitate subsequent statistical adjustment, we collected additional patient information via the baseline survey and by chart review. Age, sex, living status, ethnicity, and education were queried in standard fashion. Adherence to analgesic therapy was assessed with a single item ("Over the past 2 weeks did you take all of the medication that your doctor prescribed to treat your pain: 1 = yes, 2 = no, 3 = no medications prescribed.") Generic health status was assessed with the MOS standard form (SF)-12 physical and mental health component scores, which have demonstrated reliability and validity for assessing differences in functional status and well-being among groups of patients.[28] Disease status (no evidence disease, local/regional disease, or advanced disease), treatment status (starting active chemotherapy or radiotherapy, continuing therapy, or not on therapy), and current analgesic therapy (nonopioid, codeine/oxycodone/oxymorphone, morphine or equivalent, or fentanyl patch) were ascertained retrospectively using medical records and computerized pharmacy logs, which were available for 78% of patients.

Response Rates

One thousand seventy-three patients were screened by telephone for eligibility in the study. Of these, 718 were ineligible (most commonly due to lack of sufficient pain). Among the remaining patients (n = 355), 177 refused to answer screening questions and an additional 91 asked that enrollment be deferred to a later time (but were not ultimately enrolled). The remaining 87 patients gave preliminary informed consent, completed baseline surveys, and were randomly assigned to the intervention or control group using sealed, opaque envelopes. Randomization was conducted in blocks of 20 to assure roughly even distribution of patients among the two groups. Nine patients did not attend or arrived late for their appointments, for a final enrollment of 78.

Compared with those who did not enroll (n = 277), those enrolling in the study (n = 78) were slightly more likely to be female than male (64% *v* 56%, respectively). Of the 78 patients entering the study, 67 completed the protocol (completion rate, 87%). Of the 11 patients who failed to complete the study (five in the experimental group and six in the control group), two refused to complete follow-up, one entered hospice, one was referred to the pain clinic, one had emergency surgery during the follow-up period, one died, one asked to withdraw, and the remainder could not be reached for follow-up.

Statistical Analysis

Baseline demographic and clinical characteristics of the control and experimental subjects were compared using unpaired *t* tests for continuous data and χ^2 tests for categorical data. Changes from baseline to follow-up in average pain, pain impairment, pain frequency, and pain-related knowledge were assessed within each study group using paired *t* tests. Differences in change scores between control and experimental groups were assessed using unpaired *t* tests. Change scores are reported in both absolute terms and in units of effect of size (mean pre-post difference divided by the pooled SD of the difference).[29]

The independent effect of group assignment on average pain at follow-up was examined using multiple linear regression analysis. Three models were constructed based on preliminary bivariate analysis and the a priori hypothesis that pain at follow-up would be influenced by pain at baseline, clinical factors such as disease severity and treatment, and social factors that could influence the perception or reporting of pain. Because of the relatively small number of eligible

subjects, it was not possible to balance these factors in the trial design, as has been recommended.[30] In small trials, posthoc adjustment for covariates carries a cost in terms of precision. Nevertheless, we report these adjusted analyses as a conservative window on the effects of the intervention. Model I (the parsimonious model) examined average pain at follow-up controlling only for baseline average pain. Model II (the clinical model) adjusted for baseline average pain plus selected clinical factors likely to influence pain levels (tumor type, active receipt of cytoreductive therapy, and current use of opioid analgesics). In Model III (the clinical and social model), we introduced two covariates (age and education) that could affect patients' coping strategies and/or learning styles. Both age and education have been shown to influence learning styles among adults.[31]

Models using change scores as the dependent variable, models adjusting for missing chart-based information (using indicator variables where 1 = data present and 0 = data absent), and models that incorporated first order interactions between clinical variables and experimental group assignment all gave substantially similar results, which are therefore not reported. All *P* values are two-tailed, with 0.05 set as the level of significance. Analyses were conducted using Stata (Version 6.0; Stata Corporation, College Station, TX).[32]

RESULTS

The final panel included 67 patients, with 33 patients in the control group and 34 patients in the experimental group. Overall, the mean age of participants was 55 years, over 60% were women, and two thirds had completed at least some college. As would be expected for a population with advanced cancer, mean physical functioning was poor (MOS SF-12 Physical Component Score = 28 on a 100-point scale, compared with 38 in a national sample of patients with congestive heart failure and 44 in a sample with Type II diabetes).[26] There were no significant differences between control and experimental group patients in terms of any of the demographic or clinical variables studied; however, there were some substantial (nonsignificant) imbalances in assignment along the lines of education, tumor type, and treatment status (Table 2).

Table 2. Baseline Demographic and Clinical Characteristics of Control and Experimental Subjects*

	% of Patients	
	Control (n = 33)	Experimental (n = 34)
Age, years		
Mean	54.8	55.8
SD	12.8	12.5
Female	63.6	64.7
Lives alone	18.2	17.6
Nonwhite	21.2	23.5
Some college education	57.6	76.5
UCD Cancer Center	69.7	70.6
Leukemia or lymphoma, *v* solid tumor	6.1	20.6
Disease status		
No evidence disease	7.7	0.0
Local/regional	26.9	25.0
Advanced	65.4	75.0
Treatment status		
No cytoreductive therapy†	25.0	53.6
Beginning therapy	20.8	10.7
Continuing therapy	54.2	35.7
MOS SF-12 Physical Component Score, 0-100 scale		
Mean	29.1	26.1
SD	8.0	8.5
MOS SF-12 Mental Health Component Score, 0-100 scale		
Mean	44.6	43.9
SD	9.6	9.4

*None of the differences were statistically significant at $P < .05$.
†Chemotherapy or radiotherapy.

Table 3 lists the baseline pain experiences of the two groups. There were no significant baseline differences in average pain, functional impairment caused by pain, pain frequency, or pain-related knowledge. Among patients for whom baseline prescribing information was available, 84% of controls and 96% of experimental group patients were on opioid analgesics (World Health Organization Step 2 or 3) (data not listed in Table). Only one patient (experimental group) was on a fentanyl patch. The proportion of patients reporting that they were taking "all medications prescribed to treat pain" was similar in the intervention and control groups (38% *v* 30%, respectively; $P = .63$).

The results of the pain outcomes and pain-related knowledge comparisons are shown in Fig 1. At follow-up, patients in the experimental group experienced statistically significant (pre-post) improvements in average pain, pain-related impairment, and pain frequency ($P < .05$), whereas control group patients did not. However, the difference in change scores (intervention change *v* control change) was significant only for average pain ($P = .014$, Fig 1). Both groups achieved similar (and statistically significant) gains in pain-related knowledge. There were no significant differences in the proportion of patients demonstrating improvement in adherence to analgesic therapy (seven patients improved in the experimental group, and nine improved in the control group; $P = .52$) (data not shown).

Using multiple linear regression to control for pain at baseline, assignment to the experimental intervention was associated with a 9-point difference (on a 100-point scale) in average pain favoring the intervention at follow-up ($P < .05$, Table 4). This estimate was not substantially affected by adjusting for clinical covariates (beta coefficient = −8.25 points, $P < .05$, Table 3). After further adjustment for social factors (age and education), the estimated benefit

Table 3. Baseline Pain and Pain-Related Knowledge*

	Control (n = 33)		Experimental (n = 34)	
	Mean	SD	Mean	SD
Baseline average pain, 0-100 scale	51.8	15.5	53.2	18.0
Impairment due to pain, 0-100 scale	62.2	18.6	64.3	17.6
Pain frequency, 0-100 scale	91.7	19.4	93.4	16.6
Pain-related knowledge, % correct	66.8	17.7	65.6	17.7

*Higher scores indicate more pain and greater knowledge. Control *v* experimental group differences were not statistically significant.

declined to 6.26 points and was not statistically significant ($P = .084$).

DISCUSSION

This small randomized trial provides preliminary evidence that a carefully structured, one-time individualized education and coaching intervention has the potential to provide important clinical benefits for patients suffering from cancer-related pain. Within the intervention group, observed reductions in average pain, pain-related impairment, and pain frequency averaged about one half of a SD, a moderate effect size.[29] However, because control group patients also experienced improvements in pain control (averaging about one fourth of a SD), the difference in change scores was significant only for average pain. Nevertheless, the consistency of the findings across all three primary outcome measures supports the potential effectiveness of the intervention, underscores its promise, and most importantly, emphasizes the need for further rigorous testing in larger studies.

The mechanism by which the intervention affected patients' experiences of pain is uncertain. The benefit was not attained solely by increasing patient knowledge of cancer pain or its management, because both intervention and control patients experienced similar knowledge gains. There is likewise no evidence that the improvement was mediated by better adherence to analgesic therapy, although our adherence measure was crude, and important differences could have been missed. One plausible hypothesis is that the intervention helped patients to interact effectively with their physicians, negotiate mutually acceptable treatment plans, and attain a greater sense of self-efficacy. In other contexts, patient activation has improved outcomes by directly altering the medical care process, inducing positive self-care behaviors, and producing psychologic response-shifts (changes in perceptions of health status).[11,12,15,17,33] Such response shifts could affect perceptions of pain, tendency to attend to pain, or propensity to report pain. Additional research, emphasizing measurement of patients' psychologic states and direct observation of the patient-physician interaction, is needed to clarify these issues.

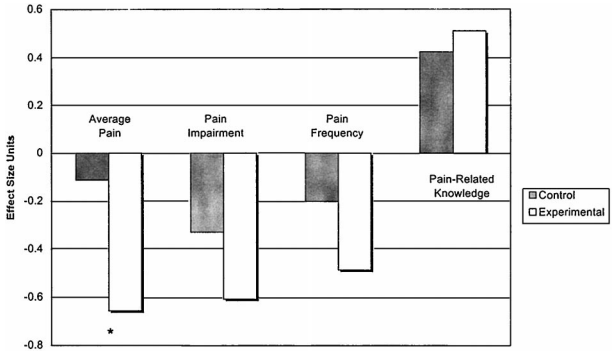

Fig 1. Effect-size differences for pain-related outcomes by treatment group. Effect sizes are expressed as the mean change for each group (control *v* experimental) divided by the pooled SD of the pre-post differences. *Statistically significant difference in change scores, P = .014.

Although this study was a randomized controlled trial, the results must be interpreted in light of several limitations. First, the sample size was small. Our results are promising but not definitive; larger trials are warranted. Second, although the investigators were unaware of patients' group assignment, patients could not be blinded to the intervention they received. To defend against possible response bias, we provided the control group with a placebo (a patient education intervention) instead of usual care. This design may have limited our ability to detect the full benefits of the intervention but was needed to distinguish between the effects of patient coaching and nonspecific attention (ie, a Hawthorne effect). Third, the majority of data were self-reported, and we did not include the physician's perspective on medication prescribing and adequacy of pain control. Fourth, the study was of relatively short duration; a more intensive intervention administered over several visits might have produced a larger treatment effect, whereas repeated measures over a longer follow-up interval would have allowed us to assess stability of the effect. Investigators seeking to confirm or extend these findings should consider the following: (1) targeting the intervention to meet the specific learning needs of various populations; (2) reinforcing the previsit intervention through telephone or in-person follow-up, perhaps coordinated with home nursing; and (3) assessing outcomes over a longer period of time. Finally, the low participation rate limits generalizability of the findings. Many patients were simply uninterested in participating, most commonly because they had little pain but sometimes because of illness or fatigue. Such patients might not be good candidates for interventions such as ours that demand sustained personal effort.

As the field of palliative care expands, efforts to improve control of cancer-related pain will continue to be an essential element of oncologic care. This preliminary study demonstrates that a brief patient-centered intervention may

Table 4. Independent Effect of Group Assignment on Average Pain at Follow-Up Using Multiple Linear Regression

Characteristic	Unadjusted		Clinical Model		Clinical and Social Model	
	Coefficient	95% CI	Coefficient	95% CI	Coefficient	95% CI
Experimental group, *v* control	−8.96	−16.0-−1.89*	−8.25	−15.7-−0.76*	−6.26	−13.4-0.87
Baseline average pain	0.72	0.50-0.93‡	0.70	0.48-0.92‡	0.67	0.46-0.88‡
Solid tumor, *v* lymphoma/leukemia			4.40	−6.6-15.4	7.56	−3.0-18.1
Receiving cytoreductive therapy			0.51	−6.9-7.9	−0.99	−8.1-6.1
Receiving opioid analgesics at baseline			1.88	−5.4-9.1	1.06	−5.8-7.9
Age					−0.37	−.65-−0.09†
Completed at least some college					−7.11	−14.6-−0.40*
Model adjusted R^2	0.42		0.40		0.48	

Abbreviation: CI, confidence interval.
*$P \leq .05$
†$P \leq .01$
‡$P \leq .001$

improve pain control among cancer outpatients. However, many questions remain. There is a continuing need to refine and evaluate approaches to pain management and determinehow such interventions can be incorporated into the comprehensive treatment of cancer pain.

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