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Side Effects From Oral Opioids in Older Adults During the First Week of Treatment for Acute Musculoskeletal Pain

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Abstract

Objectives—The authors sought to describe the frequency of short-term side effects experienced by older adults initiating treatment with opioid-containing analgesics for acute musculoskeletal pain.

Methods—This was a cross-sectional study of individuals age 65 years or older initiating analgesic treatment following emergency department (ED) visits for acute musculoskeletal pain. Patients were called by phone 4 to 7 days after their ED visits to assess the intensity of six common opioid-related side effects using a 0 to 10 scale and to assess medication discontinuation due to side effects. Propensity score matching was used to compare side effects among patients initiating treatment with any opioid-containing analgesics to side effects among those initiating treatment with only nonopioids.

Results—Of 104 older patients initiating analgesic treatment following ED visits for musculoskeletal pain, 71 patients took opioid-containing analgesics, 15 took acetaminophen, and 18 took ibuprofen. Among the patients who took opioids, at least one side effect of moderate or severe intensity (score ≥ 4) was reported by 62%. Among patients with matching propensity scores, those taking opioids were more likely to have had moderate or severe side effects than those taking only nonopioids (62%, 95% confidence interval [CI] = 48% to 74% vs. 4%, 95% CI = 1% to 20%) and were also more likely to have discontinued treatment due to side effects (16%, 95% CI = 8% to 29% vs. 0%, 95% CI = 0% to 13%). The most common side effects due to opioids were tiredness, nausea, and constipation.

Conclusions—Among older adults initiating treatment with opioid-containing analgesics for musculoskeletal pain, side effects were common and sometimes resulted in medication discontinuation.

Among adults age 65 years and older, acute pain results in approximately 4 million U.S. emergency department (ED) visits each year.[1] For older adults with acute pain, the initial treatment period may be particularly important both to reduce suffering and because the effective initial management of pain has been associated with lower rates of persistent pain and improved long-term function.[2] Despite the importance of pain management and the

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presence of guidelines for the management of persistent pain in older adults,[3] older ED patients are less likely to receive pain medication than younger patients.[1,4]

Patient and provider concerns about side effects or adverse events are common reasons why older adults are less likely than younger patients to receive analgesics.[5] However, knowledge of side effects and adverse events from opioids in older adults comes largely from studies of serious adverse events occurring in patients on long-term therapy.[6,7] The results of these studies have limited relevance for emergency care providers managing older adults with acute painful conditions. To provide appropriate advice and treatment for these patients, more information regarding outcomes after short-term treatment is needed. The purpose of this study was to describe the frequency and intensity of common side effects in older adults during the first week of treatment with opioid containing-analgesics and to compare these to side effects for patients initiating treatment with only nonopioid analgesics.

METHODS

Study Design

We conducted a cross-sectional study of analgesic side effects after ED visits by older patients with acute musculoskeletal pain. The study was approved by the University of North Carolina Chapel Hill institutional review board with waivers allowing for review of patient medical records to identify eligible patients and for contacting patients by phone to request verbal consent.

Study Setting and Population

Consecutive eligible patients were identified by daily review of ED electronic medical records. Initial eligibility criteria included age 65 years or older, an initial triage pain score of 4 or more on a 0 to 10 scale, and a discharge diagnosis consistent with acute musculoskeletal pain. The study site was a single academic ED serving a large and diverse population of older adults. At the time of phone contact, verbal informed consent was requested from eligible patients for permission to complete the phone interview and to access the patients' medical records.

Study Protocol

Acute musculoskeletal pain was broadly defined to include noninjury musculoskeletal pain as well as injuries including fractures, contusions, and sprains with onset in the past 7 days. Patients with headache, chest pain, or abdominal pain were excluded, as were patients with a history of dementia. Patients meeting initial eligibility criteria were called by phone 4 to 7 days after their ED visit, with at least three attempts made for each patient. Among patients reached by phone, additional exclusion criteria were assessed (Figure 1). Patients had to provide their own responses; participant representatives were not accepted.

Interviews were conducted by research assistants using a structured questionnaire. Each research assistant received training and completed a mock telephone call prior to conducting interviews. Research assistants were not medical providers; patients who had medical questions during the interview were asked to call the hospital help phone number. The analgesic taken was defined as the medication the patient reported having taken since the ED visit at the time of the phone interview, regardless of whether this medication had been prescribed or recommended by the emergency provider. Analgesics were categorized as opioid-containing or strictly nonopioid, the latter including both acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs). Thus, a patient who took a medication that included both an opioid and acetaminophen was categorized as taking an opioid. We did not

assess the dose or duration of treatment. Level of formal education was obtained from the patient during the interview.

Age, sex, race, whether pain was due to injury, ED pain scores, and comorbidities were extracted from the medical record using a standardized template with explicit definitions of variables. ED pain scores were recorded in the medical record by an ED nurse, usually the triage nurse. The Charlson comorbidity score was calculated to provide an overall measure of comorbid illness burden for each patient.[8] Data from interviews and extracted data were entered into a database with validation of numeric values.

Outcome measures assessed during the phone interview included the intensity of six side effects reported to be associated with opioid use in recent review articles: tiredness, nausea, constipation, vomiting, dizziness, and unsteadiness.[9,10] Side effect intensity was rated by the patient using a 0 to 10 numeric rating scale. The validity of this scale for assessing side effects has previously been described.[11] Side effect intensity was then categorized in the following manner: 0 = no intensity; 1 to 3 = mild intensity; 4 to 6 = moderate intensity; and 7 to 10 = severe intensity. We also used an a priori categorization of side effects into none or mild intensity versus moderate or severe intensity (score ≥ 4) to compare the frequency of clinically significant side effects between the two treatment groups.[12] For patients initiating treatment with both an opioid-containing analgesic and a nonopioid, we only analyzed side effects attributed to the opioid-containing analgesic. Further, patients were asked if they had discontinued their anal-gesic due to any side effect. This question was not restricted to the above six aforementioned side effects. Change in pain was calculated for each patient as the difference between the initial pain score recorded at triage and the follow-up pain score reported during the phone interview, 4 to 7 days after the ED visit.

Data Analysis

Descriptive statistics (mean, standard deviation [SD], proportions) are reported for enrolled patients versus patients who met initial eligibility criteria but were not enrolled. We also report descriptive statistics for the baseline characteristics of the study sample by type of analgesic taken (any opioid-containing medication vs. only nonopioid medications).

Because patients taking opioid-containing and only nonopioid analgesics may differ in their likelihood of experiencing side effects, we used propensity score matching to identify similar patients from the two groups. Propensity scores for the probability of receiving an opioid-containing versus only nonopioid analgesic were estimated with multivariable logistic regression using variables previously shown to influence the prevalence of side effects[13,14] or which might influence the amount of analgesic taken[15]: age, sex, race, education, comorbidity score, injury versus noninjury, and ED pain score. We did not allow for higher-order terms in the logistic regression used to estimate propensity scores. Propensity scores were estimated using PROC LOGISTIC with SAS, version 9.2 (SAS Institute, Inc., Cary, NC).

Propensity scores were used to match patients in the two treatment groups using an optimization protocol. The steps involved in the optimization protocol were: 1) rank each case based on the number of possible controls that have a propensity score of no more than ±0.1 of the propensity score of the case (i.e., a maximum radius of 0.1); 2) starting with the case with the fewest number of matching controls, randomly select up to two controls that meet the ±0.1 criteria; 3) remove the matched controls from the pool of eligible controls for subsequent matching; 4) find the case with the next fewest number of matches and again identify up to two randomly selected controls with a propensity score within ±0.1 of the case; and 5) proceed in identifying matching controls and removing them from the eligible

pool until all cases have been matched. Matching was performed using the SAS macro *psmatch_multi*.

Frequencies of characteristics used for propensity score calculation are presented by analgesic taken for the entire sample and among propensity score–matched patients. For the entire study sample and the subset of patients with matched propensity scores, outcomes for the two treatment groups are compared using the chi-square test or, where appropriate, Fisher's exact test. Changes in pain scores are compared using a t test. Statistical analyses were conducted using SAS, version 9.2 (SAS Institute, Inc.).

RESULTS

Between March 2011 and March 2012, a total of 393 patients met the initial eligibility criteria based on review of ED medical records. Of those reached by phone (n = 222), 82 (37%) were excluded based on additional information (Figure 1). Of the remaining 140 eligible patients, 36 (26%) declined participation. Enrolled patients were similar to eligible but nonenrolled patients in regard to mean ± SD age (73 ± 7 years vs. 74 ± 8 years), mean ± SD ED pain scores (7.7 ± 2.1 vs. 7.6 ± 2.0), proportion female (58% vs. 66%), and proportion for whom opioids were prescribed or recommended (68% vs. 62%). The final study sample contained 104 patients of whom 71 reported initiating treatment with opioid-containing analgesics and 33 reported initiating treatment with nonopioid analgesics. Opioid-containing analgesics taken by patients included hydrocodone/acetaminophen (n = 26), oxycodone/acetaminophen (n = 20), oxycodone (n = 20), tramadol (n = 2), or another opioid (n = 3). Among patients prescribed opioids or combinations of opioid and acetaminophen, only seven received separate prescriptions or recommendations for acetaminophen. Nonopioid anal-gesics taken by patients included acetaminophen (n = 15) and ibuprofen (n = 18). Among the 104 patients in the study sample, 16% were diagnosed with fractures. The most common locations for pain were the lower extremity (34%), back (19%), and upper extremity (19%).

In comparison to patients taking only nonopioids, those initiating treatment with any opioid-containing analgesics were younger ($p = 0.003$), had less formal education ($p < 0.001$), and less often reported experiencing injuries ($p = 0.03$; Table 1). Propensity score matching identified 50 patients taking opioid-containing analgesics and 25 patients taking nonopioid analgesics and improved covariate balance. Among matched patients, only the proportion of patients in each group completing college remained significantly different ($p = 0.03$). The mean ± SD number of days elapsed between the ED visit and the interview was similar in patients taking opioid and nonopioid analgesics for the entire sample (5.1 ± 1.0 vs. 5.4 ± 1.2) and for propensity score–matched patients (5.1 ± 0.8 vs. 5.5 ± 1.2).

Among all patients initiating treatment with opioids, commonly reported side effects of moderate or severe intensity were reported at the following frequencies: tiredness 30%, nausea 20%, constipation 20%, dizziness 17%, unsteadiness 13%, and vomiting 13% (Table 2). For those taking nonopioids, moderate or severe intensities of these side effects were only reported for nausea (6%) and vomiting (6%). Among patients initiating treatment with opioid-containing analgesics, 62% (95% confidence interval [CI] = 50% to 72%) reported a score of 4 or more (i.e., moderate or severe symptoms) for one or more of the six side effects. For the entire sample and for matched patients, side effects of moderate or severe intensity were more common among patients taking opioids than were side effects among patients only taking nonopioids (Table 3). Among propensity score–matched patients, medication discontinuation occurred more often in patients taking opioid-containing analgesics than in those taking only nonopioids. Mean decreases in pain scores from the ED

visit to the follow-up phone call were similar for patients taking any opioids versus those taking only nonopioid analgesics.

Among the entire sample (*n* = 104), 46 (44%) reported pain scores of 4 or more during phone call follow-up, and two patients taking opioid-containing analgesics and one patient taking a nonopioid revisited the ED during the first week. The mean (±SD) pain score during the follow-up phone calls for the 12 patients who discontinued their analgesic medications due to side effects was 6.3 (±3.2) versus 4.5 (±3.0) for patients who did not discontinue their analgesics due to side effects (p = 0.05).

DISCUSSION

This study assessed the frequency of side effects from opioid-containing and nonopioid analgesics among older adults during the first week of treatment following ED visits for acute musculoskeletal pain. We observed that more than half of older adults taking opioid-containing analgesics reported experiencing one or more side effects of moderate or severe intensity in the first week, and side effects led to medication discontinuation for 16% of patients. These rates were significantly higher than those of matched patients initiating treatment with only nonopioids. Moderate or severe pain 4 to 7 days after the ED visit was reported in approximately half of all patients and was also common in those patients who discontinued their analgesics due to side effects. These findings suggest that side effects pose a problem for a substantial proportion of older adults initiating treatment with opioid-containing analgesics.

Patients in the study sample who took opioids were different from those who took only nonopioids in three ways: they had higher ED pain scores, were more likely to have noninjury complaints, and had less formal education than those taking nonopioids. Higher rates of opioid use among patients with less formal education has previously been described in an ED population,[16] but this relationship has not been previously reported in older adults. Possible explanations include higher levels of pain and distress among less educated individuals or educated patients declining opioids due to greater concerns about side effects, adverse events, or addiction.

Our estimates of the frequency of side effects due to opioids are higher than those previously reported for chronic noncancer pain in adults of all ages, for which risk differences between opioids and placebo are estimated at 14% for nausea, 9% for constipation, and 6% for tiredness.[10] Higher rates of side effects from opioids in older adults may reflect slower drug metabolism,[17] reduced lean body mass,[18] or a higher proportion of patients with subclinical symptoms at baseline.

Although maximizing treatment with acetaminophen prior to initiating an opioid is recommended for the treatment of moderate or severe pain in older adults,[3] few patients in the study sample initiating treatment with opioids were simultaneously prescribed or recommended to take acetaminophen as first-line therapy. Additionally, none of the patients in our study received extended-release opioid formulations, which may be associated with reduced adverse events compared to standard preparations.[7] Anticipatory guidance regarding common side effects and provision of medication to prevent or treat these side effects may be helpful.[19] For patients who have some previous experience with opioids, a shared decision-making approach in the selection of analgesics based on the patients' prior experiences might reduce side effects and improve pain treatment.[20]

In our sample, reductions in pain scores were similar for patients taking any opioid versus only nonopioids. Because of the heterogeneity of the etiology of pain in the study sample,

and the limitations in the methods used to characterize and control for this heterogeneity or the amount of analgesic taken, we do not think that this finding can be interpreted as evidence of equivalent analgesic efficacy for opioids versus nonopioids. Evidence that opioids and nonopioids have similar short-term analgesic efficacy includes findings from a recent meta-analysis of randomized trials.[21] Because of safety concerns regarding NSAID use in older adults,[22–24] even short-term NSAID treatment must be approached with caution in this population.

In our study, enrolled patients were similar to nonenrolled patients meeting initial eligibility criteria. Patterns of analgesic use in our sample are similar to those reported for older adults using nationally representative data.[1] These findings suggest that our findings may be generalized to older ED patients initiating outpatient analgesic treatment for acute musculoskeletal pain.

LIMITATIONS

The six side effects that we assessed were selected because they are commonly reported side effects of opioid analgesics. We did not ask specifically about abdominal pain or shortness of breath, each of which might be more likely to occur in older adults taking NSAIDs. Thus, our estimate of the frequency of side effects in patients taking only nonopioid analgesics may be low. However, our assessment of whether a patient discontinued the analgesic due to a side effect was not restricted to these six side effects. The substantially higher discontinuation rates by patients taking opioids suggest that the observed difference in side effects is not simply an artifact of the side effects we chose. Because opioids have distinct central nervous system effects, patients may be more likely to attribute side effects to opioids than to nonopioids, which might result in increased reporting of side effects due to opioids. We did not examine outcomes for patients taking acetaminophen and NSAIDs separately, and we did not differentiate by type of opioid, a distinction that may be important.[25]

The sample size is small, resulting in broad CIs around estimates of the frequencies of the outcomes. The study was not designed or powered to examine the frequency of uncommon but potentially life-threatening medication-related adverse events such as falls,[26] respiratory depression,[15] upper gastrointestinal bleeding,[22] or acute kidney injury.[24] The occurrence of these less common but more serious events may be as or more important in guiding treatment decisions as the side effects reported here.

We used propensity scores to identify patients in each group who were similar in regard to potential confounders. Propensity scores are probably the optimal method for controlling for confounders in an observational study with a small sample and the presence of multiple confounders.[27] Nonetheless, education remained imbalanced after propensity score matching, and residual confounding from unmeasured covariates might also account for some of the difference in the frequency of side effects for patients taking opioids versus nonopioids. For example, older adults who work or are highly active may be less likely to take opioids and may also be less susceptible to side effects. Neither employment nor physical activity was assessed in this study.

We excluded patients who reported already taking analgesics at the time of their ED evaluations to avoid prevalent user bias.[28] However, we did not assess for lifetime exposure to analgesics, and prior analgesic exposure may have influenced medication selection. To the extent that this occurred, our estimates of the frequency of side effects for older adults initiating treatment with opioids may be lower than that for drug-naive older adults.

Our study sample encompasses a broad range of pathologies, which introduces a large amount of disease-specific variability in the duration of pain symptoms. Trajectories of pain symptoms likely influence the duration and dosage of medication use and hence indirectly influence the likelihood of side effects. A study of patients with a particular injury etiology (e.g., motor vehicle collision) or pain region (e.g., back pain) might have less variability in the chronicity of pain symptoms and improved internal validity for comparisons of both side effects and changes in pain symptoms.

CONCLUSIONS

Older adults initiating treatment with opioid-containing analgesics for musculoskeletal pain were more likely to report side effects and discontinue their analgesics compared to those taking only nonopioid analgesics. Further research is needed to determine whether compliance with guidelines for pain management in older adults, use of adjunctive medications to prevent or treat side effects, or nonpharmacologic therapy can improve outcomes for older adults discharged from the ED following visits for acute musculoskeletal pain.

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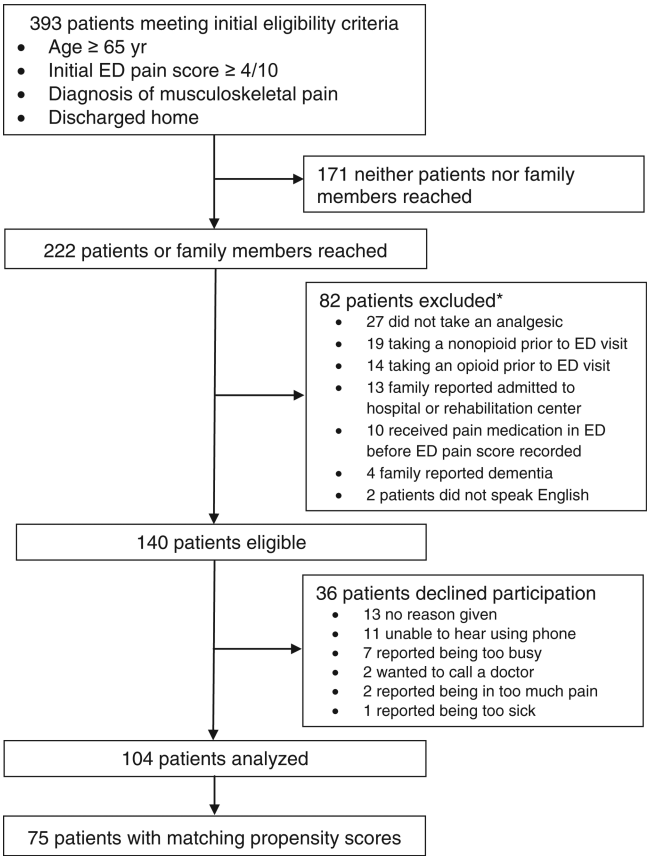

Figure 1.
Flow diagram of patient enrollment. *Not mutually exclusive.

Table 1

Characteristics of Patients Based on Analgesic Taken, for All Patients (*n* = 104) and Among Patients With Matched Propensity Scores (*n* = 75)

	All Patients		Matched Propensity Scores	
Characteristic	**Any Opioid (*n* = 71)**	**Only Nonopioid (*n* = 33)**	**Any Opioid (*n* = 50)**	**Only Nonopioid (*n* = 25)**
Age, yr	72 (±7)	76 (±7)	74 (±7)	76 (±7)
Female	44 (62)	22 (67)	33 (66)	19 (76)
White	39 (55)	21 (64)	26 (52)	15 (60)
College education or higher	15 (21)	18 (55)	13 (26)	13 (52)
Charlson comorbidity score	1.3 (±1.8)	1.2 (±1.6)	1.2 (±1.3)	1.3 (±1.6)
Injury	36 (51)	24 (73)	30 (60)	16 (64)
Initial pain score	8.0 (±2.1)	7.2 (±2.0)	7.6 (±2.3)	7.3 (±2.1)

Data are reported as mean (±SD) or n (%)

Table 2

Side Effect Intensity Reported by Medication Class (*n* = 103)

	Side Effect Intensity,% (95% CI)			
	None (0)	**Mild (1-3)**	**Moderate (4 -6)**	**Severe (7-10)**
NSAID (*n* = 33)				
Any side effect	88 (73-95)	6 (2-20)	3 (1 -15)	3 (1 -15)
Tired	100 (90-100)	0 (0-10)	0 (0-10)	0 (0-10)
Nausea	91 (76-97)	3 (1 -15)	3 (1 -15)	3 (1 -15)
Vomiting	94 (80-98)	0 (0-10)	3 (0-15)	3 (1 -15)
Dizziness	100 (90-100)	0 (0-10)	0 (0-10)	0 (0-10)
Unsteadiness	100 (90-100)	0 (0-10)	0 (0-10)	0 (0-10)
Constipation	97 (85-100)	3 (0-15)	0 (0-10)	0 (0-10)
Only opioid analgesic (*n* = 70)				
Any side effect	33 (23-45)	6 (2-14)	23 (15-34)	39 (28-50)
Tired	70 (59-90)	0 (0-5)	13 (7-23)	17 (10-28)
Nausea	74 (63-83)	6 (2-14)	11 (5-22)	9 (4-18)
Vomiting	86 (76-92)	1 (0-8)	7 (3-16)	6 (2-14)
Dizziness	80 (69-88)	3 (1 -10)	10 (5-19)	7 (3-16)
Unsteadiness	86 (76-92)	1 (0-8)	9 (4-18)	4 (2-12)
Constipation	79 (68-87)	1 (0-8)	10 (5-19)	10 (5-19)

NSAID = nonsteroidal anti-inflammatory drug.

Table 3

Outcomes One Week After ED Visits for Musculoskeletal Pain for Older Adults Taking Opioid-containing Versus Nonopioid Analgesics, for All Patients (*n* = 104) and for Patients With Matched Propensity Scores (*n* = 75)

Outcome	Any Opioid	Only Nonopioid	Risk Difference	p-value*
Side effect present†				
All patients	62 (50 to 72)	6 (2 to 20)	55 (42 to 70)	<0.001
Matched propensity scores	62 (48 to 74)	4 (0 to 20)	58 (43 to 73)	<0.001
Discontinued due to side effect				
All patients	14 (8 to 24)	6 (2 to 20)	8 (-4 to 20)	0.23
Matched propensity scores	16 (8 to 29)	0 (0 to 13)	16 (6 to 26)	0.03
Change in pain				
All patients	3.1 (3.3)	2.8 (3.1)	—	0.65
Matched propensity scores	2.6 (3.4)	2.9 (2.8)	—	0.72

Data are reported as% (95% CI) or mean (SD).

*Calculated using Fisher's exact test for difference of proportions and t-test for difference in means.

†Defined as a score of 4 or more on a 0 to 10 scale for any of the six side effects assessed.