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Concomitant Opioid and Laxative Use by Older Adults in Hospice Care in the United States, 2007

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Abstract

OBJECTIVES: To examine laxative use by individuals in hospice who were taking opioids during the last week of life.

DESIGN: Retrospective cross-sectional.

SETTING: 2007 National Home and Hospice Care Survey.

PARTICIPANTS: Individuals in hospice aged 65 and older who were taking opioids during the last week of life (N=2,825).

MEASUREMENTS: Hospice staff were asked the names of all medications and drugs that participants were taking 7 days before and on the day of death while in hospice, including any standing, routine, or as-needed medications.” Medications “used” included medications taken and as-needed medications provided in case a symptom developed. Opioids included all opioid-combination drugs. Laxatives included fibers, lubricants, stimulants, and suppositories.

RESULTS: Forty-one percent of participants had cancer as the primary hospice diagnosis, 13% heart disease, 12% debility, 11% dementia, 8% lung disease, and 15% other. Overall, 52% of opioid users used a laxative in the last week of life; the proportions of opioid and laxative users did not differ according to diagnosis. Racial minorities taking opioids had lower odds than white participants (odds ratio (OR)=0.57, 95% confidence interval (CI)=0.33–0.99) of using laxatives. Participants taking opioids enrolled in hospice for 7 days or less had lower odds of using laxatives than those enrolled for more than 7 days (OR=0.65, 95% CI=0.37–0.95), as did those in hospice inpatient, hospital, or other settings (OR=0.45, 95% CI=0.43–0.93) than those in long-term care settings. Participants using five or fewer medications had lower odds of using laxatives as

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compared to those using six to 10 (OR=6.01, 95% CI=3.88–9.32) or 11 to 25 medications (OR=13.80, 95% CI=8.74–21.80).

CONCLUSION: In 2007, slightly more than half of older adults in hospice who were taking opioids used laxatives during the last week of life. Recent quality indicators from the Centers for Medicare and Medicaid Services recommend laxative treatment when opioid therapy is initiated to prevent opioid-induced constipation and are intended to improve laxative use in individuals in hospice treated with opioids.

Keywords

opioids; laxatives; constipation; hospice; medications

Approximately 92% of all individuals in hospice take opioid analgesics for treatment of moderate-to-severe pain during the last week of life.^{1,2} Side effects of opioid analgesics include nausea, vomiting, sedation, confusion, and respiratory depression.³ Opioid-induced constipation is arguably one of the most common, persistent, and intolerable side effects that individuals undergoing opioid therapy experience.⁴ Suboptimal management of constipation can lead to severe adverse complications, including intestinal obstruction and perforation and life-threatening fecal impaction.⁵ For individuals near the end of life for whom the goal of care is optimizing quality of life, opioid-induced constipation is a significant clinical problem.

Opioid-induced constipation often occurs with an individual's first dose of an opioid. Constipation generally persists for the duration of the opioid therapy because individuals do not develop a tolerance for it.⁶ Prophylactic and symptomatic treatment of opioid-induced constipation are the most-effective approach to its management.⁷ Clinical guidelines on pain management, including those from the World Health Organization⁸ and other national organizations,^{9–13} recommend that treatment of constipation with laxatives, unless contraindicated, should start prophylactically when opioid therapy is initiated. Furthermore, recent policy changes are requiring hospice organizations to report quality indicators or face payment reductions. The Centers for Medicare and Medicaid Services adopted hospice quality-reporting measures including the Hospice Item Set, which the National Quality Forum endorsed, stipulating that, if an individual is treated with an opioid, a bowel regimen should be offered or prescribed; if not, documentation such as clinical contraindication or refusal should be provided.¹⁴

Few empirical studies have examined specific use of laxatives in hospice or palliative medicine, and to the knowledge of the authors of the current study, none have studied this topic at the national level.^{10,15,16} This study analyzed the latest available nationally representative data to examine the prevalence of use and factors associated with laxative use in older adults in hospice who were taking opioids during the last week of life. Findings from this national study will serve as a comparison for future examinations of concomitant use of opioids and laxatives, an important quality of care measure in individuals near the end of life.

METHODS

Data Source and Sample

This study used data from the 2007 National Home and Hospice Care Survey (NHHCS) conducted by the National Center for Health Statistics.¹⁷ The survey used a two-stage probability sampling design; the agencies were sampled first according to location and facility characteristics, and individuals within each agency were sampled second. The final sample included 1,545 agencies (representing approximately 11,000 agencies nationally), with 1,036 completed survey interviews (71% unweighted response rate). Of the completed interviews, 695 were from hospice agencies that were identified as hospice only (provided only hospice care) or a mixed agency that provided hospice and home health care. Up to 10 discharged individuals in hospice (deceased or alive) were sampled from each hospice-only agency, and a combination of up to 10 discharged individuals in hospice and individuals currently receiving home health were selected from mixed agencies.

This study was restricted to individuals in hospice aged 65 and older who used an opioid or opioid-combination drug during the last week of life and were discharged deceased from hospice care within 3 months before the survey interview date. In all, 2,825 individuals in hospice met the eligibility criteria for this analysis.

The NHHCS collected data on hospice agency characteristics, staffing information, and individual characteristics.¹⁷ Trained survey interviewers who met in person with hospice agency staff who had access to medical and administrative records to answer the survey questions obtained survey data. Data were obtained using a computer-assisted personal interviewing instrument.

Measures

Opioids and Laxatives—To record medications that individuals in hospice used, hospice staff were asked names of all medications and drugs the individual was taking 7 days before and on the day of his or her death while in hospice care, including any standing, routine, or as needed medications. The names of up to 25 medications, including vitamins and homeopathic remedies, were entered. An analytical variable on the count of medications used was created based on the frequency distribution (0–5, 6–10, 10–25). Based on the wording of the question, the term “medications used” was interpreted as medications that were actually taken and as-needed medications that were made available in case a symptom developed.

Medications, including opioids and laxatives, were assigned therapeutic classification codes using a modified version of the Multum Drug Classification Database System.¹⁸ Opioids included all opioid-combination drugs. Although some authorities in palliative and hospice medicine recommend that bulk laxatives should not be used in individuals receiving opioids, the Hospice Item Set, the list of quality of care indicators that the Centers for Medicare and Medicaid Services currently uses, does not specify the type of laxatives to be used—just that one should be ordered scheduled or as needed. For this study, laxatives included bulk laxatives such as psyllium and dietary fiber, lubricant laxatives such as mineral oil, detergent

laxatives such as stool softeners, saline laxatives such as milk of magnesia, stimulants such as senna, and suppositories.

Individual and Agency Characteristics—Individual characteristics included age at death, sex, race, primary hospice diagnosis at admission, number of days in hospice care, and setting of care. Numbers of comorbidities and of medications were calculated based on the sum of recorded diagnoses and medications, respectively. The counts were categorized based on their frequency distribution.

Agency characteristics included type of hospice agency, ownership, chain affiliation, number of individuals that agency currently served, metropolitan statistical area status, and census region. Most agency characteristics were collected from hospice staff, and metropolitan statistical area status and census region were determined based on agency address.

Statistical Analysis

Univariate analyses were performed to describe the individual and agency characteristics of the sample. To avoid oversaturating the final multivariate logistic regression model, two preliminary multivariate models were developed; Model 1 included all individual characteristics, and Model 2 included all agency characteristics. Only characteristics with $p < .10$ in the preliminary models were entered into the final combined individual–agency model. $P < .05$ in the final model was considered statistically significant.

Analyses were performed using SAS-callable SUDAAN (SAS Institute, Inc., Cary, NC) to take into account the complex survey design and appropriate design variables to compute correct standard errors. Sample weights were applied to provide national estimates. Estimates based on fewer than 30 sampled cases are not reported, and estimates with a relative standard error of 30% or more are considered unreliable, as are estimates based on 30 to 59 cases regardless of relative standard error.¹⁷

RESULTS

The study sample ($N=2,825$) represented approximately 648,600 hospice decedents nationwide who used opioids during the last week of life. Of hospice decedents who used opioids during the last week of life, 52.5% (representing approximately 340,180) used laxatives concomitantly. Of the study sample, 43.7% were aged 85 and older, 55.7% were female, and 92.5% were white (Table 1). Cancer accounted for the largest group of hospice discharges (40.9%), followed by heart disease (12.8%), debility (12.0%), dementia (11.1%), and lung disease (8.5%). Of the sample, 60.4% were in hospice for 8 or more days, and 45.3% received care in a private home at the time of death. Similar proportions of the sample had three or fewer comorbidities (57.3%) and used 10 or fewer medications (58.8%). The sample received care from agencies that were hospice only (65.9%), not for profit (72.0%), not chain affiliated (75.1%), and located in a metropolitan area (87.5%) (Table 2).

Preliminary multivariate regression with only individual characteristics (Model 1, Table 1) found that race and number of medications used were statistically significant at $p < .05$, and number of days enrolled in hospice and setting of care had a p -value $< .10$. The preliminary

multivariate regression with only facility characteristics (Model 2) showed that metropolitan statistical area status had a p-value <.10. These characteristics were entered into the final multivariate regression model combining individual and agency characteristics.

The final individual–agency combined model (individual characteristics shown in Table 1 and agency characteristics shown in Table 2) shows that individuals taking opioids who were black or of other races had lower odds than whites (OR = 0.57, 95% CI = 0.33–0.99) of using laxatives concomitantly. Having been enrolled in hospice for 7 or fewer days was associated with lower odds of using opioids and laxatives concomitantly (OR=0.65, 95% CI=0.37–0.95) than having been enrolled for more days, as did receiving hospice care in hospital, inpatient hospice, and other settings (OR=0.45, 95% CI=0.43–0.93) rather than in nursing homes and skilled nursing facilities. Using six to 10 medications (OR = 6.01, 95% CI = 3.88–9.32) or 11 to 25 medications (OR = 13.80, 95% CI = 8.74–21.80) was associated with higher odds of using concomitant opioids and laxatives than using five or fewer medications. Hospice decedents in micropolitan areas had lower odds of using opioids and laxatives than those in metropolitan areas (OR = 0.66, 95% CI = 0.44–0.98).

DISCUSSION

Clinical guidelines recommend that, unless contraindicated, treatment of constipation with laxatives should start prophylactically when opioid therapy is initiated.^{8–13} Recent policies that the Centers for Medicare and Medicaid Services have adopted are requiring hospice organizations to report quality-of-care measures including the Hospice Item Set, which incorporates an indicator on concomitant opioid and laxative use.¹⁴ If hospice agencies do not report or comply with these quality of care measures, they will face payment reductions.

To the knowledge of the authors of the current study, this is the first empirical study to examine concomitant opioid and laxative use in end-of-life care at the national level. Using the latest available, nationally representative survey data on hospice discharges, this study found that 52.5% of older adults in hospice taking opioids were using laxatives during the last week of life. These findings are consistent with prior smaller studies documenting that approximately 40% to 64% of individuals receiving palliative care are concomitantly prescribed a laxative and an opioid analgesic.^{15,19,20}

Previous studies have found that racial and ethnic minorities are significantly less likely to receive adequate pain management, including opioid analgesic use, than their white counterparts in a variety of healthcare settings.^{21–23} This study, with adequate sample size, adds evidence to the existing literature on racial and ethnic differences that, of older hospice decedents who were taking opioids, blacks and persons of other races had lower odds than whites of using concomitant laxatives during the last week of life.

Individuals enrolled in hospice for 8 or more days also had higher odds of using opioids and laxatives than those enrolled for fewer days. Individuals with longer hospice enrollment might have a greater length of time to develop more-severe constipation and therefore be given laxatives. Individuals receiving hospice care in nursing homes or skilled nursing facilities also had greater odds of using opioids and laxatives concomitantly than those

receiving care in inpatient facilities and other settings. Inpatient care might have focused on acute symptom management such as pain and secretions near the end of life, whereas prevention of constipation might have been prioritized less.

These findings indicate that, in individuals in hospice taking opioids, using more medications increased their odds of using concomitant laxatives during the last week of life. The odds of using concomitant laxatives was more than five times as great in individuals taking opioids who used six to 10 medications as in those using five or fewer medications and almost 13 times as great in those who used 11 to 25 medications. A previous national study found that the average number of medications used in the last week of life was 10.2, ranging from 9.5 in individuals with dementia to 11.4 in individuals with lung disease.² Taking a large number of medications in hospice presents challenges to hospice care providers, who need to find the balance between prescribing necessary medications to manage end-of-life symptoms effectively and minimizing the number of medications to avoid polypharmacy that may lead to adverse health outcomes and poor quality of end-of-life care.²⁴

There are limitations to this study. It was a cross-sectional, observational study. Although the models controlled for a number of confounding factors, the findings may reflect other unobserved factors. Causation should not be inferred. The 2007 NHHCS collected data on medications used only during the last week of life, rather than the entire hospice enrollment period. Clinical needs and medications that individuals in hospice use may fluctuate over the course of hospice enrollment. In the last days of life, when individuals may no longer be able to receive oral treatments, consciousness may diminish, or terminal delirium may develop, management of constipation may receive lower priority, and oral laxatives may be discontinued.¹² For individuals who have dysphagia, as-needed medications that can be administered rectally may be ordered for constipation as an alternative. Having more-detailed clinical information, including contraindications to laxatives and refusal to take laxatives, would have further informed the interpretation of these findings. Additionally, this study cannot discern whether medications “taken” represent those that were actually administered or simply provided as as-needed medications that were made available in the home in case the individual developed a symptom during the final dying process. Laxatives are known to be commonly prescribed on an as-needed basis for when constipation develops.⁷ Another limitation is that hospice staff who had access to medical and administrative data reported the medication data. Although survey items were asked uniformly across all sampled agencies, there might have been variations in how up to date hospice agencies kept their medication records. Over-the-counter medications and other supplements, especially those that individuals in home hospice use, might be undercounted if they were not documented in hospice records. Finally, information about on-site pharmacists may further inform these findings, but the 2007 HHCS did not capture information on these providers.

CONCLUSION

Ensuring proper use of medications in older adults, especially those receiving end-of-life care, is a recognized public health concern. The latest clinical guidelines and quality of

hospice care indicators that federal regulatory agencies have adopted recommend laxative treatment whenever opioid therapy is initiated, unless contraindicated, to prevent opioid-induced constipation. Using the latest available nationally representative data, this study found that in 2007 slightly more than half of older adults in hospice taking opioids during their last week of life were using concomitant laxatives. Factors associated with using opioids and laxatives concomitantly included race, number of days enrolled in hospice, setting of care, number of medications, and metropolitan statistical area. Findings from this national study serve as a comparison for future examinations of how concomitant use of opioids and laxatives may change over time and have implications for future actions toward improving the quality of care near the end of life. Furthermore, this study provides evidence to inform policymakers about the inclusion of the hospice quality-of-care measure on concomitant use of opioids and laxatives. As hospice agencies begin to publish this and other quality indicators reported to the Centers for Medicare and Medicaid Services in the coming years, hospices will have incentives to improve quality as it relates to this and other measures being monitored.

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Table 1. Study Sample Characteristics and Multivariate Logistic Regression of Participant Characteristics Associated with Concomitant Opioids and Laxatives Used by Older Adults in Hospice in the Last Week of Life

Characteristic	%	Model 1: Participant Only Odds Ratio (95% Confidence Interval)	Final Model: Participant and Agency Odds Ratio (95% Confidence Interval)
Participant characteristic			
Age at death			
65–74	19.4	1.06 (0.69–1.62)	
75–84	36.9	0.79 (0.55–1.14)	
85	43.7	1.00 (1.00–1.00)	
Sex			
Male	44.3	1.14 (0.81–1.60)	
Female	55.7	1.00 (1.00–1.00)	
Race			
White	92.5	1.00 (1.00–1.00)	1.00 (1.00–1.00)
Black and others	7.5	0.52 (0.30–0.88) ^b	0.57 (0.33–0.99) ^b
Primary hospice diagnosis			
Cancer	40.9	1.00 (1.00–1.00)	
Heart disease	12.8	0.66 (0.40–1.08)	
Debility	12.0	0.99 (0.58–1.67)	
Dementia	11.1	0.80 (0.48–1.34)	
Lung disease	8.5	0.54 (0.31–1.00)	
Others	14.7	0.94 (0.58–1.52)	
Days in hospice care			
7	39.6	0.60 (0.45–0.92) ^a	0.65 (0.37–0.95) ^b
8	60.4	1.00 (1.00–1.00)	1.00 (1.00–1.00)
Setting of care			
Private home	45.3	1.11 (0.95–1.56)	1.12 (0.97–1.40)
Hospital, inpatient hospice, other	23.8	0.40 (0.34–0.90) ^a	0.45 (0.43–0.93) ^b

Characteristic	%	Model 1: Participant Only	Final Model: Participant and Agency
Nursing home, skilled nursing facility	30.9	1.00 (1.00–1.00)	1.00 (1.00–1.00)
Number of comorbidities			
0–3	57.3	1.00 (1.00–1.00)	
4	42.7	1.06 (0.78–1.45)	
Number of medications			
0–5	25.6	1.00 (1.00–1.00)	1.00 (1.00–1.00)
6–10	33.2	5.21 (3.00–8.54) ^c	6.01 (3.88–9.32) ^c
11–25	41.2	12.91 (7.75–18.45) ^c	13.80 (8.74–21.80) ^c

The study sample (n=2,825) represented approximately 648,600 hospice decedents nationwide who were using opioids during the last week of life; 52.5% (n=1,413) were using laxatives concomitantly. Percentages are based on weighted data. Model 1 contains only participant characteristics. Final multivariate regression model included participant (Table 1) and agency (Table 2) characteristics.

^a p<.10

^b p<.05

^c p<.001.

Source: The 2007 National Home and Hospice Care Survey conducted by the National Center for Health Statistics.

Table 2. Study Sample Characteristics and Multivariate Logistic Regression of Agency Characteristics Associated with Concomitant Opioid and Laxative Use by Older Adults in Hospice in the Last Week of Life

Characteristic	%	Model 2: Agency Only Odds Ratio (95% Confidence Interval)	Final Model: Participant and Agency
Agency characteristic			
Hospice type			
Hospice only	65.9	0.97 (0.68–1.40)	
Hospice and home health care	34.1	1.00 (1.00–1.00)	
Ownership			
For profit	28.0	0.70 (0.37–1.34)	
Not for profit	72.0	1.00 (1.00–1.00)	
Chain affiliation			
Yes	24.9	1.34 (0.74–2.40)	
No	75.1	1.00 (1.00–1.00)	
Number of current patients			
0–20	31.9	1.11 (0.62–1.98)	
21–50	27.9	0.86 (0.54–1.38)	
51	40.2	1.00 (1.00–1.00)	
Metropolitan statistical area status			
Metropolitan	87.5	1.00 (1.00–1.00)	1.00 (1.00–1.00)
Microropolitan	9.0	0.81 (0.50–1.32) ^a	0.66 (0.44–0.98) ^b
Neither	3.5	0.90 (0.69–1.48)	0.75 (0.43–1.29)
Census region			
Northeast	17.5	0.97 (0.57–1.65)	
Midwest	26.6	0.94 (0.58–1.53)	
South	34.9	0.98(0.58–1.66)	
West	21.0	1.00 (1.00–1.00)	

The study sample (n=2,825) represented approximately 648,600 hospice decedents nationwide who were using opioids during the last week of life; 52.5% (n=1,413) were using laxatives concomitantly. Percentages are based on weighted data. Model 2 contains only agency characteristics. Final multivariate regression model included participant (Table 1) and agency (Table 2) characteristics.

Source: The 2007 National Home and Hospice Care Survey conducted by the National Center for Health Statistics.

^a $p < .10$
^b $p < .05$.

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