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Evaluation of Longitudinal Self-reported Sedation and Opioid-Induced Respiratory Depression or Overdose Risk in Patients with Cancer Receiving Outpatient Palliative Care

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Abstract

Purpose

Self-reported sedation is a distressing symptom impacting quality of life (QoL) in patients with cancer. Patients with cancer may also be at risk of experiencing opioid-induced respiratory depression (OIRD)/overdose. This study examined the association of longitudinal, self-reported sedation and OIRD/overdose risk in patients with cancer receiving outpatient palliative care.

Methods

At each visit, self-reported sedation scores and Commercially Insured health Plan Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (CIP-RIOSORD) predictive factors were collected. Data were separated between patients without (i.e., score ≤ 4) versus with (i.e., score ≥ 5) sedation and were analyzed via the Wilcoxon-Mann Whitney. Observed OIRD/overdose events were evaluated up to 6 months or patient expiration from 506 visits.

Results

At the first visit, patients without sedation and with sedation accounted for 66% (n = 172) and 34% (n = 90), respectively. For visits 1 (n = 262), 2 (n = 151), and 3 (n = 93), there was no difference in CIP-RIOSORD score between patients without or with sedation ($p > 0.05$). For visits 1 and 3, we observed weak or no associations ($r = -0.03$ to 0.12) between self-reported sedation and CIP-RIOSORD scores. At visit 2, a weak association was observed for patients without sedation ($r = 0.22$, $p \leq 0.05$). There were no observed OIRD/overdose events.

Conclusion

In patients with cancer receiving outpatient palliative care, we observed weak-to-no associations between longitudinal, self-reported sedation and prediction of OIRD/overdose risk.

INTRODUCTION

Self-reported sedation (i.e., drowsiness) is a symptom causing discomfort and suffering. Contributing factors are multifactorial, including, but not limited to, disease progression, comorbidities, psychosocial factors, and concurrent medication use. In patients with cancer, one review across 16 studies (n = 11,634) reported sedation with a prevalence of 20% [1]. In general, oversedation may impact other physical symptoms and quality of life (QoL), leading to delirium, aspiration, and/or respiratory depression [2–4].

In addition to oversedation, opioids may cause respiratory depression and overdose in patients with cancer [5]. Numerous opioid-induced respiratory depression (OIRD), overdose, and/or oversedation prediction models estimated risk and were derived from different practice environments (e.g., inpatient versus outpatient), institutions (e.g., group model integrated health system versus academic health care system), and populations (e.g., Veterans Health Administration [VHA] versus non-cancer patients) [3, 6–10]. The Commercially Insured health Plan Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (CIP-RIOSORD) assesses patient- and medication-specific OIRD/overdose predictive (i.e., risk) factors [10]. Each predictive factor is summed and stratified to a risk class to determine a probability for an OIRD/overdose event within the next 6 months. The CIP-RIOSORD demonstrates

excellent predictive accuracy for identifying patients at risk of serious OIRD or overdose [10]. In sum, the CIP-RIOSORD prediction model provides an accurate, evidence-based, patient-specific, and quantitative estimate of the risk of a future OIRD/overdose event.

Universal precautions in our outpatient palliative care practice include assessment of opioid misuse/abuse and diversion, but not an estimate of OIRD/overdose/oversedation risk. We recently evaluated opioid-induced respiratory depression (OIRD)/overdose risk in patients with cancer but did not measure observed OIRD/overdose events [11, 12]. This analysis limited the selection and implementation of a risk prediction model in our outpatient practice. Additionally, our palliative care practice captures self-reported physical symptoms as early detection or worsening of these symptoms inform interventions to avoid poor outcomes [13–15]. Whether or not self-reported sedation impacted OIRD/overdose risk was unknown. Consequently, the study objectives were to evaluate the association of longitudinal, self-reported sedation and CIP-RIOSORD-predicted OIRD/overdose risk and to determine observed OIRD/overdose events in patients with cancer receiving outpatient palliative care.

MATERIALS AND METHODS

Study design

This study was an IRB-exempt, retrospective analysis conducted at a National Cancer Institute-designated, academic, comprehensive cancer center. Data were collected from consultation visits for patients with cancer evaluated by a palliative care nurse practitioner via in-person or virtual appointment. The patient's oncologist referred new consultations to the UC San Diego Moores Cancer Center, Doris A. Howell outpatient palliative care service. The reason for consultation included management of pain and other symptoms, education about non-drug options for pain, psychosocial support, goals-of-care discussions, advance care planning, and/or a combination of reasons. Patients were at least 18 years of age, diagnosed with cancer, and had to have documentation of a visit in the electronic health record (EHR) during the data collection period. Exclusions included consultations with missing documentation of a self-reported sedation score and those beyond the third visit for a patient. We arbitrarily selected to evaluate three longitudinal visits given that a portion of these data were from a previous published study evaluating longitudinal CIP-RIOSORD scores [11].

Study Instrument

The CIP-RIOSORD is a 16-item questionnaire developed from a database of 18,365,497 patients with at least one opioid pharmacy claim between January 1, 2009, and December 31, 2013. The CIP-RIOSORD predictive factors are weighted and summed to yield a score of 0 to 146, stratified to a 7-tiered risk class, and correlated to an estimated probability ranging from 1.9 to 83.4% for an OIRD/overdose event within 6 months [10]. The CIP-RIOSORD predictive factors of substance use disorder, bipolar disorder or schizophrenia, cerebrovascular disease, kidney disease, heart failure, pancreatic disease, chronic pulmonary disease, and recurrent headache were confirmed during a health care visit (i.e., outpatient, inpatient, or ED) during the previous 6 months of a health care visit. These conditions may not have been the primary reason for the health care visit, but must have had EHR medical record documentation as either a diagnosis or one of the health care visit reasons [10].

Data Collection

The data collection period was from July 1, 2022, through March 29, 2024. All palliative care consultations occurred between January 1, 2023, and March 29, 2024. Manual data collection included patient demographics and CIP-

RIOSORD predictive factors from the EHR. Daily oral morphine equivalents (OMEs) and conversions for methadone, tapentadol, and oxycodone extended-release were performed [16–19]. At each palliative care visit, self-reported pain and drowsiness scores were collected (11-point scale, 0 [no symptom] to 10 [worst symptom]) utilizing a modified Edmonton Symptom Assessment Scale (ESAS) [20] per usual care. International Classification of Disease, 10th revision (ICD-10) and Current Procedural Terminology (CPT) codes were used to determine observed OIRD/overdose events. An OIRD/overdose event was defined as a prescription opioid poisoning per documented CPT codes (T40.0X 1A to 4A, E850.1, E850.2) plus one of the following: central nervous system or respiratory adverse event (E935.1 to .2, J80, J96, R06.81, R09.2, R09.01, R09.02, R40.1 to .4, T40.2X5A), mechanical ventilation procedure (94002, 94003), or critical care (99291, 99292) event. [10].

Statistical analysis

Self-reported sedation was defined on an ordinal scale and on a dichotomous scale. Data were separated into patients without sedation (i.e., score ≤ 4) or with sedation (i.e., score ≥ 5) [21, 22]. Between group differences in patients without and with sedation for interval data were analyzed via the Wilcoxon-Mann Whitney. Chi-squared (i.e., > 5 observations) or Fisher's exact test (i.e., ≤ 5 observations) was performed for categorical data such as self-identified race/ethnicity, cancer type, presence of metastatic disease, and frequencies for each CIP-RIOSORD predictive factor. Spearman correlations examined the association between self-reported sedation and the CIP-RIOSORD score. Data were collected on an MS Excel™ spreadsheet and analyzed using SAS version 9.4 (SAS Institute, Cary, NC). A p-value ≤ 0.05 was considered statistically significant.

RESULTS

There were 831 consultations from January 1, 2023, to March 29, 2024. Excluded consultations (n = 325) and consultations available for analysis (n = 506) are presented in Fig. 1. For visits 1, 2, and 3, the number of patients were 262, 151, and 93 respectively. For the 93 patients whereby 3 consecutive visits were completed, the number of days (mean ± SD) between visits 1 and 2 and visits 2 and 3 were 46.1 ± 33.6 and 54.7 ± 46.7 days, respectively. Patient demographic data are summarized in **Table 1**. OMEs and self-reported pain scores were higher in patients with sedation versus patients without sedation (p ≤ 0.05, **Table 1**).

Baseline (i.e., visit 1) CIP-RIOSORD predictive factors are presented in **Table 2.** For both groups, common predictive factors were morphine use (66% versus 56%) and antidepressant use (31% versus 41%, **Table 2**). CIP-RIOSORD predictive factors were similar between groups (p > 0.05). At visit 1, OIRD/overdose risk was similar in patients without sedation versus patients with sedation (mean ± SD, 21.4 ± 16.7 versus 22.2 ± 14, p > 0.05). Although CIP-RIOSORD scores remained higher in patients with sedation during subsequent visits (i.e., visits 2 and 3), there was no difference in scores between groups (p > 0.05, **Table 3**).

At visit 1, self-reported sedation was significantly higher in patients with sedation compared to patients without sedation (6.3 ± 1.3 vs. 1.4 ± 1.4, p ≤ 0.05, **Table 3**). This trend persisted across subsequent visits. For most visits, a lack of association (r = -0.03–0.12) was observed between self-reported sedation and CIP-RIOSORD scores, with a weak association for patients without sedation at visit 2 (r = 0.22, p ≤ 0.05, **Table 3**).

Observed OIRD/overdose events were evaluated from 506 palliative care visits. One-hundred and fifty-four visits (30%) involved patients who expired in less than 6 months, while 352 (70%) visits involved patients who were alive at 6 months. There were no observed OIRD/overdose events.

DISCUSSION

We assessed the association between longitudinal self-reported sedation and OIRD/overdose risk in patients with cancer receiving outpatient palliative care. In patients with and without sedation, there was no association between self-reported sedation and the CIP-RIOSORD score, except at visit 2 in patients without sedation ($r = 0.22$, $p \leq 0.05$, **Table 3);** the r-value revealed a weak association that likely lacked clinical significance. CIP-RIOSORD scores were higher in patients with sedation (**Table 2**) but no difference was observed between groups across all visits. These results suggest that longitudinal self-reported sedation did not impact CIP-RIOSORD scores and thus OIRD/overdose risk in this sample patient population. Furthermore, although CIP-RIOSORD scores changed over 3 consecutive visits, the extent of contribution of self-reported sedation on overall OIRD/overdose risk was minimal, suggesting that a baseline risk assessment may suffice.

The lack of difference in CIP-RIOSORD scores between groups may have been influenced by assuming that sedation equated to oversedation. Although other sedation scales exist (i.e., Minnesota Sedation Assessment Tool, Richmond Agitation-Sedation Scale) and describe sedation on a categorical scale, these remain observer-based scales used in the intensive care unit (ICU) and/or for palliative sedation in end-of-life care [23, 24]. The current study selected a binary cutoff of 5 to classify sedation as a dichotomous variable for three reasons. First, the optimal cutoff for sedation is likely not ≤ 4. In a study of 157 patients hospitalized in a palliative care unit, the specificity for self-reported sedation scores of 2, 3, and 4 were 0.31, 0.43, and 0.55, respectively. The accuracy of the self-reported sedation scores was also poor, with an the area under the receiver operating characteristic curve (AUC) of 0.55 [21]. Second, in Japanese patients with cancer (n = 292), the optimal cutoff for detecting self-reported sedation was 5, with a sensitivity, specificity, and AUC of 0.85, 0.9, and 0.93, respectively [22]. Third, to the best of our knowledge, there is no consensus on how to stratify a numeric value or a range of values into a categorical scale (e.g., mild, moderate, or severe), whereby severe sedation equates to oversedation. In the current study, a few patients self-reported sedation scores of 9 or 10 (n = 8, 3, and 3 for visits 1, 2, and 3); thus, it was not possible to evaluate the associated impact on CIP-RIOSORD scores.

The CIP-RIOSORD model estimated OIRD and overdose risk but not oversedation risk. OIRD, overdose and oversedation have subtle pathophysiological differences but all are treated with an opioid antagonist and may be potentially lethal. A prediction model that estimated OIRD and oversedation risk exists but was not selected because a patient-controlled analgesia (PCA) basal rate was a predictive factor that was not assessed in our outpatient study. In the absence of a combined OIRD, overdose, and oversedation model, the CIP-RIOSORD was selected due to excellent accuracy and diverse expansion. Differences between CIP-RIOSORD estimated and observed OIRD/overdose events were less than 4% [10]. The CIP-RIOSORD is a recommended predictive model for 2022 VHA/Department of Defense Clinical Practice Guidelines [25] for chronic pain management. In addition, the CIP-RIOSORD has expanded to different patient populations (e.g., older adults), clinical settings (e.g., emergency room visits), and data sources (e.g., adjudicated pharmacy claims) [26–28].

The highest proportion of CIP-RIOSORD predictive factors in patients with and without sedation were antidepressant use and morphine use (**Table 2**). These findings are consistent with another study in a different patient population (i.e., patients returning to the emergency department), where antidepressant use was common in patients with opioid-tolerance [27]. Furthermore, the 56–66% frequency of morphine use (**Table 2**) was expected given that optimal management of chronic, cancer-related pain includes the use of opioids [29].

The second study purpose was to determine observed OIRD/overdose events. The current study did not observe an OIRD/overdose event over 6 months or up to the date of patient death. An OIRD/overdose event was defined the same way Zedler et al. [10] defined observed events from the original CIP-RIOSORD study using ICD and CPT codes. We acknowledge that ICD-9/10 and CPT codes can be ambiguous, mislabeled, missed, and incorrect. However, prior

evidence suggested that ICD-9 opioid poisoning and adverse effect codes were 81% accurate in identifying observed overdose events [30].

The lack of an observed OIRD/overdose event is a novel, but preliminary finding for several reasons. First, a study limitation was the small sample size, with the number of patients decreasing across subsequent visits (**Table 2**). In our palliative care practice, this has been a consistent observation [31, 32]. Compared to other studies with larger sample sizes (n = 318,585–731,208), the prevalence of opioid overdose in the United States is less than 1.5% [7, 33] and even lower (i.e., 0.05%) in a Korean population [34]. Second, if OIRD/overdose events occurred outside of our health care system, they would not have been documented in the EHR. Third, our efforts to combat possible opioid misuse/abuse and diversion may have impacted OIRD/overdose events resulting in underestimation.

Prior to receiving palliative care at our outpatient clinical practice, all patients signed a pain contract. Pain contract elements included, but were not limited to, obtaining opioid prescriptions exclusively by palliative care providers, utilizing a single pharmacy to obtain opioid medications and consenting to random urine drug testing and/or pill counts. During most new, initial consultations, the Opioid Risk Tool (ORT) was administered [35] to establish baseline opioid misuse/abuse risk. Patients determined to be high risk by the ORT were provided a maximum 14-day supply of opioid medication. At each clinic visit, the patient-specific prescription drug-monitoring program (PDMP) was reviewed for aberrant behavior(s). We acknowledge the uniqueness of our approach and that different institutions may not implement these universal precautions.

We are reevaluating the selection and implementation of an OIRD/overdose model in our palliative care practice. Quantifying an estimated OIRD/overdose risk was informative, but we question the benefit since clinical assessment and management will continue when these symptoms occur or worsen. Further, evaluating several CIP-RIOSORD predictive factors was time-consuming; confirming a health condition predictive factor(s) from a healthcare visit(s) (e.g., outpatient, inpatient, ED, **Table 2**) involved EHR manual review. Additionally, if a healthcare visit for these conditions occurred at other institutions, these would be missed due to a lack of documentation in our EHR. We also provide inpatient palliative care services. If a model is selected, we would prefer the same model be used for both inpatient and outpatient use, of which the CIP-RIOSORD has not yet been extensively studied in hospitalized patients.

In patients with cancer receiving outpatient palliative care, we observed weak to no associations between longitudinal, self-reported sedation on OIRD/overdose risk utilizing the CIP-RIOSORD model, except for visit 2 in patients without sedation. However, a statistically significant r-value likely lacked clinical significance. These results suggest that OIRD/overdose risk remained unchanged between groups across subsequent visits and that there is minimal contribution of self-reported sedation on CIP-RIOSORD-estimated OIRD/overdose risk.

Declarations

Competing Interest:

The authors have no competing or financial interests to disclose.

Ethics approval

/Consent: This study was reviewed by the institution's IRB chair or appointed designee and was exempt from IRB requirements under category 45 CFR 46.104(d). A waiver of individual authorization for use of Protected Health Information (PHI) was granted for this study as stipulated by the HIPAA Privacy Rule, 45 CFR 164 section 513(l).

Data, material, and/or code availability

Available upon reasonable request.

Authors' contribution

All authors contributed to the study conception and design. CS, RGP, TN, LN, and JDM were responsible for data collection. JDM performed the statistical analysis and composed a draft manuscript. All authors reviewed, edited and revised previous versions of the manuscript.

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Author Contribution

All authors contributed to the study conception and design. CS, RGP, TN, LN, and JDM were responsible for data collection. JDM performed the statistical analysis and composed a draft manuscript. All authors reviewed, edited and revised previous versions of the manuscript.

Data Availability

Available upon reasonable request.

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Tables

Tables are available in the Supplementary Files section.

Figures

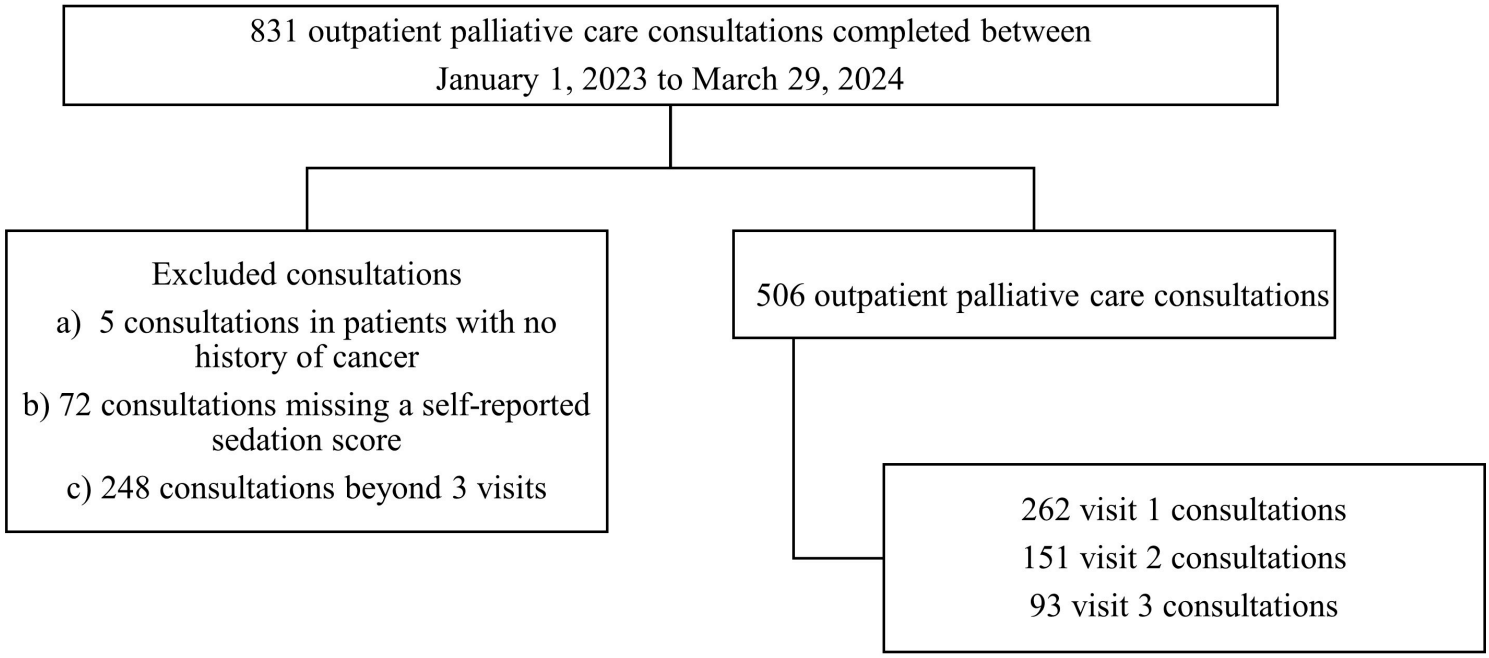


Figure 1

Study flowsheet.

Supplementary Files

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