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SHORT REPORT

Practice and documentation of palliative sedation: a quality improvement initiative

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ABSTRACT

Background

Palliative sedation (PS), the continuous use of sedating doses of medication to intentionally reduce consciousness and relieve refractory symptoms at end of life, is ethically acceptable if administered according to standards of best practice. Procedural guidelines outlining the appropriate use of PS and the need for rigorous documentation have been developed. As a quality improvement strategy, we audited the practice and documentation of PS on our palliative care unit (PCU).

Methods

A pharmacy database search of admissions in 2008 identified, for a subsequent chart review, patients who had received either a continuous infusion of midazolam (≥10 mg/24 h), regular parenteral dosing of methotrimeprazine (≥75 mg daily), or regular phenobarbital. Documentation of the decision-making process, consent, and medication use was collected using a data extraction form based on current international PS standards.

Results

Interpretation and comparison of data were difficult because of an apparent lack of a consistent operational definition of PS. Patient records had no specific documentation in relation to PS initiation, to clearly identified refractory symptoms, and to informed consent in 60 (64.5%), 43 (46.2%), and 38 (40.9%) charts respectively. Variation in the medications used was marked: 54 patients (58%) were started on a single agent and 39 (42%), on multiple agents. The 40 patients (43%) started on midazolam alone received a mean daily dose of 21.4 mg (standard deviation: 24.6 mg).

Conclusions

The lack of documentation and standardized practice of PS on our PCU has resulted in a quality improvement program to address those gaps. They also highlight the importance of conducting research and developing clinical guidelines in this area.

KEY WORDS

Palliative care, conscious sedation, deep sedation, documentation, hypnotics and sedatives

1. BACKGROUND

Palliative sedation (PS) is the intentional, continuous use of sedative medications with the goal of reducing consciousness and relieving intolerable suffering from refractory symptoms in patients who are at end of life (that is, last hours to days)[1]. A symptom is considered refractory when all possible treatments available within a tolerable time frame and risk–benefit ratio have been tried, but have not been successful[1]. Throughout the literature, the frequency of PS ranges from 2% to 52% depending on setting, research methodology, and definition[2]. Studies show that, when appropriately administered, PS does not invariably hasten death[3]. It is an essential therapy that is ethically justifiable when used appropriately with the intention of relieving intolerable suffering and not shortening life[4–6]. Common indications for PS include intractable delirium, dyspnea, seizures, and severe pain[2,7]. Controversial indications that have to be evaluated on an individual basis include sedation for psychological or existential suffering[3,8]. Midazolam, administered by continuous infusion, is the drug of choice for PS[1,2,7]. Other medications include methotrimeprazine and phenobarbital[2,9].

Over the last several years, PS has appropriately received increasing attention, and national and international guidelines have been developed to guide

practice[1,4]. In 2009, to ensure best practice and to highlight ethical issues surrounding problem practices, a framework for the use of sedation in palliative care was developed by the European Association for Palliative Care[4]. That framework addresses the issues of substandard clinical practice and abuse of PS. The injudicious use and withholding of PS are also brought to light. "Injudicious use" of PS is described as sedation with the intent of relieving symptoms, but in clinical circumstances that are not appropriate—for example, inadequate assessment for potentially reversible causes or failure to consult an expert physician. Substandard practice of PS encompasses inadequate consultation with the patient or family (or both) before PS initiation, insufficient monitoring, and inappropriate medication use and dose escalation[4]. The need for rigorous documentation before and throughout PS treatment is also a crucial element of the European Association for Palliative Care framework and many other guidelines[10].

2. AIMS

As a quality improvement strategy, our group audited the practice of PS on a 36-bed palliative care unit (PCU) in Ottawa. The patient population on the PCU included patients admitted for acute symptom management and patients receiving end-of-life care. The appropriateness of documentation in charts was selected as an important indicator of best practice. Our specific focus was to assess baseline documentation practices of PS. Determining the frequency of PS and of specific medication use were secondary goals.

3. METHODS

3.1 Study Design

A literature review was conducted to determine best practices related to PS. Those practices included rigorous documentation regarding

- explicit use of the term "palliative sedation" or "sedation."
- reasons that the symptom was regarded as refractory (summary of treatments already tried and failed).
- imminence of death.
- presence of a "do not resuscitate" order.
- informed consent from the patient or surrogate decision-maker.
- discussions concerning hydration and nutrition before implementing PS.
- ongoing assessment of sedation level and level of comfort or discomfort during PS.

A data extraction form was developed to capture the foregoing data (that is, the extent of the documentation) and the patient's demographic and medication-related information.

A search of the pharmacy database was conducted for all consecutive patients admitted to our 36-bed PCU at the Élisabeth Bruyère Hospital during 2008. All patients who received either a continuous infusion of midazolam (≥10 mg/24 h), regular parenteral dosing of methotrimeprazine (≥75 mg daily), or regular phenobarbital for the purposes of sedation were identified and included. Patients who received phenobarbital for the indication of seizure prevention were excluded.

Based on the European Association for Palliative Care recommended starting dose for midazolam infusion (0.5–1 mg/h), a cut-off of 10 mg or more in 24 hours was chosen to ensure that all potential cases of PS were identified[4]. Patients who received low-dose midazolam as an anxiolytic were then excluded by chart review.

Upon literature review, mean daily doses of methotrimeprazine for PS were varied, including 100 mg/24 h in a survey of palliative care experts and 125 mg/24 h in a previous retrospective chart review[11,12]. Again, the cut-off dose of 75 mg methotrimeprazine daily was chosen to ensure wide inclusion.

Identified charts were then independently reviewed by a team of 5 physicians for clinical documentation of the initiation and process of PS, medication use, and patient monitoring. The study received approval from the institution's Research Ethics Committee.

4. RESULTS

4.1 Patient Population

Of the 456 patients admitted to the PCU in 2008, 125 were identified as possible recipients of PS. After chart review, 32 patients were excluded: 15 who received phenobarbital as seizure prophylaxis; 4 who died before initiation of PS; 9 who received low-dose midazolam for anxiety; 3 who were already receiving PS at time of admission; and 1 for whom PS was initiated before the study period began.

Among the remaining 93 patients (20.4%) who received PS, the average age was 67 years (range: 33–93 years), and 54% were men. Of malignant diagnoses, the primary ones were cancer of the lung (n = 23, 25%), gastrointestinal tract (n = 16, 17%), and genitourinary system (n = 8, 9%). Three patients (3.2%) had a non-cancer diagnosis.

4.2 Documentation

Data interpretation and comparison were difficult because of an apparent lack of a consistent operational definition of PS. Table I details the documentation recorded in patient charts. Many patient records had no specific documentation in relation to PS initiation or no clearly identified refractory symptoms. Of documented symptoms, refractory delirium was

TABLE I Documentation recorded in 93 patient charts concerning palliative sedation

Documentation item	*(n)*	*(%)*
"Do not resuscitate" order		
Yes	93	100
No	0	0
Symptoms for which a requirement for palliative sedation is identified		
Delirium	24	25.8
Pain	17	18.3
Dyspnea	14	15.1
Anxiety	2	2.2
Seizures	0	0
Delirium and dyspnea	3	3.2
Delirium and pain	3	3.2
Other	2	2.2
None	28	30.1
Refractoriness described		
Yes	50	53.8
No	43	46.2
Informed consent explicitly stated		
Yes	32	34.4
No	38	40.9
Implied	23	24.7
Use of the term "palliative sedation" or other similar term		
"Palliative sedation"	8	8.6
"Sedation"	25	26.9
No documentation	60	64.5
Discussions before palliative sedation		
Artificial hydration	0	0
Artificial nutrition	0	0
Monitoring of sedation level		
Once or more per shift	75	80.6
Once daily	17	18.3
Less than once daily	1	1.1
Monitoring of comfort level		
Once or more per shift	75	80.6
Once daily	18	19.4
Less than once daily	0	0

most often the reason for initiation of PS (25.8%). Other common indications included pain (18.3%) and dyspnea (15.1%). All patients had a "do not resuscitate" order in place before initiation of PS. Informed consent was not documented in a significant proportion of cases, and when it was documented, the consent provider was often unclear. There were no documented discussions about artificial nutrition or hydration before PS initiation. Monitoring of sedation and comfort levels were documented once or more per nursing shift in most cases.

4.3 Medications

The initial sedating medications used for PS varied markedly:

- 54 patients (58%) were started on a single agent; 39 (42%), on multiple agents.
- 40 patients (43%) were started on midazolam alone, at a mean daily dose of 21.4 ± 24.6 mg.
- 12 patients (13%) were started on methotrimeprazine at a mean daily dose of 89.6 ± 59.6 mg.
- single-agent phenobarbital was used in 3 patients (3%).

Of patients initiated on PS with multiple medications, 28 (30%) received both midazolam and methotrimeprazine, which was the most common combination.

4.4 Timeline

Median duration of PS was 2 days (range: 0–18 days).

5. DISCUSSION AND CONCLUSIONS

Our study identified a very concerning lack of chart documentation about PS on our PCU. That lack spanned several areas, including consent discussions, the reasons that symptoms were considered refractory, discussions about hydration and nutrition, and explicit use of the term "palliative sedation." From a medicolegal perspective, absence of documentation has to be interpreted as absence of discussions, actions, and decisions, even though they likely did occur.

Thorough documentation is required to improve communication between health care professionals and to guard against unethical and problem practices of PS. Because standards for practice and documentation can now be defined through national and international PS guidelines, periodic chart audits will be an effective tool to identify documentation gaps, to recognize learning opportunities, and to foster practice change.

The frequency of PS on our PCU in 2008 (20.4% of all patients) appears somewhat high when compared with other recent reports[2]. However, our definition of PS was not limited to deep sedation, but also included light levels of sedation. The latter patients have often been excluded in previous studies. Also, the lack of consensus on a definition of PS among the clinicians on our PCU during the study period and the relative high acuity of our patients may play a role. Patients with less acute symptoms are often cared for at home or in a hospice setting, and so our PCU typically admits patients who require more complex symptom management and who are thus more likely to require

sedation. Notwithstanding those factors, our findings suggest that the threshold for using PS on our PCU has to be reviewed.

Our average duration of PS was similar to that previously reported by Maltoni *et al.* (3.9 days), Sykes and Thorns (4 days), and Fainsinger *et al.* (1.9–3.2 days)[3,13,14]. The medications used for the initiation of PS varied significantly, and the number of patients started on multiple medications was unexpected. Those findings have prompted reflection on best practice, with the goal of changing practice to the use of a single medication for initiation of PS on our PCU.

This retrospective chart review, which compared our results with current international standards, has served as a quality improvement strategy. Although studies auditing local PS practices have been published, the present review is, to the best of our knowledge, unique in looking at documentation of PS practice. Our results have become the foundation for a quality improvement program related to PS on our PCU, including the implementation of guidelines that include standardized documentation and education of staff. We anticipate that implementation of guidelines will improve documentation and highlight the need to explicitly use the term "palliative sedation." The results of our study will also serve as a useful baseline against which to measure the future impact of guidelines and staff education.

6. ACKNOWLEDGMENTS

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7. CONFLICT OF INTEREST DISCLOSURES

The authors have no financial conflicts of interest to declare.

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