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# Sedation practices in palliative care services across France: a nationwide point-prevalence analysis

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## ABSTRACT

**Objectives** Terminally ill patients may require sedation to relieve refractory suffering. The prevalence and modalities of this practice in palliative care services remain unclear. This study estimated the prevalence of all sedation leading to a deep unconsciousness, whether transitory, with an undetermined duration, or maintained until death, for terminally ill patients referred to a home-based or hospital-based palliative care service.

**Methods** We conducted a national, multicentre, observational, prospective, cross-sectional study. In total, 331 centres participated, including academic/non-academic and public/private institutions. The participating institutions provided hospital-based or home-based palliative care for 5714 terminally ill patients during the study.

**Results** In total, 156 patients received sedation (prevalence of 2.7%; 95% CI, 2.3 to 3.2); these patients were equally distributed between 'transitory', 'undetermined duration' and 'maintained until death' sedation types. The prevalence was 0.7% at home and 8.0% in palliative care units. The median age of the patients was 70 years (Q1–Q3: 61–83 years); 51% were women and 78.8% had cancers. Almost all sedation events occurred at a hospital (90.4%), mostly in specialised beds (74.4%). In total, 39.1% of patients were unable to provide consent; only two had written advance directives. A collegial procedure was implemented in 80.4% of sedations intended to be maintained until death. Midazolam was widely used (85.9%), regardless of the sedation type.

**Conclusions** This nationwide study provides insight into sedation practices in palliative care institutions. We found a low prevalence for all practices, with the highest prevalence among most reinforced palliative care providers, and an equal frequency of all practices.

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The prevalence and modalities of sedation leading to a deep unconsciousness in terminally ill patients referred to palliative care services remain unclear.

## WHAT THIS STUDY ADDS

⇒ This point-prevalence analysis reveals a low prevalence, mainly dependent on the level of care. Physicians used transitory, undetermined duration and maintained until death sedation with an equal frequency.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ These data, derived from specialised services, may guide both specialised and non-specialised physicians. Our findings may aid in the development of policies related to appropriate levels of care, and further studies on patterns involved in access to sedative practices.

## INTRODUCTION

Terminally ill patients often experience frequent and intense symptoms due to disease progression. Sedatives may be necessary to relieve refractory and intolerable suffering. Previous studies have defined sedation as the use of a sedative drug to reduce patient awareness.<sup>1</sup> Sedatives are used in the context of life-threatening acute complications, discontinuation of life-sustaining treatments and refractory suffering.<sup>2</sup> Data report a more frequent use of the subcutaneous route at home while guidelines recommend intravenous administration for emergency or continuous deep sedation.<sup>3,4</sup>

Based on the prescriber's intention, French recommendations distinguish transitory practices (reversible), those with an undetermined duration (potentially reversible) and sedation intended to

be maintained until death (irreversible). These definitions consider the first two as ‘proportional sedations’ because they induce variable duration and depth of unconsciousness proportionally to the intensity and the evolution of symptoms, while sedation maintained until death is intended to be constantly deep until death. Palliative care community has historically used sedation practices but Claeys-Leonetti law regulates since 2016 the ‘continuous and deep sedation maintained until death’ (CDSUD) in France. Law authorises CDSUD for patients with a serious, incurable and short-term life-threatening disease only. Legal framework defines three indications: (1) patient requesting CDSUD for refractory suffering, (2) or for cessation of a life-sustaining treatment with risk of unbearable suffering; (3) or patient unable to request CDSUD and physician deciding to stop a life-sustaining treatment with risk of unbearable suffering (online supplemental files 1 and 2).

Guidelines recommend early referral to specialised palliative care services when there are significant symptoms or psychosocial needs, which accounts for most cases requiring palliative sedation.<sup>2 5 6</sup> Specialised services such as home-based and hospital-based mobile teams, palliative care units (PCUs) and day hospitals are used worldwide.<sup>7</sup> In France, some acute care services and rehabilitation departments also include some specialised beds dedicated for palliative care. Palliative care networks and home-based hospitalisation services deliver palliative care at private homes or institutions for dependent old persons. All specialised services provide comprehensive care through an interdisciplinary team. The French healthcare system has implemented a referral programme depending on the complexity of the case. The mobile team represents the first-line intervention, followed by admission to a hospital bed identified as being for palliative care or to a PCU (second-line and third-line interventions, respectively).

The depth of sedation is a sensitive issue. The induced lack of communication may create difficulties for relatives and caregivers.<sup>8–10</sup> Palliative sedation does not hasten death, but some drug-induced complications may occur and patients have expressed concerns regarding this practice.<sup>11 12</sup> The international literature has focused on continuous and deep sedation until death, thus failing to represent the diverse range of practices that lead to deep unconsciousness, such as non-continuous sedation. The prevalence of these practices remains unclear, probably due to differences in definitions, practices, healthcare systems and populations.<sup>13</sup> Additionally, few studies have focused on specialised palliative care services. Most of them had small sample sizes.<sup>14</sup> Uncertainty about the prevalence in a specialised framework of care is problematic for both specialised and non-specialised caregivers, who cannot verify their practices, patients and their

relatives, who may have questions about access to this care, and investigators of large-scale research projects.

This study aimed to estimate the prevalence of sedation leading to a deep unconsciousness for terminally ill patients referred to a home-based or hospital-based palliative care service in France. The analysis describes sedation types in terms of the expected duration (transitory, undetermined or maintained until death), clinical and organisational contexts, decision-making processes, and therapeutic modalities.

## METHODS

### Study design and period

We conducted a point-prevalence analysis based on a national, multicentre, observational, prospective, cross-sectional study. Each participating centre implemented a 3-day patient-enrolment period (minimum 1-month interval between each day) between 1 September 2020 and 31 November 2020.

### Participating centres

A scientific committee contacted all palliative care and home-based hospitalisation services registered in France by the French Palliative Care Society (‘SFAP’; all acronyms in quotation marks pertain to the French names) and National Federation of Home-based Hospitalisation Services (‘FNEHAD’). All investigators were palliative care specialists. In 2020, there were 164 PCUs, 428 mobile teams (‘EMSP’), 107 palliative care networks, 901 institutions with beds identified as being for palliative care (‘LISP’) and 288 home-based hospitalisation services (‘HAD’). The minimum sample size required to ensure precision of prevalence estimates to within 5% was calculated by palliative care providers (PCU: 846; LISP: 1318; hospital-based mobile teams: 1161; home-based mobile teams/networks: 285; HAD: 2336). Recruitment reached these estimates, except for LISP and HAD services (table 1).

### Conformity

This study was carried out according to the laws governing research involving humans and the Declaration of Helsinki. Patients provided informed consent; consent forms were collected and included in the medical files. For patients already under sedation, the investigators informed the patient’s trustee, or one of their relatives. Data were stored in a computer at Bordeaux University Hospital according to the ‘Reference Methodology’ (MR-003) data protection document.

### Patient selection

Investigators identified patients with a terminal condition, that is, estimated life expectancy  $\leq 4$  weeks.<sup>15</sup> We included all terminally ill patients followed up by a participating centre who received sedation leading to a deep unconsciousness during the study period. In accordance with the guidelines for CDSUD, the

**Table 1** Prevalence of sedation (ongoing or newly administered on the day of the study) according to the type of intention and the place of care

Palliative care provider	Patients in terminal phase	All sedation types		Transitory		Undetermined duration		Maintained until death	
	N	N (%)	(95% CI)	N (%)	(95% CI)	N (%)	(95% CI)	N (%)	(95% CI)
Palliative care unit	1170	<b>94 (8.0)</b>	<b>(6.5 to 9.7)</b>	45 (3.8)	(2.8 to 5.1)	25 (2.1)	(1.4 to 3.1)	24 (2.1)	(1.3 to 3.0)
Beds identified as being for palliative care	685	<b>22 (3.2)</b>	<b>(2.0 to 4.8)</b>	4 (0.6)	(0.2 to 1.5)	9 (1.3)	(0.1 to 2.5)	9 (1.3)	(0.1 to 2.5)
Hospital-based mobile teams	1256	<b>23 (1.8)</b>	<b>(1.2 to 2.7)</b>	2 (0.2)	(0.0 to 0.5)	12 (0.9)	(0.5 to 1.7)	9 (0.7)	(0.3 to 1.4)
Home-based mobile teams and networks	937	<b>6 (0.7)</b>	<b>(0.2 to 1.4)</b>	1 (0.1)	(0.0 to 0.1)	1 (0.1)	(0.0 to 0.1)	4 (0.4)	(0.0-1.0)
Home-based hospitalisation services	1666	<b>11 (0.7)</b>	<b>(0.3 to 1.2)</b>	1 (<0.1)	(0.0 to 0.1)	5 (0.3)	(0.1 to 0.6)	5 (0.3)	(0.1 to 0.6)
<b>Total</b>	<b>5714</b>	<b>156 (2.7)</b>	<b>(2.3 to 3.2)</b>	<b>53 (0.9)</b>	<b>(0.6 to 1.2)</b>	<b>52 (0.9)</b>	<b>(0.6 to 1.2)</b>	<b>51 (0.9)</b>	<b>(0.6 to 1.2)</b>
PREVAL-S2P study, 2020.									
Total and subtotal in bold									

protocol defined a deep unconsciousness as a vigilance score of  $-4$  or  $-5$  on the Richmond scale, or the clinical equivalent ('absence of movement on call').<sup>5 16</sup> Because this study aimed to explore sedation practices comprehensively, we evaluated all practices leading to a deep unconsciousness at induction, regardless of the intended duration.

#### Data collection

Investigators collected data from the patient's file or the physician who performed the sedation, including centre characteristics (palliative care service type and team composition), patient characteristics (compliance with eligibility criteria, sociodemographic data and main pathology) and sedation characteristics (location of induction, expected duration, patient consent, collegial procedure and drugs used). According to French guidelines, the collegial procedure is a dialogue between the physician in charge, the care team and at least one physician outside of the team (online supplemental file 2). In patients who were already sedated on the day of enrolment, sedation characteristics at the time of induction were collected retrospectively.

#### Classification of sedation

Three sedation types were distinguished according to the 'SEDAPALL' classification. Proposed in 2017 by the SFAP and based on a national workshop of experts, SEDAPALL characterises palliative sedation in terms of the intended duration (transitory, undetermined or maintained until death), intended depth (proportionally variable or constantly deep) and type of consent (not obtained, obtained in advance, obtained at the time of the sedation or spontaneously requested by the patient). We classified sedation types based on the a priori intended duration of the prescriber. 'Transitory' sedations are intended to be reversible before induction, whereas those with an 'undetermined duration' are intended to be potentially reversible depending

on the needs after induction. The SEDAPALL classification system also provides a list of frequent indications for sedation types with different durations (online supplemental file 1). The study board encouraged investigators to perform the SEDAPALL training programme based on brief clinical scenarios.<sup>17</sup>

#### Statistical analysis

The primary endpoint was the prevalence of sedation among all terminally ill patients in all participating centres. The number of cases was also determined for each type of palliative care provider (PCU, LISP, hospital-based mobile teams, home-based mobile teams/networks, HAD) and sedation duration (transitory, undetermined and maintained until death). The characteristics of the sedated patients were also obtained, together with the sedation indications and characteristics (consent type, collegial procedure and therapeutic modalities). Qualitative variables are described as numbers and percentages (with 95% CIs for primary endpoints), and quantitative variables as medians with first and third quartiles (Q1–Q3). SAS software (V.9.2; SAS Institute, Cary, North Carolina, USA) was used for the statistical analysis.

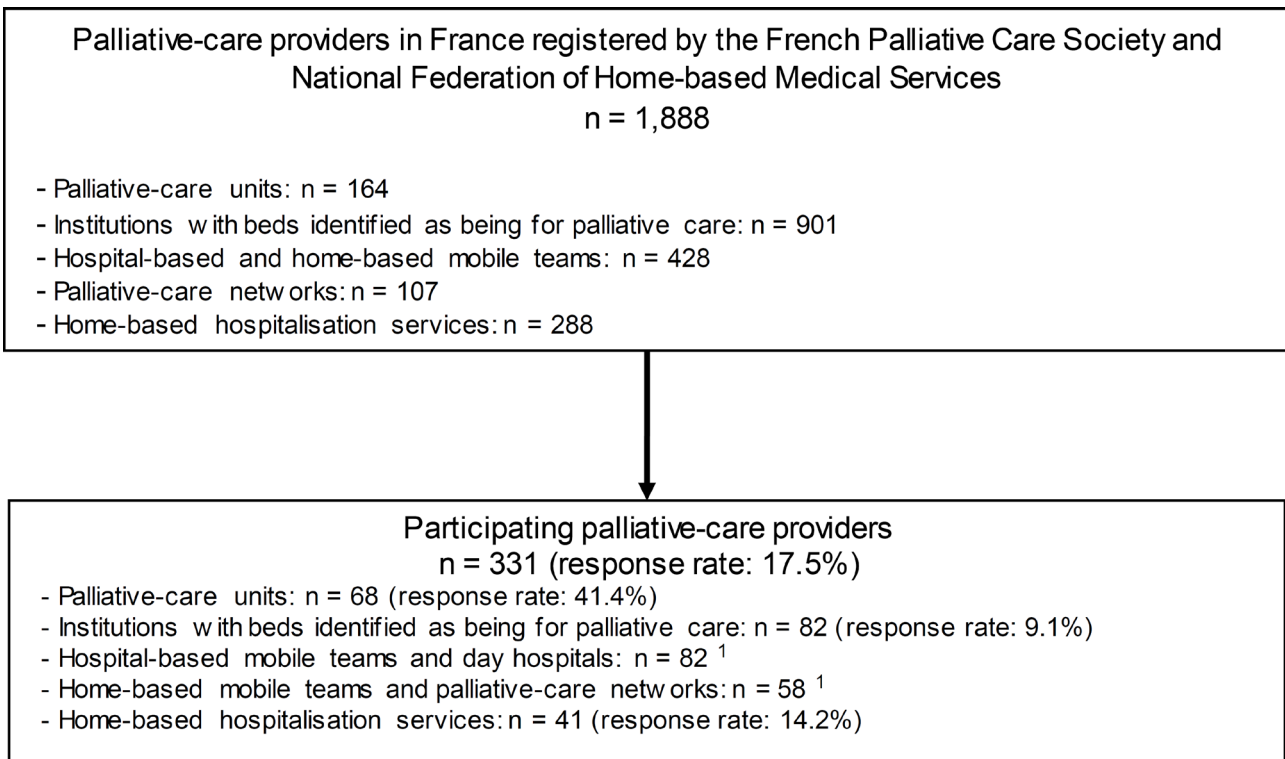
## RESULTS

#### Participating centres

Among the eligible centres nationwide, 331 participated, including academic/non-academic and public/private institutions. The institutions provided hospital-based or home-based palliative care and were representative of all palliative providers and geographical areas (figure 1). The participating centres are listed in the appendix (online supplemental file 3).

#### Sedation prevalence

The participating centres cared for 5714 terminally ill patients during the study period. In total, 156 patients received a sedation leading to a deep unconsciousness



**Figure 1** Flow chart of centres providing palliative care, and terminally ill patients enrolled in the study of sedation in palliative care services across France: PREVAL-S2P study, 2020. <sup>1</sup>Response rate not assessable due to the lack of national data about the mobile teams' setting of care and the number of palliative care day hospitals.

(overall prevalence of 2.7%; 95% CI, 2.3 to 3.2). Among the 156 sedations, 53 were transitory, 52 had an undetermined duration and 51 were intended to be maintained until death. The three sedation types had an equal prevalence (0.9%; 95% CI, 0.6 to 1.2). Finally, the prevalence of sedation was 0.7% at home (mobile teams and networks: 0.7%; 95% CI, 0.2 to 1.4; hospitalisation services: 0.7%; 95% CI, 0.3 to 1.4) and 8.0% in PCUs (95% CI, 6.5 to 9.7) (table 1).

#### Characteristics of sedated patients

The median age of the patients undergoing sedation was 70 years (Q1–Q3: 61–83 years), and 51% were women. Three-quarters of the patients had cancers (78.8%), mainly of the digestive, respiratory or gynaecological systems. Other patients had neurodegenerative diseases (7.7%), organ failure (7.1%) or multiple comorbidities (6.4%). Almost all sedations occurred in a hospital (90.4%), mostly in acute care units (84.6%). Most of the home-based sedations were performed in a private residence (8.3% of all sedations). Only two sedations were performed at an institution for dependent older people (1.3% of all sedations) (table 2).

#### Sedations types and indications

The two most frequent indications for transitory sedation were insomnia and pain, while sedation with an undetermined duration was associated mainly with cases of acute anxiety and palliative emergencies. Most of the sedations that were expected to be maintained

until death were in accordance with the indications proposed by the Claeys-Leonetti law. More than half of the patients requesting CDSUD were experiencing refractory suffering. In one-third of the cases, the decision to stop life-sustaining treatment had been made and the patient was unable to express their preference. There was only one CDSUD in a patient who refused life-sustaining treatment. Six sedations maintained until death did not accord with the indications recognised in law (patients experiencing refractory suffering, unable to request for CDSUD and without life-sustaining treatment) (table 3).

#### Sedation modalities

##### Consent

Consent was not obtained in 43.5% of cases (n=64), mainly due to the patients being unable to express their preference (n=61, 39.1%) and in a context of non-transitory sedation. In some cases, consent was obtained at the time of sedation (n=40, 25.4%), while in others (n=35, 21.5%) the patient provided consent via an advance directive. Only 11 patients spontaneously requested CDSUD.

##### Collegial procedure for sedation maintained until death

Among the 51 sedations maintained until death, a collegial procedure was implemented in 41 patients (80.4%), 39 patients' files mentioned the details of the procedure (76.5%), 31 patients' relatives received the

**Table 2** Characteristics of the patients undergoing sedation

Characteristics	Sedation (n=156)	
	N (%)	Med (Q1–Q3)
Sociodemographic		
Age (years)		70 (61–83)
Gender		
Women	80 (51)	
Men	76 (49)	
Disease characteristics		
Cancer type		
Digestive tract*	24 (15.4)	
Lung	24 (15.4)	
Gynaecological system†	18 (11.5)	
Urinary tract‡	9 (5.8)	
Brain	6 (3.8)	
ENT and upper respiratory tract	6 (3.8)	
Haematological malignancy§	6 (3.8)	
Other	30 (19.1)	
Subtotal	<b>123 (78.8)</b>	
Neurodegenerative disease		
Motor impairment (including amyotrophic lateral sclerosis)	6 (3.8)	
Cognitive impairment (including Alzheimer's and vascular)	6 (3.8)	
Subtotal	<b>12 (7.7)</b>	
Organ failure		
Acute failure	6 (3.8)	
Chronic condition	5 (3.3)	
Subtotal	<b>11 (7.1)</b>	
Multiple comorbidities		
Multiple comorbidities	<b>10 (6.4)</b>	
Place of care		
Hospital		
Acute care unit	132 (84.6)	
Rehabilitation unit	7 (4.6)	
Intensive care unit	1 (0.6)	
Long-term geriatric care unit	1 (0.6)	
Subtotal	<b>141 (90.4)</b>	
Home		
Private residence	13 (8.3)	
Institution for dependent older people	2 (1.3)	
Subtotal	<b>15 (9.6)</b>	
PREVAL-S2P study, 2020.		
*Including colorectal (n=12), pancreas (n=7), upper digestive tract (n=4) and liver (n=1).		
†Including breast (n=11), ovary (n=4) and uterus (n=3).		
‡Including prostate (n=4), kidney (n=3), bladder (n=1) and penis (n=1).		
§Including leukaemia (n=4), myeloma (n=1) and myelodysplasia (n=1).		
ENT, ear, nose and throat; Med, median; Q1, first quartile; Q3, third quartile.		

related information (60.8%) and 24 files described an external physician (47.1%).

#### Drugs

Almost all sedations used midazolam alone as the sedative (85.9%), particularly in cases of intended undetermined duration. Midazolam in combination with neuroleptics was used in one case of sedation

**Table 3** Sedation types and indications according to the SEDAPALL criteria

Intended duration	Main indication	Sedation (n=156)
		N (%)
Transitory (n=53, 34.0%)	Nocturnal sedation for insomnia	33 (21.2)
	Short sedation for refractory pain	12 (7.7)
	Acute anxiety	3 (1.9)
	Refractory dyspnoea	2 (1.3)
	Refractory agitation	2 (1.3)
Undetermined (n=52, 33.3%)	Refractory pain	1 (0.6)
	Acute anxiety	23 (14.7)
	Palliative emergency (asphyxia, haemorrhage and delirium)	22 (14.1)
	Refractory pain	7 (4.5)
Maintained until death (n=51, 32.7%)	Patient experiencing refractory suffering in the context of a poor short-term prognosis and requesting CDSUD	29 (18.5)
	Medical decision to stop life-sustaining treatment† and to perform CDSUD for patients unable to express their preference	15 (9.6)
	Outside the legal framework pertaining to the right to CDSUD*	6 (3.8)
	Patient refusing a life-sustaining treatment† and requesting CDSUD to prevent unbearable suffering	1 (0.6)

CDSUD as stated in the 2016 Claeys-Leonetti law. PREVAL-S2P study, 2020.  
 \*Patients unable to express a request for CDSUD, experiencing refractory terminal suffering and without life-sustaining treatment.  
 †Defined as all acts of prevention, investigation, treatment, or care, which have no other effect than the artificial maintenance of life.  
 CDSUD, continuous and deep sedation maintained until death.

maintained until death, while four transitory sedations were induced using ketamine. Opioids were used in 24.4% of cases, twice as often for sedation maintained until death as for those with an undetermined duration.

In around two-thirds of cases (66.0%), sedation was induced intravenously. This proportion increased to 74.5% among cases where sedation was intended to be maintained until death. Sedatives were administered via the subcutaneous route in almost 20% of cases, mainly of transitory sedation. Data collected did not identify oral drugs. Continuous flow and an additional bolus were typically used for induction, particularly in cases where sedation was maintained until death. A bolus alone was used mostly for transitory cases. A maintenance phase was implemented for half of all cases, mostly for sedation with an undetermined duration or maintained until death, and almost always with continuous flow of the sedative drugs (table 4).

#### DISCUSSION

Our study provides further insight into the prevalence of sedation for terminally ill patients referred to palliative care teams. Palliative sedation was achieved in approximately 3% of cases, mostly for patients with

**Table 4** Characteristics of sedation according to the intended duration

Characteristics	Intended duration						Maintained until death (n=51)	
	All (n=156)		Transitory (n=53)		Undetermined (n=52)		N	%
	N	%	N	%	N	%		
<b>Consent</b>								
Not given*	64	(43.5)	14	(26.4)	28	(53.8)	22	(43.1)
Given at the time of sedation	40	(25.4)	19	(35.8)	13	(25.0)	8	(15.7)
Given before sedation†	35	(21.5)	19	(35.8)	6	(11.5)	10	(19.6)
Spontaneous patient request	17	(9.6)	1	(1.9)	5	(9.6)	11	(21.6)
<b>Collegial procedure</b>								
Performed	83	(53.2)	7	(13.2)	26	(50.0)	41	(80.4)
Traceability in medical file	72	(46.2)	5	(9.4)	21	(40.4)	39	(76.5)
<b>Drugs</b>								
Sedatives								
Midazolam alone	134	(85.9)	45	(84.9)	49	(94.3)	40	(78.4)
Midazolam+neuroleptics	10	(6.4)	3	(5.7)	1	(1.9)	6	(11.8)
Ketamine	6	(3.8)	4	(7.5)	1	(1.9)	1	(2.0)
Propofol	4	(2.6)	1	(1.9)	1	(1.9)	2	(3.9)
Clorazepate	2	(1.3)	0	(0.0)	0	(0.0)	2	(3.9)
Associated drugs								
Opioids	38	(24.4)	2	(3.8)	13	(25.0)	23	(45.1)
<b>Administration modalities</b>								
Induction								
Route								
Intravenous	103	(66.0)	29	(54.7)	36	(69.2)	38	(74.5)
Subcutaneous	31	(19.9)	13	(24.5)	10	(19.2)	8	(15.7)
Unknown	22	(14.1)	11	(20.8)	6	(11.5)	5	(9.81)
Frequency								
Continuous flow+bolus	68	(43.6)	20	(37.7)	19	(36.5)	29	(56.9)
Continuous flow only	41	(26.3)	9	(17.0)	18	(34.6)	14	(27.5)
Bolus only	26	(16.6)	14	(26.4)	9	(17.3)	3	(5.9)
Unknown	21	(13.5)	10	(18.9)	6	(11.5)	5	(9.8)
Maintenance								
Route								
Intravenous	57	(36.5)	7	(13.2)	25	(48.1)	25	(49.0)
Subcutaneous	19	(12.2)	4	(7.5)	8	(15.4)	7	(13.7)
Frequency								
Continuous flow+bolus	49	(31.4)	10	(18.9)	18	(34.6)	21	(41.2)
Continuous flow only	26	(16.7)	1	(1.9)	14	(26.9)	11	(21.6)
Bolus only	1	(0.6)	0	(0.0)	1	(1.9)	0	(0.0)

PREVAL-S2P study, 2020.

\*Including patients unable to express their preferences (n=62), and cases where no consent form was collected (n=2).

†Including oral consent (n=33), and written consent via advance directives (n=2).

cancer hospitalised in specialised units. The transitory, undetermined and maintained until death types had a similar prevalence. Nocturnal sedation for refractory insomnia accounted for approximately two-thirds of the transitory cases, while palliative emergencies and refractory suffering accounted for approximately half of sedations with an undetermined duration and sedations maintained until death, respectively. Medical professionals failed to obtain proper consent in about half of the cases of non-transitory sedation. A collegial

procedure was implemented in 80% of cases with sedation maintained until death. Midazolam was the most commonly used drug regardless of the sedation type. Prescribers used the subcutaneous route in about one-quarter of the cases. Associated treatments included opioids in approximately one-quarter of the cases.

The large-scale recruitment led to a diversified sample of participating centres, including all types and locations of palliative care providers. The included patients reflect the deceased population in palliative

care structures, in accordance with our selection of terminally ill patients. The median age of our sample (70 years) was similar to the mean age of death reported by palliative care services (PCU: 72.2 years; beds identified as being for palliative care: 74.3 years). The cancer prevalence (77.4%) also approached the proportion of cancer deaths reported by palliative care services (PCU: 78%; beds identified as being for palliative care: 73%).<sup>18</sup>

The prevalence of sedation among our population was the lowest among European studies (Denmark: 3% in 2005; Netherlands: 18% in 2015), particularly considering that previous studies typically excluded cases of reversible sedation and that the frequency of sedation is increasing over time.<sup>19</sup> However, these studies included all deceased patients, not only those receiving palliative care services. Our participants referred for specialised palliative care may have a low need for such practices because of good symptom relief.<sup>20</sup> Differences in national healthcare organisations also limit the comparisons.<sup>21</sup> In particular, some investigators found an increased prevalence of sedation in countries where euthanasia and physician-assisted suicide are legal.<sup>22</sup> Physicians accustomed to the use of sedative drugs, such as anaesthesiologists, may also have performed palliative sedation without referring to a palliative care team.<sup>14</sup> Consultation with experts is yet highly recommended to secure adequate support from relatives and caregivers with respect to the complex decision-making process and to prevent unnecessary sedation.<sup>2 5 23 24</sup> Underuse of sedative practices by investigators is unlikely. Sedation is an old practice in palliative care services, and data on consideration of patients' requests for sedation maintained until death are reassuring.<sup>25</sup>

Consistent with published data, we found that palliative sedation is mainly a hospital-based practice.<sup>26</sup> Yet, acute care and rehabilitation services are the places of death in only about half of all cases.<sup>27</sup> Our results improve our understanding by demonstrating that the frequency increases with the level of multiprofessional care (mobile teams, 1.8% (95% CI, 1.1 to 2.7); services with beds identified as being for palliative care, 3.2% (95% CI, 5.6 to 9.7); and PCUs, 8.0% (95% CI, 6.5 to 9.7)). Because the French healthcare system directs complex cases toward the most reinforced structures, this finding probably reflects the level of care required by implementing a patient-centred care plan, treating refractory symptoms, performing efficient sedation and supporting the patients, relatives and caregivers.<sup>28</sup> Accordingly, there was a low prevalence in the home-care setting. The apprehension of the patient and relatives, limited availability of caregivers for close monitoring, and low accessibility to sedative drugs limit the implementation of palliative sedation at home.<sup>29</sup> This highlights the need for home-based professionals, training programmes, improved access

to drugs and guidelines for palliative sedation in non-specialised settings.<sup>2 5 30</sup>

Recent studies suggest increasing expansion of indications for palliative sedation, from physical to non-physical suffering.<sup>19</sup> These changes have also affected specialised palliative care services. In our study, insomnia or anxiety were more common indications than pain. There is a need for the evaluation of psychological and existential distress in patients, and to develop guidelines and ethical arguments for psycho-existential palliative sedation.<sup>31 32</sup>

All palliative sedation types were frequently used. This finding confirms qualitative data according to which proportional practices may lead to a period of deep unconsciousness.<sup>10</sup> This observation also implies rapid integration of CDSUD in France, probably supported by the long-term experience of palliative care teams with sedative practices. However, the proportion of patients who requested this sedation type after refusal of a life-sustaining treatment was noticeably lower in our study compared with data based on the entire deceased population.<sup>33</sup> Resuscitation therapies are accordingly infrequently offered for terminally ill patients in palliative care services.<sup>34</sup>

The low rates of consent and advance directives in the present study are concerning but are in accordance with previous studies. The high burden imposed by palliative emergencies and poor short-term prognosis may render the patient incapable of expressing their preference.<sup>35</sup> Accordingly, complex collegial procedures, such as those including a third-party physician, are rare. Previous studies have emphasised that the need for timely access to palliative care teams is often unmet.<sup>36</sup> These findings support the trend toward implementation of outpatient clinics as they allow for early intervention during the disease course.<sup>7</sup> Nurses should be systematically involved in palliative care services as they can inform physicians of patient's and family's wishes.<sup>37</sup>

This report also shows that midazolam is used for all types of sedation, in line with the recommendations.<sup>38</sup> Alternative drugs, such as associated neuroleptics, clorazepate or propofol, are mostly used for the cases of sedation intended to be maintained until death probably to promote efficient and long-lasting sleep.<sup>39</sup> The subcutaneous route provides a reliable route of administration, particularly for non-emergency sedations.<sup>20</sup> Finally, the observed low rate of opioid use is of concern, especially considering that cancer frequently induces pain requiring opioid analgesia. Guidelines also recommend that opioids should be used to improve sedation quality, particularly when sedation is maintained until death.<sup>5 20 38</sup> This finding illustrates the scarcity of pain assessment for sedated patients.<sup>24</sup> Nociception monitoring may detect opioid overdoses and insufficient analgesia.<sup>40</sup>

This study reports key characteristics of a large range of sedation practices. The analysis provides original



data in specialised palliative care services, both in hospital and at home. The investigators expertly evaluated the prescribers' intentions to classify the sedation type. Recruitment provides a large sample of palliative patients. The prospective design limited bias.<sup>26</sup> However, this study also had limitations. Despite the large sample size, some response rates were low or not assessable (no national data on structures). This observation brings uncertainty about the generalisability of the study centres, particularly for non-PCU services. In addition, although all investigators were experienced professionals, erroneous inclusion or misclassification of sedation may still have occurred and the observed sedations may have been irrelevant. Finally, we did not include cases of non-deep sedation and practices performed outside palliative care team settings.

## CONCLUSION

This nationwide collaborative study provides insight into sedation practices in terminally ill patients referred for specialised palliative care. There was a relatively low prevalence for all practices. The highest prevalence was observed in the most reinforced structures. Our findings suggest that an appropriate level of care is decisive to receive sedation. The analysis also revealed that palliative care professionals use all types of sedative practices, including sedation maintained until death at the patient's request, probably in line with a patient-centred approach of indications. Finally, our results highlight a need to obtain advanced consent and improve pain management. These data, derived from specialised services, may guide both specialised and non-specialised physicians. Our findings may aid in the development of policies related to appropriate levels of care, particularly for home-based sedation. Our results also highlight the need for further analytical studies regarding the physical, psycho-existential, social, and care-related patterns involved in access to sedative practices.

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## REFERENCES

- Morita T, Tsuneto S, Shima Y. Definition of sedation for symptom relief: a systematic literature review and a proposal of operational criteria. *J Pain Symptom Manage* 2002;24:447–53.
- Cherny NI, Radbruch L, Board of the European Association for Palliative Care. European association for palliative care (EAPC) recommended framework for the use of sedation in palliative care. *Palliat Med* 2009;23:581–93.
- Haute Autorité de Santé HAS. *Antalgie des douleurs rebelles et pratiques sédatives chez l'adulte: prise en charge médicamenteuse en situations palliatives jusqu'en fin de vie*. Saint-Denis La Plaine, 2020.
- Caraceni A, Speranza R, Spoldi E, *et al*. Palliative sedation in terminal cancer patients admitted to hospice or home care programs: does the setting matter? Results from a national multicenter observational study. *J Pain Symptom Manage* 2018;56:33–43.
- Haute Autorité de Santé, Care pathway guide. How to implement continuous deep sedation until death; 2018.
- Ferrell BR, Temel JS, Temin S, *et al*. Integration of palliative care into standard oncology care: American society of clinical oncology clinical practice guideline update. *J Clin Oncol* 2017;35:96–112.

- 7 Hui D, Bruera E. Models of palliative care delivery for patients with cancer. *J Clin Oncol* 2020;38:852–65.
- 8 Bruinsma S, Rietjens J, van der Heide A. Palliative sedation: a focus group study on the experiences of relatives. *J Palliat Med* 2013;16:349–55.
- 9 Inghelbrecht E, Bilsen J, Mortier F, *et al.* Continuous deep sedation until death in Belgium: a survey among nurses. *J Pain Symptom Manage* 2011;41:870–9.
- 10 Swart SJ, van der Heide A, van Zuylen L, *et al.* Considerations of physicians about the depth of palliative sedation at the end of life. *CMAJ* 2012;184:E360–6.
- 11 Yokomichi N, Yamaguchi T, Maeda I, *et al.* Effect of continuous deep sedation on survival in the last days of life of cancer patients: a multicenter prospective cohort study. *Palliat Med* 2022;36:189–99.
- 12 Boulanger A, Chabal T, Fichaux M, *et al.* Opinions about the new law on end-of-life issues in a sample of French patients receiving palliative care. *BMC Palliat Care* 2017;16:7.
- 13 Robijn L, Cohen J, Rietjens J, *et al.* Trends in continuous deep sedation until death between 2007 and 2013: a repeated nationwide survey. *PLoS One* 2016;11:e0158188.
- 14 Mesnage V, Bretonniere S, Goncalves T, *et al.* Enquête Du centre national des Soins Palliatifs et de la fin de Vie sur La Sédation Profonde et continue Jusqu'au Décès (SPCJD) À 3 ANS de la Loi Claeys-Leonetti. *La Presse Médicale Formation* 2020;6880:111–228.
- 15 Cordeiro FR, Griebeler Oliveira S, Zeppini Giudice J, *et al.* Definitions for palliative care, end-of-life and terminally ill in oncology: a scoping review. *Enfermeria (Montev)* 2020;9:205–28.
- 16 Morita T, Imai K, Mori M, *et al.* Defining "continuous deep sedation" using treatment protocol: a proposal article. *Palliat Med Rep* 2022;3:8–15.
- 17 Bidegain-Sabas A. A "SEDAPALL" classification of sedative practices in palliative care: validation of clinical vignettes by experts' consensus in 2017-18. 2018.
- 18 Cousin F, Gonçalves T. *Atlas des soins palliatifs et de la fin de vie en France: Deuxième édition.* 2020.
- 19 Heijltjes MT, van Thiel G, Rietjens JAC, *et al.* Changing practices in the use of continuous sedation at the end of life: a systematic review of the literature. *J Pain Symptom Manage* 2020;60:828–46.
- 20 Arantzamendi M, Belar A, Payne S, *et al.* Clinical aspects of palliative sedation in prospective studies. A systematic review. *J Pain Symptom Manage* 2021;61:831–44.
- 21 Gurschick L, Mayer DK, Hanson LC. Palliative sedation: an analysis of international guidelines and position statements. *Am J Hosp Palliat Care* 2015;32:660–71.
- 22 ten Have H, Welie JVM. Palliative sedation versus euthanasia: an ethical assessment. *J Pain Symptom Manage* 2014;47:123–36.
- 23 Mercadante S, Gregoretti C, Cortegiani A. Palliative care in intensive care units: why, where, what, who, when, how. *BMC Anesthesiol* 2018;18:106.
- 24 Robijn L, Deliens L, Scherrens A-L, *et al.* A systematic review of quality improvement initiatives for continuous sedation until death. *Palliat Med* 2021;35:670–82.
- 25 Serey A, Tricou C, Phan-Hoang N, *et al.* Deep continuous patient-requested sedation until death: a multicentric study. *BMJ Support Palliat Care* 2023;13:70–6.
- 26 van Deijck R, Hasselaar JGJ, Verhagen S, *et al.* Determinants of the administration of continuous palliative sedation: a systematic review. *J Palliat Med* 2013;16:1624–32.
- 27 Poulalhon C, Rotelli-Bihet L, Raso C, *et al.* Deaths in France: characteristics, place of death, hospitalisations and use of palliative care during the year before death. *Rev Epidemiol Sante Publique* 2018;66:33–42.
- 28 Higgins PC, Altilio T. Palliative sedation: an essential place for clinical excellence. *J Soc Work End Life Palliat Care* 2007;3:3–30.
- 29 Pype P, Teuwen I, Mertens F, *et al.* Suboptimal palliative sedation in primary care: an exploration. *Acta Clin Belg* 2018;73:21–8.
- 30 Abarshi E, Rietjens J, Robijn L, *et al.* International variations in clinical practice guidelines for palliative sedation: a systematic review. *BMJ Support Palliat Care* 2017;7:223–9.
- 31 Rodrigues P, Crokaert J, Gastmans C. Palliative sedation for existential suffering: a systematic review of argument-based ethics literature. *J Pain Symptom Manage* 2018;55:1577–90.
- 32 Ciancio AL, Mirza RM, Ciancio AA, *et al.* The use of palliative sedation to treat existential suffering: a scoping review on practices. *J Palliat Care* 2020;35:13–20.
- 33 Henry B. A systematic literature review on the ethics of palliative sedation: an update (2016). *Curr Opin Support Palliat Care* 2016;10:201–7.
- 34 Chen P-J, Liang F-W, Ho C-H, *et al.* Association between palliative care and life-sustaining treatments for patients with dementia: a nationwide 5-year cohort study. *Palliat Med* 2018;32:622–30.
- 35 Belar A, Arantzamendi M, Menten J, *et al.* The decision-making process for palliative sedation for patients with advanced cancer-analysis from a systematic review of prospective studies. *Cancers (Basel)* 2022;14:301.
- 36 Frasca M, Orazio S, Amadeo B, *et al.* Palliative care referral in cancer patients with regard to initial cancer prognosis: a population-based study. *Public Health* 2021;195:24–31.
- 37 Heino L, Stolt M, Haavisto E. The practices and attitudes of nurses regarding palliative sedation: a scoping review. *Int J Nurs Stud* 2021;117:103859.
- 38 Prommer E. Midazolam: an essential palliative care drug. *Palliat Care Soc Pract* 2020;14:2632352419895527.
- 39 Bodnar J. A review of agents for palliative sedation/continuous deep sedation: pharmacology and practical applications. *J Pain Palliat Care Pharmacother* 2017;31:16–37.
- 40 Dieudonné Rahm N, Morawska G, Pautex S, *et al.* Monitoring Nociception and awareness during palliative sedation: a systematic review. *Palliat Med* 2021;35:1407–20.