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Posted Date: 11 September 2026

doi: 10.20944/preprints202609.0956.v1

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Article

Complex Palliative Sedation at Home for Advanced Cancer Patients: A Daily Challenge to Identify Determinants

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Abstract

Hospital at Home (HaH) enables advanced cancer patients to receive end-of-life care in their preferred setting, yet evidence on home-based palliative sedation (PS) remains limited. This retrospective observational study included 113 patients who died in 2022 under the HaH Unit of the Instituto Valenciano de Oncología (Valencia, Spain). Sociodemographic, clinical, and PS-related variables were extracted from medical records. PS was required in 80 patients (70.8%). The median age was 76 years (IQR 19), 52.2% were male, and 77% lived in their own homes. Dyspnoea (43.7%) and delirium (23.7%) were the most frequent refractory symptoms leading to PS. Elastomeric infusers were used in 92.5% of cases. The median duration of PS was 1 day (IQR 2); 46.3% of patients died within 24 hours of initiation. A significant inverse correlation was found between the Barthel Index and PS duration (Spearman's Rho = −0.226, p = 0.044), indicating shorter survival after sedation in patients with greater functional dependence. No significant associations were observed between PS requirement and multimorbidity, geriatric syndromes, polypharmacy, or prior opioid use. These findings support the feasibility of complex PS at home and highlight functional status as a potential determinant of PS duration, informing protocol optimization for home-based end-of-life care.

Keywords: palliative sedation; hospital at home; advanced cancer; refractory symptoms; dyspnoea; delirium; Barthel Index; end-of-life care

1. Introduction

Hospital at Home (HaH) is a healthcare model that provides hospital-level medical and nursing care at home, offering services comparable to conventional hospitalization (1). In Spain, HaH has significantly expanded since the establishment of the first unit in Madrid in 1981 (2), with over 130 units currently operating nationwide (3). However, the distribution and scope of services vary across autonomous communities. In the Valencian Community, there are 27 HaH units, including the Instituto Valenciano de Oncología (IVO), where all patients present oncological pathologies (4). In many HaH units, advanced palliative care is crucial, enabling patients with advanced diseases to remain at home with optimal symptom management. While this type of care is central at IVO, other units manage a wider range of pathologies. A 2023 study in the Basque Country reported that 26% of HaH patients required palliative care, with some units reporting up to 39%, reflecting considerable variability (1).

The primary goal of Palliative Care in HaH is to provide effective symptom control, allowing patients to spend their final days without suffering in a dignified environment while avoiding unnecessary hospitalizations (5). Despite advancements in this care model, home-based end-of-life

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care remains a challenge in many healthcare systems, even though it is the preferred option for many patients and families. Thus, specialized professionals capable of identifying and managing refractory symptoms at home while considering the home environment are needed (6). According to the World Health Organization (WHO), approximately 40 million people could benefit from palliative care due to the increasing incidence of cancer. Proper follow-up by specialized professionals ensures symptom control. However, in some cases, symptoms remain unmanageable despite available treatments, leading to "refractory symptoms" (7).

Patients in the last days of life often experience refractory symptoms, with delirium or agitation, pain, dyspnoea, death rattle, and psychological distress being the most common (7–10). In such cases, the supervised administration of medications to reduce patient consciousness and alleviate existential and physical suffering is termed palliative sedation (7,11,12). The most frequently used medications for palliative sedation include midazolam and levomepromazine, with haloperidol, morphine, scopolamine, and hyoscine also frequently administered. On average, 4.3 drugs are used for symptom control in the final phase of life (7,9).

Several studies have analysed the use of palliative sedation at HaH. A study on home-based oncological patients reported an average duration of care of 63.9 days, with 66% of patients dying at home. Among these patients, 12% required palliative sedation due to refractory symptoms, primarily delirium and dyspnoea. The most common cancer types are gastrointestinal, pulmonary, and genitourinary. The mean time from sedation initiation to death was 2.6 days (9). Another study (10) reported that 56.34% of patients required palliative sedation, with continuous infusion being used in 94% of patients. Dyspnoea (22%) and delirium (18%) were the most common symptoms, with midazolam being the most used drug. A recent study (2024) (7) revealed that 16.7% of patients required palliative sedation, with a mean duration of two days until death, and 98% required continuous sedation. The most frequent symptoms were delirium (36.1%), pain (31.9%), and dyspnoea (25%).

Few studies have compared palliative sedation in hospital versus home settings. A study in Italy suggested that, while symptom prevalence varies between care settings, appropriate management can be effectively implemented in both. This highlights the importance of adapting palliative care protocols to home settings to ensure optimal patient care without hospitalization (13).

In recent years, an increasing number of advanced cancer patients have preferred to remain at home during their final stages, receiving home-based palliative care. HaH has proven to be an effective alternative, offering better symptom control, avoiding unnecessary transfers, and ensuring appropriate support within the family environment. Despite the growing role of HaH in managing these patients, studies focusing on the characteristics of the home-based patient population and the interventions provided in the terminal phase of life are lacking.

Within the framework of the Spanish Society of Hospital at Home, a multicentre study on end-of-life care in this care setting was proposed. As a participating centre, we analysed data from our hospital, the Instituto Valenciano de Oncología. This study aims to describe the profile of advanced cancer patients receiving home-based care from a specialized unit, the refractory symptoms requiring palliative sedation, and the therapeutic strategies employed. By collecting data, we seek to optimize care quality and facilitate decision-making in home-based end-of-life care, allowing for protocol adjustments and ensuring personalized care tailored to each patient's needs.

2. Methodology

A retrospective observational study was conducted, including patients who died between January 1 and December 31, 2022, under the care of the HaH Unit of the Instituto Valenciano de Oncología (IVO). Patients without a documented “palliative care” status in their clinical history or those transferred to a hospital for end-of-life care were excluded. Additionally, patients lacking medical records for data collection were also excluded.

Sociodemographic and clinical data were collected from patient records and routine hospital activity logs. A nonprobabilistic convenience sampling method was used, and all eligible patients

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were selected on the basis of predefined inclusion and exclusion criteria. Data collection adhered to current legislation on personal data protection and was subsequently transferred to a computerized database.

Ethical and legal requirements were met, following Good Clinical Practice principles (*Real Decreto* 561/1993, Ministry of Health and Consumer Affairs) and the Helsinki Declaration. Informed consent was not needed, as this was a retrospective study of deceased patients, ensuring full anonymization of personal data. Ethical approval was granted by the promoting hospital's Research Ethics Committee in December 2023.

Basic sociodemographic variables, including sex, age, marital status, usual residence, and living arrangements of the patients, were recorded. Additionally, healthcare-related variables were collected, such as the identification of the primary caregiver, the inclusion of an advanced care plan, the need for palliative care in the referral report, the length of stay in the unit, and the need for palliative sedation at the end of life.

Functional status was assessed via the Eastern Cooperative Oncology Group (ECOG) Performance Status. The Barthel Index was used to evaluate the ability to perform basic activities of daily living (eating, bathing, dressing, etc.), categorizing patients as independent (BI: 90–100), moderate dependence (BI: 60–89), or severe dependence (BI <60). Additionally, the Global Deterioration Scale (GDS) was employed to assess cognitive function, classifying patients according to their degree of cognitive decline as mild (GDS <4), moderate (GDS: 4–5), or severe (GDS: 6–7). Other recorded variables included the type of neoplasm, the presence of geriatric syndromes (constipation, delirium, malnutrition, pressure ulcers, and urinary incontinence), the presence of polypharmacy (use of five or more daily medications), opioid use upon admission and its morphine-equivalent dose, and the presence of multimorbidity.

2.1. Variables Related to Palliative Sedation (PS)

Variables related to palliative sedation, including medication administration devices (elastomeric infusers or electric systems), were also recorded. Refractory symptoms leading to sedation, such as delirium, dyspnoea, pain, active bleeding, vital emotional suffering, or other symptoms, were documented. Additionally, the number of required parenteral medications and the duration of palliative sedation until death were recorded.

2.2. Statistical Analysis

For the descriptive analysis, frequencies and percentages were calculated for qualitative variables, whereas means and standard deviations were computed for quantitative variables following a normal distribution. When variables did not follow a normal distribution (Kolmogorov–Smirnov test or Shapiro–Wilk test for samples ≤50), the median and interquartile range (IQR) were reported. These analyses were performed for the entire sample or differentiated by study groups, as appropriate.

For bivariate analysis, appropriate statistical tests were applied to evaluate the relationships between two variables. If both variables followed a normal distribution and were numerical, Pearson correlation coefficients and/or linear regression were used. If one variable was quantitative and the other was qualitative, Student's t test was applied when the qualitative variable had two levels, and ANOVA was used when it had three or more levels.

If the variables did not follow a normal distribution, when both were numerical, Spearman's correlation was used. When one was quantitative and the other was qualitative, the Mann–Whitney U test was applied for two-level qualitative variables, and the Kruskal–Wallis test was used for those with three or more levels. If both were qualitative, no normality check was needed, and either the χ^2 test (for r × s tables) or Fisher's exact test (for 2 × 2 tables) was used.

In the multivariate analysis, simultaneous relationships between a dependent variable and multiple independent variables were examined. If the dependent variable was quantitative,

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multivariate linear regression was performed, whereas for qualitative dependent variables, multivariate logistic regression was applied.

3. Results

3.1. Demographic and Healthcare Characteristics of the Population

The study sample consisted of 113 patients (Table 1), of whom 59 were men (52.2%) and 54 were women (47.8%). The median age was 76 years (IQR 19), with a range between 43 and 95 years. The median age for men was 77 years (IQR 14), whereas for women, it was 75 years (IQR 23). No significant differences in age were found between men and women (Mann–Whitney U test, $p = 0.277$).

With respect to marital status, data were available for 79 patients, of whom 46 (40.7%) were married, 24 (21.2%) were widowed, and 9 (8%) fell into other categories. Concerning usual residence, data were unavailable for 15 patients. Among the remaining patients, 87 (77%) lived in their own homes, 11 (9.7%) lived with other relatives, and none resided in a long-term care facility. In terms of living arrangements, the variables were recategorized into four groups: living with direct family members (spouses, partners, or children), living with a family member and a caregiver, being cared for by an external caregiver, and having no designated caregiver. Among the 113 patients, 74 (66.4%) lived with family members, 7 (6.2%) lived with a family member and a caregiver, 7 (6.2%) were under the care of an external caregiver, and 24 (21.2%) had no specific caregiver. Among 82 patients (72.6%), a family member was actively involved in their care, whereas 14 (12.4%) relied on an external caregiver.

No significant differences by sex were found in relation to age (Mann–Whitney U test, $p = 0.277$), usual residence ($\chi^2 = 0.574$, $p = 0.750$), living arrangements ($\chi^2 = 4.132$, $p = 0.127$), or marital status ($\chi^2 = 0.356$, $p = 0.069$), suggesting a homogeneous distribution of patients regardless of sex.

At the time of admission to the unit, 94 patients (83.2%) had a referral report that included the need for palliative care. Additionally, only 15 patients (13.3%) had an advanced care plan documented in their medical history. The mean length of stay in the unit was 47.5 days (SD = ±55.8).

No significant differences were found in the length of stay based on the need for palliative sedation at the end of life, as assessed via Student's t test ($p > 0.05$). However, the mean number of days was slightly greater among patients who required palliative sedation, with a mean of 37.3 days (SD = ±44.5) for those who did not receive sedation, compared with 51.7 days (SD = ±60.9) for those who did.

The care team conducted an average of 20.6 visits (SD = ±27.4) per patient during home-based hospitalization. The number of visits was greater in patients who required palliative sedation, with a mean of 23.1 visits (SD = ±31.2), than in those who did not receive sedation, with 14.9 visits (SD = ±14.5). However, these differences were not statistically significant (Student's t test, $p > 0.05$).

Table 1. Demographic and healthcare characteristics of the total population (N=113).

Variables	Total (N=113)	No PS (N=33)	PS (N=80)
Age			
Median (IQR)	76 (19)		
Sex, n (%)			
Male	77 (14)	19	40
Female	75 (23)	14	40
Marital status, n (%)			
Married	46 (40.7)	12 (36.3)	34 (42.5)
Widowed	24 (21.2)	9 (27.2)	15 (18.7)
Others/Not avalaible	43 (38.1)	12 (36.3)	31 (38.7)
Residence, n (%)			
Own home	87 (77)	28 (84.8)	59 (73.7)
Other family members' home	11 (9.7)	2 (6)	9 (11.2)
Not available	15 (13.3)	3 (9)	12 (15)

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Variables	Total (N=113)	No PS (N=33)	PS (N=80)
Identification of the primary caregiver in the medical history, n (%)	88 (77.9)	26 (78.7)	62 (77.5)
Identification of palliative care needs in the referral report, n (%)	94 (83.2)	26 (78.7)	68 (85)
Inclusion of an advanced care plan in medical history, n (%)	15 (13.3)	3 (9)	12 (15)
Record in the medical history about the patient's preferred place of death, n (%)	24 (21.2)	7 (21.2)	17 (21.2)
Days the patient stays in the HaH until death			
Mean (SD)	47.5 (±55.8)	37.3 (±44.5)	51.7 (±60.9)
Number of palliative care team visits during the UHD admission			
Mean (SD)	20.6 (±27.4)	14.9 (±14.5)	23.1 (±31.2)
Palliative sedation (PS), n (%)	80 (70.8)		

N: sample size; PS: palliative sedation; SD: standard deviation.

The clinical characteristics at admission, such as primary tumour site, Barthel Index, ECOG-PS, GDS, multimorbidity conditions, geriatric syndromes, polypharmacy and use of opioids, are shown in Table 2.

Table 2. Clinical characteristics at admission of the total population (N=113).

Variables	Total (N=113)	No PS (N=33)	PS (N=80)
Primary tumour site, n (%)			
Digestive	35 (31)	11 (33.3)	24 (30)
Breast	15 (13.3)	4 (12.1)	11 (13.7)
Gynaecologic	9 (8)	1 (3)	8 (10)
Lung	11 (9.7)	4 (12.1)	7 (8.7)
Urologic	27 (23.9)	9 (27.7)	18 (22.5)
Others	16 (14.2)	4 (12.1)	12 (15)
Barthel index, n (%)			
Independent	8 (7.1)	1 (3)	7 (8.7)
Moderate dependence	41 (36.3)	13 (39.3)	28 (35)
Complete dependence	64 (56.6)	19 (57.58)	45 (56.2)
ECOG Performance Status, n (%)			
0	3 (2.7)	0	3 (3.7)
1	16 (14.2)	3 (9)	13 (16.2)
2	24 (21.2)	9 (27.2)	15 (18.7)
3	37 (32.7)	10 (30.3)	27 (33.7)
4	33 (29.2)	11 (33.3)	22 (27.5)
Global Deterioration Scale (GDS) Index, n (%)			
Mild Cognitive Deterioration	87 (77)	27 (81.8)	60 (75)
Moderate Cognitive Deterioration	19 (16.8)	3 (9)	16 (20)
Severe Cognitive Deterioration	7 (6.2)	3 (9)	4 (5)
Multimorbidity condition, n (%)	87 (77)	24 (72.7)	63 (78.7)
Geriatric syndromes, n (%)	38 (33.6)	10 (30.3)	28 (35)
Incontinence/Urinary catheter	35 (24.8)	9 (27.2)	26 (32.5)
Constipation	30 (21.3)	11 (33.3)	19 (23.7)
Malnutrition	16 (11.3)	4 (12.1)	12 (15)
Pressure ulcers	11 (7.8)	3 (9)	8 (10)
Polypharmacy, n (%)	69 (61.1)	21 (63.6)	48 (60)
Use of opioids, n (%)	36 (31.9)	8 (24.2)	28 (35)
Mean equivalent dose of morphine in mg (SD)	57.1 (±69.2)	43.1 (±25.3)	61.3 (±77.6)

N: sample size; PS: Palliative sedation; SD: Standard Deviation; ECOG: Eastern Cooperative Oncology Group

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3.2. Characteristics of Palliative Sedation

Palliative sedation was required in 80 patients (70.8%), whereas 33 (29.2%) did not require sedation. The most used sedation device was the elastomeric infuser, which was employed in 74 patients (92.5%). The remaining 6 patients (7.5%) received sedation through an electric system.

Sedation duration did not follow a normal distribution (K-S = 0.278, $p < 0.005$), with a **m**edian of 1 day, a minimum of 0 days, a maximum of 10 days, and an interquartile range (IQR) of 2 days. The most common durations were as follows: 1 day in 37 patients (46.3%), 2 days in 13 patients (16.3%), and same-day death after sedation in 10 patients (12.5%). No significant relationship was observed between sedation duration and sex (Mann–Whitney U test, $p = 0.746$).

Regarding the refractory symptoms that led to sedation, data were missing for 24 patients (30%). The most frequent symptom was dyspnoea, which was present in 27 patients (33.75%), either as an isolated symptom (8 patients, 10%) or in combination with other symptoms (pain, emotional suffering) in 21 patients (26.25%). The second most common symptom was pain (12 patients, 15%), either alone or in combination with other symptoms, followed by emotional suffering (5 patients, 6.25%). The presence of two symptoms was observed in 10 patients (12.5%), whereas more than two symptoms were recorded in 4 patients (5%).

The number of medications used for sedation did not follow a normal distribution (K-S = 0.352, $p < 0.0001$), with a median of 4 drugs, a minimum of 1, a maximum of 7, and an IQR of 1. A linear relationship was identified between the number of drugs used and sedation duration (Spearman's Rho $r = -0.253$, $p = 0.023$), indicating that a greater number of medications was associated with shorter survival after sedation initiation.

The variables associated with the need for sedation, as identified in this study, included multimorbidity, geriatric syndromes, number of medications at admission to the Hospital at Home (HaH) Unit, the Barthel Index, the Eastern Cooperative Oncology Group (ECOG) score, and cognitive status.

Among the 113 patients, 87 (77%) had two or more chronic diseases, whereas 26 (23%) had no multimorbidity. Only one patient did not have an oncological disease (Category G), whereas 112 patients (99.1%) were oncology patients without disease-modifying treatment. The most frequent category was G, followed by F (20 patients, 17.7%) and B (15 patients). Multimorbidity was not associated with the need for sedation (χ^2, $p = 0.474$) or with sedation duration (Mann–Whitney U test, $p = 0.881$).

Geriatric syndromes were identified in 52 patients (46%), with the most prevalent being constipation (29 patients, 55.8%), malnutrition (15 patients, 28.8%), pressure ulcers (PUs) (10 patients, 19.2%) and urinary incontinence/catheter use (33 patients, 63.5%). No statistically significant associations were found between geriatric syndromes and the need for sedation (χ^2 $p = 0.710$) or sedation duration (Mann–Whitney U test, $p = 0.532$).

A total of 64.8% of patients (83) were taking five or more medications, with a median of 6, a minimum of 0, a maximum of 19, and an IQR of 5. No significant associations were found between polypharmacy and the need for palliative sedation (Mann–Whitney U test, $p = 0.376$) or disease duration (Spearman's Rho $r = -0.119$, $p = 0.292$).

Upon admission to home-based care, 31.9% of patients (36 out of 113) were already using opioids. The most administered daily morphine-equivalent dose (MED) was 10 mg, followed by 5 mg and 60 mg. No associations were found between sedation duration and the opioid dose (Mann–Whitney U test, $p = 0.088$) or between the opioid dose and the need for sedation (χ^2, $p = 0.264$).

The Barthel Index had a median score of 50, with an IQR of 43. A significant correlation was observed between age and the Barthel index, with an inverse relationship (Spearman's Rho = -2.70, $p = 0.004$), as well as between the Barthel index and sedation duration (Spearman's Rho = -0.226, $p = 0.044$), suggesting that lower Barthel index scores were associated with shorter sedation duration. However, no significant association was found between the Barthel Index score and the need for sedation (Mann–Whitney U test, $p = 0.409$). No significant differences in sedation duration were

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found based on the Eastern Cooperative Oncology Group (ECOG) score (Kruskal–Wallis H = 2.517, p = 0.472).

Table 3. Palliative sedation characteristics (N= 80).

Variables	Value n (%)	Mean (SD)
Administration device		
Elastomeric infuser	74 (92.5)	
Electric system	6 (7.5)	
Refractory symptoms motivating sedation		
Delirium	19 (23.7)	
Dysnea	35 (43.7)	
Pain	14 (17.5)	
Active bleeding	2 (2.5)	
Vital emotional suffering	5 (6.2)	
Others	38 (47.5)	
Number of refractory symptoms		
1	56 (70)	
2	17 (21.3)	
3	6 (7.5)	
4	1 (1.3)	
Number of parenteral drugs required		3.4 (1)
Days of duration until death		2 (2)

No clear relationship was observed between the need for sedation and the studied variables. However, a relationship was identified between sedation duration and both the number of medications used and the Barthel Index score. A linear regression analysis indicated that the Barthel Index was a partial explanatory factor for sedation duration (R^2 = 0.065), suggesting that higher Barthel scores were associated with shorter survival following sedation initiation. However, this factor explained only 6.5% of the variation in post-sedation survival. The resulting equation was as follows: Sedation duration = 3.051–0.20 (Barthel Index), p = 0.021.

4. Discussion

There is no doubt that home care is an area of special interest in the treatment of individuals, especially in the final stages of their lives. Several factors contribute to the need to address this topic from multiple perspectives, areas, and strategies. This article aims to make a significant contribution to this ongoing reality, to the urgent need for knowledge that can no longer wait, because it is part of the daily lives of an increasing number of people. The scientific literature indicates that the home is the preferred place for many patients to die (14-17), and similarly, the data presented here show that three out of four of our patients prefer to die at home rather than at a hospital or healthcare center, which greatly increases the need to understand the reality of home care. However, to date, we do not have much published experience regarding the process and outcomes of home palliative sedation care.

In the analysis presented here, with a range between zero and ten days, the average duration of palliative sedation was two days, with three-quarters of the patients dying during this period, a finding very similar to those reported by other authors with samples of oncology patients treated at home (18) or in the general population (19).

Similarly, the fact that there were no differences in the length of stay between the two groups, with or without palliative sedation, as has been observed in previous studies, suggests the adequacy of palliative sedation treatment and the rigor and individualization of its implementation. In this regard, this individualization is also supported by the fact that there were no differences in the choice of decreasing consciousness as a treatment for refractory symptoms on the basis of the patient's cognitive status or personal history of opioid use.

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Finally, it is important to highlight the causal prevalence of dyspnoea as the main refractory symptom justifying the use of palliative sedation, followed by delirium. These data are partially similar to those offered by Calvo et al (18) or Mercadante et al (20), with similar samples, who primarily highlight delirium.

In conclusion, we are dealing with a person, regardless of sex, with an average age of 73 years, who is mostly married, living in their own home, has multiple pathologies, consumes more than one medication daily, but has no history of opioid use at admission and no associated symptoms (geriatric syndrome, constipation, delirium, malnutrition, or pressure ulcers), with a stay time independent of whether sedation was administered, of approximately two days, and whose predominant refractory symptom is dyspnoea. This is consistent with the review by García et al (21) in 2023, which was based on a series of 23 studies that ranked the frequency of refractory symptoms in descending order: pain, dyspnoea, and delirium.

It is important to mention the possibilities for improvement in this study. One of them is that it would have been desirable to include in the analysis the study of patients' "awakenings" with discomfort during sedation, incidental pain episodes, the need for rescue interventions, or the need for dose increases owing to lack of symptomatic control, with the goal of having a more complete map of the actual quality of sedation in the evaluated patient. Another point to consider is the positive relationship between the Barthel Index (BI) score and the duration of sedation, a fact corroborated by the existence of a negative and statistically significant correlation between the BI score and sedation duration. In other words, the greater the level of functional independence is, the shorter the duration of sedation. These data should be studied in detail to understand the origin of this relationship and whether it is consistent across different studies (confirmation). This, coupled with the fact that, in a significant number of cases, the reasons for initiating palliative sedation are unclear, could suggest that the depth or level of sedation may not have been equivalent in both types of patients.

Finally, although the scientific literature presents some ambiguity regarding the use of the term palliative sedation (13,22,23), this study follows the definition of the European Association for Palliative Care, which is the use of sedative medications in terminal patients to alleviate intolerable suffering from refractory symptoms by reducing the patient's level of consciousness (12).

Author Contributions: Conceptualization, Salvador Martín-Utrilla, Antonio Mancheño-Álvaro and Enrique Sáez-Alvarez; Methodology, Salvador Martín-Utrilla, Julián Mollá-Marinas and Antonio Mancheño-Álvaro; Formal analysis, Paula Oliver de Haro, Julián Mollá-Marinas and Antonio Mancheño-Álvaro; Investigation, Paula Oliver de Haro and Enrique Sáez-Alvarez; Resources, Julián Mollá-Marinas and Antonio Mancheño-Álvaro; Data curation, Paula Oliver de Haro and Julián Mollá-Marinas; Writing – original draft, Salvador Martín-Utrilla; Writing – review & editing, Paula Oliver de Haro and Enrique Sáez-Alvarez; Supervision, Salvador Martín-Utrilla; Project administration, Salvador Martín-Utrilla and Antonio Mancheño-Álvaro; Funding acquisition, Salvador Martín-Utrilla. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the promoting hospital's Research Ethics Committee "Comité de Ética de la Investigación del Hospital Vega Baja de Orihuela, Generalitat Valenciana", register code MC-2023-067, in December 2023.

Informed Consent Statement: Informed consent was not needed, as this was a retrospective study of deceased patients, ensuring full anonymization of personal data.

Data Availability Statement: The data presented in this study are available on request from the corresponding author, with permission of Fundación Instituto Valenciano de Oncología, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available.

Conflicts of Interest: The authors declare no conflict of interest.

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