

Attitudes of palliative home care physicians towards palliative sedation at home in Italy

Sebastiano Mercadante¹ · Francesco Masedu² · Alessandro Mercadante³ · Franco Marinangeli³ · Federica Aielli⁴

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Abstract

Background Information about the attitudes towards palliative sedation (PS) at home is limited.

Aim The aim of this survey was to assess the attitudes of palliative care physicians in Italy regarding PS at home.

Design A questionnaire was submitted to a sample of palliative care physicians, asking information about their activity and attitudes towards PS at home.

Setting This is a survey of home care physicians in Italy who were involved in end-of-life care decisions at home.

Results One hundred and fifty participants responded. A large heterogeneity of home care organizations that generate some

problems was found. Indications, intention and monitoring of PS seem to be appropriate, although some cultural and logistic conditions were limiting the use of PS. Specialized home care physicians are almost involved to start PS at home. Midazolam was seldom available at home and opioids were more frequently used.

Conclusion These data should prompt health care agencies to make a minimal set of drugs easily available for home care. Further research is necessary to compare attitudes in countries with different sociocultural profiles.

Keywords Advanced cancer · Palliative sedation · Attitudes · End of life · Home care

On behalf of “Home Care Italy” group (HOCAI group)

✉ Sebastiano Mercadante
terapiadeldolore@lamaddalenanet.it; 03sebelle@gmail.com

Francesco Masedu
francesco.masedu@univaq.it

Alessandro Mercadante
simply_merka@hotmail.it

Franco Marinangeli
francomarinangeli@gmail.com

Federica Aielli
federica.aielli@univaq.it

¹ Supportive/Palliative Care Unit, La Maddalena Cancer Center, Via San Lorenzo 312, 90146 Palermo, Italy

² Department of Biotechnological and Applied Clinical Sciences, Section of Clinical Epidemiology and Environmental Medicine, University of L'Aquila, L'Aquila, Italy

³ University of L'Aquila, L'Aquila, Italy

⁴ Department of Biotechnological and Applied Clinical Sciences, University of L'Aquila, L'Aquila, Italy

Introduction

In terminally ill cancer patients, symptoms may become refractory to symptomatic agents as death approaches. Palliative sedation (PS) is defined as deliberately lowering a patient's consciousness, to relieve intolerable suffering from refractory symptoms at the end of life. PS is considered a last resort intervention in end-of-life care. This practice has been used for years with a variable incidence, ranging from 2 to 52% [1]. The large variability observed in the use of PS might be due to a lack of appropriate criteria adopted for definition of PS or different settings, population, and attitudes. The application of PS continues to be tied to a number of concerns that have limited its use in palliative care. Part of the resistance towards the use of this last resort treatment option has been the continued association of PS with physician-associated suicide and/or euthanasia [2]. This could be compounded by a lack of clinical guidelines and a failure to consider this treatment as a licit palliative care approach. Laws and regulations may impact the use of PS. On the other hand, some cultural or practical

issues may also interfere with application of this technique. Although the choice should only be dictated by an appropriate and timely decision-making based on the patients' real needs, it is often determined by cultural, ethnic, and religious factors, policies of institution, or national legislation. These aspects are even more complex at home. In the last weeks of their life, the majority of advanced cancer patients live at home, where they will spend their end of life [3]. Thus, the need of PS should more frequently occur at home. In literature, the frequency of PS at home is largely variable (13–35%) [4]. In retrospective and prospective studies in Italy, PS was performed in about 13% of patients followed at home [5, 6]. The aim of this survey was to assess the attitudes of palliative care physicians in Italy regarding PS at home.

Methods

This is a survey of physicians who were involved in end-of-life care decisions at home in Italy. The sample was chosen among a list of participants to Home Care-Italy events and of a visiting program at La Maddalena Cancer Center, in the last 3 years. Four hundred and five physicians were contacted by e-mail to take part in the study and fill in the questionnaire, if they were involved in home palliative care. E-mails were replayed for three attempts. Anonymity was warranted. As no patients' data were managed, the request for ethical approval was deemed to be unnecessary.

The questionnaire was composed by general data regarding age, gender, geographic macro-area, specialization, work setting, years of experience in palliative care (1–5; 6–10; 11–15; 16–20; >20 years) and in home care, and what percentage of work was dedicated to palliative care (100%, 76–99%, 51–75%, 26–50%, ≤25%). Other questions included information about the home care service: only home, home care and hospice care, hospice care; type of service, type of organization delivering palliative care, and type of contract. Specific questions regarding PS were the following: number of palliative sedations at home per year (≤10, 11–30, 31–50 > 50), type of sedation (proportional and progressive, deep sedation ab initio, proportional sedation and intermittent), people involved in the decision-making process (home care team, patient, family, consultant in palliative care, authorization of a responsible of the service), monitoring (clinical, scales, which scales if any), indications for sedation, symptoms, professional starting sedation, hydration (discontinuation, no changes, start hydration, according to the need), and drug availability and uses (monotherapy or combination of drugs); drugs used for sedation (all available, only limited choice), changes in case of failure (increasing the dose, increasing and combining, combination), use of opioids (continued if already started for other symptoms, used for sedation not used for other symptoms,

discontinued when starting sedation), patients' and family information and shared decisions.

Statistics

The analysis provided descriptive tabulations and summary sample statistics, relative frequencies, mean, and standard deviations for both socio-demographic factors and clinical and therapeutic variables. The analysis was devoted to assess the association patterns among classes of socio-demographic and clinical variables with the practice of home palliative sedation in the sample surveyed. The analysis used the χ^2 tests and, when the expected cell values are <5, we carried out an exact Fisher's test, setting the α error at 5%. The results have been adjusted applying Holm's method using the Dunn-Sidak correction. In case of continuous variables, for example age, we performed Spearman's correlations. The statistical analysis was performed using the statistical software STATA (version 14).

Results

One hundred and fifty participants who were involved at least in part in home care provided the responses to the questionnaire (37.1%). The mean age was 46.1 years (SD 9.2) and 75 (50.3%) were males. The characteristics of the respondents are listed in Table 1.

One hundred and seventeen (78%) physicians performed PS every time it was necessary and possible, 10 (6.7%) physicians would like to do that, but preferred to refer patients to the hospital, and 23 physicians (15.3%) did not perform PS at home. The principal reasons were by order of rank: too much complex management at home (34.8%), lack of organization (no drug availability or other) (26.1%), and other imprecise reasons (39.3%).

Of all respondents, 118 (78.7%) believed that PS at home is licit and feasible, 30 (20%) believed that it was licit but clinically difficult, and two (1.3%) would avoid to do that for defensive medicine. Of respondents who did not perform PS, 10 (43.5%) considered PS at home as a licit and possible practice, 12 (52.2%) as a licit but difficult practice at home, and one (4.3%) would prefer to avoid that, due to defensive medicine.

Analysis of respondents who performed PS at home

All physicians performing PS at home agreed that the aim of PS was to alleviate intolerable suffering due to refractory symptoms by reducing the level of patient's consciousness without hastening the process of death. All physicians stated that they periodically monitor the level of sedation. Attitudes regarding PS at home are presented in Table 2.

Table 1 Characteristics of respondents

Number of patients per year/center	208.2 (SD 181.3), range 20–1000
Macro-area of work	
North	63 (43.1%)
Center	40 (26.8%)
South	14 (9.6%)
Islands	14 (9.6%)
Background specialization	
Oncology	40 (26.8%)
Anesthesiology	32 (21.5%)
Geriatrics	10 (6.7%)
Radiotherapy	7 (4.7%)
Others or none	60 (40.3%)
Experience in palliative care	
1–5 years	53 (35.3%)
6–10 years	41 (27.3%)
11–15 years	36 (24.0%)
16–20 years	8 (5.3%)
>20 years	12 (8.0%)
Experience in home care	
1–5 years	67 (44.7%)
6–10 years	34 (22.7%)
11–15 years	31 (20.7%)
16–20 years	9 (6.0%)
>20 years	9 (6.0%)
Time spent in palliative care	
100%	73 (48.7%)
76–99%	37 (24.7%)
51–75%	18 (12.0%)
26–50%	9 (6.0%)
<25%	13 (8.6%)
Distribution work time	
Only or prevalently home care	70 (47.3%)
Half home care, half hospital	54 (36.5%)
Only or prevalently hospital	24 (16.2%)
Organization	
Public	88 (58.7%)
Private—reimbursed by HCS	29 (19.3%)
Non-profit	31 (20.7%)
Others	2 (1.3%)
Professional contract	
Employee	82 (54.7%)
Freelance	58 (38.7%)
Private—reimbursed by HCS	8 (5.3%)
Other	2 (1.3%)

There was no correlation between PS at home and responders' age ($p = 0.12$), gender ($p = 0.8$), macro-areas ($p = 0.16$), background specialization ($p = 0.23$), number of patients followed/year ($p = 0.08$), years of experience in

palliative care ($p = 0.13$), years of experience in home care ($p = 0.06$), type of service ($p = 0.77$), and knowledge of literature regarding palliative sedation ($p = 0.21$). A correlation between people who performed PS at home and percentage of work dedicated to palliative care ($p = 0.04$) was found.

Drugs

Data regarding the drugs used for PS are presented in Table 2. About 30% of the physicians did have availability to all the drugs, particularly midazolam. No specific correlations between the variables taken into consideration and the use of benzodiazepines or barbiturates were found, unless for people with a background in anesthesia, who less frequently used midazolam in comparison with oncologists ($p = 0.01$).

There was no correlation between the variables taken into consideration and the use of neuroleptics or opioids, unlike for people with a background in anesthesia who used opioids more frequently ($p = 0.001$), and people with years spent (6–15 years) in palliative care ($p = 0.03$).

Discussion

This survey provided interesting findings. The response rate was relatively high, considering that it was required for possible respondents to have some activity, even partial, in home palliative care.

The majority of the physicians specialized in anesthesiology or oncology and most of them had less than 15 years of experience in palliative care and home care. Also, organization and contracts were largely variable. This finding reflects the status of palliative care in Italy that it is a really non-homogeneous field, with different systems and organizations, despite a recent law that evidently failed in giving an order to the system [7]. The physicians' limited experience also suggests a high turnover with a high "mortality" of physicians working in palliative care, possibly because of the low salary or temporary contracts.

Palliative sedation

In terms of activities, the team organization provided different data on PS. The majority of physicians performed less than 30 PSs a year at home and most of them used a proportional approach. Of interest, a large population of physicians required advice to decide to start PS. About 50% used validated scales for monitoring the level of sedation, prevalently the Rudkin Scale. The indications for PS included both psychological and physical symptoms, with the co-presence of dyspnea and delirium being the most frequent reason to start PS. This is consistent with previous retrospective and prospective studies of PS performed at home [5, 6, 8–10].

Table 2 Data regarding palliative sedation

Number of palliative sedations at home/year	
≤10	49 (38.9%)
11–30	44 (34.9%)
31–50	25 (19.8%)
>50	8 (6.4%)
Type of sedation	
Proportional and progressive	117 (93.6%)
Deep sedation ab initio	5 (4.0%)
Proportional sedation and intermittent	3 (2.4%)
People involved in decision-making process	
Home care team, patient, family	86 (68.2%)
Home care team, patient, family, and a consultant in palliative care	39 (30.9%)
Request of authorization to responsible of the service	1 (0.8%)
Monitoring	
Clinical	65 (51.6%)
Clinical and scales	61 (48.4%)
Scales for sedation	
Richmond Agitation Sedation Scale (RASS)	15 (24.6%)
Ramsay Sedation Scale (RSS)	16 (26.2%)
Rudkin Scale	30 (49.2%)
Indications for sedation	
Refractory symptoms	24 (19.0%)
Psychological distress, anguish	1(0.8%)
Both	101 (80.2%)
Symptoms	
Pain	9 (7.1%)
Dyspnea	6 (4.7%)
Delirium	7 (5.5%)
Convulsions	1 (0.8%)
Hemorrhage	1 (0.8%)
Pain + dyspnea	15 (11.8%)
Dyspnea–delirium	60 (47.2%)
Pain + dyspnea + delirium	28 (22.0%)
Professional starting sedation	
Always physician	80 (63.5%)
Always nurse	2 (1,6%)
Indifferently	3 (2.4%)
Preferably physician	41 (32.6%)
Preferably nurse	0
Hydration	
Discontinuation	15 (12.0%)
No changes	29 (23.2%)
Start hydration	2 (1.6%)
According to the need	79 (63.2%)
Drug availability and uses	
Monotherapy	57 (45.2%)
Combination of drugs	69 (54.8%)
All drugs indicated in literature	87 (69.1%)
Drugs used for sedation (multiple choice)	

Table 2 (continued)

Midazolam	55 (43.6%)
Other benzodiazepines	75 (59.5%)
Neuroleptics	75 (59.5%)
Opioids	86 (68.2%)
Barbiturates	8 (6.3%)
Others	6 (4.8%)
Only available drugs	39 (30.9%)
Drugs used for sedation (multiple choice)	
Lorazepam	23 (59.0%)
Chlorpromazine	23 (59.0%)
Midazolam	2 (5.13%)
Prometazine	9 (23.1%)
Haloperidol	39 (100%)
Morphine	39 (100%)
Diazepam	39 (100%)
Phenobarbital	39 (100%)
Changes in case of failure	
Increasing the dose	18 (31.6%)
Increasing the dose and then combine another drug	38 (66.7%)
Combination	1 (1.7%)
Use of opioids	
Continued if already started for other symptoms	71 (56.8%)
Used for sedation not used for other symptoms	53 (42.4%)
Discontinued when starting sedation	1 (0.8%)
Communication	
Patient's information	
Always or almost	76 (60.3%)
About half of cases	33 (26.2%)
Never	17 (13.5%)
Family's information	
Always or almost	126 (100%)

The attitudes of professionals regarding PS at home are lacking in literature. A large variability was found among Northern European countries, including Belgium, the Netherlands, and the UK, possibly as a result of different organizational contexts. In in-depth qualitative interviews with a small number of general practitioners (GPs) and nurses in Belgium and the Netherlands, the GP typically made the final decision to use PS, whereas in the UK, the nurse encouraged the GP to prescribe anticipatory medication and decided when to use the prescription. The role of nurses seems to be relevant in performing and monitoring PS in the absence of the GP [11]. In another survey among nurses in the Netherlands, the GP was not present at the start of the PS in about 30% of the cases, being available when needed. Of concern, PS was considered ineffective by more than 40% of the respondents. The level of sedation was frequently unrelated to an acceptable symptom relief and changes in dosage were not based on the level of symptom intensity [12]. In a qualitative analysis of interviews with 52 GPs in Belgium, opinions diverged on the indication area for PS and on possible life-shortening intentions. Data showed GPs' possible life-shortening intentions with a need to facilitate the dying process or to avoid a futile transfer to the hospital. It is likely that to accomplish a patient's request for euthanasia, several GPs prefer a sort of slow euthanasia using PS to a lethal injection

[13, 14]. Data of the present study showed that the home care physician was always involved in starting PS; although, occasionally, PS was started by nurses. Indeed, GPs were never involved in the decision process when a home palliative care team was assisting the patient at home. Although there are no data about the role of GPs in PS in Italy, it is unrealistic to consider they have a role at the end of life. Of interest in this survey, it was absolutely stated that the intention of PS was not to hasten death. A specialized use of PS does not seem to have any detrimental effect on survival [15].

In this survey, the drugs of choice for sedation were not always available. While haloperidol, morphine, diazepam, and barbiturates were always available, midazolam was available only in a minority of the cases. A combination of drugs was often used, also as an alternative step in case of failure to obtain a sedative effect with the first-line drug. Opioids were used in combination or as sedative agents in the majority of the patients. The use of the drugs in the context of PS deserves some comments. In about 30% of the cases, not all of the drugs were available at home, particularly midazolam that is considered the drug of choice [16]. In fact, in Italy, midazolam is approved for hospital use only. It is regrettable to note that, despite a recent law released with the intent of providing a new setup of palliative care in Italy, first-choice drugs, like midazolam, are still not allowed at home, unless for home care services connected to the hospital. Indeed, when available, midazolam is the medication more frequently used for PS at home, as well as in inpatient units [6, 17]. Another controversial point is regarding the use of opioids as sedative agents. Most guidelines discourage the administration of opioids alone for purposes of palliative sedation [18]. From this data, it seems that opioids are considered sedative agents with the intent to decrease the level of consciousness. The inappropriate use of opioids can be attributed to a lack of knowledge, an intent to alleviate concomitant dyspnea, or simply to drug unavailability, while it can be excluded as an intentional means of hastening death. This approach resembles attitudes evidenced in the Netherlands, but with another intent. Although national guidelines in the Netherlands suggest that the degree of symptom control and not the level of consciousness is lowered, which determines the use of sedative agents [19]; opioids alone were administered for 22% of the patients. Of interest, physicians who were more experienced, or physicians who had consulted a palliative care expert administered only opioids significantly less often than the other physicians [20]. Higher dosages of opioids than needed could be given with an explicit aim to hasten death [21]. The use of continuous deep sedation is an increasing practice in the Netherlands, mostly performed by GPs. This is considered a regular practice, without the need of specialist advice [22], in contrast with EAPC recommendations [23]. Of concern, some patients who had previously requested but not granted euthanasia, were then sedated [14]. Taken together, these data gathered from Northern European countries,

are worrying, as a doubtful and trivial approach to PS raises the suspicion of mask euthanasia, particularly when PS is performed by GPs without any palliative care consultation, may it be on request of patients or relatives. The use of only opioids and the intent to hasten death by physicians with limited experience in palliative care make it unacceptable to manage very complex and delicate conditions, although it is often dictated by the families' and patients' request. In the USA, intentional unconsciousness until death is broadly not supported [24].

Information about attitudes on hydration at home when starting PS has never been described in literature. In this survey, an individual decision based on clinical circumstances was prevalent.

While information about PS was shared with relatives in all the cases, patients' information still had a high rate. Data about decision-making at the end of life are poor. In a Spanish study, the decision to start PS at home was shared with the patient in 45% of the cases [8]. From a clinical point of view, it is difficult to conceive this information. The onset of PS often corresponds to a moment in which the patient is no longer collaborating because of their incompetency or due to their cognitive impairment or severe suffering, for example delirium and dyspnea, unless this request would have been provided before. It is reasonable to conceive that the clinical need to start PS is proposed by an expert home care team explaining to the family members the further steps and the possible options of intervention, unless there is an advanced directive provided by the patient. A living will in Italy is not usually used, even informally, according to Mediterranean culture and habits, disposed to less autonomy or higher level of confidence with health professionals [7].

The study limitations of this survey include the convenience sample and the incomplete list of interviewed physicians existing in Italy. Nevertheless, the sample could be representative of the palliative care world in Italy.

In conclusion, this survey has shown attitudes and existing problems regarding palliative sedations at home. There are heterogeneous home care organizations, generating some problems, particularly in drug availability. While a part of the physicians is reluctant in performing PS, for cultural or organizing problems, the indications, intention, and monitoring of PS seem to be appropriate. Specialized home care physicians are almost involved to start PS at home, differently from a non-specialized and ambiguous approach reported in Northern European countries. However, midazolam is available only in hospital pharmacies and is not frequently used at home, despite being the drug of choice for PS. Indeed, opioids are used to reach the expected level of sedation. This study should prompt health care agencies to make a minimal set of drugs easily available for physicians who work in a home care team. Future studies should be performed to provide further information on an inevitable procedure, avoiding, at least in manageable cases, an urgent admission to the hospital for end-of-life care.

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Compliance with ethical standards

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