

PALLIATIVE SEDATION IN CONTROLLING THE REFRACTORY SYMPTOMS IN ONCOLOGIC PATIENTS. A BIOETHICAL APPROACH

Valentin Petre-Ciudin¹, Cornel Petre-Ciudin², Andreea A. Velnic¹, Bianca Hanganu¹, Irina Manoilescu¹, Dragos Crauciuc¹, Beatrice G. Ioan¹

¹ University of Medicine and Pharmacy "Grigore T. Popa", Iași, Romania

² „Palimed“ Palliative Care Center, Tg. Neamț, Romania

ABSTRACT

Palliative care asserts the importance of life, considering that the human beings have the right to be cared and respected until the last moment of their lives. In oncologic patients, physical symptoms in general, and pain, in particular, are enhanced by psychological, social, cultural and spiritual issues. Along with progression of the disease, symptoms may become overwhelming and refractory to usual therapeutic approaches, despite the efforts, sometimes even aggressive, to identify a tolerable therapy which does not compromise the consciousness and relieves pain. One of the solutions may be palliative sedation, which means the voluntary administration of the opioids and non-opioids drugs in adequate doses and concentrations in order to lower the consciousness as much as necessary to ameliorate one or more symptoms which are refractory to other therapies. Palliative sedation, since the proposition of its practice in the healthcare of the terminal patient, with unbearable pain, generated numerous dilemmas and debates which are still ongoing. In this paper the authors approach the issue of the palliative sedation both from medical and ethical perspectives, highlighting the importance of placing the patient in the center of the decision-making process regarding the medical

RÉSUMÉ

La sédation palliative pour contrôler les symptômes réfractaires chez les patients oncologiques. Une approche bioéthique

Les soins palliatifs affirment l'importance de la vie, considérant que les êtres humains ont le droit d'être soignés et respectés jusqu'au dernier moment de leur vie. Chez les patients oncologiques, les symptômes physiques en général et la douleur en particulier sont renforcés par des problèmes psychologiques, sociaux, culturels et spirituels. Avec la progression de la maladie, les symptômes peuvent devenir écrasants et réfractaires aux approches thérapeutiques habituelles, malgré les efforts, parfois même agressifs, pour identifier une thérapie tolérable qui ne compromet pas la conscience et soulage la douleur. L'une des solutions pourrait être la sédation palliative, qui consiste en l'administration volontaire des opioïdes et des médicaments non opioïdes en doses et concentrations adéquates, afin d'abaisser la conscience autant que nécessaire pour améliorer un ou plusieurs symptômes réfractaires à d'autres thérapies. La sédation palliative, puisque la proposition de sa pratique dans les soins de santé du patient terminal, avec une douleur insupportable, a généré de nombreux dilemmes et débats qui sont toujours en cours. Dans

Corresponding authors:

Bianca Hanganu, Irina Manoilescu
University of Medicine and Pharmacy „Grigore T. Popa“, Iasi, Romania
Email: bianca_h_no1@yahoo.com; manoilescuirina@yahoo.com

treatment and its guidance according to the risks and benefits for the patient.

Key-words: end of life, pain, palliative sedation, ethics, autonomy.

INTRODUCTION

End of life ascertains the state in which the severe health impairing, due to the evolution of a disease or to other causes, irreversibly threatens the life of a person in the near future¹.

End of life may be characterized and diagnosed according to the signs and symptoms of functional decline, such as: respiratory changes, skin color changes, drowsiness and cognitive function deterioration, marked fatigability, reduction of the food and beverages ingestion, progressive deglutition difficulties (noticed, for example, in case of orally drug administration). This period has a variable duration, from days to weeks.

The pain of the oncologic patient in the terminal stage was described by Cicely Saunders as a „total pain“, associated with numerous other physical manifestations as such: dyspnea, cough, hiccups, nausea, vomiting, hemorrhages, various types and degrees of incontinence, fatigability, insomnia, as well as psychological problems (such as fear, anxiety, desperation, apathy, negation, avoidance), social (isolation, lack of social and familial support, financial, interpersonal and emotional unsolved problems) and spiritual (existential questions regarding the suffering and death, about their meaning, regrets, guilt, denial of the faith or, on the contrary, reaffirmation of the faith).

Thus, therapeutic and palliative approach of the oncologic patient in the terminal stages of the disease must be complex, given the multitude of factors which intertwine when the patient feels the pain. Along with the progression of the disease, the pain may become refractory and overwhelming despite the efforts, many times aggressive, to identify a tolerable therapy which does not compromise the consciousness of the patient.

The endeavor intended to ameliorate the pain and suffering, regardless the methods involved, must be led according to the cardinal element of the palliative care, respectively ensuring a quality of life as good as possible for the patient and his/her family.

cet article, les auteurs abordent la question de la sédation palliative tant du point de vue médical qu'éthique, soulignant l'importance de placer le patient au centre du processus décisionnel concernant le traitement médical et son orientation en fonction des risques et des avantages pour le patient.

Mots-clés: fin de vie, douleur, sédation palliative, éthique, autonomie.

PALLIATIVE SEDATION – BEGINNING AND EVOLUTION

A suggested solution for approaching the pain and the unbearable suffering of the patient in terminal stage is palliative sedation- also called therapeutic, total, controlled sedation, or sedation at the end of life².

Although in the practice sedation dates long back, the expression „terminal sedation“ was first mentioned in the literature in 1991, when Enck referred to the utilization of sedation in order to control the symptoms in patients with advanced stages of disease³.

From that moment until today, two main stages have been outlined in the history of palliative sedation.

Between 1990 and 2000, palliative sedation attempted to delineate itself from the „growing choice in dying movement“, when physician assisted suicide had numerous supporters, who were trying to convince the stakeholders to approve this practice. Comparing palliative sedation with a kind of „slow euthanasia“ raised numerous ethical and legal aspects⁴. In 1994, Cherny and Portenoy published the first guidelines on sedation in the management of refractory symptoms. This guideline, which represented a strong background for the next ones, offers important clinical criteria to set out the refractory character of the symptoms and for the manner in which the patients are evaluated in order to decide the initiation of the palliative sedation⁵.

The period 2000-2010 was the „standardization decade“, when numerous efforts were made to standardize the practice of palliative sedation. In this time, the American College of Physician's paper position clearly specified the differences between palliative sedation and physician assisted suicide, mentioning the former as „an ethical and valid form of therapy in the provision of palliative care“. Starting with 2005, the literature replaced the formula „terminal sedation“ with „palliative sedation“^{3,4}.

PALLIATIVE SEDATION IN STATISTICAL FIGURES

Literature data show an incidence of palliative sedation that varies largely, mostly as a consequence of differences in definition of the terms, differences

across the countries or in places where it was administered. Thus, the prevalence of palliative sedation in hospices varies between 3.1% and 51%. In terms of the geographical area, in Europe, a study published in 2008 reported the lowest prevalence in Denmark - 2.5%, while the highest was in Netherlands - 10% ⁶.

Some authors stated that palliative sedation is needed for 15-35% of the patients in the final stage of the disease, and a Belgian study showed that palliative sedation was performed in 7.5% of institutionalized patients who had refractory symptoms ^{6,7,8}.

ETHICAL ISSUES IN PALLIATIVE SEDATION

Palliative sedation consists of monitored administration of drugs with sedative effects in doses and combinations aimed to diminish or abolish consciousness in patients in terminal stages of the disease, so that to control one or more symptoms that are refractory to treatment or where treatment causes unbearable side effects. The aim is to cast away untreatable suffering in a manner that is ethically acceptable both for the patient and the family and for the healthcare professionals ^{2,9}.

Palliative sedation may be intermittent, giving the patient the possibility to retrieve the physical and psychical resources needed to efficiently face his/her suffering.

As early as it was introduced in the medical practice, palliative sedation aroused numerous discussions regarding its fairness and ethical eligibility.

This debate involves different issues such as: the assimilation of palliative sedation with euthanasia by some authors, withdrawal or withholding of artificial nutrition and hydration and the manner of taking decisions in case of providing palliative sedation.

Palliative sedation versus euthanasia

Since the proposal to use it as a method to assist the terminally ill patients with unbearable symptoms, palliative sedation has been assimilated with euthanasia, as some authors considered it a „disguised, inhuman, hypocritical form of euthanasia“ or „clandestine euthanasia“. Being a kind of a practice that is still controversial concerning the ethical issues it upholds, it is fundamental to explain the defining elements and the clear delimitation from social, medical and legal unaccepted practices in most of the countries, such as euthanasia ^{2,10,11}.

Although both palliative sedation and euthanasia are extreme interventions in end of life situations, there are significant distinctions as concerned to intention, manner to perform and the expected result.

Palliative sedation aims to control refractory symptoms occurred in the context of end of life in

the oncological patients. It is performed by the administration of drugs needed to control the symptoms, respecting the principle of proportion. The aim of palliative sedation is to alleviate the symptoms and it leads to shortening the patient's life only in extreme situations.

Euthanasia aims to end the life of the patient and it is realized by administering a dose of drug meant to achieve this goal. Therefore, the aim pursued of the euthanasia, by its definition is ending the patient's life (Table 1).

Table 1. Distinction between palliative sedation and euthanasia

	Palliative sedation	Euthanasia and physician assisted suicide
Intention	Control the refractory symptoms	Ending the life
Method	Giving the needed dose of drug to control symptoms	Giving the needed dose of drug to end the life
Result	Control the symptoms Exceptionally shortening the life	End of life (by definition)

Making the decision to perform palliative sedation

Making the decision to start the palliative sedation must be grounded on a careful evaluation of the patient's condition, as well as on an accurate ethical foundation. By the principles of beneficence and non-maleficence, the healthcare team must weigh the benefits and risks associated to each therapeutic decision. In the same time, it is essential to respect the patient's autonomy, this meaning the physician must respect the decision the patient will take regarding its treatment, after an adequate information, decision expressed through the informed consent. Therefore, the competent patient may decide the limitation or refusal of the right to be informed and to take decisions.

The duty to respect the patient's autonomy also enforces the doctor to protect patients who are incompetent to take decisions regarding their treatment. Autonomy allows patients to transfer towards other persons (doctor, family members, person they trust, legal representative- for incompetent patients) the right to take decisions. Therefore, in case of incompetent patients, or patients who do not want to be part of the decision-making process, decision will be made in collaboration with their family members, who may tell what the patient would want to be done in a certain clinical state (substitute-decision making) or considering the advanced directives of the patient. It may therewith be possible that in case of lack of

such a document or in case the family/legal representative is not present, the decision be made by a doctor, following the best interests of the patient^{1,12}.

Decision to perform palliative sedation must be grounded on the premise of guaranteeing the quality of life for the patient as well as on the clinical reality (intensity of the symptoms, suffering of the patient), the patient being in the center of the decision-making process, either directly if she/ he is competent, or indirectly through the advanced directives or the opinion of its legal representative¹.

Choosing the method for sedation will consider the patient's wishes but also the severity of the symptoms, life expectancy and available medication.

In making the decision for initiating palliative sedation, the doctor who coordinates the palliative care team must also take into account the opinions of the other members of the team. It is also important that the decision should be well documented in order to specify the clinical arguments for palliative sedation, drugs to be administered, as well as withholding or withdrawing the artificial nutrition and hydration¹.

Administration of artificial nutrition and hydration

Palliative sedation may affect the ability to self-hydration and self-nutrition, according to the depth of sedation¹³, thereby withholding or withdrawal of the artificial nutrition and hydration during palliative sedation is another important ethical issue. On the one hand, supporters for maintaining the hydration and nutrition state that are necessary, given the fact that the patient cannot eat and drink by his own, and stopping them will lead to death, as well as maintaining them will prevent patient to suffer¹⁴. In the view of Craig (1994), „if it is not possible to reduce sedation to a level that enables the patient to drink, the question of hydration must be addressed to everyone's satisfaction⁴. This author also emphasizes the maintaining of artificial hydration and nutrition in cases where this inability owes directly to the effects of the sedation, except the cases when the family or the patient himself, prior to sedation, stated they do not want additional interventions¹⁵. On the other hand, supporters for withdrawal of the artificial nutrition and hydration consider the lack of an improvement by maintaining them will represent a supplementary and pointless burden¹⁴. Quill et al (1997) consider the interruption of the artificial nutrition and hydration as an integrant part of the concept of terminal sedation¹⁶, Rietjens et al (2008) suggesting even the additional definition: „the administration of drugs to keep the patient in deep sedation or coma until death, without giving artificial nutrition and hydration¹⁷. However, this definition was not accepted

amongst specialists in palliative care and represented the starting point for many debates about the medical, ethical and theological foundations of palliative care¹³. While some authors consider the prolonging of life by artificial hydration and nutrition is not a certain fact¹⁴, others point the question of the additional time a patient might have lived if he would have received nutrition and hydration¹⁵. Moreover, most of the clinicians consider, however, the maintaining of the artificial hydration and nutrition as a form to prolong patient's life¹⁴.

In making decisions regarding maintaining or withdrawal of the artificial nutrition and hydration, healthcare professionals must consider the effects these phases may have on the patient's family and/ or friends, who may see hydration and nutrition as mandatory for prolonging the life of the beloved one, as well as keeping in mind their wishes in case they request further hydration and nutrition¹⁵.

CONCLUSIONS

Oncological patient who reached the terminal stage may confront a suffering in which physical pain is associated with psychological, social, religious issues, generating the so-called „total pain“ that may become unbearable.

In palliative care, sedation is considered as the ultimate form to approach and control the symptoms with high intensity, especially physical pain.

Palliative sedation in oncological patient with refractory pain, may ease the death process and diminish the sufferance of the family members. In the same time, palliative sedation is encumbered by many ethical issues which bring into discussion the autonomy and facilitation of the benefit for the terminally ill patient, such as: the need to delineate palliative sedation to euthanasia, the opportunity to associate it with the artificial nutrition and hydration and the best manner to make the decision to initiate palliative sedation.

The careful consultations between the doctor and the patient or his/her family in a climate where the respect and thrust prevail, keeping the patient in the center of the decision-making process is mandatory for the initiation of palliative sedation.

REFERENCES

1. <https://www.coe.int/en/web/bioethics/guide-on-the-decision-making-process-regarding-medical-treatment-in-end-of-life-situations>
2. Broeckaert B, Decizii de tratament la sfârșitul vieții. In Sheila Payne, Jane Seymour,

- Christine Ingleton. *Tratat de îngrijiri paliative pentru asistenții medicali. Principii și dovezi pentru practica clinică Ediția I (traducere)*. Brașov: Fundația Casa Speranței, 2012: 463-465.
- Enck RE. Drug-induced terminal sedation for symptom control. *Am J Hosp Palliat Care*. 1991;8:3-5.
 - Henry B. Clinical guidelines for the use of palliative sedation: moving from contention to consensus. In Taboada P (Ed.). *Sedation at the End-of-life: an interdisciplinary approach*. Springer Netherlands, 2015, pp. 121-142.
 - Cherny NI, Portenoy RK. Sedation in the management of refractory symptoms: guidelines for evaluation and treatment. *J Palliat Care*. 1994;10:31-38.
 - Claessens P, Menten J, Schotsmans P, Broeckaert B. Palliative sedation: a review of the research literature. *J Pain Symptom Manag*. 2008;36:310-333.
 - Fainsinger RL, Waller A, Bercovici M, et al. A multicentre international study of sedation for uncontrolled symptoms in terminally ill patients. *Palliat Med*. 2000;14(4):257-65.
 - Claessens P, Menten J, Schotsmans P, Broeckaert B. Palliative sedation, not slow euthanasia: a prospective, longitudinal study of sedation in Flemish palliative care units. *J Pain Symptom Manag*. 2011;41(1):14-24.
 - Cowan JD, Walsh D. Terminal sedation in palliative medicine-definition and review of the literature. *Support Care Cancer*. 2001;9(6):403-7.
 - Billings JA, Block SD. Slow Euthanasia. *Journal of Palliative Care*. 1996; 12: 21-30.
 - Société Française d'Accompagnement et de Soins Palliatifs. www.sfap.org/
 - Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*, 7th edition. USA: Oxford University Press, 2001.
 - Taboada P. Sedation at the end of life. Clinical realities, trends and current debate. In Taboada P (Ed.). *Sedation at the End-of-life: an interdisciplinary approach*. Springer: Netherlands, 2015:1-14.
 - Olsen ML, Swetz KM, Mueller PS. Ethical decision making with end-of-life care: palliative sedation and withholding or withdrawing life-sustaining treatments. *Mayo Clin Proc* 2010;85:949-954.
 - Craig GM. On withholding nutrition and hydration in the terminal ill: has palliative medicine gone too far? *J Med Ethics* 1994;20:139-143.
 - Quill TE, Byrock IR. Responding to intractable terminal suffering: the role of terminal sedation and voluntary refusal of food and fluids. ACP-ASIM End-of-Life Care Consensus Panel. American College of Physicians - American Society of Internal Medicine. *Ann Intern Med*. 2000;132:408-414.
 - Rietjens JA, van Zuylen L, van Veluw H, van der Wijk L, van der Heide A, van der Rijt CC. Palliative sedation in a specialized unit for acute palliative care in a cancer hospital: comparing patients dying with and without palliative sedation. *J Pain Symptom Manag*. 2008;36:228-234.