Viewpoint

Sedation near the end of life. A plea for combined theoretical-empirical analysis

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Abstract

In this paper, we argue that many questions currently discussed with regards to good practice of palliative sedation therapy are in need of combined theoretical and empirical analysis. To substantiate our claim, we firstly define three areas of practice in which clinical as well as normative challenges occur and give examples for such challenges. In a next step and using the example of "suffering" as basis for decision-making about sedation we demonstrate how theoretical analysis can inform current controversies about the practice of sedation. We conclude with a first suggestion on how a combination of empirical and theoretical research may contribute to sound guidance on good practice of sedation near the end of life.

Introduction

Palliative sedation therapy (PST) has been defined as "monitored use of medications intended to induce a state of decreased or absent awareness (unconsciousness) in order to relieve the burden of otherwise intractable suffering […]" [1]. Sedation is an increasingly performed practice in the last phase of life [2]. At the same time, it is associated with considerable challenges which have been located on the normative as well as practical level in the literature [1, 3, 5–7]. From a clinical perspective, it is of interest that findings of survey research show considerable heterogeneity with regards to indication, substances and monitoring of sedation near the end of life, despite the existence of guidelines on PST [8–10]. From a normative perspective, it has been pointed out that sedation is associated with several unresolved challenges relevant to the definition of standards of good practice as well as regarding the distinction of sedation from unethical or illegal practices at the end of life [4, 6, 11].

In this paper, we argue that many questions currently discussed with regards to good practice of sedation are in need of combined theoretical and empirical analysis. To substantiate our claim, we firstly define three areas of practice in which clinical as well as normative challenges occur and give examples for such challenges. In a next step and using the example of "suffering" as basis for decision-making about sedation we demonstrate how theoretical analysis can inform current controversies about the practice of sedation. We conclude with first suggestions on how a combination of empirical and theoretical research may contribute to sound guidance on good practice of sedation near the end of life.

Current controversies about practical and normative aspects of sedation

Based on a systematic review of guidelines [12] and further analysis [5, 13] we propose to categorize current controversies about good practice of sedation as follows. 1. Concept and indication of PST, 2. Decision-making and consent, and 3. Monitoring and care. The aforementioned order of topics reflects the order of challenges possibly encountered when making decisions about PST for individual patients.

Concept and indication of PST

Making decisions about PST requires clarity about the concept of PST. However, theoretical as well as empirical research shows an astonishing heterogeneity regarding what is understood as PST and respective indications [5, 11, 14–16]. Such heterogeneity is associated with normative as well as practical challenges. From the normative perspective, the lack of conceptual clarity of PST is exemplified in the discussion about the concept of "intolerable suffering" as central criterion for the indication of PST. While some guidelines for example only refer to "intolerable suffering" caused by physical symptoms (e.g. pain, dyspnoea) as justifying indication, others include suffering due to so-called "psycho-existential" symptoms (e.g. fear to be a burden to others, loneliness) as appropriate indication for PST. Further, not all guidelines specify if suffering only needs to be intolerable or also refractory [12] (also see the paragraph on different concepts of suffering below). From a practical perspective, this lack of conceptual clarity poses the challenge how this ill-defined "intolerable suffering" is to be determined in clinical practice. Besides, in line with the lack of consensus on the concept of PST, comparable use of sedatives in comparable clinical situations are labelled as PST in one hospital but not in another, where the same prac-

Table 1: Normative and practical challenges of selected areas of sedation at the end of life

Element of sedation practice	Example for normative challenge	Example for practical challenge
Concept and indication	Which type of suffering should serve as indication for PST (physical symptoms versus existential suffering)?	How can "intolerable suffering" be determined in clinical practice?
Consent and decision-making	Are patients in a state of suffering capable to give autonomous informed consent?	How can informed consent for PST be elicited in a state of intolerable suffering?
Monitoring and care	Is deep continuous sedation combined with withholding or withdrawing ANH "slow euthanasia"?	How can it be evaluated whether ANH is beneficial for a sedated patient?

tice may be labelled as "symptom control" with potential "secondary sedation" [16, 17]. Not labeling the practice as sedation prevents the application of guidelines on PST. Furthermore, conceptual clarity about PST and its indication is of practical relevance for research because otherwise there will be no comparable data for example on frequency and types of sedation.

Decision-making and consent

Current guidance names informed consent as a requirement for decision-making for PST [12]. One challenge relevant from a normative and clinical perspective concerning informed consent is that patients at the end of life are often no longer able to make autonomous and well-considered choices. This may be not only due to a lack of decision-making capacity for example in the state of delirium but also in cases of severe suffering and consequently compromised ability to understand and weigh the facts relevant for making an informed decision. Next to clinical challenges in determining whether suffering patients are able to make informed decisions or whether surrogate decision makers have to be called upon, there are also normative issues related to consent and decision-making [18]. One such topic is the comparably strong role assigned to relatives regarding decision-making in some guidelines which can be a burden as well as source of conflict with regards to control about decision-making [12]. The normative foundation for such a family-oriented approach towards decision-making about PST needs further analysis.

Monitoring and care

The monitoring and the care of the patient receiving PST also present challenges which can be located on the normative and practical level. A particularly controversial normative challenge is the evaluation of sedation in combination with withholding or withdrawing artificial nutrition and hydration (ANH) from an ethical and legal perspective. In the case of deep continuous sedation without ANH, the cause of death of the patient may be the dehydration caused by the combination of the two treatment decisions (deep continuous sedation and withholding ANH), rather than the underlying disease. This could be considered as a form of "slow euthanasia" [19]. Furthermore, the withdrawal of ANH subsequent to initiation of PST with the argument that ANH is "futile" once the patient is unconscious, has been criticized as a fallacious argument [6]. There are also practical challenges related to ANH and sedation. Examples in this respect are to determine whether the provision of nutrition and/or hydration is beneficial to sedated patients or rather causes discomfort [20].

The described normative and practical challenges of sedation at the end of life are summarized in table 1.

The brief outline above demonstrates that there is an array of normative and practical challenges associated with making decisions about PST and the process of sedation itself. Of course, to show that there are such challenges not necessarily implies that a combined theoretical and empirical analysis is helpful to tackle these challenges [21, 22].

A theoretical analysis focusing for example on clarification of concepts (What do we mean by concepts like: suffering, autonomy, good end-of-life practices?) can inform the stakeholders who need to interpret and to apply those concepts in clinical practice. However, theoretical analysis alone risks to miss specific requirements of clinical practice. Thus, empirical research on the specific perspectives and needs of the stakeholders is needed. A combination of theoretical and empirical analysis can help to define concepts in a theoretically founded and at the same time applicable way.

To substantiate our claim, we provide an example of how theoretical analysis – in addition to empirical research, as described below – may contribute to defining good practice of sedation near the end of life. We do so by means of a brief analysis of the contribution of philosophical theory to clarify concepts of "suffering".

Contribution of theoretical analysis to PST practice: The example of suffering as prerequisite for indication for PST

As already mentioned, there is no generally accepted definition of suffering in the context of PST. Thus, it is unclear how the central criterion of "intolerable suffer-

ing" as a prerequisite for PST is to be understood. This lack of clarity is the root of several normative and practical challenges. Mainly they concern a) the prerogative of interpretation of suffering and b) the type of suffering addressed by PST.

a) Prerogative of interpretation refers to the question who defines suffering. On the one hand one could claim that only the suffering person, the patient affected by the suffering experience, can define whether he or she is suffering. On the other hand, one could claim that members of a palliative care team have the prerogative of interpretation as they have the duty and (the medical as well as the juridical) responsibility to decide whether PST is indicated or not.

b) Types of suffering refers to the question which symptoms, conditions and experiences should be taken into consideration to determine whether a person's suffering makes him or her eligible for PST: Should PST only be used to relieve physical symptoms (like pain and dyspnea) or also to relieve "psycho-existential suffering" (like loneliness or a sense of meaninglessness)?

A significant part of answers to these controversial issues hinges on our *understanding* of "intolerable suffering". In the theoretical debate, different concepts of suffering have been proposed, which in turn are based on divergent anthropological assumptions as well as on different assumptions regarding the goals of medicine [13]. Different concepts of suffering have different implications if applied in clinical practice:

- If suffering is understood as a mainly subjective and holistic experience [23], then the prerogative of interpretation would be on the side of the patient, and psycho-existential suffering would be addressed in the same manner as physical suffering in the context of PST.
- If suffering is understood as a mainly objective experience and if different sources of suffering can be distinguished [24], the interpretation of suffering can be intersubjective, and different types of suffering (for example physical and psycho-existential suffering) would be addressed in different manners.

In order to better understand the challenges associated with appropriate indications for PST and the role of suffering, we need to differentiate concepts of suffering and to work out their implications for clinical practice in a first step. In this respect, theoretical analysis of suffering in medical philosophy and ethics can provide an important starting point. However, such work needs to be complemented by empirical work.

Combining theoretical and empirical analysis as foundations for guidance on good clinical practice of PST

Even a comprehensive theoretical analysis of "suffering" is at risk to miss facets of the phenomenon which are relevant to determine good practice. For guiding decisions about PST, additional empirical research is required. In order to better understand the concept of suffering within the context of PST we need for example the views of clinical stakeholders regarding the value of the different theoretical concepts of suffering for determining good practice of PST. In addition, empirical information may be used to refine the theoretical concepts of suffering in light of distinct clinical features of sedation near the end of life. Such a combination of theoretical and empirical analysis will help us to define a concept of suffering which is theoretically founded and at the same time applicable in clinical practice. This concept could then form the theoretically and empirically founded basis for decision-making on PST. While we consider a combined empirical-theoretical analysis of existing challenges of PST as promising we concede that such an approach requires qualified research staff and opportunities for multi- and interdisciplinary research. Furthermore, a methodological account of how exactly theoretical and empirical analysis may be combined is necessary [21] and can also be helpful to address further normative and practical challenges in end-of-life care beyond PST.

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