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Ought the level of sedation to be reduced during deep palliative sedation? A clinical and ethical analysis

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ABSTRACT

Background Deep palliative sedation (DPS) is applied as a response to refractory suffering at the end of life when symptoms cannot be relieved in an awake state. DPS entails a dilemma of whether to provide uninterrupted sedation—in which case DPS would turn into deep and continuous palliative sedation (DCPS)—to minimise the risk that any further intolerable suffering will occur or whether to pause sedation to avoid unnecessary sedation. DPS is problematic in that it leaves the patient ‘socially dead’ by eradicating their autonomy and conscious experiences.

Aim To perform a normative ethical analysis of whether guidelines should recommend attempting to elevate consciousness during DPS.

Design A structured analysis based on the four principles of healthcare ethics and consideration of stakeholders’ interests.

Results When DPS is initiated it reflects that symptom relief is valued above the patient’s ability to exercise autonomy and experience social interaction. However, if a decrease in symptom burden occurs, waking could be performed without patients experiencing suffering. Such pausing of deep sedation would satisfy the principles of autonomy and beneficence. Certain patients require substantial dose increases to maintain sedation. Waking such patients risks causing distressing symptoms. This does not happen if deep sedation is kept uninterrupted. Thus, the principle of non-maleficence points towards not pausing sedation. The authors’ clinical ethics analysis demonstrates why other stakeholders’ interests do not appear to override arguments in favour of providing uninterrupted sedation.

Conclusion Stopping or pausing DPS should always be considered, but should not be routinely attempted.

Key messages

What was already known?

- ⇒ Most guidelines for palliative sedation fail to address whether deep palliative sedation might be interrupted in order to wake the patient.
- ⇒ The principles of autonomy and beneficence favour attempts at waking the patient, whereas the principle of non-maleficence favours uninterrupted sedation.

What are the new findings?

- ⇒ A structured clinical ethics analysis concludes that stopping or pausing deep palliative sedation must always be considered but not routinely performed.

What is their significance?

- ⇒ Clinical: Clinicians who practice deep palliative sedation should not as a main rule elevate the patient’s consciousness.
- ⇒ Research: Guidelines should state that reducing the level of sedation during deep palliative sedation must always be considered but not routinely attempted.

INTRODUCTION

Palliative sedation is applied in instances of refractory suffering at the end of life, namely when suffering cannot be sufficiently relieved in a fully awake state. Worldwide, the execution of palliative sedation is guided by ethical and clinical guidelines formulated by national health authorities, medical societies, task forces and medical and ethical experts.¹ Overall, in the different guidelines, there is agreement on key issues concerning palliative sedation.

However, there is disagreement with regard to whether attempts should be made to reduce the level of sedation in



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cases of deep palliative sedation (DPS), which is the most radical form of the treatment strategy.² Reducing the level of sedation, and ultimately waking patients, during DPS may allow the patient to regain both autonomy and the opportunity to communicate with their next of kin as death approaches. Hence, there is a strong imperative to reduce sedation, with the aim of waking the patient. The practice would entail either reducing the dose of sedatives or pausing the infusion of sedatives altogether, depending on which of these actions is judged clinically appropriate. This paper only addresses DPS, which has also been labelled ‘deep and continuous sedation until death’ and ‘deep and continuous palliative sedation’ (DCPS). Nonetheless, obviously when DCPS is stopped, it is by implication not continuous. Unlike with DPS, the decision to initiate DCPS is made with the explicit intention that the patient shall not be awakened during the procedure (hence its name), and in most cases this intention is followed through. Still, in some extraordinary cases there might be reason to reverse that decision, and if so, DCPS will not be the outcome—even though originally this was indeed the intention.

The Norwegian Medical Association’s Guidelines for palliative sedation at the end of life³ state the following with regard to DPS:

9. When it is most probable that the sedation will be maintained to the end of life, raising the patient’s level of consciousness must always be considered, and as a main rule, attempted. If it becomes clear during the waking process that the patient’s situation is still intolerable, it will be medically and ethically justifiable to recommence sedation without the patient regaining consciousness.³

In this paper, we consider the part ‘as a main rule, attempted’ in the above quotation. A recent study of DPS with propofol during the last days of life at a Norwegian department of palliative medicine did not find any cases of stopping or pausing of such sedation (and so in effect these were all, or turned out to be, cases of DCPS).⁴ Three out of the four authors of the present paper are among the authors of that study. It cannot be inferred from the data that the clinicians in charge acted contrary to the Norwegian guidelines.⁴ Nonetheless, based on clinical experience, we have reason to believe that the guidelines are commonly interpreted as close to a demand that clinicians should always try to wake the patient. If this is the case, we consider it unfortunate, for the reasons given in the following sections.

Trials of waking patients or reducing the level of sedation during DPS is not addressed in most guidelines on palliative sedation. This is also not the case in the recommended framework for the use of sedation in palliative care developed by the European Association for Palliative Care.^{5 6} However, several guidelines advocate that light and intermittent sedation

should be attempted before DPS is applied.¹ In what follows, with the aid of a well-established normative theory within healthcare ethics, we analyse the ethics of reducing the level of sedation with the intention of waking deeply sedated patients nearing the end of life.

Terminology

In the scientific literature the term ‘palliative sedation’ is applied to cover a wide range of treatments, from light and intermittent sedation during weeks or months, to DCPS until death.⁷ However, light and/or intermittent sedation over time constitutes a clinical scenario that differs considerably from that of DPS at the end of life. Palliative sedation is more than one phenomenon, as it has different levels. For example, de Graeff and Dean define the levels of palliative sedation as follows⁸:

- ▶ Mild (somnia)—the patient is awake but their level of consciousness is lowered.
- ▶ Intermediate (stupor)—the patient is asleep but can be woken to communicate briefly.
- ▶ Deep (coma)—the patient is unconscious and unresponsive.

In end-of-life care, the use of sedatives for symptomatic treatment forms part of routine medicine. When such treatment is given, sedation may occur but is not in itself a treatment goal. The distinction between this practice and palliative sedation may not be entirely clear-cut in some clinical cases. However, the main point of palliative sedation is that it is performed to manage refractory suffering when symptomatic treatment either has proven inadequate or has been judged inappropriate.⁹ In other words, this type of sedation should not be perceived as an adverse effect of routine treatment but rather as intentional and artificially induced. Within palliative medicine practice, one sometimes encounters clinical scenarios in which temporary deep sedation is indicated until a condition has resolved, or causal or symptomatic treatment has been provided. The use of sedation in such cases is not classified as DPS, and thus not covered by the ethical analysis in the present paper.

Key ethical dilemma in DPS

With DPS, clinicians face a dilemma of whether to provide uninterrupted deep sedation in order to minimise the risk that any further intolerable suffering will occur, or whether to stop or reduce the level of sedation to avoid unnecessary sedation. DPS is problematic in that it leaves the patient ‘socially dead’ by eradicating their autonomy and all conscious experiences. The horns of this dilemma concern how to establish what counts as ‘unnecessary’. Therein lies a profound challenge in DPS.

METHOD

Our analysis of the clinical ethics dilemma regarding DPS makes use of two established frameworks in

clinical ethics. First, employing principle-based ethics we apply the well-established so-called four principles approach within biomedical ethics.¹⁰ Second, in line with the six-step model for analysing clinical ethics dilemmas developed by the Centre for Medical Ethics at the University of Oslo, Norway,¹¹ we supplement the principles with a discussion of the relevant stakeholders and their views and interests. The latter discussion is meant to clarify whether there might be conflicts between the interests of patients and other stakeholders. As far as possible, we refer to data from relevant original quantitative and qualitative studies as an evidence base for our discussion of stakeholder interests.

Relevant values

In 1979, American philosophers Beauchamp and Childress formulated the ‘four principles’ approach to healthcare ethics. The latest (eighth) edition of the book in which their approach is presented, *Principles of Biomedical Ethics*, was published in 2019 and this work is probably the most well known and most used in its field.¹⁰ Within medicine, analyses of ethical challenges and dilemmas are often performed using Beauchamp and Childress’s approach and we follow suit in this paper.

Beauchamp summarises the principles of biomedical ethics as follows¹²:

1. Beneficence—obligations to provide benefits and to balance benefits against risks.
2. Non-maleficence—the obligation to avoid causing harm.
3. Respect for autonomy—the obligation to respect the decision-making capacities of autonomous persons.
4. Justice—obligations of fairness in the distribution of benefits and risks.

As far as DPS is concerned, principle 4 addresses overarching issues such as prioritising scarce healthcare resources at both the national level and across hospitals and other institutions at the local level. However, such matters fall outside the scope of this paper, and we do not consider principle 4 relevant to our discussion.

The patient’s perspective

Respect for autonomy and fulfilment of beneficence

In a medical setting, autonomy is often interpreted as a patient’s right to decline treatment. This may be labelled ethical autonomy; by contrast, empirical autonomy concerns patients’ actual ability or capacity to make competent decisions.¹³ In our analysis autonomy in both senses are relevant; in the latter sense in that sedation influences the patient’s ability to exercise autonomy, occasionally to a significant degree. Furthermore, DPS might be initiated in line with a patient’s wish for such, thereby reflecting the patient’s preferences in their current situation. Such preferences might include valuing symptom relief over the ability to exercise autonomy and experience social interaction. Providing DPS in this situation would honour patient autonomy, still without he or she having any

legal right to receive DPS; cf. sedation on demand. However, it could be argued that when the symptom burden is sufficiently severe, autonomous choice does not occur; rather, the symptoms themselves ‘speak’, such that their intensity in effect *coerces* the patient to choose DPS. Hence, in such situations, there would be a lack of freedom from external constraints and thus no genuine exercise of autonomy.

If the patient is woken (ie, sedation is stopped or sufficiently reduced) and it is found that their symptom burden has diminished, there is the possibility that both true autonomy could be exercised and social relations could be experienced. As this would benefit the patient, waking appears to satisfy both principle 3 (autonomy) and principle 1 (beneficence).

Non-maleficence

Reducing the level of sedation has the potential for causing highly distressing symptoms. However, this will not happen if deep sedation is kept uninterrupted (ie, continued). In this context, we suggest that non-maleficence would be best understood as the prevention and alleviation of symptoms. By implication, principle 2 (non-maleficence) seems to point towards not stopping or pausing sedation. Thus, we draw the conclusion that the patient’s important values are difficult to reconcile: maximum symptom relief vs the ability to exercise autonomy and experience social relations.

If, prior to treatment with DPS, a competent patient has expressed an explicit wish for DPS to be discontinued at some point, the wish must be granted not only out of respect for the patient’s autonomy, but primarily because the patient has a legal right to decline treatment (as opposed to a non-existent right to demand treatment, even though some think there should be such a right as well). By contrast, if a patient is not competent and therefore unable to express an opinion, healthcare personnel will have to face the possibility of conflicting principles of non-maleficence and beneficence, and must consider how to strike a balance between them.

Some patients require increasing doses of analgesics for sedation to be maintained during DPS, whereas others experience spontaneous awakenings after apparently successful initiation of DPS.⁴ Both phenomena indicate that in some patients there is an increasing nociceptive input to the central nervous system during DPS. Even though we lack data regarding the prevalence of this happening, case series as well as clinical experience seem to suggest that its occurrence is not rare or exceptional.⁴ This underpins that there is a real risk of some patients experiencing severe symptoms when sedation is not kept a constant during DPS.

Next of kin’s perspective

In general, it has been reported that relatives of patients are of the opinion that palliative sedation

of all types decreases the patient's distress and is appropriate because it ends suffering.¹⁴ Accordingly, even a temporary increase in a patient's experienced symptom burden when sedation is elevated is likely to cause distress to family members.

Notably, in focus group interviews, relatives did not regard the patient's loss of ability to communicate during DPS as a downside.¹⁵ However, in one study, family members wanted palliative sedation to be stopped in 2 out of 42 cases.¹⁶ In one of the two instances, the patient's wife wanted to take the patient home, while in the other there was disagreement within the family as to what should be the treatment goals.¹⁶ Good and continuous communication with family members is a crucial part of the decision-making process, but the preferences of next of kin should not be allowed to override those of the patient when the latter are beyond doubt, such that clinical decisions might conflict with the conceived best interests of the patient or run foul of the principle of non-maleficence.

Healthcare professional's perspective

Research on nurses' experiences with palliative sedation shows that some prefer intermittent sedation over DPS, particularly due to removal of the patient's ability to communicate with family members.^{17 18} Furthermore, nurses have reported that when DPS was executed, they felt 'calmed and satisfied',¹⁹ meaning unrelieved suffering in patients can be distressing to healthcare professionals. Consequently, if patients frequently experience renewed intolerable suffering when the level of sedation is decreased during DPS, one would expect that to burden professionals to a large degree. Apparently, nurses are less conflicted about DPS when the patient has been involved in the decision to start sedation.¹⁸

It can be speculated that healthcare professionals might view clinical and ethical distinctions between DPS and euthanasia as less clear-cut when there is no plan or intention to wake the patient. Research shows that in jurisdictions in which assisted dying is legal, the distinction between assisted dying and DPS is experienced as blurred by some professionals.²⁰ Therefore, when discontinuation of DPS is not even considered as a possibility, some who oppose euthanasia might feel uncomfortable about the use of DPS. If so, they may suffer moral distress due to the experience of acting contrary to their ethical convictions. However, this is not an argument in favour of waking patients; rather, it points to a need for education about ethical and clinical differences between DPS and assisted dying.

Society's perspective

In public debate, as well as in communications with individual patients who fear severe pain and/or other suffering at the end of life, DPS is often presented as a measure of last resort with regard to providing effective relief. If elevation of sedation were to become a

mandatory requirement, it probably would become common knowledge that even though DPS is an effective treatment, patients may experience new episodes of suffering when DPS has been initiated. This could erode both the wider society's trust and individual patients' trust in DPS, causing patients to become anxious about accepting the treatment. Furthermore, it would certainly have an impact on the euthanasia debate, as one of the main arguments against euthanasia is that effective symptom control can be achieved through DPS, thereby rendering euthanasia redundant at the end of life.²¹

Clinical-ethical and philosophical arguments

In both DPS and euthanasia the patient's social life and experienced suffering are ended. Despite these similarities between the two interventions, the major differences between them concern intention, procedure and outcome.²² Whereas DPS aims at ending suffering while keeping the patient alive, the goal of euthanasia is to end the patient's biological life. Additionally, drugs used in DPS are titrated to achieve symptom control, whereas in euthanasia drugs are dosed to ensure sudden, premature death.

It has been debated whether personhood is maintained during DPS, and different philosophical views have led to incompatible conclusions.² Regardless, when the patient is woken as a consequence of sedation being reduced or paused, he or she will be 'brought back to life' for a period of time.

DISCUSSION

As we have shown, the principle of autonomy yields the conclusion that a patient's request for the level of sedation to be decreased must be honoured. Additionally, the same conclusion flows from the legal right to decline treatment. However, when a patient is not able to express an opinion due to a lack of decision-making competence, it resides with the physician responsible for the patient's treatment to decide. In this decision-making process, there needs to be a weighing of the different values should these conflict. The decision should be based on multiprofessional discussion and consultation with next of kin, with special emphasis on patient-centred values. This will ensure that, on the one hand, adequate symptom relief is provided (non-maleficence) and, on the other hand, the patient is offered opportunities to exercise choice (autonomy) and take part in social relations (beneficence). In these decisions, although respect for autonomy is crucial, the principle of non-maleficence should always take precedence if there is reason to expect that the level of sedation cannot be reduced without risking awareness of intense symptoms.

Mandatory decreasing the level of sedation in cases of DPS would inevitably cause awareness of intense symptoms in at least some patients. Additionally, it would probably distress both next of kin and healthcare professionals.

In the course of DPS some patients require increased drug doses to maintain symptom control. In this clinical scenario it appears unlikely that patients could be woken without experiencing severe or even refractory suffering. Hence, stopping sedation would conflict with the principle of non-maleficence and therefore ought not to be performed. Furthermore, if competent patients express a clear desire for a deep level of sedation to be continued until death, this may be honoured in order to respect patient autonomy. Although relevant, none of the mentioned interests of the other involved parties appear to be of sufficient weight to override a patient's autonomous wish that sedation should be kept uninterrupted.

CONCLUSION

Based on our clinical ethics analysis and discussion of various arguments and taking into account the interests of all involved parties, we conclude that decreasing the level of sedation during DPS should always be considered, but not routinely performed. Whenever there is a need for a rapid increase in drug doses for the sake of maintaining sedation, it will constitute a contraindication as far as the stopping or pausing of sedation is concerned.

The decision to start palliative sedation is made by the physician after a decision-making process in which, obviously, the preferences of a competent patient must be taken into consideration. A competent patient's explicit wish for uninterrupted DPS—such that DPS by implication becomes DCPS—ought to be honoured when all other criteria for palliative sedation have been met. As noted in the Introduction, the Norwegian Medical Association's guidelines for palliative sedation at the end-of-life state that 'raising the patient's level of consciousness must always be considered, and as a main rule, attempted'.³ Although we agree with the part 'must always be considered', raising the patient's level of consciousness ought not 'as a main rule' be 'attempted' because potentially it could have very bad consequences, not only for the patient but also for those around him or her.

We conjecture that there would be a tendency among healthcare personnel to conceive of 'as a main rule' as entailing a demand that they wake patients in most cases or even in all cases, as the standard by which they should abide. To avoid the conception and hence minimise the risk of subsequent unfortunate incidents in connection with DPS, we advocate that guidelines that explicitly address the issue of waking patients or decreasing the level of sedation should instead be formulated as follows: 'must always be considered, but should not be routinely attempted'. We are also of the opinion that any guidelines on palliative sedation ought to address the issue of the possible discontinuation of DPS and should state a policy accordingly.

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