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RECOMMENDATIONS

THE USE OF SEDATIVE DRUGS

*in specialist
palliative care*

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>> PRELIMINARY REMARKS

OBJECTIVES

The aim is to provide concrete, scientifically sound recommendations for intentional sedation as a means to relieve suffering and for dealing with sedating medication in the palliative care setting.

This approach was developed considering adapted terminology, clinical data, published guidelines, ethical and medical legal analyses, and the experiences of national and international experts and interested laypeople as representatives of the non-professional public (Patient and Public Involvement (PPI)) and compiled into a multistage process.

ENGLISH VERSION

The original recommendations, definitions and accompanying texts were professionally translated. This translation was revised and adapted to ensure internal consistency with the German version and finally agreed again within the SedPall consortium.

FINANCING

These recommendations were developed as part of the joint project “SedPall - From anxiolysis to deep continuous sedation” (FK: 01GY1702A-C), which is funded by the German Ministry of Education and Research (BMBF).

SCOPE OF APPLICATION AND PURPOSE

The recommendations relate to specialist palliative care in Germany and encompass specialist inpatient palliative care (SIPC) and specialist palliative home care (SPHC). Even though they were originally developed for specialist services, these recommendations can also be used to provide support to clinical staff in the field of general palliative care. These recommendations are not a guideline and contain no grading of recommendations.

Palliative care practitioners are encouraged to take these recommendations into consideration when making a clinical assessment or when compiling diagnostic and therapeutic strategies. In no way do these recommendations aim to replace the individual responsibility of clinic staff to make the appropriate and specific decisions in relation to the individual patient after consultation with the patient or their legal representative.

METHODOLOGY

The recommendations are based on empirical data, ethical and medical legal analyses, and systematic evaluation of existing recommendations and guidelines. Additionally, the opinion of experts were included during the development process. The scientific studies were conducted during the research project “SedPall - From anxiolysis to deep continuous sedation”. The project was divided into four phases:

Phase 1

Preparation and piloting of the data collection

For the empirical analysis, a data matrix for the collection of quantitative data and interview guides for the interviews with patients, relatives, and staff to collect qualitative data were developed and piloted. During the conceptual analysis, an initial terminological framework was created to differentiate between different types of sedation.

Also, an analysis of the ethical/normative questions and problems with sedation relating to the systematic collection and categorisation of legal issues was conducted, taking into consideration the corresponding legal rulings and literature.

Phase 2

Empirical and normative analysis

Quantitative repetitive data was collected in seven recruitment centres and qualitative interviews were conducted and analysed simultaneously in 12 recruitment centres.

In parallel, the normative challenges of sedation practice (e.g., regarding indications, consent, and monitoring) were analysed on an empirical and ethical background and legal rulings in Germany were analysed in-depth.

Phase 3

Integration of the results

In this phase, the relevant study findings were processed, focus groups consulted on important/particularly controversial topics (based on the results from all subprojects) and the results of subprojects 1-4 were integrated. This includes quantitative data from the participating recruitment centres (SP1), the results from the qualitative interviews and focus groups (SP2), and the joint normative analysis of selected ethical and legal aspects of sedation (SP3 and SP4).

Phase 4

Conclusions and recommendations

The results from the various subprojects were compiled and a first draft of the recommendations was drawn up. The draft was then discussed with multiprofessional national and international experts from the fields of general and specialist palliative care, ethics, law, and the German Association for Palliative Medicine during an integration conference. The recommendations were then revised during a consensus conference; the final version was presented in a public conference.

ACKNOWLEDGEMENTS

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We would also like to say a special thank you to all the staff at the recruitment centres who played a pivotal role in the quantitative data collection, interviews, and focus groups. The project group would also like to thank all the experts who provided feedback, discussed, and finally agreed on the recommendations.

Finally, we would like to thank the members of the patient and public involvement groups in Erlangen and Munich who supported the project in many ways throughout its duration. Without the trust, provision of time resources, commitment, and valuable specialist expertise of all these participants, the development of this handout would not have been possible.

CONFLICTS OF INTEREST

The publishers state that no conflict of interest exists.

ABBREVIATIONS

SPC

Specialist Palliative Care

SPHC

Specialist Palliative Home Care

SIPC

Specialist Inpatient Palliative Care

PPI

Patient and Public Involvement

StGB

German Criminal Code

BGB

German Civil Code

BGH

German Federal Supreme Court

>> INTRODUCTION

*Terminology
and ethical/legal
classification*



SEDATION TO ALLEVIATE SUFFERING

What does this mean?

Palliative care is care and support of the most severely ill people, especially patients whose condition is very advanced and deemed incurable. The main focus is on improving quality of life and alleviating the impact of the illness.

As the disease progresses, especially in the later stages, the patient's level of consciousness may become impaired. Reduced consciousness may also be the unwanted (but accepted as necessary) effect of medication used for treatment. However, it is also possible to use medications with the intention to reduce the consciousness of the patient.

There are situations in which, to the best of our knowledge, intentional sedation is the only option to relieve suffering. There are special challenges as intentional sedation for the purpose of alleviating suffering can be achieved in various ways with different effects on the level of consciousness: temporary or continuous (until death) and from drowsiness to a state of deep unconsciousness.

This document provides recommendations for intentional sedation for the purpose of relieving suffering and for the use of potentially sedating medication in palliative care settings. These recommendations are aimed at physicians, specialist nursing staff, and members of other professions who are involved in the care of patients. The requirements for intentional sedation are formulated for specialist palliative care settings (palliative care unit, hospital support teams, SPHC).

However, palliative care is also provided outside specialised settings. The majority of palliative patients receive "generalist palliative care" (provided by family doctors, specialists in private practice, nursing services, specialist nursing staff in retirement homes, and physicians and specialist nursing staff on hospital wards).

The recommendations and information provided here could also be helpful in these contexts. However, if they cannot be implemented, then at best palliative care specialists should be involved when a decision has to be made on intentional sedation or when there is a risk of a situation that will require drug-induced sedation.

IN-DEPTH INFORMATION REGARDING TERMINOLOGY [33]

Reduced consciousness

Consciousness scoring < 0 on the RASS-PAL scale (below normal alertness) (RASS-PAL, see Bush 2014)

Sedating

Inducing a state of reduced consciousness by medical means

Sedation

The result or process of sedating

Sedated

Consciousness reduced by medical means

Intentional sedation

Result or process of sedating a patient as a means of achieving a previously defined treatment goal

Lightly sedated

Consciousness reduced by medical means to a score of -1 to -2 on the RASS PAL scale

Deeply sedated

Consciousness reduced by medical means to a point of ≤ -3 on the RASS-PAL scale

Temporarily sedated

Patient is sedated only for a certain period of time

Sedated until death

Patient is sedated continuously until his/her death

Anxiolysis

Induced reduction of anxiety

Suffering

An uncomfortable, distressing, and unwanted state

Existential suffering

Suffering that comprehensively refers to the fact that and how one lives

If the score on the RASS-PAL is ≥ 0 , this is not considered to be sedation. It is also not considered sedation if the impaired level of consciousness is not the result of medical measures.

The most frequently used term in the literature is “palliative sedation”. The recommendations here use the term intentional sedation for the purpose of relieving suffering. In this context, “intentional” means the sedation is not simply a side effect of medication used in the course of treatment but rather the sedation of the patient is intentional. The term “palliative sedation” is used inconsistently in the literature and by the public at large [1]. Its use in the description of cases by staff in the palliative care setting has also been shown to be inconsistent [2],[3]. “Palliative sedation” is often equated with deep sedation until death despite the term being more broadly defined by the EAPC.

Definitions of “palliative sedation” are subject to various limitations (indications, prerequisites, characterisation of suitable patients, etc.), which complicate the use of the term [1].

The resulting uncertainties are the reason why the term “palliative sedation” is omitted from these recommendations and simplified terminology is used instead. It can be used as a basis of in-depth discussion for indications, patients and patient groups, precautionary measures, etc. The term “sedated until death” was chosen because “terminal” is often associated with “termination”, in the sense of “intentionally ending life” (the same applies to “final” and “finalise” also in the sense of “intentionally ending life”) and the term “continuous” conceals the relationship to death.

Intentional sedation to relieve suffering must be differentiated from:

Calming

Inducing a reduction of the level of consciousness to a score of ≥ 0 on the RASS-PAL scale

Periinterventional sedation

Intentional sedation to enable a surgical procedure or other painful procedure to be carried out.

Coma

Loss of consciousness caused by illness or trauma

Since the relief of suffering by sedation occurs via a general reduction in self-awareness, the terms “symptomatic treatment” and “therapy” are often somewhat misleading. Sedation works by limiting the ability of self-awareness. However, it does not target a specific symptom, which is what is usually implied when speaking of “symptomatic” treatment. Also, only rarely does it result in an improvement in the underlying pathological processes, which is what is usually implied when speaking of “therapy”.

Potentially sedating medication can be used for anxiolysis, sedation, antiemesis, seizures, respiratory distress and pain management without the intention of inducing the effects of sedation or having to accept these effects as a consequence. However, given that sedating effects can nonetheless develop (in which case they cannot be classified as “intentional”), special precautionary measures are required. Care should be taken to avoid unthinkingly moving from a treatment in which sedation is not intended to a treatment in which a reduction in consciousness is maintained by medication.

Although transition from the accepted unintentional effects of the medication to an intentional sustained sedation can be fluid and unplanned, nevertheless, these scenarios, wherever possible, must be anticipated and controlled, and in the event that they do happen unintendedly, then they must be subject to evaluation and a conscious decision.

Therefore, these recommendations begin with the use of potentially sedating medication, even when sedating effects are not part of the planned course of treatment.

Potentially sedating medications

A wide range of different substances can have an effect on consciousness and alertness. During the development of these recommendations, the central focus was placed on benzodiazepines, neuroleptics, and opioids due to their role as substances frequently used in palliative care. We avoid the use of the word “sedative” because this is not a clearly defined pharmacological term.



EXISTENTIAL SUFFERING

As palliative care is a discipline focusing on the care and support of patients who are severely ill or dying. The patient's suffering often takes on an existential dimension and can develop into a serious psychological burden that can also become unbearable and require treatment.

Patients in a palliative care situation often, but not always, struggle to come to terms with their own mortality, illness-related limitations, a fundamental change in perspective towards their own life, and the fact that, generally, there are no more options available that offer the chance of a cure.

This situation can result in feelings of anxiety, hopelessness, and the desire to die and the sense that they are "suffering from being alive". In particular, this type of suffering can be counterbalanced by the compassion and care of relatives and those providing treatment and nursing, the available psychosocial services, and also the resilience of the patient. In this way, it is often possible to prevent that discomfort leads to existential suffering or prevent it from becoming unbearable.

The treatment of the symptom burden is usually provided by a multiprofessional team, considering the individual factors contributing to suffering. Even with the wide range of available options and approaches, in the last phase of life, there are situations in which existential suffering remains unbearable despite all supportive measures.

In these cases, sedating measures can ensure that the patient does not consciously experience their situation. There is good reason for special diagnostic and prognostic attention, because patients, from an existential perspective, can adapt to their situation in different and unforeseen ways. Especially in situations where a desire to die is linked to existential suffering, special recommendations must be followed to avoid the implemented measures being deemed a criminal offence (e.g., killing on request as per § 216 StGB).

Sedation due to existential suffering is not generally excluded in these recommendations. However, it does come with special limitations that are necessary to ensure symptom-orientated and comprehensive provision of patient care and to distinguish it from unlawful killing or unregulated assisted suicide.

IN-DEPTH INFORMATION REGARDING CHALLENGES WITH THE TERM "EXISTENTIAL SUFFERING"

Existential suffering is not precisely defined in the literature. This can lead to problems with its use and result in misunderstandings which are addressed here:

Existential suffering is - at least according to the definition proposed above - not a phenomenon that is limited to palliative care. People without a life-limiting illness can also experience existential suffering. Due to the special situation of incurable illness, however, palliative care patients often also suffer existentially.

Existential suffering may or may not be part of a mental disorder (e.g. within the context of temporary grief reactions). If it is the manifestation of a psychological disorder, it may be part of the symptoms of the disorder (e.g. depression) or the consequences of other symptoms (e.g. associated with anxiety disorder, schizophrenia). However, being a psychologically extreme situation, the association to psychological illness is understandable.

Not every person who experiences existential or unbearable existential suffering has the desire to die, and not every person with the desire to die is necessarily experiencing existential suffering. The desire to die can manifest itself in many ways. It should be viewed as a separate, and possibly existentially-motivated phenomenon.

The desire to die resulting from severe existential suffering is not necessarily permanent or autonomously formed. Generally speaking, severe suffering may even indicate that the desire to die is well considered.

In these recommendations, the term "existential suffering" is used to describe an emotion relating to one's own life. Estimating the extent of the suffering, making a prognosis, and clarifying the connection to potential psychiatric diagnoses or previous illnesses, and drawing the corresponding clinical consequences remain difficult tasks that cannot be solved by applying simple schematic solutions.

SEDATION IN COMPARISON TO OTHER END-OF-LIFE MEASURES

Intentional sedation is not conceptually or ethically limited to the care of the dying. Nevertheless, especially in the context of advanced illness, intentional sedation is a measure considered or implemented for the alleviation of suffering, and in individual cases, sedation is maintained until death. For this reason, the following section will compare sedation with other end-of-life measures.

From a legal, ethical, and medical perspective, today, intentional sedation as a means to relief of suffering is an indispensable component of palliative medical care. Within the framework of the applicable legal and medical measures, there is an obligation to help patients who are experiencing great suffering. Knowing how and under what circumstances sedation can be used is part of the fulfilment of these obligations.

Intentional sedation entails legal, ethical, and medical challenges due to the fact that the intentional induction of reduced consciousness places extreme limitations on or suspends the patient's ability to experience, express themselves, and act autonomously (see [4]) and therefore constitutes a severe intervention into the very essence of someone's personality. The partial or

complete loss of the ability to communicate, to make informed decisions on the further course of treatment, and to experience touching and personally valuable moments despite the illness, weighs heavily.

For this reason, intentional sedation can only be justified as measure provided by a trained professional under strict conditions. Intentional sedation therefore requires indication, administration, and monitoring on expert level.

Ethical and legal knowledge is required alongside medical expertise to meet the challenges of completing the care-related tasks (and obligations) while acting in a responsible and legally legitimate manner. In this sense, intentional sedation for the relief of suffering can be viewed as "end-of-life therapy" (see [5]) - even when it is not "therapy" in the sense of a complete or partial cure of the underlying illness.

A question that arises at the end of life is the continuation or initiation of life-sustaining measures, such as artificial ventilation, nutrition, and hydration (but also other measures, such as dialysis). Intentional sedation can be administered with the simultaneous renunciation of these types of treatments [6]. It should be noted, however, that sedation with simultaneous withdrawal of life-sustaining measures can significantly accelerate the onset of death [7].

From a legal perspective, this is crucial for a differentiation from killing; from a medical standpoint, the withholding/withdrawing of life sustaining measures may not be reasonable or indicated for all types of sedation or in all situations, respectively. Therefore, life-sustaining measures must be viewed separately from the question of whether, and if so, what type of sedation should be carried out. Generally, these decisions are made separately (see Chapter 9).

The question of whether a single intentional sedation measure carried out was a punishable homicide or intentionally ending life on request is also legally and ethically relevant. In theory, sedation and killing cannot be differentiated from one another because sedating medications potentially carry the risk of hastening the death of the patient and intentional sedation could be administered for the purpose of inducing the death of the patient.

For a medical measure to be deemed intentional killing, the necessary (intermediate) objective of the person administering the treatment must be to induce or hasten the death of the patient (e.g. by administering a lethal medication). This can take place with the primary intention of ending the patient's suffering. "Relief" in such cases is achieved by inducing death as a means to end suffering.

Even if the patient requested the measures, the act is deemed killing on request and in Germany this is punishable by law (§ 216 StGB). Sedation could also be used to induce death: if a very high dose (notably higher than the dose required to alleviate the suffering of the patient) is selected from the start, then administered without monitoring leading, for example, to respiratory depression or the inability to eat or drink, and as a consequence resulting (as anticipated) in the death of the patient. This is also a case of relieving the suffering of the patient by inducing death [8].

Both acts have the same primary intention: ending unbearable suffering. The question of whether intentionally killing has taken place depends on the concrete clinical procedure and execution of the sedation measures.

For intentional sedation in compliance with these recommendations, the relief or ending of suffering is the primary objective. The main difference to punishable intentional killing lies in the means chosen by the treating person to address the suffering: not to induce death, but rather - oriented to the patient's level of suffering - a medical treatment that reduces or removes the patient's ability of perceiving something.

This means that the ability of the patient to perceive their suffering is decreased or eliminated. The patient's consciousness is reduced only to the extent necessary to reduce unbearable suffering (proportional). Here, safety mechanisms have to be in place to monitor that the reduction of consciousness is not excessive, and the sedation medication does not lead to the death of the patient. The fact that the risk of hastening death cannot be ruled out in all cases, even while adhering to all specialist palliative care recommendations, and that the hastening of death may even be anticipated in some instances, will not be viewed as causing intentional harm if all appropriate safety mechanisms have been exhausted and the applied dose is limited to the amount necessary to alleviate suffering. Even then, intentional sedation follows a plan as a treatment measure to alleviate suffering and not to induce death to end suffering.

In the event of judicial review, the actual form of the sedation would allow conclusions on the intention pursued by the practitioner [9-11]. Therefore, one purpose of these recommendations is to establish an approach to ensure that no criminally punishable killing is carried out.

Current research suggests that, on average, sedation does not result in premature death [12-14]. In studies with high numbers, however, it is possible that life-shortening effects (e.g. aspiration, pneumonia, respiratory insufficiency) in some patients were statistically cancelled out or outweighed by life-sustaining effects in other patients.

Regardless of this, sedation severely compromises or even eliminates the ability to experience, hence is not possible to justify sedation on the basis of a possible life-sustaining potential. Rather, it should always be viewed against the backdrop of the limited ability to experience (which in the case of deep sedation is sometimes referred to as "social death", see [4]), with the alleviating effects only being offset in cases where there is no alternative treatment available.

Furthermore, it must be noted that there is significant scope for the misuse of sedation, especially if it is not used as a last resort to relieve suffering or if it is administered without reflection while withholding/withdrawing of life-sustaining measures or without sufficiently comprehensive monitoring.

IN-DEPTH INFORMATION REGARDING LEGAL TERMINOLOGY AND RULINGS IN GERMANY

Legal regulations can be found in the German Criminal Code and German Civil Code that target the relationship between those providing treatment and the patient. Furthermore, regarding questions relating to end-of-life issues, differentiations in judicial practice have arisen, see [15]. Knowledge of judicial rulings and the relevant norms and how they interact is necessary for the correct classification of the recommendations contained in this document.

Withholding/withdrawing of treatment

In the legal sense, withdrawing treatment takes place when, in accordance with the will of the patient, certain measure suitable for prolonging the life of the patient are omitted, limited, or discontinued to allow natural dying [16]. In this respect, it is possible to speak of a change of therapy goal by the patient, which does not result in the discontinuation of all treatment, as the term "withdrawal of treatment" suggests, but only of those treatments that no longer serve the patient's therapy goal (who has no interest in prolonging her/his life). If not specified otherwise by the patient, measures to relieve suffering will be continued. In this respect, it is correct to assume a limitation and not withdrawal of treatment [17].

This does not affect cases in which the medical indication for certain measures are no longer applicable because the treatment goal cannot (or can no longer) be achieved.

Suicide

A suicide is any deliberate act of taking one's own life. The person wishing to end their life must retain a controlling influence over the last action leading to death (known as control over the "point of no return"). This means that they carry out or refrain from this act while retaining decisive control over the course of events [19], [20]. For example, this is the case when the person wishing to commit suicide independently administers themselves lethal medication. Moreover, the suicidal person can only act on his/her own responsibility if he/she is able to form a free will - uninfluenced by mental disorders - and to act in accordance with it. Additionally, as when granting consent, the patient must be fully aware of all the relevant circumstances of the case and be capable of comprehensive consideration of the pros and cons of their own decision. Also, the person wishing to commit suicide must not be motivated by external pressures, but has to decide out of intrinsic motivation, and the decision must have a certain degree of permanence and inner conviction [21].

Assisted suicide

Suicide is not a criminal offence in Germany; hence, assisting someone in suicide is in the absence of a primary offence not a punishable offence (following § 27 StGB (Germany Criminal Code)). § 217 StGB, which defined in 2015 the commercial promotion of suicide as a punishable offence, was declared in 2020 invalid for reasons of unconstitutionality [21].

This ruling had clarified that any person wishing to end their own life has the right to accept help in committing suicide from a third party. However, providing support in suicide of another person can only be viewed as assisted suicide (and not intentional killing) when the support provided does not go beyond the contribution of assistance (see the definition of the term suicide). In this context, assistance can mean, e.g. confirming the decision to commit suicide or obtaining the lethal drug.

Euthanasia or killing on demand

Euthanasia or killing on demand occurs when a person is killed by another person who has been designated to do the killing, at the serious and explicit request of the person who wishes to die. This would be the case when a physician administers a lethal injection to the patient after the patient expressly demanded this, of their own accord, and the physician is willing to fulfil their wish. In Germany, this action is a criminal offence (§ 216 StGB).

“Demand” in this context is more than simple consent; the ending of their life is what must be of importance to the patient.

Furthermore, this demand must guide the perpetrator's actions, i.e. he/she must have been determined to perform the act of euthanasia [22]. The implicit acceptance of the life-ending action by the patient is not sufficient in this case [23]. Furthermore, in the case of a mere implicit acceptance of the administration of medication by the patient, the patient's consent would already be questionable.

Additionally, § 216 StGB could possibly be committed by a failure to act. For example, this applies in cases where a person commits suicide of their own accord but with another person present who possibly provided suicide assistance. For a long time, the German Federal Supreme Court (BGH) took the view that the authority of the suicidal person to bring about his or her own death passes to the assisting person(s) present at the moment when the suicidal person loses consciousness [24]. As a consequence, the person present is obligated to prevent the death (§ 13 (1) StGB). In principle, the BGH still adheres to this view.

However, in two judicial decisions in 2019 [25-26], this judgement was, in part, overruled. It was recognised that, for the person wishing to commit suicide who is acting of their own accord, the realisation of the moment of the death is not only foreseeable but actually pursued by them, and therefore also after inducing the inability to act, this remains solely under their responsibility [26].

Hence, it can be assumed that in scenarios where the person wishing to die has discussed their decision to commit suicide with the person present (e.g., a physician), the risk of criminal liability (§§ 216 (1), 13 (1) StGB) no longer applies, even if the person does not remove themselves from the situation before the person committing suicide loses consciousness [23, 25-26]. The decisions from the BGH do not clearly address the issue of whether - even in the case of a suicide that has not been discussed beforehand - it can be assumed that there is no transfer of responsibility to those assisting the suicide after the suicidal person has lost consciousness. Those assisting in a previously discussed suicide still remain at risk of prosecution.

Indirect Euthanasia

The term “indirect euthanasia” is used in a legal context to justify the indicated medical measures necessary during the course of a fatal illness, which may hasten the death of the patient. If the shortening of the patient's life is unintentional, and the medication is necessary to alleviate the suffering of the patient, then it is not deemed to be intentional killing even if the risk of shortening the patient's life materialises [9], [16], [23] (§§ 211-217 Rn. 56 W.F.R.).

In order to justify treatment, it is also necessary for the patient to have consented to the treatment and its risk or the treatment must be in accordance with the patient's presumed will. [27], [16]. In this case, this is primarily an “end-of-life treatment” [5], administered as a reaction to extreme suffering, and meaning the doses of medication to reduce the level of suffering to a tolerable level may hasten the death of the patient (double effect).

Liability due to failure to provide treatment or providing inadequate treatment

Conversely, those providing treatment, who enter into a medical treatment contract as per § 630a (1) German Civil Code (BGB) upon the admission of the patient, are obligated to provide the promised treatment in accordance with medical standards (§ 630a (2) BGB). If a physician does not provide the adequate treatment in accordance with medical standards ([28] § 630a Rn.116 ff.; 126 f.), e.g. an indicated sedation, then they are in clear breach of their contractual duties, intentional or negligent grievous bodily harm due to neglect is also possible (§§ 223 ff., 13 (1) StGB or § 229 (see [29], [30], [31]), S. 81 ff.; 126 ff., [32] S. 21 ff.).

Indications

1

Before sedating medication is used, the indication must be defined and documented.

SCOPE OF APPLICATION: SIPC, SPHC

2

Sedating medication can be used to relieve symptoms that patients find distressing, such as anxiety and agitation, without intending to alter consciousness.

SCOPE OF APPLICATION: SIPC, SPHC

3

Sedating medication can be used to relieve insomnia, if experienced as distressing by the patient. In this context, a temporary and reversible change in consciousness is intended (RASS-PAL <0).

SCOPE OF APPLICATION: SIPC, SPHC

4

Sedating medication can be administered to prevent suffering during or upon termination of medical measures.

SCOPE OF APPLICATION: SIPC, SPHC

5

In the case of distressing symptoms which, despite all proportionate measures to relieve them (measures administered on expert level), have not been sufficiently alleviated and remain unbearable for the patient, intentional sedation is indicated.

SCOPE OF APPLICATION: SIPC, SPHC

6

In medical crisis situations, such as acute haemorrhage or acute obstruction of the respiratory tract, in addition to opioid treatment of possible dyspnoea, intentional - if necessary deep - sedation is indicated.

SCOPE OF APPLICATION: SIPC, SPHC

7

Existential suffering is not an indication for deep continuous sedation until death without prior temporary sedation.

SCOPE OF APPLICATION: SIPC, SPHC

8

In general, the maintenance of deep sedation until death is only indicated when it can be assumed - with almost complete certainty - that a reduction in the level of sedation would lead to unbearable suffering again.

SCOPE OF APPLICATION: SIPC, SPHC

9

The wish to die is not an indication for the administration of potentially sedating medication and therefore also not for intentional sedation.

SCOPE OF APPLICATION: SIPC, SPHC

10

The desire for sedation should result in an assessment whether intentional sedation is indicated.

SCOPE OF APPLICATION: SIPC, SPHC

>> RECOMMENDATIONS

Intention / Purpose

11

Sedating medication should be administered for the purpose of relieving symptoms, relieving suffering, or preventing imminent suffering during or upon termination of medical measures.

SCOPE OF APPLICATION: SIPC, SPHC

12

Before and during intentional sedation, the team ensures that the suffering of the patient remains the central focus and that the sedating medication is not used for the purpose of reducing the burden on the family or the team.

SCOPE OF APPLICATION: SIPC, SPHC

13

Intentional sedation must not be administered to hasten the death of the patient.

SCOPE OF APPLICATION: SIPC, SPHC

14

Intentional sedation which results in a limitation of mobility, may (only) be administered without judicial authorisation if the prevention of leaving the place of residence is not the primary purpose but a side effect of the primary intended relief of suffering.

SCOPE OF APPLICATION: SIPC, SPHC

>> RECOMMENDATIONS

Decision-making process

Preliminary remarks

Consent must be given by the patient. If the patient is unable to provide consent, a legal representative should be consulted to determine the will of the patient.

15

The decision to use intentional sedation will be made in accordance with the (presumed) will of the patient.

SCOPE OF APPLICATION: SIPC, SPHC

16

Before intentional sedation, the patient or their legal representative and the treatment team must determine who is involved in the decision-making process.

SCOPE OF APPLICATION: SIPC, SPHC

17

In the case of diseases in which severe respiratory distress and/or a haemorrhage can be expected (e.g. tumours of the head or neck, motor neurone disease, COPD, pulmonary fibrosis), the option of symptom-relieving intentional sedation should be discussed in advance with the patient or their legal representative.

This conversation should be documented in the patient's record or health care planning documentation for the last phase of life.

SCOPE OF APPLICATION: SIPC, SPHC

18

The assessment of whether symptoms remain refractory and unbearable for the patient, despite all proportionate (expert delivered) measures to relieve symptoms, takes place during a multiprofessional case conference. In cases of existential suffering, psychological and pastoral competencies should be included in the case conference.

SCOPE OF APPLICATION: SIPC, SPHC

19

In cases of ethical conflict, the decision-making process relating to whether or not intentional sedation is to be administered should be supported by ethics counselling/an ethics case conference. Ethics counselling/ethics case conferences must be transparently documented in the patient's record.

SCOPE OF APPLICATION: SIPC, SPHC

20

If intentional sedation is initiated during acute episodes of symptom exacerbation, when multiprofessional discussion of the case is not possible, then this must be retrospectively carried out as soon as possible to confirm or revise the course of treatment.

SCOPE OF APPLICATION: SIPC, SPHC

21

If the use of a medication results in an unwanted reduction in consciousness, then an adjustment to the medication (dose, substance) to reverse the reduction in consciousness is to be considered or a decision must be made promptly at a case conference as to whether intentional sedation is indicated and corresponds to the (presumed) will of the patient. Only then intentional sedation - using suitable medication - is deemed appropriate.

SCOPE OF APPLICATION: SIPC, SPHC

22

The decision-making process for intentional sedation, the parties involved in the decision-making process, and the results of the decisions must be transparently documented in the patient's record.

SCOPE OF APPLICATION: SIPC, SPHC

>> RECOMMENDATIONS

Information / Consent

23

Before intentional sedation, the patient or their legal representative will be informed of all relevant indications, intentions, effects, planned duration, adverse effects, risks, potential effects on length of life (both in regard to shortening or prolongation), possible course without sedation, and voluntary nature of consent to the sedation.

SCOPE OF APPLICATION: SIPC, SPHC

24

When using medication that is not specifically used for sedation but may cause sedation as a side effect, the patient or their legal representative will be informed of this risk.

SCOPE OF APPLICATION: SIPC, SPHC

25

The treatment team must involve the patient's relatives in the process of providing information on the intentional sedation if this is the wish of the patient or their legal representative.

SCOPE OF APPLICATION: SIPC, SPHC

26

The patient, and with the patient's consent, their relatives are to be informed that the patient's ability to communicate during the use of sedating medication will be limited, especially in cases of intentional sedation. If the patient no longer possesses the capacity to consent, the legal representative of the patient should receive the necessary information.

SCOPE OF APPLICATION: SIPC, SPHC

27

To ensure the patient's right to self-determination, after providing the relevant information and a suitable time window, the patient will be asked to consent to administration of intentional sedation (informed consent).

If the patient no longer possesses the capacity to consent, the legal representative of the patient should be asked to provide the necessary consent.

SCOPE OF APPLICATION: SIPC, SPHC

28

Before the administration of intentional sedation, decisions to be made during the period of (potential) incapacity to consent should be discussed with the patient (if the patient is unable to consent, then with the patient's legal representative). The discussion covers aspects such as rituals, nursing measures, duration of sedation, targeted level of sedation, possible attempts to awaken the patient (including the possible foregoing of the same), the management of other medications, and (artificial) hydration and nutrition.

SCOPE OF APPLICATION: SIPC, SPHC

29

If intentional sedation is initiated during acute episodes of symptom exacerbation, and it is not possible to provide the necessary information, this should be provided as soon as possible, if necessary, by retrospectively informing the patient's legal representative.

SCOPE OF APPLICATION: SIPC, SPHC

30

The information process and the type of information provided are to be transparently documented in the patient's record.

SCOPE OF APPLICATION: SIPC, SPHC

>> RECOMMENDATIONS

Medication and types of sedation

31

When using sedating medication, the substance selection is based on the indication, intention, effect, and duration of the treatment and possible adverse effects.

SCOPE OF APPLICATION: SIPC, SPHC

32

Intentional sedation uses the lowest possible dose of the medication to achieve the level of sedation necessary to relieve the patient's suffering. Therefore, the dose should always ensure that the patient's suffering is reduced to a level tolerable for the patient and that the sedation level is no deeper than necessary.

SCOPE OF APPLICATION: SIPC, SPHC

33

Generally, on initiation a medication dose is chosen to achieve light to moderate sedation (RASS-PAL -1 to -2).

Subsequently, the dose is adjusted in accordance with the recommendation in 2).

SCOPE OF APPLICATION: SIPC, SPHC

34

In case of acute crisis (e.g. acute respiratory tract obstruction, severe haemorrhage), an initial medication dose to achieve a deep level of sedation (RASS-PAL \leq -3) can be selected.

SCOPE OF APPLICATION: SIPC, SPHC

35

In the event of changes in respiratory activity (bradypnea, hypoventilation) during intentional sedation, it should be critically assessed whether these changes are due to the dying phase or the medication dose. If the medication dose is found to be the cause of the change in respiration, then a dose reduction adapted to the relief of suffering should be considered. If the reduction in respiratory activity is due to the dying phase, then no dose reduction is necessary.

SCOPE OF APPLICATION: SIPC, SPHC

36

Intentional sedation should initially be administered as temporary sedation and then re-evaluated after a predefined time period.

SCOPE OF APPLICATION: SIPC, SPHC

37

Intentional sedation in case of existential suffering is initially administered as temporary sedation for a predefined time period (up to a maximum of 24 hours).

SCOPE OF APPLICATION: SIPC, SPHC

38

Benzodiazepines, e.g. midazolam, are suitable for intentional sedation. Generally, these medications are the first choice, especially for patients requiring a reduction in anxiety levels and/or anti-epileptic effects. In the case of delirium, they should only be administered in combination with antipsychotic medication.

SCOPE OF APPLICATION: SIPC, SPHC

39

Antipsychotics with sedating (secondary) effects, e.g. levomepromazine, are a suitable second choice medication for intentional sedation. They can be administered in combination with benzodiazepines in cases in which benzodiazepines alone are inadequate to achieve sufficient relief of suffering.

SCOPE OF APPLICATION: SIPC, SPHC

40

Propofol is suitable for intentional sedation in cases in which other types of medication have not resulted in sufficient relief of suffering.

SCOPE OF APPLICATION: SIPC

41

Propofol is not suitable for intentional sedation in the home care setting.

SCOPE OF APPLICATION: SPHC

42

Opioids are not suitable for use in intentional sedation. Increasing the dose of an existing opioid therapy is also not a suitable means of intentional sedation. During intentional sedation, opioid treatment to reduced pain levels and/or treat dyspnoea is continued and the dose is adjusted as needed to ensure relief of pain and/or dyspnoea.

SCOPE OF APPLICATION: SIPC, SPHC

Monitoring

43

During sedation, the situation is re-evaluated by the person administering treatment and the dose adjusted to ensure the suffering is relieved to an acceptable level and that the level of sedation is no more than that required to relieve the suffering.

SCOPE OF APPLICATION: SIPC, SPHC

44

The criteria for regular re-evaluation of the overall situation are intensity of suffering (most important criterion), level of sedation, and adverse effects.

SCOPE OF APPLICATION: SIPC, SPHC

45

The person administering intentional sedation is expected to use the patient's relatives as an important supplementary source of information during regular re-evaluation.

SCOPE OF APPLICATION: SIPC, SPHC

46

During intentional sedation, depending on the illness situation and the treatment goals, selected vital signs (e.g. respiratory rate, oxygen saturation, heart rate, and blood pressure) could additionally be monitored to ensure a stable clinical status of the patient within the framework of the agreed objectives and limits of treatment. Threshold values and corresponding consequences and reactions must be defined for monitored vital signs.

SCOPE OF APPLICATION: SIPC, SPHC

47

During deep sedation outside of the dying phase, appropriate (vital) signs and parameters should be monitored to ensure that shortening of life is avoided as far as possible.

SCOPE OF APPLICATION: SIPC, SPHC

48

The frequency of re-evaluation should be determined (and adjusted, as necessary) by the physician responsible for the intentional sedation, taking into consideration the planned type of sedation and the pharmacokinetic properties of the sedating medication. Differences between titration phase and maintenance phases have to be considered.

SCOPE OF APPLICATION: SIPC, SPHC

49

As far as possible, the intensity of suffering should be assessed by directly asking the patient or their relatives, as well as by clinical observation (e.g. facial expression, sounds like groaning and screaming, body language, movements, agitation, tachycardia, and sweating).

SCOPE OF APPLICATION: SIPC, SPHC

50

The depth intentional sedation is assessed based on reactions to being addressed and light, non-painful touching e.g. using RASS-PAL.

SCOPE OF APPLICATION: SIPC, SPHC

51

The results of the re-evaluation of intentional sedation and the resulting consequences must be transparently documented in the patient's record.

SCOPE OF APPLICATION: SIPC, SPH

*Dealing with fluids
and nutrition*



52

The decision to administer artificial hydration and/or nutrition must be made before or during sedation if the patient will no longer be able to eat and drink sufficiently on their own.

SCOPE OF APPLICATION SIPC, SPHC

53

The decision to determine whether the artificial administration of fluids and/or nutrition is indicated must be made separately from the decision on intentional sedation.

SCOPE OF APPLICATION SIPC, SPHC

54

In the case of intentional sedation, any decision on artificial hydration and/or nutrition is made with the patient or the patient's legal representative or based on the presumed will of the patient and taking into consideration possible advantages and burdens as a result of these measures with regard to the treatment goals (relief of suffering).

SCOPE OF APPLICATION SIPC, SPHC

55

The decision relating to artificial hydration and/or nutrition during intentional sedation should be transparently documented in the patient's record.

SCOPE OF APPLICATION SIPC, SPHC

*Continuation
of other measures*



56

During intentional sedation, the patient will continue to be treated in the same dignified manner as before sedation. This includes addressing the patient (also in phases during which the patient is not conscious), announcing in advance actions that involve touching the patient, and adapting the surroundings to the given situation and, if necessary, in accordance with the previously discussed wishes of the patient.

SCOPE OF APPLICATION SIPC, SPHC

57

All nursing and medical measures are to be regularly evaluated and orientated towards the well-being of the patient. The measures should be adjusted to the changing conditions during intentional sedation and in accordance with the stated or presumed will of the patient.

SCOPE OF APPLICATION SIPC, SPHC

58

Measures to ensure symptom relief and patient well-being that were implemented before the intentional sedation are normally continued, regularly re-evaluated, and adjusted if necessary.

SCOPE OF APPLICATION SIPC, SPHC

>> RECOMMENDATIONS

*Support for
relatives*

59

With the consent of the patient, the relatives should be included from the beginning in the decision-making process related to intentional sedation.

SCOPE OF APPLICATION SIPC, SPHC

60

With the consent of the patient, relatives will be regularly informed of the patient's current clinical situation and the expected course throughout the intentional sedation.

SCOPE OF APPLICATION SIPC, SPHC

61

The team offers support to the relatives regarding their emotional or spiritual needs resulting from the intentional sedation.

SCOPE OF APPLICATION SIPC, SPHC

62

The relatives are advised and, if necessary, instructed on how to support the patient during the intentional sedation and remain close to them, e.g. by talking, touching, creating a comforting atmosphere for the patient (e.g. favourite music, smells, singing well-known songs, reading aloud) and, if desired - are involved in the nursing care (e.g. mouth care).

SCOPE OF APPLICATION SIPC, SPHC

63

Before deep sedation, which is expected to continue until death, or sedation which may become deep continuous sedation, the patient and their relatives should be given the opportunity to say goodbye to one another if the situation allows it.

SCOPE OF APPLICATION SIPC, SPHC

64

After the death of the patient, the relatives will be given the opportunity to talk to members of the treatment team to discuss any remaining doubts concerning the intentional sedation.

SCOPE OF APPLICATION SIPC, SPHC

>> RECOMMENDATIONS

*Support within
the team*

65

All team members must fully understand the indications and treatment objectives of intentional sedation. The necessary discussions can take place at team meetings or during case conferences.

SCOPE OF APPLICATION SIPC, SPHC

66

The discussion of stressful situations relating to intentional sedation, e.g. a retrospective case review or conference, is recommended. The aim of these meetings is to discuss the factual and emotional challenges, help the team process stress, and continuously improve the care provided.

SCOPE OF APPLICATION SIPC, SPHC

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