CHAPTER 1
General Introduction
1.1 Background

Palliative sedation is an important aspect of palliative care, in that it provides the possibility to relieve suffering for patients in the terminal phase of life. Palliative or terminal sedation is defined as the intentional lowering of consciousness of a patient in the last phase of life to relieve suffering that is caused by refractory symptoms such as pain, delirium and dyspnoea. In that respect, it is considered to be a normal medical intervention.

Palliative sedation can be applied either intermittently or continuously. The aim of intermittent or short-term sedation is to reduce the consciousness temporarily, to relieve the patient from intractable symptoms by inducing sleep. In addition intermittent use of palliative sedation will provide the possibility to assess whether refractory symptoms persist and if a deeper palliative sedation is required. Continuous sedation until death is the most far-reaching subtype of palliative sedation, and is always administered in the final stages of life to patients who are dying and are experiencing unbearable suffering.

The estimated frequency of the use of palliative sedation varies considerably in scientific literature, partly due to differences in definition and research setting. Comparable nationwide studies show frequencies of continuous deep sedation in Europe of 2.5% up to 16% of all deaths. In a questionnaire study performed in The Netherlands amongst physicians involved in medical decisions preceding the patient’s death, Rietjens et al. reported an increase of the use of continuous deep sedation from 5.6% of deaths in 2001 to 7.1% in 2005. This increase was more pronounced for palliative sedation performed by general practitioners and for cancer patients (in 2005, 47% of sedated patients had cancer versus 33% in 2001). Given the observation that expert consultation was performed in a minority of performed palliative sedation, Rietjens et al. concluded that this practice was increasingly considered as part of regular medical practice.

Not only may a wide range of symptoms be involved during palliative sedation, but the patients’ backgrounds and circumstances, such as place of residence (home, hospice, hospital or nursing home) are also very diverse. In 2005, continuous, deep sedation until death was practised most often by medical specialists (45% of reported cases), followed by general practitioners (34%) and nursing-home physicians (19%).

1.2 RMDA guideline

Since the last decade of the previous century, palliative sedation has been extensively discussed in The Netherlands. The discussion concerned the distinction between palliative sedation and euthanasia, and the criteria and conditions that must be met in order to perform palliative sedation. In general it is argued that palliative sedation differs from euthanasia in that it is not aimed to shorten life. If carried out in accordance with good medical practice, there is no evidence that palliative sedation does shorten life. Consequently, a clear distinction should be drawn between the two.

The Dutch government recognised the importance for the medical profession to develop a national guideline for this intervention, and under the auspices of the Royal Dutch Medical Association (Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst,
RDMA) a multidisciplinary committee consisting of a medical ethicist, medical oncologists, general practitioners, nursing home physicians, nurses, an anaesthesiologist, a health lawyer, and a health scientist was appointed with the task to draw up this guideline in 2005. This guideline was revised in 2009.4

Strict recommendations were formulated limiting the application of continuous palliative sedation to terminally ill patients with a life expectancy of 1–2 weeks (box 1). In addition, palliative sedation should be performed with designated medication, and proper documentation of the decision-making process and practice regarding palliative sedation is required. Palliative sedation should be used in a proportional manner, adjusting the depth of sedation to the required degree of symptom control. This implies that medication is titrated adequately whereby ascertaining that refractory symptoms are properly alleviated, and the process of dying is not hastened.

Box 1. Recommendations for the application of continuous palliative sedation 2005/2009.4

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<th>Recommendations with regard to the decision-making process:</th>
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<td>1. One or more refractory symptoms, leading to unbearable suffering of the patient.</td>
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<td>2. Expectation that death will ensue in the reasonably near future – that is, within one to two weeks.</td>
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<td>3. In case of a cognitively competent patient, consent of the patient is required for application of continuous palliative sedation. In case of a cognitively incompetent patient the intervention should be discussed with a (legal) representative.</td>
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<td>4. Continuity of collaboration between health care workers involved in the administration of palliative sedation is important.</td>
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<td>5. Expert consultation should be obtained in cases where a physician is unsure about his/her competence in performing palliative sedation.</td>
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<td>6. The goal of palliative sedation is to relieve suffering of a patient, and not to hasten death or unnecessary prolong a patient’s life.</td>
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<th>Recommendations with regard to the performance of palliative sedation:</th>
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<td>1. The physician should be present at the start of palliative sedation.</td>
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<td>2. Midazolam is the medication of first choice for use in palliative sedation. Applying morphine as a sedative is considered a form of mismanagement in the context of palliative sedation.</td>
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<td>3. In case of continuous sedation no artificial fluid should be administered.</td>
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<td>4. Adequate documentation is required.</td>
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1.3 The participation of nurses in palliative sedation

A decision to administer palliative sedation is not a one-off decision, but part of a process and course of palliative care. The WHO definition of palliative care states that palliative care should use a team approach to address the needs of patients and their families. This extends to interventions performed within the realm of palliative care, such as palliative sedation. Although primarily developed for physicians, executive aspects of the RDMA palliative sedation guideline have consequences for tasks performed by other healthcare workers involved in palliative sedation, such as nurses. Even though in the end physicians
are legally responsible for making medical decisions, it has been shown that nurses contribute to the decision-making and wish to be involved in this process.\textsuperscript{12,13} Nurses have an important role in the use of palliative sedation: they tend to interact more continuously with patients and relatives than physicians, and are often involved in assessing the patients’ symptoms and administering the sedating medication. However, nurses sometimes find it difficult to be involved in palliative sedation, in cases where they have doubts about the indication and or performance of palliative sedation for non-physical suffering and about its potential use for accelerating death.\textsuperscript{14} Furthermore, assessment of a patients’ suffering is considered difficult in sedated patients.\textsuperscript{15} Recommendations taken from the RDMA guideline state that the physician and the nursing staff should discuss the possibilities, and the evaluation criteria, in advance. This can prevent nursing staff from finding themselves in an undesirable position during the course of the sedation.\textsuperscript{4}

1.4 Proportionality of sedation

It is clearly stated in the RDMA guideline that palliative sedation is to be applied proportionally, that is for consciousness to be lowered to the extent that is necessary and sufficient to relieve recurrence of symptoms if insufficient medication is provided.\textsuperscript{16} Along with estimating the life expectancy of patients, dealing with complex symptoms and estimating the depth of sedation during this precarious process is a big challenge for caretakers. On the one hand it is crucial to relieve the suffering sufficiently with the sedation, but at the same time it is not very preferable that the chosen depth of sedation is so deep that the process of death is accelerated. Monitoring the level of consciousness, therewith assessing that the required depth of sedation has actually been reached, is one aspect necessary to achieve this balance. Monitoring the level of consciousness in palliative sedation might also be useful when communicating decisions between health care providers and to the family of patients. The RDMA guideline, however, does not offer strict recommendations as to the manner in which sedation depth should be assessed.

From a caretakers point of view one could argue that palliative sedation is performed proportional or adequately if an adequate alleviation of symptoms is achieved. At the same time it is warranted that no adverse events during the sedation emerge. Finally the quality of dying should be high as this could help relatives and physicians in their process of bereaving.\textsuperscript{17,18}

Different authors have stated the importance of monitoring palliative sedation both for guiding the proportionality and for the appropriate documentation of the procedure in medical and nursing files,\textsuperscript{19-22} however scientific literature describing prospective research on the outcome of palliative sedation is rather scarce. Authors from a Portuguese study recently validated the use of a consciousness level in a broader spectrum of palliative care patients (sedated and non-sedated).\textsuperscript{23} Up till now it remains uncertain if their results are appropriate for a specific setting with patients being palliatively sedated.
1.5 Influencing monitoring during sedation, which factors are associated?

Proportionality of sedation remains to be key during a sedation, but when we focus on the depth of sedation itself several factor may determine the course of this depth.

In a recent study held amongst Dutch physicians,\textsuperscript{20,24} 85-95\% of the respondents reported that the \textbf{aim of palliative sedation}, which is determined before the start, was reached during sedation. One could argue that if the aim is not reached, the sedation is insufficient and the patient was either sedated to deep or to light.

The idea that continuous deep sedation is the norm in palliative sedation rather than intermittent sedation, can have a direct effect on sedation depth and the amount of sedation caretakers view as adequate. This also influences the results they will look for when monitoring sedation depth during palliative sedation.

Another factor that can influence sedation depth is the importance caretakers can adhere to \textbf{preservation of communication} with the patient during the sedation. There haven’t been studies yet supporting this thesis, but it is plausible that caretakers finding preservation of communication very important will opt for a lighter degree of sedation than those who do not find preservation of communication an important goal.

The RDMA guideline recommends that a \textbf{physician stays present} until the intended sedation depth is reached.\textsuperscript{4} Up till now there is no data suggesting physicians don’t stay with the patient until the intended sedation depth is reached. None withstanding, the possible absence of physicians can influence sedation depth when medication has to be adjusted for instance. Nurses are usually not allowed to change medication without an order by a physician, hence if a physician is not present this can cause delays in necessary adjustment of medication and can cause problems when communication between nurse and physician is not good.

Finally there is \textbf{the setting} that can influence all of the above mentioned factors. For instance problems with the presence of a physician until the depth of sedation is reached, are more frequent in a home based setting. This may be explained by the fact that a physician is usually present 24-hours a day in hospital or hospice whereas this is not always the case in a home based setting.

Well known as these factors maybe, there hasn’t been much research on which of these factors have the biggest influence on the depth of sedation and therefore may have a greater impact on its course. Thus a closer look in the context of palliative sedation, in order to help prevent over- or undersedation, is preferable.
1.6 The purpose of this thesis
At present it is still unknown to which extent the RDMA guidelines are followed. Recently, palliative sedation has come into focus because of reports by experts in the field and health care workers stating that crucial aspects of the current guidelines are too broadly defined, which might lead to unprofessional performance of palliative sedation, and in the most extreme case, to unintended death. The increase in sales of sedatives has been viewed by some as suggestive for inappropriate use of palliative sedation. The experience of the physicians and nurses with regard to the current practice and possible improvements thereof need to be assessed.

Secondly, but equally important, for palliative sedation to be proportional, monitoring the effects of sedatives would be desirable. Currently valid and reliable directives with respect to monitoring and registration of the depth of palliative sedation are lacking, making it challenging to adequately administer palliative sedation.

Hence, the purpose of this thesis is 2-fold: to assess whether the RDMA guideline for palliative sedation in the Netherlands is being followed, and to evaluate the possibility of clinical monitoring of the depth of palliative sedation by palliative care nurses. The following research questions will be addressed:

1.6.1 Evaluation of the RDMA guideline
1. What is the current practice of palliative sedation in (general) hospitals, nursing homes, hospices and GP practices? Does this practice concur with RDMA guidelines? (Chapters 2 through 5)
2. Are there differences between physicians and nurses experiences with respect to the practice of palliative sedation? (Chapters 2 and 4)
3. Which (if any) obstructions are experienced by nurses in the current practice of palliative sedation? (Chapters 2, 3 and 5)
4. What factors can influence the course of palliative sedation in a favourable outcome? (Chapter 4)

1.6.2 Providing tools to monitor sedation
5. Which instrument for monitoring the depth of sedation provides the best clinimetric properties with respect to validity and reliability? (Chapters 6 and 7)

1.7 Studies in this thesis
For this thesis, data were collected using four studies. In this paragraph a brief outline of the main characteristics are described.

1.7.1 The Amsterdam Rotterdam Sedation Study (AMROSE) questionnaire
A structured questionnaire was sent to a random sample physicians and a non-random sample nurses working in the northern and western Netherlands in home care, nursing
homes, hospices, and hospitals. The questionnaire contained questions on the patient the respondents had most recently cared for during continuous sedation until death and provided data about medical experiences of physicians and nurses with regard to the practice of palliative sedation after the introduction of the RDMA guideline for palliative sedation.

1.7.2 Questionnaire study for nurses providing medical technical assistance (MTA)
A web-based structured questionnaire was offered to nurses providing medical technical assistance (MTA) covering all of the MTA teams in the Netherlands, assessing their experiences concerning decision-making, treatment policy and communication, focussing on the last patient receiving continuous deep palliative sedation.

1.7.3 Interview study amongst nurses
In-depth semi structured face-to-face interviews were held with respondents who had stated willingness to participate in the interview in the AMROSE questionnaire. Nurses were interviewed by one of the six trained interviewers. The questions asked, elaborated on findings from the AMROSE questionnaire study focussing on patients receiving continuous palliative sedation until death.

1.7.4 Monitoring study for sedation depth
In order to assess sedation depth, observational scales for assessment of sedation depth validated in a intensive care unit setting were evaluated in two hospices in patients receiving continuous or intermitted palliative sedation. The reliability, validity and practical applicability of these observational scales were assessed for use by palliative care nurses, in order to establish the best instrument for use in a palliative sedation setting.

1.8 Relevance of this thesis
On a societal level, proper performance of palliative sedation is of increasing importance. With increase of age, the need for palliative care and with it the need for qualitive end of life treatment and care, the number of patients requiring palliative sedation is estimated to increase over the coming decades. For the individual terminally ill patient, the prospect of adequate palliative care will increase the quality of his or her life in this crucial phase, and may provide an alternative for more difficult end of life decisions.

As palliative care is also focused on the family, proper use of palliative sedation will also improve the quality of life of the loved ones by preventing them a painful experience of palliative sedation not properly performed.
References


