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MIA HYLÉN

PAIN IN INTENSIVE CARE

Assessments and patients' experience

MALMÖ UNIVERSITY

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Malmö University, Faculty of Health and Society
Department of Caring Science Doctoral Dissertation 2021:1

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That's the thing about pain.
It demands to be felt.

John Green

CONTENTS

ABSTRACT

The aim of the thesis was to translate, psychometrically test, and further develop the Behavioral Pain Scale for pain assessment in intensive care and to analyze if any other variables (besides the behavioral domains) could affect the pain assessments. Furthermore, the aim was to explore the patients' experience of pain within the intensive care.

The Behavioral Pain Scale (BPS), consisting of the domains "facial expression," "upper limbs," and "compliance with ventilator/vocalization," was translated and culturally adapted into Swedish and psychometrically tested in a sample of 20 patients (study I). The instrument was then further developed within one of the domains and tested for inter-rater reliability, discriminant validity, and criterion validity (study II). The method for analysis in both study I and II was a method specifically developed for paired, ordered, and categorical data. To describe and analyze the process of pain assessment, a General Linear Mixed Model was used to investigate what variables, besides the behaviors, could be associated with the observers' own assessment of the patients' pain (study III). Further, the patients' experiences of pain when being cared for in intensive care were explored (study IV) through interviews with 16 participants post intensive care. Qualitative thematic analysis with an inductive approach was used for the analysis.

The first psychometric tests of the BPS (study I) showed inter-rater reliability with agreement of 85%. For the discriminant validity, all domains, except "compliance with ventilator," indicated discriminant validity.

Therefore, in study II, a developed domain of "breathing pattern" was tested alongside the original version. The BPS showed discriminant validity for both the original and the developed version and an inter-rater reliability with agreement of 76-80%. When

inspecting the respective domains there was a difference in discriminant validity between the original domain of “compliance with ventilation” and the developed domain of “breathing pattern,” showing higher values on the scale for the developed domain during turning. For criterion validity, the BPS showed a higher sensitivity than the observers, who on the contrary had a higher specificity.
The General Linear Mix Model (study III) showed that heart rate could be associated with the observers’ assessments of pain. For the behavioral signs, the result indicated that breathing pattern was most associated with the observers’ pain assessment, whilst facial expression did not show any impact on the observers’ assessments.

The patients’ experiences of pain (study IV) in intensive care were described as generating a need for control; they experienced a lack of control when pain was present and continuously struggled to regain control. The experience of pain was not only related to the physical sensation but also to psychological and social aspects, along with the balance in the care given, which was important to the participants.

In conclusion, the translated and developed version of the Swedish BPS showed promising psychometric results in assessing pain in the adult intensive care patients. Still, other signs, besides behavioral, is possibly used when pain assessing and therefore information about and training in pain assessment are needed to enhance the assessments that are made. Also, the patients’ own experiences highlight the importance of individualizing and adapting pain assessment and treatment to the needs of each patient. Making them a part of the team could enhance their feeling of control, thereby supporting them in facing the experience of pain.

LIST OF PUBLICATIONS

The thesis is based on results from the following papers referred to in the text by Roman numbers. The published papers have been reprinted with permission from the publishers.

I. Hylén M, Akerman E, Alm-Roijer C, Idvall E. Behavioral Pain Scale – translation, reliability, and validity in a Swedish context. Acta Anaesthesiologica Scandinavia, 2016, 60(6). doi: 10.1111/aas.12688

II. Hylén M, Alm-Roijer C, Idvall E, Akerman E. To assess patients' pain in intensive care: developing and testing the Swedish version of the Behavioral Pain Scale. Intensive & Critical Care Nursing, 2019, 52: 28–34. doi: 10.1016/j.iccn.2019.01.003

III. Hylén M, Alm-Roijer C, Idvall E, Jacobsson H, Akerman E. Patient characteristics and vital signs that could affect pain assessments in the ICU. Submitted 210113

IV. Hylén M, Akerman E, Idvall E, Alm-Roijer C. Patients' experience of pain in the intensive care – The delicate balance of control. Journal of Advanced Nursing, 2020, 76(10): 2660–2669. doi: 10.1111/jan.14503

ABBREVIATIONS

ANI	Analgesia Nociception Index
BIS	Bispectral index
BPS	Behavioral Pain Scale
CAM-ICU	Confusion Assessment Method – Intensive Care Unit
CCN	Critical Care Nurse
CPOT	Critical-Care Pain Observation Tool
CTT	Classic Test Theory
ECG	Electrocardiography
EEG	Electroencephalogram
GLMM	Generalized Linear Mixed Model
IASP	International Association for the Study of Pain
ICU	Intensive Care Unit
LoS	Length of Stay
NRS	Numeric Rating Scale
PA	Percentage Agreement
PAD	Pain Agitation Delirium, a concept presented in the guidelines from the Society of Critical Care Medicine, 2013.
PADIS	Pain, Agitation, Delirium, Immobilization, and Sleep Disruption, a concept presented in the guidelines from the Society of Critical Care Medicine, 2018.
PCA	Patient-Controlled Analgesia
PCC	Person-Centered Care
RDR	Pupil Dilatation Reflexes
RASS	Richmond Agitation Sedation Scale
RC	Relative Concentration
RP	Relative Position
RV	Relative Rank Variation
VAS	Visual Analog Scale

INTRODUCTION

The patients cared for in intensive care are often failing in one or several vital organs and intensive care is therefore often needed for the patients' survival (1). Most patients admitted to the intensive care unit (ICU) are intubated and sedated due to the need for advanced care in supporting their organs, such as lungs, heart, and kidneys. The patients could, for example, need intensive care after surgery, cardiac arrest, or trauma. Intensive care has been described as a fight for survival, consisting of great suffering (2). A problem within the ICU is that patients have been reported to suffer from pain, both at rest and during procedures (3-7). Also, in studies involving patients' recollections post ICU, pain is commonly reported as problematic (2, 8-11).

The need to improve the assessment and treatment of pain within intensive care was highlighted in the 1990s, when it was shown that patients remember pain after being in the ICU (12). Since then, the area of pain management has been intensively researched during the last two decades and guidelines (13, 14) start with directions to assess and treat pain before anything else is considered.

The gold standard for assessing pain is always the patient's self-report, which is often done with the numeric rating scale (NRS) or the visual analog scale (VAS) (13). However, a challenge when assessing pain within intensive care is that the patients are not always communicable, due to, for example, intubation. When the patients are not able to self-report it is recommended within guidelines that instruments based on behaviors are used, such as the Behavioral Pain Scale (BPS) or the Critical-Care Pain Observation Tool (CPOT) (14). A low usage of recommended instruments for the assessment of pain within the ICUs is reported (15, 16). Reasons for this, given by the critical care nurses (CCNs), are a high workload and a lack of knowledge in pain assessment. Also, a negative attitude to instruments for pain assessment and a low belief in such instruments, are reported (17), the reason for this being that the results are not experienced as influencing the prescriptions of drugs as intended (16). This is problematic, since assessment is a key factor in

succeeding within pain management, and we need to assess the pain intensity with instruments to know how to treat it successfully.

As a new CCN in the early 21st century I was confronted with the frustration of not being able to assess when the patients were in pain. At the time, there were no instruments in Swedish for assessing pain in patients not able to communicate; instead, it was up to the individual CCN to recognize when pain was present. This resulted in a variation of individual opinions and most likely affected the pain management. A structured as well as validated and reliable way to assess the patients' pain, was much needed to enable the patients to communicate their pain when not having the voice or capacity to do so.

BACKGROUND

The context of intensive care

The ICU team

The Swedish intensive care is organized in teams coordinating the patients' care and consisting of the CCN and the assistant nurse, who work closest to the patients, together with the physician and the physiotherapist. The intensive care team has been described as intertwined with many actors concentrated around the patient in a dynamic context, constantly changing according to the priorities, depending on the patients' needs (18), and with the patient in the middle. In the interdisciplinary team, each team member possesses knowledge and abilities needed for the team to function (19) so that solutions to complex problems can be addressed in an open and flexible way (20). ICU teams differ from other healthcare teams in that they are low in temporal stability, as team members change from day to day (18, 21) and sometimes even from hour to hour. This requires effective communication skills and a trust in each other's knowledge, in order to perform in critical situations despite having no shared history. Moreover, it requires a leadership (often a physician or a CCN) that is inclusive and allows a permissive atmosphere of shared thoughts and observations as well as fostering a sense of shared responsibility for the patient care (21).

The role of the CCN

In Sweden, a specialist education of one year (60 credits) is needed to become a CCN. The CCN works closely to the patients in the high-tech environment of the ICU with constant monitoring of the patients' vital signs, ready to act when observing any signs of deterioration. The care requires specific theoretical knowledge integrated with practical skills, along with the ability of critical thinking

and the capability to evaluate initiated treatments, staying "one step ahead" (22). The CCN is also responsible for administering certain medicines, for example, analgesics and sedatives, as continuous or intermittent treatment within specific target-related prescriptions. For pain, the CCN is often in charge of assessing and managing the patients' pain, either by administering analgesics or through non-pharmacological interventions, such as massage or help changing position in bed, making the patients more comfortable. The evaluation of performed interventions through new pain assessments, is also regarded as the responsibility of the CCN in Swedish ICUs. Furthermore, the care in this context requires a closeness to the patient, in order to, by means of observation and communication, understand the patients' needs, support them, and meet the worries that arise. The competence of nursing (in intensive care) can therefore be seen as multidimensional (23), in that it includes both attending to the patients' physical and emotional needs, along with having an ethical approach, and having the ability to deal with stressful situations.

To be a patient in intensive care

The two phases of intensive care

Patients that come to the ICU are critically ill and often fail in one or several vital organs. The patients are frequently exhausted on arrival and tend to surrender to the intensive care personnel, convinced that they now know what is best. Wåhlin (24) has described the intensive care as often divided into two phases. The first phase is described as a period of drowsiness in which days and nights merge. The patient notices different treatments and caring interventions, but does not question them, and feelings of dependence and defenselessness are dominating. The dependence of the patients has also been described by Almerud et al. (25) as being forced, a feeling of vulnerability and of being observed, as an objective body. Lykkegaard and Delmar (26) describe the dependence as complex, as the patient understands that the situation is life-threatening and endures, but that it can be facilitated by compassionate caring. In the second phase (24), the most acute state is over and the long journey for recovery and to reconnect with one's body is starting. In this struggle, the will to recover and to fight for recovery is dependent on whether the patient is identifying themselves as a person rather than just as a patient, something which is stimulated by strengthening their inherent joy of life.

Presence of pain in intensive care

In studies, pain has been shown to exist both at rest, among one third of the ICU patients (5), and, even more, during procedures that are common in the ICU, such as turning, endotracheal suctioning, and tube or drain removal (6, 27, 28). However, the studies are inconclusive; for example, recent studies indicate that patients do not have as much pain as expected during procedures (29-31), which could also be a sign that pain management has improved in recent years.

Nevertheless, the patient's own experiences from the ICU in general tell a story of being vulnerable as well as indicating feelings of discomfort from, for example, endotracheal tube, noise, thirst, suctioning, and inability to talk. When asked, in studies, about their general experience of intensive care, patients also reported pain as a source of discomfort (11, 32, 33). Meriläinen et al. (8) interviewed ICU patients three months post ICU and their experiences of the ICU were described as internal and external. Internal experiences were, for example, physical, such as being in pain and not being able to describe where the pain was located, or mental, with descriptions of surreal experiences. External experiences were the patients' reflections upon events that affected them, being an object of care, or trying to interact with the caregivers, something which often failed due to lack of paths for communication.

Not many studies have focused specifically on the patients' own experiences or recollections of pain in the ICU, but existing studies show a variation of experiences. Puntillo et al. (9) focused on the recollection of procedural pain and Berntzen et al. (34) on the experience of pain after being treated with analgosedation. The patients interviewed by Berntzen et al. (34) within a week post ICU, stated that pain was not a major concern, although it still existed. Other kinds of discomfort were reported as greater problems than pain, such as hallucinations, stress, and nightmares, which challenged the patients in striving to cope with the intensive care. In the longitudinal study by Puntillo et al. (9), patients' memories of procedural pain 3-16 months post ICU were compared to the score reported by the same patients during the procedure. It was noted that the recalled score for both pain intensity and distress was significantly higher post ICU than reported during the procedure. Further, patients' recollections of the ICU after five years compared to after one year, with the ICU memory tool, showed that the emotional memory of pain persisted after five years (35). The results from Puntillo et al. (9) and Zetterlund et al. (35) indicate the experience of pain as possibly affecting the patient a long

time after the ICU and those results further point to the importance of pain assessment and management. It also seems to be of importance *when* the recollections are gathered (36), and it is recommended that memories are collected shortly after ICU discharge to avoid being compromised. The possible presence of delirium, and concomitant cognitive impairment, shortly after the ICU care, should be considered.

Definitions of pain

Historically, the definition of pain has grown from focusing on the strictly neurological, describing the pathways of "pain fibers," to a view of pain being multidimensional, consisting of both sensory and emotional experiences (37, 38). It has been debated if it is even possible to define the complex phenomenon of pain. The person experiencing the pain often does not have access to the language or vocabulary needed to describe their experience in full. The clinician, on the other hand, tends to use biomedical language to describe pain, which assumes a linear relationship between tissue damage and the sensation. This generates a risk for misinterpretation and often results in a compromise which is insufficient for both parties (39). There are different definitions of pain, from more general definitions, which are broader, to more specific and holistic definitions, taking the personal aspects into account.

The most internationally accepted and applied definition is the definition of pain from the International Association for the Study of Pain (IASP) which states that pain is: "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage" (40).The definition, which has recently been revised, notes that pain is always a personal experience and not always inferred from activity in sensory neurons, but influenced to varying degrees by different factors such as biological, physiological, and social. It also notes that we, as individuals, learn the concept of pain through life experience and that the report of pain should always be respected as such. The report of pain is not solely verbal but could be expressed through different behaviors, and the inability to communicate does of course not exclude the experience of pain. The learning of pain from life experience is new within the definition and relates to the personal or subjective aspect of experiencing pain, which is a noteworthy development (41).

Loeser and Melzack (42) defined four categories of pain – nociception, perception of pain, suffering, and pain behaviors – which are used clinically. Those four components, they claim, can help understand many different types of pain. Nociception is the neural response after tissue damage, and pain perception is how the brain perceives the pain, which is often, but not always, generated by the nociception. Suffering is the negative response induced by pain or by fear, anxiety, stress, loss, and other psychological states, and often the language of pain is used to describe suffering. Pain behaviors are the things a person does or does not do, that can be related to the presence of tissue damage and that are observable by others (42, 43).

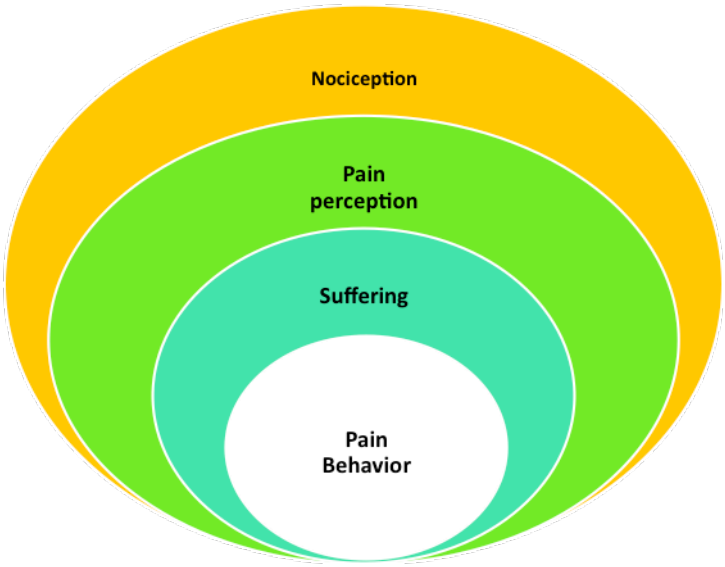

Figure 1. *Four categories of pain (43)*

Lately, pain as an experience within the intensive care has been divided into two categories: intensity and distress (10, 44, 45). The intensity is conceptualized as the severity of the pain sensation and the distress is the affective response that relates to the unpleasantness that comes with the sensation of pain. It has been shown that the two sensations are related, but there are some procedures where the intensity and the distress differ. The procedures that induce great distress are often connected to interference with breathing, such as endotracheal or tracheal suctioning or chest tube

removal. A high degree of pain intensity reported during the day, or the time before the procedure, also leads to a higher risk of pain distress. Often, if certain pain behaviors are observed prior to the procedure (grimacing, eyes closed, and moaning), there is a higher risk of pain distress for the patient during the procedure (10).

Consequently, pain for the ICU patient is not only dependent on nociception (intensity) but also on the distress experienced, which in turn seems to be dependent on the context (10). This has been noticed before, as cognitive and contextual factors tend to influence the affective dimension of pain. Patients with a perceived threat to health or life reported greater distress than patients not experiencing such threats, despite having the same reported pain intensity (46). For ICU patients, the context, or more precisely the environment in the ICU, has been described as frightening and limiting, as a place where the machines dominate, and where the patients apprehend themselves as objects and therefore feel marginalized. Although they are observed every second, they feel invisible, and there is an experience of being merged with the machines and thereby also of being read and regulated (25). Karlsson et al. (47) describe the patients' situation when awake during treatment with mechanical ventilation as a great dependence, which the patients know they have to endure in spite of suffering, being out of control and submitting to the will of others.

A more holistic approach towards understanding and treating pain is the concept of "total pain" coined by Dame Cicely Saunders (48). This concept was originally formed in relation to pain management within palliative care, but due to the many similarities with problems faced by intensive care patients it could possibly be adaptable to that area too. The concept of total pain is characterized by a multidimensional approach to understanding pain and based on the following components: physical, psychological, social, and spiritual. A combination of those four aspects helps us understand the total dimension of pain (48, 49) from a holistic perspective. Not being solely focused on the physical or biomedical aspect of tissue damage that is often underlined in current definitions (40, 41), the concept of total pain instead regards each component as equal and pain is only treated successfully when all components are dealt with. For example, the intensive care patient could experience psychological stressors such as anxiety and fear, as previously described, that contribute to the pain experience. Furthermore, social aspects, such as worrying about their family and loved ones as well as about how being sick and the

subsequent recovery will affect their future life and social role, could also contribute to the total pain experience (48).

Finally, the expression of "pain being whatever the person says it is," emphasizing the subjective aspect of pain, has been used and seems to be accepted regardless of the definition of pain adhered to (41, 42, 48).

Pain and pain assessment in intensive care

The areas of Pain, Agitation, and Delirium (PAD) are frequently bundled together when producing guidelines for the intensive care (14). This is done since pain and agitation are often treated simultaneously in the ICU patient, which is necessary in order for the patient to endure being intubated and other procedures that can be both painful and stressful. Although being bundled together, the areas of PAD are still separate with regard to both assessment and treatment. International clinical guidelines for analgesics and sedatives were published in 1995 (50) and then revised in 2002 (51). A large breakthrough within the area was probably the Clinical Practice Guidelines for the management of Pain, Agitation, and Delirium (PAD) that were published in 2013 (13) as a result of a collaboration between many of the internationally active researchers within the area. These guidelines were recently updated in 2018 (14) and two additional areas (immobility and sleep disruption; PADIS) were included. Also, in the latest guidelines (14), a panel of former ICU patients were engaged in every step.

Throughout all the former and present guidelines, pain is mentioned first and thus seems to be a key factor in succeeding in the treatment of PAD. Pain can be displayed in a similar way as anxiousness and generate a restlessness which can be misinterpreted as agitation (52). It is therefore recommended that pain is assessed and treated before escalating sedation, a concept called analgosedation, in which the pain is approached and treated before adding any sedative (53, 54). Analgosedation has been shown to be beneficial for the patients, with a reduction in the pain incidence (55) and a reduction in sedatives given (56). The guidelines (14) do not use the word analgosedation but emphasize the need for a lighter sedation approach and for the assessment of both pain and sedation being used routinely.

Instruments for assessing pain

It is recommended that pain is assessed routinely and preferably by self-report, which is considered the gold standard (14), according to the definitions. When self-reporting pain, it is, furthermore, recommended to use an enlarged, horizontal Numeric Rating Scale (NRS), which is preferred by the intensive care patients (14, 57). When awake but not able to use the NRS, a simple yes or no when asked, indicating presence or absence of pain, could be helpful (58). Unfortunately, most patients in the ICU are not able to perform any self-report due to, for example, intubation and sedation. Alternately, behaviors have been shown to be reliable indicators for pain within intensive care. Puntillo et al. (59, 60) described the behavioral pain response to pain among over 6,000 adult critical care patients as, for example, facial expressions, bodily movements, and verbal expressions. These studies have resulted in the development of instruments based on behaviors to assess pain in the ICU, when self-reports are not possible. As of 2019, nine behavioral assessment instruments have been published for critically ill adults, three of them only during the past four years (61). Awareness of the self-report as stemming from a higher mental process is argued and therefore a self-report should always be the first alternative. Behaviors are regarded as less voluntary, less controlled, and more automatic, and therefore assessing them does not measure the same dimensions as a self-report (44). Therefore, the patient's self-report tends to involve the complete experience of pain, as described in Saunders' definition of total pain (49), whereas the behavioral assessment instruments only show the presence or absence of pain. However, when lacking a self-report of the patients' pain, it is of great importance to be able to detect pain, which is why behavioral instruments are regarded as a sufficient substitute (14).

Behavioral instruments for assessing pain

Two of the existing instruments, based on behaviors, are recommended because of their high psychometric properties (14, 61): the Behavioral Pain Scale (BPS) (62) and the Critical-Care Observation Tool (CPOT) (63). Both instruments have remained the most robust scales for assessing pain in intensive care adults unable to self-report, during the last decade, and are used internationally. For that purpose, they have been translated and validated into different languages (the BPS exists in 10 languages, and the CPOT in 17 languages) (61). Both are built entirely on behaviors and are similar but differ in the current number of domains and the number of points in each domain. The CPOT (63) consists of four domains ("facial expression", "body movements", "muscle tension", and "compliance with the

ventilator" or "vocalization", whether the patient is intubated or not) and ranges from 0 to 2 points in each domain, generating 0-8 points in total. The BPS (62) was the first instrument published and initially consisted of three domains ("facial expression", "upper limbs", and "compliance with ventilation"), each domain ranging from 1 to 4 points, generating 3-12 points in total with increasing pain. In 2009, the BPS was adapted for non-intubated patients with the addition of the domain "vocalization" to complement the original instrument (BPS-NI) (64). Previously, the CPOT had been translated into Swedish (65) but not the BPS/BPS-NI.

Studies have also tried to psychometrically compare the two instruments (31, 66-68), aiming to find out which of them is superior. Over 500 patients were assessed in the studies, resulting in a conclusion that both instruments are equally good when calculating discriminant validity and inter-rater reliability with moderate to high results for both instruments. The study of Rijkenberg et al. (68) was in favor of the CPOT since the total points for the BPS increased during non-painful interventions (mouth care), Chanques et al. (66) found the BPS to be slightly more user-friendly and Severgnini et al. (31) proposed that a combination could be beneficial. The availability of both recommended instruments (the BPS and the CPOT) in Swedish could be beneficial for the development of the assessment of pain among the Swedish ICUs. Presently, no overview exists of the usages of pain-assessment instruments among the Swedish ICUs, but regarding the assessment of sedation it has been shown (among 50 of the 80 ICUs) that a majority use written guidelines and a sedation scale (69).

Effects of structural assessments of pain

It has been shown to be beneficial for the patients when pain-assessment instruments are used in a structural way, either alone or integrated in a protocol together with an assessment for sedation and/or delirium. For example, it has been concluded in studies that the duration of mechanical ventilation can be shortened as an effect of the usages of instruments (70-73). A significant reduction in length of stay (LoS) within the ICU has also been shown (71, 72), something which could, furthermore, be regarded as cost efficient. Other than that, a shift in analgesic and sedative medication has been seen (71), with less sedation given, which could indicate a previous oversedation. Chanques et al. (70) also recorded a decrease in agitation and pain among ICU patients, a result that was confirmed in the studies by De Jonghe et al. (74) and Georgiou et al. (29). Then again, there are studies that did not detect any

effects on mechanical ventilation (29, 75) or LoS (76) in the ICU, which indicates an ambiguity with regard to the effects found in these types of studies. What studies agree on, however, is the importance of education during the implementation of the instruments (70, 71, 74) in order to succeed in the adherence to the new routine.

Challenges and barriers in assessing pain with behavioral instruments

It has been stated that, regarding pain, a self-report is considered the gold standard, but in the absence of such, instruments for pain assessment based on behaviors can be a reliable and valid substitute (14). There are, however, clinical challenges related to such instruments.

One challenge regarding the BPS is that although it is supposed to assess pain, not all studies can confirm this with a comparison to the patients' self-report of pain (criterion validity). For example, the first studies to validate the BPS (62, 64, 77, 78) all tested the instrument without aiming to include the patients' self-report. This can be defended with the argument that the instrument was designed to detect pain among unconscious patients. Ahlers et al. (79, 80), on the other hand, validated the BPS and found correlations between the patients' self-report and the BPS assessments. Recently, Bouajram et al. (81) showed a weak correlation between self-reported pain and behavioral pain scales, a result that could be related to the previously discussed meaning of the self-report as stemming from a higher mental process (44). Often, it is questioned how we can be sure that it is pain that is assessed with behavioral instruments and not anything else, such as agitation, stress, etc. When those questions arise, it is important to remember that studies have shown that all behaviors on which the instruments are based correlate with pain (59, 60), and that they have been validated both within nociceptive procedures and against self-reports of pain and are therefore recommended in clinical practice guidelines (14). Stress and agitation have been shown to correlate with pain (52), which is why it is always recommended to start by evaluating the pain treatment before adding further sedation when in doubt about why the patient is agitated or stressed (analgosedation).

The instruments based on behaviors also have certain limitations that should be noted as barriers for usage among certain patient categories. For example, if the patients are too deeply sedated, this could remove the behavioral responses of pain (13). Thus, a deeply sedated patient can be in pain but lack the behaviors needed for assessment. Another area in which the instruments are limited is among the patients

with brain damage, as these patients have been shown to present different behaviors when turned over than what is observed with the instrument to detect pain (82, 83). Behaviors among patients with brain damage therefore need to be explored further, with the aim of validating present instruments. Among patients with delirium, on the other hand, there are positive results showing that the instruments, based on behaviors, could be valid for indicating pain within this group (64, 84). However, it is important to remember that an instrument for assessment can only be valid for its specific purpose and within the determined group and context for which it is designed and tested (85).

Barriers for the usage of behavioral instruments have also been shown among CCNs. Deldar et al. (17) reported that pain assessment is forgotten since there is a lack of implemented guidelines and routines. Also, the workload hinders the CCNs from assessing pain, along with the lacking knowledge about pain and pain assessment (17, 86). Another reported barrier was a suspicion regarding the accuracy of the instruments, where the CCNs considered their own personal assessment to be more adequate in assessing pain than any instrument (17, 87). Rose et al. (15) showed that CCNs were less likely to use a behavioral instrument than a self-report instrument, and this finding is supported by Payen et al. (88) and Zuazua-Rico et al. (86), where only a third of the patients were assessed with an instrument. CCNs also trusted physiological indicators (vital signs) as indicators for pain (15, 16), something that has been contradicted in the last two guidelines (13, 14) where vital signs are described only as cues for further assessment, dependent on the complexity of the ICU patient. These reported barriers among CNNs in using the recommended instruments are a challenge, since the CNNs are working close to the patients and are therefore often responsible for assessing the patients' pain.

To assess pain without instruments

Pain assessment within intensive care without the support of instruments has been described as a complex process where the observer needs to integrate the pain behaviors into the patients' context to make an appropriate judgement about pain (89). This has also been shown in postoperative care, where the nurses in surgical units are in charge of pain assessment, namely, that observations of the patients together with communication and the nurses' own previous experiences, were used as keys when assessing pain among patients (90).

When the patient is unable to communicate, the CCNs have been described to clinically reason about pain using indicators such as their own knowledge about the patient and about the procedure, and previously observed patterns (89), together with the behavioral and vital signs of the patient (91). This is done in order to anticipate risks and take appropriate action to prevent pain (89, 91). In medical records, it has been shown that behavioral descriptors are most commonly used for describing pain, along with vital signs, without an instrument for pain assessment being present (92).

However, vital signs, such as the heart rate, blood pressure, and respiratory state of the patient, still seem to influence the CCNs and be used for making decisions about pain and pain management (89, 91). Despite vital signs normally not being considered valid pain indicators and the recommendation that they should be used with caution (14, 44, 45), recent studies have been performed to validate vital signs as indicators for pain assessment (93, 94).

The study of Haslam et al. (92) reported an uncertainty with regard to being able to distinguish pain from agitation and delirium; instead, the CNNs used a combination of analgesic, sedative and anti-psychotic drugs, either simultaneously or on repeated occasions.

In conclusion, despite the recommendation to use behavioral instruments for assessing pain among adult intensive care patients (14), these are not always used (15, 16, 88). Instead, studies indicate that, within the context of ICUs, the CCNs use vital signs, former experiences, unstructured behavioral signs, and their knowledge about the patient, when assessing pain (89, 91, 92). Nevertheless, assessments performed as described above risk becoming subjective. Using an instrument for assessment is helpful in giving a structure to the observations, thus guiding the CCNs in treating the patients' pain as well as evaluating the treatment (95).

Person-centered care in regard to pain in the ICU

As pain is described as both a sensory and an emotional experience, it could be seen as individual and should therefore be regarded and met as an experience that differs dependent on each respective person (40). Person-centered care (PCC) is defined as a "middle-range theory" that has been developed based on humanistic care and therapeutic relations (96) and it is, moreover, defined as one of the six core

competencies in Swedish nursing (97). It is argued to be based on four modes of being which are at the heart of person-centeredness: being in a relation, being in a social world, being in a place, and being with self (96). The relationship, or even partnership, between the caregiver and the person in need of care, is essential in PCC. According to Ekman et al. (98), three routines are needed to initiate, integrate, and safeguard the PCC: the narrative, the partnership (which is initiated by listening to the narrative of the patient), and documenting the narrative.

The PCC within intensive care has, so far, not been studied to any great extent. A concept analysis of patient-centered nursing (not person-centered) within intensive care (99) showed the complicated relationship between the required biomedical expertise, high clinical skills, and the need for a compassionate and professional presence. Those competencies, together with seeing the patient as a unique person, when intensive care is threatening their identity, were identified as core concepts. This is supported by Cederwall et al. (100), where PCC in the weaning process (from ventilator) was examined and finding the person behind the patient was described as step one in the process. Regarding pain, PCC pain management within acute care showed the importance of organizational culture for how well pain was managed (101). A trustful relationship, successful communication, and individual pain management led to well-managed pain. In the study of Connelly et al. (102), a daily question of "What matters to you today?" posed to the patients within the ICU, generated an awareness that could potentially improve patients' experiences. One of the themes that mattered to the patients the most was "pain under control" (102).

The concept of PCC is hereafter discussed in relation to pain and pain assessment within the ICU, based on the two, previously mentioned, phases described by Wåhlin (24). The first phase is when the patient is not able to make a self-report of pain level, and the second phase is when they are able to communicate their pain and thus be more involved in their care. It should be mentioned that the phases may not be relevant for all patients to go through in that specific order and that not all patients are in both phases.

PCC related to pain in non-communicable patients

The first phase of intensive care being based on altered consciousness and dependency (24), both the narrative and the partnership, with shared decision-making, are a challenge for the CCN. The patient narrative is not easily accessed, in this phase, but it is crucial and often what makes the patient into a person (98). The

machines and the technique tend to dominate the focus of the caregivers. Almerud et al. (25) discuss the complexity of caring in intensive care with its highly technological environment, describing a situation where the machines are in focus, and where the patients perceive themselves as objects and therefore feel marginalized. The caregivers, on the other hand, describe how the technique is always present and how it is experienced to sometimes stand in the way of any interpersonal closeness with the patient. This is confirmed by McLean et al. (103), where CCNs are described as shifting between regarding the patient as a body and as a person, describing their work as "caring for them as persons but in quite a different way."

When listening to the patient's narrative, it is suggested for the caregivers, within PCC, to be open to, and willing to interpret, what this person wants to tell them (104). The caregivers have to find a way to see the person through the technology, when the patient is sedated and intubated, and find a balance so that the narrative is not lost, which is a strong wish from both sides (25). One way of doing this, that is, of not letting the machines be in focus, and of being in the social context, could be found in the thoughts of Maurice Merleau-Ponty (105), who described the body as lived in the world and with intentions to the world. Merleau-Ponty (105, 106) talks about palpation as an act performed not only with intentions to ask but also with some kind of knowledge – a kind of experienced requesting. Palpation can be performed both with the hands and with the eyes (observations), when knowing what to look for and in what angles to be able to gather information. The caregiver uses a constant palpation with the eyes and hands to observe the patient and make sure that the patient is well. Through experience, the caregivers know where to gather information, sometimes by observing the technology and sometimes by observing the patient, in an experienced requesting. Observing the patient's behaviors in a structured way, as the pain instrument assessment guides us to, makes it possible to notice when pain is present even if the patient cannot tell us.

PCC related to pain in communicable patients

In the second phase of intensive care (24), the patients felt empowered by taking part in decisions, although it was important that these decisions were on a moderate level and adapted to what could be expected of them. They did not want to take part in big decisions, for example, about their treatment, but gladly participated in decisions about their own body, such as washing, turning, and exercising. Merleau-Ponty (105) describes the need of meaning in life, something which is also

expressed in the phase of recovery. The will to recover is affected by being reminded of how life was before the disease and that this life is waiting for the person to recover. Martin Buber, mostly known for his thoughts about the two-fold relationship, also talks about what is “in between” persons (107), which should be characterized by presence, acceptance, and immediacy in order to experience the other in full. But if one of the parties tries to impose certain opinions on the other with an agenda, the conversation stops being relational as the individuality stops being accepted. Both power relations and an agenda close the openness in the relation, something the caregiver should have knowledge about and be aware of in the relation with the patient. As the technology becomes less important for survival and the patient starts to regain their body, the relationship alters. In the second phase (24), the partnership can be described as a mutual exchange of information where the challenge is for the patient to have the courage to participate and for the caregiver to show acceptance and encourage the patient to participate. To help the patient express their experience of pain as their own, and therefore unique, is of importance, thus inviting them to participate in their care.

Rationale

When patients are unable to self-report, it is important that Swedish ICUs have access to instruments for pain assessment that are valid and tested for reliability. As such, the BPS has been shown to be user-friendly and it could therefore be beneficial as translated and adapted into the context of Swedish ICUs. In the context of intensive care, it is important to be able to make quick assessments that can be used to guide treatment but also to evaluate given treatment. An instrument for pain assessment could thus help communication within the ICU team. The pain assessment could also benefit from being focused on the patient, something which could be further explored. Pain assessment is a complex process described to integrate both the behaviors and the context of the patients. This could therefore be further looked into to see if other signs are still used, in addition to behavioral signs, when assessing pain with an instrument. Additionally, to understand the concept of pain in the ICU there is a need to explore the experiences of the patients. In order to meet their demands as persons with regard to pain, an understanding of the patients’ experiences is important and could help enhance the given care.

AIM

The overall aim was to translate, psychometrically test, and further develop the Behavioral Pain Scale for pain assessment in intensive care and to analyze if any other variables (besides the behavioral domains) could affect the pain assessments. Furthermore, the aim was to explore the patients' experience of pain within intensive care.

Specific aims

To translate and adapt the Behavioral Pain Scale for critically ill intubated and non-intubated patients in a Swedish ICU context and assess inter-rater reliability and discriminant validity. (Study I)

To develop the domain of "breathing pattern" in the Swedish version of the Behavioral Pain Scale and then to test the instrument for discriminant validity, inter-rater reliability, and criterion validity. (Study II)

To examine pain assessments of observers of intubated ICU patients and analyze if there are variables, besides facial expression, upper limb movements, and breathing pattern, that affect the assessments. (Study III)

To explore the patients' experiences of pain when being cared for in intensive care. (Study IV)

METHOD

This thesis consists of four studies, three of which have a quantitative and one a qualitative approach. A summary of the studies is presented in Table 1.

Table 1. *Summary of study I-IV in regard to design, data collection, sample, participants, and analysis*

	Study I	**Study II**	**Study III**	**Study IV**
Design	Observational Quantitative	Observational Quantitative	Observational Quantitative	Explorative Qualitative
Data collection	Repeated measures	Repeated measures	Repeated measures	Interviews
Sampling	Convenience	Convenience	Convenience	Purposeful
Participants	20 ICU patients on 20 occasions.	57 ICU patients on 90 occasions*	31 ICU patients on 60 occasions*	16 participants post ICU*
Analysis	Translation, Inter-rater reliability, and Discriminant validity	Inter-rater reliability, Discriminant validity, and Criterion validity	Generalized Linear Mixed Model	Thematic analysis

**Generated from the same sample*

Assessments

Behavioral Pain Scale

The BPS (62) originally consists of three domains: “facial expression,” “upper limbs,” and “compliance with ventilation.” Each domain is comprised of four descriptors, generating a score from 1 to 4 respectively, where the scores increase with increasing pain. The total score is generated from the three domains and can range from 3 to 12 points. The BPS has later been adapted for non-intubated patients (BPS-NI) (64), where the domain of “compliance with ventilation” is replaced by a domain called “vocalization.” The BPS has previously been tested psychometrically for validity in 33 different studies (8 studies for the BPS-NI) and for inter-rater reliability in a total of 18 studies (8 studies for the BPS-NI) (61). A high psychometric score resulted in the BPS and the BPS-NI holding one of the strongest scores of behavioral scales for the ICU and they are therefore recommended for usage with adult intensive care patients who are not able to perform a self-report (14, 61). The cut-off score for the BPS has been established at >5, indicating pain that should be treated (88). The original BPS and BPS-NI are shown in Table 2. Both BPS and BPS-NI were included in the translation into Swedish and are therefore hereafter referred to as the BPS with additional description of intubated or non-intubated.

Table 2. *Original Behavioral Pain Scale (BPS and BPS-NI), reproduced with kind permission from the developers Professor Payen and Professor Chanques*

Domain	Descriptor	Points
Facial expression	Relaxed	1
	Partially tightened (e.g., brow lowering)	2
	Fully tightened (e.g., eyelid closing)	3
	Grimacing	4
Upper limbs	No movement	1
	Partially bent	2
	Fully bent with finger flexion	3
	Permanently retracted	4
Intubated: **Compliance with ventilation**	Tolerating movement	1
	Coughing but tolerating ventilation for most of the time	2
	Fighting ventilator	3
	Unable to control ventilation	4
Not intubated: **Vocalization**	No pain vocalization	1
	Moaning not frequent (≤ 3/min) and not prolonged (≤ 3 s)	2
	Moaning frequent (> 3/min) or prolonged (> 3 s)	3
	Howling or verbal complaint, including "Ow!" or "Ouch!", or breath-holding	4

Translation and adaptation of the BPS

For translation and adaptation of the Behavioral Pain Scale from English to Swedish, in study I, a translation process described by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (108) was chosen. The method consists of 10 steps: preparation, forward translation, reconciliation, back-translation, back-translation review, harmonization, cognitive debriefing, cognitive debriefing review, proofreading, and final report. For *preparation*, the original authors were contacted and permission to translate and use the BPS was obtained. The BPS was initially developed in French but, for publication, translated into English, which is why the original authors were asked how the translation was performed. As the process

included both forward and backward translations and as it is the English version that has been psychometrically tested in other studies, the English version was chosen as the original version to be translated. *Forward translation* was done separately by the author and a native Swedish-speaking professional translator, who was informed about the instrument, usage, and context. *Reconciliation* between the two versions was then performed by the research group with support from the translator. This is done to avoid that one person influences the process and in order to discuss different aspects, such as choice of words and cultural aspects within the context. *Back translation* of the reconciled version was done by two separate translators, one of them professional and the other with a background within intensive care. This was done to evaluate if preunderstanding would influence the translation. *Back translation review* is described as a comparison and compliance review between the back translation and the original instrument, with the purpose of minimizing the discrepancy between the two. *Harmonization* is the step when a definitive version of the translation is finalized and ready for *cognitive debriefing*. The translation was then tested for understandability and cognitive equivalence on a group (cognitive debriefing group) of five CCNs, especially interested in pain and who had worked within the ICU between 4 and 25 years (mean 11 years). The CCNs were also asked to grade the different descriptors (1-4 representing increasing pain) within each domain before seeing the final version, which was specific for this study (I) and not mentioned in the method. The research group then performed the *cognitive debriefing review*, where the comments of the group were taken into consideration to ensure that the translation was both literally and conceptually accurate. *Proof reading* of the instrument was done to check for minor errors within the translation, and a *Final report* aimed to provide a description of the process to document all the translation and cultural adaptation decisions.

Developing the domain of “breathing pattern”

To shift the focus from the technology to the patient, the domain of “compliance with ventilation” was developed, in study II, so as to assess the patient’s breathing pattern instead. This was done as the technical development of the ventilators had gone from having little compliance with the patient’s breathing (when the BPS was introduced) to following and adapting to the breathing in a much more sensitive way. Thus, today, cases of the patient fighting the ventilator, or the patient’s breathing in the ventilator not being controllable, as stated in the instrument, are rarely generated. Also, clinically, when caring for the patient, it was regarded as beneficial if the focus could be on the patient for all the domains of the BPS.

A review of previous studies that examined behavioral indicators for pain was done, which showed that certain patterns of breathing had the ability to be sensitive to pain, especially dyspnea and respiratory rate (109-112). Influences from pain assessment scales for children (113) were also considered, along with clinical experience expressed during the cognitive debriefing. A first draft was then presented at team meetings to a group of CCNs, assistant nurses, and physicians, to introduce, and collect their perceptions about, the instrument including the developed domain. This generated minor revision for clarity. The domain was initially tested in a pilot study on 10 intubated patients, a study which was reviewed and later included in the result.

Participants and criteria

All participants in study I-III were recruited form a convenience sample. Both intubated and non-intubated patients were included in the studies aiming to test the whole instrument. When the BPS was first tested, in study I, ICU patients were included if they were adult (>18 years) and unable to assess pain with the Numeric Rating Scale, and they were excluded if they were quadriplegic or receiving neuromuscular blockade. When the developed version was tested, in study II and III, ICU patients were included if they were adult (>18years), had been in the ICU for more than 24 hours, and needed help with turning in bed. Exclusion criteria were quadriplegic patients and patients receiving neuromuscular blockade or having unclear neurological conditions, which generated uncertainty about whether they were able to move their limbs. Needing help turning in bed was referred to as inability to turn over in bed by themselves, therefore requiring help from caregivers. In study III, only intubated patients among the included patients were eligible for data analysis.

Context

The studies were conducted at a university hospital in the southern part of Sweden. The general intensive care unit, where participants were recruited and data collected, consists of ten beds and admits patients of all ages with both medical and surgical diagnoses (including trauma). The unit consists of four double rooms and two single rooms, each staffed with one CCN and one assistant nurse caring for one or two patients, one caregiver being always present in the room. The mean LoS is 3.4 days (median 1.65) for 2020 and the unit takes care of approximately 800 patients a year. The ICU team within the unit often consists of a Physician (a specialist within intensive care), CCNs, Assistant nurses, and Physiotherapists. The unit had

guidelines for pain and sedation, based on the international guidelines of PAD (13), but no behavioral instrument for pain assessment was implemented when the studies were performed, the NRS being the only instrument used.

Instruments

The Numeric Rating Scale (NRS) (Study II and III)

For adult intensive care patients, able to perform a self-report of their pain level, the horizontal NRS is recommended to assess pain intensity (57). The NRS consists of 11 steps from 0 (no pain) to 10 (worst pain) and the patients were asked to make a subjective assessment on the scale, if possible. If the NRS could not be used, as intended, patients were asked to nod or shake their head when asked if pain was present. The NRS was also used for the observers to rate their experience of the patients' pain level in study II and III (hereafter NRS observer). The cut-off score for the NRS has been previously described and set at assessments >3 (114).

The Richmond Agitation and Sedation Scale (RASS) (Study II and III)

Sedation levels were assessed using the RASS, a 10-point scale ranging from +4 (combative) to -5 (unarousable) with 0 as the calm and alert state (115). Recommended sedation levels are at the lighter level often between 0 and -2, representing an awake and calm to briefly awake patient (14). For study III, since at all turning procedures patients were either awake or sedated (minus on the scale), the RASS was divided into two groups: 0, -1 and -2 (awake/light sedated) and -3 and -4 (deeply sedated).

Procedures for assessments and training

Assessments were performed with the BPS during procedures chosen because they were potentially painful (study I, II, III) and non-painful (study II). Repositioning or turning in bed is known and documented as a potentially painful procedure and has been used in previous studies (28, 60, 68, 78, 79) and it was therefore chosen as such when testing the BPS. In study II, the BPS was also tested, for the same patient but during a non-painful procedure, chosen to be washing with lukewarm water on the arm of the patient, a procedure which has been previously used (65). There was at least one hour between the painful and the non-painful procedure. At each procedure, two independent observers assessed the patient with the BPS, first at rest and then during the procedure. In study II and III, the BPS was shown to the observers as consisting only of the descriptors, the numbers in each domain (1-4)

being removed. This was done with the intention to focus on the description of the pain behavior for the observers and not on the numbers.

Observers in study I were recruited from the cognitive debriefing group and therefore introduced to the instrument prior to the assessments done for study purposes. In study II and III, the instrument of BPS was introduced through one-hour training sessions to all caregivers (CCNs, assistant nurses, physicians, physiotherapists) working in the unit. During the data collection, information was further given through two seminar lectures available to all caregivers.

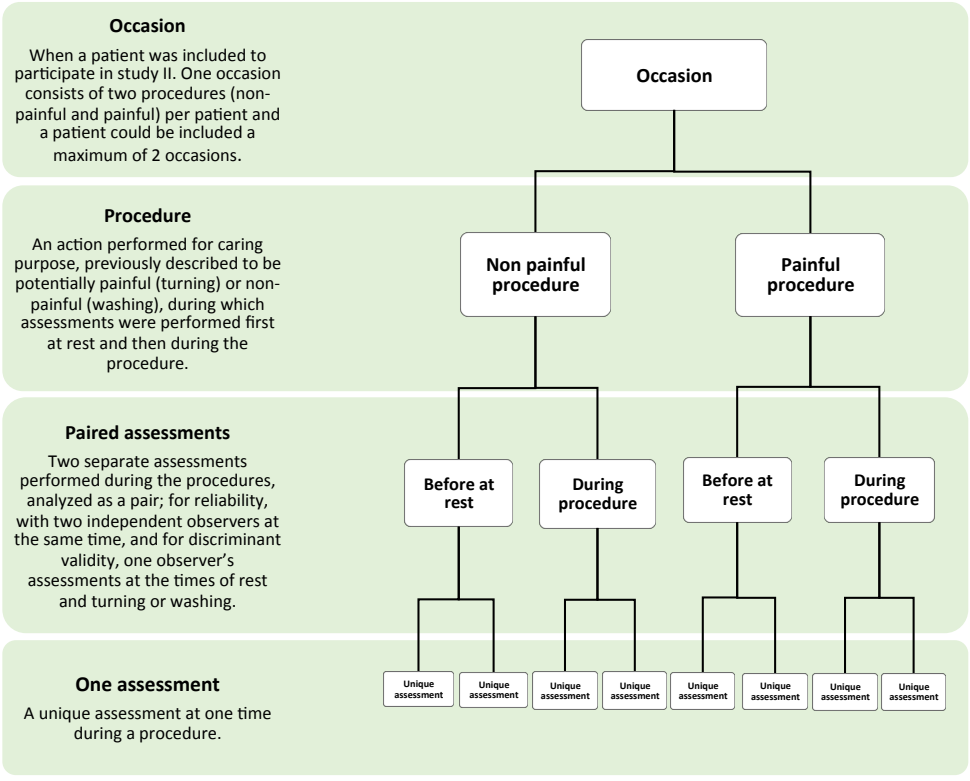

Figure 2. *Definitions of different aspects in the data collection for study II and III*

Data collection

Initially, the Swedish translation of the BPS was tested (February-April 2012) for inter-rater reliability and discriminant validity (study I) in a total of 20 procedures on 20 patients (10 intubated and 10 non-intubated), generating 80 assessments (40 paired by two CCNs) at two times during the procedure of turning, at rest, and directly after repositioning in bed. The researcher was always one of the observers and all assessments were independent. No demographic data was collected on the patients for this initial testing of the instrument, since the focus was on the instrument and its reliability and validity.

Further, the BPS including the developed domain was psychometrically tested (November 2014-March 2017) on 92 occasions consisting of two procedures each (turning in bed and washing) in a total of 59 patients (each patient was included a maximum of two times). Two patients were excluded because they were inaccessible and could therefore not give their informed consent after discharge from ICU, leaving a total of 57 patients assessed on 90 occasions. Due to the rapid change in the condition of the ICU patient, at each inclusion the patient was regarded as a new patient. In study II, all 90 occasions, 60 with intubated patients and 30 with non-intubated patients, were included. Study III only included data from the 60 occasions with intubated patients during the procedure of turning. In total, 360 paired assessments were analyzed in study II and 240 unique assessments were analyzed in study III. The steps of the data collection in study II and III are described in Table 3, including which data was used in the studies, respectively.

Vital signs were collected by the researcher (study II and III) at the same time as the two observers performed the assessments, first at rest and then during the procedure. Vital signs consisted of saturation, respiratory rate, heart rate, and blood pressure.

Table 3. *Data collection described for study II and III*

Steps in data collection, used in study II and III, respectively		Used in	
		Study II	**Study III**
Inclusion	Patients eligible for the study were included by the researcher and the head nurse of the ICU.	x	x
First assessment -at rest	Assessments at rest with the BPS (the numbers of the instrument removed) and the NRS of the observers (two independent).	x	x
	Vital signs collected by researcher.		x
Second assessment - during procedure	Procedure is performed: Turning in bed or Washing	 x x	 x
	Vital signs collected by researcher.		x
	Assessments during procedure with the BPS (the numbers of the instrument removed) and the NRS of the observers (two independent).	x	x
	Patient is asked to rate their pain on the NRS or nod/shake their head when asked about pain.	x	
Post procedure	Assessment of the RASS by the researcher in dialogue with the CCN.	x	x

Other demographic data – such as age, gender, diagnosis, length of ventilator treatment, sedation and analgesic treatment, and Simplified Acute Physiology Score (SAPS 3) (116, 117) – was collected after written consent was obtained (study II and III).

Statistical analyses

The demographics (study II and III) were summarized using descriptive statistics with the mean (SD or min-max) calculated for continuous variables and the percentage (%) for categorical variables.

To analyze discriminant validity and inter-rater reliability (study I and II), a statistical method developed especially for paired, ordered, categorical data was used (118, 119). The percentage agreement (PA) was calculated between the paired assessments, and the level of disagreement was explained with systematic disagreement for the group of observers and individual variability, when present. The method calculates systematic disagreement in the position of the assessment on the BPS between the two assessments, called Relative Position (RP) and Relative Concentration (RC), meaning the systematic disagreement in how the two assessments were concentrated on the scale. Possible values for RP and RC range from -1 to 1, where zero values indicate a lack of systematic disagreement of position and concentration, respectively. When used for inter-rater reliability, the two assessments of the observers were compared for disagreement with the hypothesis that there was a lack of disagreement between the assessments and therefore a high PA. For discriminant validity, the assessment between rest and procedure for the same observer was used with the hypothesis that for the procedure of turning there should be a higher disagreement between assessments than for the procedure of washing. Hence, a positive value on RP indicates that the observers have used a higher value for the assessments during the procedure than at rest. The Relative Rank Variance (RV) indicates if there is an individual variability among the observers that cannot be explained by the measures of systematic disagreement. RV above zero indicates the presence of such variability and an increase in RV is a sign of uncertainty in interpreting the descriptors in the domains. Statistically significant RP, RC, and RV values on at least a 5% level are indicated by 95% confidence interval (CI) not covering zero values. Analyses were calculated by means of a free program at https://avdic.se/svenssonsmetod.html.

To test for sensitivity, specificity, and accuracy (study II), the patient assessments in relation to the BPS and the NRS observer were dichotomized based on the cut-off scores, previously described, and calculated using the free software at http://vassarstats.net/. In this study, the sensitivity was defined as the ability for the BPS or NRS observer to correctly identify the individuals with pain, and specificity was defined as the ability to correctly identify the individuals without pain.

For analyzing the observers' assessments and variables possibly affecting them (study III), the Generalized Linear Mixed Model (GLMM) was chosen (SPSS ver. 26) (120). The GLMM was chosen since the data is generated from repeated

measurements/assessments (two observers for each patient) which could be correlated, not normally distributed, and since it consists of scales on different levels (nominal, ordinal, and interval). The GLMM was analyzed with binary logistic regression, Satterthwaite approximation for degrees of freedom, and robust estimation for fixed effects and coefficients. All variables were entered into the model as fixed effects. Due to the small sample size, the dependent variable, the NRS of the observer during turning, was dichotomized using the cut-off score: no pain (0-3) and pain (4-10). The independent behavioral variables of "facial expression", "upper limbs", and "breathing pattern" (BPS) were also dichotomized: no pain (first descriptor in the domain) and pain (second to fourth descriptor of the domain). The independent variables of age, heart rate, saturation, respiratory rate, blood pressure, and analgesic rate, were entered into the model as continuous variables. The rest of the independent variables of sex (0: male/1: female), RASS (light: 0 -1 and -2 / deep: -3 and -4), and diagnosis (0: surgical/1: medical), were dichotomous. The variables were initially tested in a basic model, with "facial expression", "upper limbs", and "breathing pattern". This was done since all observers were instructed at all assessments to perform an observation for these three domains; hence they could not be excluded from the model. Due to the small sample, each hypothesized variable was then added respectively to check for effects, always with the basic variables present. Two-sided tests were used with $P \leq 0.05$ to indicate statistical significance.

Experiences

To explore the patients' experiences of pain, an explorative, qualitative study (study IV) consisting of interviews was performed.

Participants and context

A total of 16 participants were included, through a purposeful sampling, between October 2015 and March 2017. Initially, 19 patients were asked about participation and consented. Three were excluded due to deteriorated conditions which prevented them from being interviewed, leaving a total of 16 participants. All participants included in the study were generated from study II, the context being the same as previously described.

A purposeful sampling was chosen in this study according to sex, age, and diagnosis, generating an equal distribution of participants: 8 women and 8 men aged

between 41 and 80 years (median=52). None had any prior ICU experience and LoS was between 1.5-22 days (median =4). Further characteristics are shown in Table 6.

Data collection

The participants were contacted, with the help of the ward nurse, within a week after discharge from the ICU, when they were considered sufficiently cognitively stable to be interviewed. If the participant's response was positive, the researcher then visited the participant, giving written and oral information about the study. If consent was obtained, an appointment was made for the interview, at a time chosen by the participant. All interviews were performed by the author (MH) in a secluded room in the ward and were recorded after permission. Interviews lasted between 9 and 61 minutes (mean=24.5, median=21.5).

It is recommended that memories are collected shortly after ICU discharge to avoid being compromised, but the possible presence of delirium, and temporary cognitive impairment, following the ICU care, should be considered (121). Therefore, the participant was assessed for delirium with the Confusion Assessment Method (CAM) – ICU (122) before the start of the interview, and if positive for delirium, a new appointment would be scheduled. However, none of the participants scored positive for delirium before the start of the interview.

A semi-structured interview guide was used, with open-ended questions asking the participants to tell the interviewer if they had had any experience of pain during their stay at the ICU. If experiences of pain were described, they were asked whether certain situations were remembered that caused pain and what they did when in pain. Probes and prompts were used to increase the richness and depth of the response (123, 124). Two pilot interviews were conducted to test the interview guide, which was perceived as being of good quality and no changes were made. Thus, both pilot interviews were included in the final analysis.

Data analysis

For the analysis of the interviews, the thematic analysis described by Braun and Clark (125) was chosen. Thematic analysis is used to identify and analyze patterns in data. As the area has previously not been described to any great extent, an inductive approach was applied (123, 125). The themes were identified at a latent level, trying to interpret beyond what is expressed by the participants and identify the underlying content in the data.

The described phases of thematic analysis were followed. These consist in first familiarizing yourself with the data, and generating initial codes which are sorted into different themes. The subsequent steps of the thematic analysis are: reviewing themes, considering the validity of individual themes in relation to the dataset, and then defining and naming themes, finding the essence in each theme (125). All interviews were verbally transcribed after completion by the author (MH). Initial coding was then done by two of the members of the research group independently, for confirmability, after which the codes were compared and perceived as equivalent. Subsequently, the codes were discussed and sorted into themes, which were elaborated into main themes and subthemes. These were further defined and refined to express the essence of each theme. All steps in the coding and defining of themes were discussed and approved by the group.

Ethical considerations

Researchers within the intensive care context need to be aware of the limitations of autonomy that exist due to illness, sedation, and communication impairments. Thus, intensive care patients are a vulnerable population and should therefore receive specifically considered protection, as stated in the Helsinki Declaration (126). The declaration further claims that research in these populations is only to be done if such research cannot be carried out in a non-vulnerable group. This statement could be resulting in an overprotection of vulnerable groups and should therefore be weighed and discussed against the beneficence of research done in these groups (127). In any case, the research should be conducted within the regular care done in the clinical context, aiming at minimizing procedures carried out for research purposes.

In the present studies (study I-III), the principle of nonmaleficence has been respected, as no additional interventions have been introduced for the patients for study purposes, and the risk for injury or discomfort has been minimal (128). The data collection was done during two common procedures: turning in bed (potentially painful) and washing the arm with a lukewarm cloth (non-painful). The studies are designed to fit with the normal care of the patients, and are therefore not intended to add any pain to the patients. The assessments were done by two observers (caregivers) separately during the procedures, and since they are used to observing the patients for pain normally, the instrument is just adding a structure to the observation which is registered for the study. In study IV, there was awareness of

how the interviews might prompt emotionally distressing memories for the patient. If needed, an appointment with a medical social worker could be arranged for further support. All data was coded for confidentiality before being analyzed and kept in secure, locked storage only available to the research group.

Beauchamp and Childress (127) introduced the "Three Condition Theory" for autonomy, consisting of intentionality, understanding, and non-control, all of which the theory sees as necessary parts of an autonomous action. Since the capacity of the intensive care patient is limited, none of the conditions above are fulfilled. The patient cannot be expected to make a decision of participation in a study during the intensive care. The Helsinki Declaration (126) then states that informed consent should be sought from legally authorized representatives, which is usually interpreted as family or next of kin. Having a critically ill family member is often a source of distress and could even be traumatic for the family, and then also being expected to make surrogate decisions regarding consent to studies is potentially overwhelming. Informed consent was therefore collected (study II-IV) after discharge from the intensive care. Patients or next of kin were informed both in writing and orally of the study and of which data was collected, with the opportunity to ask questions before written consent was collected. They were also reassured that all participation was voluntary, and that all data was treated confidentially. To eliminate any connection to the patients, the researcher did not work clinically with the patients in the ICU during the collection of data.

The access to a valid and reliable instrument for assessing pain is experienced as beneficial for the intensive care patients when they cannot perform a self-assessment. As we know that intensive care patients experience pain (14), a possibility to assess pain could be beneficial for the pain treatment. Beneficence can be discussed from two aspects, namely, the specific beneficence that is directed towards special relationships and the general beneficence that is directed beyond special relationships, to all persons (127). The specific beneficence in the present studies could apply to the relationship between the CCN and the patient. To be able to observe, assess, and understand the patients' pain, helps the CCN being able to reduce pain and support the patient in regaining control. Improving the quality of pain assessment within the ICU could be seen as general beneficence for all the patients.

The principal of justice is often seen as equal rights in access to healthcare, which is also expressed in the Swedish Health and Medical Services Act (129). Access to a valid pain instrument when not able to communicate could also be seen as a right for the intensive care patient and promotes equality for patients that cannot make a self-assessment.

Permission to conduct the studies II-IV was obtained by the Regional Ethical Review Board (Reg. no. 2014-105). For study I, no demographic data was collected, only the assessments done with the BPS before and during procedure. The assessments were done by CCNs who were used to observing the patient for behaviors indicating pain, and the instrument merely added a structure to the observations. Therefore, no consent from the patients was perceived as necessary. For confirmation, the study was assessed and approved by an ethical committee at Malmo University (HS60-11/998:3).

RESULTS

The results of this thesis are presented under the headings of Translation and development of the BPS, Patient characteristics, Assessments, and Experiences. The four studies comprising the thesis are referenced in brackets (I-IV).

Translation and development of the BPS

The process of translating and adapting the BPS (I) consisted in several results, leading to decisions within the different steps of the process described by the ISPOR group (108). During *Forward translation* and *Reconciliation,* the literal aspect was important for the research group. Both translations were largely consistent, facilitating the process, but each domain was reviewed and corrected separately. For example, the word "permanent" within the domain "upper limbs" was discussed, as well as the word describing the domain "vocalization." Synonyms and meaning in the target language were searched for before the group decided which words to use. Also, a discrepancy in translations within the domain "compliance with ventilation" for the descriptor of "tolerating movement" was discussed. The group agreed to use the translation aiming at respiration, as it was experienced as highlighting the concept of the domain. The two versions in the *Back translation* were similar and no effect of the preunderstanding of one of the translators could therefore be seen. The *Back translation review* showed that both versions were also consistent with the original version, and therefore no further changes were made.

In the *cognitive debriefing review*, the CCNs graded the descriptors of the domains correctly for all except the domain of "upper limbs" where there was uncertainty surrounding the grading. The uncertainty was identified as due to both the literality of the descriptors and the fact that the CCNs were unaccustomed to grading pain by

observing the limbs. Therefore, it was experienced as more difficult to visualize the descriptors in this domain. This resulted in small changes in the Swedish version aiming to clarify these specific descriptors. Three new CCNs were then asked to perform the grading test, which resulted in a correct grading within the domain. The finalized translation of the BPS into Swedish is seen in Table 4 (the original BPS in English is shown in Table 2).

Table 4. *Final translation of the Swedish Behavioral Pain Scale (result in study I)*

Område	Beskrivning	Poäng
Ansiktsuttryck	Avslappnat Delvis spänt (rynkad panna) Spänt (kniper ihop ögonen) Grimaserar	1 2 3 4
Armar	Helt stilla (avslappnade) Delvis böjda Helt böjda med böjda fingrar Permanent indragna mot kroppen (skyddande)	1 2 3 4
Intuberad: **Följsamhet med respirator**	Accepterar respiratorn Hostar men accepterar respiratorn mestadels av tiden Motarbetar/andas mot respiratorn Okontrollerbar andning i respiratorn	1 2 3 4
Inte intuberad: **Röstuttryck/ Vokalisering**	Inga ljud/ord som uttrycker smärta Jämrande, dock varken frekvent (<3 ggr/min) eller långvarigt (<3 sek) Jämrande, frekvent (>3 ggr/min) eller långvarigt (>3 sek) Skrik eller klagan, såsom “Aj! Oj!”, eller håller andan	1 2 3 4
	Total poäng (3-12)	

The developed domain of “breathing pattern” (Table 5) was tested (II), besides the originally translated version, in a pilot of 10 occasions. It was found valid and reliable after primary data analysis, and therefore included in the final analysis.

Table 5. *The developed domain of "breathing pattern" (andningsmönster) in Swedish (II)*

Intuberad: **Andningsmönster**	För patienten lugn/normal andning Ansträngd andning* som återgår till ursprungsläge Ansträngd andning* som kvarstår Mycket ansträngd andning* som inverkar på ventilationen av patienten i respiratorn	1 2 3 4
**Ansträngd andning definieras som debut eller progress av: hög andningsfrekvens, varierande andningsmönster med växlande hög och låg andningsfrekvens, inslag av andningspauser, ytlig andning.*		

Patient characteristics

In study II-IV, the patients were recruited from a mutual data collection, and patient demographics are shown in Table 6.

Table 6. *Patient demographics regarding study II-IV*

	Study II n= 57	**Study III n = 31**	**Study IV n = 16**
Age, Mean (SD)	67 (15)	65 (15)	64.5 (14)
SEX (%)			
Men	63	58	50
Women	37	42	50
DIAGNOSIS (%)			
Surgical (Incl. Trauma)	51	43	69
Medical	49	57	31
Intubated (%)	54	100	56
Non-intubated (%)	46	0	44
Received analgesics (%)	87	97	100

n= number, SD= standard deviation

In study II, the RASS was assessed for intubated patients as 0 in 11.7% of the turning procedures, -1 in 10%, -2 in 31.7%, - 3 in 36.7%, and -4 in 10%, indicating that patients were deeply sedated on 46.7% of the occasions.

Assessments

Inter-rater reliability

In both studies (I and II) that tested the Swedish BPS, the results indicated that the inter-rater reliability was above 76% for the percentage agreement between the assessments of the observers, which could be regarded as a high result.

The first test of inter-rater reliability (I) showed a percentage agreement of 85% for the total sum of the instrument, with RP and RC very close to 0 and the CI covering zero, indicating that no systematic disagreement on the 95% level could be demonstrated. Each domain was then further explored and did not show any statistically significant change either (see Table 7), indicating a high percentage agreement of 88-100% between observers.

Table 7. *Inter-rater reliability of the paired assessments (I) of the two observers before and during procedure is shown with 95% confidence intervals (CI)*

Domain	PA	RP	RC	RV
Facial expression (n=40)	88%	-0.02 (-0.12- +0.08)	-0.009 (-0.05-+0.03)	0.003 (0.0-0.009)
Upper limbs (n=40)	90%	-0.03 (-0.11-+0.05)	0.02 (-0.04-+0.09)	0.0006 (0.00-+0.002)
Compliance with ventilation (n=20)	95%	-0.05 (-0.14- +0.04)	0	0
Vocalization (n=20)	100%	0	0	0

n=number of paired assessments, PA=percentage agreement, RP=relative position, RC=relative concentration, and RV=relative rank variance

In study II, inter-rater reliability was again assessed with a high percentage agreement for the total sum of the instrument, both the original (intubated: 77%/non-intubated: 80%) and the developed (76%) versions. For all versions, the RP and RV were close to zero with CI covering 0, indicating that no significant systematic disagreement could be demonstrated. For each domain separately, PA, RP, and RV were analyzed, and the instrument showed stability for inter-rater reliability with no significant systematic disagreement being demonstrated (Table 8).

Table 8. *Inter-rater reliability of the paired assessments (II) of the two observers before and during both procedures is shown with 95% confidence intervals (CI)*

	Domain	PA	RP	RV
Intubated patients n=240	***Facial expression***	86%	-0.004 (-0.04- +0.03)	0.003 (0.00–0.007)
	Upper limbs	90%	0.05 (-0.01- +0.09)	0.0006 (0.0–0.002)
	Compliance with ventilation (original domain)	93%	0.004 (-0.03- +0.04)	0.0005 (0.00–0.001)
	Breathing pattern (developed domain)	88%	0.04 (-0.0002- +0.08)	0.003 (0.00–0.005)
Non-intubated patients n= 120	***Facial expression***	85%	-0.06 (-0.17- +0.04)	0.002 (0–0.006)
	Upper limbs	93%	0.008 (-0.06- +0.08)	0.0002 (0–0.0007)
	Vocalization	100%	0	0

n=paired assessments, PA=percentage agreement, RP=relative position, and RV=relative rank variance

Discriminant validity

Discriminant validity for the BPS in both studies (I and II) showed that the BPS discriminated for pain during painful procedures. However, when analyzing each domain separately it was shown that one of the domains ("compliance with ventilation") did not show any discrimination during turning (I). Therefore, the domain was developed into focusing on breathing pattern instead of the ventilator. The BPS was then tested once again (II) for comparison, and the developed domain showed improved discriminant validity compared to the original.

Discriminant validity for study I showed a PA of 28% for the total sum of the BPS, indicating that only 28% of the assessments at rest and after turning were identical. An RP of 0.64 (0.49-0.80) showed that there was a systematic disagreement with a change for higher values on the second assessment. An RV of 0.1 showed only a small presence of individual variability among the observers, which cannot be explained by the measures of systematic disagreement. For the domains (Table 9) there was a systematic disagreement for the assessments of the same observer on the scale between rest and turning for each respective domain except for the domain of "compliance with ventilation," which did not show any systematic disagreement, with a CI still covering zero.

Table 9. *Discriminant validity for each domain of the paired assessments (I) before and after repositioning, as assessed by the same observer, shown with 95% confidence intervals (CI)*

Domain	PA	RP	RC	RV
Facial expression (n=40)	63%	0.38 (0.23- 0.53)	-0.17 (-0.29- -0.05)	0.08 (0.00-0.18)
Upper limbs (n=40)	63%	0.38 (0.23-0.53)	-0.13 (-0.23- -0. 03)	0.007 (0.00-0.02)
Compliance with ventilation (n=20)	85%	0.15 (-0.03- +0.30)	0	0
Vocalization (n=20)	40%	0.6 (0.39-0.81)	0	0

n=number of paired assessments, PA=percentage agreement, RP=relative position, RC=relative concentration, and RV=relative rank variance

In study II, discriminant validity was shown, as the BPS for both intubated and non-intubated patients indicated pain during the turning procedure, something that was not seen for the washing procedure, as hypothesized (Table 10).

Table 10. *Percentage agreement (PA) and Relative position (RP) for the paired assessments for the same observers (II) for the total sum of the BPS, before and during turning/washing in intubated (developed version) and non-intubated patients, shown with 95% confidence interval (CI)*

	INTUBATED		NON-INTUBATED	
	Turning	**Washing**	**Turning**	**Washing**
PA	22%	90%	29%	90%
RP	0.65 (0.56–0.75)	0.03 (0.02-+0.07)	0.66 (0.32–0.99)	-0.06 (-0.15-+ 0.03)

The developed domain of "breathing pattern" (II) was tested alongside the domains of the original version ("facial expression", "upper limbs", and "compliance with ventilation"/" vocalization") and then all domains were compared respectively for discriminant validity (Table 11). All domains showed a significant systematic disagreement on the scale for the paired assessments, with a confidence interval not covering zero. There was a difference between the original domain "compliance with ventilation" and the developed domain "breathing pattern" with regard to PA, which was lower for "breathing pattern", and with regard to RP, which was higher, indicating a larger shift for higher values on the scale during the second assessment (pain). Still, both had CI not covering zero, showing a significant systematic disagreement.

Table 11. *Discriminant validity for the paired assessments of the same observer in each separate domain on the BPS (II), before and during turning procedure, shown with 95% confidence intervals (CI)*

	Domain	PA	RP	RV
Intubated patients	***Facial expression***	33%	0.57 (0.48–0.66)	0.09 (0.02–0.15)
n=120	***Upper limbs***	48%	0.47 (0.37–0.57)	0.05 (0.002–0.09)
	Compliance with ventilation (original domain)	71%	0.28 (0.19–0.36)	0.004 (0.00–0.01)
	Breathing pattern (developed domain)	47%	0.49 (0.39–0.58)	0.03 (0.00–0.07)
Non-intubated patients	***Facial expression***	30%	0.62 (0.38–0.86)	0.17 (0.00–0.43)
n=60	***Upper limbs***	30%	0.41 (0.11–0.71)	0.21 (0.00–0.51)
	Vocalization	70%	0.30 (0.10–0.50)	0

n=number of paired assessments, PA=percentage agreement, RP=relative position, and RV=relative rank variance

The result showed the further developed domain of "breathing pattern" having the same discriminant validity as the other domains and it was thereby perceived as more sensitive than the original domain of "compliance with ventilation." Therefore, it could be recommended that the original domain be replaced by the developed domain in the Swedish version of the BPS (Table 12).

Table 12. *Final version of the Swedish Behavioral Pain Scale (II)*

Område	Beskrivning	Poäng
Ansiktsuttryck	Avslappnat Delvis spänt (rynkad panna) Spänt (kniper ihop ögonen) Grimaserar	1 2 3 4
Armar	Helt stilla (avslappnade) Delvis böjda (spända) Helt böjda med böjda fingrar Permanent indragna mot kroppen (skyddande)	1 2 3 4
Intuberad: **Andningsmönster**	För patienten lugn/normal andning Ansträngd andning* som återgår till ursprungsläge Ansträngd andning* som kvarstår Mycket ansträngd andning* som inverkar på ventilationen av patienten i respiratorn	1 2 3 4
Inte intuberad: **Röstuttryck/ Vokalisering**	Inga ljud/ord som uttrycker smärta Jämrande, dock varken frekvent (<3 ggr/min) eller långvarigt (<3 sek) Jämrande, frekvent (>3 ggr/min) eller långvarigt (>3 sek) Skrik eller klagan, såsom "Aj! Oj!", eller håller andan	1 2 3 4
	Total poäng (3-12)	
**Ansträngd andning definieras som debut eller progress av: hög andningsfrekvens, varierande andningsmönster med växlande hög och låg andningsfrekvens, inslag av andningspauser, ytlig andning.*		

Criterion validity

Sensitivity and specificity were calculated for 50 of the 120 assessments of the patient was able to indicate experiencing pain or not by nodding or shaking their head (II). Of the 50 assessments, almost half (24) were paired with an assessment of the patient that reported experiencing pain.

Since the assessments of the patients were divided into pain – no pain, the NRS observer and the BPS were also dichotomized, using the cut-off scores previously described, before comparing them for criterion validity. The patients' own assessment was regarded as the gold standard.

Table 13. *Sensitivity, specificity, and accuracy for the BPS and the NRS observer (50 assessments) (dichotomized), in relation to the NRS of the patients, are shown with 95% confidence intervals (CI) (II)*

	Sensitivity	Specificity	Accuracy
BPS in relation to patients' assessment	0.88 (0.67–0.97)	0.58 (0.37–0.76)	0.72
NRS observer in relation to patients' assessment	0.54 (0.33–0.74)	0.80 (0.60–0.93)	0.68

BPS= Behavioral Pain Scale, NRS=Numeric Rating Scale

It was noticed that when pain was present according to the patients, the BPS had a higher sensitivity than the observers, showing that the BPS is closer to the gold standard for indicating pain. On the other hand, when patients assessed themselves as being pain free (specificity), the results were reversed, and the observers were more accurate in comparison to the patients' own assessments, indicating that the BPS is assessing pain in cases when the patients are not in pain.

Assessments of the observers

There was a discrepancy between the BPS and the assessments of the observers (II), showing that the observers were more precise in different situations when compared to the gold standard (pain – no pain according to the patients). This generated a research question of what else, besides the behavioral signs included in the BPS, could affect the observers' own subjective assessment (III).

In study III, during 60 turning procedures of intubated patients, 240 unique assessments were conducted: at rest and then during the procedure. One observation of NRS observer was missing for rest and turning, respectively. For analgesic treatment, a majority (52 procedures) were treated with infusion of oxycodone (mean 2.2 mg/hour), six were treated with remifentanil, and during two procedures

Table 14. *GLMM, all models starting with the basic model of facial expression, upper limbs and breathing pattern with added variable in each model, respectively (target: NRS observers) (n=119 assessments for all models except analgesic where n=117 assessments)*

MODEL	ADDED VARIABLE		FACIAL EXPRESSION		UPPER LIMBS		BREATHING PATTERN	
	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
0								
	–	–	1.91 (0.32–11.3)	0.371	2.98 (0.60–14.7)	0.130	3.98 (0.89–17.9)	0.063
1	***Age***							
	1.03 (0.99–1.06)	0.156	1.78 (0.52–6.12)	0.353	3.05 (1.02–9.15)	0.047	4.53 (1.44–14.2)	0.011
2	***Sex***							
	0.83 (0.30–2.32)	0.688	1.75 (0.37–8.19)	0.435	3.13 (0.86–11.4)	0.076	3.96 (1.16–13.5)	0.032
3	***Heart Rate***							
	0.97 (0.95–1.00)	0.041	1.88 (0.48–7.43)	0.360	2.98 (0.99–9.02)	0.052	3.65 (1.23–10.8)	0.020
4	***Saturation***							
	1.02 (0.87–1.19)	0.812	1.97 (0.53–7.25)	0.301	3.25 (0.98–10.8)	0.054	3.83 (1.27–11.6)	0.019
5	***Respiratory Rate***							
	1.02 (0.95–1.10)	0.586	1.98 (0.55–7.16)	0.291	3.04 (1.01–9.15)	0.048	3.77 (1.29–11.0)	0.016
6	***Systolic Blood Pressure***							
	1.01 (0.99–1.03)	0.317	1.94 (0.51–7.40)	0.326	3.17 (0.94–10.7)	0.062	3.97 (1.33–11.8)	0.014
7	***Mean Arterial Pressure***							
	1.01 (0.98–1.05)	0.416	1.93 (0.52–7.22)	0.323	3.00 (0.91–9.86)	0.070	3.98 (1.33–11.8)	0.014
8	***RASS Light/deep***							
	0.84 (0.29–2.48)	0.727	1.91 (0.45–8.14)	0.338	2.77 (0.70–10.9)	0.128	4.12 (1.14–15.0)	0.035
9	***Analgesic***							
	1.16 (0.92–1.45)	0.198	1.93 (0.52–7.18)	0.312	2.81 (0.87–9.13)	0.083	3.83 (1.26–11.6)	0.019
10	***Diagnosis***							
	0.5 (0.19–1.34)	0.148	1.89 (0.46–7.79)	0.341	2.82 (0.75–10.5)	0.110	4.75 (1.52–14.9)	0.012

the patients had no analgesics or sedatives due to awakening trial. The RASS was scored as 55% between 0- and -2 (awake or light sedation) and the rest had a score of -3 or -4 (deep sedation).

For the assessments at rest, the NRS observers indicated no pain for all except for four patients (3%), which was strengthened by the results of the BPS assessments showing a similar result (4%).

For the turning procedure, there was a difference between the NRS observer and the BPS. The observers assessed that the patients were in pain for 35% of the assessments (NRS observer) and the BPS indicated pain in 52% of the assessments.

The Generalized Linear Mix Model was performed for the pain assessments during turning. For the behavior variables ("facial expression", "upper limbs", and "breathing pattern") alone (model 0 in Table 14) showed no significant association for any of the variables with the NRS observer.

Among the hypothesized variables, no strong association was seen, except heart rate that had a reversed association. But for the behavioral domains, the association with the NRS observer was strengthened when variables were added to the model, both for upper limbs and, especially, for breathing pattern.

Experiences

The patients experienced pain within the intensive care, and the experience was described as containing different feelings, bodily as well as mental, the latter including feelings regarding social interactions (IV). This generated a need to be in control and based on this, two main themes were defined – a lack of control and a struggle for control, with subthemes for each respective theme (Figure 3).

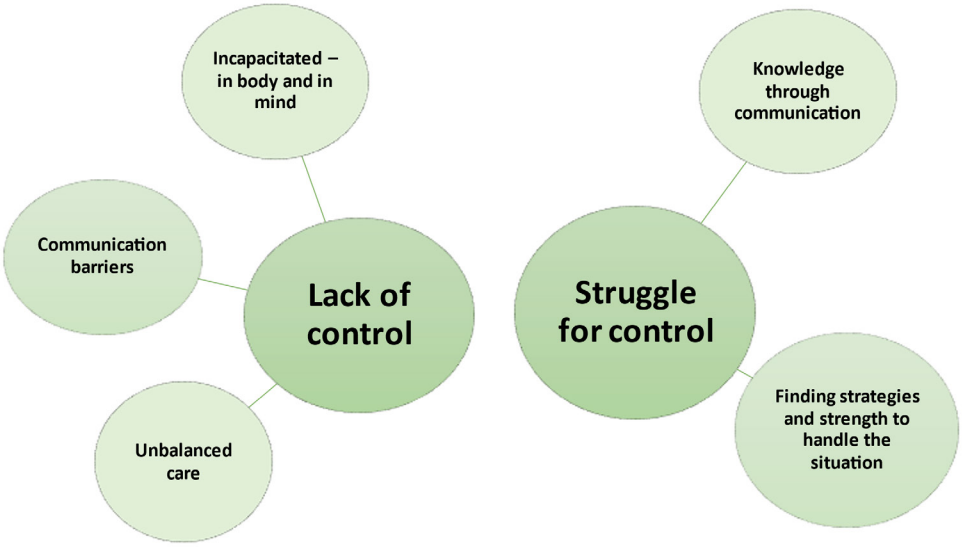

Figure 3. *Thematic map of the themes and subthemes (IV)*

Lack of control

Pain was a strong emotion that was experienced as taking over the participant's body and their world, making them unable to concentrate on anything else or to protect themselves. They needed support from the caregivers in dealing with the pain through being involved in their care, and this was facilitated by an adequate communication.

A lack of control was experienced when pain was taking over and influencing the participants, leaving them *incapacitated in body and mind.* The feelings they described were, for example, being in a fog when experiencing pain, or feelings of physical restlessness, not being able to relax or sleep. Hallucinations were also mentioned in relation to pain, but as a separate experience, as something that was disturbing but not possible to control, such as reliving the same situation over and over, or frightful situations. During procedures, pain resulted in bodily incapacitation when the participants could not do basic things themselves, such as turning over, and needed help with washing, for example. The participants knew that they needed the help and that it was for their own good, but as they also knew that it generated pain and a lack of control, it created feelings of panic and fear.

To help them with their pain, all participants received analgesics as pain relief. However, the participants described how, when *the care was unbalanced* in relation to their needs and they received dosages that were either too high or too low, the effect was the same, that is, a feeling of not being in control. Either they were affected by dosages that were too high, generating feelings of being in a fog, or the dosages were too low, allowing the pain to return. The experiences could be described as a pendulum swinging from side to side, on each side affecting the participants' ability to be in control. Balance was experienced in the middle.

Experience of pain was also related to *communication barriers*, when the participants could not communicate their pain in a way that made them feel heard, which made them experience a lack of control. A lot of energy was used in trying to make themselves understood when they were in pain, although intubation and medications interfered. Then the caregivers and their willingness to try to understand the participants played an important role. The NRS scale, and how to use it, was also considered a barrier, as a lack of prior knowledge of the scale made it almost impossible to relate to the different levels of the scale, thus hindering the pain from being assessed adequately.

Struggle for control

The constant struggle for control was experienced as a continuum. In some situations, the pendulum was in balance, that is, the care given was in balance with regard to the participants' needs and they experienced control, although this was considered a delicate state. Different approaches were therefore taken to struggle for control both physically and mentally, just as different approaches were used to overcome barriers to communication.

Knowing how pain feels, and how they had reacted to pain before, was one of the *strategies the participants found to handle their situation.* Learning their limits and knowing what would happen helped them to stay in control. Also, visualizing their progress in small steps and staying hopeful was helpful, in that it helped them to endure the pain today, knowing that it was less than yesterday.

With regard to pain treatment, a strategy was to struggle for control through balance, to be pain free not always being the goal but rather to have the least pain with as

much control as possible. They chose to swing the pendulum more or less on each side – choosing to have a little pain but not lose control, or else choosing to receive more pain relief but lose a bit more control. Pain dealt with in a fast and adequate way by the CCN made the participants experience a feeling of control over their pain. Patient-controlled analgesia (PCA) was also mentioned as helpful, as the participants did not have to depend on the attention of the CCN.

Being able to inform the caregivers of their pain was perceived as *knowledge through communication* and was dependent on a mutual willingness to communicate. Besides verbal communication, non-verbal communication, such as grimacing and clenching one's fists, was used to communicate pain. Presence, paying attention, and giving support were important factors for a good communication regarding pain. When the participants noticed that they could use the NRS adequately, and through that communicate their pain level, they felt much more in control, which was described as "speaking the same language."

METHODOLOGICAL CONSIDERATIONS

In this thesis, both quantitative and qualitative methods were applied in order to gain insight and knowledge in a field that is important for the care of intensive care patients. To assess pain is a challenge in intensive care, where the patients' self-report (the gold standard) is seldom available. Therefore, understanding and adding a structure to the process of assessment could be beneficial. Making an instrument for pain assessment available in a new language requires a thorough translation process and new psychometric testing in the target language (13), and it is important that it is done properly for the sake of the ability to assess pain as correctly as possible. Additionally, understanding the patients' experience of pain through interviews generated insights beyond the numbers of the assessments. In total, the methods of the studies complemented each other in shedding light on different areas of pain and pain assessment in intensive care.

Participants and sample

The participants were recruited from a convenience sample during almost 2.5 years (II-III), which is a long period of time and which could therefore have affected the sample and the result in different ways. There is always the possibility of changes in routines within the unit that could influence the care, and changes in how the team acts when providing the care could indirectly influence the study result. Nevertheless, no major changes in the pain/sedation strategies or routines were seen during the data collection for any of the studies (II-IV). Also, different areas might be of different importance to the team during different times; for example, after the implementation of a new routine a higher adherence is often seen (130). This could be the case also during a study, in that, initially, the protocol is followed, and the increased awareness influences the observers in how to assess and think during assessments. However, this increased awareness is at risk of decreasing during a

long data collection. To counteract such an effect, the unit was updated with information through seminars highlighting the subject of pain assessment and the importance of the study, during the data collection. Moreover, the researcher was present during all procedures to assist and to ensure the adherence to the data collection protocol without interference with the assessments. The presence of the researcher resulted in almost no missing data, which is strengthening for the studies (II and III).

The samples were generated from one site at a university hospital, whose general ICU is one of the largest in southern Sweden and has a wide range of diagnoses – medical, surgical, and trauma – of admitted patients of different ages. This was desirable since the instrument (the BPS) was originally developed to detect pain within an adult ICU population (62, 64) and should therefore be tested in a heterogeneous sample to ascertain a wide range across diagnoses. It is of importance for the sample to represent the intended population, in order to reduce the risk of sampling error (85, 124).

In previous studies, psychometrically testing instruments for pain assessments in the ICU, the sample size has varied considerably, from 30 to 105 patients included (62, 63, 65, 77, 78). Estimating the sample size when psychometrically testing instruments is something that has been discussed, as no consensus seems to exist (131, 132), which is a limitation for the studies (I, II). There is also an ethical aspect of keeping the sample as small as possible, and not putting patients at any risk of experiencing pain unnecessarily for study purposes. It has been expressed that the sample size in this kind of studies depends on the context and on what method of analyses are used (133). Studies are also seen using the subject/respondent to item ratio, when calculating sample size, although a large variation is reported. Anything between 2 and 30 respondents per item is considered acceptable (131-133). In the first study (I), the translation of the BPS was tested in a smaller sample to determine the inter-rater reliability and discriminant validity in the context of a Swedish ICU. The sample was estimated to be as small as possible but still large enough to generate at least 40 paired assessments, which was acceptable within the method of analysis. It generated evidence for a systematic disagreement in discriminant validity, and was thus a sufficient sample size for the purpose. In the data collection for studies II and III, a new domain was to be tested and compared to the original version, something which was estimated to demand a larger sample. The sample size was therefore set to a minimum of 75 to 90 occasions, generating a maximum of 360

paired assessments, which was estimated to be sufficient in performing psychometric analysis for study II.

It is also common in studies within the area of pain assessment in the ICU to include patients that are assessed many times, resulting in many assessments being from the same patient. For example, Young et al. (78) included patients to be assessed during two different occasions, Aïssaoui et al. (77) included each patient three times, and in the original article of the BPS by Payen et al. (62) each patient was assessed on one to eight different occasions. This is done since the condition of the ICU patient is described as rapidly changing and therefore each patient can be regarded as a new patient on each new occasion. Though this could be true for vital signs, it is limiting, since characteristics such as sex, age, and diagnosis are unchanged, restricting the variation of the sample. In order to avoid this limitation in the present studies, all patients were only included once in study I due to the smaller sample, and in the data collection for study II-III a limit of two occasions per patient, and never on the same day, was decided, to ensure that the data had a certain variation.

The specific experience of pain (IV) in intensive care is described as having two different dimensions, intensity and distress (10). Intensity is theoretically measured with the behavioral instruments (44), but distress has an emotional component, which is why the participants' own stories were needed as a complement to the assessments in order to gain knowledge about pain in the ICU. A purposeful sample of 16 participants was recruited from within the same sample as for study II and III, as they all had experience from the intensive care, and all had been assessed with the BPS. The sample size of qualitative research has been discussed and no consensus seems to exist regarding how many participants are needed. An inadequate sample size could threaten the generalizability of the studies, but it could be argued that the answer to the question of what is an adequate sample size lies within the chosen method (134, 135) and in the context (123). Braun and Clark (136) state that the sample size cannot be predicted, but is something the researcher revisits during the data collection process, and thematic analysis can be used in samples from 2 to 400 participants. The sample (IV) was perceived as generating a thick description of the participants' experience.

The observers that generated the assessments in study II and III were all from the intensive care team, although a majority were CCNs. It was important when psychometrically testing the BPS, that it was stable for the entire ICU team to use.

In previous studies, the BPS was only tested by CCNs exclusively (79), or with the addition of nurse assistants (77) or physicians (62), but never by the entire team. In study I, the researcher (a CCN) was one of the observers at all times and the other observer was one of the participants in the cognitive debriefing group. This approach has been used before by Chanques at al. (64), and although this was done to ensure familiarity with the BPS, problems were identified, as it could be seen that the researcher often scored higher than the other observer. Therefore, in study II it was decided that all observers should be from the team and the researcher was only present to collect vital signs during the assessments. Despite this, the majority of the observers were CCNs, which could indicate that this profession is naturally used for performing the pain assessments in the ICU.

Data collection

The data collection (I, II, III) was designed to integrate with the normal care of the patients as much as possible, not generating any additional pain for study purposes.

The procedures chosen because they were potentially painful and non-painful (II) were carefully considered. Turning was chosen since it has been shown in previous studies to be painful (14, 28, 60) and since it is used in other studies validating the BPS and other instruments for pain assessment in the ICU (78, 79). Not all studies have a design where non-painful procedures are included, but when they do a number of procedures are presented. Procedures used in various studies were: arterial catheter dressing change (64, 79), eye care (78), oral care (68), measuring non-invasive blood pressure (67), and washing with a lukewarm cloth (65). As it is known that pain always is a potential problem for the ICU patients, even at rest (14), many of the chosen procedures mentioned can be discussed. For example, eye care and oral care are procedures within areas that could be tender and irritated for the ICU patient, blisters and pressure wounds from the endotracheal tube in the mouth having been reported (137), and could therefore be painful. Also, when one of the domains of the tested instrument observes the facial area there is a risk that procedures in this area could interfere with the assessment. Consequently, the washing with lukewarm water on the arm was perceived as least painful and therefore chosen as the non-painful procedure by the research group.

When interviewing the participants (IV), there was awareness of the fragile state that they might be in, so close to the discharge from the ICU. Still, it was of importance,

and recommended, to capture their experience as close in time as was feasible (121). Taking their possible frailty into account, a semi-structured interview guide was chosen (138) when performing the interviews, and the questions were open ended and helped focus on the aim of the study in attempting to gain as much information as possible in the possibly limited amount of time available. There was also awareness of the potential to evoke unpleasant memories during the interviews. If needed, further emotional support in the shape of an appointment with a medical social worker could be arranged after the interview.

Translation and analyses

The method of translation chosen (108) was perceived as easy to follow and thorough, with the different steps explained in detail leaving the process traceable and giving it a solid structure. In the steps of forward and backward translation, the choice was made to use both professional translators and native-speaking translators that had knowledge about the context. The fact that the versions reconciled without any large discrepancies was found to strengthen the result. The cognitive debriefing, aiming to culturally adapt the instrument, added further preciseness to the translation regarding understandability. Also, including the grading of the different descriptors of the domains without visualizing the numbers, was a step added by the research group, confirming each descriptor's escalating pain level.

To psychometrically test an instrument, there are different statistical approaches. The classic test theory (CTT) is the most common and often used in studies. For pain-assessment instruments, it is recommended to test for internal consistency, inter-rater reliability, content validity, criterion validity, and discriminant validity (139). A problem arises when categorically ordered scales are handled and analyzed as data on the interval level, assuming that it is quantitative and normally distributed with an even interval between the different steps (descriptors). Even the non-parametric methods commonly used, such as the Spearman correlation coefficient, rank the assessments without taking into account that they often are paired assessments (85, 119). In the method developed by Svensson (118, 119), the ranks are tied to the pairs of data-augmented ranking. Such an approach makes it possible to analyze and identify a systematic disagreement for the group and also to separate it from the individual variability (I and II). This is helpful as it generates information about the performance of an instrument. For example, when testing for inter-rater

reliability, it is desirable that the percentage agreement is as high as possible (the assessments of the observers being as close as possible) and the RP close to zero. But if there is a systematic change for the group on the scale for higher or lower values, it could be a sign that the raters as a group interpret the scale descriptors differently and that the instrument as a whole needs to be revised. On the other hand, if the RV, calculating an observed individual variability, is above 0, it indicates a heterogeneity among participants, or the misinterpretation of a question. This could be remedied with further education and training in assessing with the instrument (140, 141).

When psychometrically testing or further developing an instrument, as was done with the BPS (I, II), it was regarded as important to be able to analyze each domain separately, which is possible with this method. Also, it was important to be able to evaluate how the instrument performed on a group as well as on an individual level. One limitation for the method of Svensson could be that it is not as widespread and used in studies as the CTT, something which influences the ability to compare the present studies to others psychometrically testing the BPS. In spite of this, the method of Svensson was chosen and seen as an appropriate method to perform a comprehensive test of the instrument, as is recommended before using it clinically.

When examining the pain assessments of the observers (III), and if something besides the behavioral domains of the BPS affected them, the data was analyzed with a Generalized Linear Mixed Model (GLMM), which takes into account that the measurements are repeated. The non-normal distribution of the variables could be a limitation which also had to be translated into dichotomous variables. For the BPS and NRS, previous cut-off values have been described and were therefore used (88, 114). For each of the domains of the BPS, no such cut-off was previously described. Therefore, it was decided, after reviewing the different descriptors of each domain, to dichotomize each domain into the descriptor of no-pain in one group and the rest of the descriptors indicating some sort of pain in the other. Thus, all variables describing pain would be separated in a similar way (no pain – pain).

For analyzing the quantitative data (IV), the thematic analysis (TA) was chosen, as it is described as a broad method with flexibility and can be used with a theoretical freedom (125). TA is used for identifying, analyzing, and reporting patterns (themes) within data and minimally organizing the dataset to be described in detail. As the intention was to search for the patients' experiences and produce an overview

generated from the dataset, without knowing what to find, this was regarded as a good choice of method. However, a limitation could be that the method is too broad, not providing the same depth as other methods could generate. Braun and Clarke (125) state that since the method is broad, certain decisions need to be made before starting the analysis. Four decisions are stated as important in how to describe the dataset, and they were taken into account. First, it was decided that the dataset should be described in relation to the aim and not in full, which would generate a more detailed and nuanced analysis regarding what was intended to be explored. Second, the inductive approach was chosen, as the aim was broad and some of the result might be lost when trying to fit it into a preexisting coding frame. Third, the latent level was chosen and not the semantic, with the intention to find the underlying meaning and ideas regarding the experience of pain. Last, the epistemology needed to be addressed, as the method could be conducted within both realist/essentialist and constructionist paradigms and it is not possible to code the data in an epistemological vacuum, as stated (125). As pain is defined as subjective (40), and as such is existing dependent on the personal experience, it should be regarded as something unique for each individual's experience and perspective. Patton (123) describes constructionist research as seeking to capture the diverse understandings and the multiple realities of people's experience of a situation, honoring the idea of multiple realities and aiming at finding the "truth" in the shared meaning and consensus among a group of people instead of some supposedly objective reality. This definition was used during the analysis to capture and formulate the thematic map.

All these decisions generated a structure and added a sense of rigor to the process (IV). Furthermore, the method was perceived as well described and accessible to follow, providing a 15-point checklist of criteria for a good thematic analysis (125, 142). Credibility is regarded as the "fit" between the participants' views and the researchers' representations of them (123). In line with this, the interviews were transcribed verbatim by the first author, who also noted initial ideas (125) in order to familiarize with the data and get a sense of the whole. Moreover, for credibility, the complete research group participated in the process of generating and reviewing themes to ensure that the result would not be based on only one person's interpretations. A limitation of the study (IV) could be that no external check was done during the process, such as asking the participants to review the result (143).

Dependability, that is, ensuring that the process is logical and traceable, was achieved through following the steps described for the method (125) and through documenting all steps and meetings for traceability. Although the method is easy to follow and well described in this stepwise approach, nuances and details could still be missed during the analysis in the attempt to describe an overview of the dataset. However, in order to try to prevent this, reflective notes were kept during the process (143) and the research group repeatedly discussed the results and the meaning of the themes.

For confirmability within the process, two separate analyses were performed when data was extracted, and initial codes were formed, which were then compared and discussed. Themes and subthemes were developed, both as an individual process and through discussions in the research group. In this method of analysis, nothing was mentioned about the preunderstanding and how to handle this. The first author is a CCN and, therefore, before analysis her preunderstanding was written down for visualization and used to add awareness during the analysis, and to assist openness.

For transferability, it should be noted that this is a sample generated from a single site and therefore generalizability should be done with caution. However, there was an attempt to include participants of different ages and diagnoses, and both men and women, with the intention to achieve variation in the sample. This could also be a limitation, as the differences in characteristics could influence how pain is experienced. The experience of pain described by the participants was similar, however, regardless of their characteristics.

DISCUSSION OF RESULTS

The four studies in this thesis resulted in a Swedish version of the BPS that was tested (I) and then further developed regarding one of the domains (II). The new version was then tested and perceived as having good psychometric properties (II), and it could therefore be recommended for clinical use. The pain-assessment process was examined and indicated that vital signs such as the patients' heart rate could affect the observers when assessing for pain (III). To complete the assessments of pain done by instruments, the patients' own experiences of pain in the ICU were sought (IV). The result tells a story of pain experienced as a lack of control, of feeling incapacitated, and of struggling to regain control by different strategies, such as gaining knowledge about their own reactions and about the context. Furthermore, the result indicates the importance of balance in the treatment and the need to successfully communicate and cooperate with the caregivers in order to achieve balance.

Assessments

Patients at rest or during non-painful procedures did not show any indicators of being in pain as assessed by the BPS (I, II, III), which is a positive result. Previous studies have indicated that patients in the ICU are in pain both at rest and during procedures (14), but this could not be seen in these studies.

To be able to psychometrically test all the domains within the instrument, the BPS was tested on both intubated and non-intubated patients (I and II), which was regarded as important in order to secure its usage in both groups. For inter-rater

reliability, the domain of "vocalization," which is exclusive for the non-intubated patients, showed a good result with a perfect percentage agreement (100%) (I and II), demonstrating that the observers agreed on every assessment. For discriminant validity, the assessments were clearly changing to a higher value during turning procedures in study I, with a low percentage agreement (40%) and the highest RP (0.6) of all the domains. However, in study II the domain of "vocalization" did not show the same reassuring result, since the assessments did not change as much during turning, which is confirmed by a higher percentage agreement (70%) and an RP of 0.3 (CI still covering zero, indicating a significant disagreement). This could be due to the difference in sample size, which is larger in study II, thereby influencing the result as the instrument is tested in a larger number of procedures. When inspecting the distribution of the assessments (II), none of the observers chose the third step in the domain, which could mean that this step needs to be revised; it may be that the limits of 3 times/minutes and 3 seconds are hard to estimate when assessing. The other recommended instrument, the CPOT, does not have these time limits specified within the domain but consists of three steps: no sound of pain, sighing/moaning, and crying out/sobbing. It would be interesting to compare the non-intubated domains of the BPS and the CPOT, especially in the Swedish translations, which is not feasible since the CPOT was only tested on two non-intubated patients and not analyzed on domain level (65).

To improve the BPS, since the domain of "compliance with ventilation" did not show any discriminant validity (I), the domain was developed to assess the patients' breathing pattern instead of the ventilator (II). The rationale for this was that, clinically, the breathing pattern was more accessible during procedures since this made the instrument focus on the patient instead of the ventilator. Also, there has been a development within the area of ventilation, with ventilators being more synchronized and with a higher compliance with the patients' own breathing. In the present study, this was perceived as producing a mismatch between the domain and clinical reality, resulting in very few high scores in this domain, which could be indicating an insensitivity for pain. Earlier, this was also noted in the study of Li et al. (144), where they did not notice any asynchrony between the patients and the ventilator during painful stimulation. The developed domain, "breathing pattern," is within the same area since it was concluded that breathing and pain interacted in a specific way (111, 112), but that could be seen more clearly when looking at the patients directly. It was important that the domain should concentrate on the quality of the breathing and not on breathing as a vital sign. Still, there should be awareness

of the fact that the patient's breathing can be influenced by other factors, such as pneumonia or high fever, which is why the domain should not solely determine if pain is present. Together, the three domains ("facial expression", "upper limbs" and "breathing pattern" / "vocalization") form the assessments, strengthening each other, although each is an important part of the entirety.

The new domain, including the descriptors, was presented to the ICU team before completion and testing (II). When the developed domain was tested (II) and compared to the original domain, both had significant disagreement between assessments at rest and during turning. But there was a difference when inspecting the RP, where the developed domain had a higher RP of 0.49 (CI 0.39–0.58), indicating that the assessment shifted more on the scale than the original domain (RP 0.28 and CI 0.19–0.36). To assess based on compliance with ventilator is not exclusive for the BPS; the other recommended instrument, the CPOT, has a similar domain based on whether the patients are tolerating or fighting the ventilator (63). In conclusion, as, in both recommended instruments, one of the domains was based on the same concept of compliance with the ventilator, which was perceived as in need of reviewing, this study (II) addressed and added a needed development, for the BPS in particular and for pain-assessment instruments in general. Still, a limitation is that the developed domain included in the instrument has only been tested within a Swedish context so far, and further studies are needed to estimate if it could be used in ICUs in other languages and in other cultural contexts.

The domain of "breathing pattern" was included as one of the behavioral signs (III) when variables affecting the pain assessments, besides the behavioral domains of the BPS, were examined. The result showed that "breathing pattern" was the domain that was associated the most, among the behavioral domains, with the observers' assessments. Although the result should be interpreted with caution, due to the small sample size, it was reassuring that the new domain seemed to be of importance to the observers' assessments.

An association was also seen between the observers' NRS assessments and heart rate (III), which raises the question of vital signs as a part of the pain assessment. This is in line with previous studies showing that vital signs are still important to CCNs when assessing for pain (89, 91). Vital signs are not recommended in the international guidelines (14); they are only to be used as cues to further assess pain with an instrument. The result (III) showed a reversed association for heart rate, that

is, a lower heart rate was associated with the NRS of the observers indicating pain. This is not logical, since often pain is connected to a high heart rate rather than a low heart rate during painful procedures (93, 94, 144). However, in the study of Chen and Chen (93) no correlation was seen between a high heart rate and the patient's self-report, which could question the validity for heart rate as pain assessor.

Furthermore, the association between low heart rate and pain assessed by the observers could be explained by the procedure, for example during turning the tracheal tube could move and cause a vasovagal reaction. Another explanation could be that, during the procedure, there was a large variation in heart rate, but since the vital signs were only collected at one point during the procedure and with the intention to collect the most extreme value, the variation was not visual in the collected data and therefore missed. To measure pain by heart rate variability is not a new phenomenon within pain assessment. There is, for example, the Analgesia Nociception Index (ANI), a method based on the ability to measure the autonomic nervous system activity and the balance between sympathetic and parasympathetic systems through heart rate variability in the electrocardiography (ECG) (145). The method has been studied in deeply sedated ICU patients and showed a significant decrease in score on the ANI during painful procedures, which was interpreted as validity for the method (146) although the ANI did not correlate with the BPS during painful procedures. This lack of correlation between the ANI and the BPS was also noted by Chanques et al. (147), and therefore the validity was questioned. However, in some situations the ANI could be useful, for example, during smaller stimulations, such as dressing change, and for negative predictive value (excluding pain) where the ANI could be used as a complement to the recommended behavioral instruments. As recommended, to use vital signs as cues could therefore be relevant in the overall procedure of pain assessment (14). Additional indicators for pain that have been evaluated are the bispectral index (BIS; computed from an electroencephalogram, EEG) and pupil dilatation reflexes (PDR; pupil size increase during painful procedures) (44). Although showing initial positive results, these methods are developed in the context of anesthesia and therefore need to be confirmed in larger studies for the intensive care use.

To assess pain in the ICU without the support of instruments seems to be a process of high complexity, which can be sensed in the result of study III. The NRS of the observers was not significantly associated with any of the behavioral signs when looking at them exclusively, but when the other variables were added to the basic

model, a stronger association could be seen to the observers' NRS for upper limbs and especially for breathing pattern. The assessment of pain without instruments has been described as complex, clinical reasoning encompassing behavioral signs, vital signs, previous knowledge about the patient, and knowledge about different procedures' potential painfulness (89, 91). Thus, it seems that the CCN takes into account not only knowledge but many different signs and cues which together form some sort of higher perception regarding the patients' pain. This clinical reasoning could be compared to Benner et al.'s concept of reasoning-in-transition (148), where a practical reasoning about the changes in a situation improves one's understanding and resolves contradiction. The expert CCN is always engaged in interpreting the present situation based on the changes in the patients' condition, something which is an ongoing clinical problem solving (148). This requires being close to the patients and learning how they react, when engaging with the patients, something which is seen as positive by the patients (IV) in enabling communication of pain and finding the balance in their pain treatment, and thus to reach control. However, not all CCNs are experts, as this demands experience and therefore takes time to develop. This could be sensed in that CCNs sometimes find it hard to distinguish pain from agitation and delirium, which results in a combination of medication being administered, seemingly on an improvisatory basis (92). There is thus a risk of sedating the patients before pain assessing them, and of the pain remaining untreated unknown to the CNNs, as a higher sedation level could conceal some of the pain behaviors. The instruments developed to assess the different states of pain, agitation, and delirium (14), are therefore crucial, helping the observer to discriminate between them and giving a structure to the assessment. Without instruments, the assessment is at risk of becoming subjective, different from time to time and person to person. Hence, it can be argued that a behavioral instrument for pain assessment, such as the BPS, always should form a base for the assessment of pain and guide the observer, allowing all to be experienced when observing.

The pain assessment with instruments was performed (II and III) by different members of the team. The usability of the BPS is important, as it should be simple for all caregivers to use and therefore easy to learn. However, besides the ICU team, family members that know the patient as a person on a much deeper level are often present. The benefit of family members as proxy observers has been reported as having a high correlation to the patients' own assessment and even, concerning pain, as having a higher agreement regarding both intensity and distress than the assessment of the CCNs (149). The family members show an understanding for

common pain behaviors, such as grimacing and body tension, but are confused in relation to the medications given, for example, mentioning that sedation would ease the pain (150). Although the family members did not feel confident in their ability to detect pain (150), the help from proxy observers could be worth exploring further in pain assessment as they generate a deeper understanding for the patients' common behaviors.

Experiences

Lack of control and Struggle for control were reported to be the two themes for the ICU patients (IV) when experiencing pain. To lack control was the overwhelming feeling that pain generated and that the participants could not defend themselves from. Believing in one's ability to control pain has been shown to affect functional status, as well as the feeling of meaning in life, for patients with chronic pain (151). Experimental research also indicates that controllability in acute pain, affects the feeling of suffering more than intensity and unpleasantness (152). Although this has yet to be further investigated to be clinically relevant, it is notable. The ICU patients' pain perception has been divided into intensity and distress (10, 52), where distress is defined as the affective response and therefore might include feelings of suffering. Many of the procedures that are commonly performed in the ICU, such as turning, respiratory exercises, and tracheal suctioning, have a higher risk of generating pain distress than intensity (10). These procedures are also mentioned by the participants (IV), as they, in their struggle for control, try to find different strategies to handle the situations where they experience pain, finding strength to cope with it. For example, with regard to positioning, it was mentioned that they endured the pain during the procedure as they knew it was good for them. To be unprepared was far worse than knowing what was planned, which helped them deal with the pain.

Apart from intensity and distress, pain was experienced as containing many different feelings, bodily and mental, not least in regard to social interactions (IV). This shows pain as a multidimensional and very complex concept in the ICU. Saunders' (48, 49) model of total pain could be helpful even in the intensive care, although it was originally generated for cancer patients in palliative care. The experiences told by the participants (IV) include the physical and psychological dimensions of being incapacitated by the overwhelming feeling of pain. The physical aspect was displayed by the restlessness and bodily movements mentioned and that the

participants could not always control. The psychological aspect has been described as the emotional component (48), including fear, which was expressed when the participants knew that they would have to face pain during procedures they knew were painful. The social component was very much present in the communication, or lack of it, between the participant and the caregiver, and it could be affected in a positive way by willingness to communicate, closeness, and proper usage of instruments for pain assessment. The spiritual component of pain was not as evident in the experiences recounted by the participants, but some of it could be seen in the hope for a better tomorrow which made them endure today, providing them with faith and belief in the future. Pain can thus, as mentioned above, be seen as multidimensional, also for the ICU patient, which has been noticed before when discussing that the patients' self-reports measure more than one dimension (44), whereas the behaviors only show the presence or absence of pain. This raises the question if the NRS is enough to generate a self-report of pain in the ICU, especially since it can be difficult to relate to if not informed about prior to use (IV).

Within the experience of pain, the state of unbalanced care was highlighted and described as receiving analgesics in dosages experienced to be either too high or too low, making the participants feel a lack of control (IV). The undertreatment and, as a result, the presence of pain, have been noticed previously (3, 4), but the perspective of overtreatment has not been reported before in this way. When receiving dosages experienced as too high the participants also reported a lack of control as when pain was present, affecting their consciousness and giving them side effects such as hallucinations, nausea, and sleep deprivation. The unbalanced care can be represented by a pendulum, swinging from side to side. On one side, pain is not eased, generating a feeling of not being in control and, on the other side, pain is overtreated, creating the same feelings of losing control. The middle represents a balance where the participants are pain free as desired, the dosage thus being adequate. To be completely pain free does not seem to be the main goal for the participants, but rather to reach a state with as little pain as possible without any side effect of the pain treatment. Patient-controlled analgesia (PCA) was mentioned as positive by the participants who had this treatment, which is in line with previous research showing it to be beneficial for patient satisfaction (153). It should be mentioned that the experience regarding the dosages of analgesics is the participants' own and that it therefore should be seen from an individual perspective, each person being unique in their need to achieve balance and control.

Person-centered care

PCC within ICUs has not been explored to any great extent, perhaps due to the difficulties of communicating with the patients and thereby of gaining an understanding of what is important to them as a person (154). When it comes to pain and pain assessment, the definition from IASP (40) states that the subjective experience is the gold standard and also that the inability to communicate pain does not negate the possibility to experience pain. Ethically, it can be seen as a human right to receive pain management (155), but this is dependent on an adequate pain assessment. When asked what was important to them, the patients answered "a pain under control" as one of the important elements when being cared for in the ICU (102), something which is confirmed in this thesis (IV), where all participants had experienced pain and being in control was regarded as a constant struggle regarding their pain experience. Therefore, the concept of pain assessment and management needs to be improved in the intensive care and there is also a need for it to be done with the patient in focus.

In the first phase (24), when the patients cannot communicate their pain in words, it is important that there are other ways for them to communicate it. The BPS was further developed to focus in all domains on the patients' behaviors instead of on the machines (II), thus being more person-centered. Pain behaviors matching the descriptors of the BPS, such as grimacing and clenching one's fist, were mentioned by the participants (IV), thereby justifying the presence of those descriptors in the instrument. We also know that CCNs generally are aware of behaviors as indicators for pain (156), but the BPS gives the assessments a structure, thus guiding the observer in what to look for. Merleau-Ponty describes the concept of palpation (105, 106) – an experienced questioning that can be done with the hands and the eyes. But when looking at a patient it is important to know what to look for, being structured, and not letting the eyes wander. As mentioned before, when discussing assessments from the perspective of Benner et al. (148), all CCNs cannot be experienced, as it is a process that takes time. However, experience enhances the ability to individualize, thereby resulting in a more person-centered care (157). The access to a pain-assessment instrument could therefore be regarded as forming a base in gaining knowledge about the ICU patient's needs for pain management. It is also a way of ensuring that the assessments are coherent, that the same language is spoken within the team, and that given treatments can be evaluated. Nevertheless, it is important to remember that instruments only constitute a guide, providing directions about how to interpret the patient and helping CCNs be experienced when observing.

In the second phase (24), the patient is more awake and can, thus, be more involved in decisions about their care. Learning what was planned helped them feel more in control and this was achieved by closeness and a willingness to communicate on the part of the caregiver (IV). The attention and closeness are also described by Karlsson et al. (158) as part of a caring communication, and a successful communication has been described by the caregivers as demanding but also rewarding (159) in maintaining the fragile relationship. But a gap can be seen between what the patient and the caregiver perceive as a successful communication (159), which illustrates that there are needs for improvement (8). Devices to improve the communication are developed continuously but still need to be implemented and strategies for this have to be embedded within the care (160). When having the knowledge and capability to make a self-report about their pain through instruments such as the NRS, the patients were empowered, as "speaking the same language" as the caregivers made them an active part of the team (IV). The partnership (98) has become more accessible but still requires a willingness from both sides to understand each other and reach the delicate balance of control that is much needed.

CONCLUSIONS

This thesis generated a translation and cultural adaptation of the Behavioral Pain Scale (BPS) into Swedish for intubated and non-intubated adult intensive care patients. The Swedish version of BPS was shown to be useful in the Swedish ICU and had good psychometric properties.

Further, the BPS was developed within one of the domains to be more focused on the patients' breathing ("breathing pattern") instead of the ventilator ("compliance with ventilation"). The new domain performed better for discriminant validity than the original domain, when psychometrically tested, and therefore it is recommended to replace the original domain with the new one, in the instrument. The BPS is to be used clinically, assessing the patients for pain, guiding the treatment, and then aiding with the evaluation of given treatment.

The BPS discriminated for pain even in a sample with a higher level of sedation, where most of the patients were sedated to RASS -2 and -3. Moreover, the BPS showed a high sensitivity (0.88) when compared to the patients' self-report of pain.

When examining the pain assessments of the observers (caregivers) statistically, it was seen that they did not base their assessments exclusively on behaviors and there was an indication that vital signs are still used for pain assessment. Therefore, to achieve equivalence in pain assessment within the ICU, there is a need to continuously discuss and train it within the team, for it to be performed in a structured way through valid instruments.

The overall experience of pain for the patients in the ICU was dependent on control: either a lack of control or a struggle for control. Pain was experienced as both

physical and psychological as well as related to social interaction. The experience of pain varied over time and in certain situations, but there was also a constant struggle for control. Control was dependent on many things; it could, however, be enhanced through finding strategies to handle the situations, for example, by the patients finding a balance between the care given and their needs. This called for a perceived good communication, including the presence of the caregiver and a willingness by the caregiver to meet the patient's needs on an individual level, thus helping the patient in gaining the fragile balance of control.

CLINICAL IMPLICATIONS

The results of this thesis give insights into how to recognize and meet the patients' pain in the ICU. Pain is a stressful and frightening situation for the patients and, thus, should be avoided.

Pain behaviors can be used as indicators for pain and are expressed by the patients as a means of communicating their pain, by, for instance, grimacing, clenching their fists, and using their body language in other ways. Pain was reported to make them physically restless, as the pain was experienced as taking over their body, indicating the power of pain on behaviors.

It is of importance to have a structure when assessing pain in the ICU and instruments based on behaviors are recommended. The translated and developed Swedish version of the Behavioral Pain Scale (BPS) was shown to be useful for assessing pain in the Swedish ICU setting, when the patients cannot give a self-report about their pain level.

The patients need the caregivers' presence, focus, and willingness to try to understand, when communicating their pain. It is important to find a balance in the pain treatment for the patients, and to be pain free is not always the goal. One vital aspect of the pain treatment is making sure that analgesics are administered in cooperation with the patients, in order to preserve their control over their situation.

Through repeated assessments, with the patient in focus, pain could be recognized, treated, and then evaluated. Using instruments can be a way of ensuring that the members of the team as well as the team and the patient speak the same language.

FUTURE RESEARCH

To confirm the reliability and validity of the Swedish version of the BPS, especially for the developed domain, further studies are needed, preferably in ICUs of different sizes and in different sites in Sweden.

Although there is, at the moment, strong evidence of behavioral signs, and the instrument based on them, being used for pain assessment, new trends within pain-related indicators, such as the bispectral index, pupil dilation reflex, and heart rate variation, should be explored. This is especially important in those rare cases when the patients have to be deeply sedated, thus showing no behaviors, and when the pain assessments therefore need to be complemented.

Moreover, the help from proxy reports is an aspect that could be further developed as a complement to the instruments. Assuming that instruments only show the intensity of the pain, family members have access to the patient's narrative and are therefore perhaps more able to understand and assess the distress experienced by the patient.

This thesis showed that there is a need to find a balance with regard to the treatment of the patients, whereas total pain relief is not always the goal. To reach this state demands a partnership and cooperation between the patient and the CCN. This thesis only explores the patients' experience of pain, but the nurses' perspective, including facilitators and barriers for reaching the necessary balance, could also add knowledge to be used when training in and discussing pain assessment.

It could also be worthwhile to explore more in depth what is influencing the intensive care patient stating that having control is more important than being pain free, and the delicate balance between control and pain.

POPULÄRVETENSKAPLIG SAMMANFATTNING

Patienter som blir inlagda på en intensivvårdsavdelning (IVA) är ofta så allvarligt sjuka att ett eller flera organsystem såsom hjärta, lungor eller njurar sviktar, vilket kräver en mer avancerad vård. De blir ofta intuberade och nersövda för att respiratorvårdas. Deras vitala parametrar övervakas kontinuerligt och sängen omgärdas därför av medicinskteknisk utrustning som ger ifrån sig ljus och ljud. Patienter har i efterhand beskrivit sin tid i intensivvård som en kamp för överlevnad och tidvis ett stort lidande. Trots att personal är konstant närvarande, berättar patienterna att de inte känt sig sedda och därför utlämnade, och deras minnen innehåller ofta obehag av törst, oro och i många fall smärta.

Smärta brukar definieras som en subjektiv upplevelse och är därför unik för varje person. På så sätt är patientens egen berättelse viktig när man mäter smärta. Inom vården används exempelvis smärtskalan Numerisk skala (NRS) där patienten själv bedömer och uppger sin smärtnivå från noll till tio (noll är ingen smärta och tio värsta tänkbara smärta). Studier har visat att patienter i intensivvård upplever smärta såväl i vila som vid vanliga omvårdnadsåtgärder som vändning, sugning i endotrakealtuben och dragning av drän. Dock är patienterna på IVA ofta nersövda och då blir förmågan att kommunicera verbalt kraftigt nedsatt. Patienterna blir då oförmögna att göra en smärtbedömning.

Istället har man sett att intensivvårdspatienterna uppvisar vissa utmärkande beteenden när de upplever smärta, både i vaket tillstånd och efter sövning. Detta har lett till att instrument som grundar sig på observationer av dessa beteenden har utvecklats för att bedöma smärta hos patienter med nedsatt kommunikationsförmåga. Ett sådant instrument är Behavioral Pain Scale (BPS) som

innebär att personalen observerar tre områden (domäner) hos vuxna intensivvårdspatienter: ansiktsmimiken, armarnas rörelser och hur patienten antingen följer respiratorn eller uttrycker smärta med rösten beroende på om patienten är intuberad eller inte. Inom varje område finns fyra smärtnivåer i stigande grad, från 1 till 4 poäng. Områdenas poäng räknas sedan samman till en totalsumma från 3 till 12. BPS är testat i ett flertal studier och används internationellt men har hittills inte varit översatt till svenska.

Det övergripande syftet med denna avhandling var att översätta, psykometriskt testa och utveckla BPS, för att användas till vuxna patienter inom svensk intensivvård, samt att analysera om andra variabler (förutom beteenden) påverkar smärtbedömningarna. Vidare avsågs att utforska patienternas erfarenheter av smärta när de vårdades på intensivvårdsavdelningen.

I den första delstudien översattes och anpassades BPS till svensk intensivvårdskontext. Instrumentet testades därefter på totalt 20 patienter (10 intuberade och 10 icke intuberade) vid vändning – en åtgärd som i hög grad riskerar att göra ont. Personal bedömde då med hjälp av BPS att patienten upplevde smärta. Instrumentet testades också med olika bedömare och resultaten visade på god överensstämmelse (reliabilitet) mellan bedömningarna.

När de olika domänerna undersöktes var för sig framkom det att domänen där följsamhet med respiratorn observeras inte gav ett lika tydligt utslag som de andra domänerna, vilket tyder på att det är mindre känsligt än de övriga för att detektera smärta. Därför ansågs det sakna validitet i denna studie.

I andra delstudien utvecklades istället en ny domän som observerar andningsmönstret på patienten istället för att observera respiratorn. BPS testades sedan för validitet och reliabilitet i både originalversionen (från första studien) och i den nya versionen där domänen ”följsamhet med respirator” ersatts med domänen ”andningsmönster” på 90 patienter (60 intuberade och 30 icke intuberade). Patienterna bedömdes med BPS både vid vändning och vid varsam tvättning med en mjuk tvättlapp på armen, varvid BPS gav utslag för smärta vid vändning men inte vid tvättning. Den nya domänen (”andningsmönster”) gav större utslag vid vändning än ”följsamhet med respirator” varför ”andningsmönster” rekommenderas att ersätta ”följsamhet med respirator” i den svenska versionen av BPS. Reliabiliteten var fortsatt god för instrumentet. Vid vissa vändningar var patienterna så vakna att de

kunde svara med nickning eller skakning på huvudet om de hade ont eller inte. I dessa fall jämfördes deras svar både med BPS och med sjuksköterskornas egen bedömning av patienternas smärta (utan stöd av instrument). Resultatet visade att patienternas upplevelse bäst överensstämde med BPS när smärta var närvarande, dock när patienterna inte upplevde smärta överensstämde detta bäst med sjuksköterskornas bedömning utan instrument.

I den tredje delstudien analyserades därför vad som påverkar sjuksköterskornas egna bedömningar av patienters smärta under bedömningssituationen i studie 2 för att se vad som var viktigt vid smärtbedömning utan instrument. Variabler som i tidigare studier visat sig påverka smärtbedömning såsom; ålder, kön, diagnos och vitala parametrar (puls, blodtryck, syresättning m.fl.) testades statistiskt i modeller tillsammans med beteendena i BPS (ansiktsuttryck, armar och andningsmönster). Endast puls visade sig ha ett signifikant samband med sjuksköterskornas egna bedömningar av alla variabler som testades. Bedömning av smärta via observationer är sammanfattningsvis en komplex process och det är därför viktigt att fortsätta ha en struktur som grund, vilket ett instrument såsom BPS tillför.

I den fjärde och sista delstudien intervjuades 16 patienter inom en vecka efter avslutad intensivvård, med fokus på deras erfarenheter av smärta under tiden på IVA. Intervjuerna analyserades kvalitativt och utmynnade i två övergripande teman; en kontrollförlust och en kamp för att återfå kontroll. Smärtan gav en kontrollförlust som både var fysisk och mental, samt visade sig i sociala sammanhang. Patienterna berättade att de upplevde smärtan som att vara i en dimma där smärtan tog över deras kroppar, utan möjlighet att värja sig. Att behandla smärtan på ett balanserat sätt var viktigt för dem, eftersom både för höga och för låga doser av smärtstillande gav upphov till kontrollförlust och obehag. Med stöd från vårdpersonalen hittade patienterna strategier i sin kamp att återfå kontrollen under deras tid på IVA. Bland annat genom visualisering av sina framsteg, att vara med och bestämma kring sin smärtbehandling och upplevelse av att kunna kommunicera sin smärta.

Avhandlingens sammanlagda resultat har utmynnat i att instrumentet Behavioral Pain Scale blivit översatt och anpassat för användning vid smärtbedömning på vuxna patienter på svenska intensivvårdsavdelningar. Under denna process har instrumentet utvecklats för att öka dess känslighet vid bedömning av smärta, testats i två studier samt funnits trovärdigt med överensstämmande resultat mellan bedömarna. Ett instrument tillför struktur vid smärtbedömningar vilket gör att

smärta kan både mätas och utvärderas på ett tillförlitligt sätt, något som är viktigt eftersom det ligger till grund för den behandling som ges. Patienterna erfar smärta som en kontrollförlust, både fysiskt, mentalt och socialt. Det är därför viktigt att personalen är närvarande och stöttar patienterna i att återfå kontrollen. Detta kan göras genom att vara villig att lyssna och vara närvarande samt genom att, om det går, göra patienten delaktig i sin smärtbehandling.

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APPENDICES

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