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Procedural and postoperative pain management in children

- experiences, assessments and possibilities to reduce pain, distress and anxiety

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"To Max and Nelly"
Abstract

Introduction

Children’s visits to hospital are often connected with painful examinations and treatments. If these situations are associated with unsuccessful alleviation of pain, the children may develop distress, anxiety and even pain sensitization. Effective pain management including pharmacological treatment and coping methods that support the children when undergoing examinations or treatments could reduce these harmful effects. Distraction methods such as serious games and music medicine are techniques to deviate attention away from procedural or postoperative pain, and these may help children create positive experiences. There is a need to examine these interventions among children in hospital.

Aim

The overall purpose of this thesis was to investigate procedural and postoperative pain management among children in hospital. The specific aims were

- to describe a group of children’s experiences of pain in conjunction with procedural pain
- to validate an observational behavioural scale for procedural pain assessment in children aged 5-16 years
- to study pain intensity and distress among children using serious games and music medicine
- to describe children’s experiences of the use of serious games and music medicine

Methods

Two hundred and twelve children who underwent a medical or surgical procedure at the Queen Silvia Children’s hospital in Gothenburg participated in one or two studies, and data were collected
with assessment scales, vital signs and interviews. All the data were analyzed using approved methods of analysis.

Results

The results showed that the children emphasized nurses who were clinically competent and that they wanted to participate in decision-making concerning distraction techniques as a complement to pharmacological treatment. An observational assessment scale, the Face, Legs, Activity, Cry and Consolability (FLACC) scale, was a valuable tool for assessing procedural pain and complementing retrospective self-reported pain and distress. Distraction techniques were helpful coping strategies for the children, who also needed to feel secure in the pain management. In children undergoing needle-related procedures, serious games reduced pain intensity, but only for those who liked the game, and the interviews showed increased wellbeing. Music medicine reduced morphine consumption and decreased the children’s distress when they underwent day surgery.

Conclusions

The conclusions of this thesis are that procedural pain can be evaluated using the FLACC scale, the children want to participate in decision-making on distraction techniques such as serious games or music medicine and these self-selected distraction techniques are also helpful coping strategies for the children.
Original papers

The thesis is based on the following papers, which are referred to by their Roman numerals in the text:

Paper I

Paper II

Paper III

Paper IV

The articles have been reprinted with the kind permission of the respective journals.
Contents

Abbreviations 8
1. Introduction 9
2. Background 12
  2.1. Pain 12
    2.1.1. Definition of pain 12
    2.1.2. Theory of gate control 13
    2.1.3. Neuromatrix theory 13
    2.1.4. Distress and anxiety in relation to pain 14
  2.2. Procedural and postoperative pain management 16
    2.2.1. Painful diagnostic and therapeutic procedures (medical
    procedures) 16
      2.2.1.1. Needle-related procedures 16
      2.2.1.2. Wound care sessions 17
    2.2.2. Surgical procedures (postoperative pain) 17
      2.2.2.1. Minor surgery 17
  2.3. Measures to assess pain, distress and anxiety 18
  2.4. Individual strategies to reduce pain, distress and anxiety 19
    2.4.1. Coping 19
  2.5. Interventions to reduce pain, distress and anxiety 20
    2.5.1. Pharmacological methods 20
    2.5.2. Coping strategies 21
      2.5.2.1. Cognitive and behavioural distraction 21
      2.5.2.1.1. Serious games 22
      2.5.2.1.2. Music medicine 23
  3. Aims 24
    3.1. Research questions 25
  4. Methods 25
    4.1. Design 25
    4.2. Participants 27
    4.3. Qualitative methods 28
      4.3.1. Data collection 28
      4.3.2. Data analysis 28
    4.3.3. Trustworthiness 29
    4.4. Quantitative methods 29
      4.4.1. Data collection 29
4.4.2. Instruments to measure pain intensity 30
4.4.3. Instruments to measure distress 32
4.4.4. Instruments to measure anxiety 33
4.4.5. Data analyses and statistics 34
4.4.6. Validity and reliability 35
4.5. Mixed-method design to evaluate serious games and music medicine 36
4.6. Ethical considerations 37
5. Results 38
5.1. Children’s experiences of pain in conjunction with procedures 38
5.2. Assessments of pain intensity when children undergo procedural pain 39
5.3. Reduction in pain intensity and distress when children use serious games or music medicine 40
5.4. Children’s experiences of the use of serious games and music medicine 41
6. Discussion 43
6.1. Discussion of the results 43
6.1.1. Assessment of pain and distress 46
6.1.2. Cognitive and behavioural distraction 47
6.1.3. Control 49
6.2. Methodological issues 50
6.3. Clinical implications 52
6.4. Conclusions 52
Summary in Swedish 53
Acknowledgements 55
References 57
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS</td>
<td>Coloured Analogue Scale</td>
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<tr>
<td>CI</td>
<td>Confidence interval</td>
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<tr>
<td>FAS</td>
<td>Facial Affective Scale</td>
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<td>FLACC</td>
<td>Face, Legs, Activity, Cry and Consolability</td>
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<td>IASP</td>
<td>International Association for the Study of Pain</td>
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<tr>
<td>ICF-CY</td>
<td>International Classification of Functioning, Disability and Health for Children and Youth</td>
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<tr>
<td>LP</td>
<td>Lumbar Puncture</td>
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<tr>
<td>r</td>
<td>Reliability coefficient</td>
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<tr>
<td>PACU</td>
<td>Post Anesthesia Care Unit</td>
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<tr>
<td>RR</td>
<td>Risk ratio</td>
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<td>SD</td>
<td>Standard deviation</td>
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<tr>
<td>STAI</td>
<td>State-Trait Anxiety Inventory</td>
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<tr>
<td>VR</td>
<td>Virtual Reality</td>
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<td>WHO</td>
<td>World Health Organization</td>
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1. Introduction

Many factors affect children’s experiences of procedural and postoperative pain. The parents’ knowledge of the procedure and their emotional support are important to the outcome in this context (1). The staff’s attitudes and care are also very important to the way children perceive the situation of procedural or postoperative pain (2). The Convention on the Rights of the Child recognizes ‘the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness’ (3). Procedural and postoperative pain management are important strategies to reach this goal.

The aim of this thesis was to investigate children’s experiences of medical and surgical procedures and to validate an observational behavioural scale for procedural pain in order to complement a self-reported pain scale and find coping strategies to reduce pain, distress and anxiety during procedural and postoperative pain.

This thesis is based on the children’s perspectives and their experiences and strategies to deal with procedural and postoperative pain. Many children endure an array of painful medical treatments starting at birth and continuing through adolescence. All children undergo a number of immunizations, and many children need to have a wound rescheduled after a trauma. Children with chronic or serious illnesses are also exposed to a number of investigations and treatments due to complications and their diagnoses (4). The children’s visits to the hospital are often associated with examinations and treatments, i.e., medical and surgical procedures. A trauma or disease is often the cause of these visits, and these conditions could themselves cause pain, distress or anxiety for the children. The children who visit the hospital for an examination or treatment often fear these procedures more than the trauma or disease itself however (5). Unlike the trauma or disease itself, the medical and surgical procedures that produce pain, distress and anxiety are related to the staff or health care system. The goal should be to reduce pain, distress and anxiety in these
situations, otherwise the children may develop a fear of health care (4, 6). Pain, distress and anxiety will develop if a medical or surgical procedure is associated with unsuccessful pain management (6, 7).

Satisfactory pain relief is necessary but not always feasible. For example, it is not possible to provide general anaesthesia for all minor procedures (8). There is a need for effective combinations of non-pharmacological and pharmacological interventions in conjunction with procedural and postoperative pain (9). Relaxation is a coping strategy that is always available to the children to deal with distress and anxiety. Relaxation is difficult to achieve in clinical settings when the children have already become distressed however (10). As a consequence, examinations and treatments become difficult to carry out. It is the health care personnel’s duty to help the children find and use coping strategies that facilitate the situation. Effective pain management could reduce the harmful and longstanding negative effects of medical and surgical procedures (6). Distress- and pain-reducing intervention has a longstanding beneficial effect on children by preventing the aggravation of the development of a pain memory (11).

The World Health Organization’s (WHO) International Classification of Functioning, Disability and Health for Children and Youth (ICF-CY) (12) works best when it is used to order complex information and bring benefits to situations such as pain in children (13). The classification may enable researchers and nurses to move beyond quantifying the character of pain, distress and anxiety, help them identify the functional consequences of these and assess and treat their functional impact in the broader context of the life of children. The ICF-CY framework has four components: 1) body functions, i.e., the physiological functions of body systems including psychological functions; 2) body structure, i.e., the anatomical parts of the body such as organs, limbs and their components; 3) activities and participation, i.e., the execution of a task or action by an individual and his or her involvement in a life situation; and 4) environmental factors, i.e., the physical, social and attitudinal environment in which people live and conduct their lives. It also considers personal factors that have not yet been classified. Personal factors involve the particular background of an individual’s life and living (14, 15). The components in ICF-CY
can help the nurse provide holistic pain management in the context of procedural and postoperative pain management.

The ability of young children to understand a process affects their ability to adapt to the available coping strategies. In contrast, older children have developed a capacity to understand the long-term consequences of examinations and treatments (16). Older children accept short-term pain more easily if they know it generates long-term benefits (17). Child development is not a linear process, however, as it is characterized by critical periods of vulnerability and sensitivity. Developmental milestones and crises in life cause temporary regression (16) that is important to take into account in the context of information and preparation (18).

The Piagetian theory suggests that children move through several stages of development and that their development can be divided into four different periods (19). The **Sensorimotor Period** characterizes the time from birth through approximately the second year. Children at this stage move from reflexive behaviours to habits. The **Preoperational Period** defines the ages of two through six years when children develop symbolic thinking, mental reasoning grows and the use of concepts increases. The **Concrete-Operation Period** follows from the age of seven through eleven years. This stage is characterized by the active and appropriate use of logical thinking. In the **Formal Operational Period**, children over eleven years develop the ability to think abstractly (16). The research in this thesis mainly takes into account the four periods of development that Piaget has demonstrated.

Further cultural factors, socioeconomic factors and the children’s earlier experiences influence the children’s appearance. For this reason there seems to be a wide variation of understanding and developmental considerations when health care staff meet the individual child (19).
2. Background

2.1. Pain

2.1.1. Definition of pain

The International Association for the Study of Pain (IASP) defines pain as a subjective experience that is completely individual. This definition takes into account both the sensory and affective dimensions of pain (20, 21). Pain may cause physical and emotional distress and anxiety in children experiencing medical or surgical procedures. Price (22) has presented an alternative definition of pain, however, that better explains how coping strategies can be useful in the multidimensional context of a painful experience: ‘Pain often occurs within a situation that is threatening, such as during physical trauma or disease. Part of the affective dimension of pain is the moment-by-moment unpleasantness, which consists of emotional feelings that pertain to the present or the short-term future, as annoyance, fear, or distress.’ (p. 393) (22) This definition describes how the physical part of pain can only explain a small part of the individual’s total pain perception.

The main reason for pain perception is the emotional thoughts that arise from the pain signals. The experience of pain from a nerve signal is processed in the brain. The brain determines if the child experiences an injury or sting/cannulation with a painful experience. In theory, the brain may choose to turn off the pain completely. In practice, children have often learned to avoid pain and all the signals that can be perceived as pain as a threat. The brain therefore often chooses to amplify the signal and give the child a feeling of discomfort (23). This is why research on coping strategies is so important for analgesia (6).
2.1.2. Theory of gate control

In 1965, Melzack and Wall presented the theory of gate control, which assumes that all pain transmission in the dorsal horn is centrally controlled. The theory of gate control includes the hypothesis of a gate that reacts to emotions or tactile stimulation. If an emotion-based coping strategy brings the children enjoyment, it inhibits the pain signals from reaching the brain. In other words, tactile stimulation and/or feelings open or close the gate, and a feeling of enjoyment closes the gate and inhibits the pain signals from reaching the brain. Conversely, a feeling of distress and anxiety opens the gate and lets the pain signals pass to the brain (24).

2.1.3. Neuromatrix theory

The neuromatrix theory of pain is a continuation of the gate control theory. Melzack presented a neuromatrix model (25) that better explains pain than the theory of gate control. The neuromatrix, which is distributed through many areas of the brain, comprises a widespread network of neurons that generates patterns, processes information that flows through it and ultimately produces the pattern that is felt as a whole body. The neuromatrix is also a psychologically meaningful unit developed from heredity and learning that represents an entire unified entity (25).

Pain perception and pain behaviour in conjunction with a medical or surgical procedure is dependent on genetically determined neural programmes and past experiences of similar procedures (26). Pain behaviour occurs mainly after the inputs have been analysed and synthesized sufficiently to produce a meaningful experience (25). The brain plasticity has adapted the pain perception and pain behaviour to past situations, but it will also continue to change pain expression during future procedures. Any factor that alters the function of pain transmission or pain modulation pathways in the neuromatrix will therefore influence pain perception and pain behaviour. The neuromatrix theory eliminates theories that describe pain as only being dependent on pain stimuli in nerves that generate a pain signal.
to the brain. Pain perception and pain behaviour is a complex model, like the immune system, which involves the whole body in the attempt to defend the person’s existence. This plastic system will also react differently from time to time (26).

The neuromatrix theory retains some key aspects of the gate control theory but gives a better description than the gate control theory of the subjectivity of the pain experience. The neuromatrix theory of pain recognizes the simultaneous convergence of many influences, including the children’s past experiences, cultural factors, emotional state, cognitive input, stress regulation and immune systems, as well as immediate sensory input. All these influences shape the neural plasticity in the brain and create a specific pain perception and action systems for the individual child. These action systems include involuntary and voluntary coping strategies used by the individual. According to this theory, prior medical and surgical procedures that were unmanageable will be the cause of pain, distress and anxiety during future procedures (27).

2.1.4. Distress and anxiety in relation to pain

Pain is a complex system of stimuli (i.e., sensory inputs), experiences (i.e., neural activities) and outputs (i.e., motor activities, affective expressions) (28). It is important for the nurses and researchers to investigate several dimensions of pain, i.e., pain intensity, distress and anxiety, to find valid pain management for each individual child. The degrees of pain intensity, distress and anxiety are often correlated to each other and sometimes difficult to separate in clinical trials and clinical practice. It is useful to separate these conditions from each other, however, whenever the staff needs to evaluate an intervention that helps children manage an examination or treatment. An example of this is an experience of pain caused by distress. In this case, treatment with analgesic drugs only has a marginal effect on pain perception. In other words, it is probably better to use other strategies. It is therefore important for a researcher to evaluate which dimensions of the pain experience a specific intervention may cause in many children.
Distress and anxiety are defined as subjective emotional responses and sensations of the mind associated with a real or experienced pain sensation. Children’s distress and anxiety are correlated with negative emotions that appear when a situation is impossible to manage. Distress and anxiety appear when children lose control and when staff threaten children’s integrity and self-control (29-31).

Distress is the response to stress that is harmful to children. Distress is the opposite of eustress, which defines mobilization and other positive responses to stress. Eustress is an important feature to manage an investigation or treatment. Distress makes it difficult to conduct an examination or treatment (32). When distress and anxiety are used in conjunction with procedures, they are also nearly always linked to some kind of painful event (29-31).

Berde and Wolfe (33) define anxiety as subjective senses of unease, dread or foreboding. Contrary to this, distress is described as a combination of pain and anxiety that are behaviourally indistinguishable. Distress means that a child reacts negatively to an investigation without knowing whether it is due to pain intensity or anxiety (33). It is also common in research to separate pain, distress and anxiety (31), or pain and anxiety (34) using different assessment tools.

Pain, distress and anxiety are the most likely causes of the development of a pain memory (35). Children who undergo repeated painful procedures develop a pain memory that makes it easier for them to recognize pain stimuli in the future. It is known that untreated and repeated painful childhood procedures lead to pain sensitization and more pain experiences in adulthood (26, 35). The goal of pain-reducing interventions in conjunction with a medical or surgical procedure is to raise wellbeing, functioning and the ability to cope with the examination or treatment in the context (6).
2.2. Procedural and postoperative pain management

Many children undergo examinations and treatments performed by medical staff. Investigations and treatments provided by health professionals during their care can be summarized by the concept of procedures. Most of these procedures involve some sort of painful experiences for the children. The reason for this may be the pain reaction to the nerve stimuli on the brain or the emotional feelings just before an examination, and treatment may give a negative perception of pain. All of these painful experiences can be summarized by the concept of procedural pain. Procedural pain care means that the child and nurse together decide how the process should be implemented. The nurse should take into account the children’s needs and alleviate the suffering of the children undergoing the procedure. The children should also feel safety and wellbeing in the situation (36). Two of the goals of pain management in paediatric nursing are to give individualized care and to involve the children in decision-making (37). Some of the most common procedures that give rise to pain, distress and anxiety in children are represented in this thesis.

The procedures in this thesis are divided into two categories: painful diagnostic and therapeutic (medical procedures), and surgical procedures (postoperative pain) according to Howard et al. (2008) (9).

2.2.1. Painful diagnostic and therapeutic procedures (medical procedures)

2.2.1.1. Needle-related procedures

Needle-related procedure is the term used for procedures that involve a needle, such as venepuncture or lumbar puncture (LP). The pain associated with examinations and treatments, such as needle-related procedures, is one of the most common physical concerns for children (4, 38, 39). The pain from these procedures has been reported to be a greater problem than the pain from the disease itself (5). The main
reason for needle fear is often the children’s previous experiences of needle-related procedures (40). The children who associate needle-related procedures with pain also develop anxiety and distress (7). If the children experience fear or anxiety, it is likely to be difficult to carry out the necessary examinations and treatments in the future (6). Despite the evidence-based beneficial effects of coping strategies to reduce needle-related pain (41), nurses continue to fail in their pain management in clinical practice (42).

2.2.1.2. Wound care sessions

Procedural pain in children undergoing wound care sessions is an intense and complex experience that frequently induces anxiety and distress based on physical and psychosocial reactions and previous experiences (43, 44). Children with burn injuries often describe the changes of dressings as the most painful experience of the treatment (45). The development of more effective methods of relieving pain associated with these care sessions is a major unmet need for health care staff. Not only is acute burn-injury pain a source of immense suffering, but it is also linked to longstanding pain and stress-related disorders. Although burn-injury pain was described as a major clinical problem over twenty years ago, researchers continue to report that burn pain remains undertreated (44).

2.2.2. Surgical procedures (postoperative pain)

2.2.2.1. Minor surgery

Eleven years ago, postoperative comfort was evaluated at the paediatric day surgery unit in Gothenburg, Sweden. Most of the children were pleased with the day care and a majority experienced adequate postoperative analgesia. Some patients experienced a high degree of pain, however, and the consumption of opioids was correlated with a high incidence of nausea and vomiting in the children (46). Published Swedish nationwide surveys also showed that
postoperative pain was a common complaint after discharge in both adults and children (47-49). Fear and anxiety appeared to be risk factors for permanent behavioural changes after surgical procedures in conjunction with the surgery (50). Pain is an important factor for behaviour changes in children (51). The children also reported, in conjunction with day surgery, that they tried to gain control and that they often experienced stress because of the equipment, which was described as unknown and frightening (52).

2.3. Measures to assess pain, distress and anxiety

The use of validated pain assessment tools is essential to improve pain management for children in clinical practice and research (53). It is a challenge to measure children’s pain, distress and anxiety. Children’s level of distress and their mental growth are two essential concerns when nurses try to attain valid self-reporting. Subjective annotations from parents and nurses are valuable complements but do not meet the need for standardization that would be useful in the evaluation of different interventions. Self-reporting of pain is considered the golden standard for older children. Behavioural observations can augment or replace the self-reports in situations in which the children are too distressed to use a self-reporting scale due to emotional or situational factors (54-56). For example, self-reporting is the most appropriate measure when evaluating methods of pain relief after the procedure. In these situations, an observational behavioural scale during the procedure augments self-reporting after the procedure (54). Self-reports are always carried out in a social context and many factors affect the child’s value of an instrument. It is therefore useful to combine observations and self-reports (57).

The staff’s assessment of children’s pain is also dependent on the children’s automatic or controlled response to the pain stimuli. An automatic response with a reflexive escape, facial grimaces and cry often gives the observer an involuntary but effective response on an emotional level. This expression generates a delayed reflection and active decision-making. A controlled pain expression from the
children with a deliberated self-report, however, generates a reflective and controlled response from the observer with no reflexive response on an emotional level (58).

It is often valuable to combine quantitative and qualitative methods when the researcher or nurse evaluates children’s experiences of pain, distress and anxiety. Quantitative and qualitative data strengthen each other in the result and conclusion. So far, most qualitative research is about the children but is not directed at them. Parent reports regarding the children have until now been a more common choice than the children’s own opinions. It is probably more valuable to obtain the children’s own views of the situation however (59).

2.4. Individual strategies to reduce pain, distress and anxiety

2.4.1. Coping

Children develop emotional self-regulation to handle the surrounding world at an early age. This self-regulation gradually develops further, leading to the use of different coping strategies. These coping strategies could be voluntary or involuntary, and unmanageable situations will often lead to involuntary and inappropriate coping strategies that worsen the situation. For example, a medical or surgical procedure could be interpreted as a threatening situation. If the children do not find effective coping strategies in these situations, they will develop and use emotional and catastrophe thinking. Emotional and catastrophe thinking often lead to increased pain perception and pain behaviour in children (60). Coping strategies that affect children’s behaviour and cognitive ability are probably a better choice as they reduce pain perception and pain behaviour in conjunction with a medical or surgical procedure. Health care staff should inform and prepare children, and their parents should be helped with information on how to use coping strategies that help the children cope with the situation, i.e., to use coping strategies that affect the children’s behaviour and cognitive ability (61).
Children’s abilities to use coping strategies differ and depend on factors such as age and social background. Coping strategies can be differentiated into two major types.

In a problem-focused coping strategy, children alter their environment so that the situation becomes manageable.

An emotional coping strategy implies instead that children change their attitudes and emotions so that the situation becomes manageable (62, 63). Medical and surgical procedures are typically conceptualized as uncontrollable and are therefore expected to be approached by emotion-focused coping, such as cognitive and behavioural distraction strategies (64).

2.5. Interventions to reduce pain, distress and anxiety

2.5.1. Pharmacological methods

Procedural and postoperative pain in children is often reduced by analgesic and sedative drugs. For example, pain intensity in conjunction with an injection is reduced with local anaesthesia such as EMLA®-cream (65) or a Rapydan® plaster (66). Children’s distress in conjunction with painful procedures is usually reduced with midazolam (67). Midazolam is sometimes insufficient in conjunction with procedural pain (68), and in surgery premedication, clonidine has been superior to midazolam in producing sedation (69). In sedation and analgesia for brief and therapeutic procedures, nitrous oxide and opioids have also been successful treatments in children (70). Paracetamol is a commonly used drug for pain relief, but ibuprofen is equal or more efficacious than paracetamol for the treatment of pain and it is equally safe (71). Diclofenac is another evidence-based, non-steroidal anti-inflammatory drug that is used to treat children suffering acute pain (72). Ketoprofen is another one (73). A combination of pharmacological methods and voluntary coping strategies is often
most successful for reducing procedural and postoperative pain in children (9). This thesis focuses mainly on individual coping strategies for children as a complement to pharmacological methods.

2.5.2. Coping strategies

Children undergoing medical or surgical procedures often find emotion-focused coping strategies helpful (74). Mind-body interventions including hypnosis, distraction and imagery may be effective, alone or as adjuncts to pharmacological interventions (75). The effects of distraction techniques have been described and confirmed at brain level using functional Magnetic Resonance Imaging (fMRI) in experimental situations. The participants were exposed to painful situations, such as cold water, and the distraction interventions proved to be pain relieving (76, 77).

Methods that engage children’s senses are commonly used in research but have been insufficiently evaluated. For example, it has not been declared whether a high level of enjoyment or engagement is necessary for children to optimize the effect of these methods (78). Theoretical hypotheses and clinical trials have been contradictory in this area (79, 80). In one study, for example, an unengaging video film was more distracting than a video game that demanded attention (81). Knowledge from clinical trials regarding interventions does not automatically lead to increased use in clinical practice however. The staff’s level of education and lack of time are confounding factors in many interventions (82).

2.5.2.1. Cognitive and behavioural distraction

*Cognitive distractions* are techniques that shift attention away from procedure-related pain or specific counter activities. Cognitive interventions include those that target mainly central mechanisms such as thoughts and feelings (83).

*Behavioural distractions* are mainly defined as interventions based on principles of behavioural science. The purpose of behavioural
distraction is to change children’s behaviour in a fearful situation. Behavioural interventions are psychological techniques based on the premise that specific, observable, maladaptive, badly adjusted behaviour can be modified by learning new, more appropriate behaviours to replace them (83).

Cognitive and behavioural distractions are both techniques that deviate attention away from procedural or postoperative pain to more enjoyable activities. Cognitive and behavioural distractions can be combined to create a cognitive-behavioural distraction. Serious games (see the definition below) can be defined as an example of cognitive-behavioural distraction. Music medicine (see the definition below), however, seems to be most associated with cognitive distraction (41).

2.5.2.1.1. Serious games

Serious games are designed for primary purposes other than pure entertainment (84). The definition of serious games usually refers to games used for training, advertising, simulation or education, designed to run on personal computers or video game consoles (85). Another context in which serious games could be used is that of children undergoing procedural pain. In this context, serious games are used to reduce pain and distress (80, 86). A serious game defines the purpose of the game, but it does not define the equipment that is used. There are several different types of equipment used for serious games.

The equipment has commonly been defined as non-immersive or immersive Virtual Reality (VR) in medical literature (80, 86). VR acts as a distracter, focusing the child’s attention away from negative stimuli to something pleasant and encouraging. VR is an interactive distracter that engages the child with visual and sound stimuli. The hypothesis is that VR helps children cope with a medical or surgical procedure, reducing pain, distress and anxiety. The idea behind VR is a simulated world that runs on a computer system. VR is a set of computer technologies that, when combined, provide interaction and engross the user’s senses. This sets it apart from other technologies such as television. The effect of VR is often based on the result of the
presence or immersion that appears (87). Immersion or presence can be measured as how strongly the attention of the user is focused on the task at hand. Immersion presence is believed to be the product of interactivity, image complexity, stereoscopic view, field of regard and the update rate of the display (88). Full immersion is achieved with a head-mounted display that blocks the user’s view of the real world and instead presents patients with a view of a computer-generated world. The helmet and headphones exclude sights and sound from the hospital environment (86). A computer screen, on the other hand, often displays non-immersive VR in which the user is connected to the virtual world but is still able to communicate with the hospital environment. The sense of presence can probably be increased in non-immersive VR, however, by using a 3D display (88, 89). It is also possible for interactive visualization without a 3D display to reduce anxiety sufficiently in the children (90). It has not been evaluated how or whether immersive or non-immersive VR should be a preferred choice to reduce pain, distress and anxiety in a child undergoing medical procedures (78). An experimental study found no differences between the helmet and the display (80).

2.5.2.1.2. Music medicine

A commonly accepted hypothesis is that music acts as a distracter focusing children’s attention away from negative stimuli to something pleasant and encouraging (91), i.e., a cognitive distraction (83). Various other hypotheses have been proposed to explain the mechanism by which music decreases pain, including modification of cognitive states, moods and emotions. Relaxation from music can also be demonstrated to lead to pleasant distraction, which serves as a mild sedative (92).

Listening to pre-recorded music has been defined as music medicine as opposed to active music therapy, in which a music therapist is involved (93).

In adults, music medicine has been shown to give relaxation during procedures and to reduce the level of pain intensity, stress and anxiety postoperatively (94-96). It has also been found to have sedative-
sparing effects and to reduce levels of stress hormones in blood samples (97, 98). A meta-analysis (93) and a systematic review (91) have also shown that it made no difference to the measured outcomes whether research-selected music or patient-selected music was used. In children, music medicine and active music therapy have mostly been studied during clinical procedures without anaesthesia, such as immunizations and dental procedures (99). Music medicine was shown to reduce pain intensity and anxiety during and after LP, and anxiety was also lower when children listened to music before LP (100). As there has been little effort to evaluate the effects and experiences of soft and relaxing music postoperatively in children (99, 101), there is a need to test music in postoperative care. There is a lack of evaluations of the postoperative effect of designed music made for relaxation (91, 97, 98). It has also not been evaluated whether children prefer relaxing or self-selected music postoperatively.

3. Aims

The overall purpose of this thesis was to investigate procedural and postoperative pain management among children in hospital. The specific aims were

- to describe a group of children’s experiences of pain in conjunction with procedural pain
- to validate an observational behavioural scale for procedural pain assessment in children aged 5-16 years
- to study pain intensity and distress among children using serious games and music medicine
- to describe children’s experiences of the use of serious games and music medicine
3.1. Research questions

- How do children experience pain in conjunction with procedures?
- How could pain intensity be assessed when children undergo procedural pain?
- Do pain intensity and distress decrease when children use serious games or music medicine?
- How do children experience the use of serious games and music medicine?

4. Methods

4.1. Design

In order to explore and find new knowledge in procedural and postoperative pain management, the researcher needs to be careful in his or her choice of study designs. The purpose in Paper I was to find knowledge about children’s experiences of wound dressings. This purpose was best answered with qualitative study design (102). The aim in Paper II was to evaluate a behavioural scale for procedural pain. This study needed a quantitative design to compare ordinal scales (103). Paper III and Paper IV in this thesis aimed to evaluate two different interventions to reduce pain, distress and anxiety. In these cases, a study design with a concurrent mixed method was required (104) (Table 1).
<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Procedure</th>
<th>Intervention</th>
<th>Design</th>
<th>Method</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Children’s experiences of procedural pain management in conjunction with trauma wound dressings</td>
<td>39 children aged 5-10 years</td>
<td>Trauma wound dressing</td>
<td>Descriptive qualitative design</td>
<td>Interviews Semi-structured</td>
<td>Qualitative data Qualitative content analysis</td>
</tr>
<tr>
<td>II</td>
<td>The FLACC(^1) behavioural scale for procedural pain assessment in children aged 5-16 years</td>
<td>80 children (29 children from paper III) aged 5-16 years</td>
<td>Peripheral venous cannulation or venous port puncture</td>
<td>Instrument testing</td>
<td>Self-reports CAS(^2) FAS(^3) Observations FLACC</td>
<td>Quantitative data Ordinal data Kappa Mann Whitney U Spearman corr. Wilcoxon signed ranks test</td>
</tr>
<tr>
<td>III</td>
<td>The use of Virtual Reality for needle-related procedural pain and distress in children and adolescents in a paediatric oncology unit</td>
<td>42 children aged 5-18 years</td>
<td>Peripheral venous cannulation or venous port puncture</td>
<td>Virtual Reality Mixed method</td>
<td>Interviews Semi-structured</td>
<td>Qualitative data Qualitative content analysis</td>
</tr>
<tr>
<td>IV</td>
<td>School-aged children’s experiences of postoperative music medicine on pain, distress and anxiety</td>
<td>80 children aged 7-16 years</td>
<td>Minor surgery Relax. music</td>
<td>Mixed method</td>
<td>Self-reports CAS FAS Short STAI(^4) Observations FLACC Morphine consumption Vital signs Heart rate Respiratory rate SaO(_2)</td>
<td>Quantitative data Ordinal data Mann Whitney U Wilcoxon signed ranks test Interval data t-test Nominal data Chi-square-test Ratio</td>
</tr>
</tbody>
</table>

1. Face, Legs, Activity, Cry and Consolability
2. Coloured Analogue Scale
3. Facial Affective Scale
4. State-Trait Anxiety Inventory
4.2. Participants

Two hundred and twelve children participated in one or two studies in this thesis. Thirty-nine children were consecutively included in Paper I, 80 children in Paper II (29 children from Paper III were also included in the analysis of Paper II), 42 children in Paper III, and 80 children were consecutively included in Paper IV. They were all recruited at the Queen Silvia Children’s Hospital in Gothenburg, Sweden.

In Paper I, the children’s wounds were acute because of minor traumas, such as bicycle accidents, burns, dog bites, fall accidents and pinch wounds. The children in this study suffered from wounds that were advanced and too serious to take care of in a primary care setting.

In Paper II, data were collected from 80 children, aged 5-16 years, who were recruited from the oncology and surgery units.

In Paper III, data were collected from 42 children, aged 5-18 years, with haematological or oncological diseases. Twenty-one participants were assigned to an intervention group and 21 children to a control group in a predetermined order. No children included in this study were in an acute crisis of their disease and all the participants had undergone the procedure at least once before.

In Paper IV, children aged 7-16 years were recruited from the day surgery unit. Children in this day surgery unit underwent arthroscopies, endoscopies, extractions of pins/nails/threads, hernias/hydroceles and superficial surgeries. Forty participants were randomized to the intervention group and another 40 participants to the control group.
4.3. Qualitative methods

4.3.1. Data collection

In Paper I, data were collected in conjunction with the children’s first visits to the specialized wound care nurse. The interviews were carried out immediately after the procedures were completed and the researcher used an interview guide with semi-structured questions. In Paper III, data were recorded on 21 participants who used VR when they underwent venepunctures or percutaneous punctures of subcutaneous venous port devices. The interviews were based on an interview guide and conducted immediately after the procedures were completed. In Paper IV, data were recorded from participants who were randomized to music medicine. Semi-structured qualitative interviews were conducted about one hour after the children left the postoperative care unit.

4.3.2. Data analysis

Content analysis is helpful in all qualitative data reduction for which the purpose is to find the core in the meaning of text (102, 105, 106). The qualitative content analysis in this thesis followed the theory description by Krippendorff (107). In addition, the abstraction from the text to the categories and themes followed the working model according to Graneheim and Lundman (108). The analysis in this thesis was inductive and discovered patterns, themes, and categories in the collected data (102). All the text in each of the studies was analyzed as one unit, and the text was chosen on the basis of the purpose of each study. The researcher then chose important meaning units from the chosen text, reduced these to condensed meaning units and created codes and categories. These categories answered the question ‘What?’ The analysis continued to find the underlying meaning, however, and developed it to a theme. These themes answered the question ‘How?’ (108)
4.3.3. Trustworthiness

All analyses need to be confirmed by trustworthiness (102). The concepts of credibility, dependability and transferability have been used to describe various aspects of trustworthiness (102, 108). Credibility evaluates how well data and processes of analysis address the intended focus. Dependability evaluates the degree to which data change over time. This involves an evaluation of how the researcher changes his or her interpretation during the analysis. Transferability evaluates whether findings can be transferred to other settings or groups (108). In Paper I and Paper IV, one researcher performed the first part of the analysis. A senior researcher then reviewed the analysis based on the selected text, categories and themes that emerged. The audit objective of this review was trustworthiness. In Paper III, two researchers conducted the first part of the analysis. A senior researcher then reviewed the analysis based on the requirements of trustworthiness.

4.4. Quantitative methods

4.4.1. Data collection

In Paper II and Paper III, self-reports and observations were collected before, during and after venepunctures or percutaneous punctures of subcutaneous venous port devices. In addition, the heart rate was measured before, during and after the procedures in Paper III. The data in Paper III were collected in a predetermined order. In Paper IV, self-reports were collected before the surgical procedure. Vital signs, self-reports and observations were measured postoperatively. Self-reports of pain, distress and anxiety were collected pre- and postoperatively on previously selected days depending on the schedule of surgery and the nurses on duty. Observations of pain intensity and qualitative interviews were also collected postoperatively. The day after surgery, all the children answered two questions by telephone:
‘What did you think of the postoperative care?’ and ‘How did you sleep the night after your visit to the paediatric day surgery unit?’ These two questions included an ordinal scale with four standardized answers, i.e. bad, not that good, good and very good. If the answer was bad or not that good, the researcher asked about the reason for the answer.

4.4.2. Instruments to measure pain intensity

Self-reports and observational scales are useful complements to each other in the complex situation of evaluating pain intensity in children (58). The Coloured Analogue Scale (CAS) (Figure 1) is a modified visual analogue scale that has been validated to measure the intensity of pain in children aged five and above. This scale is an ordinal scale (109) designed to provide gradations in colour, area and length to reflect different values of pain intensity. The children rate their pain intensity by moving a shuttle on a scale from zero (no pain) to ten (most pain) (110). The CAS has been employed to try to improve the reliability, validity and responsiveness of children using colour, area and length. This instrument has been shown to be a valid and reliable instrument in research (56).
The Face, Legs, Activity, Cry and Consolability (FLACC) scale (Table 2) is an observational scale used for pain assessment in children up to 18 years (55). The FLACC scale is an ordinal scale (109) that contains five categories, each of which is scored from zero to two to provide a total score ranging from zero to ten. The FLACC has been found to be of good interrater reliability and validity for evaluating pain after surgery, trauma, malignancy and other disease processes in infants and children up to seven years of age (111-113). An original and a revised form of the FLACC scale have previously been used in children with cognitive impairment after surgery (114). There has been little effort to validate the FLACC scale for the assessment of procedural pain (53). Despite the lack of validation, it has been used for pain assessment in various studies during procedural pain in younger (115) and older children (116). Further validation is needed for its use in procedural pain (53). Although review articles have recommended the use of the FLACC in the context of procedural pain (117), there are no studies in the literature demonstrating its validity and reliability in these contexts in children over seven years.
Table 2. FLACC (Face, Legs, Activity, Cry and Consolability)

<table>
<thead>
<tr>
<th>Categories</th>
<th>Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Face</td>
<td>No particular expression or smile</td>
</tr>
<tr>
<td>Legs</td>
<td>Normal position or relaxed</td>
</tr>
<tr>
<td>Activity</td>
<td>Lying quietly, normal position, moves easily</td>
</tr>
<tr>
<td>Cry</td>
<td>No crying (awake or asleep)</td>
</tr>
<tr>
<td>Consolability</td>
<td>Content, relaxed</td>
</tr>
</tbody>
</table>

Each of the five categories: (F) Face, (L) Legs, (A) Activity, (C) Cry and (C) Consolability, is scored from 0-2, resulting in a total score between zero and ten.

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4.4.3. Instruments to measure distress

There are different assessment tools to assess distress in children. It has been suggested that a visual analogue scale can be used for self-reports or proxy assessments of distress (118). A meta-analysis indicated that the child’s self-report of pain did not correlate strongly with the assessment of the child’s pain by the parent or the nurse
however. The perception by parents and nurses of a child’s pain and probably also distress should only be considered as an estimate of the pain or distress experienced by the child as it is not the child’s self-report (119). For this reason, these instruments should be limited to existing self-report scales that are validated for distress, as the self-report is the golden standard for children above five (120). The Facial Affective Scale (FAS) (Figure 2) is an ordinal scale (109) and one of the most valid and reliable self-report scales in this area (121-123). The FAS has also been recommended in a published review (117). On the FAS, children mark one of nine faces presented in an ordered sequence from least to most distressed on a scale of 0.04 (no distress) to 0.97 (most distress) (110).

![Figure 2. Facial Affective Scale (FAS). Printed with permission.](image)

**4.4.4. Instruments to measure anxiety**

Self-reports are the golden standard in the assessment of anxiety (120). There is a lack of valid self-report instruments that assess anxiety in conjunction with procedural pain in children however. A questionnaire that is widely used to measure anxiety in children is the State-Trait Anxiety Inventory for Children (STAIC) (124). The state form contains 20 questions for children about the way they feel at the time. There have been problems with the STAIC. In particular, children have felt that the questionnaire is too long and sometimes difficult to understand (125). Short instruments that are easy to fill in are preferred. The short STAI is easy to use and may be preferred to the STAIC (126). Items on scales should be as short as possible, though not so short that comprehensibility is lost (127). In one study,
all the children who completed the short STAI thought that the instrument was easy to fill in (128). In the end, the range for the short STAI form (Table 3) will be 6-24 points; 6 points signifies no anxiety and 24 points signifies the highest level of anxiety (126). The short STAI form is shorter than the originally STAI, which has been widely used to evaluate anxiety in studies of music in conjunction with anaesthesia (91). The short form of the STAI has previously been used to evaluate children aged 7-12 years (100).

Table 3. Short STAI (State-Trait Anxiety Inventory)

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Somewhat</th>
<th>Moderately</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel calm</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. I am tense</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. I feel upset</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. I am relaxed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. I feel content</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. I am worried</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

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4.4.5. Data analyses and statistics

Pain and distress were rated using two self-report scales (CAS, FAS) in Paper II and Paper III. In Paper IV, a third self-report scale (the short STAI) was also used to assess anxiety. One behavioural scale (FLACC) was also used in Papers II-IV to evaluate the children’s behaviour. Ordinal data should be used when a researcher chooses self-reports or observations to evaluate different behaviours, such as emotions and feelings. All ordinal data demand non-parametric statistics unlike interval data (109, 129). In this thesis, non-parametric tests were used to calculate data from all the self-report scales (CAS, FAS, short STAI) and the behavioural scale (FLACC) in Papers II-IV.
Papers III-IV calculated vital signs and Paper IV morphine consumption as interval data to find out the effects of serious games or music medicine.

In Paper IV, morphine consumption was calculated as a risk ratio (RR) (103), and the number of children who received morphine were calculated as nominal data with a chi-square test (103). This statistical method was also used to analyze the standardized questions about the children’s sleep quality and wellbeing.

Papers II-IV in this thesis were based on a power analysis of each study. Earlier studies in the evaluated areas formed the basis of these calculations. A power analysis is based on interval data and parametric statistics however (103). In this thesis, pain scores have been the primary outcome of each study and, as described above, the pain scores in this thesis were calculated with non-parametric statistics. For this reason, these power analyses were only guides to estimate the size of the study populations.

4.4.6. Validity and reliability

The concurrent validity and interrater reliability of the FLACC for children aged 5-16 years undergoing procedural pain were established in Paper II. The validity and reliability of the CAS and the FAS in children aged 5-18 years have also been established in other studies (110, 122, 130). The validity and reliability of the short STAI is limited in children. A study on procedural pain used the short STAI in children aged 7-12 years however. The children reported a significant decrease between the short STAI scores before and after a painful procedure (100). In a pilot study, 20 children aged 6-15.5 years filled in the short STAI and the STAIC-S before and after they underwent procedural pain. Spearman’s correlation test showed 0.88 before and 0.75 afterwards. Cronbach’s $\alpha$ coefficient was 0.83 before and 0.62 afterwards. There was a significant difference ($p=0.003$) before and after the procedure with the Wilcoxon signed ranks test (128).
4.5. Mixed-method design to evaluate serious games and music medicine

A mixed-method design is based on the premise that no single method ever adequately solves the problem of a research area. The mixed-method design combines qualitative and quantitative data. Different types of methods generate different types of results that vary in their susceptibility to capture the various nuances of reality. Multiple methods strengthen the possibility of providing a cross-data validity check (102). In mixed-method research, the two primary designs are concurrent and sequential. When data are collected concurrently, qualitative and quantitative data are independent of each other. In sequentially collected data, the two forms of data are related or connected (104). The purpose of sequential design is to learn from past data and to go ahead with new data collection, i.e., the data from one method is used to build on in the other. An example of this is when qualitative data collection leads to another quantitative data collection. In contrast, the purpose of concurrent design is to use different methods, i.e., quantitative and qualitative data, in the same data collection. Both methods in this data collection may be of equal importance in answering the research question. The researcher can choose different options of study designs in mixed methods however. The qualitative and quantitative methods can have equal values, but the researcher also has the possibility of prioritizing one. In case, one method is the primary method and the other becomes the secondary method the latter challenges the other method’s results (131).

Qualitative and quantitative data were collected at the same time in Paper III and Paper IV. These studies used a concurrent mixed method to answer their purposes. Paper III in this thesis uses a concurrent mixed method in which the qualitative method is the primary method. The qualitative results in this study were confirmed by quantitative data. Paper IV in this thesis uses a concurrent mixed method in which the quantitative method is the primary method. The quantitative results in this study were confirmed by qualitative themes.
4.6. Ethical considerations

In this thesis, the Regional Medical Ethics Review Board of Gothenburg, Sweden, has approved Paper I (ref. no: 359-07), Paper II (ref. no: 480-05), Paper III (ref. no: 142-07) and Paper IV (ref. no: 207-07). This means that the four ethical principles: autonomy or respect for others, beneficence, non-maleficence and justice, were considered (132).

Children are viewed as a vulnerable group in relation to research participation (133). Children are also vulnerable due to their reliance on adults for protection. The acquisition of parental permission and assent from the child requires careful navigation. There are also several legal and ethical considerations that are unique to children (134). Information about the research should be adapted to the children’s cognitive level. Young children are generally able to demonstrate a basic understanding of the purpose of research (135). The participants were exposed to serious games in Paper I and Paper III. In Paper IV, they were exposed to music medicine when they visited a clinical setting. These interventions were not used routinely in these clinical settings, though earlier studies have shown beneficial effects when serious games or music medicine were used. For this reason, the risk was minimal of adding these two interventions to the daily care. No other changes were made to the standard care, and all the children were given the usual care when they participated in the studies. All the interventions used in this thesis were also estimated to increase the children’s wellbeing. The purpose was also to implement these interventions in clinical practice.

In this thesis, all the participants were given verbal information about each study. All the parents and children who could read were also given written information. Verbal informed consent was obtained from all the participants and written consent was collected from all the parents and from children over 12 years.

In this thesis, Paper I and Paper III offered a visit to the cinema as a reward to all the participants.
A research project involving children should include research questions that cannot be answered by studying adults. The researcher should also find ways to communicate the research findings to the participants and to implement the results of the studies in clinical practice (134). No earlier study has answered the research questions in this thesis and it is impossible to obtain usable knowledge from adults. All the results in this thesis have also been implemented and reported in the clinical settings in which the studies were conducted.

5. Results

5.1. Children’s experiences of pain in conjunction with procedures

Paper I evaluated the children’s experiences of pain in conjunction with procedures. Four themes emerged from the texts that were transcribed from the interviews. The themes were clinical competence, distraction, participation and security.

The theme clinical competence emerged out of the texts that stated that the nurses’ professional performance is essential in the pain management of trauma wound dressing. The children felt comfortable when they could trust the nurse’s activities. The nurse’s clinical competence in the wound dressing session made the children feel safe in the situation.

The distraction theme showed that distraction techniques helped the children undergo trauma wound dressing. The children also felt calmness and security when they used familiar distraction techniques, such as a lollipops or serious games.

The theme participation meant that the children’s own desire to take decisions varied according to the situation. When the children felt a sense of control in the pain management, they were also prepared to participate in the decision-making. In contrast, the children turned
down decision-making in activities in which they did not feel a sense of control.

Finally, in the security theme, the children’s experiences of adequate pain management were based on their feelings of security. This feeling of security was obvious despite the fact that the approaching trauma wound dressing was sometimes associated with procedural pain.

5.2. Assessments of pain intensity when children undergo procedural pain

The FLACC behavioural scale was validated to measure pain intensity in conjunction with procedural pain, i.e., peripheral venous cannulation or venous port puncture, in children aged 5-16 years. Paper II showed that concurrent validity was supported by the correlation between the FLACC scores observed by the two researchers and the children’s self-reported ratings on the CAS during the procedure ($r = 0.59$, $p < 0.05$). A weaker correlation was found between the FLACC scores and the children’s self-reported FAS scores ($r = 0.35$, $p < 0.05$). Construct validity was demonstrated by the increase in the median FLACC score to one during the procedure compared with zero before and after the procedure ($p < 0.001$). Interrater reliability during the procedure was supported by adequate kappa statistics for all the items and the total FLACC scores ($\kappa 0.85$, $p < 0.001$). There was also a high correlation with the kappa statistics for each item in the FLACC. The result showed that the ratings by younger children were more similar between the CAS and the FAS compared with older children.
5.3. Reduction of pain intensity and distress when children use serious games or music medicine

Paper III evaluated the effects of serious games and Paper IV the effects of music medicine. Paper III evaluated the use of VR for needle-related procedural pain and distress in children and adolescents in a paediatric oncology unit. The results showed no significant differences in the FLACC, CAS, FAS or heart rate scores between the intervention group and the control group. During the procedure, the pain intensity (CAS scores) and the distress (FAS scores) increased significantly compared with before the procedure in both groups. The pain behaviour (FLACC scores) did not increase in the intervention group but increased significantly in the control group (p = 0.001). After the procedure, the pain intensity, distress and pain behaviour (scores of CAS, FAS and FLACC) decreased significantly in both groups. There was no difference in the heart rate before, during and after the procedure in the groups. The intervention group was divided into two subgroups, i.e., children who were satisfied and children who were dissatisfied with the intervention. Children who were satisfied with the VR according to the post-procedure interview showed a positive trend with lower CAS scores during (median 0.5 compared with 4, p = 0.01) and after (median 0 compared with 2.25, p = 0.005) the intervention compared with those who were dissatisfied with the intervention. The Wilcoxon signed ranks test showed that CAS scores for those who were satisfied with VR decreased more between the scores for during and after the intervention (p = 0.018) compared with those who were dissatisfied with the VR (p = 0.063).

Paper IV evaluated the effects of school-aged children’s experiences of postoperative music medicine on pain, distress and anxiety. Significantly fewer children in the music group (1/40) compared with the control group (9/40) received morphine in the PACU (p < 0.05). The RR was 0.11 (95% CI 0.015-0.828) and the absolute risk reduction was 20%. The total morphine administration was significantly lower in the music group at 4 mg (mean 0.10, SD 0.63).
compared with 30.5 mg (mean 0.76, SD 1.58) in the control group (p < 0.05). Pain scores above four were found for five children in the music group and seven children in the control group in the PACU (Post Anesthesia Care Unit). Four children with pain scores above four in the music group abstained from morphine compared with none in the control group. Two children in the control group reported pain and received morphine but were not awake enough to use the CAS, and the FLACC scores did not indicate pain. A significantly higher individual decrease in the FAS scores was found in the music group compared with the control group. No other significant differences between the two groups concerning the FAS scores, CAS scores, FLACC scores, short STAI scores and vital signs were shown. In both study groups, the CAS scores were higher and the short STAI scores lower after surgery than before.

5.4. Children’s experiences of the use of serious games and music medicine

Paper III and Paper IV described the children’s experiences of using either serious games or music medicine. The children enjoyed using these interventions and found benefit from these coping strategies in the context of procedural pain. In both papers, it was important to adapt the intervention to the procedure. The serious game needed to meet the stress during the needle-related procedure and should not disturb the procedure. In the postoperative care unit, the children preferred soft music, which made the postoperative period smoother.

Paper III evaluated the children’s experiences of VR for needle-related procedural pain and distress. Two themes emerged and represented an overall pattern for the interviews. One of these themes was ‘The VR game should correspond to the child and the medical procedure’. The theme emerged from the category ‘The remote control is difficult to steer and manage’, which is partly a challenge and partly a problem. Another category that was connected to this theme was ‘The 3D effect doesn’t add anything to the distraction.’ The children and adolescents sometimes mentioned the 3D and
enjoyed it, but nobody thought the 3D effect of this display was an important distraction that increased its presence in the VR game. A third statement supporting this first theme was ‘It is beneficial with a game that is adapted to the player and the procedure.’ The second theme in the interviews was that ‘Children enjoyed the VR game and found that it did distract them during the procedure.’ The interviews indicated that playing the game distracted children and was fun entertainment for them, but no one thought that the intervention reduced pain intensity. The theme was reflected in, among other things, statements such as ‘You concentrate on the game and don’t notice the needle.’ A theme also emerged from the statement ‘It is fun to play a game when you get stuck with a needle.’ The participants were used to playing video games at home and were familiar with the technique.

The children in Paper IV experienced the music as calming and relaxing. The interviews contained information about how and why the music helped wellbeing and made the postoperative period smoother. One theme emerged and represented an overall pattern for the interviews: ‘Postoperative music is a distracter that is calm and relaxing.’ The theme emerged from four categories and one of these categories was ‘The music is soft and it helps you to think about nature.’ The music helped the children to manage the situation and environment in the PACU. The category ‘It is beneficial with music that helps you to a good wakening’ involves music helping the children to manage and endure their pain in the PACU. One participant thought it was good with music as it protected her from other environmental noise. The category ‘You should be able to select music even if calm music probably is preferable’ indicated that children preferred to select and participate in the decisions of music medicine. The theme was finally reflected from the category: ‘The music made the technical equipment negligible and not disturbing.’ The participants thought the equipment was comfortable and it did not disturb them.
6. Discussion

6.1. Discussion of the results

It is important to have a holistic view in nursing to manage procedural and postoperative pain in children. It is not enough just to give pain medications to children. Children also require holistic caring in this context with pharmacological treatment as well as ways of voluntary coping. This goal can probably occur mainly if the nurse interprets the needs that children express in procedural and postoperative pain management. A method for achieving this goal is to use the four components of the ICF-CY because pain management in children could be based on the ICF-CY to fulfil the requirement of holistic care. The model of pain management that is presented here on the basis of ICF-CY emerged from the analyses in this thesis (Figure 3).
This thesis demonstrated a complexity of measuring and managing the multidimensional phenomenon of pain. Despite several assessment tools, there were some discrepancies in Paper III and Paper IV between the qualitative themes and the quantitative results. The children reported several beneficial effects of using serious games and music medicine, but these qualitative reports were often sparsely shown and reflected in the quantitative data. Based on Piaget’s developmental stages, one reason for this may be the children’s ability
to understand self-assessment scales (16). The neuromatrix theory also describes that the children’s pain perception is influenced by past events as well as the children’s current emotional states. In other words, the neuromatrix theory describes that the children’s experiences of pain need to be managed and evaluated from a holistic perspective (25). The children’s experience of pain is probably a complex system and several factors are involved in the explanation and aetiology of a pain problem. It is probably impossible for a practitioner, such as a nurse, to find and offer a good strategy of pain management when only one dimension, such as pain intensity, is observed and treated with analgesics (28). The components of the ICF-CY can be used to find valid interventions and assessment tools for the nurse when he or she helps children undergoing medical or surgical procedures. When children are exposed to a procedure, several factors decide how they manage the situation. Each component in the ICF-CY has to be considered for the children to bear the situation. If one of these four components defaults in the pain management, an unbearable situation results.

Body structure and body function involve children requiring analgesics to minimize the negative effects of pain signals that reach the brain. Analgesics prevent pain signals from reaching the pain system in the brain, and this means that the brain does not respond with negative emotions and physiological responses, i.e., body functions. The brain’s emotional and physiological response to pain does not only depend on the intake of analgesics however. The child's past experiences, coping and mood also affect the body functions in conjunction with procedural and postoperative pain management.

In the component activity/participation, the nurse needs to listen carefully to the children and their parents to establish a trustworthy relationship, i.e., to let the children be in control. The children also require voluntary coping strategies to increase their activity and participation in the management of their pain. For example, the children could make decisions about their care and choose to use behavioural and cognitive distraction.

Finally, environmental factors affect the children’s ability to manage their pain. Environmental factors involve the children’s experience of
the environment and not the actual environment. The nurse has the option to change the children’s view of environmental factors and to increase their ability to use voluntary coping strategies. For example, the nurse could offer the children the option to use serious games or music medicine.

The research questions in this thesis generated three main areas that provide knowledge that should be taken into consideration in order to offer children successful pain management in conjunction with medical and surgical procedures. These areas are probably important to fulfil the model of pain management above. The areas are *Assessment of pain and distress*, *Cognitive and behavioural distraction* and *Control*.

### 6.1.1. Assessment of pain and distress

The FLACC scale, CAS and FAS are three instruments that can be used to assess procedural pain in children. The experiences of pain, distress and anxiety in children are probably related to their ability to understand as well as their ability to adapt to the medical or surgical procedures, i.e., it is dependent on the developmental level of mental growth. Young children have difficulties understanding a procedure from a long-term perspective (17). Young children do not have the ability to transfer a painful experience to an appropriate level on a scale either. Not until school age can children transfer their feelings to a visual analogue scale (117).

The results in Paper II verified the concurrent and construct validity of the FLACC scale during procedural pain in children aged 5-16 years. This adds to the available information as there has been a discrepancy between recommendations for the use of the FLACC during procedural pain and validation data (53, 55, 117). The FLACC scale seems to be a valuable tool for assessing behaviour in a wide range of ages despite important developmental and cognitive differences during childhood (16, 55, 136). Paper II confirmed that the FLACC scores correlate with the children’s self-reports on procedural pain. In a previous study, the FLACC scores also complied with the children’s self-report for postoperative pain (113). Paper II also verified
construct validity in procedural pain in children aged five to sixteen years. For postoperative care, the construct of validity has previously only been established in children aged zero to seven years by measuring pre and post analgesia (111, 112).

Finally, Paper II showed a high correlation between the CAS and the FAS in young children, indicating poorer ability to discriminate between intensity of pain and distress in this age group. This finding is similar to the results of another study that showed equivalent ratings of intensity and unpleasantness up to the age of eight years (121). Like that study, the reports from older children in Paper II showed that their unpleasantness was higher, relatively, than the intensity of pain during venepunctures. In addition, Paper II showed a high correlation between the FLACC scores by the two observers, demonstrating good interrater reliability. The FLACC scale has also shown good interrater reliability in postoperative care (111, 112).

Paper II supports the recommendation from PedIMMPACT (Pediatric Initiative on Methods, Measurement and Pain Assessment in Clinical Trials) (117) to use the FLACC in children undergoing procedures and other brief, painful events. An observational scale is also a valuable complement to self-reports as the attempt to understand another person’s pain involves the behavioural reaction as well as verbal report (57, 58).

### 6.1.2. Cognitive and behavioural distraction

The goal is to offer children medical and surgical procedures without pain, distress and anxiety. Pain and anxiety both contribute to persistent fear of health care and procedures (6, 35). Several coping strategies exist that can help children cope with medical and surgical procedures (31, 137). Coping strategies may be a useful way to manage procedural and postoperative pain. One successful coping strategy is to use cognitive and behavioural distraction (83).

In this thesis, serious games and music medicine have been demonstrated as two examples of cognitive and behavioural distractions that are easy to use. In addition, the results in Paper I,
Paper III and Paper IV have demonstrated several beneficial experiences and effects of using these interventions. The children enjoyed using serious games and music medicine that helped them to endure their procedural or postoperative pain. These distracters may have helped the children gain control of the unpleasant situation and give them a feeling of being in a familiar environment. The children probably felt control and engagement in their use of serious games or music medicine, which became useful coping strategies in a threatening situation such as a medical or surgical procedure. These coping strategies are probably also easy to transfer to children in other contexts. Serious games and music medicine are transferable and could be used successfully in other clinical settings. In addition, serious games and music medicine are not time-consuming, and the time available is a complicating factor in many psychological techniques (82).

Earlier research has validated and confirmed cognitive and behavioural distractions, such as serious games and music medicine, to be beneficial to children undergoing procedural pain (41, 138). Cognitive and behavioural distractions have also been successful in combination with pharmacological treatments (139). Despite this knowledge, nurses in clinical practice do not offer these evidence-based cognitive and behavioural distractions (42). It is probably beneficial if these interventions are easy to use for both children and staff however (140). It is also important that these interventions are adapted to the children’s conditions and their reactions to the specific intervention (141). This thesis provides additional knowledge about children’s experiences of using serious games and music medicine in conjunction with procedural pain. It is hoped that the possibility of reaching evidence-based practice in this area will increase. Each child is entitled to a pain-free procedure that does not lead to persistent problems (142).

The children reported their experiences of using different coping strategies when they underwent procedural pain in Paper I and Paper III, and postoperative pain in Paper IV. Lazarus (143) established the fact that coping is an integral feature of the emotion process. A person’s wellbeing is dependent on how the individual copes with stress. If the person copes effectively, stress is likely to remain under
control. Lazarus abandoned the idea of problem-focused and emotion-focused coping as two independent types of coping. He refers to them rather as coping functions because, in most stress situations, they actually complement each other. He stated that if someone really wants to study coping styles, it might help to examine these styles interactively with the situational context and to consider central personality traits. In other words, emotions are best studied as narratives (143). This statement confirms the impact of the qualitative results in this thesis as essential to the knowledge about coping in conjunction with an examination or treatment.

6.1.3. Control

It is often easy for the children to create control and engagement when they use serious games or music medicine. Hypnotic elements have been shown to be important in the reduction in observational pain scores in children. The authors in that study emphasized that a different level of consciousness prevents the feeling of being swindled, which is an real risk in traditional distraction techniques (144). A serious game, or music medicine (91), may give the children a different level of consciousness (145). The children also control the complete distraction technique and are free to change focus between the serious game or music medicine and the procedure at any time. This feeling of control is important to many children (146). The effectiveness of a particular distracter probably depends on the individual child and his or her engagement in the specific distraction activity (147). Fanurik et al. (1993) categorized children into attenders and distracters. Attenders were children who directed their focus of attention towards the procedure. Distracters were children who directed their focus away from the procedure. In two different studies, the effects of distraction were not immediately apparent for children identified as attenders (146, 148). The children who showed negative experiences in this thesis may be attenders when exposed to distraction, which may not be a good coping strategy for these children. It is important that the children create positive memories in conjunction with the procedure. Brain plasticity will otherwise be adapted to this procedural pain and continue to worsen pain.
expression during future procedures with negative pain behaviour, i.e., the neuromatrix theory (25, 26).

6.2. Methodological issues

Children perceive their environment differently depending on their cognitive development. Based on Piaget’s theory, it is possible to divide the children into four periods (16). In this thesis, it was important to take into account the children’s ages and levels of development. Paper III and Paper IV have a wide age range while Paper I and Paper II largely follow the periods of Piaget’s development theory (16). Paper III, however, showed that the child’s individual interest in the game was more important than the age for beneficial effects. This result showed that age is only one important variable to consider in research into children.

This thesis collected data on children’s experiences of procedural and postoperative pain management. It is difficult for an adult to interview children and make a correct analysis of their answers. It is an analysis of a child’s worldview that is carried out of an adult’s worldview. The children’s abilities to understand and experience medical or surgical procedures are dependent on their developmental level of mental growth (16). It is important for the researcher to use a trustworthy interview technique and to choose useful methods of analysis. In this thesis, the interviews were based on other researchers’ experiences of interviewing children (59, 105, 106) and their experiences of qualitative content analysis (105, 106). The interviews conducted in this thesis take account of these problems and maintain credibility, dependability and transferability in the results.

The low range of pain scores in Paper II was a limitation of that study. A wide distribution of pain scores is desirable for the validation of a pain measurement tool. The low pain scores in Paper II, however, confirmed the FLACC scale response when the children only had a small change in behaviour.
There is substantial debate on whether the results of non-randomized studies are consistent with the results of randomized controlled trials on the same topic. A very good correlation has been observed between randomized and non-randomized studies, though non-randomized studies tend to show greater treatment effects. Despite a good correlation between randomized trials and non-randomized studies, randomized trials are preferred if they can be carried out (149). Paper IV in this thesis used a randomized study design.

Paper III and Paper IV did not collect interviews in the control group to compare with the interviews with children using intervention. The aims of these studies were to describe the children’s experiences of each intervention. It was the experience of the intervention that was important and not the comparison with other contexts.

The short STAI used in Paper IV needs to be validated further. The short STAI has also been used successfully in children aged 7-12 years undergoing LP (100). The short STAI may be preferable to the STAIC, which involves a long checklist and many items that sometimes become a hindrance (126).

Another limitation of Paper III and Paper IV is that the children in the control group were recruited with the knowledge that they might be given intervention but were then randomized into the group without intervention. This might have led to a sense of missing something. All the studies of cognitive and behavioural distraction seem to be some kind of open study however. It is probably impossible to create a trustworthy, blinded study with serious games or music medicine that uses equipment with loudspeakers.

Paper III evaluated the new equipment, which needed continuous updates and corrections. The equipment was expensive and hired specifically for this study. This complex situation required predetermined data collection.

Despite the methodological difficulties described above, it would seem possible to transfer and generalize the results to other children who come to the hospital to undergo an examination or treatment.
6.3. Clinical implications

Cognitive and behavioural distractions are helpful strategies in the pain management offered to children. Pain management is also facilitated through validated assessment tools, i.e., the FLACC, the CAS and the FAS. When the children choose cognitive and behavioural distraction, it is an example of pain-relieving interventions that offer the possibility to use voluntary coping strategies to manage a medical or surgical procedure. These interventions create positive feedback that helps children create positive memories of the current medical or surgical procedure. In this way, an effective cognitive and behavioural distraction will also help children undergo painful procedures in the future. In summary, cognitive and behavioural distractions, such as serious games and music medicine, are important to help children cope with medical or surgical procedures. A distraction technique that engages children’s consciousness is probably preferable, though the decision is for the children to make.

6.4. Conclusions

The conclusions of this thesis are

- FLACC is a valuable instrument for measuring procedural pain in children aged 5-16 years
- Serious games and music medicine help to raise the quality and outcome of medical and surgical procedures in children
- When children feel a sense of control in pain management they are prepared to participate in the decision-making
- Children want to choose the distraction techniques themselves
- It is important to find coping strategies that engage children
Summary in Swedish

Procedur- och postoperativ smärta hos barn

– upplevelser, mätning och coping strategier för att minska smärta, stress och rädsla

Barn som besöker sjukhuset förknippar ofta vistelsen med undersökningar och behandlingar. Om dessa procedurer också är förknippade med smärta kan barnen riskera att utveckla stress och rädsla inför kommande procedurer. För att undvika detta behöver barnen hitta strategier för att kunna hantera smärtan och för att minska stressnivån (coping). En effektiv smärtbehandling stödjer barnen till att genomgå medicinska eller kirurgiska procedurer utan att utveckla kvarstående problem med smärta och behandlingsrådsla. Serious games (dataspel utvecklat för detta ändamål) och musikmedicine är två interventioner som skulle kunna hjälpa barnen i dessa situationer.

Syftena med avhandlingen var att undersöka barns upplevelser av medicinska och kirurgiska procedurer och att validera en observationsskala som ett komplement till självskattning hos barn som genomgår procedursmärta. Syftet med avhandlingen var också att hitta coping strategier för att minska smärta, stress och rädsla.

I avhandlingen deltog sammanlagt 212 barn som genomick en medicinsk eller kirurgisk procedur.

I avhandlingen validerades observationsskalan FLACC (Face, Legs, Activity, Cry och Consolability) som ett komplement till självskattning. Avhandlingen visade att barnen önskade att den behandlande sjuksköterskan hade en god klinisk kompetens. Barnen
ville kunna välja distraktionsmetod och den valda distraktionsmetoden hjälpte dem att genomgå den smärtsamma medicinska eller kirurgiska proceduren. Serious games och musikmedicin distraherade barnen och ökade deras välbefinnande.

Slutsatser

- FLACC är en användbar skala för att utvärdera procedursmärta hos barn i åldrarna 5-16 år
- Serious games och musikmedicin bör finnas som komplement till annan smärtbehandling för barn
- När barnen känner en känsla av kontroll i sin smärthantering är de också beredda att delta i beslutsprocessen
- Barn vill välja distraktionsmetod själva
- För barn är det viktigt att hitta coping strategier som engagerar dem
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Children’s experiences of procedural pain management in conjunction with trauma wound dressings

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ABSTRACT

Aim
This paper is a report of a descriptive qualitative study of children’s (5-10 years) experiences of procedural pain when they underwent a trauma wound care session.

Background
Procedural pain in conjunction with trauma wound care often induces anxiety and distress in children. Children need to alleviate pain and avoid the development of fear in conjunction with examinations and treatments. The nurse could help children to reach this goal by using the comfort theory, which describes holistic nursing in four contexts: physical, psychospiritual, environmental and sociocultural. Few studies have focused on children’s experiences of comforting activities in conjunction with trauma wound dressings.

Methods
This study was conducted between May 2008 and January 2010. Thirty-nine participants aged five to ten were consecutively included in this study. The wound care session was standardized for all the participants, and semi-structured qualitative interviews with open-ended questions were conducted with all the children in conjunction with the procedure. All the interviews were transcribed verbatim and analysed with qualitative content analysis.

Findings
Four themes emerged: clinical competence, distraction, participation and security. The children were helped to reach comforting activities to enhance pain management.

Conclusion
Children require more than just analgesics in wound care. They also need to experience security and participation in this context. When children feel clinical competence in wound care, they trust the nurse to carry out the wound dressing and instead can focus on the distraction that increases their positive outcomes.

KEYWORDS Child - Dressing - Injuries and Wounds -Nursing - Pain

WHAT IS ALREADY KNOWN ABOUT THIS TOPIC?

Pain, distress and anxiety are still unmet problems for children in conjunction with trauma wound dressings.

The children’s memories of the last wound dressing, if this failed, will probably affect coming wound dressings in a negative way.
Non-pharmacological treatments should be used in conjunction with pharmacological treatment for the reduction of pain, distress and anxiety.

WHAT THIS PAPER ADDS

The children need to feel security and a sense of control before they can focus on the distraction that increases their positive outcomes.

The children want to participate in decision-making on distraction techniques that are well known to them but hand over the decisions on wound dressing, which is an unknown area to them.

The children are helped to reach comforting activities to enhance pain management by achieving clinical competence, distraction, participation and security.

IMPLICATIONS FOR PRACTICE

When children feel sufficient clinical competence in wound care, it affects their experience of pain, distress and anxiety.

Children are helped to use distraction as a complement to pharmacological treatment when they undergo wound care.

Distraction that engages the children’s consciousness is probably preferable because this increase the distraction effect. However, the decisions should be made by the individual child.

INTRODUCTION

Children endure an array of painful treatments starting at birth and continuing through adolescence (Blount et al. 2006). The pain and anxiety associated with wound dressing, such as burns, has often failed to meet the child’s individual needs (Miller et al. 2010). Therefore, there is an international interest in finding useful strategies to reduce anxiety and fear in this context. A trauma wound is often caused by a previous trauma, and the wound is often associated with a negative event. One example of a trauma wound is a dog bite. The child associates the wound with this incident and feelings can enhance the experience of pain associated with the rescheduling of the wound. In contrast, wounds are not always associated with a trauma. Pressure ulcers occur, for example, by a long-standing pressure and occur without an adverse event associated with the wound. Procedural pain in conjunction with trauma wound care is a multidimensional experience that frequently induces significant anxiety and distress in children. Wound care sessions that produce pain are related to the nurses or the health care system itself as opposed to the trauma. The children undergoing wound care risk developing a fear of examinations and treatments that ought to be prevented (von Baeyer et al. 2004, Blount et al. 2006). It is also not unusual for procedure-related anxiety to increase over time in injured patients. The children’s memories of the last wound dressing, if this failed, will probably affect coming wound dressings in a negative way (Summer et al. 2007). The development of a pain memory influences the children’s ability to undergo and cope with further wound dressings (Cohen et al. 2001). The reduction in anxiety is also important as it influences children’s memories of procedural pain (Rocha et al. 2009).
BACKGROUND

A wound dressing fails if the child experiences unmanageable distress and pain. A failed wound dressing can lead to a feeling of loss of control, and it then becomes impossible to find adequate coping strategies. The negative emotional feelings, i.e., fear and distress, take over the situation (Lu et al. 2007). Instead, children need to find coping strategies to manage and reduce harmful and long-standing negative effects (von Baeyer et al. 2004). These coping strategies also need to be tailored to the children’s individual development and cognitive ability (Piaget & Inhelder 1969).

The long-standing effects of under-treated pain are delayed healing, psychosocial problems and recurrent pain syndromes (Coulling 2007). This explains why adequate pain management is essential in the context of wound care (Coulling 2007). An earlier survey on wound pain found that the nurses tended to focus on the healing processes rather than the overall pain experience of the procedure. Children need a holistic approach to wound care however (EWMA 2002). Children’s own needs and the ability of the surrounding area to respond to their requests are essential in pain management. This includes the children receiving support from their parents (Power et al. 2007) and the children’s expressions being interpreted (Vaartio et al. 2008). Children’s ability to express pain is dependent on their involuntary and voluntary response to the pain stimuli. A response with a reflexive escape, facial grimaces and cry often transmits emotional reactions to the observer. In contrast, a controlled pain expression without behavioural reactions from the children does not generate emotional reactions for the observer (Craig et al. 2010). In addition, there are several pain assessment tools to measure pain in children (RCN, 2009). Pain assessment should always be followed up with treatment strategies for the children. Pain management often involves the children receiving a combination of pharmacological and non-pharmacological treatments in wound care (Howard et al. 2008).

There is a lack of knowledge about pain management in conjunction with wound care (Weinberg et al. 2000, Byers et al. 2001, Summer et al. 2007). Children need coping strategies that help them to manage trauma wound care without lasting negative memories (Blount et al. 2006, Uman et al. 2006). The children’s coping strategies in this context are voluntary or involuntary, and unmanageable situations often lead to involuntary and negative coping skills that worsen the situation. A trauma wound dressing, for example, could be interpreted as a threatening situation. Instead, the children need to use voluntary coping strategies to manage this situation (Lu et al. 2007). It is therefore important to explore coping strategies that help children who are undergoing wound care. Lazarus stated that if someone really wants to study coping styles, it might help to examine these styles interactively with the situational context and consider central personality traits. In other words, emotions are best studied as narratives (Lazarus 2006).

Most knowledge of procedural pain in children is taken from short procedures such as vaccinations. Wound dressings generate more distress and last longer than needle-related procedures. Different coping strategies are thereby required that allow the children to master longer procedures (Landolt et al. 2002). To be more precise, the suggestion here is that more knowledge of children’s experiences of longer procedures increases the possibilities of administering sufficient procedural pain management. The main goals of pain management in paediatric nursing are to give individualized care, to involve the children in decision-making and, finally, to bring about holistic nursing as defined by the comfort theory (Kolcaba & DiMarco, 2005). This theory describes holistic nursing in four contexts: physical,
psychospiritual, environmental and sociocultural. The physical context of comfort concerns the bodily sensations, the psychospiritual context of comfort concerns the internal consciousness of the self, the environmental context of comfort describes the external surroundings and, finally, the sociocultural context of comfort defines the interpersonal, family and societal relationships (March & McCormack, 2009). Holistic nursing strives to provide comfort, which involves relief, ease and transcendence in health care that is stressful. To achieve relief, children must have their specific need met and to achieve ease, children require a state of restfulness or satisfaction. Transcendence is achieved when children achieve a state in which they can rise above problems or pain. The basic assumption of the comfort theory is that all humans have a holistic response to complex stimuli such as wound care (Kolcaba, 1994). Few studies have focused on children’s experiences of comforting activities in conjunction with trauma wound dressings. Consequently, research is needed into interventions that enhance holistic comfort in children (Kolcaba & DiMarco, 2005). There are useful guidelines on pharmacological and non-pharmacological treatments to achieve sufficient pain relieving therapy (Howard et al. 2008). There are also guidelines on recognition and assessment of acute pain in children (RCN, 2009). Knowledge about comfort and holistic nursing in pain management requires exploration of dimensions on how these guidelines should be used in wound care (Kolcaba & DiMarco, 2005).

This study is one part of a research project that investigates procedural pain in children. Quantitative findings in this project showed beneficial effects of distraction by interactive games when children used this intervention in conjunction with wound dressings (Nilsson et al. 2010). The data reported in this paper amplify and clarify these quantitative findings and explain why the children felt pain relief when they underwent wound dressings.

THE STUDY

Aim
The aim of this study was to describe children’s (5-10 years) experiences of procedural pain when they underwent a trauma wound care session.

Design
This is a qualitative descriptive study. It is the method of choice when straight descriptions of phenomena are desired (Sandelowski, 2000).

Participants
Thirty-nine children were chosen consecutively for this study. Twenty-five of the children were participants in the quantitative portion of the overall research project, 12 of whom used lollipops and 13 of whom used interactive games as they underwent the trauma wound dressing. Another 14 of the participants did not receive any specific distraction strategy during the dressing. The number of children was decided to be sufficient to reach a variety of ages, genders and wounds. This number of participants also allowed data saturation. Children aged five to ten were recruited from a paediatric day-care unit. This choice of ages was based on the developmental psychologist Piaget who has offered important observations and concepts for consideration in child development. The children’s ability to understand and express pain, distress and anxiety is related to their developmental stage. Children aged five to ten gradually develop a concrete operation of thoughts, which means that they are capable of cooperation (Piaget & Inhelder 1969). Children between five and ten years have difficulties separating distress and pain compared with older children (Nilsson et al. 2008). The ability to create strategies to obtain comfort is especially important for this age group to reduce
procedural pain. All the children included in this study suffered from wounds that were advanced and too serious to be taken care of in a primary care setting. Their wounds differed in size and location, but the wound dressing was standardized for all the participants. Children with long-standing wounds, care-related pressure wounds, disease-related wounds or wounds in body areas with decreased sensitivity were excluded from this study. Children with cognitive impairments were excluded from the study, as were children or parents who did not have a good command of Swedish.

Data collection
The interviewer had met the children before the wound dressings to form a relationship with them. The study was conducted between May 2008 and January 2010. All the data were collected in conjunction with the child’s first visit to the specialized wound care nurse. She treated all the wounds, and the wound dressings were carried out in the same treatment room. The wound dressings went on for a median of 20 minutes. All the children and parents were given standardized information about analgesics before the treatment. No child used sedative drugs during the procedure. The interviews were carried out immediately after the procedures were completed. The study design contained semi-structured questions to describe children’s experiences when undergoing wound dressing sessions. The participants took part in an interview guided by open-ended questions. This interview guide included four different concepts of holistic nursing, i.e., physical, psychospiritual, environmental and sociocultural. The first questions concerned the visit to the hospital (environmental and sociocultural comfort). An example question is: *How did you feel coming here today?* Other questions concerned the children’s coping strategies for pain management (physical and psychospiritual comfort). An example question is: *What did you do today to make the wound dressing easier?* Finally, some of the questions concerned the children’s experiences of decision-making (psychospiritual and sociocultural comfort). An example question is: *What did you determine today?*

The interviewer (SN) was a pain management nurse with long experience of paediatric nursing. The interviews were recorded on an MP3 player, and all the interviews were transcribed verbatim by the researcher. The interviews lasted a median of 5.5 minutes (range 3.5-7.5 minutes). Interviewing the children immediately after the procedure meant that most of the interviews were short. The children had undergone a procedure of about 20 minutes and they were often a little tired.

Ethical considerations
The Regional Medical Ethics Review Board of Gothenburg approved the study (ref no: 359-07). All the participants received information about the study. All parents and children who could read were also given written information. Oral assent was obtained from all the children and written consent was collected from all the parents. All the children were given identical information about the procedures and the study. Young children are generally able to demonstrate a basic understanding of the purpose of research (Knox & Burkhart 2007) and the children included in this study were informed about the meaning of participating in the study.

Data analysis
All the data were read and analyzed using qualitative content analysis (Krippendorff 2004). Content analysis has been used in other analyses of interviews with children (Kortesluoma & Nikkonen, 2004, Kortesluoma et al. 2008). These analyses were carried out by two (KE + SN) of the authors, one of whom has solid experience of qualitative content analysis (KE) and
the other who is a pain management nurse (SN). The analysis continued until the underlying meaning was found. The first step was to read and reread the interviews until a sense of totality was obtained through them. The next step was to identify the unit of analysis, and transcripts were broken down into phrases and sentences. The key step of the content analysis included coding or giving meaning to the units of information. Lastly, the meaning units were sought and organized and abstracted to themes according to Graneheim and Lundman 2004.

**Trustworthiness**

In qualitative research the concepts credibility, dependability and transferability have been used to describe various aspects of trustworthiness (Patton 2001, Graneheim & Lundman 2004). Credibility of research findings deals with how well themes cover data. The credibility of this study was confirmed; the researcher found agreement among co-researchers in the analysis of the text. A senior researcher conducted an examination of the themes and confirmed that these covered the participants’ responses. Dependability means the degree of data change over time and alterations made in the researcher’s decisions during the analysis process. An open dialogue within the research team addressed the extent to which judgements about similarities and differences of content were consistent over time. Transferability refers to the extent to which the findings can be transferred to other settings. A clear distinct description of culture and context, selection and characteristics of participants, data collection and process of analysis created transferability in this study.

**FINDINGS**

Forty-one children were asked consecutively to participate in this study. One child declined to participate and one participant discontinued the wound care session. Data were finally recorded for 39 children aged 5-10 years. A majority of the children was boys (32 out of 39) and the median age was 7 years. All of the 39 children’s wounds were acute because of minor traumas, for example, bicycle accidents, burns, dog bites, fall accidents and pinch wounds.

Four themes emerged from the interview texts. These themes were clinical competence, distraction, participation and security (Table 1).

**Clinical competence**

Here, clinical competence is defined as the children experiencing the wound care as being carried out properly. The children also believed that the nurse was skilful. The theme clinical competence emerged from the texts, which stated that the children’s experience of pain management depends on the nurses’ professional performance in wound care. The interviewed children felt comfortable when they could trust the nurse’s activities. Clinical competence experienced during the wound dressing session made the children feel safe in the situation. The children emphasized that nursing activities should be careful and not quick and uninterested. One participant explained the nurse’s activities as comfortable because she did not pull the bandage, “When the bandage got stuck the nurse did not just pull, she used the salve” (Participant 14). Another nursing activity that children appreciated was the wound bath to remove the bandage. One participant described the bath as helpful, saying “mm…the wound bath and such stuff helped me to remove the bandage” (Participant 10). The children could even endure some pain if they knew that the nurse’s management was beneficial to the wound healing. One child described it as important to clean the wound and thought it was helpful “that she removed the yellow (purulence)” (Participant 30). The children’s awareness of clinical competence emerged in the sociocultural context of comfort, and the children experienced a feeling of security transmitted by the nurse. The children described that the nurse mediated clinical competence in her communication with them.
**Distraction**
The children’s use of distraction helped them to manage the procedural pain. They also appreciated choosing which distraction they preferred as a coping strategy. The distraction techniques prevented the children from developing fear or distress. The interviews indicated that children preferred to be involved in and to control their distraction techniques. One participant, for example, said, “The lollipop made me feel calm,” (Participant 20) and another participant mentioned that an interactive computer game made him relax. He said, “I was relaxed, I did not notice that she removed the stitches” (Participant 28). The children also chose and appreciated other distraction techniques such as communication with the nurse and holding the parent’s hand. If the children did not have the opportunity to use distraction techniques, however, they felt that they missed an important strategy in their pain management. One participant said, “It was not fun today, I missed the opportunity to use a computer game” (Participant 40). A distraction technique that becomes a useful coping strategy for the children makes them feel a sense of control in the unpleasant situation. The distraction technique shifted the children’s attention to something more pleasant. One participant who used a distraction technique that he liked said, for example, “You concentrated on something else” (Participant 28).

**Participation**
The theme participation involves children’s wishes about decision-making being divided into different parts. When the children felt a sense of control in the pain management, they were also prepared to participate in the decision-making. The nursing activities in the wound dressing procedure often became unknown to the child. In this situation the children handed over the decision-making to the nurse. The children chose to participate in the decision-making situations in which they felt a sense of control. One example was when they had a new bandage. One child appreciated that he “decided whether I should get a blue or a red plaster” (Participant 13). Another situation in which the children chose to make a decision was in the choice of distraction techniques. Interactive computer games and lollipops, for example, seemed to be comforting and appreciated during the trauma wound dressing. The children chose the colour and taste of the lollipops or the game paths in the interactive computer game. This participation became important to their sense of control and increased their feeling of security. One participant described this decision-making, “I wanted to do that (play an interactive computer game) and be able to choose path” (Participant 14). Another participant also appreciated choosing the colour of the lollipop, i.e., “which lollipop I should choose” (Participant 32).

**Security**
Most of the children’s experiences of adequate pain management were based on their feelings of security. The children felt comfortable being in the hospital, and several children even mentioned this event as exciting. The feeling of security was obvious despite the approaching trauma wound dressing sometimes being associated with procedural pain. A feeling of security emerged when the child knew that the wound care nurse did not only focus on the healing processes but also noticed the total pain experience. The sociocultural context of comfort made it possible for the children to mediate their needs during the procedural pain management. Out of this need, the children were safe with the pain management that the nurse created and offered. The children felt that the nurse listened to them, and this feeling made them feel secure and enjoy being in hospital. One participant said, “It is fun to come to the hospital; you can do a lot of things” (Participant 8).
DISCUSSION

Short interviews can be a problem in the analysis, but they make it easier for the children to sustain their concentration and make them more likely to answer the questions (Kortesluoma et al. 2003). In this study, the age span was five years. Cognitive development may differ between a five- and a ten-year old child, but the age span is small enough for a fairly homogeneous age group. There are other factors that are equally likely to affect children’s experiences and ability to respond to interview questions. An example is children experiencing worry and distress. The data were collected after the wound dressings when everything had been finished. The advantage of interviewing the children in conjunction with the procedure is to minimize the risk of memory bias.

The result revealed four themes that are important for children to cope with the situation. These themes are also important for children to feel comfort and the four contexts of the comfort theory are linked to these themes (see table 1).

The children interviewed in this study found several coping strategies that made it easier for them to undergo the trauma wound dressing without pain, distress or anxiety. These coping strategies helped the children to reach holistic care that enhanced their comforting activities. These comforting activities were connected to the themes that emerged in the interviews, i.e., clinical competence, distraction, participation and security. Comforting activities are positive outcomes that make children engage in health-seeking behaviours. The children’s enhancement of comfort in clinical settings is both practical and satisfying for them (Kolcaba & DiMarco, 2005).

The children’s experiences of clinical competence influenced their experiences and supported their feeling of security. They confirm the results of Kortesluoma et al. 2008 for whom the expectation was to find the clinical competence required for adequate pain management. The result is also confirmed in another study that highlights the importance of competent and knowledgeable nurses with an understanding of the needs of children (Brady 2009). Clinical competence has also been an important factor for children in other contexts, such as in the assistance of children with cancer. In that study, however, the importance of clinical competence was mentioned almost exclusively by the parents and it did not confirm the children’s experiences (Enskar & von Essen, 2000).

The children in this study appreciated and enjoyed the use of distraction techniques when they underwent procedural pain. Similar results have also been found in another study (Nilsson et al. 2009). The opportunity to choose distraction techniques, which engages the individual child, is important. The effectiveness of a particular distracter probably depends on the children and their engagement in the distraction activity (Murphy 2009). In another study, less pain was associated with greater engagement in distraction (Jeffs 2007). This finding has also been confirmed in a study that stated that it is essential to use effective distraction techniques (Astuto et al. 2002). The interviews showed that most of the participants chose some kind of distraction technique and that a majority of the children coped well with the wound care. It appears to be beneficial for children to shift their attention to something pleasant when they undergo a trauma wound care session. The distraction technique allows them to cope with and manage the situation, even if it is sometimes tough for them to manage the wound dressing. The distraction techniques helped the children to gain control of the unpleasant situation and gave them a sense of control and engagement. The hope is that these outcomes will have long-standing effects according to Cohen et al. 2001 who found successful distress management
interventions to have long-term benefits. Children’s pain memories are also related to pain management conducted in earlier procedures (Noel et al. 2009).

The participants in this study were not interested in taking part in the decision-making for the trauma wound dressing procedure. This was left to the nurse. The children did not want to participate in the decision on the type of the pharmacological procedural pain management either. The children preferred decision-making in other parts of the procedural pain management. For example, they appreciated choosing the colour of the lollipop or deciding which game path they should play in the interactive computer game. The wish by children to leave the medical decisions has also been found in other studies. The children in another study (Runeson et al. 2007) relied on the nurse’s ability to make correct medical decisions. It should probably not be taken for granted that a child wants decision-making in all parts of the procedural pain management. It is still not a matter of course, however, that children are involved in the decision-making in health care settings. Far too little attention is still paid to children’s wishes in health care. Children’s influence in care probably helps them to cope with the situation (Coyne 2008). The children in this study may not have expected to make decisions on wound dressing and they did not ask to do so. This may also be the reason for the children not mentioning it in the interviews. It is possible that more preparation would provide other findings concerning decision-making and that children might increase their ambitions to make decisions.

Finally, the children’s feeling of security became essential to achieving sufficient procedural pain management. The use of distraction seemed to be one familiar coping strategy that helped most of the children to feel secure. The children also became calm and felt secure when they felt that the wound care was professional.

CONCLUSION

Children need to experience security and participation in wound care. When children feel that there is sufficient clinical competence in the wound care, they trust the nurse to carry out the wound dressing and can instead focus on the distraction that increases their positive outcomes.

REFERENCES


Table 1. Four themes based on qualitative content analysis

<table>
<thead>
<tr>
<th>Theme</th>
<th>Context of the comfort theory</th>
<th>Central characteristics of the theme</th>
<th>Examples of meaning units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>Physical</td>
<td>Clinical competence is important because the child wants to rely on the nurse</td>
<td>When the bandage was caught the nurse did not just pull, she used the salve (Participant 14). That I should remove it (the dressing), and that she (the nurse) helped me (Participant 3). mm...the wound bath and such stuff, remove the bandage (Participant 10). That she removed the yellow (pus) (Participant 30).</td>
</tr>
<tr>
<td>Competence</td>
<td>Sociocultural</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distraction</td>
<td>Environmental</td>
<td>The distraction techniques helped the children to endure the procedural pain</td>
<td>The lollipop made me feel calm (Participant 20). I was relaxed; I did not notice that she removed the stitches (Participant 28). It was not fun today; I missed the opportunity to use an interactive computer game (Participant 40).</td>
</tr>
<tr>
<td></td>
<td>Psychospiritual</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sociocultural</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participation</td>
<td>Psychospiritual</td>
<td>The child wants to participate in decision-making on distraction that is well-known to them but not wound dressings that are often unknown</td>
<td>I decided whether I should get a blue or a red plaster (Participant 13). I wanted to do that (play an interactive computer game) and be able to choose path (Participant 14). Which lollipop I should choose (Participant 32).</td>
</tr>
<tr>
<td></td>
<td>Sociocultural</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Security</td>
<td>Environmental</td>
<td>The child feels secure in hospital, even if it is sometimes unpleasant</td>
<td>I think it is fun, but it is not fun when you are hurt (Participant 15). It is fun to come to the hospital; you can do a lot of things (Participant 8).</td>
</tr>
<tr>
<td></td>
<td>Psychospiritual</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sociocultural</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The FLACC behavioral scale for procedural pain assessment in children aged 5–16 years

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Summary

Objectives: To evaluate the concurrent and construct validity and the interrater reliability of the Face, Legs, Activity, Cry and Consolability (FLACC) scale during procedural pain in children aged 5–16 years.

Background: Self-reporting of pain is considered to be the primary source of information on pain intensity for older children but a validated observational tool will provide augment information to self-reports during painful procedures.

Methods: Eighty children scheduled for peripheral venous cannulation or percutaneous puncture of a venous port were included. In 40 cases two nurses simultaneously and independently assessed pain by using the FLACC scale and in 40 cases one of these nurses assessed the child. All children scored the intensity of pain by using the Coloured Analogue Scale (CAS) and distress by the Facial Affective Scale (FAS).

Results: Concurrent validity was supported by the correlation between FLACC scores and the children’s self-reported CAS scores during the procedure ($r = 0.59$, $P < 0.05$). A weaker correlation was found between the FLACC scores and children’s self-reported FAS ($r = 0.35$, $P < 0.05$). Construct validity was demonstrated by the increase in median FLACC score to 1 during the procedure compared with 0 before and after the procedure ($P < 0.001$). Interrater reliability during the procedure was supported by adequate kappa statistics for all items and for the total FLACC scores ($k = 0.85$, $P < 0.001$).

Conclusions: The findings of this study support the use of FLACC as a valid and reliable tool for assessing procedural pain in children aged 5–16 years.

Keywords: pain; assessment; procedure; child; FLACC

Introduction

The use of validated pain assessment tools is essential for improving pain management in children in clinical practice and research. For younger children assessment of pain is primarily based on observation of behavior (1). In older children self-report of pain should be the primary source of information on pain intensity whenever possible. In situations where the child is too distressed to use a self-report scale because of emotional or situational factors, behavioral observations can augment or
replace the self-reports (2–4). For example, when evaluating methods of pain relief, such as distraction using Virtual Reality (VR) or Guided Imagery, self-report measures after the procedure are most appropriate. In these situations an observational behavioral scale during the procedure augments self-report after the procedure (2). In one study both an observational scale, i.e. Children’s Hospital of Eastern Ontario Pain Scale (CHEOPS) (5), and self-reports with a visual analog scale (VAS) were used during distraction in 7- to 19-year-old children undergoing percutaneous puncture of subcutaneous venous port device. The CHEOPS scores were low in general, which resulted in no significant differences between groups with or without distraction (6).

The CHEOPS is one of few which has been validated for children above 7 years of age but not for procedural pain (1). As CHEOPS was considered to be too complex to use in a busy clinical setting the Face, Legs, Activity, Cry and Consolability (FLACC) scale was developed (7). This scale contains five categories, each of which is scored from 0 to 2 to provide a total score ranging from 0 to 10 (Table 1). The FLACC has been found to have good interrater reliability and validity for evaluating pain after surgery, trauma, malignancy, and other disease processes in infants and children up to 7 years of age (7–9). Both the original and revised form of the FLACC scale has been used in children with cognitive impairment after surgery (10,11). There has been little effort to validate the FLACC scale for assessment of procedural pain (1). Despite the lack of validation it has been used for pain assessment in various studies during procedural pain in both younger (12) and older children (13). In a recently published systematic review, the use of FLACC was recommended for pain assessment in children aged 3–18 years undergoing medical procedures (3). The scale has also been recommended for continued use in clinical trials in young children, until additional validation data are available (1).

The objectives of this study were to evaluate the concurrent and construct validity and interrater reliability of the FLACC during procedural pain in children aged 5–16 years undergoing peripheral venous cannulation or percutaneous puncture of a vascular port. Within the range 5–16 years, developmental differences may influence the ability of children to suppress the expression of pain. Based on the theory of development by Piaget, who presented a concrete operational stage (around 7–11 years) and formal operational stage (around 12 years), we divided the children into two age groups, i.e. 5–10 and 11–16 years (14).

### Methods

The hypothesis of this study was that FLACC is a usable instrument to observe needle-related pain. Subcutaneous venous port devices or peripheral venous cannulas were chosen as these are two common procedures for children visiting the hospital. Children scheduled for percutaneous puncture of subcutaneous venous port devices or peripheral venous cannulas were recruited from the pediatric oncology and pediatric surgery clinics at the Queen Silvia Children’s Hospital. EMLA®-crème (Astra Zeneca AB, Södertälje, Sweden; lidocaine 2.5 g·T⁻¹

### Table 1

The FLACC scale

<table>
<thead>
<tr>
<th>Categories</th>
<th>0</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face</td>
<td>No particular expression or smile</td>
<td>Occasional grimace or frown,</td>
<td>Frequent to constant frown, clenched jaw, quivering chin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>withdrawn, disinterested</td>
<td>Kicking, or legs drawn up</td>
</tr>
<tr>
<td>Legs</td>
<td>Normal position or relaxed</td>
<td>Uneasy, restless, tense</td>
<td>Arched, rigid, or jerking</td>
</tr>
<tr>
<td>Activity</td>
<td>Lying quietly, normal position, moves easily</td>
<td>Squirming, shifting back and forth, tense</td>
<td></td>
</tr>
<tr>
<td>Cry</td>
<td>No cry (awake or asleep)</td>
<td>Moans or whimper, occasional complaint</td>
<td>Crying steadily, screams or sobs, frequent complaints</td>
</tr>
<tr>
<td>Consolability</td>
<td>Content, relaxed</td>
<td>Reassured by occasional touching, hugging, or being talked to, distractable</td>
<td>Difficult to console or comfort</td>
</tr>
</tbody>
</table>

Each of the five categories (F) Face, (L) Legs, (A) Activity, (C) Cry, (C) Consolability is scored from 0 to 2, which results in a total score between 0 and 10. Printed with permission © 2002, The Regents of the University of Michigan.
and prilocaine 2.5 g was applied at least 1 h before the insertion of the subcutaneous venous port devices or peripheral venous cannulas. VR was used for distraction in some of these participants.

The Regional Medical Ethics Review Board of Gothenburg approved the study. Written informed consent was obtained from all participants after written and oral information about the study. Children with cognitive impairment were excluded from the study, as were children who did not have good command of Swedish. The original version of the FLACC scale was translated to Swedish by one of the researchers and then translated back to English by a professional interpreter. The Swedish version of the FLACC scale was then approved after verification.

The concurrent validity was estimated by comparing the FLACC scores with children’s self-reports of pain and distress. By comparison of the FLACC scores before, during and after the procedure the construct validity was tested.

In the first half of the cases two nurses familiar with the FLACC simultaneously and independently observed the patient and in the other half only one of these nurses assessed the child at same intervals. Pain assessments were recorded before, during and 5 min after the i.v. cannulation or the percutaneous puncture of a vascular port. The child scored pain intensity using Coloured Analogue Scale (CAS), and the pain distress using Facial Affective Scale (FAS). The CAS is a modified VAS that has been validated to measure the intensity of pain in children aged 5 and above. This scale was designed to provide gradations in color and width along its length, reflecting different values of pain intensity (Figure 1). The children marked pain intensity by using a shuttle transferring the evaluation to the scale from 0 to 10 on the backward side. At the same time the children reported their distress by using the faces pain scale FAS where they mark one of nine faces presented in an ordered sequence from least to most distressed on a 0.04–0.97 scale (Figure 2) (15).

Before the procedure the child scored the baseline of pain intensity and distress. A nurse flushed the needle after the puncture of the skin and applied a dressing. This procedure continued for approximately 5 min. When this part of the procedure was finished the child did a second scoring of the pain during the procedure, and then a third scoring of pain after the procedure.

Statistics

Nonparametric tests were used as it could be considered that data were not normally distributed and that the measurements lacked firm interval quality (16). For comparing the FLACC scores with the children’s self-reports of pain Spearman correlation analysis was used. Wilcoxon signed rank test was used for comparing changes in the FLACC scores before, during, and after the procedure. Agreement between observers was analyzed using simple and weighted kappa statistics. Mann–Whitney U-test determined differences between the subgroups in observed pain and self-reported levels of pain and distress. P < 0.05 was accepted as statistically significant and kappa values ≥ 0.41 were considered to reflect adequate agreement (16). The sample size was calculated from results from two
earlier studies. Observations from a study where EMLA®-crème was used for venepuncture showed that a sample size of at least 40 patients would be needed to reveal a difference of 0.65 on a 10-point VAS before and during the procedure with an 80% power and a one-tailed \( \alpha \) of 0.05 (17). Based on the results of correlation between FLACC scores and children’s self-report, a total sample size of 80 children spread in two age groups was calculated to be suitable (9).

Results
Observations were recorded in 80 children with a median age of 10.5 years ranging from 5 to 16 years. Numbers of children and demographic data in different groups are presented in Table 2.

EMLA®-crème was used in all cases except in two children, in the age group 11–16 years, who chose cold spray during the needle-related procedure.

Validity
The distribution of the scores of one of the observers during the procedure is presented in Table 3. A significant correlation was found between the FLACC scores and the children’s CAS self-reports in the whole group (\( r = 0.59, \ P < 0.05 \)) and in the age-separated age groups, i.e. 5–10 years (\( r = 0.59, \ P < 0.05 \)) and 11–16 years (\( r = 0.50, \ P < 0.05 \)). Comparing the FLACC scores and children’s FAS a weak correlation was found (\( r = 0.35, \ P < 0.05 \)). The correlation between children’s CAS and FAS was significant in both young children (\( r = 0.69, \ P < 0.05 \)) and in older children (\( r = 0.39, \ P < 0.05 \)).

The median FLACC scores increased from 0 before the procedure to 1 during the procedure (\( P < 0.001 \)). After the procedure the FLACC median score decreased from 1 to 0 (\( P < 0.001 \)) (Figure 3). The children’s median self-report CAS before, during and after the procedure were 0, 0.75, and 0, respectively, compared with FAS 0.37, 0.47, and 0.37.

Table 2
Numbers of participants and demographic data

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Girls</th>
<th>Boys</th>
<th>5–10 years</th>
<th>11–16 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>All participants</td>
<td>80</td>
<td>22</td>
<td>58</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>Patients background</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malignancy/hematology</td>
<td>38</td>
<td>13</td>
<td>25</td>
<td>17</td>
<td>21</td>
</tr>
<tr>
<td>Minor surgery</td>
<td>42</td>
<td>9</td>
<td>33</td>
<td>24</td>
<td>18</td>
</tr>
<tr>
<td>Procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venepuncture</td>
<td>56</td>
<td>12</td>
<td>44</td>
<td>30</td>
<td>26</td>
</tr>
<tr>
<td>Subcutaneous vascular port</td>
<td>24</td>
<td>10</td>
<td>14</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>Distraction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VR</td>
<td>18</td>
<td>5</td>
<td>13</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>No VR</td>
<td>62</td>
<td>18</td>
<td>44</td>
<td>30</td>
<td>32</td>
</tr>
</tbody>
</table>

VR, virtual reality.

Table 3
The number of observations related to one observers’ FLACC report-scores and the children’s CAS scores during the procedure, i.e. 80 cases

<table>
<thead>
<tr>
<th>FLACC scores</th>
<th>0</th>
<th>1–2</th>
<th>3–4</th>
<th>5–6</th>
<th>7–8</th>
<th>9–10</th>
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</thead>
<tbody>
<tr>
<td>CAS</td>
<td>14</td>
<td>4</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>&gt;0–2</td>
<td>11</td>
<td>21</td>
<td>5</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;2–4</td>
<td>2</td>
<td>6</td>
<td>5</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;4–6</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td></td>
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<td>&gt;6–8</td>
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<tr>
<td>&gt;8–10</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CAS, Coloured Analogue Scale.
The median values of FLACC, FAS, and CAS in each age group are presented in Table 4 and each subgroup during the procedure in Table 5.

The children who used VR showed better correlation between CAS and FLACC ($r = 0.81$, $P < 0.05$) compared with those without VR ($r = 0.53$, $P < 0.05$). With VR no significant correlation was found between FAS and FLACC and without VR a weak correlation was found ($r = 0.30$, $P < 0.05$). A weaker correlation between FAS and FLACC compared with CAS and FLACC was obvious in all other subgroups.

Table 4
Median scores of CAS, FAS and FLACC in each age group (before, during and after the procedure)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Before</th>
<th>During</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>5–10 years</td>
<td>CAS$^a$</td>
<td>0</td>
<td>1.25</td>
</tr>
<tr>
<td></td>
<td>FAS$^b$</td>
<td>0.37</td>
<td>0.47</td>
</tr>
<tr>
<td></td>
<td>FLACC$^c$</td>
<td>0</td>
<td>1.5</td>
</tr>
<tr>
<td>11–16 years</td>
<td>CAS$^a$</td>
<td>0</td>
<td>0.75</td>
</tr>
<tr>
<td></td>
<td>FAS$^b$</td>
<td>0.42</td>
<td>0.53</td>
</tr>
<tr>
<td></td>
<td>FLACC$^c$</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

$^a$0–10, a high score indicates pain. $^b$0.04–0.97, a high score indicates distress. $^c$0–10, a high score indicates pain.

Table 5
Median scores of CAS, FAS and FLACC in each subgroup during the procedure

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>CAS$^a$</th>
<th>FAS$^b$</th>
<th>FLACC$^c$</th>
</tr>
</thead>
<tbody>
<tr>
<td>All participants</td>
<td>0.75</td>
<td>0.47</td>
<td>1</td>
</tr>
<tr>
<td>Patients background</td>
<td>Malignancy/hematology</td>
<td>0.63</td>
<td>0.47</td>
</tr>
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<td></td>
<td>Minor surgery</td>
<td>1</td>
<td>0.59</td>
</tr>
<tr>
<td>Procedure</td>
<td>Venepunctures</td>
<td>1</td>
<td>0.53</td>
</tr>
<tr>
<td></td>
<td>Subcutaneous vascular ports</td>
<td>0.5</td>
<td>0.42</td>
</tr>
<tr>
<td>Distraction</td>
<td>VR</td>
<td>1.13</td>
<td>0.47</td>
</tr>
<tr>
<td></td>
<td>No VR</td>
<td>0.75</td>
<td>0.59</td>
</tr>
</tbody>
</table>

$^a$0–10, a high score indicates pain. $^b$0.04–0.97, a high score indicates distress. $^c$0–10, a high score indicates pain.

Table 6
Simple Kappa coefficient during the procedure

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face</td>
<td>0.85</td>
</tr>
<tr>
<td>Legs</td>
<td>0.78</td>
</tr>
<tr>
<td>Activity</td>
<td>0.83</td>
</tr>
<tr>
<td>Cry</td>
<td>0.73</td>
</tr>
<tr>
<td>Consolability</td>
<td>0.91</td>
</tr>
</tbody>
</table>

(subcutaneous venous port and peripheral venous cannulas, malignancy/hematology, and minor surgery) as well.
Interrater reliability

During the procedure the weighted kappa coefficient was 0.85 for total scores \((P < 0.001)\). Simple kappa coefficients of each category are shown in Table 6. Before and after the procedure the FLACC scores were zero in all except in nine of these 160 assessments.

Discussion

The results in this study verified concurrent and construct validity of the FLACC scale during procedural pain. This adds to available information as there has been a discrepancy between recommendations for use of FLACC during procedural pain and validation data (1,3).

The positive correlations in 80 children aged 5–16 years undergoing procedural pain \((r = 0.59)\) was similar to the correlations between self-reports and the FLACC in 30 children aged 3–7 years undergoing postoperative care \((r = 0.584)\) (9). We could also verify construct validity with differences between scores during compared with before and after the procedure. For postoperative care the construct validity has only been established in children aged 0–7 years by measuring pre- and post-analgesia (7,8).

The correlation coefficient was 0.59 in children aged 5–10 years compared with 0.50 in those aged 11–16 years. Similar findings were reported in a clinical study where better correlation was found between self-report measurement and CHEOPS in children 5–8 years than in children 9–12 years during postoperative care (18). In an experimental study, the ability to suppress expression of pain was investigated in 8- to 12-year-old children who were found capable to control nonverbal behavior suppressing their expression of pain (19). When examining the relationship between different indicators of pain and distress in children aged 4–10 years undergoing puncture of vascular ports, a high correlation was reported between the FLACC and self-reports (20). The most rapid developmental changes in children probably occur before the age of 3 and then children develop more continuous changes in their pain expression. Although this developmental change can affect pain measurement, there are no other more specific age-adjusted observational instruments. Some observational instruments were originally designed for specific ages and have later been adapted to a broader age range. In a systematic review, it was deduced that it remains to be determined if adjusted observational pain scales are needed for older children (3).

The FLACC scores correlated better with the children’s assessment of pain intensity by using CAS than their assessment of pain distress by using FAS. This scale has been shown to agree better with unpleasantness than the intensity of pain (21). Other studies have described difficulties in discriminating pain intensity from emotions, i.e. distress, with observational pain scales (3).

We found a high correlation between CAS and FAS in young children indicating poorer ability to discriminate between intensity of pain and distress in this age group. This finding is similar to the results in another study that showed equivalent ratings of intensity and unpleasantness up to the age of 8 years (22). As in that study, older children in our study also rated their unpleasantness relatively higher than the intensity of pain during minor procedures, i.e. venepunctures.

There was a tendency of the FLACC to underestimate CAS scores. As can be seen in Table 3 50 FLACC observations were correctly associated with scores 0–2 on the CAS and 12 correctly with scores >2–10. There were more than twice as many underestimations (13 observations) than overestimations (five observations). This supports a previously reported tendency of observational pain scores to be somewhat lower than self-report scores (23).

We found a high correlation between FLACC scores by the two observers demonstrating good interrater reliability \((\text{simple } \kappa = 0.73–0.91)\) in procedural pain for all categories of the FLACC scale. The FLACC scale has also shown good interrater reliability in postoperative care, kappa statistics varied between 0.52 and 0.66 (7,8).

A wide range of pain scores is preferable to evaluate validity and reliability of observational pain assessment scales (3). The low range of pain scores is a limitation of our study. Introduction of better methods for avoiding severe or moderate pain during minor procedures results in less painful experiences. Despite the low scores there were significant differences during the procedure as compared with before and after the procedure,
demonstrating good construct validity. Low scoring of pain during venepuncture with EMLA®-crème has been presented in other studies as well (17,24,25). On the other hand with the FLACC, a mean score of 7 was reported during puncture of subcutaneous ports with EMLA®-crème (20). One reason for the low scores in our study may be that the EMLA®-crème application in most cases was performed for more than 1 h before puncture. Low pain scores indicate a need for more data from other procedures with more pain to strengthen both reliability and validity of the FLACC, such as wound dressings or sutures. The FLACC has still been better validated and reliability tested in postsurgical situations (7–9). No child in the study used sedation and its result gave no further validity or reliability to the use of FLACC for procedures during nitrous oxide, such as during plastic surgeon for repair of facial lacerations (13).

In the small subgroup with VR a high correlation was found between FLACC and CAS, but there were no significant differences in either FLACC scores or CAS between the groups with and without VR.

Another limitation of our study was the 5-min delay of the self-report scores compared with the FLACC scores that were collected during the needle-procedure. This of practical reasons caused delay may have introduced memory biases and reduced the FLACC-CAS concordance.

The findings of our study lend support to the concurrent and construct validity of the FLACC as a measure of procedural pain in children aged 5–16 years. Our results confirm interrater reliability and support the use of the FLACC for both research and clinical purposes in this age group of children. This study also support the recommendation from Creltin et al. (1) and von Baeyer and Spagrud (3) to use the FLACC in children undergoing procedures and other brief painful events.

References


Accepted 6 May 2008
The use of Virtual Reality for needle-related procedural pain and distress in children and adolescents in a paediatric oncology unit

Stefan Nilsson, Berit Finnström, Eva Kokinsky, Karin Enskär

Aim: It is essential to minimize pain and distress during painful procedures in children. This study examined the effect of using non-immersive Virtual Reality (VR) during a needle-related procedure on reported pain or distress of children and adolescents in a paediatric oncology unit and surveyed their response to the use of VR-equipment during the procedure.

Method: Twenty-one children and adolescents were included in an intervention group with non-immersive VR and another 21 children and adolescents in a control group where they underwent either venous punctures or subcutaneous venous port devices. Self-reported pain and distress, heart rate and observational pain scores were collected before, during and after the procedures. Semi-structured qualitative interviews were conducted in conjunction with the completed intervention.

Results: Self-reported and observed pain and distress scores were low and few significant differences of quantitative data between the groups were found. Two themes emerged in the analysis of the interviews; the VR game should correspond to the child and the medical procedure and children enjoyed the VR game and found that it did distract them during the procedure.

Conclusion: The interviews showed that non-immersive VR is a positive experience for children undergoing a minor procedure such as venous puncture or a subcutaneous venous port access.


Introduction

Pain associated with examinations and treatments is one of the most common physical concerns for children with cancer (Blount et al., 2006; Enskär and von Essen, 2008; Hedstrom et al., 2003). Pain from procedures and treatment has been reported to be a greater problem than the pain from the malignant disease itself (Ljungman et al., 1999). During the first days in hospital the child is often exposed to multiple medical procedures (Jacob et al., 2007) and if the child associates pain with these procedures, anxiety or stress are likely to develop (Weisman et al., 1998). If the child feels fear or anxiety then necessary examinations and treatments may become difficult to carry out (von Baeyer et al., 2004). Finding ways to reduce anxiety and fear would be important to help the child or adolescent undergo these procedures experiencing a lower level of pain and stress. One of the best strategies to deal with stress is learning how to relax. However, relaxation is difficult to achieve in typical real world situations (Riva et al., 2007b). An alternate strategy to pain management could be to introduce some form of distraction to reduce the painful effects of the procedures (von Baeyer et al., 2004). A combination of pharmacologic treatments and distraction techniques has often been suggested as a way to optimize the experience of children or adolescents undergoing painful examinations and treatments (Windich-Biermeier et al., 2007). Psychological interventions may increase the pain inhibitory systems effectively in the body and reduce the pain experience for the child and thus reduce anxiety and fear (Blount et al., 2006). However, there is still today limited research on the effectiveness of such psychological interventions. Further, few of these psychological interventions have focused on modern interactive technologies that children and adolescents are familiar with, i.e. Virtual Reality (VR) (Uman et al., 2006).

The idea behind VR is a simulated world, which runs on a computer system. VR is a set of computer technologies which, when combined, provide interaction and engross the users’ senses, which sets it apart from other technologies such as television. The effect of VR is often based on the result of presence or immersion...
that appears (Schemme et al., 2001). Despite that VR is always associated with immersion, all VR systems are categorized into two main categories, i.e. immersive and non-immersive VR. Immersion or presence can be regarded as how powerfully the attention of the user is focused on the task at hand. Immersion presence is generally believed to be the product of several parameters including level of interactivity, image complexity, stereoscopic view, and field of regard and the update rate of the display (Broeren, 2007). Full immersion is reached by a head mounted display, which blocks the user’s view of the real world and presents patients with a view of a computer-generated world instead. The helmet and headphones exclude sights and sound from the hospital environment (Hoffman et al., 2008). Opposite to this, a computer screen often displays non-immersive VR where the user is connected to the virtual world but still has the possibility to communicate with the hospital environment. However, the sense of presence probably can be increased in non-immersive VR by using a three-dimensional (3D) display (Broeren, 2007; Olsson, 2003).

The education level of the hospital staff and available time are confounding factors of many psychological techniques (Polkki et al., 2003). Segerdahl suggests that procedural pain could allude to “inadequate or improper application of available information and therapies is certainly the most important reason for inadequate procedural pain relief” (Segerdahl, 2008, p. 2). VR is probably independent of these factors. Furthermore, VR could be a useful strategy to carry out relaxation (Riva et al., 2006, 2007a,b). Studies of the brain have shown that sensory stimulation with VR will reduce the pain experience during examinations and treatments (Hoffman et al., 2006; Petrovic et al., 2000). The use of immersive VR-glasses or a head-mounted display has been found to ease pain and distress during needle-related pain procedures for children (Das et al., 2005; Gershon et al., 2003; Gold et al., 2006; Sander Windich-Biermeier et al., 2007; Wolitzky et al., 2005).

**Aim**

The aims in this study were to:

- Examine and survey the effect of using non-immersive VR, i.e. a 3D display, during a needle-related procedure on reported pain or distress of children and adolescents in a paediatric oncology unit.
- Examine their response to the use of VR equipment during the procedure.

**Method**

**Sample and data collection**

Children were recruited from the paediatric oncology unit at the Queen Silvia Children’s hospital. No children or adolescents included in this study were in an acute crisis of their disease and all participants had undergone the procedure at least one time before. Data were recorded on 42 children and adolescents aged 5–18. Patient data and diagnoses are presented in Table 1. Twenty-one participants were assigned to the intervention group and 21 to a control group. Four girls withdrew from the study. The median age of these girls was 6.5 years, one with the diagnosis leukaemia, two with brain tumours and one with a solid tumour. It was necessary to exclude the data for a 15-year-old because of a technical problem with the MP3-player during the interview. Children with cognitive impairment were excluded from the study, as were children or parents who did not have a good command of Swedish.

Table 1

<table>
<thead>
<tr>
<th>Description</th>
<th>Intervention (n = 21)</th>
<th>Control (n = 21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys</td>
<td>14</td>
<td>11</td>
</tr>
<tr>
<td>Girls</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age median</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Age range</td>
<td>5–18</td>
<td>5–17</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haematological diseases</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Leukaemia</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>CNS tumour</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Other solid tumour</td>
<td>3</td>
<td>6</td>
</tr>
</tbody>
</table>

**Virtual Reality intervention**

The intervention consisted of a virtual world game/application, “The hunt of the diamonds”, developed with DCC software (Digital Content Creation) and Adobe Photoshop for the textures. The finished model was exported to an authoring tool called EON Studio. It was used to associate behaviours with the model and to develop a complete interactive 3D application. The game was displayed on a standard personal computer with high-end consumer graphics card and a 3D-display, i.e. X3D-20 Display from X3D-Technologies GmbH.

This concept is further called VR game in the context of this article.

The VR game was steered by a GyroRemote remote control from Gyration. This remote control made it possible to use a wireless steering and the movements from the remote control were synchronized with the movements in the VR game. In the intervention group the child or adolescent steered the virtual world with one hand by moving the hand up, down, left or right together with the wireless remote control.

The child or adolescent was requested to catch diamonds that were floating in an amusement park. Each diamond was worth 20 points and after 200–300 points the child or adolescent could ride either a roller coaster or a Ferris wheel. The virtual world was designed to be calming with adapted colours and sounds. These colours and sounds were based on the results of a pre-study where school-aged children were interviewed (Hansson and Jäderholm, 2005).

**Procedure**

In association with required treatments or blood-drawing procedures, children and adolescents underwent the procedures of insertion of subcutaneous venous port devices or venous punctures. All children underwent standard therapy for this needle-related procedure at the ward and chose voluntarily between either cold spray or EMLA®-crème (lidocaine 2.5 g/l and prilocaine 2.5 g/l) that was applied at least 1 h prior to the insertion of the venepuncture or subcutaneous venous port device. In the context of the scheduled needle-related procedure, intervention with the VR game was started 3–5 min before the procedure and continued until the procedure was completed.

**Measurements**

**Self-report**

Pain measurements were recorded 5 min before, during and 3–5 min after the venous puncture or insertion of the
subcutaneous venous port device in both the intervention group and the control group. The child or adolescent scored a baseline of pain intensity and distress before the procedure by using Colour Analogue Scale (CAS) (McGrath et al., 1996) and Facial Affective Scale (FAS) (McGrath et al., 1996). After the procedure the child or adolescent rated the pain intensity and distress during the procedure, and then made a third rating after the procedure. The CAS is a modified visual analogue scale that has been validated to measure the intensity of pain in children aged 5 and above. This scale is designed to provide gradations in colour, area and length, reflecting different values of pain intensity. The child or adolescent rated pain intensity by moving a shuttle on a scale from zero (no pain) to ten (most pain). At the same time the child or adolescent rated the level of distress by using FAS by marking one of nine faces presented in an ordered sequence from least to most distressed on a zero to one scale (McGrath et al., 1996).

Observations
The Face, Legs, Activity, Cry and Consolability scale (FLACC) was developed to measure observational pain in children. This scale contains five categories, each of which is scored from zero to two to provide a total score ranging from zero to ten. A high score of FLACC indicates pain in the child (Merkel et al., 1997). The FLACC scale has been recommended for use with children aged from 3 to 18 undergoing procedures (von Baeyer and Spagrud, 2007). Observational pain scales are a complement to self-report scales in many clinical situations providing different and complementary information (Hadjistavropoulos and Craig, 2002).

A nurse highly familiar with the FLACC scale observed the child or adolescent and recorded FLACC scores 5 min before, during and 3–5 min after the venous puncture or insertion of the subcutaneous venous port device. In an earlier study the same nurse evaluated the concurrent and constructed validity and the inter-rater reliability of the FLACC scale by using this scale during several needle-related procedures (Nilsson et al., 2008).

Vital signs
The child’s or adolescent’s heart rate was recorded by a pulse oximeter 5 min before and during the procedure. A nurse flushed the needle after the puncture of the skin and applied a dressing. This procedure continued for approximately 3–5 min. When this part of the procedure was finished the pulse was recorded a third time. After this record the whole session was finished and the child or adolescent left the place.

Interviews
Semi-structured qualitative interviews, based on an interview guide, were conducted with the 21 children and adolescents in the intervention group following completion of the intervention. These interviews were carried out immediately after the completing procedures to avoid impact of memory bias. The purpose of the interviews was to examine their response to the use of VR equipment during the procedure. Median time for these interviews was 8.5 min. The interviews were recorded on an MP3 player and transcribed verbatim. In addition, the children and adolescents were asked if they would like to use the VR method next time they were to undergo a needle-related procedure.

Data analysis
Quantitative data
The sample size was calculated on the results from an earlier study in the same area (Wolitzky et al., 2005). A power calculation for this study based on a difference of one and a half steps between CAS scores in the intervention group and control group with an SD of <1.5 and a power of 0.80 suggested a sample size of at least 16 participants in each group. It was decided that each group should contain 21 participants and statistical significance was set at p < 0.05. The data were analysed using the Mann–Whitney U-test to test for differences between the study groups in self-reported levels of pain and distress, observed pain and heart rate. In addition, a Wilcoxon signed rank test was used for comparing changes in CAS, FAS and FLACC scores before, during and after the procedures. Heart rate was analysed using the t-test for independent groups (comparison between intervention and control group) and using the paired t-test for comparisons over time. The results for heart rate also include 95% confidence intervals (CI).

Qualitative data
All interviews were read and analysed by using a qualitative content analysis and the texts were selected to condensed meaning units in an organized manner (Graneheim and Lundman, 2004). Each time a condensed meaning unit arose in the texts it was counted to value the magnitude. This step follows recommendations for combining quantitative and qualitative methods in content analysis (Krippendorf, 2004). The meaning units were subsequently abstracted to categories and eventually abstracted to themes (Graneheim and Lundman, 2004).

Ethical considerations
The Regional Medical Ethics Review Board of Gothenburg approved the study (Dnr:142-07). Written informed consent was obtained from all participants after written and oral information about the study.

Results
Quantitative data
The median scores, quartiles and ranges for CAS and FLACC are shown in Figs. 1–4 and median scores for FAS in Table 2. There were no significant differences of these measures between the intervention group and the control group. During the procedure the CAS and FAS increased significantly compared to before the procedure.

Fig. 1. Pain scores by CAS before, during and after the procedure in the intervention group.
in both groups. The FLACC scores did not increase in the intervention group but increased significantly in the control group. After the procedure, the CAS, FAS and FLACC decreased significantly in both groups (Table 3). The mean scores for heart rate are presented in Table 4. There was no statistically significant difference in the heart rate between the study groups. The increase in heart rate during the procedure was not statistically significant compared to before and after the procedure in either group. In the interviews, most participants in the intervention group—15 out of 21 children and adolescents—stated they would choose some variant of VR for the next needle-related procedure.

Qualitative data

Two themes emerged and represented an overall pattern for the interviews (Table 5). One of these themes was the VR game should correspond to the child and the medical procedure. For example, a VR game demanding lively movements would be a hindrance for the nurse to carry out the procedure. Lively movements also require muscle tensions, which probably affect the pain experience. In addition, the VR game needs to reach a sufficient level of presence to achieve distraction for the child or adolescent. The interviews contained information about how and why both the game and equipment must fit the child or adolescent to engage them and to make the procedure easier to go through. The theme emerged from statements such as, the remote control is difficult to steer and manage, this is partly a challenge and partly a problem. The equipment was difficult to manage and this was good for some participants because that challenge could raise the focus of the commission. The steering became for these participants a positive challenge instead of a negative hindrance in the experience of presence in the VR game. A participant said, “It (the joystick) is more easy but this was fun” (Participant J). Other children saw the remote control like an obstacle to be engaged and one participant said, “I didn’t understand how to go forward when you pushed the button” (Participant E).

Another category that was connected to this theme was the 3D effect doesn’t add anything to the distraction. The children and adolescents sometimes mentioned the 3D and also enjoyed it, but nobody thought the 3D effect from this display was an important distraction that increased its presence in the VR game. One citation from the interviews read, “I: Did you notice any difference with this screen compared with those you are used to? P: Yes, this was different but it is hard to explain how. It was special. I: Was this difference important for you? P: No, actually not” (Participant N). A third statement supporting this first theme was it is beneficial with a game, which is adapted to the player and the procedure. The VR

<table>
<thead>
<tr>
<th>Table 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median scores of FAS in the study groups before, during and after the procedure.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Before</td>
</tr>
<tr>
<td>During</td>
</tr>
<tr>
<td>After</td>
</tr>
</tbody>
</table>

FAS 0.04–0.97; a high score indicates distress. n.s., not significant.
game was attempted to be adapted to the procedure due to a designed stress-reducing environment and a wireless steering, which would not disturb the procedure. Instead of a traditional video game one participant said that “I would like to try something new” (Participant F) and another thought, “it would have been this game, those (games) home when you wave with your arms” (Participant U). The requested movements in this game made the procedure sometimes worse, for example one of the participants said, “it wasn’t good, you tense your muscles and then it will hurt more” (Participant U). A gender difference also emerged in the interviews as noted by one girl who said, “Boys play boy games. This was brightly-coloured and fit girls” (Participant C). Another boy explained “The hunt for the diamonds” as being “corny” (Participant M).

The second theme in the interviews was that children enjoyed the VR game and found that it did distract them during the procedure. The interviews indicated that playing the game distracted children and that it was fun entertainment, but no one thought that the intervention reduced pain intensity. The theme was reflected among other things from statements such as one is concentrated on the game and doesn’t notice the needle. The participants thought the intervention with VR was distracting by expressing that they didn’t feel, think or look at the needle. One participant said for an example “you think of the game and don’t notice the needle” (Participant K). They explained the effects with reasons like “I didn’t think of the pain” (Participant O). A theme also emerged from the statement it is fun to play a game when you get stuck with a needle. The participants were used to playing video games at home and were familiar with the technique. They thought it was fun to play a game during the procedure and mentioned, “it was fun and good” (Participant P) and “it was fun with the game… it was fun to play” (Participant F).

Comparisons of qualitative and quantitative data

Subgroup comparisons

The 21 children in the intervention group were divided into two subgroups based on their responses about VR in the qualitative interview. The first group was made up of 13 children who were positive about VR and expressed satisfaction with the game and equipment.

Discussion

The aims of this study were to examine whether the use of non-immersive VR during a needle-related procedure would reduce pain and distress among children in a paediatric oncology unit, and

Table 3
Comparison of changes (Wilcoxon signed rank test) in CAS, FAS, FLACC before, during and after the procedure (p-values).

<table>
<thead>
<tr>
<th></th>
<th>Before–During</th>
<th>During–After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 21)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS</td>
<td>0.018*</td>
<td>0.003**</td>
</tr>
<tr>
<td>FAS</td>
<td>0.028*</td>
<td>0.008**</td>
</tr>
<tr>
<td>FLACC</td>
<td>0.163</td>
<td>0.027*</td>
</tr>
<tr>
<td>Control (n = 21)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS</td>
<td>-0.001***</td>
<td>0.004**</td>
</tr>
<tr>
<td>FAS</td>
<td>0.028*</td>
<td>0.001*</td>
</tr>
<tr>
<td>FLACC</td>
<td>0.001**</td>
<td>-0.001***</td>
</tr>
</tbody>
</table>

*p < 0.05, **p < 0.01, ***p < 0.001.

Table 4
Mean scores and 95% confidence intervals (CI) of heart rate (beats per minute).

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 21)</th>
<th>Control (n = 21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>88.2</td>
<td>79.4–97.0</td>
</tr>
<tr>
<td>During</td>
<td>90.3</td>
<td>80.9–99.8</td>
</tr>
<tr>
<td>After</td>
<td>84.4</td>
<td>77.4–91.5</td>
</tr>
<tr>
<td>p-value</td>
<td></td>
<td></td>
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</table>

Table 5
Five categories and two themes based on qualitative content analysis.

<table>
<thead>
<tr>
<th>Categories</th>
<th>Themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>The remote control is difficult to steer</td>
<td>The VR game should correspond to the child and the medical procedure</td>
</tr>
<tr>
<td>and manage, this is partly a challenge and</td>
<td></td>
</tr>
<tr>
<td>partly a problem</td>
<td></td>
</tr>
<tr>
<td>The 3D effect doesn’t add anything to the</td>
<td></td>
</tr>
<tr>
<td>distraction</td>
<td></td>
</tr>
<tr>
<td>It is beneficial with a game, which is</td>
<td></td>
</tr>
<tr>
<td>adapted to the player and the procedure</td>
<td></td>
</tr>
<tr>
<td>One is concentrated on the game and</td>
<td></td>
</tr>
<tr>
<td>doesn’t notice the needle</td>
<td></td>
</tr>
<tr>
<td>It is fun to play a game when you get</td>
<td></td>
</tr>
<tr>
<td>stuck with a needle</td>
<td></td>
</tr>
<tr>
<td>Children enjoyed the VR game and</td>
<td></td>
</tr>
<tr>
<td>found that it did distract them during the</td>
<td></td>
</tr>
<tr>
<td>procedure</td>
<td></td>
</tr>
</tbody>
</table>

Table 6
Median scores of CAS, FAS, FLACC in two subgroups.

<table>
<thead>
<tr>
<th>Demographic data</th>
<th>Satisfied with the intervention (n = 13)</th>
<th>Dissatisfied with the intervention (n = 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age median</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Age range</td>
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<td>5–18</td>
</tr>
<tr>
<td>Boys</td>
<td>n = 8</td>
<td>n = 6</td>
</tr>
<tr>
<td>Girls</td>
<td>n = 5</td>
<td>n = 2</td>
</tr>
<tr>
<td>Before CAS</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>FAS</td>
<td>0.37</td>
<td>0.27</td>
</tr>
<tr>
<td>FLACC</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td>During CAS</td>
<td>0.5</td>
<td>4*</td>
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<tr>
<td>FAS</td>
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<td>0.48</td>
</tr>
<tr>
<td>FLACC</td>
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<td>0.5</td>
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<tr>
<td>After CAS</td>
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<td>2.25*</td>
</tr>
<tr>
<td>FAS</td>
<td>0.37</td>
<td>0.27</td>
</tr>
<tr>
<td>FLACC</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* Significantly higher (p < 0.05) compared to those who were satisfied with the intervention.

a CAS 0–10; a high score indicates pain.
b FAS 0.04–0.97; a high score indicates distress.
c FLACC 0–10; a high score indicates pain.
During–After
0.011*
0.028*
0.108
0.450
0.063
13)
0.109
107
n
0.327
8)
0.197
<
0.018*
0.05.
Pain scores by CAS before, during and after the procedure in the satisfied
During
After
Pain scores by CAS before, during and after the procedure in the dissatisfied
After
(\textsuperscript{4}).

whereas the present study
(\textsuperscript{4}) but clinical evidence
(\textsuperscript{4}). In our study design we used an autostereoscopic display to bring about a 3D effect, which may indicate that full immersive VR is superior to an autostereoscopic display in reducing pain and distress. Differences could also be the result of different choices of games.

The interviews in this study indicated that both the equipment and the game should be adapted to the procedure and the child playing the game. Although the children sometimes saw a 3D effect, they did not think it was necessary for the distraction. In another study, 16 of 22 children selected a video game compared to four children who chose VR when undergoing a needle-related procedure (\textsuperscript{4}). An adapted game and equipment without perfect 3D is probably more important for distraction and presence than raising the immersive effect by using a head-mounted display. The opposite suggestion and recommendation was described in other studies (\textsuperscript{4}; \textsuperscript{5}) but clinical evidence of positive effects during a needle-related procedure is still lacking (\textsuperscript{6}). So far, there is no evidence of the choice of immersive versus non-immersive VR in clinical practice (\textsuperscript{7}). Further research is needed to answer this question.

Another difference between the three VR studies described above (\textsuperscript{4}; \textsuperscript{5}) and this study was cultural context. Those studies using a head-mounted display during a needle-related procedure were all conducted in the USA (\textsuperscript{4}; \textsuperscript{5}; \textsuperscript{6}) whereas the present study was conducted in Sweden. In further research, cultural differences of VR would be an interesting approach.

In this study, reported pain and distress scores were low. Low scores for pain during venous punctures and subcutaneous venous port devices have been described in other studies as well (Gershon et al., \textsuperscript{4}; Windich-Biermeier et al., \textsuperscript{5}). On the other hand with the FLACC, a mean score of seven was reported during subcutaneous venous port access with EMLA-crème (Badr Zahr et al., \textsuperscript{6}). In our study, all children were familiar with the procedure, i.e. a venous puncture or an insertion of the subcutaneous venous port device. Children with cancer who had experience of needle-stick often developed a form of coping with the procedure (Windich-Biermeier et al., \textsuperscript{7}). A study reported that 7 out of 17 of the children undergoing cancer treatment were worried when they had injections and vein punctures compared with 14 out of 22 of the children off treatment (Enskaar and von Essen, \textsuperscript{8}). This may be a reason to explain why most children and adolescents

<table>
<thead>
<tr>
<th>Table 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison of changes (Wilcoxon signed rank test) in CAS, FAS, FLACC before, during and after the procedure in two subgroups.</td>
</tr>
<tr>
<td>Satisfied with the intervention</td>
</tr>
<tr>
<td>CAS</td>
</tr>
<tr>
<td>FAS</td>
</tr>
<tr>
<td>FLACC</td>
</tr>
<tr>
<td>Dissatisfied with the intervention (n = 8)</td>
</tr>
<tr>
<td>CAS</td>
</tr>
<tr>
<td>FAS</td>
</tr>
<tr>
<td>FLACC</td>
</tr>
</tbody>
</table>

*\( p < 0.05. \)

for heart rates during the intervention with VR, and the nurses also reported a significant reduction of pain with VR (Gershon et al., \textsuperscript{4}). The main difference between those two study designs (Gershon et al., \textsuperscript{4}; Wolitzky et al., \textsuperscript{5}) and the present one, except for the choice of game format, was the use of a full immersive VR, i.e. a head-mounted display, during the intervention with VR. In our study design we used an autostereoscopic display to bring about a 3D effect, which may indicate that full immersive VR is superior to an autostereoscopic display in reducing pain and distress. Differences could also be the result of different choices of games.

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![Fig. 5. Pain scores by CAS before, during and after the procedure in the dissatisfied participants.](image1)

![Fig. 6. Pain scores by CAS before, during and after the procedure in the satisfied participants.](image2)
in this study managed the procedure well with low median pain and distress scores. The FAS scores had a lower median than those reported in another study using FAS in children undergoing venous punctures (median 0.57–0.69) (Goodenough et al., 1999). Although that study included younger children, i.e. 4–10 years, this indicates that the children and adolescents in our study managed their distress during the procedure well.

The interviews showed that non-immersive VR helped the children and adolescents to manage the needle-related procedure. The positive findings from the interviews have implications for staff on paediatric oncology units who are seeking to help a child or an adolescent to cope with such procedures. The qualitative interviews added valuable information about children’s emotional reactions to non-immersive VR in the care situation not evident from the quantitative data. Children who were satisfied with the game and VR equipment reported in general low CAS scores. Children enjoying the VR equipment and game probably experienced better benefit and effect of the intervention. This conclusion supports the theme the VR game should correspond to the child and the medical procedure. The hypothesis also supports the belief that if children have the ability to self-select the distracter, the distracter will more effectively captivate their interests (Windich-Biermeier et al., 2007).

Fanurik et al. (1993) categorized children into attenders or distracters. Attendees were children who were directing their focus of attention towards the procedure. Distracters were children who were directing their focus away from the procedure. In two different studies the effects of distraction were not immediately apparent for children identified as attenders (Fanurik et al., 1993; Tsao et al., 2003). The children who were dissatisfied with VR in this study may be attenders when exposed to distraction, which may not be a good coping strategy.

The virtual world in this study was designed to provide calm experience for the participants. However, no child or adolescent reported any calming effect of the environment in the interviews, and self-reports of distress were not significantly different for the two groups. Further research is needed to explore whether the virtual world itself has any effect on distress or pain. An earlier study compared a heat and a cool virtual world but did not find any differences in the effects of the different environments; both cold and a hot environments were pain reducing in that study (Mühlberger et al., 2007).

**Methodological considerations**

Clinically significant change in acute pain of CAS is estimated to be a reduction of 2.4 cm (McConalhay et al., 2007). The lack of significant reduction of pain or distress as measured by quantitative measures may indicate the need for a larger study population; however, other research has found significant effects of VR with a small group, i.e. 20 participants (Wolitzky et al., 2005). Other reasons for the lack of quantitative differences may be the procedure, the non-immersive VR or the virtual world. However, the FLACC scores indicated different behaviours in the intervention group and this confirms that an observational pain scale is an important complement to self-report scales. The interviews lasted for a short time, on average 8.5 min, but brought the research question a more complete answer. For example, the interviews created the opportunity to analyse the thoughts of children who used a game and VR equipment.

**Conclusion**

Although the quantitative data did not confirm a reduction of pain or distress as a function of the non-immersive VR, results from the observational pain scores showed a decrease and the interviews indicated that VR could be a positive experience. Further use of VR should focus on adaptation of the equipment and the game to the procedure and the player.

**Conflict of interest statement**

None of the authors have any financial or personal relationships with participants or organizations that could inappropriately influence their work.

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**References**


School-aged children’s experiences of postoperative music medicine on pain, distress, and anxiety

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Summary

Aim: To test whether postoperative music listening reduces morphine consumption and influence pain, distress, and anxiety after day surgery and to describe the experience of postoperative music listening in school-aged children who had undergone day surgery. Background: Music medicine has been proposed to reduce distress, anxiety, and pain. There has been no other study that evaluates effects of music medicine (MusiCure®) in children after minor surgery. Methods: Numbers of participants who required analgesics, individual doses, objective pain scores (Face, Legs, Activity, Cry, Consolability [FLACC]), vital signs, and administration of anti-emetics were documented during postoperative recovery stay. Self-reported pain (Coloured Analogue Scale [CAS]), distress (Facial Affective Scale [FAS]), and anxiety (short State-Trait Anxiety Inventory [STAI]) were recorded before and after surgery. In conjunction with the completed intervention semi-structured qualitative interviews were conducted. Results: Data were recorded from 80 children aged 7–16. Forty participants were randomized to music medicine and another 40 participants to a control group. We found evidence that children in the music group received less morphine in the postoperative care unit, 1/40 compared to 9/40 in the control group. Children’s individual FAS scores were reduced but no other significant differences between the two groups concerning FAS, CAS, FLACC, short STAI, and vital signs were shown. Children experienced the music as ‘calming and relaxing.’ Conclusions: Music medicine reduced the requirement of morphine and decreased the distress after minor surgery but did not else influence the postoperative care.

Keywords: children; music medicine; nursing; pain; postoperative
Introduction

Nonpharmacological methods that make it easier for children to cope with surgical procedures have been recommended to reduce distress, anxiety, and pain (1). The use of music is one such method. Listening to prerecorded music has been defined as music medicine contrary to active music therapy, in which a music therapist is involved (2). A commonly accepted theory explaining the pain, stress, and anxiety reducing effects is that the music acts as a distracter focusing the patient’s attention away from negative stimuli to something pleasant and encouraging (3).

In adults, music medicine has been shown to provide relaxation during procedures and to reduce the levels of postoperative pain and morphine consumption (3–6). Music medicine has also been found to have sedative-sparing effects, and decreased levels of stress hormones have been demonstrated (7,8). A meta-analysis (2) and a systematic review (3) have not shown any difference between researchers’ or patients’ selected music.

In children, music medicine and active music therapy have mostly been studied during awake procedures such as immunization and dental treatment (9). In the pediatric anesthesia setting studies evaluating preoperative music found less anxiety with music (10–12). Music medicine was as effective as active music therapy. There has been little effort to study effects of postoperative music medicine in children (9). However, some positive effects were shown in an intensive care unit after cardiac surgery in children aged 1 day to 16 years (13).

The aims of this study were first to test whether postoperative music listening reduces morphine consumption or pain, distress, and anxiety after day surgery and secondly to describe the experience of postoperative music listening in school-aged children who had undergone day surgery.

Methods

Children aged 7–16 were recruited from the pediatric day surgery unit at the Queen Silvia Children’s hospital, Gothenburg, Sweden. Data were collected in previously selected days depending on the schedule of surgery and nurses on duty. Children with cognitive or hearing impairments were excluded from the study, as were children or parents who did not have a good command of Swedish and children who had dental or ear–nose–throat surgery. The Regional Medical Ethics Review Board of Gothenburg approved the study (Dnr: 207-7). All participants received oral information about the study, and all parents and children who could read also received written information. Oral informed consent was obtained from all participants, and a written consent was collected from all parents and children older than 12 years of age. Eighty protocols were allocated to music or control from of a randomized pack of cards. The protocols were placed in opaque envelopes and opened in a predetermined order. Forty participants were randomized to the music group and another 40 participants to the control group. All children got identical preoperative information about the procedures and the study. The children, parents, and staff did not know if the participant was randomized to the music group or control group until after surgery.

The music chosen, MusiCure®, was soft and relaxing. This music has earlier been used in adults (4). The music player used was Maysound®. It has two loudspeakers surrounding the participant’s head. The music player was placed in the bed for all children. In the intervention group, the music started at admission to the postoperative care unit (PACU) and continued for 45 min. In the control group, the music was never turned on.

Morphine consumption

Administration of morphine was based on predetermined guidelines with a Coloured Analogue Scale (CAS) score (14) or a Face, Legs, Activity, Cry, and Consolability (FLACC)-score (15,16). Children with a score >4 were offered morphine but the child always had the possibility to abstain from morphine.

Self-report

Pain and distress measurements by self-report were recorded preoperatively at the arrival to the ward, postoperatively when the child left the PACU and 1 h later in the day care ward. These scores reflected the same moment as measurements were collected. The children used the CAS for scoring pain intensity from 0 to 10. The Facial Affective Scale (FAS) was
used for rating the level of distress by marking one of nine faces presented in an ordered sequence from least (0.04) to most distressed (0.97) (14). The children also filled in the short form of State-Trait Anxiety Inventory (STAI) (17) in conjunction with their first and last self-report of the CAS and the FAS. This instrument is a short form of the STAI with six questions. The range for the short STAI is 6–24 points, six points signifies no anxiety and 24 points signifies the highest level of anxiety. The original STAI has been widely used to evaluate anxiety in studies of music in conjunction with anesthesia (3). The STAI was originally designed for adults but has earlier been used in adolescents for the evaluation of music in conjunction with medical procedures (18).

Observations
All observations were made by one researcher, and two experienced nurses all of whom were familiar with the pain scales. The nurses observed the children in the PACU and recorded FLACC scores every 15-min during 45 min and before the child left the PACU. The FLACC contains five categories, each of which is scored from 0 to two providing a total score ranging from 0 to 10 (15,16). Respiratory rate, heart rate, and saturation were also recorded every 15-min during the 45 min.

Interviews
Following completion of the intervention, semi-structured qualitative interviews, based on an interview guide, were conducted with the 40 children in the intervention group. The interviews were recorded using an MP3 player and transcribed verbatim. In addition, the child was asked if he or she would like to use music during any later need for surgery.

The day after the surgery a researcher asked all children two questions by telephone, i.e., ‘What did you think about the postoperative care?’ and ‘How was your sleep the night after the visit on the pediatric day surgery unit?’ These two questions had four standardized answers, i.e., bad, not so good, good, or very good. If the answer was bad or not so good the researcher asked about the reason for this answer.

Data analysis
Quantitative data
Calculation of sample size was based on expected self-reported pain scores and morphine consumption in an earlier published study of music medicine in adults (5). With a difference of one step between the CAS scores in the intervention group and control group, a standard deviation (SD) of 1.5 and a power of 0.80 at least 36 participants were needed. For a difference in morphine consumption even a lower number was needed. It was decided that each group contained 40 participants. Statistical significance was set at $P < 0.05$. The risk ratio (RR), 95% confidence intervals (CI), and absolute risk reduction for morphine consumption was calculated. Chi-square test was used to compare numbers of participants who needed morphine and anti-emetics and to analyze the telephone inquiry. Mann–Whitney $U$ test was chosen to analyze differences between the study groups in self-reported parameters and observed pain and Wilcoxon signed rank test for comparing changes before and after the procedures. Demographic data, administered medication, heart rate, and oxygen saturation were analyzed using $t$-test.

Qualitative data
All interviews were read and analyzed by using a qualitative content analysis, and the texts were selected to condensed meaning units in an organized manner (19). Each time a condensed meaning unit arose in the texts, it was counted to value the magnitude. This step follows recommendations for combining quantitative and qualitative methods in content analysis (20). The meaning units were subsequently abstracted to categories and eventually abstracted to themes (19).

Results
Quantitative data
This study was conducted between October 2007 and late October 2008. Ninety-two children were consecutively asked for participation, 12 children declined to participate, and data were finally recorded on 80 children aged 7–16, ASA I–II (Figure 1).

Demographic data, analgesics and anti-emetics administered pre- and peroperatively, and type of
surgery are presented in Table 1. No substantial differences between groups were found. Total intravenous anesthesia with propofol and alfentanil was provided in all cases except one where thiopentone and sevoflurane was used. Propofol was administered for induction in 74 cases and inhalation with sevoflurane in six cases.

Significantly, fewer children in the music group (1/40) compared to the control group (9/40) received morphine in the PACU (P < 0.05). The RR was 0.11 (95% CI 0.015–0.828), and the absolute risk reduction was 20%. Total morphine administration was significantly lower in the music group 4 mg (mean 0.10, SD 0.63) compared to 30.5 mg (mean 0.76, SD 1.58) in the control group (P < 0.05). Pain scores >4 were found in five children in the music group and in seven children in the control group in PACU. Four children with pain scores above four in the music group abstained from morphine compared to no one in the control group. Two children in the control group reported pain and received morphine but were not awake enough to use the CAS, and the FLACC did not indicate pain. Three children in the control group required anti-emetics after morphine administration. No statistically significant difference in medication between the study groups was found during the 1-h observation on the ward until the last scoring of the CAS, the FAS and the short STAI.

Figure 1
The consort E-flowchart.
this period, one child in the control group received morphine compared to no one in the music group.

A significantly higher individual decrease in the FAS scores was found in the music group compared to the control group. No other significant differences between the two groups concerning the FAS, the CAS, the FLACC, the short STAI, and vital signs were shown (Table 2). In both study groups, the CAS scores were higher and the short STAI scores lower after than before surgery.

Seventy-nine out of 80 participants answered the telephone call. Regarding the postoperative care, 61/79 of the participants were satisfied (good/very good), and 18/79 were dissatisfied (not so good/bad). The causes for dissatisfaction were pain, nausea, and dizziness. No significant difference was found between the music (6/40) and the control group (12/39). The question about first night sleep quality showed that 59/79 participants slept well (good/very good), and 20/79 had a disturbed night sleep (not so good/bad). There was no difference between the music group (10/40) and the control group (10/39). Thirty-four of the 40 children would have chosen music for a subsequent surgical procedure.

Qualitative data

One theme emerged and represented an overall pattern for the interviews; Postoperative music is a distracter that is calm and relaxing. The interviews contained information about how and why the music helped the well-being and making the postoperative period smoother. The theme emerged from four categories and one of these was; ‘The music is soft and it helps you to think about the nature.’ The music helped the children to manage the situation in PACU and one participant said; ‘It was really good, it made you feel you were going for a country walk.’ The category ‘It is beneficial with music, which helps you to a good wakening’ suggests that music helped the children to manage pain. One participant

### Table 2

<table>
<thead>
<tr>
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<th>Preoperatively</th>
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<tr>
<td>Music</td>
<td>0 (0–4.75)</td>
<td>1.88 (0–6.25)</td>
<td>2 (0–6.25)</td>
</tr>
<tr>
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<td>1.13 (0–9)</td>
<td>2.25 (0–8.5)</td>
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<tr>
<td><strong>P-value</strong></td>
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<td>0.654</td>
<td>0.472</td>
</tr>
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<td><strong>FAS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Music</td>
<td>0.47 (0.04–0.97)</td>
<td>0.37 (0.04–0.79)</td>
<td>0.37 (0.04–0.79)</td>
</tr>
<tr>
<td>Control</td>
<td>0.37 (0.04–0.79)</td>
<td>0.47 (0.04–0.79)</td>
<td>0.42 (0.04–0.79)</td>
</tr>
<tr>
<td><strong>P-value</strong></td>
<td>0.087</td>
<td>0.624</td>
<td>0.329</td>
</tr>
</tbody>
</table>

**Short STAI**

|                      |                |                         |                |
| Music                | 10 (6–24)      | 9 (6–21)                |                |
| Control              | 10 (6–17)      | 9 (6–16)                |                |
| **P-value**          | 0.608          | 0.504                  |                |

STAI, State-Trait Anxiety Inventory; PACU, postoperative care unit; FAS, Facial Affective Scale; CAS, Coloured Analogue Scale.

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thought it was beautiful with music, which gave protection from other environmental noise, ‘You woke up calm and it was beautiful, nicer than listen to babies that cry I think.’ The category ‘You should be able to select music even if calm music probably is preferable’ indicated that children preferred to select music and one participant said ‘I do not believe that you would like to use your own music, but it had probably been better if you got the possibility to select music.’ The theme was finally reflected in the category ‘The music made the technical equipment negligible and not disturbing.’ The participants thought the equipment was comfortable and did not disturb them. One participant said ‘You do not notice the equipment and you are able to communicate while you listen’.

Discussion

Morphine use was lower in the music group than in the control group during PACU stay. The reduction in morphine was consistent with the qualitative interviews where music medicine seems to be a useful complement for postoperative well-being. In adults, fewer requests for opioids have been reported with music medicine. In that study pain scores decreased with music but no differences were found for anxiety or heart rate (21). In a systematic review, music was also found to have opioid reducing effects (22). The clinical importance for reduction in postoperative nausea and vomit (PONV) is unclear. In our study, PONV were not recorded but actually three children in the control group required ondansetron after morphine administration.

Children decreased their individual FAS scores in PACU compared to preoperatively with music medicine. We did not find any other important differences in pain, distress, or anxiety between the groups with and without postoperative music medicine. Music seems to act as a distracter and actually makes the child to endure the amount of perceived pain.

An increased sound level in the staff’s working environment could be an adverse effect of music (23). In our study, the music was individually administered and the participants with music medicine appreciated this environmental exclusion. However, this might also exclude some communication between the child and the staff.

The qualitative interviews indicated that the children preferred to select and participate in the decisions of music medicine. Similar results have been found in children using Virtual Reality (24). The children in our study experienced calmness and relaxation with the researchers selected music as adults have reported with MusiCure® (4,8). These results showed that this music style regardless of age is useful postoperatively for relaxation and calmness.

Disturbed night sleep was found in 19/79 participants (24%) related to pain compared to 23/175 (13%) in an earlier study in the same unit (25).

This study has some methodological considerations. We did not collect interviews in the control group to compare with the interviews of children using music medicine. The short STAI is not validated in children but is easy to use. The short form may be preferable compared to original STAI with a long checklist and many items, which sometimes become a hindrance (17). This study did not use a blinded design for the postoperative period, which might lead to a sense of missing intervention in the control group. It could influence participants and staff’s behaviour regarding morphine administration but structured guidelines were used in order to minimize this effect. It is difficult to make a study design blinded with a nonpharmacological method because it is often impossible to create a trustworthy placebo. For that reason, it could even better to have an open study; a blinded study with a not trustworthy placebo may give false conclusions.

Conclusion

Music medicine reduced the requirement of morphine and children’s distress scores (FAS) after minor surgery but did not change observations (FLACC and vital signs) or self-reported pain (CAS) and anxiety (short STAI). Children experienced the music as ‘calming and relaxing.’

Acknowledgments

We thank all the children who participated in the study, generously gave their time and shared their experiences. We would also like to thank Britt-Marie
Karlsson and Eva Norling for data collection. Finally, we would like to thank Per Thorgaard for sharing his knowledge about postoperative music. The Ebba Danelius Foundation and the Wilhelm and Martina Lundgrens Foundation funded this research project.

Potential conflicts of interest
All authors declare that they have no conflicts of interest.

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