Having a Feel for Others' Pain

Empathie voor pijn van anderen

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Although very few people die of pain, many die in pain and even more live in pain (EFIC* declaration, 2001).

Voor mijn ouders,
Deze dag had ik graag met jullie gedeeld.

EFIC* = European Federation of IASP Chapters (IASP= International Association for the Study of Pain)

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Introduction

Pain is a phenomenon so common that almost all individuals become familiar with this sensation at some point in life. Some consider it as unavoidable and others as a challenge that has to be defeated. During the second part of the last century researchers became interested in the neurobiological source and regulation of pain, the use of assessment instruments to "objectify" pain, and treatment options for distinct patient groups and types of pain. Meanwhile we have become aware of the negative impact of pain on quality of life, recovery from surgery and survival, as well as the risk of acute pain turning into chronic pain [11, 15, 17-18, 22].

Babies and intellectually disabled individuals of all ages have often been excluded from pain studies; for long it was believed that they were unable to experience pain [20]. For infants and young children this belief was not specifically based on a scientific rationale but more on a lack of knowledge about the status of the myelinisation process of the nerves in neonates, the individual variability in drug disposition and fear of harmful side effects of analgesics and narcotics [21]. Intellectually disabled individuals have always been considered to be unable to experience or suffer from pain [24]. This misconception was partly based on absence of visible emotion during potentially painful situations, like continuing to walk with a broken hip or leg [19]. Such observations seemed more important than the knowledge that a condition is known to be (extremely) painful in individuals that are not intellectually disabled.

Fortunately enough we have done away with these misconceptions. A landmark publication of Anand and Hickey in 1987 reported huge circulatory and metabolic complications in (prematurely born) neonates after ligation of a patent ductus arteriosus without fentanyl compared to children that received fentanyl [2-3]. Since then it was acknowledged that babies are capable to feel pain and require treatment just like in older patients.

For intellectually disabled individuals there was no such specific turning point. Nevertheless, perhaps inspired by findings in young children, we have seen increasing attention for their quality of life, which includes their pain experience. This experience might be influenced by their specific characteristics, i.e. etiology of their disorders and progressive neurodegenerative diseases. Meanwhile several pain observation scales for intellectually disabled individuals in different age groups and situations have been developed [6,13,19,23,25,26].

Three pain observation scales were developed in the Erasmus MC-Sophia's Children Hospital, for three different patient groups. First came the COMFORT behavior (COMFORT-B) scale in 2000. It was adapted from the COMFORT scale which was originally developed for the assessment of distress in children between 0 to 18 years on the intensive care

unit [1,29]. The COMFORT-B scale was validated for the assessment of postoperative pain in children between zero and three years [30] and for pain assessment in children born with Down syndrome [27].

Next came the Checklist Pain Behavior (CPB) in 2003, which was developed and validated for the assessment of postoperative pain in intellectually disabled children [25]. Further study proved that item reduction was feasible, which resulted in the final CPB scale consisting of 10 items [10].

The third is the Rotterdam Elderly Pain Observation Scale (REPOS) from van Herk and coauthors which came available in 2009. It was validated for the assessment of pain in non-communicative adults and cognitively impaired elderly [31].

For all three scales we produced an instruction CD-ROM that pays attention to use of the instrument, establishing inter-rater-reliability, and – importantly – implementation of the instrument. All three pain observation scales have been implemented into daily practice of other hospitals and institutions. Train-the-trainer sessions were offered for further support of the implementation. The process of implementation and embedding in routine care has proved to be a complicated one because it requires a change in working methods. Implementation of pain assessment is considered as a first step towards improvement of pain treatment, although evidence is scarce [12].

Studies on the validity, reliability and feasibility of using these pain scales in different situations and patient groups form the basis of this thesis. Previous studies have already confirmed validity and usefulness of the COMFORT-B scale in different samples and settings [4-5, 7-9, 14, 16, 32]. Only one study evaluated suitability of the CPB for the detection of pain in intellectually disabled adults[28]. The REPOS has not yet been the subject of other studies.

The following questions form the basis of this thesis:

1. Is a shorter observation period with the COMFORT-B scale feasible?
2. What is the sensitivity to change of the COMFORT-B scale when used in patients in the pediatric intensive care unit?

3. What is the prevalence of pain in institutionalized elderly adults?
4. Is the COMFORT-B scale valid to assess pain and distress in newborns and infants with Down's syndrome?

5. What is the prevalence of pain in residents of Dutch residential homes?
6. What is the prevalence and the intensity of pain of residents of a nursing home, the characteristics of their pain and the analgesics that were prescribed to them?
7. Is pain measurement a feasible performance-indicator for Dutch nursing homes?

This thesis is divided into three sections.

I: The young and vulnerable; i.e. children admitted to the intensive care unit

This section present two studies on the COMFORT-B scale. The first deals with question 1: is a shorter observation period feasible? The second deals with question 2: if the COMFORT-B has the sensitivity to detect changes after an intervention.

II: intellectually disabled children

This section also presents two studies. The first describes an exploratory study with question 1: What is the prevalence of pain in institutionalized intellectually disabled individuals. The second deals with question 2: Is the COMFORT-B scale valid to assess pain and distress in newborns and infants with Down's syndrome?

III: Elderly with and without an intellectually disability

This section presents three studies, two of which describe the prevalence of pain in residents of, respectively, four nursing homes and three residential homes in the Netherlands. They were based on the following questions 1: What is the prevalence of pain in residents of Dutch residential homes? And Question 2: What is the prevalence and the intensity of pain of residents of a nursing home, the characteristics of their pain and the analgesics that were prescribed to them?

The third reports on the feasibility of pain assessment as a performance-indicator in a nursing home. The question it deals with was: Is pain measurement a feasible performance-indicator for Dutch nursing homes?

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PART 1

THE YOUNG AND VULNERABLE

Chapter 1

The COMFORT Behavior scale; Is a shorter observation period feasible?

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Abstract

Objective: The COMFORT behavior scale (COMFORT-B scale) has been validated for postoperative pain in 0 to 3-year-old children. Scoring is preceded by a 2-minutes observation period, which nurses may consider too long. The objective of this study was to test the reliability of a 30-seconds observation period.
Design: Observational study.
Setting: One level III intensive care unit at a university children's hospital.
Participants: Designated pain specialist and all nursing staff.
Interventions: None.
Measurements: The pain specialist and caregiving nurse each conducted a bedside COMFORT-B assessment and assigned an additional pain rating on the 11 point Numerical Rating Scale (NRS-11).
Main Results: Total COMFORT B-score for the 2-minutes observation was 17 or higher in 19% of the patients and 11% for the 30-seconds observation. The mean COMFORT-B score for the 2-minutes observation was 13.5 (SD 3.8); that for the 30-seconds observation 12.7 (SD 3.7). The mean difference therefore was 0.8 (CI 0.6-1.1, paired *t*-test, p <0.001). Sensitivity and positive predictive value for the 30-seconds observation were 0.44 and 0.80 respectively.
Conclusions: A 30-seconds COMFORT-B observation increases the risk of underscoring pain. Therefore, the two-minutes observation period should be adhered to in the interest of the patients.

Introduction

Ambuel and colleagues developed the COMFORT scale to assess distress in the pediatric intensive care setting [2]. In a randomized controlled trial in newborns and infants in our institution, the scale was validated for postoperative pain [6]. The scale's physiological items proved superfluous and were excluded, leaving a shortened version which we termed the COMFORT Behavior scale (COMFORT-B scale) [6,3,3-4, 6]. This version has also been validated to assess distress in mechanically ventilated children [3,4]. Cut point values for postoperative pain and distress were determined based on a 2-minutes observation period [8]. Therefore, and in line with the original instructions [1], nurses are instructed to observe patients for two minutes preceding the actual scoring.

In the ten years that we have been using the COMFORT-B scale, we have noted that nurses are often impatient and not always observe the patient for 2 minutes. They tend to reduce the recommended 2–minute period – even to 30 seconds. This might be understandable in view of the nurses' heavy workload. The question remains, however, whether scores assigned after a shorter observation period are still reliable? We therefore aimed to answer this question: "Does a 30-seconds observation period yield the same results as the recommended 2-minutes observation period?"

Methods

Instruments

The COMFORT-B scale asks observers to consider intensity of six behavioral manifestations: Alertness, Calmness, Respiratory response (for ventilated children) or Crying (for spontaneously breathing children), Body movements, Facial tension and Muscle tone. For each of these items, five descriptions are provided reflecting increasing intensity of the behavior in question; these are rated from 1 to 5. Summating the six ratings leads to a total score ranging from 6 to 30. Scores from 17 to 30 are thought to suggest pain or distress; these scores in combination with NRS pain of 4 or higher suggest pain [8].

The NRS-11 is a global pain rating scale which asks to rate pain intensity by number (0 = no pain and 10 = worst pain) [9]. The NRS-11 assessment is intrinsically linked to the COMFORT-B scale and expresses the expert opinion of the nurse to complement the behavioural observation with the COMFORT-B scale. This expert opinion can take patient-related, environmental characteristics into account. A nurse-led pain and distress management protocol is in place in our unit. In this protocol analgesic and sedative treatment is guided by the combination of COMFORT-B and NRS-11 scores.

Design and setting

All 133 nurses in our hospital's pediatric intensive care unit (PICU) were invited to conduct two COMFORT-B bedside observations together with the pain specialist (AB). The great majority of these nurses are trained pediatric intensive care nurses (85%) or general pediatric nurses with additional skills in PICU work (13%). They all had been routinely trained in COMFORT-B scoring, and sufficient interrater reliability had been established. In the first of the two observations either the pain specialist or the nurse singly started a 2-minute observation; after 90 seconds had elapsed, the other observer started a 30-second observation. Thus they stopped simultaneously. One of the two then lifted the patient's arm or leg to assess muscle tone, which is one of the items to be assessed. Observation period was measured with a digital timer. Both observers then independently completed the COMFORT-B scoring form and assigned an additional pain rating on the 11-point Numerical Rating Scale (NRS-11) [10]. This was always done directly after the COMFORT-B assessment, and thus in this study it was done concurrently with the 30 seconds and 2 minutes assessments. Roles were reversed for a second observation in another patient. All scores were entered in a database.

The local ethics committee was informed about the study and waived parental consent because pain observation is seen as standardized care.

Analysis

Normally distributed data are presented as mean and standard deviation (SD) and non-normally distributed data are presented as median and interquartile range (IQR). The paired *t* test was used to compare scores of the two different observation periods. ANOVA repeated measures was used to tease out the effects of observation time; 30 seconds vs. 2 minutes and observer; nurse vs. pain specialist.

We calculated the sensitivity, specificity, positive and negative predictive values of the 30-seconds COMFORT-B and NRS-11 scores in comparison to those of the 2-minutes scores, which were considered the gold standard. The cut point value for the COMFORT B scale was 17; for the NRS-11 it was 4 (suggesting pain).

Results

Observations took place in the period January until August 2009. Of the eligible 133 nurses, 118 (89%) participated in the study. The other 15 could not participate due to prolonged illness, vacation or heavy workload. The 236 observations were conducted in 80 children, of whom 60 (75%) were surgical patients.

A combination of COMFORT-B of 17 or higher and NRS-11 of 4 or higher occurred in 8 of the 236 two-minutes assessments (3.4%). In comparison; over the year 2009 we have found scores suggesting pain in only 5.3% of 12575 observations.
The mean COMFORT-B scores for the 2-minute observation was 13.5 (SD 3.8); that for the 30–second observation 12.7 (SD 3.7). The mean difference therefore was 0.8 (CI 0.6-1.1, paired *t*-test, p <0.001). In 25 observations (10.6%) the 2-minutes COMFORT-B score exceeded 17 whereas the 30-seconds score did not.
ANOVA for repeated measures with observer as a covariate revealed statistically significantly different scores for the two observation periods ($F=3.899$, $p < 0.05$). The covariate distinguishing between expert and nurse was not statistically significant ($F=2.463$, $p < 0.5$).
The sensitivity and positive predictive value for the 30-seconds COMFORT-B scores compared to the 2-minutes scores were 0.44 and 0.80 respectively. The specificity and negative predictive value were 0.97 and 0.88 respectively. For the NRS-11 the sensitivity and positive predictive value for the 30-seconds scores were 0.75 and 0.86 respectively; the specificity and negative predictive value were both 0.99.

Conclusion

From the findings of this study we may conclude that observation for thirty seconds rather than the recommended two minutes creates a greater risk of underscoring pain.
A fixed observation period increases the reliability of pain observation. From this point of view it is remarkable that not all pain observation scales provide recommendations on observation time. Van Dijk et al [7] found that only nine of 18 postoperative pain scales for infants and children provided recommendations on the observation period; ranging from five seconds to several hours. A short duration naturally is commendable for daily practice. But would five seconds be long enough to reliably establish the severity of pain? Several hours may sound more reliable but is neither realistic nor applicable for daily practice and certainly not for a PICU setting. Children would potentially suffer too long until pain relief can be expected. Therefore we feel that a two-minutes observation period is a good compromise. As an observation period of 30 seconds indeed seems to be less sensitive to pain, it is not in the interest of the patient and therefore not the best practice. We recommend maintaining a two-minutes observation period for the COMFORT behavior scale.

Limitations of the study:
The COMFORT behavior scale has a few limitations. One drawback of the scale is that a score of 3 on the item 'muscle tone' represents 'normal muscle tone' whereas a score of

3 on the item 'calmness' represents an 'anxious' state. Furthermore, it may be confusing that the COMFORT behavior scale is applied in postoperative patients [6,5] as well as in mechanically ventilated children to assess distress and sedation level [2,3,4].

These limitations suggest that in future psychometric studies a different approach from confirmatory factor analysis towards item response theory would be of interest to identify the underling empirical structure of the scale and to estimate the relative importance of items.

In our study only a small percentage of assessments suggested pain thanks to standardized pain and distress management at our PICU. To compare raters we would ideally have had a larger variability in scores. Although a limitation for the study this is a blessing in clinical practice.

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Chapter 2

The COMFORT behavior scale enables the identification of clinical meaningful differences

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Abstract

The COMFORT behavior scale (COMFORT-B scale) is widely used in pediatric intensive care units to assess young children's pain and distress [72]. It was never studied, however, if the scale is sensitive to detect changes in pain and sedation levels after treatment interventions. Answering this question was the objective of this retrospective study in our pediatric intensive care unit. The COMFORT-B scale comprises of 6 items and total scores range from 6 to 30 with scores of 17 and higher requiring an intervention. We analyzed COMFORT-B scores obtained in 797 observations, before and after an intervention, in 190 children from September 2009 to September 2010. Scores suggesting pain were seen in 758 observations with a mean COMFORT-B value of 20.0 (SD 3.7) before and 14.1 (SD 4.7) after intervention. Multilevel regression analysis on repeated measures showed a 5.9 points mean decline after intervention ($p < 0.0001$). The magnitude of the decline in COMFORT-B scores is not statistically significantly affected by number and type of interventions or time between assessments. A second dataset consisted of 39 before and after observations concerning oversedation. The median COMFORT-B score increased statistically significantly (before median 10; IQR 9-11 vs. median 11; IQR 9-12, $p=0.002$).

In case of pain or undersedation, the COMFORT-B score after a pharmacological intervention was below 17, indicating good responsiveness. This is the first study demonstrating that the COMFORT-B scale is able to detect treatment related changes. This implies that COMFORT-B assessments can effectively guide analgesic and sedation treatment in critically ill children.

Introduction

Pain assessment in neonates and young children is a very challenging aspect of pediatric care, witness the many available pain assessment scales for patients of different ages and indications [28]. The COMFORT Behavior scale (COMFORT-B scale) has gained a place in pediatric intensive care settings worldwide [3]. Adapted from the original COMFORT scale that aimed to measure discomfort in children and adult intensive care patients [1,2], the COMFORT-B scale has been validated to measure postoperative pain in 0- to 3-year-old infants [25], including those with Down syndrome [24]. Level of sedation [7,16] measured with this scale was found to be moderately to highly correlated with several other pain scales [3,9,17,25]. A scale's external validity should be established by psychometric evaluation in different samples and settings across time [4,6,7,11,16]. Sensitivity to change, defined as the ability of a measure to detect statistically significant changes after pain treatment, is a relevant psychometric property for pain instruments [18,5]. Another relevant property is responsiveness, which is the property to detect a clinically meaningful change in a clinical state [20]. Intensive care patients will receive analgesics and sedatives to relieve possible pain and distress. The question is whether the COMFORT-B scale is able to detect the intended effects of these drugs, as reflected in lower scores some time after the intervention.

We wondered, however, whether the decrease in COMFORT-B scores would be affected by type and number of drugs given different treatment approaches and time elapsed between before and after assessments. To answer this question we applied a mixed model approach.

Methods

Instruments

The COMFORT-B scale consists of six behavioral items: Alertness, Calmness, Respiratory response (for ventilated children) or Crying (for spontaneously breathing children), Body movements, Facial tension and Muscle tone. Each item has five response alternatives rated 1 to 5 describing the different intensities of the behavior in question. Summating the six ratings leads to a total score theoretically ranging from 6 to 30. A score of 17 or higher requires an intervention according to the pain and sedation protocols of the ICU. The 11-point NRS is a global pain rating scale which asks to rate pain intensity by number (0 = no pain and 10 = worst imaginable pain). It can be used for self report and proxy report [28]. The NRS assessment is intrinsically linked to the COMFORT-B assessment, adding the nurse's expert opinion taking into account contextual factors, such as

patient-related or environmental characteristics. All NRS scores in this study are proxy scores, referred to as NRS_{obs} scores.

The Nurse Interpretation of Sedation Score (NISS) is reference score to facilitate a comparison between the COMFORT-B scale and the clinical judgment of the attending nurse [16]. The NISS score is the nurse's expert opinion of the level of sedation, reflected by one of these categories: 1 Insufficient sedation; 2 Adequate sedation; 3 Oversedation.

Severity of illness was measured with the pediatric index of mortality version 2 (PIM 2) [23] and the pediatric risk of mortality score version III (PRISM III);[22]. Both scores give an estimation of the risk of mortality.

Design and setting

We conducted a retrospective cohort study. Data over 12 months (September 2009 to September 2010) were retrieved from the digital patient data management system of the pediatric intensive care unit in the Erasmus MC- Sophia Children's Hospital, Rotterdam, the Netherlands. Patients were between 0 to 18 years of age.

Data collection

Data included COMFORT-B scores, (NRS_{obs}) scores for pain and NISS scores. We created two datasets. The first included all COMFORT-B scores, NRS_{obs} scores and NISS scores indicative of pain or undersedation before analgesic, sedative or nonpharmacological intervention as well as the corresponding scores of reassessment within 120 minutes after intervention.

The second set included all COMFORT-B scores and NISS scores indicative of oversedation before tapering off analgesics or sedatives as well as the corresponding scores of reassessment between 120 minutes and 240 minutes after intervention.

COMFORT-B scores of 17 or higher combined with an NRS_{obs} score of 4 or higher were considered indicative of pain [25]. The cutoff points for sedation scores were established in a previous prospective study [16]. Undersedation: COMFORT-B scores of 23 or higher; or COMFORT- B scores of 11–22 in combination with NISS of 1. Adequate sedation: COMFORT-B scores of 11–22 in combination with NISS of 2. Oversedation: COMFORT-B scores of 6–10; or COMFORT-B scores 11–22 in combination with NISS of 3 [16,26].

Data on administered drugs were retrieved from the patient data management system. For each drug the age appropriate half-life time was checked because half-life time may bear on tapering off in case of oversedation.

Statistical Analysis

Non-normally distributed data are presented as median and interquartile range (IQR). Associations between ordinal data were determined with Wilcoxon signed ranks test. All nurses conducted five paired bedside observations with an expert COMFORT-B observer

(AB) in the period January to August 2009 as a refresher's course. The linearly weighted Cohen's kappa for each nurse was calculated. The median kappa was 0.79 for 122 nurses (IQR 0.72 to 0.86). A kappa coefficient of 0.65 or higher is considered to be sufficient [8].

To establish the sensitivity to change a multilevel regression analysis was performed with two levels, i.e. level 1 (repeated assessments within patients) and level 2 (between patients). Multilevel regression analysis was only possible for dataset 1 (COMFORT-B scores that indicated pain or undersedation); dataset 2 was too small. To perform multilevel regression analysis we applied the PROC MIXED procedure (SAS 9.2 Inc., Cary, NC, USA). The Maximum likelihood method was used for estimation purposes. Model 1 evaluated scores before and after an intervention was given across repeated measurements and patients. Model 2 also included a number of time-depending covariables related to medication: sedatives (0=not administered, 1=administered), opioids (0=not administered, 1=administered) and non-opioid analgesics (0=not administered, 1=administered). Furthermore, we added the number of simultaneously applied pharmacological treatment modalities, dichotomized into 0 in case of one intervention and 1 in case of >1 intervention. In addition, to determine the importance of time elapsed between the before and after interventions we trichotomized time elapsed into 0 (5 to 40 minutes), 1 (41 to 80 minutes) and 2 (81 to 120 minutes) as the reference time. We also tested whether the different covariables had a statistically significant effect on the decline in COMFORT-B scores (effect modification). All other data analyses were performed with SPSS version 17.0 (SPSS Inc., Chicago, Il).

Results

Over the selected twelve months period a total of 15.349 COMFORT-B assessments had been conducted in 683 children. 797 paired observations (before and after an intervention) met the inclusion criteria for analysis. These concerned 190 children, 114 boys and 76 girls with a median age of 0.4 years (IQR 0.1 to 1.9). Table 1 presents the background characteristics of these 190 children.
Dataset 1 (pain or undersedation) concerned 758 before and after observations in 185 children; dataset 2 (oversedation) 39 before and after observations. Twenty-three children were included in both datasets.

Undersedation or pain
Dataset 1 yielded a mean COMFORT-B score of 20.0 (SD 3.7) before intervention and of 14.1 (SD 4.7) after intervention. Almost three quarters (73.7%) of the 758 COMFORT-B scores after intervention were below 17. Sedatives had been administered in 390

Table 1: Children's background characteristics (N=190)

Sex: m/f; n (%)	114 (60) / 76 (40)
Age in years; 0 to 3; median (IQR) n=157	0.2 (0.0 to 0.7)
3 to 18; median (IQR) n= 33	6.5 (4.7 to 13.4)
PRISM[#]- 3 score; median (IQR)	8.5 (4.0 to 13.3)
PIM^-2 score; median (IQR)	-3.82 (-4.50 to -2.63)
Mechanically ventilated, n (%)	163 (85.8)
ECMO[*] treatment	16 (8.4)
Reason for admission	N (%)
Surgical, n (%)	121 (63.7)
Cardiothoracic	55 (45.4)
Gastrointestinal/ urogenital	32 (26.4)
Cardiorespiratory failure^	16 (13.2)
Neuromuscular	6 (5.0)
Musculoskeletal and skin	5 (4.1)
Craniofacial	4 (3.3)
Ear-nose-throat	3 (2.5)
Nonsurgical, n (%)	69 (36.3)
Cardiorespiratory failure	36 (52.2)
Gastrointestinal/ urogenital	8 (11.6)
Trauma[~]	7 (10.1)
Sepsis	5 (7.2)
Diagnostic (imaging)	4 (5.8)
Neurological	3 (4.3)
Ear-nose-throat	3 (4.3)
Metabolic	2 (2.9)
Other	1 (1.4)

[#] PRISM = Pediatric Risk of Mortality; PIM^ = Pediatric Index of Mortality
[*] ECMO = Extracorporeal membrane oxygenation
[~] Trauma included: near drowning, reanimation, hypovolemic shock and intoxication
^ These children received ECMO treatment, which is considered a surgical intervention

(51.5%), opioids in 142 (18.7%) and both in 114 (15.0%) of the observations. A non-pharmacological intervention was given in 11 (1.5%) observations. In 410 observations (54.1%) one intervention was given; in 348 cases (45.9%) two or more, with a maximum of eight. Table 2 gives an overview of mean COMFORT-B scores in relation to type of interventions, number of interventions and time between assessments.

Table 2: Dataset 1: undersedation or pain (758 before and after observations)

		COMFORT-B score before	COMFORT-B score after
Interventions	N (%)	Mean (SD)	Mean (SD)
Sedative*	390 (51.5)	20.4 (3.7)	14.2 (4.9)
Opioid**	142 (18.7)	19.4 (3.3)	13.6 (3.8)
Opioid and sedative	114 (15.0)	19.5 (4.3)	13.9 (4.8)
Sedative and analgesic	39 (5.1)	19.8 (3.4)	14.5 (4.4)
Analgesic***	36 (4.7)	19.1 (3.0)	13.9 (4.5)
Opioid and sedative and analgesic	15 (2.0)	21.5 (4.2)	16.3 (6.3)
Opioid and analgesic	11 (1.5)	20.3 (3.2)	15.8 (5.4)
Non-pharmacological	11 (1.5)	20.7 (2.9)	15.4 (6.7)
One intervention	410 (54.1)	20.0 (3.6)	14.1 (4.6)
Two or more interventions	348 (45.9)	20.1 (3.9)	14.1 (4.9)
Time to reassessment 5-40 min	97 (12.8)	21.3 (4.2)	14.7 (5.2)
Time to reassessment 41-80 min	403 (53.2)	20.1 (3.4)	14.2 (4.7)
Time to reassessment 81-120 min	258 (34.0)	19.5 (3.9)	13.7 (4.6)

*Sedatives: Midazolam, Clonidine, Esketamine, Propofol, Lorazepam, Alimemazine, Haloperidol, Chloral hydrate, Pentothal

** Opioids: Morphine, Fentanyl, Methadone

*** Analgesics: Acetaminophen, Ibuprofen

Multilevel regression analysis

The multilevel regression analysis yielded a mean decrease (b=-5.93; 95% CI -6.33 to -5.54) in COMFORT-B scores (see also Table 3, Model 1). In the second model, covariables related to type and number of pharmacological interventions and time between assessments were added. The magnitude of decline in pain scores after interventions was comparable between patients with and without sedatives. Nevertheless, there was a small albeit significant difference in that children who received sedatives had on average 0.74 points higher COMFORT-B scores than those who did not receive sedatives, both before and after intervention. The number of interventions did not significantly affect the levels of COMFORT-B scores. When we differentiate between reassessment within 40 minutes compared to when elapsed time between assessments was longer, COMFORT-B scores were 1.5 point higher. Table 3 shows the results of the multilevel regression analyses. None of the different tested covariables had a statistically significant effect on the decline in COMFORT-B scores. In other words effect modification did not emerge. Because of the small numbers non-pharmacological interventions were not included.

Table 3: Mixed modeling of hierarchical data

	b	95% CI	p-value	b	95 % CI	*p- value*
Intercept	19.71	19.32 to 20.09	**<0.0001**	18.51	17.72 to 19.30	***< 0.0001***
Before-after	-5.93	-6.33 to -5.54	**<0.0001**	-5.93	-6.33 to -5.54	***< 0.0001***
Sedatives				0.74	0.03 to 1.45	***0.04***
Opioids				0.32	-0.29 to 0.94	*0.30*
Analgesics				0.19	-0.52 to 0.94	*0.60*
Time[#] 0				1.52	0.81 to 2.23	***< 0.0001***
Time[#] 1				0.64	0.17 to 1.12	***< 0.01***
N intervention[*]				0.02	-0.51 to 0.55	0.93

[#]Time = time elapsed between assessments coding: 0 to 40 minutes equals 0; 41 to 80 minutes equals 1; 81 min to120 minutes equals 2 (reference category)

[*] Number of pharmacological treatment modalities: 0 = one intervention; 1 = 2 or more interventions.

boldfaced p-values are <0.05

b = unstandardized regression coefficient

Oversedation

Oversedation was suspected for 39 paired observations and treated by tapering off the infusion: midazolam or clonidine in 27 (69.2%), morphine in 10 (25.6%) and a combination in 2 (5.1%) observations. The median COMFORT-B score before tapering off was 10 (IQR 9-11) and after 11 (IQR 9-12) (Wilcoxon signed rank test -3.14; p=0.002). Median time to reassessment was 120 minutes (IQR 25=120 and 75=120; minimum 120, maximum 240). Time between assessments was negatively and not statistically significantly correlated to the decline in COMFORT-B scores (r= -.07, 95% CI -0.38 to -0.25,p=.68).

Discussion

The sensitivity to change of the COMFORT-B scale was clinically relevant as shown by the statistically significant decrease in mean scores. Type of intervention and time between assessments did not affect the decline in COMFORT-B scores although scores both before and after intervention were somewhat higher in case of sedation and shorter time between assessments. We expected a larger decline in scores when more than one intervention was given, but this was not the case. Patients who receive more than one intervention are usually the ones who are hard to sedate.

Because the primary objective of pain assessment is to decide whether interventions are effective, sensitivity to change is a very important psychometric property of any pain assessment instrument [18]. The COMFORT-B scale has been compared to other instruments for sedation or pain assessment but sensitivity to change has not been examined before. For sedation assessment, the COMFORT-B scale was statistically significantly

correlated to skin conductance [12] and the Nurses Interpretation of Sedation Score [16]. For pain assessment, the COMFORT-B scale had good concurrent validity when compared to the FLACC [14,17] and the Visual Analogue Scale pain [25]. The fact that the COMFORT-B scale is able to detect the effects of interventions may help to unravel causes of high COMFORT-B scores.

In our study the time to reassessment varied considerably, from 5 to 120 minutes. The optimal time for reassessment after a pharmacological intervention should perhaps be determined by administration route, as this is associated with time to reach maximum effect. An optimum therapeutic effect is strived for by a continuous infusion with an opioid or sedative, supplemented with an IV bolus dose if breakthrough pain or agitation occurs [10]. In the latter case, the effect should be measurable within minutes. An IV bolus is not always possible, however, and the alternative route might be oral, buccal or rectal administration with longer effect time. From our results, however, we find a treatment effect irrespective of time to reassessments.

In case of oversedation and drug tapering, time to reassessment should be geared to the pharmacokinetic profile of the drugs given. In our study oversedated children received midazolam, clonidine and/or morphine. In a previous, prospective unblinded study, lowering the infusion rate had effect already after one hour [10] while the age appropriate half-life time (t1/2) of midazolam in these patients was 5.5 hours [10]. This may also apply to midazolam and/or clonidine [21] (t1/2 5.6 hours) and/or morphine (t1/2 2 to 6.5 hours) [19]. To complicate matters more, clearance of e.g. midazolam might be decreased in more severely ill patients, which calls for a different time frame [27]. Because of the large inter-individual variability in pharmacokinetic and pharmacogenetic profiles it seems best to reassess at least every hour during tapering of sedatives.

After having established a scale's sensitivity to change, the next step is to establish the responsiveness, i.e. is this change clinically meaningful [20]. For the COMFORT- B scale we previously established that a COMFORT-B score below 17 should be aimed for [26]. In the current study the COMFORT-B score after an intervention did not exceed 17 in almost three quarters of the observations, which indicates a good responsiveness.

Strengths and limitations of the study

A strength of our study is the large number of assessments which enabled multilevel regression analysis instead of a simple paired t-test [15]. The model enabled to evaluate the effects of time elapsed between repeated assessments and the effect of different treatment modalities.

A limitation of this study is the risk of bias in our dataset. Nurses often do not repeat COMFORT-B assessments after a successful intervention. Our data therefore may com-

prise only a subset of the potential dataset. Despite the fact that during training the importance of reassessment is underlined, in daily practice it is often forgotten.
Another limitation is the small number of scores that suggest oversedation, therefore we could not apply the multilevel regression analysis to these scores. A possible explanation for the low number is that ICU nurses they tend to underestimate the level of sedation. From a safety perspective this is understandable because well sedated patients are less likely to autoextubate or pull out lines. However, recent research suggests that oversedation is more harmful with prolonged duration of mechanical ventilation and ICU stay [13].

Conclusion

To our knowledge this is the first study that actually demonstrates that the COMFORT-B scale is able to detect treatment related changes. The good sensitivity to change and responsiveness proved once again that the COMFORT- B scale is a valid instrument to assess pain and distress in critically ill children.

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PART II

INDIVIDUALS WITH INTELLECTUAL DISABILITIES

Chapter 3

Prevalence of pain in institutionalized intellectually disabled adults, a cross-sectional approach

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Abstract

Information about pain prevalence in institutionalized intellectually disabled individuals is scarce. This might be explained by the difficulty of pain assessment due to communication problems. We aimed to gain knowledge on pain prevalence and actual pain management in intellectually disabled individuals living in a representative special care facility in the Netherlands.

Methods: Caregivers rated the residents' present pain and overall pain during the preceding week on an 11-point numerical rating scale (NRS). Behavioral pain assessment was in addition performed with the REPOS or CPB, validated pain scales.

Results: Caregivers' ratings suggested that 47 of the 255 included residents (18%) suffered from pain either at present or during the preceding week, 14 of whom (30%) on both occasions. The NRS rating was 7 of higher for 3 residents who were not prescribed analgesics. In only one resident the REPOS assessments suggested pain at the time of assessment.

Conclusion: Ratings for nearly one out of every five residents suggested they suffered pain. This number was lower than we anticipated and could indicate that caregivers underestimate residents' pain and that pain treatment is inadequate. To prevent unnecessary suffering we advise to implement a pain protocol including the use of a validated pain measurement instrument.

Introduction

Many individuals with an intellectual disability (ID) in the Netherlands live in institutions from early life on; in 2010 the number was approximately 20.550 [8]. They have been systematically excluded from pain studies mainly because of the identifiable heterogeneity in etiology, disease stage such as progressive neurodegenerative diseases and immobility due to chronic illness [22,30]. Lack of verbal communication skills, physical handicaps and concomitant morbidity are main determining factors that make pain assessment difficult in these individuals [14,28,35]. Another problem is that they often show no overt behavioral responses to pain or distress. On the other hand, caregivers could misread behavioral responses if they are not properly trained in pain assessment [22]. It is thought, therefore, that pain may be undertreated in individuals with an ID, not only in the Netherlands, but possibly worldwide [20,10]. The more so because individuals with ID often suffer from musculoskeletal disorders, such as arthritis of the cervical spine, which are known to be painful [10]. Also severe spasticity may be associated with painful contractures, joint dislocations and mobility and posture problems [35,10]. All of these health problems may be further complicated with painful conditions such as gastritis and pneumonia [5,10,35]. In spite of all this knowledge information about the prevalence of pain in institutionalized individuals with an ID is still scarce [10]. What is known is the following. An Irish survey under caregivers estimated the prevalence of chronic pain (duration of 3 months or more) in adults with an ID at 15.4% [21,39]. Others, in the Netherlands and the USA estimated the prevalence of (chronic) pain in cognitively impaired nursing home residents at between 47% to 62% [13,40]. A pain prevalence of 84% was reported for children with an ID [6]. Relatedly, pain prevalences of up to 84% have been reported in adults with cerebral palsy, a condition often seen in individuals with an ID [12,23,19].

We report a study aimed at answering the following question: What is the prevalence of pain in individuals with an ID living in a representative special care facility in the Netherlands?

Method

Subjects and settings

The cross-sectional study was performed in a special care facility for individuals with an ID in the Netherlands housing 356 residents living on this location. This facility is run by an organization with in total 3000 employees who provide care to approximately 1450 clients on 43 locations. This institution is a representative for facilities for ID in the Netherlands [26].

This facility houses residents from 7 years to 91 years of age with minor to severe ID (maximum IQ of 70) [1]. Some residents are both intellectually and physically handicapped. All residents are represented by a legal representative [9]. These were sent a letter with detailed information about the project and were asked permission to access the medical file and to perform pain assessments in the resident in question. The study was approved by the Medical Ethics Review Board of the Erasmus University Medical Center and the institution's local board of directors.

Material and procedure

Instruments

The Numerical Rating Scale-11 (NRS) is a validated pain instrument which requires to rate pain by number (0=no pain and 10= worst pain) either by self report or proxy report [18,38]. In this study the caregivers gave a proxy rating based on specific circumstances that might relate to pain. Ratings from 4 to 10 are thought to suggest pain [29].

The Checklist Pain Behavior (CPB) has been validated for postoperative pain and daily pain in 3 to 12-year-old children with an ID [32,11]. It consists of ten behaviors to be scored as present (1) or absent (0); thus the total score ranges between 0 to 10. These behaviors are: tense face; deepening naso-labial furrows; grimace; looking sad, almost in tears; eyes squeezed; panics, panic attack; moaning, groaning; crying, sobbing; penetrating sounds of restlessness and tears. A total CPB-score of 5 or higher combined with an NRS proxy rating of 4 or higher suggests pain [33,11].

The Rotterdam Elderly Pain Observation Scale (REPOS) was validated for acute and daily pain in non-communicative adults and cognitive impaired elderly unable to express pain by self report [37]. It consists of ten behaviors to be scored as present (1) or absent (0). These behaviors are: tense face; eyes (almost) squeezed; raising upper lip; grimace; frightened fearful look; moving body parts; panicky, panics attack; moaning, groaning; sounds of restlessness, verbal expressions; breath holding, faltering respiration. A REPOS score of 3 or higher combined with an NRS proxy rating of 4 or higher suggests moderate to severe pain [37]. The interrater agreement between the four observers (based on 10 REPOS observations was excellent (intraclass correlation coefficient = 0.95).

Procedure

First, the primary researcher (AAB), a pain specialist nurse, asked caregivers if a pain observation of a resident could be carried out. Next, the caregivers were asked by one of the researchers to rate present pain as well as overall pain during the preceding week with the help of the NRS for all residents they took care of. Subsequently, one of the researchers observed all eligible residents for a two-minutes period. After the observation they completed the REPOS form or the CPB form (for residents under the age of 13 years)

[11]. Afterwards, information about the resident's medical history, analgesic prescription and co-medication prescription was collected from the medical records.

Data analysis

Data were analyzed using SPSS version 17.0 (SPSS Inc., Chicago, IL). Non-normally distributed data are presented as median and interquartile range (IQR).

The presence of one or more co-morbidities and the number of co-medication prescriptions were calculated with the multiple response analysis. The interrater reliability of the observers was calculated using the intraclass correlation coefficient. The Chi-square test was used to compare the prevalence of (spastic) paresis and self-injurious behavior between the residents with and without pain.

Results

This cross sectional study took place during four days in August 2009. Consent had been obtained for 286 residents. However, 24 residents were absent during data collection, two were in hospital and for five residents information about pain intensity was missing. The final analysis therefore concerned 255 (89%) residents. (Figure 1) The characteristics

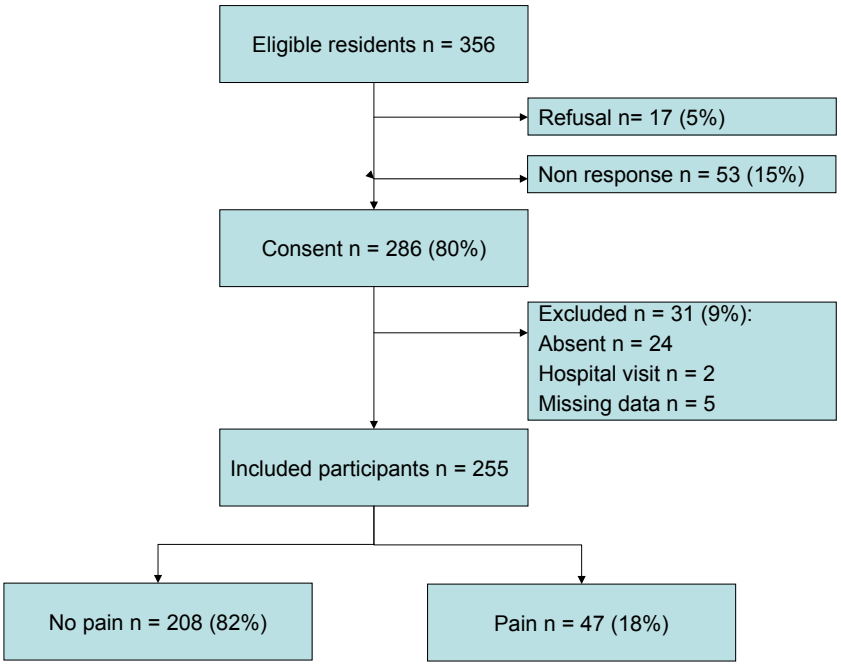

Figure 1: Overview of the residents

of the excluded 31 residents did not differ from those of the included residents (see Table 1). The median age of the residents was 43 years (IQR 34 to 51); five were younger than 13 years.

Etiology for the ID was unknown in almost half (48%) of the residents. Forty-nine residents (19%) had been born with a chromosomal anomaly, including 25 persons with Down's syndrome. Thirty-three residents (17.5%) were diagnosed with (spastic) paresis and 14 (7%) were known with self injurious behavior.

Table1: Characteristics of the residents

	Residents included N=255	Residents excluded N= 31
Male/ female, n (%)	155 (61) / 100 (39)	16 (52)/ 15 (48)
Age in years: median (IQR)	43 (34-51)	39 (19-50)
Etiology of Intellectual Disability	**N (%)**	**N (%)**
Unknown	123 (48.2)	24 (77.4)
Down syndrome	25 (9.8)	3 (9.7)
Developmental anomalies of the CNS	20 (7.8)	-
Chromosomal anomalies	24 (9.4)	1 (3.2)
Post infectious encephalopathy	18 (7.1)	2 (6.5)
(perinatal) hypoxic ischemia	15 (5.9)	-
Posttraumatic brain injury	12 (4.7)	-
Metabolic disorder	11 (4.3)	1 (3.2)
Neurodegenerative disorder	7 (2.7)	-
Relevant Co morbidities* (>100%)		
Epilepsy	70 (37.0)	1 (25.0)
Autism spectrum disorder	44 (23.3)	-
(Spastic) paresis	33 (17.5)	1 (25.0)
Scoliosis/ kyphosis	28 (14.8)	-
Psychiatric or psychological problems	26 (13.8)	1 (25.0)
Self-injurious behavior	14 (7.4)	
rheumatism/ osteoarthritis	9 (4.8)	1 (25.0)
Gastrooesophageal reflux disorder	8 (4.2)	-
Dementia	6 (3.2)	1 (25.0)
Cerebral Vascular Accident	4 (2.1)	
Neoplasm	1 (0.5)	
Diabetes mellitus	-	1 (25.0)

Analgesics prescription* (>100%)	**N = 26 (10.2%)**		**N = 2 (6.5%)**	
	Regular	**PRN**	**Regular**	**PRN**
Acetaminophen	6 (22.2)	12 (44.4)	2 (50.0)	-
NSAID's	6 (22.2)	2 (7.4)	-	-
Fentanyl	1 (3.7)	-	-	
Co-medication* (>100%)	**N = 105 (41.2%)**		**N=7 (22.6)**	
Anticonvulsants	47 (44.8)	-	5 (71.4)	-
Benzodiazepines	29 (27.6)	31 (29.5)	2 (28.6	1 (14.3)
Antipsychotics	11 (10.5)	-	1 (14.3)	-
Hypnotics	7 (6.7)	-		
Anti spastics	6 (5.7)	1 (1.0)	1 (14.3)	-
Tricyclic antidepressants	5 (4.8)	-	-	-
Lithium	1 (1.0)	-	-	-
Corticosteroids	1 (1.0)	-	-	-
Substantial pain	N = 47 (18.4%)			
Present pain NRS ≥ 4	2 (4.3)			
Preceding week: NRS ≥ 4	45 (66.0)			
Both	14 (29.8)			
Pain observation				
REPOS ≥ 3 and NRS ≥ 4	1 (0.5)			
CPB ≥ 5 and NRS ≥ 4	-			

Residents with pain

Caregivers' ratings suggested that 47 residents (18%) were in pain either at the moment of observation and/or during the preceding week. Thirty-one of the 47 (66%) residents suffered from pain during the preceding week and 2 (4%) only at present. Their median proxy NRS rating at the moment of observation was 0 (IQR 0-4); that for pain during the preceding week 6 (IQR 4-7). One of these 47 residents was assigned a REPOS score of 3 or higher at the moment of the observation combined with a proxy NRS rating of 4 or higher, suggesting pain.

Ratings for 14 (30%) of those 47 residents with pain suggested pain both at the moment of the observation and during the preceding week, median proxy NRS values were 5 (IQR 4-5) and 6 (IQR 5-7) respectively.

Ten residents with pain (25%) were diagnosed with spastic paresis versus 23 without pain (17%) (p=0.06). Self-injurious behaviour was statistically significantly more prevalent in the residents with pain than in residents without pain (17.5% versus 4.7%, p= 0.002).
For 8 of the 47 residents in pain the medical record included a medical diagnosis that could explain pain. These were: severe osteoarthritis in hip (n=1) or back (n=1), scoliosis (n=1), colic pain (n=3) and gastro-esophageal reflux disorder (n=1). One resident suffered from colic pain and luxation of the hip.

Analgesic prescription

Seven of the 47 residents with pain (14.9%) were prescribed one analgesic, four on a regular basis and three on as needed base. Twenty of the 208 residents (9.6%) without pain received regular (n=9) or as needed analgesics (n=11). Twenty-one of the residents with pain (45%) where prescribed one or more co-medication on a regular basis and eight (17%) had a PRN prescription (see Figure 2). The NRS proxy rating was 7 or higher for three residents who were not prescribed analgesics.

Pain observation in all residents

The REPOS score was 3 or higher in 26 observations. Tense face was scored as present in 53% of all REPOS observations; raised upper lip was seen in 48% of the observations. The two behaviors that were observed the most had a low positive predictive value of 8% (tense face) and 11% (deepening naso-labial furrow(s) or raised upper lip. Table 2 presents an overview of behaviors seen with positive and negative predicted values in relation to the NRS proxy rating for pain at the moment of observation.

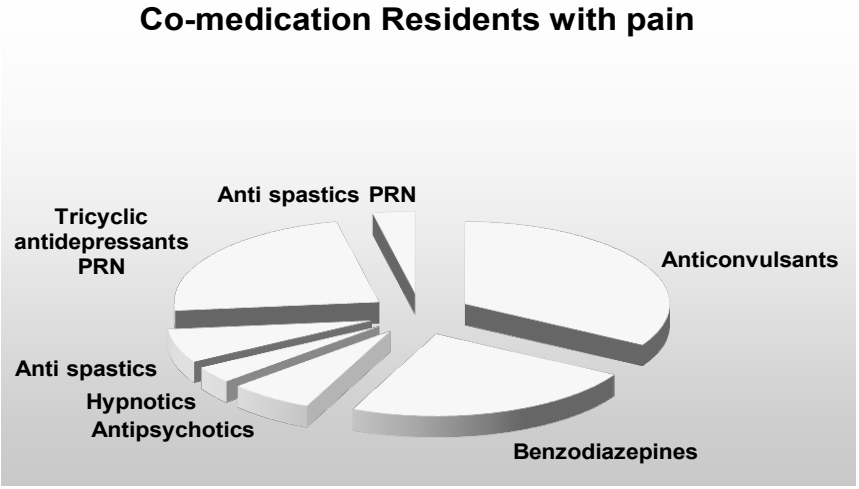

Figure 2: Co-medication in residents with pain

Table 2: items of the REPOS

	REPOS N (%)	PPV %	NNPV %
Tense face	136 (53)	8	96
raised upper lip	122 (48)	11	98
Moving body parts	40 (16)	10	95
Squeezed eyes	33 (13)	12	95
Sounds of restlessness	25 (10)	8	94
Grimace	19 (8)	15	95
Moaning, groaning	6 (2)	17	94
Panicky, panic attack	1	--	94
Breath holding, faltering respiration	1	--	94
Frightened, fearful look	0	--	94

'Abbreviations' PPV=positive predictive value; NPV= negative predictive value
'-' stands for not present in this pain observation scale.

None of the five children younger than 13 years of age had a total CPB score of 5 or higher.

Discussion

Caregivers' proxy ratings suggest that almost one-fifth of these residents suffered from pain. Ratings for three of them even suggested extreme pain (NRS proxy rating ≥ 7) both at the moment of observation and during the preceding week. These residents were not prescribed any analgesics.

The prevalence of 18% we found is low compared to the prevalence of 85% that was described for children with severe intellectual disabilities [6]. This finding is remarkable because ageing is associated with an increased risk of arthritis, cardiovascular diseases, carcinomas, seizures as well as pulmonary, embolism or gastrointestinal diseases [17]. Adults with Down syndrome, for example, are known to be at risk for an early onset of musculoskeletal disorders, degenerative changes in the cervical spine, arthritis, and osteoporosis [2,10]. We would therefore have expected to find a similarly high pain prevalence as described 85% by Breau and colleagues. However, the population, methods in terms of duration of the study, type of informant, and circumstances between the studies differ. In the study of Breau and colleagues [6] one of the parents reported the presence of pain during one year, they were probable very alert for their child's pain [25]. We asked the daily caregivers as well but it is unlikely that professional caregivers in an institute have the same perception towards the pain of their pupils as parents do [31,24]. Furthermore, in our study pain assessment was once whereas in the study of Breau and colleagues the presence of pain was assessed in 4 telephone surveys across one year.

Alarmingly, three residents for whom pain rating suggested extreme pain had no analgesic prescription at all. Undertreatment of pain in individuals with an ID is in line with international reports and also documented in cognitively impaired elderly [15,34,4,36]. In our opinion and based on literature, the low prevalence of pain found and the limited use of analgesics point at an underestimation of pain.

A possible explanation for the underestimation of pain in ID individuals might be that caregivers are unaware of neuropathological changes that may alter pain processing systems in the brain. Scherder and colleagues described such changes in different groups of patients suffering from neurodegenerative diseases such as Alzheimer disease, vascular dementia, Parkinson disease and multiple sclerosis [28,27]. For example, a neuropathological hallmark of Alzheimer's disease is white matter lesions which may cause 'central pain' due to de-afferentiation [28].

As another possible explanation: Caregivers in Dutch institutes for ID individuals usually have no medical or nursing background; they have been trained as a social pedagogical worker [16]. They probably have not been trained in pain assessment (what behavior might be indicative for pain) or pain treatment (what analgesics are useful for what conditions). Not all residents are seen by physiotherapists, who indeed have been trained to recognize pain. Some caregivers consider certain behavior, such as agitation, as typical for individuals with ID and fail to associate it with pain [3]. Besides, even with a medical background it may be hard to 'read' certain behavior as indicative for pain [10,20]. For example, Breau and colleagues found that injurious behavior was attributed to chronic pain in 30% of children [7]. That finding implies that in the other 70% self injurious behavior was attributed to a different cause. Implementation of a validated pain observation scale could help caregivers evaluate fluctuations in behavior and effects of pain medication in a more standardized way [3].

In this study we used the REPOS and the CPB at random moments, not necessarily those in which the residents are engaged in possibly painful activities. This also might have contributed to the relatively low scores. In general, it would be better to use such a scale during a possibly painful moment, e.g. washing, dressing or during physiotherapy, as was done in the original REPOS validation study [37].

Conclusion

We have reason to believe that the prevalence of pain in this study could well reflect an underestimation. To avoid underreport of pain we advise to apply pain observation scales during a potentially painful moment. A next step would be to implement in daily

care an institutional pain management protocol including pain assessment and a decision tree which helps caregivers decide what could be done to lessen a resident's pain.

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Chapter 4

The COMFORT-behavior scale is useful to assess pain and distress in 0- to 3-year old children with Down syndrome

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Abstract

Many PICUs use the COMFORT-behavior scale (COMFORT-B) to assess pain in 0- to 3-year old children. The objective of this study was to determine wheter this scale is also valid for the assessment of pain in 0 to 3 year old children with Down syndrome. These children often undergo cardiac or intestinal surgery early in life, and therefore admission to a pediatric intensive care unit. Seventy-six patients with Down syndrome were included versus 466 without Down syndrome. Pain was regularly assessed with the COMFORT-B scale and the Numeric Rating Scale (NRS). For either group, confirmatory factor analyses revealed a 1-factor model. Internal consistency between COMFORT-B items was good (Cronbach's α 0.84 to 0.87). Cut-off values for the COMFORT-B set at 17 or higher discriminated between pain (NRS pain of 4 or higher) and no pain (NRS pain below 4) in both groups. We concluded that the COMFORT-B scale is also valid for 0 to 3 year old children with Down syndrome. This makes it even more useful in the pediatric intensive care unit setting, doing away with the need to apply another instrument for those children younger than 3.

Introduction

Children receiving intensive care often undergo many painful, invasive procedures, including mechanical ventilation. Many are recovering from major surgery. The resulting pain and distress are treated with analgesic and or sedative agents. Assessment of pain and distress is therefore an important cornerstone of pediatric intensive care treatment and is increasingly used as a performance indicator. Observational tools are needed in preverbal infants and nonverbal children - i.e. mechanically ventilated or sedated children [19]. The Multidimensional Assessment of Pain Scale (MAPS) [17] and the COMFORT-behavior (COMFORT-B) scale are suitable to assess pain and have been validated for the PICU setting [21,3,8,9]. These instruments are based on the observation of typical pain behaviors such as grimacing, cry, body movements and muscle tension.

Other tools may be needed in critically ill infants with intellectual disabilities or neurological impairment because their pain expression may be atypical or less vigorous [18]. The Non-communicating Children's Pain Checklist-Postoperative Version (NCCPC-PV) [2], the Paediatric Pain Profile [7], the revised Faces, Legs, Activity, Cry and Consolability [13], and the Checklist Pain Behavior [4,20] have been validated for postoperative pain in children with intellectual disabilities, from the age of 3 to 4 years onwards. These scales require a long observation period, up to 10 minutes, or require a description of idiosyncratic behaviors. To our knowledge, no such tools are available for younger children with a suspected or known intellectual disability, let alone for the intensive care unit (ICU) setting.

Individuals with Down's syndrome have a 40 to 60% risk of congenital heart diseases and congenital gastrointestinal anomalies that require surgical repair at a young age [3,6]. We have been using the COMFORT-B scale in daily practice since 1999 in 0 to 3 year old children with Down syndrome as well. The manual of the original COMFORT scale does not exclude children with this condition, but validity of the scale for use with Down syndrome patients was not analyzed separately (personal communication Dr. Bruce Ambuel). Many of those children show hypotonia, which could affect their behavior, and thus the score on the item 'muscle tone' [16]. Also, Down syndrome has been associated with a low-pitched, hoarse cry, which could affect the score on the item 'crying' [12]. We wondered, therefore, whether the COMFORT-B scale is really valid in 0 to 3 year old children with Down syndrome.

The objective of the study reported here was to evaluate the psychometric properties of the COMFORT-B scale for the assessment of pain and distress in 0 to 3 year old children with Down syndrome and to determine whether different cut-off values should apply for them.

Methods

Subjects and Setting

The ICU of Erasmus University Medical Center - Sophia Children's Hospital, Rotterdam, the Netherlands serves as the only level III facility for children in a referral area comprising about 4 million inhabitants and 35 000 newborns/year. Admission criteria are major surgery or other conditions requiring intensive care such as trauma, sepsis and the need for mechanical ventilation. Treatment almost always involves painful and invasive procedures. To counteract the consequences, we introduced a standardized pain and distress management protocol in 1999, which has not changed substantially since that time. The key element is application of the COMFORT-B scale and Numeric Rating Scale by observation (NRS_{OBS}) for pain every 8 hour shift at set times (2-10-18 hrs) and on suspicion of pain or distress [8,21,23]. Since November 2002, all COMFORT-B and NRS_{OBS} scores are being prospectively recorded in our Patient Data Management System (PDMS).
The study has been approved by the local ethics committee of Erasmus University Medical Center. The need for informed parental/guardian consent was waived.

The study group consisted of patients with Down syndrome, who met the following criteria: ICU stay between November 2002 and April 2009, confirmed diagnosis of trisomy 21 by genetic analysis, age 0 to 36 months and scores of at least two assessments available. Children without Down syndrome admitted in the reference year 2007 served as a control group. This year is the middle year of the period 2005 (start of PDMS) up to and including 2009. We assume that 2007 is a representative reference year because the standardized mean differences (SMD) in COMFORT-B scores between 2007 versus the other years were small (0.02 to 0.08). Inclusion criteria for the control group were: ICU stay between January 2007 and January 2008, age 0 to 36 months and scores of at least two assessments available.

Instruments

The COMFORT-B scale is a pain and distress assessment instrument that asks observers to consider intensity of six behavioral manifestations: Alertness, Calmness, Respiratory response (for ventilated children) or Crying (for spontaneously breathing children), Body movements, Facial tension and Muscle tone. For each of these items, five descriptions, rated from 1 to 5, are provided reflecting increasing intensity of the behavior in question. Summating the ratings of the six behavioral manifestations leads to a score ranging from 6 to 30. Clinical cutoff scores for the COMFORT-B and NRS_{obs} for pain have been determined. The pain management protocol dictates some kind of intervention (non-pharmacological and/or pharmacological) when COMFORT-B scores of 17 or higher are combined with NRS_{obs} pain ratings of 4 or higher [23].

All nurses undergo a 2 hour COMFORT-B training program when they start to work in our unit. The program includes 10 assessments in different patients, with a qualified nurse performing the same assessments. Agreement is assessed from the linearly weighted Cohen's kappa calculated from these 10 paired assessments. This coefficient corrects for chance agreement [5]. The minimal Cohen's kappa that nurses needed to reach was 0.65. If Cohen's kappa value was below 0.65, the nurse was asked to repeat assessments until the required kappa value had been reached. Median linearly weighted kappa values were 0.81 (IQR 0.77 to 0.87) for 103 nurses.

The NRS is a validated tool that asks patients themselves or proxies to rate pain intensity by number (0=no pain at all and 10= worst imaginable pain) [24]. We refer to the NRS as applied by proxy raters as "NRS_{OBS}" to avoid confusion with the NRS for self-report. The NRS_{OBS} expresses the observer's expert opinion of the patient's level of pain, taking the patients' circumstances (disease-related, treatment related, environmental and patient specific) into account. Several studies compared the NRS_{OBS} or observed visual analog scale to observational pain assessment tools in 0 to 3 year old children [22]. These NRS_{OBS} assessments – part of the pain management protocol since 1999 – serve to differentiate between pain and distress. For instance, a high COMFORT-B score may coincide with a low NRS_{OBS} pain if the nurse knows that the child requires sedation rather than analgesia. The nurse takes this knowledge into account when applying the NRS_{OBS}. Repeating the assessments after interventions is required to monitor the effect of the intervention.
The Nurses Interpretation of Sedation Scale (NISS) is the nurse's expert opinion of the level of sedation, reflected by one of these categories: Insufficient sedation, Adequate sedation, Oversedation. The NISS is applied to infants who receive sedatives and/or opioids. This instrument is comparable to the one used by Marx et al [14]. The NISS was validated in our unit in 2005 [8].

Procedure

All COMFORT-B, NRS_{OBS} and NISS scores for the included patients were retrieved from our PDMS. The following patient data were collected from the medical records: sex; age at first assessment; reason of admission to the PICU; opioid, sedative and paracetamol administration during admission; and ventilatory status.

Statistical analysis

Data were analyzed using SPSS version 18.0 (SPSS Inc., Chicago, IL). All reported P values are two-sided, and P values of less than 0.05 are considered to indicate statistical significance. Summary statistics (mean values and percentages) of repeated pain assessments per patient served to compare results among groups and to correlate COMFORT-B

scores with NRS_{OBS} pain scores at patient level [15]. Pearson product moment correlation coefficient was applied to test the linear association between continuous variables.
The Chi-square test (or Fisher exact test in the case of low predicted cell counts) was used to compare nominal data for the two independent groups. Continuous data were presented as median (IQR). Data were compared between the two independent groups with the Mann-Whitney test or with the *t* test for normally distributed variables.
For these tests, we used all scores of the first seven days of a patient's admission. If patients had been admitted more than once, the data of the longest admission were used. This strategy was aimed at limiting the variability in number of assessments per patient.
First, to test the internal consistency of the COMFORT-B scale, Cronbach's α and corrected inter-item correlations were calculated for each of the two groups.
Second**,** to test whether the factor structure of the COMFORT-B scale is comparable between the two groups, a confirmatory factor analysis was performed with the Mplus software version 5.21 (Muthén & Muthén, Los Angeles, CA). This analysis was based on a maximum of 5 COMFORT-B scores per patient, randomly selected from all scores of the first seven days of the patient's longest admission. The following method was applied: each score was assigned a random number using the UNIFORM function in SPSS. The scores numbered 1 through 5 were entered in the analysis. Seventeen percent of patients had been assessed only 2 or 3 times because of a short admission. In those cases all scores were used in the analysis. The analysis aimed at finding a parsimonious factor model that adequately represents the empirical structure of the COMFORT-B scale for both the Down syndrome and the control group. We also tested a 1-factor model, because Van Dijk et al. earlier found a 1-factor model that adequately described the COMFORT-B scale [21]. The following performance measures of overall fit were used: (1) χ^2 test for model fit: a non-significant value indicates that the model at issue cannot be rejected. To account for the effect of sample size on χ^2 test, the χ^2/df was also used. (2) Standardized root mean square of residuals (SRMR): the lower the SRMR the better the model fits. (3) Root mean squares error of approximation (RMSEA): A value of 0.05 indicates a close fit and values up to 0.08 represent reasonable errors of approximation in the population. Parameters were estimated by the maximum likelihood mean and variance adjusted procedure.
Four models were tested: (1) Invariant error variances for corresponding items across groups; (2) Equal factor loadings across groups; (3) Equal factor means across groups; (4) Invariant residual variances for corresponding items across groups. Because the prefinal model showed that the residual covariances of two items were substantial, the final model allowed for freeing the residual covariances of these two items.
Third, for each group, the COMFORT-B score with the optimal combination of sensitivity and specificity was selected as the clinical cut-off score for pain. NRS_{OBS} values of 4 or

higher served as reference value for pain. Furthermore, the positive and negative predictive values of the COMFORT-B scale were determined for either group.
The area under the curve (AUC) of the receiver operating characteristic (ROC) curve of the Down syndrome group was compared with the AUC of the control group by testing the statistical significance of the difference between these two groups.

Results

Patient characteristics
Seventy-six patients with Down syndrome were included versus 466 without Down syndrome. The demographic characteristics are listed in Table 1. A total of 46.8% of children in the control group were mechanically ventilated, versus 73.7% in the Down syndrome group (P <0.001). Children with Down syndrome underwent significantly more often surgery for associated congenital anomalies (P<0.001). Morphine administration was significantly more frequent in the Down syndrome group (62% versus 45%, P=0.006); the same held true for midazolam (68% versus 51%, P= 0.005).

Pain assessments
Median number of COMFORT-B scores significantly differed between the two groups (P=0.023): a median (IQR) of 9 (4 to 22) in the control group versus a median (IQR) of 16 (8 to 22)] in the Down syndrome group. Mean COMFORT-B score was 12.1 (SD 1.7) in the Down syndrome group versus 12.3 (SD 1.8) in the control group (P=0.31). A total of 7% of the 7439 COMFORT-B scores across both groups were 17 or higher. The percentage of COMFORT-B scores of 17 or higher was calculated for each patient. Median (IQR) percentage per patient was 8.3 (0 to 20) in the Down syndrome group versus 6.7 (0 to 20) in the control group (P=0.48). The median percentage of NRS_{OBS} ratings of 4 or higher per patient was 0 in both groups. NRS_{OBS} pain ratings of 4 or higher were seen in 4.8% of all 6954 NRS_{OBS} pain assessments.
The Pearson product moment correlation between mean NRS_{OBS} pain and mean COMFORT-B scores per patient was 0.45 for the Down syndrome group (P<0.01) and 0.57 for the control group (P<0.01).

Sedation assessments
A median (IQR) number of 10 (1 to 41) NISS assessments in 41.1% of the 542 patients (37.7% in the control group versus 44.7% in the Down syndrome group) were recorded in the PDMS. The median (IQR) percentage of adequate sedation scores was 90.5% (78 to 100) in the control group versus 87.8% (79 to 100) in the Down syndrome group (P=0.33).

Table 1 Characteristics of the 542 subjects, by group

	Down syndrome (n=76)	Controls (n=466)	P value
Male sex, n (%)	45 (59.2)	273 (58.6)	0.92 [a]
Age in days, median (IQR)	81 [42 to 273]	119 [22 to 355]	0.22 [b]
Study period, median (IQR)	3 [1 to 6]	1 [1 to 6]	0.014 [b]
Mechanically ventilated, n (%)	56 (73.7)	218 (46.8)	<0.001[a]
Morphine, n (%)	47 (62)	209 (45)	0.006 [a]
Paracetamol, n (%)	58 (76)	332 (71)	0.36 [a]
Midazolam, n (%)	52 (68)	238 (51)	0.005 [a]
ECMO [d] treatment, n (%)	4 (5.3)	21 (4.5)	0.77 [c]
Reason of admission			
Total surgical, n (%)	54 (77.1)	313 (67.2)	0.014 [a]
Cardiothoracic	32 (59.3)	73 (23.3)	
Gastrointestinal	15 (27.8)	102 (32.6)	
Ear-nose-throat	5 (9.3)	23 (7.3)	<0.001[c]
Craniofacial	2 (3.7)	99 (31.6)	
Other surgery [e]	0 (0)	16 (5.1)	
Total non-surgical, n (%)	22 (28.9)	153 (32.8)	0.014 [a]
Cardiorespiratory failure	17 (77.3)	102 (66.7)	
Gastrointestinal / urogenital	3 (13.6)	11 (7.2)	
Metabolic	2 (9.1)	5 (3.3)	0.29 [c]
Trauma	0 (0)	13 (8.5)	
Infection / sepsis	0 (0)	11 (7.2)	
Other [f]	0 (0)	11 (7.2)	

[a] Chi-square test
[b] Mann-Whitney test
[c] Exact test
[e] Extracorporeal Membrane Oxygenation
[f] Other surgery includes urogenital, orthopaedic, dermatological surgery and tumor extirpations
[g] Other diagnoses includes intoxication, neurological problems and malignancies

Item descriptives and internal consistency

Table 2 lists the mean COMFORT-B item scores and SDs for both groups; the mean scores were derived from all scores of the first 7 days of the longest admission. There were significant differences for four items. However, the SDM between the two groups was low.

The standardized Cronbach's α's varied from 0.84 to 0.87 and all corrected item-total correlations were above 0.54 (Table 2).

Table 2 COMFORT-B item scores and internal consistency measures, by group

	Down's syndrome (1163 scores)	Controls (6276 scores)	P value [a]	SMD [b]
Items, mean (SD)				
Alertness	2.2 (1.1)	2.1 (1.1)	0.10	-0.05
Calmness	1.3 (0.7)	1.4 (0.7)	0.50	0.02
Respiratory response [c]	1.8 (0.8)	1.8 (0.8)	0.61	0.02
Crying [c]	1.3 (0.7)	1.5 (1.0)	<0.001	0.23
Physical movements	2.3 (1.0)	2.2 (0.9)	<0.001	-0.12
Facial tension	2.0 (0.6)	2.0 (0.6)	<0.001	0.12
Muscle tone	2.8 (0.6)	2.9 (0.5)	<0.001	0.21
Corrected item-total correlation	0.54 to 0.72	0.57 to 0.76		
Cronbach's α unstandardized	0.84	0.87		
Cronbach's α standardized	0.86	0.88		

[a] *t* test
[b] Standardized Mean Difference (SMD): Values of Down syndrome group minus values of control group
[c] 54.6% of the scores were scored in ventilated patients (respiratory response) and 45.4% in non-ventilated patients (crying)

Confirmatory factor analysis

Confirmatory Factor Analysis was applied on 347 scores in the Down syndrome group and 2067 scores in the control group. The most plausible model included equal factor loadings, equal residual variances, unequal error variances and unequal factor means. In this model, the item 'Calmness' appeared to be correlated with 'Respiratory response / crying'. 'Facial expression' was correlated with 'Muscle tone'. The fit indices were satisfactory (χ^2 of 101 with 19 degrees of freedom, χ^2/df of 5.3, SRMR of 0.03 and a RMSEA of 0.06). The unstandardized factor loadings varied from 0.36 for muscle tone to 0.86 for body movements both groups. The unstandardized and standardized loadings of the COMFORT-B items for the two groups are listed in Table 3.

Optimal clinical cut-off values

For both groups the clinical cut-off COMFORT-B score of 17 presented with good sensitivity (82% in the Down syndrome group and 83% in the control group) and excellent specificity (92% in the Down syndrome group and 91% in the control group). The positive predictive value was 0.32 in both groups. The negative predictive value was excellent and 0.99 for both groups.

The AUC for the Down syndrome group did not statistically significantly differ from the AUC of the control group (*P*= 0.85). See Figure 1.

Table 3 Unstandardized and standardized factor loadings for the COMFORT-B scale

		Down syndrome (347 scores)	Controls (2067 scores)
Alertness	Unstandardized	1.00	1.00
	Standardized	0.74	0.78
Calmness	Unstandardized	0.63	0.63
	Standardized	0.76	0.76
Physical movement	Unstandardized	0.86	0.86
	Standardized	0.75	0.81
Facial tension	Unstandardized	0.48	0.48
	Standardized	0.70	0.69
Muscle tone	Unstandardized	0.36	0.36
	Standardized	0.54	0.57
Respiratory response / Crying [a]	Unstandardized	0.66	0.66
	Standardized	0.68	0.63

[a] These two items were combined in the confirmatory factor analysis. Respiratory response was scored in ventilated patients and crying in non-ventilated patients.

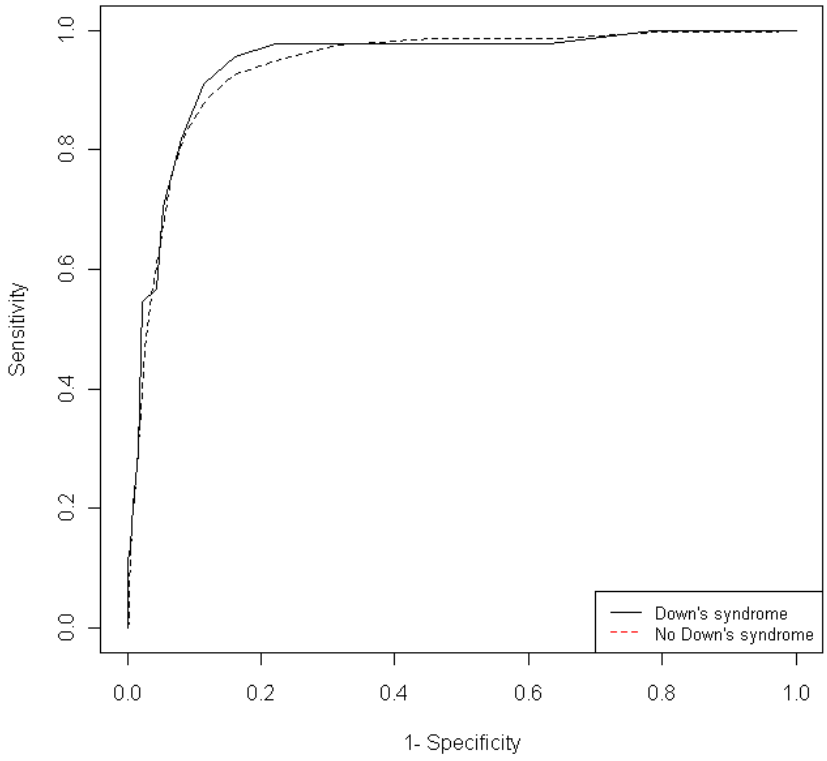

Figure 1: Receiver Operating Characteristic Curve for COMFORT-behavior with NRSOBS pain of 4-10 as state variable Down's syndrome group (solid line) and control group (dashed line)

Discussion

Psychometric properties of the COMFORT-B scale were comparable between 0 to 3 year old patients with and without Down syndrome. Confirmatory factor analysis revealed that a 1-factor model was sufficient to represent the six items of the COMFORT-B scale. The finding that more children in the Down syndrome group were mechanically ventilated and received morphine and midazolam can be explained by the fact this group included more surgical patients.

The current study confirms the 1-factor structure of the COMFORT-B scale when applied in children with and without Down syndrome in the ICU setting. Previous studies have evaluated the original COMFORT scale (eight items) in the pediatric ICU setting using exploratory [1,3] and confirmatory factor analysis [21]. All three studies identified a 1-factor solution for the six behavioral items and one or more factors for the two physiological items blood pressure and heart rate. Omitting the items blood pressure and heart rate resulted in the six-item COMFORT-B scale, which is now often used [3,21]. However, in contrast to the previous studies, the items 'Calmness' and 'Respiratory response / crying' were intercorrelated in the present study, and so were 'Facial expression' and 'Muscle tone'. These additional intercorrelations were required to reach an adequate fit of the model. Confirmatory factor analysis as applied in the present study has important advantages over exploratory factor analysis because it allows for statistical inference modeling. Exploratory factor analysis does not allow for this and gives no information about intercorrelations or significant differences in factor loadings.[10-11] Hence, we recommend the use of confirmatory factor analysis for all future studies in this field.

The mean COMFORT-B scores did not differ significantly between the two groups. The prevalence of pain was low in both groups: COMFORT-B scores were 17 or higher in about 7% of the assessments. NRS_{OBS} pain scores of 4 or higher (an indication for moderate to severe pain) were even more rare (5% of scores). The correlation coefficients between COMFORT-B and NRS pain scores were acceptable in both groups. The number of COMFORT-B scores was higher in the Down syndrome group because they were more often admitted after surgery. In practice, surgical patients are assessed more frequently. Other PICUs have reported comparable prevalences of pain using the same assessment instruments as in the present study. One study by Johansson et al in 40 PICU patients reported a median COMFORT-B score of 12 in the children who were adequately sedated [9]. The NRS_{OBS} pain ratings in that study were 4 or higher in only 6% of the assessments.

Comparing the mean item scores between the 1163 scores of the Down syndrome group and the 6276 scores of the control group, we observed some statistically significant differences. The item scores on the four items "crying", "physical activity", "facial tension"

and "muscle tone" were significantly different between the two groups. The standardized mean differences (SMD) for these items ranged from -0.12 to 0.23; therefore we see these differences as clinically not relevant. Because the mean item score for "crying" was lower, future studies using spectrographic analysis could evaluate the character of the cry of children with Down syndrome. Lind et al. observed that children with Down syndrome have a low-pitched, hoarse cry [12]. The COMFORT-B scale evaluates the intensity of the crying, not its characteristics.
Children with Down syndrome are reported to have a weaker muscle tone [26]. The mean item score for "muscle tone" was lower in the Down syndrome group, with a SMD of 0.21. The small magnitude of this difference may be explained by the fact that the COMFORT-B observer assesses muscle tone by lifting the child's arm or leg, whereas the pediatrician applies an overall assessment of hypotonia. Another explanation may be that nurses will anticipate hypotonia when assessing muscle tone in children with Down syndrome.

The optimal clinical cut-off value of the COMFORT-B scale for pain was 17 for both groups of patients with good sensitivity, specificity and negative predictive value. The positive predictive value was relatively low in both groups. This may be because distress without pain also results in a high COMFORT-B score. In our study, the NISS scores suggest that more than 80% of the children were adequately sedated. Children were treated according to the pain management protocol. More children with Down syndrome received morphine and midazolam, probably because of the higher rate of surgery in this group. The doses of morphine and midazolam did not differ between the groups. Reducing the incidence of pain is highly desirable and PICU's around the world strive for this, but this low incidence of pain may influence the psychometric evaluation of pain assessment scales.

A possible limitation of this study is that background characteristics were collected from charts. Nevertheless, all pain assessment data were retrieved from the patient data management system (PDMS) in which these data are prospectively collected at set time points during a patient's admission. The use of the PDMS assures a satisfactory level of quality and reliability of the data. The second limitation is that the sample size of the Down syndrome group was small. This is in line with other studies in this patient group and is because the incidence of Down syndrome in the Netherlands is 16 per 10,000 live births [25]. In general, it is preferable to have a smaller discrepancy between group sizes.

Conclusion

Previous studies validated the COMFORT-B scale for the assessment of pain and distress in children admitted to the PICU. Nowadays, the COMFORT-B scale has gained wide acceptance in PICUs around the world. Because the COMFORT-B scale now proved valid for 0 to 3 year old children with Down syndrome as well, there is no need to introduce yet another scale. The COMFORT-B scale may also serve as a validated outcome parameter in pharmacodynamic studies in children with Down syndrome.

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PART III

ELDERLY WITH AND WITHOUT A COGNITIVE IMPAIRMENT

CHAPTER 5

Pain prevalence and Characteristics in three Dutch residential homes

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Abstract

Background: In Anglo-Saxon countries, high prevalence rates of pain have been reported for elderly living in nursing homes, residential homes and for community-dwelling elderly. No information on pain prevalence is available for elderly living in Dutch residential homes. Methods: We performed an explorative study on pain prevalence, characteristics and treatment in three residential homes in Rotterdam, the Netherlands. Residents were interviewed using a standardized pain questionnaire. Results: The overall prevalence of pain was 69%. In case of pain, it was chronic in 93% of residents. Present pain and mean pain during the preceding week were substantial (numeric rating scale ≥ 4) in 68% and 85% of residents, respectively. Of the residents with pain, 22% did not receive any analgesics and only 3% was prescribed a strong opioid. When analgesics were prescribed, they were given only 'as needed' in 31% of residents. In a majority of residents, pain interfered with daily living and mood. Almost 60% of the elderly was convinced that pain is a part of ageing, 70% indicated that they did not always report their pain to the caregivers. Thirty-seven per cent was satisfied with the caregivers' and 39% with the doctors' attention towards pain. Conclusions: The pain prevalence rate in Dutch residential homes is similar to rates found in other Anglo-Saxon countries. Furthermore, they are also comparable to rates reported from European nursing homes. Pain treatment is insufficient and although pain interferes with daily activities and mood, elderly tend to accept pain as an unavoidable part of aging.

Introduction

Residential homes offer sheltered living in combination with additional non-complex care. Of the total population in the Netherlands aged 65 or older, 5% live in residential homes (Social and Cultural Planning Office of the Netherlands (SCP)[3] and National Institute for Public Health and the Environment (RIVM) [4]. This percentage represents the highest rate of residential care for elderly in Europe. An Exceptional Medicines Act regulates the funding of Dutch residential homes; residents only pay a small, income-related part of the costs. Residents have their own GPs, to be called in on their own initiative. In comparison with nursing homes, residential homes have fewer caregivers, with lower educational levels. As a result of improved standards of living and the widespread access to medical treatments, life expectancy is increasing. By the year 2040 approximately 25% of the Dutch population will be 65 years or older [11].

With the general ageing of the population, the number of elderly in pain is expected to rise. According to the international literature, the prevalence of pain in elderly is high. In nursing home residents, prevalence rates between 40 - 80% were found [21,29,30,34,48,33,12,39]. Similar prevalence rates have been reported in community-dwelling elderly (25-84%) [10,16,22,23,38,9,34,45,12,37] and elderly living in European residential homes (30-73%) [8],[15],[35]. For Dutch nursing homes, a pain prevalence of 68% was found in two independent studies [42,7]. These and other studies suggest that pain in the elderly is often underreported, not recognized and undertreated [34,48,50,33,31]. What's more, pain may cause depression, anxiety, sleep disruption, limitations in daily functioning and cognitive impairment – thereby reducing quality of life [25,19,50,45]. There is evidence that effective pain management can diminish these added burdens substantially [2,50].

The International Association for the study of Pain (IASP) has dedicated the 2006-07 Global Year against Pain in older persons. The aim is to improve and understand mechanisms of pain in older persons, to improve pain relief in older persons and to distribute information about pain in the elderly. So far, information on pain prevalence in Dutch residential homes for elderly is not available. With the slogan: "Pain relief should be a human right" [26] in mind, we therefore decided to explore various aspects of pain in elderly people in residential homes. The current study used the following research questions: (1) What is the prevalence of pain in elderly living in Dutch residential homes?; (2) What are the pain characteristics and intensities?; (3) Which analgesics are prescribed to residents with pain?; (4) What is the impact of pain on the residents' daily functioning and what are their suppositions about pain (treatment)?

Methods

Setting

The study was conducted as part of an implementation of pain registration program from 2003 until 2006 in three public residential homes in Rotterdam, the Netherlands. The three nursing homes aimed to improve pain treatment by the implementation of pain registration. To ultimately be able to evaluate the effectiveness of the program this study was undertaken as a baseline measurement before the introduction of the program to the caregivers.

Participants

Interviews were conducted successively in May 2003, November 2004 and September 2005 in the first, second and third residential home, respectively. All residents living in that specific home at the time of the study were invited for the interview, except those who had been diagnosed as being cognitively impaired or those suspected to be so.
The efficacy of pain registration had been proven in hospitals and, therefore, ethical clearance was waived. Nevertheless, local director boards approved participation of the study. The residents or their legal representatives were asked written permission to retrieve the medical diagnoses from the general practitioner.

Measurements and definitions

The first author of this manuscript, a clinical nurse specialist in Erasmus MC Pain Expertise Center (AAB) interviewed residents using a standardized pain questionnaire based on the Brief Pain Inventory –Dutch language version (BPI-D) [17] and the McGill Pain Questionnaire, also translated into Dutch (MPQ-DVL) [36,46]. Interviews were discontinued if a resident stated not to experience pain, neither at the time of the interview nor during the preceding week. The residents were asked to rate the intensity of present pain, the mean pain during the preceding week and the tolerable pain on an 11-point numeric rating scale (NRS; 0 = no pain and 10 = worst pain possible). The NRS has been validated for older adults and, in comparison to other pain scales, was shown the best feasible instrument with a good convergent validity, $0.96 \leq r \leq 0.97$, and test-retest reliability, spearman rank 0.68 [13,44].
Substantial pain was defined as pain ≥ 4 on the NRS; such an intensity of pain has been shown to be related to loss of function [40]. Chronic pain was defined as pain lasting at least three months. Pain was considered to be intolerable when the rating for present pain was higher than the rating that was given for tolerable pain [18].

Medical diagnoses were classified according the ICD-10 classification system.

Information on pain medication was collected either from the medication registration system or by checking the resident's medication during the interview. It was classified in steps according to the World Health Organization analgesic ladder [1,52].

To study the impact of pain on daily functioning, residents were asked if pain interfered with sleep, activities of daily living (ADL), social contacts and other daily activities. They could rate the extent of interference of pain on a four-point Likert scale (none, somewhat, fairly and much). Likewise, they were asked if they felt tensed, depressed or anxious as a result of their pain. Furthermore, we asked the residents to pronounce upon five statements about pain and pain treatment. Response categories were: agree, disagree or neutral.

Analysis

Descriptive statistics were used to summarize the results. The median and interquartile range (IQR) were used if variables were not normally distributed. Spearman's Rank correlation coefficient was used to estimate the association between non-normally distributed variables. The degree of correlation was defined according to the usual interpretation of Cohen's rule of thumb (small=0.1-0.3; median=0.3-0.5; large≥0.5) [14]. Data analysis was conducted with SPSS 14.0.

Results

A total of 202 residents lived in the three residential homes. Nineteen residents were excluded because of cognitive impairment. Of the 183 approached residents, 14 refused. The interview was not possible in 12 others for reasons of absence (6), tiredness (2) and deafness (4). So, eventually the pain questionnaire was administered to 157 (77.7%) out of 202 residents. The median age of the interviewed residents was of 88 years (IQR 83-92) (Table 1). Of these 157 respondents, 109 (69.4%) stated to experience pain and/or to have experienced pain during the preceding week (Figure 1). Five of the 48 residents who were pain free (10.4%) regularly took pain medication. Eighty-nine percent of the residents with pain could rate their present pain using the NRS; 79% could so for their mean pain during the preceding week.

Characteristics of pain

Residents most frequently suffered from diseases of the musculoskeletal system and connective tissue, diseases from the circulatory system and from endocrine, nutritional and metabolic diseases, either as primary diagnoses or co-morbidity (Table 2). Correspondingly, pain was experienced most frequently in the legs (32%), the lower back (27%) and the shoulders and arms (13%).

Table 1: Residents and pain characteristics (N=157)

	Median (IQR)
Age in years	88 (83 to 92)
Duration of stay in months	31 (14 to 56.5)
	N (%)
Residents with pain	109 (69.4)
Residents without pain	48 (30.6)
Only Residents with pain	**N (%)**
Chronic pain	101 (92.7)
Acute pain	8 (7.3)
Pain intensities	**Median (IQR)**
Present pain (n=97)	5.0 (3.0 to 7.0)
Mean pain during the preceding week (n=86)	6.0 (5.0 to 7.3)
	N (%)
Present pain $\geq$ 4 (n=97)	66 (68.0)
Mean pain during the preceding week $\geq$ 4 (n=86)	73 (84.9)
Present pain more than tolerable (n=81)	36 (44.0)

IQR=Interquartile range

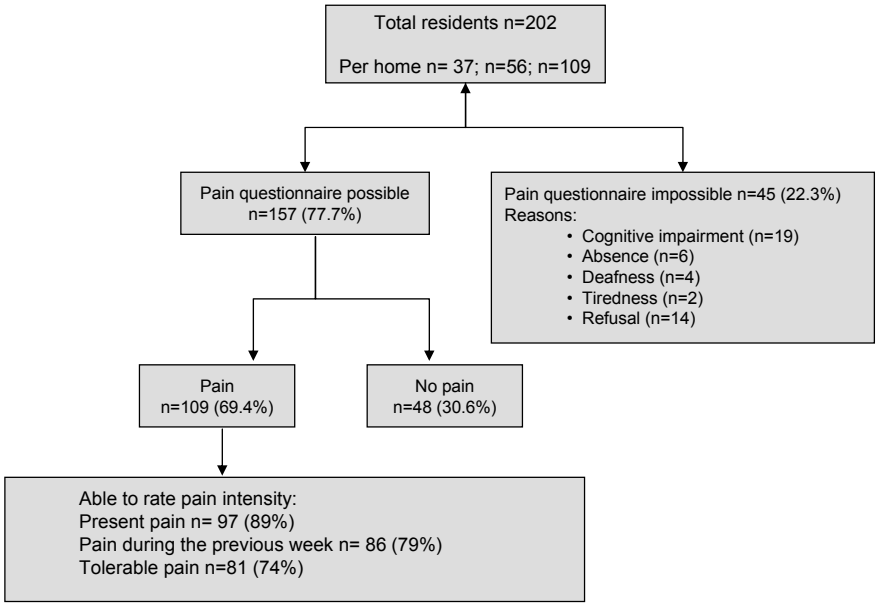

Figure 1: Flowchart of numbers of residents used in the analysis

Table 2: Primary diagnoses and co-morbidity

	Diagnosis N (%)	Co morbidity[1] N (%)
Diseases of the musculoskeletal system and connective tissue	71 (35.1)	48 (32.2)
Diseases of the circulatory system	54 (26.7)	58 (38.9)
Diseases of the nervous system	19 (9.4)	16 (10.7)
Factors influencing health status and contact with health services	12 (5.9)	-
Malignancies	11 (5.4)	12 (8.1)
Mental and behavioral disorders	11 (5.4)	16 (10.7)
Diseases of the respiratory system	4 (2.0)	16 (10.7)
Diseases of the digestive system	4 (2.0)	15 (10.1)
Endocrine, nutritional and metabolic diseases	3 (1.5)	38 (25.5)
Diseases of the skin and subcutaneous tissue	2 (1.0)	1 (0.7)
Symptoms, signs and abnormal clinical and laboratory findings	2 (1.0)	-
Diseases of the ear and mastoid process	1 (0.5)	9 (6.0)
Injury, poisoning and certain other consequences of external causes	1 (0.5)	-
Diseases of the eye and adnexa	-	11 (7.4)
Diseases of the genitourinary system	-	3 (2.0)
Diseases of blood and blood-forming organs	-	1 (0.7)
Missing	7 (3.5)	-

[1]more than one diagnosis can be given

Pain was chronic for the majority of residents with pain (93%). Most residents (54%) experienced unstable but continuously present pain, 27% episodic pain and 16% stable continuous pain. The remaining 3% was not able to describe the characteristics of their pain.

Pain intensity

The median intensity for present pain in the 97 residents who could rate their pain was 5.0 (IQR 3.0-7.0). Present pain was substantial ($\geq$4) in 66 residents (68%). Pain during the preceding week had a median intensity of 6.0 (5.0-7.3) and was substantial in 73 of 86 residents (85%). For 36 of 81 residents (44%) present pain was intolerable (Table 1).

Pain treatment

Analgesics were prescribed in 85 (78%) of the 109 residents with pain: a non-opioid analgesic (WHO step 1) in 60%, a weak opioid (step 2) in 16% and a strong opioid (step 3) in only 3% of the residents. Thus, 22% of the residents in pain did not receive pain medication. Results were similar for the 36 residents with intolerable pain: 22% received no (prescription for) pain medication, 58% a non-opioid analgesic, 14% a weak and 6% a strong opioid.

Table 3: Medication according to the WHO-ladder

	N=109 N (%)
Step 1, Non-opioid analgesics: acetaminophen and non-steroidal anti-inflammatory drugs	65 (59.6)
Step 2, Weak opioids	17 (15.6)
Step 3, Strong opioids	3 (2.8)
No pain medication	24 (22.0)
Prescription:	**(N=85)**
Around the clock	39 (45.8)
Around the clock and as needed	20 (23.5)
As needed	26 (30.6)

When analgesics were prescribed, they were given around the clock (consistent with WHO guidelines) in 69% and only 'as needed' in 31% of the residents (Table 3). The 'as needed' medication was mostly a non-opioid analgesic (89%); for 8% it was a weak opioid and for 3% a strong opioid.

Impact of pain

Half of the residents stated that pain to a various extent interfered with sleep. A majority stated that pain limited ADL and all kinds of other activities. This limitation was rated in 23-32% of the residents as somewhat and in 27-37% as fairly to much. For 36% of the residents pain interfered with social contacts; in half of them the interference was rated as fairly - much. Pain also caused the majority of the residents feeling tensed; the impact was considered fairly - much in 41% of the residents. Twelve percent felt very depressed as a result of pain; 35% to a smaller extent. About a quarter of the residents felt anxious because of the pain (Figure 2).

The mean pain intensity during the preceding week was slightly correlated with restrictions in ADL (Spearman rho coefficient ρ=0.22, 95% CI 0.04 to 0.38; p=0.04) and moderately correlated with restrictions in other activities (Spearman's rho coefficient ρ=0.48, 95% CI 0.32 to 0.61; p<0.001). There was no significant correlation between pain intensity and sleep, social contact, tension, depression or anxiety.

Perception of pain and pain treatment

Fifty-nine percent of the responding elderly with pain agreed that pain is part of ageing. Seventy-two percent of the residents with pain disagreed with the statement that they always reported pain to the nurse/general practitioner or family. About a third of the residents was satisfied with the caregivers' attention to their pain; another third was not. With respect to doctor's attention, this was considered sufficient by 39% of the residents

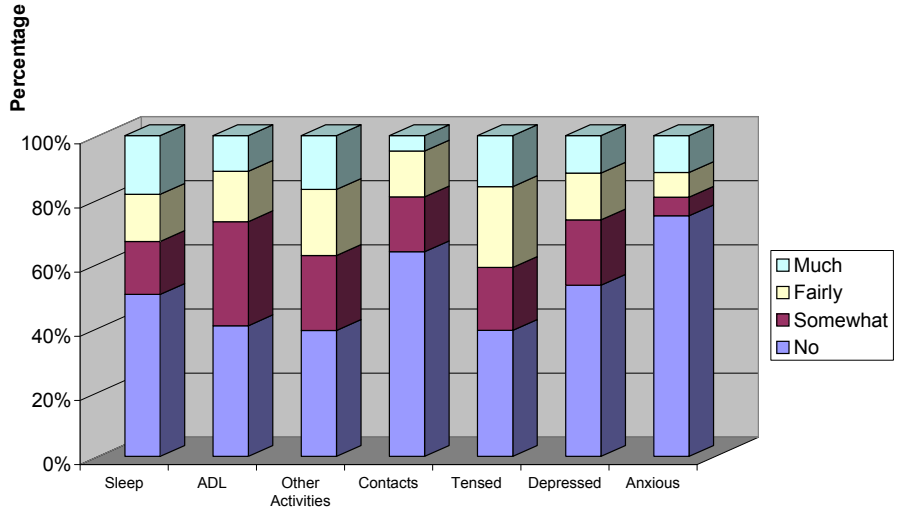

Figure 2: Impact of pain on daily functioning and mood; ADL=Activities of daily living

Table 4: Statements on pain (only residents with pain)

	Agree N (%)	Agree nor Disagree N (%)	Disagree N (%)
Pain is part of aging [a]	63 (58.9)	5 (4.7)	39 (36.4)
I always report my pain to nurses [b]	25 (23.6)	5 (4.7)	76 (71.7)
Caregiver's attention to pain is sufficient [c]	38 (36.5)	29 (27.9)	37 (35.6)
Doctor's attention to pain is sufficient [c]	41 (39.4)	31 (29.8)	32 (30.8)
I am content with the received pain treatment [b]	46 (43.4)	37 (34.9)	23 (21.7)

[a] n=107; b n=106; [c] n=104. Differences in sample size were attributable to some residents not answering the question.

and insufficient by 31% of them. Forty-three percent was satisfied with pain treatment, whereas 22% was not (Table 4).

Discussion

We found a high prevalence of pain in residential homes. Even in residents with intolerable pain, 20% received no pain treatment at all, and 58% received insufficient treatment. The 69% pain prevalence rate and the insufficient treatment for pain are similar to results reported from residential homes in other western European countries [8,15,35]. Furthermore, our findings on pain prevalence and severity in residential homes are similar to results found in nursing homes even though residents in nursing homes are generally more

ill. Likewise; the proportion of residents with pain not receiving pain medication (22%) is comparable to that found for nursing homes (25%) [5,49,50,7,42]. Several possible reasons have been proposed for insufficient treatment of pain in the elderly [5,6,43,34,15,50].

First it may be the residents' mind-set, from which stems reluctance to use medication in general and pain medications specifically [47,33]. Even if medication is prescribed there is no guarantee it is taken. Those who take already numerous pills are reluctant to ingest any more [47,20,33], in spite of the pain and the way this interferes with daily activities. Some feel that by giving up their homes and moving into a residential home they have already lost much of their independency and, although they are not satisfied with the treatment, pain control is seen as the last part of independency [33]. The fact that so many elderly are convinced that pain is a part of old age [51] and therefore unavoidable, may explain their satisfaction with the received pain treatment in this study. This may reflect low expectations rather than the appropriateness of their pain management.

Second, not all caregivers are aware that residents may be in pain. Educational level of most caregivers employed in residential homes for the elderly is lower than that of their colleagues in hospitals and nursing homes, and accordingly they seem to lack knowledge about pain and pain behavior [41,32,33,12]. In addition, high workload may lead to overlooking a resident's pain or habituation to pain problems, so that they are not longer aware of it.

Third, the general practitioners may be reluctant to prescribe a non-steroidal anti-inflammatory drug or a strong opioid for pain medication, fearing the high risk of adverse effects, e.g. renal impairment, increased pharmaco-dynamic sensitivity to opioid analgesics [23,27,47] or drug interactions as a result of poly-pharmacy [28]. Furthermore, they may not be aware that benign pain may cause much suffering.

All residents were asked whether they felt depressed, anxious or tensed as a result of pain. These concepts are regularly used in daily life and are seen as negative emotions. Forty-seven percent of the residents stated to have depressed feelings, 25% felt anxious and 61% felt tensed. Although the results are informative it remains uncertain if all the elderly meant the same by these concepts. Nevertheless, these large percentages underline the need to improve the treatment of pain in residential homes.

Limitations of this study

A limitation of this study was the reliance on the opinion of the caregivers with respect to the cognitive functioning of a resident in case a medical diagnosis was not available at the time of the interview. In retrospect, the Mini Mental State Examination would have been a more reliable and valid measure of cognitive impairment [24].

Another limitation was the fact that the residential homes were not randomly selected. Two homes were part of one organization that aimed to implement pain registration

organization wide. The other home approached the Erasmus MC Pain Expertise Center with a request for support in improving the pain situation of the elderly. These homes do not differ in population from other Dutch residential homes (Dutch Central Bureau for Statistics) but the fact that management planned to improve pain treatment could imply that the pain situation in other residential homes is even worse.

In conclusion, in this study on pain prevalence in residential homes, a total of 69% of the elderly experienced pain. Pain was almost always chronic (93%). Furthermore, two thirds of the residents experienced substantial pain (NRS score $\geq$ 4). Nevertheless, only three per cent of the residents with pain was prescribed a strong opioid as an analgesic, and 22% was prescribed no pain medication at all. Strikingly, these percentages were similar for residents with intolerable pain. We have reason to believe that elderly themselves contribute to poor pain management, being convinced that pain is a part of aging and by that unavoidable. However, according to literature, caregivers and general practitioners also seem to contribute by underestimating the impact of pain in elderly.

Recommendations

The high prevalence of pain underlines the importance for pain relieving actions. An intervention, which teaches elderly not to accept pain as an unavoidable part of aging and to understand that pain medication, is not just the taking of some more pills, but important for their quality of life, should be developed. To identify residents in need for such an education, pain registration should be considered.

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CHAPTER 6

Pain Management in Dutch Nursing Homes Leaves Much to Be Desired

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ABSTRACT

This cross-sectional multicenter study describes several aspects of pain, pain intensity, and pain treatment in a Dutch nursing home population. A standardized pain questionnaire, including the Numeric Rating Scale (NRS), was used to measure aspects of pain and intensity of present pain, pain experienced in the previous week, and tolerable pain. The eligible sample comprised 320 residents (median age 79 years), of whom 233 residents completed the questionnaire. Sixty-six percent (n = 153) experienced (mostly chronic) pain, either in the previous week (median NRS 6) or at present (median NRS 5). Intolerable pain was recorded in 41% of 100 residents. The higher the pain scores, the more interference with activities of daily living was reported. Of the 153 residents with pain, about one-fourth did not receive any pain medication, and 65 (43%) received step 1, 13 (9%) step 2, and 16 (11%) step 3 analgesics. Most residents (60%) were satisfied with pain treatment, and 21% were not. Considering the high prevalences and intensities of pain, pain management in Dutch nursing homes leaves much to be desired. Apparently, residents do not seem to expect effective pain management. Awareness and knowledge about pain assessment and treatment, however, needs to be raised. Pain measurement tools and treatment protocols should be implemented in daily practice.

Introduction

Studies conducted over the last two decades have reported similarly high prevalences of pain in older adults in different countries [5,12,17,22,26,32]. Pain may well reduce quality of life, seeing that it can lead to depression, anxiety, sleep disruption, or limitations in daily functioning and cognitive impairment [11,13,26,34]. Effective pain management, therefore, could diminish these burdens substantially [4,37]. In 2006, the International Association for the Study of Pain launched the Global Year Against Pain in Older Persons to raise awareness and promote research of pain in older adults. Of the several ways to measure pain in older adults, self-report is seen as the gold standard. In a Dutch nursing home population, two studies using the Nottingham Health Profile for self-reported pain found that 47% to 68% of residents reported pain [3]. Another self-report instrument is the Numerical Rating Scale (NRS), which has been validated in older adults and, compared with other pain scales, was deemed to be one of the most feasible, valid, and reliable in a number of studies [8,33].

The present exploratory multicenter study describes several aspects of pain, pain intensity and pain treatment in a Dutch nursing home population. The study aimed at answering the following questions: 1) What is the prevalence and intensity of pain in older adults living in Dutch nursing homes? 2) What are the characteristics of pain and which analgesics are prescribed? 3) What is the impact of pain on daily functioning?

METHODS

Design

The study was embedded in an implementation study of a daily pain registration program from 2001 to 2005 in four nursing homes: in a total of nine somatic wards (two to three per home) and two rehabilitation wards. The boards of directors of all of the nursing homes involved approved the study.

Participants

Residents without cognitive impairment were eligible for this study. They could refuse to participate at any stage during the study.

Measures

A standardized pain questionnaire based on the valid McGill Pain Questionnaire–Dutch Language Version (MPQ-DV) [24,36] was used to determine several aspects of pain (Table 1). Pain intensity was assessed by means of the NRS, which ranges from 0 (no pain) to 10

Table 1: Questionnaire with response categories (n=153)

Questions	Response categories
Previous week pain?	Yes or no
At this moment pain?	Yes or no
No pain, but receives pain medication	Yes or no
Location pain?	Body location
Pain same place(s)?	Yes or no
Since when pain?	Days / weeks / months / years
The onset of pain?	Slowly / suddenly / don't know
Pain changed?	Yes / no / don't know
Course pain?	Periodic/Constant but with varying intensity/ Constant
Pain number at this moment	0 – 10
Pain number previous week	0 – 10
Pain number tolerable	0 – 10
Pain interference with sleep previous week?	no / a little / reasonable / much
Pain interference with ADL in previous week?	"
Pain interference with other activities in previous week?	"
Did you feel tense in previous week?	"
Did you feel anxious in previous week?	"
Pain is part of aging	"
If I am in pain I always report that	Agree / not agree, not disagree / disagree
Nurses have enough attention for my pain complaints	"
Physician has enough attention for my pain complaints	"
I am satisfied about pain treatment	"

(worst possible pain). Residents themselves rated their intensity of present pain, pain in the previous week, and tolerable pain. A score of 0 represents no pain, 1-3 mild pain, 4-7 moderate pain, and ≥ 8 severe pain. A resident is thought to suffer intolerable pain when present pain intensity exceeds his or her tolerable pain rating [10].

The Pain Management Index (PMI) reflects how well pain is managed with pharmacologic interventions. The index compares the analgesic prescribed with the level of pain intensity. To construct the index, the level of pain intensity is categorized as 0 (no pain), 1 (1-3: mild pain), 2 (4-7: moderate pain), and 3 (8-10: severe pain). Residents' self-report by means of NRS for the previous week was used. The pain level was subtracted from the highest level of prescribed analgesics according to the World Health Organization (WHO) ladder, scored as 0 (no analgesics), 1 (step 1), 2 (step 2), and 3 (step 3). The PMI scores can range from - 3 (severe pain and no analgesics) to +3 (no pain and analgesics from step 3). These scores are then dichotomized: negative scores indicate inadequate

pain treatment, and scores from 0 to 3 are considered to be indicative of acceptable pain treatment [7].

Chronic pain was defined as pain lasting at least 3 months. To study the impact of pain on daily functioning in the previous week, residents rated on a 4-point Likert scale (none, a little, much, and quite much) the extent to which pain had interfered with sleep, activities of daily living (ADL), and other daily activities. Likewise, they rated effects on tension, depression, and anxiety in the previous week. We asked the residents to evaluate five statements based on the valid Pain Attitude Questionnaire [9]. Response categories were: agree, disagree, and not agree/not disagree.

The Karnofsky index was completed to assess residents' performance status. Scores range from 0, representing deceased, to 100, representing normal situation without complaints or diseases [19].

We classified residents' most painful diagnoses by the WHO International Classification of Diseases [1]. For example, post-stroke pain was classified under chapter IX (diseases of the circulatory system), severe decubitus under chapter XII (diseases of the skin and subcutaneous tissue), and pain caused primarily by arthritis under chapter XIII (diseases of the musculoskeletal system and connective tissue).

Analgesics were grouped into the steps of the WHO analgesic ladder. Step 1 consists of nonopioids (acetaminophen and NSAIDs), step 2 weak opioids (e.g., codeine), and step 3 strong opioids (e.g., morphine) [2]. Coanalgesics (adjuvants) were classified into four categories, namely, antidepressants, antiepileptics, corticosteroids, and a fourth group of anxiolytics/hypnotics/sedatives, mostly benzodiazepines. A maximum of two coanalgesics per resident were recorded.

Procedure

The researcher administered the pain questionnaire to all eligible residents. This took 3-5 days per home. If the resident reported no pain at present nor in the previous week, and did not receive analgesics, the questionnaire was discontinued. On the day that the questionnaire was administered, the caregiving nurse who knew the resident well completed the Karnofsky index for the resident in question, and demographic and medical data were extracted from medical charts.

Statistical Analyses

Data analysis was conducted with Statistical Package for the Social Sciences (SPSS) 14.0. Nonparametric data are given as median and interquartile range (IQR). Differences in demographics between the four nursing homes were analyzed by chi-squared test and Kruskall-Wallis test. The multiple linear regression method was used to identify interfer-

ences with sleep, ADL, and other activities, with pain intensity for the previous week as dependent variable. For this analysis, the answer categories were recoded into "no interference" (0) and "a little to much interference" (1). As measures, R2 and p value were used. All statistical testing took place at a .05 level of significance (two-tailed).

RESULTS

Characteristics of the Study Population

A total of 320 residents were eligible: 78, 30, 88, and 124 from each of the four participating homes (Table 2). Their median age was 79 years (IQR 73-84), and 70% were female. The median stay in the nursing home was 13 months (IQR 3-33). The median Karnofsky score was 50 (IQR 40-60). Most residents (n =131) were diagnosed with a disease of the circulatory system, followed by musculoskeletal and connective tissue diseases (n = 99) and diseases of nervous system (n = 44). Comorbidities were present in 226 (71%) residents. Diseases of the circulatory system (n = 87) and endocrine, nutritional, and metabolic diseases (n = 63) were the most prevalent comorbidities, followed by diseases of the musculoskeletal system and connective tissue (n = 48), mental and behavioral disorders (n = 38), and diseases of the nervous system (n = 28). Significant differences between the four homes were found for gender (p = .01), duration of stay (p = .03), and Karnofsky score (p = .00) (Table 2).

Characteristics of Pain and Pain Treatment

For 87 of the 320 residents (27%) the pain questionnaire could not be (fully) completed for various reasons (Fig. 1). Of the remaining 233 residents, 153 (66%) reported that they had experienced pain in the previous week, or were in pain now. For most of them (72%) the pain was chronic, and had developed either gradually (63%) or suddenly (36%). Forty-three percent of the residents described pain as periodic, 37% as constant but

Table 2: Residents characteristics by home (NH)

	NH 1 n = 78	**NH 2 n = 30**	**NH 3 n = 88**	**NH 4 n=124**	**P***
Gender female N(%)	56 (72)	25 (83)	68 (77)	74 (60)	.01
Median age in years (IQR)	79.5 (72.5 to 84.0)	80.5 (73.8 to 88.0)	81.0 (75.0 to 84.0)	78.0 (71.0 to 84.0)	.42
Median stay in months (IQR)	14.5 (6.0 to 31.3)	7.5 (2.0 to 24.8)	7.5 (3.0 to 20.8)	16.5 (3.0 to 43.0)	.03
Median Karnowsky (IQR)	40 (40 to 50)	50 (50 to 60)	40 (40 to 50)	50 (40 to 70)	.00

P* two tailed

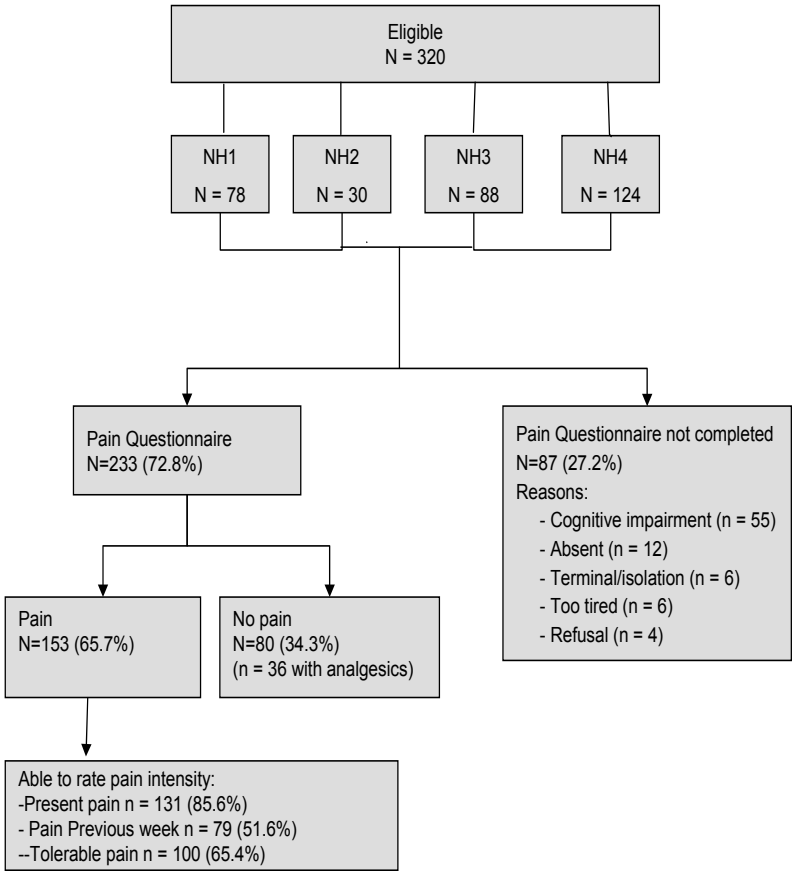

Figure 1: Flow diagram study population

with varying intensity, and 16% as constant. The most reported pain locations were legs (39%), followed by shoulder and arms (19%).

Of the 153 residents in pain either in the previous week or at present, most reported moderate or severe pain (Table 3). Median pain intensity for present pain of 131 residents was 5 (IQR 2-7), and for 79 residents who rated their pain intensity for the previous week the median was 6 (IQR 4-7). Eighty-eight residents reported an NRS ≥ 4 at present. One hundred residents were able to provide an anchor for what they considered to be tolerable pain. The majority (60%) considered a score of 4-6 as tolerable, 20% a score < 4, and 20% a score of 7-10. Of the residents, 41% reported their present pain intensity higher than their rated tolerable pain intensity.

Table 4 presents the highest prescribed analgesics according to the WHO ladder for total group (n = 320), and for those who completed the pain questionnaire (n = 233),

Table 3: Level of pain according to residents

	No pain (0) n (%)	Mild pain (1-3) n (%)	Moderate pain (4-7) n (%)	Severe pain (8-10) n (%)
Present (n = 131)	28 (21.4)	15 (11.5)	50 (38.2)	38 (29.0)
Previous week (n = 79)	2 (2.5)	9 (11.4)	36 (45.6)	32 (40.5)

Table 4: Highest prescribed analgesic according to the WHO

	Total Group N = 320	Completed Questionnaires N = 233	
		Pain (n = 153)	No pain (n=80)
No described analgesics	121 (37.8)	38 (24.8)	44 (55.0)
Prescribed analgesics			
Routine step 1 (nonopioids)	109 (34.1)	65 (425)	17 (21.3)
Routine step 2 (weak opioids)	14 (4.4)	13 (8.5)	1 (1.2)
Routine step 3 (strong opioids)	23 (7.2)	16 (10.5)	-
As-needed	53 (16.5)	21 (13.7)	18 (22.5)
Prescribed coanalgesics			
Benzodiazepines	145 (45.3)	73 (47.7)	33 (41.3)
Antidepressants	36 (11.3)	21 (13.7)	6 (7.5)
Antiepileptics	24 (7.5)	12 (7.8)	4 (5.0)
Corticosteroids	9 (2.8)	7 (4.6)	1 (1.3)

distinguished into residents reporting pain and residents reporting no pain. Of the latter group, 112 residents (48%) received regular analgesics, 39 (17%) received only as-needed analgesics, and 82 (35%) did not receive analgesics at all. The majority of the residents in pain (61%) received analgesics on a routine basis, and 38 (25%) did not receive analgesics at all. Of the 88 residents with an NRS ≥ 4 for present pain, and the 41 residents with intolerable pain at present, 19 (22%) and 12 (29%), respectively, did not receive any pain medication. Thirty-four percent of159 residents were treated inadequately as reflected by the PMI index. About one-half of the total 320 residents, and more than one-half of the 153 residents with pain, received at least one coanalgesic drug. Benzodiazepines were the most frequently prescribed coanalgesics, followed by antidepressants.

Impact and Perception of Pain and Pain Treatment

Out of the 153 residents in pain stated that pain interfered with sleep in 55%, ADL in 61%, and other activities in 53%. This interference was rated in 19%-23% as "a little" and in 30%-43% as "much" to "quite much."

Multiple linear regression analysis was used to explore these influences on the level of pain intensity for the previous week. Only one significant effect was found, the higher

Table 5: Statements about pain and pain treatment

	N*	Agree	Not agree	Neither
Pain is part of aging	145	58 (40.0)	78 (53.8)	9 (6.2)
If I am in pain I always tell the nurse	146	58 (39.7)	69 (47.3)	19 (13.0)
Nurses pay enough attention to my pain complaints	145	86 (59.3)	29 (20.0)	30 (20.7)
My physician pays enough attention to my pain complaints	144	80 (55.6)	38 (26.4)	26 (18.1)
I am satisfied about the pain treatment	146	88 (60.3)	31 (21.2)	27 (18.5)

* Differences in sample size were attributable to some residents not answering the question

the pain scores, the more interference with ADL was reported ($R^2 = 0.11$; $p = .02$). More than one-half of the residents (62%) felt a little to seriously tense, 59% felt depressed, and 31% felt anxious.

Thirty-eight percent of the respondents agreed with the statement "Pain is part of ageing." Only 37% indicated they always told the nurse if they were in pain. More than one-half agreed with the statements "nurses pay enough attention to my pain complaints" and "the physician pays enough attention to my pain complaints." Sixty percent were satisfied with pain treatment, and 19% did not agree nor disagree with this statement (Table 5).

We compared these responses between the four nursing homes involved. The proportion of residents who reported that nurses and physicians paid enough attention to their pain complaints ranged from 37% to 81%. Except for nursing home no. 4, most of residents agreed rather than disagreed with these statements. In nursing home no. 4, 45% of the residents disagreed and 37% agreed with the statement that physicians pay enough attention. The proportion of residents who were not satisfied with their pain treatment ranged between 14% (nursing home nos. 1 and 2) to 33% (nursing home no. 4).

Discussion

In the present study, we demonstrated that pain seems to be a common health problem in the nursing homes involved. Despite the use of different methods of measuring pain, others have reached a similar conclusion for the Netherlands [3,32] as well as for other countries, e.g. the United States, Canada, United Kingdom, and Norway [12,23,27,30]. The present study used one of the most reliable and valid instruments in this population, the NRS [8,33], and found that more than half of the residents reported ≥ 4 using NRS. Scores of this magnitude are thought to indicate a higher risk of functional limitations

and the need for pain treatment [31]. Therefore, our findings confirm the serious problem of pain in older adults. Each individual resident, however, experiences and quantifies pain differently. We therefore calculated intolerable pain as well, and determined that 41% of the residents may have had intolerable pain. This proportion is much higher than that reported by Smalbrugge and colleagues [32], for whom about 15% of the participants responded positively to the question of whether they experienced intolerable pain. The discrepancy is likely a result of the different ways of measuring and defining intolerable pain.

The low completion rates for pain intensity are lower than those in earlier studies, in which most moderately to severely impaired patients could report their pain using the NRS [8,33]. Because one of our exclusion criteria was a cognitive impairment, we expected a higher completion rate. However, because the cognitive level was not measured objectively we can not be certain whether the study group indeed included only residents without cognitive impairment. The completion rate for pain in the previous week was much lower (52%) than that for present pain (86%). We suggest that this may be ascribed to short-term memory problems. A pain observation scale may be helpful when residents are likely to not comprehend the NRS or may be reluctant to report pain [16,35].

The relationship between pain intensity and the use of analgesics deserves attention as well. Pain management was inadequate in 34%, as reflected by the PMI. In these cases, prescription of analgesics was not according to the steps of the WHO ladder. Undertreatment in older adults could be explained from different perspectives. First, physicians may be reluctant to prescribe analgesics for fear of side effects and medication-interaction problems [14]. Second, pain in older adults is often chronic, and this is a type of pain that nurses tend to underestimate [15,25]. Third, as this study also shows, residents may be reluctant to report their pain, assuming that pain is irrevocably associated with ageing. Satisfaction about pain treatment, for that matter, was found to differ between the four nursing homes involved. A possible explanation is that nursing staff differed in educational background and numbers. Homes with more and higher-educated nurses may be assumed to pay more attention to pain and, therefore, to include more satisfied residents. In two of the four nursing homes, no more than one-half of the residents were indeed satisfied, indicating that pain treatment in those homes leaves much to be desired. In the two homes in which satisfaction was highest, management was more directly involved and interested. This can play a crucial role in stimulating caregiving nurses to pay more attention to residents' pain.

Several researchers have established relationships between pain, on the one hand, and emotional states, such as depression and anxiety, and interference with daily activities

on the other hand [6,18,20,29]. Large correlations between pain and depression [21,28] and between pain and anxiety were found [22,32]. In the present study, we asked short questions about emotions and interferences. Only interference with ADL was significantly related to higher pain scores. Future studies would do well to include an emotion-specific instrument.

In conclusion, considering the high prevalences and intensities of pain found in the present study, it would seem that effective pain management is not yet generally accepted in Dutch nursing homes. Nevertheless, residents do not seem to expect this. We believe, therefore, that launching a global decade against pain in older adults is required to achieve a fundamental change in pain management. In the Netherlands, postoperative pain is a performance indicator for hospitals, which raises awareness of pain and improves pain assessment and management. We therefore would like to make a plea for introducing pain as a quality indicator in nursing homes. In addition, multidisciplinary pain teams, responsible for standardized pain registration and effective pain management, should be established. Valid and easy-to-use pain measurement tools and treatment protocols should be implemented.

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Chapter 7

Is pain measurement as a performance-indicator feasible for Dutch nursing homes?

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Abstract

Quality of care gains transparency with the help of performance-indicators. For Dutch nursing homes the current set of performance-indicators does not include pain. To determine the feasibility of pain assessment as performance-indicator information about pain prevalence and analgesic prescription in one nursing home was collected. Within the time span of three days pain intensity was measured in 91% of the residents, either with a numerical rating scale, a verbal rating scale or the Rotterdam Elderly Pain Observation Scale (REPOS). Pain intensity could be established in 201 out of 221 residents (91%) of the nursing home. Numerical rating was used for 72%, verbal rating for 3% and REPOS observation for 25% of the residents. Pain was substantial in 65 residents (32%), who received the following analgesic prescription: WHO step 1; 45%, WHO step 3; 12%, neuroactive agents; 5%. Thirty-eight percent of these residents were in pain and received no analgesics. Residents with substantial pain significantly more often received analgesics (p=0.007). Results suggest that pain assessment is feasible in a nursing home and would stimulate staff attention for pain. Further investigation is necessary to find out if a pain algorithm is feasible and will lead to improved pain treatment.

Introduction

In recent years, quality of care in nursing homes in the Netherlands has received greater attention. This culminated in a joint venture of the Dutch government, nursing home physicians and nurses, patient organizations and insurance companies in 2007, formed to achieve transparency and improvement in quality of care (see website BTSG).
Among the measures aimed at reaching this goal is the development of a set of performance-indicators, including prevalences of pressure ulcers, malnutrition and medication errors (Dutch Health Care Inspectorate, 2008). These outcomes are published on the Internet and therefore available for (future) clients, other nursing homes, health care insurers and the Health Care Inspectorate (see website kiesbeter). This benchmarking enables clients to make an informed choice about selecting a home and nursing homes to improve their standards of care.

The system is comparable to the Nursing Home Quality Measures (Nursing Home Quality Units, 2008) in the USA. There is one exception, however. One of the quality measures in the US is the "percent of residents who have moderate to severe pain" looking back seven days, which is missing in the Dutch system. And regrettably so, for pain is documented to be common in nursing home residents in the Netherlands as well [1;6] with prevalence ratings of 17% to 72% [2, 6, 16, 18, 21] Furthermore, pain treatment is often insufficient [6,11,27]. Up to 20-30% of the nursing home residents with moderate to severe pain receive no pain medication [22,29]. In 2002 the American Geriatric Society (AGS) already stated that the healthcare system has an obligation to provide comfort and pain management for older patients. One of their recommendations was that nursing homes should routinely conduct quality assurance and quality improvement activities in pain management [4].
To determine the feasibility of pain assessment as performance indicator we performed a check in one nursing home in Rotterdam, the Netherlands. Here, caregivers have measured residents' pain on a weekly basis since the implementation assessment in 2002. Caregivers ask the residents to rate their present pain intensity with an 11-point numerical rating scale (NRS; 0= no pain, 10 = worst pain ever). The ratings are visualized on a chart which shows if pain intensity changes and the effect of interventions. With regard to characteristics such as pain prevalence, this nursing home is comparable to other nursing homes in the Netherlands [3,25a,28].
Within the time span of three days in March 2008 we asked all residents of the nursing home who were present during that period to rate their pain by self report. Those who were unable to do this – due to a cognitive impairment, aphasia or language barrier – were observed using the Rotterdam Elderly Pain Observation Scale (REPOS) [23] during a potentially painful moment, usually during daily care or transfer [17]. Diagnosis and analgesic treatment were retrieved from the medical or nursing charts.

A medical doctor (AM) and a nurse specialist pain (AB), both trained REPOS observers, conducted pain assessments and data collection. Interrater reliability between both REPOS observers was good (Cohen's linear weighted kappa 0.76),[8].
Because the efficacy of pain assessment has already been reported and therefore, pain assessment is considered as a standard of care, ethical clearance for the implementation project was waived. Nevertheless, local director board approved the project.

Methods

Instruments

The Numerical Rating Scale (NRS) is a validated pain instrument which asks residents to rate pain intensity by number (0= no pain and 10 = worst pain ever) [7,12,13,20]. The VPS, a six-point verbal pain rating scale that has been validated for use in a nursing home [7,20], was applied when the NRS was too difficult for the resident. The REPOS is a pain observation scale consisting of 10 behavioral items. It was developed by van Herk [26b] and has been validated for residents who are unable to report pain themselves including residents with cognitive impairment and aphasia.
The REPOS observation starts with a two-minute observation period during a possible painful moment (e.g. washing and clothing); the observer scores the ten items as present or absent as they were seen. A cutoff score of 3 or higher suggests a high likelihood of pain. A high REPOS score might be the result of other emotions than pain, e.g. shame or sadness. In that case the caregivers can give a NRS < 4. This is why the REPOS is used in combination with the NRS. The NRS represents the caregiver's opinion of the client's pain taking circumstances into account [26b].
In 2007 and 2008 the REPOS was implemented in several nursing homes in Rotterdam [24].

Analysis

Non-normally distributed data are presented as the median and interquartile range (IQR). Chi-square tests were used to determine the association between nominal data. Pain was considered substantial when residents rated NRS or VPS (converted to a 10-point scale) as 4 or higher. In case of REPOS observations pain was considered substantial for any combination of REPOS ≥ 3 and nurse-assessed NRS ≥ 4.

Results

Pain was assessed in 201 of the 221 residents. Nineteen residents were absent and one resident refused participation because he considered pain assessment nonsense.

The remaining study group included 122 females (60.7%) and 79 males (39.3%) with a median age of 77 (IQR 68 to 84). One hundred and forty-four residents (71.6%) provide a NRS rating, six (3.0%) a VPS rating, and the REPOS was applied in 51 (25.4%). Figure 1 shows the distribution of the pain scales used for the four different types of wards. It appears that REPOS observation was needed for all residents in the psychogeriatric ward. NRS or VPS rating was feasible for most residents of the non-psychogeriatric wards and palliative care unit and for two-thirds of the residents on the neurotrauma ward.
The most frequent underlying condition was diseases of the circulatory system, i.e. in 30% of the 201 residents. Other diseases related to pain were those of the nervous system (14%), musculoskeletal system and connective tissue (13%), endocrine, nutritional and metabolic disease (6%) and neoplasm (3%).

Pain was substantial in 65 (32%) residents; as rated by NRS for 52 residents by VPS for 2 and by REPOS/nurse-assessed NRS for 11 residents.
Median pain intensity was 6 (IQR 4.-7) as rated by NRS; 5 (IQR 5-7) as rated by VPS and 6 (IQR 5-7) as rated by REPOS with nurse-assessed NRS 4 (IQR 4-5).
Twenty-nine (45%) residents with substantial pain received pain medication of step 1 of the WHO analgesic ladder, 8 residents (12%) received (weak) opioids (step 3 of the WHO analgesic ladder, and 3 residents (5%) received a neuroactive agent. Twenty-five residents (38%) experienced substantial pain but received no pain medication.

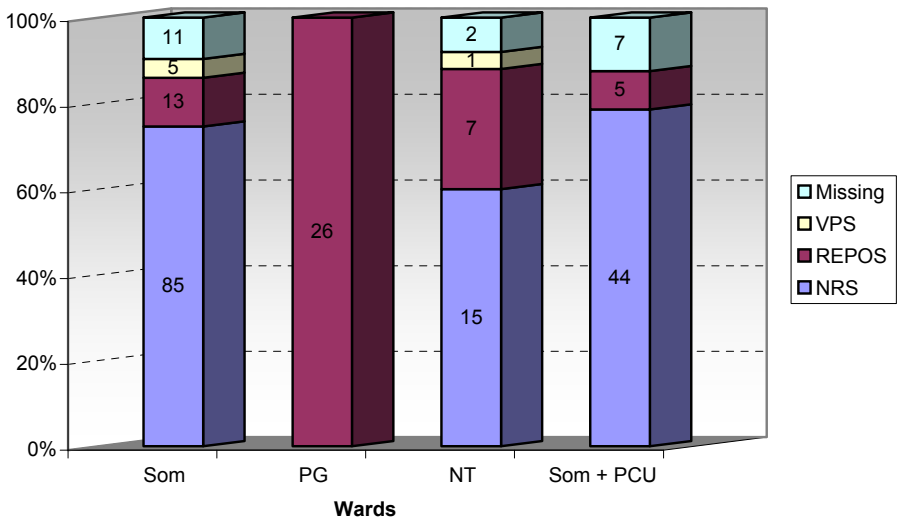

Figure 1: Used pain scales and residents per kind of ward;
abbreviations: Non-psychogeriatric= NPG; Psychogeriatric= PG; Neurotrauma =NT; Palliative Care Unit = PCU; Numerical Rating Scale =NRS; Verbal Pain Scale =VPS; Rotterdam Elderly Pain Observational Scale = REPOS

Table 1: administered pain medication to residents without and with substantial pain

	Numeric Rating Scale pain		
	NRS 0 to 3 N (%)	NRS 4 to10 N (%)	*p*
WHO step 1; analgesic:	38 (28)	29 (45)	
Acetaminophen	36	27	
NSAIDs	2	2	
WHO step 2; weak opioid	2 (1)	1 (1)	
Tramadol	2	1	0.007
WHO step 3; opioids	4 (3)	7 (11)	
Transdermal fentanyl	1	3	
Oral opioids	3	4	
Anti-neuropathic pain:	8 (6)	3 (5)	
Gabapentin (neurontin)	1	2	
Amitriptyline (tryptizol)	4	-	
Carbamazepine (Tegretol)	2	1	
Pregabalin (lyrica)	1	-	
No pain medication	84 (62)	25 (38)	
Total	136 (100)	65 (100)	

Six residents (4%) received opioids with NRS ≤ 3. Residents with NRS ≥ 4 were administered significant more analgesics (Chi-square test 12.1; p = 0.007) than those with lower NRS. Table 1 shows medication prescription in 201 residents.

Discussion

Self-report was feasible in two thirds of the residents of this nursing home the others required a REPOS observation. Two observers approached 201 residents within three days. If two observers are able to collect the information within three days it would be feasible for the caregivers to do so within one week.

Pain was substantial in one third of the residents. Although residents with substantial pain received more often analgesics, 38% of them did not at all, which suggests that pain treatment is not yet sufficient. The latter percentage is comparable with those reported in the literature, ranging from 20% to 54% [1,6,9,10,11,15,2, 6, 9-11, 15, 27]. The consequences of persistent pain or its inadequate treatment in elderly are important. The increased risk of functional impairment, falls, slow rehabilitation, cognitive impairment, mood changes, decreased socialization, sleep and appetite disturbances lead not only to a decreased quality of life but to an increase in healthcare cost [4,5]. The results of this report suggest that pain remains a relevant problem in nursing homes in the Netherlands. Regrettably, pain is not yet included in the set of performance indicators for nursing homes implemented in the Netherlands in 2008.

There is every reason to believe that adding pain assessment would stimulate the attention for pain. The question is, will it improve pain treatment as well? It seems that improvement cannot be achieved by assessment only. It is necessary to combine assessment with either a treatment decision-tree or a individualized standing order so that nursing staff can effectively intervene when pain requires treatment [14,26b]. It is important that pain is a regular theme during medical rounds. Physicians must look at the results of pain assessment and ask the caregivers if an intervention was effective. Complicated pain problems should be discussed within a multidisciplinary team. Such a team should preferably include at least a physician, a psychologist, a physiotherapist and a nurse [5,19]. In order to guarantee sufficient knowledge caregivers as well as physicians should follow training on pain assessment and pain treatment on a regular basis. The regular basis of the training assures that new personal receives the same training as sitting personal, the knowledge level about pain stays up to date and the attention for pain receives an impulse [19].

Conclusion

This study shows that pain assessment is a feasible performance indicator. Quality of pain treatment would be available on the Internet for future clients, management of nursing homes, health care insurers and the Health care inspectorate, which might stimulate the development of a best practice treatment model. Pain assessment combined with a pain treatment algorithm makes a good combination for the improvement of pain treatment in a nursing home.

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Part IV

GENERAL DISCUSSION AND SUMMARY

Chapter 8

General discussion

Introduction

Pain is a very personal experience that we all share to some extent. Life can start in pain when you are born by vacuum extraction, for example, and it may end in pain when you develop arthrosis, for example. Some will often feel pain; others only occasionally. Pain can be a symptom of tissue damage or the result of disease progression. It is the warning signal of the body informing us that it might be not safe to use an injured body part. Under very specific life-threatening situations pain can be ignored, such as in the case of the soldier with severe tissue damage who is running for his life. On the other end of the spectrum: fear for pain can result in avoidance behavior or even catastrophizing, which means that the pain is blown out of proportions [52]. Pain has a negative impact on quality of life, recovery from surgery, and postoperative survival, and acute pain may even turn into chronic pain [17, 24, 27, 32, 34]. The multifaceted character of pain is best brought out by the term 'total pain', first coined by Cicely Saunders, nurse and physician and founder of the first purpose built hospice. This concept of pain includes physical, psychological, social, emotional and spiritual elements [11].

Among the many definitions of pain the one of the International Association for the Study of Pain (IASP) is the best known. The first version was: "Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (IASP). This definition excluded non-communicative individuals (1986). However, in 2006 the IASP added a note to the original definition. The most recent definition reads: "*Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. The inability to communicate verbally does not negate the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment. Pain is always subjective*". This version asks professionals to search for other ways than communication to assess pain, because self-report, the gold standard of pain assessment, is not possible in children under the age of four, individuals with severe intellectual disability, and in the majority of individuals with speech limitations. This means that professionals have to learn to recognize the signs that might indicate pain and use a pain assessment instrument validated for those vulnerable patient groups. Partly due to knowledge deficits [3] and partly due to misconceptions, these have long been considered unable to feel pain [33].

The importance of pain assessment was underlined by the American Pain Society (APS), which in 1995 pronounced pain as the "Fifth Vital Sign", next to heart rate, blood pressure, respiratory rate, and temperature [29,31].

Prevalence

The prevalence of pain is high in children and adults with an intellectual disability (ID) and in elderly with or without dementia [57,2, 28], and is thought to be underreported and undertreated in these groups [21,26,22]. A prevalence rate of 85% has been reported for children with a severe ID [9]. For institutionalized adults with an ID we found an overall prevalence of 18% (this thesis, chapter 3), comparable to a 15% prevalence of chronic pain in adults with a severe ID [30,55]. Pain prevalences between 55 and 72%, with one outlier of 17% have been reported for elderly persons [1,4,36,40,44]. The outlier was the outcome of a large study on substantial daily pain of nursing homes residents in Alabama, USA. The low pain prevalence might be explained by the method of self-report, which resulted in a very low prevalence among residents of the psychogeriatric wards. We found a pain prevalence of nearly 70% among residents of nursing and residential homes in the period 2001-2005 [5, 51]. It is frustrating to know that this percentage has not changed in almost twenty years [13].
The following section gives an idea about numbers of individuals at risk of unrecognized pain in the Netherlands in the year 2010.

A survey among parents of healthy under 4-year-olds yielded a 30% pain prevalence [35]. In 2010 there were 188.000 children in that age group, which means that approximately 56.400 children might suffer pain.
In 2010 approximately 20.500 individuals with a severe ID lived in specialized institutions in the Netherlands. These individuals have an increased risk of pain due to the underlying disorders and possible progressive neurodegenerative diseases. At an estimated pain prevalence of 60% around 12.300 would suffer from pain.
The third group of vulnerable patients are the elderly. Old age often brings chronic pain due to, e.g., osteoporosis or arthrosis. In the Netherlands the number of over 65–year-olds for 2010 was approximately 2.5 million, 15% of the total population. Elderly in general find it difficult to report pain but for those who suffer from dementia it is extremely difficult or impossible. Approximately 230,000 individuals in the Netherlands suffer from dementia; based on a 70% pain prevalence, 161,000 of demented elderly might be in pain.
Thus, altogether some 330,000 individuals in the Netherlands in these risk groups might suffer pain and rely on the vigilance of their caregivers.

Assessment

Pain assessment instruments are indispensible to good pain treatment and prevention strategies. Many pain observation scales have been developed especially for the assessment of (postoperative) pain in young children [47,49,14,19,25,54], but only few for individuals with an ID of all ages [7,10, 15,43,53,45] and demented elderly [56,50,20].
All these scales show overt overlap. For one thing, they all tend to include facial expression, emotional states such as excitement, and body movements. Some instruments include physiological items such as heart rate, or crying, dependent on the age group.
Psychometric properties of existing pain scales which were validated for defined patient groups need some modification or should be tested again for use in other patient groups. For example, the faces, legs, activity, cry and consolability (FLACC) proved valid for children with a profound ID after adjustment [53]. In other instances a scale might prove valid for another patient group unchanged: the COMFORT-B scale proved valid to assess postoperative pain in infants with Down syndrome [45] as well.
Other observation scales, originally developed for children with a ID, have been adjusted and validated for ID in adults (the Chronic Pain Scale for Nonverbal Adults With Intellectual Disabilities; CPS-NAID) [10] or proved to be less suitable (Checklist Pain Behavior; CPB) [46]. The Rotterdam Elderly Pain Observation Scale (REPOS) was developed for elderly with speech limitations but seems to be a useful tool for adults with an ID as well although further psychometric evaluation is necessary [46].

In view of the above, developing new pain scales seems superfluous. It seems more useful to invest in ongoing psychometric evaluation of existing pain scales. In addition, it would be relevant to develop internationally accessible learning systems, such as CD-roms or E-learning modules to train caregivers how to use pain scales.
Information about the observation period is often lacking in the instructions to pain scales [48]. It is important, though, as we showed that pain assessment may not be reliable if the recommended observation period is not adhered to [6]. Further psychometric evaluation proved that the COMFORT-B scale is sensitive to change (this thesis, chapter 2). Selecting a pain scale for ones own practice should largely depend on the psychometric quality of a pain scale as well as its clinical utility.

The following case studies are examples of the use of pain assessment instruments in those individuals that are unable to report pain by self-report.

The newborn

1. Premature neonate: good practice

Johnny was born after 28 weeks gestation with a birth weight of 950 grams. He was admitted to a neonatal ward. His vital functions were stable and COMFORTneo scores of 10 confirmed that he was pain free. After 24 hours Johnny suddenly looked extremely pale and lay motionless. His belly circumference had increased and the abdomen looked glazed and bluish. A low COMFORTneo score of 7 combined with a high numerical rating scale (NRS_{obs}) score of 8 from the attending nurse confirmed that he was in pain. He was diagnosed with necrotizing enterocolitis and underwent surgery. Postoperative pain treatment according to the treatment algorithm consisted of continuous intravenous morphine and, if necessary, rescue morphine boluses. Treatment effects were evaluated by six hourly COMFORTneo observations. The scores remained between 10 and 13 combined with an NRS_{obs} score of 1 or 2. After three days the continuous morphine was slowly tapered off and was stopped after five days.

2. Premature neonate: bad practice

Jan was admitted to the neonatal intensive care unit with meconium aspiration syndrome. His condition was critical and he was ventilated at high pressures. As a result pneumothorax occurred seven times for which chest tubes were inserted. His blood pressure dropped regularly below a critical level for which he received plasma infusions and cardiotonics. This combined with a urine production of approximately 5 ml/h during the previous 48 hours resulted in severe edema. Before further treatment it was important to know his exact weight. Therefore, Jan was weighed by two ICU nurses. One held Jan and the ventilator tubes; the other the chest tubes. Although he remained stable, Jan was very pale and his face would have shown grimacing and that panicky look and hyper-alertness. Regrettably, pain assessment was not yet introduced on the ward and his pain remained unnoticed.

Over the years pain assessment and treatment in our neonatal intensive care unit has much improved. Care provision is based on the newborn individualized developmental care and assessment program (NIDCAP), which means that a child receives support during handling and during possible painful interventions. However this extra attention has not substantially reduced the number of painful procedures. In 2004 we recorded on average 14 [39] potentially painful procedures per day per infant; in 2010 this was 12 (unpublished observations).

Critically ill children

3. A child on the intensive care unit: good practice
Margriet is a 12-year-old girl born with Rett syndrome. She was operated on for scoliosis and was admitted to the pediatric intensive care unit. This morning she is screaming and looks very uncomfortable and stressed. All healthcare professionals involved and her parents suspect she is in pain. The pain consultant of this team is therefore asked to conduct a pain assessment with the Checklist Pain Behavior (CPB). This tool was specially developed and validated for the assessment of postoperative pain in children with an ID. The observation resulted in a score of 6 combined with an NRS score of 7, indicative of severe pain. An extra bolus of morphine was prescribed and after that Margriet looked more comfortable and even slept for a while.

4. A child on the intensive care unit: bad practice
Anne is a 15-year-old girl who suffers from leukemia. Her condition became critical due to pneumonia and she was admitted to the pediatric intensive care unit for the monitoring of vital signs. Pain self-report at least three times a day is common practice on this unit and Anne reports score 8, indicative of severe pain. The nurse who cares for Anne doubts whether the pain is really that severe. She is convinced that Anne seeks attention and gives none of the analgesics prescribed by the treatment algorithm.

During the past ten years most pediatric wards in the Netherlands have introduced a pain assessment instrument for which nurses receive training. In 1999 the COMFORT-B scale was implemented in the pediatric intensive care unit of the Erasmus MC-Sophia combined with a treatment algorithm. This has resulted in a constantly low pain prevalence of 7% over the last five years. An important next step would be to collaborate internationally and compare pain scores and corresponding treatments and their results in comparable patient groups.

6. Individual with an ID: good practice

Peter is 55 years old and was born with Down syndrome. Because his parents are old he lives in an institution. Peter has been diagnosed with Alzheimer disease three years ago. Another medical problem is severe eczema. Due to the itching he has scratched his skin until bleeding erosions. His caregivers are not sure, however, if besides the itching he suffers from pain. They decide to ask the physiotherapist, who has a special interest in pain observation, to conduct a pain observation with the REPOS during morning care. The REPOS score was 6 and the physiotherapist assigned a proxy NRS score of 5 indicating substantial pain. Thereupon the attending physician was informed, who prescribed an analgesic and an antihistamine as well as a skin ointment. To assure that this was effective an appointment with Peter's dermatologist was made.

5. Individual with an ID: bad practice

Elsa is a 40-year-old woman with a severe ID caused by asphyxia at birth. She lives in a home for individuals with an ID. She was diagnosed with a spastic quadriplegia and epilepsy. At times she seems uncomfortable and sobs heart-breakingly. Her visiting parents often tell the caregivers that Elsa is in pain. Pain assessment is not felt necessary in this facility. No further action is taken and Elsa's parents feel ignored and frustrated.

Although institutions for individuals with an ID show a growing interest in pain assessment, regular assessment is often not performed. This is understandable considering that most staff are social pedagogical workers with no medical or nursing background [23]. Physiotherapists have an interest in pain and treat residents for muscle tone disorders and contractures, but see only a limited number of residents. Even more complicated is the occurrence of specific pain behaviors [43,12,8,41]. We have little information about the individual daily care processes in institutions for individuals with an ID. How do the caregivers establish the presence of pain without any structured training? Without the use of a validated pain assessment instrument there is always the risk of large inter- and intra observer variability.

Pain is often undertreated in this population. Is that because caregivers lack pharmacological knowledge and fear drug-drug interactions? The majority of the individuals with an ID use more than one co-medication, such as anticonvulsants. These co-medications sometimes interfere with other medications, such as in the case of an anticonvulsant that increased fentanyl requirement during anaesthesia [42]. Obviously more studies and

notably randomized controlled trials are needed to study the pharmacokinetics and pharmacodynamics of analgesics and co-medications in individuals with an ID.

Elderly persons with dementia

8. Elderly with dementia: good practice
Mrs. Hart is a 60-year-old woman who was diagnosed with Alzheimer disease five years ago. She has developed contractures and lies in a fetal position in bed. Caregivers are very gentle during care but are worried that Mrs. Hart suffers from pain. Although Mrs Hart lays very quiet and her facial expression is somewhat tensed; REPOS scores are as low as 2. But based on the knowledge that contractures are extremely painful and on the compulsive fetal position Mrs. Hart is considered to be very uncomfortable for which proxy NRS scores of 6 or 7 was given. Based on this information she was prescribed morphine, after which her facial expression was less tense and although her favorite position remained the fetal position the caregivers concluded that she was more comfortable.

7. Elderly with dementia: bad practice
Mr. Visser lives in a psychogeriatric ward of a nursing home. Three days ago he fell out of bed and broke his upper arm. Due to the location of the fracture a cast was not possible. During washing and dressing he grimaces and tries to protect his arm. The grimacing remains unnoticed because the caregiver is busy dressing him and her attention is focused on that task. She is annoyed by Mr. Visser's efforts to protect his arm and does not associate this behavior with pain. As a result his pain remains unnoticed and untreated.

As the above examples illustrate; patients benefit from the use of pain assessment. Unfortunately the use of a pain assessment instrument is still not common practice in most nursing and residential homes. The implementation of a pain assessment instrument is difficult and compliance remains low [18]. Why is it so difficult? A number of factors might explain current practice.
First, pain management has been given little attention in the training of caregivers. This should become part of the standard education curriculum for all levels of nurses training. Caregivers may not always be aware that the elderly they care for suffer (chronic) pain.
Second, the fact that lower educated care assistants perform most care tasks in some settings will not help much either. They received only a basic training and might be less expected to have a feel for pain.

Third, over the years there have been several budget cuts which resulted in a reduction of the number of caregivers. The workload has increased, leaving little time for pain assessment.
Four, the elderly themselves are often convinced that old age comes with pain and therefore will not always tell the caregivers that they are in pain [51].

Facilitators
Imposing pain assessment as a performance-indicator may stimulate management to put effort and money in better pain management.
Systematic pain assessment will increase health professionals' awareness of residents' pain. Informing relatives about the fact that pain assessment is part of standard care may be a further incentive.
It will be helpful to create a pain team, consisting of a physician, a physiotherapist, an occupational therapist, a psychologist, a nurse and caretakers of the wards, which provides support in case of major pain problems. One of the members of this team should be on duty as pain consultant and be available for consultations. A treatment algorithm should be available to guide treatment. In case of serious pain problems it would be advisable to consult pain experts in a regional hospital.

Conclusion

Pain assessment in babies and young children, intellectually disabled (ID) children and adults and elderly with or without dementia is important and feasible. Vital for the effectiveness of a pain assessment instrument is its implementation into daily practice as well as its psychometric validation. Implementation into daily practice has proved to be difficult but not impossible. It is challenging because it requires extra training and changes in working methods. Further research is necessary to establish the best implementation method for pain assessment in institutions for individuals with an ID and in residential homes. These institutes differ from hospitals fundamentally as they focus less on pain.
This main focus of this thesis was on pain assessment and the implementation into daily care. These aspects are only part of the total picture of pain. Increasing knowledge informs us about the developing human brain and its ability to discriminate between touch and pain from 35 to 37 weeks gestational age on [16]. Other studies have documented that neuropathological changes in the brain of individuals with an ID may alter pain processing systems in the brain [38,37]. It is important that, next to the more practical aspects, these fundamental neurophysiologic aspects of pain are further explored, as well as evidence based pharmacological therapy (randomized controlled trials, meta analysis) of current analgesic and non-pharmacological pain treatment. With the gained

insights it should be possible to address pain in a more tailor-made fashion, not only at the level of assessment but on the level of treatment as well.
I will end this discussion with the following case study. Although its substance was not part of the discussion it involves a different aspect of daily care in a nursing or residential home which might influence successful implementation.

Mrs. Jansen is a 79-year-old lady who has been living in a residential home for 10 years. For thirty years she has been suffering from severe osteoporosis in her spinal column, for which she wears an orthopaedic corset. She rates her pain intensity (NRS) as 8 or 9, implying it is almost unbearable, but refuses any pharmacological treatment. Mrs. Jansen considers pain assessment as superfluous because it would continually remind her of her pain. Because caregivers have noticed that she remains in her room more often and pain seems to decrease her quality of life, they asked a nurse pain specialist to visit her. The nurse was able to persuade her to take paracetamol four times daily for one week. Mrs. Jansen then felt less pain, as evidenced by a self-report NRS score of 4. Nevertheless she refused to continue the paracetamol. She considered pain as part of her life which had to be accepted and nothing could convince her to reconsider this point of view.

Respect for individual choices is a fundamental component of a caregiver's attitude towards the needs of individual patients. As such I consider the title of this thesis: "Having a feel for others pain" as an integrated approach of the individual person "in pain".

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Chapter 9

SUMMARY

Introduction

Pain management in young children and cognitive impaired individuals is challenging. They are not able to self report their pain or to indicate that pain relief was successful or not. Three pain observation scales have therefore been developed and validated in the Erasmus MC- Sophia Children's hospital, one for each patient category.

The COMFORT behavior scale (COMFORT-B) has been validated for postoperative pain in children between zero and three years admitted to the PICU and consists of six behavioral items. Summating the six ratings leads to a total score ranging from 6 to 30. It is generally accepted that a total COMFORT-B score of 17 or higher combined with an NRS_{OBS} of 4 or higher indicates pain.

The Checklist Pain Behavior (CPB) was validated for the assessment of postoperative pain in children between three and 12 years with a cognitive impairment. Originally it consisted of 23 items and later reduced to10. These 10 behaviors are scored as present (1) or absent (0) and sum up to a total score between 0 and 10. A total CPB-score of 5 or higher combined with an NRS_{OBS} of 4 or higher indicates that the child is in pain.

The Rotterdam Elderly Pain Observation Scale (REPOS) was developed for acute and daily pain in adults and elderly unable to express pain by self report. The REPOS also consists of ten behaviors that are related to pain which are scored as present (1) or absent (0). A REPOS score of 3 or higher combined with an NRS_{OBS} of 4 or higher indicates moderate to severe pain.

Pain assessment for all three scales starts with an observation period of two minutes during a possible painful moment. To assure that the level of the score was due to pain the observation needs to be completed with an additional intrinsically linked NRS_{obs}. The NRS is a global pain rating scale that asks to rate pain by number (0= no pain, 10= worst pain ever) and can be used for self report (NRS) or proxy report (NRS_{obs}). All three pain observation scales are part of studies that form the basis of this thesis.

PART I; THE YOUNG AND VULNERABLE

Chapter one

This chapter describes a study about the duration of the observation time of the COMFORT-B scale. This scale has been used for ten years on the PICU of the Sophia's Children Hospital. Some nurses observed for a shorter period of time than the required two minutes. This is understandably if one considers their high workload but might make the

reliability of the results questionable. In this study we compared a two minutes observation with the COMFORT-B scale with an observation of 30 seconds. All 133 nurses of the PICU were invited to conduct two observations together with the researcher. Either the nurse or the researcher started the 2-minutes observation and the other observed the last 30 seconds, they reversed roles for the second observation. The mean COMFORT-B score for the 2-min observation was 13.5 (sd 3.8) and for the 30-sec 12.7 (sd 3.7). The mean difference was 0.8 (confidence interval 0.6-1.1, paired *t*-test, $p < .001$). In 11% of the observations the 2-min COMFORT-B score exceeded 17 whereas the 30-sec score did not. Based on that result the risk of missing behavior is considered too large and we therefore recommend to use the COMFORT-B in daily practice using a 2-min observation.

Chapter 2

The second chapter studied the sensitivity to change of the COMFORT-B scale taking time between assessment and reassessment into account. Sensitivity to change, defined as the ability of a measure to detect clinically important changes after pain treatment, is a relevant psychometric property for pain instruments. Therefore, a mixed model approach was applied.

SAS proc mixed modeling on 758 repeated assessments showed a mean decrease in COMFORT-B scores of 5.9 points ($p < 0.0001$). At shorter time intervals between assessments (< 40 min or 40 to 80 min) scores were statistically significantly higher, respectively 1.5 points and 0.6 points, than scores established within 81 to 120 minutes. The number of interventions did not significantly affect the levels of the COMFORT score.

This study confirms that the sensitivity to change and responsiveness of the COMFORT-B scale was excellent.

PART II; CHILDREN WITH INTELLECTUAL DISABILITIES

Chapter 3

The subject of the third chapter was to establish the pain prevalence in institutionalized intellectually disabled (ID) individuals. On many occasions they have been excluded from pain studies. For this study we asked the caregivers of individuals with an ID, in one institute, to rate their pupils actual pain as well as their overall pain during the preceding week with an 11-point numerical rating scale (NRSobs). Information about their medical history and actual analgesic prescription information was collected from their medical records.

According to the caretakers 47 (18%) out of 255 ID residents were suffering from pain either at present or during the preceding week. Seven (15%) of these 47 residents had an analgesic prescription, four on a regular basis and three on as needed base.
We concluded that the low percentage of pain that were found are probable the result of an underestimation of pain as well as undertreatment. Further research in these individuals is necessary to complete the knowledge as well as the implementation of a pain observation scale with a pain protocol and treatment algorithm in daily care.

Chapter 4
Children with Down syndrome have an increased risk for congenital heart diseases and gastrointestinal anomalies and often require major surgery before the age of one year. To ascertain that the COMFORT-B scale is a valid instrument for the assessment of pain in 0- to 3-year-old children with Down syndrome this study was started.
For this study 76 patients with Down syndrome were included and 466 without Down syndrome. The mean COMFORT-B scores between the two groups were comparable, they were for the children with Down syndrome 12.1 (SD 1.7) and 12.3 (SD 1.8) for the control group. The individual item scores for; Crying, Physical activity, Facial tension and Muscle tone were significantly different between the two groups, with a SMD that ranged from -0.12 to 0.23. The standardized Cronbach's α value varied from 0.84 to 0.87 and all corrected items – total correlations were above 0.54. We concluded that the COMFORT-B scale is also valid for 0- to 3-year-old children with Down syndrome.

PART III; ELDERLY WITH AND WITHOUT A COGNITIVE IMPAIRMENT

Chapter 5
This chapter describes a study on the prevalence of pain elderly living in a residential home. We aimed to measure the prevalence and intensity of pain in older adults living in Dutch residential homes, the characteristics of their pain and their analgesics prescriptions. Residents were interviewed using a standardized pain questionnaire which included an NRS for pain intensity and questions about the interference of pain with sleep, activities of daily living, social contacts and other daily activities, as well as if they felt tensed, depressed or anxious as a result of their pain. Furthermore, we asked the residents to pronounce upon five statements about pain and pain treatment. Analgesic use was checked from their medical chart.

Hundred and fifty-seven out of the eligible 202 residents (77.7%) completed the questionnaire; their median age was 88 years (IQR 83-92). Pain was experienced by 109 (69.4%) residents either at present and/or during the preceding week and was substan-

tial 68% and 85% of residents, respectively. Ninety-three percent of all residents suffered from chronic pain and 22% did not receive any analgesics while only 3% was prescribed a strong opioid. These analgesics were given only 'as needed' in 31% of residents. In a majority of residents, pain interfered with daily living and mood. Almost 60% of the elderly was convinced that pain is a part of ageing, 70% indicated that they did not always report their pain to the caregivers.
The pain prevalence rate in Dutch residential homes was comparable to European nursing- and residential homes. Pain treatment is insufficient and although pain interferes with daily activities and mood, elderly tend to accept pain as an unavoidable part of aging.

Chapter 6
The results that were described in chapter six were part of the same study as reported in chapter five but focussed on the prevalence and intensity of pain in older adults living in Dutch nursing homes, the characteristics of their pain and the analgesics that were prescribed to them.
The eligible sample comprised 320 residents with a median age of 79 years (IQR 73-84), of whom 233 (73%) residents completed the questionnaire. Hundred and fifty-three residents (66%) experienced (mostly chronic) pain, either in the previous week (median NRS 6) or at present (median NRS 5). Intolerable pain was recorded in 41% of 100 residents. The higher the pain scores, the more interference with activities of daily living was reported. Of the 153 residents with pain, about one-fourth did not receive any pain medication, and 65 (43%) received step 1, 13 (9%) step 2, and 16 (11%) step 3 analgesics. Most residents (60%) were satisfied with pain treatment, and 21% were not. Considering the high prevalences and intensities of pain, pain management in Dutch nursing homes leaves much to be desired.

Chapter 7
Chapter seven describes a study that intended to determine the feasibility of pain assessment as performance indicator. Therefore we performed a check on the presence of pain and collected information on analgesic prescription in one nursing home in Rotterdam, the Netherlands. We used three pain scales: the NRS, a verbal pain scale (VPS) and the REPOS. The VPS is a 6-point verbal pain rating scale and was applied when the NRS was too difficult for the resident.

Within the time span of 3 days, pain intensity was measured in 91% of the residents (201 out of 221), Numerical rating was used for 72%, verbal rating for 3%, and REPOS observation for 25% of the residents. Pain was substantial in 65 residents (32%). Further

investigation is necessary to find out if a pain algorithm is feasible and will lead to improved pain treatment.

Chapter 8

The general discussion describes the similarities and differences for the three patient categories in relation to the findings that were presented in this thesis and the relationship with the literature. The chapter ends with our main conclusions and suggestions for improvement in daily clinical practice. Areas to be explored in the (near) future are also discussed here.

Chapter 9

Contains the summary in English and Dutch

Appendices

Nederlandse samenvatting

Een goed pijnbeleid opstellen voor jonge kinderen en mensen met een verstandelijke beperking is een uitdaging. Zij kunnen eventuele pijn niet door zelfrapportage kenbaar maken en daarom is het ook vaak moeilijk het effect van pijnstillende maatregelen te beoordelen. Om dit te ondervangen hebben we in het Erasmus MC- Sophia Kinderziekenhuis pijnobservatieschalen ontwikkeld voor drie groepen mensen met een uitingsbeperking.

De COMFORT gedragschaal (COMFORT-B) is geschikt voor het meten van postoperatieve pijn bij jonge kinderen tot drie jaar. Deze schaal bestaat uit zes gedragingen die elk gescoord worden van 1 tot 5, zodat de totaalscore uitkomt tussen de 6 en 30. Bij een totaalscore van 17 of hoger gecombineerd met een pijncijfer (NRS) van 4 of hoger moet men ervan uitgaan dat het kind pijn heeft.

De Checklist PijnGedrag (CPG) is geschikt voor het meten van postoperatieve pijn bij kinderen tussen de 3 en 12 jaar met een verstandelijke beperking. De schaal uit 10 gedragingen die worden gescoord als zijnde aanwezig (1) of afwezig (0) waardoor de totaalscore tussen 0 en 10 kan liggen. Een totaalscore van 5 of hoger gecombineerd met een NRS van 4 of hoger betekent dat het kind pijn kan hebben.

De Rotterdam Elderly Pain Observation Scale (REPOS) werd ontwikkeld voor het meten van pijn bij ouderen met een uitingsbeperking. Ook de REPOS bestaat uit 10 gedragingen die als aanwezig (1) of afwezig (0) worden gescoord. Een REPOS score van 3 of hoger in combinatie met een NRS van 4 of hoger geeft aan dat er sprake is van substantiële pijn.

Deze schalen worden toegepast na een observatieperiode van 2 minuten – bij voorkeur gedurende een mogelijk pijnlijk moment. Om uit te sluiten dat het gedrag van het kind of de oudere door een andere emotie dan pijn is beïnvloed moet altijd een aanvullende NRS_{obs} score worden gegeven. De NRS is een numerieke pijnschaal die of voor zelfrapportage (NRS) of voor proxy rapportage (NRS_{obs}) gebruikt kan worden. De score loopt van 0 (geen pijn) tot 10 (ergst denkbare pijn).
Dit proefschrift beschrijft een aantal onderzoeken waarin de drie pijnobservatieschalen een rol speelden.

DEEL I; JONG EN KWETSBAAR

Hoofdstuk 1

De COMFORT gedragschaal (COMFORT-B) wordt sinds 12 jaar op de intensive care van het Sophia Kinderziekenhuis gebruikt. De laatste tijd viel het op dat sommige verpleegkundigen korter dan de voorgeschreven 2 minuten observeerden. Een kortere observatietijd is vanuit het oogpunt van een hoge werkdruk te begrijpen maar mag niet ten koste gaan van de betrouwbaarheid van een observatie. We vergeleken daarom de uitkomsten bij een observatieduur van 2-minuten met die van een observatieduur van 30 seconden. Alle 133 verpleegkundigen van de PICU werden gevraagd samen met de onderzoeker twee observaties te verrichten. Eén van beiden startte een 2-minuten observatie waarbij de tweede persoon de laatste 30-seconden mee observeerde. De rollen werden omgedraaid bij de tweede observatie.

In 11% van de 2-minuten observaties was de totaalscore 17 of hoger terwijl een dergelijk hoge score bij de 30-seconden observaties niet werd gegeven. Daarom concludeerden we dat de kans op het missen van relevante gedragingen bij een observatie van 30-seconden te groot is. Het is daarom aan te bevelen om een observatietijd van 2-minuten aan te houden.

Hoofdstuk 2

We onderzochten of de COMFORT-B schaal gevoelig is voor het meten van veranderingen tussen twee observaties. Voor een aantal observaties vergeleken we de score vóór pijnstilling met die er na. Bij de analyse werd rekening gehouden met het tijdsinterval tussen deze beide observaties. Om zoveel mogelijke beïnvloedende factoren mee te nemen werd voor de analyse multilevel regressie analyse gebruikt. De COMFORT-B score over 758 herhaalde metingen bleek gemiddeld 5,9 punten te zijn gedaald ($p < 0.0001$). Bij een kortere periode tussen de beide observaties (<40 minuten tot 80 minuten) waren de scores van de voor en nameting significant hoger, respectievelijk 1,5 punten en 0,6 punten, dan bij een langere periode van 81 tot 120 minuten. Het aantal pijnstillende maatregelen had geen invloed op de hoogte van de COMFORT-B score. Deze studie bewijst dat de COMFORT-B goed in staat is om klinische relevante veranderingen aan te tonen.

DEEL 2; MENSEN MET EEN VERSTANDELIJKE BEPERKING

Hoofdstuk 3

Er is nog nauwelijks pijnonderzoek gedaan bij mensen met een verstandelijke beperking die in een instelling wonen. Om deze lacune te vullen vroegen we de verzorgenden

in één instelling twee pijncijfers te geven voor hun cliënten, één voor pijn op dat moment en één voor de gemiddelde pijn over de voorgaande week. Hiervoor werd gebruik gemaakt van een 11-punts numeriek schaal (NRS_{obs}).
Volgens de verzorgenden hadden 47 (18%) van de 255 bewoners die in het onderzoek werden betrokken pijn, hetzij tijdens het meetmoment, hetzij in de voorgaande week. Voor slechts zeven van deze 47 bewoners (15%) waren pijnstillers voorgeschreven, vier op continue basis en drie op zo nodig basis.
Zowel het lage percentage bewoners met pijn als het lage percentage bewoners dat pijnstillers krijgt voorgeschreven wijst op de mogelijkheid dat pijn wordt onderschat en onderbehandeld. Het is daarom wenselijk meer pijnonderzoek te doen bij mensen met een verstandelijke beperking en standaard pijnmeting te introduceren. Het gebruik van een pijnmeetschaal zou moeten worden gecombineerd met een pijnbehandelingsprotocol .

Hoofdstuk 4
Veel kinderen met het syndroom van Down hebben aangeboren hartafwijkingen en afwijkingen aan het maag-darmkanaal en ondergaan vaak al voor de leeftijd van één jaar ingrijpende operaties. We wilden onderzoeken of de COMFORT-B schaal ook betrouwbaar is voor pijnobservaties bij kinderen met het syndroom van Down tussen de 0 en 3 jaar. Daarvoor vergeleken we de scores van 76 kinderen met het syndroom van Down met die van een controlegroep van 466 kinderen zonder het syndroom van Down. De gemiddelde score voor beide groepen was vergelijkbaar: De scores voor huilen, alertheid, gespannen gezicht en spierspanning verschilden weinig maar wel statistisch significant tussen de groepen De achterliggende factorstructuur van de COMFORT gedragschaal en de interne consistentie waren vergelijkbaar voor de twee groepen. Op basis van deze bevindingen concluderen wij dat de COMFORT-B schaal betrouwbaar is voor pijnobservatie bij kinderen in de leeftijd van 0-tot-3-jaar met het syndroom van Down.

DEEL 3; OUDEREN MET EN ZONDER UITINGSBEPERKING

Hoofdstuk 5
Aan de hand van een gestandaardiseerde pijnvragenlijst hebben we voor bewoners van drie Nederlandse verzorgingshuizen de prevalentie, aard en behandeling van pijn in kaart gebracht. Ook werd gelet op de pijnintensiteit (aan de hand van de NRS) en de invloed van pijn op de slaap, de algemene dagelijkse verzorging, sociale contacten en activiteiten. De bewoners werd tevens gevraagd of zij zich gespannen, gedeprimeerd of angstig voelden door pijn, en gaven hun mening over vijf stellingen betreffende pijn. In

totaal werden 202 bewoners benaderd en bij 157 bewoners (77.7%) kon een volledige pijnanamnese worden afgenomen. De gemiddelde leeftijd van deze bewoners was 88 jaar (IQR 83-92). Desgevraagd zeiden 109 (69.4%) bewoners op het moment zelf en/of in de voorgaande week pijn te hebben (gehad). Voor 68% was de pijn hevig op het moment zelf; voor 85% in de voorgaande week. Bij 93% van alle bewoners met pijn was de pijn chronisch; bij 22% werd de pijn niet behandeld; en slechts 3% kreeg een opiaat voorgeschreven. Voor 31% van degenen die pijnstillers kregen was dit op zo nodig basis. Bij het merendeel van de bewoners had pijn een negatief effect op de dagelijkse activiteiten en de stemming. Volgens bijna 60% van de bewoners hoorde pijn bij het ouder worden en 70% rapporteerde pijn niet aan de verzorgenden.
De door ons gevonden pijnprevalentie is vergelijkbaar met die in verpleeg- en verzorgingshuizen in andere Europese landen. We concluderen dat de behandeling van pijn onvoldoende is en dat bewoners van verzorgingshuizen, ondanks alle belemmeringen, pijn accepteren als een onvermijdelijk gevolg van het ouder worden.

Hoofdstuk 6
Aan de hand van dezelfde pijnvragenlijst als beschreven in hoofdstuk 5 werd de pijn in het dagelijkse leven van bewoners van vier Nederlandse verpleeghuizen in kaart gebracht. In totaal werden 320 bewoners met een gemiddelde leeftijd van 79 jaar (IQR 73-84) benaderd. Bij 233 (73%) kon de complete vragenlijst worden afgenomen. Van deze bewoners hadden 153 (66%) bewoners (meestal chronische) pijn, hetzij op het moment zelf of in de voorgaande week. Bij 41% van de 100 bewoners bij wie dit te achterhalen was bleek de pijn ondraaglijk. Hoe hoger de pijnscore, hoe negatiever de invloed van pijn op het dagelijks leven werd ervaren. Van de 153 bewoners met pijn kreeg 25% geen pijnmedicatie, 43% kregen een voorschrift uit stap 1 van de WHO-analgetische ladder, 9% uit stap 2, en 11% uit stap 3. De meeste bewoners (60%) waren tevreden over de pijnbehandeling die zij kregen; 21% was dat niet en de overigen hadden hier geen mening over. Gezien de hoge pijnprevalentie en de hoge pijnintensiteit kunnen we concluderen dat er nog veel te verbeteren valt aan het pijnbeleid in verpleeghuizen.

Hoofdstuk 7
We zijn nagegaan of pijnmeting mogelijk een prestatie-indicator kan vormen voor verpleeghuizen. De bewoners van één verpleeghuis in Rotterdam werden benaderd voor een pijnmeting en van deze bewoners werd nagegaan welke pijnstillers zij kregen voorgeschreven. Voor de pijnmeting werd gebruik gemaakt van de volgende drie pijnschalen: de NRS, een verbale 6-punts pijnschaal (VPS), of de REPOS. De VPS werd gebruikt wanneer het voor de bewoner te moeilijk was om de NRS te gebruiken. Het bleek mogelijk om met twee personen bij 91% van alle 221 bewoners binnen drie dagen een pijnmeting te verrichten. Dat was met behulp van de NRS bij 72%, de VPS bij 3%, en de

REPOS bij 25% van de bewoners. De pijn bleek hevig te zijn bij 65 bewoners (32%). Uit dit onderzoek bleek dat pijnregistratie een prestatie-indicator kan zijn. Vervolgonderzoek zal moeten uitwijzen of het gebruik van een behandel-beslisboom tot een verbetering van de pijnbehandeling zal leiden.

Hoofdstuk 8

De discussie beschrijft overeenkomsten en verschillen tussen de drie patiëntengroepen. De belangrijkste conclusies waren dat pijnregistratie bij jonge kinderen en mensen met een verstandelijke beperking mogelijk en belangrijk is. Een belangrijke voorwaarde voor succes is het gebruik van een pijnschaal waarvan de betrouwbaarheid (scoren verpleegkundigen en verzorgenden op dezelfde wijze) en validiteit (meet het instrument wat het beoogt te ment) door wetenschappelijk onderzoek is aangetoond. Vervolgens moeten de richtlijnen voor effectieve implementatie en borging opgevolgd kunnen worden.

Aanbevelingen voor toekomstig onderzoek:

Onderzoeken wat de meest effectieve strategieën zijn om pijnregistratie te implementeren en te borgen in instellingen voor mensen met een verstandelijke beperking en verzorgingshuizen. Meer onderzoek is nodig op het gebied van de neurofysiologische aspecten van pijn. Recentelijk onderzoek heeft aangetoond dat een zich ontwikkelend brein van een pasgeborene van 35 tot 37 weken al in staat is een onderscheid te maken tussen aanraking en pijn. Meer kennis is nodig over pijnprocessen in het brein van mensen met een verstandelijke beperking. Een ander onderwerp waarover de kennis nog ontoereikend is betreft de farmacologische behandeling van pijn en de wijze waarin het lichaam omgaat met pijnstillende middelen en de interactie met andere medicatie. Uiteindelijk zullen we daarmee wellicht kunnen komen tot een op het individu afgestemde pijnbestrijding.

Dankwoord

Mijn promotor Professor Dr. Dick Tibboel, beste Dick, dat ik dit hier schrijf, in mijn proefschrift, zou ik bij onze eerste kennismaking een kleine 30 jaar geleden, nooit voor mogelijk hebben gehouden. Sterker nog, ik denk dat je het toen zelf ook uitgesloten zou hebben, wat bewijst dat tijden veranderen. Ik wil je heel hartelijk danken voor je vertrouwen, dat vele malen groter bleek te zijn dan mijn zelfvertrouwen. Ik stel de samenwerking en je stimulans heel erg op prijs!

Mijn copromotor Dr. Monique van Dijk, beste Monique, ook jou ben ik veel dank verschuldigd. Niet alleen was jij degene die me al bij het schrijven van het eerste artikel aanmoedigde om over promotie na te denken je was ook altijd weer bereid om de manuscripten in allerlei staten te lezen en verbeteren. Ik weet dat mijn onzekerheid soms heel erg irritant was, toch bleef je me stimuleren om door te gaan. Ik hoop ook in de toekomst met je samen te kunnen blijven werken.

Professor Dr. Karin van der Rijt, Beste Karin, ik wil je bedanken dat je, ondanks de drukte rondom je inauguratie, bereid was om in de kleine commissie plaats te nemen. Ik hoop van harte dat het lezen van dit proefschrift minder saai voor je was dan die eindeloze rapporten voor ziekenhuizen en instellingen in de periode dat je mijn begeleider was bij de implementatie van pijnregistratie in ziekenhuizen en verpleeg- en verzorgingshuizen.

Professor Dr. Erik Scherder. Beste Erik, bedankt dat je zo enthousiast instemde om plaats te nemen in de kleine commissie en voor het meedenken bij ons Enschede artikel. Dat laatste is mede dankzij jouw inbreng zeker een beter manuscript geworden.

Professor Dr. Frank Huygen. Beste Frank, ook jou wil ik hartelijk danken voor je bereidheid om plaats te nemen in de kleine commissie en voor het aanvaarden van de taak als secretaris hierbij.

Dokter Baar, beste Frans jij behoorde samen met Monique en Dick tot de eerste die mij ervan probeerden te overtuigen dat ook ik het promotietraject zou moeten gaan bewandelen. Ik dank je hartelijk voor je enthousiaste ondersteuning bij alle onderzoeken die binnen Laurens hebben plaatsgevonden.

De overige leden van de commissie dank ik hartelijk voor hun bereidheid om zitting te nemen in de grote commissie.

Collega's zijn er, in de loop van de kleine 35 jaar dat ik in het Erasmus MC- Sophia heb gewerkt, velen geweest. Ik zal me beperken tot de mensen met wie ik in het kader van de pijn heb gewerkt.

Allereerst de collega's op het pijnkenniscentrum (PKC): Annemerle, Nanda, Rhodee, Dirk, Tilly, Wendy, Thea, George, Michael en Yvonne. Het was een gezellig tijd, eerst in 'onderhuur" op het pijnbehandelcentrum met zijn allen in één hok. (hoewel mijn aanwezigheid niet echt opgevallen is zoals ik later heb moeten vaststellen). Later op onze eigen afdeling in de catacomben van het Z-gebouw. Ik heb deze tijd, mede door jullie, als een hele goede tijd ervaren!

Na de ontmanteling van het PKC ging ik terug naar het Sophia en kwam op Sp 2480 terecht. Deze heel gezellige en vooral tropisch warme kamer deelde ik met Joke, Ilse, Ilona (heel even), Lieke en soms Annelies en Margreeth.

Sp 2480 kenmerkte zich door de altijd openstaande deur voor oude bewoners en nieuwe collega's. Ik wil als bezoekende collega's dan ook zeker noemen: Joanne, Bram, Marie-Chantal, Nynke, en Alexandra. Ondanks de vaak tropische temperatuur werd er veel gelachen en heel hard gewerkt met een grote bereidheid om elkaar te helpen en steunen. Dat laatste bleek regelmatig nodig.

Toch denk ik dat de mensen van kinder- en jeugdpsychiatrie het niet erg vonden dat we naar de Westzeedijk verhuisden. Daar kregen we op Wk 208 een hele ruime en rustige werkplek. We begonnen daar met zijn vieren maar het aantal groeide en wisselde, geheel volgens de Sophie traditie, al snel. Joke, Ilse, Gerbrich, Lieke, Marlous, Carlijn en Violet het was heel gezellig om de kamer met jullie te delen. Ik dank jullie voor de altijd aanwezige bereidheid om mee te denken en me aan te moedigen. Ieder van jullie heeft zo op zijn eigen manier en gebied een bijgedragen aan het slagen van mijn proefschrift. De goede sfeer en het feit dat iedereen voor elkaar klaar staat was er natuurlijk al tussen de collega's in het Sophie maar zo met elkaar in exil kwam die heel goed tot zijn recht.

Van deze plaats wil ik iedereen heel hartelijk bedanken voor de samenwerking! Ik mag dan verreweg de oudste zijn jullie kennis en hartelijkheid maakt dat ik me vaak heel jong (lees klein) heb gevoeld.

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Ko Hagoort, jij was de rots in de branding wanneer het op het leesbaar maken van mijn stukken aankwam. Je weet, ik was soms wanhopig wanneer ik alle voorstellen tot

aanpassing zag maar uiteindelijk bleek het resultaat een kort (wat in mijn geval op zich al een prestatie is) en bondig leesbaar stuk. Ik dank je dan ook heel hartelijk en hoop ook in de toekomst een beroep op je te mogen doen.

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Mijn paranimfen Marja Kattemölle en Annemerle Wanschers-Beerthuizen wil ik heel bijzonder bedanken. Ik ben heel blij dat jullie tijdens de verdediging naast me zullen staan, maar ook dankbaar voor de ondersteuning en hulp in de voorbereidende fase. Annemerle, jij als ervaren paranymf zorgde ervoor dat we al in een vroeg stadium aan de juiste voorbereiding werkten. Je was zelfs bereid je kleding en haarsmuk aan mij aan te passen (achteraf gezien deed je dat al af en toe in het PKC) ik voel me zeer vereerd. Ik hoop dat we nog regelmatig de tijd vinden om samen te lunchen. Marja, voor ons beide is dit een hele nieuwe ervaring. Ik was heel blij dat je de organisatie van mijn feest overnam toen je merkte dat ik er niet aan toekwam om snel te reageren. Ik hoop dat we nog lang gezellige uitstapjes en reisjes samen zullen maken.

Curriculum Vitae

Anneke Boerlage werd op 14 december 1955 te Amsterdam geboren.
Na het behalen van haar middelbare school diploma volgde zij van 1973 tot 1977 de opleiding tot algemeen verpleegkundige bij de Zr. Engelbertstichting te Rotterdam. Daaropvolgend trad zij in dienst van het Sophia Kinderziekenhuis waar zij werd opgeleid tot: kinderverpleegkundige, kinder intensive care verpleegkundige en verpleegkundig docent. Van 1982 tot 1986 werkte zij op de dialyse afdeling van het Dijkzigt ziekenhuis en volgde de opleiding tot dialyse verpleegkundige. Na zeven maanden als waarnemend hoofdverpleegkundige op de kinderafdeling van het Holy ziekenhuis te hebben gewerkt kwam zij in 1986 weer in dienst van het Erasmus MC-Sophia. Daar werkte zij op de afdeling neonatologie als afdelingsverpleegkundige en vanaf 1991 als researchverpleegkundige. In de periode 1995 tot 1998 volgde zij de studie tot Master of Science in Nursing aan de Hogeschool van Utrecht in samenwerking met de Universiteit van Cardiff. Na het behalen van deze graad werkte als researchverpleegkundige en afdelingsverpleegkundige op de afdeling neonatologie van het Erasmus MC-Sophia.
Gedurende 7 maanden in de periode 2002 en 2003 had zij gecombineerde baan als verpleegkundig specialist pijn binnen het pijnkenniscentrum van de centrum locatie en als coördinator wetenschappelijk onderzoek in het MCRZ. Dat werd een volledige baan binnen het pijnkenniscentrum en vanaf 2008 is zij werkzaam als verpleegkundig onderzoeker pijn in het Sophia Kinderziekenhuis en veranderde de aard van haar werkzaamheden in promotie onderzoek met als eindresultaat dit proefschrift.

PhD Portfolio

Name PhD student:	Anneke Boerlage
Erasmus MC Department:	Intensive Care and Pediatric surgery
Research School:	
PhD period	2008 to December 2011
Promotor:	Prof.Dr. Dick Tibboel
Co-promotor:	Dr. Monique van Dijk

PhD training

	Year	Workload (hours)
General Academinc skills		
Biomedical English Writing and Communication	2006	80
Engels presenteren en discussiëren	2008	80
The why and how of readable articles; NIHES Summercourse	2010	20
Basiscursus Regelgeving en Organisatie voor Kli-ninsch onderzoekers	2011	80
Research skills		
Statistics: Introduction to Data Analysis; NIHES summecourse	2009	80
Presentations		
NPTN; oral presentation; Lunteren	2006	50
Nederlands-Vlaams onderzoeksforum; poster pre-sentation; Antwerpen	2007	60
NVFG, presentatie REPOS; Den Bosch	2008	12
Evidenced based care congress; Amsterdam	2010	4
International conferences		
EFIC congress, Istanbul; poster	2006	40
IASP congress, Glasgow; poster	2008	40
EFIC congress, Lissabon; poster presentation	2009	40

Seminars and workshops		
2e Nationale pijncongres; Ede	2006	5
Nederlands-Vlaams onderzoeksforum	2007	5
3e Nationale pijncongres; Ede	2008	5
Pijnbeleid bij kinderen; Leuven	2009	5
4e Nationale pijncongres; Ede	2010	5
Regio bijeenkomst pijn; IKNL; Rotterdam	2011	3
Teaching activities		
4x Workshop REPOS; Palliatieve zorg; Uden/Veghel	2007	12
3e Nationale pijncongres 2 workshops REPOS	2008	6
Working with the REPOS; Palliatieve zorg; Zeist	2008	6
Train de trainer bijeenkomst CPG; 2x; Rotterdam	2008	56
Scholing CPG en COMFORT voor FT; Groningen	2008	12
Train de trainer bijeenkomst REPOS; Rotterdam	2008	16
Scholing REPOS; Pall. Care verplk; Den Bosch	2009	10
Train de trainer bijeenkomst REPOS; 2x ; Rotterdam	2009	32
Workshop pijnbeleid bij kinderen; Leuven	2009	4
Scholing pijnobservatie ID voor:artsen, orthopedagogen en fysiotherapeuten; 4x	2010	45
4e Nationale pijncongres 6/4; workshop	2010	8
Symposium: palliatieve zorg in ID; workshops	2010	6
Scholing AVG artsen: pain observatie ID	2010	3
Workshop Evidence Based Care; pijnmeten bij ouderen	2010	3
Scholing COMFORT-gedragscor	2010	16
Train de trainer bijeenkomst REPOS	2010	16
Masterclass REPOS	2011	3
Lecturing		
Evidenced-Based Nursing Courses zorgacademie	2010/2011	30
Other		
Ontwikkeling van de richtlijn pijn bij mensen met een verstandelijke beperking	2010	4
Meelezen bij de ontwikkeling van de richtlijn pijn bij kwetsbare ouderen	2010	2