Critical Pressure

pressure ulcer care in critically ill patients and hospitalised patients at large

Erik de Laat
Critical Pressure

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The studies presented in this thesis have been performed at the nursing science section of the Centre for Quality of Care Research (WOK). This centre is part of the Nijmegen Centre for Evidence Based Practice (NCEBP), one of the approved research institutes of the Radboud University Nijmegen and the Netherlands School of Primary Care Research (CaRe), acknowledged by the Royal Dutch Academy of Science (KNAW).

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Henricus Embertus Wilhelmus de Laat

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<table>
<thead>
<tr>
<th>Title</th>
<th>Names</th>
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</thead>
<tbody>
<tr>
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</tr>
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<td>Co-promotores</td>
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<td>Dr. P. Pickkers</td>
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<tr>
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<td>Prof. dr. J.G. van der Hoeven</td>
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<td></td>
<td>Prof. dr. G.J. van der Wilt</td>
</tr>
<tr>
<td></td>
<td>Prof. dr. T. Defloor (Universiteit Gent (B))</td>
</tr>
</tbody>
</table>
Contents

Chapter 1  Introduction  page 7

Chapter 2  Epidemiology, risk and prevention of pressure ulcers in critically ill patients: a literature review
J Wound Care 2006; 15: 269-275.  17

Chapter 3  Prevalence, risk factors and prevention of pressure ulcers in Dutch intensive care units. Results of a cross-sectional survey
Intensive Care Med 2001; 27(10): 1599-1605.  35

Chapter 4  Early postoperative 30° lateral positioning after coronary artery surgery: influence on cardiac output
J Clin Nurs 2006; in press.  49

Chapter 5  Implementation of a new policy results in a decrease of pressure ulcer frequency

Chapter 6  Guideline implementation results in a decrease of pressure ulcer incidence in critically ill patients
Submitted.  75

Chapter 7  Pressure ulcers: diagnostics and interventions aimed at wound-related complaints: a review of the literature

Chapter 8  General discussion  105

Summary  117
Samenvatting  123
Dankwoord  129
Curriculum Vitae  135
Introduction
INTRODUCTION

PRESSURE ULCERS, A PERSISTENT PROBLEM
Pressure ulcers are a serious and persistent problem for patients throughout the Western world. The prevalence of pressure ulcers grade I-IV ranges from 9% to 15% in hospitalised patients in the United States\(^1\). In the Netherlands the prevalence ranges from 20% to 23% in patients in general hospitals and from 13% to 18% in patients in university hospitals\(^2\).

Pressure ulcers are among the most common adverse events in nursing practise. They occur in bed or chair bound patients who are not able to perceive pressure or to react to pressure. A disturbed perception of this force occurs in patients with paralysis due to neurological disorders or medical interventions such as anaesthesia. The inability to react properly to these forces also arises in patients who are severely ill and too weak to move their bodies.

When a pressure ulcer occurs it has many consequences for patients and health care professionals. The patient suffers from painful wounds and may need to be admitted longer to the hospital or more often for the treatment of pressure ulcers. Moreover, pressure ulcers lead to a more intensive nursing and medical care\(^3\).

Within hospitalised patients, patients admitted to intensive care units (ICUs) are at a particularly high risk of developing pressure ulcers. These critically ill patients are generally not able to notice increased tissue pressure and to react accordingly, because they receive sedation, analgesics and/or muscle relaxants\(^4-6\). Moreover, their underlying disease and haemodynamic instability increase the risk of developing a pressure ulcer\(^6,7\).

The prevalence of pressure ulcers grade I-IV in the ICU varies between 14% on a short-stay unit up to 42% on a long-stay unit\(^8\).

This thesis focuses on the nature and extent of the pressure ulcer problem for patients and on the effects of the implementation of a guideline on pressure ulcer occurrence in hospitalised patients with an emphasis on critically ill patients.

DEFINITION
According to the European Pressure Ulcer Advisory Panel (EPUAP) a pressure ulcer is an area of localised damage to the skin and underlying tissue caused by pressure, shear or friction or a combination of these forces. Pressure ulcers are classified into four grades of increasing severity\(^9\).
PRESSURE ULCERS CLASSIFICATION (EPUAP)\textsuperscript{9}

**Grade 1:** non-blanchable erythema of intact skin. Discolouration of the skin, warmth, oedema, induration or hardness may also be used as indicators, particularly in individuals with darker skin.

**Grade 2:** partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion or blister.

**Grade 3:** full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through underlying fascia.

**Grade 4:** extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss.
**Etiology**

There are 4 theories about what happens in the tissue when pressure and/or shear are exerted. These theories describe (i) localised ischemia of the soft tissue\textsuperscript{10-12}, (ii) disturbance in metabolic equilibrium\textsuperscript{13,14}, (iii) reperfusion injury\textsuperscript{15,16} and (iv) sustained deformation of cells\textsuperscript{17}. The critical determinants of pressure ulcer development in all 4 theories are the intensity and duration of pressure\textsuperscript{18}. If no pressure is applied to the skin and underlying tissues, patients do not develop pressure ulcers. Whether the skin and underlying tissues will break down depends on intensity and duration of pressure and the tolerance of the tissues for these pathophysiological processes. Many factors such as age, general condition and underlying disease are thought to be associated with pressure ulcers development\textsuperscript{18}.

**Prevention**

In theory, most pressure ulcers are preventable when effective preventive measures are taken in time\textsuperscript{19}. The most important measures reduce the amount of pressure or shear forces, influence the time mechanical forces are present or increase the tissue tolerance for pressure\textsuperscript{18,19}. Generally accepted measures in practice are regular repositioning of the patient\textsuperscript{20} and/or pressure reducing mattresses\textsuperscript{20,21}. Measures that increase the tissue tolerance for pressure are less specific and more focused on maintaining or improving the general condition of the patient\textsuperscript{22}.

Considering the previously mentioned consequences of pressure ulcer development for patients, the care givers, institutions and society, efforts need to be made to prevent pressure ulcers. Measures to prevent and treat pressure ulcers are described in guidelines on pressure ulcer care\textsuperscript{9,23-26}. In 1998, a committee of the Health Council of the Netherlands evaluated the efficacy of pressure ulcer prevention and pressure ulcer treatment (pressure ulcer care)\textsuperscript{27,28}. The committee concluded that the measures taken to prevent and treat pressure ulcers varied greatly and that the compliance with the existing guidelines was inadequate. The reasons for this lack of compliance to the guidelines were (i) a lack of knowledge about these guidelines, (ii) the lack of accompanying skills, (iii) underestimation of the problem by health care institutions and (iv) vagueness about responsibilities in the management of pressure ulcers. As a consequence, the quality of care too often depends on the individual care giver. Additional barriers for insufficient compliance with preventive guidelines were the low priority given to prevention by nurses, lack of interest, not using suitable pressure-reducing devices, lack of adequate
staff and the high costs of specific aids. The lack of compliance with the guidelines results in withholding good care and continuing ineffective and inefficient care\textsuperscript{27,28}. An additional consideration in critically ill patients is the impossibility to generalise all recommendations from the guideline to this specific patient group. For instance, the majority of critically ill patients do not receive routine regular repositioning\textsuperscript{29} because a negative influence on haemodynamic parameters is assumed\textsuperscript{6}.

The Dutch government presses for quality improvement of pressure ulcer care. To stimulate the improvement of the quality of pressure ulcer prevention, the occurrence of pressure ulcers was chosen as a performance indicator for Dutch hospitals and specifically of ICU departments\textsuperscript{30,31}. A performance indicator is a measurable aspect which indicates the performance on quality, safety, efficiency and accessibility of the healthcare system in the Netherlands. The yearly performance on an indicator has to be published without restrictions and has to be accessible in the annual report or on the website of a hospital. This stimulus should encourage care givers to comply to the guidelines and encourage organisations to invest in specific aids, supervise the implementation of guidelines and execution of adequate professional skills.

**Guidelines**

The earliest guideline on pressure ulcer prevention in the world was derived from a consensus process in the Netherlands\textsuperscript{32}. After a revision in 1992\textsuperscript{33} and 2002\textsuperscript{26}, this guideline developed into an evidence based guideline on prevention and treatment of pressure ulcers. In the USA and Europe, similar guidelines were developed\textsuperscript{23,24,25}. To stimulate compliance with guidelines, it is important to view pressure ulcers as a major problem in hospitals and to offer supplementary training\textsuperscript{27,28}. Therefore, we developed a “Guideline for Pressure Ulcer Care” in the study hospital, based on national\textsuperscript{26} and international guidelines for pressure ulcer care\textsuperscript{9,23-25} and investigated its impact on clinical practice.

**AIM AND OUTLINE OF THE THESIS**

The aim of this thesis is threefold. The first aim is to gain more insight into the nature and extent of the pressure ulcer problem in hospitalised patients, especially in critically ill patients. Secondly, we investigated whether early postoperative lateral positioning to prevent pressure ulcers after coronary artery bypass surgery influenced the cardiac output negatively and whether turning procedures cause practical problems.
INTRODUCTION

Case
A 77 year old man was admitted to the intensive care unit after cardiac surgery. During a 7 hour procedure, five coronary artery obstructions were bypassed and his insufficient mitral valve was replaced by an artificial one. After the operation the application of an intra aortic balloon pump and high doses of inotropic medicines were necessary to stabilise his circulation. During the first 24 hours the patient was resuscitated twice. After 5 days with a maximum of intensive therapy the situation stabilised slowly. From then on, a long period with ups and downs followed. Six weeks after admission on the ICU, the patient was successfully weaned from the respirator. Three days later he was discharged from the ICU to the cardiac intermediate care unit. There, for the first time, the nursing staff asked a nurse consultant to evaluate severe pressure ulcers.

Before entering the patient’s room, the pressure ulcer consultant came upon his wife. She told him about the problematic course of her husband’s recovery at the ICU. She was disappointed, because on the day of admission to the nursing ward, prior to the operation, she told the nurse who assessed her husband that his skin was thin and that he had a history of pressure ulcers in former periods of illness. For unknown reasons a special mattress was not applied directly after surgery and during the first five days after the operation her husband was haemodynamically too unstable to transfer him to a special mattress. After five days a grade-III ulcer on his buttock and left heel and a grade-IV ulcer on his right heel were diagnosed. His wife knew he had a lot of pain from his ulcers. Moreover, his hospital stay was considerably lengthened as a result of the ulcers. Dressing changes were painful and took a lot of energy. Although the patient and his wife understood the severity of the patient’s condition in the post-operative period and acknowledged that more vital problems had a higher priority, in her view, her husband’s pressure ulcers were an unnecessary complication and could have been prevented if a special mattress would have been applied directly after the operation.

The patient was discharged from the hospital two weeks later. After a six week intensive home care program the patient was rehabilitated. The pressure ulcers on his buttock and left heel healed within that period. The healing process of the pressure ulcer on his right heel took more than half a year.

The third aim was to gain insight in the effects of a hospital wide program on pressure ulcer care on the occurrence of pressure ulcers in both a general hospital population, as well as in critically ill patients.

In chapter 2 the current scientific evidence in the field of epidemiology, risk factors, risk assessment and prevention of pressure ulcers in critically ill patients is reviewed. Chapter 3 reports the result of a secondary analysis of cross sectionally obtained data of the Dutch National Pressure Ulcer survey in critically ill patients.

The most important measure to prevent pressure ulcers, is regularly turning critically ill patients. However, this measure is seldom applied in critically ill patients, because a
negative influence on haemodynamic parameters is assumed. Chapter 4 reports on the results of a clinical trial in which we investigated the influence of early 30° lateral positioning after coronary artery bypass surgery and the nature and extent of practical problems caused by the turning procedures. In chapter 5 the effect of a hospital guideline for pressure ulcer care combined with the introduction of visco-elastic foam mattresses on the efficiency of the prevention and treatment of pressure ulcers in the general hospital population is described. In chapter 6 we focus on the short- and long term effect of the guideline on both the incidence and the time to the onset of pressure ulcers in critically ill patients.

Patients with pressure ulcers are confronted with symptoms of chronic wounds and impaired wound healing. In line with the first aim, chapter 7 describes the current scientific evidence in the field of diagnostics and treatment of pain, malodour and exudate from pressure ulcers and gives recommendations for practice, based on these findings. In chapter 8 the findings described in this thesis are discussed and also some suggestions for further research are provided. Finally, the findings of this thesis are summarised in English and Dutch.
REFERENCES


Epidemiology, risk and prevention of pressure ulcers in critically ill patients: a literature review

Erik de Laat
Lisette Schoonhoven
Peter Pickkers
André Verbeek
Theo van Achterberg

ABSTRACT

INTRODUCTION: This systematic literature review aims to describe the current scientific evidence on pressure ulcers and pressure ulcer care in patients admitted to Intensive Care Units (ICUs) with a view to epidemiology, risk factors, risk assessment and prevention.

METHODS: Medline, CINAHL, and The Cochrane library, were systematically searched.

RESULTS: The incidence of grade I-IV pressure ulcers ranges from 5% to 20% and the incidence of grade II-IV pressure ulcers ranges from 3% - 15%. Although several studies confirm predefined risk factors, other studies refute these risk factors. Therefore, no specific risk factors for pressure ulcer development could be identified. There is no evidence for a valid and reliable risk assessment tool. In the absence of proven effective specific preventive interventions in critically ill patients, routine turning every 2 hours on a pressure-reducing mattress remains the generally accepted standard for the prevention of pressure ulcers in immobilised critically ill patients. However, the compliance in daily practice with this standard is problematic.

CONCLUSION: Pressure ulcers in critically ill patients are still a persistent problem. It is not possible to establish one group of risk factors which predict pressure ulcer risk in critically ill patients. There are no proven effective preventive therapies.
INTRODUCTION

The prevalence of pressure ulcers in intensive care units (ICU) is between 14% and 42%1. Intensive care patients generally do not notice increased tissue pressure or cannot react accordingly due to sedation, analgesia and/or muscle relaxants2–4. Additionally, underlying disease and haemodynamic instability increase their risk of developing pressure ulcers1–4.

A pressure ulcer is an area of localised damage to the skin and underlying tissue caused by pressure, shear, friction or a combination of these factors. In Europe they are classified according to an internationally accepted grading system5–6. Defloors’ conceptual scheme of pressure ulcer occurrence suggests pressure and shear are causal factors7. Therefore, pressure-redistributing mattresses or other pressure-redistributing measures in combination with body repositioning are the main preventive measures for general and critically ill patients8–9. Tissue tolerance defines tissue susceptibility to pressure and shear7.

The literature on pressure ulcers in ICU patients from 1980 to 1995 and 1980 to 1999 was reviewed by De Laat4 and Keller et al.1. Emphasis was on epidemiology, specific risk factors, risk assessment scales and prevention in critically ill patients. They concluded the frequent occurrence of pressure ulcers in critically ill patients might be accounted for by specific risk factors and/or indicators (Box 1), although the evidence base for these was weak. Most of these risk indicators were used in risk assessment scales to identify critically ill patients at risk of developing pressure ulcers. However, there were no conclusive studies on their validation. The overall conclusion was that meaningful comparisons between the selected studies could not be made due to the heterogeneity of their methodologies, outcomes and populations. De Laat4 and Keller et al.1 recommended that future studies on pressure ulcers in critically ill patients should use the definitions and grading systems of the US National Pressure Ulcer Advisory Panel (NPUAP)5 and the European Pressure Ulcer Advisory Panel (EPUAP)6.

New interventions such as nursing mechanically ventilated patients in the prone position may result in ‘new’ pressure ulcer areas, while new types of pressure-redistributing devices have entered the market and the debate on specific risk assessment scales for critically ill patients is still ongoing. We therefore systematically reviewed the literature on pressure ulcers in ICU patients, focusing on epidemiology, specific risk factors, assessment scales and preventive measures1–4.
Box 1  Risk indicators for pressure ulcers in critically ill patients

- Duration of surgery
- Number of operations
- Faecal incontinence and/or diarrhoea
- Low preoperative protein and albumin concentration
- Disturbed sensory perception
- Moisture of the skin
- Impaired circulation
- Use of inotropic drugs
- Diabetes mellitus
- Too unstable to turn
- Decreased mobility
- High APACHE II score

METHODS

A search strategy was developed to identify eligible publications from January 1999 to May 2005 in Medline, Cinahl and the Cochrane Library. Subject headings included ‘decubitus ulcer’ or ‘pressure ulcer’ combined with ‘critical ill(ness)’, ‘critically ill patients’ (defined as patients nursed in an intensive care setting), ‘critical care (nursing)’ with all topical subheadings. We used filters for specific searches on aetiology, diagnosis, prognosis and prevention respectively. Studies of any kind on adult critically ill patients with pressure ulcers were included.

Independent searches in the three databases identified 772 items. After exclusion of duplicates (n=341), studies concerning paediatric or neonatal care (n=36), studies not concerning pressure ulcers or critically ill patients (n=289), studies without an abstract (n=27) and publications with a tutorial or narrative character (n=39), 40 publications were considered for critical review by two reviewers. We included original research with outcome parameters on:

- Pressure ulcer frequency
- Risk factors
- Risk assessment
- Prevention measures.

Studies on economics (n=4) or treatment (n=13) were excluded. Four studies were excluded due to language. Disagreements between reviewers were settled by discussion of the full paper by the first and second author. Finally, 19 studies were included in the review (Table 1).
<table>
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<tr>
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<th>Design*</th>
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<th>Sample size</th>
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<th>Risk assessment</th>
<th>Preventive measures</th>
<th>Relevant outcome measurements</th>
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<tr>
<td>Carlson et al.17</td>
<td>PC</td>
<td>medical/surgical</td>
<td>136</td>
<td>+</td>
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<td>+</td>
<td>-</td>
<td>PU Grade I-IV, Braden scale, LOS, APACHE III.</td>
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<td>Inman et al.25</td>
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<td>+</td>
<td>-</td>
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<td>-</td>
<td>-</td>
<td>PU Grade I-IV, Braden scale, LOS, Glasgow coma scale, Albumin, BMI, Neurological diagnosis, Hypertension.</td>
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<td>acute respiratory failure</td>
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<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>PU Grade I-IV.</td>
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<tr>
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<td>+</td>
<td>Degree of skin lesion, arterial blood gases, eye irritation.</td>
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<td>351</td>
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<td>PU Grade I-IV, (duration on) mattress.</td>
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<td>422</td>
<td>+</td>
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* CS=cross sectional, NRMCT=Non-randomised multi centre clinical trial, PC=prospective cohort study, PO=prospective observational, RCT=randomised controlled trial, REV=Review. APACHE=Acute Physiology and Chronic Health Evaluation, BMI=Body Mass Index, COPD=Chronic obstructive pulmonary disease, CURS=Cornell ulcer risk score, DNR=do-not-resuscitate, GCS=Glasgow coma scale, LOS=Length of stay in ICU, PU=pressure ulcer, MODS=multiple organ dysfunction score, SIRS=systemic inflammatory response syndrom, SURE=skin ulcer risk evaluation, TPN=total parental nutrition.
RESULTS

Definition and classification

Ten of the 19 studies reported data on pressure ulcer prevalence and/or incidence\(^2,3,17-24\). A clear case definition is important in epidemiological studies. In seven studies\(^2,3,17-20,23\) pressure ulcers were diagnosed using the NPUAP\(^5\) or EPUAP\(^6\) grading system. The one-digit Stirling pressure sore severity scale used by Boyle and Green\(^3\) is considered similar to the NPUAP grading system. Eachempati et al.\(^18\) did not use a grading system, although their outcome definition ‘days to stage II pressure ulcer’ implies there was one. In one study a pressure ulcer was defined as: ‘skin breakdown Yes/No’\(^24\). As skin breakdown includes conditions other than pressure ulcers, this study is not discussed with regard to epidemiological aspects.

Prevalence

One study described the prevalence of pressure ulcers in critically ill patients\(^2\). In this cross-sectional study data obtained from the Dutch national prevalence surveys in 1998 and 1999 were analysed in a secondary analysis. In a sample of 850 ICU patients, 244 grade I–IV and 155 grade II–IV pressure ulcers were counted with a mean of 2.0 ± 1.3 pressure ulcers per patient. From these numbers we derived a grade I–IV pressure ulcer prevalence of 14.4% and a grade II–IV prevalence of 9.1%.

Incidence

Five prospective cohort studies reported the incidence of pressure ulcers in critically ill patients (Table 2)\(^3,17-19,23\). Eachempati et al.’s study was conducted in two phases\(^18\). In the first, several notable circumstantial changes occurred, which may have influenced the incidence of pressure ulcers. Therefore, we only included in our review the prospective study from phase 2. Incidence of grade I–IV pressure ulcers ranged from 5.2% to 20.0%\(^3,17,23\). Incidence of grade II–IV pressure ulcers ranged from 8.0% to 15.0% in four studies\(^17,19,23\). In four studies pressure ulcer incidence was properly calculated\(^3,17,19,23\).
Table 2  Incidence of pressure ulcers in critically ill patients

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<td>prospective multi-centre analysis of prospectively obtained data</td>
<td>medical/surgical</td>
<td>534</td>
<td>Yes</td>
<td>5.2%</td>
<td></td>
</tr>
<tr>
<td>Eachempati et al.18</td>
<td>analysis of prospectively obtained data</td>
<td>surgical</td>
<td>412</td>
<td>Doubtful</td>
<td>8.0%</td>
<td></td>
</tr>
<tr>
<td>Fife et al.19</td>
<td>prospective cohort study</td>
<td>neurological</td>
<td>186</td>
<td>Yes</td>
<td>12.4%</td>
<td></td>
</tr>
<tr>
<td>Pender et al.23</td>
<td>prospective study (convenience sample)</td>
<td>medical</td>
<td>40</td>
<td>Yes</td>
<td>20%</td>
<td>15.0%</td>
</tr>
</tbody>
</table>

Location
Between 50%3,19 and 75%17 of the pressure ulcers occurred on the classic locations: the sacral area and heels. Three studies described exceptional locations of pressure ulcers in critically ill patients20-22. Due to the introduction of prone positioning and non-invasive facemask ventilation, new locations of pressure ulcers on the anterior weight-bearing sites, such as the face, thorax, iliac crest, breast and knee, are described20-22. Pelosi et al. found that most mechanically ventilated patients (75%) placed in the prone position developed pressure ulcers, the majority (63%) of which were severe22; no grading system was used. In a multi-centre randomised trial patients with acute lung injury (n=152) or acute respiratory distress syndrome (n=152) were treated conventionally in the supine position or for six or more hours in the prone position20. The number of patients with new or worsening pressure ulcers in both groups did not differ (27.5% versus 36.0%; p=0.13). However, the number of pressure ulcers of grade II or worse per patient was statistically significantly higher in patients placed for periods in the prone position (1.9 ± 1.3 versus 2.7 ± 1.7; p=0.004).

Risk factors and indicators in critically ill patients
Ten studies that aimed to identify risk factors and risk indicators in ICU patients were selected2,3,17-19,23-27. The study by Wolverton et al.24 only presented descriptive data without statistical analysis, and is therefore not discussed. Seven studies3,17-19,25-27 had a prospective design, one2 a cross-sectional design and one study23 a retrospective design. Cross-sectional and retrospective designs result in associations between the factor under study and the development of pressure ulcers, but are unable to be conclusive about the predictive value of the risk factor. Pokorny et al. described univariate associations between pressure ulcer occurrence and risk factors26. Univariate analyses do not account
for the inter-related nature of risk factors and so are an inappropriate analysis for risk-factor identification. Thus, only six studies with prospective, multivariately obtained results are discussed\textsuperscript{3,17,19,25,27}. With the exception of the study by Inman et al.\textsuperscript{25}, a randomised controlled trial, the studies had a comparable prospective cohort design.

Table 3 gives an overview of almost 50 risk factors entered in multivariate analyses in the six studies selected. The label of the risk factor is the same as used in the studies. We summarised related risk factors per group or feature. Every statistically significant risk factor found in one study was refuted by one or more statistically insignificant findings on identical or related risk factors in other studies (Table 3). Moreover, we found a large variation in methodological choices:

- There was a great variation in initial risk factors selected to examine the association between the risk factor and pressure ulcer development
- Study populations varied, including surgical,\textsuperscript{18} mixed medical and surgical,\textsuperscript{3,17} neurological\textsuperscript{19} critically ill, or were not specified\textsuperscript{25,27}
- Definitions and levels of measurement of identically labelled risk factors varied between studies
- Levels of measurement and analysis of variables under study differed
- Methods of selecting variables in a multivariate model varied between studies.

No single specific risk factor for pressure ulcer development could be identified that is generally valid in a population of critically ill patients.

Risk assessment

We found four prospective observational studies that addressed risk assessment instruments. Four tested validity\textsuperscript{3,17,19,28} and one the utility of an instrument to detect critically ill patients at high risk of pressure ulcers\textsuperscript{3}. No studies on the reliability of risk assessment instruments were found. Risk assessment instruments studied in critically ill patients were the: Waterlow scale\textsuperscript{3}, Braden scale\textsuperscript{17,19,28}, Douglas scale\textsuperscript{28}, Cubbin and Jackson scale\textsuperscript{3,28}.

Carlson et al.\textsuperscript{17} only mentioned that the mean total Braden score was significant as a predictor of the risk for pressure ulcers. Sensitivity, specificity and derived measures were not calculated, so this study is not discussed.

With the exception of one study\textsuperscript{19}, the prognostic ability of a scale to discriminate between patients with and without pressure ulcers was estimated by calculating the area under the receiver operating characteristic curve (ROC).
**Table 3  An overview of the risk factors entered into the multivariate analyses.**

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Chi-square</th>
<th>Coefficient</th>
<th>OR</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severeness of illness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>APACHE II ≥ 13</td>
<td></td>
<td>1.22</td>
<td>3.40</td>
<td>1.40</td>
<td>7.92</td>
<td>0.004</td>
</tr>
<tr>
<td>Emergency admission</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of stay</td>
<td></td>
<td>1.02</td>
<td>2.76</td>
<td>1.08</td>
<td>7.05</td>
<td>0.034</td>
</tr>
<tr>
<td>Disease related</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of stay</td>
<td></td>
<td>1.02</td>
<td>2.76</td>
<td>1.08</td>
<td>7.05</td>
<td>0.034</td>
</tr>
<tr>
<td>Circulation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular instability</td>
<td></td>
<td>2.09</td>
<td>8.11</td>
<td>3.64</td>
<td>18.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Anaemia</td>
<td></td>
<td>1.03</td>
<td>2.81</td>
<td>1.24</td>
<td>6.34</td>
<td>0.013</td>
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<tr>
<td>Sensitivity for, or reaction to pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coma/unresponsive/paralysed &amp; sedated</td>
<td></td>
<td>16.36</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sensory perception</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobility</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Days in bed</td>
<td></td>
<td>1.05</td>
<td>-0.00</td>
<td>0.02</td>
<td>0.006</td>
<td></td>
</tr>
<tr>
<td>Nutrition</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Days without nutrition</td>
<td></td>
<td>0.51</td>
<td>-0.11</td>
<td>-0.03</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>Moisture</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Faecal incontinence</td>
<td></td>
<td>1.18</td>
<td>3.27</td>
<td>1.32</td>
<td>8.30</td>
<td>0.010</td>
</tr>
<tr>
<td>Patient characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>1.08</td>
<td>0.00</td>
<td>0.01</td>
<td>0.003</td>
<td></td>
</tr>
</tbody>
</table>

**Statistically insignificant risk factors in multivariate analysis**

Severity of illness: APACHE II

Disease related: length of stay

Circulation: dopamine, epinephrine, peripheral vascular disease, too unstable to turn

Sensitivity for- or reaction on pressure: pain, spinal injury, stroke

Disease/comorbidity: coagulopathy, diabetes, head wound, hypertension, multiple organ dysfunction syndrome

Mobility: mobility/bedbound

Moisture: moisture/perspiration, faecal incontinence

Nutrition: albumin, malnutrition, obesity/underweight

Skin condition: unhealthy skin, steroids, oedema, friction

Patient characteristics: gender, age, hospital

Not included because of non-significant univariate result

Circulation: dobutamine, vasosuppressors

Sensitivity for, or reaction to, pressure: sedated

Moisture: urinary incontinence

Nutrition: reduced nutritional intake, total parenteral nutrition

Skin condition: friction

Patient characteristics: gender

OR=odds ratio; ND=not determined; CI=confidence interval; * Inman et al.’s study had no accompanying statistics. † Entered together in parametric regression model. § Likelihood Ratio Chi Square in parametric model. ‡ 95% CI is not comparable with OR.
Jun-Seongsook et al. assessed the validity of the Braden scale, Douglas scale and Cubbin and Jackson Area Risk Calculator in 112 critically ill patients. Areas under the curve were 0.71, 0.79 and 0.83 respectively. However, the study had methodological shortcomings. The sum scores of the scales at the day of pressure ulcer occurrence were used to determine risk status. In those who did not develop a pressure ulcer, sum scores of the scales at the day of discharge, transfer or death were used to determine risk status. Moreover, risk assessors were not blinded to the scores of the simultaneously scored risk assessment instruments and for patients’ pressure ulcer status. Inter-rater and intra-rater reliability were not studied.

The Cubbin and Jackson Pressure Area Risk Calculator was developed in 1991 to assess pressure ulcer risk in critically ill patients and was revised in 1999. This revised scale was tested by Boyle and Green in a sample of 188 patients, together with the Waterlow scale in a sample of 314 critically ill patients. Both scales predicted pressure ulcers rather well, considering the area under the curve (AUC) of 0.72 and 0.66 respectively. Measurements on risk status and pressure ulcer development were executed by staff nurses to familiarise them with the measurement instruments. The inter-rater and intra-rater reliability for staff nurses was not studied. The nurses were not blinded to patients’ pressure ulcer status.

Fife et al. evaluated the predictive ability of the Braden scale in 186 critically ill neurological patients. A cut-off score of 16 resulted in a false negative rate of 0% and a false positive rate of 81.9%. If a score of 13 or less was considered the trigger for preventive care, the at-risk population would decrease to 41.4%, with a positive predictive value of 27.3%, a false negative rate of 1.8% and a sensitivity of 91.4%. Fife et al. considered the Braden scale with a cut-off of 13 points as a valid and useful tool for identifying critically ill patients at increased risk of pressure ulcer development. In this study 10 trained nurses gathered the data but no inter-rater or intra-rater reliability between and within nurses was reported. The nurses were not blinded to patients’ pressure ulcer status.

Prevention

We selected three studies on the performance of measures to prevent pressure ulcers in critically ill patients and six on the effectiveness of these measures. The routine turning of immobilised critically ill patients at least every two hours has become the accepted standard of care, but there are no studies in critically ill patients to
corroborate this standard. Krishnagopalan et al. assessed professional opinion towards patient turning among ICU-physicians.9 Sixty respondents (83%) agreed that the standard of care is to turn immobile ICU patients approximately every two hours, while 90% agreed that turning immobile critically ill patients might reduce the risk of complications such as pressure ulcers. However, only 57% believed patients in their ICU received this turning care more than 50% of the time. To determine the compliance with this standard in the same study, 74 critically ill patients were observed for 566 patient hours9. Twenty-three per cent of the patients missed required turns by one or two hours, while about half remained in the supine position for four to eight hours without repositioning. A further 23% were not repositioned by staff for the entire study observation period.

In a secondary analysis of the Dutch national survey on pressure ulcer prevalence only 37% of the patients were repositioned in accordance with the guideline2.

In a randomised controlled trial (RCT) comparing efficacy of a multi-cell pulsating dynamic mattress system with conventional treatment in patients undergoing cardiovascular surgery (n=198), pressure ulcer development in patients in the dynamic pressure system group did not differ significantly from the control group34. The ‘conventional management’ was not described. A prospective non-randomised cohort study32 and a RCT35 concluded there was no specific superior device for the prevention of pressure ulcers.

As described earlier, relatively new interventions in critically ill patients have resulted in pressure ulcers occurring in new locations. New preventive devices were developed, for example, a prone head-support system to protect the face of patients mechanically ventilated in the prone position33 and new types of facemasks for patients receiving non-invasive ventilation21. In a randomised pilot study (n=8), patients with a prone head-support system had fewer pressure ulcers and less severe pressure ulcers compared with the group without prone head support33. The prone head-support system was a self-constructed device consisting of a hard plastic bowl covered with medical foam.

In patients receiving non-invasive ventilation the mask is often tightened to avoid air leakage. This may lead to facial pressure ulcers. In a randomised study Gregoretti et al. found significantly fewer pressure ulcers when a mask with a larger cushioned surface was used.21 There was a better seal between skin and mask at the level of the nasal bridge. This will lead to fewer air leaks and thus less need to tighten of the mask, which can result in harmful contact between the mask frame and the skin.
DISCUSSION

In this systematic review of the literature on epidemiological aspects, risk factors, risk assessment and prevention of pressure ulcers in critically ill patients we selected 20 studies. Our inclusion criteria were very broad and we included all the available studies on these topics. As the study aims, methodologies and endpoints of the studies varied, pooling was inappropriate. Therefore, we have discussed the studies in a narrative review. As such, our results give a valid description of the available knowledge on pressure ulcers in critically ill patients.

Epidemiology
The range of pressure ulcer incidence of all grades (5–20%) in critically ill patients between 1999 and 2005 is considerably smaller than the range between 1980 and 1999 (1–40%)\(^\text{14}\). However, due to differences in methodology and analysis, the decrease may be explained by an improvement in the methodological quality of the studies, which offer better estimates of actual prevalence and incidence. We cannot, therefore, conclude that there is a decrease in pressure ulcer development in critically ill patients.

The designs of the included studies still show some methodological shortcomings. In two\(^\text{2,18}\) the number of wounds was used in the nominator of the fraction to calculate the prevalence or incidence. However, only patients with a pressure ulcer should be counted, not the number of pressure ulcers per patient, as counting wounds leads to an overestimation of the prevalence and incidence proportions\(^\text{36,37}\). We recalculated the incidence\(^\text{18}\) and prevalence\(^\text{2}\) from the data reported.

We conclude that the more recent studies offer more reliable and valid estimates of actual prevalence and incidence, but we could not establish a decrease in pressure ulcer development in critically ill patients.

Risk factors
We could not identify specific risk factors for pressure ulcer development that are valid and discriminating in a critically ill population. Remarkably, there was a large variation in both theoretical and methodological choices.

We found a lack of theoretical arguments about potential risk factors included in the studies. It is argued that pressure and/or shear forces on the skin and underlying soft tissues cause pressure ulcers, depending on the duration and intensity of the mechanical loading and the tissue tolerance for pressure and/or hypoxaemia\(^\text{7}\). Critically ill patients...
are generally unaware of increased tissue pressure and unable to react accordingly because they receive sedation, analgesics and/or muscle relaxants\textsuperscript{2-4}. Therefore, immobility, inactivity and sensitivity for, or reaction to, pain do not discriminate between critically ill patients who are at risk and those who are not at risk. It would be advisable to exclude these known non-discriminating factors in multivariate analyses because the power of a multivariate analysis decreases as more dependent variables are included\textsuperscript{38}. With the exception of demographic variables such as age\textsuperscript{17,18,27} and gender\textsuperscript{3,18}, biometric variables, such as body mass index,\textsuperscript{19} and the APACHE instrument to assess the severity of illness\textsuperscript{17,18,27}, no validated instruments were used to measure the presence of a potential risk factor. Labels which appeared identical at first sight, such as mobility, were defined differently in the studies\textsuperscript{3,17,19}. More research is needed to define risk factors and develop instruments to measure these factors in a valid and reliable manner.

Another cause for concern was that the inclusion of potential risk factors in multivariate techniques differed strongly. In three studies statistically significant univariate associations between risk factors and pressure ulcer development were used\textsuperscript{18,19,27}. Without explaining their rationale, Boyle et al.\textsuperscript{3} included seven self-constructed factors, combining factors of the Waterlow and Cubbin and Jackson scales. In two studies the rationale for including potential risk factors in a multivariate analysis was missing completely\textsuperscript{17,25}.

No single specific risk factor for pressure ulcer development that is valid or discriminatory in either a general or specific critically ill population could be identified.

\textit{Risk assessment}

We discussed four studies addressing validation of risk assessment instruments in critically ill patients\textsuperscript{3,17,19,28}. It is remarkable that assessors were not blinded to patients’ pressure ulcer status in any of these studies. In the validation of three scales by Jun-Seongsook et al.\textsuperscript{28} the risk assessors also were not blinded to the scores on the simultaneously scored scales. This omission could introduce a serious observer bias\textsuperscript{38}. The lack of inter-observer and intra-observer reliability measurements introduced a second possible source of observer bias.

Sensitivity and specificity, and measures derived from these, are epidemiological tools in evaluating the predictive validity of diagnostic screening tests\textsuperscript{39}. In all reviewed studies the validity of risk assessment scales was studied as if they were diagnostic screening instruments\textsuperscript{40}. However, in contrast with diagnostic screening tests, risk assessment scales
are not intended to identify the existence of pressure ulcers, but the risk that pressure ulcers will occur. If preventive measures are used, the probability that a patient will develop a pressure ulcer will not remain constant over time. Use of effective prevention will alter the sensitivity and specificity of the risk assessment scale. Patients identified as being at risk will develop pressure ulcers only if preventive measures fail. Therefore, risk assessment scales should be evaluated with preventive measures included as independent predictors in multivariate models.

Fife et al. considered the Braden scale with a cut-off of 13 points to be a valid and useful tool for identifying critically ill neurological patients, who are at increased risk of pressure ulcer development. However, this cut-off point is extremely low and may lead to serious underestimation of pressure ulcer risk.

In summary, studies on predictive validity of risk assessment scales are not free from serious observer bias. Moreover, preventive measures, which alter the patient's risk, are not taking into account in these studies. Just as in prior reviews over the period 1980–1999, there is still no evidence for a valid risk assessment tool in critically ill patients.

**Prevention**

Although routinely turning immobilised critically ill patients every two hours has become an accepted standard, its execution fails in practice. Most critically ill patients are not repositioned according to this standard.

Higher-specification foam mattresses should be preferred to the standard hospital foam mattresses. We found no studies for a superior device in the prevention of pressure ulcers in critically ill patients. Some evidence was found for the use of facemasks with a large cushion surface in patients receiving non-invasive ventilation to prevent facial pressure ulcers.

**Conclusions**

The range of pressure ulcer incidence of all grades in critically ill patients between 1999 and 2005 is considerably smaller than the range between 1980 and 1999. However, due to differences in study methodology and analysis between the period before and after 1999, we cannot conclude that this decrease is the result of improved standards of care. To improve the comparability of study results in future, we recommend that prevalence and incidence studies be designed and executed in accordance with the EPUAP statement on prevalence and incidence monitoring.
No discriminatory risk factor for pressure ulcer development could be identified in the critically ill population. Also, there is no evidence for a valid risk assessment tool in critically ill patients. Although we found no evidence to support a turning regimen, we advise practitioners to comply with the accepted standard for the prevention of pressure ulcers by routinely turning every two hours on a pressure-redistributing mattress.

Some evidence was found for the use of facemasks with a large cushioned surface in patients receiving non-invasive ventilation to prevent facial pressure ulcers.

In general, there is still a need for methodologically well designed research on the epidemiological aspects, risk factors and risk assessment of pressure ulcers in critically ill patients to gain more insight in the nature and extent of this problem.
REFERENCES


Prevalence, risk factors and prevention of pressure ulcers in Dutch intensive care units: Results of a cross-sectional survey

Gerrie Bours
Erik de Laat
Ruud Halfens
Maarten Lubbers

ABSTRACT

OBJECTIVE: Evaluating the prevalence, risk factors and prevention of pressure ulcers in Dutch intensive care units (ICUs).

DESIGN: Cross-sectional design.

SETTING: Intensive Care Units of acute care hospitals that participated in the 1998 and 1999 national prevalence surveys. Data were collected on 1 day in each year.

PATIENTS: 850 patients admitted to Dutch intensive care units.

INTERVENTIONS: None.

MEASUREMENTS AND MAIN RESULTS: Six categories of data were collected: 1) characteristics of the institution, 2) characteristics of the ward, 3) characteristics of the patients (age, sex, date of admission, reason for admission), 4) risk assessment using the Braden scale and two additional risk factors (malnutrition and incontinence), 5) severity of the pressure ulcers and 6) supportive surface used. The prevalence of pressure ulcers was 28.7%. In a forward logistic regression analysis, four risk factors were significantly associated with the presence of pressure ulcers: infection, age, length of stay and total Braden score. Of the patients at high risk of developing pressure ulcers but without actual pressure ulcers, 60.5% were positioned on a support system. Only 36.8% of the patients who were determined to need repositioning were actually being turned.

CONCLUSIONS: The prevalence of pressure ulcers in Dutch ICUs is high and their prevention is flawed, especially as regards the use of support systems. Patients for whom turning is indicated are not being turned. Predicting pressure ulcers in ICU patients is difficult and needs further investigation.
INTRODUCTION
Pressure ulcers are a common but, in most cases, preventable problem among hospitalised patients. Prevalence rates in acute care hospitals have been found to vary between 4.7% and 18.6%. An extensive prevalence survey conducted in 43 Dutch acute care hospitals revealed a mean prevalence of 21.6%, with a range of 7.8%-48.8%. Patients admitted to intensive care units (ICUs) are at particularly high risk of developing pressure ulcers. These patients are generally not able to signal increased tissue pressure and react accordingly, because they have received sedation, analgesics or muscle relaxants. In most cases it is not possible to predict how long this immobility will last. In specific situations such as heart surgery, the surgery itself, anaesthesia and positive pressure ventilation may adversely affect the pump action of the heart, leading to reduced blood circulation in the skin and underlying tissues.

However, incidence and prevalence studies involving intensive care units are scarce and those studies that have been carried out reported rates ranging from 1% to 43%. Prevalence and incidence are both measures of frequency but provide different perspectives on the problem. Prevalence measures the proportion of a group affected at a particular point in time (point prevalence) or over a period of time during which the number of cases is counted (period prevalence), while incidence measures the proportion of a group initially free of pressure ulcers that develop them over a given period of time. Pressure and shearing forces are the causes of pressure ulcers and risk factors determine whether or not a pressure ulcer will develop. Insight into the variables affecting pressure ulcers will help to predict which patients are likely to develop pressure ulcers and are therefore in need of preventive procedures.

To evaluate the problem of pressure ulcers at Dutch ICUs, the following research questions were formulated:

1. What is the prevalence and severity of pressure ulcers in the Dutch ICUs participating in the national prevalence surveys in 1998 and 1999?
2. What risk factors are associated with pressure ulcers in patients admitted to an ICU?
3. Which strategies are used by Dutch ICU nurses to prevent the development of pressure ulcers; how often and when are these strategies used?
METHODS
In order to answer the above questions, a secondary analysis was performed using the databases from the Dutch national prevalence surveys conducted in 1998 and 1999 in, respectively, 40 and 37 acute care hospitals\textsuperscript{15}. All hospitals collected the data on one and the same day, i.e. on May 26\textsuperscript{th} in 1998 and on April 20\textsuperscript{th} in 1999. All types of ICU were included, such as surgical, internal medicine, paediatric and cardiac units. In each health care setting participating in the two surveys, a co-ordinator was given the primary responsibility for the study and was trained by the researcher. The training included the organisation of the survey in the institution and the use of the data collection form with special attention to the grading system and risk assessment scale used.
Data collection was conducted in such a way that each patient who had consented to participate was physically examined by two nurses. In the case of unconsciousness, the patient’s family was asked for approval. The data collection instrument designed for the national survey was based on a literature study and a Delphi Study (a method of obtaining individual judgements followed by feedback on these judgements, in order to obtain consensus), in which 34 experts in the field of pressure ulcers participated. A pilot study showed the instrument to be reliable and feasible\textsuperscript{15}. The instrument included six categories of data to be collected. The first three were the characteristics of the institution, the characteristics of the ward and the characteristics of the patients, such as age, sex, date of admission and reason for admission. The fourth category was risk assessment using the Braden scale, with two additional risk factors (malnutrition and incontinence). The Braden scale is one of the best-known and most widely used tools for evaluating pressure ulcer risk, with proven validity and reliability for risk assessment\textsuperscript{15-17}. Malnutrition was added because it was felt to be more important than the nutrition item (defined as dietary intake) included in the Braden scale. The incontinence item was added because the Braden scale does not distinguish between moist (sweating) and wet (urine).
The fifth category of data involved grading the pressure ulcers according to internationally accepted grading systems, defining a stage I as non-blanchable discolouration; stage II as partial thickness of skin loss involving the epidermis, blisters or shallow ulcers without undermining of adjacent tissue; stage III as full thickness skin loss, involving damage or necrosis of epidermis and/or dermis not extending to underlying bone, tendon or joint; and stage IV as full thickness skin loss, involving damage or necrosis of the epidermis and/or dermis extending to underlying bone tendon.
or joint. Furthermore, each pressure ulcer was linked to its identifying stage with respect to site, origin, time of first observation and dressing. The sixth category was that of the type of support surface used and the preventive interventions of repositioning and preventing malnutrition. Repositioning was defined as planned repositioning every two hours as noted in the nursing records, while preventing malnutrition was defined as the adjusting of food intake by a dietician.

In the statistical methods, the databases obtained from the two surveys (1998 and 1999) were combined for the analyses. All analyses were performed using the Statistical Package for Social Science (SPSS); all the p-values reported are two-tailed. Continuous values are reported as means and standard deviations unless otherwise indicated. Potential risk factors for pressure ulcers were assessed by logistic regression if the p-value was less than 0.05 on univariate analyses in the sample. Age and time elapsed since admission may be important risk factors; these variables were dichotomised based on the median (age 0-66 vs. older than 66; length of stay 0-4 days vs. more than 4 days).

Forward stepwise logistic regression, using the likelihood ratio test, was used to determine the risk factors associated with the presence or absence of pressure ulcers. The logistic regression model was derived from the sample of the 1998 survey and then validated in the sample of the 1999 survey using the same beta coefficients. The fit of the model was assessed by dividing the sample into ten groups with increasing estimated probabilities of pressure ulcer development. Within each group, expected rates of pressure ulcer development were calculated from the logistic model and compared with the observed rates. The Hosmer-Lemeshow goodness-of-fit statistic was obtained by calculating the Pearson chi-square statistic of observed and expected frequencies. Model discrimination was measured using the area under the receiver-operating characteristic curve, which is the same as the c-statistic. The c-statistic equals the proportion of pairs in which the predicted probability of pressure ulcers is higher for patients with pressure ulcers than for those without pressure ulcers.

For those risk factors that were statistically significant, odds ratios and their corresponding 95% confidence intervals were calculated.
RESULTS

Patient characteristics

A total of 850 ICU patients were examined during the national surveys in 1998 and 1999. Table 1 shows the characteristics of the populations in 1998 and 1999 and a combination of the two. Significant differences between the two years were only found in the prevalence of stage 2 pressure ulcers. The prevalence of pressure ulcers was 28.7%. Patients with pressure ulcers had a mean of 2.0 ± 1.26 ulcers (range 1-7). The most common sites affected were the heels and the sacrum (39.4% and 25.2%, respectively).

Table 1  Characteristics of the populations surveyed in 1998 and 1999 (PU pressure ulcer)

<table>
<thead>
<tr>
<th></th>
<th>1998 (n=423)</th>
<th>1999 (n=427)</th>
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<td>Age (mean; SD)</td>
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<td>60.0 ± 22.2</td>
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</tr>
<tr>
<td>Days since admission (mean ± SD)</td>
<td>11.2 ± 20.2</td>
<td>11.1 ± 16.3</td>
<td>11.2 ± 18.3</td>
</tr>
<tr>
<td>Median days since admission</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Median days without PU</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Median days stage I</td>
<td>6</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Median days stage II</td>
<td>17.5</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td>Median days stage III</td>
<td>20.5</td>
<td>17</td>
<td>19</td>
</tr>
<tr>
<td>Median days stage IV</td>
<td>35</td>
<td>31</td>
<td>32</td>
</tr>
<tr>
<td>Male (%; N)</td>
<td>60.8% (257)</td>
<td>58.8% (251)</td>
<td>59.8% (508)</td>
</tr>
<tr>
<td>Prevalence (%; N)</td>
<td>28.6% (121)</td>
<td>28.8% (123)</td>
<td>28.7% (244)</td>
</tr>
</tbody>
</table>

* p=0.02

Table 2 presents the raw scores on the risk factors for both years for all patients who had consented. A significant difference was only found in the moisture subscale.

Table 2  Scores on the risk factors for the total population in the 1998 and 1999 survey

<table>
<thead>
<tr>
<th>Subscales of the Braden scale*</th>
<th>1998 (n=423) mean ± SD</th>
<th>1999 (n=427) mean ± SD</th>
<th>Total (n=850) mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensory perception (1-4)</td>
<td>2.97 ± 1.22</td>
<td>2.99 ± 1.21</td>
<td>2.98 ± 1.22</td>
</tr>
<tr>
<td>Moisture* (1-4)</td>
<td>3.13 ± 1.06</td>
<td>3.47 ± 0.81</td>
<td>3.30 ± 0.96</td>
</tr>
<tr>
<td>Activity (1-4)</td>
<td>1.62 ± 1.01</td>
<td>1.49 ± 0.93</td>
<td>1.56 ± 0.97</td>
</tr>
<tr>
<td>Mobility (1-4)</td>
<td>2.28 ± 1.17</td>
<td>2.29 ± 1.18</td>
<td>2.29 ± 1.17</td>
</tr>
<tr>
<td>Dietary intake (1-4)</td>
<td>2.68 ± 0.98</td>
<td>2.72 ± 0.90</td>
<td>2.70 ± 0.94</td>
</tr>
<tr>
<td>Friction and shear (1-3)</td>
<td>1.89 ± 0.89</td>
<td>1.95 ± 0.84</td>
<td>1.92 ± 0.86</td>
</tr>
<tr>
<td>Total Braden score (6-23)</td>
<td>14.58 ± 4.27</td>
<td>14.92 ± 4.34</td>
<td>14.75 ± 4.31</td>
</tr>
<tr>
<td>Additional risk factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incontinence (1-4)</td>
<td>1.63 ± 1.02</td>
<td>1.72 ± 1.06</td>
<td>1.67 ± 1.04</td>
</tr>
<tr>
<td>Malnutrition (1-4)</td>
<td>1.51 ± 0.74</td>
<td>1.49 ± 0.67</td>
<td>1.50 ± 0.71</td>
</tr>
</tbody>
</table>

* On the Braden scale, a lower score means a greater risk; in the additional risk factors, a higher score means a greater risk; † p < 0.01.
Table 3 shows the five most important reasons for admission to the ICU as reported in the patient records. Patients admitted with cardiovascular diseases (surgical as well as non-surgical) were the largest group, although they showed the lowest percentage of pressure ulcers (22.7%). Patients with infections (including sepsis) constituted the category with the highest percentage of pressure ulcers (56.9%).

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>% (n)</th>
<th>% with pressure ulcers (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>8.5% (72)</td>
<td>56.9% (41)</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>50.7% (431)</td>
<td>22.7% (98)</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>21.6% (184)</td>
<td>39.1% (72)</td>
</tr>
<tr>
<td>Gastrointestinal disease</td>
<td>16.8% (143)</td>
<td>41.3% (59)</td>
</tr>
<tr>
<td>Trauma injury</td>
<td>6.1% (52)</td>
<td>36.5% (19)</td>
</tr>
</tbody>
</table>

Table 4 shows the prevalence of pressure ulcers in relation to surgery. This table includes only patients from the 1999 survey, because this item was not addressed in 1998. There was a significant difference in total prevalence and in the prevalence of stage 1 and stage 2 ulcers between those who had undergone surgery and those who had not. The mean duration of the surgical procedures was 3.5 (± 2.2) hours.

<table>
<thead>
<tr>
<th></th>
<th>No surgery (n=263)</th>
<th>Surgery (n=164)</th>
<th>Mean duration of surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1</td>
<td>7.2% (n=19)</td>
<td>10.4% (n=17)</td>
<td>2.6 ± 2.0 hours</td>
</tr>
<tr>
<td>Stage 2*</td>
<td>11.4% (n=30)</td>
<td>18.9% (n=31)</td>
<td>3.3 ± 2.2 hours</td>
</tr>
<tr>
<td>Stage 3</td>
<td>4.2% (n=11)</td>
<td>4.3% (n=7)</td>
<td>3.9 ± 2.7 hours</td>
</tr>
<tr>
<td>Stage 4</td>
<td>2.3% (n=6)</td>
<td>1.2% (n=2)</td>
<td>3.0 ± 2.1 hours</td>
</tr>
<tr>
<td>Total *</td>
<td>25.1% (n=66)</td>
<td>34.8% (n=57)</td>
<td>3.5 ± 2.2 hours</td>
</tr>
</tbody>
</table>

* p<0.05

Risk factors

On univariate analysis, 12 factors were significantly associated (p<0.05) with the presence of pressure ulcers: age, number of days since admission, the risk factors of malnutrition and incontinence, the six subscales of the Braden scale and the total Braden score. Of all reasons for admission, only a diagnosis of infection was significantly associated with the presence of pressure ulcers. These factors were entered into a forward logistic regression to identify significant risk factors of skin breakdown. The scores for the Braden scale were inverted to allow a comparison between the results on the subscales of the Braden scale and other risk factors.
Four factors: infection, age, length of stay and total (inverted) Braden score, were significantly associated with the presence of pressure ulcers (p<0.05). The Hosmer-Lemeshow test showed no significant differences between predicted and observed pressure ulcer rates for either the derivation (chi-square 10.6; p=0.22) or the validation sample (chi-square 12.46; p=0.19) within deciles of predicted pressure ulcer rates. This indicates a fairly good fit for the model. The c-statistic was 0.83 for both the derivation and the validation sample, indicating that the model discriminates well and retains its predictive power when applied to the validation sample.

As we were interested in the subscales of the Braden scale, a second logistic regression analysis was performed, in which the total Braden score was not entered into the regression. This analysis resulted in five factors which were significantly associated with the presence of pressure ulcers (p<0.05): infection, moisture, mobility, age and length of stay. In this model, too, the Hosmer-Lemeshow test indicated no significant differences between the observed and predicted pressure ulcer rates within the deciles (chi-square and corresponding p-value for the derivation and validation samples were 4.95; p= 0.76 and 6.48; p= 0.72 respectively). The c-statistic for both samples was 0.82, indicating that this model also seems to discriminate fairly well. Table 5 compares the two models with respect to their factors and diagnostic values. The comparison of the diagnostic values of the two logistic regression analyses shows that there were only minor differences between the two models in predicting pressure ulcers in an ICU population.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Model 1 Odds Ratio (CI 95%)</th>
<th>Model 2 Odds Ratio (CI 95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>2.42 (1.43-4.08)</td>
<td>2.49 (1.46-4.22)</td>
</tr>
<tr>
<td>Length of stay</td>
<td>4.76 (2.77-8.16)</td>
<td>4.64 (2.71-7.95)</td>
</tr>
<tr>
<td>Infection</td>
<td>2.99 (1.39-6.43)</td>
<td>3.43 (1.61-7.32)</td>
</tr>
<tr>
<td>Total (inverted) Braden score</td>
<td>1.24 (1.15-1.34)</td>
<td>-</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
<td>1.35 (1.06-1.71)</td>
</tr>
<tr>
<td>Mobility</td>
<td>-</td>
<td>1.82 (1.41-2.34)</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>52.0%</td>
<td>52.0%</td>
</tr>
<tr>
<td>Specificity</td>
<td>91.1%</td>
<td>89.9%</td>
</tr>
<tr>
<td>Positive predictive value&lt;sup&gt;a&lt;/sup&gt;</td>
<td>70.3%</td>
<td>67.4%</td>
</tr>
<tr>
<td>Negative predictive value&lt;sup&gt;a&lt;/sup&gt;</td>
<td>82.3%</td>
<td>82.1%</td>
</tr>
<tr>
<td>Correctly classified&lt;sup&gt;a&lt;/sup&gt;</td>
<td>79.8%</td>
<td>78.8%</td>
</tr>
</tbody>
</table>

<sup>a</sup> Values for the validation sample
Preventive methods

The surveys collected data on the use of support systems, the application of repositioning and the prevention of malnutrition. Dutch guidelines prescribe the use of support surfaces for patients at high risk of developing pressure ulcers, and those with pressure ulcers should preferably be positioned on a dynamic mattress or overlay, or, in the case of stage 3 or worse, on a low-air-loss or air-fluidised bed. Figure 1 shows the use of these pressure ulcer prevention devices. The figure shows that, of those patients at high risk of developing pressure ulcers (Braden cut-off \( \leq 20 \)) but without actual pressure ulcers, only 60.5% were positioned on a pressure ulcer support system. This percentage was higher for patients with pressure damage, but only reached 100% for patients with grade 4 pressure ulcers.

Figure 1  Use of support systems, by stage

Ris+: patients at high risk of developing pressure ulcers (Braden cut-off \( \leq 20 \))
1: Patients with a stage 1 pressure ulcer
2: Patients with a stage 2 pressure ulcer
3: Patients with a stage 3 pressure ulcer
4: Patients with a stage 4 pressure ulcer
Patients who had a score of less than 3 on the mobility subscale of the Braden scale, which means that they are unable to move sufficiently of their own accord, were determined to need repositioning. In such cases, only positioning on an air-fluidised bed makes repositioning superfluous according to the Dutch guidelines\textsuperscript{24}. A total of 491 patients (57.8\% of all patients) had a score less than 3 on the mobility subscale of the Braden scale. Of these 491, 23 were positioned on an air-fluidised bed, which made repositioning redundant. Thus a total of 468 patients needed repositioning. Of these, 36.8\% (n=172) were actually being repositioned.

Patients who have a score less than 4 on the additional risk item of malnutrition, which means that they have had at least a few days of decreased nutritional intake, are indicated to receive nutritional intervention. In the present sample, this applied to 334 patients (39.3\% of the total number). Of these, 38.9\% (n=130) patients were actively protected against malnutrition.

**DISCUSSION**

The prevalence of pressure ulcers in Dutch ICUs is high; in the national prevalence survey\textsuperscript{3,25} it was only surpassed by that in geriatric wards (prevalence 39.0\%). It is interesting to note that stage 2 pressure ulcers were more prevalent in this study than other stages. This finding is in agreement with those of incidence studies conducted by Carlson\textsuperscript{26} and Baldwin\textsuperscript{9}. Perhaps the duration of stage 1 is much shorter in an ICU, as patients are more seriously ill, so stage 1 pressure ulcers can deteriorate more rapidly to stage 2 or worse. This has indeed been found in a study by Derre\textsuperscript{27}, who showed that the stage 1 ulcers of 88\% of the patients in an ICU deteriorated to stage 2 or worse, a much higher percentage than in other settings\textsuperscript{26,29}.

Patients who had undergone surgery showed significantly higher prevalence of pressure ulcers than patients who had not. Various studies have shown that pressure ulcer risk in surgical patients is a considerable problem\textsuperscript{30-32}. However, the present study was a prevalence survey and we cannot decide from our data whether the ulcers occurred before or after the surgery.

The risk factors associated with pressure ulcers in the present study were age, time elapsed since admission, infection and total Braden score, while a second analysis, excluding the total Braden score, found the moisture and mobility subscales of the Braden scale to be significant. However, our study was a cross-sectional study and there may be some differences from the risk factors derived from cohort studies, as was shown
by Berlowitz and colleagues, who prospectively identified risk factors for pressure ulcers and compared these with a cross-sectional analysis in the same population. Nevertheless, most of the factors we found have also been found in previous cohort studies at ICUs. This may indicate that the use of cross-sectional analysis did not cause too much bias in the present study.

Our validation of both logistic models in a future sample (the 1999 sample) yielded significant results of fit. As regards the diagnostic statistics, however, we have to conclude that the predictive value of both models is limited. Our databases were not specifically designed for an ICU population and therefore did not include a severity score. In an ICU, severity of illness scores, such as the APACHE II or SAPS, may be more important indicators of pressure ulcer risk than the Braden scale, as was indicated in the present study by the high rate of pressure ulcers in infection (sepsis) patients. Moreover, pressure ulcers are the result of complex inter-relationships among multiple factors, rather than a few individual factors. Oot-Giromini refers to a 'web of causation' in relation to the aetiology of pressure ulcers. This also raises the question of the value of risk assessment tools, which may represent a simplification of the causation of pressure ulcers. Furthermore, the use of preventive methods intervenes between possible causes and the development of pressure ulcers. In wards with a very high standard of using preventive procedures, fewer pressure ulcers will develop, so the effect of risk factors may be different, and different risk factors may be significant from those in wards with a lower standard of prevention. In fact, the risk factors mentioned in the present study have to be interpreted as the risk that patients will develop pressure ulcers under the assumption that preventive methods are already being used. In other words, which patients develop pressure ulcers in spite of the preventive methods?

Our findings on the use of pressure ulcer prevention support systems showed that about 40% of all patients at high risk of developing pressure ulcers, but without actual pressure ulcers, and 12% of the patients with pressure ulcers were not positioned on any support system and that about 50% of the patients with stage 3 or 4 lesions were not positioned on the support system indicated. These findings reveal flaws in the preventive interventions. All patients admitted to a high or medium ICU should receive high-quality preventive care, including positioning on a support system regardless of the risk assessment score, inspection of the skin at least once a day, turning and active prevention of malnutrition.
Since almost 60% of the ICU patients are unable to move sufficiently by themselves, it was remarkable that many of these patients were not repositioned. Avoiding pressure requires manually turning or repositioning the patients according to a fixed schedule. Repositioning ICU patients is often regarded as difficult and potentially hazardous because of the presence of complex equipment and the risk of disturbing blood-gas tensions or precipitating arrhythmias\textsuperscript{38}. The importance of turning is supported by the work of Lewicki and colleagues\textsuperscript{39} who found that less frequent turning was related to the development of pressure ulcers in their sample of very high risk intra-aortic balloon pump patients.

In conclusion, the prevalence of pressure ulcers in Dutch ICUs is high and there are flaws in the prevention of these ulcers. Predicting pressure ulcers in ICU patients is difficult and needs further investigation. More attention should be paid to turning those patients unable to do so by themselves, and patients admitted to a high or medium intensive care unit should always receive high quality preventive care.
REFERENCES

Early postoperative 30° lateral positioning after coronary artery surgery: influence on cardiac output
EARLY POSTOPERATIVE POSITIONING: INFLUENCE ON CARDIAC OUTPUT

ABSTRACT

BACKGROUND: Directly following surgery, coronary artery bypass patients are not receiving routine turning every 2 hours to prevent pressure ulcers, because a negative influence on haemodynamic parameters is assumed.

AIMS AND OBJECTIVES: We investigated whether (1) early postoperative lateral position after coronary artery bypass surgery (CABG) may have a negative influence on the cardiac output (CO) and (2) whether turning procedures cause practical problems.

DESIGN: Clinical trial.

METHODS: Fifty-five coronary artery bypass patients were randomly assigned to 4 intervention regimens and underwent a 2-hour period of 30° lateral position. Fourteen patients in supine position served as a reference group. We hypothesised that 30° lateral position does not cause a relevant change in the CO.

RESULTS: Turning the patients did not have any significant influence on the cardiac index, not even in the patients in a poor haemodynamic condition. The cardiac index in 30° lateral position and supine position 2 to 8 hours postoperatively after CABG is statistically bioequivalent. No clinically relevant deviations from preset “safe” values for mean arterial pressure, right atrial pressure, pulmonary artery wedge pressure and pulmonary arterial pressure were observed, that would require ending the lateral position. There were no practical problems hindering the turning regimen, even not in the patients with an intra-aortic balloon pump.

CONCLUSIONS: Early post-operative turning of CABG patients in lateral position is an easy and feasible procedure that does not influence the cardiac index even not in patients receiving antihypertensive or inotropic/vasopressor therapy. Further research is needed to find out whether our findings are also valid in other patient groups and other position conditions.

RELEVANCE TO CLINICAL PRACTICE: If there are no strict contra-indications, lateral position has to be considered to prevent complications of continuous supine position within 2 hours after CABG patients have been admitted to the intensive care unit.
**INTRODUCTION**

Coronary artery surgery patients are admitted to an intensive care unit (ICU) after surgery. At least the first 12 to 24 hours these patients have to be considered critically ill and at high risk for complications of immobility like pulmonary complications\(^1\) and pressure ulcers\(^2\). Routine turning of patients at a minimum of every 2 hours has become the accepted standard of care to prevent pressure ulcers\(^2,5\). The semi Fowler position alternated with 30° lateral position results in the lowest interface pressure between patient skin and surface of the mattress\(^6\). Unfortunately, the majority of critically ill patients do not receive this standard care\(^5\) because a negative influence on the reliability of haemodynamic measurements\(^7,9\), and a negative effect on oxygenation\(^10-12\) and on haemodynamic parameters\(^11-13\) is assumed.

Concerning the reliability of the haemodynamic parameters, the pulmonary arterial pressure (PAP) and pulmonary artery wedge pressure (PAWP) values in the 60° lateral position differ from outcome measures in the supine position\(^7\). In a 30° lateral position, however, no clinically significant differences were found in central venous pressure (CVP), PAP and PAWP measurements when the transducer reference was the supine phlebostatic axis\(^8,9\). The importance of this leveling procedure is confirmed in a 30° lateral position with the backrest remaining at 20°\(^14\).

Studies in post operative cardiac surgery patients\(^15,16\) and other ICU-patients\(^10-12\) show a small but significant decrease in mixed venous oxygen saturation (SvO\(_2\))\(^11,12,15,16\) and in partial pressure of oxygen in arterial blood (PaO\(_2\))\(^15\) in left and right 45° lateral position. This decrease in the SvO\(_2\) occurred directly after turning, was transient within 5 minutes and was judged clinically irrelevant.

Studies on the haemodynamic effects of turning in cardiac surgical patients\(^17\) or other groups of critically ill patients\(^11,18\) however are scarce. The intervention used in the small number of studies was an extreme lateral position with an angle of 45°\(^17,18\) or 62°\(^17\) or was not specified\(^11\). The haemodynamic effects reported are “no effect”\(^11,18\) up to a significant increase on the cardiac output (CO) in left lateral position from 4.3 to 5.5 l/min/m\(^2\)\(^17\). Only in extreme 62° right lateral position a significant decrease in the mean arterial pressure (MAP) was observed\(^18\). A possible explanation for this effect is that an extreme left lateral position reinforces a hyperdynamic state by the significant increase of intra thoracic blood volume (ITBV), while the right lateral position impairs right ventricular preload and predisposes to hypotension\(^18\). No studies are available concerning the long-term
effect of 30° lateral position on the CO within 2 hours after admission of the patient to the ICU.

We hypothesised that 30° lateral position does not cause a relevant change in the CO. The aim of this study was to examine the influence of a 2-hours period of 30° lateral position within 2 to 4 hours after admission to the ICU, on the CO in post coronary bypass surgery patients.

**METHODS**

*Study design and patients*

After the approval of the Ethics Committee of our hospital the effect of lateral position was studied in a clinical trial where patients were assigned to an intervention group or to a reference group, who did not undergo a lateral position. All adult patients who had undergone isolated myocardial revascularisation and were admitted to the 14-bed intensive care department of the University Medical Centre Nijmegen in the Netherlands were eligible if: (1) they consented to participate in the study, (2) were able to lie on their side for at least 2 hours before surgery, (3) the values of the haemodynamic parameters were within safe ranges, (4) the sternum was closed, (5) no ventricular assist device was applied to support the patient’s circulation, (6) a pulmonary artery catheter (= PA-catheter) and an arterial infusion line were present.

A total of 75 patients were eligible for this study (figure 1). Three patients did not give consent to participate. The heart surgeon and the intensivist withdrew 3 patients from the study because of per-operative complications resulting in a convenience sample of 69 patients.

Fifty-five patients underwent a 2 hour period of lateral positioning. These patients were randomly assigned to one of four turning groups. Twenty-seven patients (Group A) started 2 hours, and 28 (Group B) started 4 hours after admission to the ICU. In each group, half of the patients started on their left side and half on their right. Patients with special circulatory support, comprising an intra-aortal balloon pump (IABP) (n=6) or continuous intravenous administration of a high dose positive inotropic drug (n=1) were equally distributed over the four groups (3x2 and 1x1). Patients were randomly assigned to the groups by drawing sealed envelopes. A further group of equal size that was not turned (Group C (n=14)) formed the reference group and was selected using the same inclusion criteria. This partly non-randomised procedure was the result of an evaluation of the first randomly assigned patients (n=15) to a turning group. In these patients we
found strong decreases in the CO which were assessed definitely not to be the effect of the 30° lateral position but the effect of simultaneous treatment with fluid loading, vasopressor and/or vasodilators by a physician. We felt our study would be stronger if we included a reference group to demonstrate that decreases in the CO occurred in patients in supine position as well, as result of treatment with fluid loading, vasopressor and/or vasodilators.

**Figure 1**

![Flowchart showing patient allocation and outcomes](chart)

**Measurements and equipment**

The primary outcome variable was the Cardiac Index (CI). CI measurement was carried out according to the institutional protocol by means of a closed system ice thermodilution method. In all patients a 7 F 4-lumen pulmonary catheter (Baxter Edwards Swan-Ganz) was used. Three injections of 10 ml cold (5-10 °C) glucose 5% solution were given in the proximal side in the expiration period. Cardiac output values within 10% of one another
were obtained and averaged. The average cardiac output and cardiac index were computed automatically.

For every patient ranges of values for the haemodynamic parameters were fixed to monitor the haemodynamic course during lateral position. These ranges were the so-called “safe area”. The decision rule for this safe area was: turning is not started or is stopped if the cardiac index was below 1.5 l/min/m² or if the MAP, PAWP, RAP or PAP exceeded the starting value with more than 15%. Only for the MAP also a lower limit of minus 15% of the starting value was fixed. If values were within this safe range the turning regimen could be started; if not, the regimen could not be started or had to be ended. PAWP, RAP, and PAP measurements were taken via the pulmonary artery catheter. The MAP was registered via an arterial infusion line. Monitoring of the haemodynamic parameters was performed using an 8-channel Hewlett Packard Component Monitoring System (HP-monitor). A pre-structured list was used to record reasons why patients were turned back to the supine position before the 2 hour period had elapsed.

Changes in dose or concentration of intravenous positive inotrope medication or vasodilators were recorded to interpret any changes in the CI on the patient level. Analgesics were administered according to the prescription of the intensivist. If the patient indicated to have pain in lateral position s/he was turned back. No extra analgesics were administered to maintain lateral position.

Procedure

Patients were asked to give informed consent on the day before the operation. The 30° lateral position, as described by Preston19, was adapted to the specific situation of sedated and ventilated patients in cooperation with a physiotherapist. The backrest of the bed was elevated 20° during lateral position. To support the thorax, a 30° wedge cushion was used. Intensive care nurses received instructions on how to place a patient in a 30° lateral position. Nurses recorded the starting and finishing time of every position change. Transducers were calibrated and leveled by using the phlebostatic axis14. Five minutes before turning was started, the first CI was measured and PAWP, MAP, RAP and PAP were checked. After the haemodynamic values were found to be within the safe area, the patient was turned to the 30° lateral position. The position of the bed remained unchanged14. After 120 minutes the patient was turned back to the supine position. If a patient was turned back earlier, the reason was noted on the structured list. To be sure
the transient effects of turning itself had faded, the first CI (CI2) in lateral position was
measured at 30 minutes after turning. CI3 in lateral position was measured at 120
minutes just before the patient was turned back in supine position. Once the patient was
back in supine position, the CI was measured at 30 minutes (CI4) and at 120 minutes
(CI5). MAP, RAP and PAP were measured continuously to monitor patient
haemodynamic status between two CI-measurements.

**Data analysis**

Schuirmann introduced the use of interval hypotheses for bioequivalence\(^{20,21}\). The concept
of interval hypotheses is to show bioequivalence by rejecting the null hypothesis of
bioinequivalence. In this study a (one-sided negative or positive) difference of 15% was
chosen to be the acceptable difference (within the “safe area”). If lateral positioning
would have a negative influence on the CI, there are two specific situations of interest:

- A decrease of the CI in lateral position after supine position
- An increase of the CI in supine position after lateral position.

In the first situation the hypothesis of bioequivalence reads: the decrease in the turning
group compared to the decrease in the reference group is less than 15% of the (estimated)
reference mean for CI two hours postoperatively (Group A) or four hours postoperatively
(Group B). In the second situation the hypothesis of bioequivalence reads: the increase in
the turning group compared to the increase in the reference group is less than 15% of the
(estimated) reference mean for CI two hours postoperatively (Group A) c.q. four hours
postoperatively (Group B). Schuirmann’s one-sided test procedure has been applied
making use of one-sided t-tests\(^{20,21}\). Because of small group sample sizes, a normal
distribution analysis was performed on the outcome parameter (CI) by logical and
statistical checks on skewness and normal plots\(^{22}\). There was no reason to reject the
assumption of normality.

Analyses also included chi-square test or (Fisher’s exact test when the number of
observations is less then 5) and two-sided t-tests where appropriate. A significance level
of \(\alpha = .05\) was used for all statistical tests.

**Results**

Both after 30 minutes and 120 minutes in lateral position no differences were found
between CI’s in left and right lateral position (p=0.81–0.99). Therefore overall analyses of
CI’s in left and right lateral position were carried out.
Influence of lateral position on CI

Table 1 presents the baseline characteristics of the patients in the intervention groups A and B, and in the reference group C (supine position). Table 2 presents the starting values of the haemodynamic parameters and medication 5 minutes before the first lateral position. No significant differences between groups were found.

| Table 1 Baseline characteristics of patients in group A (30° lateral position starting 2 hours postoperatively), group B (30° lateral position starting 4 hours postoperatively) and group C (supine position) |
|---------------------------------|-----------------|-----------------|-----------------|
| Patient characteristics        | Group A (n=27)  | Group B (n=28)  | Group C (n=14)  |
| Age (years)                    | 63.4 (9.6)      | 63.9 (8.9)      | 68.0 (7.6)      |
| Female (number,% )             | 5 (18.5)        | 7 (25.0)        | 5 (35.7)        |
| Body Mass Index (kg/m²)        | 26.4 (2.3)      | 26.9 (4.4)      | 26.0 (2.9)      |
| Operation characteristics      |                |                |                |
| Operative time (minutes)       | 249.2 (54.9)    | 269.4 (73.1)    | 265.1 (71.3)    |
| ECC-time (minutes)             | 96.2 (38.2)     | 105.5 (41.5)    | 107.4 (41.9)    |
| AoX (minutes)                  | 58.3 (27.9)     | 66.4 (32.9)     | 63.9 (22.9)     |

Values represent mean (standard deviation) or number (percentage). Group A=turning regimen 2 hours after admission on ICU; Group B=turning regimen 4 hours after admission on ICU; Group C=reference group (without turning regimen). ECC=extra corporal circulation; Operative time: time in operating room; AoX=aortic cross clamp. Differences are statistically non-significant.

| Table 2 Starting values of patients in group A (30° lateral position starting 2 hrs postoperatively), group B (30° lateral position starting 4 hrs postoperatively) and group C (supine position) |
|---------------------------------|-----------------|-----------------|-----------------|
| Haemodynamic parameters 5 minutes before first lateral position |
| Cl (l/m².min.)                 | A               | C₁             | B               | C₂             |
| MAP (mmHg)                     | 99.9 (14.5)     | 87.6 (9.2)     | 78.3 (10.0)     | 82.3 (8.6)     |
| PAWP (mmHg)                    | 11.8 (2.9)      | 13.8 (4.0)     | 12.9 (3.5)      | 13.1 (3.4)     |
| RAP (mmHg)                     | 10.7 (3.1)      | 11.5 (3.2)     | 12.4 (3.0)      | 12.1 (2.1)     |
| PAP (mmHg)                     | 22.8 (4.1)      | 24.0 (3.7)     | 24.0 (5.4)      | 24.6 (3.2)     |

Medication 5 minutes before first lateral position

<table>
<thead>
<tr>
<th>Medication 5 minutes before first lateral position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dopamine (µgram/kg/minute)</td>
</tr>
<tr>
<td>Dobutamine (µgram/kg/minute)</td>
</tr>
<tr>
<td>Adrenaline (µgram/kg/minute)</td>
</tr>
<tr>
<td>(Nor)adrenaline (µgram/kg/minute)</td>
</tr>
<tr>
<td>Enoximone (µgram/kg/minute)</td>
</tr>
<tr>
<td>Nitroglycerine (µgram/kg/minute)</td>
</tr>
<tr>
<td>Niproprusside (µgram/kg/minute)</td>
</tr>
</tbody>
</table>

Values for haemodynamic parameters represent mean (standard deviation). Values for medication represent mean (standard deviation) and [number of patients]. Cl=Cardiac index; MAP=Mean arterial pressure; PAWP=Pulmonary artery wedge pressure; RAP= mean right atrial pressure; PAP=Mean pulmonary arterial pressure. A=turning regimen 2 hours after admission on ICU; Group B=turning regimen 4 hours after admission on ICU; Group C=reference group (without turning regimen). Values of group A and C₁ are 2 hours postoperative; values of B and C₂ are 4 hours postoperative. Differences are statistically non-significant.
Figure 2 presents the course of the cardiac index (CI) at consecutive times in group A (30° lateral position starting 2 hours postoperatively), group B (30° lateral position starting 4 hours postoperatively) and group C (supine position).

Figure 2 Time course of cardiac index in supine and lateral position after arrival on the ICU

The standard deviations of the reference group are not displayed for reasons of clarity.

No significant differences in CI occurred.

The mean decrease of the CI after 30 and 120 minutes in lateral position in group A and B ranges from -0.19 to 0.10 ℓ/min/m². This range does not differ significantly from the corresponding range of CI-decreases in the reference group that ranges from -0.18 to 0.02 ℓ/min/m² (p ≥ 0.60, respectively p ≥ 0.95).

The mean increase of the CI after 30 and 120 minutes in supine position in group A and B ranges from 0.04 to 0.14 ℓ/min/m². This range does not differ significantly from the corresponding range of CI-decreases in the reference group that ranges from -0.11 to 0.18 ℓ/min/m² (p ≥ 0.78, respectively p ≥ 0.32).

Subsequently in all these situations the hypothesis of bioinequivalence has to be rejected (p ≤ 0.04), where in group A a difference of ≥ 0.44 ℓ/min/m² and in group B a difference of ≥ 0.42 ℓ/min/m² was assumed to imply inequivalence. The latter values are equal to 15%
of the initial overall mean of both groups A and C two hours postoperatively and B and C four hours postoperatively.

In 21 patients the CI decreased $\geq 15\%$ after 30° lateral position at 30 minutes and/or 120 minutes. The initial mean CI at -5 minutes of patients in the turning (A) and reference group (C) with a decrease $\geq 15\%$ was much higher (3.67 $\ell$/min/m$^2$) than the initial mean CI of patients with decrease $\leq 15\%$ (2.67 $\ell$/min/m$^2$)(t-test, p=0.002). The initial mean CI of patients in the turning group (A) and reference group (C) with an increase of $\geq 15\%$ was 2.47 $\ell$/min/m$^2$. This CI value differed significantly (t-test, p < 0.001) from the initial mean CI of patients in both groups with an increase $\leq$15% (3.06 $\ell$/min/m$^2$). Similar findings were found in turning group B and reference group C.

Eighteen patients whose CI decreased $\geq 15\%$, also used antihypertensive and/or inotropic/vasopressor therapy. The number of patients using antihypertensive and/or inotropic/vasopressor therapy with a decrease $\geq 15\%$ in the turning group (10/37), did not differ significantly (p=0.34) from the number of patients with a decrease $\geq 15\%$ in the control group (5/12). As illustrated in table 3, use of antihypertensive medication is not associated with a higher risk for a decrease in CI compared to the reference group (p>0.21). Moreover, patients with inotropic and/or vasopressor therapy who were turned 4 hours postoperatively tended to display a lower, and not a higher, risk of a decrease in CI compared with the control group (p=0.13).

*Early termination of the 30° position*

In 54 of the 55 patients (98%) no problems occurred during the period in 30° lateral position. These patients remained in 30° lateral position for an average of 117 minutes (sd=8; range=104-158). For practical reasons some patients had to be turned later due to other priorities in the ICU. Only one patient was turned back much earlier due to a decrease in oxygen saturation after 31 minutes during the first turning period. Further examination revealed that this patient suffered from a pneumothorax which had no obvious causal relation with the turning.

There were no practical problems (crushed infusion lines or poor rendering of curves) and no cases of IABP malfunctioning, resulting from pinching of the IABP catheter by the slightly bent position of the patient’s legs in the 30° lateral position. No signs of discomfort in lateral position in both groups were observed. Placing an ICU patient in the 30° lateral position or in supine position did not take much time. The average time recorded during the turning regimen was 3:07 minutes (sd=1:54; n=110).
Table 3  Number of patients with a decrease of ≥15% of the CI in lateral position and the use of vasoactive drugs

<table>
<thead>
<tr>
<th>Group</th>
<th>Anti hypertensive therapy at start of lateral position (n=28)</th>
<th>Inotropic or vasopressor therapy at start of lateral position (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>5/10</td>
<td>1/9</td>
</tr>
<tr>
<td>C_A</td>
<td>2/9^a</td>
<td>1/3^c</td>
</tr>
<tr>
<td>B</td>
<td>3/9</td>
<td>1/9</td>
</tr>
<tr>
<td>C_B</td>
<td>3/9^b</td>
<td>2/3^d</td>
</tr>
</tbody>
</table>

Values represent the number of patients with a decrease of ≥15% of the CI in lateral position/the total number of patients with the use of vasoactive drugs. A = turning regimen 2 hours after admission on ICU; C_A = reference group (without turning regimen) for group A; B = turning regimen 4 hours after admission on ICU; C_B = reference group (without turning regimen) for group B. Anti hypertensive therapy is defined as a continuous intra venous administration of any dose of: nicardipine, and/or nitroprusside and/or nitroglycerine (≥1 μgram/kg/min.). Inotropic or vasopressor therapy is continuous intra venous administration of: any dose of adrenaline, dobutamine, enoximone and/or dopamine (≥5 μgram/kg/min.). ^a group A vs C_A: p=0.21; ^b group B vs C_B: p=0.38; ^c group A vs C_A: p=0.45 and ^d group B vs C_B p=0.13.

DISCUSSION

From the results of this study we conclude that the CI in supine and lateral position are bioequivalent. The turning regimen did not have any significant influence on the CI in patients who were positioned in 30° lateral position 2 hours or 4 hours after surgery. We also found no indications for practical problems in supine and 30° lateral position.

An important reason not to turn ICU patients is fear of haemodynamic instability during lateral position. It is assumed that patients treated with vasoactive medication in lateral position are at higher risk for a decrease in CI than patients in supine position. In our study we found no association between a decrease in CI and turning in patients treated with antihypertensive therapy. Moreover, we found that in patients treated with inotropic or vasopressor medications, turning the patient was associated with a smaller risk for a decrease in CI. From these results, we conclude that use of vasoactive medication is not an argument to abstain from turning the patient.

Apart from the intermittent measured CI, continuously monitored MAP, RAP, PAP did not exceed the values of the safe area resulting in an early termination of the lateral position.

Doering et al.17 addressed the problem of concealing individual differences by using group means. As clinically important individual variations would be missed when using group means, we used a reference group for comparison. Indeed, we found some strong decreases in the CI in patients in 30° lateral position. At the same time we also found decreases in CI in patients who were in supine position. The number of the differences between these two groups was not statistically significant. The initial mean CI of patients with a decrease ≥15% was much higher than the initial mean CI of patients with a
decrease ≤ 15%. The initial mean CI of patients with an increase of ≥ 15% was much lower than the initial mean CI of patients with an increase ≤ 15%. Similar findings were found in turning group B and reference group C. This phenomenon is known as regression to the mean. Another explanation for these fluctuations is that they are possibly due to haemodynamic management after cardiac surgery. In the postoperative period the CI can be adequate (2.2 – 5 ℓ/min/m²), dynamic (CI > 5 ℓ/min/m²) or poor (CI < 2.2 ℓ/min/m²). Depending on additional parameters (MAP, RAP, PAP and PAWP) the patient will be treated with fluid loading, vasopressors and/or vasodilators. The outcomes of these treatment modalities are a decrease in case of a dynamic CI and an increase in case of a poor CI. Depending on the initial value of the CI the increase and decrease can therefore be much more than 15% of the initial CI²³.

In our study, in all cases of a strong decrease in CI, this CI was related to MAP, RAP, PAP and PAWP and an intensivist was consulted. The low CI’s were considered a sign of underfilling and/or the effect of treatment with vasoactive medication. Furthermore, we found that differences in CI in 30° lateral position also occurred in supine position at the same time and had to be attributed to medical treatment effects, which are not unusual the first hours after surgery²⁴²⁵. There is no indication for a relation between fluctuations in CI and the use of vasoactive medication by turning the patient.

The results of this study were established in a small non-randomly selected sample. Therefore this study should be regarded as a pilot study. Generalising the results to other patient groups should be done with caution. In contrast to our study, Doering et al.¹⁷ and Bein et al.¹⁸ found a statistically significant increased cardiac index in left lateral position that occurred at an angle of 45° to 62°. Since an angle of > 30° is not necessary for the prevention of pressure ulcers, these results are not directly applicable. However, further research is needed to find out whether our findings are also valid in other patient groups and other position conditions.

In the intervention group, patients were randomly assigned to one of the four experimental conditions, and non-randomly assigned to a reference group. This uncommon procedure was the result of an evaluation of the first randomly assigned patients (n=15). We felt our study would be stronger if we included a reference group to demonstrate that decreases in the CI occurred in patient in supine position as well, as result of treatment with fluid loading, vasopressor and/or vasodilators. The fact that patients were not randomised to a reference group may have caused selection bias, resulting in incomparable groups. However, in the baseline data and starting values, no
significant differences were found. Therefore the groups are considered comparable and we believe a valid comparison between patients in the experimental and reference group could be made.

There were no practical problems, not even in the patients with an IABP (n=6). Two nurses carried out changes in position, especially in the ICU patients with artificial ventilation. Turning the patient was feasible and not time consuming. For the prevention of pressure ulcers this is an important finding, because patients with an IABP frequently have poor haemodynamics and limited freedom of movement owing to the IABP. Therefore, they have an extra high risk of developing pressure ulcers. The sooner lateral positioning is started in this patient group the better it is\textsuperscript{2,5}.

**CONCLUSION**

The CI in 30° lateral position 2 to 4 hours postoperatively after CABG is statistically bioequivalent with the CI in supine position. Not once the procedure had to be stopped because of haemodynamic problems. In lateral position there were no practical problems (crushed infusion lines or poor rendering of curves) and there were no cases of IABP malfunctioning, resulting from pinching of the IABP catheter. Turning the patient in lateral position is an easy procedure. If there are no strict contra indications, 30° lateral position has to be considered to prevent complications of immobility like pressure ulcers within 2 hours after CABG patients have been admitted to the ICU. If lateral positioning is considered to prevent complications of immobility in post CABG-patients, a negative influence on reliability of haemodynamic parameters or a decrease in CI is not an argument to abstain from turning the patient, even not in patients receiving vasoactive medication.

Further research is needed to find out whether our findings are also valid in other patient groups and other position conditions.
REFERENCES

Implementation of a new policy results in a decrease of pressure ulcer frequency

Erik de Laat
Lisette Schoonhoven
Peter Pickkers
André Verbeek
Theo van Achterberg

ABSTRACT

OBJECTIVE: To determine the effects of a new policy on the efficiency of pressure ulcer care.

DESIGN: Series of 1-day pressure ulcer surveys before and after the implementation.

SETTING: A 900-bed University Medical Centre in the Netherlands.

PARTICIPANTS: On the days of the surveys 657 patients were included before the implementation, 735 patients at 4 months after the implementation, and 755 patients at 11 months after the implementation.

INTERVENTION: Implementation of a hospital guideline for pressure ulcer care combined with the introduction of visco-elastic foam mattresses on the efficiency of the prevention and treatment of pressure ulcers.

MAIN OUTCOME MEASURES: Comparisons before versus after the implementation were made regarding the care behaviour of nurses and the frequency of patients with pressure ulcer.

RESULTS: Inadequate prevention decreased from 19 to 4% after 4 months and to 6% after 11 months (p < 0.001) and inadequate treatment decreased from 60 to 31% (p=0.005). Excluding the use of mattresses as a positive indicator for care behaviour, we found no significant increase in adequate care to prevent pressure ulcers. Also, in adequate treatment activities, we found no significant difference. Overall, we found a significant decrease in hospital-acquired pressure ulcer frequency from 18 to 13% (p=0.003) after 4 months and 11% (p < 0.001) after 11 months.

CONCLUSION: The number of pressure ulcer patients in hospital can successfully be reduced. General measures such as the introduction of adequate mattresses and guidelines for prevention and treatment are promising tools in this respect.
INTRODUCTION
Pressure ulcers (table 1) are a persistent problem in hospitalised patients. In the Netherlands, prevalence figures range from 13% in university hospitals to 23% in general hospitals and are comparable with prevalence figures in the United States (10-15%) and Europe (8%-23%). Pressure ulcers result in patient suffering, more frequent and longer hospital admissions, more intensive nursing and medical care, and a financial burden to the health care system.

Many studies showed that the measures taken to prevent and treat pressure ulcers vary greatly and that compliance with existing guidelines is inadequate. Several factors appear to play a role: lack of knowledge about these guidelines and lack of accompanying skills of nurses, vagueness about responsibilities for the management of pressure ulcers, and the fact that pressure ulcers are seldom viewed as a priority in health care institutions.

In this study, we wanted to determine the effects of the implementation of a specific hospital guideline for pressure ulcer care combined with the introduction of a high quality pressure reducing visco-elastic foam mattress on care behaviour and the frequency of pressure ulcer patients (pressure ulcer frequency). Therefore, we measured changes in adequate prevention and treatment as well as the frequency of pressure ulcer patients before and 4 and 11 months after the introduction of this new policy.

Table 1 Pressure ulcers: definition and classification (EPUAP 1998)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Non-blanchable erythema of intact skin. Discolouration of the skin, warmth, oedema, induration, or hardness may also be used as indicators, particularly in individuals with darker skin.</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion or blister.</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through underlying fascia.</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss.</td>
</tr>
</tbody>
</table>

METHODS
Design
Before and after the implementation series of 1-day measurements were used to determine the effect of this new policy on the efficiency of pressure ulcer care and
pressure ulcer frequency. We compared care behaviour of nurses and the pressure ulcer frequency patients.

Sample
The study was carried out in the 900-bed Radboud University Nijmegen Medical Centre, the Netherlands. The Ethics Committee of the hospital approved the study and waived the need for a written informed consent.

Patients hospitalised on the days of the pressure ulcer surveys, who understood the Dutch language and agreed to the screening, were included in the study. If a patient was unable to give permission, a legal representative was asked for approval. Patients residing on the paediatric wards and psychiatric unit were not included in the study.

In a period of 30 months, six prevalence measurements were carried out. The ‘before implementation group’ consisted of 657 patients who were studied in two separate measurements in a year. One year later, 4 months after the implementation of the guideline, we included 735 patients. Eleven months after the implementation, we included 755 patients. These numbers were sufficient to detect a decrease from 20 to 15% in pressure ulcer prevalence with sufficient statistical precision ($\alpha = 0.05, \beta = 0.20$). To obtain these numbers, two successive measurements were needed in each of the two groups after the implementation.

Intervention
The intervention in this study was the implementation of the new pressure ulcer policy. A specific hospital guideline for pressure ulcer care (‘guideline’) was developed. This guideline was a specification of international guidelines for pressure ulcer care$^{13,14}$ updated with recent scientific research$^{15}$. A pressure ulcer consultant was appointed and established a network of contact nurses (one on every ward). This contact nurse was trained by the nurse consultant and introduced the new guideline in a staff meeting or clinical lesson. Also, after the official introduction of the guideline, the existence of the guideline was announced in several hospital media (newspaper, intranet). Furthermore, all hospital bed frames were equipped with a high quality pressure reducing visco-elastic foam mattress.
Measurements and instruments

For this study, we used the patient data form of the Dutch national pressure ulcer survey\textsuperscript{16}. Nurses in the study hospital were trained to use this instrument. This form included four categories of data to be collected. The first category concerned patient characteristics. The second category was a risk inventory for pressure ulcers using the Braden scale\textsuperscript{16}. Recent studies have shown that the predictive validity of currently used risk assessment instruments, e.g. the Braden scale is insufficient in hospitalised patients\textsuperscript{17-19}. In our study, we used the items of the Braden scale to describe our population and to detect differences between patient groups on the items mobility, activity, sensory perception, and friction and shear. From these factors, we know they are related to the occurrence of pressure ulcers\textsuperscript{20}.

The third category of data involved grading the pressure ulcers according to internationally accepted grading systems\textsuperscript{13,14} in four grades of increasing severity (Table 1). A Grade I pressure ulcer should be considered as an alert for potential skin damage. Preventive measures must be intensified, but it is not a wound that has to be treated\textsuperscript{21}. For each pressure ulcer, the duration of existence, the origin, and the dressing used were noted. The last category assessed preventive interventions like the type of support surface used and repositioning. Repositioning was defined as planned repositioning at least every 3 hours\textsuperscript{15}.

The form was extended with an item concerning the report of a pressure ulcer. In accordance with the guideline, pressure ulcers must be reported in the patient record, and a care plan should be written out. When a pressure ulcer was present, the report of the pressure ulcer was checked in the patient’s record.

To determine whether nurses acted in accordance with the new guideline (compliance), a decision rule was used, based on objectively observable measures described in the guideline. Adequate prevention was defined as the presence of a pressure-reducing mattress and a repositioning schedule in pressure ulcer patients or patients at high risk for pressure ulcers. Encouragement to change position or, if necessary, assistance to repositioning had to be confirmed by patient or nurse. If only one of these measures was present, prevention was judged as moderately adequate. If no measures were present, prevention was judged as inadequate. Adequate treatment was defined as the presence of a dressing according to the guideline and a care plan in the patient’s record, besides the presence of adequate prevention. If all or 3 of these measures were present, treatment
was judged as ‘adequate’. If 2 of these measures were present, treatment was judged as moderate. If only one or no measure was present treatment was judged as inadequate.

**Procedure of pressure ulcer surveys**
A team of eight registered nurses, each visiting a part of the 30 participating nursing units, and a team of contact nurses gathered the data for this pressure ulcer survey together. Before the survey, both teams were trained to fill out the forms, handle the risk assessment, and grade pressure ulcers according to the pressure ulcer classification. A skin assessment was only performed in patients at risk. Patients were considered at risk if (i) they scored 3 points or less on the items of sensory perception or mobility of the Braden scale for risk assessment or (ii) the patient had a known pressure ulcer or (iii) if there was any doubt about one of the two criteria. All patients who did not meet these criteria were considered not at risk and pressure ulcer free. Together, the contact nurse and one of the eight registered nurses assessed the patients. The patient was asked whether regular turning or assistance to it was daily routine. In case of a pressure ulcer, the patient was asked where the pressure ulcer did arise in or outside the hospital. If the patient was incapable of answering the question, we asked the nurse or looked it up in the patient’s record.

**Statistical analyses**
In this study, on the effects of policy implementation, only patients who acquired pressure ulcers during the admission were of interest. Therefore, we excluded the patients from the analysis who reported that the origin of the pressure ulcer occurred before admission to the hospital. Pressure ulcer frequency was defined as the percentage of patients with a pressure ulcer in the total sample included in this study. According to the European Pressure Ulcer Advisory Panel (EPUAP) statement on measurement of disease frequencies, pressure ulcer frequencies should be reported in two formats; the first including all pressure damage (including areas of non-broken skin; i.e. Grade I) and the second excluding grade I pressure ulcers. If a patient had more than one pressure ulcer, only the most severe ulcer was used to classify the patient. The frequency of compliance with the new policy and the pressure ulcer frequency in the preintervention period were compared with the frequencies 4 and 11 months after the implementation. Differences were tested using 2-sided chi-square tests.
Between the before- and after-implementation period, the old standard hospital mattresses were replaced by high-grade pressure-reducing mattresses. This resulted in a higher chance of a correct application of a special mattress after the implementation for all patients, independent of the care behaviour of nurses. Therefore, we analysed the compliance to the guideline with and without the choice of the mattress. All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS 12.0.1).

**RESULTS**

A total of 2147 patients were included for analysis. Table 2 summarises the patient characteristics before and 4 and 11 months after the implementation. The table summarises a small but statistically significant lower age (11 months difference) after the implementation.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Patient characteristics (n=2147) before and after implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before (n=657)</td>
</tr>
<tr>
<td>Patients</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>346 (53)</td>
</tr>
<tr>
<td>Male</td>
<td>311 (47)</td>
</tr>
<tr>
<td>Age in years mean (sd)</td>
<td>58 (18.2)</td>
</tr>
<tr>
<td>Length of stay in days median (range)</td>
<td>7.5 (0-239)</td>
</tr>
<tr>
<td>Risk factors</td>
<td></td>
</tr>
<tr>
<td>Age &gt; 65 years</td>
<td>266 (41)</td>
</tr>
<tr>
<td>Surgery past two weeks</td>
<td>210 (32)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>38 (6)</td>
</tr>
<tr>
<td>Very limited or completely immobile</td>
<td>152 (23)</td>
</tr>
<tr>
<td>Very limited response or completely unresponsive</td>
<td>42 (6)</td>
</tr>
<tr>
<td>Bedfast or chairfast</td>
<td>212 (32)</td>
</tr>
<tr>
<td>Very moist or constantly moist</td>
<td>56 (9)</td>
</tr>
<tr>
<td>Very poor or inadequate food intake</td>
<td>109 (17)</td>
</tr>
<tr>
<td>Friction and shear</td>
<td>241 (37)</td>
</tr>
</tbody>
</table>

Values represent number of patients (percentage) unless otherwise mentioned. Before=before implementation; after 4 months=4 months after implementation; after 11 months=11 months after implementation. † t=2.8 df=1410; p<0.005; * χ² =10.11; df=1; p<0.002.

The number of patients selected for screening and the presence of friction and shear forces differed statistically significantly as a result of the implementation of the new guideline and the new mattresses. One thousand and ninety-one patients were selected for a skin assessment (Table 3).
Table 3 Outcomes on care behaviour and pressure ulcer frequency

<table>
<thead>
<tr>
<th></th>
<th>Before</th>
<th>After 4 months</th>
<th>After 11 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients included in this study (n=2147)</td>
<td>(n=657)</td>
<td>(n=735)</td>
<td>(n=755)</td>
</tr>
<tr>
<td>Patients selected for screening (n=1091)</td>
<td>343/657 (52)</td>
<td>390/735 (53)</td>
<td>358/755 (47)</td>
</tr>
<tr>
<td>Patients in which prevention was needed (n=915)</td>
<td>271/657 (41)</td>
<td>338/735 (46)</td>
<td>306/755 (41)</td>
</tr>
<tr>
<td>Prevention (mattress included) 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate</td>
<td>15/271 (6)</td>
<td>28/338 (8)</td>
<td>21/306 (7)</td>
</tr>
<tr>
<td>Moderate</td>
<td>205/271 (76)</td>
<td>295/338 (87)</td>
<td>266/306 (87)</td>
</tr>
<tr>
<td>Inadequate</td>
<td>51/271 (19)</td>
<td>15/338 (4)</td>
<td>19/306 (6)</td>
</tr>
<tr>
<td>Prevention (mattress excluded)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate</td>
<td>19/271 (7)</td>
<td>32/338 (10)</td>
<td>28/306 (9)</td>
</tr>
<tr>
<td>Inadequate</td>
<td>252/271 (93)</td>
<td>306/338 (91)</td>
<td>278/306 (91)</td>
</tr>
<tr>
<td>Patients in which treatment was needed (n=176)</td>
<td>72/271 (11)</td>
<td>52/735 (7)</td>
<td>52/755 (7)</td>
</tr>
<tr>
<td>Treatment (mattress included) 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate</td>
<td>9/72 (13)</td>
<td>16/52 (31)</td>
<td>14/52 (27)</td>
</tr>
<tr>
<td>Moderate</td>
<td>20/72 (28)</td>
<td>21/52 (40)</td>
<td>20/52 (39)</td>
</tr>
<tr>
<td>Inadequate</td>
<td>43/72 (60)</td>
<td>15/52 (29)</td>
<td>18/52 (35)</td>
</tr>
<tr>
<td>Treatment (mattress excluded)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate</td>
<td>2/72 (3)</td>
<td>1/52 (2)</td>
<td>2/52 (4)</td>
</tr>
<tr>
<td>Moderate</td>
<td>9/72 (13)</td>
<td>15/52 (29)</td>
<td>12/52 (23)</td>
</tr>
<tr>
<td>Inadequate</td>
<td>61/72 (85)</td>
<td>36/52 (69)</td>
<td>38/52 (73)</td>
</tr>
<tr>
<td>Frequency of pressure ulcer patients 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade I-IV</td>
<td>121/657 (18)</td>
<td>98/735 (13)</td>
<td>82/755 (11)</td>
</tr>
<tr>
<td>Grade II-IV</td>
<td>72/657 (11)</td>
<td>52/735 (7)</td>
<td>52/755 (7)</td>
</tr>
</tbody>
</table>

Values represent number of patients (percentage). The terms (in)adequate and moderate are defined in the text. Before=before implementation, 4 months=4 months after implementation; 11 months=11 months after implementation.

1 The changes in compliance with prevention activities (mattress included) were significant (p<0.000). Without mattress these changes were statistically insignificant.

2 The changes in compliance with treatment activities (mattress included) were significant (p<0.016). Without mattress these changes were statistically insignificant.

3 Grade I-IV: Frequency of pressure ulcers patients grades I-IV in all patients (n=2147). The decreases in prevalence were significant (p<0.009). Grade II-IV: Frequency of pressure ulcers patients grades II-IV in all patients (n=2147). The decreases in prevalence were significant (p<0.011).

Care behaviour in prevention

Of the patients assessed (n=1091), 915 patients (84%) were at risk for pressure ulcer development or had a pressure ulcer grade I. The remaining 176 patients (16%) had a grade II pressure ulcer or worse.

In the patients at risk or with a pressure ulcer grade I (n=271), a pressure-reducing mattress and a repositioning schedule were required. The frequency of inadequate preventive measures decreased from 19 to 4% at 4 months and 6% at 11 months after the implementation of the guideline. This decrease resulted in a significant increase (p<0.001) in the group that received moderately adequate prevention from 76 before to 87% at both 4 and 11 months and a small increase of adequate measures from 6 before to 8 and to 7% at 4 and 11 months respectively.
Care behaviour in treatment
We found a decrease in inadequate treatment from 60% before the implementation to 31% at both 4 and 11 months after the implementation of the new policy in 176 patients who had a grade II pressure ulcer or worse (Table 3). This decrease resulted in a significant increase (p=0.005) of moderately adequate treatment from 28% before the implementation to 40 and 39% and an increase of adequate treatment from 13 before to 31 and 27% at 4 and 11 months, respectively.
To determine if the implementation had any effect on care behaviour by nurses apart from the use of the new mattresses, we also examined the changes in compliance without considering the new mattresses as an indicator. This analysis showed a non-significant trend of increasing adequate repositioning from 7 to 10% at 4 months and 9% at 11 months after the implementation. For inadequate treatment, a decreasing trend of 16% at 4 months and 12% and 11 months after the implementation of the guideline was demonstrated.

Pressure ulcer frequencies
Before the implementation, we found a pressure ulcer frequency of 18% (grades I–IV). Four months after the implementation of the new policy, we found a pressure ulcer frequency of 13% (p=0.003), and 11 months after the implementation the pressure ulcer frequency was 11% (p<0.000) (Table 3). The latest results in a difference between frequencies of 7% between ‘before the implementation’ and 11 months after the implementation. Defining pressure ulcers as grade II –IV, a significant decrease (p<0.011) from 11 to 7% at after both after 4 and 11 months was calculated.

DISCUSSION
The present study demonstrates that the implementation of a guideline for pressure ulcer care and new mattresses results in a significant decrease in the pressure ulcer frequency (grades I-IV) of 5 and 7% at 4 and 11 months, respectively. More relevantly, when defining pressure ulcers as grades II –IV ulcers, the decrease was 4% both at 4 and 11 months, respectively. However, despite the time and energy spent on education and training of the nurses, we found that the change in care behaviour was not significant when the use of the new standard mattresses was not taken into account. In contrast to a recent randomised clinical trial of Russell et al.22, our study suggests that the replacement
of the new visco-elastic mattresses has to be considered as the key component of the intervention.

Moreover, nursing care is difficult to measure because there are a lot of "in-between" activities, such as occasional assistance in position changes if a nurse finds a patient in an uncomfortable position. Strictly, this is an intervention but it was not counted as such. We cannot rule out that these “in-between” activities increased after the implementation because there was more attention for the prevention of pressure ulcers. Also, there may have been an increase in other interventions we have not measured. For example, a leaflet was developed for the patient and his family or friends with advice and instructions on preventive actions. Another strategy was stimulating family or friends to take the patient for a little walk (if allowed) instead of staying in bed during visiting hours. Perhaps the effect of this additional attention on the prevention of pressure ulcers is larger than assumed. A recent study of Bours et al.23 shows the effect of calling attention to the pressure ulcer problem in hospitals. Monitoring pressure ulcer frequencies and giving feedback result in an improvement in quality of care, and it is very important to continue conducting surveys to avoid attention moving away from this topic, which may in turn lead to a deterioration in the quality of pressure ulcer care.

Because turning patients at high risk for pressure ulcer is indisputable13,14, and preventing pressure ulcers by turning patients is a standard part of basic nursing care, every nurse should know this standard. Before the implementation of the guideline, the interval between two body positions was defined as 2 hours. Defloor concluded15,24 that turning every 4 hours on a visco-elastic foam mattress makes the most effective and feasible preventive method in terms of incidence, effort, and cost. The hospital pressure ulcer committee was hesitant to implement this finding and decided to set the interval in the new guideline on 3 hours, because more frequent turning would result in better prevention. Nevertheless, this new policy still resulted in 11% grades I-IV and 7% grades II-IV pressure ulcers frequency. Related to this discussion, we found a more serious problem: only one in ten patients who needed (assistance in) repositioning received this measure. During the surveys, we asked patients at risk if regular turning was advised or the ward nurse was asked if repositioning was administered in case the patient was not able to turn himself. Even if there was a potential risk for a socially desirable answer on this question, we found that only 10% of the patients were treated according to the guideline. An astonishing result, but in accordance with other studies1. A recent study into barriers to the implementation of pressure ulcer guidelines found that lack of
consistent leadership was a major barrier\textsuperscript{25}. Therefore, we recommend to ensure strong nursing leadership in future pressure ulcer improvements projects.

The costs for the replacement of a hospital mattress by a high-quality pressure reducing visco elastic foam mattress amount to approximately €400 per mattress. Although a cost-benefit analysis was not included in the present study, we emphasise that the investment in a visco-elastic foam mattress led to a considerable cost saving. The lifespan of a mattress is 10 years. A less expensive foam hospital mattress, but without the pressure decreasing qualities, costs about €200 per mattress. The difference of approximately €200 divided by 3650 amounts to €0.05 per day. This amount is considered negligible compared with each pressure ulcer prevented.

Two potential weaknesses of our study design should be addressed. First, incidence measures are a stronger measure for the effectiveness of prevention than prevalence or frequency measures. However, a hospital-wide survey is more feasible than an incidence study with a long follow-up time. We measured and reported the data according to the methodological and practical recommendations in the statement on prevalence and incidence monitoring of the European Pressure Ulcer Advisory Panel (EPUAP)\textsuperscript{21}. The compliance with the one-day surveys was very high. Because we wanted to explore the effect of measures within a hospital population, we only included hospital acquired pressure ulcers in our analyses. It is known that the origin of pressure ulcers is underreported in nursing charts and that nurses may give socially desirable responses to this question. To minimise this bias, we asked the patient for the origin of the pressure ulcer. Only if the patient could not answer this question, we asked the nurse or looked it up in the patient’s record.

Secondly, patients could have been counted twice in successive measurements. Since the mean length of stay was 8.3 days, it was assumed that at least a period of 4-5 weeks between the measurements was sufficient to reduce patients twice counted to a minimum. Nevertheless, incidental extreme outliers could be counted double and could not be excluded because participation of the patient was anonymous.

**Conclusion**

The pressure ulcer frequency in hospital can successfully be reduced. General measures such as the introduction of adequate mattresses and guidelines for prevention and treatment are promising tools in this respect.
IMPLEMENTATION OF A NEW POLICY RESULTS IN A DECREASE OF PRESSURE ULCERS

REFERENCES

Guideline implementation results in a decrease of pressure ulcer incidence in critically ill patients

Erik de Laat
Peter Pickkers
Lisette Schoonhoven
André Verbeek
Ton Feuth
Theo van Achterberg

Submitted.
ABSTRACT

OBJECTIVE: To describe the short-term and long-term effects of a hospital wide pressure ulcer prevention and treatment guideline on both the incidence and the time to the onset of pressure ulcers in critically ill patients.

DESIGN: Prospective cohort study.

SETTING: Adult Intensive Care Department of a University Medical Centre.

PATIENTS: Critically ill patients (n=399).

INTERVENTIONS: A guideline for pressure ulcer care was implemented at all intensive care units. Timely transfer to a specific pressure reducing device was an important part of this guideline.

MEASUREMENTS: Patient characteristics, demographics, pressure ulcer risk profile at admission, daily pressure ulcer grading and type of mattress were determined to describe the short-term and long-term effects 4 and 12 months after the implementation.

MAIN RESULTS: The incidence density of pressure ulcers grade II-IV decreased from 54 per 1000 patient days at baseline to 32 per 1000 days (p=0.001) at 12 months after the implementation. The median pressure ulcer free time increased from 12 days to 19 days (Hazard rate ratio (HRR)=0.58; p=0.02). After adjustment for differences in risk factors in a Cox Proportional Hazard model, the number of preventive transfers to special mattresses was the main indicator for the decreased risk of pressure ulcers (HRR=.22; p<0.001). The number needed to treat to prevent 1 pressure ulcer during the first 9 days was 6.

CONCLUSION: The implementation of a guideline for pressure ulcer care resulted in a significant and sustained decrease in the development of grade II-IV pressure ulcers in critically ill patients. Timely transfers to a specific mattress, i.e. transfers prior to the occurrence of a pressure ulcer, was the main indicator for a decrease in pressure ulcer development.
INTRODUCTION
Pressure ulcers are a persistent problem in hospitalised patients with prevalence rates ranging from 10% to 23%. The incidence reported in critically ill patients reaches up to 56%. Patients admitted to intensive care units (ICUs) are at a particularly high risk of developing pressure ulcers. These critically ill patients are generally not able to notice increased tissue pressure and to react accordingly because they receive sedation, analgesics and/or muscle relaxants. Moreover, their underlying disease and haemodynamic instability increase the risk of developing a pressure ulcer. From an analysis of Dutch prevalence data, we know that the prevalence of pressure ulcers in the ICU is high (29%). Pressure ulcers are a major burden in terms of patient suffering. As pressure ulcers may be considered a nosocomial complication, there are professional, economical and legal arguments to implement programs that aim to improve pressure ulcer care. Programs aimed to improve pressure ulcer care were successful in nation wide projects, specific health care institutions and in specific patient groups. These projects are based on the idea that pressure ulcers are the result of pressure and/or shear forces. Key features of these projects were: (i) pressure reduction by high quality standard mattresses, (ii) implementing a protocol of care and (iii) monitoring pressure ulcers and providing professionals with feedback. From prospective incidence studies in non-critically ill patients we know that positive short-term results in the first 3 to 6 months can be expected. To date, however, the effect of a hospital wide program for pressure ulcer care has not been studied in critically ill patients. As length of stay is known to be an independent predictor for pressure ulcers in critically ill patients, we do not expect to be able to prevent pressure ulcers in all patients on the ICU. However, we expect to be able to decrease the pressure ulcer frequency and to prolong the average time until a pressure ulcer appears. Implementation of guidelines tends to induce a novelty effect that extinguishes within a certain period. Therefore the aim of this study is to describe the short-term (3 months) and long-term (12 months) effects of the introduction of a hospital wide pressure ulcer prevention and treatment guideline (henceforth “guideline”) on the pressure ulcer incidence and pressure ulcer free time in critically ill patients admitted to the ICU for more than 48 hours. In addition, we set out to explore determinants of change, in case changes would actually occur.
MATERIALS AND METHODS

Design
A prospective cohort study was performed. Between December 2001 and June 2003 pressure ulcer development and the time to the onset of pressure ulcers were registered during three periods of 3 months each. During the first period of three months the guideline implementation was prepared in all wards and units. At the end of this period the guideline was formally implemented The second period ran from 4-6 months after the first period to study the short-term effect of the policy on incidence and the time to onset of pressure ulcers. The third period ran from 12-15 months after the first period to study the long-term effect of guideline implementation.

Study population
The Ethics Committee of the hospital approved of the study and waived the need for a written informed consent. The study was carried out in a 28-bed adult Intensive Care (IC) Department of the Radboud University Nijmegen Medical Centre in the Netherlands. The IC-department consists of two general medical & surgical units, a neurological unit and a thoracic & cardiac surgical unit.
A total of 1225 patients were eligible for this study (Figure 1). Patients were excluded from the analysis if length of stay in the intensive care unit (ICU) was shorter than 48 hours (n=780), if patients had pressure ulcers at admission to the ICU (n=34), or if the first screening of the skin was not executed within the first 48 hours after admission to the ICU (n=12). A total of 399 patients were included: 110, 130 and 159 for the first, second and third observation period, respectively.

Pressure ulcer prevention program
The guideline implemented was a specification of national25 and international guidelines for pressure ulcer care26-28 updated with recommendations emerging from research29. A pressure ulcer consultant was appointed in the study hospital and established a network of so-called contact nurses (one on every nursing ward and ICU). These contact nurses were trained by the nurse consultant and introduced the new guideline in a staff meeting or clinical lesson on the ICU’s. Also, after the official introduction of the guideline at the end of the baseline period, the existence of the guideline was announced in several hospital media (newspaper, intranet).
1225 patients admitted to the ICU during the study period

Period I baseline  
\( n = 369 \)

Period II 4-6 months  
\( n = 370 \)

Period III 12-15 months  
\( n = 486 \)

Length of stay < 48 hours  
\( n = 247 \)

Length of stay < 48 hours  
\( n = 224 \)

Length of stay < 48 hours  
\( n = 309 \)

Ulcer at admission  
\( n = 11 \)

Ulcer at admission  
\( n = 13 \)

Ulcer at admission  
\( n = 10 \)

First screening not within 48 hours  
\( n = 1 \)

First screening not within 48 hours  
\( n = 3 \)

First screening not within 48 hours  
\( n = 8 \)

Included for analyses  
\( n = 110 \)

Included for analyses  
\( n = 130 \)

Included for analyses  
\( n = 159 \)

excluded  
\( n = 780 \)

excluded  
\( n = 34 \)

excluded  
\( n = 12 \)

included  
\( n = 399 \)

Period I = baseline = 0-3 months; Period II=4-6 months after baseline; Period III = 12–15 months after baseline period.

**Measurements and instruments**

A data collection form was developed including five categories of data. The first category concerned patient characteristics such as age, sex, medical history, primary reason for admission to the ICU, length of stay at the ICU and time on mechanical ventilation. The second category assessed exceptional circumstances such as shock or resuscitation in the...
past 24 hours. The third category assessed the type of mattress used: a standard viscoelastic hospital mattress or a specific pressure-reducing mattress. We considered the preventive transfer of a patient from a standard hospital mattress to a more specific pressure-reducing mattress as an indicator of adherence to the guideline. A preventive transfer is defined as the first transfer to a specific mattress prior to pressure ulcer occurrence. The guideline prescribed these transfers in case of non-blanchable erythema or an expected immobility of more than 72 hours. The fourth category was a risk profile for pressure ulcers based on the conceptual scheme for pressure ulcer risk of Defloor\textsuperscript{30}. According to this scheme, compressive and shearing forces cause pressure ulcers. Important determinants of these forces are mobility, activity and sensory perception. Information on these determinants was collected dichotomously (present or absent). Age, major surgery, impaired food intake, and shock or resuscitation are considered determinants of tissue tolerance for pressure or decreased oxygen saturation. The last category of data involved grading the pressure ulcers in four grades of increasing severity according to internationally accepted grading systems\textsuperscript{28} (Table 1). As pressure ulcers grade I can be considered a warning sign for more serious pressure ulcers\textsuperscript{31} the study outcomes of interest were the incidence of pressure ulcers grade II-IV and the time to pressure ulcer occurrence or until censoring, the so-called pressure ulcer free time.

**Table 1 Pressure ulcers classification (EPUAP 1998)**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>non-blanchable erythema of intact skin. Discolouration of the skin, warmth, oedema, induration or hardness may also be used as indicators, particularly in individuals with darker skin.</td>
</tr>
<tr>
<td>2</td>
<td>partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion or blister.</td>
</tr>
<tr>
<td>3</td>
<td>full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through underlying fascia.</td>
</tr>
<tr>
<td>4</td>
<td>extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss.</td>
</tr>
</tbody>
</table>

**Procedure**

The first skin assessment was executed within the first 48 hours after admission. All other data were collected daily by the ICU-nurses who were responsible for the patient’s clinical care. Patients were followed until pressure ulcer occurrence, discharge, death or a length of stay of more than 8 weeks. Prior to this study, ICU-nurses were trained to fill out the forms, handle the risk profile and grade pressure ulcers according to the pressure ulcer classification. In case of doubt, nurses could consult the ward “contact nurse” or the primary investigator. The primary investigator visited all units at least two times a week.
to collect data of the first category, to collect and check the forms filled out by the ICU-nurses, to stimulate compliance with the study protocol and to answer possible questions of the nurses concerning the guideline on pressure ulcer care.

**Statistical analyses**

The main analyses in this study are calculations of the incidence density of pressure ulcers and the pressure ulcer free time in critically ill patients admitted to the ICU for more than 48 hours. These calculations were made for each of the three periods. If we would find a significant decrease in one of these outcomes over time, we aimed to seek for explanations by including confounders and the role of nurses’ compliance (preventive transfers to a special mattress) in the analyses. The pressure ulcer free time as proportion of the total length of stay was compared using analysis of variance and a chi-square test was used to compare incidences.

In addition, a Cox proportional hazards model was used to compare the pressure ulcer free time in the two follow up periods to the baseline period. Next, we included theoretically relevant patient characteristics, risk indicators and compliance (preventive transfers) with the guideline in the analysis.

The proportional hazard assumption was checked by graphic methods (log (-log survival)) for all variables entered in the model. No variable was found to violate the proportional hazards assumption.

Power-analysis was based on a clinically relevant increase of the median pressure ulcer free time of 15%, i.e. 2 days form 13 days to 15 days. With $\alpha=0.05$, we calculated that a sample size of 110 for each of the three groups would be needed to achieve a power of 80%. From management reports, we estimated that $2/3$ of the patients admitted to the ICU would be discharged within 48 hours. Therefore, at least 336 patients were needed in each period.

The number needed to treat (NNT) was obtained by taking the inverse of the absolute difference in pressure ulcer free time as estimated form the Kaplan-Meier survival curves.

The maximal follow up time was 8 weeks. If a patient had no symptoms of pressure ulcers during the follow up time, ulcer free time was censored at 56 days.

Analyses were done by intention to treat. A two-sided p-value of less or equal to 0.05 was considered significant. All statistical analyses were performed using SPSS (version 12.1).
RESULTS
Table 1 illustrates the pressure ulcer classification. Table 2 presents the main reasons for admission to the ICU of the patients included in the three different follow up periods in this study (n=399) and table 3 presents the patient characteristics. Figure 1 demonstrates the inclusion of the patient included in this study.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Main reasons for admission to the ICU; n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Period I Baseline n=110</td>
</tr>
<tr>
<td>Routine post operative surveillance</td>
<td></td>
</tr>
<tr>
<td>cardiac surgery</td>
<td>27 (25%)</td>
</tr>
<tr>
<td>general surgery</td>
<td>22 (20%)</td>
</tr>
<tr>
<td>neurosurgery</td>
<td>4 (4%)</td>
</tr>
<tr>
<td>(Multi)trauma (excl. neurotrauma)</td>
<td>6 (6%)</td>
</tr>
<tr>
<td>Neurotrauma</td>
<td>7 (6%)</td>
</tr>
<tr>
<td>Neurological diseases</td>
<td>11 (10%)</td>
</tr>
<tr>
<td>Cardiological diseases</td>
<td>5 (5%)</td>
</tr>
<tr>
<td>General medicine diseases</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Respiratory Insufficiency</td>
<td>20 (18%)</td>
</tr>
<tr>
<td>Sepsis</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Otherwise /unknown</td>
<td>3 (3%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Patient characteristics (n=399)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Period I Baseline n=110</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>42 (38%)</td>
</tr>
<tr>
<td>Male</td>
<td>68 (62%)</td>
</tr>
<tr>
<td>Age in years mean ± sd</td>
<td>59.7 ± 16</td>
</tr>
<tr>
<td>Length of ICU-stay in days median [range]</td>
<td>9 [3-56]</td>
</tr>
<tr>
<td>Mechanical Ventilation in days median [range]</td>
<td>7.5 [0-56]</td>
</tr>
<tr>
<td>Risk indicators</td>
<td></td>
</tr>
<tr>
<td>Major surgery</td>
<td>53 (48%)</td>
</tr>
<tr>
<td>Shock or resuscitation</td>
<td>18 (16%)</td>
</tr>
<tr>
<td>Immobility</td>
<td>86 (79%)</td>
</tr>
<tr>
<td>Limited response or unresponsive</td>
<td>74 (69%)</td>
</tr>
<tr>
<td>Inactivity</td>
<td>81 (76%)</td>
</tr>
<tr>
<td>Constantly moist</td>
<td>21 (20%)</td>
</tr>
<tr>
<td>Inadequate food intake</td>
<td>52 (49%)</td>
</tr>
<tr>
<td>Friction and shear present</td>
<td>65 (61%)</td>
</tr>
<tr>
<td>Indicator for prevention</td>
<td></td>
</tr>
<tr>
<td>Preventive transfer (%)</td>
<td>14/51 (28)</td>
</tr>
</tbody>
</table>
Pressure ulcer incidence

During the baseline period, we calculated a pressure ulcer grade II–IV incidence density of 54 per 1000 days. In the second period, following the implementation activities, we found a decrease to 46 per 1000 days compared to baseline. One year after the implementation the incidence density was 32 per 1000 days resulting in a significant density difference of 22 compared to baseline (Figure 2). Additionally, we determined a strong decrease in pressure ulcer incidence in the three periods from 43% in the baseline period to 37% in the second period to 28% in the third period (p=0.04).

Figure 2 Incidence of pressure ulcer density per 1000 follow up days and preventive transfers in %, for period I compared to period II and period III.

* Gr II-IV incidence density decreased from 54/1000 days at baseline to 32/1000 days in period III (p=0.012). ** Adequate mattress increased from 28% at baseline to 60% in period III (p=0.003).

Pressure ulcer free time

The mean pressure ulcer free time as proportion of the total length of stay in the three consecutive periods increased from 0.75 at baseline to 0.83 and 0.85 in the second and third period respectively (p=0.01). As illustrated in figure 3, the median time until the
onset of a grade II-IV pressure ulcer at 3 months did not differ from baseline (12 days). One year later it increased to 19 days. Over a period of 9 days (the median length of stay during the baseline period, the NNT one year after the implementation, was 6. The unadjusted hazard rate ratio (HRR) for pressure ulcer free time was 0.58 (p=0.02).

Figure 3

Kaplan Meier diagrams demonstrating the increasing pressure ulcer free time between baseline and PIII: 12-15 months (p=0.02).
**Explorative analysis**

As cohort membership was a statistically significant indicator in the Cox proportional hazards model, an explorative analysis of other relevant factors (Table 3) was performed. After adjustment for relevant baseline characteristics - i.e. age, length of ICU-stay, risk indicators and the preventive transfers-, in a backward stepwise-executed Cox proportional hazards model we found 3 statistical significant indicators. Firstly, preventive transfers to specific mattresses appeared to be a strong statistical significant indicator for the pressure ulcer free time, demonstrated by a HRR of 0.22 (p<0.001). Secondly, shock and/or resuscitation was also a significant indicator (HRR = 1.5; p<0.001). We used shock and/or resuscitation in the pressure ulcer free period as indicator for severity of illness. Finally, the indicator ‘friction and shear present’ appeared to be a significant indicator (HRR =1.3; p=0.02). Because of the HRR > 1, these indicators are associated with a decrease in the pressure ulcer free time.

Additional univariate exploration showed that during the baseline period, 14 out of 51 patients (28%) who needed transfers according to the guideline, were transferred from a standard visco-elastic hospital mattress to a more specific pressure-reducing mattress prior to pressure ulcer development. This frequency increased to 40% (23/57) in the second period and to 60% the third period (34/57) (p=0.003) (Figure 3).

**DISCUSSION**

The present study demonstrates that the hospital wide implementation of a guideline for pressure ulcer care resulted in an absolute decrease in pressure ulcer incidence density in critically ill patients, which sustained for 1 year. After the implementation the NNT was 6 during the first 9 days, i.e. we should apply preventive measures in 6 patients in order to prevent 1 additional ICU-patient from developing a pressure ulcer. The significant increase in timely transfers to a more specific pressure-reducing mattress as a measure of adherence to the guideline turned out to be a strong indicator for the reduction of pressure ulcer incidence.

Despite the fact that the effects of implementation projects can be very disappointing33 and tend to induce a short time effect that extinguishes within a certain period24, we established a positive and strong effect in the long term. Important choices in our implementation strategy were finding and supporting innovators (“contact nurses”) and investing in nurses who were enthusiastic to improve pressure ulcer care, the so called early adopters33. Important characteristics of this strategy were regular visits (twice a
Guideline Implementation

week) to the ICUs, positive feed back during the study period and organising meetings on topics concerning pressure ulcer prevention for contact nurses after the implementation of the guideline.

To appreciate these results, a few points need to be discussed. First, both the decrease in pressure ulcer incidence and the increase in the pressure ulcer free time could be attributed to the increased frequency of patient transfers to a specific pressure-reducing mattress. In our study, we considered the number of transfers before a pressure ulcer occurred as an indicator for preventive measures, as it was not possible to check other preventive measures such as actual repositioning. Therefore, the increase of transfers to a specific pressure reducing mattress before a pressure ulcer occurred is thought to be an indicator of compliance with the new guideline.

Secondly, we excluded patients who had a length of stay of less than 48 hours. These patients were mostly ICU-admissions following elective surgery. As pressure ulcers in this population often result from time spent in the operation room, naturally, ICU policy cannot influence effects of pressure ulcer risk factors during this period. For these reasons we feel our selection of patients with an ICU stay of more than 48 hours is justified. Furthermore a short length of stay on the ICU is associated with a lower incidence of pressure ulcers, which would decrease the power of the study. Nevertheless, our study does not exclude that implementation of the guideline has beneficial effects in these patients too.

Thirdly, the moment of discharge could have influenced the results. It is generally assumed that pressure damage may first appear several days after the insult to the skin and soft tissues occurred. In patients with a length of stay of, for example only 3 days, pressure damage may have occurred but not yet be visible. These pressure ulcers would not be registered, resulting in a lower incidence density. Unfortunately, it was not feasible to follow patients after their stay on the ICU. Therefore, the incidence of pressure ulcers that are attributable to the shorter stay at the ICU may be an underestimation. In accordance with this notion, we found that the NNT decrease with an increase in LOS, becoming significant at day 9 (NNT: 6). On the other hand, the shorter length of ICU-stay in period 3 (Table 3) did not turn out to be a significant confounder in the Cox proportional hazard model.
Severity of illness measured by the Acute Physiology and Chronic Health Evaluation II (APACHE II) or the Simplified Acute Physiology Score II (SAPS II) is strongly related to the occurrence of pressure ulcers in critically ill patients\textsuperscript{6,8,9}. As these scores were not a part of the daily routine in the ICU during the study periods, a limitation of our study is that these data were unfortunately not collected. We used shock and/or resuscitation in the pressure ulcer free period as indicator for severity of illness. Together with friction and shear forces, this risk indicator was found to have a statistically significant HRR in the Cox regression model, associated with a decrease in pressure ulcer free time. Naturally, these well-known risk factors were not influenced by the present study intervention.

Lastly, in our study we did not find indications for a novelty effect. At 3 months after the implementation period we found a statistically non-significant decrease in the incidence density. However, this trend continued and sustained for at least one year after the implementation period resulting in a significant decrease in the pressure ulcer density.

\textit{Conclusion}

Our study demonstrates that the hospital wide implementation of a guideline for pressure ulcer care results in a decrease in pressure ulcer incidence density grade II-IV that sustains for at least 1 year after implementation of the guideline. The number of preventive transfers to a specific mattress was the strongest significant indicator for the decrease in pressure ulcer occurrence.

Our results indicate that during a median length of stay in the ICU of 9 days, for every 6 patients treated after the implementation of the guideline, the occurrence of 1 additional pressure ulcer patient was prevented.
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Pressure ulcers: diagnostics and interventions aimed at wound-related complaints: a review of the literature

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ABSTRACT
Aims and Objectives: To describe the current scientific evidence in the field of diagnostics and treatment of pain, malodour and exudate from pressure ulcers and to give recommendations for practice, based on these findings.

Background: Patients with pressure ulcers are confronted with symptoms of chronic wounds and impaired wound healing. Assessment and treatment of these symptoms have received very little attention.

Design: Systematic literature review.

Methods: Medline, CINAHL, and Cochrane, were searched for studies on pain, malodour and exudate in patients with pressure ulcers.

Results: The McGill Pain Questionnaire, the Visual Analogue Scale and the Faces Rating Scale are useful instruments to assess pressure ulcer related pain. Strong evidence was found to support a positive effect of (dia)morphine. Some evidence was found to support a positive effect of benzydamine gel and Eutectic Mixture of Local Anaesthetic-cream. Wound malodour is subjectively assessed. In a laboratory study, it is proved that activated charcoal is capable of absorbing gas molecules causing malodour. At present, no studies are available on the odour-absorbing capacity of activated charcoal dressings in pressure ulcer patients. Exudate is a symptom of impaired wound healing. The Pressure Sore Status Tool is a valid and reliable instrument for assessing the wound healing process. There is a possible indication that hydrocolloid positively influences healing time because the absorption of exudates is more effective.

Conclusion: Little sound research has been performed on wound-related complaints in patients with pressure ulcers. Nevertheless several recommendations could be made on the present state of the art.

Relevance to Clinical Practice: Regarding pressure ulcer related pain, this review supports the intervention of local pain relieve in patients with pressure ulcers. Regarding pressure ulcer related odour and exudates, this study identifies the gaps in evidence and research.
INTRODUCTION

In 1999, the Pressure Ulcer Report from the Dutch Department of Health established that the scientific foundation for pressure ulcer care was moderate\textsuperscript{12}. Knowledge was scarce and mainly limited to infection control and surgical interventions. Few data were available on diagnostics and treatment of wound-related problems.

In the care of patients with pressure ulcers, nurses are confronted with troublesome symptoms of chronic wounds and impaired wound-healing\textsuperscript{3,5}, treatment of these symptoms has received very little attention. The amount of evidence is unclear, therefore, we performed a review of the current literature.

After an exploration of publications in four specific journals on wounds and wound care (\textit{Advances in Wound Care} (previously \textit{Decubitus}), \textit{Journal of Wound Care, Ostomy/ Wound management} and the \textit{Journal of Wound, Ostomy and Continence Nursing}) we selected three problems to focus on: pain\textsuperscript{6-8}, wound malodour\textsuperscript{9,10} and exudate\textsuperscript{11,12}. These three problems were selected because the contents of these journals indicated that they are commonly experienced by patients with pressure ulcers.

Pain is caused by irritation of the sensory nerve endings in and around the ulcer. Other sources of pain arise when the wound is cleansed (debridement), or if aids (prosthesis, tubes, drains etc.) are applied too tight, or when dressings rub against the surface of the wound\textsuperscript{3,5}. In a qualitative study, Neil et al. found that pressure ulcer patients were experiencing chronic as well as acute pain\textsuperscript{12}. Patients described their pain as: burning, stinging, sharp, stabbing and tingling. Descriptive quantitative research showed that 37.1-87\% of pressure ulcer patients were suffering from pressure ulcer pain\textsuperscript{6-8}. The most realistic estimate seems to have been made by Lindholm\textsuperscript{7}, who found a prevalence of 37.1\% in a large study (n=694).

Wound exudate and malodour are general symptoms of bacterial colonisation\textsuperscript{3,5,9,10,13}. No research has been performed into the prevalence of these problems. A qualitative study showed that leaking wounds and wet dressings are recurrent daily problems that lead to a great deal of frustration and distress. Patients feel dirty and are in danger of becoming socially isolated\textsuperscript{11,12}.

The aim of this study was, firstly, to describe current scientific evidence in the field of diagnostics and treatment of pain, wound malodour and exudate from pressure ulcers. Secondly, this study aimed to make recommendations for practice based on these findings.
OBJECTIVES AND METHODS
The literature was searched systematically for the current state of knowledge on the diagnosis of pain, wound malodour and exudate in patients with pressure ulcers and interventions used to treat these problems.

Search strategy
Medline, CINAHL and Cochrane (1991-2004) were used to search for publications on the basis of the keywords: pressure ulcer, pressure sore, decubitus ulcer, successively combined with: pain, exudate, transudate, leakage, odour and odor. Scientific publications were distinguished from opinionated, contemplative or journalistic articles using a filter for the type of publication. This filter contained the terms: randomised controlled trial, controlled clinical trial, clinical trial, meta-analysis, multicentre study, review, academic review, literature review, review of reported cases, evaluation study and guidelines.

Selection criteria
This state of the art research included every type of study and review that mentioned one of the three pressure ulcer problems studied, i.e. pain, wound malodour and exudate. Studies were included in the review if they were about patients with pressure ulcers and/or other chronic wounds. Intervention studies were accepted if their aim was to decrease pain, wound malodour and exudate, or if they contained any type of outcome measure related with these three patient problems. Publications that did not describe patient-oriented research were excluded from the review. In addition, publications on patients with non-chronic wounds (e.g. surgical wounds or trauma wounds) were excluded.

Data collection and analysis
The first author screened the abstracts of all the publications on the basis of the inclusion and exclusion criteria. If there were any doubts, the whole article was retrieved. If doubts remained on the basis of the whole article, one of the other authors was consulted to decide about inclusion or exclusion.
Results

The selection procedure resulted in 13 publications that focused on pain, wound malodour or exudate in pressure ulcer patients (or patients with other chronic wounds). One publication could not be retrieved. Furthermore, we included three important guidelines on the treatment of pressure ulcers.

Diagnosis of pain

Valid and reliable rating scales have been developed in nursing practice to measure and objectify pain. In the selected literature, three instruments had been used to measure pain in pressure ulcer patients (Table 1).

- The McGill Pain Questionnaire (MPQ) was used to provide a quantitative measure of pressure ulcer pain. This tool was selected because it provides a description of the qualities of pain, as well as a measurement of pain intensity. It was found that completion of the MPQ was difficult for some subjects, especially for those who were acutely ill. The validity and reliability of the MPQ have not been tested specifically in pressure ulcer patients. However, a great deal is known from other more general pain literature (not included in this review). This literature provides evidence for the assumed dimensions, internal consistency, construct validity and sensitivity of the MPQ.

- The Visual Analogue Scale (VAS) proved to be very suitable to measure pain intensity and was also used to measure pain in pressure ulcer patients. Pressure ulcer patients included in the study of Dallam et al. and Freeman et al. completed the VAS without any problem. The VAS consists of a horizontal line of 10 cm long, with ‘no pain’ at one end and ‘worst imaginable pain’ at the other end. Patients are asked to mark the position on the line that best reflects the intensity of their pain. Dallam et al. reported that the localised VAS score was significantly correlated with the maximum pressure ulcer stage (r=0.37; p<0.01).

- No formal tests have been performed on the target group of pressure ulcer patients, but the general literature contains sources that confirm the validity and reliability of this instrument. The Faces Rating Scale (FRS), which consists of six drawings of facial expressions in a horizontal line that vary from very unhappy to very happy, was found to correspond well with the VAS in patients with pressure ulcer pain. The scale is known to be especially useful in patients with speech problems, restricted abstract-thought abilities and children.
• The VAS and FRS were successively completed by 44 patients with pressure ulcers in the study of Dallam et al.\textsuperscript{6}. The VAS strongly correlated with the FRS ($r=0.92$; $p<0.01$). Freeman et al.\textsuperscript{20} derived a quadratic equation from the data of the Dallam study in a secondary analyses. With the use of the equation derived: $\text{VAS} = 3.33 \times (\text{FRS})^2$, the correlation ($r=0.92$) found by Dallam was confirmed. This formula allows mathematical translation of FRS findings into VAS units that have demonstrated ratio scale properties.

### Table 1  Studies on Pressure Ulcer Related Pain

<table>
<thead>
<tr>
<th>Author</th>
<th>Methods</th>
<th>Patients</th>
<th>Assessment tool/Intervention</th>
<th>Detail/Main outcomes</th>
</tr>
</thead>
</table>
| Szor and Bourguignon (1999)\textsuperscript{8} | Descriptive              | 32 PU-patients (Grade II-IV) acute, extended, and home care | MPQ (qualitative and intensity) | • 28 of 32 pain at dressing change.  
• 27 of 32 severe pain and constant.  
• Completion of the MPQ was difficult for some subjects.  
• 68% some degree of pain  
• Localised VAS score correlates with the max. PU-stage ($r=0.37$; $p<0.01$).  
• VAS and FRS are strongly positively correlated ($r=0.92$; $p<0.01$).  
• Pain scores (1-4) improved significantly 1 (p=0.003) and 12 hours (p=0.005) after diamorphine gel application.  
• Adverse events: 1 patient developed some signs of opioid toxicity.  
• Confirmation finding of Dallam et al. 1995  
• $\text{VAS} = 3.33 \times (\text{FRS})^2$. |
| Dallam et al. (1995)\textsuperscript{6} | Cross-sectional          | 44 PU-patients in a acute care setting | VAS & FRS for pain intensity  |  |
| Flock (2003)\textsuperscript{22} | Randomised, double-blind, placebo controlled crossover trial | 7 PU patients (Grade II & III) | Mixture of diamorphine and hydrogel vs placebo |  |
| Freeman et al. (2001)\textsuperscript{20} | Secondary data analyses on Dallam et al. (1995) | 44 PU-patients in a acute care setting | VAS & FRS for mathematical analyses |  |
| Jepson (1992)\textsuperscript{21} | Descriptive              | 17 PU-patients with 30 wounds     | Local application of benzydamine gel |  |
| Zeppetella et al. (2003)\textsuperscript{23} | Randomised, double-blind, placebo controlled crossover trial | 7 PU patients (Grade II & III) | Mixture of morphine and hydrogel vs placebo |  |

VAS=Visual Analogue Scale; FRS=Face Rating Scale; MPQ=McGill Pain Questionnaire; PU=Pressure Ulcer.
Interventions to reduce pain

The effectiveness of oral pain medication is well-known in the general literature. However, oral analgesics find limited application and prescription in patients with pressure ulcer pain. Only 6% of the patients in the study by Szor\(^8\) were receiving pain medication, while 75% had moderate to severe pain and 18% even complained of excruciating pain. In the study by Dallam et al.\(^6\) only 2% of the patients were receiving analgesic medication.

Three studies described specific pain-relieving measures in patients with pressure ulcers. In Jepson’s\(^21\) study 24 hours after the local application of a benzydamine gel (a non-steroid, inflammation inhibitor) to 30 wounds in 17 pressure ulcer patients, 29 of the wounds were pain-free. After 48 hours, all 30 wounds were completely pain-free. Possible side effects were not discussed.

In two randomised double-blind, placebo controlled, crossover studies\(^22,23\) the efficacy of (dia)morphine gel on pain reduction was determined. Five and seven hospice patients, respectively, with painful pressure ulcers grade II and III were included. In both studies, patients were blinded to the randomisation sequence. Gels were applied once daily and covered with standard dressings. All patients received systemic pain medication, for pain related to their malignancies. The amount of co-medication in the two treatment arms was identical. In both studies pain scores improved significantly after (dia)morphine gel application, as compared with baseline. Administration of the placebo (only gel) had no statistically significant effect on pain scores.

In Zeppetella’s\(^23\) study no adverse events specifically attributable to morphine were found. Flock\(^22\) described one patient experiencing symptoms of opioid toxicity. The strength of the fentanyl patch of this patient was increased the day prior to entering in the study. The patient developed the first signs of opioid toxicity (drowsiness, nightmares) while being on placebo treatment (hydrogel only). The patient had experienced similar symptoms of opioid toxicity during a previous attempt to increase the fentanyl dose.

Diagnostics and wound malodour

No scales are available to make objective evaluations of wound malodour. In a study by Van Rijswijk\(^24\), the subjective judgement of the patients was considered to form a measure of the presence of wound malodour. In a case study\(^25\), the level of malodour was
classified as: strong, moderate, slight and absent. This classification was operationalised in the case study, but has not been validated or tested for reliability.

**Interventions to decrease wound malodour**

No studies were found that described or tested interventions to decrease wound malodour in patients. In guidelines, the advice to counteract wound malodour is generally aimed at the treatment of bacterial colonisation or infection, considered to be the underlying cause of malodour. Treatment comprises the use of antibiotics and regular cleansing of the wound with tap water\(^3\)\(^-\)\(^5\).

One publication did not meet our inclusion criterion of applied patient research, but held implications for patient care nonetheless. Therefore, we decided to report on the results of this study. In a laboratory study, on wound models, effects of odour-absorbing dressings were explored\(^2\(^6\). The dressings used in the study contained activated charcoal, which proved to be capable of absorbing gas molecules released by metabolic processes in bacteria. Particularly these gas molecules seemed to cause the malodour. At present, no studies are available on the odour-absorbing capacity of activated charcoal dressings in pressure ulcer patients.

**Exudate diagnostics**

The presence or absence of wound exudate can be judged visually. Bates-Jensen\(^2\(^7\) developed the Pressure Sore Status Tool (PSST). It consists of 13 Likert scaled item and is used to describe the state of a pressure ulcer. There are two exudate items: type of exudate and amount of exudate. The inter-rater reliability and intra-rater reliability of the total scale are high in Enterostomal Therapy Nurses \((r > 0.90; p < 0.01)\). Face validity of the PSST has been proven by experts\(^2\(^8\).

**Interventions to reduce the problem of exudate**

In six randomised clinical trials (RCTs) the exudate-absorbing capacities of wound dressings was one of the outcomes studied\(^2\(^9\)^\(^-\)\(^3\(^4\). Eight different types of dressing were compared in the six trials (Table 2).
### Table 2 Studies on pressure ulcer related exudate

<table>
<thead>
<tr>
<th>Author</th>
<th>Methods</th>
<th>Patients</th>
<th>Intervention</th>
<th>Outcome measurement on exudate</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Banks et al. (1997)²⁹</td>
<td>RCT</td>
<td>n=61 mixed*; PU (II-III) n=20</td>
<td>Polyurethane foam vs hydrocellular membrane vs hydrocolloid</td>
<td>Mean dressing wear time</td>
<td>NS</td>
</tr>
<tr>
<td>Hondé et al. (1994)³⁰</td>
<td>Open RCT; multicentre (n=23)</td>
<td>n=168; PU (II-IV)</td>
<td>Change indicator dressing⁶ vs hydrocolloid/alginate</td>
<td>Volume scale: 0=none to IV=very abundant Mean dressing wear time</td>
<td>NS</td>
</tr>
<tr>
<td>Seaman et al. (2000)³¹</td>
<td>Open RCT; multicentre</td>
<td>n=35; PU (II-IV)</td>
<td>Hydropolymer vs hydrocolloid</td>
<td>Frequency of dressing changes</td>
<td>NS</td>
</tr>
<tr>
<td>Thomas et al. (1997a)³²</td>
<td>Open RCT; multicentre</td>
<td>n=199 mixed*; PU (II-III) n=99</td>
<td>Hydropolymer vs hydrocolloid</td>
<td>Only at the first dressing change, less dressing changes in hydropolymer group. (p=0.007).</td>
<td>NS</td>
</tr>
<tr>
<td>Thomas et al. (1997b)³³</td>
<td>Open RCT; multicentre</td>
<td>n=100 mixed*; PU (II-III) n=49</td>
<td>Hydrocolloid vs polyurethane as secondary dressing</td>
<td>% Dressing changes with no wrinkling</td>
<td>NS</td>
</tr>
<tr>
<td>Xakellis and Chrischilles (1992)³⁴</td>
<td>RCT</td>
<td>n=39; PU (II-III)</td>
<td>Hydrocolloid vs wet-to-moist saline gauze</td>
<td>Influence of presence of exudates at baseline on healing</td>
<td>Presence of exudates at baseline was sign. associated with a longer healing time (p=0.01)</td>
</tr>
</tbody>
</table>

* mixed: mixed aetiology ; ⁶: material not specified. NS: no significant difference; PU= Pressure Ulcer; II=Grade II; III=Grade III; IV=Grade IV

In five studies a hydrocolloid dressing was one of the interventions. Outcome variables included: ‘amount of exudate’ or ‘number of dressing changes because of exudate’. Only in one study was a significant difference in the number of dressing changes found. A hydropolymer dressing and a hydrocolloid dressing were compared in a study involving 100 patients with leg ulcers and 99 patients with pressure sores in the community. Statistically significant differences in favour of the hydropolymer dressing were detected for dressing leakage³². This difference probably has little clinical value, because it concerned a temporary effect that was only found directly after the introduction of the new material. An obvious explanation for this difference in the number of dressing changes is that nurses had to become used to the new dressing and first learn how to use it.
CONCLUSIONS AND RECOMMENDATIONS

This state of the art study included every type of research and any reviews on three pressure ulcer-related problems: pain, wound malodour and exudate. Our inclusion criteria were very broad. After several searches in Medline and CINAHL, we could conclude that few randomised clinical trials (RCTs) have been performed in this field. The RCTs concerned pain and exudate, but it was not possible to conduct a meta-analysis even on both issues. For exudate no uniform outcome variables were used, the interventions were too diverse and critical comments can be made about the methodological quality of these trials. Two high quality RCTs on pain interventions were identified but the interventions differed. In one study diamorphine was used\textsuperscript{22}; in the other study morphine sulphate\textsuperscript{23}. Therefore, the present review has a descriptive character, which improves insights, but inhibits drawing any definitive conclusions about effective interventions.

An important advantage of the above described supple working method, is that we now have a useful impression of the as yet poorly illuminated field of wound-related problems in pressure ulcer patients.

We found strong indications for the analgesic effect of (dia)morphine applied topically to painful pressure ulcers\textsuperscript{22,23}. The methodological quality of both studies was high. The crossover designs used have a high internal validity. In spite of the small sample sizes of n=7 and n=5, respectively, statistically significant differences were found. Generally, high internal validity is to the disadvantage of the generalisation of the findings to other patient groups with pressure ulcers. In the future, a study with a larger sample size and a mixed patient population should be performed. Nevertheless, it seems safe to recommend the prescription of (dia)morphine in guidelines as evidence based intervention for local pain relieve for the treatment in patients with pressure ulcers. In deciding on the use of (dia)morphine gel dressing the overall pain treatment in specific patients should always be carefully considered.

We only found one study describing a specific pain-relieving intervention, focusing on the use of benzydamine in patients with pressure ulcers\textsuperscript{23}. We excluded two meta-analyses on local pain relief in patients with leg ulcers from the review\textsuperscript{35-37}. These reviews reported beneficial effects of Eutectic Mixture of Local Anaesthetic-cream (EMLA). Pressure ulcers and leg ulcers are two types of chronic wounds. There are no reasons to suppose that EMLA would not have a beneficial effect in patients with pressure ulcers. We recommend to consider both benzydamine gel and EMLA as specific pain relieving
interventions in patients with severe pressure ulcer related pain, for instance in preparation of wound debridement.

From the results on malodour and exudates we cannot recommend a specific dressing. However, wound exudate and malodour are general symptoms of bacterial colonisation\textsuperscript{3-5,9,10,13}. In three of the six reviewed RCTs, wound-healing was one of the outcome variables\textsuperscript{30,31,34}. Each of these trials reported that the dressing in the experimental group had a positive effect on wound-healing. Xakellis\textsuperscript{34} compared hydrocolloid dressings to saline-gauze and found that the former led to a shorter healing time. Median time to healing for the subjects treated with hydrocolloid dressing was 9 days, with 75\% healing within 14 days if initiating therapy. Subjects treated with saline-gauze dressings had a median healing time of 11 days, with 75\% healed within 26 days (p=0.12). The power in this study to detect a difference of this magnitude was 0.48. Exudate present at baseline was significantly associated (p=0.009) with healing time. A possible explanation for these two findings is that hydrocolloid positively influences healing time because the absorption of grow inhibiting agents with hydrocolloid is more effective.

In the two other trials\textsuperscript{30,31} significant effects were found on wound-healing in favour of the experimental intervention. However, these two trials compared two different brands of dressing without explaining clearly what they contained. Another important aspect in the assessment of these trials is the possible conflict of interests of the researchers. There was no blinding at all against any aspect and the trial was sponsored by the manufacturer of the experimental dressing. The data from one of these trials\textsuperscript{30} were processed and analysed by the research department of the company that financed the trial.

Based on our results, we recommend:

\begin{itemize}
  \item using the MPQ, VAS or FRS to diagnose pressure ulcer pain;
  \item using the PSST for good wound assessment and evaluation;
  \item using (dia)morphine gel, benzydamine-gel or EMLA for pain relief;
  \item using hydrocolloid dressings in exudating wounds.
\end{itemize}

A final recommendation concerns future research. Whereas pressure ulcer prevention and wound treatment are rather well researched, little evidence could be retrieved with regard to common symptoms related to pressure ulcers. Therefore, further research should be conducted into: psychometric qualities of the MPQ, VAS and FRS in pressure ulcer patients; methods to operationalize the diagnosis of wound malodour; the effect of topical analgesia (EMLA) or benzydamines in the treatment of pressure ulcer pain; the
effect of activated charcoal dressings on pressure ulcer malodour; the effects of various types of dressing on pressure ulcer exudate and alternative interventions to decrease pain, exudate and wound malodour in pressure ulcer patients. This type of research is urgently needed, to improve nursing care in pressure ulcer patients.
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8. Szor JK, Bourguignon C. Description of pressure ulcer pain at rest and at dressing change. J Wound Ostomy Continence Nurs 1999;26:115-120.
General discussion
The aim of the work described in this thesis was (i) to gain insight into the nature and extent of the pressure ulcer problem in critically ill patients, (ii) to determine the influence of direct post operative lateral position in CABG patients on the cardiac index and whether turning procedures cause practical problems and (iii) to determine the effects of a hospital wide program on pressure ulcer care on the occurrence of pressure ulcers in both critically ill patients and hospitalised patients at large. With regard to the first aim, we conclude that pressure ulcers are still a major problem in hospitalised patients. Patients admitted to the ICU are at a particularly high risk of developing pressure ulcers (chapter 1). Although a decrease of pressure ulcers can be seen in the past 5 years, still 5% to 20% of the critically ill patients suffer from pressure ulcers (chapter 2, chapter 3). Most critically ill patients are not able to notice increased tissue pressure and to react accordingly, because they receive sedation, analgesics and/or muscle relaxants\textsuperscript{1-3}. Therefore, general determinants of pressure and shear like immobility, inactivity and sensitivity for- or reaction to pain\textsuperscript{4} in risk assessment instruments, are not discriminating between critically ill patients at risk and not at risk. Apart from immobility, inactivity and sensitivity for- or reaction to pain we could not establish a profile determined by other risk factors that predicts pressure ulcer development in critically ill patients. Moreover, there are no preventive therapies that have unequivocally proven their effectiveness. Although not supported by evidence, routine turning of critically ill patients on a traditional foam standard hospital mattress at a minimum of 2 hours has become the accepted and most important standard of care in pressure ulcer prevention\textsuperscript{5}. The second aim of this thesis addressed the cautiousness of nurses to turn critically ill patients directly after cardiac surgery. A possible explanation for this incompliance with the guideline is that a negative influence on hemodynamic parameters is assumed (chapter 4). However, in a clinical trial we found that early post-operative turning of CABG patients did not influence the cardiac index, not even in hemodynamically compromised patients that were treated with antihypertensive or inotropic/vasopressor therapy. Moreover, there were no practical problems hindering the turning regimen, not even in the patients with an intra-aortic balloon pump. With regard to the third aim, we conclude that implementation of a hospital guideline for pressure ulcer care combined with the introduction of visco-elastic foam mattresses led to a significant reduction in the number of hospitalised patients with pressure ulcers. General measures such as the introduction of adequate mattresses and guidelines for
prevention and treatment are promising tools in this respect. However, in our study on the effects of these measures, the decrease in pressure ulcer prevalence was largely attributable to the introduction of the new mattresses. Care behaviour of the nurses hardly changed (chapter 5). In critically ill patients we found that the implementation of a guideline for pressure ulcer care resulted in a significant and sustained decrease in development of pressure ulcer grade II and worse. A change in care behaviour of the caregivers leading to an earlier transfer to a specific mattress, i.e. transfer prior to pressure ulcer occurrence, was the strongest preventor in pressure ulcer development (chapter 6).

Patients with pressure ulcers are confronted with symptoms of chronic wounds and impaired wound healing like pain, mal odour, or exudate. In line with the first aim we found little sound research on these wound-related complaints. Nevertheless, several recommendations could be based on the current state of the art (chapter 7). Despite the lack of a strong evidence base for preventive measures in the literature, our study showed that adherence to a best practice guideline can result in a decrease in pressure ulcer occurrence. Yet, complete or even reasonable adherence was difficult to achieve. In retrospect, one may wonder whether prevalence or incidence was the most suitable outcome measure for measuring the effect of the guideline. Also, we will discuss what possibly hindered implementation and caused non-adherence to the newly implemented guideline.

**Prevalence or Incidence**

Prevalence and incidence are both measures of disease frequency. One day prevalence measurements and incidence studies both have advantages and disadvantages. The choice of design depends on the purpose of the study.

According to the EPUAP statement on prevalence and incidence monitoring of pressure ulcer occurrence, prevalence is the proportion of patients who have pressure ulcers at a certain point or period in time\(^6\). One problem, often discussed under the topic of length-biased sampling, is that the number of pressure ulcer patients in a one-day survey will over-represent the number of pressure ulcer patients with long ulcer duration and under-represent those with short duration of pressure ulcer presence\(^6\). For this very reason, prevalence is a gross performance indicator of pressure ulcer care. If pressure ulcer care guidelines are of low quality or the compliance with these guidelines is low, it is likely that the pressure ulcer care will be sub-optimal. This may lead to more patients with
prolonged pressure ulcers, and thus a larger probability to include these patients in a prevalence measurement. Inversely, in a situation where guidelines of high quality are well implemented, patients will experience a pressure ulcer for a shorter period of time, and thus are less likely to be included in a prevalence measurement. Furthermore, the precision (lack of random error) of a prevalence measurement depends strongly on the sample size and makes one day surveys in small populations, such as wards, less suitable.

A hospital wide incidence study was not feasible. Incidence studies require a larger time-investment than prevalence studies. Wards with a small number of pressure ulcer patients may not be motivated to invest time in this type of study. As the magnitude of the pressure ulcer problem varied between wards we chose to measure prevalence to ensure compliance with the study protocol by all participating wards. However, a variation in the number of patients with a pressure ulcer present at admission, which is not attributable to hospital policy on pressure ulcer care, might negatively or positively influence the prevalence. Therefore, to study the effect of a hospital policy, patients who have pressure ulcers at admission should be excluded (chapter 5). For this reason we preferred to use the term ‘pressure ulcer frequency’ in stead of prevalence. In case a patient had a pressure ulcer, we checked the nursing record to see whether the pressure ulcer was present at admission. If the pressure ulcer was not reported on the admission day, we counted the pressure ulcer as hospital acquired. We feel that this method rather leads to an overestimation than to an underestimation of the hospital acquired pressure ulcer occurrence.

The Dutch Health Care Inspectorate recently implemented the pressure ulcer prevalence as an important indicator for the quality of care in hospitals and is one of 27 quality indicators that evaluate the performance of hospitals. We recommend to reconsider pressure ulcer prevalence as a quality indicator for hospital performance and to replace it by hospital acquired pressure ulcer frequency.

Incidence is the proportion of persons developing new pressure ulcers during a period of time, within a particular, originally pressure ulcer free, population.

In our study in critically ill patients (chapter 6), risk was defined as the probability of pressure ulcers developing in a patient in a specific time interval. The pressure ulcer incidence proportion is a measure or estimate of average risk. This measure has some strong advantages over the prevalence of pressure ulcer patients. Interpretation of
causality or random fluctuations is possible when these fluctuations are adequately measured and included in a statistical model with sufficient power\(^{10}\). A disadvantage is that an incidence study could be more time consuming and therefore more costly. As most of the data needed for a pressure ulcer incidence study are to be reported on in daily reports, this disadvantage is only relative. Moreover, in our study, adequate reporting by health care providers on daily skin screening was among the aims of improving pressure ulcer care. Also, the ICU-nurses in the study hospital were motivated to collect data for an incidence study, because they recognised the extent of the pressure ulcer problem in critically ill patients. The time spent per day per patient to complete a screening form by the nurse, caring for the patient, was not more than 1 minute. Therefore the time factor was not an argument in our incidence study.

To study the effects of the implementation of guidelines on pressure ulcer occurrence, incidence measurements are more suitable in wards with a substantial pressure ulcer problem, e.g. IC-wards.

**Development of evidence based guidelines**

*Synthesising the knowledge is more than collecting randomised clinical trial results*

It has been argued that the poor effectiveness of- and poor compliance of care givers with guidelines on pressure ulcer care are the result of the weak evidence base of these guidelines\(^{11,12}\). This argument is based on the exclusive focus on evidence from randomised controlled trials (RCTs) as highest level of evidence for all recommendations\(^{13,14}\). The weak evidence base refers to the lack of RCTs and systematic reviews to support recommendations in the guidelines. Indeed, the RCT is the most powerful design to investigate the relationship between the presence or absence of an intervention (cause) and the presence or absence of one or more measurable effects\(^{15}\).

However, pressure ulcer guidelines are a mixture of recommendations on etiognostic -, diagnostic – and prognostic knowledge and interventions. The highest level of evidence on diagnostics and screening is based on well-performed, large prospective cohort studies\(^{16}\). Etiological questions generally cannot be randomly tested in randomised experiments either\(^{17}\). For example questions such as “does pressure cause ulcers?” and “which duration of pressure is needed to cause pressure ulcers?” cannot be studied in RCT’s in humans, because it is unethical to exert increasing pressure on body parts intentionally or to withhold proper care in the experimental or control group
respectively. These studies needs an observational design, or examination of the biological mechanism in the laboratory.

Also, in general guidelines\textsuperscript{13,14,16,18} it is suggested that every recommendation is a potential subject for rigorous research. For instance the recommendation “All interventions and outcomes should be monitored and documented” is marked with a low level of evidence. However, this recommendation is indisputable because it has a legal base, is based on professional standards, and moreover, the general idea that compliance with this recommendation is beneficial to the quality of care.

Considering these arguments on synthesising and valueing knowledge, we recommend re-evaluation of the criteria for the evidence base of specific items in the guidelines.

\textit{Synthesising the knowledge will be never ending}

Synthesising knowledge in complex guidelines is a very scrupulous process that not only answers questions but should raise questions and make gaps in evidence transparent as well\textsuperscript{11}. The current Dutch guideline on pressure ulcer care have a strong medical orientation and misses the patient perspective. The small attention in guidelines for topics as pain, exudate and malodour in patients with pressure ulcers is remarkable, especially since we found only a few studies on these topics in our systematic review on wound related problems in pressure ulcer patients. Guidelines should mention these shortcomings in evidence and clearly define the challenges for future research.

Generating evidence for all aspects of a pressure ulcer guideline is a never ending process. We contributed to this evidence by our study the effect of 30° lateral position on hemodynamic parameters (chapter 4). From this study we know that early post-operative turning of CABG patients in lateral position is an easy and feasible procedure that does not influence the cardiac index. If there are no strict contra-indications, lateral position has to be considered to prevent pressure ulcers within 2 hours after CABG to patients who have been admitted to the intensive care unit. However, early ambulation of the patient due to an increased number of off pump cardiac surgery procedures\textsuperscript{19,20}, balanced anaesthesia\textsuperscript{21,22}, and new insights on mobilising critically ill in fast track recovery plans\textsuperscript{23,24} results in a decrease of (post)operative pressure ulcer risk. Although the recommendation on turning within 2 hours is still valid in patients who are not able to turn themselves and/or are sedated in the post operative period, the necessity for repositioning of CABG-patients in general is decreasing, because the above influences make patients recover faster from their impaired reaction on pressure. Nevertheless, one
should realise that this study performed in hemodynamically compromised patients shows that repositioning had no effect on cardiac output, suggesting that in other critically ill patient groups fear of hemodynamic instability as a reason not to turn the patient should be reconsidered.

New therapies induce the need for new research to answer new questions. Example of this are pressure reduction between face and mask in patients with non invasive face mask ventilation, and new pressure reducing materials and techniques in mechanically ventilated patients with acute respiratory failure in prolonged prone position.

**GUIDELINE IMPLEMENTATION**

The guidelines for pressure ulcer care in our study can be considered a way to translate research results and clinical experience into recommendations about care procedures in clinical practice. The guidelines work as an intermediary in the implementation process. The implementation of the guideline was a carefully planned and systematic introduction to give the recommendations on pressure ulcer care a structural place in clinical practice. Considering the key-problem of failing pressure ulcer care, i.e. a lack of knowledge and accompanying skills, we chose an implementation strategy with a focus on education. This approach appeals to an intrinsic motivation to achieve optimal competence and performance. ‘Problem-based learning’ (learning happens if learners actively use the new knowledge and link it to pre-existing knowledge) - and ‘bottom-up’ methods (aimed at encouraging autonomy, initiative and experimentation) fit well in this approach. Moreover, the ‘bottom-up’ approach fits in the decentralised organisation structure. Yet, the results on change in care behaviour of nurses were poor. Some considerations on issues concerning this point have to be addressed.

**Social interaction**

In our implementation strategy, adequate care behaviour by nurses was supported by appointing a pressure ulcer consultant who established a network of ‘contact nurses’. Besides the distribution of printed materials, active methods of communication were used. The contact nurses were trained by the nurse consultant and they were instructed to introduce the new guideline on the ward by clinical lessons and meetings. However, in communication with contact nurses strong differences were reported in personal motivation and in active management by head nurses to facilitate the implementation. This illustrates that it is difficult to control the exact measures that were taken at the
bedside. This observation is supported by a previous study on the quality of pressure ulcer care in Dutch hospitals which showed a failure in active managing and controlling the effectiveness of pressure ulcer policy by head nurses and executive managers. By this failure, the actual exposure to the intervention of all nurses could be negatively influenced. This finding is emphasised by the significant improvement of care behaviour by nurses in our study on effects of guideline implementation in the ICU department. Contrary to the study on the implementation of a new hospital policy, staff nurses in the ICU were approached directly to discuss flaws in pressure ulcers care by the researcher in this study. Moreover, these staff nurses themselves advocated guideline adherence.

Using a social interaction approach is probably just as important as focusing on education. Important strategies to improve practice along a social interaction approach include using opinion leaders, organising ‘outreach visits’ (visits by respected colleagues or experts), peer assessment and the influence patients have on professionals.

**Feedback**

In our study on the effects of the implementation of a new policy on pressure ulcer frequency (chapter 5), six prevalence measurements were carried out in a period of thirty months. Giving feedback on the results of this measurement should stimulate guideline adherence. Indeed, discussing hospital performance in the hospital pressure ulcer committee should result in necessary measures to improve pressure ulcer care. Although, we reported the ward specific prevalence to the contact nurses and the head nurses of the wards, we gave no feedback on these results because we felt that giving feedback on the results on a ward level could have an unwanted effect. After all, while the statistical power to measure changes in prevalence rates on hospital level is generally sufficient, the statistical power on a ward with 20 to 30 observations is far from sufficient. This number of observations is also insufficient for adjusting for patient characteristics or case mix. It might be disappointing if efforts on a ward are not rewarded by a decrease in the pressure ulcer prevalence because of random fluctuations. Moreover, a decrease in pressure ulcer prevalence could be interpreted as a positive outcome on marginal efforts, whereas a negative effect could have a disastrous effect on the motivation to comply with the guideline. Therefore, we explained to the contact nurse en head nurse that they should interpret the ward results with caution.
For this reason we conclude that giving feedback on the results of occasional prevalence measurements is not suitable to encourage ward performance.

Financial incentives
Apart from recommendations to provide adequate preventive measures or adequate treatment of pressure ulcers, clinical guidelines are also developed to exclude unnecessary, inappropriate or even damaging care\textsuperscript{11,31}. Moreover, they are assumed to stimulate cost-effective care, which in practice is often used as a synonym for cost reduction\textsuperscript{11,31}. However, the assumption that working according to the guideline will lead to a reduction in costs is not necessarily right. This can best be illustrated by the recommendation to regularly change the position of the immobilised patient. Although our guideline recommends turning immobile patients every 3 hours, and this was shown to be an effective intervention\textsuperscript{32}, many immobile patients do not receive this care. Reasons given for non-adherence include lack of time and staffing\textsuperscript{33}. Therefore, implementing this recommendation may require extra staffing and increase costs.

Preventing a pressure ulcer is less expensive than treating a pressure ulcer\textsuperscript{34}. From the perspective of a ward manager, this rule is only valid in case a patient uses the services of a single ward. However, this will not be the case. The patient “travels” along hospital departments, nursing home facilities, rehabilitation centres, home care facilities etc. The ward where preventive measures are (not) taken is most likely not the same ward where the treatment of the pressure ulcer takes place. Cost for providing special pressure reducing devices varies between €15 to €75 per day. These cost are additional to the daily rate for nursing care, paid by the health care assurance, and are chargeable to the budget of the department where the patient stays. However, the cost for the treatment of a pressure ulcer is part of the daily rate for nursing care. The additional costs for special devices are high in ICU’s where almost all patients are at high risk for pressure ulcer development at admission. Regarding the relatively short admission time most pressure ulcers have to be treated on a nursing ward after discharge from the ICU. Managers would be more motivated to invest in pressure ulcer prevention if the expenditures directly benefit the wards where these measures are taken. Yet, in the current climate of large cuts in the health care system and the system with decentralised budgets it may not be in the interest of budget holders and managers to stimulate adherence to a guideline which increases costs. It would be of interest to perform a study on the effects of
Guideline implementation in which financial incentives are part of the implementation strategy.

Recommendation

Strategic plan needed
Pressure ulcers are considered to be a complication rather than a disease. Therefore, in contrast to diseases, there is hardly any research on the diagnosis and treatment of pressure ulcers. Moreover, historically pressure ulcers received little attention in medical research. The underestimation of the problem by policy makers and insurers resulted in only few resources for research and therefore a lack of evidence too. Areas where evidence is currently lacking may receive less attention and attract fewer resources for research in future. It is important to break through this vicious circle.

It is recommended to pressure ulcer advisory panels and wound societies to develop balanced research programs on clinical topics, to collaborate with institutions for biomedical and healthcare sciences and to raise funds from supra national organizations like the EC. Funds and network could be used to stimulate development of methodological frameworks, defining outcome parameters and the development of accompanying measurement instruments, to ensure high quality scientific research. We wish to conclude that general guidelines on pressure ulcer care are based on the best actual evidence there is. Guideline development is a scrupulous process and therefore it is costly. Moreover, the knowledge in a guideline will be temporal and has to be revised regularly. There is need for a global research network to study the gaps in these guidelines and to find solutions for questions in the area of etiology as well as questions in the area of diagnostics, treatment and prognostic factors.

Central implementation of existing guidelines in a hospital setting needs strong active management and controlling by head nurses and executive managers. Improving the quality of pressure ulcer care is a balanced process. Educational approaches to resolve a lack of knowledge are only part of the implementation process. Implementing, using an educational approach combined with a social interaction approach and financial incentives might be more successful in the prevention of pressure ulcers in a hospital setting.
REFERENCES


Summary
A pressure ulcer is an area of localised damage to the skin and underlying tissue caused by pressure, shear or friction (henceforth “pressure”) or a combination of these forces. The critical determinants of pressure ulcer development are intensity and duration of pressure. If no pressure is applied to the skin and underlying tissues during a certain length of time, patients do not develop pressure ulcers. Most pressure ulcers are preventable, therefore, if effective preventive measures are taken in time. These measures are based on three principles: (i) reducing the amount of pressure, (ii) influencing the time mechanical forces are present and (iii) applying additional measures to increase tissue tolerance for pressure.

Pressure ulcers are among the most common adverse events in nursing practice and occur in bed- or chair-bound patients who are unable to perceive pressure or to react to pressure. Patients admitted to intensive care units (ICUs) are at a particularly high risk of developing pressure ulcers. These critically ill patients are generally unable to notice increased tissue pressure and to react accordingly because they receive sleep medication, pain control medication and/or muscle relaxants. Moreover, their underlying disease and hemodynamic instability increase the risk of developing pressure ulcers.

The aim of this thesis is threefold. The first aim was to gain a better understanding of the nature and extent of the pressure ulcer problem in critically ill patients. The second aim was to investigate whether early postoperative lateral position after coronary artery bypass surgery negatively affected cardiac output. The third aim was to gain an understanding of the effects of a hospital-wide program on pressure ulcer care on the occurrence of pressure ulcers both in a general hospital population and in critically ill patients.

About one in five critically ill patients develop a grade II or worse pressure ulcer during their stay in the ICU. A systematic review (chapter 2) shows that many factors are associated with pressure ulcers, but that there is not a single specific risk factor for pressure ulcer development that is generally valid in either a general or a specific critically ill population. Making an adequate comparison of studies was impossible due to differences in research methodologies and end points. Nor is there any evidence of a risk assessment tool that validly and reliably predicts pressure ulcer risk. Important preventive measures, such as repositioning patients, are insufficiently applied.
A secondary analysis using the databases from the Dutch national prevalence surveys showed a grade I to IV pressure ulcer prevalence of 29% in critically ill patients (chapter 3). Without grade I pressure ulcers, the prevalence was 18%. Risk factors associated with pressure ulcers were infection, age, length of stay and total Braden score. Prevention of pressure ulcers was minimal: only 37% of the patients who were assessed as requiring repositioning were actually being turned.

Critical care nurses are cautious about repositioning critically ill patients because they assume that turning will have a negative influence on cardiac output. No studies were available concerning the effect of 30° lateral position on circulation within 2 hours after admission of the patient to the ICU. To investigate this assumption, we randomly assigned 55 Coronary Artery Bypass Graft (CABG) patients to 4 intervention regimens in a clinical trial (chapter 4). The patients underwent a 2-hour period of 30° lateral position. Fourteen patients in supine position served as a reference group. Turning the patients did not have any significant effect on the cardiac index. The cardiac index in 30° lateral position and supine position 2 to 8 hours postoperatively after CABG is statistically bioequivalent in patients with and without receiving antihypertensive or inotropic/vasopressor therapy. There were no practical problems impeding the turning regimen, not even in patients with an intra-aortic balloon pump. We conclude that fear of hemodynamic instability due to lateral position after coronary artery surgery is unfounded. If there are no strict contraindications, lateral position has to be considered within 2 hours after CABG patients have been admitted to the intensive care unit to prevent complications of continuous supine position.

We developed a Guideline for Pressure Ulcer Care based on national and international guidelines for pressure ulcer care and updated with recent scientific research (chapter 5). Before the implementation of this guideline, all standard hospital mattresses were replaced by high-quality pressure-reducing visco-elastic hospital mattresses. In a prospective study, we used a series of one-day measurements to assess the effect of this new policy on the efficiency of pressure ulcer care and pressure ulcer frequency. We compared care behaviour of nurses and pressure ulcer frequency in patients before and 4 and 11 months after the introduction of this new policy. Inadequate prevention decreased from 19% to 4% after 4 months and to 6% after 11 months. Inadequate treatment decreased from 60% to 31% after both 4 and 11 months. However, excluding the use of
mattresses as a positive indicator for care behaviour, we found no significant increase in adequate care to prevent pressure ulcers. We found a significant decrease in pressure ulcer frequency from 18% to 13% after 4 months and 11% after 11 months. The number of pressure ulcer patients in hospital can be reduced successfully by taking general measures such as introducing adequate mattresses. Despite the time and energy spent on educating and training nurses, we found no change in care behaviour. An implementation strategy focusing more on leadership and social interaction may produce better results.

More specifically, we studied the short-term and long-term effects of guideline implementation on pressure ulcer incidence and pressure ulcer free time in critically ill patients (chapter 6). The grade II-IV pressure ulcer incidence density decreased from 54 per 1000 person days at baseline to 32 per 1000 person days 12 months after the implementation. The median pressure ulcer free time increased from 12 days to 19 days. Apart from the introduction of new mattresses, implementation of the guideline resulted in a significant and sustained decrease in development of grade II and worse pressure ulcers in critically ill patients. Earlier transfer of critically ill patients to a specific mattress, i.e. transfer before a pressure ulcer occurred, was the strongest indicator of decrease in pressure ulcer development. In the ICU, implementation of the guideline did result in a change in care behaviour of nurses and in a significantly favourable effect on pressure ulcer incidence. This effect was sustained for at least 1 year. Our results indicate that during a median length of stay in the ICU of 9 days, for every 6 patients treated after the implementation of the guideline, the occurrence of 1 additional pressure ulcer patient was prevented.

If patients still suffer from pressure ulcers in spite of preventive measures, they usually show symptoms of chronic wounds and impaired wound healing. Assessment and treatment of these symptoms have received very little attention. In a systematic literature review (chapter 7), we established that the McGill Pain Questionnaire, the Visual Analogue Scale and the Faces Rating Scale are useful instruments for assessing pressure-ulcer-related pain. Strong evidence was found to support a positive effect of (dia-) morphine gel. Some evidence was found to support a positive effect of benzydamine gel and Eutectic Mixture of Local Anaesthetic (EMLA) cream. Wound malodour is subjectively assessed. A laboratory study demonstrated that activated charcoal is capable
of absorbing gas molecules that cause malodour. At present, no studies are available on the odour-absorbing capacity of activated charcoal dressings in pressure ulcer patients. Exudate is a symptom of impaired wound healing. The Pressure Sore Status Tool is a valid and reliable instrument for assessing the wound healing process. There is a possible indication that hydrocolloid positively influences healing time because the absorption of exudates is more effective.

Our study showed that adherence to a best practice guideline can result in a decrease in pressure ulcer occurrence. Yet, complete or even moderate adherence was difficult to achieve. In chapter 8, we discuss some factors that obstruct guideline adherence. Guidelines on pressure ulcer care are based on the best up-to-date evidence available. Guideline development is a scrupulous process, and, therefore, it is costly. Moreover, the knowledge embodied in a guideline will be temporal and must be revised regularly. Considering the limited funds available for pressure ulcer research globally, we recommend establishing a global research network to study the gaps in these guidelines and to find solutions for questions in the domain of aetiology as well as questions in the domain of diagnostics, treatment and prognostic factors. Teachers, clinicians and policymakers representing major organisations such as the AWMA, EPUAP, NPUAP and WHASA¹ should participate in this network in addition to scientists.

Central implementation of existing guidelines in a hospital setting requires strong hands-on management and monitoring by head nurses and executive managers. Improving the quality of pressure ulcer care is a balanced process. Educational approaches to dealing with knowledge gaps are only part of the implementation process. Implementing and using an educational approach in combination with a social interaction approach and financial incentives might be more successful in pressure ulcer prevention in a hospital setting.

¹ AWMA: Australian Wound Management Association; EPUAP: European Pressure Ulcer Advisory Panel; NPUAP: National Pressure Ulcer Advisory Panel (VS); WHASA: Wound Healing Association of South Africa.
Samenvatting
Decubitus is plaatselijke schade aan de huid en de daaronder liggende weefsels, veroorzaakt door druk-, schuif- en wrijfkrachten (verder “druk”) of een combinatie van deze krachten. De belangrijkste determinanten voor het ontstaan van decubitus zijn de intensiteit en tijdsduur van de druk. Als er geen druk gedurende een bepaalde tijd wordt uitgeoefend op de huid en het onderliggend weefsel zal er ook geen decubitus ontstaan. De meeste decubituswonden kunnen voorkomen worden als effectieve preventiemaatregelen worden genomen. Deze zijn gebaseerd op drie principes: (i) het verlagen van de druk, (ii) het beïnvloeden van de tijdsduur dat er druk aanwezig is op een bepaalde plaats en (iii) aanvullende maatregelen die de weefseltolerantie voor druk verhogen.

Decubitus is één van de meest voorkomende complicaties in de verpleegkundige praktijk. Het komt voor bij patiënten die bedlegerig zijn of in een (rol)stoel zitten en die niet in staat zijn om druk te voelen en/of niet op drukverschijnselen kunnen reageren door van positie te veranderen.

Intensive care patiënten zijn in het bijzonder kwetsbaar voor decubitus. Over het algemeen zijn zij niet in staat de verhoogde druk in de weefsels te voelen en/of er op te reageren, omdat zij medicijnen krijgen die hen slapend houden, de pijn verminderen en/of de spieren verslappen. Bovendien verhoogt de onderliggende ziekte, die vaak gepaard gaat met dalingen in de bloeddruk, de kans op decubitus.

Het doel van dit proefschrift is drieledig. Het eerste doel is meer inzicht krijgen in de mate en aard van het decubitusprobleem bij intensive care patiënten. Vervolgens is onderzocht of vroeg post operatieve zijlijging na coronair bypass chirurgie de cardiac output negatief beïnvloedt. Het derde doel is het verkrijgen van inzicht in de effecten van de invoering van een ziekenhuisbreed decubitusbeleid op prevalentie en incidentie van decubitus in respectievelijk de totale ziekenhuispopulatie en in de populatie van IC-patiënten.

Ongeveer één op de vijf IC-patiënten ontwikkelt een graad II decubituswond of erger tijdens het verblijf op de ICU. Een systematisch literatuur onderzoek (hoofdstuk 2) laat zien dat vele factoren geassocieerd zijn met decubitus, maar dat geen enkele factor een voorspellend vermogen heeft in alle groepen IC-patiënten. Een goede vergelijking tussen studies is niet mogelijk door de diversiteit in onderzoeksmethoden en eindpunten. Ook zijn er geen valide en betrouwbare meetinstrumenten die het risico op decubitus bij IC-
patiënten voorspellen. Belangrijke preventieve maatregelen, zoals wisselligging worden onvoldoende toegepast.

Uit een secondaire analyse van de gegevens van het Landelijk Prevalentie Onderzoek Decubitus blijkt dat de prevalentie van decubitus graad I-IV 29% is (hoofdstuk 3). Zonder graad I decubitus is de prevalentie 18%. Infectie, leeftijd, opnameduur en de totale Bradenscore waren geassocieerd met decubitus. De preventie van decubitus liet te wensen over; slechts bij 37% van de patiënten die wisselligging nodig hadden werd deze behandeling daadwerkelijk uitgevoerd.

Onder IC-verpleegkundigen bestaat terughoudendheid om patiënten wisselligging te geven, omdat aangenomen wordt dat het draaien van patiënten een negatieve invloed heeft op de circulatie (hoofdstuk 4). Onderzoek naar het effect van 30°-zijligging op de cardiac output binnen 2 uur na de opname op de ICU is niet eerder gedaan. Om dit effect te toetsen werden 55 patiënten willekeurig ingedeeld in 4 groepen met verschillende wisselliggingsschema’s. Elke patiënt werd in 30°-zijligging gelegd gedurende een periode van 2 uur. Veertien patiënten in rugligging vormden de referentiegroep. De cardiac index in 30° zijligging en rugligging tussen 2 en 8 uur na coronair chirurgie bleken statistisch bio-equivalent zelfs bij patiënten die werden behandeld met bloeddrukverhogende en/of vaatverwijdende medicatie. Ook vonden we geen praktische problemen bij het op de zij leggen van patiënten, zelfs niet bij patiënten met een intra-aortale ballon pomp. We concludeerden dat angst voor hemodynamische instabiliteit ten gevolge van zijligging na coronair bypass chirurgie ongegrond was. Als er geen strikte contra-indicaties zijn, dient zijligging binnen 2 uur na coronair chirurgie overwogen te worden om complicaties van uitsluitend rugligging te voorkomen.

Op basis van (inter)nationale richtlijnen en actueel wetenschappelijk onderzoek hebben we een ‘richtlijn decubituszorg’ samengesteld (hoofdstuk 5). Voordat de richtlijn geïmplementeerd werd zijn alle standaard ziekenhuismatressen vervangen door een kwalitatief hoogwaardig drukverlagend visco-elastisch ziekenhuismatras. In een prospectief onderzoek werd door middel van een aantal eendaags metingen het effect van het nieuwe beleid vastgesteld op de efficiëntie van de decubituszorg en de decubitusprevalentie. Het zorggedrag van verpleegkundigen en de decubitusprevalentie vóór en na de introductie van de richtlijn werden vergeleken. Het percentage inadequate
preventie daalde van 19% tot 4% na 4 maanden en bedroeg 6% na 11 maanden. Het percentage inadequate behandeling daalde van 60% tot 31% zowel na 4 als na 11 maanden. Het verschil in afname van inadequate preventie als inadequate behandeling waren beiden statistisch significant. Echter, na exclusie van het gebruik van het juiste matras als positieve indicator voor zorggedrag, werd geen significant verschil meer gevonden in adequate decubituszorg. De decubitusprevalentie daalde significant van 18% naar 13% na 4 maanden en naar 11% na 11 maanden. We concludeerden dat het aantal patiënten met decubitus in ziekenhuizen succesvol gereduceerd kan worden door algemene maatregelen, zoals een drukverlagend matras. Ondanks de tijd en energie die gestopt is in scholing en training van verpleegkundigen, konden we niet vaststellen dat het zorggedrag veranderde. Mogelijk dat een implementatiestrategie die meer gericht is op leiderschap en sociale interactie tot betere resultaten leidt.

Na de introductie van het nieuwe visco-elastische matras, onderzochten we de korte en lange termijn effecten van de richtlijnimplementatie op de efficiëntie van de decubituszorg en incidentie van decubitus bij IC-patiënten (hoofdstuk 6). In dit onderzoek werd de tijdige overplaatsing van de patiënt van een visco-elastisch matras naar een specifieker ondersteuningsvorm beschouwd als maat voor toegenomen kwaliteit van zorg. De incidentie van decubitus graad II-IV daalde significant van 54/1000 persoonsdagen vóór de implementatie van de richtlijn naar 32/1000 persoonsdagen 12 maanden na de implementatie. De mediane decubitusvrije periode steeg van 12 tot 19 dagen. Onafhankelijk van de introductie van nieuwe standaard ziekenhuismatrassen bleek de implementatie van de richtlijn te leiden tot een significante en aanhoudende daling van de incidentie van decubitus graad II en ernstiger bij IC-patiënten. De eerdere overplaatsing van de patiënten op een speciaal luchtmatras, dit is een overplaatsing naar dit matras voordat decubitus is opgetreden, bleek de sterkste voorspeller van de daling in de ontwikkeling van decubitus. Op de IC-afdeling leidde de implementatie dus wel tot gedragsverandering en een aantoonbaar gunstig effect op de incidentie van decubitus. Zelfs na 1 jaar bleef dit effect aanwezig. Uit onze resultaten blijkt dat gedurende een mediane verblijfsduur van 9 dagen op de Intensive Care afdeling, voor elke 6 patiënten, behandeld volgens de richtlijn, 1 decubituspatiënt wordt voorkomen.
Als ondanks preventieve maatregelen patiënten toch decubitus krijgen, worden zij doorgaans geconfronteerd met symptomen van een chronische wond en een verstoorde wondgenezing. De diagnostiek en behandeling van deze symptomen krijgen weinig aandacht. Door middel van een systematisch literatuuronderzoek (hoofdstuk 7) vonden we dat de McGill Pain Questionnaire, de Visual Analogue Scale en de Faces Rating Scale bruikbare instrumenten zijn om decubitus gerelateerde pijn te diagnosticeren. We vonden een sterke onderbouwing voor het positieve effect van (dia)morphine gel voor de behandeling van pijnlijke decubituswonden. Enige onderbouwing voor het pijnstillende effect was er voor benzydamine gel en Eutectic Mixture of Local Anaesthetic-creme (EMLA). Wondgeur wordt subjectief vastgesteld. In een laboratoriumstudie is aangetoond dat geactiveerd koolstof de eigenschap heeft om gasmoleculen die verantwoordelijk zijn voor de wondgeur te absorberen. Tot op heden is er geen onderzoek bij decubituspatiënten verricht naar de geurabsorberende capaciteit van verbanden, waarin geactiveerd koolstof is verwerkt. Vocht dat ten gevolge van een ontsteking uit de decubituswond lekt (exsudaat) is een symptoom van een verstoorde wondgenezing. De Pressure Sore Status Tool is een betrouwbaar en valide instrument om het wondgenezingsproces te kwantificeren. Voorts vonden we een indicatie voor de positieve invloed van hydrocolloid verbanden op de wondgenezing, omdat deze verbanden meer exsudaat absorberen.

Ons onderzoek toont aan dat het opvolgen van de richtlijnen kan leiden tot een daling van het ontstaan van decubitus. Echter, het is moeilijk te bereiken dat alle verpleegkundigen zich aan de voorgeschreven richtlijnen houden. Een aantal factoren die opvolging van de richtlijnen in de weg staan worden benoemd (hoofdstuk 8). Richtlijnen voor decubituszorg zijn gebaseerd op de meest actuele kennis. Het ontwikkelen van richtlijnen is een nauwgezet en kostbaar proces. Bovendien is de kennis die in een richtlijn wordt beschreven van tijdelijke aard en zal regelmatig geactualiseerd moeten worden. Gezien de geringe middelen die er wereldwijd zijn voor het decubitusonderzoek wordt het opzetten van een mondiaal onderzoeksnetwerk, aanbevolen om de hiaten in de richtlijn op te sporen, oplossingen te zoeken voor vragen op het gebied van etiologie, diagnose, behandeling en prognostische factoren en onderzoeksrioriteiten te stellen. In dit netwerk zouden naast wetenschappers ook
docenten, clinici en beleidsmakers zitting dienen te hebben, die grote organisaties zoals AWMA, EPUAP, NPUAP, WHASA\(^1\) vertegenwoordigen.

Voor de centrale implementatie van richtlijnen in een ziekenhuis is actieve betrokkenheid van managers nodig bij dit proces en ook om toezicht te houden op de uitvoering van de richtlijn. Het verbeteren van de kwaliteit van de decubituszorg is een uitgebalanceerd proces. Bij- en nascholing om het kennistekort op te lossen is slechts een gedeelte van dit proces. Een combinatie van deze benadering met sterke aandacht voor de sociale interactie tussen verpleegkundigen en eventuele financiële prikkels kunnen mogelijk bijdragen aan een verbetering van het implementatie succes.

\(^1\) AWMA: Australian Wound Management Association, EPUAP: European Pressure Ulcer Advisory Panel, NPUAP: National Pressure Ulcer Advisory Panel (VS), WHASA: Wound Healing Association of South Africa.
Dankwoord
Het schrijven van een proefschrift is misschien een eenzaam avontuur, maar het doorlopen van een promotietraject is dat zeker niet. Ik heb ontzettend veel meewerkende, meedenkende, steunende en vooral ook aardige mensen op deze weg ontmoet.

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moment stelde je de vraag of het woord “decubitus” voorkwam in het artikel. Toen dit enigszins verbaasd werd bevestigd en jij antwoordde dat het dan wel heel raar zou zijn als er voor dat artikel geen plaats zou zijn in een proefschrift over decubitus besefte ik dat je een gouden aanwinst was in de promotiecommissie. Hartelijk dank voor je inzet.

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Curriculum Vitae

Erik de Laat was born on December 10th, 1956, in Veldhoven, the Netherlands. In 1975, after graduating secondary school at the Scholengemeenschap Nebo-Mariënboch- Gabriëlcollege, he started his inservice education in clinical nursing at the school of nursing of the Canisius Wilhelmina Ziekenhuis in Nijmegen, and obtained his nursing diploma (A-verpleegkundige) in 1979. Subsequently he worked for 4 years as a nurse on the cardiac - and vascular surgery ward in the Radboud University Nijmegen Medical Centre. In 1984 he started his education in critical care nursing and after receiving his certificate he worked at the Intensive Care Unit for Cardiac Surgery for more than 10 years. In this period he completed his advanced teacher training and in 1997 he received a cum laude with his Masters degree in Health Sciences at the University of Maastricht, location Utrecht. From 1993 up till now he performed several policy functions at “Staf Zorg” (support staff health care policy) of the Radboud University Nijmegen Medical Centre. In this position he developed and implemented a nursing science policy. Together with the professor in nursing science and the director of Staf Zorg he has contributed to a strong position of the section of nursing science and an academic structure for nursing science.

His clinical field of interest concerns pressure ulcer patients. He has actively participated in a governmental advice committee and national and international committees on the development of guidelines on pressure ulcer prevention and treatment. Besides the scientific work described in this thesis he published articles in nursing journals on critical care nursing, the implementation of nursing science and pressure ulcer care. Moreover, he presented his work on many national and international congresses and is he associated as a guest teacher to several educational institutions.

This year he acquired a grant for the establishment of a unique multi-professional pressure ulcer treatment centre. There he hopes to develop and apply effective treatment modalities in patients with pressure ulcers. Moreover, he will contribute to the education of professionals on pressure ulcer treatment.

Zijn klinische aandachtsveld betreft patiënten met decubitus. Hij werkte actief mee aan een adviesrapport voor het ministerie van VWS en nam actief deel aan nationale en internationale comités voor de ontwikkeling van richtlijnen voor de preventie en behandeling van decubitus. Behalve de wetenschappelijke artikelen die in dit proefschrift zijn beschreven, publiceerde hij in vaktijdschriften over IC-verpleegkunde, implementatie van wetenschappelijk onderzoek en decubitus. Bovendien presenteerde hij veel van zijn werk op nationale en internationale congressen en geeft hij gastlessen aan verschillende onderwijsinstellingen.

Dit jaar verwierf hij een subsidie voor het opzetten van een uniek multi-professioneel behandelcentrum als onderdeel van een expertisecentrum op het gebied van de behandeling van decubitus. Daar hoopt hij effectieve behandelmethodes te ontwikkelen en toe te passen bij patiënten met decubitus.
Critical Pressure

pressure ulcer care in critically ill patients and hospitalised patients at large

Erik de Laat