Clinical evidence in pressure ulcer prevention in Australia using multi-layer silicone foam dressings: From research to practice change

Klinické důkazy k prevenci dekubitů v Austrálii s použitím vícevrstvého silikonového pěnového krytí: od výzkumu k změně v praxi

Professor Nick Santamaria

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MELBOURNE HEALTH

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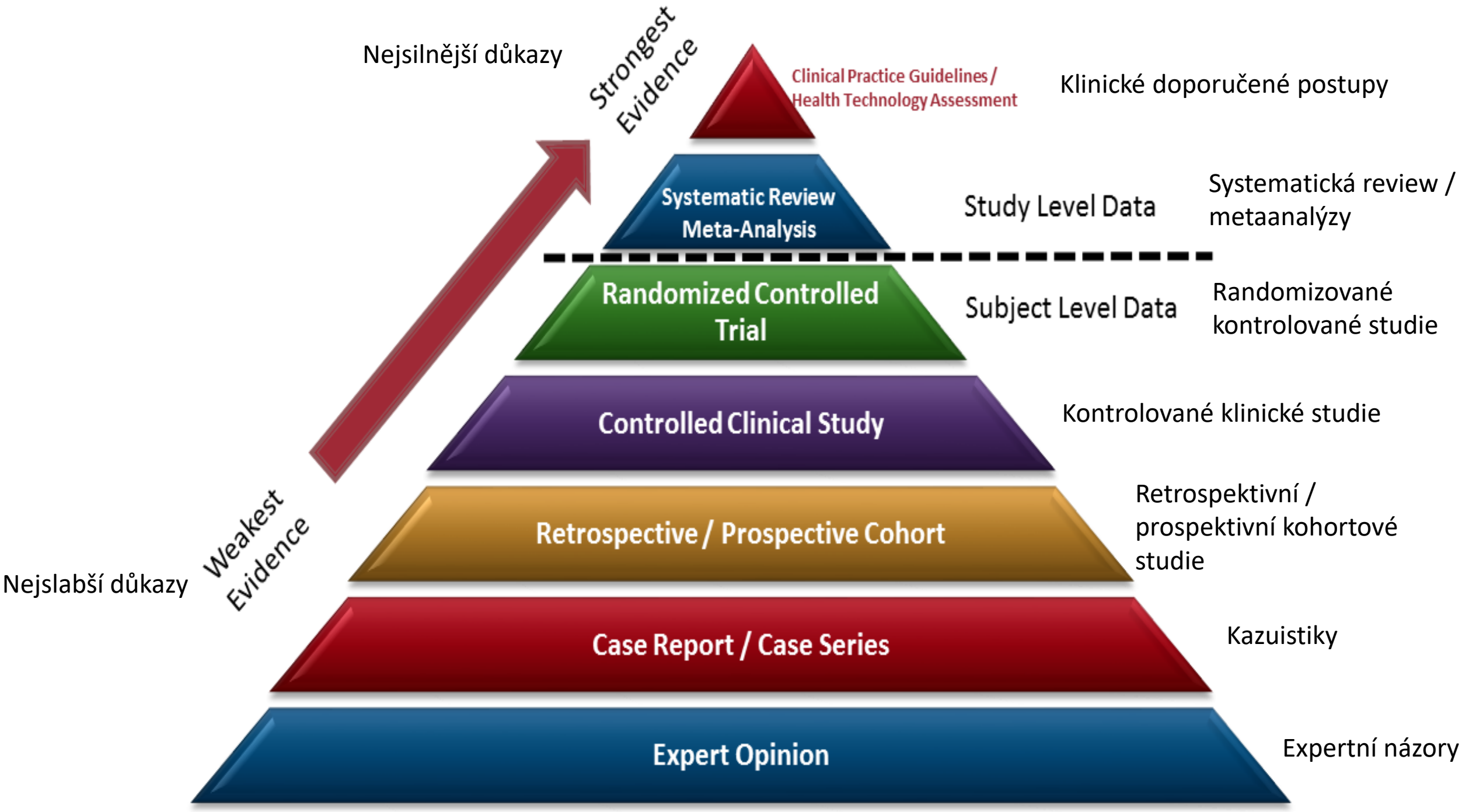
Nejsilnější důkazy
Strongest Evidence
Clinical Practice Guidelines / Health Technology Assessment
Klinické doporučené postupy
Systematic Review Meta-Analysis
Study Level Data
Systematická review / metaanalýzy
Randomized Controlled Trial
Subject Level Data
Randomizované kontrolované studie
Controlled Clinical Study
Kontrolované klinické studie
Retrospective / Prospective Cohort
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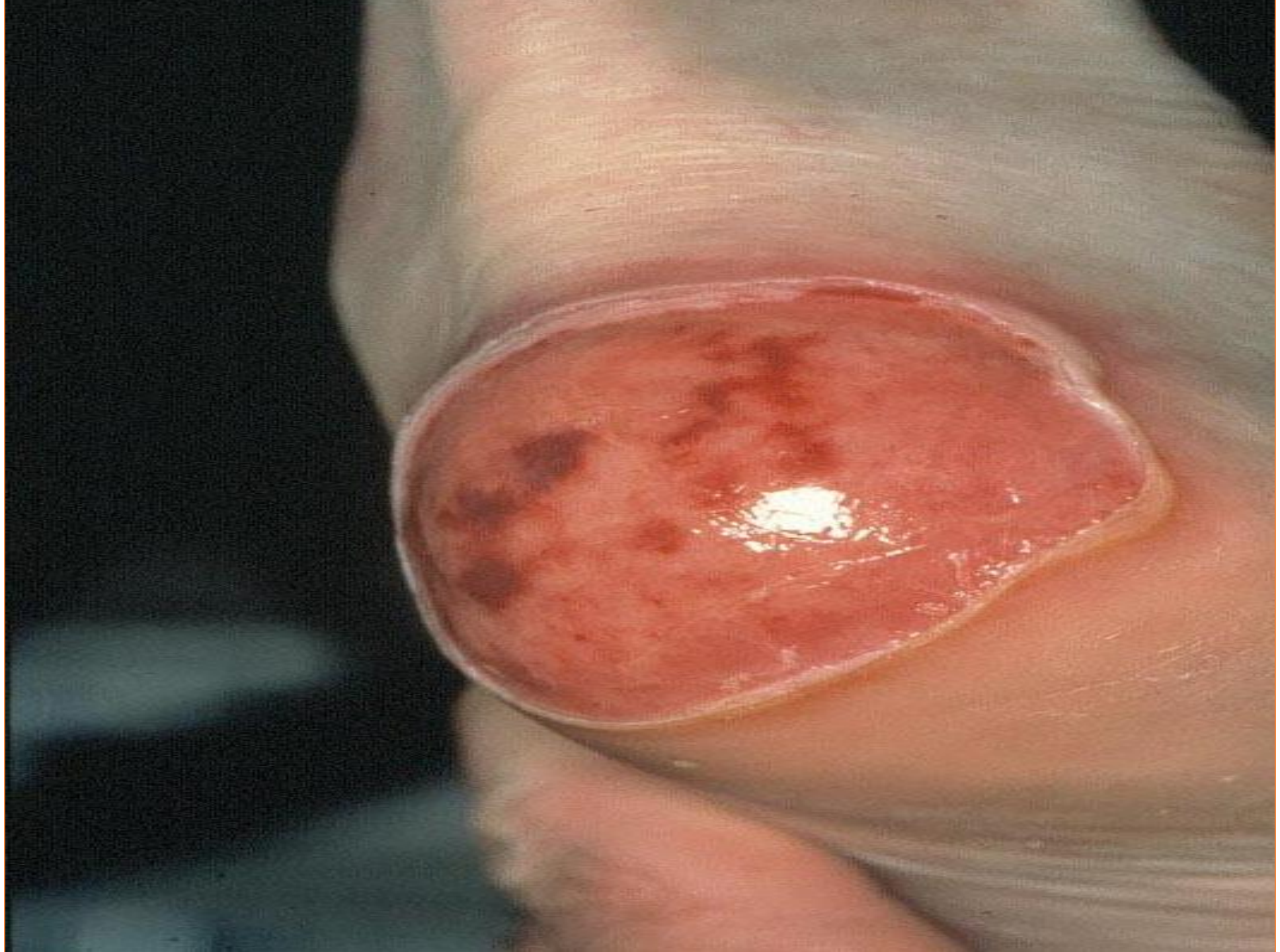
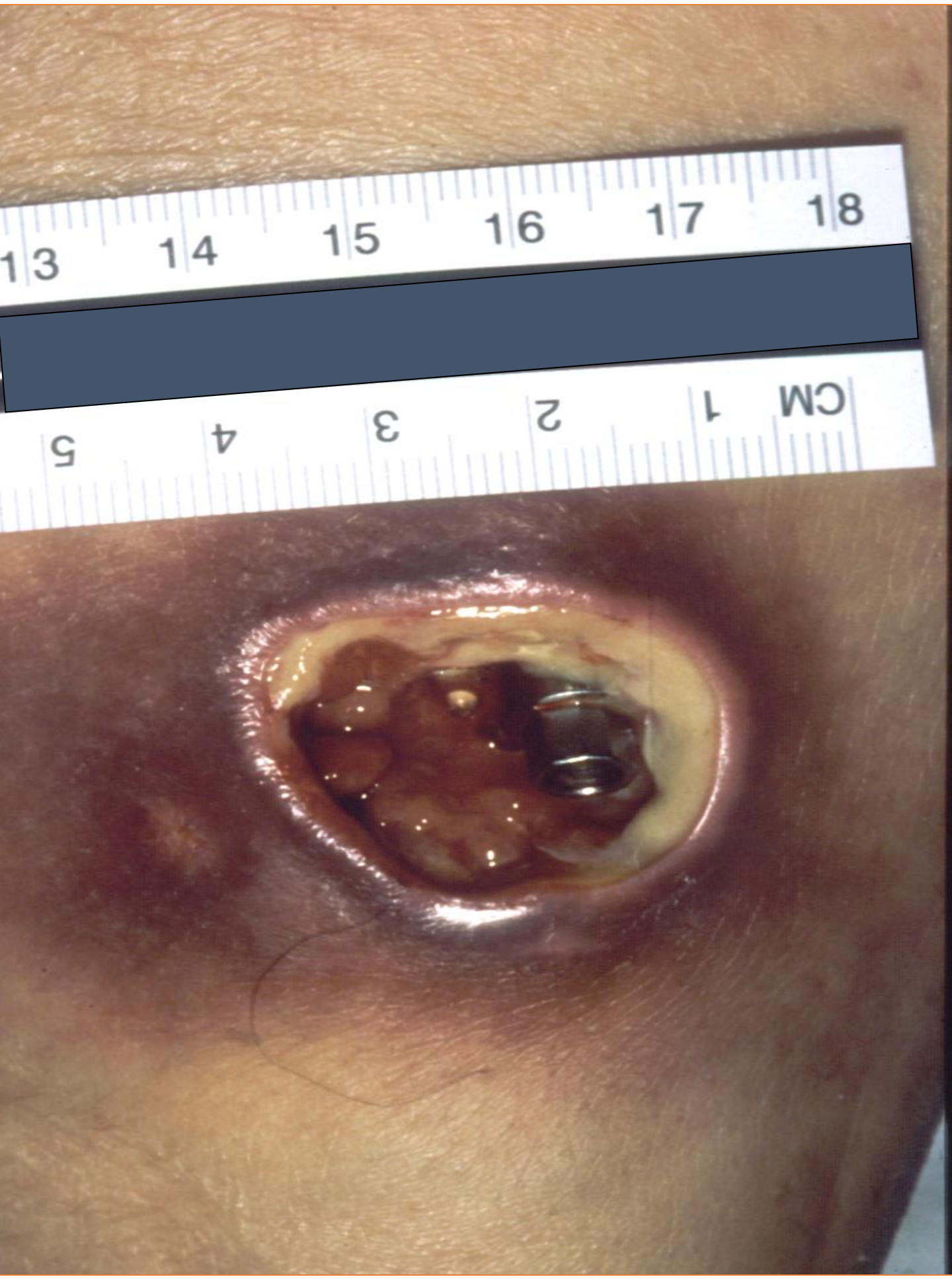
Kazuistiky
Expert Opinion
Expertní názory
Weakest Evidence
Nejslabší důkazy

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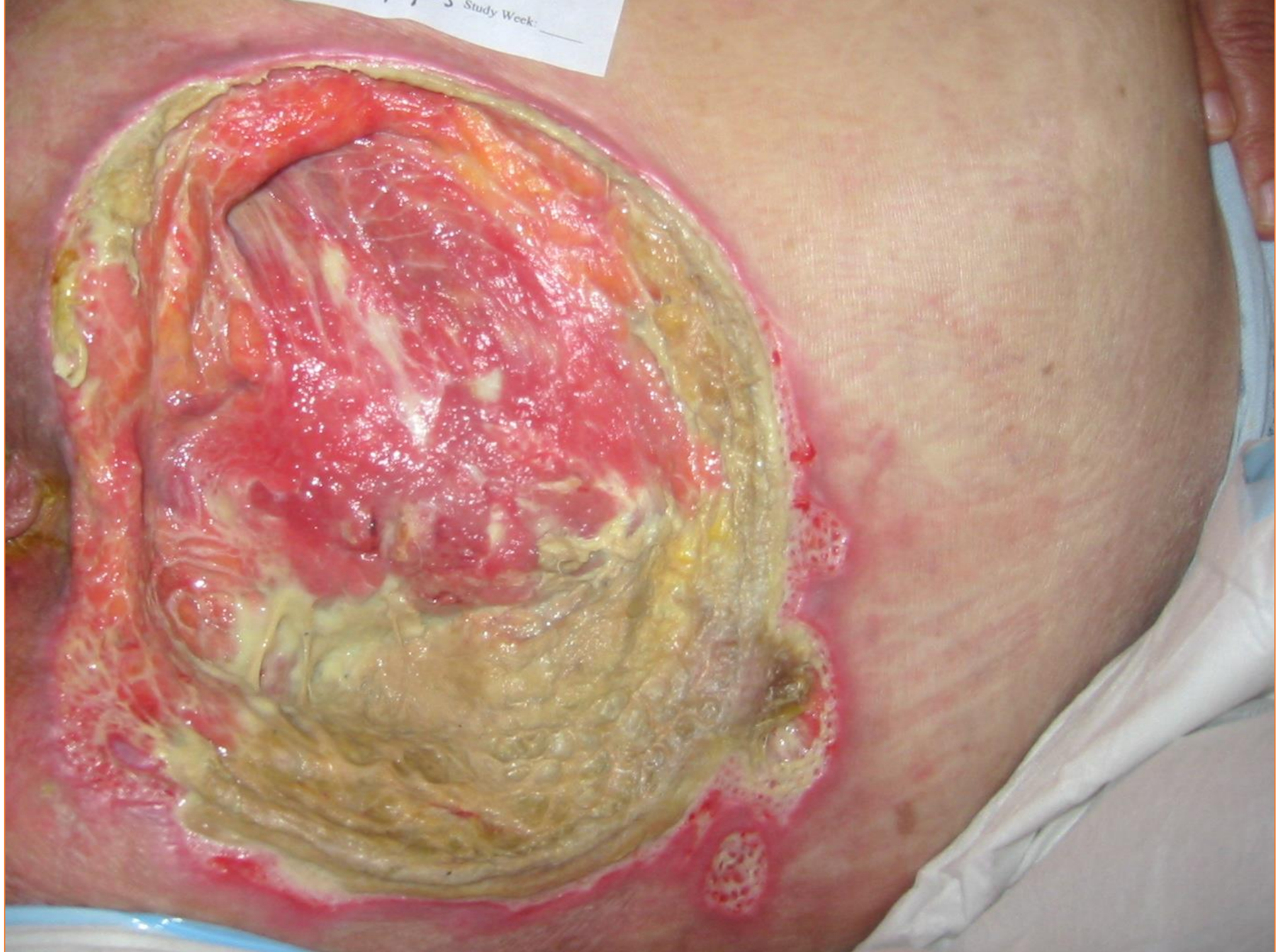
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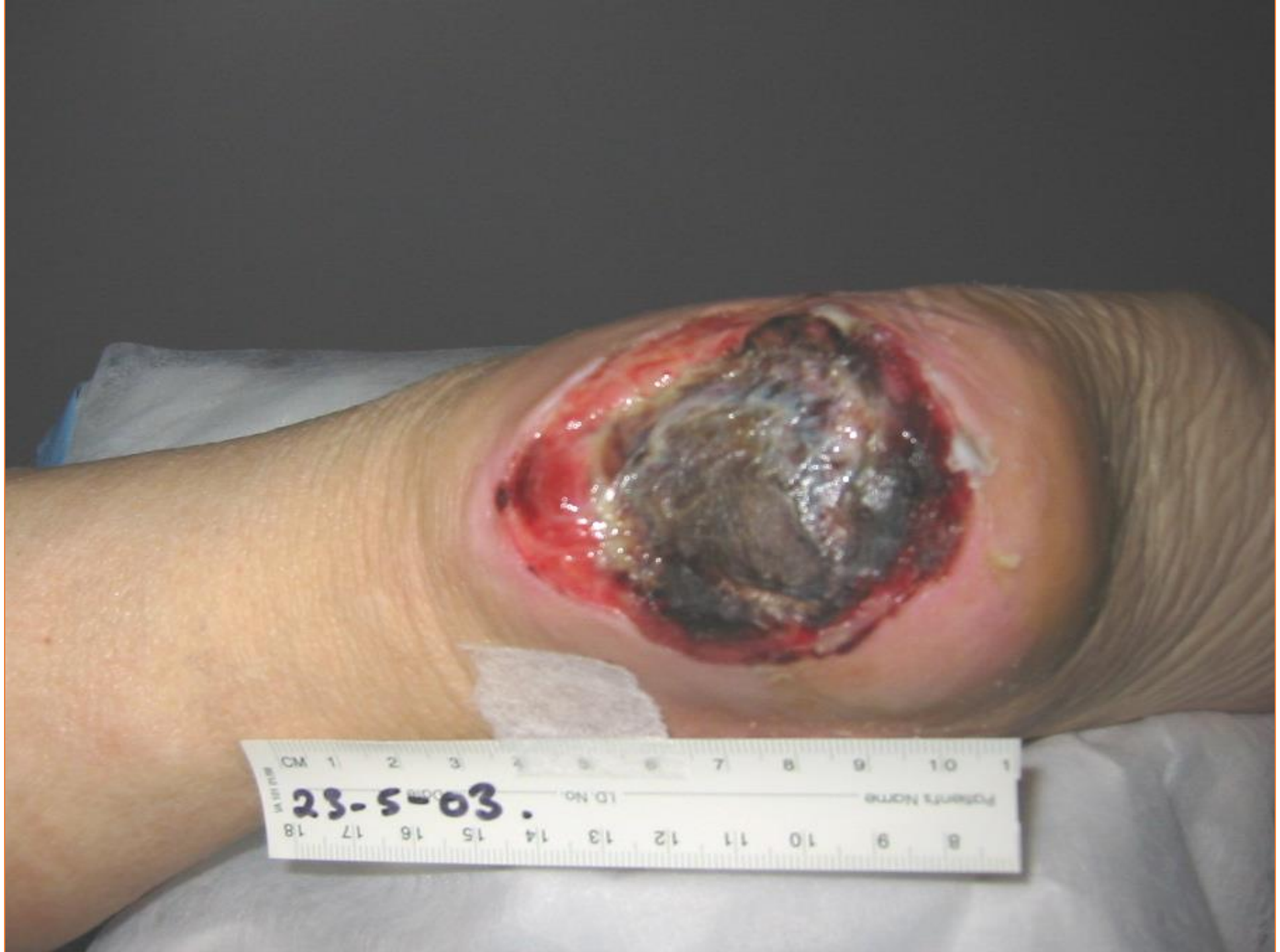
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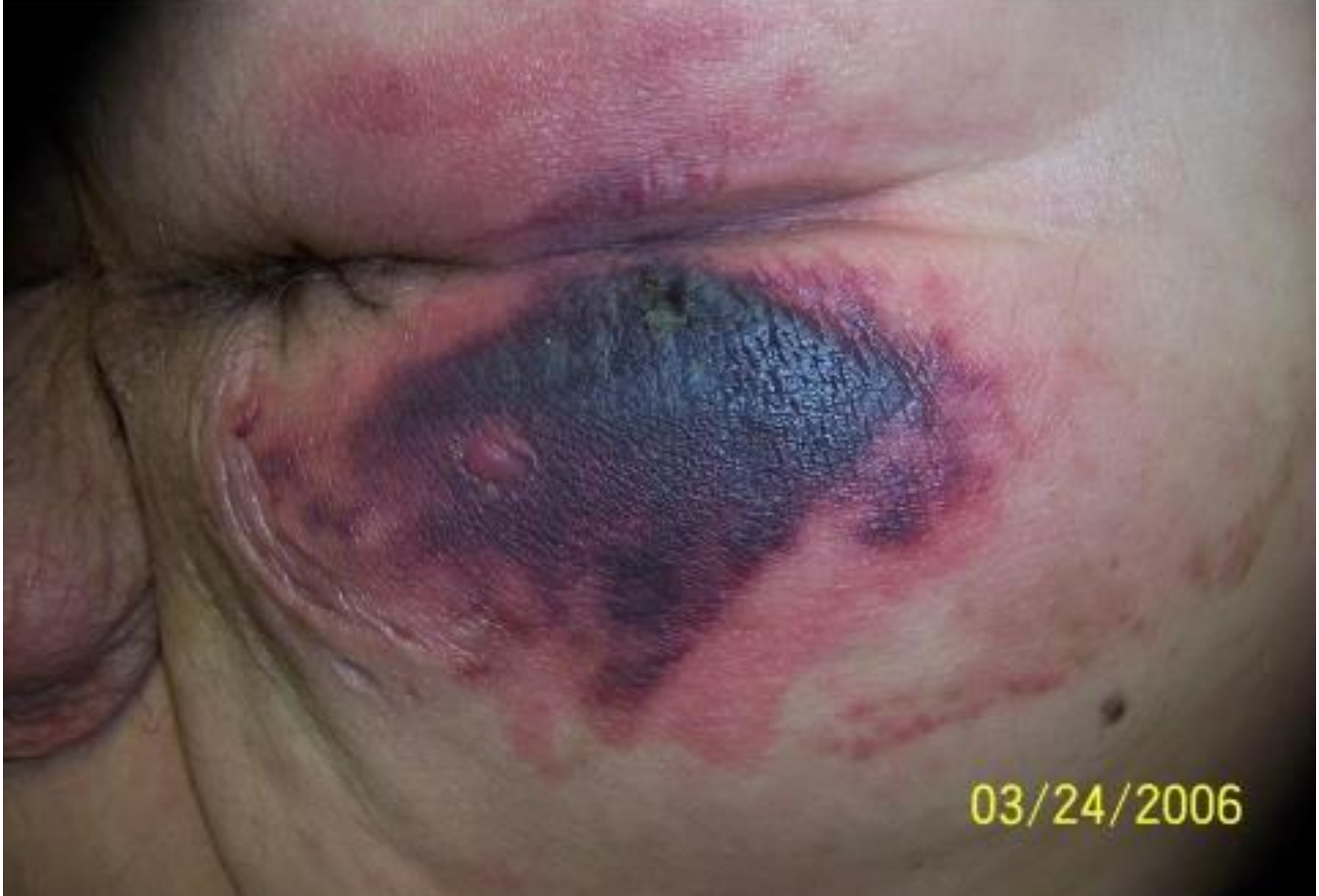
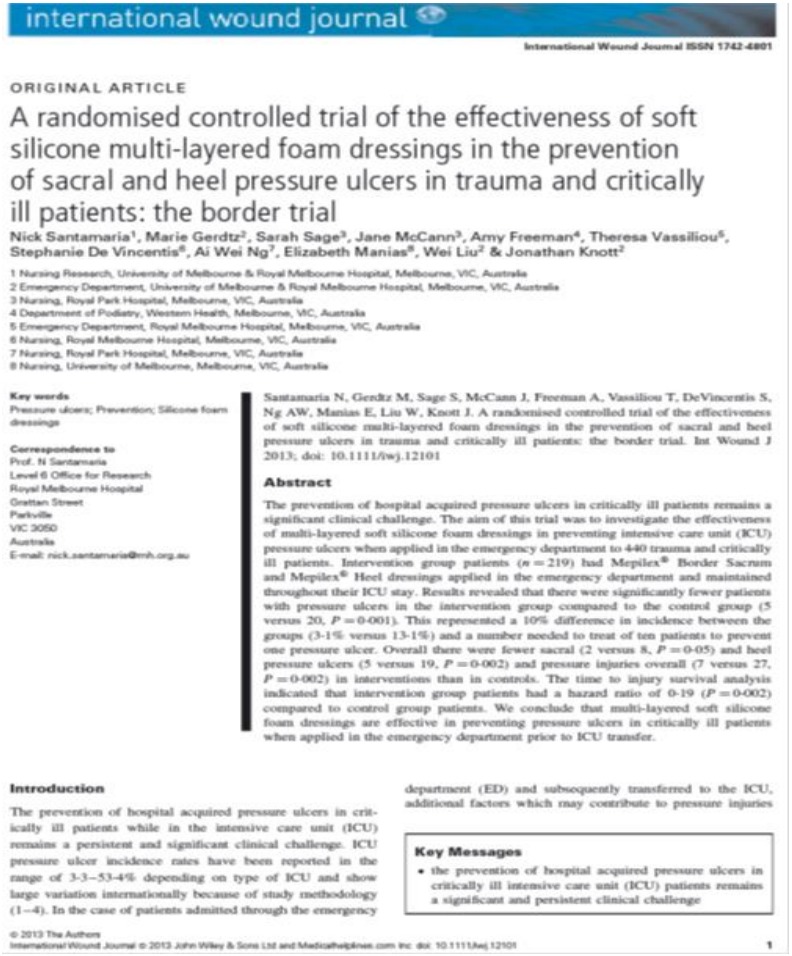

03/24/2006

Royal Melbourne Hospital Intensive Care Unit

(JIP Královské nemocnice v Melbourne)

First international randomised controlled trial into the effectiveness of dressings to prevent ICU PI

(1. mezinárodní randomizovaná kontrolovaná studie k efektivitě použití krytí v prevenci dekubitů na JIP)



international wound journal

International Wound Journal ISSN 1742-4801

ORIGINAL ARTICLE

A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial

Nick Santamaria[1], Marie Gerdtz[2], Sarah Sage[3], Jane McCann[3], Amy Freeman[4], Theresa Vassiliou[5], Stephanie De Vincentis[6], Ai Wei Ng[7], Elizabeth Manias[8], Wei Liu[2] & Jonathan Knott[2]

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Key words
Pressure ulcers; Prevention; Silicone foam dressings

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Santamaria N, Gerdtz M, Sage S, McCann J, Freeman A, Vassiliou T, DeVincentis S, Ng AW, Manias E, Liu W, Knott J. A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial. Int Wound J 2013; doi: 10.1111/iwj.12101

Abstract

The prevention of hospital acquired pressure ulcers in critically ill patients remains a significant clinical challenge. The aim of this trial was to investigate the effectiveness of multi-layered soft silicone foam dressings in preventing intensive care unit (ICU) pressure ulcers when applied in the emergency department to 440 trauma and critically ill patients. Intervention group patients ($n = 219$) had Mepilex® Border Sacrum and Mepilex® Heel dressings applied in the emergency department and maintained throughout their ICU stay. Results revealed that there were significantly fewer patients with pressure ulcers in the intervention group compared to the control group (5 versus 20, $P = 0{\cdot}001$). This represented a 10% difference in incidence between the groups (3·1% versus 13·1%) and a number needed to treat of ten patients to prevent one pressure ulcer. Overall there were fewer sacral (2 versus 8, $P = 0{\cdot}05$) and heel pressure ulcers (5 versus 19, $P = 0{\cdot}002$) and pressure injuries overall (7 versus 27, $P = 0{\cdot}002$) in interventions than in controls. The time to injury survival analysis indicated that intervention group patients had a hazard ratio of 0·19 ($P = 0{\cdot}002$) compared to control group patients. We conclude that multi-layered soft silicone foam dressings are effective in preventing pressure ulcers in critically ill patients when applied in the emergency department prior to ICU transfer.

Introduction

The prevention of hospital acquired pressure ulcers in critically ill patients while in the intensive care unit (ICU) remains a persistent and significant clinical challenge. ICU pressure ulcer incidence rates have been reported in the range of 3·3–53·4% depending on type of ICU and show large variation internationally because of study methodology (1–4). In the case of patients admitted through the emergency department (ED) and subsequently transferred to the ICU, additional factors which may contribute to pressure injuries

Key Messages

- the prevention of hospital acquired pressure ulcers in critically ill intensive care unit (ICU) patients remains a significant and persistent clinical challenge

 doi: 10.1111/iwj.12101

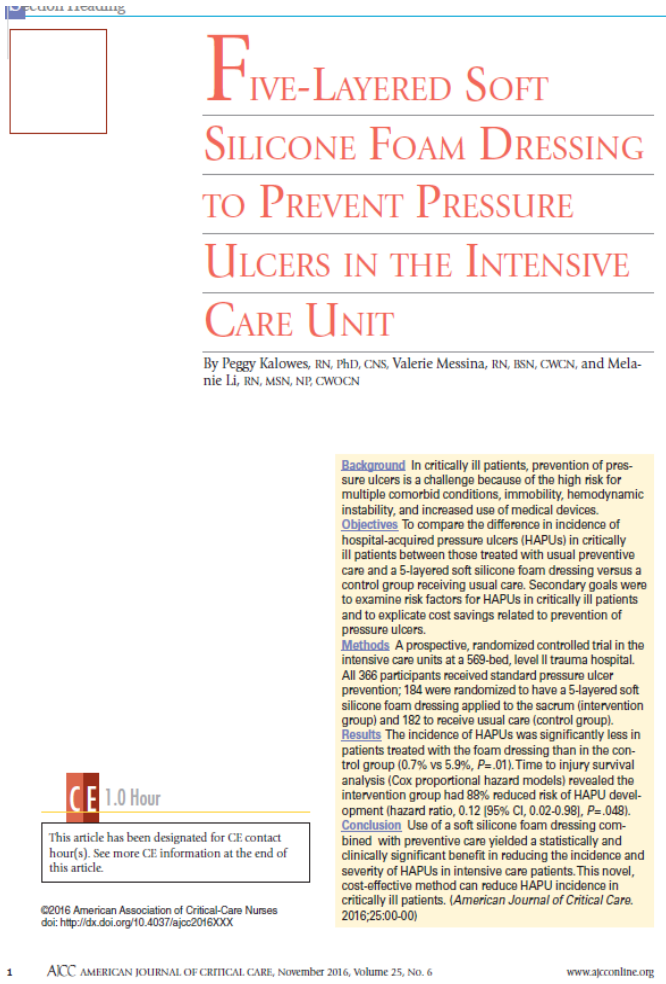
Santamaria et al. 2013 *IWJ*

- 440 ICU patients *(440 pacientů na JIP)*

- PU Incidence *(incidence dekubitů)*:
- Controls *(kontrol. skupina)* 13.1%
- Dressing *(krytí/intervenční skupina)* 3.1%

- Absolute risk reduction *(absolutní snížení rizika)* 10%
- Relative risk reduction *(relativní snížení rizika)* 80%
- Number needed to treat *(počet dnů léčby)* 10

Randomised controlled trial in USA
(Randomizovaná kontrolovaná studie v USA)



Section Reading

Five-Layered Soft Silicone Foam Dressing to Prevent Pressure Ulcers in the Intensive Care Unit

By Peggy Kalowes, RN, PhD, CNS, Valerie Messina, RN, BSN, CWCN, and Melanie Li, RN, MSN, NP, CWOCN

Background In critically ill patients, prevention of pressure ulcers is a challenge because of the high risk for multiple comorbid conditions, immobility, hemodynamic instability, and increased use of medical devices.
Objectives To compare the difference in incidence of hospital-acquired pressure ulcers (HAPUs) in critically ill patients between those treated with usual preventive care and a 5-layered soft silicone foam dressing versus a control group receiving usual care. Secondary goals were to examine risk factors for HAPUs in critically ill patients and to explicate cost savings related to prevention of pressure ulcers.
Methods A prospective, randomized controlled trial in the intensive care units at a 569-bed, level II trauma hospital. All 366 participants received standard pressure ulcer prevention; 184 were randomized to have a 5-layered soft silicone foam dressing applied to the sacrum (intervention group) and 182 to receive usual care (control group).
Results The incidence of HAPUs was significantly less in patients treated with the foam dressing than in the control group (0.7% vs 5.9%, *P*=.01). Time to injury survival analysis (Cox proportional hazard models) revealed the intervention group had 88% reduced risk of HAPU development (hazard ratio, 0.12 [95% CI, 0.02-0.98], *P*=.048).
Conclusion Use of a soft silicone foam dressing combined with preventive care yielded a statistically and clinically significant benefit in reducing the incidence and severity of HAPUs in intensive care patients. This novel, cost-effective method can reduce HAPU incidence in critically ill patients. (*American Journal of Critical Care*. 2016;25:00-00)

CE 1.0 Hour

This article has been designated for CE contact hour(s). See more CE information at the end of this article.

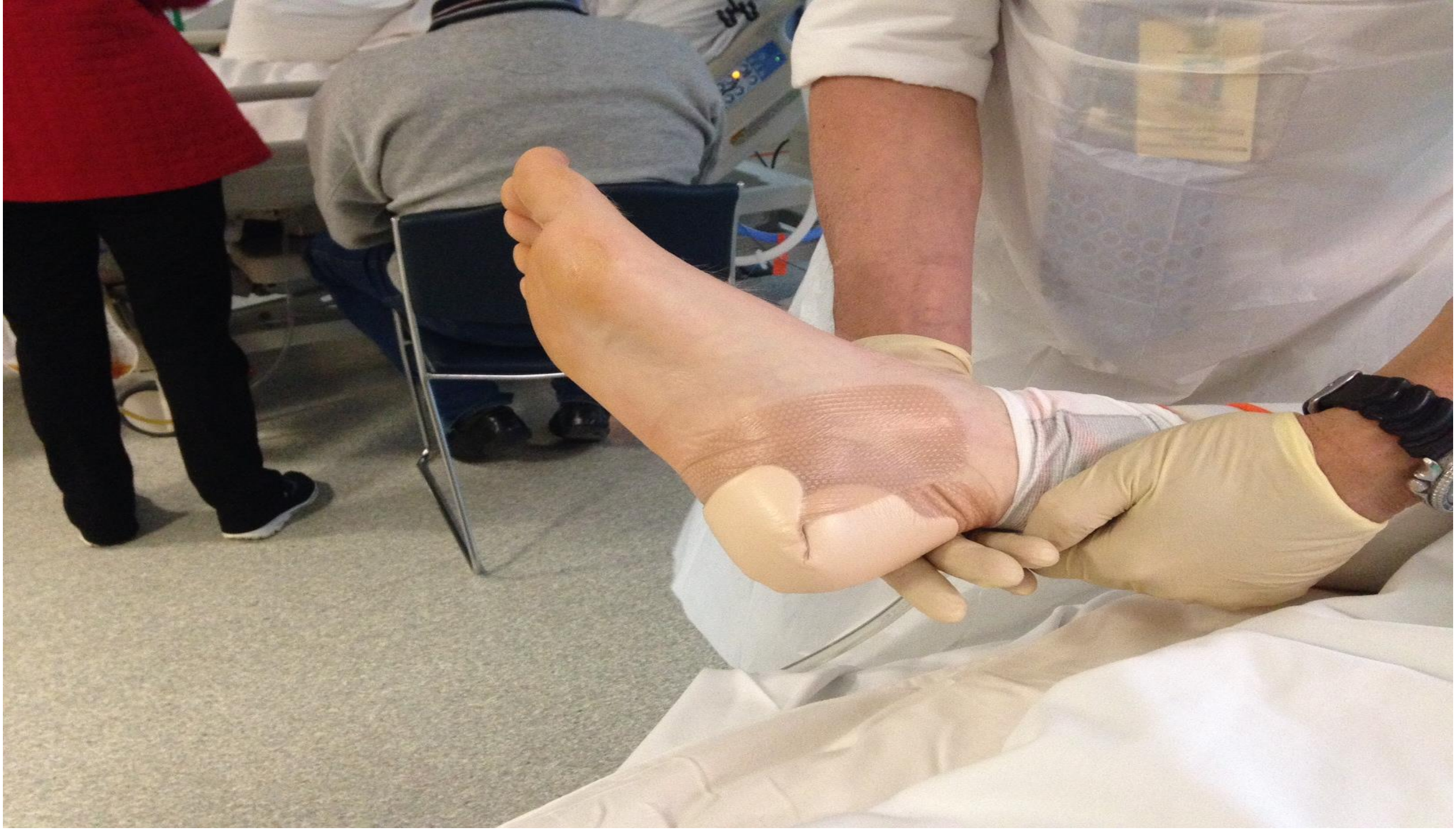
doi: http://dx.doi.org/10.4037/ajcc2016XXX

Kalowes et al 2016 *AJCC*

- 366 ICU patients *(366 pacientů na JIP)*

- PU Incidence *(incidence dekubitů)*:
- Controls *(kontrol. skupina)* 5.9%
- Dressing *(krytí/intervenční skupina)* 0.7%

- Absolute risk reduction *(absolutní snížení rizika)* 5.2%
- Relative risk reduction *(relativní snížení rizika)* 88%
- Number needed to treat *(počet dnů léčby)*15



Complete elimination of heel PI with Border Heel dressing in ICU
(Úplná eliminace dekubitů na patě s krytím Border Heel na JIP)

practice

Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II Trial

• **Objective:** Critically ill patients are at high risk of developing pressure ulcers (PU), with the sacrum and heels being highly susceptible to pressure injuries. The objective of our study was to evaluate the clinical effectiveness of a new multi-layer, self-adhesive soft silicone foam heel dressing to prevent PU development in trauma and critically ill patients in the intensive care unit (ICU).
• **Method:** A cohort of critically ill patients were enrolled at the Royal Melbourne Hospital. Each patient had the multi-layer soft silicone foam dressing applied to each heel on admission to the emergency department. The dressings were retained with a tubular bandage for the duration of the patients' stay in the ICU. The skin under the dressings was examined daily and the dressings were replaced every three days. The comparator for our cohort study was the control group from the recently completed Border Trial.
• **Results:** Of the 191 patients in the initial cohort, excluding deaths, loss to follow-up and transfers to another ward, 150 patients were included in the final analysis. There was no difference in key demographic or physiological variables between the cohorts, apart from a longer ICU length of stay for our current cohort. No PUs developed in any of our intervention cohort patients compared with 14 patients in the control cohort (n=152; p<0.001) who developed a total of 19 heel PUs.
• **Conclusion:** We conclude, based on our results, that the multi-layer soft silicone foam dressing under investigation was clinically effective in reducing ICU-acquired heel PUs. The findings also support previous research on the clinical effectiveness of multi-layer soft silicone foam dressings for PU prevention in the ICU.

• **Declaration of interest:** This research project was funded through an unrestricted research grant from Molnlycke Health care AB, Goteborg Sweden. None of the authors have competing interests to declare.

pressure ulcer; Mepilex Border heel dressing; wound dressings; critical illness; intensive care unit

N. Santamaria, RN, PhD, Professor of Nursing Research, Translational Research; **M. Gerdtz,** RN, PhD, Associate Professor of Emergency Nursing Research; **W. Liu,** RN, PhD, Assistant Professor, College of Nursing and Public Health; **S. Rakis,** RN, Grad Dip Wound Care, Clinical Nurse Consultant in Wound Management; **S. Sage,** RN, Grad Cert Wound Management, Clinical Nurse Consultant

Although standard strategies such as risk assessment, regular repositioning and the use of specialised support surfaces have been widely implemented in hospitals, pressure ulcer (PU) prevention remains a challenge, particularly among critically ill patients in the intensive care unit (ICU). Factors include the severity of the patients' illness, immobility and heavy reliance on medical devices.[1-3] The development of hospital-acquired PUs is also closely related to emergency admission for acute illnesses and prolonged stay in the emergency department (ED).[4] For trauma patients, long surgical procedures in the operating room (OR) also substantially increase the risk of PUs in ICU.[5] PUs can occur after as little as two hours of unrelieved pressure.[6] The literature

Given the challenges in PU prevention, there is a growing interest in the use of dressings as an additional prevention strategy.[1] A recent systematic review combining high-quality randomised controlled trials (RCTs), cohort studies and case series shows clear evidence of the effectiveness of multi-layer soft silicone foam dressings in the prevention of PU development, particularly among immobile ICU patients.[7] The use of wound dressings is also reported to enhance the prevention of medical device-related PUs, which are often resistant to standard strategies.[2] At the Royal Melbourne Hospital (RMH), the large Border I RCT of ICU patients conducted by our group identified a 13.1% hospital-acquired PU incidence rate among critically ill and trauma ICU patients who were transferred from the

Santamaria et al 2016 *JWC*

- 300 ICU patients *(300 pacientů na JIP)*

- PU Incidence *(incidence dekubitů)*:
- Controls *(kontrol. skupina)* 13.1%
- Dressing *(krytí/intervenční skupina)* 0%

- Absolute risk reduction *(absolutní snížení rizika)* 13.1%
- Relative risk reduction *(relativní snížení rizika)* 100%

Cost/benefit analyses of Mepilex dressings

(Analýza nákladů Mepilex obvazů)

international wound journal

International Wound Journal ISSN 1742-4801

ORIGINAL ARTICLE

The cost-benefit of using soft silicone multilayered foam dressings to prevent sacral and heel pressure ulcers in trauma and critically ill patients: a within-trial analysis of the Border Trial

Nick Santamaria[1], Wei Liu [2], Marie Gerdtz[2], Sarah Sage[3], Jane McCann[4], Amy Freeman[4], Theresa Vassiliou[2], Stephanie DeVincentis[3], Ai W Ng[3], Elizabeth Manias[1], Jonathan Knott[2] & Danny Liew[5]

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Key words
Cost-benefit; Pressure ulcers; Prophylactic dressings

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Santamaria N, Gerdtz M, Sage S, McCann J, Freeman A, Vassiliou T, DeVincentis S, Ng AW, Manias E, Liu W, Knott J, Liew D. The cost-benefit of using soft silicone multilayered foam dressings to prevent sacral and heel pressure ulcers in trauma and critically ill patients: a within-trial analysis of the Border Trial. Int Wound J 2013; doi: 10.1111/iwj.12160

Abstract

Little is known about the cost-benefit of soft silicone foam dressings in pressure ulcer (PU) prevention among critically ill patients in the emergency department (ED) and intensive care unit (ICU). A randomised controlled trial to assess the efficacy of soft silicone foam dressings in preventing sacral and heel PUs was undertaken among 440 critically ill patients in an acute care hospital. Participants were randomly allocated either to an intervention group with prophylactic dressings applied to the sacrum and heels in the ED and changed every 3 days in the ICU or to a control group with standard PU prevention care provided during their ED and ICU stay. The results showed a significant reduction of PU incidence rates in the intervention group ($P = 0{\cdot}001$). The intervention cost was estimated to be AU$36·61 per person based on an intention-to-treat analysis, but this was offset by lower downstream costs associated with PU treatment (AU$1103·52). Therefore, the average net cost of the intervention was lower than that of the control (AU$70·82 versus AU$144·56). We conclude that the use of soft silicone multilayered foam dressings to prevent sacral and heel PUs among critically ill patients results in cost savings in the acute care hospital.

Introduction

Pressure ulcers (PUs) are areas of localised damage to the skin and underlying tissue due to the combined mechanisms of pressure, shear and friction (1). Despite good clinical practice

Key Messages

- patients in the ICU and ED are known to be at high risk of PUs; studies show that using soft silicone

Patients treated with prophylactic dressings cost 3.6 times less than controls

(pacienti léčeni profylaktickými krytími, náklady jsou 3,6 krát nižší, než péče u kontrol. skupiny)

Wound Care

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OPEN

Effectiveness and Value of Prophylactic 5-Layer Foam Sacral Dressings to Prevent Hospital-Acquired Pressure Injuries in Acute Care Hospitals

An Observational Cohort Study

William V. Padula

ABSTRACT

PURPOSE: The purpose of this study was to examine the effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injury rates in acute care settings.
DESIGN: Retrospective observational cohort.
SAMPLE AND SETTING: We reviewed records of adult patients 18 years or older who were hospitalized at least 5 days across 38 acute care hospitals of the University HealthSystem Consortium (UHC) and had a pressure injury as identified by Patient Safety Indicator #3 (PSI-03). All facilities are located in the United States.
METHODS: We collected longitudinal data pertaining to prophylactic 5-layer foam sacral dressings purchased by hospital-quarter for 38 academic medical centers between 2010 and 2015. Longitudinal data on acute care, hospital-level patient outcomes (eg, admissions and PSI-03 and pressure injury rate) were queried through the UHC clinical database/resource manager from the Johns Hopkins Medicine portal. Data on volumes of dressings purchased per UHC hospital were merged with UHC data. Mixed-effects negative binomial regression was used to test the longitudinal association of prophylactic foam sacral dressings on pressure injury rates, adjusted for hospital case-mix and Medicare payments rules.
RESULTS: Significant pressure injury rate reductions in US acute care hospitals between 2010 and 2015 were associated with the adoption of prophylactic 5-layer foam sacral dressings within a prevention protocol (−1.0 cases/quarter; $P = .002$) and changes to Medicare payment rules in 2014 (−1.13 cases/quarter; $P = .035$).
CONCLUSIONS: Prophylactic 5-layer foam sacral dressings are an effective component of a pressure injury prevention protocol. Hospitals adopting these technologies should expect good value for use of these products.
KEY WORDS: Longitudinal data analysis, Pressure injury, Pressure injury prevention, pressure ulcer, Prophylactic dressing.

INTRODUCTION

Hospital-acquired pressure injuries (HAPIs) are common, costly, and deadly to acute and critically ill patients.[1] They occur in 2.5 million patients per year, costing anywhere from $500 to $150,000 per case and totaling $11 billion annually in the United States.[2,3] Moreover, full-thickness pressure injuries cause an astounding 60,000 deaths per year in the United States.[4] Hospitals face a financial burden as a result of uncompensated care for full-thickness pressure injuries due to reimbursement policies set by the Centers for Medicare & Medicaid Services (CMS).[5] In 2008, the CMS reduced payments related to hospital-acquired full-thickness pressure injuries.[6] In addition, in October of 2014, the CMS began penalizing hospitals 1% of their total reimbursements if they fell into the lowest 25th percentile with respect to composite rates of pressure injuries and other hospital-acquired conditions.[7]

These CMS policies led to implementation of prevention protocols for pressure injuries in many hospitals. Pressure injury prevention standards were introduced by the Agency for Healthcare Research and Quality (AHRQ) in 1992 and have been routinely updated by expert organizations such as the National Pressure Ulcer Advisory Panel (NPUAP) and Wound, Ostomy, Continence Nurses Society, beginning with a skin assessment and risk assessment.[8-10] Pressure injury prevention recommendations include frequent turning and repositioning; managing moisture and incontinence; selection of an appropriate support surface; managing nutrition; pressure

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Dressing data for the study described in this article were provided freely by Mölnlycke Health Care. The author has relationships as a consultant and speakers bureau member to Mölnlycke Health Care. This arrangement has been reviewed and approved by The Johns Hopkins University in accordance with its conflict of interest policies.

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Review of 1.03M patients revealed a cost reduction of $77 per patient

(data o 1,03 mil. pacientech odhalila redukci nákladů 77 USD na pacienta)

education

An estimate of the potential budget impact of using prophylactic dressings to prevent hospital-acquired PUs in Australia

- **Objective:** To estimate the potential cost saving to the Australian health-care system of introducing the use of prophylactic dressings to prevent hospital-acquired pressure ulcers (PUs) for patients with a high-risk developing a PU.
- **Method:** We estimated the costs of pressure ulceration based on conservative estimates of an incidence rate of 13% within 10% of the total admitted Australian patient population. Results from a recent large randomised control trial of prophylactic dressing used to prevent PUs in high-risk patients were then extrapolated to this population to derive a potential national cost/benefit calculation.
- **Results:** Our estimate revealed that within the high-risk population of acute hospitals, more than 71,000 patients could be expected to develop a PU annually costing AU$77,800,000 (£43,000,000). Whereas by implementing a national PU prevention initiative based on the use of prophylactic multilayer silicone foam dressings for high-risk patients, an annual saving of AU$34,800,000 (£19,700,000) could be achieved, which represents a cost benefit of 55% to the Australian health-care system.
- **Conclusion:** Our estimate of the potential cost benefit of implementing the use of prophylactic dressings to prevent hospital acquired PUs in high-risk patients uses conservative estimates of both the incidence rates of ulceration and of treatment costs. However, this is also based on one of the largest reported randomised control trials of this technique to prevent PUs. We believe that our modelling is robust yet requires replication in other countries with different health-care systems and costing structures.
- **Declaration of interest:** There was no sponsorship of this study. The authors have no conflict of interest to declare.

pressure ulcers; prevention; cost benefit; economic estimation; prophylactic dressing

The prevention of hospital-acquired pressure ulcers (PUs) presents clinicians with an ongoing challenge. Despite significant advances in the prevention of pressure ulceration through the use of risk screening tools, advanced pressure redistribution surfaces (both static and dynamic) and the wide adoption of international PU prevention clinical guidelines, there remain groups of patients that continue to develop PUs whilst in acute care.[1-4] exceed US$1.6 billion annually in the acute hospital sector.[5] While this figure is large for a country of 23 million people, it is consistent with cost estimates for comparable developed countries.[1]

Recently, there has been an increased interest in the potential for the use of soft silicone multilayer dressings as a means of preventing PUs in high-risk patient populations.[6] Research in the area of PU prevention using wound dressing products has been sporadic over the past two decades, however, the

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An annual saving of $35M to Australian public health care system if prophylactic dressings used for all high risk patients

(roční úspora 35 mil. USD australskému zdravotnímu systému, pokud se používají profylaktická krytí u všech pacientů ve vysokém riziku vzniku dekubitů)

Systematic reviews
(Systematická review)

international wound journal

International Wound Journal ISSN 1742-4801

REVIEW ARTICLE

Systematic review of the use of prophylactic dressings in the prevention of pressure ulcers

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Key words
Pressure ulcer prevention; Prophylactic dressings

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Clark M, Black J, Alves P, Brindle CT, Call E, Dealey C, Santamaria N. Systematic review of the use of prophylactic dressings in the prevention of pressure ulcers. Int Wound J 2014; doi: 10.1111/iwj.12212

Abstract

This systematic review considers the evidence supporting the use of prophylactic dressings for the prevention of pressure ulcer. Electronic database searches were conducted on 25 July 2013. The searches found 3026 titles and after removal of duplicate records 2819 titles were scanned against the inclusion and exclusion criteria. Of these, 2777 were excluded based on their title and abstract primarily because they discussed pressure ulcer healing, the prevention and treatment of other chronic and acute wounds or where the intervention was not a prophylactic dressing (e.g. underpads, heel protectors and cushions). Finally, the full text of 42 papers were retrieved. When these 42 papers were reviewed, 21 were excluded and 21 were included in the review. The single high-quality randomised controlled trial (RCT) and the growing number of cohort, weak RCT and case series all suggest that the introduction of a dressing as part of pressure ulcer prevention may help reduce pressure ulcer incidence associated with medical devices especially in immobile intensive care unit patients. There is no firm clinical evidence at this time to suggest that one dressing type is more effective than other dressings.

Description of the health problem

Management of both the duration and magnitude of the mechanical loads applied to skin and soft tissues has long been seen as the essential element of pressure ulcer prevention and management (1). These mechanical loads, for

microclimate control (defined as including management of temperature, humidity, moisture and skin surface pH) may

Key Messages

SYSTEMATIC REVIEW PROTOCOL

Effectiveness of pressure ulcer prevention strategies for adult patients in intensive care units: a systematic review protocol

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Review question/objective: The objective of this review is to identify the effectiveness of pressure ulcer (PU) prevention strategies on the incidence of hospital-acquired PUs in the intensive care unit (ICU).
More specifically, the objectives are to identify the effectiveness of utilizing PU prevention strategies such as risk assessment, skin assessment, skin care, nutrition, position and repositioning, education and training, medical devices care or other strategies designed to manage the risk factors for PU development and reduce the incidence of PUs in ICUs.

Keywords Prevention strategies; incidence; intensive care; pressure ulcer/injury; prevalence

Background

A pressure ulcer (PU) is defined as a lesion or trauma to the skin and underlying tissue resulting from unrelieved pressure, shear, friction, moisture or a combination of all these, usually appearing over a bony prominence.[1] There is wide variation reported in the prevalence of PUs in acute care patients, ranging from 12% to 19.7%,[2,3] whereas in intensive care units (ICUs) globally, PU prevalence is reported to range from 22 to 50%.[4–8] This high figure may be related to increased patient acuity in the ICU and the patient's physiological responses to critical illness.[9,10] Literature suggests that the development of PUs is associated with decreased quality of life, impaired physical function, an increased incidence of infection, higher healthcare costs and increased levels of care required.[11–14] Tayyib *et al.*[15] reviewed the risk factors of PU development in ICU. Their findings revealed that older age, increased ICU length of stay, prolonged immobility, history of cardiovascular disease and administration of noradrenaline were key risk factors for PU development.[15] All patients admitted to an ICU should be considered at risk of PU development. Key factors have been identified that contribute to PU development – pressure, shear, friction and moisture. Immobility exposes the critically ill patients to prolonged pressure, friction and shear disrupt skin integrity through mechanical forces between the skin and interface surface.[1] Humidity and temperature interplay and resulting moisture leads to maceration of the skin and skin breakdown.[1] These factors create a deleterious effect on the critically ill patient's skin integrity.[1] Literature suggests that PUs still impose burdens on healthcare organizations globally,[1,16] despite intensified PU prevention strategies developed during the past decade. Thus, PU prevention is considered a challenging problem and a quality indicator in the healthcare setting.

In response to this exigent issue, professional international organizations suggest that prevention of PUs should focus on risk assessment scales, skin care, positioning and repositioning schedules, nutritional supplementation, support surfaces and education and training programs.[17–19] Risk assessment scales are defined as instruments for scoring patients

Expert opinion
(Názory expertů)

Prevention and management of pressure injury to the heel

Authors:
Joyce Black, Nick Santamaria, Tod Brindle, Jacqui Fletcher and Paulo Alves

Pressure injuries on the heels often occur in immobile patients. The risk factors for these injuries stem from the anatomy of the calcaneus, impairments in blood flow to the foot and neuropathic disease. There are many clinical considerations in the prevention of heel pressure injury. This article addresses the epidemiology and economic impact of heel injury, identifies risk factors and differential diagnosis of their development, discusses challenges in prevention across the continuum of care, and provides guidance for selecting appropriate interventions in the prevention of heel pressure injury through the review of existing evidence.

Pressure ulcers, now termed pressure injuries (PIs) in some countries, are defined by the National Pressure Ulcer Advisory Panel as "localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue" (Edsberg et al, 2016). In adults, the heel is one of the most common areas of PI development, accounting for some of the most significant and severe PIs in both European and American clinical studies (Vanderwee et al, 2007).

Prevention of heel injury is paramount. This article addresses the epidemiology and economic impact of heel injury complications, identifies risk factors and the differential diagnosis of PI development, discusses challenges in prevention across the continuum of care, and provides guidance for selecting appropriate interventions in the prevention of heel PI through a review of the existing evidence.

Epidemiology and cost of heel pressure injuries

Heel PIs are commonly reported to be the first or second most prevalent hospital-acquired PIs (Kerstein, 2002; VanGilder et al, 2008; Jenkins and O'Neal, 2010; Salcido et al, 2010; Mulligan et al, 2011), ranging in prevalence from 2.0–41.0%. The wide range of international prevalence is due, in part, to the differing methodologies used in reporting the incidence and prevalence of heel PI and to differing health payment/reimbursement systems (Berlowitz, 2012). There is some variation in the prevalence data based on the clinical area where the study was conducted. For example, rates of heel PI vary between settings such as intensive care units (Santamaria et al, 2015), operating rooms (Shen et al, 2015), general medical/surgical wards (Gunningberg et al, 2011) and elderly care settings (Rasero et al, 2015; Ahn et al, 2016).

Even though there are few data specifically reporting on the cost of heel PIs, from the prevalence in the literature it is clear that heel PIs make up a very large proportion of all hospital-acquired PIs, therefore, it is logical that they would also make up a large proportion of costs. It has been estimated that PI costs $11bn (£7.8 bn) in the United States (Russo et al, 2008), AU$3.5 billion (£1.9 billion) in Australia (Graves et al, 2005) and £ 531 million in the United Kingdom (Guest et al, 2017).

When considering the cost of heel PIs, clinicians should think beyond the direct costs of care, i.e. the financial cost to the hospital or facility. There are also costs associated with increased length of stay and decreased efficiency of the clinical unit due to decreased patient throughput as well as opportunity costs incurred through staff time spent caring for the injury rather than undertaking other activities. Importantly, there are personal costs to the patient in the form of pain, discomfort,

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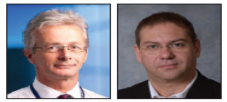
Clinical innovations: Can dressings help to prevent pressure ulcers in high-risk nursing home residents?



Author:
Nick Santamaria and Amit Gefen

The aim of this paper is to present current and emerging clinical and scientific evidence for the prevention of pressure ulcers in highly dependent aged care residents. The authors discuss recent developments in the use of multilayer silicone foam dressings used prophylactically in both the acute and nursing home settings and explain this preventative approach in the light of our current understanding of the role of cell and tissue deformations in the pathogenesis of these wounds. The authors also discuss how certain dressings can reduce the exposure to tissue deformations resulting from the mechanical loads of pressure, friction and shear in these highly vulnerable individuals.

Aged nursing home residents who are immobile (Wong, 2011; Moore and Cowman, 2012), poorly nourished (Horn et al, 2004; Banks et al, 2010), incontinent (Wong, 2011; Long et al 2012; Moore and Cowman, 2012), have ageing skin-related changes (Foreman et al, 1993), are cognitively impaired (Capon et al, 2007) and have multiple comorbidities (Santamaria et al, 2005; Kwong et al, 2009; Lyman, 2009) are highly vulnerable to the development of facility-acquired pressure ulcers (PUs). It has been clearly established that many of these vulnerable residents who do develop a facility facility-acquired PU will experience additional pain, morbidity and, in some cases, the wound will lead to amputation or the person's death (Capon et al, 2007; Kwong et al, 2009; Liao et al, 2010).

Prevalence and incidence rates for aged care facility-acquired PUs have been reported to range from 4.3% to 35.1% (Kottner et al, 2010, Long et al, 2012) and 2.5% to 25.1% (Kwong et al, 2009; 2011) respectively, although we urge caution in interpreting these figures due to the potential for differing methodologies used in conducting the prevalence and incidence surveys. The most commonly reported anatomical sites for the development of PUs are the sacrum (Kwong et al, 2010) and heels (Moore and Cowman, 2012).

New insights into the mechanisms of injury in pressure ulceration

Our understanding of the underlying mechanisms of PUs (also called pressure injuries) has for the past 80 years been based on work by Landis (1930) who proposed an absolute generic capillary closing pressure of 32 mmHg caused by direct pressure on tissues. This paper and subsequent work has, unfortunately, resulted in PUs being mistakenly thought to be principally an ischaemic event where soft tissues are compressed, for prolonged periods of time, between a bony prominence, such as the sacrum or the calcaneus and a surface resulting in capillary occlusion, hypoxia and subsequent tissue necrosis.

More recently, the involvement of bioengineers/scientists has resulted in fundamental changes to how we understand PU development based on the concept of cell and tissue deformation and direct cellular damage driven by the deformations. This is a more rapid and powerful factor than ischaemia in PU formation. In a supine patient, the forces originating from the weight of the trunk are transferred through triangular-shaped sacral bone into thin and deformable layer of skeletal muscle, subcutaneous fat and skin. Forces considerably distort and deform this layered tissue structure.

Due to the highly curved shape of the sacrum and its sharp topography, it tends to heavily distort the soft tissues between the bone and the surface, so that the cells that reside in these tissues are compressed, stretched and sheared simultaneously (Gefen et al, 2005). These forces are exacerbated if the head of the bed is elevated, which adds additional frictional forces on the skin and internal shearing sub-dermally

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Extrapolation of evidence-related to dressings for pressure ulcer prevention may compromise patient safety

This paper, written by an international group of experts in the bioengineering and clinical aspects of the design, use and evaluation of dressings for pressure ulcer prevention, addresses a central question, commonly faced by the medical device industry, clinicians and patients. The question being whether evidence obtained for a specific product can be extrapolated to other products, which are similar or lookalikes, and are made by different manufacturers. Specifically, this question is of fundamental importance to wound care clinicians and particularly in the area of dressings used in the prophylaxis of pressure ulcers (also called pressure injuries in the US and Australia). The authors thoroughly discuss recent developments and litigation in the medical device industry, relevant regulation routes in the pharmaceutical industry aimed at ensuring patient safety, and examples from the automotive industry to describe the great danger in extrapolating bioengineering and medical evidence obtained for one dressing product to other products by different manufacturers. The contents of this paper demonstrate why the question clinicians must ask before selecting a prophylactic dressing is: "Will I choose a dressing based on marketing hype and cost or, alternatively, based on published scientific, bioengineering and ultimately clinical evidence?"

In 2016, a federal jury in Dallas, Texas, in the US, ordered Johnson & Johnson and its DePuy Orthopaedics unit to pay more than $30mn in damages for patients harmed by the defective ASR metal-on-metal hip implants and $1bn in punitive damages. The jurors ruled that these metal-on-metal hip implants were defectively designed, inflicting a risk of metallosis. No clinical trials were conducted with the product before it was launched. The justification provided by the company to gain approvals for commencing clinical use of this ASR implant was that it is similar to already approved metal-on-metal hip prosthesis models.

This case places a spotlight on a central question, commonly faced by the medical device industry, clinicians and patients, of whether evidence obtained for a specific product can be extrapolated to other products, which are similar or lookalikes, and are made by different manufacturers. This question is of fundamental importance to wound care clinicians and particularly, in the area of dressings used in the prophylaxis of pressure ulcers (also called pressure injuries in the US and Australia).

An appropriate starting point for such a discussion should be the situation in the sister market to medical devices, which is the pharmaceutical industry. The pharmaceutical industry has developed unique, thorough and rigorous processes for extrapolating clinical evidence of efficacy from one product to another when it comes to generic medications. In the US, for example, by law, the Food and Drug Administration (FDA) is the regulatory body that is authorised to approve generic versions of brand-name drugs without requiring (new) research to be conducted in order to specifically prove them safe and effective, as was done

Expert opinion
(Názory expertů)

Contents lists available at ScienceDirect

Clinical Biomechanics

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Clinical and biomechanical perspectives on pressure injury prevention research: The case of prophylactic dressings

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ABSTRACT

In this perspective paper, we discuss clinical and biomechanical viewpoints on pressure injury (or pres
prevention research. We have selected to focus on the case of prophylactic dressings for pressure inju
tion, and the background of the historical context of pressure injury research, as an exemplar to illumi
of the good and not so good in current biomechanical and clinical research in the wound preventio
arena. Investigators who are conducting medical or clinical research in academia, in medical settings o
try to determine the efficacy of wound prevention and care products could benefit from applying s
principles that are detailed in this paper, and that should leverage the research outcomes, thereby co
to setting higher standards in the field.

international wound journal

International Wound Journal ISSN 1742-4801

ORIGINAL ARTICLE

Use of wound dressings to enhance prevention of pressure ulcers caused by medical devices

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7 Tissue Viability, Birmingham City University, Birmingham, UK

Key words
Consensus; Medical device; Pressure ulcers

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Black J, Alves P, Brindle CT, Dealey C, Santamaria N, Call E, Clark M. Use of wound dressings to enhance prevention of pressure ulcers caused by medical devices. Int Wound J 2013; doi: 10.1111/iwj.12111

Abstract

Medical device related pressure ulcers (MDR PUs) are defined as pressure injuries associated with the use of devices applied for diagnostic or therapeutic purposes

international wound journal

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ORIGINAL ARTICLE

Dressings as an adjunct to pressure ulcer prevention: consensus panel recommendations

Joyce Black[1], Michael Clark[2], Carol Dealey[3], Christopher T Brindle [4], Paulo Alves[5], Nick Santamaria[6] & Evan Call[7]

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Key words
Pressure ulcer prevention; Preventive dressings; ICU pressure ulcers

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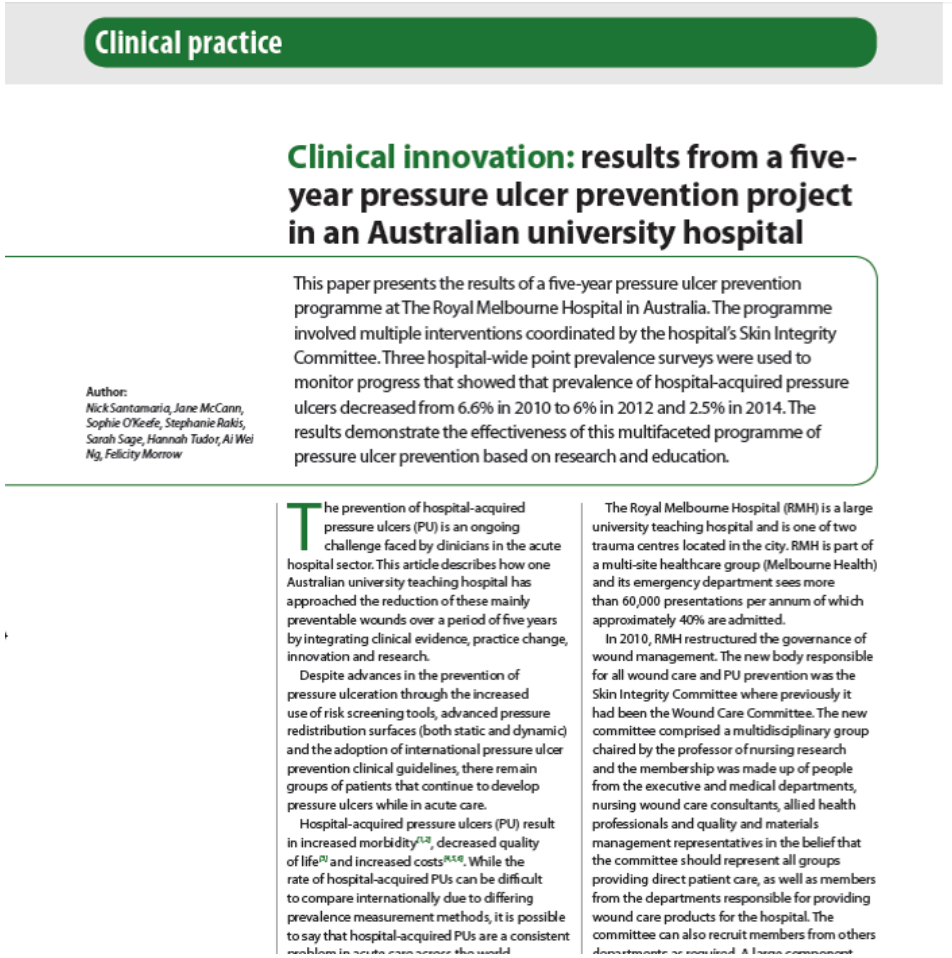
Black J, Clark M, Dealey C, Brindle CT, Alves P, Santamaria N, Call E. Dressings as an adjunct to pressure ulcer prevention: consensus panel recommendations. Int Wound J 2014; doi: 10.1111/iwj.12197

Abstract

The formulation of recommendations on the use of wound dressings in pressure ulcer prevention was undertaken by a group of experts in pressure ulcer prevention and treatment from Australia, Portugal, UK and USA. After review of literature, they concluded that there is adequate evidence to recommend the use of five-layer silicone bordered dressings (Mepilex Border Sacrum® and 3 layer Mepilex Heel®) dressings by Mölnlycke Health Care, Gothenburg, Sweden) for pressure ulcer prevention in the sacrum, buttocks and heels in high-risk patients, those in Emergency Department (ED), intensive care unit (ICU) and operating room (OR). Literature on which this recommendation is based includes one prospective randomised control trial, three cohort studies and two case series. Recommendations for dressing use in patients at high risk for pressure injury and shear injury were also provided.

Hospital-wide reductions in PI as a result of using dressings
(Plošná redukce dekubitů jako výsledek používání profylaktických krytí)



Clinical practice

Clinical innovation: results from a five-year pressure ulcer prevention project in an Australian university hospital

This paper presents the results of a five-year pressure ulcer prevention programme at The Royal Melbourne Hospital in Australia. The programme involved multiple interventions coordinated by the hospital's Skin Integrity Committee. Three hospital-wide point prevalence surveys were used to monitor progress that showed that prevalence of hospital-acquired pressure ulcers decreased from 6.6% in 2010 to 6% in 2012 and 2.5% in 2014. The results demonstrate the effectiveness of this multifaceted programme of pressure ulcer prevention based on research and education.

Author:
Nick Santamaria, Jane McCann, Sophie O'Keefe, Stephanie Rakis, Sarah Sage, Hannah Tudor, Ai Wei Ng, Felicity Morrow

The prevention of hospital-acquired pressure ulcers (PU) is an ongoing challenge faced by dinicians in the acute hospital sector. This article describes how one Australian university teaching hospital has approached the reduction of these mainly preventable wounds over a period of five years by integrating clinical evidence, practice change, innovation and research.

Despite advances in the prevention of pressure ulceration through the increased use of risk screening tools, advanced pressure redistribution surfaces (both static and dynamic) and the adoption of international pressure ulcer prevention clinical guidelines, there remain groups of patients that continue to develop pressure ulcers while in acute care.

Hospital-acquired pressure ulcers (PU) result in increased morbidity[1,2], decreased quality of life[3] and increased costs[4,5,6]. While the rate of hospital-acquired PUs can be difficult to compare internationally due to differing prevalence measurement methods, it is possible to say that hospital-acquired PUs are a consistent

The Royal Melbourne Hospital (RMH) is a large university teaching hospital and is one of two trauma centres located in the city. RMH is part of a multi-site healthcare group (Melbourne Health) and its emergency department sees more than 60,000 presentations per annum of which approximately 40% are admitted.

In 2010, RMH restructured the governance of wound management. The new body responsible for all wound care and PU prevention was the Skin Integrity Committee where previously it had been the Wound Care Committee. The new committee comprised a multidisciplinary group chaired by the professor of nursing research and the membership was made up of people from the executive and medical departments, nursing wound care consultants, allied health professionals and quality and materials management representatives in the belief that the committee should represent all groups providing direct patient care, as well as members from the departments responsible for providing wound care products for the hospital. The committee can also recruit members from others

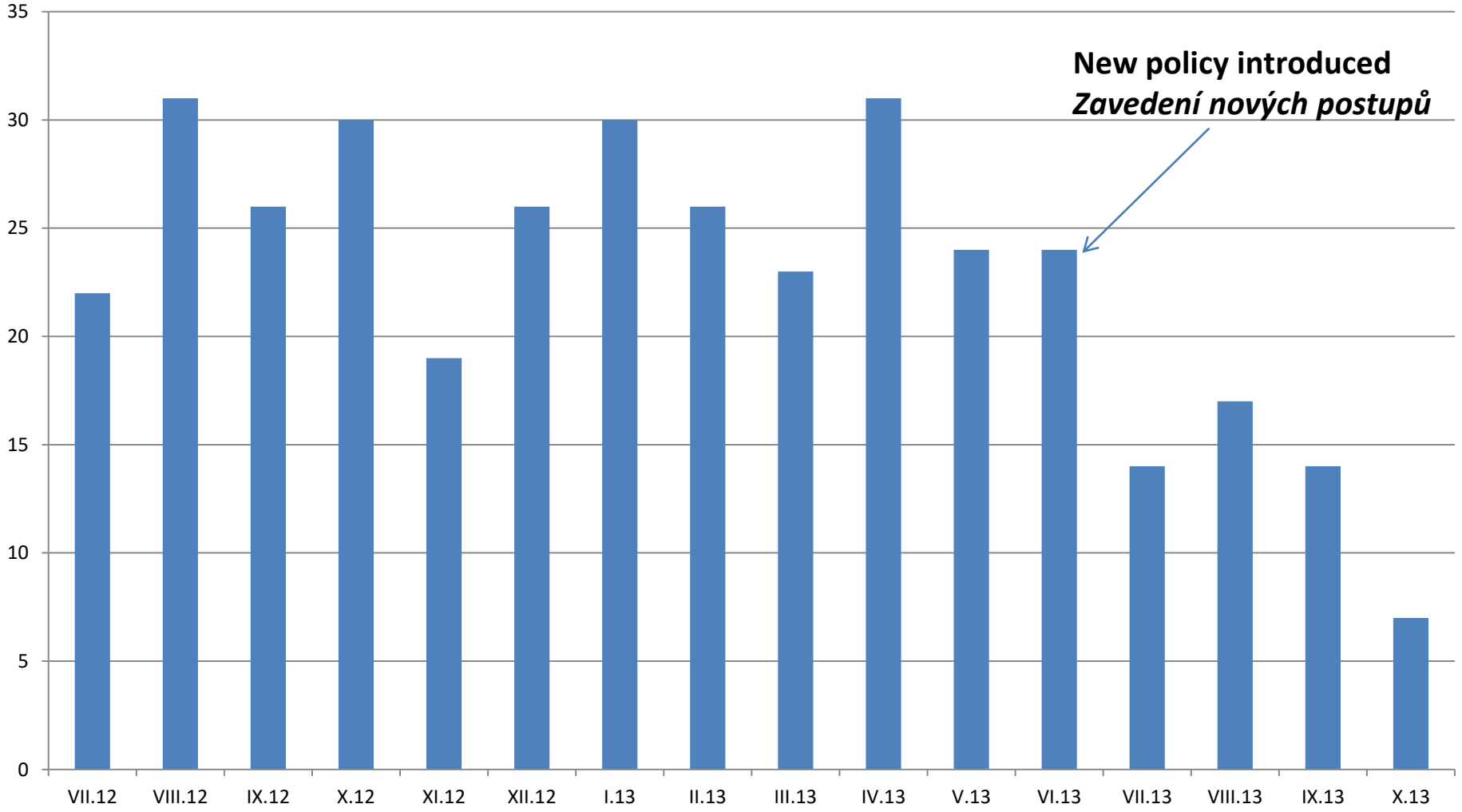
Santamaria et al 2016 *Wounds Int*

- 2400 general hospital patients
- (2 400 pacientů ve všeobecné nemocnici)

- PU Incidence (incidence dekubitů):
- Controls (kontrol. skupina) 6.6%
- Dressing (krytí/intervenční skupina) 2.5%

- Absolute risk reduction (absolutní snížení rizika) 4.1%
- Relative risk reduction (relativní snížení rizika) 63%

Pressure ulcer numbers per month 2012/13
(Počet dekubitů za měsíc v letech 2012/2013)



Pressure injury point prevalence

(Dekubity point prevalence studie)

Hospital policy change *(Změna nemocniční politiky)*

All patients assessed as “high risk” for PU development (Braden) must have Mepilex Border Sacrum and Mepilex Heel dressings applied on admission

- *Všichni pacienti, kteří jsou hodnoceni jako „ve vysokém riziku“ pro vznik dekubitů musí mít aplikována krytí Mepilex Border Sacrum a Mepilex Heel*

Additionally patients with peripheral vascular disease or neuropathic/neuroischaemic foot disease or are having major surgery must also have the dressings applied

- *Navíc pacienti s periferním cévním onemocněním nebo s neuropatickou/neuroischemickou nohou nebo s rozsáhlým chirurgickým výkonem, musí mít také aplikována profylaktická krytí*

All patients must have a risk assessment completed and documented within 4-hours of admission

- *U všech pacientů musí být provedeno hodnocení rizika vzniku dekubitů a dokumentováno do 4 h. od přijetí*

Appropriate interventions based on risk level must be implemented and documented

- *Intervence odpovídající úrovni rizika vzniku dekubitů musí být realizovány a zdokumentovány*

    Repositioning schedule (*Harmonogram polohování*)

    Surfaces (*Využité povrchy - matrace*)

    Referrals (*Doporučení k další péči*)

Mandatory annual pressure injury education for all clinical staff
(Povinné každoroční vzdělávání v oblasti dekubitů pro veškerý klinický personál)

Education for all clinical staff + clinical coders

Edukace pro veškerý klinický personál + klinické kodéry

Online education – annual requirement for all staff – current 100% uptake

Online výuka – každoroční požadavek u všech zaměstnanců – 100% účast

Wound Resource Nurses in each clinical area to promote new policy

(Sestry manažerky ran zabývající se dekubity podporují nové postupy v každé klinické oblasti)

- 70 RNs located in all clinical areas
- *70 sester manažerek ran ve všech klinických oblastech*

  - Completed 5 WoundsWest online modules + RMH education
  - *Musí absolvovat předepsané vzdělávání*
  - Responsible for education and support of the ward in all aspects of wound management and PI prevention
  - *Odpovědné za edukaci a podporu na oddělení ve všech aspektech managementu rány a prevenci tlakových zranění*
  - Conduct monthly PI policy adherence audits
  - *Provádí měsíční audity dodržování zásad a postupů v této* Design local support/activities to match characteristics of the clinical area and patient population
  - *Navrhují postupy k místní podpoře/aktivitám, které odpovídají charakteristikám klinické oblasti (specializaci) a populaci pacientů*
  - Supported by Wound CNCs
  - *Podporovány konzultantkou pro hojení ran*

Continual monitoring of policy adherence
(Kontinuální sledování dodržování postupů)

Monthly auditing of policy adherence for high-risk pts with immediate feedback to wards

- *Měsíční audit dodržování zásad pro vysoce rizikové pacienty s okamžitou zpětnou vazbou na oddělení*

"If No, Provide reason"

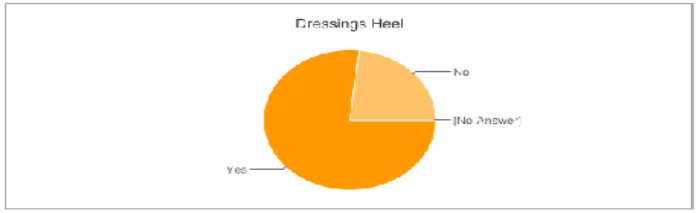
Text
Total responses for this question: 1

Response	Occurrences
Independent	1
[No Answer]	0

21. "Dressings Heel"

Single choice (one from many)
Total responses for this question: 13

Response	Count	Percentage
Yes	10	76.9%
No	3	23.1%
[No answer]	0	0.0%



"If No, Provide Reason"

Text
Total responses for this question: 3

Response	Occurrences
Oedematous	1
patient refused	1
Independent moving	1
[No Answer]	0

Effective communication of new policy
(Efektivní komunikace nových postupů)

Visual PI prevention materials in all clinical areas

Obrazové materiály k prevenci dekubitů napříč všemi klinickými oblastmi

- Directly based on PU prevention policy

Přímo založené na preventivním přístupu k oblasti dekubitů

- Simple message – “Check, Detect, Act”

Jednoduché sdělení: „Zkontroluj, detekuj, jednej“

- Consistent look – Colour same as Standard 8

Konzistentní vzhled – stejné barvy jako Standard 8

- Wall posters with decision algorithm

Postery na zeď s rozhodovacím algoritmem

- Patient chart holder reminder

Grafy s popisem stavu pacienta a upozorněním

- Wall alert for high risk patients

Upozornění na zdi u pacientů s vysokým rizikem

- Medical history sticker to identify PI

Anamnestické nálepky/označení k identifikaci dekubitů

HIGH RISK PRESSURE INJURY PREVENTION PLAN

CHECK, DETECT, ACT

Risk Assessment

- Change to any Braden sub-scale parameter
- Change in physical status

Essential Equipment

- Alternating Air Mattress insitu, active and adjusted for Pt weight
- Sacral dressing applied
- Heel dressings applied
- Heels elevated on pillows

Documentation & Communication

- PI prevention plan documented in medical history
- Skin inspection documented per shift
- Repositioning schedule documented
- Referrals to Wound CNC, Nutrition, Podiatry and OT as required
- Discussion of PI prevention plan with patient and family/carers
- Discharge planning & communication

PRESSURE INJURY PREVENTION

CHECK, DETECT, ACT

All patients on admission

- Full skin inspection (must be documented in Medical Record)
- Assess patient within 4 hours of arrival using Braden Scale to determine pressure injury risk level

High Risk Level

- Braden score 12 or less
- Peripheral Vascular Disease
- Diabetic Neuropathic/Neuroischaemic Foot Disease
- Major Orthopaedic Surgery

Minimum PI prevention measures

- Order pressure reducing air mattress and implement as soon as possible
- Off load heel pressure with longitudinally positioned pillows under each leg
- Apply appropriately sized Mepilex Border dressing to sacrum and Mepilex Heel dressing to each heel and retain with Tubifast. Inspect the skin under the dressings daily and replace every 3 days
- Commence and document repositioning schedule (minimum 2 hourly repositioning)
- Daily documentation of skin integrity in Medical Record
- Communicate PI prevention plan with all staff, patient and next of kin

MELBOURNE HEALTH

HIGH PRESSURE INJURY RISK

CHECK, DETECT, ACT

MELBOURNE HEALTH

ORIGINAL ARTICLE

A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial

Nick Santamaria[1] | Marie Gerdtz[1] | Suzanne Kapp[1] | Lauren Wilson[1] | Amit Gefen[2]

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Pressure injuries are prevalent in highly dependent aged care residents. This study investigated the clinical effectiveness of the application of the Mepilex Border Sacrum and Mepilex Heel dressings to prevent the development of facility-acquired pressure injuries. A total of 288 recently admitted residents were enrolled from 40 Australian nursing homes into a randomised controlled trial. Residents randomised to standard care (n = 150) received pressure injury prevention as recommended by international guidelines. Residents randomised to the intervention (n = 138) received standard pressure injury prevention care and had dressings applied to their sacrum and heels. Participants were comparable on demographic and physiological parameters. More residents in the control group developed pressure injuries than in the intervention group (16 vs 3, P = 0.004), and they developed more pressure injuries in total than residents in the intervention group. The results represent a relative risk reduction of 80% for residents treated with the dressings and for every 12 patients that we treated we prevented one pressure injury. Based on our findings, we conclude that the use of the Mölnlycke Mepilex Border Sacrum and Mepilex Heel dressings confers a significant additional protective benefit to nursing home residents with a high risk of developing a facility-acquired pressure injury.

KEYWORDS
aged care, pressure injury, prevention, prophylactic dressings

1 | INTRODUCTION

Pressure injuries are prevalent among highly dependent aged

incidence rates range from 2.5%[12] to 25.16%.[2] Anatomically, the sacrum[12] and heels[3] are the 2 most frequently reported sites for PI development in residents of aged care

Randomised controlled trial of the effectiveness of Mepilex dressings for the prevention of sacral and heel PU in aged care

(Randomizovaná kontrolovaná studie k hodnocení efektivity krytí Mepilex k prevenci dekubitů na sakru a patách v péči o seniory)

- High rates of PI in aged care *(vysoké počty dekubitů u starších pacientů)*
- No previous RCT of dressings for PI prevention in aged care *(absence předchozích randomizovaných studií ohledně krytí a prevence dekubitů u starších pacientů)*

- 18-month study in Australia *(18ti měsíční studie v Austrálii)*
- 40 nursing homes *(40 domů pro seniory)*
- High-risk newly admitted residents *(vysoce rizikoví nově přijatí rezidenti/obyvatelé)*
- 4-week intervention with Border Sacrum & Mepilex Heel *(4-týdenní intervence s Border Sacrum & Mepilex Heel)*

Primary endpoint: PI incidence *(Primární cíl: incidence dekubitů)*

Secondary endpoint: Cost/effectiveness *(Sekundární cíl: nákladovost/efektivita)*

Demography (n=288)
(Demografie)

	Intervention (n=138) *(intervenční sk.)* **Mean (SD)**		**Control** *(kontrolní sk.)* **(n=150) Mean (SD)**
Age *(věk)*	84 (9)		82 (12)
Gender *(pohlaví)* Male *(muž)* Female *(žena)*	 48 90		 38 112
BMI *(BMI)*	22.5 (4.8)		24.1 (6.8)
CCI Total *(Charlson Comorbidity Index)*	6 (1)		6 (2)
Braden Total *(Braden celkem)*	11 (2)		11 (2)
Immobility *(nehybnost)*	138		150
Continence *(inkontinence)*			
Urinary *(moč)* Yes/No	29/109		23/127
Faecal *(stolice)* Yes/no	29/109		27/123
Alt Air Mattress *(aktivní matrace)*	138		150

Randomised controlled trial of the effectiveness of Mepilex dressings for the prevention of sacral and heel PU in aged care (n=288)

(Randomizovaná kontrolovaná studie efektivity krytí Mepilex k prevenci dekubitů na sakru a na patách u seniorů)

Santamaria N, Gerdtz M, Kapp S, Wilson L, Gefen A.

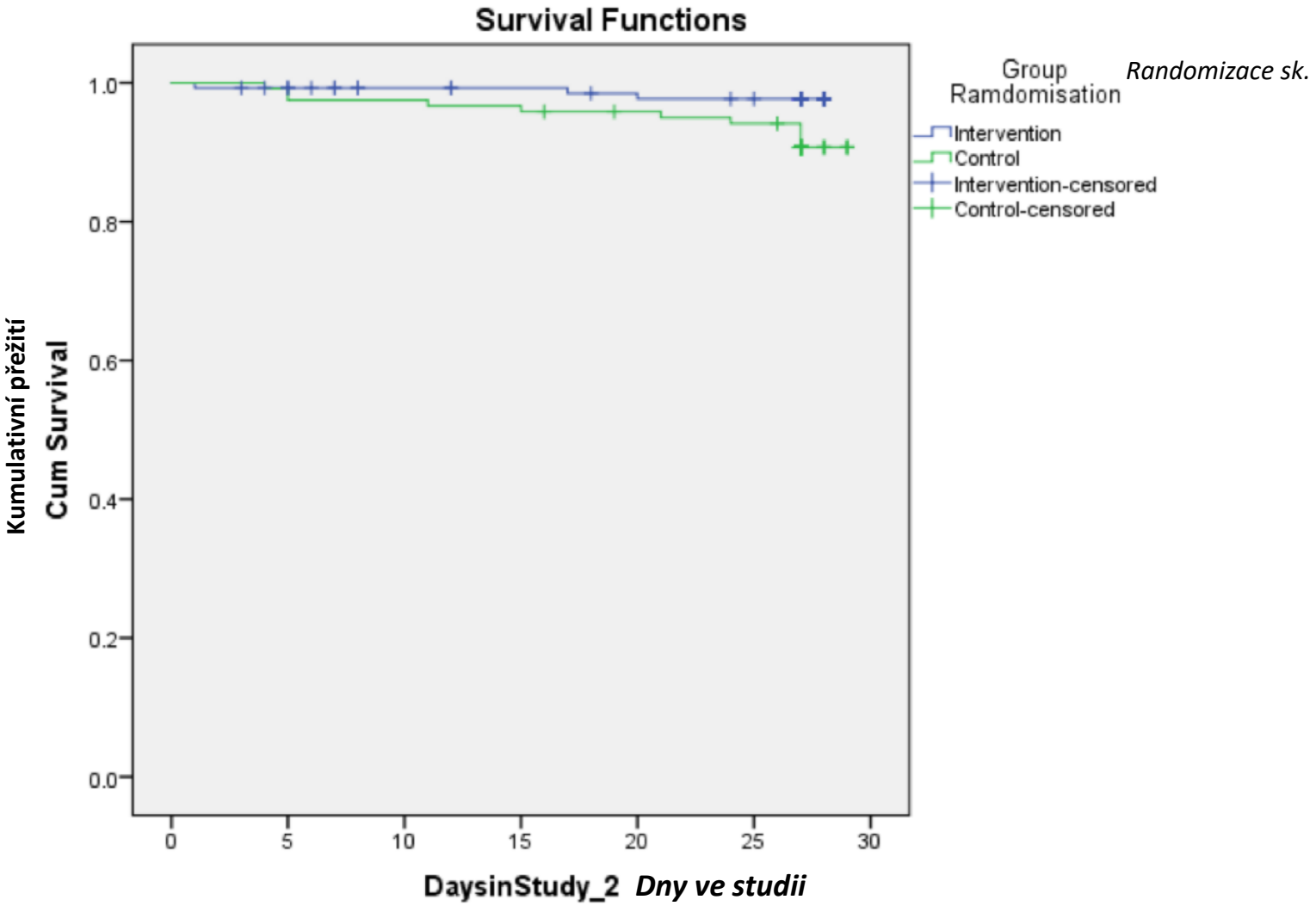
(International Wound Journal)

Pressure ulcer development *(vznik dekubitů)*	**Control** *(kontrol. sk.)* **N=150**	**Intervention** *(intervenční sk.)* **N=138**	**p**
Patients who developed PU *(pacienti, u kterých dekubit vznikl)*	16	3	0.004
Incidence (%) *(incidence v %)*	10.6	2.1	
Number of pressure ulcers *(počet dekubitů)*	18	5	0.001
Sacral pressure ulcers *(dekubity na sakru)* Stage I Stage II Stage III Stage IV DTI Unstageable	13 5 6 0 2	2 1 1	0.007
Heel pressure ulcers *(dekubity na patě)* Stage I Stage II	5 4 1	3 2 1	n.s

Pressure injury development over 4-week period

(Vývoj dekubitů v průběhu 4 týdnů)

Funkce přežití



- Intervention group incidence: 2.1%

  (incidence intervenční skupiny)

- Control group incidence: 10.6

  (incidence kontrolní skupiny)

- Relative risk reduction: 80%

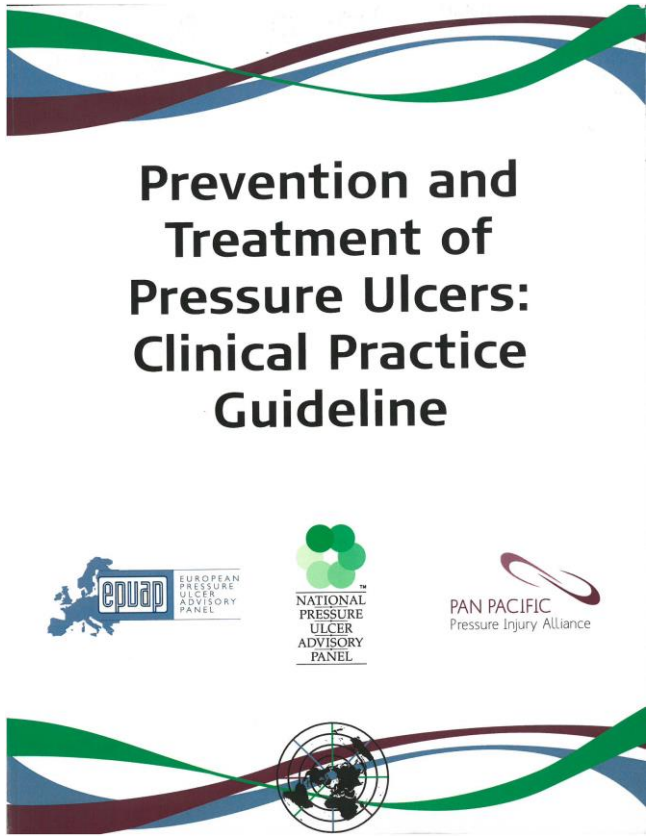
  (snížení relativního rizika)

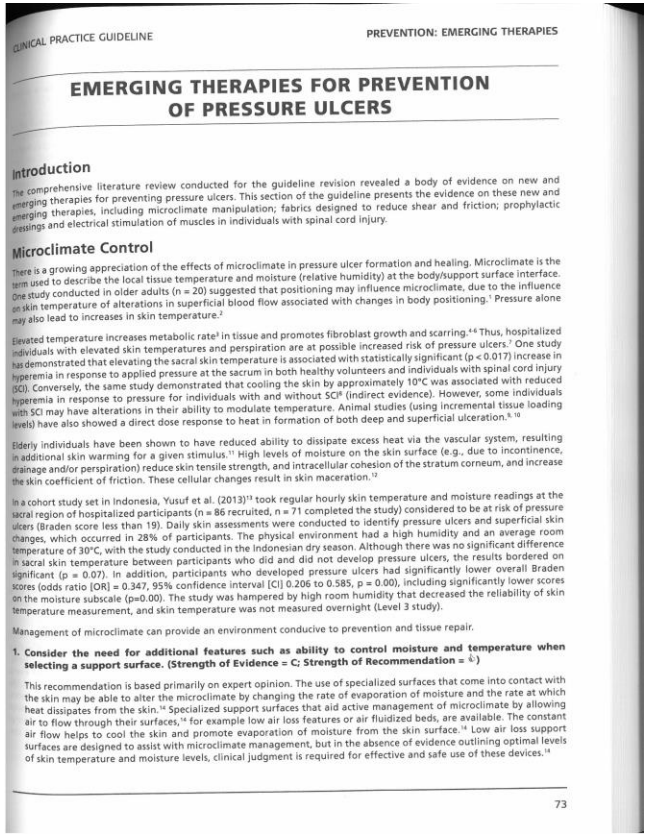
- Number needed to treat 12

  (počet dnů léčby)

International Pressure Ulcer Prevention Guidelines: Emerging Therapies

(Mezinárodní doporučení pro prevenci dekubitů: Vyvíjející se terapie)





CLINICAL PRACTICE GUIDELINE — PREVENTION: EMERGING THERAPIES

EMERGING THERAPIES FOR PREVENTION OF PRESSURE ULCERS

Introduction

The comprehensive literature review conducted for the guideline revision revealed a body of evidence on new and emerging therapies for preventing pressure ulcers. This section of the guideline presents the evidence on these new and emerging therapies, including microclimate manipulation; fabrics designed to reduce shear and friction; prophylactic dressings and electrical stimulation of muscles in individuals with spinal cord injury.

Microclimate Control

There is a growing appreciation of the effects of microclimate in pressure ulcer formation and healing. Microclimate is the term used to describe the local tissue temperature and moisture (relative humidity) at the body/support surface interface. One study conducted in older adults (n = 20) suggested that positioning may influence microclimate, due to the influence on skin temperature of alterations in superficial blood flow associated with changes in body positioning.[1] Pressure alone may also lead to increases in skin temperature.[2]

Elevated temperature increases metabolic rate[3] in tissue and promotes fibroblast growth and scarring.[4-6] Thus, hospitalized individuals with elevated skin temperatures and perspiration are at possible increased risk of pressure ulcers.[7] One study has demonstrated that elevating the sacral skin temperature is associated with statistically significant ($p < 0.017$) increase in hyperemia in response to applied pressure at the sacrum in both healthy volunteers and individuals with spinal cord injury (SCI). Conversely, the same study demonstrated that cooling the skin by approximately 10°C was associated with reduced hyperemia in response to pressure for individuals with and without SCI[8] (indirect evidence). However, some individuals with SCI may have alterations in their ability to modulate temperature. Animal studies (using incremental tissue loading levels) have also showed a direct dose response to heat in formation of both deep and superficial ulceration.[9,10]

Elderly individuals have been shown to have reduced ability to dissipate excess heat via the vascular system, resulting in additional skin warming for a given stimulus.[11] High levels of moisture on the skin surface (e.g., due to incontinence, drainage and/or perspiration) reduce skin tensile strength, and intracellular cohesion of the stratum corneum, and increase the skin coefficient of friction. These cellular changes result in skin maceration.[12]

In a cohort study set in Indonesia, Yusuf et al. (2013)[13] took regular hourly skin temperature and moisture readings at the sacral region of hospitalized participants (n = 86 recruited, n = 71 completed the study) considered to be at risk of pressure ulcers (Braden score less than 19). Daily skin assessments were conducted to identify pressure ulcers and superficial skin changes, which occurred in 28% of participants. The physical environment had a high humidity and an average room temperature of 30°C, with the study conducted in the Indonesian dry season. Although there was no significant difference in sacral skin temperature between participants who did and did not develop pressure ulcers, the results bordered on significant ($p = 0.07$). In addition, participants who developed pressure ulcers had significantly lower overall Braden scores (odds ratio [OR] = 0.347, 95% confidence interval [CI] 0.206 to 0.585, p = 0.00), including significantly lower scores on the moisture subscale (p=0.00). The study was hampered by high room humidity that decreased the reliability of skin temperature measurement, and skin temperature was not measured overnight (Level 3 study).

Management of microclimate can provide an environment conducive to prevention and tissue repair.

1. **Consider the need for additional features such as ability to control moisture and temperature when selecting a support surface. (Strength of Evidence = C; Strength of Recommendation = ↓)**

   This recommendation is based primarily on expert opinion. The use of specialized surfaces that come into contact with the skin may be able to alter the microclimate by changing the rate of evaporation of moisture and the rate at which heat dissipates from the skin.[14] Specialized support surfaces that aid active management of microclimate by allowing air to flow through their surfaces,[14] for example low air loss features or air fluidized beds, are available. The constant air flow helps to cool the skin and promote evaporation of moisture from the skin surface.[14] Low air loss support surfaces are designed to assist with microclimate management, but in the absence of evidence outlining optimal levels of skin temperature and moisture levels, clinical judgment is required for effective and safe use of these devices.[14]

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Guideline Available From: www.npuap.org

World Union of Wound Healing Societies Consensus Document 2016

(Konsenzuální dokument - Mezinárodní společnost organizací pro hojení ran 2016)

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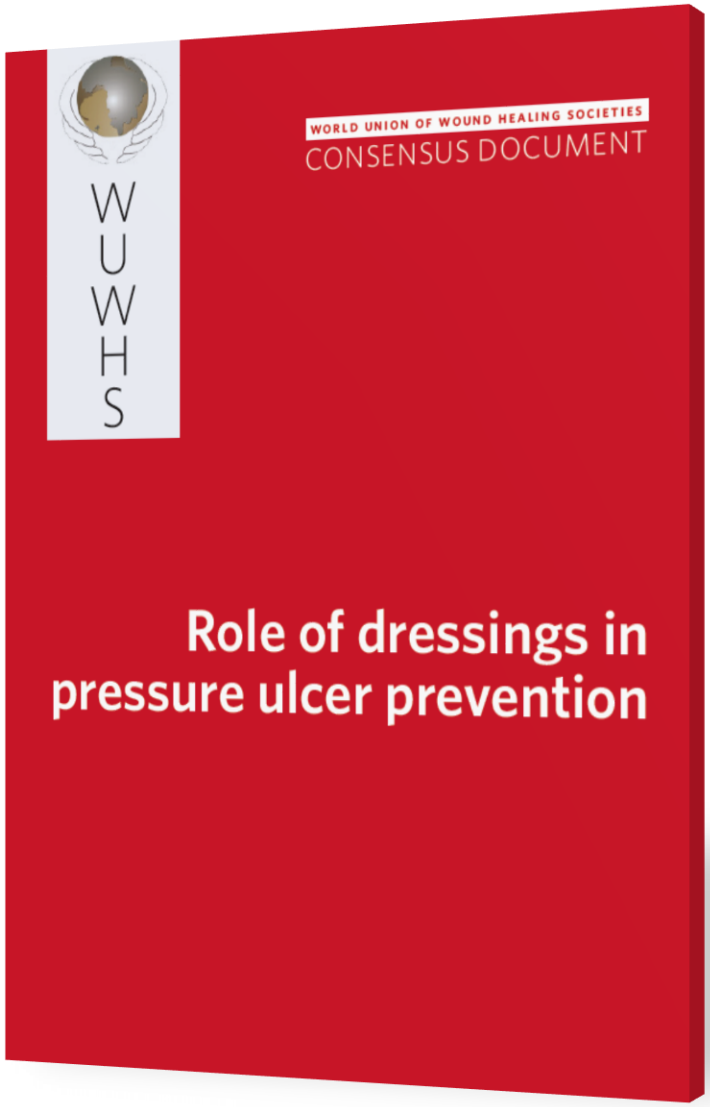

Mepilex Border dressings for preventing pressure ulcers

Medtech innovation briefing [MIB124] Published date: October 2017

Advice

Next ›

NICE has developed a medtech innovation briefing (MIB) on Mepilex Border

What is the level of evidence for the clinical effectiveness of foam dressings in PU prevention?

(Jaká je úroveň důkazů pro klinickou efektivitu pěnových krytí k prevenci dekubitů?)

	Mepilex Border	Allevyn Life	Aquacel Foam	Optifoam
• Meta-analysis/Systematic reviews	**3**	0	0	0
• Randomised controlled trials	**5**	1	0	0
• Non-randomised clinical/cohort study (Pros)	**7**	0	0	0
• Non-randomised clinical/cohort study (Retro)	**32**	2	1	0
• Case reports/Case series	**8**	2	1	0
• Expert opinion – Clin Pract Guidelines/Tech assessment	**28**	0	0	0
• Volunteer study	**2**	1	0	0
• Laboratory study	**9**	0	1	0