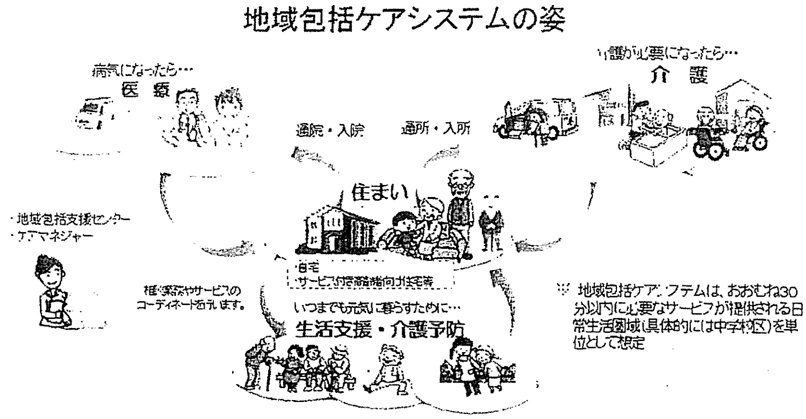

図2　地域包括ケアシステムのイメージ
（文献1）より引用一部改変）

常生活の場（日常生活圏域）で適切に提供できるような地域での体制」と定義されている．その際，地域包括ケア圏域については，「おおむね30分以内に駆けつけられる圏域を理想的な圏域として定義し，具体的には，中学校区を基本とするとしている．最終的に目指す姿は，図2[1]のような地域包括ケアシステムの構築である．高齢者の住まい，生活支援を基礎に，介護予防，医療，介護を整えることで，人口1万人程度の中学校区を単位とした，できるだけ長く暮らすことができる地域作りを目標としている．住民の安全・安心・健康を脅かす不安や危険としては，急病や病態の急変，虐待，引きこもり，地域での孤立等様々な状況が想定される．こうした問題に対応するサービスが，地域内の様々な社会資源の組み合わせやこれらを複合的に組み合わせたシステムの利用によって24時間365日を通じて提供されることが期待される．地域包括ケア報告書ではこのなかで特に，在宅医療は重要であり，この充実がなければ，このシステムは機能しないものと考えている．

現在，多くの地域でこの包括ケアシステムの構築を目指した活動が行われている．システム構築に関わる各地域の実施主体，理念，方法は様々であり，システムの中での在宅医療の位置づけもそれぞれ異なる．いずれにしても在宅医療の充実がなければ，地域包括ケアシステムの構築はできないため，中心となる事業体がどこになるかも含め，地域の実情に合わせて，柔軟に適切な在宅医療の形を形成する必要がある．

おわりに

急激に高齢化が進み社会構造が変化する中で「生活を支える」在宅医療への需要がさらに増加すると予想される．この状況に対し，住まいをベースに医療，介護，福祉サービスを含めた様々な生活支援サービスが日常生活の場（日常生活圏域）で適切に提供できるような地域での体制（地域包括ケアシステム）の構築が求められている．このシステムの構築においては，地域の高齢者数，医療提供体制等の実情に応じた柔軟な対応が必要である．地域の実践では認知症や終末期を含めた高齢患者とその家族の医学的，精神的，社会的なニーズを確認し，ニーズに応じて多職種ともに解決することができる人材が必要とされており，地域包括ケアシステムと在宅医療構築に関して，今後，老年科医の存在はより重要になると思われる．

文　献

1）厚生労働省ホームページ「在宅医療の推進について」http://www.mhlw.go.jp/seisakunitsuite/bunya/kenkou_iryou/iryou/zaitaku/index.html
2）厚生労働省報道発表資料2009年5月22日「地域包括ケア研究会報告書～今後の検討のための論点整理～」http://www.mhlw.go.jp/houdou/2009/05/h0522-1.html

Key words

在宅医療における多職種連携

独立行政法人国立長寿医療研究センター在宅連携医療部・臨床研究企画室長 千田一嘉

多職種連携は高齢者総合的機能評価（comprehensive geriatric assessment：CGA）と合わせて「老年医学の両輪」と例えられるように，超高齢社会のわが国における質が高く効率のよい在宅医療には必須である．1996年，Wangerらは高齢化に伴う慢性疾患患者の急増に，従来の臓器別・職種ごとの診療・ケア体制では機能不全をきたすため，多職種連携のチーム医療による「慢性疾患ケアモデル」を提唱した．的確な医療情報に基づく意思決定支援を踏まえた，多職種連携による医療・介護チームと患者・家族との協働作用が機能的にも臨床的にも良い結果に導く．2006年に米国老年医学会から「多職種連携の立場表明」が発表され（JAGS 54：849-852, 2006），多職種連携のケアが，①複雑な併存症を患う高齢者の複雑かつ多様なニーズに対応できる，②老年症候群のケアの過程と結果を改善する，③医療システムを改善し，介護者の負担を軽減する，さらに，多職種連携研修・教育は高齢者のケアに有用であることが提唱された．

多職種連携にはmulti-disciplinaryとinter-disciplinaryの二つの訳語がある．前者はそれぞれの職種が共有した情報（CGA）に基づいて，独立した立場で各自の職務を果たすことを指し，後者は公式にも非公式にもより開かれた，より頻回な情報交換にもとづく意思決定を共有しながら各自の専門性とその相互作用を発揮し，協働（Collaboration）・協調（Co-ordination）してケアすることであり，区別が必要である．Inter-professional work（IPW）はinterdisciplinary careとほぼ同義である．慢性かつ多種の併存症を患うことの多い高齢者のケアにおいてmultidisciplinaryな体制はより多くの人手を要し，医療・介護コストの面からも他の職種の役割まで熟知するinterdisciplinaryな姿勢が求められている．高い専門性を追求するだけではなく，職種間の隔壁を越えた幅広い視野に立って高齢者をケアできる資質が求められ，そのための研修体制の構築が重要となる．2004年，米国老年医学会誌（JAGS 52:1000-1006, 2004）の「職種間の隔壁（Disciplinary Split）：多職種チーム医療研修の阻害要因」は多職種連携を指導する者も受講者においても職種ごとで異なる心構えや文化の伝統が，多職種連携の研修を妨げると報告した．その解決策には多職種が一堂に会し，十分な時間をかけて異なる職種間の絆を固めることが，指導者と入門者にも必要とされた．わが国でも2012年に厚生労働省の在宅医療・介護推進プロジェクトにおける「在宅チーム医療を担う人材育成事業」が実施され，医療（日本医師会と在宅医療実践者）・介護・行政の三極が一堂に会し，共通の教材を用いて多職種連携を学んでいる．

Disability and Rehabilitation Assistive Technology

http://informahealthcare.com/idt
ISSN 1748-3107 print/ISSN 1748-3115 online

Disabil Rehabil Assist Technol, 2015; 10(2): 165–169

DOI: 10.3109/17483107.2013.867371

informa healthcare

PRODUCTS AND DEVICES

Development and evaluation of a self-regulating alternating pressure air cushion

Gojiro Nakagami[1], Hiromi Sanada[1], and Junko Sugama[2]

[1]*Department of Gerontological Nursing/Wound Care Management, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan and*
[2]*Wellness Promotion Science Center, Institute of Medical, Pharmaceutical and Health Sciences, Kanazawa University, Ishikawa, Japan*

Abstract

Purpose: To investigate the effect of alternating air cells of a newly developed dynamic cushion on interface pressure and tissue oxygenation levels. *Method*: This cross-over experimental study included 19 healthy volunteers. The dynamic cushion used has an automatic self-regulating alternating pressure air-cell system with 35 small and four large air cells for maintaining posture while seated. This cushion also has 17 bottoming-out detectors that automatically inflate the air cells to release a high interface pressure. To assess the effect of this alternating system, participants sat on the new cushion with an alternating system or static system for 30 min and then performed push-ups. The interface pressure was monitored by pressure-sensitive and conductive ink film sensors and tissue oxygenation levels were monitored by near-infrared spectroscopy. A reactive hyperaemia indicator was calculated using tissue oxygenation levels as an outcome measure. *Results*: The peak interface pressure was not significantly different between the groups. The reactive hyperaemia indicator was significantly higher in the static group than in the alternating group. *Conclusions*: An alternating system has beneficial effects on blood oxygenation levels without increasing interface pressure. Therefore, our new cushion is promising for preventing pressure ulcers with patients with limited ability to perform push-ups.

Keywords

Blood flow, dynamic cushion, interface pressure, pressure ulcer, prevention, push-ups

History

Received 19 June 2013
Revised 19 October 2013
Accepted 15 November 2013
Published online 9 December 2013

➤ Implications for Rehabilitation

- A dynamic cushion was developed, which consists of a uniquely-designed air-cell layout, detectors for bottoming out, and an alternating system with multiple air-cell lines.
- The alternating system did not increase interface pressure and it significantly reduced reactive hyperaemia after 30 min of sitting in healthy volunteers.
- This cushion is a new option for individuals who require stable posture but have limitations in performing scheduled push-ups for prevention of pressure ulcers.

Introduction

Pressure ulcers are common complications in elderly and acute-care patients. In Japan, the prevalence of pressure ulcers is 3.64% in acute care settings, and once a pressure ulcer develops, it tends to deteriorate because of the patient's physical characteristics, such as an extreme bony prominence, and poor medical conditions, including ageing, malnutrition or the presence of diabetes mellitus [1–3]. Once developed, pressure ulcers can cause a high cost burden. The cost for treating a pressure ulcer varies according to its severity from 1064 pounds for a Grade 1 pressure ulcer (European Pressure Ulcer Advisory Panel classification) to 10 551 pounds for Grade 4, and most of this cost is accounted for nursing time in the UK [4,5]. Therefore, the prevention and effective treatment of pressure ulcers have been increasingly gaining national attention. Pressure ulcers, which occur while patients are lying down and bedridden, have been successfully decreased because of the use of a pressure redistribution mattress. However, pressure ulcers, which occur while in the sitting position, remain a challenging issue, especially in elderly and spinal cord injury patients [6]. This is partly because of the lack of an appropriate cushion, which is properly fitted to the bony prominence of thin buttocks when remaining in the sitting position for many hours a day, thus resulting in the occurrence of bottoming out.

Cushions commonly used in the clinical setting include urethane foam and air-cell cushions [7,8]. Urethane foam redistributes interface pressure by immersion produced according to the individual's body weight. However, when patients have

Address for correspondence: Hiromi Sanada, Department of Gerontological Nursing/Wound Care Management, Graduate School of Medicine, The University of Tokyo, Faculty of Medicine Bldg. No. 5-301, Hongo 7-3-1 Bunkyo-ku, Tokyo 113-0033, Japan. Tel/Fax: +81-3-5841-3419. E-mail: hsanada-tky@umin.ac.jp

Disabil Rehabil Assist Technol, 2015; 10(2): 165–169

a low body weight (e.g. elderly Japanese patients), the cushion cannot immerse appropriately, causing a relatively high interface pressure [9]. Another way to prevent pressure ulcers under the present circumstances is to increase the contact area by enveloping the curvature of the buttocks to reduce interface pressure. However, stress to the tissues near the bony prominence of the ischial tuberosity or coccyx can remain even when applying this principle to those sitting on a cushion [10]. Additionally, because of the troublesome technique for adjusting inner air cell pressure, this tends to increase the risk of bottoming out under inappropriate inner air-cell pressure [11]. The cushions commonly used in the clinical setting are static without alternating the air cells because of the limitation of power supplying technology. This leads to a long duration of tissue loading, resulting in an increased risk of tissue hypoxia. Tissue hypoxia is caused by decreased tissue oxygenation, which finally progress to pressure ulcer development [12]. To address these problems, we developed an alternating pressure air cushion with an automatic bottoming-out releasing system.

The purpose of this study was to evaluate the effect of an alternating system on tissue oxygenation levels in healthy volunteers.

Methods

Features of the developed cushion

This automatic self-regulating alternating pressure air-cell cushion consists of 35 small and four large air cells of which height is not even, but is approximately 9 cm to provide stable seating based on our previous study of pressure mapping in elderly Japanese patients (Figure 1) [13]. Seven electromagnetic valves, two air-pressure monitoring sensors, 17 bottoming-out detectors placed to cover the bony region, an air pump, a battery and a microprocessor are incorporated into the cushion. When bottoming out, the electronic system automatically inflates the contributing air cells to release the bottoming out (Figure 2). This dynamic cushion is now commercially available in Japan (Medi-Air 1, The Yokohama Rubber Co., Ltd., Tokyo, Japan).

Study participants

We recruited healthy volunteers to participate in this cross-over experimental study under the approval of the study protocol of the local ethical committee. Written informed consent was obtained prior to the start of this study. We recruited participants balanced in body mass index. The participants' characteristics are summarised in Table 1.

Study procedure

To address the hypothesis that a cushion with an alternating system induces less tissue oxygen depletion, which results in lower levels of reactive hyperaemia than a cushion with a static system, we performed a cross-over experimental study. The participants were assigned to both the alternate and the static groups in a random order. The alternate group received a 5-min static phase with 1-min alternating phases (Figure 3). The static group received only the static phase. Participants rested for 10 min prior to the start of the protocol to allow tissue oxygenation levels to become stable. After this time, the participants were asked to stay seated at rest on the cushion with the alternating or static system for 30 min. After 30 min, they were asked to perform push-ups by raising their body off the seat by pushing on their arms of the chair [14]. Although the recommendation period of push-up for pressure ulcer prevention among spinal cord injured people is 15 min, we set 30 min for this experiment because 15 min might not induce any blood flow reduction or ischaemia which induces reactive hyperaemia [15].

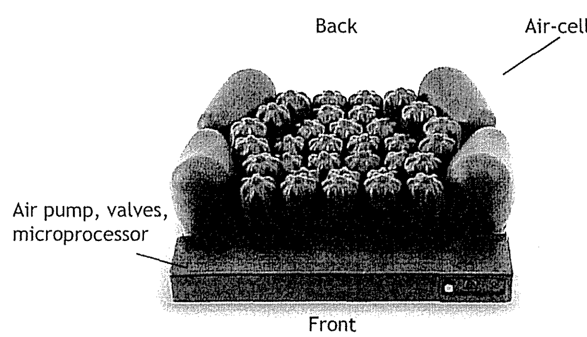

Figure 1. Composition of the dynamic air-cell cushion used. The front mechanics consists of an air pump, valves and a microprocessor, which enables the cushion to automatically adjust the inner air-cell pressure to be optimal in cooperation with the bottoming-out detecting sensors (see Figure 2). Urethane foam on the front mechanics is arranged to avoid local pressure caused by direct contact with the base.

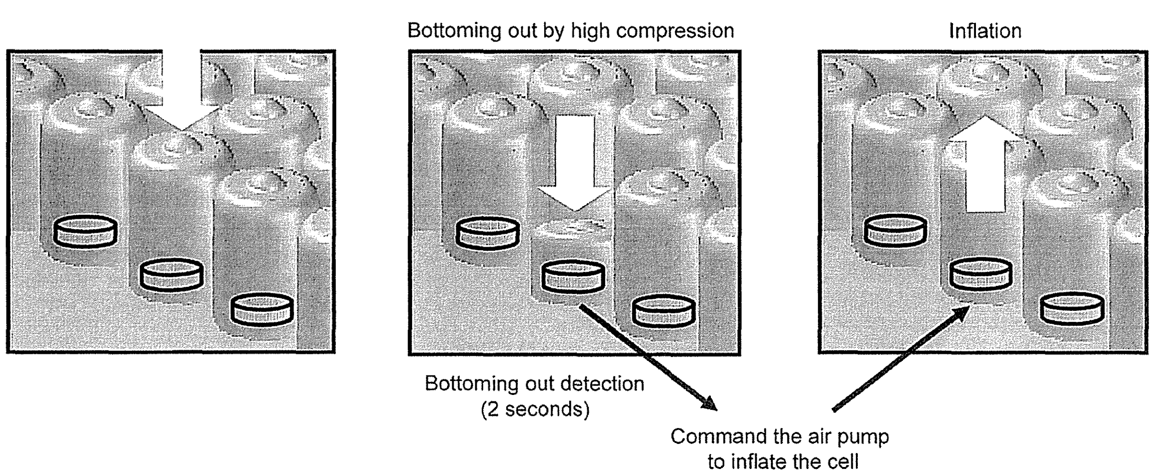

Figure 2. Bottoming-out releasing system. When the sensors detect bottoming out continuing for 2 s, the air-cell line where the bottoming out occurs will inflate to release the bottoming out.

Parameters

Interface pressure was monitored by pressure-sensitive and conductive ink film sensors (CONFORMat, Nitta Co., Osaka, Japan) [16]. The sensor mat was 471.4 mm × 471.4 mm, with a thickness of 1.8 mm. The sensor consists of 1024 cells with each sensing area of 2.2 cm^2 organised in an array of sensing resistors contained in a flexible material base. The cells contain ink, the electrical resistance of which varies with applied force, sandwiched between two layers of a polyester film. The resistance change of the sensors varies inversely with the applied force. The characteristics of the sensor for applications were as follows: the creep rate was 13.5%/2–180 s, repeatability was 3.9%, linearity was 2.9%, and hysteresis was 4.6%. The sensor was calibrated according to the manufacturer's recommendations on every measurement day. The peak pressure on the ischial tuberosity region and contact area was measured.

Table 1. Characteristics of participants.

No. of subjects	19
Age; years	32.1 (8.7)
Female	14 (73.9)
Body weight; kg	54.0 (8.8)
Body Mass Index; kg/m^2	
–18.5	5 (26.3)
18.6–25.0	12 (63.2)
25.1–	2 (10.5)

Mean with standard deviation, number (%).

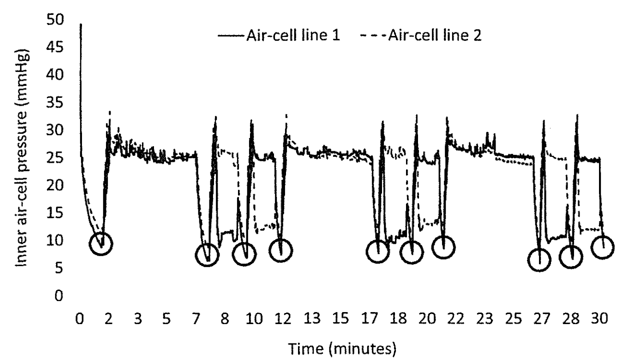

Figure 3. Automatic inner air-cell adjustment system. The circles indicate the time when the sensors detect bottoming out. This alternating cushion has two air-cell lines, thus when one air-cell line deflates for alternation, the other air-cell line (opposite air-cell line) keeps its inner air cell pressure. Initially all air cells deflate until bottoming out occurs (circle). After releasing the bottoming out, the static phase continues for 5 min at the optimal inner air cell pressure level. Thereafter, all air cells deflate again until bottoming out occurs and inflate to the optimal inner air-cell pressure level. During the first alternate phase, one air-cell line (solid line) deflates for 1 min and inflates again. During the second alternate phase, the other air-cell line (dashed line) deflates and inflates as in the first alternate phase. The static and alternate phases continue to repeat.

Tissue oxygenation was monitored by near-infrared spectroscopy (NIRO-200, Hamamatsu Photonics K.K., Hamamatsu, Japan) at a sampling rate of 2 Hz [17]. The probe was placed on the skin above the ischial tuberosity. To assess the effectiveness of the alternating system of this cushion, we calculated a reactive hyperaemia indicator (RHI) in the ischial tuberosity region. The RHI was calculated by subtracting the averaged value from the beginning to the time just before push-ups from the peak value of oxygenated haemoglobin just after push-ups (Figure 4) [18]. This measurement was based on the fact that the degree of reactive hyperaemia is dependent on the degree of congestion, which was continued under a sitting environment on the ischial tuberosity. A higher value indicates more severe congestion.

Statistical analysis

To compare parameters within the two groups, the alternating group and the static group, we used the paired *t*-test. All statistical analyses were performed using Statistical Analysis System Ver. 9.1 (SAS Institute Inc., Cary, NC). Values are presented as means with standard deviation (SD).

Results

During the course of the experiment, the peak interface pressure was not significantly different between the alternating and static groups at the right and left ischial trochanter regions ($p = 0.426$, $p = 0.975$, respectively) (Table 2). The contact area was significantly reduced in the alternating group compared with the static group ($p = 0.006$).

The RHI was significantly higher in the static group than in the alternating group ($p = 0.003$).

Discussion

This cross-over study examined the effect of an alternating system of a newly developed dynamic cushion on tissue oxygenation at the ischial tuberosity while sitting in healthy volunteers.

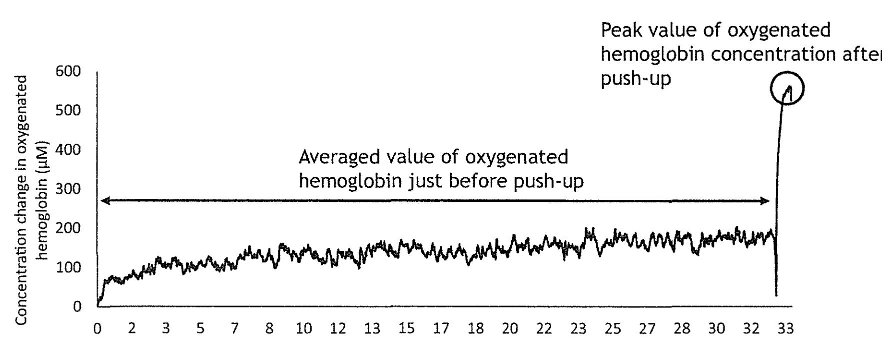

Figure 4. Schematic explanation of the reactive hyperaemia indicator. The participants were asked to stay seated at rest on the cushion for 30 min. After 30 min, they were asked to perform push-ups. The reactive hyperaemia indicator was defined as the difference between the peak value of oxygenated haemoglobin and the average value just before push-ups; a higher value indicates more severe congestion.

Table 2. Comparison of outcome parameters between the alternating and static groups.

	Alternate	Static	*p* Value
Interface pressure			
Peak pressure on IT region; mmHg			
Right	59.0 (14.3)	61.7 (15.7)	0.426
Left	72.5 (18.9)	72.7 (18.1)	0.975
Contact area; cm^2	1055.6 (257.0)	1095.2 (240.8)	0.006
Tissue oxygenation			
Reactive hyperaemia indicator; ΔμM	514.4 (281.4)	592.8 (302.6)	0.003

IT, ischial tuberosity. Mean with standard deviation.
Paired *t*-tests.

We observed reduced reactive hyperaemia by sitting on the cushion with the alternating system compared with the static system.

Interface pressure measures showed that peak interface pressure on the ischial tuberosities was unchanged, but the contact area was significantly reduced in the alternating group compared with the static group. This finding indicated that alternating air cells reduced the contact area, while certain air cell lines deflated to release interface pressure, which did not induce an unfavourable increase in peak interface pressure. Generally, the alternating pressure air system has an increased risk of high interface pressure because of a decreased contact area. Our new system did not induce an increase in interface pressure, which is acceptable for reducing the risk of pressure ulcer development. This may partly be because of the air-cell layout of the cushion used. The cushion has large air cells on the edge to support the user's posture, which might prevent unfavourable sinking of the user's body to avoid an increase in interface pressure in the region of air cells from the other air-cell line [13,19].

Notably, this cushion has a beneficial effect on tissue oxygenation using the alternating system and it maintains the users' interface pressure at a lower level than that of users on conventional, unpowered air-cell cushions [20]. Our previous study showed that mono and multi air-cell lines were significantly different in interface pressure (e.g. the mono air-cell line inflates interface pressure over time but multi air-cell lines do not). The present study showed similar values of interface pressure in the alternating and static groups, which indicates that the unique air-cell layout also contributes to the stability of interface pressure, and the number of air-cell lines in this cushion. Also, the alternating group showed reduced reactive hyperaemia compared with the static group. Taken together, our results suggested that the dynamic movement of the participant's body and pressure release during the alternating phase were effective for preserving tissue oxygenation levels. To prevent pressure ulcers while sitting, patients are recommended to perform push-ups to release interface pressure because it is relatively higher than that occurring while lying on a mattress. However, difficulty exists for individuals with a high risk of pressure ulcers because of reduced ability to support their body weight by their arms, especially in elderly patients, leading to pressure ulcer development. The present study showed the possibility of decreasing the risk of pressure ulcer development for persons who need to perform constant push-ups to reduce the effect of loading on tissue oxygenation levels. Use of our new system along with the other pressure redistributing devices would be beneficial for pressure high risk individuals under such circumstance. Additionally, we considered that the unique layout can prevent improper posture for whom without ability to conduct independent weight shifts and transfers and likely to slide forward into a "sacral seating position", which induce unfavourable shearing and cause pressure ulcer development at the coccyx region. Our experiment did not investigate such preventive effect, thus further study is needed to reveal the shear force reduction.

To date, the effect of an alternating pressure system has been investigated for individuals on a mattress. Therefore, clinicians and researchers were unable to generalise these reports to the situation for individuals on a cushion, which produces a higher interface pressure than lying on a mattress [21]. The current study results could have a significant impact for selecting an appropriate cushion for pressure ulcer prevention while sitting.

Because tissue oxygenation differs among individuals, we standardised values using averaged values from the beginning of the experiment to just before performing push-ups. We also attempted to reduce individual differences by adopting a cross-over experimental design using the same participant for both the alternating and the static systems. Higher RHI values indicate a more severe degree of blood congestion because of interface pressure applied while seated. We assumed that severe blood congestion induces a higher level of reactive hyperaemia. This assumption would be true at least in healthy volunteers. A previous study reported that spinal cord injured patients have a reactive hyperaemia response, which is not substantially different from able-bodied subjects [22]. Therefore, it is reasonable to generalise our results to this population. Further investigation on the effectiveness of the alternating system on tissue oxygenation in elderly or spinal cord injury patients is required.

Declaration of interest

The authors alone are responsible for the content and writing of this article.

The cushion used in this study was co-developed and provided by The Yokohama Rubber Co., Ltd., Japan. Professor Hiromi Sanada holds patents of the principle mechanics of the cushion.

References

1. Sanada H, Miyachi Y, Ohura T, et al. The Japanese Pressure Ulcer Surveillance Study: a retrospective cohort study to determine the prevalence of pressure ulcers in Japanese hospitals. WOUNDS 2008; 20:176–82.
2. Thomas DR. Issues and dilemmas in the prevention and treatment of pressure ulcers: a review. J Gerontol A Biol Sci Med Sci 2001;56: M328–40.
3. Smith BM, Guihan M, LaVela SL, Garber SL. Factors predicting pressure ulcers in veterans with spinal cord injuries. Am J Phys Med Rehabil 2008;87:750–7.
4. Bennett G, Dealey C, Posnett J. The cost of pressure ulcers in the UK. Age Ageing 2004;33:230–5.
5. Beeckman D, Schoonhoven L, Fletcher J, et al. EPUAP classification system for pressure ulcers: European reliability study. J Adv Nurs 2007;60:682–91.
6. Eslami V, Saadat S, Habibi Arejan R, et al. Factors associated with the development of pressure ulcers after spinal cord injury. Spinal Cord 2012;50:899–903.
7. Hamanami K, Tokuhiro A, Inoue H. Finding the optimal setting of inflated air pressure for a multi-cell air cushion for wheelchair patients with spinal cord injury. Acta Med Okayama 2004;58:37–44.
8. de Abreu DC, Takara K, Metring NL, et al. Interference of different types of seats on postural control system during a forward-reaching task in individuals with paraplegia. Int J Rehabil Res 2012;35: 208–13.
9. Iizaka S, Nakagami G, Urasaki M, Sanada H. Influence of the "hammock effect" in wheelchair cushion cover on mechanical loading over the ischial tuberosity in an artificial buttocks model. J Tissue Viability 2009;18:47–54.
10. Wagnac EL, Aubin CE, Dansereau J. A new method to generate a patient-specific finite element model of the human buttocks. IEEE Trans Biomed Eng 2008;55:774–83.

11. Werner P, Perkash I. Warning mat to signal air seat cushion failure. Arch Phys Med Rehabil 1982;63:188–90.
12. Mayrovitz HN, Smith J. Heel-skin microvascular blood perfusion responses to sustained pressure loading and unloading. Microcirculation 1998;5:227–33.
13. Urasaki M, Nakagami G, Sanada H, et al. Interface pressure distribution of elderly Japanese people in the sitting position. Disabil Rehabil Assist Technol 2011;6:38–46.
14. Merbitz CT, King RB, Bleiberg J, Grip JC. Wheelchair push-ups: measuring pressure relief frequency. Arch Phys Med Rehabil 1985; 66:433–8.
15. Consortium for Spinal Cord Medicine Clinical Practice Guidelines. Pressure ulcer prevention and treatment following spinal cord injury: a clinical practice guideline for health-care professionals. J Spinal Cord Med 2001;24:S40–101.
16. Gutierrez EM, Alm M, Hultling C, Saraste H. Measuring seating pressure, area, and asymmetry in persons with spinal cord injury. Eur Spine J 2004;13:374–9.
17. Wong FY, Nakamura M, Alexiou T, et al. Tissue oxygenation index measured using spatially resolved spectroscopy correlates with changes in cerebral blood flow in newborn lambs. Intensive Care Med 2009;35:1464–70.
18. Sprigle S, Linden M, Riordan B. Characterizing reactive hyperemia via tissue reflectance spectroscopy in response to an ischemic load across gender, age, skin pigmentation and diabetes. Med Eng Phys 2002;24:651–61.
19. Tasker LH, Shapcott NG, Watkins AJ, Holland PM. The effect of seat shape on the risk of pressure ulcers using discomfort and interface pressure measurements. Prosthet Orthot Int 2013. [Epub ahead of print]. doi: 10.1177/0309364613486918.
20. Fujikawa J, Nakagami G, Akase T, et al. Evaluation of pressure redistribution using new dynamic cushion for the elderly. Jpn J Pressure Ulcers 2010;12:28–35 (in Japanese).
21. Goetz LL, Brown GS, Priebe MM. Interface pressure characteristics of alternating air cell mattresses in persons with spinal cord injury. J Spinal Cord Med 2002;25:167–73.
22. Hagisawa S, Ferguson-Pell M, Cardi M, Miller SD. Assessment of skin blood content and oxygenation in spinal cord injured subjects during reactive hyperemia. J Rehabil Res Dev 1994;31:1–14.

Geriatrics Gerontology INTERNATIONAL Medline Indexed

Geriatr Gerontol Int 2014

Clinical validity of the estimated energy requirement and the average protein requirement for nutritional status change and wound healing in older patients with pressure ulcers: A multicenter prospective cohort study

Shinji Iizaka,[1] Toshiko Kaitani,[2] Gojiro Nakagami,[1] Junko Sugama[3] and Hiromi Sanada[1]

[1]*Department of Gerontological Nursing/Wound Care Management, Division of Health Sciences and Nursing, Graduate School of Medicine, The University of Tokyo, Tokyo,* [2]*School of Nursing, Sapporo City University, Hokkaido, and* [3]*Division of Health Sciences, Graduate School of Medical Science, Kanazawa University, Ishikawa, Japan*

Aim: Adequate nutritional intake is essential for pressure ulcer healing. Recently, the estimated energy requirement (30 kcal/kg) and the average protein requirement (0.95 g/kg) necessary to maintain metabolic balance have been reported. The purpose was to evaluate the clinical validity of these requirements in older hospitalized patients with pressure ulcers by assessing nutritional status and wound healing.

Methods: This multicenter prospective study carried out as a secondary analysis of a clinical trial included 194 patients with pressure ulcers aged ≥65 years from 29 institutions. Nutritional status including anthropometry and biochemical tests, and wound status by a structured severity tool, were evaluated over 3 weeks. Energy and protein intake were determined from medical records on a typical day and dichotomized by meeting the estimated average requirement. Longitudinal data were analyzed with a multivariate mixed-effects model.

Results: Meeting the energy requirement was associated with changes in weight ($P < 0.001$), arm muscle circumference ($P = 0.003$) and serum albumin level ($P = 0.016$). Meeting the protein requirement was associated with changes in weight ($P < 0.001$) and serum albumin level ($P = 0.043$). These markers decreased in patients who did not meet the requirement, but were stable or increased in those who did. Energy and protein intake were associated with wound healing for deep ulcers ($P = 0.013$ for both), improving exudates and necrotic tissue, but not for superficial ulcers.

Conclusions: Estimated energy requirement and average protein requirement were clinically validated for prevention of nutritional decline and of impaired healing of deep pressure ulcers. **Geriatr Gerontol Int 2014; ••: ••–••.**

Keywords: dermatology, energy, nursing, nutrition, wound.

Introduction

Energy and protein are indispensable in promoting pressure ulcer (PrU) healing, because they serve important roles as fuel for various cells, including inflammatory cells and fibroblasts, and as components of tissue repair.[1–4] Energy and protein intake also protect against loss of weight and lean mass in the elderly.[5] The current recommended macronutrient intake for patients with PrU is generally 30–35 kcal/kg of energy and 1.25–1.5 g/kg of protein.[6] However, the appropriateness of these values is controversial without adequate evidence, and thus the recommended intake levels vary among different guidelines.[6–8] Nutritional requirements are generally determined based on the level at which metabolic balance is maintained, considering probability of deficiency.[9] Maintaining metabolic balance is of particular importance for patients with PrU, because the condition itself causes increased catabolism.[10,11] The current recommendations in PrU guidelines, however, are extrapolated from clinical trials that evaluated the effect of oral nutritional supplements in promoting

Accepted for publication 26 September 2014.

Correspondence: Mr Shinji Iizaka RN PhD, Department of Gerontological Nursing/Wound Care Management, Graduate School of Medicine, The University of Tokyo, Faculty of Medicine Bldg. no. 5-308, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan. Email: iizaka-tky@umin.ac.jp

wound healing, but that less clearly evaluated changes in nutritional status.[12–14] In these studies, determining optimal intake levels has also been complicated by the fact that most studies have set a uniform supplementation regimen (e.g. 200 mL of supplements) for a relatively homogeneous group with limited inclusion criteria.

Several recent studies have reported energy and protein requirements based on metabolic measurements. A meta-analysis reported average resting energy expenditure and calculated an estimated energy requirement of 29.2 kcal/kg with an activity factor.[15] Another study investigated nitrogen balance and proposed an average protein requirement of 0.95 g/kg.[10] These estimated dietary requirements seem validated to maintain temporal metabolic balance. However, their clinical validity with changes in physiological status, including weight changes or wound healing, remains unclear. The safety of these requirements also needs to be evaluated, because excessive protein intake could have negative effects on frail older patients, such as increased urea synthesis in the liver and decreased renal function.[16]

The aim of the present multicenter prospective cohort study was to evaluate the clinical validity of the estimated energy and average protein requirements proposed in previous metabolic studies by assessing the short-term changes in nutritional status, wound status, and adverse effects in older patients with PrU.

Methods

Study design

This multicenter prospective cohort study was carried out as a secondary analysis of a clustered nonrandomized controlled trial conducted across Japan between March and October 2009. The purpose of the original trial was to investigate the effect of advanced wound management provided by trained wound, ostomy and continence Nurses (WOCN) on PrU healing. The hospitals were non-randomly assigned to either the intervention WOCN group or the control WOCN group. The intervention group provided advanced wound management including ultrasonographic diagnosis and so on for patients as required, according to PrU status.[17] The control group provided usual wound care. Because the intervention program did not include nutritional care, the two groups were comparable in terms of nutritional management.

Participants

A total of 29 hospitals were recruited from across Japan (14 general hospitals, 12 university hospitals and 3 long-term facilities). Patients with at least one PrU who were hospitalized during the study period were included. Those who were discharged within 1 week were excluded. The current analysis included only patients aged ≥65 years ($n = 268$). Exclusion criteria in the current analysis were patients who died during follow up ($n = 6$), those who underwent amputation ($n = 2$) and those whose weight was not measured at entry ($n = 66$), because weight was required to calculate nutritional intake.

Procedures

This survey used the pooled data of both groups. Clinicians in both groups provided standard wound care based on Japanese guidelines for PrU treatment, including wound dressings, topical agents, cleansing, continence care and pressure-redistributing care.[7] All patients received an individualized nutritional plan as determined by local doctors and dietitians based on their clinical condition.

Patients were followed for 3 weeks or until hospital discharge. Nutritional status and biochemical indicators of adverse effects were evaluated at baseline and at 3 weeks. PrU status was re-evaluated weekly by local WOCN. Nutritional intake was evaluated at baseline. Before the survey was initiated, researchers explained data collection, including anthropometric measurements using illustrations, to WOCN. The study protocol was approved by the ethical committee of the Graduate School of Medicine at the University of Tokyo (#2436) and by each participating institution. Written informed consent was obtained from all patients or from their proxy.

Data collection

Patient demographics, including age, sex, comorbidities and the Braden scale as an indicator of PrU risk status, were collected from medical charts.[18]

Nutritional status was evaluated based on weight, body mass index, anthropometric measurements and biochemical tests. Weight data were collected from the medical chart. Ward nurses in each institution measured weight at least once a month as the usual care by chair- or bed scales based on the patient's functional level. Arm circumference and triceps skin-fold thickness were measured at the middle of the non-dominant upper-arm using a plastic measure by each local WOCN to calculate arm muscle circumference (AMC) based on the standard procedure.[19] Serum levels of albumin, C-reactive protein, blood urea nitrogen (BUN) and creatinine were measured according to the hospital's standard procedures, and data were collected from the preceding week's medical charts. The estimated glomerular filtration rate (eGFR) was evaluated as a marker of adverse effects of protein intake.

Each WOCN evaluated wound location, wound severity (according to the DESIGN-R tool), type of support surface and number of ulcers. In patients with multiple PrU, the most severe lesion, defined as that with the highest DESIGN-R total score, was targeted. The DESIGN-R tool evaluates PrU severity using seven criteria: depth, exudate, size, inflammation/infection, granulation tissue, necrotic tissue and pocket (undermining).[20,21] A total DESIGN-R score ranging from 0 (healed) to 66 (most severe) was calculated from the six items, excluding depth, to determine the overall severity of PrU. Depth was classified as either superficial, including persistent redness and dermal wounds, or deep extending to the subcutaneous tissue. The wound area, including undermining, was measured by a tracing film (VISITRAK; Smith & Nephew, London, UK).[22]

Nutritional intake was evaluated based on nursing records from a typical day at baseline. Nursing records contained data on the proportion of dietary intake at each meal, and the content and volume of all supplements and infusions. Data on the energy and protein content of each meal were also collected from the dietary menus. If patients were temporally fasted (e.g. before a gastrointestinal examination), dietary assessment was carried out the following day. Daily energy and protein intake per bodyweight were calculated. For nutrients given orally and enterally, the digestion/absorption efficiency was assumed to be 90%, based on the dietary reference for Japanese, whereas efficiency for nutrients given parenterally was 100%, to adjust for differences in nutritional routes.[23] Nutritional intake was included in the analysis as a continuous or a categorical variable. The cut-off points were set at 30 kcal/kg for energy and 0.95 g/kg for protein.[10,15] A protein requirement of 0.75 g/kg was used for patients with renal insufficiency.[10]

Statistical analysis

Descriptive data are expressed as mean (SD) for continuous variables and *n* (%) for categorical variables. All analyses were carried out with SAS version 9.3 (SAS Institute, Cary, NC, USA).

Relationships between nutritional intake and changes in outcome variables were evaluated with an interaction term using a linear mixed-effects model that included follow-up weeks as a repeated variable with a first-order autoregressive covariance structure. Outcome variables were nutritional status (body mass index, AMC and serum albumin) and wound status (DESIGN-R scores and area) over a 3-week period. For wound status, the model was stratified by wound depth, because healing time varied by depth.[21] All models were adjusted for baseline levels of outcome variables. Covariates for the full adjusted models included patient characteristics (age, sex, comorbidities and Braden score), facility type, baseline nutritional status, nutritional route, allocated groups (intervention *vs* control), the interaction of time-effect and allocated groups, wound location, baseline DESIGN-R depth and total score, types of support surfaces, and the number of ulcers. For changes in BUN and eGFR, the same protocol was used with stratification by renal insufficiency (eGFR <60 mL/min/1.73 m^2).[24]

Results

Among 194 eligible patients, 128 (66.0%) were recruited from general hospitals, 48 (24.7%) from university hospitals and 18 (9.3%) from long-term care hospitals. Patient demographic data are shown in Table 1. The mean patient age (SD) was 80.7 years (7.5 years), and 47.9% were women. Deep ulcers accounted for 63.4% of lesions. The most frequent route of nutrition was parenteral nutrition alone (34.0%). The mean (SD) of energy and protein intake per day were 18.9 kcal/kg (13.2 kcal/kg) and 0.61 g/kg (0.60 g/kg), respectively. The correlation between energy and protein intake was 0.87 ($P < 0.001$). A total of 45 (23.2%) patients met the requirement for energy, and 63 (32.5%) met the requirement for protein.

After 3 weeks, 157 patients were examined at follow up. Of these, PrU had healed in 42. The reasons for dropout were death ($n = 17$), discharge ($n = 16$) and other ($n = 4$). In the preliminary analysis, there were significant associations between energy and protein intake as a continuous variable, and changes in weight, serum albumin and AMC in the fully adjusted models ($P < 0.05$ for each). The association between nutritional intake and PrU healing was significant for deep PrU ($P < 0.05$), but not for superficial PrU.

When energy intake was classified according to the estimated requirement, patients receiving <30 kcal/kg had decreased weight (interaction; $P < 0.001$), AMC ($P = 0.003$) and serum albumin level ($P = 0.016$), and their DESIGN-R total scores for deep PrU ($P = 0.008$) had not improved after 3 weeks in the adjusted model (Fig. 1). All of these parameters increased in those who received ≥30 kcal/kg/day. Similar trends were observed for the protein intake (Fig. 2). The association of protein intakes meeting the average requirement with changes in AMC ($P = 0.059$) and DESIGN-R total score for deep PrU ($P = 0.168$) showed similar trends, but did not reach significance.

Changes in DESIGN-R subscores and area were then evaluated as outcomes for deep PrU (Fig. 3). Energy intake meeting the estimated requirement was associated with decreased wound depth score ($P = 0.006$), granulation tissue score ($P = 0.015$), necrotic tissue score ($P = 0.023$) and possibly exudate score ($P = 0.069$) after 3 weeks in the adjusted model. Protein intake

Table 1 Demographic characteristics at baseline (n = 194)

Variables	Categories	Values
Mean age, years (SD)		80.7 (7.5)
Sex, *n* (%)	Female	93 (47.9)
	Male	101 (52.1)
Comorbidities, *n* (%)	Infectious disease	68 (35.1)
	Cerebrovascular disease	65 (33.5)
	Diabetes	38 (19.6)
	Cardiovascular disease	32 (16.5)
	Cancer	31 (16.0)
	Hypertension	31 (16.0)
	Orthopedic disease	25 (12.9)
	Dementia	23 (11.9)
	Renal disease	16 (8.3)
	Electrolyte abnormality	16 (8.3)
	Peripheral nervous disease	13 (6.7)
	Others	55 (28.4)
Mean Braden scale (SD)		11.8 (3.1)
Ulcer locations, *n* (%)	Sacrum	91 (46.9)
	Greater trochanter/ischial tuberosity	31 (16.0)
	Coccyx	30 (15.5)
	Lower extremity	25 (12.9)
	Others	17 (8.7)
Wound depths, *n* (%)	Deep	123 (63.4)
	Superficial	71 (36.6)
Mean DESIGN-R scores (SD)	Depth	3.6 (1.7)
	Exudates	2.1 (1.6)
	Size	5.7 (2.7)
	Inflammation/infection	0.5 (1.4)
	Granulation tissue	3.0 (2.6)
	Necrotic tissue	2.0 (2.1)
	Pocket	1.9 (5.1)
	Total score	15.2 (9.8)
Support surfaces, *n* (%)†	Air	135 (70.0)
	Foam	58 (30.0)
No. wounds (%)	Two or more	52 (26.8)
Mean weight, kg (SD)		46.4 (10.8)
Mean body mass index, kg/m^2 (SD)†		19.4 (3.6)
Mean arm muscle circumference, cm (SD)†		19.2 (2.8)
Mean serum albumin level, g/dL (SD)†		2.7 (0.6)
Mean serum C-reactive protein level, mg/dL (SD)†		7.1 (7.6)
Mean serum blood urea nitrogen level, mg/dL (SD)†		30.8 (27.2)
Mean serum creatinine level, mg/dL (SD)†		1.1 (1.2)
Mean hemoglobin level, g/dL (SD)†		10.5 (2.1)
Nutritional routes, *n* (%)	None	5 (2.6)
	Orally	49 (25.2)
	Enterally	25 (12.9)
	Parenterally	66 (34.0)
	Orally and enterally	15 (7.7)
	Orally and parenterally	13 (6.7)
	Enterally and parenterally	16 (8.3)
	All routes	5 (2.6)
Mean energy intake. kcal/kg/day (SD)		18.9 (13.2)
Mean protein intake, g/kg/day (SD)		0.61 (0.60)

†Data were missing for support surfaces (n = 1), body mass index (n = 10), arm muscle circumference (n = 17), albumin level (n = 16), C-reactive protein level (n = 7), blood urea nitrogen level (n = 5), creatinine level (n = 5) and hemoglobin level (n = 5) within the study period.

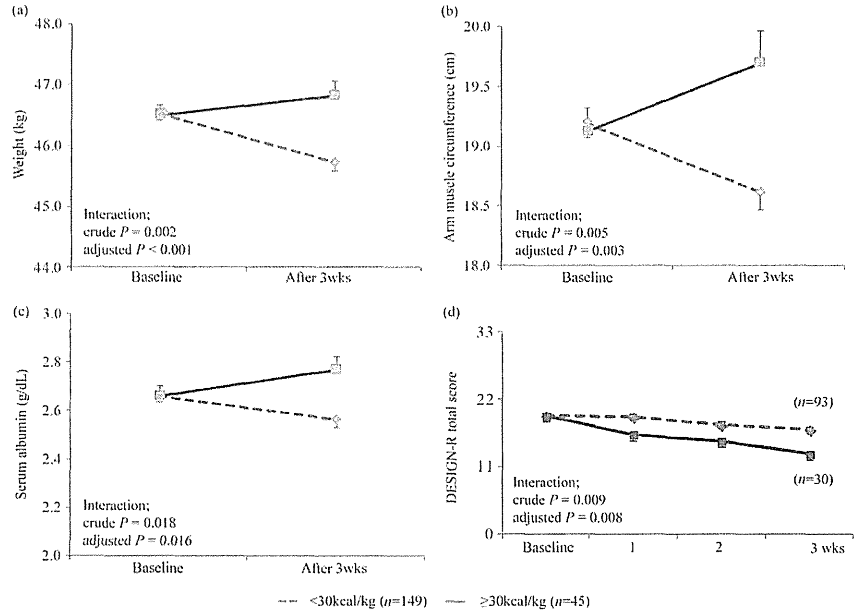

Figure 1 Intakes meeting the estimated energy requirement (30 kcal/kg), and changes in nutritional and wound status after 3 weeks. Outcomes were (a) weight, (b) arm muscle circumference, (c) serum albumin level,and (d) DESIGN-R total score for deep pressure ulcers. Solid lines show the group that met the requirement ($n = 45$) and dotted lines show the group that did not meet the requirement ($n = 149$). The crude *P*-values are for an interaction term from the adjusted model for baseline level of each outcome. The adjusted *P*-values are for an interaction term from the fully adjusted model of other confounders. Points, estimates; bars, standard errors.

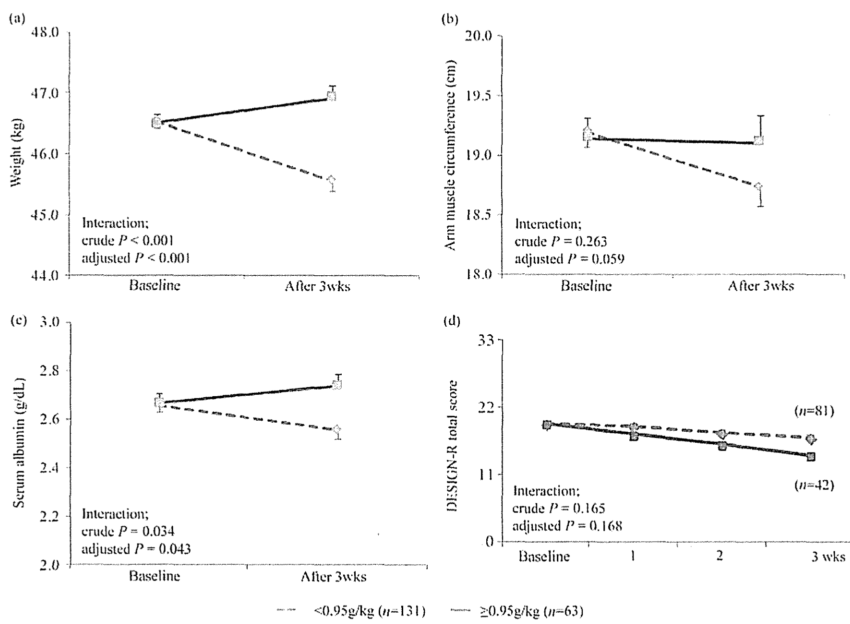

Figure 2 Intakes meeting the estimated average protein requirement (0.95 g/kg), and changes in nutritional and wound status after 3 weeks. Outcomes were (a) weight, (b) arm muscle circumference, (c) serum albumin level and (d) DESIGN-R total score for deep pressure ulcers. Solid lines show the group that met the requirement ($n = 63$) and dotted lines show the group that did not meet the requirement ($n = 131$). The crude *P*-values are for an interaction term from the adjusted model for baseline level of each outcome. The adjusted *P*-values re for an interaction term from the fully adjusted model of other confounders. Points, estimates; bars, standard errors.

meeting the average requirement was related to decreased exudate score ($P = 0.004$), and possibly decreased necrotic tissue score ($P = 0.096$).

For patients with renal insufficiency, BUN decreased ($P = 0.005$) and eGFR increased ($P = 0.041$) after 3 weeks in those who received intakes less than the average protein requirement of 0.75 g/kg/day, whereas both levels were stable in those who received ≥0.75 g/kg/day in the adjusted model (Table 2). In patients with renal sufficiency who met the average requirement, eGFR decreased slightly.

Discussion

The present multicenter prospective study showed that the energy and protein intakes meeting the average requirements (30 kcal/kg and 0.95 g/kg, respectively) reported in previous metabolic studies were associated with changes in most nutritional parameters and with deep wound healing in older patients with PrU.[10,15] These results were independent of confounding factors including patient demographics, hospital type and wound status.

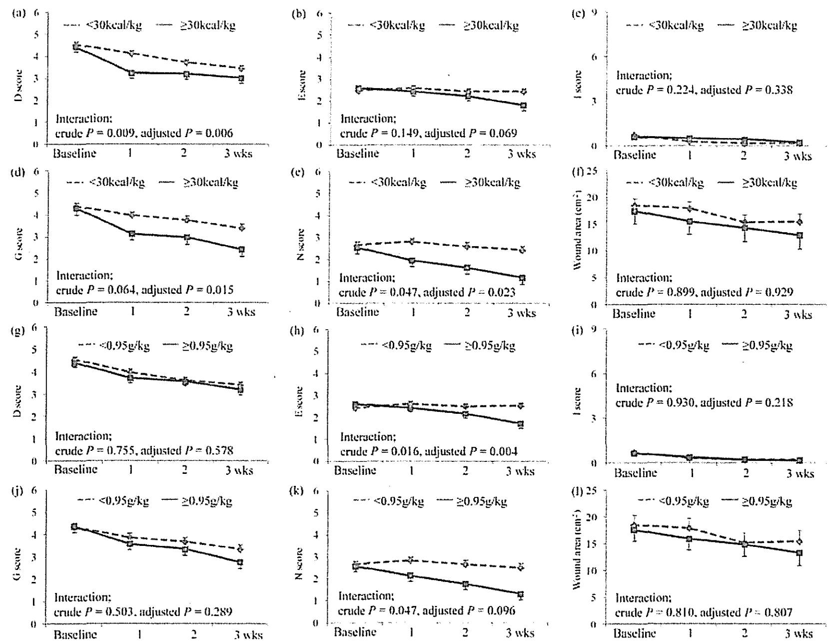

Figure 3 Intakes meeting the nutritional requirements and subsequent changes in DESIGN-R subscores for deep pressure ulcers. Each plot shows the relationships between energy and protein intakes dichotomized by the estimated requirement (a–f) for energy and (g–l) for protein, and (a,g) the depth score, (b,h) the exudates score, (c,i) the inflammation/infection score, (d,j) granulation tissue score, (e,k) necrotic tissue score and (f,l) measured wound area. Solid lines show the group that met the requirement ($n = 30$ for energy and $n = 42$ for protein intake) and dotted lines showed the group that did not meet the requirement ($n = 93$ for energy intake and $n = 81$ for protein intake). The crude P-values are for an interaction term from the adjusted model for baseline level of each outcome and the adjusted P-values are for an interaction term from the fully adjusted model of other confounders. Points, estimates; bars, standard errors.

After 3 weeks, nutritional marker levels had decreased in patients receiving less than the requirement, but were stable or increased in patients receiving more. Past studies have evaluated the effect of nutritional intake on wound healing,[13,14,25] but the effects on nutritional status markers in patients with PrU, whose metabolic conditions are altered by the damage of PrU, remain controversial.[10,11] One reason for the conflicting results could be the narrow range of dietary intake at relatively high levels even of the control groups, masking differences in nutritional change between groups.[13,25,26] In our observational study, in contrast, large variability in nutrient intake was observed; some patients' nutritional status had worsened after 3 weeks because of inadequate intake. This heterogeneous situation allows evaluation of the suitability of the requirements using nutritional indicators.

The energy requirement cut-off (30 kcal/kg) used in the present study was similar to the low end of the guideline range (30–35 kcal/kg) for patients with PrU and intake level of the control groups in previous clinical trials of wound healing. In contrast, the protein requirement in the present study (0.95 g/kg) was less than that in previous studies and in the guideline (>1.2 g/kg, in general).[6,13,14,25,26] Another study on chronic wounds reported that individuals with a mean protein intake of 1.85 g/kg showed an increase in serum prealbumin, whereas individuals receiving 1.65 g/kg showed no increase.[27] These discrepancies can be attributed to the different goals of nutritional management. Clinical trials have aimed to facilitate the improvement in wound status or nutritional markers, whereas our methodology proposed a cut-point for intake level at which nutritional markers were improved or decreased. In addition, the definition of the average requirement as the value that meets the true requirement for 50% of the group could cause discrepancies, because the intake level might be inadequate for the remaining 50% of individuals.[9,23] The average requirements were slightly higher than the mean intake in previous observational studies, which reported <25 kcal/kg energy and <1.0 g/kg protein intake.[11,28] In addition to the setting differences, study design might influence reported intake levels for patients with PrU. The present study showed that more than half of the patients did not meet the average requirement, indicating that a huge gap remains between usual care and guideline recommendations supported by the intervention study. Though higher intake will meet the requirements for most individuals, the present study helps to

Table 2 Protein requirement, and changes in blood urea nitrogen level and renal function

Patients with	Protein intakes	Blood urea nitrogen level, mean (95% CI)			Estimated glomerular filtration rate, mean (95% CI)		
		Baseline	Follow up	*P**	Baseline	Follow up	*P**
Renal sufficiency	<0.95 g/kg (*n* = 59)	19.3 (17.4–21.2)	18.1 (15.8–20.4)	0.683	102.2 (98.1–106.4)	113.6 (108.1–119.2)	0.002
	≥0.95 g/kg (*n* = 47)	20.1 (18.0–22.3)	17.4 (14.9–20.0)		103.6 (98.9–108.2)	92.6 (86.4–98.9)	
Renal insufficiency	<0.75 g/kg (*n* = 64)	45.7 (41.4–49.9)	28.4 (22.8–34.0)	0.005	34.9 (31.3–38.4)	55.8 (50.9–60.6)	0.041
	≥0.75 g/kg (*n* = 19)	44.0 (36.2–51.8)	43.1 (31.9–54.3)		35.1 (28.7–41.6)	41.4 (31.4–51.3)	

**P*-values for the interaction term of the full-adjusted model.

confirm the minimum intake necessary to avoid nutritional decline, not optimal intake, when ideal enhanced intake levels cannot be achieved.

Our finding that nutrient intake was not related to wound healing for superficial PrU is consistent with a previous retrospective study carried out in nursing homes.[29,30] Because superficial PrU have only partial tissue loss and heal faster than deep PrU, the effects of nutrition on healing could likely be small compared with the effects of other factors. The relationship between estimated energy requirements and deep PrU healing is an interesting result, because the requirement was originally determined for resting energy expenditure maintenance, and not for wound healing. The average protein requirement, however, was less clearly associated with changes in wound status, even for deep ulcers. Considering the preliminary result for a continuous variable, the suitability of the cut-off point rather than the protein intake itself might have weakened the association, because the cut-off point was originally determined for patients in a long-term facility.[10] Nevertheless, the influence of nutrient requirements might be observed in the specific characteristics of wound healing, such as reduced exudate and necrotic tissue, and improvement in lesion depth and granulation tissue for deep PrU. Inadequate intake can compromise the early phase of deep PrU wound healing from the inflammatory phase to the proliferative phase, because energy and amino acids play important roles in immune function, inflammatory cell migration, proinflammatory cytokine expression and extracellular matrix formation.[3,4,31,32]

Even for patients with renal insufficiency, the average requirement of 0.75 g/kg did not have a detrimental effect on renal function, whereas protein intake <0.75 g/kg improved BUN and eGFR. These findings suggest that lower protein intake might protect the renal function, but could impair nutritional status and wound healing.[33] Careful clinical monitoring is required when providing a dietary plan for patients with PrU and renal insufficiency.

There were several limitations of the present study. A time lag between nutrient intake and subsequent changes could exist, and this study had a relatively short follow-up period. However, longer follow-up might not be feasible because of possible dropouts in acute care settings. A strong correlation between energy and protein intake complicated the differentiation of their effects. Further controlled studies are required to determine the appropriate energy–protein balance. Dietary assessment was based on nursing records from each hospital on a single day. Anthropometry were measured by multiple nurses, though they all received pretraining. Also, weight measurements were based on each hospital's manual and device. These methodologies could have produced measurement errors, but increased the feasibility of a multicenter survey. The present study had several limitations, but is a first step in considering the nutritional requirements for patients with PrU.

In conclusion, the estimated energy requirement (30 kcal/kg) and the average protein requirement (0.95 g/kg) have adequate clinical validity as minimum requirements for maintaining nutritional status and accelerating wound healing in older patients with PrU.

Acknowledgments

This study was funded by a Health Labor Sciences Research Grant (2008–2009). We greatly appreciate the help of wound, ostomy and continence nurses at each hospital in data collection. All authors were involved in research design, recruitment, data collection, data analysis and the editorial process, and all approved the final version of the manuscript.

Disclosure statement

The authors declare no conflict of interest.

References

1 Sherman AR, Barkley M. Nutrition and wound healing. *J Wound Care* 2011; **20**: 357–367.

2 Broughton G, Janis JE, Attinger CE. The basic science of wound healing. *Plast Reconstr Surg* 2006; **117**: 12–34.

3 Hudgens J, Langkamp-Henken B, Stechmiller JK, Herrlinger-Garcia KA, Nieves C Jr. Immune function is impaired with a mini nutritional assessment score indicative of malnutrition in nursing home elders with pressure ulcers. *JPEN J Parenter Enteral Nutr* 2004; **28**: 416–422.

4 Lim Y, Levy MA, Bray TM. Dietary supplementation of N-acetylcysteine enhances early inflammatory responses during cutaneous wound healing in protein malnourished mice. *J Nutr Biochem* 2006; **17**: 328–336.

5 Houston DK, Nicklas BJ, Ding J *et al.* Dietary protein intake is associated with lean mass change in older, community-dwelling adults: the Health, Aging, and Body Composition (Health ABC) Study. *Am J Clin Nutr* 2008; **87**: 150–155.

6 European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel. *Treatment of Pressure Ulcers: Quick Reference Guide*. Washington DC: National Pressure Ulcer Advisory Panel, 2009.

7 The Japanese Society of Pressure Ulcers Guideline Revision Committee. JSPU guidelines for the prevention and management of pressure ulcers (3rd Ed.). *Jpn J PU* 2014; **16**: 12–90.

8 Association for the Advancement of Wound Care (AAWC). *Association for the Advancement of Wound Care (AAWC) Guideline of Pressure Ulcer Guidelines*. Malvern, PA: AAWC, 2010.

9 FAO/WHO/UNU Committee. *Energy and Protein Requirements*. WHO technical report series #724. Geneva: World Health Organization, 1985.

10 Iizaka S, Matsuo J, Konya C, Sekine R, Sugama J, Sanada H. Estimation of protein requirements according to nitrogen balance for older hospitalized adults with pressure ulcers according to wound severity in Japan. *J Am Geriatr Soc* 2012; **60**: 2027–2034.

11 Sergi G, Coin A, Mulone S *et al.* Resting energy expenditure and body composition in bedridden institutionalized elderly women with advanced-stage pressure sores. *J Gerontol A Biol Sci Med Sci* 2007; **62**: 317–322.

12 Stratton RJ, Ek AC, Engfer M *et al.* Enteral nutritional support in prevention and treatment of pressure ulcers: a systematic review and meta-analysis. *Ageing Res Rev* 2005; **4**: 422–450.

13 Ohura T, Nakajo T, Okada S, Omura K, Adachi K. Evaluation of effects of nutrition intervention on healing of pressure ulcers and nutritional states (randomized controlled trial). *Wound Repair Regen* 2011; **19**: 330–336.

14 Breslow RA, Hallfrisch J, Guy DG, Crawley B, Goldberg AP. The importance of dietary protein in healing pressure ulcers. *J Am Geriatr Soc* 1993; **41**: 357–362.

15 Cereda E, Klersy C, Rondanelli M, Caccialanza R. Energy balance in patients with pressure ulcers: a systematic review and meta-analysis of observational studies. *J Am Diet Assoc* 2011; **111**: 1868–1876.

16 Knight EL, Stampfer MJ, Hankinson SE, Spiegelman D, Curhan GC. The impact of protein intake on renal function decline in women with normal renal function or mild renal insufficiency. *Ann Intern Med* 2003; **138**: 460–467.

17 Kaitani T, Nakagami G, Sanada H. Cost-effectiveness of conservative sharp wound debridement for pressure ulcers offered by wound, ostomy and continence nurses: a propensity score matching analysis. *J Wound Technol* 2013; **21**: 6–10.

18 Bergstrom N, Braden BJ, Laguzza A, Holman V. The Braden Scale for Predicting Pressure Sore Risk. *Nurs Res* 1987; **36**: 205–210.

19 Japanese Anthropometric Reference Data. *Jpn J Nutr Assessment* 2002; **19**: 1–82 (in Japanese).

20 Matsui Y, Furue M, Sanada H *et al.* Development of the DESIGN-R with an observational study: an absolute evaluation tool for monitoring pressure ulcer wound healing. *Wound Repair Regen* 2011; **19**: 309–315.

21 Sanada H, Iizaka S, Matsui Y *et al.* Clinical wound assessment using DESIGN-R total score can predict pressure ulcer healing: pooled analysis from two multicentre cohort studies. *Wound Repair Regen* 2011; **19**: 559–567.

22 Sugama J, Matsui Y, Sanada H *et al.* A study of the efficiency and convenience of an advanced portable Wound Measurement System (VISITRAK). *J Clin Nurs* 2007; **16**: 1265–1269.

23 Expert Committee for Dietary Reference Intakes for Japanese. *Dietary Reference Intakes for Japanese, 2010*. Tokyo, Japan: Daiichi Shuppan Publishing Co. Ltd., 2009 (in Japanese).

24 Japanese Society of Nephrology. Evidence-based practice guideline for the treatment of CKD. *Clin Exp Nephrol* 2009; **13**: 537–566.

25 Cereda E, Gini A, Pedrolli C, Vanotti A. Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalized older adults: a randomized controlled trial. *J Am Geriatr Soc* 2009; **57**: 1395–1402.

26 Desnevesa KJ, Todorovicb BE, Cassara A, Croweb TC. Treatment with supplementary arginine, vitamin C and zinc in patients with pressure ulcers: a randomised controlled trial. *Clin Nutr* 2005; **24**: 979–987.

27 Pompeo M. Misconceptions about protein requirements for wound healing: results of a prospective study. *Ostomy Wound Manage* 2007; **53**: 30–44.

28 Dambach B, Sallé A, Marteau C *et al.* Energy requirements are not greater in elderly patients suffering from pressure ulcers. *J Am Geriatr Soc* 2005; **53**: 478–482.
29 Bergstrom N, Horn SD, Smout RJ *et al.* The National Pressure Ulcer Long-Term Care Study: outcomes of pressure ulcer treatments in long-term care. *J Am Geriatr Soc* 2005; **53**: 1721–1729.
30 Bergstrom N, Smout R, Horn S, Spector W, Hartz A, Limcangco MR. Stage 2 pressure ulcer healing in nursing homes. *J Am Geriatr Soc* 2008; **56**: 1252–1258.
31 Takeda T, Koyama T, Izawa Y, Makita T, Nakamura N. Effects of malnutrition on development of experimental pressure sores. *J Dermatol* 1992; **19**: 602–609.
32 Iizaka S, Sanada H, Nakagami G *et al.* Estimation of protein loss from wound fluid in older patients with severe pressure ulcers. *Nutrition* 2010; **26**: 890–895.
33 Bauer J, Biolo G, Cederholm T *et al.* Evidence-based recommendations for optimal dietary protein intake in older people: a position paper from the PROT-AGE Study Group. *J Am Med Dir Assoc* 2013; **14**: 542–559.

international wound journal
International Wound Journal ISSN 1742-4801

ORIGINAL ARTICLE

Microclimate and development of pressure ulcers and superficial skin changes

Saldy Yusuf[1,3], Mayumi Okuwa[1], Yoshie Shigeta[1], Misako Dai[1], Terumi Iuchi[1], Sulaiman Rahman[2], Awaluddin Usman[2], Sukmawati Kasim[3], Junko Sugama[1], Toshio Nakatani[1] & Hiromi Sanada[4]

1 Clinical Nursing Department, Kanazawa University, Ishikawa, Japan
2 Wound Care Clinic, ETN Centre, Makassar, Indonesia
3 Wound Care Clinic, Griya Afiat, Makassar, Indonesia
4 Department of Gerontological Nursing/Wound Care Management, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan

Key words
microclimate; pressure ulcer; superficial skin changes; skin temperature; skin moisture

Correspondence to
J Sugama, PhD, RN
Clinical Nursing Department
Kanazawa University
5-11-80 Kodatsuno
Kanazawa City
Ishikawa
920-0942
Japan
E-mail: junkosgm@mhs.mp.kanazawa-u.ac.jp

doi: 10.1111/iwj.12048

Yusuf S, Okuwa M, Shigeta Y, Dai M, Iuchi T, Rahman S, Usman A, Kasim S, Sugama J, Nakatani T, Sanada H. Microclimate and development of pressure ulcers and superficial skin changes. Int Wound J 2015; 12:40–46

Abstract

This study aims to evaluate the microclimate and development of pressure ulcers and superficial skin changes. A prospective cohort study was conducted in an acute care ward in Indonesia. Risk factors for pressure ulcers and superficial skin changes were identified based on the Bergstrom Braden conceptual model. Microclimate data were collected every 3 days for 15 days while the development of pressure ulcers and superficial skin changes was observed every day. Pressure ulcers and superficial skin changes were developed in 20 of the 71 participants. Total mean difference in skin temperature was higher for patients with pressure ulcers and superficial skin changes ($0{\cdot}9 \pm 0{\cdot}6°C$) compared with controls ($0{\cdot}6 \pm 0{\cdot}8°C$) ($P = 0{\cdot}071$). Binary logistic regression predictor values for pressure ulcers and superficial skin changes were 0·111 for type of sheet and 0·347 for Braden Scale results. In conclusion, difference in skin temperature seems to be a predictor for pressure ulcer development and superficial skin changes, while synthetic fibre sheets are able to maintain a beneficial microclimate.

Introduction

Pressure ulcers have become a global problem in both Western and Asian countries, developed and developing countries and in all health care settings. In 2006, the prevalence of pressure ulcers in Europe was 18·1% (1) and in the United States, it was 15%, with an incidence of 7% (2). However, in 2008, the incidence of pressure ulcers in Indonesia was 28·4% (3), which is higher than other areas in Asia, such as Hong Kong with an incidence of 25·16% (4) and Japan with an incidence of 3·64% (5).

According to Bergstrom Braden conceptual model (6), development of pressure ulcers is based on two primary factors: pressure and tissue tolerance. The pressure factor is determined by intensity and duration, whereas tissue tolerance is commonly influenced by intrinsic factors (from the patients) and extrinsic factors (from the external environment). Until now, a preventive approach was only based on pressure factors, which focused in two modalities in clinical settings: turning position and application of expensive support surfaces. Meanwhile, exploration into tissue tolerance seems to have been overlooked.

Key Messages

- pressure ulcers have become a global burden in both developed and developing countries; however, several contributing or confounding factors of pressure ulcers are still unknown.
- thus, the aim of this study was to evaluate the role of microclimate in development of pressure ulcers and superficial skin changes and to validate the role of hospital bed sheet to reduce incidence of pressure ulcers and superficial skin changes
- the first step of analysis was to investigate microclimate status between pressure ulcers and skin changes group compared with normal skin group. Independent t-test confirmed that the skin temperature status between groups ($P = 0{\cdot}07$) was marginally significant. Further

analysis conducted using binary logistic regression confirmed the role of hospital bed sheet with the odds ratio of 0·111 and a 95% confidence interval (CI) of 0·012–1·032
- our finding confirmed that development of pressure ulcers and superficial skin changes are related to increasing of microclimate status (skin temperature); besides, hospital bed sheet has a potential role to reduce incidence of pressure ulcers and superficial skin changes by creating physiological microclimate environment
- this study illuminated a new pathological process in pressure ulcers development and also suggested a new modality to prevent pressure ulcers

In 2009, European Pressure Ulcer Advisory Panel (EPUAP) and National Pressure Ulcer Advisory Panel (NPUAP) redefined the definition of pressure ulcers as a localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear (2). However, this new definition and classification system have not elucidated the scope of the problems. Moreover, these two important pressure ulcer advisory panel agree that several contributing or confounding factors are still unknown; hence, this research is important to investigate the role of microclimate on pressure ulcers development.

According to Gefen's mathematical model, microclimate conditions will affect skin tolerance leading to superficial skin changes (7). The terms of superficial skin changes also has been proposed by the Shifting the Original Paradigm Expert (8). Using the term 'superficial skin changes', we also capture blanchable erythema, maceration, dermatitis, and categories I and II pressure ulcers in this study.

Microclimate concept

Nowadays, the microclimate (external environment) between patient's skin and support surfaces has been recognised as a missing factor in the pathological process of pressure ulcers (9,10). At present, microclimate refers to skin temperature and skin moisture (9), but it may or may not include air movement (10). However, in this study, we consider microclimate to mean skin temperature and skin moisture between patient's skin and support surface.

Skin temperature

Previous studies have investigated skin temperature as the quantitative measurement of pressure ulcer development (11–16) and some more studies found that development of diabetic ulcers (17–19) and chronic venous diseases (20–22) can also be predicted by skin temperature. As a microclimate variable, skin temperature has been correlated with the level of tissue injury in animal study (23) and in human study, it has been shown to increase by 1·2°C in 24–96 hours before pressure ulcers develop (24).

Skin moisture

Presence of moisture has been known as the subjective indicator of pressure ulcer development, as it used as a subscale of Braden Scale (6) and a quantitative measurement to predict pressure ulcers (25). Increased skin moisture also contributes to maceration and skin breakdown (26), it weakens the stratum corneum, leading to skin damage by external forces (27). Moreover, a positive linear correlation has been found between skin moisture and the coefficient of friction (28). Conversely, an excessive dryness of the skin leads to damage by cracking (29).

Interaction between skin and textiles

In addition, any surface that has contact with the skin has a potential to alter the microclimate (30), including the contact between textiles and skin (29,31). Thus, the bed climate has an important function in preventing pressure ulcers (32). In fact, most standard hospital beds are covered by plastic, which is an impermeable barrier. Although a plastic bed cover is useful for protecting a mattress (33), it cannot maintain a good physiological microclimate (34). Therefore, the purpose of this study was to evaluate the relationship between microclimate and the development of pressure ulcers and superficial skin changes.

Methods

Research design

This was a cohort prospective study with purposive sampling.

Settings and participants

The research was conducted in an acute care setting in Wahidin Sudirohusodo Hospital, Makassar, a regional hospital which served eastern Indonesia during dry season (March to October 2012). This ward has 354 beds with each room containing 4–6 beds. The hospital bed dimensions were $190 \times 90 \times 13$ cm (length, wide and thick), made from foam mattress and covered by plastic. The hospital beds' mattress was covered by 100% cotton sheet. In this study, we also used synthetic fibre sheets randomly, which were made up of 42% cotton and 58% polyester.

Average room temperature of 30°C and room humidity of 60% were the ventilation systems based on windows without using air conditioning. As there is no information about cut-off point of Braden Scale in acute care setting in Indonesia, we used a Braden Scale score of 18 or lower (at risk) as the inclusion criteria. Patients aged 18 years or above, and with no presence or history of pressure ulcers and/or skin changes on admission day were included. Exclusion criteria were refused to participate and contraindication for lateral turning. Patients and/or family members gave an informed consent. The skin colour of the participants is Asian colour with yellow or brown without dark skin tones.

Data collection

Factors associated with pressure ulcers development were investigated based on the Bergstrom Braden frame concept (6). Data were collected through patient measurements, medical records, and observation of each patient and the environment. These data included demographic data (age, gender, medical diagnosis), Braden Scale, underpad status, interface pressure, type of bed, vital signs (blood pressure, pulse, respiratory rate and body temperature), room climate (room temperature and humidity) and microclimate (skin temperature and skin moisture).

Microclimate was measured at the sacrum area as the targeted area and at periumbilical skin as the control site. To identify targeted area, we made an imaginary line connecting the spina iliaca anterior superior dextra and sinistra. The observed area was 5 cm below this line alongside the midvertebralis line. Meanwhile, we measured the periumbilical skin area within 5 cm in diameter as the control area.

Room climate (temperature and humidity), type of bed sheet and vital signs were also recorded. First, we measured skin temperature and skin moisture at the periumbilical area as the control area. Then, participants' skin temperature and skin moisture at the sacral area were measured. We put a multipad sensor on the sacral area to record the interface pressure. These measurements were repeated every 3 days from admission until the 15th day, or whenever pressure ulcers and superficial skin changes occurred. Daily skin inspections were performed to identify the development of pressure ulcers and superficial skin changes.

Instruments used

Interface pressure was measured using a multipad sensor (Palm-Q, Kanagawa, Japan). This device has five sensors with a range of 0–200 mmHg and an accuracy of ±3 mmHg. Skin temperature was measured using an infrared digital thermometer (Raytek ST 60; Fluke Company, Santa Cruz, CA) with a measurement ranging from 30 to 600°C and an accuracy of ±1%. This thermometer was a non contact sensor, so we used a 7-cm guideline between the sensor and the skin to maintain the same relative distance on different days. Skin moisture was measured using a Corneometer® CM 825 (Courage+Khazaka Electronic GmbH, Koln, Germany). The measuring system is based on capacitance measurement of a dielectric medium with a measurement time of 1 second. This device has an accuracy of ±3 arbitrary units (au) and a range of 0–120 au. Room climate (temperature and humidity) was recorded using a hygrometer. When participants left their beds, we delayed measuring for at least 15 minutes for acclimatisation. All measurements were taken between 08:00 AM and 12:00 AM to avoid the circadian rhythm effect.

Pressure ulcers development was evaluated based on the EPUAP staging systems and the category of superficial skin changes was evaluated by a wound expert panel. Daily skin observation was performed to evaluate the development of pressure ulcers. Determination between non blanchable erythema and blanchable erythema was conducted by finger pressure or transparent plastic at the erythematous area. To reduce bias, all measurements and observations were made by single investigator.

Ethical considerations

This study was conducted with an approval from the ethics committee of the Department of Medical Sciences, Kanazawa University (Ref. No. 301) and Wahidin Sudirohusodo Hospital (Ref. No. LB.3·2/3·2.2/00221/2011). The study purpose and procedures were explained orally to participants and their family members before they gave their informed consent; moreover, participants had the right to drop out from the research without giving any explanation.

Data analysis

Skin temperature, skin moisture and interface pressure data were averaged from at least three values within the range of measuring devices to obtain daily mean. Then we calculated total mean days by using daily mean as numerator and number of observation days as denominator. Since another data were single data, we directly calculated total means.

Descriptive data were analysed using univariate analysis to delineate the characteristics of the participants. The Chi-square test and the Fisher's exact test were performed to evaluate patient characteristics between the group of patients with superficial skin changes and without skin changes.

Furthermore, we used the independent t-test to evaluate the role of the microclimate between the group with pressure ulcers and superficial skin changes and the group with no skin changes. All descriptive data were identified as n (%), while continuous data were identified as mean ± standard deviation. To predict the development of pressure ulcers and superficial skin changes against independent variables, we used binary logistic regression analysis. In the univariate analysis, we established $P = 0{\cdot}05$ as the level of significance, whereas in multivariate analysis, all variables with $P = 0{\cdot}1$ were entered into binary logistic regression. All statistical analyses were performed using the Statistical Package of Social Sciences (SPSS) version 16·0 software (SPSS Inc., Chicago, IL).

Results

Of the assessed 188 participants, we excluded 102 for several reasons: 29 already had pressure ulcers, 19 declined to participate, 33 had pain, 1 had skin maceration, 19 had critical health conditions and 1 was uncooperative. Thus, 86 participants were included and received informed consent; however, at the end of study, only 71 participants remained. Twenty had pressure ulcers and superficial skin changes while 51 had no skin changes. The most common wound type was category II pressure ulcer ($n = 6$, 30·0%) (Table 1) and the most common location was in the lower sacral area ($n = 11$, 47·8%) (Table 2).

There was a significant difference in gender between those with pressure ulcers and superficial skin changes versus those with no skin changes ($P = 0{\cdot}010$). An independent t-test showed that the total mean Braden Scale score was lower in the group with pressure ulcers and superficial skin changes ($M = 10{\cdot}8$, SD $= \pm 2{\cdot}2$) compared with the group with no skin changes ($M = 15$, SD $= \pm 1{\cdot}7$) ($P < 0{\cdot}000$). All of the subscale Braden Scale scores showed a significant difference

Table 1 Type of skin changes

Type of skin changes	*n* (%)
Pressure ulcer category I	5 (25·0)
Pressure ulcer category II	6 (30·0)
Blanchable erythema	5 (25·0)
Maceration	3 (15·0)
Dermatitis	1 (15·0)

Table 2 Distribution of skin changes based on locations

Locations	*n* (%)*
Lower sacrum	11 (47·8)
Sacrum	6 (26·2)
Buttock	2 (8·7)
Trochanter	3 (13·0)
Lumbar	1 (14·3)

*Some participants have skin changes in more than one location.

of $P < 0{\cdot}05$ (Table 3). In a comparison of the total skin temperature difference between the sacrum and the control area, the difference was marginally significant in the group with superficial skin changes compared with that in the group with no skin changes ($P = 0{\cdot}071$) (Table 4).

From all of the significant differences, we performed multivariate analysis using the binary logistic regression backward mode at the significance level of $P = 0{\cdot}1$. After adjustment, the variables of gender, type of sheet, underpad and total mean difference were excluded and two risk factors remained: type of sheet and Braden Scale score. Type of sheet had an odds ratio of 0·111 and a 95% confidence interval (CI) of 0·012–1·032. The Braden Scale score had an odds ratio of 0·347 and a 95% CI of 0·206–0·585 (Table 5).

Discussion

To the best of our knowledge, this research represents one of the few microclimate studies in clinical setting. As mentioned in the literature review, several studies have investigated microclimate in clinical setting (24,25), another studies have investigated skin temperature in laboratory setting (34–35) and other studies have used mathematical models to explore skin temperature (7,36) in correlation with development of pressure ulcers.

Table 3 Demographics and characteristics of patients with skin change development

Participants characteristics	Skin changes ($n = 20$)	No skin changes ($n = 51$)	*P*-value
Age, mean ± SD	51·7 ± 16·4	48·8 ± 14·5	0·483
Gender, *n* (%)			
Male	7(35·0)	35(68·6)	0·010
Female	13(65·0)	16(31·4)	
Braden score (mean ± SD)	10·8 ± 2·2	15·0 ± 1·7	0·000
Sensory perception	2·6 ± 1·1	3·2 ± 0·8	0·024
Moisture	1·8 ± 0·4	3·1 ± 0·5	0·000
Activity	1·0 ± 0·2	1·3 ± 0·5	0·007
Mobility	1·7 ± 0·5	2·4 ± 0·6	0·000
Nutrition	2·5 ± 0·6	3·0 ± 0·4	0·006
Friction and shear	1·2 ± 0·4	2·0 ± 0·2	0·000

Pressure ulcers and superficial skin changes

In this study, we found that the most common anatomic location of pressure ulcers and superficial skin changes was in the lower sacrum region (coxygeus, intertriginous; 27%), similiar with previous study (37). It can be understood by the fact that impact of high pressure over bony prominences leads to internal damage (38), while influence of microclimate leads to a decrease in skin tolerance, which results in superficial skin problems (7). Thus, in correlation with Bergstom Braden conceptual concept, microclimate seems to be related to skin tolerance problems (6).

A previous prevalence study conducted in USA found that in acute care setting, the classified 86 ulcers were categorised as unspecified ulcers (37). There were still ongoing discussion on how to differentiate pressure ulcers and other superficial skin problems, such as moisture lesion, incontinence-associated dermatitis, intertriginous dermatitis and moisture-associated skin damage (39–43). Hence, in this study, we use superficial skin changes as a proposed term by SOPE expert panel (8) to denote non pressure ulcers findings.

Additionally, we found that the mean Braden Scale score was lower in the group with pressure ulcers and superficial skin changes than in the group with no skin changes (10·8 ± 2·2 and 15·0 ± 1·7; $P < 0{\cdot}00$). In Indonesia, the Braden Scale has been translated into Indonesian and has been demonstrated to have a sensitivity of 80% and a specificity of 54% with a cut-off point of 12 in Intensive Care Units (44). We also found that the Braden Scale has an odds ratio of 0·347 with a negative coefficient, meaning that an increasing Braden Scale score indicates a reduced risk of pressure ulcers.

Microclimate findings

Using infrared thermography, skin temperature has been reported to have high correlation ($r = 0{\cdot}999$) in comparison with contact sensor and high reliability (0·937) (13). In this study, we found that skin temperature can be used to identify the risk of pressure ulcer development and superficial skin changes. We found that total skin temperature differences among groups were marginally significant ($P = 0{\cdot}071$). This finding is consistent with Sae-Sia *et al.* (24) who found that skin temperature increases by 1·2°C in 24–96 hours before pressure ulcers develop.

As postulated by Sae-Sia *et al.* (24), there are two possible linking for increasing temperature: first, prolonged pressure from body weight at sacrum point results in occlusive skin blood flow leading to inflammation and second, accumulation between sacrum skin and support surfaces (24). In this study, all of the hospital beds are foam mattress, covered by plastic, which possibly create heat accumulation between patient skin and support surfaces. Moreover, average macroclimate (room) temperature of 30°C also stimulated increasing microclimate temperature.