

JSPU Guidelines for the Prevention and Management of Pressure Ulcers (3rd Ed.)

The Japanese Society of Pressure Ulcers Guideline Revision Committee

Committee Chairperson : *Ryoji Tsuboi¹⁾

Vice Chairperson : Makiko Tanaka²⁾

Committee Members : Takafumi Kadono³⁾, Yayoi Nagai⁴⁾, Katsunori Furuta⁵⁾,
Yasuhiro Noda⁶⁾, Yusuke Sekine⁷⁾, Toshiko Kaitani⁸⁾,
Hitomi Kataoka⁹⁾, Hiromi Nakagawa¹⁰⁾, Taku Iwamoto¹¹⁾,
Masakazu Kurita¹²⁾, Mikio Kinoshita¹³⁾, Yuta Kurashige¹⁴⁾,
Gojiro Nakagami¹⁵⁾, Shoko Kakizaki¹⁶⁾, Masami Hidaka¹⁷⁾,
Hideyuki Hirose¹⁸⁾, Masaharu Sugimoto¹⁹⁾, Masako Miyajima²⁰⁾,
Madoka Noguchi²¹⁾, Mayumi Okuwa²²⁾, Mihoko Ishizawa²³⁾,
Yukiko Kinoshita²⁴⁾, Masayo Sobue²⁵⁾, Yoko Murooka²⁶⁾,
Yuko Matsui²⁷⁾, Tomoko Ohura²⁸⁾

Advisers : Chizuko Konya²⁹⁾, Shigeru Ichioka³⁰⁾, Junko Sugama²²⁾,
Hideko Tanaka²⁶⁾, Kayoko Adachi¹⁶⁾, Takeo Nakayama³¹⁾

Trustee : Yoshiaki Miyachi³²⁾

1) Tokyo Medical University, Department of Dermatology; 2) Yamaguchi Prefectural University, Faculty of Nursing and Human Nutrition; 3) University of Tokyo Faculty of Medicine, Department of Dermatology; 4) Gunma University Graduate School of Medicine, Department of Dermatology; 5) National Center for Geriatrics and Gerontology, Department of Clinical Research and Development; 6) Kinjo Gakuin University College of Pharmacy; 7) Tokyo Medical University Hospital, Department of Pharmacy; 8) Sapporo City University School of Nursing, Adult Nursing; 9) Yamagata University School of Medicine, Department of Nursing; 10) Yokohama Soei University Faculty of Nursing; 11) Tomei Atsugi Hospital, Department of Plastic Surgery; 12) Kyorin University School of Medicine Department of Plastic Surgery; 13) Tokyo-Nishi Tokushukai Hospital, Department of Plastic and Reconstructive Surgery; 14) Tokyo Medical University Hachioji Medical Center, Department of Dermatology; 15) University of Tokyo Graduate School of Medicine, Division of Health Science and Nursing, Department of Gerontological Nursing/ Wound Care Management; 16) Sempo Tokyo Takanawa Hospital, Department of Clinical Nutrition; 17) Hyogo University of Health Sciences, School of Rehabilitation, Department of Physical Therapy; 18) Research Institute, National Rehabilitation Center for Persons with Disabilities; 19) Kobegakuin University Faculty of Rehabilitation; 20) Wakayama Medical University, Department of Health and Nursing Sciences; 21) Kobe University Hospital; 22) Kanazawa University Faculty of Health Sciences, Institute of Medical, Pharmaceutical and Health Sciences; 23) Nara Medical University School of Medicine, Faculty of Nursing; 24) Gifu University Hospital Health Administration Center; 25) JA Aichi Konan Kosei Hospital; 26) Shukutoku University School of Nursing and Nutrition; 27) Kanazawa Medical University, School of Nursing, Department of Human Science and Fundamental Nursing; 28) Seijoh University Faculty of Care and Rehabilitation, Division of Occupational Therapy; 29) Kanazawa Medical University School of Nursing; 30) Saitama Medical University, Department of Plastic and Reconstructive Surgery; 31) Kyoto University School of

* Correspondence : Ryoji Tsuboi, MD, PhD
Department of Dermatology, Tokyo Medical University
6-7-1 Nishishinjuku, Shinjuku-ku, Tokyo 160-0023, Japan
Tel & Fax : (+ 81)-3-3340-1855
E-mail : tsuboi@tokyo-med.ac.jp

Public Health, Department of Health Informatics; 32) Kyoto University Graduate School of Medicine, Department of Dermatology.

Abstract

The Japanese Society of Pressure Ulcers (JSPU) has compiled an English version of the updated third edition of the Guidelines for the Prevention and Management of Pressure Ulcers. The guidelines set forth here include a collection and discussion of medical issues specific to Japan as well as new evidence from research conducted abroad. Clinical questions (CQs) and their analyses were organized in the order of treatment followed by prevention: topical agents, dressings, surgical intervention, general management, rehabilitation, risk assessment, skin assessment, skin care, repositioning, support surfaces, patient education, outcome management, and QOL/pain. Each recommendation was assigned one of five ratings (A, B, C1, C2 and D). A CQ discussing the so-called “wrap therapy” used in Japan was also included. As a new approach, algorithms and flow-charts were prepared for each topic. The present guidelines provide the best and most comprehensive recommendations currently available to health care professionals worldwide.

Introduction

1. Background

In 2005, the Japanese Society of Pressure Ulcers published “Guidelines for Local Treatment of Pressure Ulcers”¹⁾ and followed this in 2009 by a revised edition, “Guideline for Prevention and Management of Pressure Ulcers”²⁾. The current guidelines represent the culmination of an effort headed by the Fourth Academic Education Committee to present an up-to-date set of guidelines in article format incorporating new evidence collected since the publication of the last edition. In addition to these new guidelines, a handbook designed for quick reference, containing photographs and diagrams to facilitate the prevention and management of pressure ulcers, has been published.

While Europe and North America jointly published NPUAP/EPUAP guidelines for pressure ulcers in 2009³⁾, the guidelines set forth here were designed with due consideration of medical issues specific to Japan. This fact, together with the volume and quality of the data gathered, as well as the recommendation ratings provided, make the current set of guidelines fundamentally superior to the latest revised edition in terms of clinical utility.

Special attention was paid to a number of issues in the compilation of the new guidelines, including the following:

- 1) The addition of new Clinical Questions (CQs).
- 2) The inclusion of CQs reflecting the latest medical issues and the recommendations tailored specifically to the conditions of clinical practice.
- 3) The inclusion of a CQ on the so-called “wrap therapy” used in Japan.

4) A journal-style format consisting of discussion of treatment followed by that of prevention.

5) Inclusion of algorithms and flow-charts.

2. Purpose and Scope

The purpose of the present guidelines is to provide the best and most comprehensive recommendations possible, based on the most recent and reliable evidence, for the treatment of pressure ulcers for the benefit of the full range of health care professionals who are in any way involved in the management and prevention of this condition. Crucially, the recommendations offered in the guidelines have been formulated with a view to addressing the special needs of such health care professionals in their respective clinical settings and to helping them to make the best clinical decisions possible in their circumstances.

It should be noted that while these guidelines aim to be comprehensive in their scope, they are also designed to maximize the expertise and experience of the individual health care professional and the resources available in each particular clinical setting in order to achieve the best possible outcome for individual patients and their family or caretakers. By means of these new guidelines, we hope to set a new and higher standard for pressure ulcer care in Japan through improvements in the quality of pressure ulcer prevention and management, as well as in the better guidance which health care professionals will be able to offer patients and their families.

3. Guideline Developers

The present guidelines are the result of a collaborative effort between members of the Fourth Academic Education Committee of the Japanese Society of Pressure Ulcers (see list of authors), and incorporate

some of the aims and contents of the “Guidelines for Local Treatment of Pressure Ulcers”¹⁾ (first ed., 2005) and the “Guideline for Prevention and Management of Pressure Ulcers”²⁾ (Second edition, 2009). A list of those who participated in the development of these past editions is presented below, by way of acknowledging their valuable efforts.

First Edition (2005)¹⁾

Yoshiki Miyachi (Chairperson), Hiromi Sanada (Vice Chairperson), Junko Sugama, Takao Tachibana, Motonari Fukui, Katsunori Furuta, Toshiko Kaitani, Keiko Tokunaga, Toshio Nakajo, Yoshio Mino, Takehiko Oura, Hiroaki Oka, Masahiro Tachi, Toru Fujii, Takahiko Moriguchi, Takeo Nakayama, Takashi Nagase, Masaharu Sugimoto, Masami Hidaka.

Second Edition (2009)²⁾

Masutaka Furue (Chairperson), Hiromi Sanada (Vice Chairperson), Takao Tachibana, Takafumi Kadono, Toshiko Kaitani, Hiroaki Oka, Takashi Nagase, Masahiro Tachi, Takeo Nakayama, Makiko Tanaka, Mayumi Okuwa, Junko Sugama, Noriko Matsui, Yukie Kitayama, Keiko Tokunaga, Kayoko Adachi, Shingo Okada, Masami Hidaka, Hideyuki Hirose, Chizuko Konya.

4. Method

1) Sources of Evidence

The databases used to assemble relevant information were MEDLINE (Pubmed), Ichushi online database, CINAHL, and ALL EBM Reviews which include the Cochrane Database Systematic Reviews, ACP Journal Club, Database of Abstracts of Reviews of Effect (DARE) and Cochrane Central Register of Controlled Trials (CCTR). The information was sourced from various other relevant guidelines, as well as data assembled by individual contributors. This information was assembled from January, 1980 to June, 2011. Systematic reviews and clinical trials, especially randomized clinical trials, were prioritized. When these sources were unavailable, observational studies such as cohort studies and case-control studies were collected. In the event that the latter were unavailable, the range of acceptable sources was expanded to include case series. As a rule, evidence dealing chiefly with the outcome index was prioritized; however, for the Clinical Questions dealing with nursing, evidence focusing on QOL as the chief outcome measure was also used. Animal studies and basic research was not included. As a rule, medical

equipment, materials, topical medications, and dressings mentioned in the present guidelines are obtainable in Japan. If any are unavailable in Japan, this fact has been duly noted.

2) Evidence level and recommendation rating

The criteria for determining the evidence levels and ratings for recommendation of the present guidelines were formulated with reference to the Japanese Guidelines for the Management of Stroke 2009,³⁾ the Minds Reference Guide 2007 for Writing Clinical Practice Guidelines,⁴⁾ and Clinical Practice Guidelines for Skin Cancer⁶⁾.

(1) Classification of Evidence Levels

I : Systematic reviews/ meta-analyses

i) Randomized controlled trials only

ii) Randomized controlled trials, cohort studies, case-control studies

iii) Sources not including i) and ii)

II : Randomized controlled trials

III : Non-randomized controlled trials

(Including historical controlled trials,* and self-controlled studies)

IV : Analytical epidemiological research (in cohort studies and case-control studies)

(Includes retrospective cohort studies, historical controlled studies,**time series analyses, self-controlled studies)

V : Descriptive studies (case reports and case series)

(Including non-controlled intervention studies and cross-sectional studies)

VI : Expert opinion of specialist committees or individuals. Not based on patient data.

The evidence levels of each guideline used to determine the recommendation ratings have not been described.

*An historical controlled trial is a form of intervention study done in order to test the efficacy of a new form of treatment, and requires approval by the ethics committee of the relevant institution before it is performed. Unlike the randomized controlled study in which subjects are divided into a randomized intervention group and the control group, and the outcomes for each group are compared, the historical controlled trial examines cases which were observed at some time in the past for a comparison of their treatment outcomes with those of the intervention group receiving a new treatment.

**An historical controlled study, like the historical

controlled trial, examines cases which were observed at some time in the past for comparison with an intervention group receiving a new form of treatment. However, it differs from the historical controlled trail in that it is a form of observational study conducted as a part of daily consultation rather than an intervention study conducted for the purposes of testing a new form of treatment.

(2) Recommendation Ratings

A : Strongly recommended because supported by adequate evidence.

B : Recommended because supported by some evidence

C1 : May be considered because supported by limited evidence

C2 : Not recommended because no supporting evidence found

D : Not recommended because of invalid or possibly harmful findings

* ‘Evidence’ is defined as the findings of clinical trials and epidemiological research.

(3) Criteria for Determining Recommendation Rating

The criteria for determining the recommendation ratings have been carried over from the previous editions^{1,2)} A rating of A therefore requires one Level I or high quality Level II source of evidentiary support. However, any systematic review not dealing exclusively with randomized controlled trials weakens the strength of the rating. A rating of B requires at least one source of inferior quality Level II or high quality Level III evidence, or failing this, an extremely high quality source of Level IV evidence. However, randomized controlled trials with small numbers of subjects and industry sponsorship earn a lower rating. A rating of C1 requires an inferior Level II-IV, or a high quality Level V, source of evidence, or alternatively a Level VI evidence source endorsed by the committee. A rating of C2 is based on sources lacking valid evidence, or providing invalid evidence, while a rating of D is based on high-quality sources with invalid or harmful findings.

The commentary and recommendations in guidelines published outside Japan were referred to frequently for their value in helping us to establish the criteria for determining the ratings presented here.

In some of the CQs for which there was a paucity of evidence relating directly to pressure ulcers, the range of sources was broadened to include those

dealing with injuries and cutaneous ulcers as well. In such cases, however, the strength of the recommendation was accordingly lowered.

The endorsement of the guideline committee was required for inclusion into the guidelines of treatments which earned the rating C1, insofar as such treatments were deemed valuable for clinical practice, even if they lacked sufficient evidence.

5. Funding and Conflict of Interest

Funding for the compilation of the present guidelines was provided entirely by the Japanese Society of Pressure Ulcers and does not derive in any part from other organizations or industries. Further, the content of each rating was decided by a vote of the guideline revision committee. If any member of the guideline revision committee was found to have a conflict of interest in connection with any item, he or she was asked to abstain from voting on the item in question.

6. Definition of Terms

The definition of the terms used in the present guidelines conforms to that laid down by the Technical Definitions Committee of the Japanese Society of Pressure Ulcers. A separate set of terms was prepared herein for use with the DESIGN and DESIGN-R scales published by the Japanese Society of Pressure Ulcers to reflect the unique history and development of this project.

7. Peer Reviews and Plans for Future Revisions

The present guidelines were made possible by the contributions and peer reviews of numerous members of the guideline revision committee and based on the unanimous approval of all of the members, arrived at through the process of debate and discussion. During this process, feedback from other members of the Japanese Society of Pressure Ulcers was sought at two symposia held by the Society. Members were also encouraged to submit their opinions via the Society’s website.

The present guidelines will be revised under the leadership of the Academic Education Committee of the Japanese Society of Pressure Ulcers at intervals of every several years.

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From DESGIN to DESIGN-R

In 2002, the Academic Education Committee of the Japanese Society of Pressure Ulcers announced the DESIGN (Depth, Exudate, Size, Inflammation/Infection and Necrosis) scale in answer to needs: namely, first, the need for a means of assessing pressure ulcers according to severity, and second, for a means of quantifying aspects of the treatment process in terms of the wound parameters of depth, exudate, size, inflammation/infection, granulation, and necrosis.

Although scales with similar purposes, such as the Bates-Jansen's Pressure Sore Status Tool (PSST)¹⁾, NPUAP's Pressure Ulcer Scale for Healing (PUSH)²⁾, and Ohura's Assessment of Pressure Ulcer-Healing Process (PUHP)³⁾ have already been put to practical use, each scale presents some difficulties which DESIGN attempts to address. DESIGN was developed on the basis of expert opinion and incorporates four features, namely, its ability to: 1) quantify severity of pressure ulcers and the healing process 2) monitor intervention in term of each of the parameters mentioned above and changes in wound surface 3) provide a standard and convenient tool for use in the clinical setting and 4) be compatible with international standards for care and intervention.

In order for such a scale to be readily accepted, it was necessary to test its inter-rater reliability, content validity, construct validity, concurrent validity and predictive validity. When DESIGN was developed,

testing of its predictive validity was omitted⁵⁻⁸⁾ with the result that questions were raised as to its fitness to quantitate the severity of patients' conditions, although there was no question as to its ability to assess changes in the condition of individual cases. Thus with a view to realizing a scale which would enable the health care professional not only to evaluate pressure ulcer progression but also predict its severity reliably and accurately, revision of the scale was begun in 2005. Since DESIGN had already been widely used clinically, some preconditions were called for, that is, the seven parameters measured by DESIGN-P (P indicates 'pocket' or 'undermining') were to remain unaltered. In order to make this feasible, first, a large-scale (2598 cases) retrospective case-series study was conducted, followed by a prospective case-series study with 1003 cases. For each study, a large number of subjects were enrolled in both the healing and non-healing groups using the Cox hazard analysis.

As a result, the parameters were ranked according to their weight as follows: pocket, size, inflammation/infection, granulation tissue, exudates, and necrosis. A positive correlation was found among these parameters, excluding inflammation/infection, where a higher degree of severity was accompanied by a higher weighting of the individual parameters⁹⁻¹¹⁾. In terms of background information, a comparatively large number of aged persons were enrolled. The facilities examined were mostly university hospitals and the number of home care settings was small. However, when Cox hazard analysis was conducted using these factors as adjusted variables, there was no change in weighting, demonstrating that the bias in terms of the age and types of institution had no effect on the scale's weighting.⁹⁾

In order to make the statistically calculated weightings more convenient for clinical use, the weighted values were simplified to be multiples of 3. Comparison of the weightings before and after their simplification showed that correlation was high at 0.991 while also affirming that the procedure did not influence severity evaluation. Finally, the depth parameter values were found to be unrelated to the weighted values but rather to reflect the status of the pressure ulcer. For this reason it was not included in the total score. In order to draw attention to the fact that weighting had been added as a novel feature, the

name of the scale was changed from DESIGN to DESIGN-R with 'R' standing for 'rating.' In 2008 DESIGN-R was published and has since been widely used throughout the Japan as a pressure ulcer assessment scale with acceptable predictive validity.

References

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Algorithm for Prevention and Management of Pressure Ulcers

The decision tree (**Fig. 1**) illustrates the process by which procedures for the prevention and/or management of pressure ulcers in the target population may be designed.

First, subjects are given a general physical examination and their risk of developing pressure ulcers is assessed. In cases in which there is no risk of developing pressure ulcers, the condition of the subject continues to be monitored regularly. In cases where there is risk of developing pressure ulcers, local inspection of the skin is performed and the presence or absence of pressure ulcers is confirmed. In the absence of pressure ulcers, a suitable regimen of preventive care (**Fig. 6**) or general care (**Fig. 4**) may be designed and implemented. If a pressure ulcer is found, **Fig. 7 or 5** may be consulted in order to design an effective care regimen for treatment. **Fig. 2 and 3** may be also consulted in order to determine the most suitable treatment modality, such as conservative treatment or surgical intervention. Following successful implementation of this phase of patient care, risk of further occurrence (or recurrence) of pressure ulcers, the patient's general physical condition, and state of existing pressure ulcers may be assessed as appropriate.

Table of Clinical Questions (CQ)s and Accompanying Recommendations

Clinical questions (CQ)s and their accompanying recommendations are shown in **Table 1~13**.

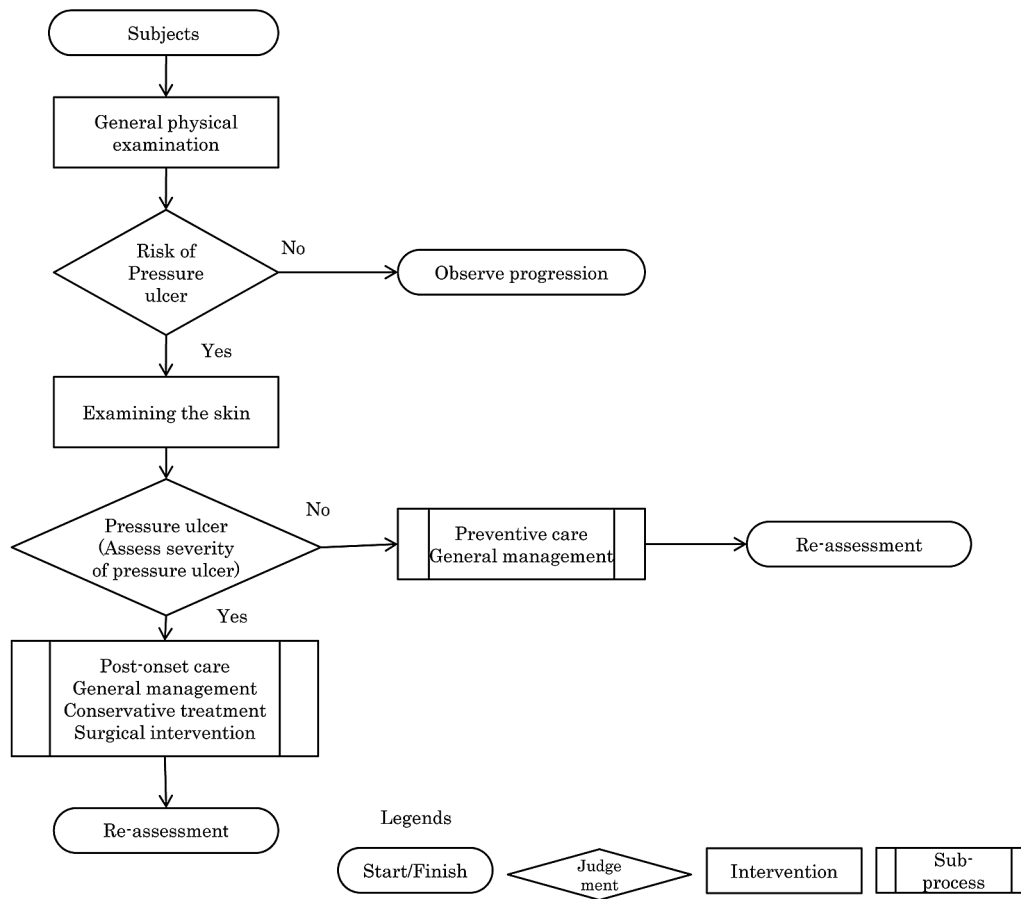


Fig. 1 Algorithm illustrating options for prevention and management of pressure ulcers

Table 1 Topical agents

Clinical Question		Rating	Recommendation
CQ 1.1	Which topical agents are recommended to treat acute pressure ulcers?	C1	Oleaginous preparations such as zinc oxide, dimethyl isopropylazulene, white petrolatum, with a high degree of efficacy in protecting wound surfaces, and silver sulfadiazine may be considered.
CQ 1.2	Which topical agents are indicated in cases with suspected deep tissue injury (DTI)?	C1	Close monitoring of the wound is important. Oleaginous preparations such as zinc oxide, dimethyl isopropylazulene and white petrolatum may be considered.
CQ 1.3	Which topical agents are recommended for cases involving redness/purpura?	C1	It is important in cases of redness/purpura to protect the wound surfaces. Dimethylisopropylazulene and white petrolatum may be used for this purpose.
CQ 1.4	Which topical agents are recommended for cases involving blistering?	C1	White petrolatum or zinc oxide may be used to protect the wound surface.
CQ 1.5	Which topical agents are recommended to treat erosions and shallow ulcers?	C1	Zinc oxide or dimethyl isopropylazulene may be used. Alprostadil alfadex, bucladesine sodium, or lysozyme hydrochloride may also be used to promote re-epithelialization.
CQ 1.6	Are topical agents recommended if pain accompanies the pressure ulcer?	C2	There is no evidence supporting the use of topical agents to alleviate pain.
CQ 1.7	Which topical agents are recommended for pressure ulcers with excessive exudate?	B	Cadexomer-iodine and povidone-iodine sugar are both highly absorbant and are recommended for pressure ulcers with excessive exudate.
		C1	Dextranomer and iodine ointment may be considered.
CQ 1.8	Which topical agents are recommended in pressure ulcers with minimal exudate?	C1	Ointments with emulsion bases are preferred. Silver sulfadiazine may be considered to treat infected wounds while tretinoin tocoferil may be considered to treat uninfected wounds.
CQ 1.9	How should a pressure ulcer be cleaned?	C1	Cleanse the pressure ulcer using isotonic saline or tap water in sufficient quantities to reduce the microbial count on the wound surface.
CQ 1.10	How should pressure ulcers be disinfected?	C1	Wound cleansing is usually adequate to prevent infection. However, if the wound is clearly infected or if there is excessive exudate or pus, the wound may be disinfected using antiseptics prior to cleansing.
CQ 1.11	Which topical agents are recommended for pressure ulcers accompanied by infection and inflammation?	B	Cadexomer-iodine, silver sulfadiazine, and povidone-iodine sugar are recommended for their ability to control infections.
		C1	Fradiomycin sulfate-trypsin, povidone-iodine, iodine ointment, and iodoform gauze may be considered.
CQ 1.12	Which topical agents are recommended to accelerate granulation formation in pressure ulcers with deficient granulation formation?	B	Aluminium chlorohydroxy allantoinate, trafermin, tretinoin tocoferil and povidone-iodine sugar, all of which are known to accelerate granulation formation, are recommended.
		C1	Alprostadil alfadex, bucladesine sodium, or lysozyme hydrochloride may be considered.
CQ 1.13	Which topical agents are recommended in pressure ulcers with deficient granulation formation and suspected critical colonization?	C1	Topical medications with an anti-microbial properties, such as cadexomer-iodine ointment, povidone-iodine sugar, iodine ointment, or silver sulfadiazine may be used.
CQ 1.14	Which topical agents are recommended for wound reduction in pressure ulcers with sufficient granulation formation?	B	Alprostadil alfadex, aluminum chlorohydroxy allantoinate, trafermin, bucladesine sodium, and povidone-iodine sugar are recommended.
		C1	Zinc oxides, dimethyl isopropylazulene, extract from hemolyzed blood of young calves, and lysozyme hydrochloride may be used.
CQ 1.15	Which topical agents are recommended if necrotic tissue is observed?	C1	Cadexomer-iodine, silver sulfadiazine, dextranomer, bromelain or povidone-iodine sugar may be considered.
CQ 1.16	Which topical agents are recommended when undermining has occurred?	C1	If the undermining is covered by necrotic tissue, the wound surfaces should first be cleaned. Also, if there is excessive exudate, povidone iodine-sugar may be used. If the amount of exudation is minimal, consider using trafermin or tretinoin tocoferil.

Table 2 Dressings

Clinical Question		Rating	Recommendation
CQ2.1	Which dressings are recommended to treat acute pressure ulcers?	C1	In order to protect the wound surface while allowing daily monitoring of the condition, transparent film dressings or dressings designed to treat dermal wounds may be used.
CQ 2.2	Which dressings are indicated in pressure ulcers with suspected deep tissue injury (DTI)?	C1	In order to protect the wound surface while allowing daily monitoring of the condition, either transparent film dressings or dressings designed to treat dermal wounds may be considered.
CQ 2.3	Which dressings are recommended for pressure ulcers involving redness/purpura?	C1	In order to protect the wound surface while allowing daily monitoring of the condition, either film dressings or dressings designed to treat transparent dermal wounds may be considered.
CQ 2.4	Which dressings are recommended for cases involving blistering?	C1	While leaving the blisters intact, consider using a transparent film dressing to protect the wound surface. A dressing for dermal wounds that allows observation may also be considered.
CQ 2.5	Which dressings are recommended for treating erosions or shallow ulcers?	B	A health insurance-covered hydrocolloid dressing used to treat dermal wounds is recommended. A hydrocolloid dressing used to treat subcutaneous wounds is also an option, but is not covered by health insurance.
		C1	Health insurance-covered dressings designed to treat dermal wounds, such as hydrogel, polyurethane foam sheets, alginate foam dressing, and chitin membrane may be considered. Dressings designed to treat subcutaneous wounds, such as hydrogel, hydropolymer, polyurethane foam, polyurethane foam/soft silicone, alginate, and chitin membrane can also be employed with equal effect, but are not covered by health insurance.
CQ 2.6	Which dressings are recommended for pressure ulcers involving pain?	C1	Dressings cannot remove pain but can lessen it by protecting the wound surface and maintaining a moist environment conducive to wound healing. When changing dressings, perform adequate pain assessment and apply a hydrocolloid, polyurethane foam, polyurethane foam/soft silicone, Hydrofiber [®] , chitin membrane, or hydrogel.
CQ 2.7	Which dressings are recommended in pressure ulcers with excessive exudate?	B	Recommend using polyurethane foam dressings, which can absorb excess exudates.
		C1	Dressings normally used for subcutaneous wounds as well as dressings used to treat deeper wounds involving muscle and bone, such as alginate/CMC, polyurethane foam/soft silicone dressings, alginate, alginate foam, chitin membrane, Hydrofiber [®] , or hydropolymer dressings, may be applied.
CQ 2.8	Which dressings are recommended for pressure ulcers with minimal amounts of exudates?	B	Using a hydrocolloid dressing is recommended.
		C1	Using a hydrogel may be considered.
CQ 2.9	Which dressings are recommended for infected and inflamed pressure ulcers?	C1	Consider using topical agents to suppress infection. Alternatively, silver-containing Hydrofiber [®] or alginate silver may be used.
		C2	Alginate is sometimes used to dress wounds with excessive exudates because of its superior absorptive ability, but cannot be recommended here due to its inability to suppress infection.
CQ 2.10	Which dressings are recommended for promoting granulation tissue formation in pressure ulcers where it is deficient?	C1	Alginate, hydrocolloid, hydropolymer, polyurethane foam, polyurethane foam/soft silicone, chitin membrane and Hydrofiber [®] may be considered.
CQ 2.11	Which dressings are recommended in pressure ulcers with deficient granulation tissue formation and suspected critical colonization?	C1	Consider using silver-containing Hydrofiber [®] or alginate silver.
CQ 2.12	Which dressings are recommended to promote the reduction of the size of wounds with adequate/normal granulation tissue formation?	B	Using silver-containing Hydrofiber [®] , alginate silver, or alginate is recommended.
		C1	Hydrocolloid, hydrogel, hydropolymer, polyurethane foam, polyurethane foam/soft silicone dressing, alginate foam, chitin membrane, Hydrofiber [®] , alginate/CMC are also options, depending on the amount of exudate present.
CQ 2.13	Which dressings are recommended when necrotic tissue is present?	C1	If surgical debridement or topical agents capable of removing necrotic tissue are unavailable, hydrogel may be considered.
CQ 2.14	Which dressings are recommended if undermining is found?	C1	If necrotic tissue is present within the undermining, first remove this through lavation. If the amount of exudate is excessive, consider using alginate, silver-containing Hydrofiber [®] , or alginate silver.
CQ 2.15	Is the so-called 'wrap dressing' * effective in treating pressure ulcers?	C1	Wrap dressings can be considered for use whenever medically approved dressings are unavailable or difficult to obtain on a continual basis, such as in a home based medical care. However, use of the wrap dressing should be supervised by a physician with an adequate knowledge of pressure ulcer care and only after the patients and their family have been instructed in the procedure and given their consent. * 'Wrap dressing' is a dressing technique of covering wounds with non-medically approved (unsterilized) and non-adhesive commercially available plastic wrap.

Table 3 Surgical Intervention

Clinical Question		Rating	Recommendation
CQ3.1	Is surgical debridement indicated when signs of infection/inflammation of the pressure ulcer are present?	C1	Surgical debridement may be conducted if there is evidence of pus, foul odor, or osteomyelitis accompanying the infection.
CQ3.2	What is the optimal timing for the surgical debridement of necrotic tissue in pressure ulcers?	C1	Surgical debridement may be considered when a clear line of demarcation between necrotic and healthy tissue is visible.
		C1	Surgical debridement is considered when preexisting infection has been brought under control.
CQ 3.3	Is surgical incision or debridement recommended if undermining is present?	C1	Surgical incision or debridement may be considered for treating undermining which fails to respond to more conservative treatments.
CQ3.4	When is surgical debridement indicated?	C1	Conservative treatments are the preferred option, but surgical debridement may be performed when infection/inflammatory signs are under control.
		C1	Surgical debridement may be considered for patients with a D3 or D4 pressure ulcer.
		C1	Surgical debridement may be considered according to the location of the infected pressure ulcer, the volume and extent of the necrotic tissue, the blood supply to the surrounding tissue, and the patient's level of pain tolerance.
CQ3.5	When is reconstructive surgery indicated?	C1	Reconstructive surgery may be considered for D3~D4 pressure ulcers that do not respond to conservative treatment.
		C1	Surgical reconstruction may be considered for ulcers showing a non-advancing edge and scar formation.
		C1	Reconstructive flap surgery following sequestration may be considered as a therapeutic option for osteomyelitis in pressure ulcers.
CQ 3.6	Which reconstructive surgical procedure is considered especially effective for pressure ulcers?	C1	There are numerous options for reconstructive surgery for pressure ulcers, but insufficient evidence on the outcome of any of these procedures. For this reason, no single surgical procedure can be recommended as applicable to all cases.
CQ3.7	What kind of physiotherapy is recommended for pressure ulcers with low amounts of granulation tissue?	C1	Negative pressure wound therapy (NPWT) may be considered for the treatment of wounds following debridement of infectious or necrotic tissue.

Table 4 General management

Clinical Question		Rating	Recommendation	
Preventive general management	CQ4.1	Which underlying medical conditions may entail the risk of leading to pressure ulcers?	C1 Pelvic fractures, diabetes mellitus, cerebro-vascular diseases, and spinal cord injuries potentially lead to pressure ulcer formation due to patient immobility.	
	CQ4.2	What form of nutritional intervention is recommended for the prevention of pressure ulcers in malnourished patients?	B For patients suffering from protein-energy malnutrition (PEM), using an enhanced energy and protein supplement after due consideration of any underlying conditions is recommended.	
	CQ4.3	How should patients incapable of oral intake of nutrition and hydration be fed?	C1 Consider supplying the required nutrition by enteral tube-feeding. When this is not possible, consider parenteral feeding.	
	CQ4.4	What indices can be used to assess the level of malnutrition as a risk factor for pressure ulcers?	C1	In the absence of inflammation or dehydration, serum albumin levels may be used.
			C1	Rate of weight loss may be considered for use.
			C1	Consider using the rate of food intake or the amount of food consumption as an index.
			C1	Consider using Subjective Global Assessment (SGA).
C1	Mini Nutritional Assessment (MNA) may be used with elderly patients.			
General management after occurrence	CQ4.5	When is the systemic administration of antibiotics (antimicrobials) indicated in patients with an infected pressure ulcer?	C1 If physical examination findings or test results indicate advancing cellulitis and osteomyelitis, necrotizing fasciitis, bacteremia, or sepsis, consider administering systemic antibiotics. If only symptoms of local infection are found, administration of systemic antibiotics need not be considered.	
	CQ4.6	Which antibiotics (antimicrobials) are recommended for treating infection?	C1 Consider using empiric antibiotics to suspected pathogens common in clinical settings. Reconsider using more specific antibiotics to pathogens by referring the results of susceptibility testing.	
	CQ4.7	Which underlying conditions may pose a risk of prolonging the healing of pressure ulcers?	C1 Malignant tumors and cardiovascular diseases should be considered as factors which may prolong the healing of pressure ulcers.	
	CQ4.8	Should a nutritional screening and assessment be performed for pressure ulcer patients?	C1 A nutritional screening and assessment and nutritional intervention may be considered if required.	
	CQ4.9	How much nutrition in general should be provided to pressure ulcer patients?	B	In order to ensure adequate energy for healing of pressure ulcers, recommend providing patients with 1.5 times the basal energy expenditure (BEE).
			B	Recommend providing additional protein as required.
	CQ4.10	Should the diet of pressure ulcer patients be supplemented with any specific nutrients?	C1 Patients' diet may be supplemented with zinc, arginine, and ascorbic acid to prevent deficiencies of these nutrients.	
	CQ4.11	Should a registered dietician or multidisciplinary nutritional team participate in the care of pressure ulcer patients?	C1 Participation by a registered dietician or multidisciplinary nutrition support team in the care of pressure ulcer patients may be recommended.	
CQ4.12	Should body weight be used as a means of assessing the efficacy of nutritional supplementation in pressure ulcer patients?	B Recommend using body weight as a means of assessing the effectiveness of nutritional supplementation if edema or dehydration can be ruled out.		

Table 5 Rehabilitation

Clinical Question		Rating	Recommendation
Risk assessment	CQ 5.1 Which factors account for pressure ulcer development in chronic spinal cord injury patients?	B	For patients with a history of pressure ulcers, vigilance is recommended to prevent recurrence.
Preventive care	CQ 5.2 Which methods are effective for preventing pressure ulcer development in spinal cord injury patients?	C1	Conducting rehabilitation while monitoring interface pressure may be considered.
	CQ5.3 What type of cushion should be used with elderly patients in a seated position to prevent pressure ulcers?	B	A pressure-redistributing seat cushion for individuals with spinal cord injury is recommended to prevent pressure ulcer development while seated.
	CQ5.4 Should limitations be set on the length of time in which the individual remains continuously seated?	B	Limitations on sitting time should be set if the elderly individual is unable to reposition without assistance.
	CQ5.5 At what intervals should the seated individual be repositioned?	C1	Repositioning every 15 min is recommended for seated individuals who are capable of changing their body position without assistance.
	CQ5.6 Should the individual's posture while seated be considered?	C1	The alignment and balance of the seated individual's body should be considered.
	CQ5.7 Should donut-type devices be used?	D	Donut-type devices are not recommended.
	CQ5.8 What kind of physical modality can be used to treat muscular atrophy?	C1	Consider using electric stimulation therapy.
	CQ5.9 What kind of therapeutic exercise can be used to treat joint contracture?	C1	Consider using passive range of motion exercises.
	CQ5.10 Should tissue overlying bony prominences be massaged?	D	Massaging areas covering bony prominences is not recommended.
	Care after occurrence	CQ5.11 How can daily use of the wheelchair by patients with shallow pressure ulcers be facilitated?	C1
Conservative treatment	CQ5.12 What kind of physical modality can be used for patients with infected pressure ulcers?	C1	Hydrotherapy may be considered.
	CQ5.13 What kind of physical modality can be used for pressure ulcers containing necrotic tissue?	C1	Consider hydrotherapy or pulsatile lavage with or without suction.
	CQ5.14 What kind of physical modality can be used to promote wound reduction?	B	Implementing electrical stimulation therapy is recommended.
C1		Near infrared therapy, ultrasonic therapy, or electromagnetic therapy may be considered.	

Table 6 Risk assessment

Clinical Question		Rating	Recommendation
CQ6.1	Is risk assessment effective in predicting the development of pressure ulcers?	B	Use of risk assessment scales is recommended for predicting pressure ulcer development.
CQ6.2	Which risk assessment scale should generally be used?	B	Use of the Braden Scale is recommended for most situations.
CQ6.3	What method of assessment used for elderly patients?	C1	Assessing the risk factors for pressure ulcer development may be considered.
CQ6.4	Which risk assessment scale is recommended for use with the elderly?	C1	The OH Scale may be used with bedridden elderly patients.
		C1	The K Scale may be used with bedridden elderly patients in hospital.
CQ6.5	Which risk assessment scale is recommended for pediatric patients?	C1	The Braden Q Scale may be considered for risk assessment in pediatric patients.
CQ6.6	Which risk assessment scale is recommended for spinal cord injury patients?	C1	The SCIPUS scale may be considered for risk assessment in spinal cord injury patients.
CQ6.7	Which risk assessment scale is recommended for subjects in a home-care setting?	C1	A pressure ulcer risk assessment scale specifically designed for patients in a home care setting may be used.

Table 7 Skin assessment

Clinical Question		Rating	Recommendation
CQ 7.1	How can the depth of pressure ulcers be predicted?	C1	The prediction of d1 pressure ulcer prognosis may be based on the presence of double erythema (graduated redness) away from a bony prominence.
		C1	Ultrasonography may be used.
		C1	The ABI (ankle brachial index) may be used to predict the depth of pressure ulcers in the heel region.
CQ7.2	How can redness/d1 stage pressure ulcer be identified?	C1	The transparent disk method or the finger method may be considered.
CQ7.3	Which methods can be used to identify deep tissue injury (DTI)?	C1	Palpate the area to see whether pain, induration, edema, or changes in skin temperature (warm or cool) are present in comparison with the adjacent tissue.
		C1	Consider using ultrasonography.

Table 8 Skin care

Clinical Question		Rating	Recommendation	
Preventive care	CQ8.1	What kind of skin care is recommended for patients suffering from urinary and/or fecal incontinence in order to prevent development of pressure ulcers?	C1	After cleansing with an appropriate cleansing agent, skin emollients can be applied to the anal/genital area and to the peripheral skin.
	CQ8.2	What type of preventive skin care is recommended for use on bony prominences in elderly patients?	B	Transparent film dressings and other dressings with a low-friction external surface are recommended.
	CQ8.3	What kind of skin care is recommended for patients undergoing surgery in a supine position?	C1	A transparent film dressing can be applied to the sacral area.
	CQ8.4	What kind of skin care is recommended for non-invasive ventilation patients to prevent pressure ulcer formation at the face mask contact site?	C1	A transparent film dressing or a hydrocolloid dressing may be used for this purpose.
Care after occurrence	CQ8.5	How should the skin surrounding a pressure ulcer be cleansed in order to promote pressure ulcer healing?	C1	Cleansing with a mildly acidic cleansing agent may be considered.
	CQ8.6	In cases with urinary and/or fecal incontinence, what kind of skin care is recommended to promote pressure ulcer healing?	C1	Skin emollients can be applied to the peripheral skin after cleansing with an appropriate cleansing agent.

Table 9 Repositioning

Clinical Question		Rating	Recommendation	
Preventive care	CQ9.1	How frequently should the bed bound patient be repositioned to prevent pressure ulcer?	C1	Consider repositioning the patient at least every two hours.
	CQ 9.2	How frequently should bed bound patient be repositioned when a support surface is being used?	C1	When a visco-elastic foam mattress is being used, consider repositioning the patient at least every four hours.
			C1	When a double-layer air-cell mattress overlay is being used, consider repositioning the patient at least every four hours.
	CQ 9.3	When repositioning bed bound patients, what positions should be undertaken to avoid pressure ulcer formation?	C1	A 30- and 90-degree angle for the laterally recumbent position may be considered.
CQ 9.4	How can patients in intensive care be repositioned in order to prevent pressure ulcer formation?	C1	The patient may be repositioned in an electric rolling hospital bed.	
Care after occurrence	CQ 9.5	What positions should be undertaken to promote healing in patients with pressure ulcers in the gluteal region?	C1	Any position besides the 30-degree tilted side-lying position or head-of-bed elevated position may be undertaken.

Table 10 Support surfaces

Clinical Question		Rating	Recommendation
Preventive care	CQ10.1	Should support surfaces be used to lower the incidence of pressure ulcers?	A Use of support surfaces is strongly recommended in order to lower the incidence of pressure ulcers.
	CQ10.2	Which support surface is recommended for completely immobile patients?	B Recommend using an alternating-pressure air mattress overlay/replacement.
			C1 Consider using a foam mattress replacement.
	CQ10.3	Which support surface is recommended for prevention of pressure ulcers in elderly individuals?	B Recommend using a double-layer air-cell mattress.
			C1 An alternating-pressure air mattress overlay/ replacement, air-filled mattress overlay, or foam mattress may also be used.
	CQ10.4	Which support surfaces are recommended for prevention of pressure ulcers in intensive care patients?	B Recommend using a low air pressure mattress.
			C1 A low-air-loss bed, an alternating-pressure air mattress overlay, or an air-filled mattress replacement may also be considered.
	CQ10.5	Which tools, including support surfaces, are effective in preventing the development of pressure ulcers during perioperative periods?	B Support surfaces on the operating table are recommended for patients at risk of developing pressure ulcers.
			B In addition to using support surfaces, visco-elastic pads or gel applied to the heel area, cubital region, and other areas with bony prominences is recommended during operations.
			C1 During and after operations, an alternating-pressure air mattress overlays/replacement may be used.
			C1 The bead bed system may be used during surgery for patients undergoing surgery to repair femoral-neck fracture.
	C1 Thermoactive viscoelastic foam overlay may be used for patients who will undergo cardiac surgery.		
CQ10.6	Which support surfaces can be used to facilitate care for convalescent patients in a home-care setting?	C1 An automatic turning air mattress may be used.	
CQ10.7	Which support surfaces provide the greatest comfort both while awake and sleeping?	B Using an alternating-pressure air mattress replacement is recommended.	
		C1 For terminally ill patients, an alternating-pressure air mattress with automatic adjustment to the patient's weight and position may be considered.	
CQ10.8	What precautions should be taken when using foam mattresses?	C1 Monitor the deterioration of the foam due to fatigue.	
Care after occurrence	CQ10.9	Which support surfaces are recommended for promoting healing in d1, d2, and D3~D5 pressure ulcers?	A Use of an air-fluidized bed or low-air-loss bed is strongly recommended to promote healing in D3~D5 pressure ulcers or pressure ulcers in multiple sites.
			C1 Use of an alternating-pressure air mattress with automatic adjustment for the patient's position and weight function replacement, an alternating-pressure large-cell ripple mattress, a double-layer air-cell mattress, or a low air pressure mattress may be considered to promote healing in d2 or deeper pressure ulcers.
			C1 Use of an air-filled mattress overlay may be considered to promote healing in d1/2 pressure ulcers.
			C1 Use of an alternating-pressure air mattress with automatic adjustment to the patient's weight and position may be considered after flap reconstruction for pressure ulcers.

Table 11 Patient education

Clinical Question		Rating	Recommendation	
Preventive care	CQ 11.1	How can patients and their family or caregivers be educated to prevent the development or recurrence of pressure ulcers?	C1	Education/training in repositioning and using support surfaces can be carried out .
			C1	Periodic telephone consultations with a health care professional and/or remote assessment of the patient’s skin condition using electronic visual media may be done.
			C1	Education by an e-learning system led by the health care professional may be given.
			C1	Education/training in any or all of the following may be given: the etiology of ulcers, risk factors, staging, principles of wound healing, nutritional support, program of skincare and skin inspection, and management of incontinence.
Care after occurrence	CQ11.2	How should patients/family/caregivers be educated/trained in the care of existing pressure ulcers?	C1	Consider informing patient/family/caregiver how to contact an appropriate medical center for help in the event the pressure ulcers worsen.

Table 12 Outcome management

Clinical Question		Rating	Recommendation
CQ12.1	Which measures should be undertaken in a hospital care setting to prevent pressure ulcers?	A	Choice of support surface based on the Braden Scale is strongly recommended.
		C1	Choice of support surface based on the OH Scale may be considered.
		C1	Deployment of a multidisciplinary wound care team may be considered.
		C1	Assignment of wound ostomy and continence nurse may be considered.
		C1	Introduction of reimbursement system for pressure ulcer high risk patient care may be considered.
		C1	Implementation of comprehensive programs and protocols may be considered.
CQ12.2	Which measures are recommended for pressure ulcer prevention in long-term care facilities?	C1	Implementation of comprehensive programs and protocols may be considered.
		C1	Use of an algorithm incorporating the Braden Scale to implement preventive care may be considered.
CQ12.3	Which measures are recommended to promote healing of pressure ulcers in a hospital care setting?	C1	Deployment of a multidisciplinary wound care team may be considered.
		C1	Introduction of reimbursement system for pressure ulcer high risk patient care may be considered.
		C1	Assignment of wound ostomy and continence nurse may be recommended.
CQ12.4	Which measures are recommended to promote healing of pressure ulcers in a long-term care facility?	B	Deployment of a multidisciplinary wound care team is recommended.
		C1	Implementation of comprehensive programs and protocols may be considered.

Table 13 QOL/ Pain

Clinical Question		Rating	Recommendation
CQ13.1	How can the quality of life (QOL) of pressure ulcer patients be assessed?	C1	The QOL of the patients may be assessed along physiological, psychological, and social parameters.
CQ13.2	For which stage of pressure ulcer is pain assessment recommended?	C1	Pain may be assessed at any stage of pressure ulcer.
CQ13.3	When should pain assessment be conducted?	C1	Pain assessment may be conducted at any time (regardless of whether topical intervention is being administered).
CQ 13.4	Which tools can be used to assess pressure-ulcer-related pain?	C1	Pain may be assessed using a validated scale.

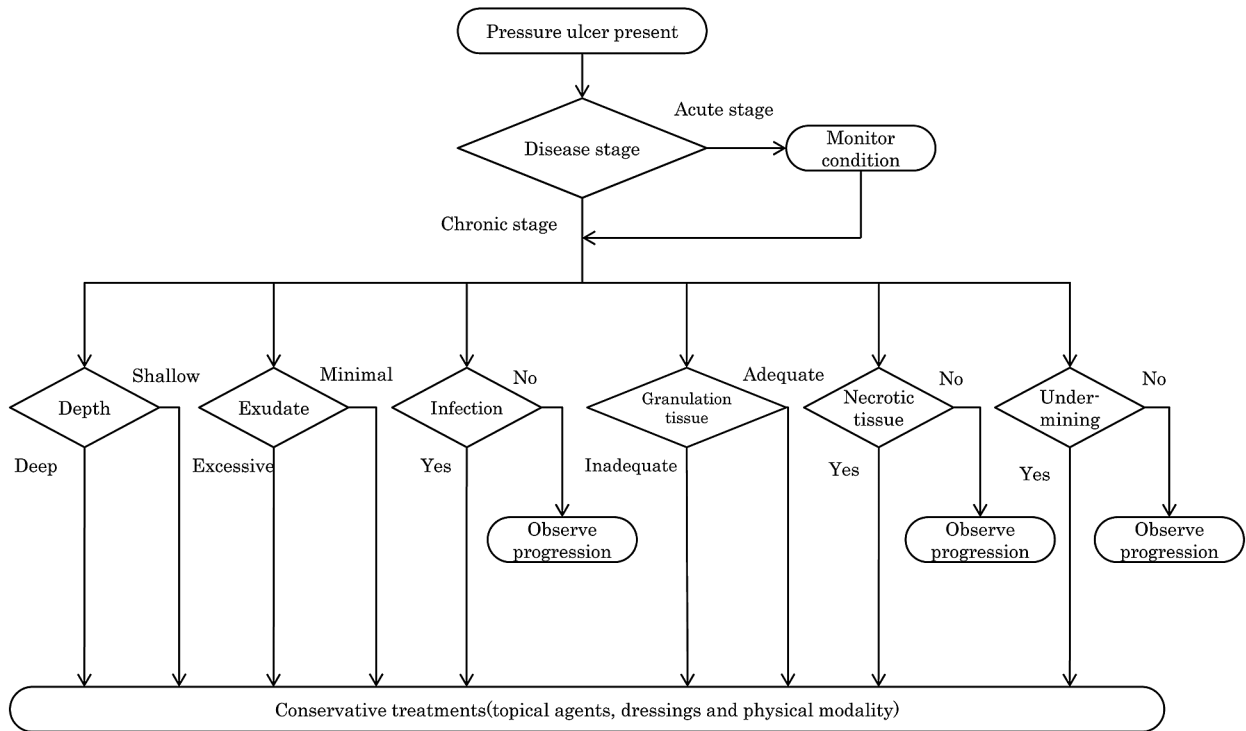


Fig. 2 Algorithm illustrating conservative treatments

Guidelines

CQ 1 Topical agents

CQ 1.1 : Which topical agents are recommended to treat acute pressure ulcers?

[Recommendation] Oleaginous preparations such as zinc oxide, dimethyl isopropylazulene, white petrolatum, with a high degree of efficacy in protecting wound surfaces, and silver sulfadiazine may be considered.

[Rating] C1

[Analysis] At present, observations of only a most general nature exist regarding the choice of topical agents for the treatment of acute pressure ulcers¹⁾. As a first step, it is critical to ascertain the cause of the injury before considering the type of topical therapy to employ. This is underscored by the fact that in many cases of acute pressure ulcers, the presence of deep tissue damage may at first go unnoticed, and lead naturally to an exacerbation of the condition. For this reason, the basic considerations when employing topical therapy to treat acute pressure ulcers include maintaining an optimally moist environment conducive to wound healing while closely monitoring for changes in the condition of the wound itself. Typically, oleaginous preparations that are known to be highly

efficacious in protecting wound surfaces, such as white petrolatum, are preferred for treatment¹⁾. If the ulcer surface is infected, silver sulfadiazine and similar preparations with nonspecific anti-bacterial properties are recommended, as antibiotic topical agents typically fail to produce the desired effect.

References

- 1) Kawakami S, Shimada K : Treatment of acute pressure ulcers. *Modern Physician*, 28 : 506-507, 2008. (Level VI) (Japanese)

CQ 1.2 : Which topical agents are indicated in cases with suspected deep tissue injury (DTI)?

[Recommendation] Close monitoring of the wound is important. Oleaginous preparations such as zinc oxide, dimethyl isopropylazulene and white petrolatum may be considered.

[Rating] C1

[Analysis] At present, only expert opinion exists regarding the choice of topical agents for the treatment of deep tissue injuries (DTI). The term DTI was proposed by the NPUAP (2007) to define a condition in which the appearance of overlying skin conceals the actual extent of damage to underlying tissue, which becomes more apparent with time as the

wound evolves into deeper layers of tissue¹⁾.

If deep tissue injury is suspected, pressure should be relieved immediately and the condition of the wound closely monitored. The wound may be occluded if necessary, but in a manner which will allow the condition of the wound to be readily monitored. Zinc oxide, dimethyl isopropylazulene, or white petrolatum and other oleaginous preparations are recommended.

References

- 1) Kadono T : Deep tissue injury. *Rinsho Hifuka*, 63 (5) : 38-41, 2009. (Level VI) (Japanese)

CQ 1.3 : Which topical agents are recommended for cases involving redness/purpura?

[Recommendation] It is important in cases of redness/purpura to protect the wound surfaces. Dimethyl isopropylazulene and white petrolatum may be used for this purpose.

[Rating] C1

[Analysis] Only expert opinions are available to treat non-blanchable redness and purpura. Treatments prioritize the protection of wound surfaces and tend to focus on the types of dressing used for this purpose. In cases which call for treatment using topical agents, white petrolatum or similar, petrolatum-based topical agents are preferred for their ability to stimulate wound healing while protecting the wound surfaces. Although dimethyl isopropylazulene in a petrolatum-based preparation is sometimes used for the treatment of non-blanchable redness and purpura because of its anti-inflammatory properties and reducing effects on edema¹⁾, its efficacy is generally low.

References

- 1) Nakamura I, Ozaki M, Watanabe B : Anti-inflammatory effects of azulene. *Rinsho Hifuka*, 12 : 769-778, 1958. (Level VI) (Japanese)

CQ 1.4 : Which topical agents are recommended for cases involving blistering?

[Recommendation] White petrolatum or zinc oxide may be used to protect the wound surface.

[Rating] C1

[Analysis] The choice of topical agent for the treatment of blisters is based only on expert opinion.

Treatments prioritize wound surface protection and tend to focus on the type of dressing used for this purpose. However, blisters may be punctured if tense, and ruptured blisters may require treatments usually employed for erosions and ulcers. In cases where topical agents are employed, white petrolatum or similar petrolatum-based topical agents are preferred for their ability to stimulate wound healing while protecting the wound surface. Although zinc oxide in a petrolatum-based preparation is customarily employed for this purpose not only because of its locally astringent effects and mildly antiseptic properties, but also for its ability to protect the wound surface and reduce inflammation while promoting tissue regeneration¹⁾, its efficacy is generally weak.

References

- 1) Edited by the Japanese Pharmacopoeia Instruction Manual Editorial Committee. *The Japanese Pharmacopoeia, Fourteenth Edition: Text with Annotations*, 1257-1259, Hirokawa Publishing Company, Tokyo, 2001. (Level VI) (Japanese)

CQ 1.5 : Which topical agents are recommended to treat erosions and shallow ulcers?

[Recommendation] Zinc oxide or dimethyl isopropylazulene may be used. Alprostadiol alfadex, bucladesine sodium, or lysozyme hydrochloride may also be used to promote re-epithelialization.

[Rating] C1

[Analysis] The choice of topical agent for the treatment of erosion and shallow ulcers is based only on expert opinion. As the treatment of erosion and shallow ulcers should prioritize protecting the wound surface and maintaining an optimally moist environment, the choice of dressing becomes crucial. White petrolatum or other preparations with a petrolatum base are often chosen for their efficacy in promoting wound healing while protecting the wound surface. Although zinc oxide, available as a petrolatum-based ointment, is not highly efficacious, it possesses mild, locally astringent, protective, and antiseptic, properties while simultaneously reducing inflammation and promoting tissue regeneration. Dimethyl isopropylazulene, also available in a petrolatum base, is well-known for its anti-inflammatory properties and its reducing effect on edema¹⁾, but its efficacy is generally low.

Alprostadi^l alfadex, available in a preparation using Plastibase[®], is effective in stimulating wound healing by promoting re-epithelialization, skin blood flow, and angiogenesis²⁾. While being a potent pro-circulatory agent, it is sometimes irritant to the skin. Bucladesine sodium possesses superior absorbancy due to its macrogol base and is recommended for cases with excessive exudate. Other effects of bucladesine sodium are: reduction of ulcer size, wound contraction, local pro-circulatory effects, angiogenesis, granulation tissue promotion, and re-epithelialization. Lysozyme hydrochloride is available in an emulsion base and is used with the aim of reducing wound size. While promoting keratinocyte and fibroblast growth, lysozyme hydrochloride is minimally irritant to the skin.

In summary, zinc oxide, and dimethyl isopropylazulene, as well as alprostadi^l alfadex, bucladesine sodium, and lysozyme hydrochloride are assigned Rating for Recommendation C1 for their efficacy in promoting re-epithelialization.

References

- 1) Nakamura I, Ozaki M, Watanabe B, et al : Anti-inflammatory effects of azulene. *Rinsho Hifuka*, 12 : 769-778, 1958. (Level VI) (Japanese)
- 2) Imamura S, Sagami S, Ishibashi Y, et al : Clinical study of prostaglandin E1 ointment (G-511 ointment) in chronic skin ulcers. Well-controlled comparative study with lysozyme chloride ointment. *J Clin Ther Med*, 10 : 127-147, 1994. (Level II) (Japanese)

CQ 1.6 : Are topical agents recommended if pain accompanies the pressure ulcer?

[Recommendation] There is no evidence supporting the use of topical agents to alleviate pain.

[Rating] C2

[Analysis] Randomized controlled trials using topical applications of morphine to relieve pain associated with pressure ulcers have been conducted outside Japan,^{1,2)} but the use of morphine is not common in this country. However, pain control during the acute phase of pressure ulcer is critical. Also, as many patients are incapable of reporting sensations of pain themselves, the task of bearing in mind the patient's susceptibility to pain and the possible need to administer suitable analgesics devolves upon the attending physician. Xylocaine jelly is among the topical medications sometimes used in Japan to

relieve pain, although its usefulness for this purpose has yet to be established. In summary, there is still insufficient evidence to recommend the use of topical agents for the relief of pain associated with pressure ulcers.

References

- 1) Flock P : Pilot study to determine the effectiveness of diamorphine gel to control pressure ulcer pain. *J Pain Symptom Manage*, 25 : 547-554, 2003. (Level II)
- 2) Zeppetella G, Paul J, Ribeiro MD : Analgesic efficacy of morphine applied topically to painful ulcers. *J Pain Symptom Manage*, 25 : 555-558, 2003. (Level II)

CQ 1.7 : Which topical agents are recommended for pressure ulcers with excessive exudate?

[Recommendation]

1. Cadexomer-iodine and povidone-iodine sugar are both highly absorbant and are recommended for pressure ulcers with excessive exudate.

[Rating] B

2. Dextranomer and iodine ointment may be considered.

[Rating] C1

[Analysis] Cadexomer-iodine, fibrinolysin-deoxyribonuclease-containing ointment, dextranomer and dextrin-polymer-base were tested to determine their relative efficacy in alleviating excessive exudation in pressure ulcers. The results of the test indicated an improvement rate of 65.8% for cadexomer-iodine in comparison with fibrinolysin-deoxyribonuclease-containing ointment (46.2%), demonstrating a statistically greater effect for the former ($p < 0.05$)¹⁾.

The study also indicated an improvement rate of 65.2% for cadexomer-iodine in comparison with dextranomer (18.2%), likewise demonstrating the statistically significantly greater efficacy of the former ($p < 0.01$)²⁾. On the other hand, cadexomer-iodine showed an efficacy rate of 33.3% in comparison with the dextrin-polymer-base (24%) with no significant difference in efficacy observed³⁾.

The ameliorative effect of povidone-iodine sugar on exudation has been compared with that of lysozyme hydrochloride ointment in two studies, and with that of ointment containing extract from hemolyzed blood of young calves in one study. The latter study demonstrated a significantly higher efficacy rate of

25% for povidone-iodine sugar in comparison with 0% for ointment containing extract from hemolyzed blood of young calves ($p < 0.01$)⁴⁾.

The two studies comparing the efficacy rate of povidone-iodine sugar and lysozyme hydrochloride have yielded opposite results, with one study indicating an efficacy rate of 25% for povidone-iodine sugar and 33.3% for lysozyme hydrochloride and no statistically significant difference in the results⁵⁾, while the second study indicated an efficacy rate of 49.1% for povidone-iodine sugar and 27.8% for lysozyme hydrochloride and a statistically greater efficacy rate for the former ($p < 0.01$)⁶⁾.

Further, a retrospective analysis of a case in which the DESIGN score decreased following the application of povidone-iodine sugar failed to establish any relationship between the amount of exudate and the decrease in the DESIGN score⁷⁾.

The ameliorative effect of dextranomer and iodine ointment on exudation has been documented in past case reports. Of the five cases reported, four demonstrated a decrease in the initially medium to high levels of exudation following treatment with dextranomer⁸⁾. Furthermore, case reports have documented a significant improvement in the DESIGN-R score and the E score in DESIGN following iodine ointment treatment^{9,10)}.

In summary, for the treatment of excessive exudation cadexomer iodine and povidone-iodine sugar are assigned a rating of B, while dextranomer and iodine ointment are assigned a rating of C1.

References

- 1) Kukita A, Ohura T, Aoki T, et al : Clinical evaluation of NI-009 on various cutaneous ulcers. Comparative study with Elase-C Ointment. *J Clin Ther Med*, 6 (4) : 817-848, 1990. (Level II) (Japanese)
- 2) Ishibashi Y, Ohkawara A, Kukita A, et al : Clinical evaluation of NI-009 on various cutaneous ulcers. Comparative study with Debrisan. *J Clin Ther Med*, 6 (4) : 785-816, 1990. (Level II) (Japanese)
- 3) Anzai T, Shiratori A, Ohtomo E, et al : Evaluation of clinical utility of NI-009 on various cutaneous ulcers. Comparative study with base. *J Clin Ther Med*, 5 (12) : 2585-2612, 1989. (Level II) (Japanese)
- 4) KT-136 Skin Ulcers Comparative Study Group : Comparative clinical study of sugar and povidone-iodine ointment (KT-136) and solcoseryl ointment (SS-094 : Ointment). *Jpn Pharmacol Ther*, 17 (4) : 1789-1813, 1994. (Level II) (Japanese)
- 5) Saito Y, Furuse Y, Ishii T, et al : A clinical randomized comparative study of povidone-iodine-sugar ointment (U-PASTA KOWA) versus combined ointment with lysozyme hydrochloride ointment (REFLAP Ointment) and povidone-iodine-sugar ointment (U-PASTA KOWA) on decubitus. *Jpn Pharmacol Ther*, 22 (5) : 2403- 2413, 1994. (Level II) (Japanese)
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CQ 1.8 : Which topical agents are recommended in pressure ulcers with minimal exudate?

[Recommendation] Ointments with emulsion bases are preferred. Silver sulfadiazine may be considered to treat infected wounds while tretinoin tocoferil may be considered to treat uninfected wounds.

[Rating] C1

[Analysis] There are no evidence-based reports besides expert opinion recommending topical agents for the treatment of minimally exudative wounds¹⁻³⁾. Emulsion-base ointments are typically recommended for such wounds, both by reason of their high moisture content and penetrating ability. Emulsion-

base ointments also have the added benefit of promoting water retention in dry wound surfaces. A representative example of such an emulsion-base topical agent is silver sulfadiazine, which possesses antibacterial properties and softens necrotic tissue, and tretinoin tocoferil, which promotes granulation tissue formation¹⁻³⁾.

In summary, silver sulfadiazine and tretinoin tocoferil are assigned a recommendation of C1 for the treatment of minimally exudative wounds.

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CQ 1.9 : How should a pressure ulcer be cleaned?

[Recommendation] Cleanse the pressure ulcer using isotonic saline or tap water in sufficient quantities to reduce the microbial count on the wound surface.

[Rating] C1

[Analysis] In the one published systematic review comparing wound cleansing solutions and cleansing techniques¹⁾, pressure ulcers cleaned with isotonic saline (VulnopurTM) containing aloe vera, silver chloride, or decyl glucoside (59 cases) showed a demonstrable improvement in their PSST (Pressure Sore Status Tool) scores (P = 0.025) compared to those cleaned only with isotonic saline (74 cases).

No significant difference was noted in the PSST score of pressure ulcers cleaned with either isotonic saline only (four cases) or with tap water only (four cases). With regard to the cleansing techniques, no significant difference was noted in treatment effect between the so-called ‘ whirlpool ’ method (24 cases) and more conventional lavation (18 cases). Of the 36 cases featured in one comparative case report²⁾ 6 out of 19 cases cleaned with 50 ml isotonic saline and 5 out of 29 cases cleaned with 100 ml isotonic saline demonstrated an increase in microbial count, whereas no increase in microbial count was observed in any of

the 12 cases cleaned with 200 ml isotonic saline.

In summary, while wound cleansing is effective in speeding recovery, there is no evidence to endorse a particular cleansing solution or method. Pressure ulcers may be cleaned adequately by using sufficient quantities of isotonic saline or tap water.

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CQ 1.10 : How should pressure ulcers be disinfected?

[Recommendation] Wound cleansing is usually adequate to prevent infection. However, if the wound is clearly infected or if there is excessive exudate or pus, the wound may be disinfected using antiseptics prior to cleansing.

[Rating] C1

[Analysis] A systematic review of various studies selected by their quality and dealing with the retardative effect of povidone-iodine on wound healing¹⁾, has shown that the majority of cases arguing against the use of povidone-iodine were either *in vitro* or animal model studies whereas 71% of the highly ranked human studies supported its use. Further, 57% of the studies with the highest impact factor supported its use as an antiseptic. There are only scanty data regarding the relationship between symptoms of infection and retardation of healing due to use of antiseptics and it is not at all clear that povidone-iodine has a toxic or retardative effect on wound healing.

The 1994 AHCPR guidelines²⁾ claim that lavation with isotonic saline is sufficient for cleansing infected pressure ulcers and that cleansing solutions and antiseptics are unnecessary. On the other hand, the EPUAP guidelines of 1999³⁾ state that use of antiseptics is indicated in cases in which there are clear signs of infection and abnormally large amounts of exudates or pus.

In summary, even at the wound stage at which debridement and infection control are normally called

for, cleansing with isotonic saline or tap water is sufficient in most cases. However, in cases in which there are clear symptoms of infection, the wound may be disinfected by using povidone-iodine.

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CQ 1.11 : Which topical agents are recommended for pressure ulcers accompanied by infection and inflammation?

[Recommendation]

1. Cadexomer-iodine, silver sulfadiazine, and povidone-iodine sugar are recommended for their ability to control infections.

[Rating] B

2. Fradiomycin sulfate-trypsin, povidone-iodine, iodine ointment, and iodoform gauze may be considered.

[Rating] C1

[Analysis] A randomized controlled trial with 60 subjects comparing cadexomer-iodine with dextranomer demonstrated significant decreases in levels of pus ($p < 0.05$)¹⁾, one of the assessment categories in the study, following treatment with cadexomer-iodine.

Another randomized controlled trial comparing silver sulfadiazine with a placebo group (total 77 subjects) reported a significant anti-microbial effect ($p < 0.01$) in 64.7% and 27% of the subjects, respectively. In an open randomized controlled trial comparing povidone-iodine sugar with lysozyme hydrochloride involving 141 subjects, 32.8% and 14.8% of the subjects, respectively, reported a significant improvement in microbial infection rate ($p < 0.05$)³⁾. On the other hand, while there are case reports concerning fradiomycin sulfate-trypsin, povidone-iodine, iodine

ointment, and iodoform, there is as yet little evidence on their anti-microbial effect.

In summary, in cases in which there are clear symptoms of infection, cadexomer-iodine, silver sulfadiazine, and povidone-iodine sugar are recommended as a means of controlling the infection. Fradiomycin sulfate-trypsin, povidone-iodine, iodine ointment, and iodoform may be used for treatment on a daily basis.

References

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CQ 1.12 : Which topical agents are recommended to accelerate granulation formation in pressure ulcers with deficient granulation formation?

[Recommendation]

1. Aluminium chlorohydroxy allantoinate, trafermin, tretinoin tocoferil and povidone-iodine sugar, all of which are known to accelerate granulation formation, are recommended.

[Rating] B

2. Alprostadil alfadex, bucladesine sodium, or lysozyme hydrochloride may be considered.

[Rating] C1

[Analysis] Aluminium chlorohydroxy allantoinate: One study of the effect of aluminium chlorohydroxy allantoinate on the acceleration of granulation formation involved a randomized controlled trial using solcoseryl (extract from hemolyzed blood of young calves)¹⁾. The results for each of the 27 subjects enrolled showed a significantly greater increase in granulation formation when compared with the control group.

Trafermin: Although a randomized controlled trial comparing the efficacy of trafermin with that of

povidone-iodine sugar, GM-CSF and low concentration of fibroblast growth factor in reducing wound size does exist²⁻⁵⁾, the data on granulation formation are not shown. However, one historical controlled trial⁶⁾ has reported a significantly greater granulation formation effect for trafermin in comparison with the control. The study further reported that trafermin was especially efficacious when administered in the early stages of treatment and enhanced the treatment effect. Although the evidence level for trafermin is IV, this medication merits recommendation on the basis of case series reports documenting its efficacy as well as the expert opinions given in its favor^{7,8)}.

Tretinoin tocoferil: In the two existing open randomized controlled trials comparing the granulation formation effect of tretinoin tocoferil with that of lysozyme hydrochloride and bendazac ointment^{9,10)}, tretinoin tocoferil was observed to have a significantly greater effect than either of the controls.

Povidone-iodine sugar: An open randomized trial comparing povidone-iodine sugar with lysozyme hydrochloride reported a superior granulation formation effect for lysozyme hydrochloride than for povidone-iodine sugar¹¹⁾.

Alprostadil alfadex: Although there is a randomized trial comparing the wound reduction effect of alprostadil alfadex with that of lysozyme hydrochloride¹²⁾ with the exception of expert opinion, there are no studies attesting to the granulation formation effect of alprostadil alfadex.

Bucladesine sodium: At present two random controlled trials exist comparing the effect of bucladesine sodium, lysozyme hydrochloride, and macrogol ointment on accelerating granulation formation. In both reports, bucladesine sodium reportedly showed an accelerative effect equal to that of lysozyme hydrochloride, but significantly greater than that of macrogol ointment^{13,14)}. However, at present there are no studies documenting its effect on granulation formation.

Lysozyme hydrochloride: Two open randomized trials have been conducted comparing lysozyme hydrochloride with bendazac ointment (evidence level II)¹⁵⁾. In addition, there are currently two randomized trials comparing lysozyme hydrochloride with povidone-iodine or lysozyme hydrochloride containing povidone-iodine sugar^{16,17)}, although no study has yet been conducted to determine whether

there is a significant difference between these agents in their ability to accelerate granulation formation.

In summary, the evidence level indicated in the previous edition of the guidelines has been modified and one medication has been added to the list of recommendations on the basis of the above considerations. The determination of which topical agents to use in a given situation calls for an assessment of the properties of each topical agent and the condition of the wound in question.

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CQ 1.13 : Which topical agents are recommended in pressure ulcers with deficient granulation formation and suspected critical colonization?

[Recommendation] Topical medications with an anti-microbial properties, such as cadexomer-iodine

ointment, povidone-iodine sugar, iodine ointment, or silver sulfadiazine may be used.

[Rating] C1

[Analysis] Although critical colonization is a serious pathological condition which has the potential to delay wound recovery in pressure ulcers, there are as yet no controlled studies dealing specifically with this condition. Further, although two case studies exist which mention the anti-microbial effect of iodine ointment^{1,2)} and one evidence level III report which compares the effect of cadexomer-iodine ointment and povidone-iodine sugar, only one study deals specifically with pressure ulcers³⁾.

The use of the above-mentioned topical agents is recommended on the basis of the case studies mentioned as well as expert opinion⁴⁻⁶⁾.

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CQ 1.14 : Which topical agents are recommended for wound reduction in pressure ulcers with sufficient granulation formation?

[Recommendation]

1. Alprostadil alfadex, aluminum chlorohydroxy allantoinate, trafermin, bucladesine sodium, and povidone-iodine sugar are recommended.

[Rating] B

2. Zinc oxides, dimethyl isopropylazulene, extract from hemolyzed blood of young calves, and lysozyme hydrochloride may be used.

[Rating] C1

[Analysis] An open randomized trial with 44 subjects comparing alprostadil alfadex and lysozyme hydrochloride found that treatment with the former resulted in a significantly greater reduction ratio in wound size ($p < 0.05$)¹⁾.

Similarly, an open randomized trial with 54 subjects comparing aluminum chlorohydroxy allantoinate and ointment containing extract from the hemolyzed blood of calves found that treatment with the former resulted in a significantly greater reduction in wound size ($p < 0.05$)²⁾. Trafermin produced a significantly greater reduction in wound size ratio ($p < 0.05$) when compared with a placebo in an open randomized trial ($n = 119$)³⁾. A randomized controlled trial comparing bucladesine sodium and macrogol ($n = 91$) showed that treatment with the former resulted in a significantly greater ($p < 0.05$) reduction in wound size⁴⁾. A randomized controlled trial comparing povidone-iodine sugar and trafermin ($n = 63$) showed that both agents produced an equal reduction in wound size. Similarly, a randomized controlled trial ($n = 68$) comparing lysozyme hydrochloride with bucladesine sodium resulted in equal wound size reduction ratio⁶⁾. However, it is unclear whether or not the percentage of wound size reduction was measured following adequate granulation formation. In view of the wound treatment process, in actual clinical practice it is advisable to assess epithelialization after sufficient granulation formation has been confirmed.

In view of the information given above and the actual conditions of clinical practice, alprostadil alfadex, aluminum chlorohydroxy allantoinate, trafermin, bucladesine sodium, and povidone-iodine sugar are recommended for reducing wound size. Zinc oxide, dimethylisopropylazulene, extract from hemolyzed blood of young calves, or lysozyme hydrochloride may also be used.

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CQ1.15 : Which topical agents are recommended if necrotic tissue is observed?

[Recommendation] Cadexomer-iodine, silver sulfadiazine, dextranomer, bromelain

or povidone-iodine sugar may be considered.

[Rating] C1

[Analysis] The wound debridement efficacy of cadexomer-iodine, fibrinolysin-deoxyribonuclease, dextranomer, and dextrin polymer (base) has been documented in a controlled study which reported a significantly greater improvement rate ($p > 0.01$) of 45.5% for cadexomer-iodine in comparison with fibrinolysin-deoxyribonuclease (18.8%)¹⁾. A comparison of cadexomer-iodine with dextranomer showed an efficacy rate of 71.4% and 45.5%, respectively, with no significant difference observed between these two agents²⁾. Likewise a comparison of dextrin polymer (base) showed an efficacy rate of 8.3% and 26.7%, respectively, and no significant difference between

the two was observed³⁾.

At present the use of silver sulfadiazine for wound debridement is endorsed only by expert opinion. As yet there are no studies endorsing its use for this purpose.

The ability of the emulsion base to penetrate the skin and to soften and fuse necrotic tissue largely accounts for the wound-cleaning effects of silver sulfadiazine⁴⁾.

A case report comparing the effectiveness of dextranomer with that of bromelain in debriding necrotic tissue indicated a reduction in the number of cases of tissue necrosis from six cases to one⁵⁾.

Two separate studies have reported a moderate to high level of wound debridement efficacy of 57% and 72.5% for bromelain^{6,7)}.

The first of two controlled trials comparing the wound debridement efficacy of povidone-iodine sugar and lysozyme hydrochloride showed a 41.7% efficacy rate for povidone-iodine sugar and 66.7% for lysozyme hydrochloride ointment⁸⁾. The second controlled trial of povidone-iodine sugar with lysozyme hydrochloride indicated an efficacy rate of 34.2% and 31.1%, respectively⁹⁾. A similar study comparing ointment containing extract from hemolyzed blood of young calves with povidone-iodine sugar indicated an efficacy rate of 12.5% for the latter, and 23.1% for the former. No significant difference was observed¹⁰⁾. Further, a retrospective study of cases showing a reduction in DESIGN scores following povidone-iodine sugar treatment failed to indicate any correlation between tissue debridement and decrease in DESIGN score¹¹⁾.

In summary, cadexomer-iodine, sulfadiazine silver, dextranomer, bromelain, and povidone-iodine sugar are assigned a recommendation rating of C1.

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CQ 1.16 : Which topical agents are recommended when undermining has occurred?

[Recommendation] If the undermining is covered by necrotic tissue, the wound surfaces should first be cleaned. Also, if there is excessive exudate, povidone iodine-sugar may be used. If the amount of exudation is minimal, consider using trafermin or tretinoin

tocoferil.

[Rating] C1

[Analysis] There are a limited number of references dealing with the application of topical agents on pressure ulcers which list undermining among their assessment categories. In general, however, in cases in which a undermining is found, all necrotic tissue should be removed from its interior and the wound surface cleansed. Caution needs to be exercised to prevent the occasional secondary infection.

A case-series on the efficacy of povidone-iodine sugar with undermining as one of its evaluation items has demonstrated the ameliorative effect of the compound¹⁾.

Although a case-control study with an evidence level of IV examining the effect of trafermin on undermining has demonstrated an ameliorative effect, the results were not significantly different from that of the comparison group²⁾.

At present, the use of tretinoin tocoferil is endorsed only by an expert opinion.

In summary, povidone-iodine sugar is indicated for the treatment of cases with excessive exudate, while tretinoin tocoferil is indicated for cases with low amounts of exudate.

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CQ 2 Dressings

CQ 2.1 : Which dressings are recommended to treat acute pressure ulcers?

[Recommendation] In order to protect the wound surface while allowing daily monitoring of the condition, transparent film dressings or dressings designed to treat dermal wounds may be used.

[Rating] C1

[Analysis] Recommendations for the use of dressings to treat acute phase pressure ulcers are supported only by expert opinion¹⁾. It is important to

determine the cause of acute phase pressure ulcers. Since the condition of tissue localized in and around acute phase pressure ulcers has a propensity to worsen rapidly, frequent and regular monitoring of the wound condition is vital. For this reason, a transparent dressing which will allow visual monitoring is recommended.

Transparent film dressings are recommended for the protection of erythematous areas from friction or shear. Before applying the transparent film dressing, cleanse the skin where the dressing is to be applied. If there are any noticeable changes to the wound condition, replace the dressing with a new one. As a rule dressings should be changed at a frequency of once per week.

References

- 1) Kawakami S, Shimada K : The treatment of acute phase pressure ulcer. *Modern Physician*, 28 (4) : 506-507, 2008. (Level VI) (Japanese)

CQ 2.2 : Which dressings are indicated in pressure ulcers with suspected deep tissue injury (DTI)?

[Recommendation] In order to protect the wound surface while allowing daily monitoring of the condition, either transparent film dressings or dressings designed to treat dermal wounds may be considered.

[Rating] C1

[Analysis] There are no studies examining the efficacy of dressings on the treatment of deep tissue injuries (DTI). Because DTI tends to progress more deeply into underlying tissue, frequent monitoring of the wound is vital. For this reason, a transparent dressing that will allow observation of the wound condition is recommended. Transparent film dressings are recommended for the protection of erythematous areas from friction or shear. Before applying the polyurethane dressing, cleanse the skin where the dressing is to be applied. If there are any noticeable changes in the condition of the wound, replace the dressing with a new one. As a rule dressings should be changed at a frequency of once per week.

CQ 2.3 : Which dressings are recommended for pressure ulcers involving redness/purpura?

[Recommendation] In order to protect the wound surface while allowing daily monitoring of the

condition, either transparent film dressings or dressings designed to treat dermal wounds may be considered.

[Rating] C1

[Analysis] There are ten Evidence Level V case reports documenting the use of hydrocolloid for the treatment of redness. However, these case reports do not deal specifically with pressure ulcers with the redness/purpura, but also include discussion of pressure ulcers at other stages, and therefore do not specifically address the efficacy of hydrocolloid in the treatment of redness/purpura¹⁾.

Before applying the transparent film dressing, cleanse the skin where the dressing is to be applied. The dressing should be changed at a frequency of once per week. Continue visual monitoring of the redness or purpura through the dressing. If the tissue damage progressed from the epidermis to the dermis, change treatment for erosion or shallow ulcers. Again, in order to ensure that these steps can be taken when necessary, a transparent dressing which allows visual monitoring is highly recommended.

References

- 1) Ito T, Takahashi R, Suzuki C, et al : The use of hydrocolloid dressing in the treatment of pressure ulcer. *Jpn J Nur Sci*, 20 (12) : 75-80, 1995. (Level V) (Japanese)

CQ 2.4 : Which dressings are recommended for cases involving blistering?

[Recommendation] While leaving the blisters intact, consider using a transparent film dressing to protect the wound surface. A dressing for dermal wounds that allows observation may also be considered.

[Rating] C1

[Analysis] The use of dressings for blisters is supported only by expert opinion¹⁾. A transparent film dressing is recommended for the protection of blistering areas from friction or shear. Before applying the transparent film dressing, cleanse the skin where the dressing is to be applied. As a rule dressings should be changed at least once per week. If the blisters are tense, they may be punctured and drained to relieve pressure¹⁾. If the blisters are ruptured and the wound begins to penetrate to the dermis, switch to a treatment for erosion or shallow ulcers. Again, in

order to ensure that these steps can be taken when necessary, a transparent dressing which allows visual monitoring is highly recommended.

References

- 1) Kishinabe M : How to treat blister?, Guideline for local treatment of pressure ulcers. Miyachi Y, Sanada H ed, 145-149, Medical Review Co., Ltd, Tokyo, 2007. (Level VI) (Japanese)

CQ 2.5 : Which dressings are recommended for treating erosions or shallow ulcers?

[Recommendation]

1. A health insurance-covered hydrocolloid dressing used to treat dermal wounds is recommended. A hydrocolloid dressing used to treat subcutaneous wounds is also an option, but is not covered by health insurance.

[Rating] B

[Recommendation]

2. Health insurance-covered dressings designed to treat dermal wounds, such as hydrogel, polyurethane foam sheets, alginate foam dressing, and chitin membrane may be considered. Dressings designed to treat subcutaneous wounds, such as hydrogel, hydro-polymer, polyurethane foam, polyurethane foam/soft silicone, alginate, and chitin membrane can also be employed with equal effect, but are not covered by health insurance.

[Rating] C1

[Analysis]

• Hydrocolloid: One systematic review¹⁾ and one meta-analysis²⁾ have examined the use of hydrocolloid for the topical treatment of pressure ulcers. The systematic review compared hydrocolloid to wet-to-moist saline gauze dressings and found hydrocolloids to be superior to the latter in terms of wound size reduction, absorption of exudates, frequency of replacement, pain felt when dressing is changed, side effects, and cost. However, because stage III pressure ulcers are included in the study, the specific relevance of the findings to erosions and shallow ulcers remains unclear. The meta-analysis²⁾ found hydrocolloid 72% more effective (odds ratio: 1.72) than wet-to-moist gauze or paraffin-gauze dressings, but omits any discussion of the depth of the wounds observed in the study. Because the specific relevance of these results to erosions and shallow ulcers is not clear, the

methods described here have been assigned the recommendation rating of B.

• Hydrogel: Two randomized controlled trials have examined the healing rate following use of various dressings^{3,4}. These studies found no significant difference in efficacy between wet-to-moist gauze dressings and hydrocolloids. Furthermore, as the study included stage III and IV pressure ulcers, the specific relevance of the findings to cases of erosions and shallow ulcers remains unclear. For this reason, the methods discussed here have been assigned the recommendation rating of C1.

• Hydropolymer: One randomized controlled trial⁵ examined the efficacy of hydropolymer on healing rate. In a comparison of hydropolymer with hydrocolloid using stage II and III pressure ulcers, the study found no significant difference in healing time or healing rate. As the study was designed as a superiority trial, we cannot be certain that the efficacy of the hydropolymer was equal to that of the hydrocolloid.

For this reason the methods discussed here have been assigned the recommendation rating of C1.

• Polyurethane foam: A randomized controlled trial⁶ comparing the healing rate for stage II pressure ulcers treated with saline gauze dressings or polyurethane foam found no significant difference in the time required for wound closure, but the frequency required for changing the dressings was significantly lower for polyurethane foam ($p < 0.001$). However, because no significant difference in time required for wound closure was found, the methods discussed here have been assigned the recommendation rating of C1.

• Polyurethane foam/soft silicone: One randomized controlled trial examined the recovery rate in stage II pressure ulcers after use of polyurethane foam dressings but found no significant difference with the use of hydropolymer dressing⁷. For this reason, polyurethane foam/soft silicone dressing has been given a recommendation rating of C1.

• Alginate foam, chitin membrane, and alginate: No studies addressing the use of these dressings on erosions and shallow ulcers exist. Recommendations for their use are supported only by expert opinion.

References

1) Heyneman A, Beele H, Vanderwee K, et al : A syste-

matic review of the use of hydrocolloids in the treatment of pressure ulcers. *J Clin Nurs*, 17 (9) : 1164-1173, 2008. (Level I)

- 2) Singh A, Haler S, Menon GR, et al : Meta-analysis of randomized controlled trials on hydrocolloid occlusive dressing vs conventional gauze dressing in the healing of chronic wounds. *Asian J Surg*, 27 (4) : 326-332, 2004. (Level I)
- 3) Mulder GD, Altman M, Seeley JE, et al : Prospective randomized study of the efficacy of hydrogel, hydrocolloid, and saline solution-moistened dressings on the management of pressure ulcers. *Wound Repair Regen*, 1 (4) : 213-218, 1993. (Level II)
- 4) Thomas DR, Goode PS, LaMaster K, et al : Aceman-nan hydrogel dressing versus saline dressing for pressure ulcers. *Adv Wound Care*, 11 (6) : 273-276, 1998. (Level II)
- 5) Thomas S, Banks V, Bale S, et al : A comparison of two dressings in the management of chronic wounds. *J Wound Care*, 6 (8) : 383-386, 1997. (Level II)
- 6) Payne WG, Posnett J, Alvarez O, et al : A prospective, randomized clinical trial to assess the cost-effectiveness of a modern foam dressing versus a traditional saline gauze dressing in the treatment of stage II pressure ulcers. *Ostomy Wound Manage*, 55 (2) : 50-55, 2009. (Level II)
- 7) Maume S, Van De Looverbosch D, Heyman H, et al : A study to compare a new self-adherent soft silicone dressing with a self-adherent polymer dressing in stage II pressure ulcers. *Ostomy Wound Manage*, 49 (9) : 44-51, 2003. (Level II)

CQ 2.6 : Which dressings are recommended for pressure ulcers involving pain?

[Recommendation] Dressings cannot remove pain but can lessen it by protecting the wound surface and maintaining a moist environment conducive to wound healing. When changing dressings, perform adequate pain assessment and apply a hydrocolloid, polyurethane foam, polyurethane foam/soft silicone, Hydrofiber[®], chitin membrane, or hydrogel.

[Rating] C1

[Analysis]

• Hydrocolloid: One systematic review¹ examines the pain associated with pressure ulcers, but does not address the relationship between pain and different types of dressing. Only one cross-sectional study² examines this relationship and reports a significantly

greater efficacy in diminishing pain for hydrocolloid than for saline gauze dressings or transparent film dressings ($p < 0.02$). For this reason, hydrocolloid has been given a recommendation rating of C1 in terms of pain reduction.

Because pressure ulcers may cause considerable pain, adequate pain assessment is required. Because the pain-reducing properties of the hydrocolloid dressing are most effective within a occlusive or moist environment^{3,4} it may be used to lessen pain experienced when dressings are changed. However, when used on fragile skin, it should be removed with utmost care in order to avoid damaging tissue.

• Polyurethane foam: Two randomized controlled trials have examined the pain associated with pressure ulcers^{5,6}. Of these studies, one compared hydrocolloid to polyurethane foam and reported a significantly lower level of pain associated with polyurethane foam when the dressings were changed ($p < 0.005$). However, the second study, examining the pains reported by patients when saline gauze dressings and polyurethane film dressings were simultaneously used, to the pains reported when polyurethane foam was used, stated that there was no significant difference between these two groups in terms of the pain or degree of discomfort reported when the dressings were removed. On these grounds, polyurethane foam has been assigned a recommendation rating of C1.

• Polyurethane foam/soft silicone: A case report examining the pain associated with the use of various types of dressing claimed that 93% of patients treated with polyurethane foam/soft silicone dressings experienced no pain when the dressings were being changed and that all subjects reported satisfaction with the use of this product; recommendation rating C1.

• Hydrofiber[®]: One case report examined the pain associated with pressure ulcers on the basis of results obtained from 23 patients who were treated with Hydrofiber[®]. Although the study found that Hydrofiber[®] was effective in reducing pain 90% or more in stage II~IV pressure ulcers, no comparison to other types of dressing was included in the study.

Chitin: One case report examined the analgesic effect of chitin dressings in 32 patients and found that of the 19 patients who were successfully assessed, 15 reported less pain when dressings were being

changed⁹. However, no statistical data have been offered in the study to corroborate this claim.

*Hydrogel: There are no studies assessing the efficacy of hydrogel dressings in reducing or relieving pain when dressings are being changed. However, its use is endorsed by expert opinion.

References

- 1) Pieper B, Langemo D, Cuddigan J : Pressure ulcer pain : A systematic literature review and national pressure ulcer advisory panel white paper. *Ostomy Wound Manage*, 55 (2) : 16-31, 2009. (Level I)
- 2) Dallam L, Smyth C, Jackson BS, et al : Pressure ulcer pain : assessment and quantification. *J Wound Ostomy Continence Nurs*, 22 (5) : 211-215, 1995.
- 3) Hashizume K, Kitaya R, Tsurumi M, et al : Clinical effect of occlusive dressing Comfeel on decubitus. *J New Rem Clin*, 46 (10) : 1348-1360, 1997. (Level V) (Japanese)
- 4) Asakura K, Takahashi R, Suzuki C, et al : Utility of occlusive dressing Comfeel on decubitus. *Jpn J Med Pharm Sci*, 33 (1) : 87-200, 1995. (Level V) (Japanese)
- 5) Banks V, Bale S, Harding K : The use of two dressings for moderately exuding pressure sores. *J Wound Care*, 3 (3) : 132-134, 1994. (Level II)
- 6) Banks V, Bale S, Harding K : Superficial pressure sores : comparing two regimens. *J Wound Care*, 3 (1) : 8-10, 1994. (Level II)
- 7) Hurd T, Gregory J, Jones A, et al : A multi-centre in-market evaluation of ALLEVYN Gentle Border. *Wounds UK*, 5 (3) : 32-44, 2009. (Level V)
- 8) Parish LC, Dryjski M, Cadden S, et al : Prospective clinical study of a new adhesive gelling foam dressing in pressure ulcers. *Int Wound J*, 5 (1) : 60-67, 2008. (Level V)
- 9) Ueyama T : Treatment of the decubitus by the flocculent chitin. *J New Rem Clin*, 43 (2) : 291-299, 1994. (Level V) (Japanese)

CQ 2.7 : Which dressings are recommended in pressure ulcers with excessive exudate?

[Recommendation]

1. Recommend using polyurethane foam dressings, which can absorb excess exudates.

[Rating] B

[Recommendation]

2. Dressings normally used for subcutaneous

wounds as well as dressings used to treat deeper wounds involving muscle and bone, such as alginate/CMC, polyurethane foam/soft silicone dressings, alginate, alginate foam, chitin membrane, Hydrofiber[®], or hydropolymer dressings, may be applied.

[Rating] C1

[Analysis] The one systematic review which discusses the use of polyurethane foam dressings does not mention its efficacy in absorbing exudates as an outcome. Nonetheless, a randomized controlled trial²⁾ found that polyurethane foam was significantly more effective ($p < 0.001$) in absorbing exudates than hydrocolloids, and for this reason the use of polyurethane foam has been assigned the recommendation rating of B.

On the other hand, alginate/CMC (carboxymethylcellulose), polyurethane foam/soft silicone, alginate, chitin membrane, Hydrofiber[®], and hydropolymer, are not discussed in any high-evidence level studies and so they have been assigned the recommendation rating of C1.

Beele et al. examined the effect of silver-containing alginate/CMC and non-silver-containing alginate/CMC in a randomized controlled trial using 36 patients with moderate to high levels of exudates from pressure ulcers or varicose ulcers and found significantly higher level of wound-size reduction in patients treated with silver-containing alginate dressings ($p = 0.017$)³⁾. However, due to the fact that this study fails to assess the capacity of these dressings to absorb exudates, the methods discussed here have been assigned a recommendation rating of C1.

A randomized controlled trial⁴⁾ compared the ability of polyurethane foam/soft silicone and hydropolymer to absorb exudates and found that while there was no statistical difference in absorptive capacity between these two types of dressing, polyurethane foam/soft silicone dressings were superior in preventing damage and maceration to skin in the wound periphery ($p < 0.05$). Because there was no difference in the absorptive capacity of these dressings, their use has been assigned the recommendation rating of C1.

The use of alginate, alginate foam, chitin membrane Hydrofiber[®], and hydropolymer dressings is addressed only in case reports; recommendation rating: C1⁵⁻¹⁰⁾.

References

- 1) Heyneman A, Beele H, Vanderwee K, et al : A systematic review of the use of hydrocolloids in the treatment of pressure ulcers. *J Clin Nurs*, 17 (9) : 1164-1173, 2008. (Level I)
- 2) Bale S, Squires D, Varnon T, et al : A comparison of two dressings in pressure sore management. *J Wound Care*, 6 (10) : 463-466, 1997. (Level II)
- 3) Beele H, Meuleneire F, Nahuys M, et al : A prospective randomized open label study to evaluate the potential of a new silver alginate/ carboxymethylcellulose antimicrobial wound dressing to promote wound healing. *Int Wound J*, 7 (4) : 262-270, 2010. (Level II)
- 4) Maume S, Van De Looverbosch D, Heyman H, et al : A study to compare a new self-adherent soft silicone dressing with a self-adherent polymer dressing in stage II pressure ulcers. *Ostomy Wound Manage*, 49 (9) : 44-51, 2003. (Level II)
- 5) Harada S, Nakanishi H, Kawabata Y : Clinical Evaluation of SORBSAN (Calcium alginate fiber dressing) for the treatment of skin ulcer. *J New Rem Clin*, 10 (2) : 473-495, 1994. (Level V) (Japanese)
- 6) Tsukada K : Usefulness of sponge- type alginate gel dressing on tissue granulation of pressure ulcers. *Jpn JPU*, 5 (1) : 27-32, 2003. (Level V) (Japanese, English abstract)
- 7) Ueyama T : Treatment of the decubitus by the flocculent chitin. *J New Rem Clin*, 43 (2) : 291-299, 1994. (Level V) (Japanese)
- 8) Coutts P, Sibbald R : The effect of a silver-containing Hydrofiber[®] dressing on superficial wound bed and bacterial balance of chronic wounds. *Int Wound J*, 2 (4) : 348-356, 2005. (Level V)
- 9) Parish LC, Dryjski M, Cadden S : Prospective clinical study of a new adhesive Gelling foam dressing in pressure ulcers. *Int Wound J*, 5 (1) : 60-67, 2008. (Level V)
- 10) Ohura T : Clinical experience with a new hydropolymer dressing. *Jpn JPU*, 4 (1) : 105-110, 2002. (Level V) (Japanese, English abstract)

CQ 2.8 : Which dressings are recommended for pressure ulcers with minimal amounts of exudates?

[Recommendation]

1. Using a hydrocolloid dressing is recommended.

[Rating] B

[Recommendation]

2. Using a hydrogel may be considered.

[Rating] C1

[Analysis]

• Hydrocolloid: One meta-analysis exists addressing the use of hydrocolloid dressing for local treatment of pressure ulcers¹⁾. In this study, hydrocolloid was found to be 72% more effective in healing pressure ulcers than conventional saline gauze dressings or paraffin-gauze dressings (odds ratio: 1.72). However, as no mention is made of the capacity of each type of dressing to absorb exudates, the recommendation merits a level of B.

Hydrogel: Two randomized controlled trials have examined the efficacy of hydrogel in promoting granulation tissue formation^{2,3)}, but a comparison with saline gauze dressings and hydrocolloid dressings failed to show a significant difference in this regard. While the study deals with the treatment of stage II~IV pressure ulcers, it does not address the efficacy of hydrogel dressings for the treatment of pressure ulcers with low amounts of exudates and therefore merits a recommendation rating of only C1.

References

- 1) Singh A, Haler S, Menon GR, et al : Meta-analysis of randomized controlled trials on hydrocolloid occlusive dressing vs conventional gauze dressing in the healing of chronic wounds. *Asian J Surg*, 27 (4) : 326-332, 2004. (Level I)
- 2) Thomas DR, Goode PS, LaMaster K, et al : Acemanan hydrogel dressing versus saline dressing for pressure ulcers. *Adv Wound Care*, 11 (6) : 273-276, 1998. (Level II)
- 3) Mulder GD, Altman M, Seeley JE, et al : Prospective randomized study of the efficacy of hydrogel, hydrocolloid, and saline solution-moistened dressings on the management of pressure ulcers. *Wound Repair Regen*, 1 (4) : 213-218, 1993. (Level III)

CQ 2.9 : Which dressings are recommended for infected and inflamed pressure ulcers?

[Recommendation]

1. Consider using topical agents to suppress infection. Alternatively, silver-containing Hydrofiber[®] or alginate silver may be used.

[Rating] C1

2. Alginate is sometimes used to dress wounds with

excessive exudates because of its superior absorptive ability, but cannot be recommended here due to its inability to suppress infection.

[Rating] C2

[Analysis] One systematic review¹⁾ has addressed the use of silver-containing Hydrofiber[®] in the context of wound infection and inflammation. In 26 randomized controlled trials dealing with the use of silver in the localized treatment of acute phase and chronically contaminated and infected wounds failed to detect a significant difference in the infection rate as an outcome. Due to this observation, it was concluded that there is inadequate evidence to support the use of silver as a means of suppressing infection. Further, even in their systematic review, which documents the efficacy of silver in the treatment of infected wounds, Toy and Macera state that there is insufficient evidence to endorse the use of silver-containing foam dressings to treat chronically contaminated and infected wounds²⁾.

Three randomized controlled trials have addressed the use of silver alginate to suppress infection in pressure ulcers³⁻⁵⁾. The studies found that silver-containing alginate/CMC not only resulted in a greater reduction in wound size than non-silver-containing alginate/CMC, ($p = 0.017$), but also in a significantly better healing rate four weeks into treatment ($p = 0.044$). On the basis of these findings, it was concluded that silver-containing alginate/CMC has a significantly greater effect on promoting healing in pressure ulcers and suppressing infection. On the other hand, other studies report disparate results, with Trial et al. claiming that a comparison of alginate and silver-containing alginate failed to show any difference in the clinical scores for infection⁴⁾, and Meaume et al. claiming that while there was no statistically significant difference in wound infection rate after use of silver-containing alginate (33%) and alginate (46%), the healing rate for silver-containing alginate was appreciably higher ($p = 0.024$)⁵⁾. On the basis of these findings, silver-containing Hydrofiber[®] or silver alginate may be used to treat infected or inflamed wounds. However, when the evidence from the systematic reviews^{1,2)} is taken into account, it is clear that the use of these dressings to treat infected wounds is not supported by adequate evidence. In addition, because of the unavailability in Japan, and varying silver content, of some of the products

examined in the aforementioned studies, the ability of these dressings to suppress infections cannot be clearly assessed. Therefore the methods discussed here have been assigned the recommendation rating of C1.

Alginate is sometimes used for its superior absorptive qualities to treat pressure ulcers with large quantities of exudates. However, as it has no demonstrable ability to suppress infection, its use is not recommended.

One randomized controlled trial examined the use of alginate on infected wounds⁵⁾. The study found that in 71 cases of varicose ulcer and 28 cases of pressure ulcer all requiring infection suppression, no difference in result was seen in wound infection rate between the groups treated with alginate and silver-containing alginate⁵⁾. On the basis of the reports, we may conclude that although alginate is sometimes used for its superior ability to absorb exudates, it has no demonstrable ability to suppress wound infection and therefore cannot be recommended.

References

- 1) Storm-Versloot MN, Vos CG, Ubbink DT, et al : Topical silver for preventing wound infection, Cochrane Wounds Group, Cochrane Database of Systematic Reviews 2010, Issue 3. Art. (Level I)
- 2) Toy LW, Macera L : Evidence-based review of silver dressing use on chronic wounds. *J Am Acad Nurse Pract*, 23 (4) : 183-192, 2011. (Level I)
- 3) Beele H, Meuleneire F, Nahuys M, et al : A prospective randomized open label study to evaluate the potential of a new silver alginate/carboxymethylcellulose antimicrobial wound dressing to promote wound healing. *Int Wound J*, 7 (4) : 262-270, 2010. (Level II)
- 4) Trial C, Darbas H, Lavigne JP, et al : Assessment of the antimicrobial effectiveness of a new silver alginate wound dressing : a RCT. *J Wound Care*, 19 (1) : 20-26, 2010. (Level II)
- 5) Meaume S, Vallet D, Morere MN, et al : Evaluation of a silver-releasing hydroalginate dressing in chronic wounds with signs of local infection. *J Wound Care*, 14 (9) : 411-419, 2005. (Level II)

CQ 2.10 : Which dressings are recommended for promoting granulation tissue formation in pressure ulcers where it is deficient?

[Recommendation] Alginate, hydrocolloid, hydropolymer, polyurethane foam, polyurethane foam/soft silicone, chitin membrane and Hydrofiber[®] may be considered.

[Rating] C1

[Analysis]

*Alginate: There is one systematic review examining the use of silver-containing dressings¹⁾ and one randomized controlled study examining the use of alginate to treat pressure ulcers²⁾. The systematic review does not draw any conclusions regarding the efficacy of silver-containing dressings in promoting granulation tissue formation, while the randomized controlled trial reported that significantly greater reductions in wound size were achieved with the use of hydrocolloid following treatment with alginate than with the use of hydrocolloid alone ($p < 0.01$). However, as the study did not examine the effect of using alginate alone, the recommendation level merits a rating of C1.

*While there are randomized controlled trials examining the use of hydrocolloid, hydropolymer, polyurethane foam, and polyurethane foam/soft silicone, none of these studies reports on the effect of these dressings on granulation tissue formation; recommendation level: C1.

*Chitin and Hydrofiber[®] are addressed only in case reports. As the evidence level is low, the recommendation rating given is C1.

References

- 1) Carter MJ, Tingley-Kelley K, Warriner RA 3rd : Silver treatments and silver-impregnated dressings for the healing of leg wounds and ulcers : A systematic review and meta-analysis. *J Am Acad Dermatol*, 63 (4) : 668-679, 2010. (Level I)
- 2) Belmin J, Meaume S, Rabus MT, et al : Investigators of the sequential treatment of the elderly with pressure sores (STEPS) trial. Sequential treatment with calcium alginate dressings and hydrocolloid dressings accelerates pressure ulcer healing in older subjects : a multicenter randomized trial of sequential versus nonsequential treatment with hydrocolloid dressings alone. *J Am Geriatr Soc*, 50 (2) : 269-274, 2002. (Level II)

CQ 2.11 : Which dressings are recommended in pressure ulcers with deficient granulation tissue

formation and suspected critical colonization?

[Recommendation] Consider using silver-containing Hydrofiber[®] or alginate silver.

[Rating] C1

[Analysis] A systematic review using indications of critical colonization as a measure compared the effect of silver-containing Hydrofiber[®] and other types of dressing on wound size reduction and healing rate¹⁾. However, this study failed to arrive at any conclusions regarding pressure ulcers where critical colonization was suspected due to insufficient granulation tissue formation. Of the randomized controlled trials discussed in the systematic review²⁾, although significant reductions in wound size were reported ($p = 0.0019$), only 8% of the subjects enrolled were pressure ulcer patients. There is also one randomized controlled trial examining the effect of silver-containing alginate on varicose ulcers requiring infection suppression and pressure ulcers. In a comparison of silver-containing alginate and non-silver-containing alginate on 24 cases of varicose ulcer in the critical colonization phase or at risk of infection and 12 cases of pressure ulcer, the study found that while there was no exacerbation of infection in either group, significantly greater reductions in wound size were achieved in the silver-containing alginate group ($p = 0.017$). However, because the number of pressure ulcer patients enrolled was small, and no discussion about granulation formation in these cases was included, the methods discussed here have been assigned a recommendation rating of C1.

References

- 1) Beam JW : Topical silver for infected wounds. *J Athl Train*, 44 (5) : 531-533, 2009. (Level I)
- 2) Munter KC, Beele H, Russell L, et al : Effect of a sustained silver-releasing dressing on ulcers with delayed healing : the CONTOP study. *J Wound Care*, 15 (5) : 199-206, 2006. (Level II)
- 3) Beele H, Meuleneire F, Nahuys M, et al : A prospective randomized open label study to evaluate the potential of a new silver alginate/carboxymethylcellulose antimicrobial wound dressing to promote wound healing. *Int Wound J*, 7 (4) : 262-270, 2010. (Level II)

CQ 2.12 : Which dressings are recommended to promote the reduction of the size of wounds with

adequate/normal granulation tissue formation?

[Recommendation]

1. Using silver-containing Hydrofiber[®], alginate silver, or alginate is recommended.

[Rating] B

[Recommendation]

2. Hydrocolloid, hydrogel, hydropolymer, polyurethane foam, polyurethane foam/soft silicone dressing, alginate foam, chitin membrane, Hydrofiber[®], alginate/CMC are also options, depending on the amount of exudate present.

[Rating] C1

[Analysis] The one systematic review¹⁾ examining the effect of silver-containing Hydrofiber[®] concluded that while wound reduction could be achieved in the short term, Hydrofiber[®] could not be recommended for promoting wound healing due to the paucity of evidence; recommendation rating B.

In their randomized controlled trial, Beale et al. reported the efficacy of silver alginate on wound-size reduction, but their comparison of silver-containing alginate/CMC and non-silver-containing alginate/CMC concluded that the use of silver-containing alginate led to greater reductions in wound size compared to alginate alone ($p = 0.017$) and therefore to a stronger wound healing effect²⁾. On the basis of this conclusion, the use of silver-containing alginate has been assigned a recommendation rating of B.

Although the wound reduction effect of alginate is mentioned in a systematic review by Madhuri et al., the study failed to offer clear proof of this assertion³⁾. In a randomized controlled trial⁴⁾, the result of a comparison of alginate and dextranomer paste found that wounds treated with alginate showed greater reduction in size. Further, in an eight-week experiment one group of subjects was treated with alginate for the first four weeks, then with a combination of alginate and hydrocolloid for the next four weeks. Another group was treated for eight weeks with hydrocolloid alone. A comparison of the results indicated greater reductions in wound size for the former ($p < 0.01$). Accordingly the methods discussed here have been given the recommendation rating of B.

On the basis of these reports, consider using silver-containing Hydrofiber[®], silver alginate, or alginate when attempting to achieve wound-size reduction in cases with adequate granulation formation.

A systematic review claiming greater efficacy in wound-size reduction for hydrocolloid in a comparison with saline gauze dressings⁵⁾ also states that no significant difference in efficacy was found in a comparison of hydrocolloid with alginate, hydrogel, and polyurethane foam. For this reason, the use of hydrocolloid has been accorded the same recommendation rating of C1 as the other types of dressing previously discussed.

Although a number of randomized controlled trials have examined the other types of dressing, including hydrogel, hydropolymer, and polyurethane foam, none of these studies documented evidence pertaining to their efficacy in wound reduction. Polyurethane foam/soft silicone, alginate foam, chitin, Hydrofiber[®], and aliginat/CMC have been discussed in case reports only; recommendation rating: C1.

From these reports, any of the dressings discussed above, namely hydrocolloid, hydrogel, hydropolymer, polyurethane foam, polyurethane foam/soft silicone, alginate foam, chitin, Hydrofiber[®], and aliginat/CMC can be used according to the amount of exudates.

References

- 1) Carter MJ, Tingley-Kelley K, Warriner RA, et al : Silver treatments and silver-impregnated dressings for the healing of leg wounds and ulcers : A systematic review and meta-analysis. *J Am Acad Dermatol*, 63 (4) : 668-679, 2010. (Level I)
- 2) Beele H, Meuleneire F, Nahuys M, et al : A prospective randomized open label study to evaluate the potential of a new silver alginate/ carboxymethylcellulose antimicrobial wound dressing to promote wound healing. *Int Wound J*, 7 (4) : 262-270, 2010. (Level II)
- 3) Madhuri R, Sudeep S, Rochon P : Treatment of pressure ulcers : A systematic review. *JAMA*, 300 (22) : 2647-2662, 2008. (Level I)
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- 5) Heyneman A, Beele H, Vanderwee K, et al : A systematic review of the use of hydrocolloids in the treatment of pressure ulcers. *J Clin Nurs*, 17 (9) :

1164-1173, 2008. (Level I)

CQ 2.13 : Which dressings are recommended when necrotic tissue is present?

[Recommendation] If surgical debridement or topical agents capable of removing necrotic tissue are unavailable, hydrogel may be considered.

[Rating] C1

[Analysis] One randomized controlled trial examined the use of hydrogel and dextranomer paste in connection with the removal of necrotic tissue and reported no significant difference in the rate of removal of necrotic tissue for either type of dressing. The recommendation level assigned to these dressings is therefore C1. In addition to these studies, Parnell et al. have published a case report in which hydrogel with endopeptidase was used to treat stage II and III pressure ulcers assessed clinically as infected and requiring removal of necrotic tissue²⁾. The stage II and III pressure ulcers which had not been treated for three months prior to commencement of the study healed in an average of 3.3 weeks and 6.5 weeks, respectively, but the effect of hydrogel could not be assessed because it was used in combination with other dressings.

References

- 1) Colin D, Kurring PA, Yvon C : Managing sloughy pressure sores. *J Wound Care*, 5 (10) : 444-446, 1996.
- 2) Parnell LK, Ciufi B, Gokoo CF : Preliminary use of a hydrogel containing enzymes in the treatment of stage II and stage III pressure ulcers. *Ostomy Wound Manage*, 51 (8) : 50-60, 2005.

CQ 2.14 : Which dressings are recommended if undermining is found?

[Recommendation] If necrotic tissue is present within the undermining, first remove this through lavation. If the amount of exudate is excessive, consider using alginate, silver-containing Hydrofiber[®], or alginate silver.

[Rating] C1

[Analysis] One case report claimed favorable results for the use of alginate inside the undermining, after granulation formation and reduction in the size of the undermining were achieved (Evidence Level V)¹⁾.

No studies have been published on the efficacy of silver-containing Hydrofiber[®] and silver alginate

when applied to undermining, and the method is endorsed only by expert opinion (Evidence Level VI). When using these dressings inside the wound pocket, care must be taken not to force the dressing too deeply into the cavity or cause undue pressure on the surrounding tissue surfaces. If necrotic tissue remains, prioritize debridement.

References

- 1) Tsukada K : Usefulness of sponge-type alginate gel dressing on tissue granulation of pressure ulcers . Jpn JPU, 5 (1) : 27-32, 2003. (Japanese, English abstract)

CQ 2.15 : Is the so-called ‘wrap dressing’ * effective in treating pressure ulcers?

[Recommendation] Wrap dressings can be considered for use whenever medically approved dressings are unavailable or difficult to obtain on a continual basis, such as in a home based medical care. However, use of the wrap dressing should be supervised by a physician with an adequate knowledge of pressure ulcer care and only after the patients and their family have been instructed in the procedure and given their consent.

* ‘Wrap dressing’ is a dressing technique of covering wounds with non-medically approved (unsterilized) and non-adhesive commercially available plastic wrap.

[Rating] C1

[Analysis] A comprehensive survey of evidence pertaining to the ‘wrap’ method of dressing wounds showed that while there is an abundance of case reports and comments by specialists, there is only one randomized clinical trial, and two non-randomized clinical trials systematically comparing this dressing to standard dressings.

A non-randomized controlled trial involving subjects with class III~IV class pressure ulcers (according to the NPUAP guidelines), found a significantly greater reduction in wound size after 12 weeks following the use of wrap dressings in comparison to the control dressings, as indicated by the DESIGN scores ($p = 0.011$)¹⁾. The cure rate and the exacerbation rate were the same. Furthermore, a randomized clinical trial conducted jointly involving NPUAP class II~II adult pressure ulcer patients found no significant difference in effect between wrap dressings and

the comparison group across three parameters, the DESIGN-R score, the PUSH score, and changes in wound size²⁾. However, the cost of wrap dressings was appreciably lower than that of other types of dressing. Further, in a non-randomized controlled trial involving adult patients³⁾, no difference was recorded in midpoint of treatment period for wrap dressings and conventional dressings ($p = 0.92$). However, the daily cost of wrap dressings was significantly lower. In all three of these clinical trials there was no difference between wrap and other types of dressing in terms of worsening symptoms or deleterious effects. However, one case report⁴⁾ claimed that there were two cases in which symptoms worsened as a result of the use of wrap dressings.

On the basis of the reports discussed above, and in accordance with the official position of the 2010 Board of the Japan Society of Pressure Ulcers, the use of officially approved dressings is recommended for the treatment of pressure ulcers. As a non-medically approved item, the wrap dressing may be considered for use in home based medical care and other settings in which the continued use of approved dressings maybe difficult. However, its use should be supervised by a physician with an adequate knowledge of pressure ulcer care and only after the patients and their family have been instructed in the procedure and given their consent.

References

- 1) Takahashi J, Yokota O, Fujisawa Y, et al : An evaluation of polywvinylidene film dressing for treatment of pressure ulcers in older people. J Wound Care, 15 (10) : 449-454, 2006. (Level III)
- 2) Mizuhara A, Bito S, Onishi S, et al : The therapeutic effectiveness of wrap therapy: A study comaring wrap therapy to standard therapy per current guidelines. Jpn JPU, 13 (2) : 134-141, 2011. (Level II) (Japanese, English abstract)
- 3) Ueda T, Shimokubo S, Honda K, et al : The evaluation of food-wrap treatment for pressure ulcers. Jpn JPU, 8 (4) : 551-559, 2006. (Level III) (Japanese, English abstract)
- 4) Moriyama Y : Severe complication associated with inadequate wet dressing therapy:benefits and risks of so-called “wrap therapy”. Jpn J Dermatol, 120 (11) : 2187-2194, 2010. (Level V) (Japanese, English abstract)

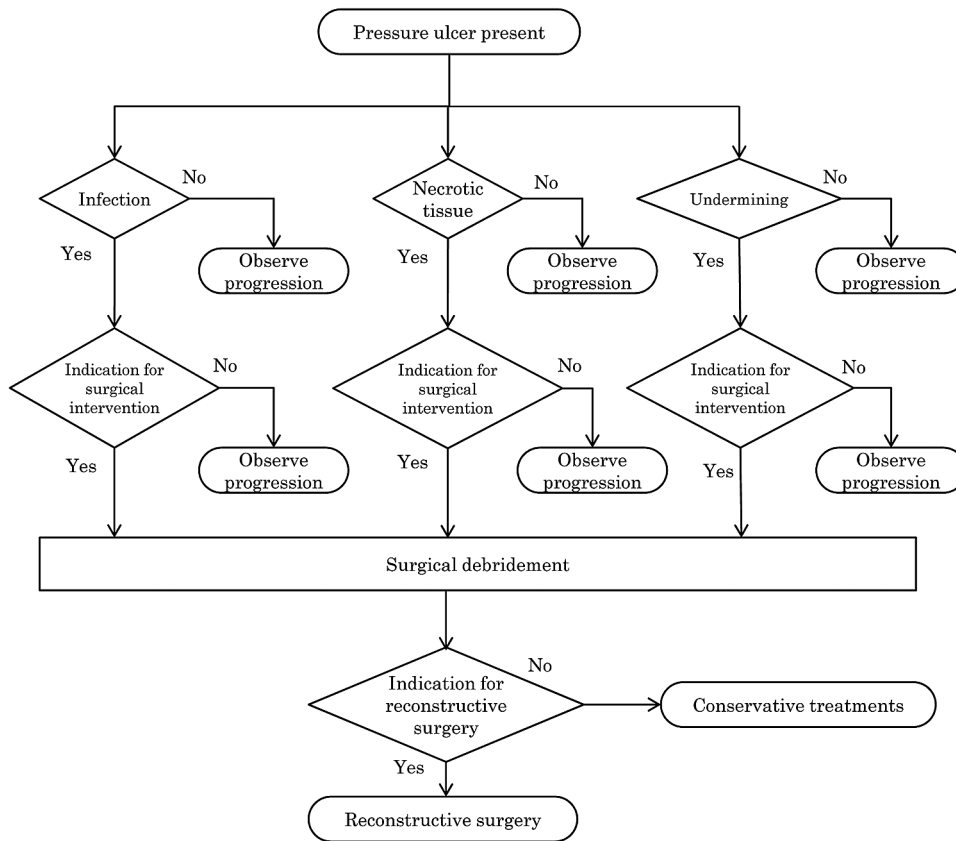


Fig. 3 Algorithm illustrating options for surgical interventions

CQ 3 Surgical Intervention

In cases requiring surgical intervention for the treatment of pressure ulcers, the use of anesthetics, postoperative positioning, and other perioperative matters must be managed with care. The timing and extent of the surgery will largely be determined by the general state of the patient’s physical health as well as the condition of the specific area targeted for intervention.

As indicated in the “Algorithm on the prevention and management of pressure ulcers” (Fig. 1), surgical intervention is seen as one option for local treatment of pressure ulcers.

Importantly, ‘Pressure ulcer present’ in the “Algorithm on surgical intervention” (Fig. 3) is to be understood as referring to patients who have already received systemic care and predictive assessment, but whose existing pressure ulcers have proved resistant to conservative forms of treatment, such as topical agent and dressing.

Determining the optimal area of the pressure ulcer to be treated with surgical intervention and deciding the best timing for the procedure are often difficult. For this reason, we have decided to discuss the

indications for reconstructive surgery separately from any discussion of the condition of the pressure ulcer as a local factor more pertinent to the question of whether or not surgical debridement should be employed. Surgical treatment of undermining is also addressed in a separate CQ as a factor resistant to conservative treatment.

Further, given the fact that even deep ulcers (D3) do not always require reconstructive surgery but may be treated successfully with conservative treatments that promote granulation tissue formation to achieve wound closure, the general topic of surgical treatment has been divided into surgical debridement and reconstructive surgery for more separate discussion. In addition, the use of negative pressure wound therapy (NPWT) to treat wounds resulting from the removal of necrotic tissue following surgical debridement is considered in CQ in this section.

CQ 3.1 : Is surgical debridement indicated when signs of infection/inflammation of the pressure ulcer are present?

[Recommendation] Surgical debridement may be conducted if there is evidence of pus, foul odor, or

osteomyelitis accompanying the infection.

[Rating] C1

[Analysis] Surgical debridement should be considered when infected pressure ulcers prove resistant to systemic antibiotic administration or topical antiseptics and dressings. Local abscesses and retention fluid should be lanced and drained to prevent expansion into surrounding intact tissue and/or progression to systemic sepsis.

The presence of hardened and thickened necrotic tissue (eschar) accompanied by fever, local inflammation (redness, swelling, and pain), and foul odor may point to an underlying pus-filled abscess. For this reason an incision into a portion of the necrotic tissue is recommended to confirm the presence of pus¹⁾. Especially in cases in which the nidus of infection in the necrotic tissue has caused sepsis, it is strongly recommended that first, the abscess be incised and the sinus and fistula be drained as soon as possible, and second, that the necrotic tissue be removed completely if the patient's condition allows.

Indeed the efficacy of surgical debridement in controlling infections associated with pressure ulcers has been corroborated by the findings of a controlled study²⁾. Furthermore, two guidelines issued by NPUAP/ EPUAP³⁾ and WOCN⁴⁾ assign the "Strength of Evidence" rating of C to surgical debridement in the presence of advancing cellulitis, crepitus, fluctuance, and/or sepsis secondary to ulcer-related infection. The remaining sources dealing with surgical interventions for the treatment of infection are general, textbook descriptions with limited utility.

There are at present no high-level studies dealing with the efficacy of surgical treatment of osteomyelitis accompanying pressure ulcers. However, a cohort study comprising 50 cases of osteomyelitis unrelated to pressure ulcers has reported a lowered recurrence rate following wide resectioning of degraded bone tissue⁵⁾.

References

- 1) Bergstrom N, Bemet M, Carlson C, et al : Pressure ulcer treatment. Clinical practice guideline : Quick reference guide for clinicians. No.15. Rockville, MD : U. S. Department of Health and Human Services. Public Health Service, Agency for Health Care Policy and Research. AHCPR Pub, No.95-0653, 1994.

- 2) Galpin JE, Chow AW, Bayer AS, et al : Sepsis associated with decubitus ulcers. *Am J Med*, 61 (3) : 346-350, 1986. (Evidence level: IV)
- 3) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel : Surgery for Pressure Ulcers. Prevention and treatment of pressure ulcers: clinical practice guideline, 96-99, National Pressure Ulcer Advisory Panel, Washington DC, 2009.
- 4) Ratliff CR, Tomaselli N : WOCN update on evidence-based guideline for pressure ulcers. *J Wound Ostomy Continence Nurs*, 37 (5) : 459-460, 2010.
- 5) Simpson AH, Deakin M, Latham JM : Chronic osteomyelitis. The effect of the extent of surgical resection on infection-free survival. *J Bone Joint Surg Br*, 83 (3) : 403-407, 2001. (Evidence level: IV)

CQ 3.2 : What is the optimal timing for the surgical debridement of necrotic tissue in pressure ulcers?

[Recommendation]

1. Surgical debridement may be considered when a clear line of demarcation between necrotic and healthy tissue is visible.

[Rating] C1

[Recommendation]

2. Surgical debridement is considered when pre-existing infection has been brought under control.

[Rating] C1

[Analysis] In cases in which infection has resulted in tissue necrosis, any attempt to remove the necrotic tissue too rapidly may result in severe pain and bleeding in the wound margins. Surgical debridement is recommended after the acute phase (about 3 weeks) when the demarcation line between necrotic tissue and the surrounding intact tissue has become clear^{1,2)}.

Necrotic tissue which is allowed to remain within the wound bed or on the edges of the pressure ulcers may evolve into a nidus of infection and impede the wound healing process. For this reason, the two guidelines previously cited recommend not only surgical but also autolytic, enzymatic, mechanical, or biosurgical (maggot therapy) debridement as treatment options^{1,2)}.

References

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Continenace Nurs. 2010 Sep-Oct; 37 (5) : 459-460. [Update of Wound Ostomy and Continenace Nurse Society: Guideline for Prevention and Management of Pressure Ulcers. Adv Skin Wound Care, 18 (4) : 204-208, 2005]

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CQ 3.3 : Is surgical incision or debridement recommended if undermining is present?

[Recommendation] Surgical incision or debridement may be considered for treating undermining which fails to respond to more conservative treatments.

[Rating] C1

[Analysis] The presence of undermining raises the possibility of necrotic tissue underlying the formation. In such cases, surgical intervention to lance and drain, or debride, the abscess, sinus tract, or bursa should be considered if no improvement results from more conservative treatments such as wound cleansing, or application of topical agents. However, a thorough systemic assessment should be made, including an assessment of the patient's propensity to bleed, before the undermining is incised with the aid of the appropriate tools to stop bleeding¹⁾. In cases of pressure ulcers of long duration or with an exceptionally large cavity (DESIGN score of P3 or higher), surgical incision of the undermining should be considered²⁾. On the other hand, Kosaka et al³⁾. argue that a preoperative incision to the skin overlying the undermining may lead to scar contracture and hamper reconstructive flap surgery; hence the undermining should be allowed to remain if there is no infection. However, in cases in which surgical intervention is ruled out, incision of the pocket is still preferable to only continuing more conservative forms of treatment.

References

- 1) Whitney J, Phillips L, Aslam R, et al : Guidelines for the treatment of pressure ulcers. Wound Repair Regen, 14 (6) : 663-679, 2006.
2) Nakamura M, Ito M : Slide-swing Plasty for the

Repair of Pressure Ulcers I : Operation Techniqu. Jpn JPU, 2 (3) : 236-243, 2000. (Level VI) (Japanese, English abstract)

- 3) Kosaka M, Morotomi T, Suzuki H : Selection of perforator flaps for sacral pressure ulcers with a subdermal pocket. Jpn JPU, 4 (3) : 371-378, 2002. (Level V) (Japanese, English abstract)

CQ 3.4 : When is surgical debridement indicated? [Recommendation]

1. Conservative treatments are the preferred option, but surgical debridement may be performed when infection/inflammatory signs are under control. [Rating] C1

2. Surgical debridement may be considered for patients with a D3 or D4 pressure ulcer. [Rating] C1

3. Surgical debridement may be considered according to the location of the infected pressure ulcer, the volume and extent of the necrotic tissue, the blood supply to the surrounding tissue, and the patient's level of pain tolerance.

[Rating] C1

[Analysis] Surgical debridement is generally indicated when the pressure ulcer infection has been brought under control and the necrotic tissue or degraded granulation tissue fails to respond to conservative treatments. The NPUAP/EPUA and WOCN guidelines recommend "maintenance debridement" for the acute phase.

This form of treatment is indicated for wound stage D3 or deeper. Due to the long recovery period required when the pressure ulcer has invaded muscle tissue and penetrated to the bone (D4), surgical debridement is recommended in order to expedite recovery³⁾.

As indicated above, surgical debridement can prove either too invasive or insufficient. This fact needs to be considered pre-operatively when evaluating the balance of risk and benefit of the procedure to the patient^{1, 2, 4, 5)}.

References

- 1) Ratliff CR, Tomaselli N : WOCN update on evidence-based guideline for pressure ulcers. J Wound Ostomy Continenace Nurs. 2010 Sep-Oct; 37 (5) : 459-460. [Update of Wound Ostomy and Continenace Nurse Society: Guideline for Prevention and Management of

Pressure Ulcers. *Adv Skin Wound Care*, 18 (4) : 204-208, 2005]

- 2) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel: Debridement. In: Dealey C, Cuddigan J, eds. *Prevention and treatment of pressure ulcers: clinical practice guideline*. 77-80, National Pressure Ulcer Advisory Panel, Washington DC, 2009.
- 3) Motegi S : Consideration for Better Treatment of Pressure Ulcers Based on My Experienc. *Jpn JPU*, 2 (1) : 57-64, 2000. (Level V) (Japanese, English abstract)
- 4) Kurita M, Ichioka S, Oshima Y, et al : Orthopaedic POSSUM scoring system: An assessment of the risk of debridement in patients with pressure sores. *Scand J Plast Reconstr Surg Hand Surg*, 40 (4) : 214-218, 2006. (Level: IV)

CQ 3.5 : When is reconstructive surgery indicated?
[Recommendation]

1. Reconstructive surgery may be considered for D3~D4 pressure ulcers that do not respond to conservative treatment.

[Rating] C1

2. Surgical reconstruction may be considered for ulcers showing a non-advancing edge and scar formation.

[Rating] C1

3. Reconstructive flap surgery following sequestration may be considered as a therapeutic option for osteomyelitis in pressure ulcers.

[Rating] C1

[Analysis] Two cohort studies^{1,2)} of direct suturing and skin grafts support performing wound closure under infection-free conditions. Although these studies deal with general wounds and not pressure ulcers in particular, the findings are worth listing for their value in assessing surgical indication.

Surgical reconstructive surgery is recommended for D3 or D4 pressure ulcers, which penetrate beyond subcutaneous tissue³⁾. When the wound depth extends beyond the subcutaneous tissue in areas normally favoring pressure ulcer formation, tissue characteristically having low blood supply such as the bone cortex, ligaments, joints and tendons capsules, are often exposed in the wound bed. When pressure ulcers fail to close after conservative treatment, surgical intervention to repair the wound should be

considered rather than continue a less effective regimen⁴⁾.

An advancing wound edge fibrosis and scar formation surrounding the pressure ulcer are signs of delayed wound healing⁵⁾. Debridement of such fibrotic/scar tissue typically creates a wound penetrating beyond the subcutaneous tissue. In such cases, reconstructive surgery should be seriously considered, as mentioned above.

Surgical removal or sequestrectomy often leaves a skin defect extending beyond the subcutaneous tissue. The need for surgical repair should seriously be considered in such cases.

References

- 1) Kizek TJ, Robson MD, Kho E : Bacterial growth and skin graft survival. *Surg Forum*, 18 : 518-519, 1967. (Level: I)
- 2) Robson MC, Lea CE, Dalton JB, et al : Quantitative bacteriology and delayed wound closure. *Surg Forum*, 19 : 501-502, 1968. (Level: I)
- 3) Disa JJ, Carlton JM, Goldberg NH : Efficacy of operative cure in pressure sore patients. *Plast Reconstr Surg*, 89 (2) : 272-278, 1992. (Level: IV)
- 4) Motegi S : Consideration for Better Treatment of Pressure Ulcers Based on My Experienc. *Jpn JPU*, 2 (1) : 57-64, 2000. (Level V) (Japanese, English abstract)
- 5) Ichioka S, Ohura N, Nakatsuka T : Benefits of surgical reconstruction in pressure ulcers with a non-advancing edge and scar formation. *J Wound Care*, 14 (7) : 301-305, 2005. (Level: V)
- 6) Whitney J, Phillips L, Aslam R : Guidelines for the treatment of pressure ulcers. *Wound Repair Regen*, 14 (6) : 663-679, 2006.

CQ 3.6 : Which reconstructive surgical procedure is considered especially effective for pressure ulcers?

[Recommendation] There are numerous options for reconstructive surgery for pressure ulcers, but insufficient evidence on the outcome of any of these procedures. For this reason, no single surgical procedure can be recommended as applicable to all cases.

[Rating] C1

[Analysis] Surgical reconstruction is indicated for pressure ulcers in which complications have been brought under control, and wound infection and

necrotic tissue have been removed by systemic, conservative, physiotherapeutic, or surgical treatment. If the decision is made to perform surgical debridement and reconstructive surgery simultaneously, any tissues involved in the pressure ulcer such as skin, granulation tissue, necrotic tissue, subdermal sinuses, abscesses, bursae, and bone must first be removed surgically¹⁾. According to one study, there is no significant difference in the cure rate between simultaneous and two-stage surgery²⁾.

Within the past several years, three retrospective case controlled studies have been published comparing the recurrence rate among patients who received underwent surgical procedures³⁻⁵⁾. However, due to the small number of cases in each study, and the lack of standardization or uniformity in perioperative management and care, the cure and recurrence rates claimed by these reports cannot be assessed with any accuracy.

References

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- 3) Nojima K : The surgical Treatment of Pressure Ulcers : Analysis of 92 cases. *Tokyo Jikei-kai Ika Daigaku Zasshi*, 119 (6) : 441-453, 2004. (Level: V) (Japanese, English abstract)
- 4) Kuwahara M, Tada H, Mashiba K, et al : Mortality and recurrence rate after pressure ulcer operation for elderly long-term bedridden patients. *Ann Plast Surg*, 54 (6) : 629-632, 2005. (Level: V)
- 5) Wong TC, Ip FK : Comparison of gluteal fasciocutaneous rotational flaps and myocutaneous flaps for the treatment of sacral sores. *Int Orthop*, 30 (1) : 64-67, 2006. (Level: V)

CQ 3.7 What kind of physiotherapy is recommended for pressure ulcers with low amounts of granulation tissue?

[Recommendation] Negative pressure wound therapy (NPWT) may be considered for the treat-

ment of wounds following debridement of infectious or necrotic tissue.

[Rating] C1

[Analysis] Negative pressure wound therapy (NPWT) is designed to control the wound healing process under negative pressure conditions by covering the whole wound surface with an airtight dressing.

The various kinds of NPWT equipment featured in review articles and guidelines are commercially available. When using any of these products, the wound surface should first be sealed air-tight using the sponge specially provided for this purpose. A pressure of -125mmHG is typically recommended¹⁻³⁾.

The WOCN⁴⁾ and NPUAP/EPUAP guidelines⁵⁾ assign NPWT an evidence level of (B) for its efficacy in rapidly reducing wound depth, and improving the healing rate and granulation tissue formation. Further, two meta-analytical studies^{1,2)} rated NPWT more highly than conventional treatments for its efficacy against chronic skin ulcers, such as diabetic, stasis, and pressure ulcers, and trauma. However, a randomized controlled trial⁶⁾ failed to demonstrate a significant difference between the efficacy of the VAC[®] system and treatments based on wet-to-dry dressings or topical agents.

NPWT is an option for treating pressure ulcers when infection/necrosis is controlled. However, there are no grounds for prioritizing it over other treatments.

References

- 1) Ubbink DT, Westerbos SJ, Evans D, et al : Topical negative pressure for treating chronic wounds. *Cochrane Database of Systematic Reviews* 2008, Issue 3. Art. No.: CD001898. DOI : 10. 1002/14651858. CD001898.pub2. (Level: I).
- 2) Wanner MB, Schwarzl F, Strub B, et al : Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study. *Scand J Plast Reconstr Surg Hand Surg*, 37 (1) : 28-33, 2003. (Level: II)
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based guideline for pressure ulcers. *J Wound Ostomy Continence Nurs*, 37 (5) : 459-460, 2010.

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CQ 4 General management

CQ 4.1 : Which underlying medical conditions may entail the risk of leading to pressure ulcers?

[Recommendation] Pelvic fractures, diabetes mellitus, cerebro-vascular diseases, and spinal cord injuries potentially lead to pressure ulcer formation due to patient immobility.

[Rating] C1

[Analysis] The following is evidence pertaining to co-morbidity risk factors for pressure ulcer development.

A study involving participants with no pressure ulcers at the time of admission to a chronic care hospital reported a correlation between cerebro-vascular accidents and the development of pressure ulcers¹⁾. Further, according to a study of the database of nursing homes²⁾, as well as the results of a study conducted under similar conditions³⁾, pelvic fractures, diabetes mellitus, and peripheral vascular disease were found to be positively correlated to the incidence of pressure ulcer formation. Similarly, the outpatient records of 75,158 cases demonstrated a positive correlation between pressure ulcer formation and malignant tumors, Alzheimer’s disease, congestive heart failure, rheumatoid arthritis, osteoporosis, deep venous thrombosis, diabetes mellitus, urinary tract infections, cerebro-vascular diseases, Parkinson’s disease and chronic obstructive pulmonary disease. In addition, the Wound Healing Society in the United States has reported spinal cord injuries as a risk factor in the development of pressure ulcers.

The disease states mentioned above may be considered risk factors for the development of pressure ulcers. However, other reports contradict these findings. For the purposes of the present guidelines, the comorbidity findings for pelvic fractures, diabetes mellitus, cerebro-vascular accidents, as well as the spinal injuries mentioned by the American guidelines are cited for their potential relevance as risk factors.

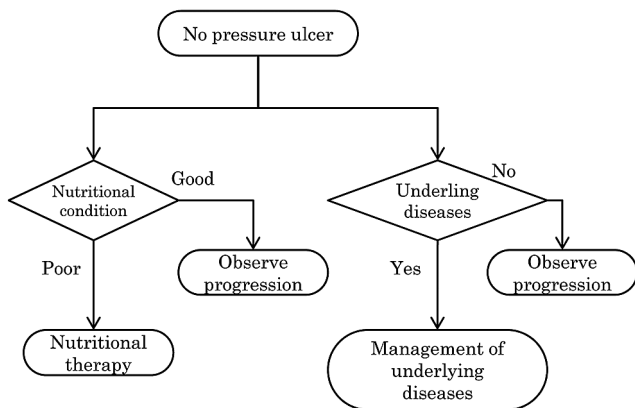


Fig. 4 Algorithm illustrating options for general management of pressure ulcer prevention

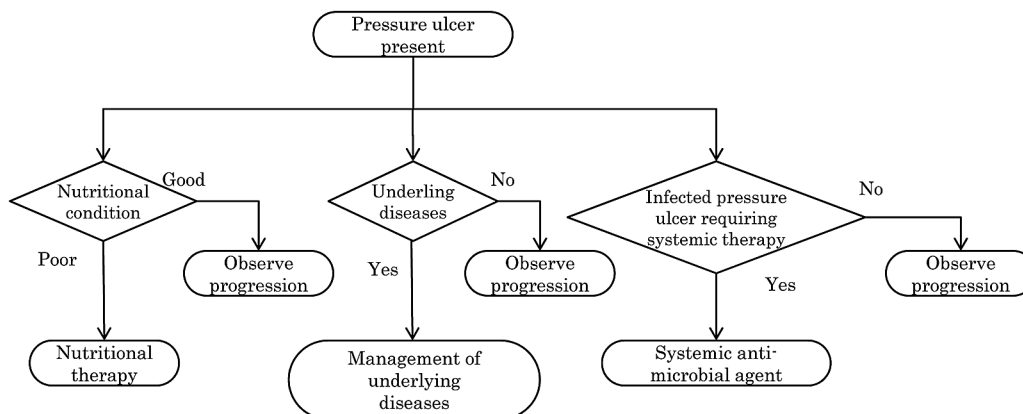


Fig. 5 Algorithm illustrating general management after occurrence of pressure ulcer

References

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- 5) Stechmiller JK, Cowan L, Whitney JD, et al : Guidelines for the prevention of pressure ulcers. *Wound Repair Regen*, 16 (2) : 151-168, 2008.

CQ 4.2 : What form of nutritional intervention is recommended for the prevention of pressure ulcers in malnourished patients?

[Recommendation] For patients suffering from protein-energy malnutrition (PEM), using a enhanced energy and protein supplement after due consideration of any underlying conditions is recommended.

[Rating] B

[Analysis] A high-calorie, high-protein dietary supplement was found to be effective in promoting healing of pressure ulcers among PEM (protein-energy malnutrition) patients who are unable to obtain the requisite quantities of these nutrients from their regular meals^{1,2)}.

According to the Cochrane Database Systematic Review¹⁾, four studies examined the effects of dietary supplementation on pressure ulcers. In these studies the addition of 200 kcal to the total daily caloric intake over 15 days markedly decreased the rate of occurrence of pressure ulcers in comparison with the control group (295 cases, or 40.6%; 377 cases, or 47.2%)³⁾. A study of the effect of supplemental feeding in patients with femoral fractures similarly demonstrated an improvement in clinical course, in addition to diminished incidence of complications⁴⁾.

Dietary supplementation in patients with hip fractures, which are known to increase highly the risk for pressure ulcer development, demonstrated both a low rate of occurrence of Stage II pressure ulcers and in cases in which pressure ulcers eventually developed, a longer interval before occurrence⁵⁾.

On the basis of the evidence level of these studies, nutritional intervention is assigned the recommendation rating of B with the proviso that the underlying condition of the patient, if any, be duly considered.

References

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- 5) Houwing RH, Rozendaal M, Wouters-Wesseling W, et al : A randomised, double-blind assessment of the effect of nutritional supplementation on the prevention of pressure ulcers in hip-fracture patients. *Clin Nutr*, 22 (4) : 401-405, 2003. (Level II)

CQ 4.3 : How should patients incapable of oral intake of nutrition and hydration be fed?

[Recommendation] Consider supplying the required nutrition by enteral tube-feeding. When this is not possible, consider parenteral feeding.

[Rating] C1

[Analysis] Although a randomized controlled trial demonstrated that tube feeding clearly increased food intake and resulted in significantly higher albumin and total protein levels after 1.2 weeks in comparison with the control group ($p < 0.001$), no significant effect was seen in terms of pressure ulcer prevention. There are in fact no useful studies on the relationship

between the method of feeding and pressure ulcer prevention, and existing recommendations are based on expert opinion or represent the perspective of particular guidelines. The NPUAP/EPUAP quick reference guide states that patients should be fed by enteral tube or intravenously if oral food intake is insufficient²⁾.

Similarly, the Japanese guidelines for intravenous and enteral feeding state that enteral feeding should be used as much as possible in cases where oral food intake is insufficient, and that intravenous feeding should be performed if enteral feeding is not possible or insufficient³⁾. The manner in which the patient is fed should be decided after due consideration of the prognosis, goals of treatment, and individual differences.

References

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- 2) European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : quick reference guide. National Pressure Ulcer Advisory Panel, Washington DC, 2009.
- 3) Japanese Society for Parenteral and Enteral Nutrition : Practical guidelines for parenteral and enteral nutrition 2nd Ed, 7-8, Nankodo, Tokyo, 2007. (Japanese)

CQ 4.4 : What indices can be used to assess the level of malnutrition as a risk factor for pressure ulcers?

[Recommendation]

1. In the absence of inflammation or dehydration, serum albumin levels may be used.

[Rating] C1

2. Rate of weight loss may be considered for use.

[Rating] C1

3. Consider using the rate of food intake or the amount of food consumption as an index.

[Rating] C1

4. Consider using Subjective Global Assessment (SGA).

[Rating] C1

5. Mini Nutritional Assessment (MNA) may be

used with elderly patients.

[Rating] C1

[Analysis] Normally in a clinical setting, biochemical measures such as serum albumin levels, as well as physiological parameters, food intake rate, and nutritional assessment and screening tools are used to assess risk.

In analytical epidemiological studies of pressure ulcer risk, total protein, serum albumin, and prealbumin values are examined to determine risk. Among these, the serum albumin or prealbumin level is a commonly used index of pressure ulcer risk. Low serum albumin values indicate high risk for pressure ulcers¹⁻⁷⁾. Values below 3.5 g/dl indicate a particularly high risk.¹⁻⁶⁾ However, because the serum albumin level varies depending on inflammation, dehydration and other factors, this index merits a Recommendation Rating of no higher than C1.

Body weight measurements can be performed easily without the aid of special apparatuses, and is the most convenient tool for assessing the nutritional state of the patient. Decrease in body weight is thought to be a risk factor for pressure ulcers. Among newly patients at the Stage III or IV pressure ulcers, a decrease in % usual body weight (UBW) is reportedly correlated to increased pressure ulcer risk⁸⁾. Haydock and Hill report that moderately to severely under-nourished surgical patients showed a decrease in body weight of 9.6% and 19.6%, respectively, and wound healing was impaired more than in patients assessed to be in 'good' condition ($p < 0.001$)⁹⁾. In a cohort study examining the risk for pressure ulcers at Stage II or higher among in-patients who were either bed-ridden or confined to a sitting position, a decrease in body weight was reported to be a significant risk factor for pressure ulcer development¹⁰⁾. According to the EAUAP nutritional guidelines, undesirable weight loss, defined as weight loss exceeding 10% of normal body weight over 6 months, or exceeding 5% over 1 months, may point to malnutrition, and requires regular monitoring of the patient's body weight¹¹⁾. On the basis of the quality of the publications from which this information is taken, the recommendations given here merit the rating of C1.

Although there is not sufficient evidence establishing a relationship between eating rate and pressure ulcers, among the cases of pressure ulcer

documented in Japan, a rate of food intake below 75% of food offered has been documented in 48% of pressure ulcer patients¹²⁾. Further, the amount of food intake is one of the categories included on the Braden Scale for pressure ulcer risk assessment, with a rate of food intake below 50% thought to entail a significantly higher risk for pressure ulcer development¹³⁾. Use of the food intake rate as an index of malnutrition is assigned a recommendation rating of C1.

The Subjective Global Assessment, published by Detsky et al. in 1987, is widely used as a comparatively precise tool for assessing the nutritional state of patients. However, it has been assigned the Recommendation Rating of C1 due to the fact that at present only expert opinion supports the relationship between SGA and pressure ulcer prevention.

In a cross-sectional study of three assessment tools for evaluating the nutritional state of patients, namely the mini nutritional assessment: MNA, bioelectrical impedance analysis: BIA, and Barthel index: BI, the MNA was found to have the strongest correlation to the risk of pressure ulcer development. Further, a cross sectional study of MNA and other, similar assessment tools reported that screening patients' nutritional status may be a more effective indicator of pressure ulcer risk than serum albumin and prealbumin values¹⁴⁾. Because at present there are no useful studies examining the relationship between nutritional assessment tools and pressure ulcer risk, the recommendation rating of C1 has been assigned to the data given here.

References

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- 2) Pinchcofsky-Devin GD, Kaminski MV Jr : Correlation of pressure sores and nutritional status. *J Am Geriatr Soc*, 34 (6) : 435-440, 1986. (Level IV)
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- 4) Nakajo T, Oishi S : Prevention of pressure ulcer and nutrition management: Cutoff values of serum albumin and hemoglobin. *Geriatr Med*, 40 (8) :

- 1023-1028, 2002. (Level VI) (Japanese)
- 5) Konagaya M, Takasaki K : The development of nutritional index for pressure ulcer incidence. *Jpn J PU*, 2 (3) : 257-263, 2000. (Level IV) (Japanese, English abstract)
- 6) Sugiyama M, Nishimura A, Ohura T, et al : Effect of nutritional care for prevention and treatment for pressure ulcers: Health and labor sciences Research Grants (H10-Comprehensive Research on Aging and Health-012). 37-45, 2000. (Level IV) (Japanese)
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- 13) Hengstermann S, Fischer A, Steinhagen-Thiessen E, et al : Nutrition status and pressure ulcer : what we need for nutrition screening. *J Parenter Enteral Nutr*, 31 (4) : 288-294, 2007. (Level IV)
- 14) Langkamp-Henken B, Hudgens J, Stechmiller JK, et al : Mini nutritional assessment and screening scores are associated with nutritional indicators in elderly people with pressure ulcers. *J Am Diet Assoc*, 105 (10) : 1590-1596, 2005. (Level V)

CQ 4.5 : When is the systemic administration of antibiotics (antimicrobials) indicated in patients with an infected pressure ulcer?

[Recommendation] If physical examination findings or test results indicate advancing cellulitis and osteomyelitis, necrotizing fasciitis, bacteremia, or sepsis, consider administering systemic antibiotics. If only symptoms of local infection are found, administration of systemic antibiotics need not be considered.

[Rating] C1

[Analysis] An effort was made to identify specific disease states in cases of infected pressure ulcers which required the systemic administration of antibiotics. However, given the generally accepted notion that failure to administer systemic antibiotics entails an intolerable risk to the patient's health, there are no controlled studies examining the differences in the effect of administering or not administering systemic antibiotics. Our recommendations here are therefore based on published guidelines or reviews. The NPUAP/EPUAP guidelines recommend using 'systemic antibiotics for individuals with clinical evidence of systemic infection, such as positive blood cultures, cellulitis, fasciitis, osteomyelitis, systemic inflammatory response syndrome, or sepsis, if consistent with the individual's goals'¹⁾. The WOCN guidelines similarly endorse the view that systemic antibiotics should be administered, as needed, in cases of bacteremia, sepsis, advancing cellulitis and osteomyelitis²⁾.

From a clinical point-of-view, if the physical examination findings or the test results are found to correspond to the condition of a given patient, consider the administration of systemic antibiotics. However, for cases in which the infection is local, there is no evidence to support the use of systemic antibiotics. For such cases, refer to the sections dealing with conservative treatment or surgical treatment.

References

- 1) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : clinical practice guideline, National Pressure Ulcer Advisory Panel, Washington DC, 2009.
- 2) Wound Ostomy Continence Nurses Society : Guidelines for prevention and management of pressure ulcers. 2nd edition, WOCN clinical practice guidelines series 2, 2010.

CQ 4.6 : Which antibiotics (antimicrobials) are recommended for treating infection?

[Recommendation] Consider using empiric antibiotics to suspected pathogens common in clinical settings. Reconsider using more specific antibiotics to pathogens by referring the results of susceptibility testing.

[Rating] C1

[Analysis] There are no studies at present indicating the best choice of systemic antibiotic for infected pressure ulcers. In the NPUAP/EPUAP guidelines, 'Antibiotics should be chosen based on confirmed antibiotic susceptibilities of the suspected or known pathogens. For life-threatening infections, empiric antibiotics should be based on local antimicrobial susceptibility patterns, and re-evaluated when definitive cultures become available'¹⁾. In the present guidelines as well, the immediate administration of antibiotics appropriate to the suspected pathogen is recommended.

References

- 1) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : clinical practice guideline, National Pressure Ulcer Advisory Panel, Washington DC, 2009.

CQ 4.7 : Which underlying conditions may pose a risk of prolonging the healing of pressure ulcers?

[Recommendation] Malignant tumors and cardiovascular diseases should be considered as factors which may prolong the healing of pressure ulcers.

[Rating] C1

[Analysis] Evidence relating to co-morbidity diagnoses was assembled because of their potential importance as factors influencing the healing of pressure ulcers, including chronic wounds. The majority of the information found was comprised of expert opinions and case reports, with only two analytical-epidemiological and case-controlled studies^{1,2)}.

The rate of healing in pressure ulcers among cardiovascular patients was found to be significantly lower according to a cohort study of pressure ulcer patients¹⁾. According to the findings of another cohort study of cancer patients with pressure ulcers and other types of skin ulcer²⁾, cancer patients showed a

significant lower rate of healing than non-cancer patients. Further, according to expert opinion in Japan³⁾, the exacerbation of diabetes mellitus, malignancies, liver cirrhosis, or peripheral vascular disease impeded the healing rate of pressure ulcers.

In summary, malignancies and cardiovascular diseases can be cited as comorbidity factors which may prolong the healing of pressure ulcers. Although specific epidemiological figures cannot be given for lack of data, a general care regimen which includes management of the patient's condition and nutrition is recommended in order to hasten healing of pressure ulcers in patients whose general health has been adversely affected by their disease state.

References

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- 2) McNeas P, Meneses KD : Pressure ulcers and other chronic wounds in patients with and patients without cancer: a retrospective, comparative analysis of healing patterns. *Ostomy Wound Manage*, 53 (2) : 70-78, 2007. (Level IV)
- 3) Mino Y : The latest basic information: How to treat a refractory pressure ulcer?. *JPN J Clin Nurs (Rinsho Kango)*, 27 (9) : 1377-1382, 2001. (Level VI) (Japanese)

CQ 4.8 : Should a nutritional screening and assessment be performed for pressure ulcer patients?

[Recommendation] A nutritional screening and assessment and nutritional intervention may be considered if required.

[Rating] C1

[Analysis] Assessing the nutritional status of the pressure ulcer patient and instituting the nutritional regimen most appropriate for each case has been found to contribute to improving the patient's health¹⁾. The NPUAP/EPUAP quick reference guide²⁾ also recommends that screening and assessment of the patient's nutritional status be conducted when the patient is admitted to hospital, shows changes in health condition, or shows evidence of retardation of wound healing.

References

- 1) Donini LM, De Felice MR, Tagliaccica A, et al : Nutritional status and evolution of pressure sores in geriatric patients. *J Nutr Health Aging*, 9 (6) : 446-454, 2005. (Level IV)
- 2) European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : quick reference guide, National Pressure Ulcer Advisory Panel, Washington DC, 2009.

CQ 4.9 : How much nutrition in general should be provided to pressure ulcer patients?

[Recommendation]

1. In order to ensure adequate energy for healing of pressure ulcers, recommend providing patients with 1.5 times the basal energy expenditure (BEE).

[Rating] B

[Recommendation]

2. Recommend providing additional protein as required.

[Rating] B

[Analysis] Two systematic reviews have examined the effect of nutrition on pressure ulcers^{1,2)}. The NPUAP/EPUAP guidelines recommend 30~35 kcal/kg of body weight as the basic energy requirement³⁾. A randomized controlled study⁴⁾ of nutritional intervention in patients with pressure ulcers found that the intervention group, who were given 300 kcal in addition to their daily diet (1.55 times the BEE), showed a significantly greater reduction in wound surface area and a faster wound healing rate 8 weeks after the intervention than the control group, who were given only 1.16 times the BEE. Because this study eliminated factors unrelated to nutrition and used the same nutritional source for all of its subjects, it merits the Recommendation rating of B.

With regard to the quantity of protein in the diet, greater reduction in the wound surface area was seen in patients who had received large quantities of protein (energy ratio 25%) via enteral tube feeding compared to those who had received only the standard diet⁵⁾. Further, a group of under-nourished patients who had received large quantities of protein in their diet either via enteral tube feeding or as a dietary supplement (24% protein; 61g/L) reportedly

showed a greater reduction in wound surface area after 8 weeks compared to the group who had received only 14% protein (37g/L)⁶⁾. However, because the number of subjects was small and the experimental design was inadequate, these data have been assigned a low Evidence Level. On the other hand, a randomized controlled study examining the effect of providing patients with a diet augmented with larger quantities of specific nutrients as required, demonstrated an improved PUSH scores and wound healing rate in the intervention group, although a comparison of energy content and amount of added protein with wound healing rate and PUSH scores showed no difference⁷⁾. However, the study employed a relatively small number of cases and failed to explain the relationship between individual nutrients, pressure ulcer healing rate, and PUSH scores. The NPUAP/EPUAP guidelines³⁾ recommend 1.25~1.5g/kg/day according to the severity of the symptoms³⁾, but because there are no recent studies on the basis of which specific recommendations can be made, we have not indicated any specific amount for protein supplementation.

References

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- 2) Stratton RJ, Ek AC, Engfer M, et al : Enteral nutritional support in prevention and treatment of pressure ulcers : a systematic review and metaanalysis. *Ageing Res Rev*, 4 (3) : 422-450, 2005. (Level I)
- 3) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : clinical practice guideline. National Pressure Ulcer Advisory Panel, Washington DC, 2009.
- 4) Ohura T, Nakajo T, Okada S, et al : Evaluation of effects of nutrition intervention on healing of pressure ulcers and nutritional states : randomized controlled trial. *Wound Rep Reg*, 19 : 330-336, 2011. (Level II)
- 5) Chernoff RS, Milton KY, Lipschitz DA : The effect of a very high-protein liquid formula on decubitus ulcers healing in long term tube-fed institutionalized patients. *J Am Diet Assoc*, 90 : A-130, 1990. (Level II)
- 6) Breslow RA, Hallfrisch J, Guy DG, et al : The importance of dietary protein in healing pressure ulcers. *J*

Am Geriatr Soc, 41 (4) : 357-362, 1993. (Level II)

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CQ 4.10 : Should the diet of pressure ulcer patients be supplemented with any specific nutrients?

[Recommendation] Patients' diet may be supplemented with zinc, arginine, and ascorbic acid to prevent deficiencies of these nutrients.

[Rating] C1

[Analysis] Of the systematic reviews examining nutritional supplementation for the prevention and healing of pressure ulcers, one deals specifically with the supplementation of zinc, while two are concerned specifically with ascorbic acid¹⁾.

With regard to zinc, one study reported no significant difference in pressure ulcer healing rate between ten individuals who had been administered 200mg/day of zinc sulphate and eight individuals who had been administered a placebo over 1~2 months²⁾. However, the study was inadequate because of the small number of cases, and the lack of clarity regarding the treatment procedures, food intake, nutritional status, and serum zinc level. The NPUAP/EPUAP guidelines³⁾ recommend that 40mg/day or more of zinc be given as a nutritional supplement to patients with zinc deficiency. However, because there are no high-evidence level studies examining the efficacy of zinc supplementation for pressure ulcer healing, the information discussed here has been assigned a Recommendation Rating of C1.

Randomized controlled trials^{4,5)} examining the therapeutic effect of ascorbic acid on pressure ulcer healing found that 500 mg of ascorbic acid administered twice daily over one month resulted in a 85% reduction in wound surface area compared with 43% for the placebo group. However, because each group in the study was comprised of only ten subjects, and because there are no other studies providing useful information, we have confined our recommendation only to supplementing the patient's diet with enough ascorbic acid to prevent a deficiency.

Only one historical controlled study dealing with arginine supplementation exists to date⁶⁾. In this study, 18 functional spinal injury patients who were

also suffering from pressure ulcers were given 9g/day of arginine until the pressure ulcers completely healed. The rate of healing was then compared with that of the control group consisting of patients who had been treated in the past for spinal injuries. The result indicated that the period required for total healing of the pressure ulcers in the experimental group was significantly shorter than that for the control. However, because the control group used in the study consisted of patients who had been involved in a separate, past study, and because there was inadequate information regarding nutritional status and lack of uniformity in the conditions, we were unable to assign a Recommendation Rating higher than C1.

References

- 1) Stratton RJ, Ek AC, Engfer M, et al : Enteral nutritional support in prevention and treatment of pressure ulcers : a systematic review and metaanalysis. *Ageing Res Rev*, 4 (3) : 422-450, 2005. (Level II)
- 2) Norris JR, Reynolds RE : The effect of oral zinc sulfate therapy on decubitus ulcer. *J Am Geriatr Soc*, 19 : 793-797, 1971. (Level II)
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- 4) Taylor TV, Rimmer S, Day B, et al : Ascorbic acid supplementation in the treatment of pressure-sores. *Lancet*, 2 (7880) : 544-546, 1974. (Level II)
- 5) Ter Riet G, Kessels AG, Knipschild PG : Randomized clinical trial of ascorbic acid in the treatment of pressure ulcers. *J Clin Epidemiol*, 48 (12) : 1453-1460, 1995. (Level II)
- 6) S Brewer, K Desneves, L Pearce, et al : Effect of an arginine-containing nutritional supplement on pressure ulcer in community spinal patients. *J Wound Care*, 19 (7) : 311-316, 2010. (Level III)

CQ 4.11 : Should a registered dietician or multidisciplinary nutritional team participate in the care of pressure ulcer patients?

[Recommendation] Participation by a registered dietician or multidisciplinary nutrition support team in the care of pressure ulcer patients may be recommended.

[Rating] C1

[Analysis] A study of the economic viability of a nutrition support team (NST) in pressure ulcer management found that two years after deployment, the incidence of pressure ulcers fell from 14.9% to 5.85% (roughly 1/3 of the original rate) in the study population and that the cost of treating pressure ulcers substantially fell in the second year of the NST's operations. Two other studies have reported similar findings with regard to the economic viability of the NST^{2,3)}. Another study reported an improvement in the patients' condition as a result of intervention by the NST, but because the number of cases was small, no statistical data were given.

The EPUAP nutritional guidelines recommend that for grade III and IV pressure ulcers, a multidisciplinary team assess the basic metabolic rate of the patient and monitor the amount of exudates from the wound⁵⁾.

All of the studies examined are unanimous in asserting the need for preventive intervention and recommend appropriate nutritional assessment, as well as intervention by the registered dietician or the NST. However, none of the studies mentioned gives specific data concerning the efficacy of this form of intervention in promoting pressure ulcer healing.

References

- 1) Okude K, Higashiguchi T, Fukumura S, et al : Economic effect of pressure ulcers management based on nutrition therapy. *J Jpn Soc Parenteral Enteral Nutrition*, 17 (4) : 29-33, 2002. (Level V) (Japanese, English abstract)
- 2) Onoki K, Isozaki T, Yonekawa O, et al : Medical economic effect of nutrition support team (NST) in a general hospital in Japan. *Med J Seirei Hamamatsu General Hospital*, 4 (1) : 23-27, 2004. (Level V) (Japanese)
- 3) Toma T, Kitanishi M, Hasegawa K : Clinical outcomes of femoral neck fracture with nutrition support team. *Central Japan J of Orthopaedic Surgery & Traumatology*, 48 (4) : 659-660, 2005. (Level V) (Japanese)
- 4) Ohara H, Kurihara Y, Dohi M : Improvement effect of nutritional management on the long term hospitalized patients. *Jpn J National Med Service*, 59 (6) : 300-305, 2005. (Level V) (Japanese)
- 5) European Pressure Ulcer Advisory Panel : Nutrition-

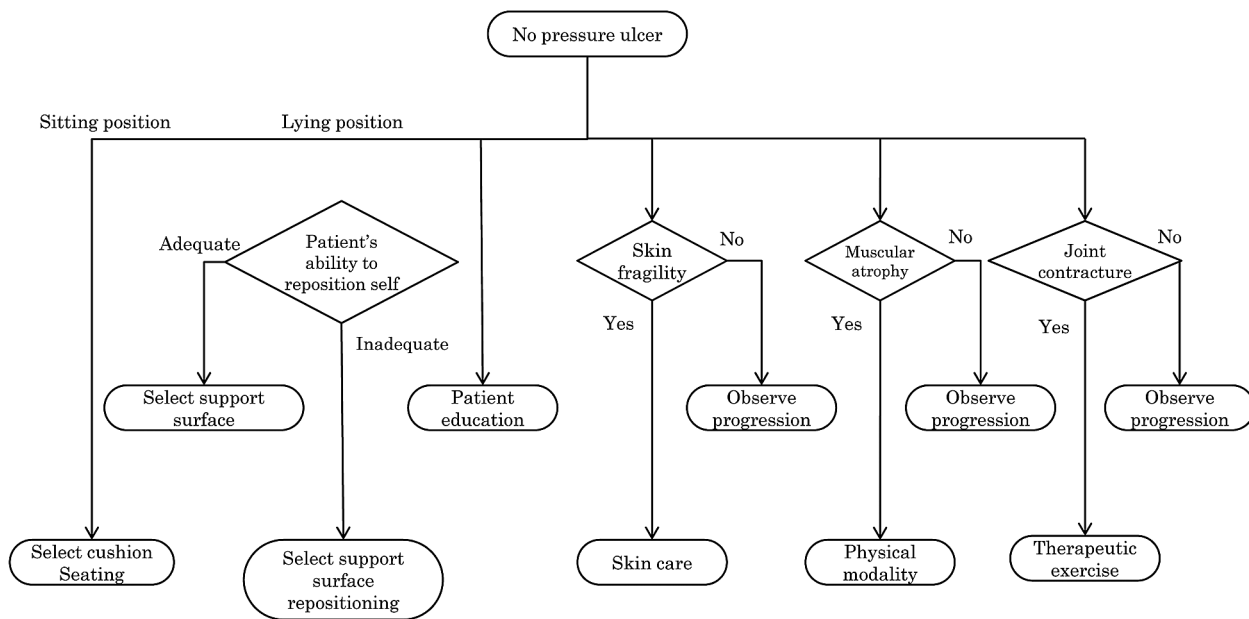


Fig. 6 Algorithm illustrating preventive care options

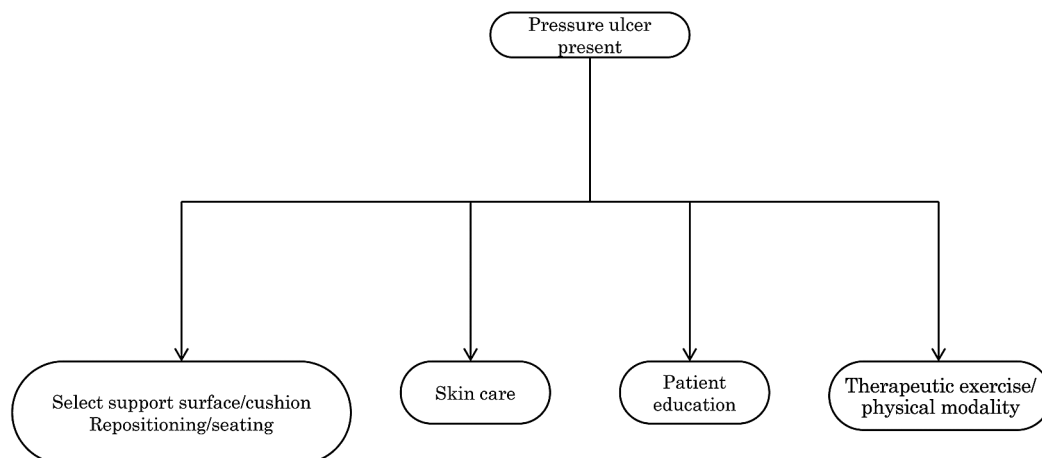


Fig. 7 Algorithm illustrating care options after occurrence of pressure ulcer

al guidelines for pressure ulcer prevention and treatment. Registered charity No : 1066856, European Pressure Ulcer Advisory Panel, 2003.

CQ 4.12 : Should body weight be used as a means of assessing the efficacy of nutritional supplementation in pressure ulcer patients?

[Recommendation] Recommend using body weight as a means of assessing the effectiveness of nutritional supplementation if edema or dehydration can be ruled out.

[Rating] B

[Analysis] A randomized controlled study examining the effectiveness of nutritional intervention in pressure ulcer patients found that the intervention

group showed a significantly greater increase in body weight 12 weeks after commencement of the study compared with the control group ($p < 0.001$), which showed no change in body weight at all¹. Further, the wound size in the intervention group decreased more rapidly than in the control group ($p < 0.001$). The results of this study have been deemed reliable because factors unrelated to nutrition but affecting the pressure ulcers were controlled. Accordingly, body weight is recommended as an index for assessing whether the patient has received adequate nutrition.

Further, the NPUAP/EPUAP guidelines² recommend that, if the body weight of a pressure ulcer patient decreases, the patient should be given

sufficient calories to restore body weight. However, edema and dehydration should first be ruled out as potential causes of fluctuations in body weight.

References

- 1) Ohura T, Nakajo T, Okada S, et al : Evaluation of effects of nutrition intervention on healing of pressure ulcers and nutritional states : randomized controlled trial. *Wound Repair Regen*, 19 : 330-336, 2011. (Level II)
- 2) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : clinical practice guideline. National Pressure Ulcer Advisory Panel, Washington DC, 2009.

CQ 5 Rehabilitation

CQ 5.1 : Which factors account for pressure ulcer development in chronic spinal cord injury patients?

[Recommendation] For patients with a history of pressure ulcers, vigilance is recommended to prevent recurrence.

[Rating] B

[Analysis] A systematic review¹⁾ which has examined the factors leading to pressure ulcer development among chronic spinal cord injury patients found gender (greater susceptibility of men), length of time following appearance of the wound, complete injury rather than partial injury, the presence of deep vein thrombosis, presence of pneumonia, history of pressure ulcers, to be relevant factors. No relationship was found between age and degree of injury. Among studies conducted in Japan, some have reported that all pressure ulcers recur within 14 years²⁾, or that the recurrence may lead to sepsis or death³⁾. The Recommendation Rating of B is assigned to these evidence sources in view of the apparently serious consequences of recurrence.

References

- 1) Gelis A, Dupeyron A, Legros P, et al : Pressure ulcer risk factors in persons with spinal cord injury Part2 : The chronic stage. *Spinal Cord*, 47 : 651-661, 2009. (Level I)
- 2) Hirose H, Niituma J, Iwasaki Y, et al: An approach to determine situations in which pressure ulcers occur in patients with spinal cord injury. *Jpn J PU*, 12 (2) : 118-125, 2010. (Level IV) (Japanese, English ab-

stract)

- 3) Imai K, Kadowaki T, Aizawa Y : Standardized indices of mortality among persons with spinal cord injury : Accelerated aging process. *Ind Health*, 42 (2) : 213-218, 2004. (Level IV)

CQ 5.2 : Which methods are effective for preventing pressure ulcer development in spinal cord injury patients?

[Recommendation] Conducting rehabilitation while monitoring interface pressure may be considered.

[Rating] C1

[Analysis] Hirose et al¹⁾ have compared the length of time that elapsed between discharge from hospital following treatment for pressure ulcers and readmission for recurrence among patients who received rehabilitation either with or without monitoring interface pressure. The results of the study demonstrated a significantly lower incidence of recurrence among patients when their interface pressure was monitored during rehabilitation ($p < 0.02$). Further, three separate studies²⁻⁴⁾ on pressure ulcer prevention for spinal cord injury patients performed at multiple rehabilitation facilities in Japan reported that seat-type pressure measuring devices are extremely useful in gauging pressure on the buttocks and in providing feedback to the patient during rehabilitation. On this basis, we have assigned the recommendation rating of C1 to this section.

References

- 1) Hirose H, Niituma J, Iwasaki Y, et al : An approach to determine situations in which pressure ulcers occur in patients with spinal cord injury. *Jpn J PU*, 12 (2) : 118-125, 2010. (Level IV) (Japanese, English abstract)
- 2) Morita T, Maeda J, Sakuma F, et al : A case study of a spinal cord injury (SCI) patient who developed a pressure ulcer after changing his wheelchair cushion and life-style-Physical therapy intervention of the treatment of pressure ulcer in SCI-. *Physical Therapy Japan*, 35 (3) : 104-109, 2008. (Level V) (Japanese)
- 3) Matsubara H, Hirose H, Hama Y : Fabrication of seating cushion for a person with spinal cord injury and hip disarticulation. *J Jpn Acad Prosthetists Orthotists*, 12 (1) : 48-53, 2004. (Level V) (Japanese)
- 4) Kaneko M, Nakashima M, Kurosaki S, et al : Indi-

vidually planned visits for self-care guidance and livelihood support by co-medical staff could prevent pressure ulcer recurrence in a patient with spinal injury. *Jpn J PU*, 132-136, 2010. (Level V) (Japanese, English abstract)

CQ 5.3 : What type of cushion should be used with elderly patients in a seated position to prevent pressure ulcers?

[Recommendation] A pressure-redistributing seat cushion for individuals with spinal cord injury is recommended to prevent pressure ulcer development while seated.

[Rating] B

[Analysis] A randomized controlled trial comparing the efficacy of three types of pressure-redistributing seat cushions designed for spinal cord injury patients with that of a segmented foam cushion (8cm in thickness) in preventing pressure ulcers¹⁾ found that while the rate of pressure ulcer development decreased significantly in the tissue overlying the ischial bone as a result of the use of pressure-redistributing seat cushions (p = 0.04), there was no measurable change in the rate of pressure ulcer development in the coccyx and sacral areas. However, there is a case report published in Japan claiming that the application of a segmented air cushion 10 cm in thickness to the ischial area of three elderly patients did not result in the development of pressure ulcers²⁾. On the basis of these data, the methods discussed here are assigned a recommendation rating of B.

References

- 1) Brienza D, Kelsey S, Karg P, et al : A randomized clinical trial on preventing pressure ulcers with wheelchair seat cushions. *J Am Geriatr Soc*, 58 : 2308-2314, 2010. (Level II)
- 2) Hirose H, Tanaka H, Mawaki A, et al: Case studies of coccygeal pressure ulcers caused by improper wheelchair seating. *Jpn J PU*, 13 (1) : 54-60, 2011. (Level V) (Japanese, English abstract)

CQ 5.4 : Should limitations be set on the length of time in which the individual remains continuously seated?

[Recommendation] Limitations on sitting time should be set if the elderly individual is unable to reposition without assistance.

[Rating] B

[Analysis] A randomized controlled trial involving 57 patients in two orthopaedic wards examined the effect of limiting the time patients could sit in chairs placed near their beds¹⁾. The study indicated that limiting sitting time to two hours or less resulted in a significantly lower rate of pressure ulcer formation compared to unlimited sitting time (p < 0.001). The NPUAP/EPUAP guidelines, which cite the same study, assign the data a recommendation rating of B and endorse the view that seating time should be limited, although they do offer specific recommendations on the length of sitting time²⁾.

On the basis of these considerations, we have also decided to recommend only that seating time be limited without offering any specific recommendations regarding permissible seating time.

References

- 1) Gebhardt K, Bliss MR : Preventing pressure sores in orthopedic patients is prolonged chair nursing detrimental. *J Tissue Viability*, 4 (2) : 51-54, 1994. (Level II)
- 2) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : clinical practice guideline. National Pressure Ulcer Advisory Panel, Washington DC, 2009.

CQ 5.5 : At what intervals should the seated individual be repositioned?

[Recommendation] Repositioning every 15 min is recommended for seated individuals who are capable of changing their body position without assistance.

[Rating] C1

[Analysis] There are no published studies to date addressing the question of optimal intervals for body repositioning for wheelchair-bound individuals who are capable of changing their body position without assistance. However, the WOCN guidelines¹⁾, as well as the Centers for Medicare and Medicaid²⁾, recommend an interval of 15 minutes.

On the basis of this information, we recommend that wheelchair-bound individuals capable of repositioning on their own do so at regular 15 minute intervals, although it should be noted that there is no clear evidence endorsing this recommendation.

References

- 1) Ratliff CR, Bryant DE : Wound, Ostomy, and Continence Nurses Society (WOCN) : Guideline for prevention and management of pressure ulcers. WOCN clinical practice guideline No.2. WOCN, Glenview, IL, 2003.
- 2) CMS Manual System : Pub. 100-07 State Operations, Provider Certification, Transmittal 4. Guidance to Surveyors for Long Term Care Facilities, 2004.

CQ 5.6 : Should the individual's posture while seated be considered?

[Recommendation] The alignment and balance of the seated individual's body should be considered.

[Rating] C1

[Analysis] To date there exist only one case report and two guidelines addressing the question of the effect that prolonged sitting has on pressure ulcers. According to the case report¹⁾, three patients at a nursing home for elderly with shallow ulcers in the coccygeal area underwent rehabilitation with the assistance of a trained physical therapist who chose body positions and support surfaces according to exercise physiological principles to lessen pressure on the wounds. As a result of this treatment, the pressure ulcers healed successfully even while the patients remained in their wheelchair. The NPUAP/EPUAP guidelines recommend 'selecting a posture that is acceptable for the individual and minimizes the pressures and shear exerted on the skin and soft tissues'²⁾. The WOCN guidelines also state "special attention to the individual's anatomy, postural alignment, distribution of weight"³⁾.

On the basis of the above information, measures to prevent pressure ulcer development can be implemented even while the patient remains confined to a sitting position; recommendation rating C1.

References

- 1) Hirose H, Tanaka H, Mawaki A, et al : Case studies of coccygeal pressure ulcers caused by improper wheelchair seating. *Jpn J PU*, 13 (1) : 54-60, 2011. (Level V) (Japanese, English abstract)
- 2) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : Clinical practice guideline. National Pressure Ulcer Advisory Panel,

Washington DC, 2009.

- 3) AHCPR : AHCPR Supported clinical practice guidelines. 3. Pressure ulcers in adults : Prediction and prevention, Clinical practice guideline Number 3, AHCPR Pub. No.92-0047.

CQ 5.7 : Should donut-type devices be used?

[Recommendation] Donut-type devices are not recommended.

[Rating] D

[Analysis] A case report investigating the effect of various types of cushion on the development of pressure ulcers in hospitalized elderly patients indicated that donut-shaped devices either conduced to the development of pressure ulcers or worsened existing cases¹⁾. The NPUAP/EPUAP guidelines similarly recommend, 'Avoid use of synthetic sheepskin pads; cutout, ring, or donut type devices; and water-filled gloves'²⁾. The WOCN guidelines also state, 'Avoid foam rings, foam cutouts, or donut type devices'³⁾.

The preponderance of evidence suggests that donut-shaped devices should be avoided; recommendation rating D.

References

- 1) Crewe RA : Problems of rubber ring nursing cushions and a clinical survey of alternative cushions for ill patients. *Care Sci Pract*, 5 (2) : 9-11, 1987. (Level V)
- 2) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : clinical practice guideline. National Pressure Ulcer Advisory Panel, Washington DC, 2009.
- 3) AHCPR : AHCPR Supported clinical practice guidelines. 3. Pressure ulcers in adults : prediction and prevention, Clinical practice guideline Number 3, AHCPR Pub. No.92-0047.

CQ 5.8 : What kind of physical modality can be used to treat muscular atrophy?

[Recommendation] Consider using electric stimulation therapy.

[Rating] C1

[Analysis] Although there is a case report¹⁾ and a case series²⁾ examining the use of neuromuscular electric stimulation therapy to treat muscular atro-

phy, these reports are concerned only with how to maintain muscular layer thickness and what changes to make in the daily activity of individuals, but do not address the issue of pressure ulcer prevention. The review of the literature pertaining to this topic is of a general nature, discussing the effect on muscle cross-sectional area, but omitting discussion of pressure ulcers. Moreover, the two case reports cited earlier focus on electric stimulation therapy using implanted electrodes, while their remarks concerning surface electrodes are based solely on expert opinion. For these reasons, while the use of electric stimulation therapy to treat muscular atrophy can have positive effects on the prevention of pressure ulcers, their use merits a recommendation rating of no higher than C1 due to the lack of sufficient evidence.

References

- 1) Bogie KM, Wang X, Triolo RJ : Long-term prevention of pressure ulcers in high-risk patients : A single case study of use of gluteal neuromuscular electric stimulation. *Arch Phys Med Rehabil*, 87 (4) : 585-591, 2006. (Level V)
- 2) Sanjeev A, Triolo RJ, Kobetic R, et al : Long-term user perceptions of an implanted neuroprosthesis for exercise, standing, and transfers after spinal cord injury. *J Rehab Res Develop*, 40 (3) : 241-252, 2003. (Level V)
- 3) Giangregorio L, McCartney N : Bone loss and muscle atrophy in spinal cord injury : Epidemiology, fracture prediction, and rehabilitation strategies. *J Spinal Cord Med*, 29 (5) : 489-500, 2006. (Level VI)

CQ 5.9 : What kind of therapeutic exercise can be used to treat joint contracture?

[Recommendation] Consider using passive range of motion exercises.

[Rating] C1

[Analysis] Three randomized controlled studies¹⁻³⁾ and one case report⁴⁾ discuss the use of therapeutic exercise to treat joint contracture in individuals at risk of developing pressure ulcers. Neither report found therapeutic exercise to be effective in preventing joint contracture and in addition make no mention of pressure ulcers. In another case report, Shimizu addresses the issue of joint contracture and therapeutic exercise and claims that the use of passive exercises was effective in improving the range of

movement and decreasing the size of pressure ulcers, but fails to offer precautionary advice on how to implement passive exercises, and recommends passive exercises involving the elbow and knee joints for treatment of pressure ulcers in the sacral region. These reports fail to clarify whether such exercises are sufficient completely to prevent joint contracture. However, because passive exercises are effective in maintaining or improving range of movement, which in turn can prevent joint contracture, they have been assigned the recommendation rating of C1.

References

- 1) AM Moseley, RD Herbert, EJ Nightingale, et al : Passive stretching does not enhance outcomes in patients with plantar flexion contracture after cast immobilization for ankle fracture : a randomized controlled trial. *Arch Phys Med Rehabil*, 86 (6) : 1118-1126, 2005. (Level II)
- 2) TM Steffen, LA Mollinger : Low-load, prolonged stretch in the treatment of knee flexion contractures in nursing home residents. *Phys Ther*, 75 (10) : 886-897, 1995. (Level IV)
- 3) Harvey LA, Batty J, Crosbie J, et al : A randomized trail assessing the effects of 4 weeks of daily stretching on ankle mobility in patients with spinal cord injuries. *Arch Phys Med Rehabil*, 81 (10) : 1340-1347, 2000. (Level II)
- 4) Fox P, Richardson J, MCInners B, et al : Effectiveness of a bed positioning program for treating older adults with knee contractures who are institutionalized. *Phys Ther*, 80 (4) : 363-372, 2000. (Level II)
- 5) Shimizu M, Shibata S : Effect of passive range of motion exercise for treatment of stage IV pressure ulcer in late-stage elderly. *Nihon Kango Gakkai Ronbunshu Rounenkango*, 38 : 155-157, 2007. (Level V) (Japanese)

CQ 5.10 : Should tissue overlying bony prominences be massaged?

[Recommendation] Massaging areas covering bony prominences is not recommended.

[Rating] D

[Analysis] One systematic review and two randomized controlled trials examine the use of massage in pressure ulcer care and management. In the systematic review¹⁾, although claims are made regarding the efficacy of massage therapy in improving skin

temperature and subcutaneous blood circulation, none of these claims are supported by statistically significant findings. Further, the same work indicates that a large number of studies reviewed recommend avoiding massaging bony prominences. A randomized controlled trial²⁾ involving 144 subjects scoring 20 or lower on the Braden Scale and at high risk of pressure ulcers examined the use of skin cream when massaging the individual. The study found that there was no statistical difference in the rate of pressure ulcer development in relation to the use of skin cream when massaging. The WOCN guidelines³⁾ also state that strong massaging should be avoided. In summary, the evidence given above generally indicates that massaging bony prominences should be avoided; recommendation rating D.

References

- 1) Duimel-Peeters IG, Halfens RJ, Berger MP, et al : The effects of massage as a method to prevent pressure ulcers. A review of the literature. *Ostomy Wound Manage*, 51 (4) : 70-80, 2005. (Level I)
- 2) Duimel-Peeters IG, Halfens R, Ambergen AW, et al : The effective of massage with and without dimethyl sulfoxide in preventing pressure ulcers : A randomized, double-blind cross-over trial in patients prone to pressure ulcers. *Int J Nurs Stud*, 44 : 1285-1295, 2007. (Level II)
- 3) Catherine R Ratliff : WOCNNs evidence based pressure ulcer guideline. *Adv Skin Wound Care*, 18 (4) : 204-208, 2005.

CQ 5.11 : How can daily use of the wheelchair by patients with shallow pressure ulcers be facilitated?

[Recommendation] A suitable sitting posture, an appropriate support cushion, and limitation on sitting time may be considered.

[Rating] C1

[Analysis] To date there exist only one case report and two guidelines addressing the question of what effect a sitting posture has on pressure ulcers. According to the case report¹⁾, three patients at an elderly care facility with shallow ulcers in the coccygeal area underwent rehabilitation with the assistance of a trained physical therapist who chose body positions and support surfaces according to kinesiology to lessen pressure on the pressure ulcers. As a result of this procedure, the pressure ulcers

healed successfully even while the patients remained in their wheelchair. The NPUAP/EPUAP guidelines²⁾ recommend re-evaluating the patients' pressure ulcer state, and on the basis of the findings, selecting an appropriate cushion, limiting sitting time, and determining the effects of posture to avoid pressure on the wound area to enable the patient to continue using the wheelchair. For these reasons, the methods described above are assigned the recommendation rating of C1.

References

- 1) Hirose H, Tanaka H, Mawaki A, et al : Case studies of coccygeal pressure ulcers caused by improper wheelchair seating. *Jpn J PU*, 13 (1) : 54-60, 2011. (Level V) (Japanese, English abstract)
- 2) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : Clinical practice guideline. National Pressure Ulcer Advisory Panel, Washington DC, 2009.

CQ 5.12 : What kind of physical modality can be used for patients with infected pressure ulcers?

[Recommendation] Hydrotherapy may be considered.

[Rating] C1

[Analysis] The NPUAP/EPUAP guidelines state considering a course of whirlpool for reducing bioburden and infection¹⁾. Although hydrotherapy providing agitation and turbulence to the water by mixing air and water by turbines in a tank has not been found to effective in suppressing infection, according to expert opinion²⁾ it is effective in reducing the bacterial load in wounds, thereby promoting wound healing. For this reason this form of therapy has been assigned the recommendation rating of C1.

References

- 1) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : clinical practice guideline. National Pressure Ulcer Advisory Panel, Washington DC, 2009.
- 2) Burke D, Ho C, Saucier M, et al : Effects of hydrotherapy on pressure ulcer healing. *Am J Phys Med Rehabil*, 77 (5) : 394-398, 1998. (Level IV)

CQ 5.13 : What kind of physical modality can be used for pressure ulcers containing necrotic tissue?

[Recommendation] Consider hydrotherapy or pulsatile lavage with or without suction.

[Rating] C1

[Analysis] Based on expert opinion, the NPUAP/EPUAP guidelines¹⁾ state to consider a course of whirlpool as an adjunct for wound cleansing and facilitating healing. The same guidelines further state to consider a course of pulsatile lavage with suction for wound cleansing and debridement. In Japan the Hubbard tank is used in wound cleansing procedures, but no studies assessing its efficacy have been published to date. Given these considerations, the methods described here have been assigned the recommendation rating of C1.

References

- 1) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers : clinical practice guideline. National Pressure Ulcer Advisory Panel, Washington DC, 2009.

CQ 5.14 : What kind of physical modality can be used to promote wound reduction?

[Recommendation]

1. Implementing electrical stimulation therapy is recommended.

[Rating] B

2. Near infrared therapy, ultrasonic therapy, or electromagnetic therapy may be considered.

[Rating] C1

[Analysis] One meta-analysis¹⁾ and one systematic review²⁾ have compared the relative efficacy of electrical stimulation therapy and conventional therapies for treating pressure ulcers, including chronic ulcers. The recommended parameters for electrical stimulation therapy diverge widely in these studies, but the results reported for this form of treatment are uniformly positive. Randomized controlled studies using both direct micro-current stimulation³⁾ as well as high-voltage current stimulation⁴⁾ report wound reduction. On these grounds these methods have been assigned the recommendation rating of B.

Of the studies examining the effect of phototherapy on pressure ulcer, two randomized controlled trials^{5,6)} and one case report⁷⁾ specifically examine the use of

near infrared therapy. These studies have found near infrared therapy to be effective in promoting wound reduction. Although near infrared irradiation was found to increase blood flow in the wound periphery with significantly positive effects on wound healing⁷⁾, the mechanism underlying this phenomenon has not yet been explained and for this reason this technique has been assigned a recommendation rating of C1. Ultrasound/ultraviolet-C irradiation has been found to reduce wound size⁸⁾, but the way in which each intervention produces these results has not been clarified. In addition, the one randomized controlled trial¹²⁾ examining the efficacy of low-level laser irradiation on wound healing has not reported significant improvement^{8,9)}.

Although the systematic review of ultrasound therapy has reported less than adequate results for this form of therapy, in a case report, Maeshige et al.¹¹⁾ state that ultrasound therapy had a positive effect on reducing wound size. For this reason, ultrasound therapy has been assigned the recommendation rating of C1.

Non-thermal pulsed electromagnetic therapy¹²⁾ showed a positive effect on the reduction of wound size, but this modality is assigned the recommendation rating of C1 due to the small size of randomized clinical trial.

References

- 1) Gardner S, Frantz R, Schmidt F : Effect of electrical stimulation on chronic wound healing : A meta-analysis. *Wound Repair Regen*, 7 (6) : 495-503, 1999. (Level I)
- 2) Regan MA, RWTeasell, DL Wolfe, et al : A systematic review of therapeutic interventions for pressure ulcers after spinal cord injury. *Arch Phys Med Rehabil*, 90 : 213-231, 2009. (Level I)
- 3) Stefanovska A, Vodovnik L, Benko H, et al : Treatment of chronic wound by means of electric and electromagnetic fields. Part2. Value of FES parameters for pressure sore treatment. *Med Biol Eng Comput*, 31 (3) : 213-220, 1993.
- 4) Pamela E, Karen E, Campbell RN, et al : Electrical Stimulation Therapy Increases Rate of Healing of Pressure Ulcers in Community-Dwelling People With Spinal Cord Injury. *Arch Phys Med Rehabil*, 91 (5) : 669-678, 2010.
- 5) Schubert V : Effects of phototherapy on pressure

ulcer healing in elderly patients after a falling trauma. A prospective, randomized, controlled study. *Photodermatol Photoimmunol Photomed*, 17 (1) : 32-38, 2001.

- 6) Dehlin O, Elmstahl S, Gottrup F : Monochromatic phototherapy in elderly patients : A new way of treating chronic pressure ulcers?. *Aging Clin Exp Res*, 15 (3) : 259-263, 2003.
- 7) Kurokawa M, Yamada N, Hanemori Y, et al : Effect of linear polarized near infrared therapy for pressure ulcers. *Geriatr Med* 40 (8) : 1165-1170, 2002. (Japanese)
- 8) Nussbaum EL, Biemann I, Mustard B : Comparison of ultrasound/ ultraviolet-C and laser for treatment of pressure ulcers in patients with spinal cord injury. *Phys Ther*, 74 (9) : 812-823, 1994.
- 9) Lucas C, van Gemert MJ, de Haan RJ : Efficacy of low-level laser therapy in the management of stage III decubitus ulcers : A prospective, observer-blinded multicentre randomized clinical trial. *Lasers Med Sci*, 18 (2) : 72-77, 2003.
- 10) Flemming K, Cullum N K, Cullum N, et al : Therapeutic ultrasound for pressure ulcer. *Cochrane Database of Systematic Reviews*. Issue 4, 2009.
- 11) Maeshige N, Terashi H, Sugimoto M, et al : Evaluation of combined use of ultrasound irradiation and wound dressing on pressure ulcer. *J Wound Care*, 19 (2) : 63-68, 2010.
- 12) Salzberg CA, Stephanie A, Frnncisco JP, et al : The effects of non-thermal pulsed electromagnetic energy on wound healing of pressure ulcers in spinal cord-injured patients : A randomized, double-blind study. *Wounds*, 7 (1) : 11-16, 1995.

CQ 6 Risk assessment

CQ 6.1 : Is risk assessment effective in predicting the development of pressure ulcers?

[Recommendation] Use of risk assessment scales is recommended for predicting pressure ulcer development.

[Rating] B

[Analysis] Deeks¹⁾ published a systematic review in which the validity of seven risk assessment scales, namely, the Norton, Gosnell, Knoll, Braden, Waterlow, PSPS, and Andersen scales, were evaluated in terms of the parameters of sensitivity, specificity, and pressure sore incidence rates. However, differences in sample size and target population varied widely

according to scale, rendering their relative utility for predicting, and therefore preventing, pressure ulcer occurrence unclear at best. On the other hand, the occurrence of pressure ulcers can be reduced if the appropriate preventive interventions are conducted on the basis of information obtained from risk assessment scales.

Another systematic review²⁾ assessing the Braden, Norton, and Waterlow scales in terms of the parameters of clinical judgment and predictive validity subjected the odds ratio of the three scales (4.08, 2.16, and 2.05, respectively) and the odds ratio of clinical judgment (1.69) to meta-analysis and found that the risk assessment scale was effective in predicting the occurrence of pressure ulcers.

In summary, the reports given above demonstrate that the use of risk assessment scales with the appropriate interventions can reduce the rate of occurrence of pressure ulcers significantly.

References

- 1) Deeks JJ : Pressure sore prevention: Using and evaluating risk assessment tools. *Br J Nurs*, 5 (5) : 313-320, 1996. (Level I)
- 2) Pancorbo-Hidalgo PL, Garcia-Fernandez FP, Lopez-Medina IM, et al : Risk assessment scales for pressure ulcer prevention: a systematic review. *J Adv Nurs*, 54 (1) : 94-110, 2006. (Level I)

CQ 6.2 : Which risk assessment scale should generally be used?

[Recommendation] Use of the Braden Scale is recommended for most situations.

[Rating] B

[Analysis] The efficacy of the Braden Scale and the Norton Scale for predicting pressure ulcer occurrence was examined in a cohort study using two randomly assigned groups, the ‘turning group’ in which subjects’ body position was rotated, and the ‘non-turning group’¹⁾. The results showed that the subjects in the non-turning group developed Grade II or higher pressure ulcers at a significantly higher rate than the turning group. Further, a comparison of the sensitivity, specificity, and the odds ratio of both scales, when applied to the non-turning group, demonstrated the equivalence of these two scales.

An Internet search using ‘Braden Scale’ as the key word produced a systematic review²⁾ of nine

studies dealing with the predictive validity of the Braden Scale. However, due to the fact that the cut-off value varied widely from 14~20 points, no agreement could be found among these studies.

Another article³⁾ dealing with a cohort study using the Braden Scale found that use of this scale enabled a 50~60% reduction in the incidence of pressure ulcers, as well as reductions in costs associated with specialty bed rentals and pressure reduction mattress overlays.

In summary, the Braden Scale has proved effective in both predicting pressure ulcer occurrence as well as reducing costs associated with pressure ulcer care. As such, the adoption of this scale is recommended as part of a prevention program.

References

- 1) Defflor T, Grydonck MFH : Pressure Ulcers: validation of two risk assessment scales. *J Clin Nurs*, 14 (3) : 373-382, 2005. (Level IV)
- 2) Brown SJ : The Braden Scale. A review of the research evidence. *Orthop Nurs*, 23 (1) : 30-38, 2004. (Level I)
- 3) Bergstrom N, Braden B, Boynton P, et al : Using a research-based assessment scale in clinical practice. *Nurs Clin North Am*, 30 (3) : 539-551, 1995. (Level IV)

CQ 6.3 : What method of assessment used for elderly patients?

[Recommendation] Assessing the risk factors for pressure ulcer development may be considered.

[Rating] C1

[Analysis] A retrospective cohort study¹⁾ of six risk factors (basic mobility, morbid bony prominence, articular contraction, malnutrition, skin moisture, edema) stipulated by the Ministry of Health, Labor, and Welfare in Supplement No. 4 of the Clinical Practice for Pressure Ulcer Development (March 6, 2006) studied the odds ratio of two groups, the non-pressure ulcer group and the pressure ulcer group. The study found the odds ratio of the 173 bedridden subjects enrolled in the study to be 4.0 for morbid bony prominence, 15.9 for articular contraction, 3.8 for malnutrition, and 3.1 for edema. Logistic regression found the odds ratio for articular contraction to be 11.2, the largest figure obtained, indicating the seriousness of this risk factor.

References

- 1) Kaigawa K, Moriguchi T, Oka H, et al : Analysis of the pressure ulcer risk in bedridden patients, *Jpn JPU*, 8 (1) : 54-57, 2006. (Level IV) (Japanese, English abstract)

CQ 6.4 : Which risk assessment scale is recommended for use with the elderly?

[Recommendation]

1. The OH Scale may be used with bedridden elderly patients.

[Rating] C1

[Recommendation]

2. The K Scale may be used with bedridden elderly patients in hospital.

[Rating] C1

[Analysis] A case control report¹⁾ using the Ohura Risk Assessment Scale to evaluate four risk factors, namely, the state of consciousness, degree of sacral bony prominence, edema, and articular contracture in 95 pressure ulcer patients and 318 non-pressure ulcer patients found a significant difference between the total average score for the pressure ulcer group (6.7) and that of the non-pressure ulcer group (3.4). The Ohura Risk Assessment Scale has since been revised and is now accepted as an highly accurate OH scale.

The reliability and predictive validity of the K Scale have been examined in a prospective cohort study of hospitalized bedridden elderly patients²⁾. The study found that in terms of reliability, the K Scale did not require as high a level of experience or skill in the user as the Braden Scale. Further, an assessment of the predictive validity of the K Scale found the specificity of the underlying subscales to be 29.0% whereas that of the trigger subscales was 74.2%. These results demonstrated the clinical significance of the K Scale as an effective tool for predicting the development of pressure ulcers by observing the changes in interface pressure, moisture, and shear within a short period of time.

References

- 1) Fujioka M, Hamada Y : Usefulness of the Ohura risk assessment scale for predicting pressure ulcer development, *Jpn J PU*, 6 (1) : 68-74, 2004. (Level IV) (Japanese, English abstract)
- 2) Okuwa M, Sanada H, Sugama J, et al : The Reliability

and Validity of the K Scale for Predicting Pressure Ulcer Development for the Elderly. *Jpn J PU*, 3 (1) : 7-13, 2001. (Level IV) (Japanese, English abstract)

CQ 6.5 : Which risk assessment scale is recommended for pediatric patients?

[Recommendation] The Braden Q Scale may be considered for risk assessment in pediatric patients.

[Rating] C1

[Analysis] A prospective cohort study¹⁾ was conducted with 332 pediatric in-patients with acute diseases (21 days old to 8 years old) to determine the predictive validity and cut-off value for the Braden Q Scale. For a cut-off point of 16 or lower, the sensitivity was 88%, the specificity was 58%, the positive predictive value was 15%, the negative predictive value was 98%, and the likelihood ratio was 2.11. This study supports the efficacy of the Braden Q Scale as equivalent to that of the Braden Scale used with adult subjects.

The Braden Q Scale is used by the WOCN Clinical Practice Guideline²⁾ as a pediatric risk assessment scale.

References

- 1) Curley MAQ, Razmus IS, Roberts KE, et al : Predicting pressure ulcer risk in pediatric patients : The Braden Q Scale. *Nurs Res*, 52 (1) : 22-33, 2003. (Level IV)
- 2) Wound Ostomy and Continence Nurses Society : Guideline for Prevention and Management of Pressure Ulcers, 4 , WOCN Society, Mount Laurel, NJ, 2010.

CQ 6.6 : Which risk assessment scale is recommended for spinal cord injury patients?

[Recommendation] The SCIPUS scale may be considered for risk assessment in spinal cord injury patients.

[Rating] C1

[Analysis] The Spinal Cord Injury Pressure Ulcer Scale (SCIPUS) comprises 15 parameters: level of activity, mobility, complete spinal cord injury, urine incontinence or constantly moist, autonomic dysreflexia or severe spasticity, age, tobacco use/smoking, pulmonary disease, cardiac disease or abnormal ECG, diabetes or hyperglycemia, renal disease, impaired cognitive function, internment in a nursing home or hospitalization, albumin or total protein, and hematoc-

rit (hemoglobin). A retrospective cohort study¹⁾ of the efficacy of this scale for pressure ulcer risk assessment in spinal cord injury patients reported a high degree of reliability and validity. However, it should be borne in mind that as no similar study has been conducted in Japan, results may vary when the scale is used with Japanese subjects.

References

- 1) Salzberg CA, Byrne DW, Cayten CG, et al : A new pressure ulcer risk assessment scale for individuals with spinal cord injury. *Am J Phys Med Rehabil*, 75 (2) : 96-104, 1996. (Level IV)

CQ 6.7 : Which risk assessment scale is recommended for subjects in a home-care setting?

[Recommendation] A pressure ulcer risk assessment scale specifically designed for patients in a home care setting may be used.

[Rating] C1

[Analysis] The Pressure Ulcer Risk Assessment Scale for the Home Care Setting (home care setting version of the K Scale) combines the K Scale with care capacity assessment. A prospective cohort study¹⁾ using this scale rated its predictive validity very highly. However, as this study was conducted in a medium-sized city, differences in results may be expected due to variations in family structure and care capacity. These considerations need to be borne in mind before using this scale.

References

- 1) Murayama S, Kitayama Y, Okuwa M, et al : Development of a pressure ulcer risk assessment scale for the home-care setting. *Jpn J PU*, 9 (1) : 28-37, 2007. (Level IV) (Japanese, English abstract)

CQ 7 Skin assessment

CQ 7.1 : How can the depth of pressure ulcers be predicted?

[Recommendation]

1. The prediction of dI pressure ulcer prognosis may be based on the presence of double erythema (graduated redness) away from a bony prominence.

[Rating] C1

[Recommendation]

2. Ultrasonography may be used.

[Rating] C1

[Recommendation]

3. The ABI (ankle brachial index) may be used to predict the depth of pressure ulcers in the heel region.

[Rating] C1

[Analysis] Sato, et al.¹⁾ have examined the development of non-blanchable erythema characterizing Stage I pressure ulcers (NPUAP) in order to determine the utility of clinical signs for pressure ulcer prognosis. From their observations, they concluded that the presence of double erythema (graduated redness), non-blanchable erythema confirmed by glass plate compression, erythema away from a bony prominence, or expanding erythema predicted the development of tissue defects penetrating to the dermis or even to underlying tissue. In particular, the prognostic value of double erythema and erythema away from a bony prominence for Stage I pressure ulcers was extremely high, and helpful in predicting the deterioration of d1 pressure ulcers.

In their study of 12 cases, Aoi, et al. determined that the level of deep tissue injury could be predicted on the basis of an initial macroscopic observation of the patient and ultrasound findings²⁾. The study relied on four types of images, among which those of the discontinuous fascia and heterogeneous hypoechoic areas had greatest diagnostic value. Further, ultrasonography proved useful for predicting tissue loss in cases where the depth of the pressure ulcer was otherwise unclear.

Another study of 27 cases of pressure ulcer in the heel region examined the relationship between ABI (Ankle Brachial Index) findings at the initial examination and the final stage of pressure ulcer development³⁾. The ABI value for d1 and d2 pressure ulcers in the heel region was 0.87, and 0.48 for wounds of level D3 or deeper in the heel region. The ROC analysis yielded an ABI outlier value of 0.6. The ABI can be used to predict the depth of pressure ulcers in the heel region.

In conclusion, the accuracy of the prognosis of pressure ulcer progression can be increased through close observation of erythema and the use of methods such as ultrasonography and ABI.

References

- 1) Sato M, Sanada H, Konya C, et al : Prognosis of stage I pressure ulcers and related factors. *Int Wound J*, 3 (4) : 355-362, 2006. (Level V)

- 2) Aoi N, Yoshimura K, Kadono T, et al : Ultrasound assessment of deep tissue injury in pressure ulcers: Possible prediction of pressure ulcer progression. *Plast Reconstr Surg*, 124 (2) : 540-550, 2009. (Level V)

- 3) Okuwa M, Sanada H, Sugama J, et al : Relationship between heel pressure ulcer severity and the ankle brachial index among bedfast elderly patient. *Jpn J P U*, 9 (2) : 177-182, 2007. (Level V) (Japanese, English abstract)

CQ 7.2 : How can redness/d1 stage pressure ulcer be identified?

[Recommendation] The transparent disk method or the finger method may be considered.

[Rating] C1

[Analysis] A controlled study by Vanderwee et al. examined the reliability and diagnostic accuracy of the transparent disk method and the finger method for identifying Stage I pressure ulcers (EPUAP)¹⁾. The concordance rate of the two methods was higher than 90%, and Cohen's k co-efficient was higher than 0.6, both indicating a high level of agreement. In terms of diagnostic accuracy as well, these methods yielded a very high degree of agreement irrespective of the attending nurses' length of experience.

Although at present there are no further high-evidence-level reports on the topic, both of the methods discussed here, namely the transparent disk method and the finger method, as well as palpation, can be considered for use in identifying redness/d1 pressure ulcer because of the ease with which they can be performed in a clinical setting.

References

- 1) Vanderwee K, Grypdonck M, De Bacquer D, et al : The reliability of two observation methods of nonblanchable erythema, Grade 1 pressure ulcer. *Appl Nurs Res*, 19 (3) : 156-162, 2006. (Level V)

CQ 7.3 : Which methods can be used to identify deep tissue injury (DTI)?

[Recommendation]

1. Palpate the area to see whether pain, induration, edema, or changes in skin temperature (warm or cool) are present in comparison with the adjacent tissue.

[Rating] C1

[Recommendation]

2. Consider using ultrasonography.

[Rating] C1

[Analysis] According to the NPUAP classification, a suspected DTI is categorized as a 'purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.' Although the NPUAP advisory panel states that the extent of deep soft tissue damage may be difficult to detect from skin surface appearance, they discuss changes in skin sensation and assessment by palpation as valid clinical findings¹⁾. The clinical findings from palpation may provide useful information for identifying DTI.

Ultrasonography can be used as an objective means of assessing DTI, according to one case report²⁾. The use of the CT scan, MRI, or ultrasonography, in addition to macroscopic observation and palpation, is recommended for an objective assessment of the condition. Of these various methods, only ultrasonography is mentioned in connection with pressure ulcer assessment.

References

- 1) Black J, Baharestani MM, Cuddigan J, et al : National Pressure Ulcer Advisory Panel. National Pressure Ulcer Advisory Panel's update pressure ulcer staging system. *Adv Skin Wound Care*, 20 (5) : 269-274, 2007.
- 2) Nagase T, Koshima I, Maekawa T, et al : Ultrasonographic evaluation of an unusual peri-anal induration: a possible case of deep tissue injury. *J Wound Care*, 16 (8) : 365-367, 2007. (Level V)

CQ 8 Skin care Preventive Care

CQ 8.1 : What kind of skin care is recommended for patients suffering from urinary and/or fecal incontinence in order to prevent development of pressure ulcers?

[Recommendation] After cleansing with an appropriate cleansing agent, skin emollients can be applied to the anal/genital area and to the peripheral skin.

[Rating] C1

[Analysis] Incontinence is associated with the

occurrence of superficial pressure ulcers (partial thickness wounds). One randomized controlled study compared the severity of pressure ulcers in incontinent patients following the use of soap or a mildly acidic cleansing agent¹⁾. The results of this study indicated a significant reduction in the occurrence of Grade I pressure ulcers (pressure ulcers without skin defect) following the use of the mildly acidic cleansing agent. Two non-randomized clinical trials^{2,3)} and one historical control study⁴⁾ examined the incidence of pressure ulcers after cleansing only, or after the application of skin emollients to the anal and genital areas and to the peripheral skin. In both groups the incidence of pressure ulcers declined; in one study, however, no statistically significant difference was reported³⁾. A before-and-after comparison of 136 subjects interned in a long-term care facility found that the number of cases of skin trouble declined from 68 to 40 subjects, while the rate of occurrence of Stage I and II pressure ulcers declined from 19.9% to 8.1% ($p < 0.01$)⁵⁾. Some of the skin care products mentioned in the sources cited are unavailable here in Japan although comparable products can be obtained.

On the basis of the above data, the application of skin emollients to the anal/ genitalia area to the peripheral skin after cleansing with an appropriate cleansing agent is assigned a recommendation rating of C1.

References

- 1) Cooper P, Gray D : Comparison of two skin care regimes for incontinence. *Br J Nurs*, 10 : S6, S8, S10 passim 2001. (Level II)
- 2) Thompson P, Langemo D, Anderson J, et al : Skin care protocols for pressure ulcers and incontinence in long-term care : A quasi-experimental study. *Adv Skin Wound Care*, 18 : 422-429, 2005. (Level III)
- 3) Clever K, Smith G, Bowser C, et al : Evaluating the efficacy of a uniquely delivered skin protectant and its effect on the formation of sacral/buttock pressure ulcer. *Ostomy Wound Manage*, 48 (12) : 60-67, 2002. (Level III)
- 4) Dealey C : Pressure sores and incontinence : a study evaluating the use of topical agents in skin care. *J Wound Care*, 4 : 103-105, 1995. (Level III)
- 5) Hunter S, Anderson J, Hanson D, et al : Clinical Traial of a prevention and treatment protocol for skin breakdown in two nursing homes. *J Wound Ostomy*

Continnence Nurs, 30 (5) : 250-258, 2003. (Level III)

CQ 8.2 : What type of preventive skin care is recommended for use on bony prominences in elderly patients?

[Recommendation] Transparent film dressings and other dressings with a low-friction external surface are recommended.

[Rating] B

[Analysis] According to one study, transparent film dressings applied to the sacral area resulted in a significant decrease in the rate of occurrence of pressure ulcers¹⁾. Another study using both smooth surface dressings and transparent film dressings on the left and right sides of the greater trochanter found an absence of pressure ulcer formation in both groups, and a significantly lower incidence of non-blanchable erythema in the low-friction external surface dressing group²⁾.

References

- 1) Ito Y, Yasuda M, Yone J, et al : Polyurethane film dressing applied to the sacral area for prevention of pressure ulcers. Jpn J PU, 9 (1) : 38-42, 2007. (Level IV) (Japanese English abstract)
- 2) Nakagami G, Sanada H, Konya C, et al : Evaluation of a new pressure ulcer preventive dressing containing ceramide 2 with low frictional outer layer. J Adv Nurs, 59 (5) : 520-529, 2007. (Level III)

CQ 8.3 : What kind of skin care is recommended for patients undergoing surgery in a supine position?

[Recommendation] A transparent film dressing can be applied to the sacral area.

[Rating] C1

[Analysis] In a randomized controlled trial, Imanishi et al. compared the rate of occurrence of postoperative pressure ulcers in supine patients with and without transparent film dressings¹⁾. Of the 103 subjects without the dressings, 22 developed pressure ulcers, whereas in the 98 subjects with dressings, only 10 developed pressure ulcers, demonstrating a statistically significant difference between the two groups ($p = 0.049$). However, in view of the fact that the BMI of all of the subjects was within the normal range, the relevance of these results to patients with pronounced bony prominences cannot be ascertained.

In summary, the transparent film dressing is

recommended for application to the sacral area in patients who will undergo surgery in a supine position; Rating C1. However, it should be noted that this form of treatment is not covered by Japanese National Health Insurance.

References

- 1) Imanishi K, Morita K, Matsuoka M, et al : Prevention of postoperative pressure ulcer by a polyurethane film patch. J Dermatol, 33 (3) : 236-237, 2006. (Level II)

CQ 8.4 : What kind of skin care is recommended for non-invasive ventilation patients to prevent pressure ulcer formation at the face mask contact site?

[Recommendation] A transparent film dressing or a hydrocolloid dressing may be used for this purpose.

[Rating] C1

[Analysis] Weng examined the rate of pressure ulcer occurrence in 90 non-invasive ventilation patients¹⁾. The subjects were divided into three groups, namely the control group and the transparent film and hydrocolloid dressing groups and the rate of occurrence of Stage I pressure ulcers among them was compared. The rate of pressure ulcer occurrence was 96.7% in the control group, 53.3% in the transparent film dressing group, and 40% in the hydrocolloid dressing group, showing a significant difference with the control group ($p < 0.01$).

In Japan also, one case report examined the use of hydrocolloid dressings with patients placed on a non-invasive respirator and found evidence of pressure ulcer formation in only two of the 30 cases examined²⁾. Pressure ulcers resulting from the use of medical devices have previously been cited as a matter of concern. The present guidelines have therefore included discussion of this topic as well.

References

- 1) Weng MH : The effect of protective treatment in reducing pressure ulcers for non-invasive ventilation patients. Intensive Crit Care Nurs, 24 (5) : 295-299, 2008. (Level III)
- 2) Tanaka M, Sakaki Y : Prevention of pressure ulcer in the nose/cheeks due to mask application in non-invasive positive pressure ventilation -Effects of the use of a skin barrier-. Jpn J PU, 10 (1) : 35-38, 2008. (Level V)

Care after occurrence

CQ 8.5 : How should the skin surrounding a pressure ulcer be cleansed in order to promote pressure ulcer healing?

[Recommendation] Cleansing with a mildly acidic cleansing agent may be considered.

[Rating] C1

[Analysis] Skin surrounding a pressure ulcer contains insoluble proteins, lipids and other contaminants, and therefore requires cleansing in the same manner as healthy skin¹⁾. One study comparing the rate of healing in pressure ulcers before and after a regimen of cleansing peripheral skin using either a sterile saline solution or a mildly acidic cleansing agent found that the latter shortened the healing time of pressure ulcers at any stage²⁾. Further, the rate of healing among cases of Stage II pressure ulcers cleansed with the mildly acidic cleansing agent was 1.79 times faster than the sterile saline solution group.

As yet there are no reports as to the specific types of cleansing agents that promote healing in pressure ulcers. However, one study comparing the effect of a mildly acidic cleansing agent and a mildly acidic ceramide-containing cleansing agent reported a reduction in the quantity of scales and microbes as well as an increase in the amount of ceramide after use of the mildly acidic ceramide-containing cleansing agent³⁾. Accordingly, if maintaining the normal physiological function of the skin is sufficient to prevent epithelialization of the skin surrounding the wound, a mildly acidic cleansing agent containing skin-protective agents is the best option. Absent this option, a mildly acidic cleansing agent is preferred to conventional soap. In summary, a mildly acidic cleansing agent is the preferred option for cleansing the skin surrounding a pressure ulcer wound in order to promote wound healing; Rating C1.

References

- 1) Konya C, Sanada H, Sugama J, et al : Skin debris and micro-organisms on the periwound skin of pressure ulcers and the influence of periwound cleansing on microbial flora. *Ostomy Wound Manage*, 51 (1) : 50-59, 2005.
- 2) Konya C, Sanada H, Sugama J, et al : Dose the use of a cleanser on skin surrounding pressure ulcer in order people healing?. *J wound care*, 14 (4) : 169-171, 2005. (Level III)

- 3) Ishikawa S, Togashi H, Tamura S, et al : Influence of new skin cleanser containing synthetic pseudo-ceramide on the surrounding skin of pressure ulcers. *Jpn J PU*, 5 (3) : 508-514, 2003.

CQ 8.6 : In cases with urinary and/or fecal incontinence, what kind of skin care is recommended to promote pressure ulcer healing?

[Recommendation] Skin emollients can be applied to the peripheral skin after cleansing with an appropriate cleansing agent.

[Rating] C1

[Analysis] Two non-randomized controlled studies comparing healing time between a control group whose skin was cleansed using a cleansing agent only and an experimental group whose skin was covered with a protective cream after cleansing found that healing time shortened and the healing rate improved significantly in the latter group^{1,2)}.

On the basis of these data, in order to promote pressure ulcer healing, the application of skin emollients on the peripheral skin is recommended in cases of fecal and/or urinary incontinence, as with prevention of pressure ulcers, following cleansing with an appropriate cleansing agent.

References

- 1) Thompson P, Langemo D, Anderson J, et al : Skin care protocols for pressure ulcers and incontinence in long-term care : a quasi-experimental study. *Adv Skin Wound Care*, 18 (8) : 422-429, 2005.
- 2) Dealey C : Pressure sores and incontinence : a study evaluating the use of topical agents in skin care. *J Wound Care*, 4 (3) : 103-105, 1995.
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CQ 9 Repositioning

CQ 9.1 : How frequently should the bed bound patient be repositioned to prevent pressure ulcer?

[Recommendation] Consider repositioning the patient at least every two hours.

[Rating] C1

[Analysis] One systematic review dealing with the frequency of body repositioning demonstrated that under optimal conditions provided by the use of a support surface, body repositioning performed every

four hours was equally effective for preventing pressure ulcer formation as repositioning every two hours¹⁾. Further, the NPUAP/EPUAP guidelines state that, ‘Repositioning frequency will be determined by the individual’s tissue tolerance, his/her level of activity and mobility, his/her general medical condition, the overall treatment objectives, and assessments of the individual’s skin condition’²⁾. The WOCN guidelines recommend to schedule regular repositioning and turning for bed and chair bound individuals³⁾. Neither guidelines state specific intervals at which the patient’s body should be repositioned; nor are there any studies conducted in Japan to date which address this question with respect to patients at high risk of developing pressure ulcers. In view of the fact that the present guidelines aim to address issues relating to pressure ulcer care and management in a diversity of care settings, such as home, institution, and hospital, we recommend that the patient be repositioned at least every two hours.

References

- 1) Krapfl LA, Gray M : Does regular repositioning prevent pressure ulcers?. *J Wound Ostomy Continence Nurs*, 35 (6) : 571-577, 2008. (Level I)
- 2) National Pressure Ulcer and Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers, clinical practice guideline, National Pressure Ulcer Advisory Panel, Washington DC, 2009.
- 3) Wound, Ostomy and Continence Nurses Society : Guideline for prevention and management of pressure ulcers. WOCN clinical practice guidelines no. 2 Glenview, IL, 2003.

CQ 9.2 : How frequently should bed bound patient be repositioned when a support surface is being used?
[Recommendation]

1. When a visco-elastic foam mattress is being used, consider repositioning the patient at least every four hours.

[Rating] C1

[Recommendation]

2. When a double-layer air-cell mattress overlay is being used, consider repositioning the patient at least every four hours.

[Rating] C1

[Analysis] Two randomized controlled trials have

been published to date dealing with body repositioning for nursing home residents^{1,2)}. The subjects were divided into the 2-hour and 3-hour repositioning groups using a standard hospital mattress and a 4-hour and 6-hour repositioning group using a support surface (visco-elastic foam mattress 15cm in thickness), and the rates of pressure ulcer development among them was assessed¹⁾. As a result, the 4-hour repositioning group showed a significantly lower rate of Grade II pressure ulcer development ($p = 0.002$). Further, a study comparing pressure ulcer formation rates between a control group (comprised of subjects laterally positioned for 2 hours and supinely positioned for 4 hours) and the experimental group (comprised of subjects laterally positioned for 4 hours and supinely positioned for 4 hours) using a visco-elastic mattress 7cm in thickness failed to demonstrate a significant difference in pressure ulcer development rate among these groups²⁾. The subject enrolled in these studies, however, differ in respect to their body size, weight, and other factors, from their counterparts in Japan, and for this reason the application of the methods outlined in the aforementioned studies to patients in Japan may entail some risk, and offer no guarantee of yielding similar results. On the other hand, a case controlled study dealing with patients in a convalescent hospital assessed the development of erythema among patients supinely positioned on a double-layer air-cell mattress overlay³⁾. The patients were repositioned at intervals of two hours or greater, and their skin was observed at 2, 4, and 5 hours from commencement of the experiment for indications of erythema. As a result, 4 hours was found to be the upper limit at which patients could be maintained in one position without the development of erythema. After 5 hours, 50% of patients were found to have developed indications of erythema.

The NPUAP/EPUAP guidelines state that, “Frequency of repositioning will be influenced by variables concerning the individual and support surface in use”⁴⁾.

Because both evidence sources involve a specific group of subjects using a specific type of support surface, and therefore provide findings with limited applicability, they are assigned the recommendation rating of C1.

References

- 1) Defloor T, De Bacquer D, Grypdonck MH, et al : The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers. *Int J Nurs Stud*, 42 (1) : 37-46, 2005. (Level II)
- 2) Vanderwee K, Grypdonck MH, De Bacquer D, et al : Effectiveness of turning with unequal time intervals on the incidence of pressure ulcer lesions. *J Adv Nurs*, 57 (1) : 59-68, 2007. (Level II)
- 3) Nakashima F, Toyoda T : Evaluation of pressure ulcer development in patients who underwent positional changes at intervals of 2 hours or more. *Jpn J P U*, 5 (1) : 37-41, 2003. (Level IV) (Japanese English abstract)
- 4) National Pressure Ulcer and Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers, clinical practice guideline, National Pressure Ulcer Advisory Panel, Washington DC, 2009.

CQ 9.3 : When repositioning bed bound patients, what positions should be undertaken to avoid pressure ulcer formation?

[Recommendation] A 30- and 90-degree angle for the laterally recumbent position may be considered.

[Rating] C1

[Analysis] A randomized controlled trial involving elderly patients interned in an acute phase care hospital compared the rate of pressure ulcer development between the experimental group, comprised of patients in a 30-degree tilted side-lying position and two control groups, one comprised of patients in a supine position plus 90-degree side-lying position, and the other, comprised of patients in only a supine position. The study found no significant difference in the rate of pressure ulcer development among these groups. However, more than 80% of subjects in the 30-degree tilted side-lying position group complained of discomfort.

The 30-degree tilted side-lying position requires patients to support their body weight with their gluteal muscles. However, due to the decline in nutritional health as well as muscular atrophy resulting from inactivity, bed bound patients in Japan tend to show more prominent bony prominences in the buttock region. For this reason, the body position of the patient should be chosen in accordance with the

wishes of the patient or the physical stature of the patient, rather than adhering strictly to the 30-degree tilted side-lying position; recommendation rating C1.

References

- 1) Young T : The 30° tilt position vs the 90° lateral and supine position in reducing the incidence of non-blanching erythema in a hospital inpatient population: A randomized controlled trial. *J Tissue Viability*, 14 (3) : 88-96, 2004. (Level II)

CQ 9.4 : How can patients in intensive care be repositioned in order to prevent pressure ulcer formation?

[Recommendation] The patient may be repositioned in an electric rolling hospital bed.

[Rating] C1

[Analysis] Patients in intensive care with unstable vital signs pose a greater difficulty to the attending nurse who must periodically reposition the patient. A historical cohort study¹⁾ conducted at a cardiac treatment center examined the rate of pressure ulcer development among cardiac patients during the period in which they were repositioned manually at 2 hour intervals by nursing staff compared to the period in which they were repositioned in an electric rolling hospital bed. The results indicated that the rate of pressure ulcer development in the period during which the electric rolling hospital bed was used was significantly lower ($p < 0.001$). Because the electric rolling hospital bed featured in the study were equipped with various functions, it is difficult to establish the efficacy of any single one of these functions for the prevention of pressure ulcers. In Japan, due to cost considerations and the difficulty of technical maintenance, few health care institutions are equipped with high-tech rolling hospital beds. For the above reasons, the use of electric rolling hospital bed is assigned the recommendation rating of C1.

References

- 1) Gregor S, Kerstin F, Enrico Z, et al : Kinetic therapy reduces complications and shortens hospital stay in patients with cardiac shock, a retrospective analysis. *Eur J Cardiovasc Nurs*, 6 (1) : 40-45, 2007. (Level IV)

CQ 9.5 : What positions should be undertaken to promote healing in patients with pressure ulcers in

the gluteal region?

[Recommendation] Any position besides the 30-degree tilted side-lying position or head-of-bed elevated position may be undertaken.

[Rating] C1

[Analysis] Two non-randomized self-controlled studies conducted in Japan have addressed the question of which body positions are best for patients with pressure ulcers in the gluteal region. One study¹⁾ compared the shape of the wounds after a period in 30- and 90-degree side-lying positions and found that a total of 5 wounds demonstrated a change in shape, while 4 did not (changes in cross-sectional area of the wound in the 'changed' group; 72.3; in the 'non-changed' group; 8.2, $p = 0.04$). Similar results were found with the 30-degree head-of-bed elevated position group. The ratio of change in the cross-sectional area of the wounds was statistically significant, at 0.16 for the 'changed,' and 1.36 for the 'non-changed,' groups ($p = 0.02$). In a separate study²⁾ measuring pressure on healthy skin and the thickened tissue of the wound periphery in patients in a 30-degree tilted side-lying position and 30-degree head-of-bed elevated position demonstrated significantly higher maximal pressure ($p = 0.01$, $p = 0.05$) as well as significantly higher average pressure ($p = 0.01$, $p = 0.03$) on the thickened tissue. Both above-mentioned studies examined pressure ulcers among bed bound elderly patients.

The so-called 30-degree rule was become widespread as a means of preventing pressure ulcers, and has also been applied to the management of existing pressure ulcers. However, it should be borne in mind that this rule may have the effect of prolonging recovery if applied in all cases regardless of the physical stature of the patient. We recommend that a body position most suitable to the physical stature and wound condition of the patient be chosen, rather than adhering strictly to the 30-degree rule. On the basis of these considerations, we have assigned these evidence sources a recommendation rating of C1.

References

- 1) Kitagawa A, Konya C, Omote S, et al : Effects of changing body position on pressure ulcer morphology and blood circulation. *Jpn J P U*, 5 (3) : 494-502, 2003. (Level III) (Japanese English abstract)
- 2) Okuwa M, Sugama J, Sanada H, et al : Measuring the

pressure applied to the skin surrounding pressure ulcers while patients are nursed in the 30° position. *J Tissue Viability*, 15 (1) : 3-8, 2005. (Level III)

CQ 10 Support surfaces

CQ 10.1 : Should support surfaces be used to lower the incidence of pressure ulcers?

[Recommendation] Use of support surfaces is strongly recommended in order to lower the incidence of pressure ulcers.

[Rating] A

[Analysis] There are five systematic reviews and meta-analyses which compare the use of standard hospital mattresses with other types of support surface¹⁻⁵⁾. All of these studies found that support surfaces are significantly superior to standard hospital mattresses in preventing pressure ulcers. On the basis of this evidence, the use of support surfaces has been assigned a recommendation rating of A. Furthermore, the NPUAP/EPUAP guidelines⁶⁾ state, "Do not base the selection of support surfaces solely on the perceived level of risk for pressure ulcer development or the category/stage of any existing pressure ulcers" and, "Choose a support surface that is compatible with the care setting" underscoring the need to consider pressure ulcer risk, patients' preferences, and care settings when choosing a support surface.

References

- 1) Cullum N : Support surface for pressure ulcer prevention. *EBM reviews Cochrane Database Syst Rev*, 3 : CD001735, 2004. (Level I)
- 2) Reddy M, Gill SS, Rochon PA : Preventing pressure ulcers, a systematic review. *JAMA*, 296 (8) : 974-984, 2006. (Level I)
- 3) Whittmore R : Pressure-reduction support surfaces : A review of the literature. *J Wound Ostomy Continence Nurs*, 25 (1) : 6-25, 1998. (Level I)
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- 5) McInnes E, Jammali-Blasi A, Bell-Syer SE, et al : Support surfaces for pressure ulcer prevention. *Cochrane Database Syst Rev*, 13 (4) : CD001735, 2011. (Level I)
- 6) National Pressure Ulcer and Advisory Panel and Eu-

European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers, clinical practice guideline. National Pressure Ulcer Advisory Panel, Washington DC, 2009.

CQ 10.2 : Which support surface is recommended for completely immobile patients?

[Recommendation]

1. Recommend using an alternating-pressure air mattress overlay/ replacement.

[Rating] B

[Recommendation]

2. Consider using a foam mattress replacement.

[Rating] C1

[Analysis] The NPUAP/EPUAP guidelines endorse the use of alternating pressure air mattresses overlays/replacement for patients who cannot be repositioned frequently, adding that this method is endorsed by the highest evidence rating¹⁾. Two randomized controlled studies which examined the incidence of pressure ulcer development among completely immobile patients found that, although foam mattress replacements were more effective than foam mattress overlay, the incidence of pressure ulcers was still high at 25%, indicating generally poor efficacy²⁾. Berthe et al. have also reported that no significant difference was found between standard hospital mattresses and foam mattress replacements in the incidence of pressure ulcer development³⁾. On the basis of these data, the use of foam mattress replacements earns a recommendation rating of C1.

References

- 1) National Pressure Ulcer and Advisory Panel and European Pressure Ulcer Advisory Panel : Prevention and treatment of pressure ulcers, clinical practice guideline. National Pressure Ulcer Advisory Panel, Washington DC, 2009.
- 2) Vyhidal SK, Moxness D, Bosak KS, et al : Mattress replacement or foam overlay? A prospective study on the incidence of pressure ulcers. *Appl Nurs Res*, 10 (3) : 111-120, 1997. (Level II)
- 3) Berthe JV, Bustillo A, Melot C, et al : Does a foamy-block mattress system prevent pressure sores? A prospective randomized clinical trial in 1729 patients. *Acta Chir Belg*, 107 (2) : 155-161, 2007. (Level II)

CQ 10.3 : Which support surface is recommended

for prevention of pressure ulcers in elderly individuals?

[Recommendation]

1. Recommend using a double-layer air-cell mattress.

[Rating] B

[Recommendation]

2. An alternating-pressure air mattress overlay/ replacement, air-filled mattress overlay, or foam mattress may also be used.

[Rating] C1

[Analysis] Six randomized controlled studies published outside Japan¹⁻⁶⁾, and one randomized controlled study published in Japan⁷⁾, have examined the relationship between various types of support surfaces and the incidence of pressure ulcer development among elderly patients.

The studies published outside Japan examined the efficacy of alternating-pressure large-cell ripple mattresses^{1,2)}, air-filled mattress overlays³⁾, visco-elastic foam mattresses^{4,6)}, and convoluted foam mattresses⁵⁾ and found that alternating-pressure large-cell ripple mattresses and visco-elastic foam mattresses showed no difference in their efficacy in preventing pressure ulcers, citing differences in support surface types and the condition of the individual patients as the reason. A comparison of air-filled mattress overlay and other control mattresses showed no significant difference in efficacy. On the other hand, convoluted foam mattresses showed significantly higher efficacy than other control mattresses in preventing pressure ulcers. Nonetheless, the pressure ulcer development incidence was 26.6%, indicating that convoluted foam mattresses were generally ineffective at prevention and could not be recommended for use; recommendation rating C1. In a randomized controlled trial involving Japanese subjects, double-layer air-cell mattress, single-layer air-cell mattress overlay, and standard hospital mattress were associated with a pressure ulcer development incidence of 3.4%, 19.2%, and 37.0%, respectively, with double-layer air-cell mattress showing a significantly lower incidence than the others ($p < 0.01$)⁷⁾. The same study found that the double-layer air-cell mattress was similarly effective in a 45-degree head-of-bed elevated position. On the basis of these results, the use of the double-layered air-cell mattress has been assigned a recommendation rating of B.

For elderly patients, the risk of pressure ulcers, especially in areas with bony prominences, and the particular care setting should also be considered when choosing the most appropriate support surfaces.

References

- 1) Bliss MR : Preventing pressure sores in elderly patients : a comparison of seven mattress overlays. *Age Ageing*, 24 (4) : 297-302, 1995. (Level II)
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- 3) Lazzara DJ, Buschmann MT : Prevention of pressure ulcers in elderly nursing home residents- : Are special support surfaces the answer?. *Decubitus*, 4 (4) : 42-48, 1991. (Level II)
- 4) Russell LJ, Reynolds TM, Park C, et al : Randomized clinical trial comparing 2 support surfaces : Results of the prevention of pressure ulcers study. *Adv Skin Wound Care*, 16 (6) : 317-327, 2003. (Level II)
- 5) Kemp MG, Kopanke D, Tordecilla L, et al : The role of support surfaces and patient attributes in preventing pressure ulcers in elderly patients. *Res Nurs Health*, 16 (2) : 89-96, 1993. (Level II)
- 6) Gunningberg L, Lindholm C, Carlsson M, et al : Effect of visco-elastic foam mattresses on the development of pressure ulcers in patients with hip fractures. *J Wound Care*, 9 (10) : 455-460, 2000. (Level II)
- 7) Sanada H, Sugama J, Matsui Y, et al : Randomized controlled trial to evaluate a new double-layer air-cell overlay for elderly patients requiring head elevation. *J Tissue Viability*, 13 (3) : 112-121, 2003. (Level II)

CQ 10. 4 : Which support surfaces are recommended for prevention of pressure ulcers in intensive care patients?

[Recommendation]

1. Recommend using a low air pressure mattress.

[Rating] B

[Recommendation]

2. A low-air-loss bed, an alternating-pressure air mattress overlay, or an air-filled mattress replacement may also be considered.

[Rating] C1

[Analysis] There are five randomized controlled trials conducted outside Japan¹⁻⁵⁾, and four randomized controlled trials conducted within Japan

examining the incidence of pressure ulcer among patients admitted to the ICU or CCU⁶⁻⁹⁾.

The studies conducted outside Japan examined the efficacy of low air-loss beds, alternating-pressure air mattress overlays, air-filled mattress overlays, water mattresses, and air-filled mattress replacement in pressure ulcer prevention. The efficacy of low air-loss beds varied according to study^{1,2)} while air-filled mattress overlays and water mattresses showed no significant difference when compared with other control mattresses⁴⁾. Although the air-filled mattress replacements were associated with a significantly lower incidence of pressure ulcer development than the controls⁵⁾, these results could not be corroborated by any studies done in Japan⁶⁾. On the basis of the evidence presented above, the recommendation rating of C1 has been assigned to the items discussed here. A number of controlled trials examining the incidence of pressure ulcers among Japanese subjects endorsed the use of alternating-pressure air mattress overlays as an effective means of lowering the incidence of pressure ulcers⁷⁻⁹⁾. Subsequently, a clinical controlled trial compared the efficacy of alternating-pressure air mattress overlays, foam mattress overlays/ replacements and control mattresses found that low air pressure mattresses were associated with a significantly lower rate of pressure ulcer development (6%) than the control mattresses (28%; $p < 0.05$)⁷⁾. On the basis of the evidence presented above, these items have been assigned the recommendation rating of B.

Owing to advances in medical treatments, the severity of the condition of patients admitted into the ICU and CCU has been increasing yearly along with the risk of pressure ulcer development. Accordingly, differences in care settings should be among the issues considered when selecting an appropriate support surface.

References

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CQ 10.5 : Which tools, including support surfaces, are effective in preventing the development of pressure ulcers during perioperative periods?

[Recommendation]

1. Support surfaces on the operating table are recommended for patients at risk of developing pressure ulcers.

[Rating] B

[Recommendation]

2. In addition to using support surfaces, viscoelastic pads or gel applied to the heel area, cubital region, and other areas with bony prominences is recommended during operations.

[Rating] B

[Recommendation]

3. During and after operations, an alternating-pressure air mattress overlays/replacement may be

used.

[Rating] C1

[Recommendation]

4. The bead bed system may be used during surgery for patients undergoing surgery to repair femoral-neck fracture.

[Rating] C1

[Recommendation]

5. Thermoactive viscoelastic foam overlay may be used for patients who will undergo cardiac surgery.

[Rating] C1

[Analysis] There are one systematic review¹⁾ one meta-analysis²⁾ and six randomized controlled trials³⁻⁸⁾ which compare pressure ulcer development incidence among perioperative patients.

The systematic reviews reported that the use of support surfaces on the operating table had a positive effect on lowering the incidence of pressure ulcers, but failed to mention which support surfaces were most effective in achieving this result.

The studies published outside Japan were chiefly concerned with assessing the efficacy of gel or viscoelastic pad, alternating-pressure air mattress overlays/ replacement, bead bed system, and thermoactive viscoelastic foam overlay. The gel or visco-elastic pad were associated with a significantly lower incidence of pressure ulcer development than the control mattresses^{3,4)}. The results of using the alternating-pressure air mattress overlays/ replacement during surgery, however, varied according to study and no clear conclusion could be reached regarding its efficacy in preventing pressure ulcers^{5,6)}. Although a significantly lower incidence of pressure ulcer occurrence (15.6%) was associated with the use of the bead bed system than with the controls, the bead bed system cannot be considered as an effect means of reducing pressure ulcer development due to the high rate of pressure ulcer occurrence⁷⁾. Fechtinger et al. have reported that there was no significant difference in efficacy between thermoactive viscoelastic foam overlay and the control group⁸⁾. No randomized controlled studies examining these support surfaces have been conducted in Japan. On the basis of these data, the use of gel or visco-elastic pad has been given a recommendation rating of B, while the other types of support surface have been assigned a rating of C1.

The use of this evidence in Japan should be

preceded by a careful consideration of the surgical procedure involved, the surgical environment, and risk to the patient. The surgical procedures discussed in the above-mentioned studies involved maintaining the lithotomy position or supine position for three continuous hours in general, vascular, gynecological, cardiac, or femoral surgical procedures for treating femoral neck fractures.

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CQ 10.6 : Which support surfaces can be used to

facilitate care for convalescent patients in a home-care setting?

[Recommendation] An automatic turning air mattress may be used.

[Rating] C1

[Analysis] In one self-controlled trial by Melland et al., patients in a home-care setting and a long-term care facility reported no difference in comfort levels when using an automatic turning air mattress than when using conventional bedding. The same subjects also reported experiencing very good quality of sleep ($p = 0.024$). Furthermore, one in 17 subjects developed pressure ulcers in the four-week period during which the automatic turning air mattress was used. A self-controlled trial conducted in Japan reported that the caregiver's burden was lessened and no pressure ulcers reported during a two-week period in which this mattress was used²⁾.

The automatic turning air mattress may be used in order to facilitate the activity of caregivers in a home care setting and to improve the patient's quality of sleep, but the basic purpose of this device is to assist the work of the caregiver. The caregiver still needs to ensure that the patient's body is repositioned on a regular basis.

References

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CQ 10.7 : Which support surfaces provide the greatest comfort both while awake and sleeping?

[Recommendation]

1. Using an alternating-pressure air mattress replacement is recommended.

[Rating] B

[Recommendation]

2. For terminally ill patients, an alternating-pressure air mattress with automatic adjustment to the patient's weight and position may be considered.

[Rating] C1

[Analysis] One systematic review¹⁾ and two randomized controlled trials^{2,3)} conducted outside Japan have examined the quality of sleep and comfort levels experienced by patients who were used an alternating-pressure air mattress replacement. The systematic review found that the comfort levels reported by the patients were significantly higher for the alternating-pressure air mattress overlays/replacement than for the control group. Furthermore, the two- and four-cell types were considered more comfortable¹⁾. In addition, 18.9% of patients complained about the alternating-pressure air mattress replacement while 23.3% complained about the alternating-pressure air mattress overlay, indicating a significantly lower number of complaints for the former ($p < 0.05$)²⁾. Grindley et al. surveyed terminal patients about their preferences and found that 62.5% preferred the alternating-pressure air mattress with automatic adjustment to the patient's weight and position, 12.5% preferred the alternating-pressure air mattress overlay, and 25.0% preferred the standard mattress ($p < 0.05$)³⁾.

When choosing a mattress, consider the patients' preferences as well as pressure ulcer development risk and pressure ulcer stage.

References

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CQ 10.8 : What precautions should be taken when using foam mattresses?

[Recommendation] Monitor the deterioration of the foam due to fatigue.

[Rating] C1

[Analysis] Foam mattresses will degrade with the

passage of time. One of the causes of the degradation of quality is fatigue. Fatigue is seen when distortions in the contours of the mattress remain even after the weight or source of pressure has been removed. Two analytical epidemiological studies have examined the problem of fatigue in urethane foam mattresses^{1,2)}.

These studies found that 66 urethane foam mattresses 5~10 years after their purchase had compressed an average of 10.7 ± 6.0 mm (range 0-30 mm) from fatigue. Use of urethane foam mattresses which had compressed an average of 11mm as a result of fatigue significantly increased interface pressure values compared with new mattresses ($p < 0.05$)¹⁾. Further, the study examined the degree of fatigue according to contact points on the body including the buttocks, knees, shoulder joints, head, and heel, found that fatigue was most visible in the area of the mattress in direct contact with the buttocks ($p < 0.05$)²⁾.

On the basis of these data, urethane mattresses should be checked periodically for signs of fatigue, especially in the areas that come into frequent or prolonged contact with the buttocks.

References

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CQ 10.9 : Which support surfaces are recommended for promoting healing in d1, d2, and D3~D5 pressure ulcers?

[Recommendation]

1. Use of an air-fluidized bed or low-air-loss bed is strongly recommended to promote healing in D3~D5 pressure ulcers or pressure ulcers in multiple sites.

[Rating] A

[Recommendation]

2. Use of an alternating-pressure air mattress with automatic adjustment for the patient's position and weight, an alternating-pressure large-cell ripple mattress, a double-layer air-cell mattress, or a low air pressure mattress may be considered to promote healing in d2 or deeper pressure ulcers.

[Rating] C1

[Recommendation]

3. Use of an air-filled mattress overlay may be considered to promote healing in d1/2 pressure ulcers.

[Rating] C1

[Recommendation]

4. Use of an alternating-pressure air mattress with automatic adjustment to the patient's weight and position may be considered after flap reconstruction for pressure ulcers.

[Rating] C1

[Analysis] The NPUAP/EPUAP¹⁾, WOCN²⁾, and the Wound Healing Society³⁾ guidelines recommend the use of special beds. The basis for their recommendation is found in five randomized controlled trials^{4-6, 8, 9)} which found that the use of low-air-loss beds and air-fluidized beds was more effective for wound healing and contraction rates. The efficacy of alternating-pressure air mattress with automatic adjustment to the patient's position and weight function replacement was examined in a randomized controlled trial involving patients who had received flap surgery for pressure ulcers involving fascia, muscle and bone⁷⁾ as well as in a randomized controlled trial involving stage II~IV pressure ulcer patients¹¹⁾. Neither study found a significant difference in effect between the bed type in question and the controls. Bliss examined the efficacy of alternating-pressure large cell ripple mattresses in a randomized controlled trial involving stage II~IV pressure ulcers and found that they were significantly more effective than the controls in promoting healing¹⁰⁾. On the other hand, Lazzara and Bushmann conducted a randomized controlled trial involving stage I and II pressure ulcer patients to examine the efficacy of air-filled mattress overlays in promoting wound healing, and found no statistically significant difference with the control groups¹²⁾.

One historical controlled trial¹³⁾ and one non-controlled intervention study¹⁴⁾ conducted in Japan using stage II~IV pressure ulcer patients found that use of double-layer air-cell mattresses was more conducive to wound reduction than single-layer air-cell mattresses ($p < 0.05$)¹³⁾. The low air pressure mattresses were also found to be more effective in wound reduction and skin regeneration than air-filled mattress overlays ($p < 0.05$)¹⁴⁾.

On the basis of the data presented above, the use of

air-fluidized beds and low-air-loss beds is strongly recommended for patients diagnosed with stage III or IV, or D3~D5 pressure ulcers or with pressure ulcers in multiple sites. However, in Japan the use of air-fluidized beds, low-air-loss beds and other equipment of this nature is limited by cost and difficulty of maintenance to very few health care institutions. Furthermore, as with prevention measures, the choice of support surface involves not only the condition of the patient's pressure ulcers but also a variety of other factors, each of which requires due consideration.

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CQ 11 Patient education

CQ 11.1 : How can patients and their family or caregivers be educated to prevent the development or recurrence of pressure ulcers?

[Recommendation]

1. Education/training in repositioning and using support surfaces can be carried out .

[Rating] C1

[Recommendation]

2. Periodic telephone consultations with a health care professional and/or remote assessment of the patient's skin condition using electronic visual media may be done.

[Rating] C1

[Recommendation]

3. Education by an e-learning system led by the health care professional may be given.

[Rating] C1

[Recommendation]

4. Education/training in any or all of the following may be given: the etiology of ulcers, risk factors, staging, principles of wound healing, nutritional support, program of skincare and skin inspection, and management of incontinence.

[Rating] C1

[Analysis] There are one randomized controlled trials, one non-randomized controlled trial, one cohort study, and numerous case reports pertaining to patient education.

Instructions in repositioning including positioning, posture in using the wheelchair, and maintaining correct sitting posture can be carried out to prevent the development of pressure ulcers. Further, the measurement of pressure on various points of the body in turn leads to a better understanding of prevention as well as risk assessment, as reported in a number of published case studies¹⁻³⁾.

With regard to the efficacy of consultations with health care professionals, one randomized controlled trial has reported that knowledge of pressure ulcer prevention among the consultation group was higher than among the control group as a result of monthly telephone contact after discharge in addition to enhanced education given to the participants prior to discharge from hospital⁴⁾. However, the content of the instruction was not specified nor was the statistical significance documented. A non-randomized controlled trial⁵⁾ comparing the efficacy of periodic intervention using video images as an educational tool, periodic telephone intervention, and telephone counseling as freely chosen by the patient, found that reports of pressure ulcers were highest among the video group although the differences among the groups were not statistically significant. The larger number of reports among the video group is thought to be due to the higher rate of detection resulting from the increased opportunities for visual contact with health care professionals. Further, the fact that pressure ulcers detected among the video group were generally less advanced suggests that this mode of education/consultation was effective for early detection as well. However, the remote video and telephone consultations featured in these two foreign studies are not covered by the National Health Insurance in Japan. On the other hand, the viability of these methods is being considered within the context of home nursing care in Japan.

According to one cohort study, e-learning implemented as a form of visual educational method succeeded in raising awareness about pressure ulcers among the participants, as demonstrated by test results⁶⁾. Although such methods do not directly affect the rates of occurrence or healing of pressure

ulcers among the participants, they have proved effective as educational tools.

The WOCN Clinical Practice Guidelines⁷⁾ has a section on education on the topics including the etiology of ulcers, risk factors, staging, principles of wound healing, nutritional support, program of skincare and skin inspection, and management of incontinence; however, these are based on expert opinion.

In summary, education of the patient/family/caregiver, while succeeding in raising knowledge of pressure ulcers, failed directly to affect the rates of occurrence or recurrence of pressure ulcers.

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CQ 11.2 : How should patients/family/caregivers be educated/trained in the care of existing pressure ulcers?

[Recommendation] Consider informing patient/family/caregiver how to contact an appropriate medical center for help in the event the pressure ulcers worsen.

[Rating] C1

[Analysis] A search of the currently existing sources under ‘education’ failed to produce any reports based on clinical trials. The WOCN Practice Guideline recommends contacting a health care professional in the event of any complications, but this, too, is based on expert opinion.

At present, there are no clinical trials endorsing the methods described above. For this reason, educational and/or training methods endorsed only by expert opinion can be considered.

References

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CQ 12 Outcome management

CQ 12.1 : Which measures should be undertaken in a hospital care setting to prevent pressure ulcers?

[Recommendation]

1. Choice of support surface based on the Braden Scale is strongly recommended.

[Rating] A

[Recommendation]

2. Choice of support surface based on the OH Scale may be considered.

[Rating] C1

[Recommendation]

3. Deployment of a multidisciplinary wound care team may be considered.

[Rating] C1

[Recommendation]

4. Assignment of wound ostomy and continence nurse may be considered.

[Rating] C1

[Recommendation]

5. Introduction of reimbursement system for pressure ulcer high risk patient care may be considered.

[Rating] C1

[Recommendation]

6. Implementation of comprehensive programs and protocols may be considered.

[Rating] C1

[Recommendation]

[Analysis] Comfort's meta-analysis¹⁾ of nine studies found after a search using the key words, 'Braden' and 'support surface,' examines the choice of support surfaces based on risk assessment conducted with the Braden Scale at acute treatment facilities and university hospitals. Comfort's study found that the odds ratio of pressure ulcer development in the group using support surfaces chosen on the basis of risk assessment using the Braden Scale was 0.335 (95% CI = 0.220~0.508). This report demonstrates a high level of efficacy in using Braden Scale risk assessment as a basis for choosing a support surface for pressure ulcer prevention, and is therefore strongly recommended.

An historical controlled study by Takagi et al. evaluated the criteria for selecting support surfaces based on the OH scale, using as the experimental group, 445 patients, and as the control group, 354 patients, hospitalized in a general hospital with 198 beds²⁾. The results of the study indicated that the rate of pressure ulcer development in the experimental group was significantly lower ($p < 0.05$), thus demonstrating the utility of the algorithm based on the OH Scale for choosing appropriate support surfaces for pressure ulcer prevention.

A longitudinal study by Granick et al. examined the efficacy of prophylactic treatment administered to 690 patients at an university hospital by an interdisciplinary wound care team³⁾. The results of the study demonstrated that the prevalence of pressure ulcers declined steadily from the first, through the second and third years of intervention ($p < 0.05$). A comparison of the number of new cases of pressure ulcers in the first and third years shows a significant decline ($p < 0.005$). In addition, several cohort studies have reported a decrease in the number of both existing pressure ulcer cases and new cases following intervention by a multidisciplinary wound care team consisting of physicians, nurses, dietitians, occupational therapists, pharmacologists, registered dieticians, and administrative staff at general and acute phase treatment facilities. These data demonstrate the efficacy of multidisciplinary wound care team in

preventing pressure ulcers.

An historical controlled study conducted by Sobue et al. examined the prevalence of pressure ulcers in hospital before and after group training by a wound ostomy and continence nurse⁴⁾. The results of the study indicated that the rate of pressure ulcer development was significantly lower ($p < 0.05$) three years after, compared to six months before, commencement of training. These data suggest that employing a wound ostomy and continence nurse may have a significantly positive effect on the prevention of pressure ulcers.

One prospective cohort study involving 190 wound ostomy and continence nurses (111 nurses who introduced the afore-mentioned reimbursement system (see item 5 above), and 79 who did not) found that the estimated incidence of pressure ulcer development in reimbursement system-introduced hospital was significantly lower than that in non-introduced hospitals ($p = 0.008$)⁵⁾. These results indicate that the reimbursement system can produce a significant decrease in the incidence of pressure ulcer development.

A meta-analysis examining the effect of utilizing clinical paths on the formation of pressure ulcers in post-operative femoral neck fracture patients⁶⁾ found the odds ratio for pressure ulcer development to be 0.48 (95% CI = 0.30~0.75) in 2935 subjects across six comparative studies. An historical controlled study by de Laat et al. involving 399 adult patients in an intensive care unit of an university hospital (28 beds) examined the efficacy of a care regimen for prevention of pressure ulcer based on the Dutch AHCPR/EPUAP guidelines⁷⁾. The three-month mark was established as a baseline, and changes in patients' condition were monitored from months 3 to 6 and months 12 to 15 after implementation of the protocol. The results indicated a significant reduction in the rate of pressure ulcer development ($p = 0.04$). In addition, there are a number of cohort studies which have examined the efficacy of comprehensive pressure ulcer prevention regimens. As can be seen, measures utilizing clinical paths, guidelines, and comprehensive programs have proved to be effective in preventing pressure ulcer development. However, as the source of evidence is based only on the meta-analysis of clinical paths in post-operative femoral neck fracture patients and on some cohort studies, the

methods reviewed here have been assigned a recommendation rating of C1.

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CQ 12.2 : Which measures are recommended for pressure ulcer prevention in long-term care facilities?

[Recommendation]

1. Implementation of comprehensive programs and protocols may be considered.

[Rating] C1

2. Use of an algorithm incorporating the Braden Scale to implement preventive care may be considered.

[Rating] C1

[Analysis] The efficacy of pressure ulcer prediction based on the Braden Scale, prevention programs, skin care regimens, nutritional supplementation, skin

consultation with WOC nurses and similar comprehensive care for pressure ulcers at two long-term care facilities (facility A, 150 beds; facility B, 110 beds) have been examined in a longitudinal study¹⁾. The results indicated that there was a significant decrease in the rate of pressure ulcer development four months after commencement of the program (P = 0.02), suggesting that the adoption of comprehensive programs and protocols at long-term care facilities is effective in preventing pressure ulcer development.

An historical controlled study of the efficacy of a Braden Scale-based pressure ulcer prevention algorithm employed at a special elderly care facility (120 beds) found a marked decrease in the prevalence of pressure ulcer nine months after the implementation of the algorithm as compared to nine months prior to implementation (P < 0.01)²⁾. This evidence suggests that the use of algorithms based on the Braden Scale at long-term care facilities is effective for pressure ulcers prevention.

References

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CQ 12.3 : Which measures are recommended to promote healing of pressure ulcers in a hospital care setting?

[Recommendation]

1. Deployment of a multidisciplinary wound care team may be considered.

[Rating] C1

[Recommendation]

2. Introduction of reimbursement system for pressure ulcer high risk patient care may be considered.

[Rating] C1

[Recommendation]

3. Assignment of wound ostomy and continence nurse may be recommended.

[Rating] C1

[Analysis] A longitudinal study conducted by Ogawa et al. involving 48 patients with pressure ulcers at a general ward and a nursing ward examined the efficacy of a multidisciplinary wound management team in pressure ulcer healing rate¹⁾. The study reported a significant improvement in the DESIGN scores six months after the start of the team's activities as compared to scores obtained six months prior to the commencement of their activities ($p < 0.05$), strongly indicating the positive effect of such multidisciplinary teams on wound healing.

A prospective cohort study examined the impact of introducing reimbursement system for high risk patients on pressure ulcer healing at a total of 59 health care facilities, including advanced treatment facilities, regional central hospital, and general hospitals²⁾. The study reported that the DESIGN scores for patients in facilities that introduced reimbursement system had decreased during three weeks significantly more compared to those patients in facilities that had no billable services ($p = 0.002$). Further, multiple regression analysis using the decrease in the DESIGN score as a dependent variable found a significant correlation between pressure ulcer healing and the implementation of the aforementioned care ($p < 0.001$). This data suggests that the introduction of reimbursement system for high risk patient care has a positive impact on the healing of pressure ulcer.

Two case reports examined the impact of care provided by wound ostomy and continence nurse at a nursing ward in a coloproctological facility³⁾. In the first of these reports, improvement was seen in patients' pressure ulcers as a result of the selection of proper support surface by wound ostomy and continence nurse. The second study failed to assess the effect of care administered by wound ostomy and continence nurse on cases of prolonged recovery caused by contamination of the wounds by urine. In the former, the deployment of wound ostomy and continence nurse as one of the conditions stipulated in the introduction of reimbursement system for high risk patient care can be seen as a major contributing factor in the success of these services. Taken as a whole, these data suggest that the care administered by wound ostomy and continence nurse has a positive impact on the healing of pressure ulcers.

References

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CQ 12.4 : Which measures are recommended to promote healing of pressure ulcers in a long-term care facility?

[Recommendation]

1. Deployment of a multidisciplinary wound care team is recommended.

[Rating] B

[Recommendation]

2. Implementation of comprehensive programs and protocols may be considered.

[Rating] C1

[Analysis] A randomized controlled trial involving 44 nursing homes (intervention group, 21; control group, 23) assessed the efficacy of a multifunctional wound care team in promoting pressure ulcer healing and found that the intervention group showed a higher healing rate than the control group ($P = 0.07$) with a hazard ratio of 1.73 ($P = 0.003$)¹⁾. This data indicate that the deployment of a multifunctional wound care team at a long-term care facility is likely to have a positive impact on the healing rates of pressure ulcer. However, it should be noted that only 80% of the enrolled patients suffered from pressure ulcers, while 20% had leg ulcers.

A historical controlled study compared healing time of pressure ulcers among patients at a long-term care facility (77 beds) who were either administered a care protocol based on guidelines or treated according to conventional methods²⁾. The subjects were divided into three groups based on three time frames: before

intervention, immediately after intervention, and three years after intervention. Using healing of pressure ulcer in each group as the end-point, the survival curve was assessed by the Log rank test. The results of this assessment found a significant difference between each of the three groups in terms of the duration required for pressure ulcer healing (Log rank = 9.49, $P < .01$). These data suggest that the adoption of comprehensive programs such as guideline-based protocols at long-term care facilities has a positive effect on promoting healing of pressure ulcers.

References

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CQ 13 QOL/ Pain

CQ 13.1 : How can the quality of life (QOL) of pressure ulcer patients be assessed?

[Recommendation] The QOL of the patients may be assessed along physiological, psychological, and social parameters.

[Rating] C1

[Analysis] A longitudinal multivariate analysis was conducted on the basis of reports filed every six months by nursing home residents in which the participants reported the relationship between changes in their QOL and the prevalence of their pressure ulcers. The results of the study indicated an inverse relationship between the prevalence of pressure ulcers (Stage II or higher) and the sense of autonomy, security, and psychological well-being reported by the patients at six-month intervals¹⁾. Another cross-sectional study using the SF-36TM (a widely accepted scale used to assess 'Health Related Quality of Life') to examine the physical functionality ($p < 0.001$), social functionality ($p < 0.001$), self-care ($p = 0.010$), and mobility ($p = 0.001$) of pressure ulcer patients confined to their home reported significantly lower scores in these categories. A cross-sectional study has reported high scores for bodily

pain in home care pressure ulcer patients ($p = 0.042$)²⁾. Further, a descriptive and transversal study conducted by Blanes et al. reported that among outpatients with traumatic spinal cord injuries, the average mental health scores for those patients suffering from pressure ulcers were significantly lower in comparison with those of who did not suffer from pressure ulcers ($p = 0.001$)³⁾. Clearly, the fact that the QOL of patients is influenced significantly by the presence of pressure ulcers, makes a careful assessment of patients' QOL imperative.

According to ten quantitative studies and 21 qualitative studies selected through systematic review, there are 11 factors which are thought to influence the health-related QOL of pressure ulcer patients⁴⁾. These are: physical impact and limitation, impact of pressure ulcer symptoms, need versus impact of interventions, impact on general health and consequences, psychological impact, perceived etiology (anger felt by patients who associated their development of pressure ulcers with perceived inadequacies in health care), need for knowledge, social impact, healthcare provider-patient relationships, impact on others, and financial impact. It should be noted that although this article is a systematic review, its scope is restricted to a compilation of quantitative and qualitative studies. For this reason, the study has been assigned the recommendation rating of C1.

References

- 1) Degenholtz HB, Rosen J, Castle N, et al : The association between changes in health status and nursing home resident quality of life. *Gerontologist*, 48 (5) : 584-592, 2008. (Level IV)
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- 3) Blanes L, Carmagnani MI, Ferreira LM : Quality of life and self-esteem of persons with paraplegia living in São Paulo, Brazil. *Qual Life Res*, 18 (1) : 15-21, 2009. (Level V)
- 4) Gorecki C, Brown JM, Nelson EA, et al : Impact of pressure ulcers on quality of life in older patients: a systematic review. *J Am Geriatr Soc*, 57 (7) : 1175-1183, 2009. (Level I)

CQ 13.2 : For which stage of pressure ulcer is pain assessment recommended?

[Recommendation] Pain may be assessed at any stage of pressure ulcer.

[Rating] C1

[Analysis] A cross-sectional study of 32 patients recruited from acute care settings, extended care settings, and home care settings with stage II, III, and IV pressure ulcers found that 75% reported mild pain, while 18% reported excruciating pain¹⁾. Another cross-sectional study based on an interview of 44 patients in an acute care setting reported a correlation between the VAS (visual analog scale) and stage of pressure ulcer ($r = 0.37$, $P < 0.01$), with a positive correlation between the depth of the wound and the intensity of pain²⁾. However, pain has reportedly accompanied even relatively shallow wounds¹⁾. Accordingly, pain assessment is necessary at every stage of pressure ulcer for the accurate assessment of patients' QOL.

References

- 1) Szor JK, Bourguignon C: Description of pressure ulcer pain at rest and at dressing change. *J Wound Ostomy Continence Nurs*, 26 (3) : 115-120, 1999. (Level V)
- 2) Dallam L, Smyth C, Jackson BS, et al: Pressure ulcer pain: assessment and quantification. *J Wound Ostomy Continence Nurs*, 22 (5) : 211-218, 1995. (Level V)

CQ 13.3 : When should pain assessment be conducted?

[Recommendation] Pain assessment may be conducted at any time (regardless of whether topical intervention is being administered).

[Rating] C1

[Analysis] According to a cross-sectional study conducted on 32 patients with stage II, III, or IV pressure ulcers interned at acute care, extended care, and home care settings using the MPQ (McGill pain questionnaire), 87.5% reported feeling pain when their dressings were changed, and 84.4% reported similar sensations when at rest¹⁾. Furthermore, 42%

of the patients reported continuous pain. These data indicate the need to assess pain levels in pressure ulcer patients not only when treatment is administered but also when the patients are at rest.

References

- 1) Szor JK, Bourguignon C : Description of pressure ulcer pain at rest and at dressing change. *J Wound Ostomy Continence Nurs*, 26 (3) : 115-120, 1999. (Level V)

CQ 13.4 : Which tools can be used to assess pressure-ulcer-related pain?

[Recommendation] Pain may be assessed using a validated scale.

[Rating] C1

[Analysis] A cross-sectional study based on interviews of 44 patients with Stage I-IV pressure ulcers interned in an acute care facility found that the degree of pain reported by the patients in the interviews correlated with the VAS (visual analog scale; $r = 0.59$, $P < 0.1$) as well as with the FRS (faces pain rating Ssle; $r = 0.53$, $P < 0.1$)¹⁾.

Another cross-sectional study of 47 patients with Stage II-IV pressure ulcers found that 94.6% of patients who reported pressure-ulcer-related pain showed a correlation between their FRS and MPQ (McGill pain questionnaire) scores ($r = 0.90$, $P < 0.001$)²⁾. These data indicate that the VAS, FRS, and MPQ subjective rating systems are able accurately to measure the degree of pain felt by pressure ulcer patients and are therefore appropriate tools for the assessment of pressure-ulcer-related pain.

References

- 1) Dallam L, Smyth C, Jackson BS, et al : Pressure ulcer pain: assessment and quantification. *J Wound Ostomy Continence Nurs*, 22 (5) : 211-218, 1995. (Level V)
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