CLINICAL TRIAL

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The effectiveness of two silicone dressings for sacral and heel pressure ulcer prevention compared with no dressings in high-risk intensive care unit patients: a randomized controlled parallel-group trial

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Summary

Background There is a high incidence of pressure ulcers in high-risk settings such as intensive care. There is emerging evidence that the application of dressings to pressure ulcer predilection areas (sacrum and heels) improves prevention strategies.

Objectives To determine whether preventive dressings, applied to the sacrum and heels of high-risk patients in intensive care units, in addition to standard prevention, reduces the incidence of pressure ulcers.

Methods Between June 2015 and July 2018, a randomized, controlled, two-arm, superiority pragmatic study was performed with a concealed 1 : 1 allocation to the intervention and control group. Patients assigned to the intervention group had dressings applied to the sacrum and heels.

Results In total, 7575 patients were screened for eligibility and 475 patients were included and allocated to both groups. Finally, 212 patients in the intervention group and 210 in the control group were analysed. The mean age was 63·5 years and the majority of patients were male (65·4%). The cumulative pressure ulcer incidence category II and above was 2·8% in the intervention, and 10·5% in the control group ($P = 0·001$). Compared with the control group, the relative risk in the intervention group was 0·26 [95% confidence interval (CI) 0·11–0·62] and the absolute risk reduction was 0·08 (95% CI 0·03–0·13).

Conclusions The results indicate that the application of dressings, in addition to standard prevention, in high-risk intensive care unit patients is effective in preventing pressure ulcers at the heels and sacrum.

What's already known about this topic?

- Pressure ulcers are severe soft tissue injuries and wounds, which occur worldwide in all healthcare settings.
- Despite preventive interventions, pressure ulcers still develop.
- There is emerging evidence that dressings help to prevent pressure ulcers.

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Conflicts of interest

U.B.-P. has received honoraria from Cassiopea, Galderma, Johnson & Johnson, LEO and Pierre Fabre Dermocosmetique. J.K. has received honoraria from Mölnlycke Health Care, 3M and Stryker.

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What does this study add?

- The incidence of pressure ulcers in intensive care units among high-risk patients remains high.
- The application of dressings to the sacrum and heels, in addition to standard preventive measures, reduces the relative and absolute risks for the development of pressure ulcers.
- The application of preventive dressings at the heels and sacrum seems to be feasible in intensive care settings.

Pressure ulcers (PUs) are severe forms of skin and tissue lesions caused by prolonged mechanical deformation of soft tissues between stiff internal structures such as bones or tendons and external support surfaces or medical devices. Adults in supine and semi-Fowler position mainly develop PUs at the heels and at the sacral area.[1] PU prevalence and incidence is high especially in high-risk settings including geriatric, long-term or intensive care.[2–4] PUs severely affect quality of life[5] and in the latest Global Burden of Skin Disease Study, PUs were assigned the highest disability index.[1] PU occurrence in healthcare settings is widely accepted as an unwanted adverse outcome in patient care.[6–8]

State-of-the-art PU prevention includes the identification of PU risk and the application of preventive measures. As mobility and activity limitations are the most important PU risk factors,[9] the cornerstone of PU prevention is repositioning, elevation and offloading of heels, early mobilization and the use of special support surfaces.[2]

There is emerging evidence that the application of dressings to PU predilection areas may help to prevent PUs.[2,10,11] Preventive dressings on intact skin might reduce friction between the skin and the support surfaces and therefore reduce shear forces within the skin and underlying soft tissues.[12,13] To increase hospital patient safety, the Clinical Quality and Risk Management of the Charité – Universitätsmedizin Berlin (Germany) decided to investigate whether these dressings are also effective in high-risk intensive care unit (ICU) patients at its facilities.

The primary objective of this study was to determine whether preventive multilayered soft silicone foam dressings applied to the heels and sacrum, in addition to standard prevention, reduced the cumulative PU incidence category II, III, IV and deep tissue injury (DTI) compared with standard prevention alone in ICU patients who were at high or very high PU risk.

Materials and methods

Trial design

A randomized, controlled, two-arm, superiority pragmatic study was performed with a 1 : 1 allocation to the intervention or control group. The study was approved by the local ethics committee at the Charité – Universitätsmedizin Berlin (approval number: EA1/190/14) and was registered at ClinicalTrials.gov (NCT02295735) on 20 November 2014. No important changes were made after study commencement.

Participants

ICU patients aged 18 years or older, within 6 h of admission to an ICU, at high or very high PU risk with an expected minimum length of stay of at least 3 days were considered eligible. The assessment of high or very high PU risk of the ICU patient was assessed by the research staff in close communication with the ICU staff and according to the classification of the hospital PU prevention standard.[14] According to the hospital standard, the risk assessment was based on mobility and care dependency. Informed consent was obtained from the patients or their legal representatives before or after inclusion as soon as the patients or the legal representatives were able to do so. ICU patients who were at the end of life or with existing PUs at any stage according to the National and European Pressure Ulcer Advisory Panels (NPUAP/EPUAP) 2014 classification system, or trauma at the heels and sacrum, or known allergies to the preventive dressings were excluded. ICU patients who were positioned on air-fluidized beds and patients who could not be repositioned owing to medical reasons (e.g. cardiovascular instability) were not considered eligible, because the patient could not be moved for dressing applications and skin inspections.

Settings and locations

The study was conducted in a tertiary care hospital from June 2015 to July 2018 at the Charité – Universitätsmedizin Berlin, Germany. Patients were recruited from seven ICUs including surgical, cardiovascular, gastroenterology, nephrology, anaesthesiology and neurology ICUs. The mean number of beds per ward was 14 (range 10–24). Study personnel walked rounds twice daily (including weekends and holidays) on all participating ICUs between 07·00 h and 19·00 h enabling a daily recruitment period of 18 h. In the case of a potentially eligible patient, a researcher from the study team checked the

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inclusion and exclusion criteria using a screening form. If eligible, the patient was included and randomized.

Interventions

All included patients from ICUs who had high or very high PU risk received PU prevention according to the hospital standard. Besides PU risk scoring, the standard care included instructions for skin inspection within 6 h after admission and, depending on the risk, the following preventive measures: (i) patient information, (ii) daily skin inspection at least twice daily, (iii) mobilization, (iv) use of special support surfaces, (v) repositioning and (vi) heel flotation.[14]

For patients in the intervention group, dressings were applied on both heels (Mepilex® Border Heel, Mölnlycke Health Care, Gothenburg, Sweden) and on the sacral areas (Mepilex® Border Sacrum, Mölnlycke Health Care) according to manufacturer's instructions in addition to the standard care. Care was taken that the dressings were applied correctly and that no other skincare products were used between the skin and the dressings. The dressings were renewed every 3 days and the skin underneath the dressings was checked daily. In cases where dressings became soiled or dislodged, they were changed immediately. Dressings remained on the skin during the whole study period, including transfers to other wards or transfers for diagnostic or therapeutic purposes.

In both groups, included patients were followed up at least once daily by the study team in order to ensure study compliance, correct dressing use and fit, to assess the skin and to document the health condition and PU risk.

The follow-up visits stopped when one of the following occurred: (i) the patient was no longer at 'high' or 'very high' PU risk and no sacral or heel PU developed, (ii) a heel or sacral PU that developed within the study period had completely healed, (iii) an adverse event (AE) related to the preventive dressings occurred, (iv) the patient wished to withdraw, (v) a severe form of protocol violation occurred (e.g. nonwearing of the dressings for more than 24 h), (vi) the patient died or (vii) the patient was transferred to another setting outside the university hospital campus or was discharged.

Kick-off meetings at the participating ICUs, daily follow-up visits by the study team and monthly status reports on recruitment at the participating ICUs were provided to improve adherence to the study protocol. In addition, laminated patient cards were posted at or near beds. These cards included essential study information and contact details of the study team, and served as a reminder.

Outcomes

The primary outcome was the cumulative incidence of PU category II, III, IV, unstageable and DTI at heels or sacrum. PUs were categorized according to the NPUAP/EPUAP 2014 classification system.[2] The occurrence of a new PU of any category was assessed and documented daily during the study period.

Members of the study team, independently from the ward staff, conducted skin and tissue inspections daily and were aware of the group assignment. The study team members were instructed about the study design, procedures, data collection and documentation methods before carrying out the inspections. A 1-h skin inspection and PU classification instruction was provided, followed by an online examination (PuClas3)[15] for all researchers performing skin examinations.

Secondary outcomes were the incidence density (proportions of PUs per 1000 bed days) of PU category II and higher, the cumulative incidence and incidence density of PU category I (nonblanchable erythema) and higher. The total number of days free of PU categories I or II and higher at the heels and sacrum was also measured.

PU risk was measured according to the hospital standard and the Braden scale. The Braden scale is a standardized six-item PU risk assessment instrument with scores ranging from 6 (high PU risk) to 23 (no PU risk). The reliability of this score in the study setting has been previously confirmed.[16]

Other variables assessed at baseline were demographic characteristics (age, sex, smoking status), body mass index (BMI), main medical diagnoses at admission and prior to the ICU stay (coded according to the International Classification of Diseases 10), presence of diabetes mellitus or tetraplegia, the length of stay in the emergency department (ED) or on peripheral wards prior to the ICU stay. Data regarding urine and/or stool incontinence, type of support surfaces and positioning intervals were observed daily by direct observations. The skin phototype of participants was classified according the Fitzpatrick classification ranging from I (white skin, never tans) to VI (dark brown/black skin, tans deeply).[17,18]

In the intervention group, harms were classified into device deficiency (DD), AEs and adverse device effect. A DD was defined as inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. An AE was defined as any untoward medical occurrence, unintended disease, injury or clinical sign related to the investigational dressings.

Sample size

A study of independent cases and controls with one control per case was planned. Available data from the hospital quality management system indicated that the average PU incidence at the ICUs was 0·06 per month. We expected a cumulative PU incidence for experimental participants to be 0·01 [relative risk (RR) 0·17]. In order to test this hypothesis, 211 experimental patients and 211 control patients were needed to reject the null hypothesis that the PU incidence in the intervention and control groups is equal with a probability (power) of 0·8. The type I error probability associated with this test of the null hypothesis is 0·05 (two-sided). We used the χ^2-test statistic to evaluate this null hypothesis. To prevent a possible loss of follow-up of 10%, we planned to include 464 patients.

An interim analysis was conducted after 50% of the sample ($n = 232$) had completed the study. We planned to stop the

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study after the interim analysis, if the conditional power based on the observed data after 50% of recruitment was less than the 60% required to reject the null hypothesis.[19]

Randomization

A simple randomization with a 1 : 1 allocation as per computer-generated randomization table was used. The randomization table was created independently from the study team at the Department of Biometry and Clinical Epidemiology at the Charité – Universitätsmedizin Berlin. Sequentially numbered, opaque, sealed envelopes containing the group assignment were prepared and used. The data manager, who was not involved in any study procedures, prepared the envelopes. On the morning of the daily recruitment, approximately five to eight consecutive envelopes were taken for potential use during the day. After a patient was included and baseline data were collected, the study personnel opened the next numbered envelope and the patient was allocated to the intervention or control group. Based on the randomization logs there was no evidence of selection bias.

Blinding

Owing to the nature of the intervention, caregivers and the study team were not blinded. The data manager was blinded throughout the study.

Statistical methods

Depending on the levels of measurement (nominal, ordinal, continuous) variables were described using absolute and relative frequencies or arithmetic means, medians and spread parameters (minimum, maximum, interquartile ranges and SDs).

The primary outcome PU incidence category II, III, IV, DTI at the heels and/or sacrum was compared using the χ^2-test. This was the main analysis of this primary outcome. An α level of 5% (two-sided) was applied. Kaplan–Meier analysis was used to compare the times to development of a new PU between groups. A generalized linear model (GEE) analysis was conducted to adjust for different baseline covariates regarding the primary outcome. All statistical analyses were based on the intention-to-treat (ITT) principle. The ITT population included all participants who gave informed consent prior to or after randomization. Postrandomization exclusions occurred only for reasons of missing consent.

Secondary outcomes were analysed in a similar way. The χ^2-test or t-tests were applied to compare groups. In cases where the normality assumption was violated, the Mann–Whitney U-test was used rather than t-test. Results of these secondary outcomes were considered exploratory. All statistical analyses were performed using SPSS version 25 (IBM, Armonk, NY, U.S.A.).

Results

Participant flow

In total, 7575 ICU patients were screened for eligibility and 475 ICU patients (6·3%) were included. Overall, 238 patients were allocated to the intervention and 237 patients were assigned to the control group. In total, 23 patients (4·8%) personally declined participation after randomization. Additionally, 17 patients in the intervention group and 13 patients in the control group were excluded after randomization, e.g. because seeking informed consent was not possible owing to death and/or nonavailability of legal representatives. Finally, 422 patients (88·8%) were analysed, these were all patients who provided informed consent. A detailed description of the participant flow is shown in Figure 1.

Recruitment

The recruitment period was from 1 June 2015 to 26 July 2018. The study stopped after the required number of patients had been included.

Baseline data

Demographic and sample characteristics are shown in Table S1 (see Supporting Information). The mean (± SD) age of ICU patients was 63·5 years (± 15·4). The majority of the ICU patients were male (65·4%), the mean BMI was 26·5 kg m^{-2} (± 4·9) and most ICU patients had a Fitzpatrick skin phototype of II (75·1%). In total, 171 ICU patients (40·5%) were affected by diabetes mellitus and 10 patients (2·4%) had tetraplegia. Besides a slight imbalance regarding the proportions of sex, both groups were comparable.

Outcomes and estimation

Data relating to 422 ICU patients were analysed. Patients were followed up for an average of 12·6 days (± 12·7) (Table 1). The longest follow-up period was 130 days. The Mann–Whitney U-test showed that the follow-up periods were statistically significantly different between the intervention and control groups ($P = 0·006$).

Primary outcome

Numbers and proportions of all incident PU cases and categories are shown in Table 2. The cumulative incidence of PUs ranging from category II to DTI was 6·6% (28 of 422). The difference between groups was statistically significant ($P = 0·001$). The RR in the intervention group compared with the control group was 0·26 (95% CI 0·11–0·62). The absolute risk reduction was 0·08 (95% CI 0·03–0·13). Therefore, the number needed to treat was 12·3 (95% CI 29·9–7·8).

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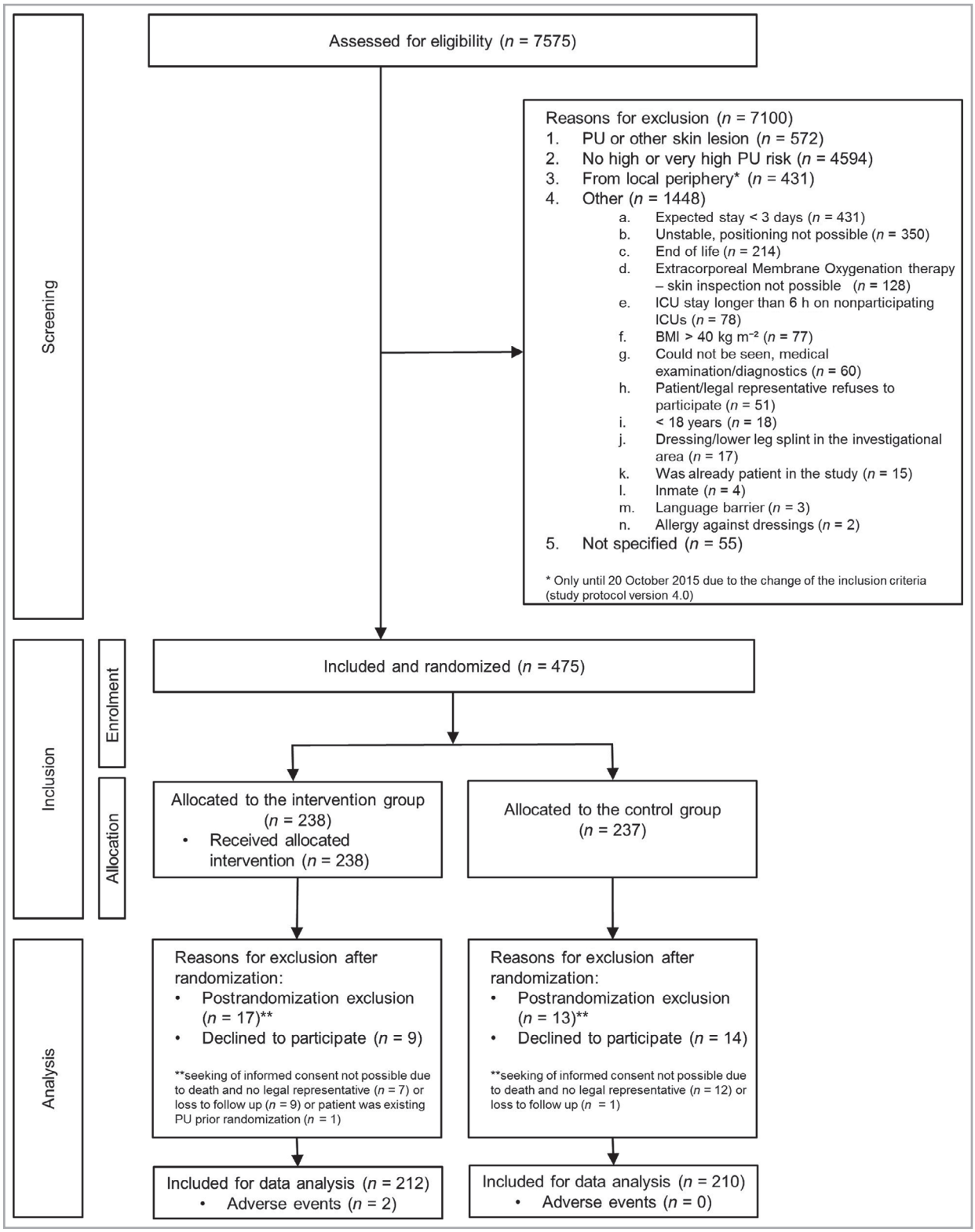

Fig 1. Flowchart outlining the flow of participants throughout the study.
PU, pressure ulcer; ICU, intensive care unit; BMI, body mass index.

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Table 1 Follow-up period

	Intervention group (n = 212)	Control group (n = 210)	Total (n = 422)	Mann–Whitney U-test (P-values)
Follow-up period, days				
Mean (SD)	11·0 (10·3)	14·3 (14·6)	12·6 (12·7)	0·006
Median (IQR)	8 (4–14)	10 (6–17)	9 (5–16)	
Min–max, days	1–68	1–130	1–130	

IQR, interquartile range.

Table 2 Pressure ulcer (PU) location and incidence (cumulative)

	Intervention group (n = 212)	Control group (n = 210)	Total (n = 422)	Pearson χ^2-test, P-values
PU incidence, n (%)	6 (2·8)	28 (13·3)	34 (8·1)	< 0·001
PU sacrum, n (%)	6 (2·8)	23 (11·0)	29 (6·9)	–
Category I	0	4	4	–
Category II	4	10	14	–
Category III	0	1	1	–
Category IV	0	0	0	–
Category DTI	2	8	10	–
PU heel right, n (%)	0 (0·0)	2 (1·0)	2 (0·5)	–
Category I	0	1	1	–
Category II	0	1	1	–
Category III	0	0	0	–
Category IV	0	0	0	–
Category DTI	0	0	0	–
PU heel left, n (%)	0 (0·0)	3 (1·4)	3 (0·7)	–
Category I	0	1	1	–
Category II	0	1	1	–
Category III	0	0	0	–
Category IV	0	0	0	–
Category DTI	0	1	1	–
PU categories, n (%)				
PU category I	0 (0·0)	6 (2·9)	6 (1·4)	0·013
PU category II to DTI	6 (2·8)	22 (10·5)	28 (6·6)	0·001
PU category III to DTI	2 (0·9)	10 (4·8)	12 (2·8)	0·006
PU category IV to DTI	2 (0·9)	9 (4·3)	11 (2·6)	0·018
PU category DTI	2 (0·9)	9 (4·3)	11 (2·6)	0·018

DTI, deep tissue injury.

Secondary outcomes

The cumulative PU incidence of PUs ranging from category I to DTI was 8·1% (34 of 422) for the whole sample (Table 2). The most common location was the sacral area and most PUs were category II. The cumulative incidence was 2·8% (six of 212) in the intervention group and 13·3% (28 of 210) in the control group. This difference was statistically significant ($P < 0·001$). No PU classified as category IV was identified in either group.

The PU incidence rates are shown in Table 3. The differences between groups were statistically significant ($P = 0·001$) when category I PUs were included/excluded.

The mean (± SD) time to PU development (category II to DTI) for the whole sample was 12·1 days (± 12·2). In the intervention group, the mean time for PU development was 10·8 days (± 10·1) and 13·5 days (± 13·8) for the control group. The difference between the groups was statistically significant ($P = 0·025$).

The Kaplan–Meier plots for PU categories II to DTI are shown in Figure 2. The mean survival time was 60·7 days [SEM 4·1, 95% confidence interval (CI) 52·7–68·7] in the intervention group and 89·0 days (SEM 9·8, 95% CI 69·7–108·2) in the control group. The difference between the two groups was statistically significant ($P = 0·01$).

Results of the GEE analysis regarding the development of PUs ranging from category II to DTI in both groups are

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Table 3 Pressure ulcer (PU) incidence density rate

	Intervention group (n = 212)	Control group (n = 210)	Total (n = 422)	Mann–Whitney U-test, P-values
Incidence density rate per 1000 bed days				
PU category II to DTI	7·8	30·5	19·1	0·001
PU category II to DTI	8·0	37·6	22·8	< 0·001

DTI, deep tissue injury.

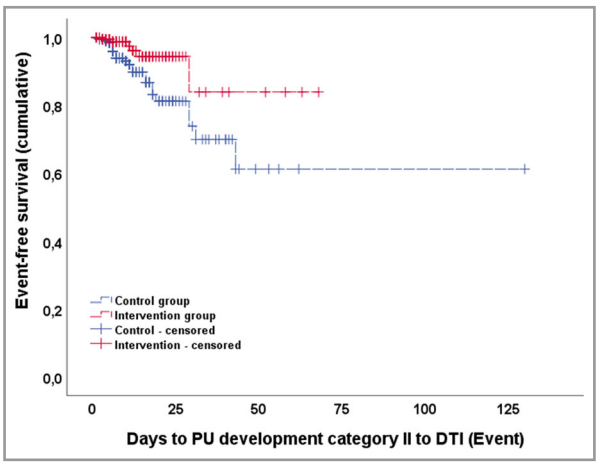

Fig 2. Event-free survival for pressure ulcer (PU) ranging from category II to deep tissue injury (DTI).

shown in Table 4. The model was adjusted for group allocation, follow-up time, age, diabetes mellitus and procedures prior to being transferred to the ICU (staying in the ED, staying in the operating room, staying for diagnostic reasons). ICU patients in the intervention group (β −1·312, odds ratio 0·269; P = 0·006) developed statistically fewer PUs ranging from category II to DTI compared with the control group. All other predictors were not statistically significant.

Harms

In total, two AEs occurred. One patient reported burning pain and warm sensation under the sacral dressing. No signs of inflammation or impaired skin integrity were seen. The dressing application was stopped immediately and the patient wished to withdraw. After the product application was stopped, the burning pain and warm sensation decreased. The outer layers of the skin of another patient peeled under the sacral dressing after application. No signs of inflammation were seen. The product application was not stopped and the patient terminated the study.

Discussion

There were limitations to this study. Performance and detection bias may have occurred because patients, caregivers and study personnel were not blinded to the study procedures and randomized allocation. A selection bias might also have occurred. However, because all eligible patients were screened during the recruitment period and randomized according to the planned order, a selection bias is considered unlikely. We used a simple 1 : 1 randomization as per computer-generated randomization tables. Study groups were similar regarding demographic and other characteristics, and observed imbalances regarding sex were minor. Owing to outliers, the maximum follow-up time was longer in the control group compared with the intervention group, but the medians were similar and an effect on the primary outcome is unlikely. Moreover, the a-priori-defined end-of-study criteria numbers (iii) (an AE related to the preventive dressings occurred) and (v) (protocol violation) were not in line with the ITT principle. However, neither of these criteria were applied in the

Table 4 Generalized linear model for the dependent variable ranging from pressure ulcer (PU) category II to deep tissue injury

			Hypothesis test				
Parameter	β	SEM	Wald χ^2-test	df	P-values	Odds ratio	95% CI
Group (0 = control; 1 = intervention)	−1·312	0·478	7·538	1	**0·006**	0·269	0·105–0·687
Follow-up time	0·022	0·012	3·482	1	0·062	1·022	0·999–1·046
Age	−0·007	0·014	0·287	1	0·592	0·993	0·966–1·020
Diabetes mellitus (0 = no; 1 = yes)	0·668	0·408	2·684	1	0·101	1·951	0·877–4·340
Stay in ED (0 = no; 1 = yes)	−0·823	0·524	2·464	1	0·117	0·439	0·157–1·227
Stay in operating room (0 = no; 1 = yes)	0·226	0·605	0·139	1	0·709	1·253	0·383–4·105
Stay for diagnostic reason (0 = no; 1 = yes)	0·198	0·411	0·232	1	0·603	1·219	0·545–2·729
Braden scale score	−0·025	0·137	0·033	1	0·856	0·975	0·745–1·276
Constant	−2·014	1·499	1·807	1	0·179	0·133	–

CI, confidence interval; ED, emergency department, β, regression coefficient, df, degrees of freedom.

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trial. Furthermore, we did not collect information about PUs at body areas other than the heels and sacrum.

A major strength of this study was the pragmatic procedure. Pragmatic studies are able to measure realistic treatment effects in daily clinical routines compared with highly standardized randomized controlled trials (RCTs).[20] Demographic characteristics such as age and sex are comparable to previous studies in this setting.[21–24] The proportions of postrandomization exclusions were within the range of other RCTs in this setting.[13,25,26] The majority of PUs occurred at the sacral area, which is in alignment with other published research results.[23] However, patients in our sample were at higher PU risk compared with other studies.[4,13,23,27]

As ICU care organization and staff characteristics are setting-specific, generalizability to other ICUs in other regions or countries might be limited. However, the local hospital standard PU prevention corresponds to the international state-of-the-art approach[2] and the direction of the shown treatment effect is consistent with results of previous RCTs.[11,28]

Results of this pragmatic RCT indicate that the additional use of preventive dressings at the two most important PU predilection areas substantially reduces the development of new PUs at these areas. The absolute risk reduction of 8% was higher than expected, but might be explained by including only high-risk and very high-risk ICU patients. This effect estimate is based on category II PUs and above, which is a major strength of this study compared with other RCTs in this area.[29] As category I PUs are not wounds, the clinical relevance of this outcome is questionable and the measurement error of this outcome is high.[30] However, when category I PUs were included the absolute risk reduction was 10%, which is similar to the treatment effect of the primary outcome and also similar to the results of a cluster RCT in high-risk residents in aged care.[29] Additionally, the adjusted analysis for key prognostic factors showed that the allocation to the intervention group was the only significant factor, which strengthens our conclusions.

The principle underlying mode of action of the investigated dressings is lower friction between the outer dressing and the support surfaces, thus reducing shear within the skin and underlying soft tissues.[31,32] Other types of dressings are used for PU prevention and study results are mixed.[33,34] Therefore, compared with many other areas in PU prevention research, direct head-to-head comparisons are urgently needed to support clinical decision making.[35]

As the observed treatment effect is consistent with previous study results using the same dressing[13,23,29] and the AEs were minor, we conclude that the use of the investigated dressing in addition to standard care is effective in preventing PUs in high-risk ICU patients. Compared with other established preventive measures, such as the use of special support surfaces, repositioning, floating heels and mobilization,[2] this additional intervention can be easily implemented. Although the treatment effect was substantial, PUs in the intervention group still occurred. This indicates that PU prevention is still not optimal.

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References

1 Hay RJ, Johns NE, Williams HC *et al.* The global burden of skin disease in 2010: an analysis of the prevalence and impact of skin conditions. *J Invest Dermatol* 2014; **134**:1527–34.
2 National Pressure Ulcer Advisory Panel European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance. *Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline*. Washington DC: National Pressure Ulcer Advisory Panel, 2014.
3 Tomova-Simitchieva T, Akdeniz M, Blume-Peytavi U *et al.* [The epidemiology of pressure ulcer in germany: systematic review]. *Gesundheitswesen* 2019; **81**:505–12 (in German).
4 Petzold T, Eberlein-Gonska M, Schmitt J. Which factors predict incident pressure ulcers in hospitalized patients? A prospective cohort study. *Br J Dermatol* 2014; **170**:1285–90.
5 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* 2009; **57**:1175–83.
6 Kottner J, Lahmann N. [Comparative quality measurements part 3: funnel plots]. *Pflege* 2014; **27**:41–9 (in German).
7 Unbeck M, Sterner E, Elg M *et al.* Design, application and impact of quality improvement 'theme months' in orthopaedic nursing: a mixed method case study on pressure ulcer prevention. *Int J Nurs Stud* 2013; **50**:527–35.
8 Kottner J, Hahnel E, Lichterfeld-Kottner A *et al.* Measuring the quality of pressure ulcer prevention: a systematic mapping review of quality indicators. *Int Wound J* 2018; **15**:218–24.
9 Coleman S, Nixon J, Keen J *et al.* A new pressure ulcer conceptual framework. *J Adv Nurs* 2014; **70**:2222–34.
10 Clark M, Black J, Alves P *et al.* Systematic review of the use of prophylactic dressings in the prevention of pressure ulcers. *Int Wound J* 2014; **11**:460–71.
11 Moore ZE, Webster J. Dressings and topical agents for preventing pressure ulcers. *Cochrane Database Syst Rev* 2018; **12**:CD009362.
12 Park KH. The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence-associated dermatitis in intensive care unit patients. *J Wound Ostomy Continence Nurs* 2014; **41**:424–9.
13 Santamaria N, Gerdtz M, Sage S *et al.* A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial. *Int Wound J* 2015; **12**:302–8.
14 Hauss A, Greshake S, Skiba T *et al.* [Systematic pressure ulcer risk management: results of implementing multiple interventions at Charite – Universitatsmedizin Berlin]. *Z Evidenz Ges* 2016; **113**:19–26 (in German).
15 Beeckman D, Schoonhoven L. European Pressure Ulcer Advisory Panel. PuClas3 eLearning Module. University Centre for Nursing and Midwifery and European Pressure Ulcer Advisory Panel, 2014. Available at: https://puclas3.ucvvgent.be/ (last accessed 17 November 2019).
16 Kottner J, Dassen T. Pressure ulcer risk assessment in critical care: interrater reliability and validity studies of the Braden and Waterlow scales and subjective ratings in two intensive care units. *Int J Nurs Stud* 2010; **47**:671–7.

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17 Magin P, Pond D, Smith W *et al.* Reliability of skin-type self-assessment: agreement of adolescents' repeated Fitzpatrick skin phototype classification ratings during a cohort study. *J Eur Acad Dermatol Venereol* 2012; **26**:1396–9.
18 Roberts WE. Skin type classification systems old and new. *Dermatol Clin* 2009; **27**:529–33, viii.
19 Lachin JM. A review of methods for futility stopping based on conditional power. *Stat Med* 2005; **24**:2747–64.
20 Thorpe KE, Zwarenstein M, Oxman AD *et al.* A pragmatic-explanatory continuum indicator summary (PRECIS): a tool to help trial designers. *CMAJ* 2009; **180**:E47–57.
21 Shahin ES, Dassen T, Halfens RJ. Incidence, prevention and treatment of pressure ulcers in intensive care patients: a longitudinal study. *Int J Nurs Stud* 2009; **46**:413–21.
22 Tayyib N, Coyer F, Lewis PA. A two-arm cluster randomized control trial to determine the effectiveness of a pressure ulcer prevention bundle for critically ill patients. *J Nurs Scholarsh* 2015; **47**:237–47.
23 Kalowes P, Messina V, Li M. Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit. *Am J Crit Care* 2016; **25**:e108–19.
24 Schaller SJ, Anstey M, Blobner M *et al.* Early, goal-directed mobilisation in the surgical intensive care unit: a randomised controlled trial. *Lancet* 2016; **388**:1377–88.
25 Allingstrup MJ, Kondrup J, Wiis J *et al.* Early goal-directed nutrition versus standard of care in adult intensive care patients: the single-centre, randomised, outcome assessor-blinded EAT-ICU trial. *Intensive Care Med* 2017; **43**:1637–47.
26 Girardis M, Busani S, Damiani E *et al.* Effect of conservative vs. conventional oxygen therapy on mortality among patients in an intensive care unit: the oxygen-ICT randomized clinical trial. *JAMA* 2016; **316**:1583–9.
27 Manzano F, Navarro MJ, Roldan D *et al.* Pressure ulcer incidence and risk factors in ventilated intensive care patients. *J Crit Care* 2010; **25**:469–76.
28 Marshall C, Shore J, Arber M *et al.* Mepilex border sacrum and heel dressings for the prevention of pressure ulcers: a NICE medical technology guidance. *Appl Health Econ Health Policy* 2019; **17**:453–65.
29 Santamaria N, Gerdtz M, Kapp S *et al.* A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial. *Int Wound J* 2018; **15**:482–90.
30 Kottner J, Raeder K, Halfens R, Dassen T. A systematic review of interrater reliability of pressure ulcer classification systems. *J Clin Nurs* 2009; **18**:315–36.
31 Levy A, Gefen A. Assessment of the biomechanical effects of prophylactic sacral dressings on tissue loads: a computational modeling analysis. *Ostomy Wound Manage* 2017; **63**:48–55.
32 Call E, Pedersen J, Bill B *et al.* Enhancing pressure ulcer prevention using wound dressings: what are the modes of action? *Int Would J* 2015; **12**:408–13.
33 Cortés OL, Salazar-Beltrán LD, Rojas-Castañeda YA *et al.* Use of hydrocolloid dressings in preventing pressure ulcers in high-risk patients: a retrospective cohort. *Invest Educ Enferm* 2018; **36**:e11.
34 Forni C, D'Alessandro F, Gallerani P *et al.* Effectiveness of using a new polyurethane foam multi-layer dressing in the sacral area to prevent the onset of pressure ulcer in the elderly with hip fractures: a pragmatic randomised controlled trial. *Int Wound J* 2018; **15**:383–90.
35 Haesler E, Kottner J, Cuddigan J. The 2014 International Pressure Ulcer Guideline: methods and development. *J Adv Nurs* 2017; **73**:1515–30.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website:

Table S1 Demographic and sample characteristics at baseline.

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