ORIGINAL CLINICAL REPORT

OPEN

Effect of Hospital Linens on Unit-Acquired Pressure Injuries for Adults in Medical ICUs: A Cluster Randomized Controlled Trial

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OBJECTIVES: Researchers have shown in laboratory studies that different types of fabrics were associated with changes in skin moisture, friction, shear, and temperature that may predispose patients to pressure injury. There was an association between type of fiber used in hospital linens and pressure injury development in previous clinical studies. We examined if bed linens made from a newly developed synthetic fiber fabric affected occurrence rate, time to development, and severity of unit-acquired pressure injury in critically ill adult inpatients.

DESIGN: Cluster randomized controlled trial.

SETTING: Five adult medical ICUs within one quaternary care center in the Midwest United States.

PATIENTS: Patients were assigned to a unit based on bed availability. In total, there were 3,332 patients in the study.

INTERVENTIONS: Participating medical ICUs were randomly assigned to cotton fiber or synthetic fiber linens for the first 6 months of the study period, and assignment reversed after a 14-day washout period for the final 6 months.

MEASUREMENTS AND MAIN RESULTS: Unit-acquired pressure injury occurrence rate, time to first unit-acquired pressure injury, and severity were evaluated using generalized mixed effect models with patient as a random effect, and a marginal Cox proportional hazards model with repeated admissions from the same patient accounted for by use of a sandwich estimator of the variance. There were 1,706 patients on cotton fiber linens and 1,626 patients on synthetic fiber linens. Groups were similar on demographics except race and admitting diagnosis groupings. Occurrence rate ($p = 0.99$), time to development ($p = 0.99$), and maximum severity of unit-acquired pressure ($p = 0.86$) were similar between groups before and after controlling for race and admitting diagnosis groupings.

CONCLUSIONS: Linen type did not affect unit-acquired pressure injury occurrence rate, severity, or timing. Standard unit-acquired pressure injury prevention efforts may be more cost-effective than investment in synthetic fiber linens.

KEY WORDS: bedding and linens; clinical trial; intensive care units; occurrence rate; pressure ulcer; prevention

Pressure injuries are a global healthcare concern and pressure injury prevention has become a priority across all healthcare settings. Patients in critical care settings are at greater risk for developing pressure injuries than those in noncritical care settings (1, 2). Age, mobility, perfusion, and

DOI: 10.1097/CCE.0000000000000336

vasopressor use are significant predictors for pressure injury development in the ICU environment among other factors (3, 4), and ICU mortality risk is greater for patients presenting with an existing pressure injury (5). Mortality for older adults is two times higher for those with a pressure injury compared with those without (6). The Hospital Value-Based Purchasing Program initiated by the Department of Health and Human Services rewards hospitals for the quality of care they provide and no longer reimburses hospitals for treating stage 3 and 4 hospital-acquired pressure injuries (HAPIs) (7). Researchers using simulation models plus cost data from existing literature estimated that costs in the United States related to HAPIs could surpass $26.8 billion annually based on estimates that it costs $10,708 to treat patients that develop a pressure injury while hospitalized (8). Prevention of HAPI and subsequent complications are important quality of life issues for patients and financial issues for hospitals.

Cotton fiber fabrics used in hospital linens were implicated in HAPI development due to changes in skin-to-fabric shear force that occurs in a more humid dermal microclimate (9, 10). Fabrics made of synthetic fibers were developed for the purpose of altering microclimate and thus reducing shear force that contributes to HAPI. Researchers demonstrated that fabrics made of cotton or synthetic fibers alter dermal microclimate in different ways (11). Studies conducted to evaluate the effect of bed linens made from synthetic fibers on HAPI development in the acute care setting were mostly positive. Researchers using retrospective chart review found a significant association between HAPI and linen type after ICU and medical-surgical unit switched from standard cotton linens to synthetic linens (12, 13). Authors reporting on two separate quasi-experimental sequential design studies involving patients admitted to a medical unit and patients admitted to a critical care unit found decreases in HAPI when cotton linens were replaced with synthetic linens and a subsequent increase in HAPI when cotton linens were returned (14). Researchers reported a significant association between HAPI occurrence rates based on linen type for pooled cohort results in both studies. Experimental research on the effect of linen type on HAPI in the medically ill critical care patient population is absent from the literature. Our prospective, experimental study was designed to evaluate the effect of bed linen fabric type on unit-acquired pressure injuries (UAPIs) in a large sample of medically ill critical care patients.

SPECIFIC AIMS

The primary aim of this study was to compare the occurrence rate of UAPI for patients using traditional cotton linens and newly developed synthetic linens. Secondary aims were to compare time to develop the first UAPI and maximum severity of UAPI.

METHODS

This was a cluster randomized controlled trial.

Setting and Sample

Five medical ICUs (MICUs) within a large quaternary care medical center located in the Midwestern United States participated. All units reported to a single nursing director but each unit had their own nursing management team. Clinical nurses were hired onto specific units but floated to other units to meet staffing needs. Physician staff (attending physicians, fellows, residents, interns) were assigned to teams in each unit and reported to a single medical director. Staffing patterns and level of training were identical across units. All staff members had extensive and on-going training in pressure injury assessment and prevention techniques and wound care treatment. Patient admission criteria for units were identical.

Patients were admitted to a specific MICU based solely on bed availability by hospital admitting personnel. Units were randomly assigned to control or experimental arm for 6 months at the beginning of the study with the experimental and control linen assignments switched after a 14-day washout period. During washout, the new experimental units were oriented to the synthetic linens and the new control units returned to standard cotton linens used prior to the study. All patients admitted to one of the five units after the study period commenced were included. Patients excluded from analysis were those who were placed in prone position anytime during their MICU stay, admitted for less than 24 hours, readmitted to the MICU during the same hospitalization, or admitted during the washout period. Data for patients transferred from one study unit to another unit were used only if the receiving unit was in the study arm as the sending unit.

The Institutional Review Board of the Cleveland Clinic Foundation approved this study (number 13-752) as minimal risk research with a waiver of informed consent prior to study initiation.

Sample size calculations were performed for the primary endpoint of UAPI rate using historical data from these units and the sample size simulation program described by Reich et al (15). It was assumed that 8.7% of patients using cotton linens would develop UAPI and that multiple UAPI would result in a 10% increase in the total number of observed UAPI. We assumed that MICU mean length of stay would be 5 days leading to an estimated UAPI rate of 1.9 per 100 patient days. It was expected that across the five MICUs, the monthly enrollment would be 720 patients and that a conservative 20% of patients might fail to meet inclusion criteria. It was also expected that a 30% decrease in UAPI would be clinically relevant even though in unpublished studies by the synthetic linens manufacturing company, a 50% or higher decrease in UAPI with synthetic linens was found. Enrollment and data collection were estimated to be 3 months per study period and a between cluster variance of 0.01. Based on assumptions and expectations, there would be 80% power to detect decreases of 35% or larger even if the baseline UAPI rate was 25% less than expected (1.43 per 100 unit days). A sample size of 3,456 patients was estimated.

Intervention

The intervention was bed linens marketed under the name DermaTherapy by Standard Textile (Cincinnati, OH) that were applied to the standard MICU bed used in all units. The linens are made from synthetic fibers woven to create an ultra-smooth, silk-like fabric. All nursing staff members were trained on application of the synthetic linens, study aims, and safe patient handling when using the linens. Synthetic linens were maintained during all days of care in patients randomized to the intervention units, with one exception, transfer to the operating room. Upon return from the operating room to the intervention units, synthetic linens were reapplied. The control arm was standard cotton linens. Bed linens in both groups included pillow case, draw sheet, top sheet, and fitted sheet that fit standard and bariatric hospital beds. Bed linens were changed daily and on an as-needed basis, and both linen types were laundered by the hospital laundry service using the same laundry services and supplies. Air-permeable absorbent dry pads were allowable in both groups when needed for excessive excretions. Linen carts were populated with the linen type per unit assignment. Staff were discouraged from using linens from another unit. Research nurses rounded on all five units daily for 2 months, including weekends and holidays, to assure that units received the assigned linens, and disruptions in the linen distribution process were minimal. Monitoring was reduced after 2 months and discontinued after units changed their linen assignments at 6 months as the intervention was implemented with high fidelity.

Education of all nurses was standardized. All newly hired MICU nurses completed an ICU residency class that included 2 hours of skin/wound care. Nurses interested in functioning as a unit-based skin care resource nurse completed an 8-hour class devoted to skin and wound care, pressure injury staging, atypical wounds, and negative pressure wound therapy. Hands-on practice allows nurses to apply negative pressure dressings and insert external fecal containment devices. The wound team provided real time wound education with the nursing staff when they consulted on patients in the unit. Additionally, MICU nurses participated in pressure injury prevention rounds, which provided knowledge reinforcement.

Outcomes and Data Collection

The MICU nurses assessed patients' skin at unit admission and every shift as standard practice and documented their assessment in the electronic medical record (EMR) that was date and time-stamped. Certified wound ostomy continence (WOC) nurses were available for consultation if nurses were unsure how to stage or describe a wound. Pressure injuries were documented using the National Pressure Injury Advisory Panel's staging classification system (16). Hospital protocol required clinical nurses to document all stages of pressure injuries in the EMR. The WOC nurse was consulted for all HAPI and higher stage pressure injuries that were present at admission. In cases in which WOC nurse had documented wound staging, their assessment was used in place of the documented stage entered by clinical nurses. Only UAPIs that were on body surfaces in regular contact with bed linens were abstracted from the EMR, thus excluding UAPIs caused by tubing, devices, dressings, and

drains. Data were only collected on UAPI, not preexisting pressure injuries. Trained research nurses examined every patient every day for the first 6 months of the trial to ensure that clinical nurses were accurately describing wounds in the EMR and to ensure consults to wound care nurses were requested when needed. Data were abstracted from the EMR after patients were discharged.

Factors that may impact study outcomes were abstracted from a billing database and the EMR. These included admitting diagnosis, length of stay, admitting source (emergency department, direct admission, internal or external transfer), and patient characteristics of age, sex, and race. Variables abstracted from the EMR within the first 24 hours of admission were weight, Braden score (lower score reflects greater risk for skin breakdown), laboratory values (albumin, total protein when available at admission), and medical comorbidities used in the Charlson Comorbidity Index (higher comorbidity index and raw score reflect higher morbidity rates). The Acute Physiology and Chronic Health Evaluation (APACHE) III score, a mortality prediction model calculated on every patient within the first 24 hours of admission, was retrieved from a Medical Operations database.

Statistical Methods

Data were summarized using frequencies and percentages for categorical factors and means and SDs for continuous measures. Comparisons of factors across patient groups were performed using Pearson chi-square tests for unordered factors, Wilcoxon rank-sum tests for ordered factors, and two-sample *t* tests for continuous measures. Missing data were imputed using fully conditional specification methods for arbitrary missing data patterns. All categorical factors were imputed using a generalized logit for unordered variables, while ordered factors used a cumulative logit link function. Ten imputation datasets were created using all demographic variables, group, and primary outcome variables, as the missing data rate was low, at ~10%. Comparisons of groups were made using generalized linear models and combined across datasets. The percentage of patients with at least one UAPI and the rate of UAPI injuries per 1,000 patient days (number of UAPI/MICU length of stay) were calculated. Mixed effect logistic and Poisson regression models were used to evaluate differences in the occurrence rate and rate of occurrence of UAPI, respectively. In these models, a random effect for patient was included to account for multiple admissions by the same patient in the study. Time to first UAPI was evaluated using a marginal Cox proportional hazards model after adjusting for diagnosis and race. In this model, the effect of repeated admissions from the same patient was accounted for by use of a sandwich estimator of the variance. Analyses were performed using SAS software (Version 9.4; SAS Institute, Cary, NC). A significance level of 0.05 was assumed for all analyses.

RESULTS

A total of 3,332 patients were enrolled, 1,706 in the cotton linen and 1,626 in the synthetic linen groups. **Figure 1** presents patient allocation. Patients were fairly evenly matched by treatment group, only race and diagnostic categories differed. The synthetic linen group had more African Americans and patients with respiratory or hematologic admitting diagnoses compared with the cotton-linen group. Baseline demographic data are presented in **Table 1**.

The UAPI rate during the study period was similar to the historical UAPI rate immediately prior to study initiation. The number of UAPI among study participants was 87 (synthetic linens $n = 41$ vs cotton linens $n = 46$), and there were no differences in UAPI rates between synthetic and cotton-linen groups after adjusting for time period, race, and diagnosis ($p = 0.99$). There were also no differences in time to develop the first UAPI (4.65/1,000 patient days for synthetic vs 4.89/1,000 patient days for cotton linens; $p = 0.80$) and maximum severity of UAPI in the MICU (stage 1–2: 34 for synthetic vs 30 for cotton linens; stage 3–4: 2 for synthetic vs 1 for cotton linens; unadjusted $p = 0.81$; adjusted $p = 0.86$) (**Fig. 2**). Despite controlling for race differences between groups, African American patients had lower odds of UAPI compared with other races (**Table 2**). There was no difference in UAPI occurrence rate based on pre- versus post-intervention crossover washout period ($p = 0.45$).

DISCUSSION

Characteristics of patients in our sample were similar to those reported in the literature. Patients' mean age and sex were similar to other reports (12, 17–19), suggesting that our findings are generalizable based

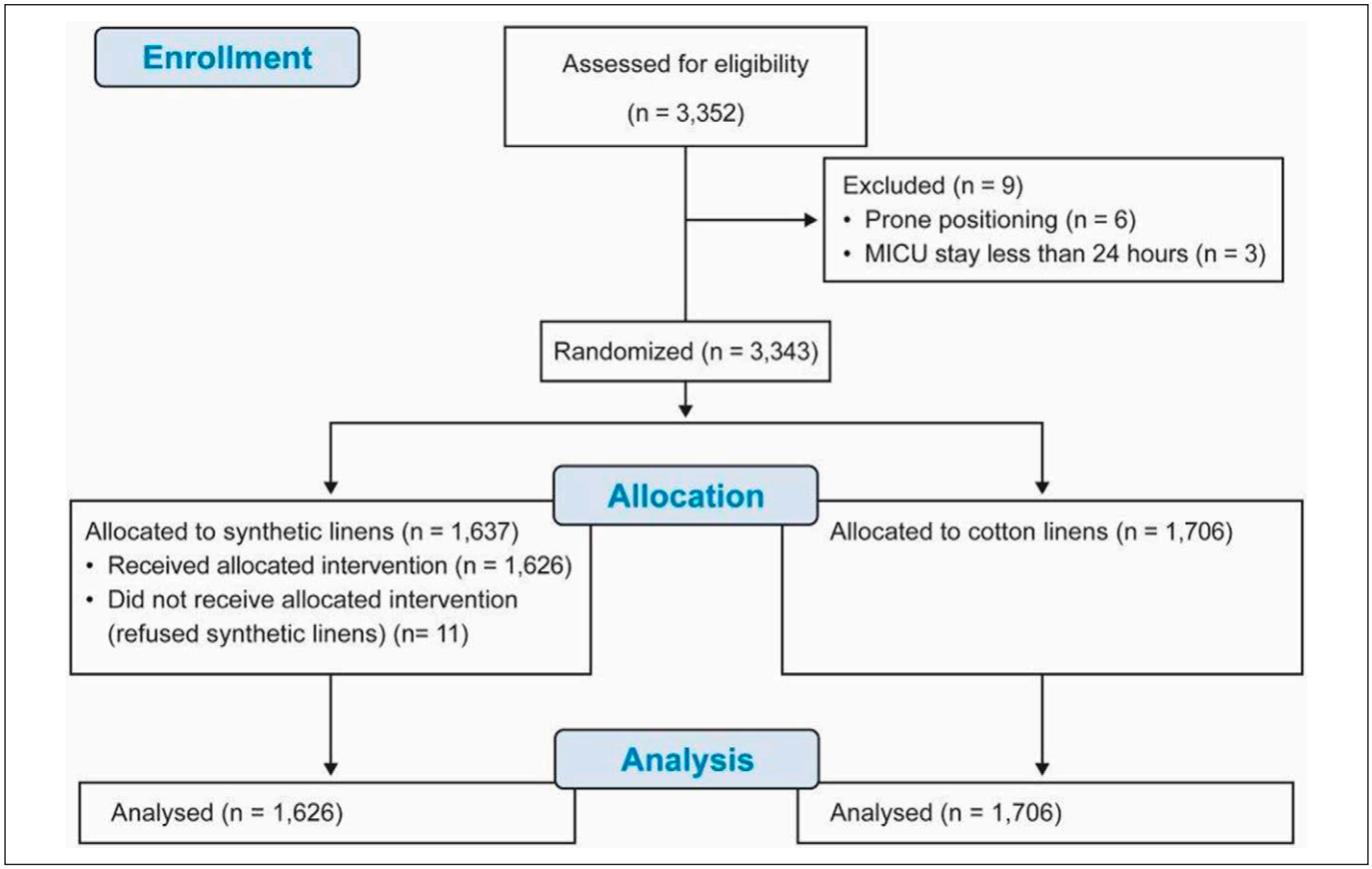

Figure 1. Patient flow chart. MICU = medical ICU.

on demographics. Our mean APACHE III score was also congruent with results from other published studies (20–22), representing the high acuity of patients in this study; therefore, this patient sample should be at greater risk for UAPI based on acuity (1).

In our study, the UAPI occurrence rate, time to develop UAPI, and severity of UAPI in the MICU were similar by linen group. Our UAPI occurrence rate of 2.70% per patient on cotton sheets was lower than the pooled estimates of the 95% CI rate of 10–25.9% reported by Chaboyer et al (23) and lower than UAPI rates in critical care settings (24); however, our rates were based on HAPI occurrences that involved body parts in contact with linens, not all HAPI. Our HAPI occurrence rate was also lower than that of reports of the impact of bed linens on UAPI (13, 14). We hypothesized that this most likely reflected the emphasis placed on high quality routine skin assessments and prevention strategies that were in place prior to initiation of the research study. Alternately, organizational factors may have an impact on UAPI rates but were not taken into account in their pressure injury research (24, 25). If our hypothesis is true that UAPI rates are a microcosm of caregiver and organizational factors, the type of linen used would not be a differentiating factor in UAPI development. Although our hospital's low UAPI occurrence rate at baseline could have represented a basement effect, there was a null effect that represented no trend that synthetic linens were responsible for HAPI on body surfaces that touched linens. We believe that no additional recruitment would likely lead to a significant finding. It is possible that in other sites that initiated research on bed linens, use of new bed linens could have prompted caregivers to alter assessment or interventions associated with HAPI occurrence rate (Hawthorne effect), especially since their HAPI occurrence rates were high prior to study initiation.

Only three reports were found in the literature on linen type and UAPI rates in the acute care setting. Our findings differed from those by other authors who found that synthetic linens led to a decrease in UAPI rates compared with usual-care cotton linens in the ICU setting (12–14). Differences between our findings and that of other researchers may be due to

TABLE 1.
Summaries of Demographic Characteristics From Imputed Datasets

Baseline Factors	Total (*n* = 3,332)	Cotton (*n* = 1,706)	Synthetic (*n* = 1,626)	*p*
Age, yr, mean ± SE	60.14 ± 0.28	60.31 ± 0.39	59.97 ± 0.40	0.55[a]
Sex, *n* (%)				
Male	1,766 (53.00)	909 (53.31)	857 (52.69)	0.72[b]
Race/ethnicity, *n* (%)				
White	2,115 (63.48)	1,104 (64.74)	1,011 (62.16)	0.028[b]
Black	1,038 (31.14)	500 (29.28)	538 (33.09)	
Other	179 (5.38)	102 (5.98)	77 (4.74)	
Unit length of stay, d, mean ± SE	6.17 ± 0.12	6.27 ± 0.17	6.07 ± 0.17	0.42[a]
Weight (kg), mean ± SE	85.38 ± 0.54	85.36 ± 0.75	85.40 ± 0.80	0.97[a]
Charlson Comorbidity Index category, *n* (%)				
0	592 (17.75)	282 (16.53)	310 (19.03)	0.56[c]
1–2	1,292 (38.76)	691 (40.51)	600 (36.92)	
3–4	892 (26.76)	440 (25.78)	452 (27.79)	
5 or more	557 (16.73)	293 (17.18)	264 (16.25)	
Acute Physiology and Chronic Health Evaluation III score, mean ± SE	67.20 ± 0.50	66.79 ± 0.71	67.63 ± 0.71	0.40[a]
Admission source, *n* (%)				
External transfer	946 (28.40)	485 (28.43)	461 (28.36)	0.48[b]
Emergency department	1,452 (43.57)	730 (42.81)	721 (44.36)	
Direct admit	80 (2.40)	37 (2.17)	43 (2.65)	
Internal transfer	854 (25.63)	454 (26.58)	401 (24.63)	
Diagnosis categories, *n* (%)				
Cardiovascular	1,068 (32.05)	544 (31.88)	524 (32.23)	0.002[b]
Gastrointestinal	485 (14.56)	261 (15.29)	224 (13.79)	
Respiratory	1,052 (31.56)	523 (30.66)	529 (32.52)	
Hematologic	261 (7.85)	110 (6.47)	151 (9.29)	
Other	466 (13.99)	268 (15.71)	198 (12.18)	
Medical ICU Braden score, mean ± SE	15.43 ± 0.05	15.42 ± 0.07	15.45 ± 0.08	0.82[a]
Protein, g/dL, mean ± SE	6.18 ± 0.02	6.19 ± 0.03	6.17 ± 0.03	0.62[a]
Albumin, g/dL, mean ± SE	3.07 ± 0.01	3.08 ± 0.02	3.05 ± 0.02	0.26[a]

[a]Generalized linear model.
[b]Logistic regression.
[c]Proportional odds logistic regression.

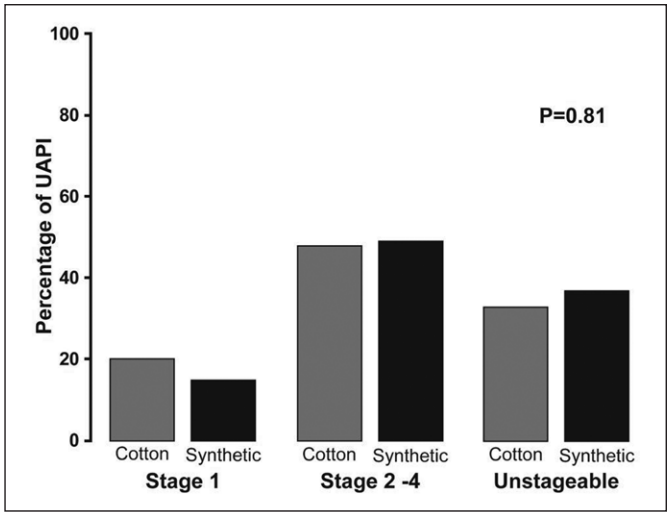

Figure 2. Severity box plot for unit-acquired pressure injuries (UAPIs).

multiple factors. The quasi-experimental sequential (14) and retrospective chart review (12, 13) designs were less robust than our cluster randomized controlled trial. Researcher groups failed to control for differences in patient characteristics or hospital factors between groups (12–14). African American patients in our study were less likely to develop UAPI in both univariate and adjusted analyses regardless of higher numbers in the intervention group; thus, attention to potential group differences is important.

The likelihood for threats to internal validity of findings was greater with less robust designs. In two of the reports discussed above (13, 14), it is unclear if UAPI caused by devices, dressings, tubes, and drains common in ICU settings that would be unrelated to skin surface contact with linens were included in the count of UAPI. Ultimately, the UAPI rates could have been falsely inflated. We purposely excluded UAPI on body surfaces not associated with contact with linens, which could explain our lower UAPI rate.

When designing future research on UAPI based on linen type, our lower rate should be used to calculate an optimal sample size, as it is unknown if larger sample size and, therefore, a larger UAPI rate would have led to separation between groups. Only one report was found in which researchers conducted a multi-site randomized controlled trial that exclusively tested synthetic fiber linens and UAPI rate (26). Despite that study participants were adults treated in nursing homes, the calculated sample size was much smaller than ours, and analysis plans differed, authors found a low rate of UAPI that was similar between groups. The low rates

TABLE 2.
Pressure Injury Occurrence Rate and Time to First Pressure Injury After Adjustment

		Pressure Injury Occurrence Rate		Time to First Pressure Injury	
Parameter	**Level**	**Rate Ratio (95% CI)**	***p***	**Rate Ratio (95% CI)**	***p***
Linen	Cotton	1.00 (reference)		1.00 (reference)	
	Synthetic	1.00 (0.66–1.53)	0.99	1.06 (0.67–1.67)	0.80
Time period	First	1.00 (reference)		1.00 (reference)	
	Second	1.12 (0.73–1.71)	0.61	1.18 (0.75–1.84)	0.47
Body system	Cardiovascular	1.00 (reference)		1.00 (reference)	
	Gastrointestinal	0.66 (0.32–1.37)	0.27	0.95 (0.45–1.98)	0.88
	Respiratory	0.75 (0.47–1.21)	0.24	0.71 (0.43–1.18)	0.19
	Hematologic	0.43 (0.13–1.40)	0.16	0.57 (0.18–1.81)	0.34
	Other	0.66 (0.31–1.38)	0.27	0.70 (0.31–1.59)	0.40
Race	White	1.00 (reference)		1.00 (reference)	
	Black	0.51 (0.30–0.86)	0.012	0.56 (0.33–0.96)	0.03
	Other	0.63 (0.24–1.67)	0.36	0.48 (0.16–1.43)	0.19

of UAPI in both the van Leen et al (26) study and our study could reflect a basement effect and the need for larger sample sizes to truly learn the effect of linen type on UAPI.

Ultimately, synthetic fiber linens were designed to effect HAPI by decreasing shear force through changes to microclimate, providing more air flow and lower humidity. Researchers demonstrated in laboratory and computer models that shear force and microclimate play a role in pressure injury development (10, 11, 27), but load plays a greater role (28). The degree to which shear force and microclimate affects HAPI in the clinical environment has yet to be determined. If the impact of shear force on HAPI is small, then synthetic linens would have minimal influence. The potential benefit of synthetic fiber linens could have been lost during hospital laundry procedures since harsh detergents and high temperatures are typically used: however, based on company communication before we initiated the study, linen fiber properties were retained after 100 washes.

LIMITATIONS

Despite our use of experimental design, large sample size, and multivariable analysis, there are some limitations to our study that need to be addressed. The primary limitation is the setting of one quaternary care medical center. If, as authors suggest (26, 27), organizational and nurse factors are associated with HAPI rates, multicenter studies would help to eliminate the homogeneity found in one site with a strong HAPI assessment and prevention program. Further rigorous research is warranted at sites with less robust HAPI prevention measures and where occurrence rate and prevalence rates are higher. The study population was adult medically ill critical care patients, and results may not be generalizable to other acute care or critical care populations. Blinding patients, caregivers, and study staff to the intervention was not possible. However, MICU assignment was based on bed availability with all patients having equal chance of assignment to control and experimental arms by hospital personnel blinded to the study. The intervention was completed over a 1-year period. Research is needed to learn if the properties within synthetic linens were retained after long-term, repeated, hospital laundry cycles.

CONCLUSIONS

This is the first randomized controlled trial to examine the effect of bed linens on HAPI in the critical care setting. Standard HAPI prevention efforts may be more cost-effective than the investment in synthetic fabric bed linens. Investment in synthetic bed linens may be warranted in settings that lack the organizational and unit-level resources necessary to implement rigorous pressure injury assessment, prevention, and treatment strategies.

ACKNOWLEDGMENTS

We acknowledge Nancy M. Albert, PhD, CCNS, CCRN, FCCM, FAAN, who assisted with study inception and design, analysis interpretation, and revisions made in the article before resubmission and acceptance.

1 Wound Care Consult Team, Cleveland Clinic, Cleveland, OH.

2 Quantitative Health Sciences, Cleveland Clinic, Cleveland, OH.

3 Office of Nursing Research and Innovation, Cleveland Clinic, Cleveland, OH.

This study was jointly sponsored by Standard Textile (Cincinnati, OH) and Precision Fabrics Group (Vinton, VA).

The authors have disclosed that they do not have any potential conflicts of interest.

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This study has been registered with ClinicalTrials.gov: ClinicalTrials.gov Identifier: NCT02925741.

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