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Research paper

Implementation of a risk-stratified intervention bundle to prevent pressure injury in intensive care: A before–after study

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ABSTRACT

Background: Hospital-acquired pressure injury is an enduring problem in intensive care. Several intensive care–specific pressure injury risk assessment tools have been developed, but to date, only the COMHON Index has been aligned with risk-stratified preventative interventions.
Objectives: The aim of this study was to evaluate the effectiveness of a risk-stratified intervention bundle to reduce pressure injury in intensive care and to assess compliance with bundled interventions.
Methods: A controlled before–after study was undertaken. All patients admitted to a single intensive care unit were included. Standard care was provided in the before phase, and the risk-stratified intervention bundle was implemented in the after phase. The primary outcome measure was pressure injury incidence.
Results: The sample comprised 761 intensive care admissions. In the after phase, pressure injury incidence was reduced (2.1% vs 3.9%; 46% relative risk reduction), injury severity was lower, and there were fewer pressure injuries on the sacrum, buttocks, and heels. Logistic regression modelling identified three significant factors associated with pressure injury development: intensive care length of stay (odds ratio: 1.2); COMHON Index admission score (odds ratio: 1.2), and the before phase (odds ratio: 4.2). In the after phase, individual intervention compliance was variable (range: 40%–100%), but the all-or-nothing compliance was poor (33%).
Conclusions: Implementation of bundled preventive measures associated with COMHON Index risk level reduced pressure injury incidence. Likewise, injury severity decreased, and the location of pressure injuries changed following the intervention. The results from this study support the use of risk-stratified interventions to prevent pressure injury in intensive care. However, further research is needed to examine the effectiveness of the COMHON Index bundle before it can be recommended for widespread clinical practice.

1. Introduction

Patients admitted to intensive care units (ICUs) are critically ill and susceptible to adverse events associated with their admission,[1] including hospital-acquired pressure injury (PI). PI has been defined internationally as localised damage to the skin and/or underlying tissue resulting from pressure with or without shear (EPUAP et al., 2019). The severity of such injuries can be categorised

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using a classification system, ranging from Stage 1 PI (non-blanchable erythema) to Stage 4 (full-thickness tissue loss) and unstageable and suspected deep tissue injury; (depths unknown) (EPUAP et al., 2019). PIs may also occur on the mucous membranes as opposed to the skin and may be device related (EPUAP et al., 2019). Compared to acute patients, ICU patients are at a greater risk of developing a PI,[2] with significant consequences for patients including pain and decreased quality of life.[3] For the health system, PIs result in increased length of stay and billions of dollars in treatment costs.[4,5] Internationally, ICU-acquired PI prevalence across over 1100 ICUs and 90 countries has been reported as 16.2%, with a European prevalence of 20%.[6] PI prevention is therefore a crucial component of safe patient care, which requires further improvement in the ICU context.

The vulnerability of ICU patients to PI is due to risk factors associated with critical illness including hypotension, hypoxia, respiratory failure, and haemodynamic instability. Length of stay and intensive treatment–related factors such as ventilation, sedation, and neuromuscular-blocking agent use also contribute to PI risk.[7] Subsequently, PI risk assessment and prevention for critically ill patients should take such factors into account, and setting-specific risk assessment tools are becoming more readily available.[8] The COMHON Index[9,10] is an ICU-specific risk assessment tool, which assesses five components of PI risk: level of COnsciousness (using the Richmond Agitation-Sedation Scale[T1]), Mobility, Haemodynamics, Oxygenation, and Nutrition. These components, or subscales, are scored between 1 and 4 and summed to categorise PI level of risk (low-risk sum score: 5–9; moderate risk: 10–13; high risk: 14–20). The tool is sensitive to small changes in patient condition[9,12] and has demonstrated superior inter-rater reliability when compared to general tools in Spanish (COMHON Index *k*: 0.89–0.93; Braden Scale *k*: 0.74–0.81; Norton Scale *k*: 0.72–0.73)[9] and Australian (sum score intraclass correlation [ICC]: [2,1]; COMHON Index: 0.90; Braden Scale: 0.66; Norton Scale: 0.77; Waterlow score: 0.47)[12] ICU settings, with near-perfect inter-rater reliability in Chinese (ICC: [1,1] 0.973)[13] and Turkish ICUs (ICC: [1,1] 0.998).[14]

However, risk assessment alone does not prevent PI and must be used to inform preventative intervention use. There are many interventions available, including use of support surfaces, repositioning, and prophylactic dressings,[15] with a systematic review indicating that bundling of interventions is effective to prevent PI.[16] More recent studies support this[17–21] and indicate that nursing workload and/or cost may also decrease.[19,22] Although many bundles include risk assessment, most use non-ICU-specific tools and, notably, do not use a risk assessment outcome (i.e., risk score or level) to inform intervention implementation. Rather, many use a "catch all" approach and apply interventions to all patients or those grouped overall as "at risk". Potentially, this may result in either underuse of interventions, placing patients at risk of harm, or overuse, incurring a resource burden.[23]

There is a need to provide support and guidance for PI-preventative intervention use in the ICU, based on a setting-specific risk assessment,[24], which is particularly relevant, given that ICU nurses' PI prevention knowledge and practice is often found to be lacking.[25–27] Recently, a risk-stratified bundle of PI interventions, using the COMHON Index, was developed via professional consensus with PI experts from 35 countries.[24] Expert consensus matched evidence-based PI-preventative interventions, identified via systematic review,[15] to the COMHON Index levels of risk. It was developed with the intention to guide clinicians to implement a set of evidence-based interventions, providing a minimum set of PI-preventative interventions, which could then be individualised based on the assessment of individual patient risk factors using clinical judgement. To emphasise, individualisation is particularly important; a risk-stratified bundle approach offers a set of interventions, which can be applied relative to individual risk, ensuring a *minimum* level of patient safety,[24] particularly where in practice PI prevention measures or clinician knowledge may be lacking.[25–27] From this point, interventions are able to be adapted or varied based on the patient's specific risk factors if necessary. This approach is more nuanced to individualisation than bundles that apply interventions to all patients while also minimising resource misuse. However, to date, effectiveness of the COMHON Index bundle has not been tested in practice.

1.1. Aim

Against the background described earlier, the primary aim of this study was to evaluate the effectiveness of a risk-stratified intervention bundle to reduce PI in the ICU. The secondary aim was to assess compliance with implementation of the COMHON Index bundle.

2. Methods

2.1. Design

A before–after study was designed to evaluate the effectiveness of using the risk-stratified bundle to reduce PI in the ICU. The study was conducted between January and August 2023. The before and after phases were 3 months' duration, separated by a 2-month wash-out period to prevent cross-contamination between phases. Education sessions were conducted during the wash-out period to prepare nursing staff members to use the bundle. In both the phases, the COMHON Index (version 2.1; available in several languages via https://wfccn.org/comhon-index) was used to assess PI risk. During the before phase (January–March 2023), standard PI prevention practice was provided for all patients, and baseline and PI incidence data were collected. In the after phase (June–August 2023), the bundle was implemented for all patients. Based on the PI risk level, between four and 11 interventions were mandated for each patient. As the risk-stratified bundle was not designed to prevent device-related PIs, they were not included. Thus, the primary outcome measure was PI incidence (any location; excluding device-related PIs), defined as the number of ICU episodes (admissions), where $\geq$1 PI of any stage was acquired out of total episodes across the study periods.

2.2. Setting and sample

The setting was a 22-bed general ICU in Granada, Spain, with around 1300 admissions annually. Admission criteria are based on national and international scientific society recommendations.[28] All patients admitted to the ICU during the before and after phases were eligible for inclusion in the study, including those with an existing PI on admission to the ICU (the COMHON Index does not score existing PIs). Demographic data, such as age, gender, previous PI, body mass index, Acute Physiology and Chronic Health Evaluation (APACHE) II, and Sequential Organ Failure Assessment (SOFA) admission scores, were collected on admission to the ICU to enable baseline comparison between the phases.

2.3. Standard practice

In the study ICU, in the before phase, standard PI prevention practice was to assess PI risk using the COMHON Index and apply preventative measures, such as heel off-loading and repositioning, following the recommendations set out in local protocols adapted from the international guideline.[29,30] Interventions were

implemented based on nurses' clinical judgement of individual patients. All ICU beds were equipped with active support surface mattresses.

2.4. Intervention

In the after phase, the risk-stratified intervention bundle was implemented for all patients. It mandates a minimum intervention set for each risk level (see Supplementary File 1: Appendix). However, interventions may be excluded if contraindicated. The bundle mandates a minimum set of interventions according to the risk level; however, additional interventions should always be considered based on nurses' clinical judgement and assessment of individual patient risk factors.

2.5. Data collection

Twice weekly, project nurses reviewed each patient's chart (admitted on the day and in the preceding days since the last chart review) to verify and note the presence of any ICU-acquired PI. The project nurses each had over 20 years' experience in the ICU, with extensive experience of chart review and data collection, including several studies using the COMHON Index. Charts were subsequently reviewed twice weekly for the duration of their ICU admission. The project nurses met regularly throughout the project to review data collection and resolve any data discrepancies. Follow-up was ceased at 30 days, or at ICU discharge or death, whichever occurred first. If a patient was readmitted to the ICU at a later date, the readmission was recorded as a new ICU admission (i.e., a new episode of care). In the after phase, twice weekly, project nurses recorded each patient's PI risk level and compliance (yes/no) with the COMHON Index bundle interventions. When an ICU-acquired PI was identified, its presence and stage were verified by project nurses who followed up the stage of the injury during chart reviews until the end of follow-up. Each PI was recorded only once, with its most severe stage recorded as the final outcome. Time to PI was recorded as the time taken to develop the initial injury, regardless of the final stage.

2.6. Data analysis

Data were analysed using IBM SPSS Statistics for Windows, Version 28.0 (IBM Corp: Armonk, NY).[31] The unit of analysis was ICU episodes of care (admissions). For each phase, PI incidence (any location and stage; excluding device-related PIs) was calculated using the formula (numerator/denominator) x 100%, where the numerator is the number of episodes with $\geq$1 ICU-acquired PI and the denominator is the total number of ICU episodes. Baseline characteristics are described using mean (M) with standard deviation (SD) for scale variables and proportions (%) for categorical variables. The exact ICU length of stay (days) was calculated using ICU admission and discharge dates and times. Differences were analysed using *t*-tests for scale variables and Chi square or Fisher's exact tests for categorical variables. The primary outcome measure (PI incidence) was analysed using Fisher's exact test. Direct logistic regression (forced entry) was used to determine predictive factors for ICU-acquired PI. This approach is used when there are a small number of predictor variables and when it is unclear which of the variables will best predict the outcome.

The area under the receiver operating characteristic curve (AUC) was used to summarise the overall accuracy of the COMHON Index admission score, with optimal cut-off scores determined using the Youden's index. The AUC was compared between the before and after phases. Performance of the COMHON Index was further summarised using sensitivity, specificity, and positive and negative predictive values. As calculated by Cobos-Vargas et al.,[32] risk ratios were calculated to compare the risk of PI development between patients at high risk (score $\geq$14) and those at lower risk.

In the after phase, compliance for each intervention for each risk level was assessed using proportions. If an intervention was contraindicated or deemed to be not applicable or an alternative intervention was used, the intervention was assessed as being compliant. Unless contraindicated, bundled interventions should be applied for all patients all of the time,[33] according to their risk level. Differences in all-or-nothing compliance rates were analysed using the Chi square test, and differences in overall compliance were analysed using one-way analysis of variance. Compliance with individual interventions was described using proportions, and differences were analysed using Chi square or Fisher's exact tests. Missing data were excluded from analyses.

2.7. Ethical approval

Patient participants (or their legal representative) were provided with oral and written information and provided signed informed consent. Formal ethics approval was received from the Biomedical Research Ethics Committee of Granada (reference: 0368-N-23).

3. Results

3.1. Sample characteristics

There were 761 ICU admissions, of which 50.2% ($n = 382$) were in the before phase. On admission, the sample characteristics of the before and after phases were similar (see Table 1), and proportions in the low- (63.1% vs 64.4%), moderate- (25.4% vs 23.7%), and high-risk (11.5% vs 11.9%) categories were similar ($p = 0.869$).

3.2. ICU-acquired pressure injuries

Excluding device-related PIs, ICU-acquired PI incidence in the before phase was 3.9% (15/382), compared to 2.1% (8/379) in the after phase ($p = 0.203$). Although the rates are low, this represents a 46% relative risk reduction between the phases. In the after phase, patients who developed PI had significantly higher admission APACHE II ($p < 0.001$) and SOFA scores ($p < 0.001$) and longer ICU stays ($p < 0.001$). In both the phases, patients with PI had significantly higher COMHON Index admission scores ($p < 0.001$ and $p < 0.001$) and higher mortality ($p = 0.006$ and 0.025). See Table 2.

Across both the phases, there were 45 ICU-acquired PIs (25 PIs in 15 patients in the before phase and 20 PIs in eight patients in the after phase). See Table 3. A third (32.0%, $n = 8$) of PIs in the before phase were Stage 3, compared to 5.0% ($n = 1$) in the after phase. However, there was double the proportion of Stage 2 PIs in the after phase (60.0%, $n = 12$ versus 28.0%, $n = 7$). Most PIs in the before phase were located on the sacrum or buttocks (56.0%, $n = 14$), of which three were Stage 3, whereas a smaller proportion was found in these areas in the after phase (40.0%, $n = 8$), and none were Stage 3. There was only one Stage 1 heel PI and no hip PI in the after phase, compared to two Stage 1 and one Stage 3 heel PIs and one Stage 2 hip PI in the before phase. There were fewer occipital PIs in the before phase ($n = 2$)—although one was Stage 3—than in the after phase ($n = 5$), which had no Stage 3 injuries. Of the eight patients in the before phase who were admitted to the ICU with an existing PI, only one subsequently developed a single ICU-acquired PI. None of the four patients in the after phase who were admitted with an existing PI developed an ICU-acquired PI. Time to PI was longer in the after phase (M: 14 days, SD: 7) than in the before phase (M: 10 days, SD: 7) ($p = 0.095$).

Table 1
Sample characteristics ($n = 761$).

		Before	After	Significance p
Intensive care admissions % (n)		50.2 (382)	49.8 (379)	–
Age in years, mean (SD)		63.2 (15.4)	63.9 (16.0)	0.513[1]
Gender % (n)	Male	65.4 (250)	60.9 (231)	0.226[2]
	Female	34.6 (132)	39.1 (148)	
*Previous history of pressure injury, % (n)		0.5 (2/374)	1.3 (5/374)	0.448[3]
Pressure injury present on admission, % (n)		2.1 (8/382)	1.1 (4/379)	0.384[3]
**Body mass index, mean (SD), n		27.5 (4.7), 382	27.9 (6.0), 376	0.364[1]
APACHE II admission score, mean (SD), n		10.1 (7.9), 382	9.9 (5.1), 379	0.694[1]
SOFA admission score, mean (SD), n		4.3 (2.3), 382	4.1 (2.5), 379	0.274[1]
COMHON Index admission score, mean (SD), n		9.4 (3.5), 382	9.3 (3.5), 379	0.827[1]
Intensive care length of stay (days), mean (SD), n		3.1 (3.7), 382	3.4 (5.1), 379	0.405[1]
Mortality % (n)		8.6 (33/382)	8.7 (33/379)	1[3]

*missing data $n = 13$, **missing data $n = 3$, [1]t-test, [2]Chi square test, [3]Fisher's exact test.
APACHE: Acute Physiology and Chronic Health Evaluation; COMHON: COnsciousness, Mobility, Haemodynamics, Oxygenation, and Nutrition; SD: standard deviation; SOFA: Sequential Organ Failure Assessment.

Table 2
Characteristics of patients with and without ICU-acquired pressure injury by phase.

			No pressure injury	Pressure injury present	Significance p
Mean age in years (SD), n		Before	63.0 (15.4), 367	66.9 (15.8), 15	0.337[2]
		After	64.0 (16.0), 371	62.1 (14.1), 8	0.745[2]
Gender % (n)	Male	Before	96.0 (240)	4.0 (10)	1[1]
	Female		96.2 (127)	3.8 (5)	
	Male	After	97.0 (224)	3.0 (7)	0.157[1]
	Female		99.3 (147)	0.7 (1)	
*Previous history of pressure injury % (n/N)		Before	0.6 (2/359)	0 (0/15)	1[1]
		After	1.1 (4/367)	14.3 (1/7)	0.091[1]
Pressure injury present on admission % (n/N)		Before	1.9 (7/367)	6.7 (1/15)	0.276[1]
		After	1.1 (4/371)	0 (0/8)	1[1]
**Mean body mass index (SD), n		Before	27.6 (4.7), 367	26.1 (5.1), 15	0.243[2]
		After	27.9 (6.0), 368	26.6 (4.6), 8	0.529[2]
APACHE II admission score (SD), n		Before	9.9 (7.9), 367	13.8 (7.7), 15	0.063[2]
		After	9.7 (4.9), 371	18.9 (4.2), 8	< 0.001[2]
SOFA admission score (SD), n		Before	4.3 (2.3), 367	4.1 (2.4), 15	0.706[2]
		After	4.0 (2.4), 371	8.9 (2.4), 8	< 0.001[2]
COMHON Index admission score (SD), n		Before	9.2 (3.5), 367	12.3 (3.4), 15	< 0.001[2]
		After	9.2 (3.4), 371	16.0 (2.5), 8	< 0.001[2]
Intensive care length of stay (days), SD, n		Before	3.0 (3.3), 367	7.2 (8.5), 15	0.073[2]
		After	2.9 (3.4), 371	28.5 (6.8), 8	< 0.001[2]
Mortality % (n/N)		Before	7.6 (28/367)	33.3 (5/15)	0.006[1]
		After	8.1 (30/371)	37.5 (3/8)	0.025[1]

*Missing data $n = 13$, **Missing data $n = 3$, [1]Fisher's exact test, [2]t-test, [3]Chi square test
APACHE: Acute Physiology and Chronic Health Evaluation; COMHON: COnsciousness, Mobility, Haemodynamics, Oxygenation, and Nutrition; ICU: intensive care unit; SD: standard deviation; SOFA: Sequential Organ Failure Assessment.

Table 3
Characteristics of pressure injuries ($n = 45$).

		Site											
	Pressure injury stage	Sacrum	Buttock	Heel	Occiput	Elbow	Back	Ankle	Hip	Foot	Thigh	Other	**Total**
Before	Stage 1	6		2	1			1					**10**
	Stage 2	3	2				1		1				**7**
	Stage 3	2	1	1	1	2						1	**8**
	Total	**11**	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**0**	**0**	**1**	**25**
After	Stage 1	1		1	3	1				1			**7**
	Stage 2	4	3		2		2				1		**12**
	Stage 3					1							**1**
	Total	**5**	**3**	**1**	**5**	**2**	**2**	**0**	**0**	**1**	**1**	**0**	**20**

To determine predictive factors associated with ICU-acquired PI, a logistic regression model was tested, which contained four scale (APACHE II score, SOFA score, COMHON Index score, ICU length of stay) and one categorical (before/after phase) predictor variables. The predictor variables entered into the model were those found to be associated with PI (see Table 2). The full model was statistically significant (X^2 [5, $n = 761$] = 65.98, $p < 0.001$) and explained between 8.3% (Cox and Snell R square) and 35.0% (Nagelkerke R squared) of the variance in PI incidence and correctly classified 97.0% of cases. Three variables made a unique statistically significant contribution. The strongest predictor of PI was ICU length of stay; for each additional day in the ICU, patients were 1.2 times

more likely to develop an ICU-acquired PI (odds ratio [OR]: 1.17, 95% confidence interval [CI]: 1.11–1.24; $p < 0.001$). Similarly, for each point increase in the COMHON Index admission score, patients were 1.2 times more likely to develop a PI (OR: 1.16, 95% CI: 1.02–1.32; $p = 0.025$). Patients in the before phase were over four times more likely than those in the after phase to develop a PI (OR: 4.26, 95% CI: 1.27–14.34; $p = 0.019$).

3.3. Sensitivity and specificity

The AUC was calculated for each phase. In the before phase, the AUC was acceptable (76.9%, 95% CI: 66.0–87.8) but was outstanding in the after phase (92.9%, 95% CI: 89.4–96.5). The difference was significant ($p = 0.006$). The coordinates of each curve were calculated to determine optimal cut-off scores based on sensitivity and specificity and using the Youden's index. In the before phase, the optimal cut-off score to predict PI was $\geq$10, giving a sensitivity of 80.0% and specificity of 64.9%. In the after phase, the optimal cut-off score was $\geq$12, giving a 100% sensitivity and 84.9% specificity. In the before phase, the risk of developing a PI with a score of $\geq$10 was 2.3 times greater, whereas in the after phase, the risk associated with a score $\geq$12 was 6.6 times greater. Predictive accuracy was substantially better in the after phase (85.2%) than in the before phase (65.5%). Values were also calculated based on a cut-off score of $\geq$14 (i.e., high risk), for comparison (see Supplementary File 2: Diagnostic performance of the COMHON Index).

3.4. After phase: Compliance with interventions

In the after phase, following the admission assessment, a further 522 risk assessments were made. Two-thirds (67.1%, $n = 349$) were assessed to be at a low risk (see Table 4). Across all three risk levels, where complete intervention compliance data were available, the overall compliance was 80.7%; however, the all-or-nothing compliance was 32.7% (159/486). The all-or-nothing compliance for each risk level was low and was significantly different between risk levels ($p < 0.001$). It was lowest for moderate-risk cases. Although the overall compliance was good (80.7%), it was lowest for moderate-risk cases (74.8%), and the differences between risk levels were significant ($p < 0.001$).

The compliance rates for each intervention, according to risk level, are shown in Table 4. Compared to other interventions, compliance with 8-hourly risk assessment was particularly low across all risk levels. Although the overall compliance with repositioning frequency was relatively high (86.6%), it was significantly lower in the moderate- and high-risk groups ($p < 0.001$). Heel off-loading compliance was also high, but it was significantly lower in the moderate-risk group than in the high-risk group ($p < 0.001$).

3.5. PI cases: compliance with interventions

There were 15 patients who developed 25 ICU-acquired PIs in the before phase and eight patients who developed 20 ICU-acquired PIs in the after phase. The characteristics of patients that developed PIs in the after phase ($n = 8$) are shown in Table 5. Assessment of intervention compliance is shown based on the most recent assessment of PI risk prior to identification of the PI. In all but one assessment, the intervention compliance was suboptimal. Notably, in all cases where a sacral PI developed, a prophylactic sacral dressing had been implemented. Similarly, in the single case where a heel PI developed, heel off-loading and heel dressings had been implemented.

4. Discussion

The results from this study are encouraging. In terms of the primary outcome of ICU-acquired PI incidence (excluding device-related PI), although the baseline rate of 3.9% was low, use of the intervention bundle resulted in an even lower rate of 2.1% in the after phase. These incidence rates compare very favourably with those reported in the global literature previously.[34–37] In two previous studies, in the same ICU, PI incidence was reported at 15.4%[32] and 21.6%.[38] However, in the former study, only patients with an ICU stay of more than 3 days were included, and in both studies, a significant proportion of patients were admitted with COVID pneumonia. In a pre-COVID study in Spain, the ICU PI incidence was reported as 8.1%.[37] In a recent review, it was concluded that there was physical evidence to suggest that critically ill patients with COVID-19 are at a greater risk of developing PIs due to systemic thrombogenic microvascular injury resulting in compromised blood perfusion to organs such as the skin.[39]

Arguably, the lower the rate is to start with, the harder it is to implement interventions that have a significant impact on reducing it further. Although the absolute risk reduction of 1.8% (the difference between the before and after incidence) is small, it represents a relative risk reduction of 46% (the percentage change between the before and after incidence), with patients in the before phase being over four times more likely to develop an ICU-acquired PI. However, in the after phase, although compliance with individual interventions was good (between 80% and 98%), with the exception of 8-hourly risk assessment (41%), across all risk levels, all-or-nothing compliance was only 33%. Clearly, there is potential for further reduction of ICU-acquired PIs if compliance is improved. The reasons for this poor level of compliance are unclear. The main areas where improvements could be made are around the frequency of risk assessment and repositioning of moderate- and high-risk patients. This may require a cultural shift around these practices. Intervention compliance in the after phase indicates that the 8-hourly assessment frequency was suboptimal (41% overall) and that the repositioning frequency (at least 2-hourly) for moderate- and high-risk patients was also suboptimal (54% and 61%, respectively). As well, heel off-loading was suboptimal for moderate-risk patients (72%). In a previous study, in the same ICU, compliance with 8-hourly risk assessment was better (59–85%), but the repositioning frequency was poor for low- and moderate-risk patients (22% and 20%, respectively), though it was similar for high-risk patients (59%).[38] Potentially, in the current study, nurses may have been actively over-riding the mandated interventions based on their clinical judgement of need, perhaps focussing more on individual patient risk factors. Further qualitative research would help to inform the clinical reasoning behind nursing actions or lack thereof.

When intervention compliance was analysed with respect to the eight patients who developed 20 PIs in the after phase, there was 100% intervention compliance in the assessment review in only one case right before the PI occurred. Arguably, with greater clinical vigilance, it would be relatively simple to improve compliance across all bundle interventions. Previous ICU studies using bundled interventions to prevent PI have reported overall intervention compliance rates of 79%[40] and 78%[20] and between 55% and 60%,[21] though no studies were found that reported all-or-nothing compliance. The overall compliance of 81% found in our study compares favourably.

As well as reducing PI incidence, our results suggest that use of the risk-stratified bundle may be protective to some degree, by helping to delay the onset of PI. Patients who developed ICU-acquired PIs in the after phase were sicker, had higher PI risk scores, and had longer ICU length of stay than those in the before

Table 4
After phase: Compliance with interventions by risk level.

Risk level	Intervention	Sample *N*	Compliance % (*n*)				Significance *p*	Comments
			Low	Moderate	High	Total		
All patients on admission	Pressure injury risk assessment within 2 h of ICU admission	370	*83.1 (196/236)	*76.4 (68/89)	*73.3 (33/45)	*80.3 (297/370)	0.186	Based on risk level assessed at ICU admission
All patients	Pressure injury risk assessed once every 8 h	518	40.1 (139/347)	48.1 (39/81)	35.6 (32/90)	40.5 (210/518)	0.234	If the patient was admitted less than 8 h previously, the intervention was assessed as compliant.
	Incontinence pads	508	99.7 (339/340)	98.8 (79/80)	100 (88/88)	99.6 (506/508)	0.381	Patients were continent in 111 (21.8%) cases. In most cases of incontinence, patients were managed using indwelling urinary catheters and/or faecal containment devices (77.1%, $n = 307$). In the remainder, continence pads were used in nearly all cases (97.8%, 89/91).
	Low risk: reposition at least 4-hourly Moderate/high risk: reposition at least 2-hourly	501	100 (343/343)	53.8 (42/78)	61.3 (49/80	86.6 (434/501)	< 0.001	Low-risk cases: 66.8% ($n = 229$) were able to move themselves, and 29.7% ($n = 102$) were too unstable to move. Moderate-risk cases: 20.5% ($n = 16$) were able to move themselves, and 20.5% ($n = 16$) were too unstable to move. All noncompliant cases (47.4%, $n = 36$) were repositioned 4-hourly. High-risk cases: no patients were able to move themselves, and 25.0% ($n = 20$) were too unstable to move. The noncompliant cases were repositioned 3-hourly (3.8%, $n = 3$) or 4-hourly (35.0%, $n = 28$).
Moderate-/high-risk patients	Off-load heels (moderate/high risk)	168	X	71.6 (58/81)	94.3 (82/87)	83.3 (140/168)	< 0.001	A heel offloading device was deemed not applicable in 7.4% ($n = 6$) of moderate-risk cases and 1 (1.1%) high-risk case.
	Moderate risk: reactive mattress high risk: reactive or active mattress	169	X	100 (81/81)	100 (88/88)	100 (169/169)	–	In all cases, active mattresses were provided as standard care.
High-risk patients	Seat cushion when sat out	85	X	X	100 (85/85)	100 (85/85)	–	In all cases, the seat cushion intervention was deemed not applicable.
	Sacral dressing	88	X	X	96.6 (85/88)	96.6 (85/88)	–	Sacral dressings were deemed not applicable in three cases (3.4%). Sacral dressings were also applied in 29.6% ($n = 24$) of moderate-risk cases and 1.4% ($n = 5$) of low-risk cases.
	Heel dressing	88	X	X	90.9 (80/88)	90.9 (80/88)	–	Heel dressings were deemed not applicable, or an alternative method was used in two (2.3%) cases. Heel dressings were also applied in 27.2% ($n = 22$) of moderate-risk cases and 1.4% ($n = 5$) of low-risk cases.
	Hip dressing	88	X	X	90.9 (80/88)	90.9 (80/88)	–	Hip dressings were also applied in 28.4% ($n = 23$) of moderate-risk cases and 1.2% ($n = 4$) of low-risk cases.
	Oral nutrition supplements	88	X	X	97.7 (85/87)	97.7 (85/87)	–	In nearly all high-risk cases (96.6%, $n = 84$), oral supplements were deemed nonapplicable. In only three cases where oral supplements were applicable, they were not provided in two cases.
**Overall mean compliance % (SD, *n*)			80.0 (16.4, 333)	74.8 (13.5, 77)	88.7 (8.8, 76)	80.7 (15.4, 486)	< 0.001	
**All-or-nothing compliance % (*n*)			39.9 (133/333)	10.4 (8/77)	23.7 (18/76)	32.7 (159/486)	< 0.001	

**Incomplete data $n = 36$, X = not indicated for risk level.
ICU: intensive care unit; SD: standard deviation.

Table 5
After phase: Characteristics of ICU-acquired pressure injuries and intervention compliance.

Patient ID	Risk level on admission	Pressure injury *n*	Pressure-injury site (stage)	Time to pressure injury (ICU days)	Previous assessment risk level	Intervention compliance	Comments
A37	High	5	Sacrum (S2)	5	High	70% (7/10)	• Not risk-assessed 8-hourly • Heel dressing not applied • Hip dressing not applied • Sacral dressing applied
			Elbow (S3)	22	Moderate	80% (4/5)	• Not risk-assessed 8-hourly • Sacral dressing applied
			Buttocks (S1)	22			
			Occiput (S2)	23	Moderate	75% (3/4) (reposition frequency not recorded)	• Not risk-assessed 8-hourly
			Back (S2)	25			
A154	High	1	Buttock (S2)	1	High	89% (8/9) (reposition frequency not recorded)	• No oral supplements • Sacral dressing applied
A260	High	3	Back (S2)	15	High	80% (8/10)	• Not risk-assessed 8-hourly • Reposition frequency 3-hourly
			Occiput (S2)	19	High	80% (8/10)	• Not risk-assessed 8-hourly • Reposition frequency 4-hourly
			Elbow (S1)	19			
A276	Moderate	1	Sacrum (S1)	16	Moderate	80% (4/5)	• Not risk-assessed 8-hourly • Sacral dressing applied (but not mandated)
A293	High	3	Sacrum (S2)	12	High	80% (8/10)	• Reposition frequency 4-hourly • Heels not offloaded • Sacral dressing applied
			Thigh (S2)	17	High	80% (8/10)	• Not risk-assessed 8-hourly • Reposition frequency 4-hourly
			Occiput (S1)	17			
A304	High	2	Foot (S1)	2	High	80% (8/10)	• Not risk-assessed 8-hourly • Reposition frequency 4-hourly
			Occiput (1)	12	High	90% (9/10)	• Reposition frequency 4-hourly
A359	High	3	Heel (S2)	6	High	100% (10/10)	• Heels offloaded and heel dressings applied
			Occiput (S2)	6			
			Sacrum (S2)	21	High	90% (9/10)	• Reposition frequency 4-hourly
A367	Moderate	2	Occiput (1)	6	Moderate	80% (4/5)	• Not risk-assessed 8-hourly
			Sacrum (2)	16	High	90% (9/10)	• Not risk-assessed 8-hourly

S1 = Stage 1, S2 = Stage 2, S3 = Stage 3.
ICU: intensive care unit.

phase. Our regression analysis identified that overall, the risk of developing an ICU-acquired PI increased by 1.2 times for each extra day in the ICU. In the after phase, 65% (13/20) of PIs occurred after at least 2 weeks in the ICU, and the average time until a PI developed was 14 days compared to 10 days in the before phase. Whilst this difference was not statistically significant, the magnitude of difference is clinically significant. However, further studies are required to test this effect. Previous studies have confirmed that ICU length of stay is associated with PI development.[41–43] Notably, of the 8 patients who developed PI in the after phase, their average length of stay in the ICU was 28.5 days, and all except one developed more than one PI. In comparison, the average length of stay of the 15 patients who developed PIs in the before phase was 7.2 days. Our regression analysis also indicated that the risk of developing an ICU-acquired PI was increased by 1.2 times per each point increase in the COMHON Index admission score. Furthermore, our *a posteriori* analysis of optimal cut-off scores indicated that a higher COMHON Index admission score in the after phase ($\geq$12) was predictive of ICU-acquired PI compared to an admission score of $\geq$10 in the before phase. This supports previous contentions that predictive validity is confounded by the implementation of preventative interventions.[14,44] Previous studies have reported cut-off scores for the COMHON Index ranging from $\geq$11[45] and $\geq$13[46] to $\geq$14;[32] however, two of these studies derived optimal cut-off scores using moving average scores.[45,46] The sensitivity (100%) and specificity (85%) found in the after phase with a cut-off score of $\geq$12 compare favourably to those found in these three studies.[32,45,46]

Whilst interventions were mandated and recorded in the after phase, they were provided *ad hoc* in the before phase, based on the clinical judgement of individual nurses, but implementation rates were not recorded. An earlier observational study of standard care in the same ICU[38] reported varying compliance with the same interventions as those used in the after phase in the current study. In particular, compliance with repositioning frequency (range: 20.0–58.8%), use of sacral dressings (23.5%), and use of hip dressings (2.9%) were poor. In that study, the prevalence of ICU-acquired PI was 21.9%, with nearly half (43.7%) of all PIs found on the sacrum.

In terms of ICU-acquired PIs, there was a similar number in each phase. However, it is notable that there were fewer Stage 3 PIs (5%, $n = 1$ versus 32%, $n = 8$) in the after phase, which is clinically significant. In previous ICU studies, the proportion of severe PIs (i.e., Stage 3, Stage 4, and suspected deep tissue injury) has been reported to be between 22.5% and 28% in Australia,[2,47] 39% in the United States,[48] and 41% (stages 3 and 4) in France.[42] In comparison, the proportion of severe PIs found in our study in the after phase was very low (5%). Additionally, we found fewer PIs on the sacrum or buttocks (40%, $n = 8$ versus 56%, $n = 14$) and only one heel PI and no hip PIs in the after phase. These results suggest that the mandated use of prophylactic dressings at these sites for high-risk patients was effective. In addition to reducing the incidence of PI, it is also clinically important to reduce the severity of the injury. Such data are not sufficiently captured by reporting simple incidence data, and when baseline (control) and intervention incidence rates are both low, rates of injury severity may be the defining factors.

4.1. Limitations

The main limitations derive from the single-centre nature of the study, the moderate sample size, and the low baseline PI incidence rate in the before phase. As with all nonblinded studies, there was

potential for participants to have altered their practices because they were aware of being observed. In common with all nonexperimental designs, there are multiple factors that may have influenced outcomes; therefore, the results should be considered in this context. Further studies using randomised controlled trials are required to establish cause and effect. Nevertheless, the results from this study are reflective of real-world practice. Another limitation is related to the level of compliance with some of the interventions in the after phase, especially regarding the repositioning of moderate- and high-risk patients. In this study, the use of preventative measures was not recorded in the before phase; it would be beneficial to collect such data in future studies for comparison. The project nurses in this study were very experienced in auditing; however, inter-rater reliability of chart auditing was not undertaken prior to project commencement; thus, there was potential for some inaccuracies of data recording.

5. Conclusions

The implementation of the bundle of preventive measures associated with the risk level measured with the COMHON Index reduced the incidence rate of PIs. Likewise, the severity decreased, and the location of PIs changed compared to the period prior to the intervention. The results from this study support the use of risk-stratified interventions to prevent PIs in the ICU. However, further research is needed to examine the effectiveness of the COMHON Index bundle before it can be recommended for widespread clinical practice. In particular, the effect of bundle compliance on PI incidence should be investigated. Only interventions supported by randomised controlled trials were implemented within the COMHON Index bundle. Other interventions, which are supported by lower levels of evidence, may have a complementary effect and should continue to be utilised in clinical practice until evidence indicates otherwise.

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CRediT authorship contribution statement

Cobos-Vargas: conceptualisation, data curation, investigation, methodology, project administration, writing—review and editing. **Fulbrook:** conceptualisation, formal analysis, investigation, methodology, project administration, writing—original draft, writing—review and editing, supervision. **Lovegrove:** conceptualisation, investigation, methodology, writing—original draft, writing—review and editing. **Acosta-Romero:** data curation, investigation, project administration. **Camado-Sojo:** data curation, investigation, project administration. **Colmenero:** methodology, data curation, investigation, writing—review and editing.

Conflict of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability statement

Data will be made available on reasonable request from the authors.

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Supplementary data

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