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Effectiveness of Additional Measures for the Prevention of Pressure Injuries in an Intensive Care Unit: A Retrospective Cohort Study

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Abstract: Background/Objectives: Pressure injuries (PIs), an indisputable indicator of the quality of care, have a higher incidence in intensive care units (ICUs). Our objective was to determine whether the "unprotected" patients, after applying additional protective measures, developed PIs. **Methods:** A historical cohort study was carried out in an adult ICU. Of the 811 patients admitted in 2022, 400 were selected. All of them were subjected to the ICU PI Prevention Protocol, and those with a moving average of the COMHON Index ≥11 were given two additional measures: a multilayer dressing on the sacrum, and anti-equinus and heel-pressure-relieving boots. **Results:** A total of 36 patients presented with PI (cumulative incidence of 9%). Significant differences were observed in the mean length of stay and in the disease severity score (APACHE-II). Most of the pressure ulcers were located on the sacrum, followed by the heel. Prior to the appearance of the PI, the sacral dressing was applied to 100% of the patients, while the anti-equinus and heel-pressure-relieving boots were only applied to 58.3%. Of the 36 patients with PIs, 52.8% had a PI on the sacrum and 22.2% on the heel. **Conclusions:** Focusing only on those who presented with PI, we observed that the considered measures were not effective in preventing PI in all patients. We should analyze the individual characteristics of these patients and verify whether the Prevention Protocol was followed, in order to determine how they could have been prevented or whether they were the so-called unavoidable PIs.

Keywords: pressure injury; moving average of the COMHON Index; additional measures; prevention; intensive care unit

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This study was not registered.

1. Introduction

The presence of pressure injuries (PIs) in hospitalized patients is currently an undisputed indicator of the quality of care. PIs, referred to as pressure ulcers until 2016 [1], are the result of ischemic necrosis at the level of the skin and subcutaneous tissues, generally caused by pressure exerted on a bony prominence [2], and are considered to be a mainly preventable adverse event of hospitalization [3]. Therefore, nursing professionals make constant efforts to reduce their incidence. Intensive care units (ICUs) are the perfect setting for the development of PIs, due to the characteristics of the patients who are admitted there. Although no patient is completely free from the risk of

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developing a PI, those in the ICU are at higher risk due to neurological conditions, reduced mobility, altered body mass index (BMI), the use of vasopressors, nutritional deficiencies, etc. [4]. The occurrence of PIs in critically ill patients is associated with exposure to various factors inherent to their condition, the care provided, the treatment, and/or inadequate prevention (i.e., ineffectiveness or scarcity of preventive measures, or low priority given to their prevention). This results in the incidence rates of hospital-acquired PIs in ICUs being ten times higher compared to other hospital units [5,6].

PIs, although preventable in a high percentage of cases, continue to be a true epidemic, with significant human and economic costs. The treatment of PIs has significant direct, indirect, and intangible costs. Among the foremost are the time spent by professionals, the cost of materials, increases in hospital stay, and the costs related to complications. The indirect costs include the restrictions on the work activity of patients and caregivers, costs of informal care or special equipment, years of life lost, legal costs, use of social health resources, etc. The intangible costs include the alteration of body image, stigmatization, pain, suffering, and impacts on quality of life, among others [7]. In short, the treatment of PIs incurs high costs for both patients and for the healthcare system, in addition to the impact on the quality of life of both the patient and their family. This means that early intervention is essential for people at risk of developing PIs [8].

The prevention of PIs, being less costly than treatment, is the key intervention to protect patients from unnecessary harm. This requires an individualized care process aimed at reducing or controlling risk factors [9].

However, the premise that some PIs are inevitable is increasingly recognized and accepted, and a consensus has been reached that there are certain intrinsic and non-modifiable factors—such as unstable hemodynamic status with repositioning, cardiovascular compromise affecting oxygenation and tissue perfusion, shock state, and the use of invasive measures—where the implementation of certain strategies for the prevention of PIs is contraindicated [5,10–12]. Given this evidence, there is a need to develop and implement proactive, specific, and multifactorial preventive interventions aimed at critically ill patients, whose high susceptibility to the development of PIs is related to the complexity of their clinical situation and their limited mobility [13]. Following this line, in an attempt to take a step further in addressing the challenge of protecting these critical patients from PIs, we applied a series of "Additional Preventive Measures" that were added to those included in the "PI Prevention Protocol" of our ICU. These additional measures are justified, as they are included in the "International Consensus on Preventive Interventions for PI According to Risk Level for Critical Patients" [14]. Therefore, the purpose of this research was to determine whether, despite incorporating additional measures for the prevention of PI, critically ill patients developed PIs.

Study Objective

The objective of this research was to determine, through a retrospective analysis, the occurrence of PIs in ICU patients identified as "unprotected" (moving average of the COMHON Index ≥ 11) after the implementation of two additional preventive measures.

2. Materials and Methods

The data were collected from digital medical records through the Critical Care Manager software program, where all of the care provided to the patients was recorded daily. The APACHE-II score was collected from the specific database in our ICU, managed exclusively by a responsible medical professional.

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2.1. Design

This was a historical cohort study conducted during the year 2022. This study is reported in accordance with the STROBE reporting guidelines for observational research (cohort studies).

2.2. Study Setting and Sampling

Unit Description

This study was conducted in the adult ICU of a tertiary university hospital—specifically, at the Complejo Hospitalario Universitario de Canarias, part of the public network of the Servicio Canario de la Salud, on the island of Tenerife (Spain), which serves as a reference hospital for a population of 465,751, expanding to 1,650,228 for the care of kidney transplant and cardiac surgery cases [15]. The ICU has 24 beds for the admission of critically ill patients due to medical and surgical conditions, as well as those recovering from cardiac surgery. The unit was staffed with medical personnel, two nursing supervisors, and five nursing teams, composed of 14 nurses and 7 auxiliary nursing technicians each, who worked in 12-hour shifts, with a nurse-to-patient ratio of 1:1.71.

At the time of the study, the following care measures were standardized in this ICU for the prevention of PIs: (1) risk assessment for PI at the time of admission, (2) risk reassessment every twenty-four hours, (3) moisture control, (4) pressure minimization, (5) oxygenation control through arterial blood gas analysis every three or four hours, and (6) enteral or parenteral nutrition with blood monitoring of electrolytes and proteins. Additionally, all admitted patients were subjected to the "PI Prevention Protocol" of our unit (Table 1).

Table 1. PI Prevention Protocol applied to the study patients.

PI Prevention Protocol for the ICU of the Complejo Hospitalario Universitario de Canarias
Incorporate a dynamic mattress on the bed.
Monitor the skin thoroughly during bathing and when performing position changes.
Perform a proper drying of the skin, without friction and with subsequent application of hydration.
Avoid excessive use of clothing under the patient (tucked-in sheets and folded sheets).
Apply hyperoxygenated fatty acids to those at-risk areas.
Apply barrier products in areas exposed to moisture (e.g., areas of breast folds, abdominal folds) or exposed to urinary and/or fecal incontinence.
Make postural changes every 2-3 hours.
Use special surfaces for pressure management.
Keep the heels pressure-free and use multilayer dressings.
In neurocritical patients, closely monitor the occipital area and use offloading devices such as multilayer dressings or viscoelastic surfaces.
Measure the risk of PUs using the COMHON Index scale [11,12,16].
Calculate the moving average [17] of the COMHON Index to determine the level of protection that the patient has against PI.
The specific protocol for patients in the prone position:
Apply multilayer dressings or viscoelastic surfaces to at-risk areas (e.g., forehead, cheeks, chin, acromion, breasts, abdomen, genitals, knees, tibial plateau, dorsum of the foot, and toes).
Perform mobilizations of the hips and the upper and lower limbs to relieve local pressure.
Strictly monitor the areas where monitoring and/or therapeutic devices are placed, to prevent the occurrence of iatrogenic injuries.

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For this study, two additional measures for the prevention of PIs were added, which were applied to those patients whose moving average of the COMHON Index was equal to or greater than 11 [16–18]. These additional measures consisted of the use of multilayer dressings in the sacral area and the placement of anti-equinus and heel-pressure-relieving boots.

2.3. Population, Sample, and Sampling

The study population consisted of 811 patients over 18 years old who were admitted to the ICU during the year 2022. For the calculation of the sample size, the formula for estimating proportions in finite populations was used, with a confidence level of 95%, a margin of error of 0.05, and an expected proportion of 50%, which resulted in a minimum of 395 patients. Ultimately, 400 patients from the population who met the study's inclusion criteria were included; their selection was carried out randomly, starting with the first patient who met the inclusion criteria, until the total sample was reached.

2.4. Inclusion and Exclusion Criteria

Patients who had the following recorded in their medical history were included: the moving average of the COMHON Index, the use or non-use of the additional measures proposed in this study (i.e., multilayer dressing on the sacrum, anti-equinus and heel-pressure-relieving boots), and the presence or absence of PIs.

Those patients who did not have some of the aspects considered as inclusion criteria recorded in their medical history were excluded.

2.5. Study Subjects

The subjects were patients over 18 years old who were admitted to the ICU of the Complejo Hospitalario Universitario de Canarias during the year 2022. In this unit, patients with various pathologies and those who had undergone cardiac surgery were admitted. The patients were grouped into three categories, according to their diagnosis: medical, surgical, and cardiac surgery. The data used to calculate the incidence of PIs were collected from the first day of admission until the discharge/death of the patient, or for a maximum of 35 days' stay in the unit.

2.6. Instruments for Data Collection

For the assessment of the risk of PI, the specific COMHON Index scale for intensive care was used [19]. For the calculation of the level of protection against the occurrence of PI, the technique of a continuously updated three-day moving average was used, which is the arithmetic mean of the risk score values obtained with the COMHON Index [18,20]. To measure the severity of the disease, the APACHE-II score (an acronym in English for "Acute Physiology And Chronic Health Evaluation II") was used, which is a classification system for the severity or seriousness of diseases [21]. This is applied within the first 24 hours after the patient's admission to the ICU and yields an integer value between 0 and 67. A higher score corresponds to more severe diseases and a greater risk of death, influencing the predisposition of critically ill patients to develop PIs [18,20–23]. The source of the information used in this study for data collection was the records from the Critical Care Manager TM v.8.2 system (Picis Inc.), where the nurse responsible for the patient's care recorded the variables included in this study, except for the APACHE-II score, which was recorded by the ICU doctor assigned to this task at the time of the patient's admission and noted in a specific database, where these data were collected.

2.7. Description of the Variables

2.7.1. Dependent Variable

The dependent variable was the presence or absence of PIs.

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2.7.2. Independent Variable

- Moving average of the COMHON Index: minimum value of 5, and maximum of 20. Values equal to or greater than 11 indicate that the patient is not protected against the occurrence of PIs.

-Additional measures:

-Application of multilayer dressing on the sacrum

- Placement of anti-equinus and heel-pressure-relieving boots

-Other independent variables considered in this study included the following: age (in years), sex (male or female), days of stay in ICU, reason for ICU admission (medical diagnosis, surgical diagnosis, or cardiac surgery diagnosis), performance of postural changes prior to the appearance of the PI, anatomical location of the PI (sacrum, heel, malleolus, buttock, forehead, cheekbone, chin, acromion, breasts, abdomen, genitals, knees, tibial plateau, dorsum of the foot, toes, etc.), number of PIs per patient, body mass index (BMI) [24–26], and APACHE-II score.

2.8. Statistical Analysis

Categorical variables are expressed as frequencies and percentages.

Quantitative and ordinal variables are expressed as means and standard deviations or medians and interquartile ranges (25-75), depending on whether the data followed a normal or asymmetric distribution, respectively. Proportional comparisons were conducted using chi-squared tests or Fisher's exact test, as appropriate.

Group comparisons of quantitative and ordinal variables were performed using the Mann–Whitney test. Values of $p<0.05$ were considered significant.

Data analyses were conducted using the SPSS 25.0 statistical package (IBM, 2017, Armonk, NY).

2.9. Ethical Aspects

This study was conducted in accordance with the guidelines of the Declaration of Helsinki and was approved by the Clinical Research Ethics Committee of the University Hospital Complex of the Canary Islands for the Province of Santa Cruz de Tenerife, with the reference code CHUC_2021_66 (Pro LPP_2).

3. Results

Of the 400 patients in our sample, 36 developed PIs, corresponding to an incidence of 9%. The average stay in the ICU was 8.61 days, and the patients who developed PIs were admitted for a median of 15 days (IQR: 8-26 days). The sample had a mean age of 64.4 years, and 64.75% were men. In Table 2, the clinical and demographic characteristics of the cohort are presented based on the presence or absence of PIs. No statistically significant differences ($p<0.005$) were found when comparing patients with and without PIs in terms of age, sex, BMI, and diagnosis upon ICU admission. Significant differences were found when comparing the two groups in terms of their mean duration of stay in the ICU (in days) and their APACHE-II scores.

Table 2. Clinical and demographic characteristics of the patients.

CHARACTERISTICS	NO PI n=364	PI n=36	*P-VALUE*
Median age, years (IQR)	66 (56.25-75)	66.50 (62-75.50)	0.41

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Sex			0.32
Men, n (%)	233 (64)	26 (72.2)	
Women, n (%)	131 (36)	10 (27.8)	
Average length of stay in ICU, days (IQR)	2.50 (1-6)	15 (8-26)	*P*<0.001
Body mass index (BMI), (IQR)	27.68 (24.68-31.01)	29.71 (24.60-32.47)	0.35
APACHE-II score (IQR)	12(7-17)	18.50(12-26.50)	0.002
Diagnosis, n (%)			
Medical	152 (41.8)	18 (50)	0.42
Surgical	105 (28.8)	11 (30.6)	
Cardiac surgery	107 (29.4)	7 (19.4)	

PI (pressure injury), APACHE-II (Acute Physiology and Chronic Health Evaluation). The data are expressed in frequencies (%) or medians (IQR: interquartile range P25-P75).

In the patients who presented with PIs, the average time of appearance of the first PI was 7.31 (SD 6.41) days, and the mean moving average of the COMHON Index on the first day of the appearance of the PI was 13.44 (SD 3.39).

Of the 36 patients who presented with PIs, some had more than one PI (see Table 3), resulting in a total of 49 PIs.

Table 3. Number of PIs per patient.

Number of PIs	Patients with PIs n = 36 (%)
One	26 (72.2)
Two	7 (19.4)
Three	3 (8.3)

Data are expressed as frequencies (%).

The most PIs were located on the sacrum, followed by the heels, gluteus, malleolus, occipital area, and other locations not specified in the registry (see Table 4).

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Table 4. PI distribution by anatomical location.

Location of PI	n = 49	(%)
Sacrum	22	44.9
Heel	12	24.5
Gluteus	8	16.3
Malleolus	2	4.1
Occipital	1	2
Other locations	4	8.

Data are expressed as frequencies (n) and percentages (%).

Table 5 shows that 100% of patients with PIs were given the additional preventive measure of a multilayer dressing on the sacrum, while anti-equinus and heel-pressure-relieving boots were provided to only 58.3% of patients with PIs, on a preventive basis. It should be noted that, during this period, there were problems with the supply of this material in our hospital, which could justify these data.

Table 5. Application of additional measures in patients with PIs.

Additional Measures	Patients with PIs n (%)
Multilayer sacral dressing	36(100)
Anti-equinus and heel-pressure-relieving boots	21 (58.3)

Data are expressed as frequencies (%).

These data show that despite having applied the multilayer dressing on the sacrum as an additional preventive measure for all patients, 22 presented a sacral PI. Regarding the additional measure of anti-equinus and heel-pressure-relieving boots, which were only provided to 21 out of 36 patients who had PIs, Table 6 shows the distribution of PIs in the heel and malleolus in patients wearing or not wearing such boots.

Table 6. Presence of PI in the heel and malleolus related to the application of anti-equinus and heel-pressure-relieving boots.

Anti-Equinus and Heel-Pressure-Relieving Boots	Heel PI n = 12	Malleolus PI n = 2
Yes	5(41,6)	2(100)
No	7(58,3)	0(0)

Data are expressed as frequencies (%).

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The results obtained showed that even after applying these additional measures to patients with a moving average of the COMHON index ≥11, which indicates that the patient is "not protected" against the appearance of PIs by the usual protective measures, the patients developed PIs. This led us to analyze whether the 36 patients who presented with PIs underwent postural changes every 2-3 hours, as required in our ICU's PI Prevention Protocol. We found that 13 (26.1%) patients did not undergo postural changes in the hours prior to the onset of PIs.

4. Discussion

At present, the incidence and prevalence of PIs in seriously ill patients admitted to the ICU remain high, despite a great deal of knowledge about appropriate prevention strategies [27,28]. The results obtained in this study show a cumulative PI incidence of 9%. The calculation of this rate did not exclude patients who presented with PIs in the first 24h after admission to the ICU because, as this was a retrospective study, the records did not differentiate whether the patients had been admitted with PIs or whether they developed after admission to the ICU. If we had discounted them, our cumulative PI incidence rate would have been 7.25%—data more consistent with our latest studies [17,18,20,29]. Coinciding with other studies, when analyzing age, sex, and reason for admission, we found no significant differences between patients with and without PIs. With respect to BMI, we did not observe any significant differences, unlike other studies [25]; although it should be noted that the patients in our study had an average BMI corresponding to overweight values. On the other hand, we observed a significant relationship between the time spent in the ICU and the incidence of PIs, coinciding with other studies [16–18,20,29,30]. However, we observed a relationship between the APACHE-II score and the presence of PIs. This result is consistent with other studies that established a relationship between the APACHE-II score and the occurrence of PIs [31–33], but is not consistent with previous studies conducted in our ICU, in which it was observed that the severity of the disease—determined through the APACHE-II score—was not an independent risk factor for developing a PI, since it is calculated only during the first 24 hours after admission. Therefore, it is not representative of the severity of the disease during the several-day ICU stay; in addition, it could be attributed to the influence of the nursing care received by our patients [18,20,29]. The median APACHE-II score of patients with PIs was 18.50, with an IQR of 12-26.50. In the literature, the APACHE-II score is taken as a predictor of mortality. A score between 15 and 19 is associated with 25% mortality, values between 20 and 24 with 40% mortality, and values of 25-29 with 55% mortality [21,22].

The value of the moving average of the COMHON Index corresponding to the day on which patients presented their first PI was 13.44, in accordance with other studies where a score ≥11 [18,20] was identified as the optimal cut-off point and was associated with the risk of presenting PIs. The most frequent location of PIs was the sacrum, followed by the heels—data that coincide with the findings of other studies [34–40] for patients admitted to the ICU. The majority of patients who developed PIs had only one, and almost one-third of them had two or more PIs.

As for performing postural changes every 2-3 hours—a measure included in our ICU's PI Prevention Protocol—just over one-quarter of patients with PIs were not subjected to this. This could have been justified by the patient's clinical situation at that time, e.g., the presence of hemodynamic and respiratory involvement [41–43].

Regarding additional measures, the multilayer dressing on the sacrum was applied to all patients preventatively, but this did not prevent almost half of the PIs presented from being located in that area. The anti-equinus and heel-pressure-relieving boots (which could not be applied to all patients due to problems with the supply of this material during the study) were also not shown to be an effective measure in all patients, since most of the patients who had PIs in the heels and all of those who had PIs in the malleolus used them. This, according to Gefen et al. [44], could be related to the concept of individual susceptibility to PIs, which depends on integrated body system functions and is dynamic and extremely difficult to predict in seriously ill patients.

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5. Limitations

The reason that only 58.3% of patients with PIs were wearing anti-equinus and heel-pressure-relieving boots prior to the onset of PIs was mainly due to discontinuity in the supply of this material. Another potential limitation of this study may have been the interactions of other variables not considered here.

6. Conclusions

Of the 400 patients included in this study, only 36 (9%) had PIs. Most of the PIs were located on the sacrum, followed by the heels—precisely the two areas in which additional measures for PI prevention were applied. All patients with PIs on the sacrum had a multilayer dressing on the sacrum, and most patients with PIs on the heels had anti-equinus and pressure-relieving boots. If we focus only on patients who had PIs despite the additional measures applied, we can conclude that these measures were not effective in preventing PIs in these areas in all patients. The individual characteristics of these patients should be analyzed, and it should be determined whether all of the measures included in the Prevention Protocol were carried out, in order to find out whether the PIs could have been prevented or whether they were so-called unavoidable PIs.

We propose that upcoming research within our line of investigation should focus on analyzing the profile characteristics of critically ill patients with pressure injuries who are under severe, life-threatening conditions.

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Institutional Review Board Statement: This study was carried out in accordance with the Declaration of Helsinki and was approved by the Clinical Research Ethics Committee of the University Hospital Complex of the Canary Islands for the Province of Santa Cruz de Tenerife, with the reference code CHUC_2021_66 (Pro LPP_2).

Informed Consent Statement: Patient consent was waived given the retrospective nature of the data collection, as determined by the ethics committee.

Data Availability Statement: The data used in this research are confidential and are stored in a coded and anonymized database, managed by the research group in accordance with Spanish regulations. However, raw data may be shared with researchers who contact the corresponding author, provided they submit a reasoned and justified request.

Public Participation Statement: There was no public participation in any aspect of this research.

Guidelines and Standards Statement: This manuscript was written in accordance with the Statement on Strengthening Reporting of Observational Studies in Epidemiology (STROBE): Guidelines for Reporting Observational Research (Cohort Studies).

Use of Artificial Intelligence: No AI or AI-assisted tools were used in the writing of any aspect of this manuscript.

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Abbreviations

The following abbreviations are used in this manuscript:

AI	Artificial Intelligence
APACHE-II	Acute Physiology And Chronic Health Evaluation Score II
COMHON	Consciousness Level–Mobility–Hemodynamics–Oxygenation–Nutrition
IBM	International Business Machines
BMI	Body Mass Index
LPP	Pressure Injury
NY	New York

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