ESTIMA
Brazilian Journal of Enterostomal Therapy

ORIGINAL ARTICLE
https://doi.org/10.30886/estima.v23.1644_IN

Medical device–related pressure injury in an intensive care unit: an observational study**

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ABSTRACT

Objective: To analyze the incidence of Medical Device-Related Pressure Injury (MDRPI) in a general adult intensive care unit. **Method:** A cross-sectional study conducted in an intensive care unit of a university hospital in Rio de Janeiro, from May to September 2022. The sample consisted of 70 patients with at least one medical device. Patients readmitted during the study period were excluded. Data were collected starting on the third day of hospitalization and analyzed using Stata software. **Results:** The incidence of medical device–related pressure injury was 18.57%. The most affected site was the auricle (62%), and the device most frequently causing injury was the orotracheal tube (61.54%). No statistically significant associations were identified between sociodemographic and clinical characteristics and the occurrence of MDRPI among participants. A length of stay equal to or greater than 16 days increased the likelihood of this type of injury by sevenfold. **Conclusion:** The incidence of MDRPI in the investigated unit was related to patients' length of stay. MDRPI risk assessment and skin integrity assessment at admission and on a daily basis are necessary, in addition to documenting the actions implemented in medical records.

KEYWORDS: Patient safety. Pressure ulcer. Intensive care unit. Equipment and supplies. Stoma therapy.

Lesão por pressão relacionada a dispositivo médico em uma unidade de terapia intensiva: estudo observacional

RESUMO

Objetivo: Analisar a incidência de Lesão por Pressão Relacionada a Dispositivo Médico (LPRDM) em uma unidade de terapia intensiva geral adulto. **Método:** Estudo transversal, realizado em uma unidade de terapia intensiva de um hospital universitário do Rio de Janeiro, de maio a setembro de 2022. A amostra foi composta por 70 pacientes com pelo menos um dispositivo médico. Foram excluídos aqueles readmitidos durante o período do estudo. Os dados foram coletados a partir do terceiro dia de internação e analisados pelo software Stata. **Resultados:** A incidência de lesão por pressão relacionada a dispositivo médico foi de 18,57%. O local mais acometido foi o pavilhão auricular (62%); o dispositivo que mais causou lesão foi o tubo orotraqueal (61,54%). Não foram identificadas associações estatisticamente significativas entre características sociodemográficas e clínicas e ocorrência de LPRDM nos participantes. O tempo de internação igual ou superior

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Section Editor: Manuela de Mendonça F. Coelho
Received: Sep. 7, 2024 | Accepted: Jun. 21, 2025.
How to cite: Faustino Junior JC, Almeida LF, Nascimento DC, Paula VG, Lisboa CD, Mesquita AMF. Medical device–related pressure injury in an intensive care unit: an observational study. ESTIMA, Braz. J. Enterostomal Ther., São Paulo, v.23, e1644, 2025. https://doi.org/10.30886/estima.v23.1644_IN
**Origin of the article: Derived from the Course Completion Paper, Prevalence of medical device–related pressure injury in an intensive care unit, submitted to the Postgraduate Program in Nursing, Residency modality, of the State University of Rio de Janeiro, 2023.

a 16 dias aumentou em 7 vezes a chance de ocorrência desse tipo de lesão. **Conclusão:** A incidência de LPRDM na unidade investigada relacionou-se ao tempo de internação do paciente. A avaliação de risco da LPRDM e avaliação da integridade da pele, no momento da admissão e diariamente, são necessárias, além dos registros das ações implementadas em prontuários.

DESCRITORES: Segurança do paciente. Lesão por pressão. Unidade de terapia intensiva. Equipamentos e provisões. Estomaterapia.

Lesión por presión relacionada con dispositivos médicos en una unidad de cuidados intensivos: estudio observacional

RESUMEN

Objetivo: Analizar la incidencia de lesión por presión relacionada con dispositivo médico (LPRDM) en una unidad de cuidados intensivos generales de adultos. **Método:** Estudio transversal realizado en una unidad de cuidados intensivos de un hospital universitario de Río de Janeiro, de mayo a septiembre de 2022. La muestra estuvo compuesta por 70 pacientes con al menos un dispositivo médico. Se excluyeron aquellos readmitidos durante el periodo del estudio. Los datos se recolectaron a partir del tercer día de hospitalización y se analizaron mediante el *software* Stata. **Resultados:** La incidencia de LPRDM fue del 18,57%. El sitio más afectado fue el pabellón auricular (62%); el dispositivo que más causó lesión fue el tubo orotraqueal (61,54%). No se identificaron asociaciones estadísticamente significativas entre las características sociodemográficas y clínicas y la ocurrencia de LPRDM en los participantes. El tiempo de hospitalización igual o superior a 16 días incrementó en 7 veces la probabilidad de ocurrencia de este tipo de lesión. **Conclusión:** La incidencia de LPRDM en la unidad investigada se relacionó con el tiempo de hospitalización del paciente. La evaluación del riesgo de LPRDM y de la integridad de la piel, en el momento del ingreso y de forma diaria, son necesarias, además del registro de las acciones implementadas en la historia clínica.

DESCRIPTORES: Seguridad del paciente. Úlcera por presión. Unidades de cuidados intensivos. Equipos y suministros. Estomaterapia.

INTRODUCTION

Pressure injuries are localized damage to the skin and/or underlying tissue, usually over bony prominences or related to medical or other devices, resulting from prolonged pressure or pressure in combination with shear[1]. Medical Device-Related Pressure Injuries (MDRPI) are defined as tissue damage resulting from the use of devices applied for therapeutic or diagnostic purposes[2,3].

Currently, it is proposed that MDRPI result from the interaction of a device or object in contact with the skin, directly or indirectly, including implanted devices, for example, cardiac pacemakers, ventriculoperitoneal catheters, orthopedic prostheses, and implantable neurological electrodes, generating sustained pressure over long periods and deforming both superficial and underlying tissues. As a consequence of this pressure, this type of injury has a shape similar to that of the device used[1,4].

Among the devices associated with a higher risk of injury are those used for feeding and respiration, tubes, compression stockings, pulse oximeters, cervical collars, catheters, drains, adhesives, and orthopedic equipment. The orotracheal tube and nasogastric tube present higher rates of MDRPI, with an incidence of 3.1%[2].

The most common sites of anatomical involvement are the auricle, urethral meatus, and nostrils. These injuries are frequently associated with longer lengths of stay in Intensive Care Units (ICUs), impaired mobility due to sedation or inability to move, as well as a greater number of devices and longer duration of device use[5].

MDRPI account for more than 30% of pressure injuries occurring in hospitals, especially in ICUs, where the number of devices applied to patients and the length of hospitalization are greater when compared with other units[6]. In addition, costs related to hospital-acquired pressure injuries may reach approximately US$10,708 per patient on average, with a total cost of US$26.8 billion in the United States, considering 2.5 million reported cases[7]. In Brazil, studies on the prevalence and incidence of MDRPI are still incipient and do not demonstrate costs comparable to international data[5].

Certain factors contribute to tissue impairment resulting from the use of medical devices, such as the inability to perceive pressure due to sedation or neurological damage; the duration of device use in contact with the skin; inadequacy of device design in relation to skin structure, such as size and rigidity that do not properly conform to the application site; or lack of knowledge among professionals involved in MDRPI prevention care[1].

These care measures are related to repositioning and removal of devices, as well as proper adjustment and fixation. Another important aspect to be discussed is the wide variability in prevalence and incidence, the latter ranging from 1.4 to 121%, indicating heterogeneity of data when compared with patients in clinical and ICU[8,9]. This reinforces that there are patient-related, device-related, and nursing care–related factors that require detailed assessment regarding their particularities and their relationship with the development of MDRPI.

In association with clinical observations, the international consensus on MDRPI states that the topic is poorly studied, yet it presents high magnitude and significant repercussions for patients, especially in settings with a high density of equipment, with intensive care being a typical scenario for this occurrence[1].

The need for knowledge of the main factors involved in the occurrence of MDRPI is justified by the possibility of developing prevention guidelines, such as educational programs; care protocols; and acquisition of devices appropriate to patient-specific characteristics, including review of device fixation methods, pressure sites, and standardization of the use of preventive dressings.

OBJECTIVES

This study aimed to analyze the incidence of medical device–related pressure injuries in a general adult intensive care unit.

METHODS

This is a cross-sectional study that used the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) tool[10], conducted in a general adult ICU of a university hospital in the city of Rio de Janeiro, from May to September 2022.

The study setting is a unit specialized in the care of adult patients requiring intensive monitoring and treatment. This environment has ten beds, advanced technology, and a multidisciplinary team composed of physicians, nurses, physical therapists, and other health professionals to manage complex and critical cases. In addition, this ICU usually provides care for a variety of clinical conditions, such as respiratory, neurological, and metabolic diseases, among others.

The hospital is part of the Unified Health System (Sistema Único de Saúde – SUS), and patient admissions occur through the bed regulation system of the state of Rio de Janeiro. The unit serves as a teaching and clinical practice setting for undergraduate students and health professionals undergoing training and continuing education, as well as providing internship opportunities.

Patients admitted to the unit during the data collection period with at least one medical device in direct contact with the skin or mucous membranes were included. Patients readmitted during the study period were excluded to avoid data duplication, since MDRPI had already been recorded during the first admission, and also because the calculation of the incidence of this type of injury is related to the number of patients who developed MDRPI rather than the number of lesions.

The sample consisted of 70 patients, and data collection was carried out at the study site starting on the third day of hospitalization of the participants, considering evidence that the time elapsed between the initiation of medical device use in the ICU and the detection of MDRPI ranged from 1.25 hours to 19 days[2].

Patient-related variables studied included date of hospital and ICU admission, source of admission, sex, ethnicity, age, comorbidities, use of vasoactive amines and/or sedation, length of stay, and risk of pressure injury at admission assessed using the Braden Scale. Device-related variables included number, type, presence, location, and stage of MDRPI, according to the international consensus[3].

Data were entered into Microsoft Excel® and analyzed using Stata software version 16.0. In the descriptive analysis, the distribution of sociodemographic, clinical, and device-related information was presented. For qualitative variables, absolute numbers and frequencies were calculated. For quantitative variables, measures of central tendency (mean and median) and dispersion (minimum and maximum) were calculated.

Pearson's $\chi 2$ test was used to assess the presence of associations between risk factors, considered independent variables, and the outcome of interest, defined in this study as the occurrence of MDRPI. Logistic regression techniques were applied to identify the odds ratio for the occurrence of MDRPI in sample strata of interest, with the reference category defined as "No" or the category representing, according to the literature, the lowest risk or the best outcome. The significance level adopted throughout the analysis was 5%.

This study was approved by the institution's Research Ethics Committee under opinion no. 4.747.146 and is part of a larger project entitled "Analysis of care practices in ICUs.".

RESULTS

Of the 70 patients evaluated, there was a predominance of females (61.43%), White race (52.86%), and the presence of comorbidities (81.43%). Among these, the most frequent was systemic arterial hypertension (54.29%). The mean age of the patients was 56.85 years (SD±19.45). The mean length of hospital stay was 9.07 (SD±18.9) days.

The mean number of devices was 3.18 (SD±1.13). The devices most frequently used by participants were the pulse oximeter (100%), followed by the indwelling urinary catheter (82.86%). The use of vasoactive medications was observed in 26 (37.14%) patients, and sedatives in 37 (52.86%).

The incidence of MDRPI among participants was 18.57%, being more frequent in the auricle (61.54%). Most injuries were categorized as unstageable (38.46%) or deep tissue injury (38.46%). It was observed that the main type of device causing the injury was the orotracheal tube (61.54%) (Table 1).

No statistically significant associations were identified between sociodemographic and clinical characteristics and the occurrence of MDRPI among participants. Only the category referring to a length of stay equal to or greater than 16 days was associated with MDRPI, increasing the likelihood of occurrence by sevenfold (Table 2).

No statistically significant associations were identified between the number of devices and Braden Scale categorization at admission with the occurrence of MDRPI among participants. However, a higher number of MDRPI was observed in patients with shorter lengths of hospital stay (Table 3).

DISCUSSION

In this study, female patients predominated, unlike other studies in which males were more prevalent[11]. However, the occurrence of MDRPI showed no significant difference between men and women, contrasting with data from the literature that demonstrate a higher prevalence of MDRPI among male patients[8,12]. Most of the patients investigated were White, as observed in another study[13], and this characteristic was associated with the presence of MDRPI, similar to findings from another investigation that showed a higher prevalence of device-related injuries among White patients[12].

Table 1. Characterization of the occurrence of Medical Device-Related Pressure Injury among participants (n=70). Rio de Janeiro (RJ), 2022.

Variables	N	%
Presence of MDRPI		
No	57	81.43
Yes	13	18.57
MDRPI location		
Auricle	8	61.54
Inguinal region	2	15.38
Cervical region	1	7.69
Nostril	1	7.69
Finger	1	7.69
MDRPI stage		
Deep tissue injury	5	38.46
Unstageable	5	38.46
Stage 1	2	15.38
Stage 2	1	7.69
Type of device		
Orotracheal tube	8	61.54
Indwelling urinary catheter	2	15.38
Tracheostomy cannula	1	7.69
Pulse oximeter	1	7.69
Nasoenteric tube	1	7.69
Braden Scale at admission		
Low risk	32	45.71
High risk	28	40
Moderate risk	10	14.29

MDRPI: Medical Device-Related Pressure Injury.

Pressure injuries may be underdiagnosed in patients with darker skin, as early skin changes, such as erythema, are not visually evident in these individuals. This contributes to a false impression of lower incidence or delayed detection. However, assessment may be challenging in certain circumstances. The area under the device in individuals with darker pigmentation should be palpated to assess the presence of edema and temperature changes[3].

Comorbidities were present in most of the patients analyzed. Some conditions, in particular, affect the skin, compromise the healing process, and increase the risk of tissue breakdown, such as diabetes, renal, cardiovascular, pulmonary, neuromuscular, connective tissue and skin diseases, and immunosuppression[14]. Authors indicate that some of these conditions reduce tissue tolerance to mechanical pressures exerted by devices or influence the development of uncontrolled edema, making the microclimate more susceptible to injury[1]. However, based on the results of this study, no relationship was observed between the presence of comorbidities and the occurrence of MDRPI.

The mean age of the population in this study was 56.68 years, similar to that reported in another study[15]. These data differ from other investigations in which most patients were older than 70 years[16-18], increasing the likelihood of structural skin damage[19].

The mean length of hospital stay (9.07 days) was shorter when compared with other studies[11,12]. This finding is relevant, given that prolonged contact time between the device and the skin increases the probability of developing lesions in the underlying area[11].

It was observed that patients had an average of three devices, with the orotracheal tube, indwelling urinary catheter, pulse oximeter, and nasoenteric tube being the most frequently used, differing from a study that reported the use of 6 to 8 devices[2]. This finding may be understandable, as these devices are commonly used in the monitoring of critically ill patients. However, in certain circumstances, improper use may lead to tissue injury due to incorrect selection, adjustment, or placement, and even during handling[11].

Table 2. Association between sociodemographic and clinical characteristics and the occurrence of Medical Device-Related Pressure Injury (n=70). Rio de Janeiro (RJ), 2022.

Variables	Medical Device-Related Pressure Injury				OR	95%CI	P value*
	Yes		No				
	n	%	n	%			
Sex							
Female	8	18.60	35	81.40	1.05	0.291–3.468	0.993
Male	5	18.52	22	81.48	1	-	
Age group (years)							
18 to 41	1	6.67	14	93.33	1	-	0.229
42 to 65	7	28	18	72	5.4	0.296–26.420	
Over 65	5	16.67	25	83.33	2.8	0.598–49.562	
Length of stay (days)							
3 to 5	6	12.50	42	87.50	1	-	0.113
6 to 10	4	26.67	11	73.33	2.54	0.609–10.623	
11 to 15	0	0	1	100	†	†	
16 or more	3	50	3	50	7	1.14–42.969	
Ethnicity							
White	7	18.92	30	81.08	1	-	0.981
Brown	4	17.39	19	82.61	0.902	0.232–3.502	
Black	2	20	8	80	1.071	0.185–6.192	
Has comorbidities							
Yes	11	19.30	46	80.70	1.315	0.254–6.807	0.743
No	2	15.38	11	84.62	1	-	
Systemic arterial hypertension							
Yes	8	21.05	30	78.95	1.44	0.419–4.938	0.561
Diabetes mellitus type 1							
Yes	0	0	2	100	†	†	0.493
Chronic obstructive pulmonary disease							
Yes	0	0	5	100	†	†	0.268
No	13	20	52	80			
Chronic kidney disease							
Yes	1	8.33	11	91.67	0.540	0.270–1.081	0.316
No	12	20.69	46	79.31	1	-	
Use of vasoactive drugs							
Yes	7	26.92	19	73.08	2.33	0.687–7.916	0.167
No	6	13.64	38	86.36	1	-	
Use of sedatives							
Yes	8	21.62	29	78.38	1.54	0.450–5.296	0.487
No	5	15.15	28	84.85	1	-	
Use of orotracheal tube							
Yes	7	25.93	20	74.07	0.463	0.136–1.567	0.210
Use of tracheostomy							
Yes	3	37.50	5	62.50	0.320	0.065–1.561	0.144
Indwelling urinary catheter							
Yes	13	22.81	44	77.19	†	†	0.056
Nasoenteric tube							
Yes	9	25.71	26	74.29	0.372	0.102–1.351	0.124
Nasogastric tube							
Yes	1	100	0	0	†	†	0.035‡

OR: odds ratio; 95% CI: 95% confidence interval.
*□2 test; †not calculable due to absence of event occurrence; ‡category with statistically significant p-value.

Table 3. Association between the number of devices and Braden Scale at admission with the occurrence of Medical Device-Related Pressure Injury (n=70). Rio de Janeiro (RJ), 2022.

Variables	Medical Device-Related Pressure Injury				OR	95%CI	P value*
	Sim		Não				
	n	%	n	%			
Number of devices							
One	0	0	7	100	†	†	0.094
Two	0	0	14	100	†	†	
Three	2	16.67	10	83.33	1	-	
Four	10	30.30	23	69.70	2.17	0.401–11.781	
Five	1	25	3	75	1.66	0.109–25.432	
Braden Scale at admission							
High risk	7	25	21	75	2.33	0.603–9.023	0.459‡
Moderate risk	2	20	8	80	1.75	0.269–11.359	
Low risk	4	12.5	28	87.5	1	-	

OR: odds ratio; 95% CI: 95% confidence interval.
*□2 test; †not calculable due to absence of event occurrence; ‡category with statistically significant p-value.

Despite the need for their use in various situations, medical devices may cause structural skin damage due to heat, moisture, and pressure, which may be intensified in cases of immobility, impaired sensory perception, and communication deficits[5]. In this study, the most frequently used devices were the pulse oximeter and the indwelling urinary catheter, as reported in other studies[1,13]. However, one investigation showed that most MDRPI were caused by the orotracheal tube and the indwelling urinary catheter16, corroborating the findings of the present study, which demonstrated a higher occurrence of MDRPI associated with the use of the orotracheal tube. Authors report that injuries resulting from respiratory devices account for approximately 68% of MDRPI, mainly involving the orotracheal tube, generally due to inadequate fixation, impaired tissue perfusion, difficulty in device mobilization, and consequent damage to the oral cavity[5].

Respiratory devices are associated with high rates of injury, according to data from a study conducted in the United States, ranging from 30% to 70% of MDRPI in critically ill patients, with emphasis on noninvasive ventilation masks and the orotracheal tube[9]. This may be related to inadequate device selection, as well as inappropriate sizes and shapes. Devices manufactured with less rigid materials represent an important advantage in the prevention of MDRPI. These devices should be assessed for physical mobility and should avoid direct contact with the skin, thereby minimizing the development of injuries[9,17].

The results showed that most MDRPI were unstageable or deep tissue injuries, contrasting with data from another study in which stage 1 and 2 injuries predominated, accounting for 58%; deep tissue injury accounted for 15%; and stage 3, 4, and unstageable injuries accounted for 22%20. In another study, however, stage 2 injuries predominated, with no stage 4, unstageable, or deep tissue injuries identified1. It is assumed that the findings of the present study may be related to the use of sedatives, which favor reduced mobility and loss of sensory perception and, consequently, increase the likelihood of pressure injury occurrence[4]. Strategies adopted to prevent MDRPI include periodic inspection of the skin under and around the device, repositioning, and the use of dressings to minimize tissue damage caused by shear forces[4].

The underlying area between the skin and the device should be observed, the device repositioned, fixation sites alternated, and the area kept free of debris and moisture[19].

In this study, the most frequent device-related injuries occurred in the auricle, corroborating findings from other studies[5,16]. This may be explained by inadequate device fixation and the lack of skin inspection in this area. In this context, the need to keep the auricular region free from pressure is emphasized, with cushioning provided through the use of appropriate dressings, such as multilayer silicone foam dressings[17]. In addition, injuries resulting from respiratory devices account

for approximately 68% of MDRPI, mainly involving the orotracheal tube, generally due to inadequate fixation, impaired tissue perfusion, difficulty in mobilizing the device, and consequent damage to the oral cavity[5]. Respiratory devices are associated with high rates of injury, representing between 30% and 70% of MDRPI in critically ill patients, with particular emphasis on the use of noninvasive ventilation masks and the orotracheal tube[19]. With regard to the orotracheal tube, it is recommended that the auricular region be kept protected during its fixation[19]. In the unit where the study was conducted, fixation of the orotracheal tube was performed using fabric tape, exerting sustained pressure on the facial and lip areas, particularly on the auricle, thereby exponentially increasing the risk of injury.

A length of stay equal to or greater than 16 days was associated with the occurrence of MDRPI, increasing the likelihood of occurrence sevenfold. Data found in the literature indicate that the risk of device-related injury increases by 66% when device placement is extended beyond 24 hours[20]. Authors also report that patients using a medical device have a 2.4-fold higher risk of developing device-related injury compared with those who do not use such devices5, with a higher prevalence of MDRPI observed in long-term care units19. An integrative review showed an MDRPI rate of 19.9%, whereas 14.3% were pressure injuries in the sacral region, 10.2% in the heel, and 8.8% in the buttocks[2].

No statistically significant associations were identified between the number of devices and Braden Scale categorization at admission and the occurrence of MDRPI among participants. However, a higher number of MDRPI was observed in patients with shorter lengths of stay. Authors have shown that a short length of stay does not necessarily indicate lower clinical severity. Patients who rapidly progress to hemodynamic instability and/or require invasive interventions in the first hours of hospitalization often present an increased risk of skin injuries[20].

As a limitation of this study, it should be noted that it was conducted in a single unit and that there was low patient turnover in the sector studied, which prevented an increase in the sample size during the research period. In addition, associations between MDRPI incidence and the preventive measures implemented in the studied unit were not assessed. In light of the findings of this study, further investigations are recommended on the prevalence of medical device–related pressure injuries in other contexts, using methods that allow for analysis and a better understanding of the complex interaction of risk factors in the development of MDRPI, taking into account the preventive measures adopted.

CONCLUSION

The incidence of MDRPI in the unit investigated was related to patients' length of stay. The study revealed the importance of preventive strategies and continuous monitoring, based on the implementation of appropriate care protocols, staff training, and the use of suitable support devices that may reduce this adverse event. The need for training becomes evident, particularly with regard to MDRPI risk assessment and skin integrity evaluation, at admission and on a daily basis, for proper care planning, in addition to recording the actions implemented in medical records.

Acknowledgments: Not applicable.

Author contributions: JCFJ: Formal analysis, Conceptualization, Data curation, Writing – original draft, Investigation, Methodology, Validation, Visualization. LFA: Formal analysis, Conceptualization, Data curation, Writing – original draft, Writing – review and editing, Investigation, Methodology, Validation, Visualization. DCN: Formal analysis, Conceptualization, Data curation, Writing – original draft, Writing – review and editing, Investigation, Methodology, Validation, Visualization. VGP: Writing – original draft, Writing – review and editing, Validation, Visualization. CDL: Writing – original draft, Writing – review and editing, Validation, Visualization. AMFM: Writing – original draft, Writing – review and editing, Validation, Visualization.

Availability of research data: All data were generated or analyzed in the present study.

Funding: Not applicable.

Conflict of interest: None declared.
Research ethics committee approval: Approved by the Research Ethics Committee of the State University of Rio de Janeiro, under opinion no. 4.747.146/2022; part of the project "Analysis of care practices in intensive care units." Certificate of Presentation for Ethical Consideration no. 41871820.7.0000.5282.

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