





# Oropharyngeal tube-related pressure injury in critically ill patients: a prospective cohort study

*Lesão por pressão relacionada ao tubo orotraqueal em pacientes críticos: coorte prospectiva*

*Lesiones por presión relacionadas con el tubo orotraqueal en pacientes críticos*

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## ABSTRACT

**Objective:** to investigate the incidence, risk factors, and characteristics of oropharyngeal tube (OPT)-related pressure injury in critically ill patients. **Method:** a prospective cohort study conducted in the adult Intensive Care Unit of a university hospital from May to July 2023. Patients using an orotracheal tube OPT for more than 24 hours were included; those with skin pathologies were excluded. Participants were monitored until OPT removal, discharge, transfer, or death. **Results:** the incidence of pressure injury was 32.8%. Mucosal Membrane Injury (28.6%) and Stage 2 (28.6%) were the predominant classifications. The lips and labial commissure (52.4%) were the most affected sites. Fever, pulmonary dysfunction, elevated C-Reactive Protein scores, and low Glasgow Coma Scale scores were risk factors ( $p < 0.05$ ). **Conclusion:** evidence-based interventions are necessary to reduce the rate of these injuries.

**Descriptors:** Nursing; Patient Safety; Equipment and Supplies; Intubation; Pressure Ulcer.

## RESUMO

**Objetivo:** investigar a incidência, os fatores de risco e as características da lesão por pressão relacionada ao tubo orotraqueal em pacientes críticos. **Método:** coorte prospectiva, desenvolvida em uma unidade de terapia intensiva adulto de um hospital universitário, de maio a julho de 2023. Foram incluídos pacientes em uso de tubo orotraqueal há mais de 24h e excluídos aqueles com patologias cutâneas. Os participantes foram acompanhados até a remoção do tubo orotraqueal, alta, transferência ou óbito. **Resultados:** a incidência de lesão por pressão foi de 32,8%. Lesão em Membranas Mucosas (28,6%) e de Estágio 2 (28,6%) foram as classificações predominantes. Lábios e comissura labial (52,4%) foi o sítio mais acometido. Febre, disfunções pulmonares, elevado score de Proteína C Reativa e baixo escore na escala de Coma de Glasgow foram fatores de risco ( $p < 0,05$ ). **Conclusão:** intervenções baseadas em evidências são necessárias para diminuir a taxa dessas lesões em pacientes em usos de tubo orotraqueal.

**Descritores:** Enfermagem; Segurança do Paciente; Equipamentos e Provisões; Intubação; Lesão por Pressão.

## RESUMEN

**Objetivo:** investigar la incidencia, los factores de riesgo y las características de las lesiones por presión relacionadas con el tubo orotraqueal en pacientes críticos. **Método:** estudio de cohorte prospectivo, realizado en una unidad de cuidados intensivos de adultos de un hospital universitario, de mayo a julio de 2023. Se incluyeron pacientes que utilizaron tubo orotraqueal durante más de 24 horas y se excluyeron aquellos con patologías cutáneas. El seguimiento de los participantes se realizó hasta la retirada del tubo orotraqueal, el alta, el traslado o el fallecimiento. **Resultados:** la incidencia de lesiones por presión fue del 32,8 %. Las lesiones de las mucosas (28,6 %) y las lesiones de grado 2 (28,6 %) fueron las clasificaciones predominantes. Las zonas más afectadas fueron los labios y la comisura labial (52,4 %). Los factores de riesgo fueron fiebre, disfunción pulmonar, elevación de la proteína C reactiva y baja puntuación en la Escala de Coma de Glasgow ( $p < 0,05$ ). **Conclusión:** es necesario que se realicen intervenciones basadas en la evidencia para reducir la tasa de estas lesiones.

**Descriptorios:** Enfermería; Seguridad del Paciente; Equipos y Suministros; Intubación; Úlcera por Presión.

## INTRODUCTION

Medical devices are widely used in Intensive Care Units (ICUs) for various diagnostic, therapeutic, and monitoring purposes<sup>1</sup>. The use of pulse oximeters, oropharyngeal tubes (OPTs), gastric, vascular, arterial, and bladder catheters, although crucial for sustaining the life of critically ill patients, can intensely compress soft tissues and/or mucous membranes or subject them to shear forces, contributing to the development of medical device-related pressure injury (MDRPI)<sup>2</sup>.

The oropharyngeal tube is a device made of polyvinyl chloride (PVC), polyurethane, or silicone, with a flexible design, composed of a body, pilot balloon, and cuff. It is used in orotracheal intubation and functions to maintain a clear airway and enable ventilation in patients requiring respiratory support<sup>3,4</sup>.

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The OPT is an essential device for life support and is widely used in the ICU. However, its use is not without complications. Pressure injury is a potential complication, especially with improper fixation and prolonged use of the OPT. Patient-related factors and the quality of care also contribute to this adverse event, such as altered level of consciousness, physical immobility, multiple organ dysfunction, use of vasoactive drugs, nutritional deficiencies, and prolonged hospitalization<sup>5</sup>. This issue has recently gained prominence and has become an important indicator of the quality of care provided<sup>6</sup>.

Although MDRPIs are a growing threat to patient safety and quality of care in the ICU, only a few studies have captured information on MDRPI in critically ill patients, which complicates data comparison and demonstrates that scientific production on the distribution, characteristics, and determinants of these injuries is incipient.

A study conducted in Jordan identified a 38.1% prevalence of medical device-related pressure injuries, predominantly observed in the sacrum and heel. These findings indicated that injuries disproportionately affected older individuals, those hospitalized in public institutions, and patients requiring prolonged hospitalization<sup>7</sup>. Similarly, a prevalence of 37.5% was identified in Turkey<sup>8</sup>.

Given the currently incipient correlation between the occurrence of these injuries and the use of devices like the OPT, the objective of this study was to investigate the incidence, risk factors, and characteristics of oropharyngeal tube-related pressure injury in critically ill patients.

## METHOD

This is a prospective, single-arm cohort study. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) – cohort studies guidelines were used for reporting this study.

The population included patients admitted to the adult ICU of a large university hospital in the Central-West region of Brazil, during a three-month follow-up, with data collected daily from May to July 2023 by trained and calibrated researchers. Individuals aged  $\geq 18$  years, using an OPT for at least 24 hours, were included. Patients with skin pathologies were excluded.

Follow-up lasted from the patient's enrollment in the study until medical device removal, discharge, transfer, or death.

The ICU in question has ten beds, two of which are isolation rooms, all equipped with the necessary support to provide intensive care to critically ill patients admitted to the unit. Prior to data collection, eligible patients whose autonomy was preserved were invited to participate voluntarily in the research. For patients with compromised autonomy, the researcher approached the legal guardian with the same procedure.

The approaches were conducted using clear and accessible language, explaining the research objective, data collection method, and ethical aspects; furthermore, the researcher remained available to clarify any doubts. Upon agreement, they were asked to read the Informed Consent Form (ICF) and, subsequently, sign the document. For patients with compromised autonomy, the ICF was read and signed by the patient's legal guardian.

After consent, patient data were collected from medical records, and skin integrity in contact with medical devices was monitored daily. If an OPT-related PI was suspected, standardized photographs were taken of the site and sent, without identification, to two independent stomatherapists to perform the MDRPI diagnosis and its classification. Discrepancies were resolved through consensus meetings.

Sociodemographic variables were studied, including age and sex, and clinical variables, considering the reason for admission, duration of OPT use, length of ICU stay, duration of mechanical ventilation, anasarca, comorbidities, Braden scale, MDRPI classification, time elapsed until MDRPI occurrence, fever, medications in use, laboratory exams (hemoglobin, erythrocytes, albumin, C-reactive protein (CRP), leukocytes, and platelets), completion of the Acute Physiology and Chronic Health Evaluation II (APACHE II), Simplified Acute Physiology Score III (SAPS III), Richmond Agitation-Sedation Scale (RASS), and Glasgow Coma Scale.

The data obtained were entered and recorded in a Google Sheets® spreadsheet and subsequently analyzed using absolute and relative frequency distributions. Descriptive and inferential statistical analyses were performed using Statistical Package for Social Sciences – IBM SPSS® software, version 25.0, applying the Kolmogorov-Smirnov test to determine data distribution normality, Chi-square tests for qualitative variables, and Mann-Whitney tests for quantitative variables related to the incidence of OPT-related pressure injury and the variables studied. A significance level of 5% was considered for all tests. Relative Risk (RR), with a 95% confidence interval (CI), was used to estimate the magnitude of associations.

This study adhered to international and national ethical norms and guidelines for research involving human beings and had its protocol approved by the Research Ethics Committee linked to the responsible institution, obtaining a consolidated opinion and the certificate of presentation for ethical appreciation (CAAE).

## RESULTS

Of the eligible patients (n=66), two were excluded due to Stevens-Johnson Syndrome. Thus, the sample comprised 64 patients, the majority of whom were male (59.4%), with a mean age of 48.7 ( $\pm 17.58$ ) years, a history of smoking (45.3%), and people with comorbidities, predominantly systemic arterial hypertension (43.8%) and diabetes mellitus (25%). It was observed that 35.9% presented with anasarca and 62.5% had a fever. The majority of patients used antibiotics (98.4%), sedatives (92.2%), and anticoagulants (81.3%).

Tables 1 and 2 present the association analyses performed regarding the risk of injury occurrence and the participant characterization variables.

**Table 1:** Qualitative sociodemographic and clinical variables of patients according to the occurrence of medical device-related pressure injury. Campo Grande, MS, 2023

Variable		MDRPI		Total n(%)	p-value	Relative Risk [CI95%]
		Yes n(%)	No n(%)			
Gender	Female	10(38.5)	16(61.5)	26(40.6)	0.426*	1.53
	Male	11(28.9)	27(71)	38(59.4)		[0.53-4.41]
Age group	≤ 50 years old	11(28.2)	28(71.8)	39(60.9)	0.327*	0.59
	> 50 years old	10(40)	15(60)	25(39.1)		[0.20-1.70]
Anasarca	Yes	11(47.8)	12(52.2)	23(35.9)	0.055*	2.84
	No	10(24.4)	31(75.6)	41(64.1)		[0.96-8.41]
Reason for hospitalization: surgical	Yes	2(16.7)	10(83.3)	12(18.8)	0.308*	0.35
	No	19(36.5)	33(63.5)	52(81.2)		[0.07-1.75]
Reason for admission: sepsis	Yes	4(30.8)	9(69.2)	13(20.3)	1.000†	0.89
	No	17(33.3)	34(66.7)	51(79.7)		[0.24-3.31]
Reason for hospitalization: other	Yes	15(34.1)	29(65.9)	44(68.8)	0.747*	1.21
	No	6(30)	14(70)	20(31.2)		[0.38-3.78]
Comorbidity	Yes	17(32.7)	35(67.3)	52(81.2)	0.966*	0.97
	No	4(33.3)	8(66.7)	12(18.8)		[0.26-3.68]
SAH	Yes	9(32.1)	19(67.9)	28(43.8)	0.920*	0.95
	No	12(33.3)	24(66.7)	26(56.2)		[0.33-2.72]
DM	Yes	7(43.8)	9(56.3)	16(25)	0.282*	1.89
	No	14(29.2)	34(70.8)	48(75)		[0.59-6.07]
Pulmonary dysfunction	Yes	8(61.5)	5(38.5)	13(20.3)	0.021†	4.68
	No	13(25.5)	38(74.5)	51(79.7)		[1.30-16.86]
IDP	Yes	3(23.1)	10(76.9)	13(20.3)	0.510†	0.55
	No	18(35.3)	33(64.7)	51(79.7)		[0.13-2.26]
COPD	Yes	5(45.5)	6(54.6)	11(17.2)	0.481†	1.93
	No	16(30.2)	37(69.8)	53(82.8)		[0.51-7.24]
Renal dysfunction	Yes	2(22.2)	7(77.8)	9(14)	0.706†	0.54
	No	19(34.6)	36(65.5)	55(86)		[0.10-2.87]
Cardiac dysfunction	Yes	3(37.5)	5(62.5)	8(12.5)	1.000†	1.27
	No	18(32.1)	38(67.9)	56()		[0.27-5.89]
Oncological	Yes	1(14.3)	6(85.7)	7(10.9)	0.410†	0.31
	No	20(35.1)	37(64.9)	57(89.1)		[0.03-2.74]
History of smoking	Yes	12(41.2)	17(58.6)	29(45.3)	0.184*	2.04
	No	9(25.7)	26(74.3)	35(54.7)		[0.71-5.88]
Fever	Yes	17(42.5)	23(57.5)	40(62.5)	0.033*	3.70
	No	4(16.7)	20(83.3)	24(37.5)		[1.07-12.81]
Used antibiotics	Yes	21(33.3)	42(66.7)	63(98.4)	1.000†	---
	No	---	1(100)	1(1.6)		---
Used anticoagulants	Yes	19(36.5)	33(63.5)	52(81.3)	0.308*	2.88
	No	2(16.7)	10(83.3)	12(18.7)		[0.57-14.54]
Used sedative	Yes	21(35.6)	38(64.4)	59(92.2)	0.163*	---
	No	---	5(100)	5(7.8)		---
Used corticosteroid	Yes	15(34.1)	29(65.9)	44(68.8)	0.747*	1.21
	No	6(30)	14(70)	20(31.2)		[0.38-3.78]
Used anti-inflammatory	Yes	10(37)	17(62.9)	27(42.2)	0.539*	1.39
	No	11(29.7)	26(70.3)	37(57.8)		[0.48-3.98]

**Notes** PI: Pressure injury; MV: mechanical ventilation; SAH: Systemic Arterial Hypertension; DM: Diabetes Mellitus; IDP: Infectious-parasitic diseases; COPD: Chronic obstructive pulmonary disease \*Chi-square Test; †Fisher's Exact Test

**Table 2:** Association analysis between the occurrence of medical device-related pressure injury and continuous sociodemographic and clinical variables of the patients. Campo Grande, MS, Brazil, 2023.

Variable	PI	Mean±SD	p-value*
Age	Yes	52.6±15.2	0.290
	No	46.8±18.5	
Duration of mechanical ventilation	Yes	11.4±7.8	0.832
	No	12.3±11.3	
Braden	Yes	10.8±1.6	0.799
	No	11±2.1	
RASS	Yes	-3.8±1.3	0.222
	No	-3.5±1.1	
Glasgow	Yes	9.8±3.5	0.135
	No	11.5±3.1	
SOFA	Yes	7.8±3.9	0.396
	No	6.9±3.7	
SAPS 3	Yes	61.3±14.8	0.466
	No	60.2±13.9	
APACHE	Yes	25.2±4.8	1.000
	No	24.9±6.9	
NUTRIC	Yes	4.7±1.4	0.782
	No	4.7±1.8	
Hemoglobin	Yes	10±1.9	0.489
	No	10±3.1	
Erythrocyte	Yes	3.4±0.71	0.896
	No	3.5±0.9	
Leukocytes	Yes	13038±8399.4	0.531
	No	11267.6±5225.3	
Platelets	Yes	230620.4±106939.9	0.258
	No	259171.3±122877.9	
CRP	Yes	149.4±130.7	0.018
	No	86.5±52.2	
Albumin	Yes	2.4±0.64	1.000
	No	2.6±0.91	
Duration of oropharyngeal tube use	---	8.7±5.3	0.200

**Notes:** \*Mann-Whitney Test; PI: Pressure injury; SD: Standard deviation; RASS: Richmond Agitation Sedation Scale; SOFA: Sequential Organ Failure Assessment; SAPS 3: Simplified Acute Physiology Score; APACHE: acute physiology and chronic health evaluation; CRP: C-reactive protein.

Compared to non-exposed individuals, the relative risk of developing OPT-associated PI was: 4.68 (RR=4.68; 95% CI: 1.30-16.86) times higher in patients with pulmonary dysfunction and 3.70 times higher in patients with fever (RR=3.70; 95% CI: 1.07-12.81). Elevated C-reactive protein (CRP) scores were associated with the incidence of OPT-related PI (p=0.018). Conversely, patients with higher Glasgow Coma Scale scores (p=0.135) showed a lower risk of developing injury.

Table 3 presents the characteristics of pressure injuries associated with oropharyngeal tube use.

**Table 3:** Characteristics of pressure injuries associated with the use of an orotracheal tube. Campo Grande, MS, 2023

Characteristics		n	f (%)
Oropharyngeal tube-related injury	Yes	21	32.8
	No	43	67.2
	1	1	4.8
	2	6	28.6
Classification	Mucosal injury	6	28.6
	Unstageable injury	5	23.8
	Deep tissue injury	3	14.3
	Lip/labial commissure	11	52.4
	Face	6	28.6
	Oral mucosa	5	23.8
	Auricular region	4	19.1
Location*	Tongue	2	9.5
	Labial mucosa	1	4.8

**Note:** \*multiple response.

The overall incidence of OPT-related PI was 32.8% (21/64). Regarding staging, the injuries were mostly classified as: mucosal injury (28.6%), stage 2 (28.6%), and unstageable (23.8%). The most affected anatomical sites were the lips/labial commissure (52.4%), face (28.6%), and oral mucosa (23.8%). The device usage time was  $8,7 \pm 5,3$  days.

## DISCUSSION

In this study, the incidence of OPT-related PI was 32.8%, which aligns with studies conducted previously<sup>7,8</sup>. However, these findings are considerably higher than the 20.9% reported in an ICU in São José, Santa Catarina (Brazil)<sup>9</sup>.

The discrepancy in data may be justified by the different clinical profiles of the patients. In the Santa Catarina study<sup>9</sup>, most patients were admitted to the ICU for post-operative monitoring, whereas in the Turkish study<sup>8</sup>, patients had various diagnoses, predominantly respiratory, similar to the present study.

Corroborating the literature, the most affected sites by injuries were the lips and adjacent structures, such as the labial commissure and oral mucosa<sup>10</sup>. Furthermore, the auricular region, the fourth most affected anatomical site in this study, accounted for a high rate of injuries in similar studies<sup>11,12</sup>.

This result is possibly related to the quality of the preventive care provided, considering rotation of the OPT placement site in the mouth, tension of the fixation strap, among others, and the use of manufactured versus industrialized fixation devices.

An Israeli study showed a significant advantage for fixation with Anchorfast Hollister® compared to standard cloth fixation<sup>13</sup>. Conversely, a randomized study in Turkey showed that using a specific industrial bandage for OPT fixation yielded better results regarding the risk of developing PI, tendency for displacement, fixation failure, or remaining fixed<sup>14</sup>.

Regarding staging, the OPT injuries were consistent with research from Turkey<sup>8</sup>, which identified stage 2, followed by mucosal injury and unstageable injury, as the most recurrent. The adverse event occurs in these regions due to the medical equipment itself and the fixation methods used for the OPT, as some devices exert more pressure than these areas can withstand. As a consequence of constant, intense pressure combined with shear forces, the skin in contact with the fixation and the device ruptures or forms blisters characteristic of stage 2, or it undergoes tissue damage of unconfirmed depth because it is covered by slough or eschar<sup>2</sup>.

It was observed that pulmonary dysfunction, fever, high CRP values, and low Glasgow Coma Scale scores were risk factors for developing OPT-associated PI in critically ill patients. This finding may be explained by these conditions often requiring longer mechanical ventilation times.

Considering pulmonary dysfunction, the continuous pressure and friction generated by the OPT on the oral mucosa and nearby skin, as well as by the fixation, can compromise skin integrity, contributing to MDRPI, especially in critical patients who are immobile and have greater difficulty with decubitus changes and pressure relief. Furthermore, the pathology itself causes local and systemic oxygenation problems, increasing the risk of tissue hypoxia in areas constantly pressed by devices<sup>15,16</sup>.

Regarding fever, it is noted that the condition increases metabolism and sweating, making the environment around the OPT and fixation damp and warm, which contributes to increased friction and pressure in contact areas<sup>16</sup>.

Moreover, fever can raise body temperature to a point that compromises the anatomical and physiological structure of the skin<sup>17</sup>. Such factors can contribute to the mechanism of PI formation. Furthermore, fever is an organic response mediated by inflammatory cytokines. Therefore, fever is an indicator of biochemical changes, which can also contribute to the formation of pressure injuries<sup>15,17</sup>.

The association between high CRP values and the development of pressure injury may be related to this biomarker compromising the cellular integrity of the skin and being associated with organic dysfunctions that also compromise the structure and function of epithelial cells<sup>18,19</sup>. All these circumstances facilitate the occurrence of MDRPI and support these results.

Patients with low Glasgow Coma Scale scores have reduced levels of consciousness, such as those in a coma, with severe neurological impairment, or high levels of sedation, often presenting a diminished ability to report discomfort or pain, as well as reduced mobility and spontaneous movements, which are protective factors against PI<sup>20,21</sup>. Additionally, the altered level of consciousness, combined with the presence of medical devices, increases the risk of PI<sup>1</sup>.

### Study limitations

This study has limitations related to the small sample size, short follow-up period, the lack of association between fixation types and the development of pressure injury, and the insufficient investigation of the relationship between vasoactive drug use and the incidence of OPT-related MDRPI. Thus, more research, especially multicenter and robust studies, should be conducted to demonstrate the magnitude of the problem, map risk factors, and investigate the impact of quality improvement programs on the incidence of this type of injury in critically ill patients.

### CONCLUSION

The incidence of pressure injury related to OPT use was 32.8%. The injuries were predominantly classified as mucosal membrane injury, followed by stage 2 injury. The lips, including the labial commissure, were the anatomical site most frequently associated with PI. Pulmonary dysfunction, high CRP scores, low Glasgow Coma Scale scores, and fever are risk factors for MDRPI from OPT use.

The study contributes to raising the visibility of PI caused by OPTs in the ICU as a significant and preventable adverse event, and also to improving the quality of care provided. In this regard, it provides professionals with resources for assessing the sites most affected by PI and identifying patients at higher risk, in order to detect early signs of injury, evaluate OPT fixation and maintenance, using safe devices and skin protection barriers, perform device position changes to minimize local pressure, and implement early interventions and reduce complications.

Furthermore, it highlights the need for more research on the topic to fill knowledge gaps and generate a level of evidence for constructing predictive scales and for developing specific and effective nursing interventions.

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#### Authors contributions

Conceptualization, A.R.S. and O.P.F.; methodology, A.R.S. and J.B.F.; software, O.P.F. and M.A.F.J.; validation, M.A.F. and O.P.; formal analysis, A.R.S. and J.B.F.; investigation, A.R.S. and J.B.F.; resources, O.P.F. and M.A.F.J.; data curation, A.R.S., J.B.F., O.P.F. and M.A.F.J.; manuscript writing, A.R.S.; review and editing, A.R.S., O.P.F. and M.A.F.J.; visualization, A.R.S.; supervision, A.R.S. and O.P.F.; project administration, A.R.S., J.B.F. and O.P.F. All authors read and agreed with the published version of the manuscript.

#### Use of artificial intelligence tools

Authors declare that no artificial intelligence tools were used in the composition of the manuscript “*Oropharyngeal tube-related pressure injury in critically ill patients: a prospective cohort study*”.