

FREE COMMUNICATION**SAFETY INCIDENTS CLASSIFIED AS CLINICAL PROCESS/
PROCEDURE IN HOSPITALIZED PATIENTS DURING THE
COVID-19 PANDEMIC****HIGHLIGHTS**

1. Safety incidents during the COVID-19 pandemic
2. High prevalence of incidents in the Clinical Process/Procedure category
3. High frequency of pressure ulcers in SARS patients
4. Healthcare risk management in the pandemic

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ABSTRACT

Objective: Compare reported patient safety incidents related to a clinical process/procedure among patients with laboratory-confirmed COVID-19 diagnosis and with Severe Acute Respiratory Syndrome (SARS) caused by another infectious or undetermined agent and the other patients. **Results and discussion:** retrospective, documentary study approved by the ethics committee in a public teaching hospital in southern Brazil. In the study, 2,191 notifications and records of COVID-19 between March and September 2020 were used. The data were submitted to descriptive analysis with frequencies of the variables in the data set, Fisher's test to determine the associations between outcomes (classification/process/problem) and calculation of relative risk to measure its strength. The incidence of pressure ulcers was almost 3.7 times higher in patients with SARS. In the others, various tube-related incidents and events associated to the surgical process predominated. **Conclusion:** Intensive nursing care for patients with SARS, risk management and strengthening of good practices for the safety of all patients were relevant.

KEYWORDS: Patient safety; COVID-19; Risk management; Notification; Nursing team.

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INTRODUCTION

A first-rate health system provides care safe and free of harm care to patients, except those associated with the natural course of disease. Patient safety is directly related to the quality of the health system. In this regard, Patient Safety Incident (PSI) is an event or circumstance that could have resulted, or did result in unnecessary harm to a patient; and, in turn, Adverse Event (AE) is an incident that results in harm to the patient. These concepts related to safety incidents are contained in the International Classification for Patient Safety (ICPS) of the World Health Organization. The ICPS consists of 10 classes and 48 key concepts, including the Clinical Process/Procedure category¹.

The rate of Adverse Events (AEs) in middle and low-income countries was approximately eight (8%), of which 83% could have been avoided and 30% led to death². In Brazil, in 2021, more than 200,000 incidents were notified to ANVISA, of which more than 90% occurred in hospital institutions. Of these safety incidents, more than half caused harm to patients³. In addition to the Patient Safety Incidents (PSIs), health institutions have faced complex challenges over the past two years related to providing first-rate care to patients affected by the SARS-CoV-2 virus, which caused the COVID-19 pandemic⁴.

Undeniably, before the COVID-19 pandemic, little was known about its impact on patient safety, as well as on the consequences of the interruption of mechanisms for identifying issues related to the pandemic^{5,6}. Some factors associated with coping with the disease contributed to the occurrence of incidents, such as: the increase in the number of complex patients to be treated by health professionals, the emergency formation of new work teams and the intensified pace or amount of work that generated a high level of stress, and these factors were obstacles to the voluntary reporting of incidents^{2,6}. Moreover, the fear of contamination in patient care combined with the use of Personal Protective Equipment (PPE) during exhaustive working hours by professionals increased the risk of incidents in health services.

It should be noted that health organizations must be able to record and measure the occurrence of patient safety incidents, as they are the main source of information for proper risk management and definition of barriers and instruments for their prevention and recurrence, as well as for the minimization of risks during the provision of assistance in health services⁷.

The present study aimed to compare Patient Safety Incidents (PSI) classified as a clinical process/procedure among hospitalized patients with a laboratory-confirmed diagnosis of COVID-19 and patients with Severe Acute Respiratory Syndrome (SARS) caused by another infectious agent or undetermined, as well as other patients admitted to Complexo Hospital de Clínicas of the Federal University of Paraná (CHC-UFPR).

RESULTS AND DISCUSSION

Quantitative, retrospective and documentary study whose secondary data were extracted from the patient safety incident notification control worksheet and the control worksheet for patients with SARS at CHC-UFPR, from March 1st to September 30, 2020. In the first stage, in 2021, analysis of these notifications in the electronic notification system was carried out, which included hospitalized patients with other diseases and patients with laboratory-confirmed COVID-19 diagnosis. Each notified incident was read and classified according to the ICPS, and the data were organized in an Excel® file. In the second stage, the diagnosis of patients who suffered PSI were classified according to the presence of SARS-CoV-2, SARS by another infectious agent and not SARS, which were called exposure categories.

The data were submitted to descriptive analysis with simple and relative frequency estimation of the variables, in general. Subsequently, descriptive statistics of the classification and process/problem were performed according to the presence of SARS-CoV-2, SARS and non-SARS. For this last analysis, the association between each outcome (classification and process/problem) and exposures to SARS-CoV-2 x SARS, SARS-CoV-2 x non-SARS and SRAS x non-SARS were verified using the chi-square test or Fisher's exact test. To check the intensity of the associations, relative risk (RR) was calculated under 95% confidence interval. Tests were considered significant when $p < 0.05$, and analyzes were performed using SPSS® 21.0. The study was approved by the Research Ethics Committee of the CHC-UFPR under protocol C.A.A.E no 36675220.0.0000.0096.

Analysis of the objectives

Of the total 2,191 PSI notifications, 1,737 (79.3%) concerned SARS-free patients, 230 (10.5%) were related to patients with Severe Acute Respiratory Syndrome caused by SARS-CoV-2, and 224 (10.2%) were related to patients with SARS caused by other infectious agents or negative laboratory results for SARS-CoV-2. The data showed that the ICPS clinical process/ procedure class was prevalent in the three exposure categories.

In a stratified manner, patients with SARS-CoV-2 had 30% more incidents related to the ICPS class Clinical process/procedure than patients with other SARS (RR=1.3; 95%CI 1.1 – 1.5; $p = 0.002$) and 60% more incidents in this class compared to patients without SARS (RR=1.6; 95%CI 1.4 – 1.7; $p < 0.001$). In turn, comparison between patients with SARS due to another infectious agent or not determined and patients without SARS showed that patients with SARS had 20% more incidents associated with Clinical process/procedure (RR=1.2; 95%CI 1.0 – 1.4; $p = 0.019$). As can be seen, patients with SARS-CoV-2 or SARS caused by another infectious or undetermined agent are more likely to suffer an incident classified as a Clinical process/procedure. Chances are higher in patients with SARS-CoV-2.

In the Clinical Process/Procedure class, general care stands out as responsible for 625 (65.3%) of all recorded incidents, of which 123 (84.8%) among patients with SARS-CoV-2, 78 (71, 6%) among SARS and 424 (60.3%) among non-SARS patients. Patients with SARS-CoV-2 had 20% more incidents related to the general care problem than patients with SARS caused by another infectious agent or not determined agent (RR=1.2; 95%CI 1.0 – 1.3; $p = 0.010$) and 40% more incidents compared to patients without SARS (RR=1.4; 95% CI 1.3-1.5; $p<0.001$). The main process/problem in this class was pressure ulcer. Patients with SARS-CoV-2 were found to develop 3.7 times more pressure ulcers compared to patients without SARS (RR=3.7; 95% CI 3.0-4.5; $p<0.001$). Patients with SARS caused by another or undetermined infectious agent developed 3.5 times more pressure ulcers compared to patients without SARS (RR=3.5; 95% CI 2.8-4.3; $p<0.001$).

The second most prevalent process/problem was inadequate procedure/treatment/intervention, in 251 (26.2%) of the occurrences. This category included weaknesses in various tube-related interventions and incidents related to the surgical process. Patients with SARS-CoV-2 had 70% fewer incidents classified as a procedure/treatment/intervention compared to patients without SARS (RR=0.3; 95% CI 0.2-0.5; $p<0.001$) and patients with SARS caused by another infectious agent or not determined had 50% fewer incidents compared to patients without SARS (RR=0.5; 95% CI 0.3-0.8; $p<0.002$).

DISCUSSION OF FINDINGS

Most incidents were classified in the clinical process/procedure class. In this class, it was evident that many incidents occurred during the general care provided to patients with SARS, especially those with SARS-CoV-2. The main factors that contributed to the

occurrence of these incidents were the accelerated process of recruiting health professionals during the pandemic; absence of all necessary training; fatigue from reduced teams; and fear of contracting COVID-19⁸.

Although institutional efforts related to training people have been made, these may have been insufficient in addressing all protocols and procedures, in view of the singularities in clinical environments and workflows. The present study demonstrated an almost four times higher frequency of pressure ulcers (PU) in SARS patients compared to non-SARS patients. In patients with COVID-19, particularly, there are differences in the pathophysiological findings of pressure ulcers that contribute to their onset, such as systemic coagulopathy, hypercatabolism and nutritional deficit, combined with the tendency of this population to clinical and hemodynamic instabilities⁹.

These injuries may be associated with the prone position, which, although beneficial for the patient's respiratory system, contributes to the development of pressure ulcers on the face and neck. These injuries are also correlated with less frequent repositioning of patients due to the efforts of health care professionals to reduce the number of these workers in the wards/exam rooms in order to limit exposure to the coronavirus and preserve personal protective equipment. These measures restricted the presence of visitors and family members, leaving patients unaccompanied for a long time^{6,10}.

In a study of the prevalence of pressure ulcers in patients with obesity and COVID-19 carried out in four intensive care units of a heart hospital in the city of New York, United States, the authors found that the prevalence was exponentially higher in this population compared to any period prior to the pandemic¹¹.

In contrast, in another hospital in the USA, there was a 44% reduction in the number of pressure ulcers acquired in the hospital environment in patients with COVID-19, in the period of June and July 2020, compared to the period of March to May 2020. The patients remained in a serious clinical status from March to July 2020. Therefore, this reduction in PU was attributed to the implementation of a health learning system that begins with the identification of weaknesses in care; projected implementation of practical interventions based on evidence and intuition of frontline workers, as well as subsequent evaluation with possible adjustments and dissemination of results within the medical institution and to the external community¹⁰.

Incidents involving process/problem, procedure, treatment and intervention were the second most prevalent type of incident in the clinical process/procedure class. The present study found that patients with SARS had fewer incidents of this kind compared to patients without SARS. This can be explained by the significant restriction of surgeries in patients with SARS, either because of the risk posed to health professionals, or because of the greater risk of unfavorable outcomes for patients¹². Therefore, it should be noted that the impact of the pandemic on other patients whose treatment was delayed, discontinued or cancelled due to organizational change processes must be managed¹³.

FINAL CONSIDERATIONS

The study points to the importance of institutional learning from the analysis of patient safety incident reports, especially in exceptional situations, as was the period of the COVID-19 pandemic. The significant number of incidents related to pressure ulcers points to the important role of nursing in the care of patients with SARS, mainly because these patients demand greater assistance and surveillance, requiring intensive care and additional efforts from the nursing team, as it is a matter of providing care to highly complex patients, who are known to develop more injuries than others due to the previously described factors.

On the other hand, patients without SARS suffered more various tube-related

incidents and incidents related to the surgical process, and so the nursing team increasingly needs to work towards risk management and strengthening adherence to the good patient safety practices established in the institution. Hospitalized patients are exposed to risks, regardless of the diagnosis, requiring constant surveillance from the health team. The fact that the data come from spontaneous notifications of the first seven months of the pandemic, a period in which the number of notifications was lower than that recorded in previous periods, and that the presentation of results was restricted to one of the ten ICPS classes are limitations of this study.

Therefore, the development of other studies on PSI notifications throughout the pandemic period is recommended to establish proof, or non-proof, of the profile presented, as well as to associate other sources of data on incidents such as the analysis of medical records and on-site assessments.

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