


RESEARCH

Nursing care and prevalence of adverse events in prone position: Characteristics of mechanically ventilated patients with severe SARS-CoV-2 pulmonary infection

María Dolores Rodríguez-Huerta RN, MSc¹ | Ana Díez-Fernández RN, PhD^{2,3}  |
 María Jesús Rodríguez-Alonso RN¹ | María Robles-González RN¹ |
 María Martín-Rodríguez RN⁴ | Alberto González-García RN, PhD^{3,5}

¹Intensive Care Unit, La Princesa University Hospital, Madrid, Spain

²Faculty of Nursing, Universidad de Castilla-La Mancha, Cuenca, Spain

³Centro de Estudios Sociosanitarios, Universidad de Castilla-La Mancha, Cuenca, Spain

⁴Nuestra Señora de Sonsoles Hospital, Ávila, Spain

⁵Faculty of Health Sciences, University of Granada, Granada, Spain

Correspondence

Ana Díez-Fernández. Centro de Estudios Sociosanitarios, Universidad de Castilla-La Mancha, Calle Santa Teresa de Jornet s/n, Cuenca 16071, Spain.
 Email: ana.diez@uclm.es

Abstract

Background: Because of the coronavirus disease 2019 (COVID-19) pandemic, the use of prone positioning has dramatically increased in the intensive care unit (ICU). Because this manoeuvre is related to several complications, it must be performed in a protocolized manner by the appropriate personnel.

Aim: To determine the prevalence of adverse events (AEs) in patients admitted to the ICU with a diagnosis of COVID-19-related acute respiratory distress syndrome (C-ARDS) undergoing mechanical ventilation in prone position (PP).

Design: Descriptive ambispective study of patients admitted to the ICU diagnosed with C-ARDS undergoing mechanical ventilation who were in the PP at least once.

The number of PP manoeuvres and the time spent in the PP were recorded for each subject. AEs proportions and frequencies were calculated, and analysis of variance was used to assess mean differences in the number of manoeuvres and total hours in PP stratified by the number of facial pressure ulcers. IBM SPSS Statistics v.25.0. and EPIDAT 4.1 software were used.

Results: Forty-four patients were analysed, and 130 PP manoeuvres were performed. The most frequently observed AEs were facial oedema in 26 patients (80.3%) and facial pressure ulcers in 20 (60.6%). There was a significant positive association between the time spent in PP and the development of facial pressure ulcers ($P < .001$). Enteral nutrition was well tolerated, and no serious AEs or sentinel events were noted.

Conclusion: Despite the stressful, demanding situation during the peak of the pandemic, the large number of PP manoeuvres, and long duration spent in this position, no serious AEs occurred. This study highlights the need to implement preventive measures to avoid the development of pressure ulcers secondary to prone positioning.

Relevance to practice: Prone positioning requires a nursing protocol to prevent the occurrence of AEs that may reduce the quality of nursing care.

KEYWORDS

adverse events, COVID-19, nursing care, pressure ulcers, prone position

1 | INTRODUCTION

Severe respiratory symptoms caused by the new viral disease coronavirus disease 2019 (COVID-19) appear after an average period of 5 or 6 days in approximately 20% of the patients, of whom 5% require admission to intensive care units (ICUs) and mechanical ventilation.¹ During the pandemic, ICUs worldwide have been overwhelmingly occupied by patients diagnosed with COVID-19-related acute respiratory distress syndrome (C-ARDS).² The overall mortality rate in Spanish ICUs, according to the ELVIN-HELICS registry in 2018, was 9.52%.^{3,4} Since the beginning of the pandemic, this rate has dramatically increased to 20%, highlighting the severity of COVID-19 and the extreme situation in Spanish ICUs during the pandemic.

The results of several studies^{5,6} conducted in the last 15 years support the use of the prone position (PP) in conjunction with other interventions, such as lung protective ventilation strategies; therefore, it is currently a highly recommended intervention in ARDS patients. The response may differ from one patient to another, but the PP results in improvements in respiratory mechanics and gas exchange and a decrease in lung heterogeneity, potentially decreasing the risk of the development of ventilation-induced lung injury.⁷

Regarding mortality, a systematic review published in 2017 including eight trials comparing prone and supine positions in adults on mechanical ventilation reported a reduction in mortality when PP was used for longer than 12 hours in patients with moderate-to-severe ARDS ($\text{PaO}_2/\text{FIO}_2 < 200$ mm Hg).⁸

The World Health Organization (WHO) recommends placing patients with severe C-ARDS ($\text{PaO}_2/\text{FIO}_2 < 150$ mm Hg) undergoing mechanical ventilation in the PP for more than 12 hours per day, provided that sufficient experienced personnel are available to support the safe implementation of the manoeuvre.⁹ The Spanish Ministry of Health, following the WHO recommendations during the COVID-19 pandemic, instructed health care professionals to place patients in the PP as soon as possible and to have them remain in that position for at least 16 hours when their $\text{PaO}_2/\text{FIO}_2$ was < 150 mm Hg, while providing a high oxygen concentration.¹⁰

Nevertheless, the PP has been associated with the development of potential complications.^{11,12} Recent data from three systematic reviews revealed a significantly increased risk of developing pressure ulcers and endotracheal tube (ETT) obstruction while in the PP than when in the supine position.^{8,11,13,14} Adverse events (AEs)—defined as the accidental loss or displacement of invasive devices such as vascular accesses, catheters, or drains; malposition or accidental removal of the ETT; corneal and lingual injuries; vomiting or intolerance of enteral nutrition (EN); and haemodynamic or respiratory destabilization—have been reported.^{13,15}

During the COVID-19 pandemic, there has been an important increase in the workload handled by nursing professionals.¹⁶ The use of the PP dramatically increased, offering a unique opportunity to refine and improve clinical protocols, more accurately establish the prevalence of AEs and complications, and elucidate the role of nursing care in the prevention and treatment of such complications. Furthermore, owing to the challenging and complex nature of the position

What is Known About the Topic

- The application of the prone position for at least 12 hours for patients with moderate/severe C-ARDS has been recommended by the WHO and national health agencies.
- The prone position in patients undergoing mechanical ventilation is associated with an increased risk of adverse events, especially pressure ulcers and endotracheal tube obstruction.
- To prevent adverse effects, a multidisciplinary effort must be made to perform this manoeuvre with the utmost care and safety.

What this Paper Adds

- Despite the high number of pronations and the time spent in that position observed, no serious AEs were recorded in this study and enteral nutrition was generally well tolerated.
- A need to improve the protocol for nursing care in these patients was detected, developing a detailed consensus protocol emphasising the use of devices for the prevention of facial pressure ulcers.

and the inability of the patient to participate in the manoeuvre, at least five health care professionals are needed to place a patient in the PP; therefore, possible areas of improvement in the implementation of this important intervention were also identified.

2 | AIM

The aim of this study was to determine the prevalence of AEs in patients admitted to the ICU with a diagnosis of C-ARDS undergoing mechanical ventilation in the PP. The secondary aims were (a) to assess the severity of the identified AEs and their consequences; (b) to analyse the procedures and protocols related to the manoeuvre to determine areas for improvement in the nursing care provided to patients in the PP; and (c) to describe the frequency and duration of prone positioning during the COVID-19 pandemic.

3 | METHODS

3.1 | Design

This is a descriptive ambispective study conducted in the adult ICU of the “La Princesa” University Hospital in the region of Madrid (Spain). Cases from March 6, 2020 (beginning of ICU admissions for this disease), to April 1, 2020 (study inception), were analysed retrospectively, and additional cases were analysed prospectively until May

31, 2020. This period included the peak incidence of ICU admissions during the pandemic, with the last admission on May 16, 2020. The study concluded once new COVID-19 admissions ceased and when those patients who remained in the ICU did not require further PP manoeuvres. We included consecutive patients admitted to the ICU with a confirmed diagnosis of C-ARDS undergoing mechanical ventilation who placed in the PP at least once during their management in the ICU.

3.2 | Ethical and research approvals

The study was approved by the Ethics Committee of “La Princesa” University Hospital, Madrid, Spain (registration number 4105, report 10/20). The need to obtain written informed consent was waived because of the lockdown and the fact that prone positioning was considered part of the routine management of patients with C-ARDS. Patient anonymity was guaranteed by proper codification according to the Spanish Organic Law 3/2018 of December 5 on the Protection of Personal Data.

3.3 | Study variables and measurement

With regard to the PP manoeuvres, we analysed (a) the total number of PP manoeuvres; (b) the total number of manoeuvres per patient; (c) the duration of each PP session (hours); and (d) the total cumulative number of hours spent in the PP per patient.

The studied AEs were as follows: (a) the appearance, location, size, and degree of severity of pressure ulcers related to PP (excluding other sores) according to the International Pressure Ulcer Classification System of the National Pressure Injury Advisory Panel and the European Pressure Ulcer Advisory Panel¹⁷; (b) the frequency of accidental device removal during the PP manoeuvre; (c) frequency of ETT obstruction or mispositioning while in the PP; (d) the frequency of vomiting while in the PP; (e) intolerance of EN (based on whether it was interrupted when the patient was in the PP); and (f) sentinel events, defined by the Joint Commission as a patient safety event that led to permanent harm, severe temporary harm with an intervention required to sustain life, or death.¹⁸

We also collected demographic and clinical variables, including sex, age, and a previous history of diabetes mellitus, arteriopathy, obesity, and malnutrition.

The times between the ICU admission, intubation, and the first PP manoeuvre were calculated in hours.

3.4 | Procedure

Data were collected until May 31, 2020. As of that date, the individual data collection notebooks were kept in a locked office in the ICU.

The PP manoeuvres were medically indicated on a daily basis depending on the patient's status. There was no standardized protocol

regarding the specific indication for and duration of each manoeuvre. The need for further PP sessions was determined based on a patient's individual response.

For the manoeuvre, an established protocol was followed. The PP team included five members: two physiotherapists, one auxiliary nurse, one assistant to the auxiliary nurse, and one nurse or one intensive care physician at the head of the patient whose role was to control and protect the airway. To prevent pressure ulcers, pressure relief mattresses were used in all beds, hyper-oxygenated fatty acids were applied to protect pressure points, and the patient's arms and head were re-positioned every 2 to 3 hours. In addition, a protective head pillow (Gentle Touch®; Mizuho OSI, California, United States) was used when not contraindicated. Finally, the bed was placed in the anti-Trendelenburg position (8–12°) to avoid gastric regurgitation and prevent bronchial aspiration.

3.5 | Statistical analysis

The participants' characteristics are presented as the means \pm SDs. Both the absolute and relative frequencies were used for qualitative variables. Proportions were calculated, and group comparisons were made with EPIDAT 4.1 software. Analysis of variance was used to assess the mean differences in prone positioning manoeuvres and the total hours spent in the PP stratified by the number of facial pressure ulcers. Pairwise post hoc hypotheses were tested using Bonferroni's correction for multiple comparisons. Statistical significance was set at $P \leq .05$. Statistical analyses were performed with IBM SPSS Statistics v.25.0.

3.6 | Data collection and bias minimization

The principal investigator and five co-investigators (five trained ICU nurses) collected the data from the clinical records and made observations during routine care. To minimize potential information bias that could have led to missed events, commentary records and hospital AE communication records were also reviewed.

4 | RESULTS

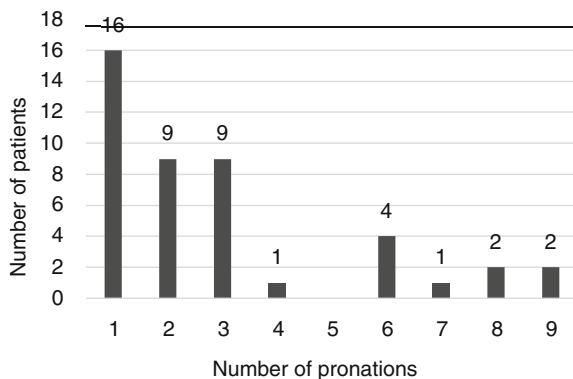
Of the 106 patients with a confirmed diagnosis of C-ARDS who were admitted to the ICU from March 6, 2020, to May 31, 2020, a total of 44 were included in the study. Of these, 11 were studied retrospectively, which meant that it was not possible to properly record all AEs; therefore, they were included only in the assessment of PP-related variables. Thirty-three patients were included in the analysis of AEs. The flow diagram of the inclusion and exclusion of patients is shown in Figure S1.

The characteristics of the sample are presented in Table 1. The mean patient age was 64.4 ± 9.0 years (range 30–78 years), and there were 14 women and 31 men. No differences between the sexes were

TABLE 1 Characteristics of the study sample

	Total (n = 44)
Age (yr)	64.4 ± 9.0
Diabetes (%)	10 (22.7%)
Arteriopathy (%)	—
Obesity (%)	11 (25%)
Malnutrition (%)	2 (4.5%)
Hours from admission in the ICU to ETI	
In the first hour of admission	23 (52.3%)
2 to 24	10 (22.7%)
25 to 48	4 (9.1%)
>48 h	7 (15.9%)
Hours from admission to first pronation	
1 to 24 h	11 (25.0%)
25 to 48 h	9 (20.5%)
49 to 72 h	8 (18.2%)
73 to 120 h	7 (15.9%)
>120 h	9 (20.4%)
Hours from ETI to first pronation	
1 to 24 h	22 (50.0%)
25 to 48 h	8 (18.2%)
49 to 72 h	5 (11.4%)
73 to 120 h	3 (6.8%)
>120 h	6 (13.6%)
Total hours in prone position; n (%); average hours per category	
1 to 24 h	11 (25.0%); 18.1 h
25 to 48 h	14 (31.8%); 39.0 h
49 to 72 h	7 (15.9%); 65.3 h
73 to 120 h	3 (6.8%); 79.0 h
>120 h	9 (20.5%); 176.2 h
Total number of pronation's manoeuvres	130
Number of pronation's per patient (mean ± SD)	3.0 ± 2.4

Abbreviations: ETI, endotracheal intubation; ICU, intensive care unit.

**FIGURE 1** Distribution of total number of pronation manoeuvres per patient**TABLE 2** Type, frequency, and description of the adverse events related to prone positioning

Type of adverse event	Total (%)	Description/comments
Facial oedema	26 (81.3)	Variable intensity that was solved by supination.
Eye injury	4 (12.5)	Conjunctival oedema and small conjunctival effusion.
Endotracheal tube obstruction	1 (3.0)	
Device's accidental removal	2 (6.1)	Removal of nasogastric tube.
Other potentially serious adverse effects	4 (12.1)	Haematuria. Ulcer pressure on the chin, complicated by herpes that covered the whole perioral and chin area. Important haematoma and oedema in the right eye (exophthalmos and hard eyeball). Previously acquired to the manoeuvre, tracheal (cleft) injury. Unable to ventilate when PP.
Sentinel events	0	No events were recorded.

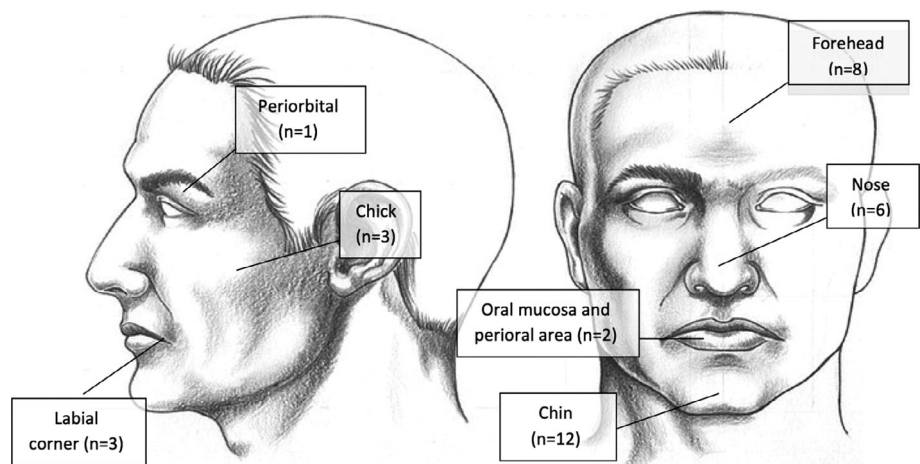
found in terms of the previous diseases recorded in the clinical history (data not shown). More than half of the participants (52.3%) were intubated within the first hour after admission, and 22 were placed in the PP for the first time within the first 24 hours after endotracheal intubation. Of the included patients, seven had a tracheostomy at the time of the first PP manoeuvre.

A total of 130 PP manoeuvres were performed during the study period. The total number of manoeuvres per patient is presented in Figure 1. The average number of PP manoeuvres per patient was 3.0 ± 2.4 , with 16 patients who were placed in the PP only once and nine who were placed in the PP more than five times.

Episodes of vomiting and the tolerance of EN while in the PP are shown in Figure S2. Of the 33 prospectively studied patients, 29 received EN while in the PP, and only two patients (6.1%) had episodes of vomiting. Both of those patients underwent many PP manoeuvres (seven and nine, respectively). One of those patients experienced vomiting and regurgitation in more than half of the seven manoeuvres the patient underwent, making it necessary to interrupt EN during the subsequent manoeuvres. The other patient experienced vomiting appeared during fewer than 50% of the PP manoeuvres.

The prespecified AEs are presented in Table 2. Facial oedema was the most common AE, and it was observed in 81.3% of the patients, followed by eye injuries in 12.5%. Other identified AEs were accidental device removal, which occurred in only two patients (6.1%) and one case of ETT obstruction (3.3%). No sentinel events occurred, but four potentially serious events were recorded: haematuria, herpes

FIGURE 2 Distribution of grade I and II face pressure ulcers in the total sample. Adapted with permission of the author (Arturo Arreola). Available from: <https://tolonet.wordpress.com/category/dibujos-a-lapiz/>



complicating a pressure ulcer, ocular haematoma, and difficulty in ventilation while in the PP because of previous tracheal injury, which resolved favourably.

In addition, 20 patients (60.6%) developed grade I and II facial pressure ulcers, which were recorded jointly as a result of their rapid evolution from grade I to grade II. Ten patients developed one pressure ulcer, five patients developed two, and five patients developed three. The distribution of the specific affected regions is depicted in Figure 2. The most prevalent site was the chin ($n = 12$; 32.2%) followed by the forehead ($n = 8$; 22.9%) and the nose ($n = 6$; 17.1%). Finally, out of the 35 facial pressure ulcers, 15 (42.9%) were <2 cm in size, 12 (34.3%) were between 2 and 4 cm, seven (20%) were between 4 and 6 cm, and one (2.9%) was ≥ 6 cm in size; the latter ulcer was located on the patient's chin.

The mean differences in the number of PP manoeuvres and total number of hours spent in the PP stratified by the number of facial pressure ulcers are presented in Table S1. Our results indicate that patients who spent an average of 35.5 ± 33.8 cumulative hours in this position did not develop facial pressure ulcers; however, those who spent more time in the PP did develop facial pressure ulcers (64.6 ± 34.1 mean hours in patients with one lesion to 154.8 ± 82.6 mean hours in patients with three facial pressure ulcers). Similarly, patients who were placed in the PP relatively more times developed more facial pressure ulcers ($P < .001$ for both parameters).

Five patients (15.2%) developed one grade I and II pressure ulcer in the thoracic or abdominal region. The size of the ulcer ranged from 2 cm ($n = 2$) to 5 cm ($n = 1$). Finally, eight (24.2%) patients developed pressure ulcers on the upper or lower extremities. None of these lesions were larger than 2 cm. Grade III pressure ulcers developed in three patients. Two were located at the site of the tracheostoma, and one was located on the knee. No grade IV pressure ulcers were recorded during the study.

5 | DISCUSSION

In the present study, we were able to evaluate the effects of prone positioning in a relatively large number of cases in a short period of

time, and most patients underwent multiple PP manoeuvres, each of which lasted many hours. We found that facial oedema and facial pressure ulcers were the most common AEs, whereas EN was generally well tolerated even during long-term prone positioning. No other serious AEs or sentinel events occurred, despite the extremely difficult working conditions experienced during the peak of the pandemic.

During the pandemic, human and material health care resources had to be adapted to an unprecedented scenario in a very short period of time. This resulted in a particularly difficult situation. First, the number of ICU beds was nearly tripled (from 20 to 52) and had to be located in other hospital areas. Second, the resulting excessive workload required the drafting of new, less experienced staff who had to be rapidly trained how to place a patient in the PP, working whenever possible with experienced staff (at least with an expert nurse or physician at the patient's head).

Nevertheless, the mortality rate of COVID-19 patients in our ICU was 26.4%, which is slightly lower than the 31% reported in a recent multicentre Spanish study.¹⁹ These figures are even somewhat better than those presented in a recent study that reported that ICU mortality consistently declined from 50% to near 40% as the pandemic progressed across nations and continents.²⁰

Prone positioning was applied in 41.5% of patients admitted to the ICU with a diagnosis of COVID-19. Facial pressure ulcers were the most common AE, occurring in 60% of patients. Girard et al reported a prevalence of facial pressure ulcers of 29.4%,¹¹ and Lucchini et al reported a prevalence of grade I and II pressure ulcers of 5% on the chin and 6% on the cheekbone (including two grade IV pressure ulcers).¹⁵

The frequency of facial pressure ulcers found in our study is greater than those reported in two systematic reviews (Mora-Arteaga et al and Munshi et al) in which pressure ulcers occurred in 34% and 43% of cases, respectively.^{8,21} From a clinical point of view, we consider it important to differentiate pressure ulcers based on the severity and extent, given the different impacts they have in terms of treatment and patient morbidity. Not all studies described the grade of the pressure ulcers, and the mean time spent in the PP varied substantially across studies, which does not allow for a comparison to be made with our results.

Furthermore, in our study, 75% of the facial pressure ulcers developed in patients who underwent multiple PP manoeuvres and who remained in the PP for more than 24 consecutive hours. Importantly, all facial pressure ulcers were grade I and II, and there were no detected high-grade ulcers (III and IV). Low-grade facial pressure ulcers have less serious consequences, and none of our patients needed special care or treatment. Once their condition improved and prone positioning was no longer performed, the skin fully recovered in all patients.

Interestingly, in previous studies, the procedure for the manoeuvre was similar to that used in our unit,¹⁵ except for the use of special head pillows, which were not protocolized. We observed a clear relationship between the number and duration of PP manoeuvres and the appearance of face pressure ulcers, which is in line with the results reported by Lucchini et al.¹⁵ Different strategies have been proposed to prevent the appearance of facial pressure ulcers, together with several aspects of good practice with regard to prone positioning.²² In addition, more frequent changes in the position of the face,²³ rather than relying on special head pillows or circular cushions, are probably needed to minimize this complication.

Two of the three grade III pressure ulcers were located near the tracheostomy, where it is difficult to efficiently relieve the pressure while the patient is in the PP. They occurred in very critically ill patients with long stays in the ICU, and taking into account the complex characteristics of these patients, the incidence of grade III ulcers in the present study can be considered to be low. Different strategies, such as the mandated use of protective dressings to pad the skin or the adoption of a standardized perioperative tracheostomy care bundle, including suture removal within 7 days, neutral positioning of the head and neck, or the perioperative use of hydrocolloid dressings, have been proposed to manage and prevent pressure ulcers in this complicated area.^{24,25}

Given all of the above, we have identified several areas for improvement. The UK Intensive Care Society recommends alternating the position of the head and arms every 2 to 4 hours,²³ which was part of the protocol during the study, but owing to the extreme workload in the unit and the lack of experienced staff, this was not adhered to for all patients and on all shifts. In addition, the adequacy of the head pillow we used in our unit, which is designed for short surgical procedures, should be further evaluated, as the maintenance of a neutral position of the head might have prevented more the need for more frequent changes in head position.

It is important to improve the recording of postural changes of the head, arms, and other supporting points through the use of a checklist. The need to improve the reporting of pressure injuries was also detected. The retrospectively reviewed medical records and nursing charts often failed to adequately report and describe these lesions, perhaps, because they were low grade and healed once the causative factor had been resolved.

Finally, as a consequence of the lessons we have learned, we propose to continue observing these events in the future during the normal operation of the ICU with improved recording of the incidence and extent of these events in the nursing charts.

With regard to other AEs, the observed incidence of intolerance of nutrition and vomiting (6.1%) was lower than those reported by Gattinoni et al (7.6%)¹³ and Taccone et al (29.1%)²⁶ but higher than that reported by Lucchini et al.¹⁵ In a recent review²⁷ on nutritional support in critically ill COVID-19 patients, the use of EN was found to be feasible and safe and was not related to an increased risk of gastrointestinal or pulmonary complications. This highlighted the convenience of the post-pyloric placement of a feeding tube in many patients and the importance of an angle of head elevation from 10° to 25° in patients receiving EN while in the PP to decrease the risk of these AEs.²⁷

The loss of devices occurred only in two patients, no sentinel events occurred, and all four potentially serious events were resolved favourably. One case of ETT obstruction (3.3%) occurred while the patient was in the PP; this is a much lower incidence than those reported in other studies of 50.6%²⁶ and 4.9%.²⁸ However, comparisons between AEs among studies should be made with caution because sample sizes and procedures can be varied considerably.

In the present study, the lack of serious AEs may be because of the fact that the procedure was always performed with an experienced person (experienced nurse or physician) at the head of the patient who directed the manoeuvre. In addition, precautionary aspiration of endotracheal secretions was performed prior to the manoeuvre.

5.1 | Limitations

Our study has several limitations that should be acknowledged that could affect the validity and reliability of the results. First, the cross-sectional design prevented us from making causal inferences. Second, as mentioned, the recording of postural changes was neither systematic nor comprehensive, which could have resulted in missed events. Even though postural changes were supposed to occur every 2 to 3 hours according to the protocol, they were not recorded by all shifts, making it impossible to determine whether the patients' heads and arms were not moved or the manoeuvres were not recorded. Finally, we could not compare the outcomes of prone and supine positioning because of the conditions during the pandemic.

5.2 | Implications and recommendations for practice

In clinical practice, in order to improve the care and prevention of pressure ulcers, it is important (a) to appropriately determine the advantages or disadvantages of the use of a head pillow; (b) to standardize the performance and recording of postural changes to the head, arms, and other pressure points by means of a checklist; (c) to continue to observe these events in the future under normal circumstances by correctly and thoroughly recording the occurrence and characteristics of these events in the nursing charts; and (d) to improve the safety of the manoeuvre. A new protocol should specify

all the relevant actions needed to safely perform the manoeuvre. All relevant ICU staff members should be trained, the frequency of head postural changes when the special cushion is used should be reviewed, and a care checklist and special nursing activity records should be adopted for this specific situation.

6 | CONCLUSIONS

Our study allows us to conclude that despite the large number of manoeuvres and the long time spent in the PP, no serious AEs occurred, despite the particularly difficult situation at the time. As expected, the longer the time spent in the PP and the greater the number of sessions, the greater the risk of skin lesions. However, owing to the implementation of the usual preventive measures and a protocol that was followed for the manoeuvre, prone positioning did not lead to the development of deep ulcers that required complicated treatments.

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ETHICS STATEMENT

This research has been approved by the Ethics Committee of the Medical Research of the “La Princesa” University Hospital, Madrid, Spain, with registration number 4105 (Report 10/20). The committee waived the written informed consent because of the lockdown and the consideration that prone positioning was considered part of the treatment of ARDS. Each participant was assigned a code to protect the data and affiliation, thus fulfilling the Organic Law 3/2018 of December 5 on the Protection of Personal Data and the Guarantee of Digital Rights and the application of Regulation (EU) 2016/679 of the European Parliament and Council of April 27, 2016, and repealing Directive 95/46/EC on General Data Protection Regulation (RGPD).

DATA AVAILABILITY STATEMENT

Data can be available after reasonable request to the authors.

ORCID

Ana Díez-Fernández  <https://orcid.org/0000-0002-7673-986X>

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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