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Pressure ulcers in patients with COVID-19 acute respiratory distress syndrome undergoing prone positioning in the intensive care unit: A pre- and post-intervention study

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Abstract

Background: Prone positioning has been widely used to improve oxygenation and reduce ventilator-induced lung injury in patients with severe COVID-19 acute respiratory distress syndrome (ARDS). One major complication associated with prone positioning is the development of pressure ulcers (PUs).

Aim: This study aimed to determine the impact of a prevention care bundle on the incidence of PUs in patients with COVID-19 ARDS undergoing prone positioning in the intensive care unit.

Study Design: This was a single-centre pre and post-test intervention study which adheres to the Standards for Reporting Implementation Studies (StaRI) guidelines. The intervention included a care bundle addressing the following: increasing frequency of head turns, use of an open gel head ring, application of prophylactic dressings to bony prominences, use of a pressure redistribution air mattress, education of staff in the early identification of evolving PUs through regular and rigorous skin inspection and engaging in bedside training sessions with nursing and medical staff. The primary outcome of interest was the incidence of PU development. The secondary outcomes of interest were severity of PU development and the anatomical location of the PUs.

Results: In the pre-intervention study, 20 patients were included and 80% (n = 16) of these patients developed PUs, comprising 34 ulcers in total. In the post-intervention study, a further 20 patients were included and 60% (n = 12) of these patients developed PUs, comprising 32 ulcers in total. This marks a 25% reduction in the number of patients developing a PU, and a 6% decrease in the total number of PUs observed. Grade II PUs were the most prevalent in both study groups (65%, n = 22; 88%, n = 28, respectively). In the post-intervention study, there was a reduction in the incidence of grade III and deep tissue injuries (pre-intervention 6%, n = 2 grade III, 6% n = 2 deep tissue injuries; post-intervention no grade III ulcers, grade IV ulcers, or deep tissue injuries were recorded). However, there was an increase in the number of
of unstageable PUs in the post-intervention group with 6% (n = 2) of PUs being classified as unstageable, meanwhile there were no unstageable PUs in the pre-intervention group. This is an important finding to consider as unstageable PUs can indicate deep tissue damage and therefore need to be considered alongside PUs of a more severe grade (grade III, grade IV, and deep tissue injuries).

**Conclusion:** The use of a new evidence-based care bundle for the prevention of PUs in the management of patients in the prone position has the potential to reduce the incidence of PU development. Although improvements were observed following alterations to standard practice, further research is needed to validate these findings.

**Relevance to Clinical Practice:** The use of a new, evidence-based care bundle in the management of patients in the prone position has the potential to reduce the incidence of PUs.

**KEYWORDS**
care bundle, pressure ulcers, prone positioning, ventilation

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**INTRODUCTION**

The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causing coronavirus disease 2019 (COVID-19) has led to an exponential increase in demand for intensive care services worldwide. The high proportion of patients with COVID-19 requiring additional respiratory support has placed unprecedented demand on intensive care unit (ICU) services, necessitating rapid expansion of ICU infrastructure, capacity, and staffing in many countries. 

Acute respiratory distress syndrome (ARDS) is a serious complication of COVID-19 that occurs in 20%–41% of patients with severe disease. 

Prone positioning is a technique used to help patients with ARDS which involves placing patients on their abdomen. The purpose of prone positioning is to improve lung function and facilitate gas exchange. 

Prone positioning improves mortality in ARDS by optimizing lung recruitment, reducing lung strain, and improving oxygenation, and has been applied extensively in the management of COVID-19 pneumonia. While the benefits of prone positioning far outweigh the risks, placing patients with ARDS in prone position may put them at risk of other complications, including pressure ulcers (PUs) of the skin and soft tissues.

PUs are defined as ‘a localized injury to skin and/or underlying tissue, usually over a bony prominence, as a result of prolonged mechanical loading in the form of pressure, or pressure in combination with shear’. Patients in the ICU develop PUs in several dependent areas including the forehead, chin, cheeks, shoulder (anterior), elbow, chest (breasts), genitalia (particularly male), anterior pelvic bones (iliac crests and ischium), knees (patella), dorsal feet and toes, and nose.

Positioning patients with ARDS in the prone position has been shown to improve oxygenation, compared with the supine position. However, a higher frequency of PUs has been reported in patients in the prone position. A randomized controlled trial comparing early, long-standing (16 h) prone positioning to supine positioning, explored whether extended prone positioning was associated with PU development. The study, conducted in individuals with severe ARDS (n = 466), found the incidence of new PUs to be significantly higher in prone position compared with supine position when measured by days in ICU (13.92 vs. 7.72 per 1000 ICU days, p = .002). 

A clinical review by Moore et al set out to identify and review evidence-based recommendations developed to facilitate the selection and application of preventative interventions aimed at reducing PU development in patients ventilated in the prone position. This review recommended...
focused prevention strategies, including skin assessment and care, off-loading, and pressure redistribution and preventative dressings in an effort to contribute to a reduction in the incidence and prevalence rates.\textsuperscript{11} Given the proportion of patients undergoing prone positioning in ICU during the current COVID-19 emergency,\textsuperscript{11} it was anticipated that the incidence of PUs would increase substantially, given the available evidence surrounding the development of PUs predating the COVID-19 global pandemic. Further to this, to our knowledge no prior implementation studies have been undertaken in this area, and as such, the authors set out to identify novel methods based on the available evidence to prevent PU development in this patient cohort. A set of evidence-based interventions were implemented and a care bundle was devised. A care bundle can be defined as a group of evidence-based interventions which, when provided together, can provide a better outcome than if each intervention is performed individually.\textsuperscript{12}

2 | METHODS

2.1 | Research question

How does the incidence of PU development in intubated and ventilated patients with ARDS secondary to COVID-19 pneumonia undergoing prone positioning in the ICU vary pre- and post-implementation of a prevention care bundle? A comparison between groups.

2.2 | Study design

This was a pre- and post-intervention study.

2.3 | Study context

The Standards for Reporting Implementation Studies (StaRI) guidelines were adhered to in the reporting of this pre- and post-test intervention study.\textsuperscript{13} This pre- and post-intervention study came about following completion of a clinical study assessing the incidence of PUs in patients receiving adjuvant treatment in the form of prone positioning for severe ARDS secondary to COVID-19 in the ICU of a large tertiary hospital. The study was completed between March and May 2020, and following this, a clinical need emerged to develop a new intervention addressing the early identification, and prevention of PUs in patients in the prone position with ARDS secondary to COVID-19.

2.4 | Study site

This study was conducted in the ICU of a large tertiary hospital in the Republic of Ireland comprising a total of 23 ICU beds.

2.5 | Population and sample

A cohort of 20 patients who underwent prone positioning were recruited to the pre-intervention study, and a new cohort of 20 patients was then recruited to the post-intervention study. This was a convenience sample of 20 consecutive patients recruited in both the pre- and post-intervention phases. Patients were recruited following a retrospective review of ICU admissions during the specified time frames, with those patients who met the inclusion criteria being included in the study.

2.6 | Eligibility criteria

Patients were eligible for inclusion if they met all of the following inclusion criteria:

- Age $\geq 18$
- Admission to the ICU
- Diagnosis of laboratory conformed SARS-CoV-2 infection
- Diagnosis of ARDS as defined by the Berlin definition.\textsuperscript{14}
- Undergoing prone positioning

2.7 | Intervention

Standard practice during the initial study undertaken between March and May 2020 included:

- Use of head turns
- Use of a closed gel ring to aid in endotracheal (ET) tube stability
- Use of barrier cream
- Use of a redistribution air mattress

Following completion of the initial study and analysis of results, the decision was made to develop a new care bundle for PU prevention. The Skin Wounds and Trauma (SWaT) Centre in the RCSI University of Medicine and Health Sciences was consulted and a collective clinical decision was made on how best to change the local protocol relating to the care of patients in the prone position. This included the implementation of various preventative interventions as supported by a review of the available literature surrounding best practice recommendations.\textsuperscript{11,15,16} These interventions included:

- Increasing the frequency of head turns in patients undergoing prone positioning
- Adopting the use of an open gel head ring (see Figures 1 and 2)
- Application of prophylactic dressings to all bony prominences
- Use of a pressure redistribution air mattress
- Education of staff in the early identification of evolving PUs through regular and rigorous skin inspection
- Engaging in bedside training sessions with nursing and medical staff
Reliability in the application of the care bundle was ensured through staff education sessions that were conducted in the ICU and at ward level. These sessions focused on providing staff members with the knowledge to appropriately manage patients in the prone position as well as the evidence-based interventions outlined above. Educational materials used to assist in this process included a training video created by the authors in the simulation lab, as well as laminated prone positioning guidelines to adhere to infection control policies. In addition to this, a mobile application (app) was developed for staff to access the prone positioning guidelines as a means to provide additional information to staff. The care bundle was implemented in December 2020. Following the implementation, a post-intervention study was undertaken between January and March 2021.

2.8 | Primary outcome

The primary outcome was the incidence of PUs as defined by the European Pressure Ulcer Advisory Panel guidelines pre- and post-implementation of a PU prevention care bundle.

2.9 | Secondary outcomes

The secondary outcomes included characterization of the PUs and assessed the following:

- Grade of PUs
- Anatomical location of PUs

Severity of illness was also explored between groups as a secondary outcome by assessing Sequential Organ Failure (SOFA) scores and PaO₂/FiO₂ ratio. SOFA score provides an objective measure of the severity of organ dysfunction in six organ systems (respiratory, haematological, hepatic, cardiovascular, renal, and neurologic). Meanwhile, the partial pressure of oxygen (PaO₂) as a ratio of the fraction of inspired oxygen (FiO₂) (PaO₂/FiO₂), measured by arterial blood gas analysis, was used to assess the degree of hypoxemia. This PaO₂/FiO₂ ratio is an index used to classify the severity of ARDS and was collected on all of the included participants. Finally, body mass index (BMI) was explored between groups as a possible contributor to PU development. BMI is an objective measure of body fat based on weight and height. Previous studies have found that BMI has been associated with the development of PUs in patients treated with mechanical ventilation who had acute lung injury.

2.10 | Ethical considerations

Permission to conduct the study and access the patient records was provided by the hospital clinical audit committee (Ref: CA-921). Given that this was classified as a clinical audit and data were collected retrospectively, consent from participants was not a requirement.

2.11 | Data collection

Pre-intervention data were collected between March 2020 and May 2020. Post-intervention data were collected between January 2021 and March 2021. In this study, data were retrospectively obtained from the electronic health records. It is routine practice for PUs to be recorded in the clinical record. Departmental practice is to use the European Pressure Ulcer Advisory Panel guidelines to assess PU grade and all nursing staff are trained in using these guidelines. Additional data were extracted from the electronic patient record which included details such as frequency of head turns, SOFA score, and PaO₂/FiO₂ ratio. This was then inputted onto a predesigned data extraction table. Data extraction was completed by three authors (NME, OF, and EB).

2.12 | Data analysis

Data were entered onto Stata by Stata Corp for Windows version 16 and analysed using descriptive statistics to determine means and SDs.
3 | RESULTS

3.1 | Participant characteristics

Twenty patients were included in the pre-intervention study (Table 1). 90% ($n = 18$) were male and 10% ($n = 2$) were female. The mean age was 52.25 years (range 27–75 years), with the average ICU length of stay being 16.1 ± 12.22 days.

Of the 20 patients included in the post-intervention study, 50% ($n = 10$) were male and 50% ($n = 10$) were female. The mean age was 57.55 years (range 29–83 years), with the average ICU length of stay being 23.95 ± 15.63. Mean BMI for patients in the pre-intervention group was 37.12 ± 9.02 and mean BMI for patients in the post-intervention group was 31.35 ± 6.98. These results indicate that body weight to height ratios were within a healthier range for patients in the post-intervention group, with a lower mean BMI than the pre-intervention group.

The mean baseline SOFA score for patients in the pre-intervention group was 8.5 ± 1.88 compared with 5.75 ± 2.73 in the post-intervention group. Admission PaO$_2$/FiO$_2$ in the pre-intervention group was 25 ± 10.61 compared with 15.4 ± 4.39 in the post-intervention group. These results indicate that patients in the post-intervention group had lower SOFA and PaO$_2$/FiO$_2$ scores than those in the pre-intervention group.

3.2 | Implementation results

The mean number of prone positioning sessions undertaken by each individual in the pre-intervention study was 3.2 ± 1.24, totalling 53.3 ± 21.56 (mean ± SD) hours in the prone position. For the post-intervention cohort, the number of individual prone positioning sessions increased to 5.15 ± 2.7, with the mean total hours spent in prone position again increasing to 83.63 ± 45.41. Patients in the post-intervention group had more frequent prone sessions and spent a longer number of hours in the prone position.

Head turn frequency was assessed in both the pre and post-intervention groups. The mean time (in hours) between each head turn in the pre-intervention study was 8.3 ± 0.85 (range 6–10.13 h). Head turn frequency increased in the post-intervention study, with a mean time (in hours) between head turns of 4.4 ± 2.7 (range 2–12 h).

4 | RESULTS: PRIMARY OUTCOME

In the pre-intervention study, 80% ($n = 16$) of patients developed PUs, comprising 34 PUs in total. In the post-intervention study, 60% ($n = 12$) developed PUs, comprising 32 PUs in total. Thus, a 25% reduction in the number of patients developing a PU was observed.

### TABLE 1 Patient characteristics, prone and head turn variables, and pressure ulcer incidence (initial vs. follow-up study)

<table>
<thead>
<tr>
<th></th>
<th>Pre (2020)</th>
<th>Post (2021)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Sex: Male/female, n (%)</td>
<td>18 (90)/2 (10)</td>
<td>10 (50)/10 (50)</td>
</tr>
<tr>
<td>Age (mean in years)</td>
<td>52.3 ± 12.7</td>
<td>57.6 ± 15.2</td>
</tr>
<tr>
<td>BMI (mean)</td>
<td>37.1 ± 9</td>
<td>31.4 ± 7</td>
</tr>
<tr>
<td>Admission PaO$_2$/FiO$_2$</td>
<td>25 ± 10.6</td>
<td>15.4 ± 4.4</td>
</tr>
<tr>
<td>Admission SOFA score</td>
<td>8.5 ± 1.9</td>
<td>5.8 ± 2.7</td>
</tr>
<tr>
<td>Average length of stay in ICU (days)</td>
<td>16.1 ± 12.2</td>
<td>24 ± 15.6</td>
</tr>
<tr>
<td>Number of prone sessions (mean)</td>
<td>3.2 ± 1.2</td>
<td>5.2 ± 2.7</td>
</tr>
<tr>
<td>Total hours in prone position (mean)</td>
<td>53.3 ± 21.6</td>
<td>83.6 ± 45.4</td>
</tr>
<tr>
<td>Mean frequency of head turns (hours)</td>
<td>8.3 ± 0.9</td>
<td>4.4 ± 2.7</td>
</tr>
<tr>
<td>Min/max frequency of head turns (hours)</td>
<td>6/10</td>
<td>2/12</td>
</tr>
<tr>
<td>Use of corticosteroids</td>
<td>20% ($N = 4$)</td>
<td>40% ($N = 8$)</td>
</tr>
<tr>
<td>Incidence of pressure ulcer development n (%)</td>
<td>80% ($N = 16$)</td>
<td>60% ($N = 12$)</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index; ICU, intensive care unit; SOFA, Sequential Organ Failure. Percentages rounded to nearest whole number.

### TABLE 2 Pressure ulcer incidence by grade and site (initial vs. follow-up study)

<table>
<thead>
<tr>
<th></th>
<th>Pre (2020)</th>
<th>Post (2021)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number pressure ulcers developed</td>
<td>34</td>
<td>32</td>
</tr>
<tr>
<td>Grade of pressure ulcer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade I</td>
<td>8 (23)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Grade II</td>
<td>22 (65)</td>
<td>28 (88)</td>
</tr>
<tr>
<td>Grade III</td>
<td>2 (6)</td>
<td>0</td>
</tr>
<tr>
<td>Grade IV</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unstageable</td>
<td>0</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Deep tissue injury</td>
<td>2 (6)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>34 (100)</td>
<td>32 (100)</td>
</tr>
<tr>
<td>Site of pressure ulcer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nose</td>
<td>8 (23)</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Sacrum</td>
<td>5 (15)</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Chin</td>
<td>3 (9)</td>
<td>5 (16)</td>
</tr>
<tr>
<td>Lip/corner of mouth</td>
<td>4 (12)</td>
<td>9 (28)</td>
</tr>
<tr>
<td>Toe</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Heel</td>
<td>3 (9)</td>
<td>0</td>
</tr>
<tr>
<td>Forehead</td>
<td>1 (3)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Sternum/chest</td>
<td>4 (12)</td>
<td>4 (13)</td>
</tr>
<tr>
<td>Knee</td>
<td>0</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Arm</td>
<td>0</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Eyebrow/eyelid</td>
<td>1 (3)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Shin</td>
<td>0</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Penis</td>
<td>0</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Cheek</td>
<td>5 (15)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Total</td>
<td>34 (100)</td>
<td>32 (100)</td>
</tr>
</tbody>
</table>

Percentages rounded to nearest whole number.
through use of the care bundle. Although a reduction in PU incidence was demonstrated, the actual number of PUs remained high with 34 PUs observed in the pre-intervention study, and 32 PUs in the post-intervention study, demonstrating a 6% decrease in the number of PUs.

5 | RESULTS: SECONDARY OUTCOME

The secondary outcomes of the study aimed to assess the severity and anatomical location of PU development pre- and post-intervention (Table 2). During the pre-intervention study, grade II PUs were the most prevalent (65%, n = 22). A further 23% (n = 8) of individuals developed grade I PUs, with 6% (n = 2) of patients developing grade III PUs and an additional 6% (n = 2) developing deep tissue injuries (Table 2).

On completion of the follow-up study, grade II PUs were the most prevalent (88%, n = 28). A total of 6% (n = 2) of PUs were classified as grade I, with a further 6% (n = 2) classified as unstageable. As can be seen in Table 2, the nose was the most common site for PU development in the pre-intervention study (23%, n = 8). Other common sites included the sacrum (15%, n = 5), cheek (15%, n = 5), sternal/chest wall (12%, n = 4), and lip/corner of mouth (12%, n = 4). On completion of the follow-up study, the lip/corner of mouth was the area with the highest incidence of PU development (28%, n = 9). Other locations included the chin (16%, n = 50) and sternal/chest wall (13%, n = 4).

6 | DISCUSSION

The major findings from this study are as follows: PU incidence was high in patients undergoing prone positioning during mechanical ventilation for COVID-19-related ARDS. A bundled intervention was applied, including dressings, education, and procedural changes such as more frequent head-turning. In a post-test study, the cumulative duration of prone mechanical ventilation was increased. Nonetheless, the bundle was associated with a decreased incidence of PU development.

A number of randomized controlled trials highlight the benefits associated with prone positioning in the management of patients with ARDS. A paper by Guérin et al published in the New England Journal of Medicine demonstrated a marked reduction in 28 and 90-day mortality among patients with severe ARDS undergoing prolonged prone positioning in ICUs. Improved oxygenation was highlighted as a contributing factor to this improvement in patient outcome, along with enhanced protection from ventilator-induced lung injury. Following the rapid spread of SARS-CoV-2 on a global scale, the use of prone positioning for the management of ARDS in this particular cohort has been extensively employed. According to the European Pressure Ulcer Advisory Panel, the use of extended periods of prone positioning should be avoided unless deemed necessary for the management of the patients’ underlying condition. As alluded to above, ARDS constitutes such an underlying condition. Studies conducted among patients with COVID-19 ARDS have highlighted the degree to which improved oxygenation and respiratory mechanics secondary to prone positioning contributes to increased overall survival in this patient cohort.

Despite the significant benefits, prone positioning has been associated with a higher incidence of PU development, something which, as demonstrated in this report, has remained true during the COVID-19 pandemic. Studies published prior to the COVID-19 pandemic have demonstrated that PUs are higher among patients in the prone position compared with those in the supine position. A recent clinical case report by Perrillat et al on facial PUs in patients undergoing prone positioning during the COVID-19 pandemic hypothesized that both the significant influx of patients and the involvement of non-specialist nurses in ICUs has led to an increased incidence of severe facial PUs. While limited data exists on how best to prevent PU development, the guidelines proposed by Perrillat et al advise use of frequent head turns on those who are intubated and ventilated as well as the use of pressure redistribution support surfaces as a means to offload pressure from both facial and bodily prominences. The use of prophylactic dressings is also highlighted as an additional measure for the prevention of PU development.

Taking the above into consideration, the primary outcome of the study was to assess incidence of PU development in those patients with severe COVID-19 ARDS undergoing prone positioning in the ICU. Twenty (20) patients were included in the pre-intervention study, of which 80% (n = 16) developed PUs, comprising 34 PUs in total. On account of this high incidence of PUs, the local protocol for management of patients in the prone position was reviewed and alterations made in line with the international guideline on prevention and treatment of PUs/injuries. The post-intervention study, completed between January and March 2021, again consisted of 20 patients, of which 60% (n = 12) developed PUs, comprising 32 PUs in total. This represents a 25% reduction in the number of patients developing a PU. This is possibly secondary to the successful implementation of the care bundle coupled with staff education focused on the appropriate management of patients in the prone position as well as the evidence-based interventions needed to reduce PU incidence. This incidence is also consistent with the findings of a study by Rodríguez-Huerta et al, where the incidence of facial PUs in patients undergoing prone positioning was 60.6%.

Although a reduction in PU incidence was demonstrated, the actual number of PUs remained high. One possible explanation for this is the widespread use of corticosteroids, notably dexamethasone, among patients included in the post-intervention study. This therapeutic intervention, which had become standard practice by the time the post-intervention study was being completed, was not being routinely administered during completion of the pre-intervention study. In this present study, 20% (n = 4) of patients in the pre-intervention group were treated with corticosteroids compared with 40% (n = 8) in the post-intervention group. Systemic corticosteroids are associated with a significant number of side effects, affecting various organ systems, including the skin. A previous study discussing
side effects from the use of systemic corticosteroids highlighted some of these dermatological manifestations, including the development of thin, fragile skin, predisposing individuals to a variety of injuries.27 Similarly, it has been demonstrated that corticosteroid use perioperatively can contribute to PU development,28 particularly in individuals with critical illness.29 Thus, although steroids have undoubtedly improved outcomes in patients with COVID-19,26 health care staff should be aware of the increased potential for PU development.

It is important to mention severity of illness within both groups. SOFA scores were calculated in all patients at baseline. Patients in the pre-intervention group had, on average, higher SOFA scores and higher admission PaO2/FIO2 ratios. It is therefore difficult to conclude if more patients in the pre-intervention group developed a PU based on severity of illness.

It was observed that the mean BMI in patients in the pre-intervention group was higher compared with the post-intervention group. Studies prior to the COVID-19 pandemic have found that patients in ICU who are overweight are more likely to develop PUs and that particular attention must be given to prevent PUs in these patients.19 It is well understood that PUs develop as a result of body-weight forces which continuously distort tissues and cause cell deformation which disrupts the cytoskeleton and ultimately results in cell death.30 Therefore, the magnitude of the force of bodyweight and/or external surfaces undoubtedly have a role in play in PU development.

Gender differences were observed between both groups. In the pre-intervention group, 90% of patients \( (n = 18) \) were male and 10% \( (n = 2) \) were female. Meanwhile in the post-intervention group, 50% of patients \( (n = 10) \) were male and 50% \( (n = 10) \) were female. Because of the body fat composition differences in males and females, this could have accounted for increased PU incidence observed in the study and future research is needed to further explore the impact of gender on PU incidence.

A secondary outcome of interest was to assess the severity of PUs, classified according to the European Pressure Ulcer Advisory Panel7 grading system. Although grade I and II PUs constituted most of PUs in both the pre- and post-intervention studies, the post-intervention study showed a reduction in the incidence of grade III PUs and deep tissue injuries. In the pre-intervention study, 6% of ulcers \( (n = 2) \) were categorized as grade III and a further 6% \( (n = 2) \) were categorized as deep tissue injuries. In the post-intervention study, no grade III PUs, grade IV PUs or deep tissues injuries were recorded, with 6% \( (n = 2) \) of ulcers being unstageable as per the European Pressure Ulcer Advisory Panel.7 guidelines. It is important to mention the significance of unstageable PUs when interpreting these results. Unstageable PUs are more common among ICU patients compared with general hospital patients and are considered to be a more severe grade of PU.31 Unstageable PUs are characterized by full thickness tissue loss with slough or eschar on the surface with unstageable depth.7

Location of PU development was also assessed as part of the secondary outcomes. The most common sites for PU development were the lip/corner of mouth \( (n = 9 \text{ ulcers}) \), chin \( (n = 5 \text{ ulcers}) \), and sternum/chest wall \( (n = 4 \text{ ulcers}) \). It is important to note that despite patients spending protracted periods of time in the prone position, incidence of PUs on the posterior aspect of the body, including the sacrum and heels, can still occur. This was exemplified in our pre-intervention study, where 15% \( (n = 5) \) of PUs were observed on the sacrum and 9% \( (n = 3) \) were observed on the heel. This highlights the continued need to monitor sites where PUs classically develop.32 Furthermore, an unexpected finding was the location of PUs on the lower body in the post-intervention study. Although the number of PUs at the sacrum and heels decreased from the pre-intervention study compared with the post-intervention study, PUs developed in other locations throughout the lower body in the post-intervention study that was not observed in the pre-intervention study. In the post-intervention study, PUs developed on the shin \( (3\% , \ n = 1) \), penis \( (3\% , \ n = 1) \), and knee \( (3\% , \ n = 1) \). The development of PUs at these anatomical sites presents potential limitations of the bundle. The bundle is largely focused on interventions to decrease PUs on the upper body and face; however, this study has highlighted the need for future research in this area, with a focus on PU prevention on the lower as well as upper body.

In addition, it was noted that a reduction in PU development on the nose and cheek occurred in the post-intervention study. Incidence of PU development on the nose decreased from 23% \( (n = 8) \) in the pre-intervention group to 9% \( (n = 3) \) in the post-intervention group, and the incidence of PU development on the cheek decreased from 15% \( (n = 5) \) in the pre-intervention group to 3% \( (n = 1) \) in the post-intervention group. This reduction may be attributed to the use of open gel head rings, as well as enhanced staff education, increased frequency of head turns, and the application of prophylactic dressings. From a staff education perspective, this involved running an awareness campaign at ward level to highlight the need to avail of prophylactic dressings in patients receiving non-invasive ventilation via face masks, something which may have further contributed to the reduction in nasal and cheek PU incidence in the post-intervention study. It is however, important to consider that PUs often do not develop on the surface of the skin for some time, and by the time macroscopic visible tissue damage is evident, the damage to the underlying tissues is often severe.33 This inability to visually detect damage is largely because of the microscopic scale of damage, with the death of a few cells or small groups of cells.30 In many cases, such cell death events may occur over very short time intervals, even within minutes, and may undergo natural and spontaneous repair by the body without progressing towards and evolving into a visible PU.30 This means that even though the damage cascade may start, and the process of cell death begins, early intervention can prevent further damage from progressing to a macroscopic scale. However, in other cases, the microscopic cell death damage initiates a damage cascade that results in the initiation and progression of a clinically significant PU.30 It could be argued that in those patients in which visible PUs were observed in the ICU, the damage cascade started hours or even days earlier, and potentially at ward level as a result of
non-invasive ventilation masks, for example. This warrants further research to substantiate this theory.

An increase in PU development was observed on the lip/corner of mouth in the post-intervention study. Although the reasoning for this remains unclear, it is potentially due in part to the increased time patients spent in the prone position in the post-intervention study. Furthermore, damage caused by repositioning the ET tube secondary to increased frequency of head turns may have been a contributing factor. On the other hand, while head turn frequency increased in the post-intervention study compared with the pre-intervention study (mean [SD], pre: 8.3 ± 0.9, post: 4.4 ± 2.7), some patients in the pre- and post-intervention phases, spent protracted periods of time without head turning and this could also have contributed to PU development at these locations. Future research is needed to further investigate how ET tube repositioning and head turns contribute to PU development at this location.

7 | LIMITATIONS

It is important to mention that there was a significant time lapse of 7 months between the pre- and post-intervention study. This was because of multiple factors which included the development of the care bundle, the time required to train staff, and the subsequent timing of the surge of ICU admissions with COVID-19 intubated and ventilated patients with ARDS secondary to COVID-19 pneumonia. A further limitation associated with this time lapse is the degree to which standard care and management of patients with ARDS secondary to COVID-19 pneumonia admitted to ICU changed. By way of example, many patients in the post-intervention study were treated with corticosteroids. A further limitation of the present study is that bundle adherence was not formally assessed. It could be implied that the care bundle was not strictly adhered to by staff as evidenced by the difference in SDs observed in the pre intervention group compared with the post-intervention group. However, it is important to mention that this was a retrospective study, and that future prospective studies in this area would include the use of formal measures of care bundle compliance, as have been described in numerous studies in the ICU setting. Finally, data collectors depended on the reliability of data inputted on the electronic patient records to determine PU grade. This is a limitation that could be avoided in future studies by using a prospective study design, and ensuring a blinded assessor is responsible for grading PUs which would ensure inter-observer agreement.

8 | CONCLUSION

Prone positioning improves oxygenation and survival among patients with ARDS secondary to COVID-19 pneumonia. However, it is of crucial importance to highlight the potential complications that may arise from prone positioning so that preventative strategies can be implemented in a timely manner. In the pre-intervention study, completed between March and May 2020, 80% of patients (n = 16) developed a PU. Following the care bundle intervention, which was based on international best practice, the incidence of PU development dropped by 25% in the post-intervention study, completed between January and March 2021, where 60% of patients (n = 12) developed a PU. However, despite this decreased incidence in the number of patients developing a PU, the actual number of PUs did not decrease substantially. There were 34 PUs observed in the pre-intervention study and 32 PUs in the post-intervention study, representing a decrease of 6%. Future research with a larger sample size with no break between stages is needed to further evaluate the factors associated with PU development in patients with ARDS secondary to COVID-19 pneumonia admitted to the ICU. This would aim to facilitate a reduction in incidence of this adverse patient outcome.

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