Effects of modular new prone positioning tools in patients with acute respiratory distress syndrome due to COVID-19: A randomized controlled trial

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Research Article

Keywords: modular new prone positioning tools, acute respiratory distress syndrome, COVID-19, randomized controlled trial

Posted Date: June 6th, 2023

DOI: https://doi.org/10.21203/rs.3.rs-3025735/v1

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Abstract

Background

Prone position (PP) ventilation has become an effective and simple treatment for acute respiratory distress syndrome (ARDS) due to COVID-19; however, prolonged prone position not only leads to patient discomfort, but also reduces patient compliance, and is prone to causing adverse events such as pressure injuries, pain, and dizziness. We aim to explore the effects of modular new prone positioning tools in patients with ARDS due to COVID-19.

Methods

168 patients with ARDS due to COVID-19 were selected; however, 92 were later disqualified. 76 patients were randomly assigned to the observation group (n = 38) and the control group (n = 38). The observation group used modular new prone positioning tools to implement prone ventilation therapy while the control group used soft pillows to implement prone ventilation therapy. Comfort indicators (including time spent implementing PP, duration of PP, number of postural adjustments during PP, and duration time when first needing to adjust position), adverse events (including artificial airway kinking, shortness of breath, dizziness, and stress injury), and efficacy indicators (including intubation and mortality) were collected. The feeling of comfort, the occurrence of adverse events, and the efficacy of two groups of patients were also evaluated.

Results

The observation group had shorter time spent implementing PP (2.74 ± 0.86 vs. 4.64 ± 1.02, P < 0.001), longer duration of PP (14.02 ± 1.01 vs. 13.03 ± 0.66, P < 0.001), duration time when first needing to adjust position (59.89 ± 12.73 vs. 36.57 ± 8.69, P < 0.001), and lower number of postural adjustments during PP (11.03 ± 2.67 vs. 17.95 ± 2.58, P < 0.001) in comparison with the control group. No significant differences in intubation (9 vs. 11, P = 0.602) and mortality (4 vs. 6, P = 0.602) were found in both groups. However, in terms of adverse events, the observation group showed lower artificial airway kinking (5 vs. 23, P < 0.001), pain (7 vs. 21, P = 0.001), shortness of breath (2 vs. 9, P = 0.022), dizziness (0 vs. 5, P = 0.021), and stress injury (7 vs. 26, P < 0.001) than the control group.

Conclusion

Utilizing modular new prone position tools to implement prone ventilation therapy not only improves the efficiency of prone position execution and patient comfort, but also reduces the incidence of adverse events. However, it cannot change the intubation rate and mortality rate of patients.
Background

Acute respiratory distress syndrome (ARDS) is a common critical illness that seriously threatens patients' lives, with the main clinical manifestations being intractable hypoxemia and refractory acute respiratory failure[1]. 20–41% of patients with severe COVID-19 can progress to ARDS, with a mortality rate of up to 65%[2, 3]. Due to shortage of effective treatment for patients with COVID-19, supportive care for patients is especially significant[4]. Prone positioning reduces mortality in intubated and mechanically ventilated patients with moderate to severe ARDS[5, 6]. Moreover, it improves ventilation-perfusion ratio[7–9], increases lung volume[10, 11], and more uniformly distributes pleural pressure[12].

In health care systems overrun by patients with COVID-19, prone positioning (PP) in non-intubated, spontaneously breathing patients with ARDS has become widely used[13, 14]. Several guidelines have listed PP as one of the common treatment strategies for patients with severe ARDS[15, 16]. Studies have shown that the duration of ventilation in the prone position < 12 h/d is less effective and does not effectively improve the survival rate of patients, so it is recommended that the duration of ventilation in the prone position > 12 h/d[15]. In addition, for patients with severe ARDS, there is an expert consensus that patients need to be ventilated in the prone position for at least 12 h/d[17]. However, the traditional prone position uses ordinary soft pillows, which are loose and soft in texture, and the soft pillows sink in height during use, resulting in pressure on the patient's orbital area, chest, and abdomen for a long time, which can easily lead to pressure sores, nerve damage, facial tissue damage, and deep vein thrombosis[18]. In addition, patients feel uncomfortable with this prone position and tend to tolerate this prone position for only a short time, resulting in frequent assistance from nurses or caregivers due to changing positions. It further increases the risks of skin injury to the patients as well as the workload of nurses or caregivers. Therefore, we designed modular new prone positioning tools and used them for prone ventilation in ARDS patients due to COVID-19 to improve patient comfort while reducing related complications and to provide a clinical reference for the safe implementation of prone ventilation therapy in the future.

Materials and methods

Study design

This study was designed as a single-center, parallel randomized controlled trial. The study protocol was conducted in accordance with the Declaration of Helsinki and was approved by the Medical Ethics Committee of Shanghai Fourth People's Hospital Hospital (No. SYLL2023008). We registered the study in the Chinese Clinical Trial Registry (No. ChiCTR2300068220).

Participants

The study was performed at Shanghai Fourth People's Hospital Hospital from December 2022 to February 2023.
Patients were eligible for inclusion if they were older than 18 years of age, had COVID-19 confirmed by positive SARS-CoV-2 reverse transcription polymerase chain reaction testing on nasopharyngeal or oropharyngeal swabs, hypoxemic respiratory failure, required at least 40% oxygen (via low- or high-flow oxygen devices) or noninvasive positive pressure ventilation, a PaO2/FiO2-ratio of less than 150 mmHg for more than an hour and were being in an intensive care unit (ICU) or a monitored acute care unit. Patients were excluded from the trial if they: supplementing oxygen with a method besides HFNO or NIV, inability to assume prone, endotracheal intubation is immediately necessary, severe hemodynamic instability, a prior COVID-19 pneumonia intubation, pregnancy, and not being able to comprehend study material either in writing or orally.

All patients who fulfilled the inclusion criteria were approached, and either the participant, an independent witness, or a patient representative provided written informed consent.

**Randomization and blinding**

An independent researcher randomized 1:1 ratio to a control group or observation group using random sequences generated by the SAS Statistics program version 9.4 (SAS Institute Inc. Cary, NC). Assignments will be enclosed in sequentially numbered, opaque-sealed envelopes to hide the participant allocation. The patients, caregivers, and therapists cannot be blinded after being assigned to the clinical intervention because of the nature of the intervention. Prior to the completion of all data analysis, the outcome assessors and data statisticians will not be aware of the treatment allocation.

**Study intervention**

In the observation group, modular new prone positioning tools (including head pad, chest pad, elbow pad, knee pad, and ankle pad) were used to implement prone ventilation therapy (Fig. 1). Specific operation method includes several steps as follows: the head is padded with a head pad, chest padded in chest pad, extremities are padded with elbow pads, knee pad, and ankle pad (Fig. 2). The control group used traditional prone ventilation positioning therapy, in which soft pillows were placed on the head, chest, knees, and ankles while the patient's upper limbs were placed parallel to the sides of the body or the sides of the head (Fig. 3).

Patients in both groups had a target duration of prone position at least 12 h/d, with 1 to 3 breaks (1 to 2 hours each) if needed. The protocol called for daily prone positioning sessions to continue until one of the following halting criteria was reached: intubation, death, discharge from the ICU or acute care unit, or clinical improvement defined as the use of standard nasal cannula or open face mask with an oxygen flow rate of $\leq 5 \text{ L min}^{-1}$ for 12h. Attending clinicians could withdraw the patient from the trial at any time if they considered PP unsafe.

Standard care was provided during the study period in both groups in accordance with clinical practice in the participating hospitals. Despite not being protocolized, intravenous sedation was permitted. The attending clinician had the final say over intubation; however, local regulations were respected. Although liberal prone posture was part of the clinical standard of care for mechanically ventilated patients with
COVID-19 satisfying criteria for moderate to severe ARDS, positioning following intubation was not protocolized.

**Outcome measures**

A total of 4 physicians and 8 nurses were selected as quality controllers to ensure that there were quality controllers on duty in each shift, and data was collected after unified training on judgment criteria, judgment timing, and recording methods of evaluation indexes. The primary outcomes were time spent implementing PP, duration of PP, number of postural adjustments during PP, and duration time when first needing to adjust position. Secondary outcomes included intubation, mortality, and adverse events within 30 days of enrollment.

**Statistical analysis**

Statistical analysis was carried out using SPSS Statistics, version 22.0 (SPSS Inc., Chicago, IL, USA). If the distribution of the variables was normal or skewed, continuous variables were expressed as the mean standard deviation (SD) or medians (25th to 75th centiles). The Kolmogorov-Smirnov test for normality and the Bartlett's test for homogeneity of variance were used for data analysis. We also utilized the chi-square test (or Fisher's exact test if appropriate) and the unpaired t-test (or the Wilcoxon rank-sum test depending on statistical distribution) for quantitative (or qualitative) data, respectively. We compared clinical and demographic variables between patients with observation group vs. control group. Statistical significance was determined when the result had a corresponding $P$ value $<$ 0.05.

**Results**

We randomly assigned 76 of the 168 patients who were eligible for evaluation between December 2022 and February 2023 to either the control group (38 patients) or the observation group (38 patients) (Fig. 4). The baseline characteristics were equally distributed amongst these two study groups (Table 1).
Table 1
Baseline characteristics of the study participants.

<table>
<thead>
<tr>
<th></th>
<th>control group (n = 38)</th>
<th>observation group (n = 38)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, n (males/females)</td>
<td>22/16</td>
<td>26/12</td>
<td>0.342</td>
</tr>
<tr>
<td>Age (years), mean ± SD</td>
<td>61.87 ± 7.82</td>
<td>59.63 ± 8.77</td>
<td>0.286</td>
</tr>
<tr>
<td>BMI (kg/m^2), mean ± SD</td>
<td>28.53 ± 2.54</td>
<td>27.97 ± 3.26</td>
<td>0.232</td>
</tr>
<tr>
<td>Obesity (BMI ≥ 30 kg/m^2), n (%)</td>
<td>8 (21)</td>
<td>12 (32)</td>
<td>0.297</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>17 (45)</td>
<td>22 (58)</td>
<td>0.251</td>
</tr>
<tr>
<td>Chronic cardiovascular disease, n (%)</td>
<td>17 (45)</td>
<td>13 (34)</td>
<td>0.348</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>16 (42)</td>
<td>11 (29)</td>
<td>0.231</td>
</tr>
<tr>
<td>Chronic pulmonary disease, n (%)</td>
<td>4 (11)</td>
<td>6 (16)</td>
<td>0.497</td>
</tr>
<tr>
<td>Chronic kidney disease, n (%)</td>
<td>3 (8)</td>
<td>2 (5)</td>
<td>0.644</td>
</tr>
<tr>
<td>HFNO, n (%)</td>
<td>27 (71)</td>
<td>32 (84)</td>
<td>0.169</td>
</tr>
<tr>
<td>FiO₂ (%), mean ± SD</td>
<td>67.37 ± 8.91</td>
<td>69.47 ± 7.24</td>
<td>0.262</td>
</tr>
<tr>
<td>SpO₂ (%), mean ± SD</td>
<td>90.97 ± 2.91</td>
<td>91.39 ± 3.00</td>
<td>0.536</td>
</tr>
<tr>
<td>PaO₂ (kPa), mean ± SD</td>
<td>8.69 ± 0.66</td>
<td>8.80 ± 0.57</td>
<td>0.451</td>
</tr>
<tr>
<td>PaO₂/FiO₂ ratio, mean ± SD</td>
<td>13.13 ± 2.05</td>
<td>12.79 ± 1.51</td>
<td>0.419</td>
</tr>
<tr>
<td>SpO₂/FiO₂ ratio, mean ± SD</td>
<td>137.28 ± 18.08</td>
<td>133.04 ± 15.48</td>
<td>0.276</td>
</tr>
</tbody>
</table>

BMI: Body mass index; HFNO: High-flow Nasal Oxygen

The observation group had shorter time spent implementing PP (2.74 ± 0.86 vs. 4.64 ± 1.02, P < 0.001), longer duration of PP (14.02 ± 1.01 vs. 13.03 ± 0.66, P < 0.001), duration time when first needing to adjust position (59.89 ± 12.73 vs. 36.57 ± 8.69, P < 0.001), and lower number of postural adjustments during PP (11.03 ± 2.67 vs. 17.95 ± 2.58, P < 0.001) compared with the control group (Table 2).
No significant differences in intubation (9 vs. 11, \( P = 0.602 \)) and mortality (4 vs. 6, \( P = 0.602 \)) were found in both groups (Table 3). However, in terms of adverse events, the observation group showed lower artificial airway kinking (5 vs. 23, \( P < 0.001 \)), pain (7 vs. 21, \( P = 0.001 \)), shortness of breath (2 vs. 9, \( P = 0.022 \)), dizziness (0 vs. 5, \( P = 0.021 \)), and stress injury (7 vs. 26, \( P < 0.001 \)) than the control group (Table 3). Especially with regards to the stage and the site of stress injury, the two groups of patients had a predominance of stage and stage , and the observation group showed lower stage (6 vs.18, \( P = 0.003 \)) and stage (1 vs.8, \( P = 0.013 \)) than the control group. In addition, the observation group exhibited lower stress injury to the face (3 vs.12, \( P = 0.009 \)), chest (5 vs.21, \( P < 0.001 \)), and knees (1 vs.7, \( P = 0.025 \)) in comparison with the control group (Table 3).
Table 3
Secondary outcomes for the study cohort

<table>
<thead>
<tr>
<th></th>
<th>control group (n = 38)</th>
<th>observation group (n = 38)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intubation,n (%)</td>
<td>11(28.9)</td>
<td>9(23.7)</td>
<td>0.602</td>
</tr>
<tr>
<td>mortality,n (%)</td>
<td>6(15.8)</td>
<td>4(10.5)</td>
<td>0.497</td>
</tr>
<tr>
<td>artificial airway kinking,n (%)</td>
<td>23(60.5)</td>
<td>5(13.2)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Pain,n (%)</td>
<td>21(55.3)</td>
<td>7(18.4)</td>
<td>0.001</td>
</tr>
<tr>
<td>Shortness of breath,n (%)</td>
<td>9(23.7)</td>
<td>2(5.3)</td>
<td>0.022</td>
</tr>
<tr>
<td>Dizziness,n (%)</td>
<td>5(13.2)</td>
<td>0(0)</td>
<td>0.021</td>
</tr>
<tr>
<td>Stress injury,n (%)</td>
<td>26(68.4)</td>
<td>7(18.4)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Stage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>,n (%)</td>
<td>18(47.4)</td>
<td>6(15.8)</td>
<td>0.003</td>
</tr>
<tr>
<td>,n (%)</td>
<td>8(21.1)</td>
<td>1(2.6)</td>
<td>0.013</td>
</tr>
<tr>
<td>Site</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Face,n (%)</td>
<td>12(31.6)</td>
<td>3(7.9)</td>
<td>0.009</td>
</tr>
<tr>
<td>Chest,n (%)</td>
<td>21(55.3)</td>
<td>5(13.2)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Knee,n (%)</td>
<td>7(18.4)</td>
<td>1(2.6)</td>
<td>0.025</td>
</tr>
<tr>
<td>Other,n (%)</td>
<td>2(5.3)</td>
<td>0(0)</td>
<td>0.152</td>
</tr>
</tbody>
</table>

Discussion

While prone positioning ventilation can improve symptoms and mortality in patients with ARDS due to COVID-19, it may cause patients feel uncomfortable over a long period of time, and even lead to adverse effects such as pressure injuries, pain, and dizziness. Currently, the application of prone position tools (such as soft pillows, cushions, and frame) during prone position surgery and prone position ventilation is aimed at reducing adverse events such as pressure injuries and nerve injuries. Minnis et al. reported that using Tony prone support, a polyurethane foam fold support cushion, can reduce the incidence of pressure marks and neuropathias, as well as minimizing the risk of orbital and maxillofacial injury during spinal surgery or chronic pain procedures in the prone position[19]. Similar findings were investigated by Ruhland et al., wherein applying a polyurethane cushions to the thoracic, pelvis, and head of two patients in prone position ventilation due to ARDS and COVID-19 can prevent pressure injuries[20]. Moreover, Sun et al. found that using protective cushions around the orbit can avoided orbital compartment syndrome[21]. However, there are currently no RCT studies on the use of prone positioning tools for
improving patient comfort and reducing adverse events during prone ventilation. Our RCT study found that modular new prone positioning tools can effectively enhance the comfort of patients during prone positioning and reduce adverse events such as artificial airway curvature, pressure injuries, and dizziness in contrast with soft pillows. However, there is no significant difference in intubation rates or mortality.

Long-term prone positioning has several disadvantages. Patients may experience discomfort and various adverse events (e.g., muscle fatigue and stress), leading to muscle pain and stiffness, incompletely expansion of lungs, breathing difficulties, chest oppression, which further results in hypoxemia, dizzy symptoms, and increased the risk of stress injury[22]. To address these issues, current clinical practice commonly utilizes regular repositioning that provides a comfortable position. In the past, ordinary soft pillows were commonly used in the ward, which had a soft texture and a tendency to sink during use. It generated pressure on the patients’ eye sockets, chest, and abdomen, which could result in conjunctival congestion, pressure injuries, and limited respiratory function. Additionally, it required frequent assistance from a nurse or a caregiver to assist with positioning. It not only increased the risk of tracheal stenosis, obstruction, and even accidental detachment of the tube during positioning, but also added the workload of the nurse or the caregiver. Based on this, we designed modular new prone position tools, which consist of five modules: the head pad, chest pad, elbow pad, knee pad, and ankle pad, which can reduce the risk of pain and pressure injuries during the prone position. Among them, the head pad has a unique "U"-shaped recess design, which can distribute the weight of the head over the entire face when the patient is in prone position, avoid pressure on the orbital area, and reduce the risk of intraocular congestion. Additionally, the hollow design allows for an artificial airway to pass through without bending or moving out of place. Furthermore, the unique recess design of the chest pad can ensure that the chest and abdomen are suspended in air when the patient is in prone position, thus reducing the risk of dyspnea and dizziness caused by pressure on the chest during prone position ventilation. In our study, we observed significant differences in the rates of adverse events, such as pain, shortness of breath, dizziness, and pressure injuries between the observation group and the control group during the period of prone position. This suggests that modular new prone position tools can reduce the incidence of adverse events during prone positioning ventilation.

The extreme long duration of executing the prone position ventilation not only increases the workload of nurses or caregivers, but also causes discomfort to the patients during the execution, or even rejection of cooperation. Therefore, it is necessary to shorten the duration of executing the prone position ventilation. In addition, prolonged prone position ventilation can lead to discomfort in patients, including pain, dizziness, and dyspnea, which often requires frequent changes in position to ameliorate the situation. However, frequent changes in position during prone positioning ventilation can lead to fluctuations in blood pressure, curved artificial airways, and other complications, which not only affects the effectiveness of prone positioning ventilation, but also increases the difficulty of treatment for the underlying disease; consequently, the outcome and prognosis of the patient was impacted[23]. In our study, we observed that compared to soft pillows, modular new prone position tools could significantly shorten the time spent executing PP and the number of changes in position during PP while extending the duration of PP and the duration time when first needing to changes in position. This suggests that the
modular new prone position tools can promote the efficiency of prone position execution and enhance patient comfort. The modular new prone position tools are made of high-density sponge with a medium hardness, which complies with the principles of human biomechanics and ensures enough support for the patient’s head, chest, elbows, knees, and ankles in the prone position, thus improving their comfort. And its modular design is based on the comfortable posture of human prone position, which helps patients quickly achieve a comfortable prone position that avoids any posture adjustments. However, the results of this study showed that there was no significant difference in the mortality rate and intubation rate between the two groups, possibly due to the fact that both groups were able to receive prone position ventilation, with no significant differences in the treatment methods and mechanisms either. What’s more, although the control group patients spent less time in the prone position due to discomfort, this did not influence their overall outcomes.

Conclusion

The prone position ventilation exhibits some drawbacks with regard to increased workload and feeling of discomfort. However, our modular new prone position tools overcome these problems. Our research indicated that utilizing modular new prone position tools for prone ventilation therapy not only improves the efficiency of prone position execution and patient comfort, but also reduces the incidence of adverse events. Nevertheless, it cannot change the intubation rate and mortality rate of patients. This set of tools has great potential in patients who require prone position ventilation treatment clinically. In the future, we plan to conduct multicenter studies with larger sample sizes to further validating the conclusions of this study, and thereby promoting its clinical promotion and application.

Abbreviations

PP
Prone position
ARDS
Acute respiratory distress syndrome
COVID-19
Coronavirus disease 2019
SARS-CoV-2
Type 2 betacoronavirus of SARS-like symptoms
PaO2/FiO2
Arterial partial pressure of oxygen/Fraction of inspired oxygen
ICU
intensive care unit
HFNO
high-flow nasal oxygen
NIV
non-invasive ventilation.

**Declarations**

**Authors’ contributions**

The clinical experiment was created, the data was analyzed, and the article was written by DH, XK, and WS. The experiment's feasibility analysis was performed by YL, LX, and AZ, who were also in charge of the article's general management and supervision as well as its quality control and review. Data collection and trial evaluation fell within the purview of YZ, MX, and JW. All authors have evaluated and given their approval for the article's submission.

**Funding**

This work was supported by the Research Launch Project of The Fourth People's Hospital Affiliated to Tongji University (Grant Number sykyqd02001).

**Availability of data and materials**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

**Ethics approval and consent to participate**

The studies involving human participants were reviewed and approved by the Medical Ethics Committee of Shanghai Fourth People's Hospital (No. SYLL2023008). The patients/participants provided their written informed consent to participate in this study. For the publication of any potentially identifiable photos or data in this article, the individual(s)' written informed consent has been obtained.

**Consent for publication**

Available if requested.

**Competing interests**

The authors declare that they have no competing interests.

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References


Figures
Figure 1

modular new prone positioning tools

Figure 2

modular new prone positioning tools therapy
Figure 3

traditional prone ventilation positioning therapy
Figure 4

CONSORT flow diagram of randomized and analyzed participants.