The Effects of Prone Positioning in Spontaneously Breathing Tetraplegic Patients with Respiratory Impairment: A Retrospective Cohort Study Protocol

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The authors declare no conflicts of interest.

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Abstract

Background: Patients with high cervical spinal cord injuries frequently experience respiratory impairment due to paralysis of the intercostal and abdominal muscles. Although prone positioning has been shown to improve oxygenation and secretion clearance in various patient populations, its effects in spontaneously breathing tetraplegic patients remain insufficiently studied. This study aims to evaluate the physiological effects, feasibility, and safety of prone positioning in this complex and vulnerable population.

Methods: This retrospective cohort study will analyze routinely collected clinical data from spontaneously breathing tetraplegic patients who underwent prone positioning at Heidelberg University Hospital. Parameters including oxygen saturation (SpO_2), arterial blood gases, respiratory rate, and secretion mobilization will be assessed before, during, and after prone positioning. Data from July 10, 2017 to February 28, 2025 will be included. Statistical analyses will incorporate both descriptive and inferential methods appropriate for paired data.

Discussion: The study is expected to provide foundational evidence on the effects of prone positioning in non-intubated tetraplegic patients with respiratory impairment. Findings may inform clinical decision-making and contribute to the development of evidence-based positioning protocols in spinal cord injury care.

Trial registration: German Clinical Trials Register (DRKS), DRKS00038033

Keywords

Tetraplegia; Spinal cord injury; Prone positioning; Spontaneous breathing; Respiratory impairment; Non-invasive respiratory support; Intensive care; Oxygenation; Secretion clearance.

Introduction

Background

Prone positioning, defined in this study as rotation between 135° and 180°, is well established in the management of patients with acute respiratory distress syndrome (ARDS), where it improves ventilation–perfusion matching, gas exchange, and secretion clearance. (1). These benefits arise from the recruitment of dorsal lung regions, redistribution of perfusion, and enhanced secretion drainage. (2, 3).

Tetraplegic patients differ from typical ARDS populations. Their respiratory limitations stem primarily from neuromuscular impairment of respiratory and accessory muscles following spinal cord injury, rather than intrinsic pulmonary disease. As a result, they are predisposed to ineffective coughing, secretion retention, atelectasis, and respiratory deterioration. Strategies that maintain spontaneous breathing and reduce the need for invasive ventilation are therefore of great clinical relevance. (4,5).

Rationale

To date, no systematic evaluation exists regarding the effects of prone positioning in spontaneously breathing tetraplegic patients. While the physiological rationale from ARDS literature suggests potential benefit, the unique pathophysiology of tetraplegia necessitates tailored evidence.

Objectives

The primary objective is to evaluate the effects of prone positioning on oxygenation, secretion mobilization, and complications in spontaneously breathing tetraplegic patients with respiratory impairment. Secondary objectives include assessment of vital signs, blood gas parameters, intubation rates, and length of ICU, hospital stay and in-hospital mortality.

Methods and Design

Study aim

To evaluate the physiological and clinical effects of prone positioning in spontaneously breathing tetraplegic patients with respiratory impairment.

Study Design

This retrospective, single-center cohort study will be conducted at the Center for Orthopedics, Trauma Surgery, and Paraplegiological Center, Heidelberg University Hospital. Routine clinical data from patients treated between July 10, 2017 and February 28, 2025 will be analyzed.

Study Setting

The study will be conducted at the Center for Orthopedics, Trauma Surgery and Paraplegiology, Heidelberg University Hospital, in collaboration with the Center for Orthopedics, Trauma Surgery, and Paraplegiological Center.

Participants

Patients' recruitment will be performed as shown in the Strobe flow chart (Figure 1)

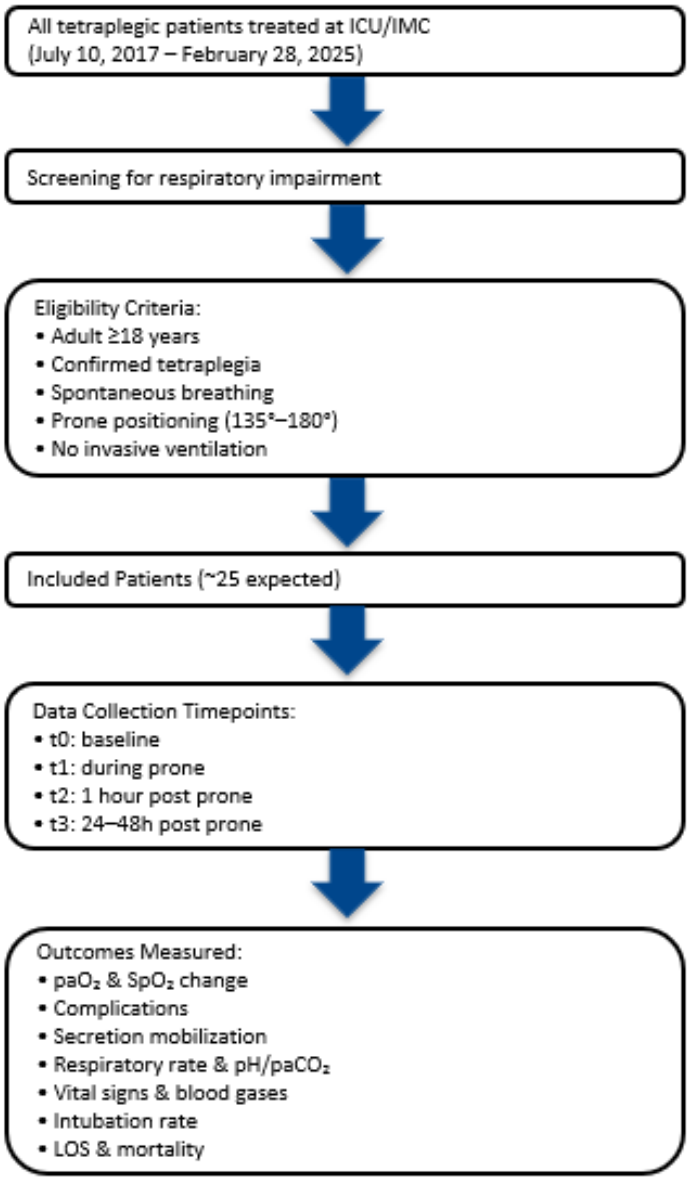

Figure 1 STROBE flow chart for the inclusion of study patients

Legend:
ICU: Intensive Care Unit
IMC: Intermediate Care Unit
SpO_2: Peripheral oxygen saturation
paO_2: Arterial partial pressure of oxygen
$paCO_2$: Arterial partial pressure of carbon dioxide
pH: Measure of acidity/alkalinity of arterial blood
LOS: Length of stay

Inclusion criteria:

- adults ≥18 years
- confirmed complete or incomplete tetraplegia
- spontaneous breathing
- prone positioning performed for respiratory support

Exclusion criteria:

- invasive mechanical ventilation

Intervention

Prone positioning between 135° and 180° will be evaluated as performed by the clinical care team. As this is a retrospective study, no intervention is initiated by investigators.

Data Collection

For each patient, baseline and demographic data will be collected. These include age, sex, height, weight, body surface area, and the American Society of Anesthesiologists (ASA) classification. In addition, the admission diagnosis and the specific paraplegic diagnosis will be recorded, including the neurological level of injury, the ASIA Impairment Scale, relevant comorbidities, and any prior therapies. Furthermore, the patients' medication history and pre-existing medical conditions will be documented. As this is a retrospective observational study without prospective allocation to interventions, sequence generation, allocation concealment, and blinding are not applicable. All data are derived from routine clinical documentation without randomization or group assignment and no active recruitment is performed.

During each prone positioning intervention, several variables will be systematically collected. Vital signs, including heart rate, respiratory rate, oxygen saturation, and blood pressure, will be recorded. The type of prone position (135° or 180°) as well as the duration and number of prone sessions will be documented. In addition, blood gas

analyses will be performed, including pH, arterial oxygen partial pressure (PaO_2), carbon dioxide partial pressure ($PaCO_2$), base excess, and oxygen saturation. Potential complications such as catheter dislodgement, facial edema, pressure ulcers, aspiration, or vomiting will be noted. Patient tolerance will be assessed using the Richmond Agitation-Sedation Scale (RASS) and an anxiety rating. The need for analgesia and sedation will be documented alongside the mode of oxygen delivery (room air, nasal cannula, high-flow nasal cannula [HFNC], or non-invasive ventilation [NIV]) and its corresponding parameters, including inspired oxygen fraction (FiO_2), flow, and positive end-expiratory pressure (PEEP). Furthermore, secretion clearance and mobilization will be evaluated. If prone positioning is discontinued, the reason for termination will also be recorded.

Outcome measures

The primary endpoint will be the change in oxygenation parameters (PaO_2 and SpO_2) before and after prone positioning (t0–t3). This outcome directly reflects the physiological rationale of the intervention and is expected to be sensitive to short-term effects. In addition, any complications related to prone positioning, such as catheter dislodgement, pressure ulcers, facial edema, aspiration, or vomiting, will be systematically assessed.

Secondary endpoints include secretion mobilization (quantified by the number of suctioning episodes), changes in respiratory rate and pH/$PaCO_2$, tolerance of positioning, and length of ICU, hospital stay and in-hospital mortality. Also Changes in additional vital signs such as heart rate, blood pressure, and respiratory rate, as well as further blood gas parameters including pH, carbon dioxide partial pressure ($PaCO_2$), and base excess. Moreover, the rate of intubation among the studied patients will be documented.

Data collection will follow a predefined timeline to ensure consistency and comparability across all patients. Baseline measurements will be obtained immediately before the initiation of prone positioning (t0). Additional measurements will be taken during the prone positioning intervention itself (t1). Follow-up data will then be collected one hour after the intervention (t2). A further evaluation will be conducted 24 to 48 hours after the

intervention, or immediately prior to the indication for a subsequent prone positioning session (t3). This standardized sequence of time points allows the assessment of both immediate and short-term effects of prone positioning.

Statistical Analysis

All collected data will be entered into a structured electronic database (Microsoft Excel 365) and subsequently analyzed using SPSS version 31.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics will be applied to summarize baseline characteristics and outcome variables. Continuous data will be reported as means with standard deviations when normally distributed, or as medians with interquartile ranges when distributions are non-normal. Categorical variables will be presented as absolute numbers and percentages. Paired statistical tests (Wilcoxon signed-rank test or paired t-test, depending on distribution) will be used to assess within-patient changes between measurement time points. Categorical data will be analyzed using McNemar's test. Repeated-measures exploratory models (e.g., linear mixed models) may be used to evaluate trends across t0–t3. Missing data will be managed through complete-case analysis, and the extent and pattern of missingness will be reported. Significance will be set at $p < 0.05$. Given the retrospective design and the rarity of the patient population, the expected cohort size is small, with a maximum of approximately twenty-five patients. For this reason, no formal sample size calculation has been performed, and the statistical power of inferential testing will be limited. The analyses are therefore primarily descriptive and hypothesis-generating. Because this is a retrospective study based on routine clinical data without any prospective interventions, no independent data monitoring committee is required. The study is monitored internally by the principal investigator and the study team in accordance with institutional standards and no external auditing is planned. The study will follow institutional quality and data protection standards, and oversight is provided internally by the principal investigator and the study team

Discussion

This study will provide the first systematic evaluation of prone positioning in spontaneously breathing tetraplegic patients with respiratory impairment. By analyzing real-world data from a tertiary care center, the findings may contribute to clinical practice by offering insights into the feasibility, safety, and potential benefits of this intervention.

One of the main strengths of the study is that it will be the first to systematically investigate prone positioning in this rare patient population. In addition, the study benefits from detailed clinical data collection spanning a period of more than seven years, which ensures that a wide range of relevant variables will be available for analysis. However, several limitations must be acknowledged.

Bias and limitations

- *Selection bias:* Only patients for whom prone positioning was clinically indicated are included, which may reflect more severe cases.
- *Documentation bias:* Retrospective documentation may vary in completeness and accuracy.
- *Confounding variables:* Variability in neurological injury level, comorbidities, and baseline respiratory function may influence outcomes.
- *Heterogeneous intervention:* Differences in angle (135° vs. 180°), duration, and frequency of prone sessions introduce variability.
- *Small sample size:* Expected cohort ≤25 patients limits statistical power and generalizability.
- *Single-center design:* Reduces external validity.

Despite these limitations, the findings may inform future prospective studies and contribute valuable insights into respiratory management in tetraplegic patients.

List of abbreviations

ARDS: acute respiratory distress syndrome ICU: intensive care unit IMC: intermediate care unit HFNC: high-flow nasal cannula NIV: non-invasive ventilation FiO_2: fraction of inspired oxygen PEEP: positive end-expiratory pressure PaO_2: arterial partial pressure of oxygen $PaCO_2$: arterial partial pressure of carbon dioxide ASA: American Society of Anesthesiologists ASIA: American Spinal Injury Association Impairment Scale RASS: Richmond Agitation-Sedation Scale DRKS: German Clinical Trials Register

Declarations

Ethics approval and consent to participate

This study is conducted in accordance with the Declaration of Helsinki and the professional code of conduct of the State Chamber of Physicians of Baden-Württemberg. The study protocol has already been reviewed and approved by the Ethics Committee of the Medical Faculty of Heidelberg University (approval number: S-152/2025). Any important protocol amendments (e.g., changes to study objectives, eligibility criteria, outcomes, or analysis methods) will be submitted to the Ethics Committee of the Medical Faculty of Heidelberg University for approval. In addition, any modifications will be updated in the German Clinical Trials Register (DRKS, DRKS00038033) to ensure transparency. Because of the retrospective nature of the study, which is based on pseudonymized routine clinical data, the requirement for individual patient consent was waived. Data management adheres to institutional IT security standards. All data will be pseudonymized during collection and analysis and will be anonymized once the study purpose allows. The dataset will be securely stored for ten years within the hospital's data center. Access to the pseudonymized study dataset is restricted to the principal investigator and authorized members of the study team. No external parties will have access to the raw data. An anonymized version of the dataset may be made available upon reasonable request after publication, in accordance with institutional policies and data protection regulations.

Use of artificial intelligence tools: Language editing were assisted by a large language model (ChatGPT, OpenAI). The authors reviewed and take full responsibility for the final content.

Consent for publication

Not applicable. No identifiable personal data are included.

Availability of data and materials

The datasets generated and analyzed are not publicly available due to data protection regulations but may be requested from the corresponding author.

Competing interests

The authors declare no competing interests.

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Authors' contributions

LZ conceived and drafted the study protocol and coordinated nursing methodology. OINA assisted with study design and data preparation. CH provided clinical expertise and supervision. RK performed data extraction and statistical analysis. HW contributed clinical oversight. SOD ensured methodological rigor and final approval of the manuscript. All authors approved the final version.

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