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Commentary

Pairing spontaneous awakening and breathing trials to improve weaning of intensive care unit patients: A Systematic Review Protocol

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Abstract

Background: The ICU nursing role is to minimize the agitation and suffering experienced by mechanically ventilated sedated patients while facilitating effective and safe clinical care, seeking to optimize outcomes for service users and health systems. This can be achieved with bundled EBP interventions. One care bundle for those patients is the "Awakening and Breathing Coordination, Delirium Monitoring and Management, and Early Mobility" (ABCDEF) bundle. It deploys tailored, patient-centered pharmacological and non-pharmacological therapies for implementation in ward management and clinical practice. It seeks to shatter the paradigm of extended mechanical ventilation and associated sedation for ICU patients by guiding clinical decision-making and interventions algorithmically.

Method: Randomized controlled studies will be included for the present systematic review with adult and pediatric patients who have been managed using the Awakening and Breathing Coordination protocol compared to the routine care in the ICUs. The Cochrane Library (Wiley), MEDLINE (PubMed), Scopus, and Web of Science electronic databases will be searched for articles published in English. The clinical outcomes of interest include successful weaning, incidence/prevalence of VAP, sedation level, and reduced stay in the ICU/hospital stay time. The reviewers will independently extract data with a standard form, recording observations concerning the reviewed studies' research design, population, clinical interventions and outcomes, and techniques of data collection and analysis. Their independent findings will then be compared to check for consistency, and in the event of contrasting findings or interpretations, a third-party research expert will arbitrate.

Results: The evidence from this review would particularly assist nursing decision-making on using spontaneous awakening trials and spontaneous breathing trials in combination for ventilated patients.

Conclusion: The results could drive evidence-based practice to improve the quality of care for mechanically ventilated sedated patients in ICUs by building on the safety and clinical effectiveness of Randomized controlled trials.

Protocol registration: PROSPERO CRD42022344884

Keywords: Intensive care units, Sedation, Spontaneous awakening trial, Spontaneous breathing trials, Weaning.

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1. Introduction

1.1 ICU care for mechanically ventilated sedated patients (MVSPs)

ICU nursing clinical practice caring for mechanically ventilated sedated patients (MVSPs) entails evidence-based practice (EBP) for holistic care, including with regard to psychosocial wellbeing (e.g., stress and anxiety), as well as biomedical symptoms and pain management. The majority (85%) of MVSPs receive sedatives at some point to minimize anxiety and discomfort associated with life disruption, the intensive care unit (ICU) ambiance, and mechanical ventilation (MV) itself (1). More specifically, non-stop IV infusions of sedatives are used to facilitate invasive MV with minimized injury and patient suffering (2). However, the drawbacks of this common treatment approach include prolonged MV, ventilator-related issues, deficits in cognition (e.g., PTSD and delirium), lower patient self-efficacy, and prolonged ICU hospitalization; the latter makes patients more vulnerable to ICU-specific issues (e.g., ICU-acquired infections), and multiples the cost of care and impacts for patients and their families (as well as health systems), increasing morbidity and mortality and reducing health resource optimization (3).

Aside from the potential negative impacts of sedation in itself, its administration can lead to under- or over-sedation, which exacerbates negative impacts on patients and health system resources. Sedation management is an important aspect of coordinated and integrated holistic care for MVSPs. If patients are over-sedated, they are vulnerable to incidental risks such as aspiration, respiratory depression, falls, prolonged MV, delayed recovery, and increased reintubation, and risk of pneumonia. Under-sedation can cause patients to be distressed and agitated, with particular clinical risks of self-extubating and injury, patient-ventilator desynchrony, and over-consumption of oxygen (4).

Although, sedation is generally successful in reducing patient anxiety and agitation, it does entail intrinsic risks and major psychological and physiological negative impacts. The ICU nursing role in these circumstances is to minimize the agitation and suffering experienced by MVSPs while facilitating effective and safe clinical care, seeking to optimize outcomes for service users and health systems. This can be achieved with bundled EBP interventions, especially for MVSPs subject to extended sedation and MV treatment programmes. One care

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bundle for MVSPs is the "Awakening and Breathing Coordination, Delirium Monitoring and Management, and Early Mobility" (ABCDEF) bundle. ABCDEF embeds optimum EBP concerning both analgesia and sedation for MVSPs, with consideration of psychological symptoms, immobility, and ventilator management for ICU patients. It deploys tailored, patient-centred pharmacological and non-pharmacological therapies for implementation in ward management and clinical practice. The "Awakening and Breathing Coordination Trials" (ABC) protocol (within the eponymous ABCDEF bundle) seeks to shatter the paradigm of extended MV and associated sedation for MVSPs by guiding clinical decision-making and interventions algorathemically (5).

1.2 Spontaneous Awakening Trial (SAT) and Spontaneous Breathing Trial (SBT)

The "Spontaneous Awakening Trial" (SAT) is designed to enable early cessation of MV for MVSPs based on attentive screening, at baseline and on a daily basis thereafter, as opposed to the default of registering patient waketime just prior to beginning the ventilator weaning process (6) . Initial screening of MVSP readiness for SAT and trial tolerance encompasses no current agitation, active myocardial ischemia during the previous day, indication for sedative infusion in the event of active seizures, use of neuromuscular blockers, or increased intracranial pressure.

SAT is integrated into the ABC protocol with "Spontaneous Breathing Trial" (SBT) (6). to reduce MVSPs', need for ventilation if they meet the commensurate clinical prerequisites. Patient safety for the administration of SBT is indicated by light vasopressor deployment (determined according to particular patient needs), no agitation (i.e., no clinically significant agitation or discomfort), making an autonomous and spontaneous effort at inspiration during a five-minute period, and sufficient oxygenation (SpO2 ≥88% for ≤50% inspired oxygen, and ≤8 cm H2O positive end-expiratory pressure (PEEP)). Based on these criteria of extubating tolerance, ICU nurses can decide whether awakened, non-sedated patients can begin to be weaned off MV.

Numerous studies conducted in international contexts have combined SAT and SBT in various configurations and reported promising results that could potentially drive EBP adoption, but many clinical practitioners remain reluctant to change the time-honoured (if less effective) conventional practices for MVSPs in ICUs (5, 6) . Additionally, ICUs were the main focus of attention during the COVID-19 pandemic; the initial rationale for "lockdown" public health policies was to prevent ICU units from being overwhelmed, which was also related to a lack of MVs, in both developed and developing countries (7) . ICU clinicians are often prevented from providing optimum EBP for their patients due to system deficiencies (e.g., a lack of sufficient resources, overcrowding, and understaffing), and intrinsic contextual difficulties, such as stringent infection control requirements, which were exacerbated during the COVID-19 pandemic (8). This situation could have been ameliorated if there had been a priori protocols and institutional policies (e.g., concerning bed allocation) available to guide nurses (5). The current review gathers data to explore the clinical safety and effectiveness as well as the practical feasibility of implementing the ABC protocol as a consistent EBP intervention to improve the quality of care delivered to MVSPs in ICUs.

2. Objective and review question

The objective of this review is to ascertain the clinical effectiveness and impacts of paired SAT–SBT protocol for MVSPs.

Consequently, it seeks to answer the PICO question below:

How does paired SAT–SBT protocol for MVSPs in ICUs affect weaning?

Population: MVSPs (during weaning).

Intervention: Paired SAT–SBT.

Comparison: MVSPs receiving normal weaning.

Outcome: Clinical outcomes (including successful weaning, incidence/prevalence of VAP, sedation level, reduced stay in ICU/hospital stay time).

3. Method

3.1 Standards

This systematic review protocol was developed using the "Preferred reporting items for Ssystematics reviews and Meta-analysis protocol" (PRISMA-P) (9) .

3.2 Registration

This systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) CRD42022344884:

(https://www.crd.york.ac.uk/prospero/#recordDetails).

As this study does not involve human participants directly, there is no need for ethical approval.

3.3 Study eligibility criteria

3.3.1 Inclusion

- Published in English.
- Quantitative randomized controlled trials (RCTs).
- Populations of adult (≥18 years old) and paediatric (<18 years old) MVSPs in ICUs.
- Intervention group patients receiving paired SAT–SBT protocol (ABC protocol).
- Control groups receiving conventional care.
- Studies reporting the following outcome measures:
- Primary outcome: days of weaning from MV.
- Secondary outcomes: ICU and hospital mortality rate (proportion), length of ICU stay (days), sedation level (Richmond Agitation Sedation Scale, RASS), ventilator-associated pneumonia (VAP) incidence (Clinical Pulmonary Infection Score, CPIS).

3.3.2 Exclusion

- Research proposals.
- Conference abstracts.
- Secondary and tertiary studies.
- Studies evaluating clinical tools.
- Institutional guidelines.
- Letters, editorials, case reports, commentaries, systematic reviews.

3.4 Search strategy

The Cochrane Library (Wiley), MEDLINE (PubMed), Scopus, and Web of Science electronic databases will be searched for articles published in English using the keywords adumbrated below, using Boolean operators:

ISI: TS = (Ventilator Weaning OR Respirator Weaning OR Mechanical Ventilator Weaning) AND TS = (Mechanical ventilation OR Artificial Respiration OR Artificial Respirations OR Mechanical Ventilations OR Mechanical Ventilation) AND TS = (Sedatives and Hypnotics OR Sedative and Hypnotic OR Hypnotic and Sedative OR Hypnotic Effect OR Hypnotic Effects OR Sedatives OR Sedative OR Hypnotics OR Hypnotic OR Sedative Effect OR Sedative Effects).

PubMed: (Sedatives and Hypnotics OR Sedative and Hypnotic OR Hypnotic and Sedative OR Hypnotic Effect OR Hypnotic Effects OR Sedatives OR Sedative OR Hypnotics OR Hypnotic OR Sedative Effect OR Sedative Effects) AND (Mechanical Ventilation OR Artificial Respiration OR Artificial Respirations OR Mechanical Ventilations)) AND (Ventilator Weaning OR Respirator Weaning OR Mechanical Ventilator Weaning)

Scopus: TITLE-ABS (“Sedatives and Hypnotics” OR “Sedative and Hypnotic” OR “Hypnotic and Sedative” OR “Hypnotic Effect” OR “Hypnotic Effects” OR “Sedatives” OR “Sedative” OR “Hypnotics” OR “Hypnotic” OR “Sedative Effect” OR “Sedative Effects”) AND TITLE-ABS (“ Mechanical ventilation” OR “Artificial Respiration” OR “Artificial Respirations” OR “Mechanical Ventilations”) AND TITLE-ABS (“Ventilator Weaning” OR “Respirator Weaning” OR “Mechanical Ventilator Weaning”).

Methodological filters will additionally be imposed to restrict the retrieved hits to primary studies; the strategy used for searching will be modified and adapted according to the particular features of each searched database.

Grey literature encountered during the searching process (e.g., from the bibliographies of relevant studies) with adequate pertinent data may be considered for analysis.

3.5 Determination of eligibility

Studies potentially eligible for inclusion will be independently analysed in full-text versions by two reviewers, and those they deem suitable will be scrutinized by the principal investigator. In cases where two articles are published contemporaneously, the one with more comprehensive data will be included. In any cases of conflicts between the reviewers, a third-party researcher may be invited to arbitrate.

3.6 Data extraction

Each of the reviewers will independently extract data with a standard form, recording observations concerning the reviewed studies' research design, population, clinical interventions and outcomes, and techniques of data collection and analysis. Their independent findings will then be compared to check for consistency, and in the event of contrasting findings or interpretations a third-party research expert will arbitrate.

3.7 Bias risk analysis

Included studies' risk of bias will be independently evaluated and classified as "low", "high" or "unclear" risk by two authors using Cochrane Collaboration domain-based evaluation (10), and their findings will be confirmed by a third author. The domains comprise attrition, detection, selection, performance and other biases.

3.8 Data synthesis

A systematic review narrative table will adumbrate the features of reviewed studies, including the following: ICU and hospital length of stay, ICU and hospital mortality, national context, participant characteristics, sample size, sedation level, time context, VAP incidence and prevalence, and ventilator duration (days; mean, SD). The standard error and mean difference will be identified for studies comparing these two mean values. If the reviewed studies yield sufficient data, a random effect meta-analysis can be undertaken, with h, I^2, and Q statistics being deployed to assay between-studies heterogeneity (11). I^2 values of 0-40%, 30–60%, 50–90%, and 75–100% may indicate negligible (insignificant), moderate, substantial, and significant heterogeneity (respectively). Tau square will also be used to indicate total heterogeneity.

Publication bias will be measured using beg, egger, funnel plot, and Harbor tests. Meta regression or subgroup analysis will be deployed when convenient in cases of significant heterogeneity (as per categorical or continuous variables). The main continuous variable of concern is ventilator days (the main outcome for the studied interventions), which will be analysed with the mean difference (MD) and standardized mean difference (SMD) summary statistics (11). When meta-analysis is not possible, narrative synthesis can be implemented to present and organize days of ventilation logically, with the integration of all heterogeneous data. Corresponding authors of reviewed studies will be approached in cases where more supplementary data or explanation is required. In the event that they fail to reply within a fortnight, the available data will be used, or the paper will not be included in subsequent analysis. Secondary outcomes synthesis may be used according to the type and quantity of data reported by the studies.

3.9 Ethics and dissemination

As mentioned previously, this study does not directly involve human participations; it systematically reviews studies from peer-reviewed mainstream healthcare research journals (which ultimately insure conventional ethical consideration at the level of individual empirical studies). No concerns about privacy and anonymity therefore arise. The findings will be disseminated via publication in a peer-reviewed journal.

4. Discussion

This systematic review can be used to drive EBP to improve the quality of care for MVSPs in ICUs by building on the safety and clinical effectiveness of RCTs. It may particularly assist nursing decision-making on using SAT and SBT in combination for ventilated patients. The analysis is expected to identify avenues requiring further research. The evidentiary sstrengths will be categorized using GRADE (12).

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