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Lateral positioning for critically ill adult patients (Protocol)

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[Intervention Protocol]

Lateral positioning for critically ill adult patients

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

We aim to assess the effect of the lateral position compared to other body positions on patient outcomes (mortality, morbidity and clinical adverse events during and following positioning) in critically ill adult patients. We will examine the single use of the lateral position (that is on the right or left side) and repeat use of the lateral position(s) in a positioning schedule (that is lateral positioning). We plan to undertake subgroup analysis for primary disease and condition, severity of illness, the presence of assisted ventilation and angle of lateral rotation.

BACKGROUND

Routine patient positioning in the intensive care unit (ICU) prophylactically promotes comfort, prevents pressure ulcer formation and may reduce the incidence of deep vein thrombosis, pulmonary emboli, atelectasis and pneumonia (Banasik 2001; Keller 2002; Krishnagopalan 2002; Nielsen 2003; Schallom 2005). Routine positioning usually involves moving the patient between the right and left lateral position. However, this side-to-side rotation is often interrupted with another body position such as the supine or semi-recumbent position (Kim 2002; Shively 1988). Two-hourly turns are standard practice for the prevention of complications associated with prolonged bed rest (Ahrens 2004; Doering 1993; Krishnagopalan 2002). Yet, empirical research has not established the optimal frequency of routine positioning (Ahrens 2004; Shively 1988).

During routine positioning, the order of sequence between body positions is often at the discretion of the clinician and may be based on convenience or custom (Doering 1993; Evans 1994). However, for some critically ill patients the choice of body position may be important in providing a therapeutic benefit rather than maintaining the routine indiscriminately. That is, in some instances goal-directed therapeutic positioning may take precedence over routine positioning to help improve physiological function and aid recovery (Evans 1994; Griffiths 2005). The length of time in the chosen therapeutic position may extend beyond the standard two hours or may be shortened, based on the effectiveness of the chosen position in improving outcomes.

The lateral position is recommended as a therapeutic body position in unilateral lung disease (Thomas 1998; Wong 1999). In particular, lying on the side of the healthier lung with the relatively healthy lung dependent (inferior) may improve arterial oxygenation. This is a finding consistently reported across numerous studies, regardless of whether participants are spontaneously breathing (Remolina 1981; Seaton 1979; Sonnenblick 1983; Zack 1974) or mechanically ventilated (Banasik 1987; Banasik 1996; Gillespie 1987; Ibañez 1981; Kim 2002; Rivara 1984). However, the optimal length of time patients should remain on their side for therapeutic benefit is unknown. Nor is it clear what impact changes in arterial oxygenation have on the incidence of morbidity or mortality.

A recent meta-analysis of three randomized trials found evidence supporting patient positioning with the good lung down in mechanically ventilated patients with unilateral lung disease. Higher oxygen tensions were found in this dependent lateral position compared to the supine or opposite lateral position (Thomas 2007). However, sample size and publication bias may have influenced the magnitude and direction of the treatment effect. Results of non-randomized trials have suggested that some individuals may demonstrate a paradoxical effect with the good lung down. These individuals demonstrate better oxygenation with their diseased lung in the dependent lateral position (Chang 1989; Choe 2000;

Seaton 1979; Zack 1974). Furthermore, the recent meta-analysis identified that the primary condition varied across trials and included postoperative coronary artery bypass graft (CABG) patients and patients with bilateral and unilateral lung disease (Thomas 2007). However, no subgroup analysis, heterogeneity testing or sensitivity analysis of the methodological quality was conducted. Therefore, the strength of evidence remains unclear.

Other qualitative overviews have reported similar conclusions to the recent meta-analysis (Nielsen 2003; Wong 1999). However, systematic and rigorous methods were not utilized within these reviews to minimize bias. Both reviews included non-randomized studies, quality assessment was absent in one review (Nielsen 2003) and was based on the levels of evidence hierarchy without appraisal of trial design within the other review (Wong 1999). Furthermore, systematic reviews and meta-analyses conducted in the related area of continuous lateral positioning do not examine outcomes specifically attributed to the right or left lateral position (Choi 1992; Delaney 2006; Goldhill 2007). Currently, no systematic review has comprehensively and rigorously examined the effect of the right and left lateral position as a single or repeated therapy for critically ill adult patients.

Patient positioning is a fundamental nursing activity (Evans 1994; Hawkins 1999). However, lateral positioning performed routinely may not be suitable for all ICU patients. Some authors have called for its cautious use in patients susceptible to cardiopulmonary and circulatory dysfunction (Bein 1996; Wilson 1994; Winslow 1990; Yeaw 1996). Patients may exhibit hypoxaemia, dyspnoea, arrhythmias or hypotension upon turning (Banasik 2001; Gawlinski 1998; Summer 1989; Winslow 1990). In the past, ICU participants have been withdrawn from lateral positioning trials due to 'intolerance to a position change' (Gavigan 1990; Shively 1988; Tidwell 1990). Even though positioning intolerance has not been sufficiently defined, the presence of respiratory and haemodynamic instability is commonly cited. Yet research evidence on the significance of respiratory and haemodynamic deterioration appears limited. Quantitative analysis of haemodynamic variables frequently monitored in ICU was not possible in one review due to weaknesses in trial design and lack of adequate reporting of the included trials (Thomas 2007).

Previous research acknowledges that some critically ill patients may experience significant transient changes in oxygen transport variables during repositioning. However, it is argued that for the vast majority of critically ill patients the reduction in oxygen transport variables such as mixed venous oxygen saturation (SvO₂) returns to baseline within five minutes and is unlikely to lead to adverse outcomes (Gawlinski 1998; Tidwell 1990; Winslow 1990). Currently, no systematic review on lateral positioning has examined the incidence of clinical adverse events which may contribute to impairment in tissue oxygenation. Furthermore, no current evi-

dence-based clinical practice guidelines exist on how to manage ICU patients who demonstrate changes in their monitored variables upon turning.

Although lateral positioning is a simple non-invasive respiratory therapy, uncertainty about its effect in critically ill adult patients continues to exist. A systematic review of studies that have investigated the incidence of mortality, morbidity and clinical adverse events during and following lateral positioning is required to provide the best evidence on body position during critical illness. The results of the present review may inform the development of evidence-based clinical practice guidelines and identify areas for future research.

OBJECTIVES

We aim to assess the effect of the lateral position compared to other body positions on patient outcomes (mortality, morbidity and clinical adverse events during and following positioning) in critically ill adult patients. We will examine the single use of the lateral position (that is on the right or left side) and repeat use of the lateral position(s) in a positioning schedule (that is lateral positioning). We plan to undertake subgroup analysis for primary disease and condition, severity of illness, the presence of assisted ventilation and angle of lateral rotation.

METHODS

Criteria for considering studies for this review

Types of studies

We will consider all randomized or quasi-randomized clinical trials including those of cross-over design that evaluate the effect of the lateral position as a single or repetitive therapy in patients in a critical care area.

Table 1. Pertinent definitions of the body positions of interest

Body position	Definition
Lateral position	The lateral position is described as side lying with pillows strategically placed along the patient's back, and possibly buttocks, and a pillow placed between the patient's flexed legs to prevent adduction and internal rotation of the hip. Patients are rolled to the right or left side but the degree of rotation from the horizontal plane may vary in clinical practice. Rotation may be between 30 to 60 degrees, but up to 90 degrees. The head of the bed may also be elevated while

Types of participants

We will include trials involving adult patients (aged 16 years and older) classified as critically ill.

We define critically ill participants as:

- patients diagnosed with an acute impairment of one or more of the vital organ systems that may be life-threatening (for example acute respiratory failure due to pneumonia, pulmonary oedema or acute respiratory distress syndrome, acute cardiac failure due to myocardial infarction, or acute liver failure due to fulminant hepatitis); or
- patients diagnosed with an acute disease, injury or condition requiring admission to a critical care area (ICU, coronary care unit (CCU) or cardiothoracic unit (CTU)) for advanced physiological monitoring, support or intervention (for example diabetic ketoacidosis, severe burns, blunt abdominopelvic trauma, or postoperative cardiopulmonary bypass surgery).

In addition, we will consider a trial eligible for inclusion if the trial provides its own definition of critical illness or describes the eligible population as critically ill without providing a specific definition. In this case, only trials located in a critical care area will be considered.

We will exclude trials investigating children, pregnant women or patients with spinal cord injury exclusively, or inclusively with these subgroups exceeding 10%, from the review. Furthermore, we will also exclude trials located within the operating theatre.

Types of interventions

The use of the lateral position as a single or repeated therapy for critically ill adult patients is the intervention of interest for this review.

We will consider trials that compare at least one lateral position (that is the right lateral or left lateral position) with one of the following body positions to be eligible for inclusion (definitions are tabulated in Additional Table 1):

Table 1. Pertinent definitions of the body positions of interest (Continued)

	the patient is on their side. Synonyms include the lateral dependent position, lateral decubitus position, lateral recumbent position, lateral tilt, lateral rotation and side lying. A lateral positioning schedule repeatedly utilizes the right and left lateral position. However, lateral rotation may be interrupted with another body position such as the supine or semi-recumbent position; therefore, the order of sequence may vary. Furthermore, a specialized automated bed may perform continuous lateral positioning in the form of kinetic therapy (greater than 40 degree rotation on each side) or continuous lateral rotational therapy (CLRT) (less than 40 degree rotation on each side). CLRT synonyms include continuous postural oscillation or continuous axial rotation.
Supine position	The supine position is described as the patient lying flat on their back with the face looking upwards. Synonyms include the flat backrest position and dorsal recumbent position.
Semi-Fowler's position or semi-recumbent position	The semi-Fowler's position is described as the supine position with 30 degree head elevation; whereas the semi-recumbent position may increase the degree of head elevation up to 45 degrees. Synonyms include 30 ° to 45 ° head elevation, head of bed (HOB) elevation or backrest elevation.
Fowler's position or high Fowler's position	The Fowler's position is the supine position with 60 degrees head elevation; whereas the high Fowler's position is sitting upright in bed at 90 degrees.
Prone position	The prone position is described as front lying with the person lying on their abdomen with one or both arms at their sides and head turned toward one side. The Sims position is a modified prone position (semi-prone). Synonyms of the prone position include the ventral decubitus position.
Trendelenburg position	The Trendelenburg position is described as the supine position with the head of the bed lower than the foot; the bed is inclined downwards, usually by 10 degrees. This position elevates the feet, legs and trunk above the person's head. A modified Trendelenburg position involves elevating the legs only, up to 30 degrees. Synonyms include head-down tilt.
Reverse Trendelenburg position	The reverse Trendelenburg position is described as elevating the head while lowering the legs without hip flexion (that is the bed is not jack-knifed). The bed is inclined approximately 30 to 45 degrees in reverse to the Trendelenburg position. In this position, the head is elevated above the trunk, legs and feet with the feet at the lowest point of the sloping bed. Synonyms include vertical positioning.
A positioning schedule	For this review, a positioning schedule is defined as a sequence of pre-determined body positions utilized in succession. The total duration of the positioning

- opposite lateral position;
- supine position;
- semi-Fowler's or semi-recumbent position;

- Fowler's position or high Fowler's position;
- prone position;
- reverse Trendelenburg position; and
- Trendelenburg position.

We have set a minimal duration for the intervention. Trials must maintain the position of interest for 10 minutes or more to be eligible for inclusion. We will consider kinetic therapy and continuous lateral rotation therapy if separate data is provided for the right and left lateral position. The optimal degree of rotation from the horizontal plane and degree of head of bed (HOB) elevation in the lateral position is unknown; therefore, we will include all descriptions of the lateral position and its synonyms.

We will include trials with co-interventions equally applied across all groups.

We will exclude trials with co-interventions applied to only one randomized group.

Types of outcome measures

Primary outcomes

- in-hospital mortality (mortality within the critical care area and mortality prior to discharge from hospital);
- incidence of morbidity (with particular focus on pulmonary and cardiovascular morbidity); and
- clinical adverse events during or following positioning (with particular focus on cardiopulmonary events, for example hypoxaemia, cardiac arrhythmias, refractory hypertension, hypotension and other indicators of haemodynamic compromise such as alternations in oxygen delivery determinants or global indices of tissue oxygenation).

Secondary outcomes

- pulmonary physiology (oxygenation indices and pulmonary artery pressures);
- vital signs (respiratory rate, heart rate, blood pressure, temperature);
- duration of assisted ventilation;
- length of stay in the critical care area;
- length of stay in hospital; and
- differences in patient comfort or satisfaction (any measure reported by the trial investigators).

We will consider trials that report at least one primary or secondary outcome of interest for inclusion; however, primary outcomes will be the focus of the review.

We will exclude trials that include pressure ulcer formation as the sole primary outcome.

Search methods for identification of studies

Electronic searches

We will conduct a literature search of the following electronic bibliographic databases: Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, current issue), MEDLINE (ISI) (1950 to date), CINAHL (EBSCOhost) (1982 to date), AMED (EBSCOhost) (1985 to date), LILACS (Virtual Health Library) (1982 to date) and ISI Web of Science (1945 to date).

We will search the following electronic databases of higher degree theses for relevant unpublished trials: Index to Theses (1950 to date), Australian Digital Theses Program (1997 to date) and Proquest Digital Dissertations (1980 to date).

We will use major subject headings and text words with truncation (*) for each database.

We will enter the search terms: 'lateral position*', 'lateral turn*', 'lateral rotation*', 'side lying', 'postur*', 'critical care', 'intensive care', 'critical* ill*' and 'ventilat*' as single terms or in combination to identify potentially relevant citations in databases with limited search functions.

We will develop a comprehensive search strategy for MEDLINE to locate the participants, intervention and comparisons of interest. This search will be adapted to other databases with more advanced search functions (see [Appendix 1](#)).

We will combine phase one to three of the highly sensitive search strategy for randomized controlled trials (RCTs) located in the Cochrane Handbook for Systematic Reviews of Interventions with the MEDLINE search strategy to identify relevant trials in this database ([Higgins 2006](#)). We will adapt the RCT filter for other databases in order to identify relevant trials.

We will impose no language restrictions.

Searching other resources

We will handsearch the reference list of relevant articles for additional trials.

We will handsearch the following journals: *American Journal of Critical Care* (1992 to date) and *Australian Critical Care* (1991 to date) to identify potentially relevant trials, including trials reported in conference proceedings. Furthermore, we will contact experts in the field to help identify additional references or unpublished reports.

Data collection and analysis

Two authors (NH and DG) will work independently to search for relevant trials within the search strategy and assess their eligibility

for inclusion using specific inclusion and exclusion criteria. Each author will independently perform data extraction and quality assessment of eligible trials using a Cochrane Anaesthesia Review Group standardized data extraction form adapted for this review. We will pilot the standardized forms using a representative sample of trials to ensure consistency of reporting between the authors. We will revise the tools if we find inconsistencies or misinterpretations. We will resolve any disagreements by consensus, with adjudication by a third party (TB) if consensus is not reached. If there is insufficient information to extract relevant data, we will contact the trial authors, where possible, to obtain any missing information.

Screening and trial selection

We will screen titles and abstracts extracted from the search strategy for relevancy to the review. We will exclude bibliographic citations that clearly do not meet the inclusion criteria. We will retrieve the full text of any trials and reports that are considered potentially eligible to assess for inclusion in the review against the eligibility criteria. We will compare the results of the independent screening and eligibility assessment and decide the final selection of trials for inclusion by consensus.

Data extraction and quality assessment

We will extract data about the types of participants, standard management, intervention and comparison body positions and outcomes. The duration of the intervention and data collection intervals may vary between trials. Such differences in trial design may account for differences in outcomes; therefore, we have chosen to examine outcomes at different time points during and following the intervention.

We will use the following composite time points, commonly reported within the literature, to group the findings on primary outcomes:

- immediately at 0 minutes (immediate turning response);
- between 1 to 10 minutes (early turning response);
- between 11 to 30 minutes (short-term turning response);
- between 31 minutes and 119 minutes (intermediate turning response);
- at two hours (benchmark turning response);
- greater than two hours but prior to next position change (delayed turning response); and
- following conclusion of the positioning therapy (positioning schedule response).

If there are sufficient data, any outcomes reported at a specific time during or following the intervention will be compared to outcomes grouped within the set time points.

We will appraise the methodological quality of each trial and will include assessment of bias (selection, performance, detection and attrition). We will grade the method of treatment allocation and concealment of the allocation as either adequate, unclear, inadequate or not described, as recommended by the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2006). We will assess other aspects of methodological quality using a standardized checklist with each individual component recorded as yes, no or unclear. The primary author will enter the data into the Review Manager Software (RevMan 5.0) with verification of data entry conducted independently.

Data synthesis and analysis

We will summarize trials that meet the inclusion criteria in tables to enable comparison of trial characteristics and individual components of the quality assessment. We will tabulate the bibliographic details of trials excluded from the review with the reason for exclusion documented. We will discuss the level of agreement between review authors during the screening, data extraction and critical appraisal process in a narrative form. We will visually inspect the summary tables of included trials to identify substantial clinical heterogeneity amongst trials. If there are two or more randomized trials with comparable populations undergoing similar interventions, we will implement a meta-analysis with a random-effects model using RevMan 5.0 software. If there is clear evidence of poor homogeneity between trials, we will undertake a narrative summary of the findings.

We will quantitatively analyse outcomes from comparable trials to estimate each trial's treatment effect with 95% confidence intervals (CI). We will compare the results graphically within forest plots with relative risk (RR) as the point estimate for dichotomous outcomes and weighted mean difference (WMD) for continuous outcomes. We will calculate standardized mean difference (SMD) if different scales are used to measure continuous outcomes across trials. We will conduct a meta-analysis of pooled data to provide a summary statistic of effect if the combined data has minimal statistical heterogeneity.

We will examine indicators of morbidity and clinical adverse events separately. If there is insufficient data for a meta-analysis on individual components, we will analyse compound pulmonary morbidity, cardiovascular morbidity and any other system morbidity. We will group clinical adverse events for qualitative analysis using the following classification of severity: severe (unintentional event or complication that is associated with morbidity and mortality), moderate (unintentional event or complication requiring immediate medical intervention but not directly associated with morbidity and mortality) and mild (self-limiting event or complication that is transient in nature, requiring no medical intervention).

We will test for homogeneity between trials for each outcome using the Cochran's Q statistic with P less than or equal to 0.10. We will formally test for the impact of heterogeneity by using the I-squared (I^2) test (Higgins 2002). An I^2 threshold of greater than 50% will

be set to indicate that variation across trials due to heterogeneity is substantial. We will seek to examine possible sources of substantial heterogeneity through a narrative summary of trial characteristics and quality.

Clinical heterogeneity may exist due to the nature of the inclusion criteria. Body position effects may differ between disease states and severity of illness amongst patients. Positive pressure ventilation may alter the effects of turning compared to spontaneous unassisted breathing. Therefore, we will undertake subgroup analysis to examine possible clinical variability when the I^2 statistic is less than 50% but heterogeneity remains statistically significant. We will analyse outcome data from trial populations rather than individuals to explain possible sources of variability.

We will examine differences in populations based on:

- primary disease, injury or condition;
- severity of illness (only trials with validated definitions, scales or scoring systems will be analysed for differences in findings due to differences in severity of illness);
- the presence of assisted ventilation (for this review, assisted ventilation is considered to be any form of positive pressure, including non-invasive ventilation and continuous positive airway pressure (CPAP)); and
- variations in the positioning technique (trials that rotate patients equal to or greater than 45 degree from the horizontal plane will be compared to trials that rotate patients less than 45 degrees).

Data pooled within a meta-analysis will undergo a sensitivity analysis. We will analyse individual components of the standardized quality assessment separately to examine their impact on the review's findings. It is not feasible to blind health professionals providing the intervention and it is impractical to blind the patient in a procedural trial on positioning; therefore, we will not subject participant and caregiver blinding to sensitivity analysis. We

will compare the results with or without trials by addressing adequate randomization, adequate concealed allocation, outcome assessor blinding, standard management and co-interventions applied equally across groups, and loss to follow up of less than 20% with an intention-to-treat analysis. We will undertake a sensitivity analysis based on the choice of summary statistic and on the presence of outlying trials. In addition, we are aware that requests for missing data from trial authors may or may not be successful. If the author does not respond, or it is not possible to find authors, we will include the trial in question in the review but will analyse its inclusion and exclusion for overall effect on the results as part of the sensitivity analysis. We will consider assessment for publication bias through funnel plots if there are more than 10 included trials. A large number of trials are required to provide moderate power for detection of publication bias (Higgins 2006).

Inferences of the review will be guided by the quality of the evidence. The discussion on the review's findings will include the strength of evidence and the limitations, including potential biases. The clinical implications of the review will be discussed, the gaps in the research will be identified and recommendations for future research suggested.

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* Indicates the major publication for the study

APPENDICES

Appendix I. MEDLINE (1950 to date)

No. #	Search terms
1	MH:exp=Critical Care
2	MH:exp=Life Support Care

(Continued)

3	MH:exp=Critical Illness
4	TS="critical care"
5	TS="intensive care"
6	TS="coronary care"
7	TS="cardiothoracic unit"
8	TS=(ICU or ITU or CCU or CTU)
9	TS="critical* ill*"
10	MH:exp=Respiration, Artificial
11	MH:exp=Ventilators, Mechanical
12	TS="artificial* respirat*"
13	TS="mechanical* ventilat*"
14	TS="positive pressure ventilat*"
15	TS="non invasive ventilat*"
16	(#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15)
17	TS=("lateral position*" or "lateral rotat*" or "lateral recumben*" or "lateral turn*" or "lateral decubit*" or "lateral tilt*")
18	TS=("side lying" or "side position*")
19	(TI=lateral or AB=lateral) and MH:exp=Posture
20	TI="dependent position*" or AB="dependent position*"
21	#17 or #18 or #19 or #20
22	MH=Prone Position
23	MH=Supine Position
24	MH=Head-down Tilt
25	TS="supine position*"

(Continued)

26	TS="dorsal position*"
27	TS=recumben*
28	TS="horizontal position*"
29	TS="prone position*"
30	TS="ventral decubit*"
31	TS=("head down*" or "head tilt*")
32	TS=Trendelenburg
33	TS="vertical position*"
34	TS="degree* position*"
35	TS=("backrest elevat*" or "head elevat*")
36	TS=(semi-Fowler* or Fowler*)
37	TS=(semi-recumben* or semirecumben*)
38	TS=sitting
39	TS="upright position*"
40	(TI= position* or AB= position*) and MH:exp=Posture
41	#22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40
42	#21 or #41
	(combined with MEDLINE RCT filter)

HISTORY

Protocol first published: Issue 3, 2008

CONTRIBUTIONS OF AUTHORS

Conceiving and designing the review: Nicky Hewitt (NH)

Co-ordinating the review: NH

Undertaking manual searches: NH, David Glanville (DG)

Screening search results: NH, DG

Organizing retrieval of papers: NH

Screening retrieved papers against inclusion criteria: NH, DG

Appraising quality of papers: NH, DG

Abstracting data from papers: NH, DG

Writing to authors of papers for additional information: NH

Providing additional data about papers: NH

Obtaining and screening data on unpublished studies: NH, DG

Data management for the review: NH

Entering data into Review Manager (RevMan): NH, TB

RevMan statistical data: NH

Other statistical analysis not using RevMan:

Double entry of data: (data entered by person one: NH ; data entered by person two: Tracey Bucknall (TB))

Interpretation of data: NH, TB

Statistical inferences: NH, TB

Writing the review: NH, TB

Securing funding for the review: NH, TB

Guarantor for the review (one author) NH

Person responsible for reading and checking review before submission: TB

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

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