Reducing the risk of ventilator-acquired pneumonia through head of bed elevation

Libby Keeley

ABSTRACT
Background: It has been suggested that placing critically ill ventilated patients in a semirecumbent position minimizes the likelihood of nosocomial pneumonia.

Aim: This pilot study explores whether the incidence of ventilator-acquired pneumonia (VAP) can be reduced by elevating the head of the bed to 45°.

Methods: The design is quantitative in nature, using a randomized controlled trial. The method involves adult ventilated patients being randomly assigned to one of two positions, i.e. 45° raised head of bed (treatment group) or 25° raised head of bed (control group). Data collection relied upon the diagnosis of clinically suspected and microbiologically confirmed pneumonia defined by the Consensus Conference on VAP.

Results: Thirty patients were included in the study – 17 in the treatment group and 13 in the control group. Results showed that 29% (five) in the treatment group and 54% (seven) in the control group contracted VAP ($P < 0.176$).

Conclusions: There was a trend towards a reduction in VAP in the patients nursed at 45°. However, because of the sample size this difference did not reach statistical significance.

Key words: Aspiration pneumonia • Care bundle • Gastric aspiration • Head of bed elevation • Ventilator-acquired pneumonia

INTRODUCTION
Ventilator-acquired pneumonia (VAP) is defined by the American Thoracic Society (1996) as ‘… the specified type of nosocomial pneumonia that occurs after the first 48 h of initiating mechanical ventilation’.

VAP occurs in a high percentage (5–25%) of ventilated patients (Ibrahim et al., 2001; Michalopoulos and Geroulanos, 2003). Those adults who die of acute respiratory distress syndrome have a very high incidence (70%) of VAP. Moreover, VAP is the leading cause of death among hospital-acquired infections, exceeding the rate of death as the result of central line infections, severe sepsis and respiratory tract infections in the non-intubated patient.

VAP also prolongs time spent on the ventilator, length of intensive care unit (ICU) stay and length of hospital stay after discharge from the ICU (Rello et al., 1996). Strikingly, VAP adds an estimated cost of $40 000 to a typical hospital admission (Tablan et al., 2004).

Organisms causing VAP generally fall into two groups: those causing early-onset VAP (<4 days of mechanical ventilation) and those causing late-onset VAP (>4 days of mechanical ventilation) (Craven and Steger, 1996; George et al., 1998). Early-onset organisms are typically antibiotic-susceptible, community-acquired bacteria, while late-onset organisms are commonly antibiotic-resistant, hospital-acquired organisms.

Ventilated patients have numerous factors that increase their susceptibility to VAP, which have been summarized by Cook et al. (1998). Aspiration of infected oral and gastric secretions has been proposed as a major factor in the aetiology of VAP (Torres et al., 1992). Mechanical ventilation is associated with high rates of hospital-acquired pneumonia because the endotracheal tube bypasses upper respiratory tract defences, allows for pooling of oropharyngeal secretions, prevents effective cough and can be a source of infection. In addition, several authors have shown that colonization of the oropharynx and stomach with potentially pathogenic organisms may precede the
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development of VAP (Craven and Steger, 1996; Centre for Disease Control and Prevention, 1997; George et al., 1998).

The use of histamine-2 receptor blockers for the prevention of gastrointestinal bleeding may also increase the incidence of VAP (Cook et al., 1998). These raise the intragastric pH, which in turn enhances gastric colonization with pathogens that commonly cause pneumonia. Placement of nasogastric feeding tubes may facilitate the reflux of bacteria from the gut. The nasogastric tube does impair the closure to the upper oesophageal sphincter and prevents lower oesophageal sphincter closure (Hardy, 1988). However, Satiani et al. (1978) found a reduction of gastro-oesophageal reflux during surgery when nasogastric tubes were in place as a result of the venting mechanism reducing the volume of intragastric contents and gastric pressure.

It has been suggested that patient position may influence reflux and microaspiration of infected gastric contents and thus the incidence of VAP. A number of Spanish groups (Ibanez et al., 1992; Torres et al., 1992; Orozco-Levi et al., 1995) have evaluated the efficacy of a semirecumbent position in relation to aspiration. These small studies all reported a decreased frequency of gastro-oesophageal reflux and aspiration with semirecumbent positioning.

There have been two larger randomized controlled trials of the semirecumbent position on the incidence of VAP. The first study by Drakulovic et al. (1999) randomized participants by a computer-generated list into two patient groups: one supine (control) and the other 45° head up (treatment). The incidence of VAP (the primary outcome) was reduced from 27/47 (57%) in the control group to 5/39 (13%) in the treatment group ($P = 0.003$). The authors of this well-conducted study conclude ‘Placing critically ill ventilated patients in a semi-recumbent position minimizes the likelihood of nosocomial pneumonia. Reducing the incidence of nosocomial pneumonia leads to decrease in antibiotic costs and length of stay in the Intensive Care and hospital’. This study is widely quoted in systematic reviews of the prevention of VAP and has resulted in 45° head of bed elevation being included in increasingly popular ventilation care bundles (Ferrer and Artigas, 2001; Collard et al., 2003; American Thoracic Society, 2005).

The second trial (Van Nieuwenhoven et al., 2006) attempted to replicate the Drakovic study and randomized ventilated patients to supine position (10° head up) or semirecumbent position (45° head up). Although 221 patients were randomized, the target elevation in the treatment group was not achieved, the average head of bed elevation being only 28° (versus 10° in the control group). There was no difference in the incidence of VAP.

A number of other studies have demonstrated the difficulty in achieving the 45° head-up positioning suggested by Drakulovic et al. (1999). These studies consistently demonstrate that patients are routinely nursed at between 20 and 30° head up despite guidelines recommending more extreme head up positioning (Evans, 1994; Grap et al., 1999, 2003; Cook et al., 2002). Indeed, the current mean bed head elevation at the author’s institution was found to be 25° in a random selection of patients prior to commencing the current study. It is not known whether there is any benefit in increasing the degree of bed head elevation from 25° to 45° recommended by Drakulovic.

This study aims to compare the effect of the current standard degree of bed head elevation (25°) with 45° bed head elevation on the incidence of VAP.

METHODS

The degree of bed head elevation to be used in the control group was established by measuring the current degree of bed head elevation on the trial ICU. The angle of the head of the bed was measured on a random selection of patients using a protractor and plumb line.

Adult ventilated patients who met the inclusion criteria were placed in two groups and randomly assigned to one of two positions, i.e. 45° raised head of bed (treatment group) or for the control group, 25° raised head of bed (current practice within the ICU).

Exclusion criteria:

- Previous intubation within the last 30 days.
- Recent abdominal surgery with vacuum dressing that requires changes of patient position to either gain a seal or renew the dressing.
- Severely obese patients who are unable to tolerate head elevation of 45°.
- Haemodynamic instability (i.e. mean arterial pressure below 60 mmHg for more than 30 min) refractory to colloid therapy or inotropic support.
- Patients receiving renal replacement therapy whose body position results in insufficient flow to continue therapy.
- Pregnancy.
- Spinal surgery or trauma that necessitates nursing the patient flat.
- Patients intubated for more than 12 h prior to admission to ICU.
Inclusion Criteria
The necessary ethical permission was gained from both the Trust and the Local Research Ethics Committee. Consent was obtained from patients (where possible) or assent from next of kin in the case of the unconscious patients. This permission was gained by the nurse caring for the patient within 24 h of inclusion. The patients (if conscious) or relative (if the patient was unconscious) were given an information sheet and allowed time to read and digest the information. They were then asked to sign consent (in the case of the patient) or assent (in the case of the relative) for inclusion into the study. If the relatives were particularly distressed by the circumstances relating to the patient’s admission, or they were not available within 24 h of inclusion, they were not approached and the patient was not included in the study. Of the 57 patients or relatives who were approached for inclusion into the study, three (all relatives) declined. Reasons for declining were previous poor experience with research trials (one), unwilling to take responsibility for decision that may affect care of loved one (one) and unwilling to take part in any discussion/information exchange regarding the study (one).

All critical care patients intubated within 12 h were eligible for inclusion. All patients were routinely subjected to standard ICU practices likely to influence the incidence of nosocomial pneumonia in the mechanically ventilated patient, including the following:

Nutrition
Nasogastric tubes used were Ryles, size 12 (Pennine Health Care, London Road, Derby, UK, product code RT-2012) or size 14 (product code RT-2014). Fine-bore tubes were not used during the trial period because normal practice was to insert them once the patients were conscious and managing continuous positive airway pressure (CPAP). Where enteral feeding was not established, parenteral nutrition and glutamine were used. (This was at the decision of the physician in charge). Patients who were receiving parenteral nutrition had a nasogastric tube in situ as continued trials of enteral nutrition were repeated unless surgery dictated otherwise. While enteral feed was not being delivered, the nasogastric tube remained on free drainage. Gut decontamination was given to trauma patients who were not established on enteral feed. This selective decontamination was ceased when enteral feed was established, with the exception of the selective digestive-tract decontamination (SDD) gel.

Gastric ulceration prophylaxis
Ranitidine was administered to those patients who were not established on enteral feed. Those patients who had a history of gastric ulceration or who were considered ‘high risk’ and who were not established on nasogastric feed received omeprazole according to normal practice on the ICU based on the ventilation care bundle.

All patients were nursed with one pillow beneath their head in an effort to nurse all patients with the same angle of neck flexion. Ventilator tubing was not changed during the trial period. Closed-circuit suction was used and changed every 24 h as per the manufacturer’s instruction.

Pressure area care continued as normal protocol for the ICU, i.e. every 2–4 h repositioning, either side lying or supine, always maintaining the required angle of bed head elevation.

Mean arterial pressure was recorded to track the use of inotropic therapy, ensuring that those patients nursed at 45° were not requiring increased support (requirement of ethics committee).

Other variables recorded at the end of the study protocol were sex, diagnosis (medical or surgical), white cell count <4 × 10⁹/L or >12 × 10⁹/L, temperature >38.3°C, antibiotics, ventilation, sedation score or Glasgow Coma Score, age and Acute Physiology and Chronic Health Evaluation (APACHE) II score.

Randomization to treatment (45°) or control (25°) group
Patients were randomized to treatment (45°) or control (25°) groups by taking a sealed opaque envelope from a box of identical shuffled envelopes. The random selection was made by the nurse recruiting the patient to the trial. These envelopes were prepared by an independent person at the start of the trial in batches of 50 and were in equal numbers for each group. The envelopes contained instruction to nurse the patient at either 45° or 25° raised head. The instructions within the envelopes were then attached to the patient’s bedside monitor so that the nurse was aware of which position to nurse their patient in. The patient position was also entered onto the observation chart on the clinical information system in a tick box format.

End of the study protocol:

- patient extubation (or decannulation in the tracheostomy patients);
- death;
- first successful weaning trial, i.e. first trial (of at least 1 h) on CPAP.

Withdrawal from the protocol:

- at the request of the patient or the next of kin;
- change in the patient’s condition, which meant that they fulfilled the exclusion criteria;
transfer of the patient to another critical care department;
• increase in ventilatory requirements requiring the patient to be nursed prone to improve oxygenation;
• change in the patient’s position, which meant that they were out of their randomized position for more than 6 h in 24 h.

Follow-up period
In surviving patients, follow-up was continued for 72 h after a study end-point had been reached. Final study outcome was documented at 72 h after the study end-point had been reached.

Chest radiography was only interpreted as an outcome in the follow-up period if a chest X-ray had been ordered by the physician. If there were no chest X-rays during this period, it was assumed that the patient did not clinically require one, and thus it was unlikely that the patient had developed VAP (although other outcomes were still collected).

Pneumonia was diagnosed as either clinically suspected or microbiologically confirmed according to the criteria defined by the Consensus Conference on Ventilator Acquired Pneumonia (Rello et al., 2001):

Clinical suspicion of pneumonia:
• New and persistent infiltrates on chest radiography most likely to be associated with pulmonary infection and at least two of the following three criteria:
  • fever (temperature >38.3°C unmasked by paracetamol);
  • leucopenia or leucocytosis (white blood cell count <4 × 10⁹/L or >12 × 10⁹/L);
  • purulent tracheal secretions.

Microbiologically confirmed pneumonia:
• The presence of clinical suspicion of pneumonia.
• At least one pathogenic microorganism in tracheobronchial aspirate, bronchoalveolar lavage or protected specimen brush, with bacterial growth above the defined thresholds for positive cultures of blood or pleural fluid or both.

Tracheobronchial aspirate was obtained without prior administration of saline in a standard sputum trap (Pennine product code MST-3070). For fiberoptic bronchoscopic examinations (Olympus, Keymed, Southend On Sea, Essex, Model no. BF IT240), patients were premedicated with propofol or midazolam (they may already have been receiving either of these agents as continuous sedation while being ventilated). No local anaesthetics were administered, and suction was avoided. Bronchoalveolar lavage and protected specimen brush were done in the areas most prominently affected on chest radiograph or in one segment of the lower lobes in cases with diffuse infiltrates. Bronchoalveolar lavage was done by instillation of three 50-mL aliquots of saline, and the first aspirated portion was discarded.

The results from this study were analysed with the assistance of a statistician using the Minitab computer package. The statistical hypothesis testing and estimation procedures used from this statistical package were the chi-squared test for association and the two-sample t-test and confidence interval.

The mean results were calculated and the data checked for normal distribution to ensure that the subsequent measures of central tendency and significance test methods were mathematically valid. Where data was normally distributed, the mean results were calculated. Both parametric and non-parametric methods of statistical analysis were required because the data comprised nominal, ordinal and interval and were both symmetrical and skewed.

The controlled variable of body position was analysed using the chi-squared test. This was used to determine whether there was any association between the two nominal variables of body position and incidence of VAP. The chi-squared test was used because the data are nominal and not of an interval/ratio level of measurement.

RESULTS
Data were collected over a period of 3.5 months from 18 April 2005 to 1 August 2005. This resulted in a sample size of 54 patients. Following randomization, 29 patients were allocated to the 45° (treatment) group and 25 patients were allocated to the 25° (control) group. Patient enrolment and allocation are summarized in Figure 1. The baseline characteristics of the enrolled patients are listed in Table 1. There were no significant differences between the groups at randomization.

Incidence of VAP
Five of the treatment group (29%) developed VAP, four confirmed and one suspected.

Seven of the control group (54%) developed VAP, five confirmed and two suspected. This 25% reduction in the incidence of VAP did not reach statistical significance (P = 0.176).

Of those patients that developed VAP, the diagnosis was made on the following days:
• day 2, one patient;
• day 3, one patient;
• day 4, two patients;
day 5, four patients;
day 6, two patients;
day 7, two patients.

Of the 12 patients with VAP, three were suspected, i.e. there was no positive microbiology, and nine were confirmed with positive microbiology. Of these confirmed cases, four had methicillin-resistant *Staphylococcus aureus*, two had *Pseudomonas aeruginosa*, one had *Candida albicans* and two had coliforms.

**Ventilator hours**
The average number of hours ventilated for those patients without VAP was as follows:
- 63.1 h in the control group;
- 61.5 h in the treatment group;

The average number of hours ventilated for those patients with VAP was as follows:
- 172.5 h in the control group.
- 160 h for the treatment group.

**Tracheostomy**
Of the 12 patients who developed VAP, 11 had tracheostomies.

In five of these instances, the tracheostomy was performed before the diagnosis of VAP was made, on day 3, 4 or 5 of the patient’s stay. In six of these instances, the tracheostomy was performed after the diagnosis of VAP was made, between days 3 and 8 of the patient’s stay.

**Mortality of VAP patients**
Of the 12 patients who developed VAP, eight died. From the treatment group of five patients who developed VAP, four died (three in ICU and one following discharge to the ward). From the control
group of seven patients who developed VAP, four died (all in ICU). Thus, the ICU mortality rate of those patients who developed VAP was 50%, with a hospital mortality rate of 58%.

**DISCUSSION**

The aim of this study was to test the hypothesis that there is a reduction in VAP when ventilated patients are nursed with the head of the bed elevated to 45° compared with 25°. Data were collected over a period of 3-5 months, resulting in a sample size of 30 patients.

From the available data, it is clear that there are numerous factors that may contribute to the occurrence of VAP, of which failing to elevate the head of the ventilated patient sufficiently may be one. Studies of prevention of VAP are notoriously difficult because of the numerous confounding variables and the difficulty in accurately defining the occurrence of VAP. Hubmayr (2002) states that ‘There are major limitations to the existing studies of the epidemiology of ICU acquired pneumonias. Some fail to distinguish between nosocomial pneumonia and VAP’. This view is supported by Guyatt et al. (1995) who found that ‘…terminology and definitions may significantly affect the epidemiology of VAP’.

This study found a clinically relevant difference in VAP rates between the two groups, although this difference was not statistically significant. Unfortunately, the small sample size of this study may have resulted in a type 2 error (failure to detect a difference where one exists). Lowe (1993) discussed the problems of overconcern with probability values in that results, which might look interesting might be dismissed as unimportant because of a ‘statistical non-significant’ test of significance, which does not relate to the likely size of that effect. A power calculation based on the current results suggests that a study of 130 patients would be required to detect a 25% reduction in VAP with a power of 0.8 (Lenth, 2006).

If this study is to produce reliable outcomes, the proportional differences in occurrence of VAP must be shown to be because of the treatment difference that was instigated (the angle of the bed head) and not because of the confounding variables in the patient’s premorbid state or in the treatment they received unrelated to the study. In the case of all confounding variables tested, there was no significant difference between the treatment and control groups. Therefore, none of the attributes discussed showed any difference between the two groups.

The limitations of sample size could have been overcome by prolonging the length of the study to capture a larger sample or by making the study multicentre. The large number of patients who were withdrawn (14) because of less than 24 h ventilation also contributed to the small sample size. Nine patients were withdrawn who expressed discomfort or who wished to be nursed in positions other than those to which they were randomized. When gaining assent from the relatives, they were reassured that if the patient asked for a position change to increase their comfort, it would be done. Thus, a significant number of the samples was withdrawn. As this was a small hypothesis, generating study intention to treat analysis was not performed, but similar numbers were withdrawn in the treatment and control groups.

According to Hubmayr (2002) ‘The duration of mechanical ventilation and antibiotic exposure prior to the onset of VAP are considered the most important factors in the incidence, microbiology and severity’. These two factors were not outcome measures of this study, although it is possible from the data collected to comment on the length of ventilation prior to diagnosis. The majority of those patients with VAP were

### Table 1 Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Treatment (45°) group (n = 17)</th>
<th>Control (25°) group (n = 13)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female sex</td>
<td>9 (53)</td>
<td>8 (62)</td>
<td>0.638</td>
</tr>
<tr>
<td>Mean age</td>
<td>64</td>
<td>68</td>
<td>0.354</td>
</tr>
<tr>
<td>Mean APACHE II score</td>
<td>20</td>
<td>20</td>
<td>0.479</td>
</tr>
<tr>
<td>WCC &lt;4 × 10^9/L or &gt;12 × 10^9/L</td>
<td>7 (41)</td>
<td>8 (62)</td>
<td>0.269</td>
</tr>
<tr>
<td>Temperature &gt;38.3°C</td>
<td>4 (23)</td>
<td>3 (23)</td>
<td>0.977</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>13 (76)</td>
<td>10 (76)</td>
<td>0.977</td>
</tr>
<tr>
<td>Oral endotracheal tube</td>
<td>15 (88)</td>
<td>12 (92)</td>
<td>0.713</td>
</tr>
<tr>
<td>NG feed</td>
<td>6 (35)</td>
<td>6 (46)</td>
<td>0.547</td>
</tr>
<tr>
<td>Ranitidine gut prophylaxis</td>
<td>9 (75)</td>
<td></td>
<td>0.141</td>
</tr>
</tbody>
</table>

APACHE, acute physiology and chronic health evaluation; NG, naso-gastric; WCC, white cell count.

Percentages in parentheses. No patient received selective digestive-tract decontamination gel.
diagnosed on day 5, i.e. approximately 120 h after ventilation. Thus, four patients (33%) were ventilated for 120 h before developing VAP. This is supported by Cook et al. (1998) who found that the risk of VAP peaks around day 5 of mechanical ventilation. Although the causative organisms were identified, the choice of antibiotic and length of therapy were not discussed. Antibiotics may eradicate susceptible organisms early in a patient’s stay or encourage the emergence of resistant organisms later in the patient’s stay. In systematic reviews (D’Amico et al., 1998; Nathens and Marshall, 1999), strategies including intravenous antibiotics showed a beneficial effect on survival. Data on the use of systemic antibiotics alone to prevent VAP are conflicting (Mendelli et al., 1989; Sirvent et al., 1997).

The ventilator care bundle suggests elevating the patient’s bed head to greater than 30°. This is a low-risk intervention that may reduce the incidence of VAP compared with the supine position. This work has also shown that to implement this angle of bed head elevation, constant and careful measurement is required because, as indicated by the head of bed survey and supported by the two studies by Grap et al. (1999, 2003), nurses overestimate the degree of bed head elevation.

Whether 30° head elevation is sufficient to reduce the risk of VAP remains unclear. Elevation in excess of 30° may be less acceptable to the patient who is not heavily sedated and may hamper positioning the patient on their side. This was evidenced by the number of patients withdrawn/not enrolled because of difficulties in achieving the 45° position. Whether ventilation was impaired by this inability to turn the patients fully is not demonstrated by this study and remains unclear.

CONCLUSIONS
The findings of this pilot study do not provide sufficient evidence to support changing clinical practice. However, the observed trend towards a reduction in the incidence of VAP by increasing the angle of bed head elevation from 25° to 45° warrants further investigation. An adequately powered study to assess the effect of different degrees of bed head elevation on VAP rates, mortality and patient comfort is certainly required.

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