Manual vs Automated Lateral Rotation to Reduce Preventable Pulmonary Complications in Ventilator Patients

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Purpose To estimate effect sizes for a trial to compare preventable pulmonary complications (PPCs), turning-related adverse events, mechanical ventilation duration, intensive care unit (ICU) length of stay, and ICU mortality between patients randomized to 2-hourly manual or continuous automated lateral rotation.

Methods Randomized controlled trial pilot study with 15 patients selected randomly from eligible medical-surgical ICU patients from 2 tertiary hospitals and assigned randomly to the manual-turn or automated-turn protocol for up to 7 consecutive days. A radiologist blinded to group and site assessed serial chest radiographs for PPCs. Repeated-measures analysis with linear mixed models was used to estimate change in PPC score, and Wilcoxon rank sum or Fisher exact test was used to compare group differences in the secondary outcomes.

Results Of 16 patients enrolled, 12 (75%) completed the study. Data from 15 patients, 7 manual turn and 8 automated turn, were analyzed. Between-group differences in PPC incidence (67% overall), change in PPC score ($\beta = 0.15$, manual turn and $\beta = -0.44$, automated turn), and secondary outcomes were not significant ($P > .05$). Standardized effect sizes were small to moderate for the outcome variables. A sample size of 54 patients would be needed to detect statistically significant between-group differences in PPC over time.

Conclusions The incidence of PPCs in adult patients receiving mechanical ventilation in a medical-surgical ICU was high. Automated turning decreased PPCs with time but had little effect on secondary outcomes. Safety outcomes were not substantially different between groups. A modest efficacy effect supported reduced PPCs with automated turning to the lateral position. (*American Journal of Critical Care.* 2015;24:24-32)

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Because of their reduced mobility, patients receiving mechanical ventilation in the intensive care unit (ICU) are at high risk for preventable pulmonary complications (PPCs). Such PPCs as atelectasis and pneumonia prolong the duration of mechanical ventilation and length of stay in the ICU and increase morbidity, mortality, and health care costs.[1-4] Guidelines for reducing PPCs in patients receiving mechanical ventilation[5-8] recommend elevating the head of the patient's bed at least 30°. Despite the fact that manual turning every 2 hours is the standard of care in the ICU,[9] guideline authors make no recommendation for horizontal positioning (ie, lateral rotation) because little evidence is available on the effectiveness of such positioning.

Evidence suggests that ICU patients are not turned every 2 hours[10-13] for a variety of reasons, including patients' medical instability and/or discomfort and other demands competing for nursing staff time. Specialty beds that provide continuous, automated lateral rotation theoretically avoid stimulation of the sympathetic nervous system by an abrupt change in position and relieve staff from regular turning. Consistent evidence, albeit of variable rigor, has demonstrated that automated turning reduces PPCs, but this mechanical therapy adds to ICU cost of care and thus is used selectively. Furthermore, up to 39% of patients do not tolerate automated turning[14-16] and require termination of the therapy or use of sedation to promote tolerance.

Automated turning has been tested in randomized controlled trials with medical-surgical ICU patients who are receiving mechanical ventilation,[14,16-22] and researchers in all but 2 studies[17,20] reported a significant reduction in PPCs. Researchers in 2 studies[16,22] reported shorter ICU stays in patients receiving automated turning, and researchers in another study[16] also reported decreased duration of mechanical ventilation. None of the trials demonstrated differences in mortality. Research design limitations, however, have prevented a legitimate comparison of automated and manual turning for efficacy and safety.[23] A particular concern is the lack of control over manual turning, which has served as the control group intervention in studies of turning with a specialty bed; consequently, there is no evidence that automated turning is as effective or more effective than 2-hourly manual turning.

> Intensive care patients are not turned every 2 hours for a variety of reasons.

Neither the safety of manual turning nor the safety of automated turning has been studied systematically, and turning-related adverse events can influence adherence to turning protocols. We conducted a pilot study for a randomized controlled trial to test the efficacy and safety of 2-hourly manual and continuous, automated turning. The purpose of the pilot study was to estimate effect sizes to determine the sample size needed for the randomized controlled trial to compare PPCs, turning-related adverse events, duration of mechanical ventilation, length of stay in the ICU, and ICU mortality in medical-surgical ICU patients receiving mechanical ventilation who were randomized to manual or automated lateral rotation.

Materials and Methods

Study Design and Participants

This parallel-group, completely randomized, experimental pilot study (ClinicalTrials.gov NCT00542321) was conducted in 2 ICUs at 2 tertiary, nonprofit, teaching hospitals after approval by the institutional review boards of the university and hospitals. Study units were an 18-bed

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medical-surgical ICU and a 24-bed medical ICU. In most cases, the patient's legally authorized surrogate signed the informed consent form. Reconsent for continued study participation was elicited daily from those patients who were able to provide it.

All patients admitted to a study unit intubated and receiving mechanical ventilation or intubated after ICU admission were assessed by a nurse investigator for study eligibility. Demographic information was entered into a site-specific enrollment log. By using a spreadsheet with computer-generated sequences of random numbers,[24] eligible patients were randomly selected to approach for study participation. If selected to approach, the care provider verified that the patient could accept random assignment to a turning intervention and informed consent was sought. When informed consent was obtained, the randomization spreadsheet was used to assign the patient to intervention group: 2-hourly manual turn (standard-of-care control group) or automated turn (experimental group).

Eligible patients were at least 18 years of age and had received mechanical ventilation through an oral endotracheal tube for 8 hours or less before protocol activation. Patients were excluded for any of the following: pulmonary mass, pneumothorax, hemothorax, pleural effusion, or other potential source of compression atelectasis at the time of assessment as determined by chest radiograph, radiology report, or physician communication; systolic blood pressure less than 90 mm Hg with vasopressor support; injuries requiring immobilization; head injury requiring intracranial pressure monitoring; intubation within the preceding 2 weeks; and weight 159 kg or greater (a limitation of the automated turning bed). Patients participated in the study until 1 of the following occurred: 7 consecutive days on protocol, discontinuance of mechanical ventilation, death, transfer from study unit, or consent revoked. Follow-up continued until ICU discharge.

Manual turning included ≥ 45° lateral turn, head-of-bed elevation ≥ 30°, and dedicated nurses to ensure compliance.

Turning Interventions

Manual Turn. Patients were turned manually every 2 hours from the back to the left side to the back to the right side. Salient aspects of the protocol included a lateral turn of at least 45° to promote drainage of secretions; elevation of the head of the patient's bed at least 30° to reduce risk of aspiration in the lateral and back positions[5]; use of dedicated nurses to ensure frequency, angle, and duration of turn; and tracking of compliance with the intervention protocol and adverse events associated with turning. Study nurses assessed adherence to the manual turn protocol every 10 minutes; they measured and recorded angle of turn and repositioned the patient as needed and/or documented the reason for protocol violation.

Automated Turn. The Triadyne Proventa (Arjo-Huntleigh) bed was used for automated turning. Adjustable body packs were used to support the head, arms, and legs of the patient during rotation. The rotation angle was programmed to 45° in the lateral positions. Salient aspects of this protocol included lateral rotation to the maximum angle; essentially continuous rotation (rotation was paused for short periods as needed for care and diagnostic tests); elevation of the head of the patient's bed at least 30° to reduce risk of aspiration; built-in timer to monitor bed movement in the programmed positions; and tracking of compliance with the intervention protocol and adverse events associated with turning. The acclimation mode, which provides a gradual increase in the degree of rotation over several hours from 25° to the maximum lateral angle, was used to help the patient adjust to automated turning. Thereafter, rotation was programmed at the maximum angle for the duration of time on protocol.

Study Procedures

Study nurses remained at the bedside throughout the manual-turn patient's lateral rotation time and continuously when an automated-turn patient was on protocol. Demographic, clinical, and Acute Physiology and Chronic Health Evaluation (APACHE) II[25] data were collected from the medical record by 2 investigators independently for assessment of interrater reliability.

A mini-bubble protractor (KCI, Inc) was placed on the patient's chest at the second anterior intercostal space to measure angle of turn and at the lowest portion of the back upper bed frame to measure the angle at which the head of the bed was elevated. Turn time, position, and angle (manual-turn group); adverse events; head-of-bed angle; daily reconsent; and comments were entered directly into a spreadsheet on the study site computer.

A battery-powered angle sensor (SMARTTOOL Smart Level, M-D Building Products) was added to the base of the mattress at the head of the Proventa bed. The signal was captured every 1 second, and angle sensor output (0-5 V) was converted to angle of turn in degrees.

CXR Date and Time: _ _ / _ _ / _ _ _ _ _ _ _ _ Study ID Code _ _ _

Location	None	Subsegmental	Segmental	Lobar	Unknown	Other pathology	Impression A = atelectasis P = pneumonia CT = can't tell
RUZ	0	1	2	3	9		A P CT
RMZ	0	1	2	3	9		A P CT
RLZ	0	1	2	3	9		A P CT
LUZ	0	1	2	3	9		A P CT
LMZ	0	1	2	3	9		A P CT
LLZ	0	1	2	3	9		A P CT

CXR = chest radiograph
LLZ = left lower zone
LMZ = left middle zone
LUZ = left upper zone
PPC = preventable pulmonary complication
RLZ = right lower zone
RMZ = right middle zone
RUZ = right upper zone

Figure 1 Preventable pulmonary complications coding sheet.

At the completion of follow-up for each patient, digital chest radiographs were deidentified, labeled with code number, and uploaded to the radiologist's computer for interpretation. PPCs were operationally defined as radiographic evidence of atelectasis or pneumonia. The radiologist completed a PPC coding sheet (Figure 1) for each radiograph by checking boxes for lung zone(s) involved and extent and type of infiltrate. If the patient had more than 1 radiograph per day, the image with the greatest pathology score was used. Severity of PPCs was determined by the product of the extent and lung zone of abnormality, with possible scores varying from 0 (no PPCs) to 18 (lobar PPCs in 6 lung zones). One chest radiologist, blinded to study site and treatment group, interpreted selected radiographs twice, 4 months apart, for assessment of intrarater reliability of coding. Estimates for validity and reliability of the PPC coding sheet in a previous study[26] included a content validity index of 0.93 and intrarater and interrater reliabilities of 0.95 or higher.

Outcome Measures

The primary outcome was the incidence and progression or resolution of PPCs, assessed by interpreting serial chest radiographs taken before, during, and after study participation. Incidence was defined as presence of PPCs on any chest radiograph during the study when the prestudy chest radiographs showed none. Progression or resolution of infiltrate was determined by change from one chest radiograph to the next; higher severity defined progression of PPCs and lower severity defined resolution of PPCs. Secondary outcomes were turning-related adverse events, duration of mechanical ventilation, ICU length of stay, and ICU mortality rate. Nonserious turning-related adverse events will be reported at a later time; for this article, serious turning-related adverse events were defined as changes in medical condition that are life-threatening and require intervention. Duration of mechanical ventilation was defined as number of days the patient received mechanical ventilation in the ICU, ICU length of stay as number of days in the study unit, and ICU mortality rate as the percentage of study patients who died from any cause while in the ICU.

Statistical Analysis

Variables were compared by the Pearson χ^2 or Wilcoxon rank sum (2-sided) test with SAS software (version 9.3, SAS Institute Inc). Interrater reliabilities were estimated with percentage agreement, with 90% agreement or greater considered acceptable. Intrarater reliability for PPC coding was estimated with the Cohen κ coefficient,[27] with 0.60 or greater considered acceptable.[28] To assess compliance with the manual-turn protocol, time lying on the right and left sides was calculated and divided by total time on protocol to derive the percentage of time spent in the lateral position. Complete fidelity to

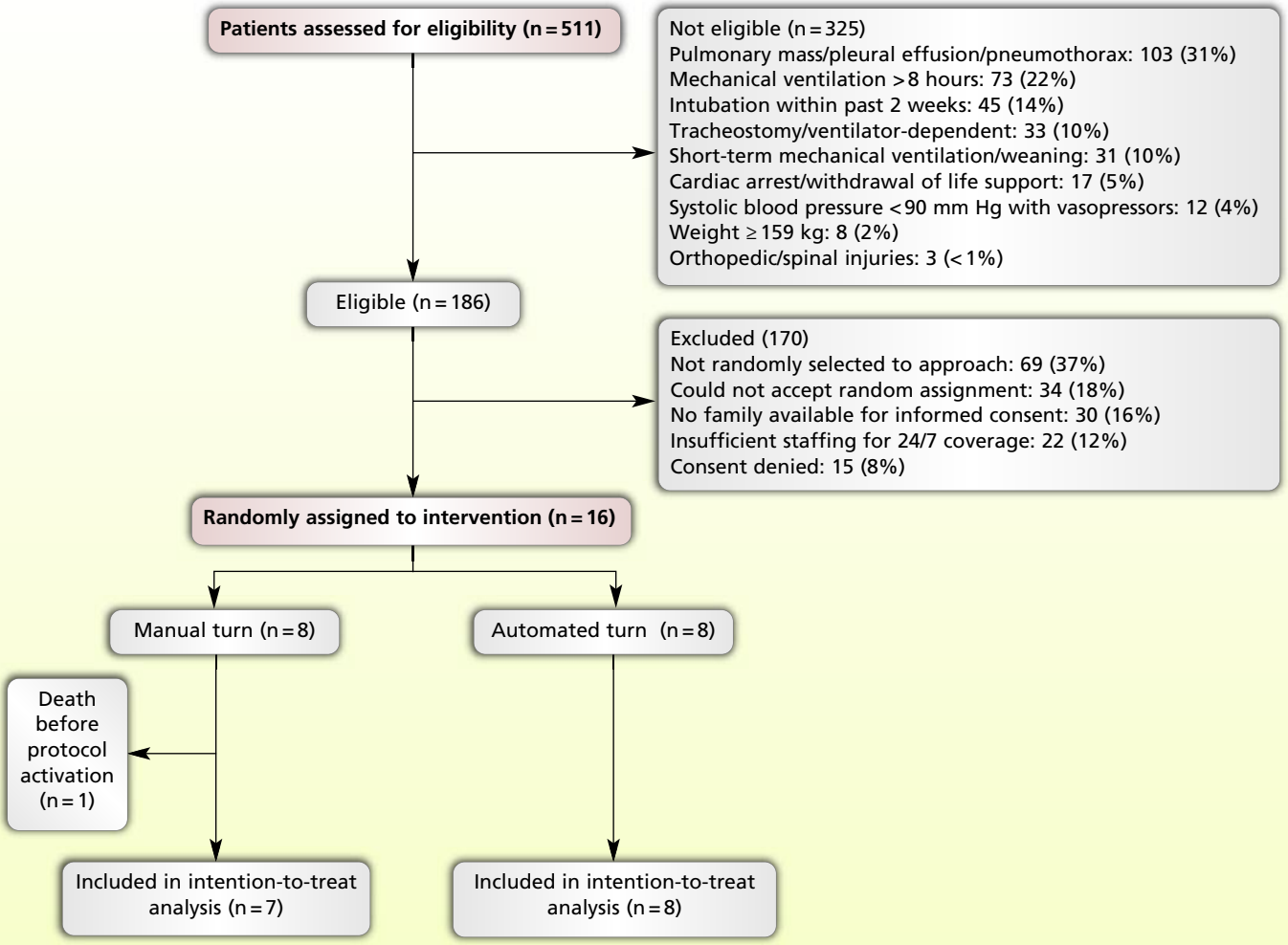

Figure 2 Participant flow diagram of a multisite trial pilot study of manual versus automated lateral rotation to reduce preventable pulmonary complications. The diagram includes detailed information on reasons for patient exclusion.

the manual-turn protocol would yield 50% time in a lateral position; the a priori criterion was set at 80% of that, or 40% time in a lateral position. For the automated-turn group, the total time of rotation was divided by time on protocol to derive the percentage of time the patient had automated turning; the criterion for protocol compliance was 80% or greater.

Incidence rate of PPC was calculated for those patients who did not have PPCs at study enrollment. Repeated-measures analysis with linear mixed models[29] was used to compare changes in PPC scores with time between the 2 groups. Number of turning-related adverse events was tabulated by patient and compared between intervention groups with the Wilcoxon rank sum test. The Wilcoxon rank sum test also was used to compare group differences in duration of mechanical ventilation and ICU length of stay. Differences in ICU mortality were analyzed with the Fisher exact test. Alpha was .05 for all analyses.

Results

Participant Flow

We assessed 511 patients for eligibility in 8.6 months of recruitment, and 495 (97%) were excluded for the reasons shown in Figure 2. Most patients assessed (n = 325, 64%) were not eligible for study participation. Sixteen patients were enrolled, and 12 (75%) completed the study protocol. Reasons for not completing the study protocol included the following: could not keep patient positioned (manual turn), clinicians objected to the experimental bed (automated turn), experimental bed malfunction (automated turn), and protocol never activated because of cardiac arrest and death (manual turn). The latter patient was dropped from the analysis; the others were included in the intention-to-treat analysis based on group assignment. Of the demographic and clinical characteristics, only endotracheal tube size ($P = .007$) and sex ($P = .04$) were different

between study sites; therefore, the sites were combined for further analyses.

The 16 enrolled patients were evenly divided by site and turning group assignment. Of the patients on protocol, 7 (47%) were from one site and 8 (53%) from the other. Seven patients (47%) were randomized to the manual-turn group and 8 (53%) to the automated-turn group. Patient characteristics by group are shown in Table 1. All patients had respiratory failure as the primary or secondary diagnosis.

Protocol Conduct and Data Quality

Assessment parameters of protocol conduct and data quality are shown in Table 2. A total of 148 chest radiographs were coded for PPCs, with a mean of 10 radiographs per patient. Of those chest radiographs, 50 (34%) were randomly selected for repeat interpretation by the study radiologist.

Efficacy Outcome

PPC prevalence was 79% before the study, 93% during the study, and 79% after the study. The incidence of PPCs was 67%, with no statistically significant difference between groups. The rates of change per day in PPC score (slopes) were $\beta = 0.15$ for the manual-turn group and $\beta = -0.44$ for the automated-turn group; the differences were not significant ($F = 2.36$; $df = 1, 9.56$; $P = .16$). Based on the standardized effect size[30] of time by group interaction ($d = 0.39$), a sample size of 54 patients (27 per group) would be needed to detect this effect on PPC score as significant with 80% power and an α of .05.

Secondary Outcomes

We found no statistically significant differences between groups in turning-related adverse events, duration of mechanical ventilation, ICU length of stay, or ICU mortality; standardized effect sizes[30] were 0.12, 0.17, 0.53, and 0.09, respectively. ICU length of stay was affected by an extreme outlier in the automated-turn group who stayed in the ICU for 90 days. Twelve serious adverse events occurred in 7 patients (47%), and 2 of those events (17%) were probably or possibly related to turning: dysrhythmia, inadvertent extubation, and ventilator malfunction in the manual-turn group and death, dysrhythmia, hypoxemia, hypertension, and ventilator disconnect in the automated-turn group. Overall, duration of mechanical ventilation was positively correlated with APACHE II score ($r = 0.56$, $P = .04$); ICU length of stay was positively, but not significantly, correlated with APACHE II score ($r = 0.33$, $P = .22$).

Table 1
Patients' demographic, clinical and outcome characteristics, stratified by group assignment[a] (N = 15)

Characteristic	Manual-turn group (n = 7)	Automated-turn group (n = 8)
Age, mean (SD), y	54 (12)	58 (11)
Sex, No. (%) of patients		
Male	3 (43)	4 (50)
Female	4 (57)	4 (50)
Race/ethnicity, No. (%) of patients		
White	6 (86)	6 (75)
Black	1 (14)	1 (12)
Pacific Islander	0 (0)	1 (12)
Hispanic	2 (29)	1 (12)
Fraction of inspired oxygen, mean (SD)	0.71 (0.32)	0.65 (0.24)
Pao_2, mean (SD), mm Hg	146 (114)	105 (34)
Systolic blood pressure, mean (SD), mm Hg	127 (34)	118 (13)
Surgery, No. (%) of patients		
None	5 (72)	5 (62)
Abdominal	1 (14)	1 (12)
Other	1 (14)	2 (25)
COPD comorbid,[b] No. (%) of patients	4 (57)	0 (0)
Enteral feeding, No. (%) of patients	5 (71)	4 (50)
APACHE II score,[c] mean (SD)	27 (9)	24 (5)
Days on study protocol, mean (SD)	3.7 (2.3)	3 (2.3)
Days of mechanical ventilation, mean (SD)	5.2 (4.3)	6 (5)
Days in ICU, median (interquartile range)	8.2 (3.6-14.9)	11.1 (5.4-23.4)
ICU mortality, No. (%) of patients	2 (29)	2 (25)

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; COPD, chronic obstructive pulmonary disease; ICU, intensive care unit.
[a] Percentages may not total 100 because of rounding.
[b] Significant difference ($P \leq .05$).
[c] APACHE II score can vary from 0 to 71, with higher score associated with greater disease severity and risk of death; modified Glasgow Coma Scale was used to compute APACHE II score.

Discussion

The findings from this pilot study suggest that automated turning may confer a modest efficacy advantage over manual turning for reducing the frequency of PPCs over time in adult patients receiving mechanical ventilation in medical-surgical ICUs. Our pilot study addressed limitations of previous randomized controlled trials by use of a completely randomized experimental design, rigorous testing of both the manual and automated turning protocols, blinding of the outcome assessor, and estimation of the reliability of chest radiographic interpretation. Others[23] have noted that less rigorously controlled trials than ours tend to show a greater effect for automated turning. Similar to McIntyre and colleagues,[20] we chose PPC as our dependent variable rather than only pneumonia because (1) the 2 conditions are

Table 2
Assessment parameters of protocol conduct and data quality

Parameter	Value
Protocol deviations, No. of participants	
Failure to abort turning when stopping rule should have been invoked	1
1.25-hour delay in manual turn per physician request to evaluate serial ventilator adjustments	1
Patient enrolled with exclusion criterion	1
Patient turned with head of bed flat for 12 hours after lumbar puncture	2
Compliance with measurement of turn angle, mean (SD), %	
Manual turn	92 (11)
Automated turn	100 (0)
Compliance with turn angle ≥ 45°,[a] mean (SD), %	
Manual turn	87 (11)
Automated turn	33 (24)
Compliance with time in the lateral position, mean (SD), %	
Manual turn	94 (5)
Automated turn	91 (4)
Angle of turn,[a] mean (SD), degrees	
Manual turn	51 (5.1)
Automated turn	34 (5.0)
Reproducibility of demographic, clinical, APACHE, and outcome data	90% (interrater reliability, percentage agreement)
Reproducibility of PPC coding[b]	0.41 (intrarater reliability, K coefficient)

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; PPC, preventable pulmonary complication.
[a] $P \leq .01$.
[b] Indicates fair agreement.[28]

difficult to differentiate on physical examination and chest radiographs and (2) atelectasis frequently leads to pneumonia, suggesting that they are parts of a continuum that moves from noninfectious to infectious complication.

Compared with manual turning, automated turning appears to better reduce progression/accelerate resolution of, but not prevent, PPCs. The modest efficacy effect size is consistent with the findings of previous studies wherein investigators found a reduction in noninfectious (eg, atelectasis)[14,21] and/or infectious (eg, pneumonia)[14,16,18,19,22] PPCs in adult patients receiving mechanical ventilation in medical-surgical ICUs. In the 2 studies[17,20] with no significant reduction, the mean turn angle was 25° or less, compared with 34° in the present study; other trials in this population of patients did not report the actual turn angle. Thus, turn angle may affect outcome(s). Although automated-turn rotation time exceeded our threshold, mean angle of turn did not. Such factors as the patient's body weight, anthropometrics, and position in bed affect the turn angle.[31] In routine practice, turn angles achieved with automated turning are likely to fall short of 45°.

Maintaining time in and angle of lateral rotation was a challenge with patients who were confused, able to self-turn, or sedated lightly. Despite the use of turning wedges and pillow supports for the manual turn, patients "slipped out" of the turn angle to a position more representative of a quarter-turn. Without dedicated turning staff to readjust the turn angle, many patients are unlikely to benefit optimally from secretion mobilization during manual lateral rotation.

The serious adverse events associated with both manual and automated turning suggest that lateral rotation in ICU patients receiving mechanical ventilation is not a benign intervention, and close monitoring of patients is indicated regardless of turning method. Our pending detailed analysis of nonserious adverse events may inform secondary interventions to promote patients' tolerance of lateral rotation.

It is notable that most patients had PPCs before study enrollment; indeed, pulmonary disease most likely contributed to the need for intubation and mechanical ventilation. Increased prevalence of PPCs during the study, despite turning, reinforces the high risk for pulmonary morbidity with intubation and mechanical ventilation. Some resolution of PPCs occurred, particularly in the automated-turn group, as the PPC prevalence after the study was either equivalent to (manual turn) or less than (automated turn) the during-study level. Nonetheless, PPC rates were high before, during, and after study participation, making a strong argument for further research on ways to reduce PPCs in ICU patients receiving mechanical ventilation.

The major limitation of this pilot study is reliance on changes detected on chest radiographs for determination of PPC. Previous lateral rotation study reports did not address reproducibility of chest radiographic interpretation. Others[32,33] have noted the low sensitivity of chest radiographs in the assessment of PPCs; we found only fair agreement by a lone expert[34] thoracic radiologist with repeated assessment. Previous reliability testing of the PPC coding sheet[26] was done by abstraction of PPC data from radiology reports rather than reinterpretation of the radiographs. Although the study radiologist had access to serial radiographs for each patient, she did not

have access to patients' demographic or clinical information or consultation with others. Therefore, misclassification of PPCs was a potential threat in this study, albeit a threat equally applied to both groups.

Conclusions and Implications

Results of this pilot study suggest that continuous automated turning may be more efficacious than manual turning every 2 hours for reducing PPCs in adult patients receiving mechanical ventilation in medical-surgical ICUs. The incidence of PPCs in this population was high. The number of adverse events, mechanical ventilation duration, ICU length of stay, and ICU mortality were not substantially different between turning methods. The standardized effect size indicates that 54 patients would be needed to test the hypothesis that automated turning has greater efficacy than manual turning when the turning interventions are maximized. Our pilot data support the conclusions of previous trials with little control over the turning interventions that automated turning may confer an advantage for reducing PPCs in ICU patients receiving mechanical ventilation.

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