HEMODYNAMIC CHANGES ASSOCIATED WITH MANUAL AND AUTOMATED LATERAL 
ROTATION IN MECHANICALLY VENTILATED 
INTENSIVE CARE UNIT PATIENTS

A DISSERTATION 
SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS 
FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN NURSING

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON 
SCHOOL OF NURSING 
BY 
SHANNAN K. HAMLIN, M.S.

MAY, 2010
To the Dean for the School of Nursing:

I am submitting a dissertation written by Shannan K. Hamlin and entitled "Hemodynamic Changes Associated with Manual and Automated Lateral Rotation in Mechanically Ventilated Intensive Care Unit Patients." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing.

Sandra K. Hanneman, PhD, RN, FAAN
Committee Chair

We have read this dissertation and recommend its acceptance:

Accepted

Dean for the School of Nursing
Acknowledgments

The student thanks Sandra K. Hanneman, PhD, RN, FAAN, for her patient mentoring as chair of the dissertation committee; the members of the committee – Mara M. Baun DNSc, RN, FAAN; Robert F. Lodato, M.D., PhD; and Nikhil Padhye, PhD – for their patience, expertise and guidance; and Audrius Brazdeikis, PhD, for his expertise in developing the specialized computer software. The student thanks her devoted family – Tim, Ashley, Mom, and Dad – for their love, patience, and unlimited encouragement.

This research was supported by the American Association of Critical-Care Nurses Mentorship Grant, American Association of Critical-Care Nurses Houston-Gulf Coast Chapter Research Grant, Society of Critical Care Medicine Norma J. Shoemaker Nursing Research Grant and the Texas Medical Center Howell Nursing Research Grant.
Objective: To investigate hemodynamic responses to lateral rotation.

Design: Time-series within a randomized controlled trial pilot study.

Setting: A medical intensive care unit (ICU) and a medical-surgical ICU in two tertiary care hospitals.

Patients: Adult patients receiving mechanical ventilation.

Interventions: Two-hourly manual or continuous automated lateral rotation.

Measurements and Main Results: Heart rate (HR) and arterial pressure were sampled every 6 seconds for > 24 hours, and pulse pressure (PP) was computed. Turn data were obtained from a turning flow sheet (manual turn) or with an angle sensor (automated turn). Within-subject ensemble averages were computed for HR, mean arterial pressure (MAP), and PP across turns. Sixteen patients were randomized to either the manual (n = 8) or automated (n = 8) turn. Three patients did not complete the study due to hemodynamic instability, bed malfunction or extubation, leaving 13 patients (n = 6 manual turn and n = 7 automated turn) for analysis. Seven patients (54%) had an arterial line. Changes in hemodynamic variables were statistically significant increases (p < .05), but few changes were clinically important, defined as ≥ 10 bpm (HR) or ≥ 10 mmHg (MAP and PP), and were observed only in the manual-turn group. All manual-turn
patients had prolonged recovery to baseline in HR, MAP and PP of up to 45 minutes ($p \leq .05$). No significant turning-related periodicities were found for HR, MAP, or PP. Cross-correlations between variables showed variable lead-lag relations in both groups. A statistically, but not clinically, significant increase in HR of 3 bpm was found for the manual-turn group in the back compared with the right lateral position ($F = 14.37, df = 1, 11, p = .003$).

**Conclusions:** Mechanically ventilated critically ill patients experience modest hemodynamic changes with manual lateral rotation. A clinically inconsequential increase in HR, MAP, and PP may persist for up to 45 minutes. Automated lateral rotation has negligible hemodynamic effects.
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A Institutional Review Board Approvals and Informed Consent

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Summary of Study

The dissertation consists of three major sections. The proposal represents the work that was approved by the Dissertation Committee during the proposal defense. The manuscript, “Hemodynamic Changes Associated with Manual and Automated Lateral Rotation in Mechanically Ventilated Intensive Care Unit Patients,” contains the findings. The appendices include the Institutional Review Board (IRB) approvals and informed consent documents (Appendix A), the study Operations Manual (Appendix B), information on the digitized acquisition of data (Appendix C), two publications related to the study (Appendices D and E), data analysis tables that are not reported in the manuscript (Appendix F), and the student’s curriculum vitae (Appendix G).

The study design was a time series embedded within a randomized clinical trial pilot study of turning interventions (Sandra K. Hanneman, Principal Investigator, ClinicalTrials.gov: NCT00542321) to address the dissertation research specific aims: (a) describe hemodynamic responses to the turning interventions, (b) compare hemodynamic responses between turning intervention groups, and (c) compare within group hemodynamic responses between the back and right and left lateral positions. The aims were achieved with automated signal processing and ensemble averaging.

During the proposal defense, the Dissertation Committee recommended adding: (a) checks of the hemodynamic monitoring systems and 2-point calibration procedures for the monitors and arterial transducers, and (b) the variable pulse pressure as a surrogate for stroke volume; the dissertation proposal was revised accordingly. The IRBs of the University of Texas Health Science Center at Houston, The Methodist Hospital (TMH) and St. Luke’s Episcopal Hospital (SLEH) approved the study and change requests. The IRB approvals and accompanying consent forms are in Appendix A.
With the approval of the Chair of the Dissertation Committee, three changes were made in the study after the first obligatory defense. All hemodynamic data collected from participants in the randomized clinical trial pilot study were used instead of just 24 hours of data as proposed. Patients who did not have an arterial line were included, and their heart rate data were analyzed. These changes were made to accommodate barriers to recruitment described later in this summary. The projected sample size was reduced to a final sample size of 13 patients based on the results of the planned interim power calculations, which showed that data from 13 patients provided adequate power to detect clinically important between-group differences in heart rate and mean arterial pressure and within-group differences in heart rate, mean arterial pressure and pulse pressure between the back and lateral positions. The *a priori* sample size estimates had been based on data from a study that used one measurement post-turn.

A pilot study to test study protocols was conducted with the first patient (P001, manual turn group), who was enrolled after 30 days of recruitment at TMH. Such problems occurred with automated data acquisition as redundancy, unequal sampling frequencies, and different time stamps for data collected simultaneously. Audrius Brazdeikis, PhD, was consulted to assist with data acquisition problems; information about the digitized acquisition of data is in Appendix C. The manual-turn flow sheet was suboptimal and required revision to improve functionality and provide comprehensive documentation of patient turning. Despite these problems, quality data were obtained, and P001 was included in the study sample.

The manufacturer of the automated turning bed agreed to add a sensor to the bed to continuously measure angle of turn. Drs. Brazdeikis and Padhye programmed data acquisition and integration of automated turn angles with the heart rate, mean arterial pressure, and pulse pressure data; thus allowing nearly continuous measurement of these variables. Laboratory testing of the bed with the angle sensor
showed that sensor measurement reflected a gradient with respect to leveling of the transducer at the phlebostatic axis, and Dr. Padhye developed the height-adjusted model, described in the article published in the conference proceedings of the IEEE Engineering in Medicine and Biology Society and in the dissertation manuscript, to correct for this.

The major problem encountered during patient recruitment at TMH was the refusal of one intensivist to allow recruitment of his patients; this limited the eligible patients who could be recruited for the study. Patient recruitment at SLEH increased the number of eligible patients for recruitment. Problems encountered at both sites were inadequate research staff assistance to provide protocol coverage for 24 hours a day for up to 7 consecutive days and staff nurse and physician requests to leave patients in the back position due to "instability."

The Methodist Hospital used the HP Component Monitoring System (CMS, Phillips Medical Systems, Andover, MA) through study patient P011 when the hospital changed monitors in all the intensive care units to the Solar 8000 (Marquette, Milwaukee, WI). This change in equipment was easily accommodated because SLEH used the Solar 8000 monitor; the data acquisition system used at SLEH was used at the TMH site for the remainder of the study.

During patient recruitment and data collection, a manuscript titled "Adverse Hemodynamic Effects of Lateral Rotation during Mechanical Ventilation" was published (Appendix D); this article discusses the physiological basis for hemodynamic changes with lateral rotation. The methods and early results from one manual-turn group patient and one automated-turn group patient were reported in the article titled "Cardiovascular Impact of Manual and Automated Turns in the ICU" (Appendix E). The results of the study are reported in the manuscript "Hemodynamic Changes Associated with Manual and Automated Lateral Rotation in Mechanically Ventilated Intensive Care Unit Patients"
included in this document. Although reported in the manuscript, more detailed results of autocorrelation function, cross-correlations and two-way repeated-measures analysis of variance are presented in Appendix F of this document. Also included in Appendix F is a brief report of sham-turn experiments that were done to explore if hemodynamic response to lateral rotation may be explained by psychological anticipation of the turn.
MULTI-SITE RANDOMIZED CLINICAL TRIAL OF HORIZONTAL POSITIONING
TO PREVENT AND TREAT PULMONARY COMPLICATIONS IN
MECHANICALLY VENTILATED CRITICALLY ILL PATIENTS:
HEMODYNAMIC SUBSTUDY

A DISSERTATION PROPOSAL
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DECEMBER, 2006
Research Plan

Specific Aims

Mechanically ventilated critically ill patients are at high risk for developing pulmonary complications from prolonged immobility. Historically, nursing has recognized the pathophysiologic impact of prolonged immobility on critically ill patients, prompting the standard of lateral turning every 2 hours. A study, however, found 23% of critically ill patients observed were not repositioned for more than 8 hours (Krishnagopalan, Johnson, Low, & Kaufman, 2002) and, although no studies have been found on the appropriate angle of turning, it is unlikely patients are turned to the recommended angle of ≥ 45° with this position maintained for the 2-hour turning period. Automated lateral rotation, or kinetic therapy, defined as continuous, gradual turning along the longitudinal axis to ≥ 40° on each side by a specialty bed (Ahrens, Kollef, Stewart, & Shannon, 2004; Centers for Disease Control and Prevention [CDC], 2004), has been suggested as a solution to the pulmonary complications of prolonged immobility (Delaney, Gray, Laupland, & Zuege, 2006).

Lateral rotation in mechanically ventilated patients has been shown to adversely affect patient hemodynamics (Gawlinski & Dracup, 1998a), with studies showing a greater change in the left versus the right position (Jones & Dean, 2004; Nakao et al., 1986). Although adverse hemodynamic effects related to lateral positioning are typically transient (Lewis et al., 1997), clinicians are often reluctant to laterally position patients who are hemodynamically unstable.

Mechanically ventilated critically ill patients represent a large population at risk for the hazards of immobility, with pulmonary and hemodynamic hazards as the ones most likely to contribute to morbidity and mortality in the intensive care unit (ICU) setting. A pilot study of a multi-site randomized clinical trial of the efficacy and safety of horizontal positioning (manual 2-hourly turning or experimental automated turning) to reduce
preventable pulmonary complications in mechanically ventilated critically ill patients will be conducted (Sandra K. Hanneman, Principal Investigator). Given the acuity of this patient population, the adverse hemodynamic effects of positive pressure ventilation, and possible adverse effects of lateral rotation on hemodynamics, hemodynamic response to the two turning interventions will be evaluated in a substudy. The hemodynamic substudy will specifically address turning-related hemodynamic adverse events in the two turning groups as hemodynamic compromise is likely to have implications for morbidity, mortality and protocol adherence.

This proposal is for a substudy of hemodynamic responses to turning. Funding to conduct the hemodynamic substudy has been obtained from the American Association of Critical-Care Nurses (AACN) Mentorship Grant and the AACN-Houston Gulf Coast Chapter. The objective is to evaluate the extent to which lateral positioning poses a hemodynamic safety risk. The hemodynamic substudy will contribute evidence for clinical practice by rigorous comparison of hemodynamic response to two turning interventions: the standard-of-care 2-hourly manual turn and the experimental continuous automated turn.

The specific aims of the hemodynamic substudy are to:

1. Describe hemodynamic responses to the turning interventions,
2. Compare hemodynamic responses between turning intervention groups, and
3. Compare within group hemodynamic responses to right and left lateral positioning.

The hypotheses are that (a) there will be greater hemodynamic changes after turning in the manual-turn group patients compared with the automated-turn group patients using a time-series design with nearly continuous heart rate (HR), mean arterial pressure (MAP) and pulse pressure (PP) monitored for ≥ 24 hours; and (b) within-group hemodynamic changes will be greater in the left and right lateral positions than in the back position.
Background and Significance

Several studies, including at least four randomized clinical trials (Ahrens et al., 2004; deBoisblanc et al., 1993; Raoof et al., 1999; Traver, Tyler, Hudson, Sherrill, & Quan, 1995), have been done on positioning and preventable pulmonary complications in mechanically ventilated critically ill patients. Design limitations, however, have contributed to conflicting findings and absence of clear implications for practice. Of particular concern is the lack of control over manual turning, which has served as the control intervention in studies of turning with a specialty bed (i.e., kinetic therapy), and hemodynamic tolerance to kinetic therapy has not been examined systematically.

In critically ill patients, mechanical ventilation may be a life-sustaining intervention aimed at maintaining homeostasis by increasing arterial oxygen content. The benefits of positive pressure ventilation may be countered, however, by the negative hemodynamic effects of increased intrathoracic pressure. The extent to which positive pressure ventilation alters cardiovascular function is dependent on cardiac reserve, biventricular functioning, circulating blood volume, blood flow distribution, autonomic tone, lung volume, intrathoracic pressure, and the surface pressures on the remainder of the circulation (Pinsky, 2005).

The Hemodynamics of Venous Return

Independent of the heart, adequacy of venous blood flow depends on a sufficient vascular pressure to move the blood toward the right heart and a lower counter resistance to create a sufficient venous return gradient. Three factors affect blood return to the heart from the venous circulation (Guyton & Hall, 2000): (a) right atrial pressure ($P_{ra}$), which exerts a backpressure impeding venous return; (b) mean systemic filling pressure ($P_{ms}$), which is the pressure in the peripheral vasculature driving venous blood flow to the right heart (Jacobsohn, Chorn, & O’Connor, 1997); and (c) resistance to venous return (RVR), reflecting both resistance and capacitance of the circulation.
between the peripheral vessels and the right atrium. Ohm's Law states venous return is characterized specifically by the following equation (Thomson, 1984):

$$\text{Venous Return} = \frac{P_{ms} - P_{ra}}{RVR}$$

where the numerator is the pressure gradient for venous return ($P_{ms} - P_{ra}$) and the denominator is the resistance to venous blood flow (Bendjelid, 2005). $P_{ms}$ is a critical component and is influenced by blood volume, the elastic properties of the systemic vessels and the pressure surrounding them (Pinsky, 2000). When the $P_{ra}$ increases (counter resistance) to equal $P_{ms}$ (i.e. pressure pushing blood toward the heart), the pressure gradient for venous return is zero and venous return will cease (Guyton & Hall, 2000). The greater the volume of blood in the venous circulatory system, the greater is the $P_{ms}$ because extra volume within the vasculature exerts pressure on the walls of the vessels (Guyton & Hall, 2000). Even though veins have a large capacity and are highly compliant, if the resistance in the veins rises, blood backs up in all parts of the systemic circulation and venous return falls (Guyton & Hall, 2000). When $P_{ra}$ is reduced below $P_{ms}$, venous return increases (Fessler, Brower, Wise, & Permutt, 1992). As $P_{ra}$ is reduced further, venous return will reach a maximum level (critical downstream pressure [P_{crit}]) which cannot be exceeded despite further decreases in $P_{ra}$.

Venous return is a primary determinant of cardiac output (Guyton & Hall, 2000). One role of the heart is to lower $P_{ra}$ to allow optimal drainage from the venous system and filling of the heart chambers (Bendjelid, 2005). In the regulation of cardiac output, venous return is influenced by peripheral circulation factors. These include (a) blood volume, (b) venous dilatation, and (c) patency of the large veins (i.e., inferior vena cava and superior vena cava; Guyton & Hall, 2000). Venous return, and therefore cardiac output, may be decreased by low circulating blood volume (absolute or relative
hypovolemia), acute venous dilation (as may occur with sepsis), and/or obstruction of a vena cava (e.g., superior vena cava syndrome).

**Adverse Hemodynamic Effects of Mechanical Ventilation**

Normal ventilatory mechanics and heart-lung interactions change with mechanical ventilation. Instead of negative intrathoracic pressure during inspiration, the ventilator delivers volume under pressure into the lungs, producing positive intrathoracic and airway pressures during inspiration. Positive pressure ventilation and other sources of high intrathoracic pressure can reduce venous return and shift the interventricular septum to the left, impairing left ventricular filling and cardiac output (Bryan-Brown, 1986; Goodnough-Hanneman, 1993).

Higher levels of positive end-expiratory pressure (PEEP), often applied to increase functional residual capacity (Luecke et al., 2004) in cases of pulmonary inflammation, edema and infiltration, are associated with a greater rise in intrathoracic pressure. As the lungs expand from positive pressure, the chest wall is pushed outward and the diaphragm downward while the cardiac fossa is pushed in upon itself, shifting the septum toward the left ventricular cavity and constraining left ventricular filling (Mitchell et al., 2005). Using a canine model, Cabrera and colleagues (1989) found a positive linear relation between elevated \( P_{ra} \) and pericardial pressure that was associated with increased PEEP and independent of acute lung injury, reflecting the transmission of airway pressure to the pericardial surface as the heart is squeezed.

An adequate preload from venous return is paramount to the heart's ability to deliver oxygenated blood to the tissues (i.e., oxygen delivery \([\dot{D}O_2]\)). According to the Frank-Starling mechanism, cardiac preload is defined as the ventricular fiber length at end-diastole; clinically, preload refers to the left ventricular end-diastolic volume (Luecke et al., 2004). The greater the end-diastolic volume, the greater is the force of ventricular contraction (Jacobsohn et al., 1997; Opie, 1998). Relative or absolute hypovolemia
reduces preload and stroke volume with a subsequent decrease in cardiac output and \( \dot{D}O_2 \). Relative hypovolemia may occur with positive pressure ventilation when venous return is decreased from the increase in intrathoracic pressure. This mechanism may be manifested with the initiation of positive pressure ventilation, PEEP, continuous positive airway pressure and with large tidal volumes and other hyperinflation modalities (Goodnough-Hanneman, 1993; Goodnough, 1985). In such circumstances, the patient may require transient hydration to compensate for the reduced venous return.

A linear relationship exists among level of PEEP, lung compliance, and intrathoracic pressure which in turn is directly associated with venous return, stoke volume, and cardiac output on the basis of the Frank-Starling mechanism (Mitchell et al., 2005; Pinsky, Desmet, & Vincent, 1992; Pinsky, Matuschak, & Klain, 1985). PEEP levels of 15 cm H\(_2\)O can reduce ventricular stroke volume by as much as 50% (Cassidy & Mitchell, 1981). Using an animal model, Mitchell and colleagues (2005) demonstrated that, at higher levels of PEEP, right ventricular diameter was greater with reduced left ventricular end-diastolic volume from constrained filling, suggesting a leftward septal shift. Peters and colleagues (1993) corroborated this finding by evaluating regional distribution of labeled red blood cells in spontaneously breathing volunteers placed on continuous positive airway pressure and found that, within minutes, blood was shifted from the intrathoracic to the abdominal compartment; left ventricular red blood cell counts were reduced by 10% and remained diminished throughout continuous positive airway pressure breathing. Assuming a total blood volume of 4000 mL and an intrathoracic blood volume of approximately 2000 mL and given the fact that one-half the blood loss during a hemorrhage originates from the intrathoracic vascular bed (Echt, Duweling, Gauer, & Lange, 1974), such a reduction in volume would correspond to a 400 mL hemorrhage, representing a notable reduction in blood volume. Cardiac output, and therefore \( \dot{D}O_2 \), may be significantly affected by this abrupt reduction in central circulating
volume. Clinically, these positive pressure-induced hemodynamic changes result in a reduced MAP which may be profound and require rapid intravascular volume expansion (Jardin et al., 1981).

Unfortunately, vital signs such as HR and blood pressure can be unreliable indicators of circulating volume (Lopes et al., 2007). When changes do occur they are typically late indicators of reduced circulating volume because compensatory mechanisms buffer against hypotension (Convertino, Cooke, & Holcomb, 2006). For example, MAP which is determined by blood flow and arterial vasomotor tone, may not be reduced in states of decreased venous return if reduced SV is compensated for by increased HR thereby maintaining adequate CO (Gunn & Pinsky, 2001; Leonetti et al., 2004). Arterial PP (systolic blood pressure [SBP]-diastolic blood pressure [DBP]) on the other hand, is determined by left ventricular SV, HR and arterial tone (Gunn & Pinsky, 2001). Given that arterial tone and HR remain relatively constant over a single mechanical breath, a change in PP is solely reflective of a change in SV (Gunn & Pinsky, 2001; Michard, 2005). In other words, PP is an immediate and more accurate predictor of preload since it is not acutely dependent on arterial tone or HR. Leonetti and colleagues (2004) demonstrated this concept with 12 patients with hemochromatosis who were undergoing regular phlebotomy. An average volume of 375 ml was withdrawn over a period of 6.4 minutes. Using a Finometer device to derive beat-to-beat SV from blood pressure waveforms, the researchers found a graded reduction of beat-to-beat SV during phlebotomy which was still significant at the end of the recovery period (5 minutes after blood withdrawal was completed). Pulse pressure was significantly reduced both during and after phlebotomy while changes in HR did not reach significance. Mean arterial pressure was significantly reduced only during the post-phlebotomy period. Cooke and colleagues (2006) showed similar results using an equal number of unmatched hemorrhagic shock trauma patients without head injury who survived (n=15) compared
with non-survivors (n = 15). Hemodynamic data were collected every 3 minutes from trauma incident pickup to delivery via medical evacuation helicopter. Both groups had similar HR and MAP values but PPs were significantly lower in patients who died than in patients who survived.

Within the thorax, the heart is a pressure chamber within a pressure chamber. That is, independent of the heart itself, changes in intrathoracic pressure affect the pressure gradient for venous return to the right ventricle and systemic outflow from the left ventricle (Pinsky, 2005). In most circumstances, as lung volume increases, diaphragmatic descent increases, shifting some of the increased intrathoracic pressure to the intra-abdominal cavity (Van Den Berg, Jansen, & Pinsky, 2002). Because a large proportion of the venous blood is then in the abdomen, increased intrathoracic pressure may actually increase the $P_{ms}$, thereby serving as a mechanism to blunt the adverse hemodynamic effects of positive pressure ventilation and reduced venous return (Pinsky, 2000). However, in such circumstances as intra-abdominal hypertension, which may be caused by acute pancreatitis (Rosas et al., 2007), diaphragmatic descent is limited and increases in intrathoracic pressure compromise venous return and systemic outflow.

Increased intrathoracic pressure also affects the hydraulic determinants of venous return. In patients receiving mechanical ventilation, $P_{ms}$-$P_{ra}$ may not represent the effective gradient for venous return (Brienza, Revelly, Ayuse, & Robotham, 1995). Similar to normal negative-pressure ventilation, during positive pressure ventilation, venous return becomes maximal when $P_{ra}$ is reduced to a pressure below zero ($P_{crt}$) (Fessler, Brower, Shapiro, & Permutt, 1993), which represents the minimal downstream pressure for venous return. Positive pressure ventilation increases critical downstream pressure to a level greater than the $P_{ra}$, suggesting increased pressure on the surface of the veins (Fessler et al., 1992). Since further reductions in $P_{ra}$ fail to increase venous return, the effective downstream pressure for venous return must be the critical
downstream pressure and not $P_{ra}$. Therefore, the pressure gradient for venous return during positive pressure ventilation is (Fessler et al., 1993):

$$\text{Venous Pressure Gradient} = P_{ms} - P_{crit}$$

where $P_{crit}$ is the critical downstream pressure.

Animal studies have shown that $P_{ms}$ and $P_{ra}$ rise equally, thereby preserving the pressure gradient (Fessler, Brower, Wise, & Permutt, 1991; Nanas & Magder, 1992). Jellinek and colleagues (2000) corroborated this finding in 10 patients undergoing implantation of defibrillator devices. This procedure involves induced ventricular fibrillation for threshold testing of the device with periods of circulatory arrest long enough (5 - 7.5 seconds) to measure $P_{ms}$ (Fessler et al., 1991). The investigators found that increasing mean airway pressure from 0 to 15 cm H$_2$O with PEEP increased $P_{ra}$ and $P_{ms}$ equally; thus, the calculated pressure gradient for venous return ($P_{ms} - P_{ra}$) remained unaffected by the increase in intrathoracic pressure. These data suggest that positive pressure ventilation with PEEP decreases venous return by: (a) altering the conductance of venous blood flow, and/or (b) elevating $P_{crit}$ greater than $P_{ra}$ (Fessler et al., 1993; Fessler et al., 1992).

If reduced venous return is not the result of a reduced venous pressure gradient, then the vasculature itself may be to blame. When the pressure in the vena cava is below the $P_{crit}$, a vascular waterfall condition exists, demonstrating the dynamics of freely-falling liquids (Badeer & Hicks, 1992; Fessler et al., 1992). When vascular waterfall conditions exist, changes in pressure downstream from the waterfall have no influence on flow; the pressure at the outflow site of the vena cava is no longer the effective downstream pressure for venous return but instead becomes the pressure at an upstream location where the pressure remains constant and below the $P_{crit}$ despite pressure changes in the venae cavae (Fessler et al., 1993; Fessler et al., 1992). In other words, when positive pressure is applied, pressure within the intrathoracic venae cavae increases (Fessler et
al., 1993) as the external surface pressure surrounding at least a portion of the large veins is in excess of the outflow pressure at the distal end of the compression site, creating a vascular waterfall upstream from the right atrium (Fessler et al., 1991; Permutt & Riley, 1963). Flow then becomes proportional to the difference between the upstream pressure and the external pressure surrounding the vessel, and changes in the downstream pressure have no influence on flow (Badeer & Hicks, 1992).

Interestingly, the superior vena cava in all body positions remains widely patent during positive pressure ventilation, with and without PEEP, in contrast to the inferior vena cava where sharply localized increases in pressure suggest localized narrowing (Fessler et al., 1993). In an animal model, Theres and colleagues (1999) showed that with PEEP levels of 5 cm H$_2$O, inferior vena cava flow decreased to 87% of that without PEEP ($p = .01$). Using two-dimensional echocardiography in supine patients with respiratory failure, Mitaka and colleagues (1989) reported that as PEEP levels increase, the dimension of the inferior vena cava increases and the collapsibility index (percentage of expiratory decrease in inferior vena cava dimension) decreases suggesting a progressive increase in resistance to venous return.

Changes in intrathoracic pressure affect cardiac performance (Buda et al., 1979). For example, PEEP can induce a 30 - 50% decrease in venous return (Fessler et al., 1992). In 10 patients with acute respiratory distress syndrome, increase in level of PEEP was associated with progressive decline in cardiac output, MAP, and left ventricular dimension, as well as septal bulging into the left ventricle; HR did not change with progressive levels of PEEP (Jardin et al., 1981). Volume resuscitation likely improves the negative hemodynamic effects of positive pressure ventilation. Evidence shows that patients who have an adequate circulating volume tend to have a smaller fall in cardiac output (Magder, Lagonidis, & Erice, 2001; Qvist, Pontoppidan, Wilson, Lowenstein, & Laver, 1975).
Adverse Hemodynamic Effects of Lateral Rotation

In the ICU, vertical position changes are nursing interventions to manage hemodynamic instability, prevent aspiration, and promote comfort while lateral position changes prevent pulmonary complications and pressure ulcers. Giuliano, Scott, Brown, and Olsen (2003) evaluated the effects of three backrest positions (0°, 30°, and 45°) on HR and MAP in 26 critically ill patients (96% were mechanically ventilated). The results showed no significant differences in HR between vertical positions and although significance was found in MAP, the difference (2.1 mm Hg) was not clinically important (83.4 mm Hg at 0° and 81.3 mm Hg at 45°). In the randomized clinical trial pilot study, head of bed (HOB) will be ≥ 30° to reduce the risk of aspiration (Centers for Disease Control and Prevention [CDC], 2004).

Nakao and colleagues (1987) studied the effects of positioning on the shape and size of the inferior vena cava using echocardiography in patients without evidence of cardiac disease. They reported a significant decrease in vessel diameter and area in both the right lateral and left lateral positions compared with the supine position, with the smallest diameter and area found in the left lateral position. The shape of the inferior vena cava was round in the right lateral, oval in the supine, and slit-like in the left lateral positions. The collapsibility index in this study was found to be five times larger in the supine position compared to the right lateral position, and due to the small vessel size, it could not be assessed in the left lateral position. Fessler and colleagues (1993) reported direct PEEP-induced inferior vena cava compression that was more prominent in the left lateral position in an animal model. They concluded that greater inflation of the right lung leads to greater inferior vena cava compression when lying in the left lateral position.

Lateral position changes in mechanically ventilated patients result in an 8 – 12% decline in $\text{SvO}_2$ (Jesurum, 1997; Weissman et al., 1984). A significant reduction in $\text{SvO}_2$ has been found immediately after lateral turning (Gawlinski & Dracup, 1998a; Lewis et
al., 1997; Winslow, Clark, White, & Tyler, 1990), with most studies reporting a greater decrease in the left versus the right lateral position (Gawlinski & Dracup, 1998a; Lewis et al., 1997). Likewise, studies in healthy humans and animals have shown significant changes in HR and blood pressure with lateral positioning (Fessler et al., 1993; Jones & Dean, 2004; Nakao et al., 1986; Pump, Talleruphuus, Christensen, Warberg, & Norsk, 2002), with the greatest negative effect in HR and blood pressure in the left lateral position (Jones & Dean, 2004). Although typically transient, with recovery to baseline values in ≤ 5 minutes (Gawlinski & Dracup, 1998a; Lewis et al., 1997; Shively, 1988; Winslow et al., 1990), patients with limited cardiopulmonary reserve may experience more dramatic and prolonged hemodynamic changes (Gawlinski, 1993).

In mechanically ventilated patients, Banasik and Emerson (2001) reported no significant differences in hemodynamic variables in relation to position. However, Bein and colleagues (Bein, Metz, Keyl, Pfeifer, & Taeger, 1996) reported a significant decrease in MAP in the right lateral position and a hyperdynamic state in the left. Both of these studies captured hemodynamic data after a 15-minute rest period post-turning using a cross-sectional design (Banasik & Emerson, 2001; Bein et al., 1996). The hemodynamic substudy will use a time-series design to better capture patterns of hemodynamic responses to the turning interventions. HR, MAP and PP collected in 6-second intervals over ≥ 24 hours across 2-hourly turns (control group) or continuous automated turning (experimental group) is expected to yield useful data on hemodynamic response to turning and lateral position.

**Clinical Relevance**

Turning patients is a fundamental nursing intervention to reduce the hazards of immobility. Automated turning is more costly than manual turning, resulting in the use of “specialty beds” only for very high risk patients. The future randomized clinical trial will address limitations of previous randomized clinical trials by rigorous testing of both the 2-
hour manual turning control intervention and the automated turning experimental intervention. The findings from the randomized clinical trial should provide evidence to guide practice: equivalence of the two turning protocols or superiority of one over the other in terms of efficacy and safety.

Hemodynamic compromise is expected to be the greatest safety issue associated with the two turning protocols in mechanically ventilated ICU patients. The findings from the substudy will provide a better understanding of hemodynamic response to lateral rotation than currently exists, by virtue of the nearly continuous capture of HR, MAP and PP response to both manual and automated turning for ≥ 24 hours. The proposed approach is expected to provide data across a range of physiologic stability and instability. Important implications for practice would be heightened hemodynamic monitoring of patients with interventions (manual or automated turning and right or left positioning) that are associated with greater hemodynamic compromise and clear guidelines to abort the offensive procedure if hemodynamic recovery time falls outside the expected (Gawlinski & Dracup, 1998a) hemodynamic recovery time range (i.e., > 5 minutes).

Preliminary Studies

Preliminary testing was conducted on (a) the accuracy and precision of the automated turn bed’s digital angle display, (b) accuracy of HOB angle using a mini bubble protractor, (c) automated and manual turn protocols, and (d) data acquisition procedures. The first three preliminary studies will be discussed in detail elsewhere with dissemination of the randomized clinical trial pilot study and only the findings relevant to the hemodynamic substudy are presented here. The data acquisition, management, and analysis procedures are specific to the proposed hemodynamic substudy.
Accuracy and Precision of Horizontal and Vertical Head-of-Bed (HOB) Angles

The randomized clinical trial pilot study research team tested accuracy and precision of the angles of the digital display on the automated-turn bed (Triadyne Proventa™, KCI, San Antonio, TX) against a digital protractor (Bosch DWM40L Miter Finder Digital Protractor/Angle Finder, Leinfelden-Echterdingen, Germany). Comparisons were made at various (a) lateral rotation angles in the back to right, right to back, and left to back automated turn positions; and (b) vertical angles. The intraclass correlation coefficient was .96 (95% CI [.89, .99]) for horizontal angle and .99 (95% CI [.89, 1.0]) for vertical angle, indicating excellent precision of the digital displays on the Proventa bed. The Bland-Altman procedure (Altman & Bland, 1983; Bland & Altman, 1986) was used to quantify bias of the Proventa digital displays for horizontal and vertical angles. The horizontal and vertical angle bias estimates were minor and clinically inconsequential.

Accuracy of the measurement of HOB angle for the manual turn intervention was tested with a mini bubble protractor (KCI, Inc., San Antonio, TX) against the digital protractor in the randomized clinical trial pilot study units. The mini and digital protractors had good agreement with no systematic trends. Thus, the mini protractor will be used to measure HOB elevation in the randomized clinical trial pilot study and hemodynamic substudy.

Testing of the Turning Protocols

The manual-turn protocol was tested at the study sites. Horizontal turn angles varied from 45 to 55°, and angle was not related to direction of turn or study unit. The time it took two investigators to turn a mechanically ventilated critically ill patient on a standard ICU bed varied from 2 to 6 minutes; time to turn was not related to direction of turn. The automated-turn protocol was tested with the Proventa bed in a Center for Nursing Research laboratory using investigators as subjects. Average turning times were as follows: back → left = 1.82 ± 0.11 minutes, left → back = 4.15 ± 1 minute, back → right
= 1.61 ± 0.2 minutes, right → back = 4.25 ± 0.77 minutes. The time was longer for the Proventa bed to make the turn from either side to back than vice versa. The total time for a complete rotational cycle to the left or right was 6 ± 1 minute and 12 minutes for a complete cycle of back to left to back to right to back turning.

Testing of Hemodynamic Data Acquisition, Management and Analysis Procedures

Data acquisition procedures were tested on a patient with the manual-turn protocol at TMH. Date, time, HR, SBP and DBP were successfully captured and written to a computer file every 1024 milliseconds for > 30 hours. Mean arterial pressure and PP variables were calculated from the raw SBP and DBP data. The 1024 millisecond data were aggregated into 5-second bins to provide uniform frequency sampling between testing sites (5-second sampling frequency at SLEH site). Using 3 standard deviations (SD) from the mean, ≤ 0.3% of the raw data were outliers and ≤ 0.9% of the raw data were missing data for the variables HR, MAP and PP. Ensemble averages were computed for HR, MAP and PP data within the four turning categories: 1) back → left, 2) left → back, 3) back → right, and 4) right → back. Each turn category included three or more individual turns. Using computer programming scripted in S-Plus 8.0 (Insightful, Inc., Seattle, WA), ensemble averaged data were placed in 12-second bins starting 15 minutes before the turn (pre-turn period) and 45 minutes after the turn (post-turn period). The first 5 minutes of the pre-turn period was considered the baseline interval. Starting at the end of the baseline interval, testing intervals of 5-minutes duration were moved forward in 1-minute increments, comparing the baseline interval with each testing interval. A first-order autoregressive model was used to account for the autocorrelated nature of the data (Box & Jenkins, 1976). Results showed a statistically and clinically significant increase in HR (≤ 22 bpm), MAP (≤ 22 mmHg), and PP (≤ 19 mmHg), with prolonged recovery time to baseline values by as much as 45 minutes. Graphical display of the ensemble averaged data showed an increase in variable response associated
with all turns. The turning times were imprecise, and turns were identified as
perturbations in the data; all were within 10 minutes of the recorded turning time. A
larger 12-second aggregated sampling interval was chosen for analysis to reduce high
autocorrelation of the data. By reducing autocorrelation, a lower-order autoregressive
model was found to be optimal using the Akaike information criterion (Akaike, 1974).
Based on the frequency sampling used for data analysis, data aggregation was
subsequently changed from 5 seconds to 6 seconds.

Research Design and Methods

The hemodynamic substudy will describe the hemodynamic safety risks associated
with two turning protocols: 2-hourly manual and continuous automated turning. The
specific aims of the hemodynamic substudy are to:

1. Describe hemodynamic responses to the turning interventions,
2. Compare hemodynamic responses between turning intervention groups, and
3. Compare within-group hemodynamic responses to right and left lateral positioning.

Overview

The randomized clinical trial pilot study will use a two-group (manual lateral
rotation or automated lateral rotation), completely randomized experimental design.
Prospectively, eligible patients who are randomly selected, able to accept random
assignment, and consent to study participation will be randomly assigned to one of two
positioning protocols to compare preventable pulmonary complications, turning-related
adverse events, mechanical ventilation duration, ICU length of stay and ICU mortality
rate by study group. Within the randomized clinical trial design, the hemodynamic
substudy will use an observational time-series design to capture HR, MAP and PP
responses to the turning interventions (Figure 1). The randomized clinical trial pilot study
will involve application and monitoring of the turning intervention until mechanical
ventilation is discontinued or for 7 days, whichever occurs first. The hemodynamic
Figure 1. Within-site two-group (automated lateral rotation or manual lateral rotation) experimental design with observational time series hemodynamic substudy
substudy will involve hemodynamic data collection for ≥ 24 contiguous hours during a patient's participation in the randomized clinical trial pilot study.

**Setting and Sample**

Two sites will be used for the study: SLEH and TMH in Houston, TX. St. Luke’s Episcopal Hospital’s 7 South ICU will provide medical and surgical patients, and the Medical ICU at TMH will provide medical patients.

The 7 South ICU has 19 beds. In 2005, the average daily census was 17 patients. Of the 1,122 admissions, 411 (37%) were on mechanical ventilation. The most common diagnoses were respiratory failure, renal failure and postoperative bowel surgery. The mean (± SD) age of the mechanically ventilated patients was 62 (± 17) years, comparable to the age of patients who were not mechanically ventilated (61 ± 17 years). Mean mechanical ventilation duration was 10 (± 16) days (range of 1 – 57 days). Patients on mechanical ventilation stayed in the 7 South ICU for an average 8 (± 8) days, compared with an average ICU length of stay of 3.6 (± 2.6) days for patients who did not require mechanical ventilation. Of the 411 patients who received mechanical ventilation, 66% were on the ventilator for ≤ 7 days and 34% for > 7 days. The gender and ethnic composition of patients was 49% female, 51% male, 13% Hispanic, 27% African American/Black, 57% Caucasian/White, and 3% other.

A 24-bed unit, the Medical ICU at TMH had an average daily census of 22 patients in 2005. Mean (± SD) age of the patients was 60 (± 17) years; 41% of unit patients were on mechanical ventilation with mean mechanical ventilation duration of 9.5 (± 12.8) days. The most common diagnoses were respiratory failure and sepsis. Gender and ethnic distributions were: 52% female, 48% male, 12% Hispanic, 24% African American/Black, 56% Caucasian/White, and 8% other.

*A priori* estimates of sample sizes needed to test Hypotheses 1 and 2 were determined from published data and theoretical expectations. Sample size estimates
were based on HR and MAP data obtained from 12 mechanically ventilated critically ill patients positioned in the supine, left and right lateral positions (Bein et al., 1996) for the manual-turn group and lesser changes by 50% in the automated-turn group. The expectation for less change in HR, MAP and PP in the automated group takes into account the limitations of the angle of turn with the experimental bed; lateral turn angles with the bed will be ≤ 45° whereas the angles will be ≥ 45° in the manual-turn group. Heart rate and MAP range data from Bein et al. were converted to SD using the range method for estimating SD (Hurlburt, 1994). Hemodynamic values in relation to positioning were as follows, expressed as median ± SD: HR in the supine, 80 ± 20.6 bpm; left lateral position, 97 ± 21 bpm; and right lateral position, 98 ± 23.7 bpm; MAP in the supine, 85 ± 17.7 mmHg; left lateral position, 88 ± 15.7 mmHg; and right lateral position, 72 ± 16.7 mmHg. Standard deviations smaller by 0.5 were used for the automated-turn group, based on less variability expected due to a less steep turn angle with the automated bed versus the manual turn. Supine values from Bein and colleagues were used as the baseline values from which change with lateral positioning was computed.

Sample size was estimated for Hypothesis 1 (HR, MAP and PP will exhibit greater change after turning in the manual-turn group patients compared with the automated-turn group patients) with α = 0.05 and power = 0.80, and a one-sided means test for two samples; 148 patients (74 patients per group) will be needed to detect a significant difference in HR; 160 patients (80 patients per group) will be needed to detect a difference in MAP. Data were not found for estimating sample size for PP, but it is expected to mirror that for MAP because PP and MAP are both derived from the SBP and DBP values.

To estimate sample size needed to test Hypothesis 2 (HR, MAP and PP will exhibit greater change in the left and right lateral positions compared with the back position),
the same medians and SDs discussed above were used to determine change with positioning. Comparisons were made between lateral and back positions using a one-sided means test for one sample with $\alpha = 0.05$ and power $= 0.80$. In the manual-turn group, the estimated sample size is 11 patients to detect a difference in HR and 16 patients to detect a difference in MAP in the lateral positions, compared with the back position. For the automated turn group, 39 patients will be needed to detect a difference in HR and 60 patients to detect a difference in MAP based on changes 50% less than those expected with the manual turn.

The above calculations estimate that the sample size required to test the hypotheses is 160 patients (80 patients per group). Because the data from Bein and colleagues (1996) were collected 15 minutes after turning, an interim, retrospective power calculation will be performed after data have been collected from 12 subjects ($n = 6$ control and $n = 6$ experimental group) to better estimate sample size with the time-series data from this study. If power $\geq 0.80$ requires substantially more patients, the study findings will serve as pilot data for future study.

**Inclusion criteria** for the randomized clinical trial pilot study and hemodynamic substudy are: receiving mechanical ventilation and placement on protocol within 8 hours of intubation and the initiation of mechanical ventilation. **Exclusion criteria** include conditions that cause compression atelectasis and/or are contraindications to turning: (a) pulmonary mass, pneumothorax, hemothorax, pleural effusion, and other sources of compression atelectasis; (b) hemodynamic instability (defined as SBP $< 90$ mm Hg with vasopressor support); (c) orthopedic injuries requiring traction; (d) head injury requiring intracranial pressure monitoring; (e) unstable spinal injuries; (f) rib fractures; (g) intubation within the previous 2 weeks to control for the presence of residual preventable pulmonary complications; and (h) body weight $\geq 350$ pounds (experimental bed limitation).
Random selection and random assignment. Simple random sampling will be used to select potential patients using an Excel spreadsheet with a probability formula of .678 for random selection and .50 for group assignment. Random selection and random assignment will be balanced by site to determine comparability of the treatment groups with regard to practice patterns, policies, and procedures (e.g., airway and ventilator management), and non-specialty beds used for clinical care. After determination of eligibility and informed consent, patients will be assigned randomly (with 1:1 probability) to the manual or automated turning group using a randomization database with computer-generated random numbers.

Interventions for the Randomized Clinical Trial Pilot Study

Manual Turn. The salient aspects of the protocol include ≥ 45° lateral turn to promote lobe-over-lobe drainage of secretions; head-of-bed (HOB) ≥ 30° to reduce risk of aspiration in the lateral and back positions (CDC, 2004); use of dedicated research nurses to ensure frequency and angle and duration of turn; and tracking of compliance with the intervention protocol, including attrition and adverse events associated with turning. Adherence to the manual turn protocol will be assessed by study nurses every 10 minutes; they will measure and record angle of turn and reposition the patient as needed and/or document reason for protocol violation.

Automated Turning. The TriaDyne Proventa bed will be used for automated turning. Salient aspects of this protocol are lateral rotation to a ≥ 40° angle; essentially continuous rotation with a 90° arc (rotation will be paused for short periods as needed for such care as linen change); HOB elevation ≥ 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, including attrition and adverse events associated with turning.
Measurements

Heart rate, MAP and PP will be used to determine hemodynamic response to the turning interventions. Data will be obtained with a physiologic monitor (HP Component Monitoring System (CMS), Philips Medical Systems, Andover, MA or Solar 8000, Marquette, Milwaukee, WI) and arterial line pressure transducer (Edwards Lifesciences, PX600F and PX284, Irvine, CA). Both physiologic monitors have HR sampling accuracy ± 1% and MAP precision of ± 1 mm Hg over 24 hours with accuracy of ± 2% (exclusive of the transducer; Marquette Medical Systems, 1998; Philips Medical Systems, 2003). The pressure transducer has a precision of ± 1 mm Hg over 8 hours and accuracy of ± 1 mm Hg (Edwards Lifesciences, 2006).

Heart rate and blood pressure will be captured every 6 seconds for ≥ 24 hours during turning interventions. Hemodynamic data from the CMS will be directly transferred via RS232 serial interface to a laptop computer using a custom-written software application. Data will then be directly downloaded into a computer file every 1024 milliseconds and aggregated to every 6 seconds. For the Solar 8000 monitor, BedMaster (Excel Medical Electronics, Jupiter, FL) software will be used to communicate with the hospital’s Unity Network to download hemodynamic data every 6 seconds to a computer file.

Data Collection Procedures - After a patient has been enrolled in the randomized clinical trial pilot study, participation in the hemodynamic substudy will begin at a time convenient for the Principal Investigator. At each study site, a study laptop computer connected to a physiologic monitor will capture hemodynamic data and save it to a computer file. Within 8 hours of the completion of hemodynamic data collection, HR, SBP, DBP, and MAP will be: (a) downloaded from the study laptop computer to a memory stick; (b) imported into a SPSS database; and (c) saved on three CDs (patient file, master copy, and back-up master copy). Pulse pressure will be calculated (SBP-DBP) automatically after patient data have been imported into the SPSS database. For
patients in the manual-turn group, turning direction (back, left, or right) will be manually entered into the SPSS database from the randomized clinical trial pilot study turning flow sheet; the automated-turn group’s position will be obtained automatically using the built-in angle sensor. Subjects will be enrolled in the randomized clinical trial pilot study until (a) consent is revoked, (b) mechanical ventilation is discontinued, (c) transfer from study ICU, (d) patient death, or (e) 7 days in the study. Subjects will remain in the hemodynamic substudy for ≥ 24 hours.

Data Analysis

For the hemodynamic substudy, before modeling the outcome data, detailed descriptive analysis will be performed on all data collected, sample distributions described and statistical assumptions assessed. Ensemble averaging (Lodato & Jubran, 1993) will provide an initial graphic description of individual subject data including hemodynamic recovery response time (Specific Aim 1). Within-subject autocorrelation function will be used to evaluate for periodicities that correspond to the same time period as lateral turning; every 2, 4 or 6 hours in the manual-turn group and ≤ 12 minutes for the automated-turn group. Cross-correlation between HR and MAP, HR and PP, and MAP and PP will be used to describe within-subject hemodynamic associations during lateral rotation (Specific Aim 1). The Student’s t-test will be used to compare hemodynamic responses to the turning interventions between groups (Specific Aim 2) and repeated measures one-way analysis of variance (ANOVA) will be used to compare hemodynamic responses to left and right lateral positioning (Specific Aim 3). A Mann-Whitney U test will be used as an alternative if initial testing suggests the distribution is not normal (Specific Aims 1 and 2). The F test will be used to test comparison data for equal variances. If variance is found to be unequal, the non-parametric Kruskal-Wallis test will be used. Alpha will be .05.
Limitations

Limitations of the hemodynamic substudy include (a) circadian rhythm may mask short-term periodicity in turning patterns (Cugini et al., 1993; Sothern et al., 1995; Veerman, Imholz, Wieling, Wesseling, & van Montfrans, 1995), (b) the manual-turn protocol does not allow for precise recording of turning times, and (c) not all mechanically ventilated ICU patients have an arterial line. However, as discussed under Preliminary Studies, the perturbations in hemodynamic data are expected to allow identification of turning time within a 10-minute time window.

Timeline

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<th>STUDY MONTH</th>
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<td>Pilot hemodynamic substudy with manual turn protocol</td>
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<td>Interim analysis for power calculation</td>
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Protection of Human Subjects

The Institutional Review Boards (IRB) at The University of Texas Health Science Center at Houston, SLEH, and TMH have approved the randomized clinical trial pilot study and hemodynamic substudy. Written informed consent will be obtained from subjects, if they are able to provide it, or their family/legal representative. Patient cognitive function may change over the course of mechanical ventilation. If consent is originally obtained from a family member, the patient will be consented to remain in the
study when able to do so. Because the subjects represent a vulnerable population, they will be given the opportunity to re-consent on a daily basis as able.

Potential risks to subjects are listed in the consent form and are expected to occur in < 18% of subjects, regardless of group assignment. Although lateral positioning of mechanically ventilated patients has minimal adverse events, patients with unilateral lung disease are at risk for hypoxemia when the “sick” lung is down (Banasik & Emerson, 1996). Others have shown that the hypoxemia is transient, and oxygenation returns to baseline within minutes (Jesurum, 1997). Patients who are volume depleted or have limited cardiac reserve are at risk for transient hemodynamic compromise with recovery to baseline within minutes (Gawlinski & Dracup, 1998a; Lewis et al., 1997).

Adults ≥ 18 years old will be included in the study. Gender and racial/ethnic distribution will reflect the population from which subjects are drawn; no subject will be excluded on the basis of gender or race/ethnicity.

**Risks to the subjects.**

**Characteristics.** Patients from the 7 South medical-surgical ICU at SLEH and the medical intensive care unit (MICU) at TMH will be randomly selected for potential study participation, without regard for gender or race/ethnicity. All subjects will be critically ill, on mechanical ventilation, and ≥ 18 years of age. Study sites are adult ICUs and rarely accept patients < 18 years of age. Inclusion criteria are receiving mechanical ventilation and ability to be placed on protocol within 8 hours of intubation and the initiation of mechanical ventilation. Exclusion criteria are pulmonary mass, pneumothorax, hemothorax and pleural effusion; hemodynamic instability (SBP < 90 mm Hg with vasopressor support); orthopedic injuries requiring traction; head injury requiring intracranial pressure monitoring; unstable spinal injuries; rib fractures; intubation within the previous 2 weeks, and body weight ≥ 350 pounds.
Sources of Materials. Research material for the hemodynamic substudy will include measurements of HR, SBP, DBP and MAP, obtained from the bedside clinical monitor, and angle of the subject's lateral rotation, obtained from a study laptop computer. For the automated-turn group, angle of turn will be automatically entered into the computer using a built-in turn angle sensor. For the manual-turn group, the angle of lateral rotation measured with a mini bubble protractor will be manually entered into the computer.

Potential Risks. Potential physical risks (and associated intervention group) include: hypoxemia in patients with unilateral pulmonary pathology or severe bilateral pulmonary pathology (manual and automated turns), hemodynamic compromise (manual and automated turns), disconnection of tubes and catheters (manual and automated turns), pain (manual and, to a lesser extent, automated turns), discomfort (manual and automated turns), and skin breakdown (manual turn). Potential psychological risks include anxiety and/or agitation from continuous movement and/or "fear of falling" (automated turn). There is scant data on the likelihood of the physical risks, so estimates are based on clinical experience; < 2% of subjects are likely to have serious hypoxemia, hemodynamic compromise or disconnection of tubes with the turning interventions. Previous research has shown tachycardia, hypotension, and decreased oxygen saturation with manual turning; however, in all but the sickest patients, values returned to baseline within 5 minutes of the turn. A higher percentage of subjects (~ 30%) is expected to experience pain/discomfort from the turning interventions, with greater frequency and intensity associated with the manual turn. Frail, elderly and cachectic patients in the manual turn group may develop skin breakdown. The manual turn is expected to be associated with the greatest risk and that is the standard of care. The only alternative is to leave the patient immobile in the back position, with the attendant risks of development of preventable pulmonary complications and pressure ulcers. Loss of confidentiality is a socio-legal risk.
Adequacy of protection against risks.

**Recruitment and informed consent.** The principal investigator (PI) and co-investigators will call the 7 South ICU and MICU every 4 hours and speak with the charge nurse to identify when a patient is admitted on mechanical ventilation or placed on mechanical ventilation after unit admission. The investigators will evaluate the potential subject for study eligibility. If eligible, the patient is randomly selected and acceptance by the physician or nurse of random assignment to turning group is obtained, the patient/family will be approached by a nurse investigator for consent to study participation. Most potential subjects will have cognitive impairment from critical illness and/or sedation. If the patient is unable to provide informed consent, a family member or legal guardian will be approached for consent. The investigator will explain the study, review the consent form with the family/guardian (or read it to the potential subject while holding the consent in the patient's visual field) and allow time for questions, clarification and discussion with other family members.

**Protection Against Risk.** Several procedures will help protect subjects against physical risks. The attending physician, or designee, will provide approval of random assignment to turning intervention prior to solicitation of subject/family consent to participate, and this will reduce the chances of enrolling medically unstable patients who are unlikely to tolerate lateral rotation. The research assistants or investigators will abort either turning intervention and place the patient supine for the following: (a) cardiopulmonary arrest, (b) ≥ 20 mm Hg change in MAP sustained for 5 minutes, or (c) ≥ 30 beats per minute change in HR sustained for 5 minutes, (d) ≥ 5% decrease in SpO₂ sustained for 5 minutes, or (e) supraventricular tachycardia, ventricular tachycardia/fibrillation or multifocal ventricular ectopy ≥ 5/minute. All personnel who will be involved with turning subjects are experienced ICU nurses. Indeed, the turning protocols mandate closer attention to subject response than occurs in the most optimal
clinical environment. Thus, study procedures and experienced personnel are likely to be highly effective in protecting subjects from study-related physical harm. In the event the physical changes are clinically important and/or sustained, the turn will be aborted, the subject placed in the supine position, and the adverse event recorded. The clinical staff will be notified of subject pain for medication as appropriate. Most patients on mechanical ventilation have standing orders for analgesia as needed for comfort. Study patients will receive much closer monitoring by study nurses than is received during routine clinical care.

Psychological risks will be reduced by frequent reminders of what the subjects may expect and the sensations they may feel (i.e., anticipatory guidance), and the importance of turning for prevention of the hazards of immobility.

Loss of confidentiality will be minimized in several ways. A unique study ID number will be assigned at the time of random assignment to intervention group; the study ID will be used to keep the subject’s data separated from others and will be the only identifier entered into the study database. The master file linking subjects and data and the signed consent will be kept in a locked file cabinet in a locked office in the Center for Nursing Research. The importance of maintaining subject confidentiality will be emphasized in research team training. The electronic database and subject records will use the study ID for identification. All randomized clinical trial pilot and hemodynamic substudy data will be disseminated without the ability to identify individual subjects.

The data safety and monitoring plan for the randomized clinical trial pilot study will consist of monthly meetings of the research team to formally review study progress including (a) number, gender, race and ethnicity of potential subjects screened and subjects enrolled and completed; (b) consent and re-consent processes, dropouts and reasons; (c) quality of data obtained; (d) revisions to the Operations Manual; (e) all adverse events – expected, unexpected, serious and non-serious; (f) training needs of
the research team; (g) protocol compliance and adherence; and (h) effectiveness of the randomization procedures at each study site. All protocol deviations and adverse events will be reported within 2 hours to the PI (via pager or voice mail) and site coordinator (Dr. Gusick at SLEH; Ms. Hamlin at TMH); these individuals will evaluate the deviation and/or adverse event within 8 hours of occurrence and complete the site adverse event log. The PI will report in writing serious adverse events that are expected and unexpected to the University of Texas Health Science Center at Houston Committee for the Protection of Human Subjects within 24 hours, using the form provided in the institution's integrated Research Information System (iRIS). The site coordinators will report in writing serious adverse events to their respective IRBs according to institutional policy.

**Potential benefits of the proposed research to the subjects and others.**

There will be no benefits to the subjects from participation in this study, although they will receive more vigilant monitoring and will experience increased turning frequency, intensity and duration compared with routine clinical care. Efficacy and safety of the turning interventions have been compared neither adequately nor systematically. The findings from the randomized clinical trial pilot study and hemodynamic substudy will inform the randomized clinical trial, and the randomized clinical trial findings are expected to provide valid, reproducible, and clinically useful information on efficacy and safety of manual and automated turning.

**Importance of the knowledge to the gained.**

The findings from the randomized clinical trial will provide data on the efficacy and safety of two turning interventions for critically ill mechanically ventilated patients. The efficacy of automated turning with a specialty bed has been examined in several trials, but protocol adherence was inadequate, adverse events were not reported, and manual turning (standard of care and control group) was not controlled. Because the cost of automated turning is higher than manual turning, compliance with the standard of care
has been shown to be abysmal, and both serious and non-serious adverse events may plague both turning interventions, the hemodynamic substudy and proposed randomized clinical trial will provide information to guide decisions about turning mechanically ventilated critically ill patients. Both study interventions are expected to pose physical and psychological risks, but the potential risks are greater with the standard of care and will be no greater in the study than occur in clinical practice. The vigilant monitoring provided by study nurses may reduce the duration of adverse events that occur.

**Relevance to Public Health**

The future randomized clinical trial and the hemodynamic substudy are expected to yield findings that will improve the health of mechanically ventilated critically ill patients by preventing, slowing the progression and/or accelerating the resolution of preventable pulmonary complications; and identifying turning-related hemodynamic safety concerns. Equal or superior efficacy and safety of the study turning interventions will have an impact on both quality and cost of critical care nursing services.

**Inclusion of Children**

Children between the ages of 18 and 21 years will be included in the study. Children less than 18 years of age will be excluded from the study based on the abundant literature demonstrating the effects of growth through approximately age 18 years on pulmonary function variables (Murray, 1976) pertinent to the development of preventable pulmonary complications. Children under the age of 18 years are rarely admitted to the study units, which are adult ICUs.

**Inclusion of Women and Minorities**

Women and minorities will be included as they are represented in the patient bases of the study sites. No gender or minority subgroup analyses are planned because we are unaware of evidence suggesting gender, ethnic or racial differences in pulmonary or hemodynamic function that would be affected by or affect lateral rotation.
Study Sites

St. Luke’s Episcopal Hospital: St. Luke’s Episcopal Health System is a faith-based, non-profit organization comprised of SLEH in the Texas Medical Center, St. Luke’s Episcopal Health Charities, St. Luke’s Community Medical Center-Woodlands, and Kelsey – Seybold Management. SLEH Texas Medical Center is a tertiary/quaternary care teaching hospital serving the greater Houston area with patients from over 70 countries. SLEH was the first hospital in Texas designated as Magnet status for nursing excellence by the American Nurses Credentialing Center. It provides over 24 clinical services with specialties in cardiology, cardiovascular surgery, orthopedics, high-risk obstetrics, digestive disorders, oncology and urology. It is home to the Texas Heart Institute founded by Denton Cooley in 1962 and has been consistently rated among the top 10 cardiology and heart surgery centers in the nation by US News and World Report. SLEH is the primary adult teaching hospital for Baylor College of Medicine and is affiliated with the University of Texas Health Science Center at Houston. The facility is licensed for 946 beds, 44 operating rooms, and 125 critical care beds. The hospital has over 31,000 adult admissions annually, and over 12,000 inpatient surgeries a year. The number of ICU admissions in FY 05 was 6,618 (21% of total hospital admissions). It employs over 1400 RNs with a case mix index of 1.8. SLEH is affiliated with several schools of nursing: University of Texas Health Science Center at Houston, Texas Woman’s University, Houston Baptist University and Prairie View A & M University.

The Methodist Hospital: Generating $1.09 billion in net patient revenue in 2003, TMH System includes TMH in the Texas Medical Center and three community-based hospitals (Methodist Willowbrook, Methodist Sugarland, and San Jacinto Methodist). Founded in 1919, TMH is an urban, tertiary, 900-bed academic health center with five ICUs and over 34,000 inpatient and 1,500 MICU admissions per year. U.S. News and World Report (2005) named TMH as one of America’s top hospitals in neurology and
neurosurgery, heart and heart surgery, and urology. TMH has been a Magnet
designated institution since 2002, employing over 1,700 nurses (associate degree 20%,
baccalaureate degree 55%, diploma 16%, masters degree 6%, and doctoral degree
<1%).
References


March 16, 2010

Joseph E. Parrillo, MD, FCCM  
Editor-in-Chief, Critical Care Medicine  
Society of Critical Care Medicine  

Dear Dr. Parrillo,

Enclosed is a manuscript for review for possible publication in Critical Care Medicine entitled, “Hemodynamic Changes Associated with Manual and Automated Lateral Rotation in Mechanically Ventilated Intensive Care Unit Patients.” The manuscript is 22 pages long and includes 3 tables and 2 figures.

I have no financial interests to declare. Grant funds were used to pay rental costs of the experimental-group bed used for the study.

Sincerely,

Shannan K. Hamlin, MSN, RN, ACNP, CCRN  
University of Texas School of Nursing at Houston  
Center for Nursing Research, Room 592  

(office)  
(fax)
Hemodynamic Changes Associated with Manual and Automated Lateral Rotation in Mechanically Ventilated Intensive Care Unit Patients

Shannan K. Hamlin, MSN, RN, PhD Student
University of Texas Health Science Center at Houston School of Nursing
Acute Care Nurse Practitioner, The Methodist Hospital

Key words: Blood pressure, ensemble averaging, heart rate, hemodynamic monitoring, intensive care unit, lateral rotation
ABSTRACT

Objective: To investigate hemodynamic responses to lateral rotation.

Design: Time-series within randomized controlled trial.

Setting: Two tertiary care hospitals.

Patients: Adult patients receiving mechanical ventilation.

Interventions: Two-hourly manual or continuous automated lateral rotation.

Measurements and Main Results: Heart rate (HR) and arterial pressure were sampled every 6 seconds for > 24 hours, and pulse pressure (PP) was computed. Turn data were obtained from a turning flow sheet (manual turn) or with an angle sensor (automated turn). Within-subject ensemble averages were computed for HR, mean arterial pressure (MAP), and PP across turns. Sixteen patients were randomized to either the manual (n = 8) or automated (n = 8) turn. Three patients did not complete the study due to hemodynamic instability, bed malfunction or extubation, leaving 13 patients (n = 6 manual turn and n = 7 automated turn) for analysis. Seven patients (54%) had an arterial line. Changes in hemodynamic variables were statistically significant increases (p < .05), but few changes were clinically important, defined as ≥ 10 bpm (HR) or ≥ 10 mmHg (MAP and PP), and were observed only in the manual-turn group. All manual-turn patients had prolonged recovery to baseline in HR, MAP and PP of up to 45 minutes (p ≤ .05). No significant turning-related periodicities were found for HR, MAP, or PP. Cross-correlations between variables showed variable lead-lag relations in both groups. A statistically, but not clinically, significant increase in HR of 3 bpm was found for the manual-turn group in the back compared with the right position (F = 14.37; df = 1, 11; p = .003).

Conclusions: Mechanically ventilated critically ill patients experience modest hemodynamic changes with manual lateral rotation. A clinically inconsequential increase
in HR, MAP, and PP may persist for up to 45 minutes. Automated lateral rotation has negligible hemodynamic effects.
Mechanically ventilated critically ill patients are at high risk for developing such preventable pulmonary complications as ventilator-associated pneumonia and atelectasis. A standard of care to reduce preventable pulmonary complications is lateral rotation every 2 hours. Lateral rotation in mechanically ventilated intensive care unit (ICU) patients has been shown to adversely affect hemodynamics (Gawlinski & Dracup, 1998a), with studies showing a greater change in the left versus the right position (Jones & Dean, 2004; Nakao et al., 1986). Although adverse hemodynamic effects related to lateral position are typically transient (Lewis et al., 1997), clinicians may be reluctant to laterally position mechanically ventilated patients who are critically ill.

Positive pressure ventilation can reduce venous return (Fessler et al., 1992), with subsequent reduction in cardiac output (Pinsky et al., 1985; Qvist et al., 1975). Lateral positioning may augment adverse hemodynamic effects in mechanically ventilated patients, particularly when they are turned to the left side. The diameter and area of the inferior vena cava are smaller in the left lateral than the right lateral position, presumably due to compression of the inferior vena cava from the liver (Nakao et al., 1987). In mechanically ventilated patients, the weight of the hyperinflated right lung may further compress the inferior vena cava, particularly if the patient is on positive end-expiratory pressure (Fessler et al., 1993). However, a decrease in blood pressure in both lateral positions, compared with the back position, has been demonstrated in several studies (Jones & Dean, 2004; Pump et al., 2002). Gawlinski and Dracup (1998a) found recovery of blood pressure to baseline values within 5 minutes, suggesting that the effect of lateral rotation is transient. Because compression of the inferior vena cava, and resultant decrease in venous return, would be maintained throughout time in the lateral position, the transient effects on blood pressure suggest either (a) patient compensation, or (b) the hemodynamic response is to the physical act of turning and not the lateral position per se. Research on the hemodynamic effects of lateral rotation generally has been
limited by the use of discrete, point-in-time measurements in patients turned manually and the studies have been of short duration, which does not reflect the reality of the frequent changes in physiologic status of the mechanically ventilated critically ill patient. The hemodynamic effects of automated turning have not been systematically evaluated.

We conducted a pilot study for a randomized clinical trial (RCT) to compare the efficacy and safety of two turning interventions (ClinicalTrials.gov: NCT00542321). As a component of the safety assessment, we examined the turning-related hemodynamic responses in the two turning groups: manual turning every 2 hours (standard of care and control group) and continuous automated turning with a kinetic therapy bed (experimental group). Changes in heart rate (HR), mean arterial pressure (MAP) and pulse pressure (PP) were assessed as hemodynamic responses to the turning interventions. Using a time-series design with automated signal processing and ensemble-averaging, HR, systolic blood pressure (SBP), diastolic blood pressure (DBP), and MAP were captured every 6 seconds for > 24 hours; PP was computed from SBP and DBP.

**Materials and Methods**

The research protocol was approved by the Institutional Review Boards of the University and the two participating hospitals. Sixteen adult patients were recruited over a period of 8.6 months from two ICUs in two tertiary care hospitals: an 18-bed medical-surgical ICU and a 24-bed medical ICU. Study units were contacted by a clinical investigator every 4 hours to inquire about potential study patients from the unit charge nurse. All patients admitted to the study units intubated, or who were intubated during their ICU stay, were assessed for study eligibility. Inclusion criteria were receiving mechanical ventilation and able to be placed on protocol within 8 hours of intubation and the initiation of mechanical ventilation. Exclusion criteria included conditions that cause compression atelectasis and/or are contraindications to turning: (a) pulmonary mass,
pneumothorax, hemothorax, pleural effusion, and other sources of compression
atelectasis; (b) hemodynamic instability, defined as SBP < 90 mm Hg with vasopressor
support; (c) orthopedic injuries requiring immobility; (d) head injury requiring intracranial
pressure monitoring; (e) unstable spinal injuries; (f) rib fractures; (g) intubation within the
previous 2 weeks to control for the presence of residual preventable pulmonary
complications; and (h) body weight ≥ 159 kg, an experimental bed limitation. After
eligibility was determined, a randomization database (Padhye, Cron, Gusick, Hamlin, &
Hanneman, 2009) was used for determination of random selection and random
assignment. If the patient was selected to approach, the physician or nurse accepted
random assignment of turning intervention, and written informed consent was obtained,
the patient was assigned randomly to the manual or automated turn group for up to 7
consecutive days.

Interventions

Manual Turning. The salient aspects of the protocol included ≥ 45° lateral turn;
head-of-bed (HOB) ≥ 30° to reduce risk of aspiration in the lateral and back positions
(CDC, 2004); use of dedicated research nurses to ensure frequency, angle, and duration
of turn; and tracking of compliance with the intervention protocol, including attrition 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 reason for protocol violation.

Automated Turning. The TriaDyne Proventa bed (Kinetic Concepts, Inc., San
Antonio) was used for automated turning. Salient aspects of this protocol were lateral
rotation to a ≥ 40° angle; essentially continuous rotation (rotation was paused for short
periods as needed for such care as linen change); HOB elevation ≥ 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, including attrition and adverse events associated with turning. Study nurses measured the maximum angle and direction of turn every hour.

**Study Procedures**

Hemodynamic data were obtained with a physiologic monitor (HP Component Monitoring System, Philips Medical Systems, Andover, MA or Solar 8000, Marquette, Milwaukee, WI) and arterial line pressure transducer (Edwards Lifesciences, PX600F or PX284, Irvine, CA). Manufacturers of the physiologic monitors report accuracy of ± 1% for HR and ± 2% for MAP, exclusive of the transducer, and precision of ± 1 mmHg over 24 hours (Marquette Medical Systems, 1998; Philips Medical Systems, 2003). The pressure transducer has accuracy of ± 1 mmHg and precision of ± 1 mmHg over 8 hours (Edwards Lifesciences, 2006). Heart rate and blood pressure from the HP Component Monitoring System were directly transferred via RS232 serial interface to a laptop computer using a custom-written software application in the LabView programming environment (National Instruments, Austin, TX), directly downloaded into a computer file every 1024 milliseconds, and aggregated to every 6 seconds. For the Solar 8000 monitor, BedMaster (Excel Medical Electronics, Jupiter, FL) software was used to communicate with the hospital’s Unity Network (General Electric/Marquette) to download hemodynamic data to a computer file every 6 seconds. Pulse pressure was calculated (SBP - DBP) automatically after the data were imported into the database.

The Proventa bed was equipped with a built-in angle sensor for this study. Automated turn angles were saved to a computer file every 1 second. The signal (0 - 5V) was converted to angle data (< 2.5 voltage = negative angle = left turn and 2.5 - 5 voltage = positive angle = right turn) using the formula 20 * (voltage - 2.5). For patients in the manual-turn group, turning direction (back, left or right) was manually entered into the hemodynamic database from the RCT pilot study database; the automated-turn
group patient positions were obtained from the angle sensor data. Patient demographics, treatment variables and group assignment were retrieved from the RCT database.

Data Management and Analysis

SPSS (version 17.0, SPSS Inc., Chicago, IL) and TIBCO Spotfire S+ (Version 8.1, TIBCO Software, Inc.) software programs were used for data management and analyses. The data were examined for outliers, defined as ≥ 3 standard deviations from the mean, and missing data; both were replaced with linear interpolation. Ensemble averaging (Lodato & Jubran, 1993) was used to assess within-subject hemodynamic responses. Data were evaluated for 1) graphical characteristics of increase or decrease in the variable for the manual-turn group and 95% confidence interval overlap for the automated-turn group; 2) statistical significance; 3) clinical significance; and, in the manual-turn group, 4) recovery time, defined as length of time for the value to return to baseline. A change ≥ 10 bpm in HR and ≥ 10 mmHg in MAP and PP and ≥ 5 minutes for recovery time were determined *a priori* as clinically important changes.

For the manual-turn patients, HR, MAP, and PP data were segregated into two turn categories: back → left and back → right. Using scripts developed in S+ by the third author (NSP), ensemble-averaged data were placed in 12-second bins starting 15 minutes before the turn (pre-turn period) and ending 45 minutes after the turn (post-turn period). The first 5 minutes of the pre-turn period was considered the baseline interval. Starting at the end of the baseline interval, data intervals of 5-minute duration were moved forward in 1-minute increments to statistically compare the baseline interval with each subsequent test interval. With a first-order autoregressive (AR) model (Yaffee, 2000) to account for the autocorrelated nature of the data, ensemble averages were computed from individual turns within each turn category to compare mean baseline data with mean data during and after the turn and estimate recovery time back to
baseline. For each variable, the patient's maximum magnitude of change was identified from the statistically significant differences in the first 15 minutes from the baseline interval. Differences beyond this time frame could be attributed to factors unrelated to the turn.

For the automated-turn patients, HR, MAP and PP were segregated into 10° angle bins from 0° to ≤ - 30° on the left and 0° to ≥ 30° on the right for a total of eight angle bins (four per quarter turn). The last bin on each side was an 'open' bin due to variable maximum angles obtained with the automated bed (± 30° to ± 60°). Bin angles from - 10° to 10° were considered the back position. Two databases were used for analyses of automated-turn patient data. Database A contained the maximum amount of data by excluding only those data gaps > 1 minute and turns with < 5 minutes of data. Database B further excluded data with sudden angle stoppage or changes of angle, which occurred when the bed was reset to the center, to select the best segment of data for autocorrelation function (ACF) and cross-correlation analyses that require equally-spaced, continuous data.

The transducer was not re-leveled during automated turning. To account for hydrostatic pressure effects related to change in pressure transducer height from the established zero-reference point, a correction formula was developed by the third author (NSP) based on the concept of precession (Padhye, Hamlin, Brazdeikis, & Hanneman, 2009). The height-adjusted model was computed as: \( \text{MAP} = \text{MAP}_0 + a(1 - \cos(\theta/5)) - b\sin(\theta) \), where \( \text{MAP}_0 \) is a constant level, \( \theta \) is the angle of rotation, \( a \) is the precession arm length, and \( b \) is the asymmetry arm of the measurement point from the bed's axis of rotation. The maximum displacement estimate from the regression model was 13.6 cm which would equate with a 10 mmHg change in pressure. For blood pressure, height-adjusted analyses using mean data were 4 – 10 mmHg lower than without the height adjustment. The height adjustment correction was not applied to PP because it is the
difference between SBP and DBP, two quantities that are both equally affected by the height change. Pulse pressure therefore, reflects a difference that is independent of height.

Longitudinal mixed effects models (Petrie & Sabin, 2005) with first-order AR structure were used to compute ensemble averages. The models determined a mean value for each angular bin and an overall mean value; the 95% confidence interval of the overall mean estimated variability. Analysis of variance was used to compare HR, MAP and PP changes between back → right and back → left positions. In the automated-turn group, the differences between means in different angle bins were compared because the continuous turning made differences between dynamic and equilibrium changes moot. Angle bins in the back position were combined and then compared separately with angle bins in the left and right positions.

Within-subject ACF and cross-correlations were calculated for HR, MAP, and PP. For the manual-turn group, number of lags was equal to the length of time-series data and included at least two 8-hour cycles (2-hour positioning from back → left → back → right) of data. Lag time was 300 for the automated-turn group to include at least 2 cycles of 12-minute complete turn data (back → left → back → right). Autocorrelation function graphs were examined for periodicities that correspond to the same time period as lateral turning: every 2, 4, or 6 hours in the manual-turn group and ≤ 12 minutes in the automated-turn group. Cross-correlation graphs were examined for a significant relation between the correlated variables as well as the direction and magnitude of relation. Differences between groups were evaluated with two-way repeated-measures analysis of variance.

Continuous variables are expressed as mean ± standard deviation, with the 95% confidence interval when appropriate. Categorical variables are summarized as frequencies and percentages.
Power Calculations

No data were available to estimate sample size a priori; therefore, power calculations with $\alpha = .05$, $n = 6$ in the manual-turn group, and $n = 7$ in the automated-turn group were computed a posteriori using the within-group means and standard deviations of the difference between back and lateral positions. Within-group power was determined with the one-tailed one-sample test of means against the clinically important difference (10 bpm or mmHg). Between-group power was determined with the one-tailed two-sample test of means. Power was $\geq 96\%$ to detect differences in HR, MAP, and PP between the back and lateral positions in the manual-turn and the automated-turn groups. Power exceeded 89\% for HR and MAP changes between groups. To achieve adequate power, 169 patients per group would be needed to detect clinically important between-group differences in PP. Consequently, the study was adequately powered to detect clinically important changes in HR and MAP and within-group changes in PP, but not clinically important PP changes between turning-intervention groups.

Results

Sixteen patients were enrolled in the study, with 13 patients included in the analysis. Attrition was 19\%; two patients were unable to complete the study because of hemodynamic instability (manual-turn group) or equipment malfunction (automated-turn group), and one patient was extubated < 5 hours after enrollment (manual-turn group). Patient demographic and clinical characteristics are summarized in Table 1. The sample included seven males and six females between the ages of 38 and 77 years. Six patients (46\%) were randomly assigned to the control group and seven (54\%) to the experimental group. Data collection time varied from 27 hr 17 min to 168 hr 25 min. Heart rate data were collected in all patients, and blood pressure data were collected in the seven patients (54\%) who had an arterial line placed for clinical purposes. Differences in patient characteristics were not statistically significant between the
manual and automated turn groups. Standardized residuals were ≤ ± 2 for all hemodynamic variables, suggesting normal distribution of the data (Altman, 1991). The length of time-series data used in the analysis for each subject varied from 16,247 to 99,095 data points (79:11 ± 51:19 hours for the manual-turn group and 75:31 ± 55:13 hours for the automated-turn group) and was not significantly different between groups (p = .90). Combined outlier and missing values represented ≤ 3.4% of the data. Turning was maintained for 94% of the time subjects were on protocol and mean turn angle was 50 ± 5° for the manual-turn group; these values were 91% and 32 ± 3°, respectively, for the automated-turn group. Turn angle, obtained from the RCT database measurements, was significantly different between groups (p = .003), but not between study sites (p = .94). Within-subject mean (± standard deviation) changes in HR, MAP, and PP and recovery time across all turns and positions for each patient in the manual-turn group are presented in Table 2. Mean (± standard deviation) changes in HR, MAP, and PP across all turns and positions for each patient in the automated-turn group are shown in Table 3.

**Ensemble Averages of the Manual-Turn Group.** The number of individual turns per patient varied from 3 to 19. Lateral turns induced changes in HR, MAP and PP (Figure 1). Visual inspection of the ensemble averages showed that the recorded turning time was imprecise. The graphed data suggest that actual turn time varied by up to ± 10 minutes of the recorded turn time. Even with imprecise turn times, graphical displays of the manual-turn data clearly show hemodynamic responses to turning both in the individual turns and ensemble-averaged data, with prolonged recovery times back to baseline. Changes in HR varied from −1 to +22 bpm. Two patients showed clinically important changes in HR in the left position and two patients in the right position. With the exception of one patient in the back → left position, all patients showed a prolonged
recovery time in HR from 9 to ≥ 45 minutes after turning. Figure 1 A-2 shows the HR ensemble averages for patient P001 as an example.

Four of six (67%) manual-turn patients had an arterial line. Two patients had statistically and clinically significant increases in MAP with position that varied from +13 to +22 mmHg. Magnitude of change was not different between back → left (+22 mmHg) and back → right (+21 mmHg) lateral rotation. All patients except one had prolonged recovery times that varied from 9 to 43 minutes before the MAP returned to baseline. Figure 1B-2 shows the MAP ensemble averages for P001. Four patients had statistically significant changes in PP associated with manual turning: three patients showed an increase and one patient a decrease, but only one of these was a clinically important change, with the greatest magnitude of +23 mmHg in the back → left position. Three patients had prolonged PP recovery time of up to 43 minutes. Figure 1 C-2 shows the PP ensemble averages for P001.

**Ensemble Averages for the Automated-Turn Group.** The percentage of data used in this analysis varied from 76% to 100%, with 87 to 817 turns within each bin; the total number of data points used in the analysis varied from 11,252 to 84,314. Because the patients were in constant motion, recovery time could not be calculated. Automated turning induced changes in HR, MAP, and PP. Figure 2 shows the ensemble averages for patient P008 as an example. Three of the seven (43%) patients had a statistically significant HR response to left and right turning compared with the back position (Table 3). However, the changes were not clinically important; the maximum response was ± 2 bpm when compared with the back position. Three of the seven automated-turn group patients (43%) had an arterial line. All three patients had a statistically significant decrease in MAP when turned to the left and right positions compared with the back position; the magnitude of response varied from -4 to -9 mmHg, which was not clinically important. All three patients had a statistically significant change in PP in both the left
and right positions compared with the back position; the changes were not clinically important, with the maximum response $\leq 5$ mmHg.

**Autocorrelation Function and Cross-Correlations.** For the manual-turn group, complete time-series data were used for the ACF and cross-correlation analyses, and the number of data points varied from 16,247 to 99,095. With ACF, small (.10-.29; Cohen, 1988), statistically significant correlations were found in three patients for MAP and one patient for PP; however, the times did not correspond to turn times. For the automated-turn group, the best continuous segment of data (Database B) was used; the total number of data points varied from 4,490 to 9,456 (8% - 48% of the data collected), and the total number of turns within each bin varied from 65 to 85. No significant correlations were found for HR, MAP, or PP. Within-subject cross-correlations between HR and PP were significant for all patients, with variable magnitude, direction and lag time. HR and MAP were significantly correlated in three patients, and MAP and PP were significantly correlated in one patient; magnitude, direction and lag time were variable.

**Two-Way Repeated Measures Analysis of Variance.** There was a statistically significant change in HR for the manual-turn group in the back compared with the right lateral position ($F = 14.37$, $df = 1, 11$, $p = .003$). Although the effect was large (partial eta squared $= .57$), the change (3 bpm) was not clinically important. No other within-group differences in position or position by group interaction were significant. Between-group differences in HR, MAP and PP were not significant.

**Discussion**

In this RCT pilot study of manual vs. automated lateral rotation in a sample of medical-surgical mechanically ventilated ICU patients from two tertiary hospitals, there were statistically significant changes in HR, MAP and PP with manual turning; the HR and MAP changes were clinically important in 50% of the patients and PP changes in 25%. Time for the hemodynamic parameters to return to baseline values was highly
variable and, in some cases, HR did not recover to baseline within the observation period of 45 minutes after a turn. Although all patients with an arterial line in the automated-turn group had a statistically significant change in MAP and all but one in PP in the lateral position, less than half had a statistically significant change in HR and none of the hemodynamic changes were clinically important. Furthermore, the MAP differences were not statistically significant with the height-adjusted model that was developed to control for the inability to re-level the transducer with automated lateral rotation. Because there were no statistically significant differences between groups in the measured patient demographic or clinical characteristics, these results indicate that automated turning does not adversely affect hemodynamic status and may be the preferred turning intervention when patients are at risk for hemodynamic instability. Such patients may exhibit clinically important hemodynamic changes when turned manually to ≥45°, as was exhibited in half of the patients in the manual-turn group.

Based on the extant literature and physiologic considerations that conspire to reduce venous return in mechanically ventilated patients, we expected to see a decrease in MAP with lateral rotation. Furthermore, we expected a greater MAP decrease in the left lateral position, compared with the right. Others have demonstrated increased oxygen consumption and decreased mixed venous oxygen saturation when patients were turned laterally, with the greatest decrease in the left lateral position (Gawlinski & Dracup, 1998a; Lewis et al., 1997; Shively, 1988; Winslow et al., 1990). Because recovery to baseline was within minutes of the turn in these studies, a transient increase in peripheral use of oxygen due to muscle activity (Gawlinski & Dracup, 1998a) is a plausible explanation. In the present study, as shown in Figure 1, marked increases in HR and MAP with manual turns were reproducible and transient, suggesting that the physical turning maneuver produced a sympathetic nervous system response that abated with time in the lateral position. Inconsistent with the findings of others (Bein et
al., 1996), we did not find differences in HR or MAP between the left and right lateral positions. Bein and colleagues (1996) observed an increased HR in the left and right positions and decreased MAP on the right side 15 minutes after a manual turn, whereas in our patients the changes abated before then. The recovery time differences may be related to different patient populations, turning protocols and sampling densities. Although the mean APACHE II score was higher in our study (26 vs. 20), all patients in the Bein study had acute respiratory failure and were receiving inotropic therapy, in contrast to 38% and 46% of our patients, respectively; were turned to a 62° lateral angle compared with 50° in the present study; and one measurement was made after 15 minutes in the lateral position compared with our nearly continuous measurement.

We used PP as a surrogate for stroke volume. Our study was not powered to detect between-group differences in PP, but the differences are likely to be small given that a sample size of 338 patients would be needed to find a clinically meaningful effect. It may be that, in our study, turn angles were insufficiently steep to compress the inferior vena cava. Patients were laterally rotated to 90° in those studies in which differences in left and right positions were found (Jones & Dean, 2004; Nakao et al., 1987).

The modest increases in hemodynamic values that were maintained with time in a lateral position reflect the real impact of the lateral position, and these changes are not of clinical consequence. We defined clinically important changes as those exceeding what would be considered to reflect biological variability (Emerson & Banasik, 1994) and not as changes that would suggest the need to discontinue lateral rotation. The patient whose data are shown in Figure 1 had the greatest magnitude of response to turning of all the patients; thus, these data represent the "worst-case" scenario in the study sample. Clinicians considered this patient and others we studied to be too hemodynamically unstable to turn. Had turning been aborted on these grounds, such patients could conceivably be in the back position for days, putting them at risk for a host
of pathological sequelae. One enrolled patient could not complete the study because SBP fell below a rotation “stopping rule” in the back position. It should be noted that patients with hemodynamic instability, defined for this study as SBP < 90 mmHg on vasopressor support in the back position, were either not eligible or were dropped from the study if hemodynamic stability was not achieved within 4 hours. Thus, our findings do not apply to mechanically ventilated patients who are hemodynamically compromised according to our definition. If the SBP was ≥ 90 mmHg in the back position, with or without vasopressor support, the patient was turned according to protocol, and all patients tolerated lateral rotation with respect to hemodynamic status.

Our study findings provide an uncommon characterization of nearly-continuous hemodynamic response to lateral rotation with manual and automated turning methods. Ensemble averaging offers advantages for characterizing such time-dependent data as HR, MAP and PP. This method acknowledges the autocorrelation inherent in the values of nearly-continuous measures and thus represents a more precise approximation of the real physiological state than point-in-time measurements. We used 6-second sampling to minimize signal noise and dampen variability that is not of clinical interest. Whereas ensemble averaging improves precision, it does not improve accuracy, and the accuracy of MAP and PP in this study may have been affected by changes in the level of the transducer relative to the phlebostatic axis with the turning interventions. Every manual turn required manipulation of the head-of-the-bed and horizontal angle, and the automated turn constantly shifted the relation between transducer and phlebostatic axis. We did not systematically re-level the arterial transducer with changes in patient position. In the manual-turn group, the magnitude of clinically significant differences in MAP were equivalent in the left and right positions. A hydrostatic pressure effect would be expected to produce differences in magnitude between left and right lateral positions. The correction formula we applied to the MAP data in the automated-turn group has not
been tested systematically beyond the small sample studied here. Nonetheless, mean differences in MAP with and without the height-adjusted model were < 10 mmHg. Other design features also minimized inaccuracy of the blood pressure variables. We used the graphical changes in each variable to denote the time of the turning maneuver; an increase in each variable was reproducible for nearly every turn as illustrated in the example in Figure 1. We then compared pre-turn with post-turn data for each patient and averaged the mean across all turns in the same direction for that patient. Finally, we computed the mean change for all patients in each group. This approach decreased statistical error. We assessed change as clinically important by eliminating that due to biological variability. The absence of clinically important findings with the ensemble averaging method was validated by the absence of significant ACF related to turning times, albeit less than half of the automated-turn data could be used in this analysis.

Conclusions and Implications

Clinicians caring for mechanically ventilated critically ill patients must ensure patient safety while attempting to prevent the hazards of immobility. Lateral rotation every 2 hours is a standard-of-care intervention to minimize complications associated with immobility. Previous research has demonstrated adverse hemodynamic effects, albeit transient, with lateral rotation. Clinicians are therefore often reluctant to turn patients, fearing hemodynamic compromise in an already physiologically-compromised patient.

The findings from this study indicate that medical and surgical mechanically ventilated ICU patients may experience hemodynamic changes when manually turned to ≥ 45°, but these changes are transient and related to the turning maneuver. No differences between left and right lateral rotation should be anticipated. A modest change in hemodynamic response to lateral positioning may persist for up to 45 minutes or more, but the magnitude of change in HR, MAP or PP is tolerated clinically and
patients can safely remain in the lateral position for the 2-hour turn period. Automated lateral turning in a specialty bed designed to turn to a ≥ 40° angle appears to have no adverse hemodynamic effects, and, although not tested for such in this study, may be a useful turning method for patients with hemodynamic instability. Clinicians are urged to reconsider hemodynamic compromise as an absolute contraindication to lateral rotation, and anticipate increases in HR, MAP, and PP which are likely to subside within 15 minutes after the turning maneuver.

Acknowledgments

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References


Table 1

Patient demographic and clinical characteristics (N = 13).

<table>
<thead>
<tr>
<th>Patient Characteristic</th>
<th>Result</th>
<th>P Value</th>
</tr>
</thead>
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<tr>
<td>Age (years), range (M ± SD)</td>
<td>38 - 77 (57 ± 11.9)</td>
<td>P = .38</td>
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<tr>
<td>Manual-Turn</td>
<td>38 - 77 (54 ± 11.9)</td>
<td></td>
</tr>
<tr>
<td>Automated-Turn</td>
<td>45 - 75 (60 ± 10.7)</td>
<td></td>
</tr>
<tr>
<td>Gender (male (%), female (%))</td>
<td>7 (46%), 6 (54%)</td>
<td>P = .76</td>
</tr>
<tr>
<td>Manual-Turn</td>
<td>3 (50%), 3 (50%)</td>
<td></td>
</tr>
<tr>
<td>Automated-Turn</td>
<td>4 (57%), 3 (43%)</td>
<td></td>
</tr>
<tr>
<td>APACHE II score, range (M ± SD)</td>
<td>15 - 36 (26 ± 5.9)</td>
<td>P = .19</td>
</tr>
<tr>
<td>Manual-Turn</td>
<td>18 - 36 (29 ± 6.6)</td>
<td></td>
</tr>
<tr>
<td>Automated-Turn</td>
<td>15 - 29 (24 ± 4.8)</td>
<td></td>
</tr>
<tr>
<td>Vasopressor, number (%) patients requiring</td>
<td>6 (46%)</td>
<td>P = .41</td>
</tr>
<tr>
<td>Manual-Turn</td>
<td>4 (67%)</td>
<td></td>
</tr>
<tr>
<td>Automated-Turn</td>
<td>2 (33%)</td>
<td></td>
</tr>
<tr>
<td>PEEP (cmH\textsubscript{2}O), range (M ± SD)</td>
<td>0 - 12.5 (M = 5.3 ± 3.1)</td>
<td>P = .94</td>
</tr>
<tr>
<td>Manual-Turn</td>
<td>0 - 12 (M = 5.3 ± 3.6)</td>
<td></td>
</tr>
<tr>
<td>Automated-Turn</td>
<td>0 - 12.5 (M = 5.4 ± 3.0)</td>
<td></td>
</tr>
<tr>
<td>Duration of data collection, hours:min (M ± SD)</td>
<td>27:18 to 168:25 (80:06 ± 52:33)</td>
<td>P = .73</td>
</tr>
<tr>
<td>Automated-Turn</td>
<td>27:18 to 161:46 (75:13 ± 55:29)</td>
<td></td>
</tr>
<tr>
<td>Diagnosis, number (%) of patients</td>
<td>Respiratory Failure – 4 (31%)</td>
<td>P = .22</td>
</tr>
<tr>
<td>Manual-Turn</td>
<td>Neurological – 4 (31%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other – 5 (38%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Respiratory Failure – 3 (50%)</td>
<td></td>
</tr>
<tr>
<td>Automated-Turn</td>
<td>Neurological – 1 (17%)</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other – 2 (33%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Respiratory Failure – 1 (14%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Neurological – 3 (43%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other – 3 (43%)</td>
<td></td>
</tr>
</tbody>
</table>

Note. M, Mean; SD, Standard Deviation; APACHE, Acute Physiology and Chronic Health Evaluation; PEEP, positive end-expiratory pressure
Table 2

Summary of within-subject ensemble-averaged mean ± standard deviation (SD) of change (Δ) and recovery time in heart rate (HR), mean arterial pressure (MAP), and pulse pressure (PP) with lateral position in the manual-turn group (n = 6). Baseline pre-turn data (back position) was compared to lateral turn data (left or right); p ≤ .05 up to 15 minutes after baseline was considered significant.

<table>
<thead>
<tr>
<th>Patient (Length of time-series data in hours and minutes)</th>
<th>HR ( \Delta ) HR ± SD (Beats per minute)</th>
<th>MAP ( \Delta ) MAP ± SD (mmHg)</th>
<th>PP ( \Delta ) PP ± SD (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recovery Period Range (Minutes)</td>
<td>Recovery Period Range (Minutes)</td>
<td>Recovery Period Range (Minutes)</td>
</tr>
<tr>
<td>P001 (28 hr, 54 min)</td>
<td>B→L = +22 ± 15(^\dagger) B→R= +17 ± 12(^\dagger) 24(^\dagger) to ≥ 45(^\dagger)</td>
<td>B→L = +22 ± 15(^\dagger) B→R= +19 ± 13(^\dagger) 17(^\dagger) to 43(^\dagger)</td>
<td>B→L = +23 ± 16(^\dagger) B→R= +18 ± 12(^\dagger) 5(^\dagger) to 10(^\dagger)</td>
</tr>
<tr>
<td>P005 (74 hr, 36 min)</td>
<td>B→L = +4 ± 2(^<em>) B→R= +6 ± 4(^</em>) 9(^<em>) to 32(^</em>)</td>
<td>B→L = +13 ± 9(^<em>) B→R= +21 ± 14(^</em>) 16(^<em>) to ≥ 37(^</em>)</td>
<td>B→L = +8 ± 5(^<em>) B→R= +9 ± 6(^</em>) 19(^<em>) to ≥ 43(^</em>)</td>
</tr>
<tr>
<td>P006 (165 hr, 09 min)</td>
<td>B→L = +3 ± 2(^<em>) B→R= +4 ± 2(^</em>) ≥ 44(^<em>) to ≥ 46(^</em>)</td>
<td>B→L = -3 ± 2(^<em>) B→R= +4 ± 2(^</em>) 9(^<em>) to 19(^</em>)</td>
<td>B→L = -2 ± 1(^<em>) B→R= -3 ± 2(^</em>) 4(^<em>) to ≥ 39(^</em>)</td>
</tr>
<tr>
<td>P009 (27 hr, 04 min)</td>
<td>B→L = +9 ± 6(^<em>) B→R= +15 ± 10(^</em>) 9(^<em>) to ≥ 46(^</em>)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>P011 (79 hr, 01 min)</td>
<td>B→L = +1 ± 0.71 B→R= -1 ± 0.71(^<em>) ± 1 to 16(^</em>)</td>
<td>B→L = -4 ± 2.82 B→R= +3 ± 2(^<em>) ± 1 to 16(^</em>)</td>
<td>B→L = +4 ± 2(^<em>) B→R= +6 ± 4(^</em>) 6(^<em>) to 13(^</em>)</td>
</tr>
<tr>
<td>P012 (101 hr, 03 min)</td>
<td>B→L = +12 ± 8(^<em>) B→R= +8 ± 5(^</em>) 34(^<em>) to ≥ 38(^</em>)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Note. B, back position; L, left lateral position; R, right lateral position; \( p ≤ .05 \); \( \dagger \) Clinical Significance; N/A, not applicable (no arterial line).
Table 3
Summary of within-subject ensemble-averaged mean ± standard deviation (SD) of change (Δ) in heart rate (HR), mean arterial pressure (MAP), and pulse pressure (PP) with lateral position in the automated-turn group (n = 7). Comparisons between back and lateral turn (left or right) data. MAP changes are shown with and without the height-adjusted model (See text).

<table>
<thead>
<tr>
<th>Patient (Length of time-series data in hours and minutes)</th>
<th>HR Δ HR ± SD (Beats per minute)</th>
<th>MAP Δ MAP ± SD (mmHg)</th>
<th>PP Δ PP ± SD (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P002 (38 hr, 27 min)</td>
<td>B - L = +0.16 ± 0.13</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>B - R= +0.07 ± 0.00</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>R - L = +0.27 ± 0.24</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>P003 (48 hr, 12 min)</td>
<td>B - L = +0.09 ± 0.14</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>B - R= -0.19 ± 0.04</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>R - L = +0.28 ± 0.10</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>P007 (27 hr, 18 min)</td>
<td>B - L = +0.10 ± 0.02</td>
<td>B - L = -9.10 ± 0.31*</td>
<td>B - L = -5.27 ± 0.53*</td>
</tr>
<tr>
<td></td>
<td>B - R= -0.11 ± 0.12</td>
<td>B - R= -7.64 ± 0.79*</td>
<td>B - R= -5.14 ± 0.43*</td>
</tr>
<tr>
<td></td>
<td>R - L = +0.22 ±0.15</td>
<td>R - L = -1.47 ± 0.47</td>
<td>R - L = -0.13 ± 0.96</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Height Adjusted</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B - L = -0.10 ± 0.78</td>
<td>B - L = -0.10 ± 0.78</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B - R= -0.08 ± 0.02</td>
<td>B - R= -0.08 ± 0.02</td>
<td></td>
</tr>
<tr>
<td></td>
<td>R - L = -0.02 ± 0.76</td>
<td>R - L = -0.02 ± 0.76</td>
<td></td>
</tr>
<tr>
<td>P008 (142 hr, 16 min)</td>
<td>B - L = +0.75 ± 0.59*</td>
<td>B - L = -4.76 ± 0.12*</td>
<td>B - L = -1.33 ± 0.16*</td>
</tr>
<tr>
<td></td>
<td>B - R= -0.91 ± 0.33*</td>
<td>B - R= -4.44 ± 0.07*</td>
<td>B - R= +0.31 ± 0.24*</td>
</tr>
<tr>
<td></td>
<td>R - L = +1.66 ± 0.92</td>
<td>R - L = -0.32 ± 0.19</td>
<td>R - L = -1.65 ± 0.08</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Height Adjusted</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B - L = +0.19 ± 0.54</td>
<td>B - L = +0.19 ± 0.54</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B - R= -0.53 ± 0.71</td>
<td>B - R= -0.53 ± 0.71</td>
<td></td>
</tr>
<tr>
<td></td>
<td>R - L = +0.72 ± 0.14</td>
<td>R - L = +0.72 ± 0.14</td>
<td></td>
</tr>
<tr>
<td>P010 (80 hr, 36 min)</td>
<td>B - L = -1.83 ± 0.50</td>
<td>B - L = -6.18 ± 0.77*</td>
<td>B - L = -1.10 ± 0.08</td>
</tr>
<tr>
<td></td>
<td>B - R= -0.13 ± 0.33*</td>
<td>B - R= -4.22 ± 0.49*</td>
<td>B - R= +0.43 ± 0.03</td>
</tr>
<tr>
<td></td>
<td>R - L = -1.71 ±0.16</td>
<td>R - L = -1.95 ±0.28</td>
<td>R - L = -1.52 ±0.05</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------</td>
<td>---------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td></td>
<td>Height Adjusted</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>B - L = +0.24 ± 0.28</td>
<td>B - R= -0.50 ± 0.74</td>
<td>R - L = +0.74 ±0.46</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>P014 (31 hr, 08 min)</th>
<th>B - L = +0.80 ± 0.36</th>
<th>N/A</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B - R= -0.38 ± 0.17</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>R - L = +1.18 ±0.18</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>P016 (161 hr, 43 min)</th>
<th>B -L  =-0.36  ± 0.31</th>
<th>N/A</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B -R= -1.20 ± 0.01*</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>R - L = +0.84 ±0.33</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. B, back position; L, left lateral position; R, right lateral position; * p ≤ .05; N/A, not applicable (no arterial line or no recovery time calculation due to the constant motion of the automated turn bed)
Figure 1. Ensemble averages for (A) heart rate (HR), (B) mean arterial pressure (MAP), and (C) pulse pressure (PP) with individual turns (1) and ensemble average mean with 95% confidence interval (2) in P001 with back → left position. Time in minutes is displayed on the X axis. Heart rate in beats per minute (bpm), MAP in mmHg or PP in mmHg is displayed on the Y axis. The solid black vertical line at time = 15 minutes (min) is the recorded turn time. Each colored line in Figures A-1, B-1, and C-1 represents an individual turn. There are a total of four back → left turns for HR (A-1), MAP (B-1) and PP (C-1). The first 5 minutes of the data represent the baseline period.

For HR (A-1), the red line (Turn #3) shows missing data starting at 12 minutes that reflect 22 outliers in the dataset; Turn #3 was not included in the ensemble-averaged data. Each individual turn with the exception of the black line (Turn #1) shows an increase in HR surrounding the turn with variable recovery time. A-2 represents the ensemble averaged data from three individual back → left turns (black line) with the 95% confidence interval (blue lines). HR increased 22 bpm with back → left position, with no return to baseline values within the 45-minute post-turn time interval.

For MAP (B-1), each individual turn with the exception of the black line (Turn #1) shows an increase in MAP surrounding the turn with variable recovery time. Figure B-2 represents the ensemble-averaged data from the four individual back → left turns (black line) with the 95% confidence interval (blue lines). MAP increased 22 mmHg with back → left position, with recovery time of 43 minutes.

For PP (C-1), each individual turn with the exception of the black line (Turn #1) shows an increase in PP surrounding the turn with variable time for return to baseline. C-2 represents the ensemble-averaged data from four individual back → left turns (black line) with the 95% confidence interval (blue lines). PP increased 23 mmHg with recovery to baseline within 5 minutes.
Figure 2. Ensemble average for (A) heart rate (HR), (B) mean arterial pressure (MAP), and (C) pulse pressure (PP), with mean and 95% confidence interval, for one patient (P008) by bins of turn angles. Angle bins from 1 to 16 are displayed on the X axis. HR in beats per minute (bpm), MAP in mmHg, or PP in mmHg is displayed on the Y axis. Angle bin numbers 4 and 5 contain data from 817 turns captured during extreme right lateral positions with bed angles between +30° and +60°. Angle bin numbers 1, 8, 9 and 16 include data captured while in the back position with bed angles from +10° to -10°. Angle bin numbers 12 and 13 include extreme left lateral turn data from bed angles ≤ -30°. Heart rate varied from 85 to 90 bpm. Mean arterial pressure varied from 73 to 79 mmHg. Pulse pressure varied from 50 to 54 mmHg. Mean HR, MAP, and PP data for each specific angle bin is represented by the circle within each 95% confidence interval bar.
Institutional Review Board Approvals and Informed Consent Forms

Sandra Hanneman, PhD, RN, FAAN
UT-H - SN - Center For Nursing Research

NOTICE OF CONTINUING REVIEW APPROVAL

HSC-SN-05-0271 - Multi-Site Randomized Clinical Trial of Horizontal Positioning To Prevent and Treat Pulmonary Complications in Mechanically Ventilated Critically Ill Patients: A Pilot Study

PI: Sandra Hanneman, PhD, RN, FAAN

PROVISOS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consents, etc.

NOTE: If this study meets the federal registration requirements and this is an investigator-initiated study, or if the PI is the study sponsor or holds the IND/IDE applicable to this study, and no one else has registered this trial on the national registry, you are required to register this trial on the national registry at www.clinicaltrials.gov in order to publish results in any of the key peer-reviewed journals. For further information contact Gena Monroe at...

APPROVED: By Expedited Review and Approval

REVIEW DATE: February 2, 2010

APPROVAL DATE: February 25, 2010 EXPIRATION DATE: 1/31/2011

Upon review, the CPHS finds that this research is being conducted in accord with its guidelines and with the methods agreed upon by the principal investigator (PI) and approved by the Committee. This approval, subject to any listed provisions and contingent upon compliance with the following stipulations, will expire as noted above:

CHANGES: The PI must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.

INFORMED CONSENT: Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed
consent must also sign the consent document. Attached is the approved and validated informed consent form. You must discard all previous informed consent documents being used and replace them with this stamped validated version. Please note that only copies of the appropriately dated, stamped approved informed consent form can be used when obtaining consent.

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner which ensures subject confidentiality.
Certificate of Continuing Review

BOARD ACTION DATE: May 26, 2009
DATE OF EXPIRATION: May 25, 2010

Sponsor: N/A
Protocol #: N/A
PAC #: 18-0002-05
PI: Sandra Hanneman, PhD, RN, RAAN
PI #: H-0004-TX
City/State: Houston, TX
Hospital: The Methodist Hospital

Study Title: Multi-Site Randomized Clinical Trial of Horizontal Positioning to Prevent and Treat Pulmonary Complications in Mechanically Ventilated Critically ILL Patients: A Feasibility Study

The following were approved for the above study:
- Protocol, version date 07-19-05, Protocol amendment dated 01-04-06 (sub-study)
- Informed Consent Form, version dated 06-05-06

Informed Consent Form Note: If the informed consent form was modified by the Board, the approved version date is the board action date.

The following members abstained from deliberations and voting: none

ALL CONDITIONS OF APPROVAL PREVIOUSLY ESTABLISHED BY PAC, IRB FOR THIS RESEARCH PROJECT CONTINUE TO APPLY

Institutional Review Board Designee

www.pacirb.com
A Compass Point Research Company
November 25, 2008

Gary M. Gusiclc, DSN, RN, CNS
Nursing Service, CVRR
St. Luke’s Episcopal Hospital

Project #2736
“Multi-Site Randomized Clinical Trial of Horizontal Positioning to Prevent and Treat Pulmonary Complications in Mechanically Ventilated Critically Ill Patients”

Dear Dr. Gusiclc:

Thank you for your response to the request by the St. Luke’s Episcopal Hospital Institutional Review Board at their October 15, 2008 meeting. The recommendations of the committee have been satisfied by your response and I am pleased to inform you that the above referenced protocol is approved for continuation according to institutional guidelines.

Continued review of the study will be required as follows:

a. Annually
b. Prior to any change in the protocol
c. Promptly after unanticipated problems (adverse events)
d. After any other unusual occurrence

The method of review will be by written summary.

Dated copies of the approved informed consents are attached for use as the “master” for copying for research subjects’ signatures.


Frank A. Redmond, M.D., Ph.D.
Chair
Institutional Review Board

FAR/are
INFORMED CONSENT FORM TO PARTICIPATE IN A CLINICAL RESEARCH TRIAL

Protocol Title: Multi-site Randomized Clinical Trial of Horizontal Positioning to Prevent and Treat Pulmonary Complications in Mechanically Ventilated Critically Ill Patients

Protocol No.: N/A

Principal Investigator: Sandra K. Hanneman, PhD, RN, FAAN

Sites: The Methodist Hospital

DESCRIPTION AND/OR PURPOSE

You are invited to take part in the research study named above to see if two ways of turning patients on a respirator (breathing machine) makes a difference in lung complications. The study is being done in the intensive care unit (ICUs) at The Methodist Hospital by Dr. Hanneman, a nurse researcher at the University of Texas School of Nursing at Houston who is credentialed to conduct this study at The Methodist Hospital and Shannan Hamlin, MSN, RN, ACNP, an advanced practice nurse at The Methodist Hospital. We plan to have about 250 patients in the study. We have checked with your medical doctor to make sure it is safe for you to take part in this study.

PROCEDURES

Patients who are on a respirator in the ICU are turned every 2 hours to lower the chance of lung complications such as pneumonia. You will be turned whether you are in the study or not. If you are in the study, you will receive one of two turning protocols: (1) the routine turning by nurses every 2 hours or (2) continuous turning on a special bed. Which protocol you get will be decided by chance (like flipping a coin). You will stay in the turning protocol until you no longer need the respirator, leave the ICU or drop out of the study.

In both turning protocols, a nurse will monitor you every 10 to 60 minutes to see if you are comfortable, and measure the angle of the turn. The nurse will get information about you (like age, gender, race, ethnicity, height, weight) and your medical information (like diagnosis, blood test results, vital signs) from your medical chart. At the end of the study, the investigators will send copies of your chest X-rays to a radiologist at the University of Texas Medical School at Houston to diagnose lung complications for study purposes only. The radiologists at this hospital will look at your chest X-rays as usual for your care.

RISKS AND DISCOMFORTS

Risks to you from being in this study are:
• Pain and discomfort from turning
• Increase or decrease in blood pressure and heart rate from turning
• Increase or decrease of oxygen in the blood from turning
• Disconnection of tubes or catheters with turning
• Feeling of falling out of bed if you happen to get the protocol with the special bed
• There may be other known and/or unknown risks to you or an unborn baby or fetus that you may wish to discuss with your research nurse or Principal Investigator.

If you have pain or discomfort, the nurse may give you medicine to make you more comfortable.

You will be monitored closely to see how the turning protocol affects your blood pressure, heart rate and oxygen level. If changes are serious ones, the nurse will stop the turn. The nurse also will re-connect tubes or catheters that get disconnected.

**BENEFITS**

You may not benefit from this study. The information we learn may benefit the care of future ICU patients on a respirator.

**ALTERNATIVE TREATMENT**

This study is voluntary. If you do not want to be in this study, you still will be turned by the ICU nurses and you may be turned on a special bed.

**NEW FINDINGS**

New information may be learned while you are in the study. This new information will be given to you so you can decide if you want to remain in the study or drop out.

**VOLUNTARY PARTICIPATION**

You may choose to be in this study or not be in the study. Your choice will not affect the care you receive in the ICU. If you don't want to be in the study the first time you are asked to take part, we will not ask you again. If you choose to be in the study and then change your mind, you can drop out of the study at any time without loss of benefits to which you may be otherwise entitled. The length of time you are in the study depends on how long you are on a respirator in the ICU. A study nurse will ask you every day if you want to stay in the study or drop out.

You may be removed from the study without your consent for the following reasons: a) it is in your best interest to be taken out of the study; b) you do not follow the study schedule; c) you experience an injury or illness or other side effects; or d) the study is terminated prematurely. The Institutional Review Board can also stop the study at any time.

**EARLY WITHDRAWAL AND/OR TERMINATION**

You may be taken out of the study even if you would like to continue, if: 1) your research nurse decides the effects of turning you is causing serious problems with your heart rate, blood pressure, or oxygen level or 2) the study is canceled by the Institutional Review Board.
CONFIDENTIALITY

Data Privacy – Confidentiality – Authorization to Disclose Health Information

Release of Health Information – If you decide to take part in this study, information about your health may be used or disclosed for the purposes of conducting this study. This information may include information from your medical record that is relevant to this study, such as your medical history, medications, test results, diagnoses, treatments, operative reports (reports from operations that you have undergone), and discharge summaries. Information collected by the research nurse and/or research staff specifically for this study, such as test results, could also be used or disclosed.

Individuals that may use or release this information include: the research staff and the hospital staff. These individuals may release this information to the Institutional Review Board and other regulatory agencies.

The information released to the above listed individuals will not contain your name, social security number, or any other personal information. However, authorized representatives of the Institutional Review Board or other regulatory agencies may review records containing personal information to make sure that the study information is correct. Because of the need to provide information to these parties, absolute confidentiality cannot be guaranteed.

Use of Information – This information may be used to determine whether you meet all requirements for participation in the study, to monitor your healthcare during the study, to enable the research team to answer the scientific questions for which the study was designed, and to ensure that the study has been done properly. Examples of the use of this information are as follows: the research staff may use the information to prepare reports or publications of the study results; they may also provide overall study results, including your information, to other researchers who are conducting turning-related studies; agencies that fund the research, including the National Institutes of Health; members of the study’s Data Safety and Monitoring Board; and the institutional review boards of the hospitals and universities participating in this study. The researchers may reanalyze the data from this study in the future or combine it with data from other studies for analysis.

Once your information has been released, it is no longer protected by US federal regulations relating to data privacy and could be used or re-disclosed in ways other than those listed in this section of the consent form.

You have the right to see and receive a copy of your records related to the study for as long as the researchers have this information in their possession. However, you might not be allowed to see these records until after the study has been completed.

Authorization to Disclose – By signing this consent form, you authorize disclosure of information and review of your medical records by the authorized people as described in this section of the consent form. You do not have to authorize this disclosure of information. However, if you do not, you will not be able to participate in this study.

IRB Version Date: 08-05-06

Patient initials ________________________

IRB NUMBER: IISC-SN-05-0271
IRB APPROVAL DATE: 3/10/2009
IRB EXPIRATION DATE: 02/28/2010
Expiration of Authorization – Because this information is being disclosed for research use, there is no expiration date for the authorization to disclose and use this information. The research team may keep and continue to use your study information for many years. Your research nurse may need to add to or correct information about you even after your study participation is over, including providing updates of your health status if that is important to the purpose of the study. The review of your medical records (discussed above) may also take place after the study is over. This authorization will remain in effect unless you revoke it.

Revoking Authorization to Disclose – If you stop participating in this study, you also have the right to revoke (withdraw) your authorization to disclose information. Revoking your authorization means taking back the permission you gave the research nurse to disclose information about you. If you revoke your authorization, the research team will not use or release any more information about you after receiving your request.

If you want to revoke your authorization, you must do so in writing to the study’s principal investigator. You can get a revocation form from the principal investigator or you can write a letter to the principal investigator:
Sandra K. Hammeman, PhD, RN, FAAN
The University of Texas School of Nursing at Houston

You may revoke your authorization at any time. However, once you do so, you can no longer continue to participate in the study.

COMPENSATION

You will receive no payment or other compensation for being in the study.

COSTS

It will not cost you or your insurance company anything for you to be in the study. Study costs, including rental fees for the special bed, will be paid for by research grants.

RESEARCH-RELATED INJURY

It is the position of The Methodist Hospital that neither Methodist nor its employees, officers, directors or agents of Methodist are responsible for research-related injuries.

If you are injured from taking part in this study, please understand that The Methodist Hospital and the investigators will not provide monetary compensation or free medical care. Please understand that the necessary facilities and care will be available to you just as they are to the community in general. There is no compensation for research-related injury. If you have concerns about your insurance coverage, you may want to contact your insurance carrier.
You do not give up any of your legal rights by signing this consent form.

WHO TO CONTACT

You should report any problems or research-related injury to Dr. Hanneman at (24-hours a day).

If you have questions or concerns about your rights as a research subject you should contact James V. Roberts, Jr., Chairman of the Patient Advocacy Council, Inc. Institutional Review Board, the IRB overseeing the conduct of this trial at The Methodist Hospital at Collect calls are accepted.

STUDY FUNDING

The Principal Investigator is not being paid to conduct this clinical trial.

SIGNATURE SECTION

The study, as well as the risks, benefits, alternatives, procedures and purpose have been explained to me. I have been given ample opportunity to ask questions of Dr. Hanneman and/or the research staff and have received answers that fully satisfy those questions. I understand I will receive a copy of the signed and dated informed consent form.

Signed Name of Patient

Patient’s Signature Date and Time

Legally Authorized Representative’s Signature Date and Time
(as defined by state law)

Relationship to Patient

Printed Name of Person Obtaining Consent

Person Obtaining Consent’s Signature Date and Time

IRB NUMBER: HSC-SN-05-0271
IRB APPROVAL DATE: 3/10/2009
IRB EXPIRATION DATE: 02/28/2010
My signature below indicates that I have verified with the potential participant that the study risks, benefits, alternatives, procedures, and purpose have been explained and that he/she was given the chance to ask questions and receive satisfactory answers.

Printed Name of Witness

Witness' Signature

Date and Time

Printed Name of Investigator

Investigator's Signature

Date and Time

IRB NUMBER: HSC-SN-05-0271
IRB APPROVAL DATE: 3/10/2009
IRB EXPIRATION DATE: 02/28/2010
FAMILY CONSENT TO TAKE PART IN RESEARCH STUDY

Study Name: Multi-site randomized clinical trial of horizontal positioning to prevent and treat pulmonary complications in mechanically ventilated critically ill patients (HSC-SN-05-0271)

Principal Investigator: Sandra K. Hanneman, PhD, RN, FAAN

INVITATION FOR YOUR FAMILY MEMBER TO PARTICIPATE

You are invited to give consent for your family member ______________ to take part in the research study named above to see if two ways of turning patients on a respirator (breathing machine) makes a difference in lung complications. The study is being done in intensive care units (ICUs) at St. Luke’s Episcopal Hospital and The Methodist Hospital by Dr. Hanneman, a nurse researcher at the University of Texas School of Nursing at Houston; Dr. Gary Gusick, an advanced practice nurse at St. Luke’s Episcopal Hospital; and Shannan Hamlin, MSN, RN, ACNP, an advanced practice nurse at The Methodist Hospital. We have checked with your family member’s medical doctor to make sure it is safe for him or her to take part in this study.

You may choose to allow your family member to be in this study or not be in the study. Your choice will not affect the care he or she receives in the ICU. If you don’t want your family member to be in the study the first time you are asked, we will not ask you again. If you agree to let your family member be in the study and then change your mind, you can remove him or her from the study at any time. The study would last as long as your loved one is on a respirator in the ICU.

This research project has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston as HSC-SN-05-0271.

WHAT IS THE STUDY ABOUT? WHAT WILL HAPPEN IF YOUR FAMILY MEMBER TAKES PART?

Patients who are on a respirator in the ICU are turned every 2 hours to lower the chance of lung complications such as pneumonia. Your family member will be turned whether he or she is in the study or not. If you consent for your family member to be in the study, he or she will receive one of two turning protocols: (1) the routine turning by nurses every 2 hours or (2) continuous turning on a special bed. Which protocol he or she gets will be decided by chance (like flipping a coin). He or she will stay in the turning protocol until off the respirator, out of the ICU or drops out of the study.

In both turning protocols, a nurse will monitor your family member every 10 to 60 minutes to see if he or she is comfortable, and measure the angle of the turn. The nurse will get information about the patient (like age, gender, race, ethnicity, height, weight) and medical information (like diagnosis, blood test results, vital signs) from his or her medical charts. At the end of the study, the investigators will send copies of his or her chest X-rays to a radiologist at the University of Texas Medical School at Houston to diagnose lung complications for study purposes only. The radiologists at this hospital will look at your family member’s chest X-rays as usual for his or her care.

OTHER TREATMENTS
This study is voluntary. If you do not want your family member to be in this study, he or she still
will be turned by the ICU nurses and may be turned on a special bed.

TIME COMMITMENT
Your family member will not need to commit any time to this study since turning is part of his or
her regular ICU care.

RISKS AND BENEFITS
Risks to your family member from being in this study are:
- Pain and discomfort from turning
- Increase or decrease in blood pressure and heart rate from turning
- Increase or decrease of oxygen in the blood from turning
- Disconnection of tubes or catheters with turning
- Feeling of falling out of bed if you happen to get the protocol with the special bed

If your family member has pain or discomfort, the nurse may give medicine to make him or her
more comfortable. Your family member will be monitored closely to see how the turning protocol
affects his or her blood pressure, heart rate and oxygen level. If changes are serious ones, the
nurse will stop the turn. The nurse also will re-connect tubes or catheters that get disconnected.

Your family member may not benefit from this study. The information we learn may benefit the
care of future ICU patients on a respirator.

CONFIDENTIALITY
Another risk to your family member from being in this study is that his or her name and
identifying information could become known to others not involved in the study or ICU care. We
will put a study code number on all the study records and, at the end of your family member’s
taking part in the study, his or her name will be deleted from all study records. We will delete his
or her name and the hospital name from the copies of chest X-rays that are sent to the study
radiologist. We will keep your signed consent form and a master list linking your family
member’s name with his or her study code number in a locked file cabinet in a locked office at
the University of Texas School of Nursing at Houston for 5 years after the end of the study. At
that time, those documents will be shredded. The study findings will be presented and
published, but we will not identify your family member.

COST AND COMPENSATION
It will not cost you, your family member or the insurance company anything for your family
member to be in the study. Study costs, including rental fees for the special bed, will be paid for
by research grants. Neither you nor your family member will receive payment or other
compensation for being in the study.

COMPENSATION FOR INJURY
If your family member is injured from taking part in this study, please understand that The
University of Texas Health Science Center at Houston, St. Luke’s Episcopal Hospital, The
Methodist Hospital and the investigators will not provide monetary compensation or free medical
care. Please understand that the necessary facilities and care will be available to your family.
member just as they are to the community in general. There is no compensation for research-related injury. You should report any problems or research-related injury to Dr. Hanneman at [contact information], and to the Committee for the Protection of Human Subjects at [contact information]. You will not give up any of your legal rights or those of your family member by signing this consent form.

QUESTIONS?
If you have questions, concerns or research-related injuries, please report them to Dr. Hanneman at [contact information] and to the Committee for the Protection of Human Subjects at [contact information].

AUTHORIZATION FOR THE USE AND DISCLOSURE (RELEASE) OF PROTECTED HEALTH INFORMATION
You request and direct the hospital (St. Luke’s Episcopal Hospital or The Methodist Hospital) to release your family member’s clinical records to Dr. Sandra K. Hanneman and her research staff. The purpose of the requested use and release is to conduct the research study above, in which your family member is taking part.

This authorization permits St. Luke’s Episcopal Hospital and The Methodist Hospital to release all of your family member’s clinical records that the hospital provider has in its possession, including information relating to medical history, mental or physical condition and any treatment and tests received by the patient while in the hospital. The hospital may not withhold or alter treatment based on your completion of this authorization.

The personal information may be shared with other researchers who are conducting turning-related studies; agencies that fund the research, including the National Institutes of Health; members of the study’s Data Safety and Monitoring Board; and the institutional review boards of the hospitals and universities participating in this study. Any potential receiver of your family member’s personal information identified in this paragraph, except for St. Luke’s Episcopal Hospital and The Methodist Hospital, may re-release the information because they are not subject to the same Federal and Texas privacy laws. However, the patient’s protected health information will be identified by a study code number, not by any personal identifiers such as his or her name, birthplace or hospital record number.

Dr. Hanneman’s research team members who obtain access to your family member’s health information as part of this research study may not use the information for purposes other than this study, except as otherwise permitted by law.

You may change your mind and revoke (cancel) this authorization in writing at any time.

The results of the study may be published and presented at meetings. Neither your family member’s name nor any other personal health information that identifies him or her will be used when the study findings are reported to others.
Unless otherwise canceled, this authorization will expire in 10 years. You may cancel this authorization to access your family member's clinical records by mailing or faxing a written notice to:

Sandra K. Henneman, PhD, RN, FAAN

CONSENT OF NEXT OF KIN
By signing below, I acknowledge that this nursing research study has been explained to me in a way that I understand, my questions have been answered, I volunteer my family member to take part in the study, I can drop my family member out of the study any time I want to if he or she is still unable to give consent, and that my family member will be turned even if he or she is not in this study.

Printed Name of Patient

Printed Name of Family Member

Family Member's Signature    Date and Time

Relationship to Patient

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent    Date & Time

This study (HSC-SN-05-0271) has been reviewed by the Committee for the Protection of Human Subjects of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the Committee office at ( .

Consent Form for HSC-SN-05-0271
IRB APPROVAL DATE: 3/10/2009
IRB EXPIRATION DATE: 2/28/2010
Appendix B

Hemodynamic Substudy Operations Manual

ICU Turning Study

Hemodynamic Changes Associated with Manual and Automated Lateral Rotation in Mechanically Ventilated Intensive Care Unit Patients

May 2007

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AACN Houston-Gulf Coast Chapter Research Grant

Principal Investigator:

Shannan K. Hamlin MSN, RN, ACNP, CCRN
University of Texas School of Nursing at Houston
The Methodist Hospital
Tel: ___________

Dissertation Chair:

Sandra K. Hanneman, PhD, RN, FAAN
University of Texas School of Nursing at Houston
Tel: ___________
Background and Purpose

Mechanically ventilated critically ill patients are at high risk for developing pulmonary complications from prolonged immobility. Historically, nursing has recognized the pathophysiologic impact of prolonged immobility on critically ill patients, prompting the standard of lateral turning every 2 hours. However, a recent study found that 23% of critically ill patients observed were not repositioned for more than 8 hours (Krishnagopalan et al., 2002). Automated lateral rotation therapy is reported to be a solution to the pulmonary complications of prolonged immobility. Funding was obtained to conduct the pilot study for a randomized clinical trial (RCT) to evaluate the efficacy and safety of both manual and automated lateral turning for reducing preventable pulmonary complications in mechanically ventilated critically ill patients. Given the acuity of this patient population, the adverse hemodynamic effects of positive pressure ventilation and possible adverse effects of lateral rotation on hemodynamics, hemodynamic response to the two turning interventions will be evaluated in a substudy. The contents of this operations manual provide guidance for the hemodynamic substudy.

Specific Aims and Hypotheses

The specific aims of the hemodynamic substudy are to: (a) describe patient hemodynamic response, defined as changes in heart rate (HR), mean arterial pressure (MAP) and pulse pressure (PP), to manual and automated turning interventions; and (b) compare hemodynamic responses between turning intervention groups. The hypotheses for the hemodynamic substudy will be tested using a time-series design with nearly continuous HR, MAP and PP monitored for > 24 hours and are: (a) within-group hemodynamic changes will be greater in the left and right lateral positions than in the back position, and (b) there will be greater hemodynamic changes after turning in the manual-turn patients compared with the automated-turn patients.
Study Design

The RCT will use a two-group (manual lateral rotation or automated lateral rotation) completely randomized experimental design (Figure 1). Prospectively, randomly selected mechanically ventilated intensive care unit (ICU) patients will be randomly assigned to one of the positioning protocols to compare preventable pulmonary complications, turning-related adverse events, mechanical ventilator duration (MVD), ICU length of stay (LOS), mortality rate, and intervention cost by study group. Within the RCT design, an observational time-series design will be used in the hemodynamic substudy to capture HR, MAP and PP responses to the turning interventions.

Independent Variable

1) Manual or automated turning

Dependent Variables

1) Heart rate (HR)

Conceptual definition: Heart rate is the frequency per minute with which electrical activity depolarizes and then re-polarizes the heart to produce a ventricular contraction.

Operational definition: HR is the numeric value, averaged over 6 seconds, obtained from a physiologic monitor (Hewlett Packard, M1046b, Philips Medical Systems, Andover, MA or Solar 8000, Marquette, Milwaukee, WI) using a 5-electrode limb lead system.

2) Mean arterial pressure (MAP)

Conceptual definition: MAP is the average pressure within the arterial circulation throughout the cardiac cycle.
Figure 1. Within-site two-group (automated lateral rotation or manual lateral rotation) experimental design with observational time-series hemodynamic substudy.
Operational definition: MAP is the numeric value obtained by:

\[
\text{Systolic} + \left(\text{Diastolic} \times 2\right) \div 3
\]

and averaged over 6 seconds, from an intraarterial catheter connected to a disposable pressure transducer (Edwards Lifesciences, PX600F or PX284, Irvine, CA).

3) Pulse pressure (PP)

Conceptual definition: Pulse pressure is the indirect measure of left ventricular stroke volume or intravascular fluid volume status.

Operational definition: Pulse pressure is the numeric value obtained by subtracting the arterial diastolic blood pressure (DBP) from the arterial systolic blood pressure (SBP) and averaged over 6 seconds.

Hemodynamic Substudy Protocol

A pilot study will be conducted to evaluate and refine procedures for a multi-site RCT with mechanically ventilated critically ill patients. As part of this pilot study, a hemodynamic substudy will be conducted to evaluate hemodynamic response to the turning interventions.

Overview

Horizontal changes in posture have been advocated since 1957 (Svanberg), and have been embraced by nursing since the classic article by Olson (1967) on the hazards of immobility; turning patients from side to back to side every 2 hours has been the standard of care in ICUs since that time. Critically ill patients who are mechanically ventilated are on bed rest, and are at high risk for developing complications from prolonged immobility with pulmonary and hemodynamic hazards as the ones most likely to contribute to morbidity and mortality in the ICU setting. The standard of care is lateral rotation ≥ 45° for manual positioning. Despite limited evidence to support horizontal postural changes, several mechanical technologies for turning (i.e. kinetic therapy) have
been introduced in the clinical setting over the years, and industry proclaims automated
turning can improve patient outcomes and reduce cost of care (KCI, 2005). The multi-
site RCT will systematically compare the efficacy and safety of reducing preventable
pulmonary complications in mechanically ventilated critically ill patients with manual and
automated lateral turning.

The hemodynamic substudy will specifically address turning-related adverse
events within and between the two turning groups as hemodynamic compromise is likely
to have the greatest adverse effect and therefore implications for morbidity, mortality and
protocol adherence. Although a nursing standard of care, frequent repositioning of the
already compromised ICU patient may increase oxygen utilization and negatively impact
tenuous cardiopulmonary reserves (Gawlinski, 1993). Giuliano, Scott, Brown, and Olsen
(2003) evaluated the effects of three backrest positions (0°, 30°, and 45°) on HR and
MAP in 26 critically ill patients (96% were mechanically ventilated). Using repeated
measures ANOVA, the results showed no significant differences in HR \( F(2,24) = .043, P
= .95 \) and, although significance was found in MAP \( F(2,24) = 3.47, P = .05 \), the
difference (2.1 mm Hg) was not clinically important (83.4 mm Hg at 0° and 81.3 mm Hg
at 45°).

Research has shown that lateral rotation in the mechanically ventilated critically
ill population results in an 8% to 12% decline in mixed venous oxygen saturation (S\( \text{\textit{v}} \)\( \text{\textsubscript{o}} \)\textsubscript{2})
and a 20% to 30% increase in oxygen consumption (\( \text{\textit{V}} \)\( \text{\textsubscript{O}} \)\textsubscript{2}; Jesurum, 1997; Weissman et
al., 1984). A significant reduction in S\( \text{\textit{v}} \)\( \text{\textsubscript{o}} \)\textsubscript{2} has been found immediately after lateral
turning (Gawlinski & Dracup, 1998b; Lewis et al., 1997; Winslow et al., 1990), with most
studies reporting a greater decrease in the left versus the right lateral position (Gawlinski
& Dracup, 1998b; Lewis et al., 1997). Research concerning hemodynamic response to
lateral positioning in the critically ill patient is limited and offers nebulous guidelines for
care delivery. Even in cases where hemodynamic compromise occurs with lateral
rotation, it is clinically useful to know if recovery to baseline occurs, and the time to recovery, so that nurses can make bedside decisions regarding turning. The specific aims of this hemodynamic substudy are to: 1) describe patient hemodynamic response, defined as changes in heart rate (HR), mean arterial pressure (MAP) and pulse pressure (PP), to manual and automated turning interventions; and 2) compare hemodynamic responses between turning intervention groups. Heart rate, MAP and PP collected every 6 seconds for > 24 hours will be used as hemodynamic response indicators.

Patient Selection

The RCT clinical investigators will identify patients as potentially eligible for study participation and evaluate patients for inclusion and exclusion criteria. When a patient meets the eligibility criteria, and after obtaining physician or nurse acceptance of random assignment to turning intervention and patient or family consent for study participation, the patient’s initials will be entered into a randomization database for automated determination of selection for study participation. The inclusion and exclusion criteria below are for the RCT. All patients enrolled in the RCT pilot study will be enrolled in the hemodynamic substudy.

Inclusion Criteria

Mechanically ventilated

Placement on protocol within 8 hours of intubation and initiation of mechanical ventilation

Exclusion Criteria

Pulmonary mass, pneumothorax, hemothorax, pleural effusion, and other sources of compression atelectasis

Hemodynamic instability, defined as SBP <90 mm Hg with vasopressor support

Orthopedic injuries requiring traction
Head injury requiring intracranial pressure monitoring
Unstable spinal injuries
Rib fractures
Intubation within the previous 2 weeks
Body weight ≥ 350 pounds (experimental bed limitation)

**Instruments**

**Physiologic Monitors**
- Hewlett Packard (HP) (M1046b, Philips Medical Systems, Andover, MA)
- Solar 8000 (Marquette, Milwaukee, WI)

**Pressure Transducers**
- Edwards Lifesciences (PX600F, Irvine, CA)
- Edwards Lifesciences (PX284, Irvine, CA)

**Treatment Protocols**

**Manual Turning.** The salient aspects of the manual turning protocol (Appendix A) include ≥ 45° lateral turn; head-of-bed (HOB) ≥ 30° to reduce risk of aspiration in the lateral and back positions (CDC, 2004; Collard, Saint, & Matthay, 2003; Orozco-Levi et al., 1995; Torres et al., 1992); use of dedicated nurses to ensure frequency, angle and duration of turn every 2 hours; and tracking of compliance with the intervention protocol, including attrition and adverse events associated with turning.

**Automated Turning.** The salient aspects of the automated turning protocol (Appendix A) are lateral rotation to ≥ 40° angle; essentially continuous rotation (rotation will be paused for short periods as needed for such care as linen change); HOB elevation ≥ 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, including attrition and adverse events associated with turning.
Data Collection and Entry

The principal investigator (PI) will assemble and prepare equipment and supplies needed for data collection and bring them to the patient’s bedside. The data collection, management and analysis procedures are detailed in Appendix C. In brief, the ECG and blood pressure monitoring being done for clinical purposes will be carefully checked to ensure adequate quality of HR and blood pressure signals. The time of the start and end of the time-series hemodynamic monitoring will be noted on the Hemodynamic Substudy Flow Sheet (Appendix D).

Data Entry

At each study site, a laptop computer connected to a physiologic monitor will capture hemodynamic data and save it to a computer file. Within 8 hours of the hemodynamic data collection, HR, SBP, DBP, and MAP will be: 1) downloaded from the study laptop computer to a memory stick, 2) imported into a SPSS (version 17.0, SPSS Inc., Chicago, IL) database, and 3) saved on three CDs (patient file, master copy, and back-up master copy). Pulse pressure will be calculated (SBP-DBP) automatically after patient data have been imported into the SPSS database. For patients in the manual-turn group, turning direction (back, right, or left) will be manually entered into the SPSS database from the RCT pilot study turning flow sheet; the automated turning group’s position will be obtained automatically using a custom-designed angle sensor. Subjects will be enrolled in the RCT pilot study until (a) revocation of consent, (b) discontinuance of mechanical ventilation, (c) transfer from study ICU, (d) death, or (e) completion of 7 days on study protocol. Subjects will remain in the hemodynamic substudy for > 24 hours.

Patients will be identified by a code number on all data collection materials (Turning Flow Sheet, Hemodynamic Substudy Flow Sheet, patient’s files on study laptop and desktop computers, and CDs) with:

○ Site and unit
Study ID Code + HS (Hemodynamic Substudy; i.e. PXXXHS)

Group assignment

Data Management and Analysis

Data Management

Data cleaning is the process of visually inspecting the data for outliers, consistency and completeness (Polit & Hungler, 1995). Mean values will be computed to determine outlier values. Data cleaning procedures will be done in SPSS on the raw data; replacement of outliers (labeled ‘999’) and missing data and statistical analyses will be performed on cleaned data. The dependent variables, HR, MAP, and PP, will undergo cleaning procedures and statistical analysis.

Missing Data

Time-series analysis should contain no missing data as observations need to be equidistant from one another (Yaffee, 2000). Because a time-series analysis will be used to analyze the within-subject data, a time-oriented strategy will be used to replace missing data. Linear interpolation is based on the assumption that a change at one end of an interval (e.g., two data points for the variable HR) measured on two separate scales (e.g. time and HR) corresponds to a regular, linear change at the other end allowing the estimation of values within the interval (Gravetter & Wallnau, 1985). All missing data will be replaced in SPSS using the linear interpolation function.

Extreme Values (Outliers)

Extreme values, or outliers, are significantly different from the remaining values (Friedman, Furberg, & DeMets, 1998) and can have a profound effect on time-series analyses as observations are weighted by their absolute distance to the series mean (McCleary, 1980). Given that the variable MAP is derived from a system that is highly sensitive to catheter movement and interruptions in continuous pressure monitoring from such interventions as flushing and blood draws, frequent outliers are expected in the
dataset. Outliers will be defined as any value that is more than 3 standard deviations away from the mean of the sample distribution (Gravetter & Wallnau, 1985). Variability in physiologic data tends to be high; therefore, allowances need to be made if the data do not follow a normal distribution in order to capture natural data that is meaningful. Using 3 standard deviations from the mean as the outlier criterion would mean a 0.26% chance of obtaining a value that lies outside what would normally be expected (Sonnad, 2002). Outliers will be treated as missing data and replaced using linear interpolation (Yaffee, 2000). Outliers will be identified during the data cleaning process, replaced with ‘999’ as a flag, and subsequently replaced with a predicted value derived from linear interpolation using SPSS.

**Statistical Analysis**

Patients’ data will be analyzed by the hemodynamic substudy PI using SPSS (version 17.0, SPSS Inc., Chicago, IL) and TIBCO Spotfire S+ 8.1 (TIBCO Software, Inc.) statistical software. The variables of HR, MAP and PP will be described and compared between the two randomized groups. The initial approach to data analysis will be a global evaluation of individual responses and associations with the turning interventions, followed by successive analyses aimed at progressive comparisons of within-group data, and culminating with between-group analyses. Autocorrelation function (ACF) will use the dense time series to describe individual hemodynamic responses to the turning interventions followed by cross-correlation analysis between (a) HR and MAP, (b) HR and PP, and (c) MAP and PP to evaluate both within-subject and within-group relations between the variables. A two-way repeated measures analysis of variance (ANOVA) will be used to evaluate within-group and between-group means to test the hypotheses, respectively, that there will be greater hemodynamic changes in the left and right lateral positions than in the back position, and greater hemodynamic changes in the manual-turn group than the automated-turn group. An interim analysis
will be performed after data have been collected from 12 subjects (n = 6 control and n = 6 experimental group) and power calculated. If the interim analysis shows power ≥ 80%, the hemodynamic substudy will be terminated.

**Descriptive Statistics**

Descriptive statistics will be computed on the variables HR, MAP and PP using compiled turn data for each patient. The following descriptive statistics will be obtained to describe and summarize the time-series data (Altman, 1991; Norman & Streiner, 2003; Riffenburgh, 1999):

- Frequency distribution and histogram
- Evaluation of distribution using skewness (measure of asymmetry), kurtosis (measure of flatness or peakedness), and the normal curve superimposed on the histogram
- Measures of central tendency: mean, median, and mode
- Measures of variability: range, standard deviation, minimum, maximum and standard error of the mean

Parametric analyses using ANOVA assume: independent observations, normal distribution of means, and equal variances in the groups. Because each randomly selected subject’s data are used to derive a mean, the assumption is the data represent independent observations. To evaluate distribution symmetry, skewness, kurtosis and a histogram with a superimposed normal curve will be used to test for a normal distribution. The Mann-Whitney *U* test will be used as an alternative if the distribution is not normal. The *F* test will be used to test comparison data for equal variances.

**Ensemble Averaging**

Ensemble averaging (Lodato & Jubran, 1993) will be used to assess within-subject hemodynamic responses. Data will be evaluated for (a) graphical characteristics
of increase or decrease in the variable for the manual-turn group and 95% confidence
interval overlap for the automated-turn group, (b) statistical significance, (c) clinical
significance; and, in the manual-turn group recovery time, defined as length of time for
the value to return to baseline. A change ≥ 10 beats per minute (bpm) in HR and ≥ 10
millimeters of mercury (mm Hg) in MAP and PP and ≥ 5 minutes for the recovery time
will be considered clinically important changes.

For the manual-turn patients, HR, MAP, and PP data will be segregated into two
turn categories: back → left and back → right. Using scripts developed in S-Plus by Dr.
Nikhil Padhye, ensemble-averaged data will be placed in 12-second bins starting 15
minutes before the turn (pre-turn period) and ending 45 minutes after the turn (post-turn
period). The first 5 minutes of the pre-turn period will be considered the baseline interval.
Starting at the end of the baseline interval, data intervals of 5-minute duration will be
moved forward in 1-minute increments to statistically compare the baseline interval with
each subsequent test interval. With a first-order autoregressive model (Yaffee, 2000) to
account for the autocorrelated nature of the data, ensemble averages will be computed
from individual turns within each turn category to compare mean baseline data with
mean data during and after the turn and estimate recovery time back to baseline.

For the automated-turn patients, HR, MAP and PP will be segregated into 10°
angle bins from 0° to ≤ 30° on the left and 0° to ≥ 30° on the right for a total of eight
angle bins (four per quarter turn). The last bin on each side will be an 'open' bin due to
variable maximum angles obtained with the automated bed. Bin angles from -10° to 10°
will be considered the back position. Two databases will be used for analyses of
automated-turn patient data. Database A will contain the maximum amount of data by
excluding only those data gaps > 1 minute and turns with < 5 minutes of data. Database
B will further exclude data with sudden angle stoppage or changes of angle, which may
occur when the bed is reset to the center, to select the best segment of data for ACF and cross-correlation analyses that require equally-spaced, continuous data.

**Time-series Analysis**

Time-series analyses examine variable changes over time using serial correlation. In other words, the value of the variable at time 1 is related to and affects the value at time 2 and so on, implying temporal order is important (Norman & Streiner, 2003). Time-series analyses allow time-oriented questions to be addressed (Norman & Streiner, 2003) to help understand hemodynamic response to the turning interventions. Autocorrelation function will be used to analyze individual hemodynamic changes in response to lateral rotation.

**Autocorrelation Function**

Autocorrelation function is the correlation of one variable against a time-shifted version of itself. Time will be measured in lags for the purpose of determining within-subject variability to position changes, thereby establishing causal relations over time (Schmitz, 1990). The lag is the process of taking one data point in a time series and back-shifting the correlation one lag or one time period (Yaffee, 2000). The direction (lagged forward or backward) of the time shift is unimportant because the ACF is symmetrical about lag 0 (McCleary, 1980). The value of lag 0 is always a perfect correlation of 1.0 since it is correlated against itself (Yaffee, 2000). As the lags get larger, the autocorrelations become smaller, as the effects of one event on subsequent ones usually dissipate over time (Norman & Streiner, 2003). Periodicities, or recurrent peaks and troughs at regular intervals, can then be observed on a plot in which autocorrelated values have been time lagged, providing a description of the temporal pattern of serial dependence (Riffenburgh, 1999; Schmitz, 1990).

The ACF analysis will produce a plot with ACF values between 0 (no correlation) and +1.0 (perfect correlation) with a 95% confidence interval (CI) band which indicates
little or no correlation as the values approach zero. If periodicities are absent indicating no change in ACF shape during the > 24-hour time period, then the ACF values should begin at lag 0 with a perfect correlation of 1.0 and gradually diminish over time concluding in the 95% CI band or just below it. If periodicities are found, the time in which the periodicities occur will be determined. If periodicities occur during turn times, this will indicate significant turning-related hemodynamic changes. Cross-correlations will help to further describe the data by evaluating within-subject associations between HR and MAP, HR and PP, and MAP and PP using individual time-series data.

Within-subject ACF will be calculated for HR, MAP, and PP. For the manual-turn group, number of lags will be equal to the length of time-series data and will include at least two 8-hour cycles (2-hour positioning from back → left → back → right) of data. Lag time will be 300 for the automated-turn group to include at least 2 cycles of 12-minute complete turn data (back → left → back → right). Autocorrelation function graphs will be examined for periodicities that correspond to the same time period as lateral turning: every 2, 4, or 6 hours in the manual-turn group and ≤ 12 minutes in the automated-turn group.

**Cross-Correlations**

Cross-correlations will be done to describe the associations between HR and MAP, HR and PP, and MAP and PP in association with the turning intervention. Cross-correlation is the time-shifted (lagged) covariance between two time series used to identify between-series correlation through time (Riffenburgh, 1999). The correlation is based on the differences between the two variables, not on their individual variability through time (Riffenburgh, 1999). In other words, if two variables (e.g., HR and MAP) show periodicities at the same time (rise and fall together), the correlation will be high. Unlike ACF, cross-correlation measures not only the strength of the relationship (i.e., correlation coefficient), but also the direction (McCleary, 1980; Schmitz, 1990). Cross-
correlations will be computed on each subject’s HR, MAP and PP and graphs examined for a significant relation between the correlated variables as well as the direction and magnitude of relation.

**Two-Way Repeated Measures Analysis of Variance**

Two-way repeated measures ANOVA will be used to test for group differences in HR, MAP and PP according to position and group. The literature suggests positive pressure ventilation impairs venous return to the heart (Mitaka et al., 1989), particularly in the left lateral position (Fessler et al., 1993). Different hemodynamic effects associated with positioning (left or right) are therefore anticipated.

The independent variables are the turning intervention (manual versus automated) and position (Left or right) and the dependent variable is HR, MAP, or PP. Separate analyses will be done for HR, MAP, and PP; thus, a Bonferroni adjustment will be used with alpha of .017 (Pallant, 2007). A strength of the design is that the same subjects are repeatedly measured in the right and left positions using the same intervention (manual or automated turning); therefore, any differences found between treatments cannot be attributed to individual differences, leaving a true treatment effect or experimental error as plausible explanations for rejecting the null hypothesis (Gravetter & Wallnau, 1985). The repeated measures design allows greater precision in estimating true turning intervention effects (Altman, 1991).

Each subject’s HR, MAP and PP time-series data will be sorted and compiled according to position (back, left or right) and intervention group (manual or automated) and a two-way repeated measures ANOVA computed in SPSS. F-ratios will be used to determine if the differences found in the means are statistically significant ($\alpha \leq .017$).

**Data Storage and Back-Up**

All hemodynamic substudy materials will be kept at the University of Texas School of Nursing in a locked file cabinet in a locked office on a card-access controlled...
floor. Electronic data will be: 1) stored on a computer protected by a firewall (shielded from direct connection to the internet) at the University of Texas School of Nursing which is systematically backed up every 24 hours, and 2) saved on the study laptop and desktop computers and three CDs (patient file, master copy, and back-up master copy). The study laptop computers will be password-protected for access and automatically shut down after 5 minutes of non-use.

Records and Reports

Continuing review reports will be sent annually to the Institutional Review Boards of The University of Texas Health Science Center at Houston, The Methodist Hospital and St. Luke’s Episcopal Hospital. An annual progress report will be sent to the American Association of Critical-Care Nurses (AACN), and a final report submitted to the funding organizations at the conclusion of the Hemodynamic Substudy. All reports and documentation of approvals will be kept at the University of Texas Health Science Center at Houston School of Nursing. The findings from the hemodynamic substudy will be submitted to a peer-reviewed journal (e.g., Critical Care Medicine) for publication.
References


APPENDIX A: Intervention Protocols

Manual Turning (Control Group)

1. Verify group assignment and signed consent form is in patient's chart. Record patient’s Study ID, Site, Unit and data collector (D.C.) codes and Turn Date on the Turning Flow Sheet.

2. If turning between 17:00 and 19:00 and patient able, re-consent patient for study participation and document in the Daily Consent column of the Turning Flow Sheet.

3. Note time and enter in Start Turn column. Turn patient to lateral (≥ 45°) position and put body in proper alignment using pillows or blankets. Ensure that all tubes and catheters are free from tension and visible. Assess with RASS and record score in Comments column of the Turning Flow Sheet.

4. Place head of bed (HOB) ≥ 30° according to patient tolerance. Note time and enter in End Turn column on the Turning Flow Sheet. Enter the Turn Position on the Turning Flow Sheet, using “Back,” “Left,” or “Right” as appropriate.

5. Assess patient comfort and explain expected benefits (e.g., secretion mobilization, prevention of bed sores, etc.) from maintaining position as long as possible.

6. Document patient signs and symptoms and adverse events (SSAE) that occurred during turning on the Turning Flow Sheet. If Other SSAE, enter codes 150 and/or 250 and write in Comments column. If the number of SSAE exceeds three, enter the additional SSAE code(s) in the Comments column.

7. Measure angle of turn with study protractor placed at the 2nd anterior intercostal space with the protractor flat (“feet”) end on the midline chest. Allow several seconds for bubble to stabilize. Read degree of angle to the closest 5° interval and record on the Turning Flow Sheet in the column labeled Turn Angle.

8. Measure HOB elevation with study protractor. Place protractor “feet” firmly against the lowest part of the back upper bed frame. Allow several seconds for bubble to stabilize. Read degree of angle to the closest 5° interval and record on the Turning Flow Sheet in the column labeled HOB.

9. In the left and right position, check patient for signs of intolerance and shifts in position every 10 minutes and re-measure angle of turn. Record Obs Time, Turn Angle, and SSAE, as appropriate, on the Turning Flow Sheet. Note: Do not measure angle of turn every 10 minutes when patient is in the Back position.

10. 2 hours following last turn, turn patient to Back position, raise HOB ≥ 30° according to patient tolerance; assess patient comfort; and document date and time turn started and completed, Back position, patient discomfort and any SSAE that occurred during turning on the Turning Flow Sheet.

11. Repeat steps 2 – 10 every 2 hours until the patient transfers out of the ICU, dies, is no
longer receiving mechanical ventilation, has been in the study for > 7 days, or consent is revoked.

Automated Turning (Experimental Group)

Initial Set Up

1. Verify group assignment and signed consent form in patient’s chart. Record patient’s Study ID, Site, Unit and data collector (D.C.) codes and Turn Date on electronic Turning Flow Sheet on the study laptop computer.

2. Press menu button on bed control panel at foot of bed. Select Timer. Verify hours > 40° and hours < 40° are zero. If not, press setup button then press clear meter option. Return to Timer and verify hours are zeroed. Press Exit.

3. Place patient in proper body alignment. Shoulders must be up against headrest pillows at head of bed.

4. Place HOB > 30° according to patient tolerance. Measure HOB elevation with study protractor. Place protractor “feet” firmly against the lowest part of the back upper bed frame. Allow several seconds for bubble to stabilize. Read degree of angle and record in HOB column on the study laptop Turning Flow Sheet.

5. Tell the patient, regardless of level of consciousness, that you are going to activate automated turning and he or she may experience a sense of falling but the pads will prevent falling out of the bed. Program the bed to 45° angle of turn (MAX setting) with 0 pauses for left, back and right turns. Continue with setting following prompts to clear all lines and tubes. Select Acclimation Mode YES and press Rotation ON. Record time in the Start Turn column on the study laptop Turning Flow Sheet.

6. Observe patient for 10 min and assess patient comfort. Explain expected benefits from the automated turning (e.g., secretion mobilization, prevention of bed sores, etc.)

7. After 10 min, and while bed is taking patient to 45°, observe patient comfort level. When 45° is achieved measure angle of turn with protractor and record in Turn Angle column on the study laptop Turning Flow Sheet. Also record ObsTime, side of turn (Turn Position), patient discomfort and any signs, symptoms and/or adverse events (SSAE) noted in the first 10 min of automated turning. If other SSAE, enter Codes 150 and/or 250 and write in Comments column. If the number of SSAE exceeds three, enter the additional SSAE code(s) in the Comments column. Press Rotation ON.

Ongoing Rotation

8. Every hour while bed is taking the patient to 45°, observe patient comfort level. When 45° is achieved, measure angle of turn with protractor and record in Turn Angle column on the study laptop Turning Flow Sheet. Record date (Turn Date) and Obs Time, side of turn (Turn Position), HOB measured with protractor, patient discomfort and any turning-related SSAE on the on the study laptop Turning Flow Sheet. Assess with RASS and record score in the Comments column of the Turning Flow Sheet.
9. Press Select Status to verify rotation settings at 45° angle of turn (MAX setting) with 0 pauses for left, back and right lateral turns. Put/ensure patient in proper body alignment with all lines and tubes clear at HOB and press Rotation ON to resume automated turning.

10. When assessing hourly turn between 17:00 and 19:00 each day and patient is able, re-consent patient for study participation, and document in the Daily Consent column on the study laptop Turning Flow Sheet. Obtain elapsed turning time for both > 40° and < 40° from bed Timer, record in Bed Timer column and reset timer to zero.

Repeat steps 8 and 9 every hour and step 10 daily until patient transfers out of the ICU, dies, is no longer receiving mechanical ventilation, has been in the study for > 7 days, or consent is revoke.
Appendix B: Turning Flow Sheet

Turning Flow Sheet

Study ID:  Site Code:  Unit Code:  Group:

Please use columns according to the color code.

Every new event or change (collector, date, position, re-consent, etc.)

Every new observation

<table>
<thead>
<tr>
<th>D. C.</th>
<th>Turn</th>
<th>Turn</th>
<th>Start</th>
<th>End</th>
<th>Obs</th>
<th>Daily</th>
<th>Bed</th>
<th>HOB</th>
<th>Obs</th>
<th>Turn</th>
<th>SSAE1</th>
<th>SSAE2</th>
<th>SSAE3</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code</td>
<td>Date</td>
<td>Position</td>
<td>Turn</td>
<td>Turn</td>
<td>Date</td>
<td>Consent</td>
<td>Timer</td>
<td>Time</td>
<td>Angle</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix C: Hemodynamic Substudy Procedures

Data Collection

Equipment and Supplies Assembly

1. Study cart
2. 3 Memorex Recordable Compact Discs, CD-R, 700 MB, 80 minute
3. 1 CD writable pen
4. Removable flash drive (Sony, 06D28C8BV, San Jose, CA)
5. Study laptop computer (Hewlett-Packard Compaq, nc6400, Palo Alto, CA)
6. HP docking station (Hewlett Packard, EN488AA, Palo Alto, CA)
7. HP power cable (Hewlett Packard, 384023-001, Palo Alto, CA)
8. Excel program (Microsoft Corporation, Redmond, WA)
9. SPSS (Version 17.0, SPSS Inc., Chicago, IL)
10. TIBCO Spotfire S+ 8.1 (TIBCO Software, Inc.)
11. BedMaster System (Excel Medical Electronics, Inc., Jupiter, FL)
12. LabView (ReadLogFile_v33a, National Instruments, Austin, TX)
13. CaptureEvents_v21 (National Instruments, Austin, TX)
14. Syringe 3 cc
15. ECG electrodes
16. Alcohol pads
17. Shaving razor
18. Tape, double-sided
19. 24" non-compliant tubing
20. Small screwdriver
21. Scissors
22. Tape measure
23. IV pole with transducer mount attachment
24. Physiologic monitor
25. Ladder

Equipment and Supplies Preparation

1. Label 1 CD with patient study number + HS (hemodynamic substudy; i.e. 001HS) using CD writable pen to be used as patient file
2. Label 1 CD with 'master copy' using CD writable pen
3. Create the following files on master copy CD:
• Hemodynamic Substudy
• Individual patient files (e.g., Patient #P001 HS) with subfiles:
  o SPSS Database
  o SPSS Output
4. Label 1 CD with 'back-up master copy' using CD writable pen
5. Create the following files on back-up master copy CD:
   • Hemodynamic Substudy
   • Individual patient files (e.g., Patient #P001 HS) with subfiles:
     o SPSS Database
     o SPSS Output

Data Collection Procedure
1. Note date and time on Hemodynamic Substudy Flow Sheet when hemodynamic substudy begins
2. Perform EKG and transducer checks and record findings on Hemodynamic Substudy Flow (Appendix D) Sheet
3. Check 5-lead electrodes secured to patient's skin
4. Replace loose electrodes (Noone, 1992)
   • Before electrodes placed on chest, wipe the skin with alcohol and allow to dry completely
   • If patient’s chest is hairy, shave small patch of skin to allow the adhesive-backed electrode disk to contact the skin
   • Avoid placing electrodes over bony prominences, joints or skin folds
   • Acceptable ECG tracing will have: (Hudak, Gallo, & Benz, 1990)
     o Narrow, stable baseline
     o Free from artifact
     o Sufficient QRS amplitude to activate alarms
     o Identification of P waves
   • Avoid ECG monitoring artifact by careful electrode placement
     o Place 4 limb electrodes at Left Arm (LA), Right Arm (RA), Left Leg (LL), Right Leg (RL) positions (see diagram below)
     o Place a 5th electrode in the V1 position (Drew et al., 2005)
       ▪ Position 'C' on diagram
       ▪ Fourth intercostal space, right sternal border
5. Check all arterial pressure monitoring connections are secure
6. Check pressure bag adequately inflated by inspecting white pressure indicator
   - Knob is protruding outward with pressure line visible indicating at least 300 mm Hg pressure (Darovic & Zbilut, 2002)
7. Inspect pressure monitoring system tubing and connections for air bubbles
   - If air bubbles present, remove with 3 cc syringe and discard
   - Flush arterial pressure monitoring system with rapid flush pigtail, until all visible blood is removed from pressure monitoring system
8. Ensure arterial line tubing and connections remain off patient
   - Even minimal movement of the pressure monitoring tubing produces an externally induced whip artifact from movement of the fluid within the system (Darovic & Zbilut, 2002)
9. *Level the transducer* using 30 cm ruler aligned at level of the transducer and the mid-heart or mid-axillary line (Gardner & Hollingsworth, 1986)

- Most important step in pressure monitoring system (Gardner & Hujcs, 1993)
- Zeroing process compensates for offset caused by hydrostatic pressure differences in the transducer, amplifier, oscilloscope, recorder, and digital displays (Gardner, 1992)
10. Turn the stopcock closest to the transducer to the horizontal position (off to the pressure system) and open to atmospheric pressure
11. Press the zero button on the bedside physiologic monitor
12. Observe the numeric reading of arterial pressure reads zero
13. Return the stopcock arm to the vertical position (opening the pressure system)
14. Re-zero transducer with any change in HOB or lateral position change
15. Perform calibration to verify accurate reproduction of the pressure signal using the hydrostatic pressure method (Darovic & Zbilut, 2002)
   • Attach flushed 24-inch noncompliant tubing to transducer stopcock at the “zeroing port” and cap distal end (Hazinski, 2002)
   • Uncap the distal end of the tubing and the transducer stopcock is turned “open” between the transducer and tubing (“off” to patient)
   • When the uncapped distal end of the tubing is held at the zero reference point (mid-heart or mid-axillary line) the monitor should display a pressure of 0
   • Using a tape measure, raise the distal end of the tubing to exactly 27.2 cm above the zero reference point
     o Creates column of water 27.2 cm high exerting a pressure of 27.2 cm H$_2$O on the transducer
27.2 cm of H₂O is equal to 20 mm Hg pressure (1.36 cm H₂O = 1 mm Hg pressure)

- The monitor digital display should read a pressure of 20 mm Hg
- Repeat testing for:
  - 68 cm = 50 mm Hg
  - 136 cm = 100 mm Hg
  - 163.2 cm = 120 mm Hg
- If digital display readings are not 0, 20, 50, 100, or 120 mm Hg, repeat leveling the transducer procedures and repeat 2-point calibration
- If readings remain inaccurate, change the transducer and repeat leveling the transducer and calibration

16. Check the *dynamic response* of the system using square wave test

- Dynamic response is the ability of the fluid-filled pressure monitoring system to accurately reproduce pressure variations of the arterial pressure signal on the amplifier/monitor (Darovic & Zbilut, 2002; Imperial-Perez & McRae, 1997)
- Two factors affect systems accuracy (Imperial-Perez & McRae, 1997)
  - Natural frequency (fₙ), which refers to the number of oscillations per second, produced by the system after it is exposed to a pressure signal and
  - Damping coefficient
- Evaluate the response generated on the bedside physiologic monitor when the rapidly closing valve on the continuous flush device (fast flush) is activated and released quickly
  - Print strip of each square wave test and attach to Hemodynamic Substudy Flow sheet using double-sided tape every 4 hours
  - Document on Hemodynamic Substudy Flow Sheet evaluation of testing, system assessment (e.g. air bubbles found) and intervention(s) taken (e.g. air bubbles removed with 3 cc syringe and discarded)
  - A check mark (✓) indicates optimally dampened system with no intervention
  - **Optimally Damped System**
    - Waveform shows sharp upstroke which terminates in a flat line at the maximal indicator and
    - Followed by an immediate and rapid downstroke which extends below the baseline with only 1 or 2 oscillations within 0.12 second (minimal ringing) with a quick return to baseline
Observed waveform (Imperial-Perez & McRae, 1997)

- Intervention:
  - No adjustment necessary

- Overdamped System
  - Waveform shows slurred upstroke of square wave, when waveform does not extend below baseline after rapid flush, and there is no ringing after flush

Observed waveform (Imperial-Perez & McRae, 1997)

- Intervention:
- Check for blood clots, blood in catheter, or air bubbles in the system and remove with 3 cc syringe
- Check for kinks in line
- Check all connections secure
- Repeat and print square wave test and evaluate
- If after 3 repeated square wave tests, system indicates overdampened system, notify site coordinator within 10 minutes and document in comment section of Hemodynamic Substudy Flow Sheet

o **Underdamped System**
  - Waveform characterized by numerous oscillations above and below baseline following fast-flush
  - Monitored pressure wave displays false-high systolic pressure (overshoot) and possibly false-low diastolic pressure with ringing artifacts on waveform

![Observed waveform](image)

(Imperial-Perez & McRae, 1997)

- Intervention:
  - Remove all air bubbles from system (especially pinpoint air bubbles) with 3 cc syringe
  - Repeat and print square wave test and evaluate
  - If after 3 repeated square wave tests, system indicates overdampened system, notify site coordinator within 10
minutes and document in comment section of Hemodynamic Substudy Flow Sheet

17. Repeat steps 5-16: (Imperial-Perez & McRae, 1997)
   • If the accuracy of the pressure readings are questioned and/or
   • After disconnection of the transducer from the pressure cable
   • Once every 24 hours

18. Shake ECG wires and arterial line pressure tubing for 5 seconds at beginning and end of data collection period in order to create purposeful artifact to identify beginning and end of data collection

19. Note date and time at end of the study period on
   • Hemodynamic Substudy Flow Sheet

20. Make 3 copies of Hemodynamic Substudy Flow Sheet

21. Give 1 copy to:
   • Hemodynamic Substudy Principal Investigator (PI)
   • Master files
   • Back-up files

**Computer Set-Up for The Methodist Hospital**

1. Installing RS-232 card:
   • Place patient on portable monitor because vital signs cannot be monitored during installation of RS-232 card (approximately 20 minutes)
   • Remove RS-232 card from antistatic package (static will damage card).
   • Using a 6-foot ladder insert the RS-232 into slot #9 of the CPU (monitor) with screw insert closest to installer — using some force, click card into place and secure with screw
   • Reconfigure monitor → on the monitor go to ‘Monitor Set-up’ → ‘Operating Modes’ → password is 14432 → ‘Change Operating Mode’ → ‘Config’ → ‘Confirm’ → wait a few seconds then ‘Monitor Set-Up’ → ‘RS232’ → confirm the following RS-232 card configuration settings (Philips CMS):
     o Port #1 Computer: ON
     o Baud rate #1: 38400
     o Tx/Rx order #1: LOW/HIGH
   • Finally, click ‘Monitor Set-up’ → ‘Resume Monitoring’
   • Reconnect patient to monitor
2. Connect 9 pin cable from physiologic monitor to laptop computer
   • Will need ladder to reach back of monitor
   • Cable attaches to RS-232 card (slot #9) at back of monitor in port #1 (located closest to wall)
3. Tighten the screws using a screwdriver to secure the connections
4. Secure cable connection to laptop using screwdriver to tighten screws
5. Turn study laptop computer on
6. Check the configuration settings on the physiologic monitor
   • On the monitor go to 'Monitor Set-up' → 'Operating Modes' → password is 14432 → 'Change Operating Mode' → 'Config' → 'Confirm' → wait a few seconds then 'Monitor Set-Up' → 'RS232' → confirm the following RS-232 card configuration settings (Philips CMS):
     o Port #1 Computer: ON
     o Baud rate #1: 38400
     o Tx/Rx order #1: LOW/HIGH
     o If changes made to configuration settings click 'Save Settings'
   • Finally, click 'Monitor Set-up' → 'Resume Monitoring' → when checking configuration will temporarily lose monitored data because not monitoring at that point
7. Log into SafeBoot
   • Put in User name:
   • Put in Password:
8. Log into computer
   • Control + Alt + Delete to login
   • Check 'Workstation only'
   • Put in User name:
   • Put in Password:
9. Check 4 study icons are present on laptop computer
   • Randomization db.xls
   • Philips SCS_v3
   • ReadlogFile_v33a
   • CaptureEvents_v21
   • Philips CMS folder
10. Open CaptureEvents_v21
- Click the 'Stop' button
- Save as: Save as: patients study ID #.txt (i.e. #XXXHS.txt)
- Under 'Header' type in #XXXHS.txt
- Click the arrow button upper left hand corner to run the Capture Events program
- When a significant event occurs type the event under 'Add Notes/Comments' → then click 'update'
- Notice events will be displayed with time stamp in the 'Captured Notes' section
- Identify manual turn patients bed angle
  - In the 'Inclinometer Angle (deg) box type in:
    - '0' for supine
    - '-45' for left turn at 45°
    - '+45' for right turn at 45°
  - Click 'Update'
  - Notice patient angle will be displayed under the 'Captured Events' box

11. Open Philips CMS_V3 program to begin collecting data
- Check the small box labeled 'HR for CMS'
- Save as: patients study ID #.dat (i.e. #XXXHS.dat)
- Under 'Filename' type in #XXXHS.dat → save to C: drive under 'TMH', CMS, XXXHS.dat
- Click ‘Search for Servers’
- Check HR, Press (#1/4), SPO₂ (#1/#2), Resp (#1/4)
- Click ‘Tune Selected Servers’
- Click ‘Start Logging’ to start data collection
- Periodically check saved file (in C: drive under TMH, CMS, XXXHS.dat) is logging data by monitoring size of file increase
  - Will NOT be able to view program actually logging data

12. When 24-hour data collection is completed:
- Click ‘Stop’ to stop data collection in the Philips SCS_v3 program
- Click ‘Stop’ to stop capturing events in the CaptureEvents_v21 program

13. Open LabView (ReadLogFile_v33a) → separate HR and BP into separate columns by
- Selecting 'File location' and opening it (data must be in '.dat' format)
- Wait until data is processed and displayed (long files take a while)
- Select 'Save to file'
- Data will be saved in the same folder (as original file), separated into HR, SBP, DBP

**Computer Set-Up for St. Luke’s Episcopal Hospital**

1. Connect router to Solar 8000 physiologic monitor
   - Black cord (NETGEAR switching adapter) to electrical outlet and power connection on router
   - From back of monitor remove red cable in the Ethernet port and place in the 1st port next to power connection on router
   - Place one end of blue cord in 2nd port on router and the other end into the Ethernet port at the back of monitor
   - Place one end of gray cord to 3rd port on router next to blue cord and other end to laptop computer USB port on back of docking station
   - Ensure patient’s data is displayed on unit computer

2. Log in to computer
3. Click on BedMaster program on desktop → populates every monitor that is on unity network → click on study patient’s bed number in 7S 1 or 2
4. Select ‘Clear All’ to uncheck all parameters
5. Check HR and ART
6. Check ‘enable logger → ‘5 seconds’ → check ‘enable vital signs log file → type in C:PXXXHS.dat
7. Separate data into separate columns using LabView
8. Open LabView (ReadlogFile_V21) → separate HR and BP into separate columns by
   - Selecting ‘File location’ and opening it (data must be in ‘.dat’ format)
   - Wait until data is processed and displayed (long files take a while)
• Select ‘Save to file’
• Data will be saved in the same folder (as original file), separated into HR, SBP, DBP

**Importing Raw Hemodynamic Data to SPSS**

1. Open SPSS program
2. For TMH data there will be separate files for ABP and HR → for SLEH data file is one file containing HR and BP (NBP or arterial line) data
3. Click ‘Open an existing data source’ → click on ‘More files..’ → change the ‘Files of type:’ to ‘Data (*.dat)’ → locate the ‘PXXXHS.dat’ file from → click ‘Open’
4. PXXXHS data appears in the Text Import Wizard
   • Does your text file match a predefined format? → click ‘No’ → click ‘Next’
   • How are your variables arranged? → click ‘Delimited’
   • Are variable names included at the top of our file? → click ‘No’ → click ‘Next’
   • The first case of data begins on which line number? → click ‘1’
   • How are your cases represented? → click ‘Each line represents a case’
   • How many cases do you want to import? → select ‘The first...cases’ and type in ’XXXXXX’ (representing the exact 24 hour data) or click ‘All of the cases’ if you want the entire dataset
   • Which delimiters appear between variables? →
     o For TMH data click ‘Other:’ and place ‘/’ in the box → notice that the date (which was separated by ‘/’ now is separated into different columns of month, day, then year
     o For SLEH data click ‘Tab’, ‘Space’ and ‘Other:’ and place ‘/’ in the box → notice that the ECG and NBP and/or ART data is now separated into different columns
   • What is the text qualifier? → click ‘None’
   • For TMH data from Philips monitor:
     o Variable name → for V1 Data format ‘Do Not Import’ V2 type in ‘DAY’ with Data format ‘Numeric’, V3 type in ‘YEAR’ with Data format ‘Numeric’, V4 type in ‘TIME’ with Data format ‘Numeric’, V5 type in ‘SBP’ with Data format ‘Numeric’ and V6 type in ‘DBP’ with Data format ‘Numeric’ → click ‘Next’
For SLEH data from Solar 8000 monitor:

<table>
<thead>
<tr>
<th>Variable name</th>
<th>Data format</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1</td>
<td>Do Not Import</td>
</tr>
<tr>
<td>V2</td>
<td>Do Not Import</td>
</tr>
<tr>
<td>V3 type in 'DATE'</td>
<td>Date/Time dd:mm:yyyy</td>
</tr>
<tr>
<td>V4 type in 'TIME'</td>
<td>Date/Time hh:mm:ss</td>
</tr>
<tr>
<td>V5</td>
<td>Do Not Import</td>
</tr>
<tr>
<td>V6 type in 'HR'</td>
<td>Numeric</td>
</tr>
<tr>
<td>V7</td>
<td>Do Not Import</td>
</tr>
<tr>
<td>V8</td>
<td>Do Not Import</td>
</tr>
<tr>
<td>V9 type in 'SBP'</td>
<td>Numeric</td>
</tr>
<tr>
<td>V10 type in 'DBP'</td>
<td>Numeric</td>
</tr>
<tr>
<td>V11 type in 'MAP'</td>
<td>Numeric</td>
</tr>
<tr>
<td>V12</td>
<td>Do Not Import</td>
</tr>
<tr>
<td>V13</td>
<td>Do Not Import</td>
</tr>
<tr>
<td>V14</td>
<td>Do Not Import</td>
</tr>
<tr>
<td>V15</td>
<td>Do Not Import</td>
</tr>
<tr>
<td>V16</td>
<td>Do Not Import</td>
</tr>
<tr>
<td>V17</td>
<td>Do Not Import</td>
</tr>
<tr>
<td>V18</td>
<td>Do Not Import</td>
</tr>
</tbody>
</table>

- Would you like to save this file format for future use? → click ‘No’
- Would you like to paste the syntax? → click ‘No’ → click ‘Finish’
- Save the SPSS raw data file → click ‘File’ → ‘Save as’ → under ‘Save in:’ place in file ‘PXXXHS’ → ‘File name:’ type in ‘PXXXHS_ABP_Raw Data.sav’ for TMH data and ‘PXXXHS_Raw Data.sav’ for SLEH data

5. Place HR data (TMH) into SPSS database → Click ‘Open an existing data source’ → click on ‘More files..’ → locate the HR.dat file → click ‘OK’

6. HR data appears in the Text Import Wizard →
- Does your text file match a predefined format? → click ‘No’ → click ‘Next’
- How are your variables arranged? → click ‘Delimited’
- Are variable names included at the top of our file? → click ‘No’ → click ‘Next’
- The first case of data begins on which line number? → click ‘1’
- How are your cases represented? → click ‘Each line represents a case’
• How many cases do you want to import? → select 'The first...cases' and type in 'XXXXXX' (representing the exact 24 hour data)
• Which delimiters appear between variables? → click 'Other:' and place '/' in the box → notice that the date (which was separated by '/') now is separated into different columns of month, day, then year
• What is the text qualifier? → click 'None'
• Variable name → for V1 type in 'MONTH' with Data format 'Numeric' V2 type in 'DAY' with Data format 'Numeric', V3 type in 'YEAR' with Data format 'Numeric', V4 type in 'TIME' with Data format 'Numeric' and V5 type in 'HR' with Data format 'Numeric' → click ‘Next’
• Would you like to save this file format for future use? → click ‘No’
• Would you like to paste the syntax? → click ‘No’ → click ‘Finish’
• Save the HR raw data file → click ‘File’ → ‘Save as’ → under ‘Save in:’ place in file 'PXXXHS' → ‘File name:’ type in 'PXXXHS_HR_Raw'

7. Merge BP data with HR data (TMH) by clicking 'Data' → ‘Merge files...’ → ‘Add variables...’ → click ‘An external SPSS data file’ → click ‘Browse...’ → select the HR data file → click ‘Open’ → click ‘Continue’
8. Save the file under the name ‘PXXXHS_Raw_Dataset’

Importing Raw Turning Angle Data to SPSS
1. Import raw voltage (VI Logger) data directly into SPSS database → DATE, TIME, and VOLTAGE
2. Create ‘ANGLE’ variable next to ‘VOLTAGE’ variable
3. Compute angle data → click ‘Transform’, ‘Compute Variable’ → under ‘Target Variable:’ type in ‘ANGLE’ → under ‘Numeric Expression:’ type in ‘(20*(VOLTAGE-2.5))’
4. Copy excel voltage data including Date, Time, Voltage and Angle
5. Paste voltage data directly into raw SPSS database after the ‘COMMENT’ variable → align data and times before pasting data → note frequency of turning data from VI Logger will be every 1 second

Creating Variable Mean Arterial Pressure for Raw Database (TMH Data Only)
1. Add the variable ‘MAP’ to the raw database → move the ‘HR’ variable to just before ‘SBP’ variable by clicking and dragging → insert new variable after ‘DBP’ titled ‘MAP’ by going to ‘Variable View’ at the bottom left screen → column #8 type in ‘MAP’ → width ‘3’ → decimals ‘0’
2. Click on ‘MAP’ → click ‘Transform’ then ‘Compute Variable...’ → under ‘Target Variable:’ type in ‘MAP’

3. Click under ‘Numeric Expression:’ to symbol ‘( )’ (parentheses sign) → within the parentheses move the variable SBP over using the right arrow key → click the ‘+’ sign → insert another ‘( )’ → within the second parentheses insert the variable DBP using the arrow key then the * (multiplication sign) followed by 2 → finally insert ‘/’ (division sign) then 3 → click ‘OK’ → the complete formula should be:

\[(SBP + (DBP \times 2)) / 3\]

**Creating Variable Pulse Pressure for Raw Database (TMH and SLEH)**

1. Add the variable ‘PP’ to the raw database → insert new variable after ‘MAP’ titled ‘PP’ by going to ‘Variable View’ at the bottom left screen → column #9 type in ‘PP’ → width ‘3’ → decimals ‘0’

2. Click on ‘PP’ → click ‘Transform’ then ‘Compute Variable...’ → under ‘Target Variable:’ type in ‘PP’

3. Click under the variables column ‘Systolic Blood Pressure’ then click the right arrow button to move the SBP variable to the box titled ‘Numeric Expression:’ → then select the ‘-’ (subtraction sign) → then click the ‘Diastolic Blood Pressure’ and the right arrow key to create SBP – DBP numeric expression → finally click ‘OK’ → the complete formula should be:

\[SBP - DBP\]

**Creating SPSS Raw Database**

1. Click ‘Variable View’ → input the following:

   **DATE**
   - **Type**: Date → Click on ‘Type’ box and select ‘Date’ → scroll down to ‘dd-mmm-yyyy’ → then click ‘OK’
   - **Width**: 11 → click on the ‘Width’ box and use the drop down menu to select using the up (↑) and down (↓) arrows ‘11’
   - **Decimals**: 0 → click on the ‘Decimals’ box and use the drop down menu to select using the up (↑) and down (↓) arrows ‘0’
   - **Label**: None
   - **Values**: None
   - **Missing**: None
   - **Columns**: 10 → click on the ‘Columns’ box and use the drop down menu to select using the up (↑) and down (↓) arrows ‘10’
- **Align**: Center → click on the 'align' box and use the drop down menu to select 'center'
- **Measure**: Nominal → click on the 'Measure' box and use the drop down menu to select 'Nominal'

### TIME
- **Type**: Date → Click on 'Type' box and select 'Date' → scroll down to 'hh:mm:ss.ss' → then click 'OK'
- **Width**: 11 → '11' should appear in the 'Width' column
- **Decimals**: 2 → '2' should appear in the 'Decimals' column
- **Label**: None
- **Values**: None
- **Missing**: None
- **Columns**: 10 → click on the 'Columns' box and use the drop down menu to select using the up (↑) and down (↓) arrows '10'
- **Align**: Center → click on the 'align' box and use the drop down menu to select 'center'
- **Measure**: Nominal → click on the 'Measure' box and use the drop down menu to select 'Nominal'

### T.REL (Relative Time)
- **Type**: Numeric → click on 'Width' → type in '5' → click on 'Decimal Places' → type in '0' → then click 'OK'
- **Width**: 5 → '5' should appear in the 'Width' column
- **Decimals**: 0 → '0' should appear in the 'Decimals' column
- **Label**: Relative Time → click on 'Label' column → type in 'Relative Time'
- **Values**: None
- **Missing**: None
- **Columns**: 10 → click on the 'Columns' box and use the drop down menu to select using the up (↑) and down (↓) arrows '10'
- **Align**: Center → click on the 'align' box and use the drop down menu to select 'center'
- **Measure**: Scale → click on the 'Measure' box and use the drop down menu to select 'Scale'

### GROUP (Group Assignment)
- **Type**: Numeric → click on 'Type' box and select 'Numeric' → 'Width' type in '1' → 'Decimal Places' type in '0' → then click 'OK'
- **Width**: 1 → '1' should appear in the 'Width' column
- **Decimals**: 0 → ‘0’ should appear in the ‘Decimals’ column
- **Label**: Group Assignment → type in ‘Group Assignment’
- **Values**:
  - Click on ‘value’ box in data editor → under ‘value:’ box type in ‘1’ then in ‘value label’ box type in ‘Control Group’ then click ‘Add’
  - Click on ‘Value:’ box and type ‘2’ then in ‘value label’ box type in ‘Experimental Group’ then click ‘Add’
  - Click ‘OK’
- **Missing**: None
- **Columns**: 10 → click on the ‘Columns’ box and use the drop down menu to select using the up (↑) and down (↓) arrows ‘10’
- **Align**: Center → click on the ‘align’ box and use the drop down menu to select ‘center’
- **Measure**: Nominal → click on the ‘Measure’ box and use the drop down menu to select ‘Nominal’

**HR (Heart Rate)**
- **Type**: Numeric → click on ‘Width’ → type in ‘3’ → click on ‘Decimal Places’ → type in ‘0’ → then click ‘OK’
- **Width**: 3 → ‘3’ should appear in the ‘Width’ column
- **Decimals**: 0 → ‘0’ should appear in the ‘Decimals’ column
- **Label**: Click on the ‘Label’ box and type in ‘Heart Rate (bpm)’
- **Values**: None
- **Missing**: Click on ‘Missing’ box to bring up ‘Missing Values’ box → click ‘Discrete missing values’ and in the first box below type in 999 → click ‘OK’
- **Columns**: 10 → click on the ‘Columns’ box and use the drop down menu to select using the up (↑) and down (↓) arrows ‘10’
- **Align**: Center → click on the ‘align’ box and use the drop-down menu to select ‘center’
- **Measure**: Scale → click on the ‘Measure’ box and use the drop down menu to select ‘Scale’

**SBP (Systolic Blood Pressure)**
- **Type**: Numeric → click on ‘Width’ → type in ‘3’ → click on ‘Decimal Places’ → type in ‘0’ → then click ‘OK’
- **Width**: 3 → ‘3’ should appear in the ‘Width’ column
- **Decimals**: 0 → ‘0’ should appear in the ‘Decimals’ column
- **Label**: Click on the 'Label' box and type in 'Systolic Blood Pressure (mm Hg)'
- **Values**: None
- **Missing**: Click on 'Missing' box to bring up 'Missing Values' box → click 'Discrete missing values' and in the first box below type in 999 → click 'OK'
- **Columns**: 10 → click on the 'Columns' box and use the drop down menu to select using the up (↑) and down (↓) arrows '10'
- **Align**: Center → click on the 'align' box and use the drop-down menu to select 'center'
- **Measure**: Scale → click on the 'Measure' box and use the drop down menu to select 'Scale'

**DBP (Diastolic Blood Pressure)**
- **Type**: Numeric → click on 'Width' → type in '3' → click on 'Decimal Places' → type in '0' → then click 'OK'
- **Width**: 3 → '3' should appear in the 'Width' column
- **Decimals**: 0 → '0' should appear in the 'Decimals' column
- **Label**: Click on the 'Label' box and type in 'Diastolic Blood Pressure (mm Hg)'
- **Values**: None
- **Missing**: Click on 'Missing' box to bring up 'Missing Values' box → click 'Discrete missing values' and in the first box below type in 999 → click 'OK'
- **Columns**: 10 → click on the 'Columns' box and use the drop down menu to select using the up (↑) and down (↓) arrows '10'
- **Align**: Center → click on the 'align' box and use the drop-down menu to select 'center'
- **Measure**: Scale → click on the 'Measure' box and use the drop down menu to select 'Scale'

**MAP (Mean Arterial Pressure)**
- **Type**: Numeric → click on 'Width' → type in '3' → click on 'Decimal Places' → type in '0' → then click 'OK'
- **Width**: 3 → '3' should appear in the 'Width' column
- **Decimals**: 0 → '0' should appear in the 'Decimals' column
- **Label**: Click on the 'Label' box and type in 'Mean Arterial Pressure (mm Hg)'
- **Values**: None
- **Missing**: Click on 'Missing' box to bring up 'Missing Values' box → click 'Discrete missing values' and in the first box below type in 999 → click 'OK'
• **Columns**: 10 → click on the ‘Columns’ box and use the drop down menu to select using the up (↑) and down (↓) arrows ‘10’
• **Align**: Center → click on the ‘align’ box and use the drop-down menu to select ‘center’
• **Measure**: Scale → click on the ‘Measure’ box and use the drop down menu to select ‘Scale’

**PP (Pulse Pressure)**

• **Type**: Numeric→ click on ‘Width’ → type in ‘3’ → click on ‘Decimal Places’ → type in ‘0’ → then click ‘OK’
• **Width**: 3 → ‘3’ should appear in the ‘Width’ column
• **Decimals**: 0 → ‘0’ should appear in the ‘Decimals’ column
• **Label**: Click on the ‘Label’ box and type in ‘Pulse Pressure (mm Hg)’
• **Values**: None
• **Missing**: Click on ‘Missing’ box to bring up ‘Missing Values’ box → click ‘Discrete missing values’ and in the first box below type in 999→ click ‘OK’
• **Columns**: 10 → click on the ‘Columns’ box and use the drop down menu to select using the up (↑) and down (↓) arrows ‘10’
• **Align**: Center → click on the ‘align’ box and use the drop-down menu to select ‘center’
• **Measure**: Scale → click on the ‘Measure’ box and use the drop down menu to select ‘Scale’

**DIRECTION (Direction of Turn)**

• **Type**: Numeric→ click on ‘Width’ → type in ‘1’ → click on ‘Decimal Places’ → type in ‘0’ → then click ‘OK’
• **Width**: 1 → ‘1’ should appear in the ‘Width’ column
• **Decimals**: 0 → ‘0’ should appear in the ‘Decimals’ column
• **Label**: Click on the ‘Label’ box and type in ‘Direction of Turn’
• **Values**:  o Click on ‘value’ box in data editor → under ‘value:’ box type in ‘0’ then in ‘value label’ box type in ‘Back’ then click ‘Add’  o Click on ‘Value:’ box and type ‘1’ then in ‘value label’ box type in ‘Right’ then click ‘Add’  o Click on ‘Value:’ box and type ‘2’ then in ‘value label’ box type in ‘Left’ then click ‘Add’
Click on 'Value:' box and type '3' then in 'value label' box type in 'Sham Turn' then click 'Add'
Click 'OK'

- **Missing:** none
- **Columns:** 10 → click on the 'Columns' box and use the drop down menu to select using the up (↑) and down (↓) arrows ‘10’
- **Align:** Center → click on the 'align' box and use the drop down menu to select 'center'
- **Measure:** Nominal → click on the 'Measure' box and use the drop down menu to select 'Nominal'

**COMMENT**

- **Type:** String → click on 'Width' → type in ‘20’ → click on 'Decimal Places' → type in ‘0’ → then click ‘OK’
- **Width:** 20 → ‘20’ should appear in the ‘Width’ column
- **Decimals:** 0 → ‘0’ should appear in the ‘Decimals’ column
- **Label:** None
- **Values:** None
- **Missing:** None
- **Columns:** 8 → click on the ‘Columns’ box and use the drop down menu to select using the up (↑) and down (↓) arrows ‘10’
- **Align:** Center → click on the 'align' box and use the drop down menu to select 'center'
- **Measure:** Nominal → click on the 'Measure' box and use the drop down menu to select 'Nominal'

2. Save the database by clicking 'File' → 'Save As...' → find the patients file in the 'Save in:' box → in the 'File name:' box type in 'PXXXHS_Raw_Database' → click 'Save'

**Inserting ‘GROUP’ Variable**

1. Click 'Transform' → 'Compute Variable' → under 'Target Variable:' type in 'GROUP' → under 'Numeric Expression:' type in ‘1’ for control group or ‘2’ for experimental group → click 'OK' → when asked 'Change existing variable?' click 'OK'

2. Save the file

**Inserting the ‘DATE’ Variable Data**

1. Click on the ‘DATE’ variable → on row #1 type in the date using the format ‘dd-mmm-yyyy’
2. Copy the current date in row #1
3. Click on row #2
4. Click the left mouse and hold and drag until the end of the first date period
5. Click right mouse — click ‘Paste’ to insert day #1 date
6. Click the row below day #1 (starting day #2) and type in day #2 date using the format ‘dd-mmm-yyyy’
7. Copy day #2 day
8. Click on the row below day #2 starts
9. Click the left mouse and hold and drag until the end of the second day (and end of 24-hour data collection)
10. Click right mouse — click ‘Paste’ to insert day #2 date

**Inserting 'DIRECTION' Variable Data for Manual Turn Patients**

1. Using the manual turn flow sheet → correlated time with the patients turn angle
2. Insert turn angle under the 'DIRECTION' variable (0=back, 1=right, 2=left)
3. Copy the number that corresponds to the turn angle for that time
4. Click on the row below where the first turn time/angle was imputed
5. Click the left mouse key and hold and drag down the ‘DIRECTION’ variable until the next turn angle to highlight the specific turn time
6. Click the right mouse key — click ‘Paste’ to insert the turn angle value into the highlighted area

**Removing Blank Lines from End of Database**

1. Open patient's completed database
2. Go to end of file by clicking ‘Ctrl’ (control key) and ‘End’
3. Highlight the entire row by clicking on the left column/area containing the numbers → row will be highlighted from ‘DATE’ to ‘COMMENT’
4. Go to row just below the actual ending of data collection → hold the ‘Shift’ key and click the left column/area containing row numbers and all lines between will become highlighted from ‘DATE’ to ‘COMMENT’ should highlight as well as all lines in between
5. Click ‘Backspace’ key to remove all rows without data

**SPlus Script to Align Data**

1. Using Raw databases → separate each variable into separate databases: *must be careful to use exact lower cases and upper cases as below*

   P001.HR with variables DATA, TIME, HR
   P001.BP with variables DATA, TIME, BP
   P001.angle with variables DATA, TIME, ANGLE
2. Incorporate each individual database into SPlus

3. Run script titled 

   ![image](timedate.combination.function.scc) 

4. Run script titled 

   ![image](S-Plus Script.scc) 

**Data Cleaning Procedure**

1. Identify outliers in the data by calculating mean and standard deviation (SD) for the variables HR, MAP, and PP

2. Open a blank word document for recording mean and SD data for each variable → title the word document Variable Descriptive Statistics POOXHS

3. Click on the variable HR → click ‘Analyze’ → ‘Descriptive Statistics’ → ‘Descriptives...’ → place the HR variable using the right arrow key into the box labeled ‘Variables(s):’ → click ‘Options...’ check ‘Mean’, ‘Std. deviation’ → under the ‘Display Order’ box check ‘Variable list’ → click ‘OK’

4. Copy the descriptive statistics box from the SPSS Output and past into the word document Descriptive Statistics POOXHS for use as a reference

5. Repeat steps 3-4 for the variables SBP, DBP, MAP, and PP

6. Round to the nearest whole number by rounding up if ≥ 0.5 and down if < 0.5

7. On the word document with descriptive statistics, calculate outlier criteria using 3 standard deviations from the mean as follows for example:

   - Mean = 133
   - Standard deviation = 14 → 14 X 3 = 42
   - Outlier data = <91 and >175
     - 133 (mean) - 42 (SD X 4) = 91
     - 133 (mean) + 42 (SD X 4) = 175

8. Review each variable (HR, MAP, and PP) for outliers → click ‘Data’ → ‘Select Cases...’ → check ‘If condition is satisfied’ then click the ‘If...’ key → select the HR variable and use the right arrow key to move the variable to the box → use the ‘<’ key to indicate ‘less than’ followed by the variables less than criteria XX (ie. 11) → click ‘Continue’ → under ‘Output’ check ‘Copy selected cases to a new dataset’ → in the ‘Dataset name:’ box type in ‘HR_Outliers_lessthan_XX’ → pull up the new outliers database → save the outlier
database onto the desktop computer and memory stick → print 1 copy of each variables outlier database and place in patient’s file → repeat the steps above to locate SBP, DBP, MAP, and PP outliers

9. Save ‘PXXXHS_Database’ before replacing outliers

10. Replace outlier data with ‘999’ after reviewing print-outs of variable outlier data → save the new dataset as ‘PXXXHS_OutliersReplaced’

11. Continue data cleaning by evaluating for data consistency → looking for data in one part of the data set which is compatible to another part of the data set (e.g., 3 minute period of blood draw will give missing values for MAP)

• Starting with HR column, review data looking for unusual patterns of data (i.e. no data, extreme data, etc) over a distinct time period suggesting a cause for the unusual data such as 2 minute period of erratic HR followed by a 2 minute period of no HR data suggesting ECG lead change

12. Explain in the COMMENT column unusual patterns or comments provided on patient’s Turning Flow Sheet correlating information with corresponding DATE and TIME

13. Repeat #8-12 for the variables MAP, and PP

14. Save the newly cleaned data set to file name ‘PXXXHS_Dataset_OutliersReplaced’ once outliers and data consistency procedures are completed for the variables HR, MAP and PP

15. Place Memorex Recordable Compact Disc, CD-R, 700 MB, 80 minute-patient file in Drive (E:) and close door → under ‘File’ at the top left corner screen, click ‘Save as...’ → under ‘Save as’ drop down box, click on ‘CD-RW Drive (E:)’ → click ‘Save’

16. Click the ‘X’ at the top right corner page to close the file

17. Remove Memorex Recordable Compact Disc, CD-R, 700 MB, 80 minute-patient file CD from the computer and place it in protective plastic case

18. Place Memorex Recordable Compact Disc, CD-R, 700 MB, 80 minute-master copy in Drive (E:) and close door → under ‘File’ at the top left corner screen, click ‘Save as...’ → under ‘Save as’ drop down box, click on ‘CD-RW Drive (E:)’ → click ‘Save’

19. Click the ‘X’ at the top right corner page to close the file

20. Remove Memorex Recordable Compact Disc, CD-R, 700 MB, 80 minute-master copy CD from the computer and place it in protective plastic case

21. Place Memorex Recordable Compact Disc, CD-R, 700 MB, 80 minute-back-up master copy in Drive (E:) and close door → under ‘File’ at the top left corner screen, click ‘Save as...’ → under ‘Save as’ drop down box, click on ‘CD-RW Drive (E:)’ → click ‘Save’

22. Click the ‘X’ at the top right corner page to close the file
23. Remove Memorex Recordable Compact Disc, CD-R, 700 MB, 80 minute-back-up master copy CD from the computer and place it in protective case

Replacing Outliers and Missing Data Procedure
1. Replace missing data (and outliers labeled with 999) by clicking ‘Transform’ in the top toolbar → 'Replace Missing Values…'
2. Click ‘HR’ then the arrow button to place the ‘HR’ variable in the ‘New Variables’ box → a new variable is created in the ‘New Variables’ box called HR_1=SMEAN(HR)
3. Change the New Variable name → in the ‘Name and Method’ box below the ‘New Variables’ box → in the ‘Name’ box change the new HR variable name to ‘HR_RMV’ to mean new HR variable with Replaced Missing Values → click ‘Change’
4. Click under ‘Method:’ ‘Linear interpolation’
5. Repeat steps 1-4 for MAP, and PP → click ‘OK’
6. Click ‘Variable View’ at the bottom left corner of screen → under the new variable HR_RMV change:
   - **Type:** Numeric → click on ‘Width’ → type in ‘3’ → click on ‘Decimal Places’ → type in ‘0’ → then click ‘OK’
   - **Width:** 3 → ‘3’ should appear in the ‘Width’ column
   - **Decimals:** 0 → ‘0’ should appear in the ‘Decimals’ column
   - **Label:** Click on the ‘Label’ box and type in ‘Heart Rate (mm Hg) with Replaced Missing Values’
   - **Values:** None
   - **Missing:** None
   - **Columns:** 7 → click on the ‘Columns’ box and use the drop down menu to select using the up (↑) and down (↓) arrows ‘6’
   - **Align:** Center → click on the ‘align’ box and use the drop-down menu to select ‘center’
   - **Measure:** Scale → click on the ‘Measure’ box and use the drop down menu to select ‘Scale’
7. Click on new variable MAP_RMV change:
   - **Type:** Numeric → click on ‘Width’ → type in ‘3’ → click on ‘Decimal Places’ → type in ‘0’ → then click ‘OK’
   - **Width:** 3 → ‘3’ should appear in the ‘Width’ column
   - **Decimals:** 0 → ‘0’ should appear in the ‘Decimals’ column
• **Label:** Click on the 'Label' box and type in 'Mean Arterial Pressure (mm Hg) with Replaced Missing Values'

• **Values:** None

• **Missing:** None

• **Columns:** 8 → click on the 'Columns' box and use the drop down menu to select using the up (↑) and down (↓) arrows '7'

• **Align:** Center → click on the 'align' box and use the drop-down menu to select 'center'

• **Measure:** Scale → click on the 'Measure' box and use the drop down menu to select 'Scale'

8. Click on new variable PP_RMV change:

• **Type:** Numeric → click on 'Width' → type in '3' → click on 'Decimal Places' → type in '0' → then click 'OK'

• **Width:** 3 → '3' should appear in the 'Width' column

• **Decimals:** 0 → '0' should appear in the 'Decimals' column

• **Label:** Click on the 'Label' box and type in 'Pulse Pressure (mm Hg) with Replaced Missing Values'

• **Values:** None

• **Missing:** None

• **Columns:** 7 → click on the 'Columns' box and use the drop down menu to select using the up (↑) and down (↓) arrows '7'

• **Align:** Center → click on the 'align' box and use the drop-down menu to select 'center'

• **Measure:** Scale → click on the 'Measure' box and use the drop down menu to select 'Scale'

9. Save the new database with missing values replaced onto the desktop computer by clicking 'File' at top left corner screen → 'Save as...' → 'My Documents' → 'Hemodynamic Substudy' → 'Patient #XXXHS' → under 'File Name' in bottom screen type in 'PXXXHS_Missing Values Replaced' → click 'Save'

10. Save the file on the patients master copy and back-up master copy CD

**Descriptive Statistics Procedures**

1. Open cleaned patient database → click 'Analyze' → 'Descriptive Statistics' → 'Frequencies' → move the variables HR, MAP, and PP to the 'Variables(s)' box → click 'Statistics' at the bottom of the 'Frequencies' screen → under 'Central Tendency' check 'Mean', 'Median', 'Mode' → under 'Dispersion' check 'Std.deviation', 'Minimum',
'Maximum', 'S.E. mean' → under 'Distribution' check 'Skewness' and 'Kurtosis' → click
'Continue' → click 'Charts...' at the bottom of the screen → 'Histograms:' and check 'With
normal curve' → click 'Continue' → finally click 'OK'

2. Save each patients descriptive statistics SPSS output

**Ensemble Averaging Procedures**

1. Using aligned data (hemodynamic data with turning data) from SPlus script run ensemble
    average SPlus script using individual patient HR, MAP and PP data
2. Save ensemble average data

**Autocorrelation Function and Cross-Correlation Procedures**

1. Using aligned data (hemodynamic data with turning data) from SPlus script run ACF and
cross-correlation analysis using SPlus script from individual patient HR, MAP and PP data
2. Save ACF and cross-correlation output

**Two-Way Repeated Measures ANOVA Procedures**

1. Using HR, MAP and PP data separated by position (back, left and right) individual mean
data is combined with other within group data and a mean calculated (i.e.
   Manual_Back_HR and Automated_Back_HR)
2. Run two-way repeated measures ANOVA in SPSS
3. Save output
### Appendix D: Hemodynamic Substudy Flow Sheet

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Study ID</th>
<th>Electrodes Secure</th>
<th>Connections Secure</th>
<th>Pressure Bag Inflated</th>
<th>Tubing Free of Air Bubbles</th>
<th>Tubing Off Patient</th>
<th>Transducer Leveled to Mid-Axillary Line</th>
<th>Square Wave Testing And Interventions</th>
</tr>
</thead>
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Appendix C
Digitized Data Acquisition

The CMS monitor collects both waveform and numeric signals. Waveforms are sampled at 12-bit resolution - either 500 Hz (ECG) or 125 Hz (arterial blood pressure). Every 1024 ms, numerics are derived from corresponding waveforms and then averaged for display. For heart rate (HR) values less than 40 beats per min (bpm), a moving average of every two beats is used to derive the average HR, every four beats for HR 41 to 100 and every 8 beats for HR values greater than 100 bpm. Systolic and diastolic arterial blood pressure data are measured with every pulse.

A customized software application written in C# language by Dr. Brazdeikis allowed access to the CMS monitor’s numeric data through a RS232 interface card. A 9-pin cable was used to connect the RS232 interface card with the serial port of a laptop computer. The student selected HR, systolic and diastolic blood pressure to be collected. The software program would first communicate with the monitor to verify which numeric data are available for access. All data were then transmitted in packets called messages. When the monitor responded with a list of message IDs or available numeric data (HR, blood pressure, respiratory rate, etc.), a message was sent to the monitor requesting continuous receipt of a set of the selected numeric data with date and time stamp. All data received from the monitor were identified by the message ID (HR, systolic blood pressure, and diastolic blood pressure) and saved to a designated text file every 1024 ms; whatever data were available at the 1024 ms time point were written to file and saved. The study variables therefore had unequal sampling frequencies with lines of missing data since the HR variable was sampled at 500 Hz and the arterial blood pressure at 125 Hz.

Dr. Brazdeikis reprogrammed the CMS monitor software to save only one raw database with no missing lines of data. Aggregating the data to 6 seconds rendered the differing sampling frequencies irrelevant. For the manual-turn group, turn position (back, left, or right) was manually incorporated into the raw database. Automated turn angles (0° to ± 60°) at a sampling
rate of every 1 second were imported into the raw SPSS (Version 17.0, SPSS Inc., Chicago, IL) database.

Dr. Padhye developed a script in TIBCO Spotfire S+ 8.1 (TIBCO Software, Inc.) to align the hemodynamic variables and turn angles with a single time variable. The script aggregated the data for each variable into 6-second bins and created a uniform time grid beginning at the earliest time point and ending at the latest time point. All variables were then projected onto the uniform grid and exported to an Excel file and then imported into SPSS for analysis.

With the Solar 8000 monitor, waveforms are sampled at 8-bit resolution with ECG at 500 Hz and arterial blood pressure at 120 Hz. Numerics for HR are based on a moving average of every 8 beats while arterial blood pressure (systolic and diastolic) is measured with every pulse.

The Solar 8000 monitor operates using the GE Medical Systems Information Technologies Unity Network which is a hospital communication link used for sharing such hospital information as patient monitoring and laboratory data. The Unity Network uses industry standard equipment such as Ethernet cabling and communication protocols (TCP/IP family). BedMaster software (Excel Medical Electronics, Inc., Jupiter, FL) is an independent program that uses this open architecture to retrieve patient data from the Unity Network. The BedMaster program was purchased and installed on study laptop computers. Using a router, the study laptop computer was connected to the bedside monitor’s Ethernet port to gain access to the Unity Network while still allowing patient monitoring data to be viewed from the bedside monitor and the ICU’s central monitoring station. The hospital’s IP address was entered into BedMaster’s network setup. When the BedMaster program was launched from the study laptop computer, all hospital Unity Network patient monitoring devices available for access were displayed on the program’s main dialog screen. After selecting the study patient’s physiologic monitor location, HR and arterial blood pressure (systolic, diastolic and mean) were selected at a 6-second sampling rate. Date and time stamped HR and blood pressure data were then
written and saved to a computer file. Turn data were imported into the raw data files. The S+ script was then used to properly align the hemodynamic and turn data.
Hemodynamic Effects of Turning

Adverse Hemodynamic Effects of Lateral Rotation During Mechanical Ventilation

Shannan K. Hamlin, MSN, RN, ACNP, CCRN; Sandra K. Hanneman, PhD, RN, FAAN; Sheryln Wachtel, MSN, RN, CNS; Gary Gusick, DSN, RN, CCNS

Turning critically ill, mechanically ventilated patients every 2 hours is a fundamental nursing intervention to reduce the negative impact of prolonged immobility from preventable pulmonary complications such as ventilator-associated pneumonia and atelectasis. Unfortunately, when coupled with positive pressure ventilation, the benefits of turning may come at the expense of cardiovascular function. Clinicians should closely monitor the hemodynamic response to turning mechanically ventilated patients, and if compromise is observed, the degree and duration of compromise may provide guidance to the appropriate intervention.

Keywords: Hemodynamics, Lateral rotation, Mechanical ventilation.

As aerobic living organisms, human beings depend on oxygen for survival. In fact, in the struggle against death from any cause, the battle becomes the restoration or maintenance of adequate tissue oxygen delivery (DO$_2$) and consumption (VO$_2$). The lungs, heart, and vasculature work in concert to maintain adequate DO$_2$ and VO$_2$. In many critically ill patients, mechanical ventilation is a life-sustaining intervention to increase arterial oxygen content. The benefits of positive pressure ventilation (PPV), however, may be countered by the negative hemodynamic effects of increased intrathoracic pressure (ITP). The extent to which PPV alters cardiovascular function depends in part on (1) cardiac reserves, (2) biventricular function, (3) circulating blood volume, (4) blood flow distribution, (5) autonomic tone, (6) lung volume, (7) ITP, and (8) surface pressures on the remainder of the circulation.

In addition to adverse hemodynamic effects, mechanically ventilated patients are at risk of developing pulmonary complications from prolonged immobility, such as ventilator-associated pneumonia and atelectasis. Nurses have long recognized the negative impact of prolonged immobility on critically ill patients, prompting the standard of care of lateral rotation every 2 hours. Recent reports, however, indicate that patients are not being turned every 2 hours. Krishnagopalan and colleagues observed that 97% of intensive care unit (ICU) patients were not turned every 2 hours; 50% of the patients were supine for 4 to 8 hours, and 23% were not repositioned for more than 8 hours. Investigators...
of a study of chronically critically ill ICU patients who were physiologically stable also found that patients were not turned every 2 hours. Still others found that the average turning frequency was longer than 5 hours for a variety of medical and surgical patients on mechanical ventilation. Automated lateral rotation with kinetic therapy, defined as the continuous gradual turning along the longitudinal axis to greater than or equal to 40 degrees on each side by a specialty bed, may help to prevent the pulmonary complications of prolonged immobility. Kinetic therapy may be an antidote to the low compliance with the 2-hourly turning standard of care for the mechanically ventilated patient. However, kinetic therapy is expensive and has hazards of its own.

**Nurses have long recognized the negative impact of prolonged immobility on critically ill patients.**

Lateral rotation in mechanically ventilated patients can reduce mixed venous oxygen saturation ($SvO_2$) up to 12%, with most studies reporting a greater decrease in the left versus the right position. Even in studies of healthy human beings and animals, investigators have reported significant changes in the heart rate and blood pressure with lateral positioning with the greatest negative effect in the left lateral position. Although adverse hemodynamic effects are typically transient, with recovery-to-baseline values less than or equal to 5 minutes, patients with limited cardiopulmonary reserves may experience more dramatic and prolonged hemodynamic changes. Given that kinetic therapy devices may be programmed for pauses in turning, clinicians need to consider the potential adverse hemodynamic consequences of PPV with manual turning or automated lateral rotation therapy. The following discussion focuses on the physiological basis for the adverse hemodynamic effects during PPV, especially when coupled with lateral rotation. This review may stimulate clinicians to increase the surveillance for hemodynamic compromise during turning of mechanically ventilated patients and provide guidance for both timely and appropriate interventions.

**The Hemodynamics of Venous Return**

An adequate preload from venous return is paramount to the heart’s ability to deliver oxygenated blood to the tissues (ie, $Do_2$). According to the Frank-Starling mechanism, cardiac preload is defined as the ventricular fiber length at end-diastole; clinically, preload refers to the left ventricular end-diastolic volume. Central venous pressure can be considered a right-sided preload indicator. The greater the end-diastolic volume, the greater the force of ventricular contraction. Relative or absolute hypovolemia reduces preload and stroke volume with a subsequent decrease in cardiac output and $Do_2$. Relative hypovolemia may occur with PPV when venous return is decreased from the increase in ITP. This mechanism may be manifested with the initiation of PPV, positive end-expiratory pressure (PEEP), continuous positive airway pressure (CPAP), and with large tidal volumes and other hyperinflation modalities. In such circumstances, the patient may require transient hydration to compensate for the reduced venous return.

During normal negative pressure breathing, with inspiration, the expanding lungs create negative ITP as the respiratory muscles contract and the pressures within the tracheobronchial tree and alveoli become subatmospheric. This process creates a “vacuum” that augments the flow of blood from the low-pressure, low-resistance, large-volume venous circulation to the right atrium. The process of venous blood flow involves an interplay of the physical principles of hydraulics, pressure, flow, and resistance. Poiseuille law is used to explain how the flow within a vessel is highly dependent on the vessel’s radius or degree of constriction and opposing vasodilation.

**Resistance** = **Pressure** / **Flow**

Pressure is defined as the mean intraluminal force within the vessel; flow is the volume of blood passing through the vessel per unit of time; and resistance is the impedance to blood flow through the vessels.

Ohm law further emphasizes the extent to which blood flow is dependent on sufficient pressure with an acceptable range of counterresistance to propel the blood forward. The relation between flow, pressure, and resistance is represented by:

**Flow** = - **Pressure** / **Resistance**

Resistance to flow is determined by blood viscosity, length of the vascular bed, and vessel radius or diameter, with vessel diameter being the most influential factor.

Blood viscosity may play an important role in venous flow rate, especially with patients who are hypovolemic, because viscous blood tends to “drag” in the vasculature and significantly increases flow resistance. Thus, independent of the heart, adequacy of venous blood flow is dependent on a sufficient vascular...
pressure to move the blood toward the right heart and a lower counterpressure to create a sufficient venous return gradient.

Three factors affect the venous return to the heart from the venous circulation\textsuperscript{31}: (1) right atrial pressure ($P_{ra}$), which exerts a back-pressure impeding venous return, (2) mean systemic filling pressure ($P_{ms}$), which is the pressure in the peripheral vasculature driving venous blood flow to the right heart,\textsuperscript{23} and (3) resistance to venous return (RVR), which reflects both resistance and capacitance of the circulation between the peripheral vessels and the right atrium. Returning to Ohm law, venous return is characterized more specifically by the following equation\textsuperscript{31}:

$$\text{Venous return} = \frac{P_{ms} - P_{ra}}{\text{RVR}}$$

where the numerator is the pressure gradient for venous return ($P_{ms} - P_{ra}$), and the denominator, RVR, is the resistance to venous blood flow.\textsuperscript{33} $P_{ms}$ is a critical component and is influenced by the blood volume, the elastic properties of the systemic vessels, and the pressure surrounding them.\textsuperscript{34}

The greater the volume of blood in the venous circulatory system, the greater the value of $P_{ms}$ because extra volume within the vasculature exerts pressure on the walls of the vessels.\textsuperscript{31} Although veins have a large capacity and are highly compliant, if resistance in the veins rises, blood backs up in all parts of the systemic circulation and venous return falls (Figure 1).\textsuperscript{31} When $P_{ra}$ is reduced below $P_{ms}$, venous return increases.\textsuperscript{35} As $P_{ra}$ is reduced further, venous return will reach a maximum level (critical downstream pressure) which cannot be exceeded despite further decreases in $P_{ms}$.

Venous return is a primary determinant of cardiac output.\textsuperscript{31} One role of the heart is to lower $P_{ms}$ to allow optimal drainage from the venous system and filling of the heart chambers.\textsuperscript{33} In the regulation of cardiac output, venous return is influenced by peripheral circulation factors. These include (1) blood volume, (2) venous dilatation, and (3) patency of the large veins (ie, inferior vena cava and superior vena cava).\textsuperscript{33} Venous return and therefore cardiac output may be decreased by low circulating blood volume (absolute or relative hypovolemia), acute venous dilation (such as that which may occur with sepsis or neurogenic shock), and/or obstruction of a vena cava (eg, superior vena cava syndrome).

**Venous return is a primary determinant of cardiac output.**
of high ITP can reduce venous return and shift the interventricular septum to the left, impairing the left ventricular filling and cardiac output.\textsuperscript{26,36}

High levels of PEEP, often applied to increase functional residual capacity\textsuperscript{25} in cases of pulmonary inflammation, edema, and infiltration, are associated with rises in ITP. As the lungs expand from positive pressure, chest wall is pushed outward, and the diaphragm is pushed downward, while the cardiac fossa is pushed upon itself, shifting the septum toward the left ventricular cavity (Figure 3) and constraining the left ventricular filling.\textsuperscript{17,18}

Within the thorax, the heart is a pressure chamber within a pressure chamber; that is, independent of the heart itself, changes in ITP affect the pressure gradient for venous return to the right ventricle and systemic outflow from the left ventricle.\textsuperscript{2} In most circumstances, as lung volume increases, diaphragmatic descent increases, shifting some of the increased ITP to the intra-abdominal cavity.\textsuperscript{37,38} Because a large proportion of the venous blood is then in the abdomen, increased ITP may actually increase the Pa, thereby serving as a mechanism to blunt the adverse hemodynamic effects of PPV and reduced venous return.\textsuperscript{34} However, in circumstances such as intra-abdominal hypertension, which may be caused by disease processes such as acute pancreatitis, bowel ischemia, and trauma, diaphragmatic descent is limited, and increases in ITP compromise venous return and systemic outflow.

Increased ITP also affects the hydraulic determinants of venous return. In patients receiving mechanical ventilation, Pms - Pm may not represent the effective gradient for venous return.\textsuperscript{41} Similar to the normal negative pressure breathing, during PPV, venous return becomes maximal when \( P_m \) is reduced to a pressure below zero (\( P_{\text{net}} \)), which represents the minimal downstream pressure for venous return. Positive pressure ventilation increases critical downstream pressure to a level greater than the \( P_{\text{net}} \), suggesting an increased pressure on the surface of the veins.\textsuperscript{39}

Animal studies have shown that \( P_{\text{ms}} \) and \( P_m \) rise equally, therefore preserving the pressure gradient.\textsuperscript{42,43}

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Jellinek and colleagues\(^4\) corroborated this finding in 10 patients undergoing implantation of defibrillator devices. This procedure involves an induced ventricular fibrillation for the threshold testing of the device, with periods of circulatory arrest long enough (3-7.5 seconds)\(^4\) to measure \(P_{\text{max}}\). The investigators found that increasing the mean airway pressure from 0 to 15 cm \(H_2O\) with PEEP increased \(P_a\) and \(P_{\text{max}}\) equally. These data suggest that PEEP with PEEP decreases venous return by (1) altering the conductance of venous blood flow and/or (2) elevating \(P_{\text{eff}}\) greater than \(P_{\text{max}}\).\(^4\,5\)

A linear relation exists among the level of PEEP, lung compliance, and ITP, which in turn is directly associated with venous return, stroke volume, and cardiac output on the basis of the Frank-Starling mechanism.\(^5\,14\,15\) Positive end-expiratory pressure levels of 15 cm \(H_2O\) can reduce ventricular stroke volume by as much as 50%.\(^4\) Using an animal model, Mitchell and colleagues\(^17\) demonstrated that at higher levels of PEEP, right ventricular diameter was greater with reduced left ventricular end-diastolic volume from constrained filling, suggesting a leftward septal shift. Peters and colleagues\(^18\) corroborated this finding by evaluating the regional distribution of labeled red blood cells in spontaneously breathing volunteers placed on CPAP and found that within minutes, blood was shifted from the intrathoracic to the abdominal compartment. Left ventricular red blood cell counts were reduced by 10% and remained diminished throughout CPAP breathing. Cardiac output and therefore \(D_o\) may be significantly affected by an abrupt reduction in central circulating volume. Clinically, these positive pressure-induced hemodynamic changes result in a reduced mean arterial pressure which may be profound and require rapid intravascular volume expansion especially in the patient with cardiac dysfunction.\(^19\)

If reduced venous return is not the result of a reduced venous pressure gradient, then the vasculature itself may be to blame. When the pressure in the vena cava is below the \(P_{\text{cap}}\) condition called "vascular waterfall" exists.\(^17\,20\) When vascular waterfall conditions exist, changes in pressure downstream from the waterfall (ie, after the waterfall) have no influence on flow. The pressure at the outflow site of the vena cava is no longer the effective downstream pressure for venous return.\(^18\,55\) In other words, when positive pressure is applied, pressure within the intrathoracic vena cava increases.\(^18\) When the external surface pressure surrounding at least a portion of the large veins is in excess of the outflow pressure at the distal end of the compression site, a vascular waterfall is created upstream from the right atrium.\(^56\,57\) Flow then becomes proportional to the difference between the upstream pressure and the external pressure surrounding the vessel. Changes in the downstream pressure have no influence on flow.\(^50\)

Interestingly, the superior vena cava in all body positions remains widely patent during PPV, with and without PEEP, in contrast to the inferior vena cava where sharply localized increases in pressure suggest localized narrowing.\(^18\,52\) Nakao and colleagues\(^5\) reported that as PEEP levels increase, the dimension of the inferior vena cava increases, and the collapsibility index (percentage of expiratory decrease in inferior vena cava dimension) decreases, suggesting a progressive increase in resistance to venous return. Nakao and colleagues\(^5\) studied 15 patients with emphysema and 10 control patients without pulmonary or heart disease. By cineangiography, the control group showed a patent inferior vena cava during inspiration and expiration. In patients with emphysema, there was often a complete arrest of the upward movement of blood flow in the inferior vena cava throughout inspiration, and forward flow could be detected only during expiration. These findings suggest that the application of PEEP and any positive pressure modality in patients with respiratory pathology may potentially decrease venous return.

Changes in ITP may affect cardiac performance.\(^5\) For example, PEEP can induce a 30% to 50% decrease in venous return.\(^15\) In 10 patients with acute respiratory distress syndrome, increase in level of PEEP was associated with progressive decline in cardiac output, mean arterial pressure, and left ventricular dimension, as well as septal bulging into the left ventricle; heart rate did not change with progressive levels of PEEP.\(^49\) Volume resuscitation likely improves the negative hemodynamic effects of PPV. Evidence shows that patients who are volume loaded tend to have a smaller fall in cardiac output.\(^56\,57\)

**Adverse Hemodynamic Effects of Lateral Rotation**

Nakao and colleagues\(^5\) studied the effects of positioning on the shape and size of the inferior vena cava using echocardiography in patients without evidence of cardiac disease. They reported a significant decrease in vessel diameter and area in both the right lateral and left lateral positions compared with the supine position, with the smallest diameter and area found in the left lateral position. The shape of the inferior vena cava was round in the right lateral, oval in the supine, and slitlike in the left lateral positions. The collapsibility index in this study was found to be 5 times larger in the supine position compared to the right lateral position, and due to the small vessel size, it could not be assessed in the left lateral position. Fessler and colleagues\(^18\) reported a direct PEEP-induced inferior vena cava compression...
that was more prominent in the left lateral position in an animal model. They concluded that greater inflation of the right lung leads to greater inferior vena cava compression when lying in the left lateral position.

**CONCLUSION**

Critically ill, mechanically ventilated patients are complex and challenging to manage. Clinicians share responsibility for (1) ensuring that patients have adequate $\text{DO}_2$ and (2) preventing ventilator-associated complications such as pneumonia and atelectasis through frequent lateral repositioning. Mechanical ventilation is an essential lifesaving intervention used in the ICU to restore and maintain adequate $\text{DO}_2$. Unfortunately, the benefits of this intervention may come at the expense of cardiovascular function. Negative hemodynamic effects of PPV coupled with lateral rotation include (1) increased pericardial pressure with constrained left ventricular filling; (2) reduced venous return; (3) reduced mean arterial pressure, stroke volume, and cardiac output; (4) change in the determinants of the venous pressure gradient; (5) reduced $\text{SvO}_2$; and (6) inferior vena cava compression that creates a vascular waterfall condition which is more pronounced in the left lateral position. Although typically transient (≤5 minutes), patients with reduced intravascular volume or limited cardiopulmonary reserves may experience greater and more prolonged hemodynamic compromise than those with adequate circulating volume and cardiopulmonary reserves.

Kinetic therapy may prevent pulmonary complications from prolonged immobility but may contingently induce adverse hemodynamic effects. In contrast to manual lateral rotation, there has been little research on hemodynamic response to automated lateral rotation therapy. Research is needed on the hemodynamic response to kinetic therapy, with and without pauses in rotation. Because kinetic therapy turning is more gradual than manual turning to the lateral position and the patient is in constant motion, adverse hemodynamic effects may be mitigated. However, a pause in rotation, particularly in the left lateral position, may result in transient hemodynamic compromise similar to what might be seen with manual lateral rotation.

Clinicians are advised to monitor the hemodynamic response to both manual and automated turning in mechanically ventilated patients. If hemodynamic compromise is observed, the degree and duration of compromise may provide guidance to the appropriate intervention. Clearly, lateral rotation should be suspended if the compromise is clinically important. A modest transient compromise, with parameters returning to baseline within 5 minutes, may simply require vigilant monitoring to see if the compromise becomes more serious with changes in patient condition. In some cases, hydration may be considered to treat relative or absolute hypovolemia.

Perhaps one of the greatest challenges in critical care practice is on balancing the benefit and harm from a treatment. In this article, we have reviewed the physiological basis of compromised hemodynamic function from mechanical ventilation and lateral rotation. Persistently high rates of preventable pulmonary complications and the disconcerting literature citing low compliance with turning mechanically ventilated patients in the ICU warrant attention from clinicians and researchers alike. One goal of care is to reduce preventable pulmonary complications without compromising $\text{DO}_2$ and $\text{VO}_2$. Turning patients with manual or automated lateral rotation may not accomplish this goal for every mechanically ventilated patient across varying conditions of physiological stability, and vigilant surveillance is warranted.

**References**


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ABOUT THE AUTHORS
Shannan K. Hamlin, MSN, RN, ACNP, CORN, is a doctoral student at The University of Texas School of Nursing at Houston as well as an acute care nurse practitioner and research fellow at The Methodist Hospital.

Sandra K. Hanneman, PhD, RN, FAAN, is the Jerold B. Katz Distinguished Professor for Nursing Research and associate dean for research and director of the Center for Nursing Research at The University of Texas Health Science Center at Houston.
Sheryln Wachtel MSN, RN, CNS, is a doctoral student at The University of Texas School of Nursing at Houston and a clinical nurse specialist at Christus Spohn Hospital Corpus Christi.
Gary Gusick, DSN, RN, CCNS, is a clinical nurse specialist at St Luke's Episcopal Hospital.

Address correspondence and reprint requests to: Shannan K. Hamlin, MSN, RN, ACNP, CCRN, The Methodist Hospital, 6565 Fannin St, Mailbox MGJ11-02, Houston, TX 77030 (shamlin@tmhs.org).

Call for Student Abstracts
Dimensions of Critical Care Nursing would like to issue a call for abstracts from undergraduate and graduate nursing students for a new section called, “Student Abstracts.” Both undergraduate and graduate nursing students in the area of critical care conduct much good research, and I would like to share the results of this research with our readers. So many times, the results of this research is presented in the classroom setting and not disseminated to others. Here is an opportunity for those students to publish their abstracts.

If you would like to submit your research abstract, you must be either an undergraduate or a graduate nursing student. Your research must be related to the area of critical care nursing. Please submit the following:

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No more than 2 paragraphs summarizing the research and its findings
Please submit the abstract to DCCN at:

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Abstract— Mechanically ventilated patients in the intensive care unit (ICU) are typically turned manually by nursing staff to reduce the risk of developing ventilator-associated pneumonia and other problems in the lungs. However, turning can induce changes in the heart rate and blood pressure that can at times have a destabilizing effect. We report here on the early stage of a study that has been undertaken to measure the cardiovascular impact of manual turning, and compare it to changes induced when patients lie on automated beds that turn continuously. Heart rate and blood pressure data were analyzed over ensembles of turns with autoregressive models for comparing baseline level to the dynamic response. Manual turning stimulated a response in the heart rate that lasted for a median of 20 minutes and was of magnitude 5 to 13 bpm. The corresponding response in mean arterial pressure was 11 to 19 mm Hg, lasting for 8 to 21 minutes. There was no discernible response of either variable to automated turns.

I. INTRODUCTION

Mechanical ventilation is a common intervention in the intensive care unit (ICU) aimed at providing vital oxygen to tissues. Sedation, paralysis, and mechanical ventilation itself impedes a patient’s ability to mobilize and expel rapidly accumulating secretions thereby increasing the risk for developing ventilator-associated pneumonia (VAP) and death. This risk is mitigated by the practice of turning patients from side-to-side periodically to mobilize stationary secretions. Nursing staff in the ICU are generally wary of a possible destabilizing influence of turning on cardiovascular variables, such as heart rate and blood pressure. Adverse cardiovascular responses to turning, although common, should return to baseline values (pre-turn values) in ≤ 5 minutes [1].

Recently, some ICUs have experimented with the introduction of automated beds that continuously rotate the plane of the bed around a lengthwise axis through the center of the bed. The expectation is that continuous turning will reduce the risk of developing VAP by increasing secretion mobilization [2]. However, cardiovascular response to continuous side-to-side movement has not been determined.

Our ongoing randomized clinical trial (RCT) study design is aimed at measuring the cardiovascular response to manual and automated turning in ICU patients (ClinicalTrials.gov: NCT00542321). In this preliminary report we present the methods developed for analysis over an ensemble of turns of autocorrelated heart rate and blood pressure data, illustrated with a case study of two participants: one manually and one automatically turned.

It is found that manual turns induce increases in heart rate and blood pressure that last several minutes, regardless of the direction of the turn. There are four types of turns: patients can be turned from lying on their back to lying with 45 degree inclination to their left or to their right, and reverse turns from either side to lying on their back. Ensemble averages were computed for all turns within each turn category. For the automated turns, angles were measured continuously and an ensemble average was computed across all turns. The blood pressure measurements needed correction due to angle-dependent changes in the height of the transducer used to measure blood pressure. The heart rate and corrected blood pressure did not show a statistically significant response to the automated turns.

II. METHODS

A. Settings and Subjects

Randomized selection and assignment to manual and automated turning groups is being used for enrollment of participants into the study. Potential participants are patients admitted to ICUs at The Methodist Hospital (TMH) and St. Luke’s Episcopal Hospital (SLEH) in the Texas Medical Center. The Institutional Review Boards approved the study. The manual-turn patient was a 77 year-old Hispanic male, with a primary diagnosis of pneumonia with severe sepsis, body weight of 68 kg, and APACHE II (severity of illness measure) score of 25. The automated-turn patient was a 53 year-old Caucasian male, with a primary diagnosis of pneumonia, body weight of 157 kg, and APACHE II score of 22.

B. Data Collection

A data acquisition system for the TMH site was implemented in C# (Microsoft Visual Studio .NET 2003, Microsoft Inc. Redmond, WA) to collect heart rate and
arterial blood pressure data via a serial port from the Philips CMS hospital monitoring system. The BedMaster software (Excel Medical Electronics, Inc. Jupiter, FL) was used for the SLEH site to collect physiological data from Solar 8000 monitors (GE/Marquette, Milwaukee, WI) every six seconds via the Unity Network (GE Medical Systems Information Technologies). The monitoring systems provided systolic and diastolic values of the blood pressure waveform and heart rate for a minimum of 24 hours on each subject. Mean arterial pressure (MAP) was calculated as a weighted sum of systolic (weight = 2/3) and diastolic (weight = 1/3) blood pressure values.

In the case of participants who were randomly assigned to the manual-turn group, times and directions of the turns were noted by the research nurse. Turns were approximately two hours apart. Turn times denote the beginning of the turns, but they were estimated and noted after the turn was over, which introduced an uncertainty of up to ±5 minutes in the turn times. Cushions were used to maintain a chest angle ≥ 45 degrees to the vertical.

The automated beds (Triadyne Proventa, Kinetic Concepts, Inc., San Antonio, TX) had air-filled mattresses and rotation was accomplished by alternately inflating and deflating sections of the mattress. The bed rotation cycle time was approximately 12 minutes, with variation of up to 90 seconds depending on patient weight. The built-in angle measurement had some deficiencies for the requirements of the study. At our request, the company outfitted the research beds with a second angle sensor for a real-time angle of turn readout from the research beds. The angle data were read into the VI Logger (National Instruments, Austin TX) using a 12-bit data acquisition module (NI USB-6008, National Instruments, Austin, TX) at a sampling rate of one second.

The measured angles corresponded to the mattress frame angle at the head of the bed, which could be different from the chest angle of a person lying on the air-filled mattress. We conducted an experiment with four healthy subjects to estimate the empirical correction to the calibration curve that allowed us to estimate chest angles that were accurate within 5 degrees. The sensor data conversion (voltage to angle), calibration, angle correction, and time synchronization across the physiological and the angle of turn data were implemented in LabView software (National Instruments, Austin, TX).

C. Statistical Signal Processing

Heart rate and blood pressure data were extracted for each manual turn starting 15 minutes before the turn and extending 45 minutes past the turn time. Data were resampled into uniform 12-second bins. The larger sampling interval was chosen to reduce high autocorrelation in the original data. Extreme outliers that were beyond a 3-interquartile range spread from the first and third quartiles of the distribution were discarded to reduce impact on generalized least squares models that were used subsequently. Ensemble averages were computed of all turns that belonged to a turn category (back-to-left, left-to-back, back-to-right, and right-to-back). One back-to-left turn was excluded because it showed a physiological response to the turn that substantially preceded the noted time of turn. Statistical signal processing was scripted in S-Plus 8.0 (Insightful, Inc., Seattle, WA.)

Individual turns as well as ensemble averages were analyzed to determine the time required for each variable to return to baseline values. The baseline interval was defined to be the first 5 minutes of each turn, a time interval that ends approximately 10 minutes before the noted turning time. This choice ensures that the baseline interval ended before the turn, even after accounting for the uncertainty in the noted time of turn.

The time to return to baseline was estimated using generalized least squares models that took into account the autocorrelation structure of the variables [3]. Each model compared the 5-minute baseline to a 5-minute test interval. The first test interval began at the end of the baseline interval and starting points of subsequent test intervals were moved forward in 1-minute increments. Models were intercept-only models, i.e. the mean level was compared taking into account the autoregressive (AR) structure. Order of AR structure was decided by minimizing the Akaike information criterion for each additional parameter that was estimated [4]. Since the first order AR(1) structure was optimal in all but two instances, model order was fixed at one for uniform treatment. During the dynamic response phase, the intercept-only model is not expected to fit the data well. Statistically significant differences vanish when the variable approaches a quiescent state that has statistical properties similar to the baseline interval. It is valid to extend this approach from individual turns to the ensemble average since the mean of all processes with identical AR parameters is also an AR process.

Automated turn data were binned into 10-degree angle bins that were also distinguished by direction of movement so that a picture of the entire rotation cycle could be obtained. Thus, bins were numbered from 1 to 5 for rotation from 0 degrees (lying on back) to 50 degrees to the right, 6 to 10 on the way back from right to the center, 11 to 15 from 0 degrees to 30 degrees to the left, and 16 to 20 on the way

<table>
<thead>
<tr>
<th>Turn</th>
<th>Duration of Response</th>
<th>Magnitude of Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back-to-Left</td>
<td>45+ min</td>
<td>9 bpm</td>
</tr>
<tr>
<td>Left-to-Back</td>
<td>13 min</td>
<td>5 bpm</td>
</tr>
<tr>
<td>Back-to-Right</td>
<td>27 min</td>
<td>12 bpm</td>
</tr>
<tr>
<td>Right-to-Back</td>
<td>13 min</td>
<td>13 bpm</td>
</tr>
</tbody>
</table>

The magnitude of response is the maximum difference between the autocorrelation-adjusted mean of test intervals and the baseline. The duration of response is the time for return to baseline.

*No return to baseline within observation window.
back from left to the center. All available turns were accepted from the longest time interval that had no more than 1 minute of missing data, and in which there were no sudden changes of angle. Sudden changes of angle can occur at times when the bed is stopped and the research staff resets the bed to the center.

The automated turn data were analyzed using longitudinal mixed effects models that allowed random intercept (change of mean level) for each turn in each angular bin, and provided an estimate of the fixed effect intercept (overall mean level) after accounting for autocorrelation structure.

The magnitude of the response varied between 11 and 19 mm Hg (see Table II and Fig. 2). Autocorrelation AR(1) parameters for baseline MAP ranged from 0.48 to 0.99, with median value 0.78. In the turns to the side, i.e. away from the center, the duration of response for heart rate was longer and the magnitude of response for MAP was slightly higher.

In automated continuous turns there is no evidence of a response of heart rate (see Fig. 3) and blood pressure (see Fig. 4) to turning. The blood pressure had an apparent angle-dependence, which disappeared upon correction due to change in the height of the measurement transducer and/or tubing. The correction was computed on the basis of a model $MAP = MAP_0 + a(1 - \cos(\theta/5)) - b\sin(\theta)$, where $MAP_0$ is a constant level, $\theta$ is the angle of rotation, $a$ is the precession arm length, and $b$ is the asymmetry arm of the measurement point from the bed's axis of rotation. Precession angle was assumed to be linearly related to the rotation angle, and a regression model was used to estimate $a$ and $b$. The model (see Fig. 4) takes into account the change in height of a point on the surface of the bed that is away from the axis of rotation, as well as movement of the center of the bed due to a precession effect from the air-filling mechanism. Slippage of the patient on the bed surface can also enhance the precession effect. The maximum displacement estimate resulting from the regression model was approximately 10 cm.

### III. RESULTS

Manual turns were observed to induce a response in heart rate and blood pressure. The heart rate response lasted for a median of 20 minutes before returning to baseline level. The magnitude of the response varied between 5 and 13 bpm (see Table I and Fig. 1). Autocorrelation AR(1) parameters for baseline heart rate ranged from 0.55 to 0.67, with median value 0.62. The blood pressure response lasted between 8 and 21 minutes before returning to baseline level. The response appears to be related to the process of turning.

### TABLE II

<table>
<thead>
<tr>
<th>Turn</th>
<th>Duration of Response</th>
<th>Magnitude of Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back-to-Left</td>
<td>12 min</td>
<td>19 mm Hg</td>
</tr>
<tr>
<td>Left-to-Back</td>
<td>21 min</td>
<td>11 mm Hg</td>
</tr>
<tr>
<td>Back-to-Right</td>
<td>14 min</td>
<td>16 mm Hg</td>
</tr>
<tr>
<td>Right-to-Back</td>
<td>8 min</td>
<td>16 mm Hg</td>
</tr>
</tbody>
</table>

The magnitude of response is the maximum difference between the autocorrelation-adjusted means of test intervals and the baseline. The duration of response is the time for return to baseline.

### IV. DISCUSSION

Cardiovascular response to manual turning of a patient in the ICU was measured in the variables of heart rate and blood pressure. The magnitude of response in both variables would be considered clinically important, and the responses lasted for a median 13 minutes after the turn. In the ensemble averages, the largest heart rate response was 13 bpm and the largest MAP response was 19 mm Hg. The response appears to be related to the process of turning.
allow us to investigate more rigorously the question of whether the direction of turns is related to the duration and magnitude of the cardiovascular response.

REFERENCES
Appendix F

Data Analysis Tables

Autocorrelation Function (ACF) results. Summary of statistically significant correlations found in the ACF analysis of mean arterial pressure (MAP) and pulse pressure (PP) for the manual-turn group patients. Small correlations (maximum 0.20) do not correspond to turn times of 2, 4, and 6 hours.

<table>
<thead>
<tr>
<th>Subject</th>
<th>MAP Correlation</th>
<th>MAP Time</th>
<th>PP Correlation</th>
<th>PP Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>P005</td>
<td>0.18</td>
<td>06:57</td>
<td>0.20</td>
<td>06:18</td>
</tr>
<tr>
<td></td>
<td>0.12</td>
<td>24:25</td>
<td>0.11</td>
<td>18:03</td>
</tr>
<tr>
<td></td>
<td>0.11</td>
<td>45:19</td>
<td>0.08</td>
<td>52:36</td>
</tr>
<tr>
<td></td>
<td>0.07</td>
<td>52:40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P006</td>
<td>0.10</td>
<td>82:33</td>
<td>N.S.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.12</td>
<td>96:54</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P011</td>
<td>0.18</td>
<td>18:37</td>
<td>N.S.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.10</td>
<td>39:15</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

N.S., not significant. Time is from lag 0 (time 00:00) in hours and minutes.
Cross-correlation results. Within-subject cross-correlations were computed among all hemodynamic variables for the seven patients who had an arterial line. The number of lags corresponded to the length of time series data for the manual-turn group (16,247 – 99,095) and 300 for the automated-turn group. The magnitude of the correlation corresponds to the actual significant correlation value and time of significant correlation corresponds to the length of time away from lag 0 (time 00:00) in hours and minutes (min) using 6-second sampling frequency.

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>HR and MAP</th>
<th>HR and PP</th>
<th>MAP and PP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Direction</td>
<td>Magnitude</td>
<td>Time</td>
</tr>
<tr>
<td>P001 Manual</td>
<td>N.S.</td>
<td>HR leading PP</td>
<td>Negative</td>
</tr>
<tr>
<td>P005 Manual</td>
<td>MAP leading HR</td>
<td>HR leading PP</td>
<td>Negative</td>
</tr>
<tr>
<td>P006 Manual</td>
<td>HR leading MAP</td>
<td>HR leading PP</td>
<td>Positive</td>
</tr>
<tr>
<td>P011 Manual</td>
<td>N.S.</td>
<td>PP leading HR</td>
<td>Positive</td>
</tr>
<tr>
<td>P007 Automated</td>
<td>HR leading MAP</td>
<td>HR leading PP</td>
<td>Negative</td>
</tr>
<tr>
<td>P008 Automated</td>
<td>N.S.</td>
<td>HR leading PP</td>
<td>Positive</td>
</tr>
<tr>
<td>P010 Automated</td>
<td>N.S.</td>
<td>HR leading PP</td>
<td>Positive</td>
</tr>
</tbody>
</table>

Magnitude of correlation: small = .10 to .29, medium = .30 to .49, large = .50 to 1.0 (Cohen, 1988). HR, heart rate; MAP, mean arterial pressure; N.S., not significant; PP, pulse pressure.
Results of Within-subject Two-Way Repeated Measures Analysis of Variance

<table>
<thead>
<tr>
<th></th>
<th><strong>HR</strong></th>
<th></th>
<th><strong>MAP</strong></th>
<th></th>
<th><strong>PP</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>df</strong></td>
<td><strong>F</strong></td>
<td><strong>p</strong></td>
<td><strong>df</strong></td>
<td><strong>F</strong></td>
<td><strong>p</strong></td>
</tr>
<tr>
<td><strong>Position</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2, 22</td>
<td>1.64</td>
<td>.22</td>
<td>2, 10</td>
<td>4.31</td>
<td>.05</td>
</tr>
<tr>
<td><strong>Position/Group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2, 11</td>
<td>3.86</td>
<td>.04</td>
<td>2, 5</td>
<td>2.78</td>
<td>.11</td>
</tr>
</tbody>
</table>

* Significant ($p < .02$); $df$ = degrees of freedom ($df$, error $df$), $F = F$ statistic, $p = probability$; HR, Heart rate; MAP, Mean arterial pressure; PP, Pulse pressure

Mean Values by Position and Group for Two-Way Repeated Measures Analysis of Variance

<table>
<thead>
<tr>
<th>Position</th>
<th>Group</th>
<th><strong>HR</strong></th>
<th><strong>MAP</strong></th>
<th><strong>PP</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Left</td>
<td>Manual</td>
<td>96</td>
<td>84</td>
<td>61</td>
</tr>
<tr>
<td></td>
<td>Automated</td>
<td>80</td>
<td>91</td>
<td>59</td>
</tr>
<tr>
<td>Back</td>
<td>Manual</td>
<td>94</td>
<td>84</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td>Automated</td>
<td>81</td>
<td>88</td>
<td>59</td>
</tr>
<tr>
<td>Right</td>
<td>Manual</td>
<td>97</td>
<td>90</td>
<td>67</td>
</tr>
<tr>
<td></td>
<td>Automated</td>
<td>81</td>
<td>90</td>
<td>58</td>
</tr>
</tbody>
</table>

HR, Heart rate; MAP, Mean arterial pressure; PP, Pulse pressure
Sham Turn Experiments

Sham testing was conducted to determine if psychological anticipation of the lateral rotation might explain the hemodynamic changes with the manual turn. An increase in heart rate or mean arterial pressure associated with turning could represent anticipation of stimulation or discomfort, rather than the physical maneuver of turning. The baseline period was defined as 2 minutes with no patient stimulation (e.g., movement or talking). "Sham" was operationalized as stating to the patient “We are going to turn you now,” and then waiting 2 minutes before starting the turn. After the sham period of the experiment, the head-of-bed (HOB) was lowered from $\geq 30^\circ$ to $0^\circ$, followed by 2 minutes of inactivity (“after HOB down”). Lowering the patient’s HOB was used to assess the hemodynamic response to arousal and/or movement. This pre-turn physical stimulation would be expected to carry over to the post-turn period. Finally, the patient was turned laterally and the heart rate and mean arterial pressure were measured for $\geq 2$ minutes.

Three critically ill, mechanically ventilated patients participated in the sham experiments. All patients had a Richmond Agitation Sedation Scale (RASS) score of $\pm 1$ and were able to assist with turning. The mean ± standard deviation of heart rate and mean arterial pressure for each condition is shown in the table. Two one-way repeated measures analysis of variance tests, with Bonferroni adjustment for two comparisons ($P \leq 0.025$), were conducted, one for heart rate and one for mean arterial pressure with the following conditions: (a) pre-sham, (b) sham, (c) HOB down, (d) after HOB down, and (e) turn. The differences in heart rate and mean arterial pressure by condition were not significant: $F = 1.92, df = 4, p = 0.20$ for heart rate; $F = 1.31, df = 4, p = 0.34$ for mean arterial pressure. The findings from these experiments did not suggest that hemodynamic changes associated with lateral rotation are related to anticipation of the manual turn.
Table. Mean ± standard deviation heart rate and mean arterial pressure by condition.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Heart Rate Mean ± SD</th>
<th>Mean Arterial Pressure Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Sham</td>
<td>99 ± 10.2</td>
<td>101 ± 23.2</td>
</tr>
<tr>
<td>Sham</td>
<td>101 ± 10.6</td>
<td>97 ± 18.2</td>
</tr>
<tr>
<td>HOB Down</td>
<td>93 ± 6.1</td>
<td>90 ± 30.2</td>
</tr>
<tr>
<td>After HOB Down</td>
<td>95 ± 3.5</td>
<td>88 ± 24.0</td>
</tr>
<tr>
<td>Turn</td>
<td>103 ± 7.9</td>
<td>102 ± 22.5</td>
</tr>
</tbody>
</table>

HOB, head-of-bed; Pre-sham, baseline period of inactivity; Sham, tell patient going to turn followed by delay; HOB down, lowering HOB from ≥ 30° to 0°; After HOB down, 2 minutes of inactivity after HOB down; Turn, lateral turn
Appendix G

CURRICULUM VITAE

Shannan K. Hamlin, PhD, RN, ACNP, CCRN

EDUCATION:

University of Texas Health Science Center at Houston, Houston, Texas
2010 PhD Nursing

University of Texas Health Science Center at Houston, Houston, Texas
2000 MSN Nursing

Houston Baptist University, Houston, Texas
1993 BSN Nursing

PROFESSIONAL POSITIONS:

The Methodist Hospital
Houston, Texas
Acute Care Nurse Practitioner 2005-present

The University of Texas M. D. Anderson Cancer Center
Houston, Texas
Acute Care Nurse Practitioner 2000-2005

St. Luke's Episcopal Hospital
Houston, Texas
Critical Care Float Nurse 1997-1999

Columbia Bayshore Medical Center
Pasadena, Texas
ICU Staff Nurse 1995-1996

The Methodist Hospital
Houston, Texas
ICU Staff Nurse 1994-1995
PROFESSIONAL MEMBERSHIPS:

American Association of Critical-Care Nurses 1996-present
Houston-Gulf Coast Chapter 1996-present

Sigma Theta Tau International 1999-present

American Academy of Nurse Practitioners 2000-present

Society of Critical Care Medicine 2000-present

Southern Nursing Research Society 2004-present

Council for the Advancement of Nursing Science 2004-present

PUBLICATIONS:


PRESENTATIONS:

Paper


Poster session


AWARDS AND RECOGNITION:

2010  PhD Faculty Research Award for outstanding dissertation in clinical nursing research, PhD Program, School of Nursing, University of Texas Health Science Center at Houston

2008  Outstanding Performance in Nursing Award, District 9 Texas Nurses Association

2001 – present  Fundamentals of Critical Care Support Instructor, Society of Critical Care Medicine

2000 – present  Advanced Practice Nurse – Acute Care Nurse Practitioner, Texas State Board of Nurse Examiners

1997 – present  CCRN certification, American Association of Critical-Care Nurses Certification Corporation

1991 – present  ACLS Provider, American Heart Association

GRANTS:

Hamlin, S. K. (Sandra K. Hanneman, PhD, RN, Mentor). Multi-site randomized clinical trial of horizontal positioning to prevent and treat pulmonary complications in mechanically ventilated critically ill patients: A pilot and hemodynamic sub-study. Mentorship Grant, American Association of Critical-Care Nurses (AACN), 2006, $10,000.

