Inhaled Nitric Oxide and Safe Transport

Predicting Cardiac Dysrhythmias During Ventilatory Weaning

Hemodynamic Effects of Lateral Turning

Thermoregulation Head Wrap for Infants

Surrogate Education on Informed Consent

Postoperative Delirium After Cardiac Surgery

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2014

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An Official Publication of the American Association of Critical-Care Nurses
Important Risk Information

NEXTERONE (amiodarone HCl) Premixed Injection is contraindicated in patients with:
- Known hypersensitivity to any of the components of NEXTERONE, including iodine
- Cardiogenic shock
- Marked sinus bradycardia
- Second- or third-degree atrio-ventricular (AV) block unless a functioning pacemaker is available

NEXTERONE should be administered only by physicians who are experienced in the treatment of life-threatening arrhythmias, who are thoroughly familiar with the risks and benefits of amiodarone therapy, and who have access to facilities adequate for monitoring the effectiveness and side effects of treatment.

- Hypotension is the most common adverse reaction seen with intravenous amiodarone. In clinical trials, treatment-emergent, drug-related hypotension was reported in 16% (288/1836) of patients treated with intravenous amiodarone. Clinically significant hypotension during infusions was seen most often in the first several hours of treatment and appeared to be related to the rate of infusion. Monitor the initial rate of infusion closely and do not exceed the recommended rate. In some cases, hypotension may be refractory and result in a fatal outcome. Treat hypotension initially by slowing the infusion; additional standard therapy may be needed, including: vasopressors, positive inotropic agents and volume expansion.

- In 4.9% (90/1836) of patients in clinical trials, drug-related bradycardia that was not dose-related occurred while patients were receiving intravenous amiodarone for life-threatening VT/VF. Treat bradycardia by slowing the infusion rate or discontinuing NEXTERONE. Treat patients with a known predisposition to bradycardia or AV block with NEXTERONE in a setting where a temporary pacemaker is available.

- Elevations of blood hepatic enzyme values ALT, AST, GGT are commonly seen in patients with immediately life-threatening VT/VF. In patients with life-threatening arrhythmias, the potential risk of hepatic injury should be weighed against the potential benefit of NEXTERONE therapy. Carefully monitor patients receiving NEXTERONE for evidence of progressive hepatic injury. In such cases, consider reducing the rate of administration or withdrawing NEXTERONE.

- Like all antiarrhythmics, NEXTERONE may cause worsening of existing arrhythmias or precipitate a new arrhythmia. Monitor patients for QTc prolongation during infusion with NEXTERONE. Reserve the combination of amiodarone with other antiarrhythmic therapies that prolong the QTc to patients with life-threatening ventricular arrhythmias who are incompletely responsive to a single agent.

- There have been postmarketing reports of acute-onset (days to weeks) pulmonary injury in patients treated with intravenous amiodarone. Findings included pulmonary infiltrates and masses on X-ray, bronchospasm, wheezing, fever, dyspnea, cough, hemoptysis, and hypoxia. Some cases have progressed to respiratory failure or death. Two percent (2%) of patients were reported to have acute respiratory distress syndrome (ARDS) during clinical studies involving 48 hours of therapy. Pulmonary toxicity including pulmonary fibrosis is a well-recognized complication of long-term amiodarone use.

- Amiodarone inhibits peripheral conversion of thyroxine (T4) to triiodothyronine (T3) and may cause increased T4 levels, decreased T3 levels, and increased levels of inactive reverse T3 (rT3) in clinically euthyroid patients. Amiodarone can cause either hypothyroidism or hyperthyroidism. Evaluate thyroid function prior to treatment and periodically thereafter, particularly in elderly patients, and in any patient with a history of thyroid nodules, goiter, or other thyroid dysfunction. Because of the slow elimination of amiodarone and its metabolites, high plasma iodide levels, altered thyroid function, and abnormal thyroid function tests may persist for several weeks or even months following NEXTERONE withdrawal.

- The most important adverse reactions were hypotension, asystole/cardiac arrest/pulseless electrical activity (PEA), cardiogenic shock, congestive heart failure, bradycardia, liver function test abnormalities, VT, and AV block. The most common adverse reactions leading to discontinuation of intravenous amiodarone therapy were hypotension (1.6%), asystole/cardiac arrest/PEA (1.2%), VT (1.1%), and cardiogenic shock (1%).

- Drug Interactions
  - Since amiodarone is a substrate for CYP3A4 and CYP2C8, drugs/substances that inhibit these isoenzymes may decrease the metabolism and increase serum concentration of amiodarone.
  - Amiodarone inhibits p-glycoprotein and certain CYP450 enzymes, including CYP1A2, CYP2C9, CYP2D6, and CYP3A. This inhibition can result in unexpectedly high plasma levels of other drugs which are metabolized by these CYP450 enzymes or are substrates for p-glycoprotein. HMG-CoA reductase inhibitors that are CYP3A4 substrates in combination with amiodarone have been associated with reports of myopathy/rhabdomyolysis. Limit the dose of simvastatin in patients on amiodarone to 20 mg daily. Limit the daily dose of lovastatin in patients on amiodarone to 40 mg. Lower starting and maintenance doses of other CYP3A4 substrates (e.g., atorvastatin) may be required.
  - Some drugs/substances are known to accelerate the metabolism of amiodarone by stimulating the synthesis of CYP3A4 (enzyme induction). This may lead to low amiodarone serum levels and potential decrease in efficacy. Fluoroquinolones, macrolide antibiotics, and azoles are known to cause QTc prolongation. There have been reports of QTc prolongation, with or without TdP, in patients taking amiodarone when fluoroquinolones, macrolide antibiotics, or azoles were administered concomitantly.

Please see Brief Summary of Full Prescribing Information on the following pages.
Waiting in the ICU: Not an option.

**Nexterone is ready when every second counts.**

<table>
<thead>
<tr>
<th>PRODUCT CODE</th>
<th>STRENGTH/VOLUME</th>
<th>CONCENTRATION</th>
<th>NDC #</th>
<th>PACK FACTOR (carton/case)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2G3451</td>
<td>150 mg/100 mL</td>
<td>1.5 mg/mL</td>
<td>43066-150-10</td>
<td>12</td>
</tr>
<tr>
<td>2G3450</td>
<td>360 mg/200 mL</td>
<td>1.8 mg/mL</td>
<td>43066-360-20</td>
<td>10</td>
</tr>
</tbody>
</table>

To learn more, call the Baxter Center for Service at **888-229-0001** or visit **www.nexterone.com**.

**Indications**

**NEXTERONE** (amiodarone HCl) Premixed Injection is indicated for initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation (VF) and hemodynamically unstable ventricular tachycardia (VT) in patients refractory to other therapy. NEXTERONE also can be used to treat patients with VT/VF for whom oral amiodarone is indicated, but who are unable to take oral medication. During or after treatment with NEXTERONE, patients may be transferred to oral amiodarone therapy.

Use NEXTERONE for acute treatment until the patient’s ventricular arrhythmias are stabilized. Most patients will require this therapy for 48 to 96 hours, but NEXTERONE may be safely administered for longer periods if necessary.

NEXTERONE should be administered only by physicians who are experienced in the treatment of life-threatening arrhythmias, who are thoroughly familiar with the risks and benefits of amiodarone therapy, and who have access to facilities adequate for monitoring the effectiveness and side effects of treatment.

**Nexterone (amiodarone HCl) Premixed Injection**

Please see Important Risk Information and Brief Summary of Full Prescribing Information on adjacent pages.

Store in carton to protect from light until ready to use.

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amiodarone with other antiarrhythmic therapies that prolong the QTc to patients with QTc prolongation during infusion with NEXTERONE. Reserve the combination of amiodarone at a much higher loading dose concentration and much faster rate of infusion than recommended [see Dosage and Administration (2) in full prescribing information].

5.1 Hypotension

Hypotension is the most common adverse reaction seen with intravenous amiodarone. In clinical trials, treatment-emergent, drug-related hypotension was reported as an adverse effect in 285 (16%) of 1786 patients treated with intravenous amiodarone. Clinically significant hypotension during infusions was seen most often in the first several hours of treatment and was not dose related, but appeared to be related to the rate of infusion. Hypotension necessitating alterations in intravenous amiodarone therapy was reported in 3% of patients with permanent discontinuation required in less than 2% of patients. Treat hypotension initially by slowing the infusion; additional standard therapy may be needed, including: the following: vasopressor drugs, positive inotropic agents, and volume expansion. Monitor the initial rate of infusion closely and do not exceed the recommended rate [see Dosage and Administration (2) in full prescribing information]. In some cases, hypotension may be refractory and result in a fatal outcome [see Adverse Reactions (6.2) in full prescribing information].

5.2 Bradycardia and Atrio-ventricular Block

In 80 (4.9%) of 1836 patients in clinical trials, drug-related bradycardia that was not dose-related occurred while they were receiving intravenous amiodarone for life-threatening VT/VF. Treat bradycardia by slowing the infusion rate or discontinuing NEXTERONE. In some patients, inserting a pacemaker is required. Despite such measures, bradycardia was progressive and terminal in 1 patient during the controlled trials. Treat patients with a known predisposition to bradycardia or AV block with NEXTERONE in a setting where a temporary pacemaker is available.

5.3 Liver Enzyme Elevations

Elevations of blood hepatic enzyme values [alanine aminotransferase (ALT), aspartate aminotransferase (AST), and gamma-glutamyl transferase (GGT)] are commonly seen in patients with immediately life-threatening VT/VF. Interpreting elevated AST activity can be difficult because the values may be elevated in patients who have had recent myocardial infarction, congestive heart failure, or multiple electrical defibrillations. Approximately 54% of patients receiving intravenous amiodarone in clinical studies had baseline liver enzyme elevations, and 13% had clinically significant elevations. In 81% of patients with both baseline and on-therapy data available, the liver enzyme elevations either improved during therapy or remained at baseline levels. Baseline abnormalities in hepatic enzymes are not a contraindication to treatment.

Acute, centrolobular confluent hepatocellular necrosis leading to hepatic coma, acute renal failure, and death has been associated with the administration of intravenous amiodarone at a much higher loading dose concentration and much faster rate of infusion than recommended [see Dosage and Administration (2) in full prescribing information]. In patients with life-threatening arrhythmias, the potential risk of hepatic injury should be weighed against the potential benefit of NEXTERONE therapy. Carefully monitor patients receiving NEXTERONE for evidence of progressive hepatic injury. In such cases, consider reducing the rate of administration or withdrawing NEXTERONE.

5.4 Proarrhythmia

Like all antiarrhythmic agents, NEXTERONE may cause a worsening of existing arrhythmias or precipitate a new arrhythmia. Proarrhythmia, primarily torsades de pointes (Tdp), has been associated with prolongation, by intravenous amiodarone, of the QTc interval to 500 ms or greater. Although QTc prolongation occurred frequently in patients receiving intravenous amiodarone, Tdp or new-onset VF occurred infrequently (less than 2%). Monitor patients for QTc prolongation during infusion with NEXTERONE. Reserve the combination of amiodarone with other antiarrhythmic therapies that prolong the QTc to patients with life-threatening ventricular arrhythmias who are incompletely responsive to a single agent.

5.5 Pulmonary Disorders

Early-onset Pulmonary Toxicity

There have been postmarketing reports of acute-onset (days to weeks) pulmonary injury in patients treated with intravenous amiodarone. Findings have included pulmonary infiltrates and masses on X-ray, bronchospasm, wheezing, fever, dyspnea, cough, hemoptysis, and hypoxia. Some cases have progressed to respiratory failure or death.

ARDS

Two percent (2%) of patients were reported to have adult respiratory distress syndrome (ARDS) during clinical studies involving 48 hours of therapy.

Pulmonary Fibrosis

Only 1 of more than 1000 patients treated with intravenous amiodarone in clinical studies developed pulmonary fibrosis. In that patient, the condition was diagnosed 3 months after treatment with intravenous amiodarone, during which time the patient received oral amiodarone. Pulmonary toxicity is a well-recognized complication of long-term amiodarone use. [see package insert for oral amiodarone].

5.6 Loss of Vision

Cases of optic neuropathy and optic neuritis, usually resulting in visual impairment, have been reported in patients treated with oral amiodarone. In some cases, visual impairment has progressed to permanent blindness. Optic neuropathy and neuritis may occur at any time during therapy. A causal relationship to the drug has not been clearly established. Perform an ophthalmic examination if visual symptoms of visual impairment appear, such as changes in visual acuity and decreases in peripheral vision. Re-evaluate the necessity of amiodarone therapy if optic neuropathy or neuritis is suspected. Perform regular ophthalmic examinations, including fundoscopy and slit-lamp examination, during administration of NEXTERONE.

5.7 Long-Term Use

There has been limited experience in patients receiving intravenous amiodarone for longer than 3 weeks. See package insert for oral amiodarone.

5.8 Thyroid Abnormalities

Amiodarone inhibits peripheral conversion of thyroxine (T4) to triiodothyronine (T3) and may cause increased T4 levels, decreased T3 levels, and increased levels of inactive reverse T3 (rT3) in clinically euthyroid patients. Amiodarone is also a potential source of large amounts of inorganic iodine and can cause either hyperthyroidism or hypothyroidism. Evaluate thyroid function prior to treatment and periodically thereafter, particularly in elderly patients, and in any patient with a history of thyroid nodules, goiter, or other thyroid dysfunction. Because of the slow elimination of amiodarone and its metabolites, high plasma iodide levels, altered thyroid function, and abnormal thyroid function tests may persist for several weeks or even months following NEXTERONE withdrawal.

There have been postmarketing reports of thyroid nodules/thyroid cancer in patients treated with amiodarone. In some instances hyperthyroidism was also present [see Adverse Reactions (6.2) in full prescribing information].

Hyperthyroidism and Thyrotoxicosis

Hyperthyroidism occurs in about 2% of patients receiving amiodarone, but the incidence may be higher among patients with prior inadequate dietary iodine intake. Amiodarone-induced hyperthyroidism usually poses a greater hazard to the patient than hyperthyroidism because of the possibility of thyrotoxicosis and arrhythmia breakthrough or aggravation, all of which may result in death. There have been reports of death associated with amiodarone-induced thyrotoxicosis. Consider the possibility of hyperthyroidism if any new signs of arrhythmia appear.

Identify hyperthyroidism by relevant clinical signs and symptoms, subnormal serum levels of thyroid stimulating hormone (TSH), abnormally elevated serum free T4, and elevated or normal serum T3. Since arrhythmia breakthroughs may accompany amiodarone-induced hyperthyroidism, aggressive medical treatment is indicated, including, if possible, dose reduction or withdrawal of amiodarone. Amiodarone hyperthyroidism may be followed by a transient period of hypothyroidism.

The institution of antithyroid drugs, β-adrenergic blockers or temporary corticosteroid therapy may be necessary. The action of antithyroid drugs may be especially delayed in amiodarone-induced thyrotoxicosis because of substantial quantities of preformed thyroid hormones stored in the gland. Radioactive iodine therapy is contraindicated because of the low radioidine uptake associated with amiodarone-induced hyperthyroidism.

When aggressive treatment of amiodarone-induced thyrotoxicosis has failed or amiodarone cannot be discontinued because it is the only drug effective against the resistant arrhythmia, surgical management may be an option. Experience with thyroidectomy as a treatment for amiodarone-induced thyrotoxicosis is limited, and this form of therapy could induce thyroid storm. Therefore, surgical and anesthetic management require careful planning.

Neonatal Hypo- or Hyperthyroidism

Amiodarone can cause fetal harm when administered to a pregnant woman. Although amiodarone use during pregnancy is uncommon, there have been a small number of published reports of congenital goiter/hypothyroidism and hyperthyroidism associated with oral administration. Inform the patient of the potential hazard to the fetus if NEXTERONE is administered during pregnancy or if the patient becomes pregnant while taking NEXTERONE.
6 ADVERSE REACTIONS

5.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In a total of 1368 patients in controlled and uncontrolled clinical trials, 14% of patients received intravenous amiodarone for at least one week, 5% received it for at least 2 weeks, 2% received it for at least 3 weeks, and 1% received it for more than 3 weeks, without an increased incidence of severe adverse reactions. The mean duration of therapy in these studies was 5.6 days; median exposure was 3.7 days.

The most important adverse reactions were hypotension, astylole/atrial arrhythmia, electrical activity (PEA), cardiac shock, congestive heart failure, bradycardia, liver function test abnormalities, AV, and AV block. Overall, treatment was discontinued for about 9% of the patients because of adverse reactions. The most common adverse reactions leading to discontinuation of intravenous amiodarone therapy were hypotension (1.6%), astylole/atrial arrhythmia/PEA (1.2%), AV (1.1%), and cardiacogenic shock (1%).

Table 4 lists the most common (incidence >2%) adverse reactions during intravenous amiodarone therapy considered at least possibly drug-related. These data were collected in clinical trials involving 1368 patients with life-threatening VT/VF. Data from all assigned treatment groups are pooled because none of the adverse reactions appeared to be dose-related.

Table 4: ADVERSE REACTIONS IN PATIENTS RECEIVING INTRAVENOUS AMIODARONE IN CONTROLLED AND OPEN-LABEL STUDIES (1.2% INCIDENCE)

<table>
<thead>
<tr>
<th>Study Event</th>
<th>Controlled Studies (n=814)</th>
<th>Open-Label Studies (n=1022)</th>
<th>Total (n=1836)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body as a whole</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td>24 (2.9%)</td>
<td>13 (1.2%)</td>
<td>37 (2.0%)</td>
</tr>
<tr>
<td>Cardiovascular System</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bradycardia</td>
<td>49 (6.0%)</td>
<td>41 (4.0%)</td>
<td>90 (4.9%)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>18 (2.2%)</td>
<td>21 (2.0%)</td>
<td>39 (2.1%)</td>
</tr>
<tr>
<td>Heart arrest</td>
<td>29 (3.5%)</td>
<td>26 (2.5%)</td>
<td>55 (2.9%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>166 (20.2%)</td>
<td>123 (12.3%)</td>
<td>288 (15.8%)</td>
</tr>
<tr>
<td>Ventricular tachycardia</td>
<td>15 (1.8%)</td>
<td>30 (2.9%)</td>
<td>45 (2.4%)</td>
</tr>
<tr>
<td>Digestive System</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver function tests normal</td>
<td>35 (4.2%)</td>
<td>29 (2.8%)</td>
<td>64 (3.4%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>29 (3.5%)</td>
<td>43 (4.2%)</td>
<td>72 (3.9%)</td>
</tr>
</tbody>
</table>

Other adverse reactions reported in less than 2% of patients receiving intravenous amiodarone in controlled and uncontrolled studies included the following: abnormal kidney function, atrial fibrillation, diarrhea, increased ALT, increased AST, lung edema, nodal arrhythmia, prolonged QT interval, respiratory disorder, shock, sinus bradycardia, Stevens-Johnson syndrome, thrombocytopenia, VF, and vomiting.

6.2 Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of amiodarone. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Body as a Whole: anaphylactic/anaphylactoid reaction (including shock), fever

Cardiovascular: hypotension (sometimes fatal), sinus arrest

Dermatologic: toxic epidermal necrolysis (sometimes fatal), exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, skin cancer, pruritus, angioedema

Endocrine: syndrome of inappropriate antidiuretic hormone secretion (SIADH)

Hematologic: pancytopenia, neutropenia, hemolytic anemia, aplastic anemia, thrombocytopenia, agranulocytosis, granuloma

Hepatic: hepatitis, cholestatic hepatitis, cirrhosis

Injection Site Reactions: pain, erythema, edema, pigment changes, venous thrombosis, phlebitis, thrombophlebitis, cellulitis, necrosis, and skin sloughing

Musculoskeletal: myopathy, muscle weakness, rhabdomyolysis

Nervous System: hallucination, confusional state, disorientation, and delirium, pseudotumor cerebri

Pancreatic: pancreatitis

Renal: renal impairment, renal insufficiency, acute renal failure

Respiratory: bronchospasm, possibly fatal respiratory disorders (including distress, failure, and ARDS), bronchiolitis obliterans organizing pneumonia (possibly fatal), dyspnea, cough, hemoptysis, wheezing, hypoxia, pulmonary infiltrates and/or mass, pleuritis

Thyroid: thyroid nodules/thyroid cancer

Vascular: vasculitis

7 DRUG INTERACTIONS

Since amiodarone is a substrate for CYP3A and CYP2C8, drugs/substances that inhibit these isoenzymes may decrease the metabolism and increase serum concentration of amiodarone.

Amiodarone inhibits p-glycoprotein and certain CYP450 enzymes, including CYP1A2, CYP2C9, CYP2C19, and CYP3A. This inhibition can result in unexpectedly high plasma levels of other drugs which are metabolized by those CYP450 enzymes or are substrates for p-glycoprotein.

HMG-CoA reductase inhibitors that are CYP3A4 substrates in combination with amiodarone has been associated with reports of myopathy/rhabdomyolysis.

Limit the dose of simvastatin in patients on amiodarone to 20 mg daily. Lower the daily dose of lovastatin to 40 mg. Lower starting and maintenance doses of other CYP3A4 substrates (e.g., atorvastatin) may be required.

Some drugs/substances are known to accelerate the metabolism of amiodarone by stimulating the synthesis of CYP3A (enzyme induction). This may lead to low amiodarone serum levels and potential decrease in efficacy.

Fluoroquinolones, macrolide antibiotics, and azoles are known to cause QTc prolongation. There have been reports of QTc prolongation, with or without TdP, in patients taking amiodarone when fluoroquinolones, macrolide antibiotics, or azoles were administered concomitantly.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy Category D

Reproductive and teratology studies performed in rabbits and rats at doses of up to 100 mg/kg per day (about 4 times the maximum recommended human dose on a body surface area basis) revealed no evidence of embryotoxicity at 5 mg/kg and no teratogenicity was observed at any dosage in rabbits. Maternal toxicity and embryotoxicity were observed in rats in the 100 mg/kg group.

Use NEXTERONE during pregnancy only if the potential benefit to the mother justifies the risk to the fetus.

8.2 Labor and Delivery

It is not known whether the use of amiodarone during labor or delivery has any immediate or delayed adverse effects.

8.3 Nursing Mothers

Amiodarone and one of its major metabolites, desethylamiodarone (DEA), are excreted in human milk, suggesting that breast-feeding could expose the nursing infant to a significant dose of the drug.

8.4 Pediatric Use

The safety and effectiveness of amiodarone in pediatric patients have not been established; therefore, the use of amiodarone in pediatric patients is not recommended.

8.5 Geriatric Use

Clinical studies of amiodarone did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Carefully consider dose selection in an elderly patient.

10 OVERDOSAGE

There have been cases, some fatal, of amiodarone overdose. Effects of an inadvertent overdose of intravenous amiodarone include hypotension, cardiacogenic shock, bradycardia, AV block, and hepatotoxicity. Treat hypotension and cardiacogenic shock by slowing the infusion rate or with standard therapy: vasopressor drugs, positive inotropic agents, and volume expansion. Bradycardia and AV block may require temporary pacing. Monitor hepatic enzyme concentrations closely. Amiodarone is not dialyzable.

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Editorial

FINDING OUR OPTIMAL SCOPE OF PRACTICE

By Richard H. Savel, MD, and Cindy L. Munro, RN, PhD, ANP

Although one of us is indeed a nurse practitioner (NP), the other, a physician, recently had the opportunity to expand a critical care team with the help of a critical care NP. It was an extremely positive experience. In fact, this nurse (we’ll call her Jane, which is not her real name) allowed us to interview her and share her personal journey from becoming a bedside critical care nurse to a critical care NP in the same intensive care unit (ICU).

We believe a discussion of Jane’s personal career path is highly relevant, representing the kinds of decisions and choices we all make as we go through our careers. Also, we feel her story reflects some recent national recommendations that have been made regarding the role of nurses and advanced practice practitioners in the current health care environment.1-5

A Focus on Critical Care Nursing

Jane decided to go into nursing when she was in her second year of college. She had sustained an injury while playing softball and had a positive experience with the nurse who cared for her. Although she briefly contemplated going the premedical route, she decided that direct patient contact appealed to her most, so she pursued a nursing degree.

Jane always considered critical care nursing while in nursing school. What she found most appealing was what she called “managing the instability” and “the challenge and adrenaline” of such work. She completed nursing school and worked for 2 years on a general surgical patient floor, where she gained familiarity and experience in the care of non–critically ill surgical patients. She found that caring for these patients was rewarding but said she wanted something more challenging out of her nursing career.

She then took a position working as a bedside critical care nurse in a surgical ICU with occasional progressive care shifts. She gained the experience she longed for, working with critically ill patients. She managed people with acute respiratory distress syndrome, septic shock, aneurysmal subarachnoid hemorrhage, anastomotic leaks, acute renal failure, complex arrhythmias, anaphylactic shock, and abdominal compartment syndrome (just to name a few!), not to mention all the complex psychosocial and end-of-life issues that come with caring for patients with these problems. She loved it. It was difficult, but she knew that going in. She was particularly proud of the close professional relationships she’d developed with nursing colleagues and intensivists. She felt that her input was valued and
valuable. She felt important and felt that her presence mattered, plus she loved the complexity and relished the challenges.

Jane enjoyed the combination of medical science and emotional connection. It was highly rewarding to be able to use her understanding of fundamental physiology and pathophysiology to save lives, especially when the situation was high stakes and high stress—often the norm in the ICU. Equally important, though, was the need for her to talk with families about what was going on with their loved ones and to allow human touch to make all the difference, whether it was holding the hand of a family member who just realized his or her loved one was dying or reassuring a patient recovering from surgery that all was well.

**Becoming a Nurse Practitioner**

Jane first heard about becoming an NP from a colleague who was in the middle of her first year of an NP program. It sounded appealing to Jane, who thought such a career path might potentially integrate nursing and medicine. She began her NP program while working in critical care nursing.

Jane wanted to expand her scope of practice while remaining true to her nursing roots. In the first year she took 2 classes per semester, 2 days a week. She liked the challenge of going back to graduate school, including her pharmacology, pathophysiology, and research classes. She found the breadth of her clinical rotations challenging as well. She was pleased with her decision.

Her first clinical position as an NP was working in the outpatient office of a group of orthopedic surgeons. Jane had been an athlete her entire life, and thought it would be interesting to work with that population of patients. She felt she could connect with them and wanted to obtain a better understanding of what those patients were going through both emotionally and physically.

Her clinical role was to care for patients after orthopedic surgery, make follow-up telephone calls, and evaluate patients with outpatient orthopedic surgery emergencies in the office. Eventually she realized that outpatient medicine might not be the best fit for her temperament and personality. That became dramatically clear to her when, while caring for a patient who had come in having a seizure, she realized how much she missed the challenges of inpatient medicine. Although she enjoyed the professional working relationships she developed with the surgeons in the outpatient setting, she longed more for the connection she developed as part of the inpatient, critical care, multidisciplinary team.

**A New Perspective**

Jane recently took a position working as a critical care nurse practitioner in the same ICU where she had worked previously as a critical care bedside nurse. She joined a team of house officers, critical care fellows, and attending intensivists. It was awkward at first, because the bedside nurses were asking her questions rather than her asking questions of the team.

Initially, she was concerned about being more independent and wondered if she was “doing the right thing.” But she had ample support, both from the bedside nurses and the attending intensivists. Everyone wanted her to succeed. She now looked at things differently. She quickly got up to speed with doing procedures such as central lines and arterial lines and learning other new techniques, but always with a continued focus on patient safety.

Most importantly, she started to see critical care research and literature differently. She was now looking more closely at articles she might have skimmed in the past. She was gaining a clearer understanding of the importance of the critical care research literature and how to figure out the “right” way to do things. She began to see that the literature was dynamic, and that the “right way” last week might not be the best way this week. She found that managing uncommon clinical disease processes can be common in an ICU, and she gained the necessary skills to quickly find clinically relevant and accurate answers to sometimes esoteric questions. Finally, her role on the team was changing in terms of caring not only for 1 or 2 patients, but helping to care for all the patients in the ICU.

**About the Authors**

Richard H. Savel is coeditor in chief of the *American Journal of Critical Care*. He is director, surgical critical care at Maimonides Medical Center and professor of clinical medicine and neurology at the Albert Einstein College of Medicine, both in New York City. Cindy L. Munro is coeditor in chief of the *American Journal of Critical Care*. She is associate dean for research and innovation at the University of South Florida, College of Nursing, Tampa, Florida.
Each of our journeys is unique; we each must find our own best path to personal and professional fulfillment.

This took some adjustment time, but she found her new role to be rewarding.

**Looking Back, Looking Forward**

After we spent some time interviewing Jane and hearing her story, we realized there were some important conclusions we could draw. First, each of our journeys is unique; we each must find our own best path to personal and professional fulfillment. Secondly, we each should decide with pride that we will “practice to the full extent of our education and training.” For some of us that could mean pursuing a graduate degree; for others it might mean speaking up at a staff meeting or starting a quality improvement or research project. For still others—presumably for most of us—it might be feeling pride at a job well done, such as notifying a rapid response team early so a patient can be saved or having a patient smile at us when we relieve his or her pain.

Practicing to the full extent of our education and training is important, but it is also essential that we remind each member of the multidisciplinary team that his or her job is important and valuable. We want bedside critical care nurses to remember that their jobs are of the utmost importance. It is well known how physically and emotionally demanding critical care can be. We want to take a moment to thank critical care nurses for their hard work and for everything they do.

Our journeys vary. For some, becoming an advanced practice practitioner may be part of our journey. But we want everyone to remember that being a bedside nurse is a profoundly important professional role, and that practicing to the full extent of one’s education and training does not necessarily mean leaving the bedside.

**ACKNOWLEDGMENT**

We would like to thank “Jane” for being so generous with her time, for sharing her story with us, and for allowing us in turn to share it with the readers of AJCC.

**FINANCIAL DISCLOSURES**

None reported.

**REFERENCES**


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Clinical Pearls

The Influence of Multifaceted Education Before Surgery

Delirium is the most common postoperative psychiatric condition in intensive care units (ICUs) and can lead to increased complications and costs. Chevillon and colleagues found that multifaceted education on what patients can expect in the ICU before surgery may decrease delirium and anxiety, and shorten the duration of mechanical ventilation. Patients with hearing impairments are at increased risk of postoperative delirium, as well as longer duration of mechanical ventilation and ICU stay. The authors recommend the following:

• Before surgery, provide patients with multifaceted education regarding what to expect after surgery.
• Discuss and explain the equipment, sights, and sounds of the ICU. Include devices such as an endotracheal tube, a ventilator, restraints, venodynes, a Swan-Ganz catheter, and an incentive spirometer.
• Review the patients’ history and physical condition before they are received from the operating room to assess for hearing impairment.
• Ensure that patients who need hearing aids have them placed and activated early in the ICU stay.

See Article, pp 164-171

Using Cardiac Dysrhythmia to Predict Weaning Tolerance

What evidence can you use to evaluate whether your patient is tolerating weaning from mechanical ventilation? An increase in cardiac dysrhythmia should be included in this list. Changes in intrathoracic pressure can alter the autonomic nervous system and the balance between sympathetic and parasympathetic innervation, resulting in changes in heart rate variability (HRV). In a study of HRV during weaning Hammash and colleagues found the following:

• There were more supraventricular ectopic beats during weaning compared to baseline.
• Sympathetic dominance increased sinus node depolarization and a reduced R to R interval.
• Changes in HRV during weaning predicted occurrence of dysrhythmias.

Although HRV is not presently monitored in real time, it may, in the future be a useful measure of autonomic dysfunction and be one more factor in determining weaning success.

See Article, pp 118-127

Pleth Variability and Responsiveness to Fluid Administration

Have you used the Pleth Variability Index (PVI) in your unit to determine how responsive a patient will be to fluid administration, that is, will fluid actually increase the cardiac output? The PVI measures variation in pulse oximetry waveform amplitude during respiration. Since too much fluid may be associated with increased morbidity and mortality and only half of those treated with fluid resuscitation show cardiac output improvement, it is important to know if this index works. In a study to determine the ability of the PVI to predict fluid responsiveness after cardiac surgery Maughan and colleagues found the following:

• Maximum predictive value of the PVI was poor in both intubated and spontaneously breathing patients.
• They concluded that the PVI had insufficient discrimination to predict fluid responsiveness.
• They reported that theirs was the second report that the index does not predict responsiveness following cardiac surgery.

Although noninvasive measures to evaluation a patient’s status are preferred, some may not be effective and should not be adopted simply because they are “newer” or easier to obtain.

See Article, pp 172-175

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FEVER IN TRAUMA PATIENTS: EVALUATION OF RISK FACTORS, INCLUDING TRAUMATIC BRAIN INJURY

By Victoria Bengualid, MD, Goutham Talari, MD, David Rubin, MD, Aiham Albaeni, MD, Ronald L. Ciubotaru, MD,1 and Judith Berger, MD

Background The role of fever in trauma patients remains unclear. Fever occurs as a response to release of cytokines and prostaglandins by white blood cells. Many factors, including trauma, can trigger release of these factors.

Objectives To determine whether (1) fever in the first 48 hours is related to a favorable outcome in trauma patients and (2) fever is more common in patients with head trauma.

Method Retrospective study of trauma patients admitted to the intensive care unit for at least 2 days. Data were analyzed by using multivariate analysis.

Results Of 162 patients studied, 40% had fever during the first 48 hours. Febrile patients had higher mortality rates than did afebrile patients. When adjusted for severity of injuries, fever did not correlate with mortality. Neither the incidence of fever in the first 48 hours after admission to the intensive care unit nor the number of days febrile in the unit differed between patients with and patients without head trauma (traumatic brain injury). About 70% of febrile patients did not have a source found for their fever. Febrile patients without an identified source of infection had lower peak white blood cell counts, lower maximum body temperature, and higher minimum platelet counts than did febrile patients who had an infectious source identified. The most common infection was pneumonia.

Conclusions No relationship was found between the presence of fever during the first 48 hours and mortality. Patients with traumatic brain injury did not have a higher incidence of fever than did patients without traumatic brain injury. About 30% of febrile patients had an identifiable source of infection. Further studies are needed to understand the origin and role of fever in trauma patients. (American Journal of Critical Care. 2015; 24:e1-e5)

1Deceased.

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 COMPUTER-ASSISTED INTERVENTIONS TO IMPROVE QTc DOCUMENTATION IN PATIENTS RECEIVING QT-PROLONGING DRUGS

By Kristin E. Sandau, RN, PhD, CNE, Sue Sendelbach, RN, PhD, CCNS, Linda Fletcher, MHI, Joel Frederickson, PhD, Barbara J. Drew, RN, PhD, and Marjorie Funk, RN, PhD

Background Many medications commonly used in hospitals can cause prolonged corrected QT interval (QTc), putting patients at risk for torsade de pointes (Tdp), a potentially fatal arrhythmia. However, documentation of QTc for hospitalized patients receiving QT-prolonging medications is often not consistent with American Heart Association standards.

Objective To examine effects of education and computerized documentation enhancements on QTc documentation.
Methods  A quasi-experimental multisite study among 4011 cardiac-monitored patients receiving QTc-prolonging medications within a 10-hospital health care system was conducted to compare QTc documentation before (n=1517), 3 months after (n = 1301), and 4 to 6 months after (n = 1193) an intervention. The intervention included (1) online education for 3232 nurses, (2) electronic notifications to alert nurses when a patient received at least 2 doses of a QT-prolonging medication, and (3) computerized calculation of QTc in electronic health records after nurses had documented heart rate and QT interval.

Results  QTc documentation for inpatients receiving QTc-prolonging drugs increased significantly from baseline (17.3%) to 3 months after the intervention (58.2%; P < .001) within the 10 hospitals and had increased further 4 to 6 months after the intervention (62.1%, P = .75). Patients at larger hospitals were significantly more likely to have their QTc documented (46.4%) than were patients at smaller hospitals (26.2%; P < .001).

Conclusion  A 3-step system-wide intervention was associated with an increase in QTc documentation for patients at risk for drug-induced TdP, and improvements persisted over time. Further study is needed to assess whether increased QTc documentation decreases occurrence of drug-induced TdP.

(American Journal of Critical Care. 2015;24:e6-e15)
Inhaled Nitric Oxide to Improve Oxygenation for Safe Critical Care Transport of Adults With Severe Hypoxemia

By Nicholas R. Teman, MD, Jeffrey Thomas, RN, Benjamin S. Bryner, MD, Carl F. Haas, RRT, Jonathan W. Haft, MD, Pauline K. Park, MD, Mark J. Lowell, MD, and Lena M. Napolitano, MD

Background Inhaled nitric oxide (iNO) is a rescue treatment for severe hypoxemia in the intensive care unit setting.

Objective To evaluate the effectiveness and safety of iNO in adult patients with severe hypoxemia before and during transport to a tertiary care center.

Methods Prospective data were examined in a retrospective cohort study. Patients with severe hypoxemia and cardiopulmonary failure (n=139) at referring hospitals in whom conventional therapy was unsuccessful were treated with iNO in the intensive care units in anticipation of transfer to a tertiary center. Treatment with iNO was initiated by the critical care transport team in 114 patients and continued in 25 patients. Arterial blood gas analysis was done before and after iNO treatment.

Results Patients treated with iNO had significant improvement in oxygenation: mean (SD) for PaO2 increased from 60.7 (20.2) to 72.3 (40.6) mm Hg (P=0.008), and mean (SD) for ratio of PaO2 to fraction of inspired oxygen (P:F) increased from 62.4 (26.1) to 73.1 (42.6) (P=0.03). Use of iNO was continued through transport in 102 patients, all of whom were transported without complication. The P:F continued to improve, with a mean (SD) of 109.7 (73.8) from 6 to 8 hours after arrival at the tertiary center (P<0.001 relative to values both before and after treatment). Among patients treated with iNO, 60.2% survived to discharge. In 35 nonresponders, iNO was discontinued, and 15 patients could not be transferred owing to life-threatening hypoxemia; 2 were later transferred on extracorporeal membrane oxygenation. Of 18 patients transported without iNO, 9 (50%) survived.

Conclusions Use of iNO significantly improves oxygenation of patients with severe hypoxemia and allows safe transfer to a tertiary care center. (American Journal of Critical Care. 2015; 24:110-117)
Acute respiratory distress syndrome (ARDS) affects nearly 200,000 patients in the United States each year.\(^1\) Mortality in ARDS has steadily improved but is still greater than 25%.\(^2\) Severe ARDS, characterized by a ratio of PaO\(_2\) to fraction of inspired oxygen (P:F) of 100 or less, is associated with 45% mortality.\(^3\) Several treatments can improve survival in patients with ARDS, including low tidal volume ventilation (6-8 mL/kg of ideal body weight), high positive end-expiratory pressure, and prone positioning.\(^4,5\) The role of inhaled nitric oxide (iNO) is less clear. Inhalation of nitric oxide can improve oxygenation in the short-term, as manifested by increased PaO\(_2\) and the P:F ratio.\(^6,7\) However, this improvement in oxygenation is transient, with no difference compared with improvement associated with conventional therapy after 24 hours.\(^8\)

Patients with severe respiratory failure benefit from transfer to tertiary care centers that can provide advanced ventilation treatments and salvage therapies.\(^9\) But transport of these critically ill patients can be challenging, because most of the patients have severe hypoxemia that requires advanced mechanical ventilation with high mean airway pressures, hypercarbia, acidosis, and hypotension that requires use of vasopressors. Although not currently recommended as routine therapy for ARDS, iNO potentially has use as rescue therapy for severe refractory hypoxemia to stabilize a patient’s condition for transport to a tertiary center.\(^15\) The purpose of this study was to determine the effect of iNO on oxygenation and stabilization for transport in critically ill patients with cardiopulmonary failure.

### Methods

**Patients and Study Design**

Prospectively collected data in an institutional database were reviewed retrospectively in a cohort study of adult patients treated with inhalation of nitric oxide between July 2007 and August 2012. Treatment was initiated by the critical care transport team of the University of Michigan Medical System, Ann Arbor, Michigan (Survival Flight), in anticipation of a patient’s transfer to an intensive care unit in the medical system. The study was approved by the appropriate institutional review board with waiver of informed consent.

**Transport Algorithm**

In 2006, a multidisciplinary team (surgical critical care, emergency medicine, adult respiratory care) established an algorithm for use by Survival Flight to stabilize the condition of adult patients with severe hypoxemia and ARDS for transport to a tertiary center (Figure 1). Because the University of Michigan Medical System is a regional referral center for patients with severe ARDS and receives referrals for patients with severe hypoxemia, the intent of the algorithm was to provide safe critical care during transport of these patients to the center. The critical elements of stabilization per the algorithm are lung-protective ventilation with low tidal volumes and positive end-expiratory pressure, recruitment maneuvers, pressure-control ventilation, inverse-ratio ventilation, and, when these measures are unsuccessful, inhalation of nitric oxide. The algorithm also includes criteria based on arterial blood gas analysis for safe transport (including arterial pH > 7.30 and PaO\(_2\) > 60 mm Hg).

A detailed and rigorous educational program on iNO for the Survival Flight transport team was developed to ensure safety and competency in the use of iNO for adult patients with severe hypoxemia. Additional educational efforts were initiated to achieve competency in advanced mechanical ventilation.
Consensus Definition of ARDS
- $\text{PaO}_2$ to $\text{FiO}_2$ ratio $\leq 200$
- Bilateral infiltrates consistent with pulmonary edema on frontal chest radiograph
- Requirement for positive pressure ventilation via endotracheal tube
- No clinical evidence of left atrial hypertension. If measured, pulmonary artery wedge pressure $\leq 18$ mm Hg.
- All criteria must occur together within a 24-hour interval

Calculating a P:F Ratio
Arterial $\text{PaO}_2$ divided by $\text{FiO}_2$
Example: $\text{PaO}_2 = 90$, $\text{FiO}_2 = 0.60$
$90/0.6 = \text{P:F ratio of 150}$

PEEP = Anti-Derecruitment Pressure

Clamp the Endotracheal Tube
- During all circuit change intervals
- Before and after opening the ventilator circuit for recruitment maneuvers and medication administration
- Clamp the tube for $\leq 10$ sec

Consider placement of an arterial catheter

Chest Tubes
- For Survival Flight patients, empiric chest tube placement may be required for patients in unstable condition because chest radiographs may not be readily available

(9) Inhaled Nitric Oxide
- Use the Inovent delivery system
- LTV is the only ventilator Survival Flight will use for nurse-administered NO in adults and children
- Administer 40 ppm as a test dose
- Definition of a positive iNO response:
  - $>10\%$ increase in P:F ratio
  - Decrease in PA pressures of $20\%$
  - “Subjective response”
- Discontinue iNO if no objective or no subjective response
- If response to iNO is positive, titrate the drug dose down in $10$-ppm increments
- If patient’s status deteriorates during titration, increase iNO dose to the previous effective level
- Minimum dose for transport $20$ ppm unless tried on a lower dose at the referring institution

Contact respiratory care supervisor (pager 1550) for consultation

(1) Medical Management
- Check ionized calcium
  - If $<1.3$ and patient is hypotensive, give calcium gluconate or calcium chloride
- Check arterial pH
  - If $<7.3$, consider administering sodium bicarbonate ($\text{PCO}_2 < 60$) or Tham ($\text{PCO}_2 > 60$) after consultation with receiving medical staff
- If mean arterial BP $<60$
  - Initiate Levophed infusion
  - Consider vasopressor infusion at $0.04$ units/min
- Assess adequacy of sedation and neuromuscular blockade
  - fentanyl, Versed, Nimbex PRN

(2) Mimic Settings
- If on VCV, target expired, not set tidal volume (ensure no leak)

(3) Lung-Protective Ventilator Settings
- Pplat $< 30-35$ cm H$_2$O
- VT $6$ mL/kg ideal body weight
- PEEP $12-15$ cm H$_2$O

(4) Oxygen Target
- $\text{O}_2$ sat $\geq 88\%$ and or $\text{PaO}_2 \geq 60$ mm Hg

(5) Recruitment Maneuver
- Use an anesthesia bag with pressure manometer
- Apply a moderate amount of pressure ($40$ cm H$_2$O) for an extended time ($40$ sec) while monitoring the patient’s status
- Abort procedure if patient decompensates

(6) Maximum PEEP
- Highest level patient will tolerate (hemodynamic parameters)
- Maximum level of PEEP that the ventilator is able to deliver
- LTV max PEEP $= 20$ cm H$_2$O

(7) Inverse-Ratio Ventilation
- Do not exceed $3:1$ I:E ratio with inverse-ratio ventilation (minimize auto-PEEP)

(8) Auto-PEEP
- Measurement procedure
  - Press the “Insp/Exp Hold” until it displays “Exp Hold”
  - Press again and hold the button down until the auto-PEEP value is displayed
  - Release button
  - If patient effort is detected or high-pressure alarms are detected, this procedure is aborted
- Interventions for auto-PEEP
  - Slow respiratory rate, shorten inspiratory time, bronchodilators
  - Monitor for cardiovascular compromise if auto-PEEP refractory to interventions

Figure 1 Algorithm for stabilization and management of patients with ARDS in preparation for transport.

Abbreviations: ARDS, acute respiratory distress syndrome; FiO$_2$, fraction of inspired oxygen; I:E, ratio of inspiratory time to expiratory time; iNO, inhaled nitric oxide; LTV, lap-top ventilator; OSH, outside hospital; PEEP, positive end-expiratory pressure; Pplat, plateau pressure; PRN, as needed; sat, saturation; VCV, volume control ventilation; VT, tidal volume.
techniques, including recruitment maneuvers. The Survival Flight staff are dually licensed as registered nurses and paramedics. In addition to requiring a minimum of 5 years of clinical nursing experience (mean staff nursing clinical experience > 20 years), Survival Flight has an extensive 6-month competency-based education for new hires. A specific detailed ARDS educational curriculum, including the administration and pharmacological properties of iNO and advanced mechanical ventilation treatments for severe hypoxemia, is part of the orientation for all critical care transport staff.

Ongoing educational efforts for the Survival Flight team include a weekly grand rounds case review of each ARDS case with the medical director and transport team with input from the critical care team on strategies that can be used to optimize safe transport of patients. Mandatory biannual advanced respiratory workshops are led by 2 Survival Flight staff members who are also licensed as respiratory therapists. In these sessions, iNO and advanced mechanical ventilation treatments are reviewed in detail, including converting patients from modes that cannot be used with the transport ventilator to transport modes that can be used to achieve optimal alveolar recruitment. Additional multidisciplinary meetings are held with the critical care team to review and revise the ARDS transport algorithm.

Protocol for Inhalation of Nitric Oxide

The transport ventilators used during the time of prospective data collection were the Pulmonetic LTV 1000 and 1200 (Pulmonetic Systems). Nitric oxide was delivered via the INOmax DSIR (Ikaria, Inc). Initially, a test dose of 40 ppm of nitric oxide was administered. An objectively positive response was defined as an increase in PaO2 greater than 10%. A subjectively positive response was at the discretion of the Survival Flight team and was defined as an improvement in a patient’s clinical appearance, hemodynamic status, or oxygen saturation, without a corresponding increase in PaO2. If a patient did not have a positive response, iNO therapy was discontinued. If a patient had a positive response, the dose was decreased in 10-ppm increments to a minimum of 20 ppm. Inhalation of nitric oxide was not discontinued if the treatment had been started before arrival of the Survival Flight team or if the gas had been administered for longer than 30 minutes.

Data Collection

Prospective data were collected for all adult critically ill patients with severe hypoxemia or cardiopulmonary failure transported by the Survival Flight team. Individual patient data from the Survival Flight transport record were transferred to a prospective institutional database, and outcome data were included.

Statistical Analysis

In order to determine a patient’s response to iNO, results of arterial blood gas analysis done before iNO treatment was started were compared with the results of the first arterial blood gas analysis after iNO began. Categorical variables between survivors and nonsurvivors were compared by using χ² analysis. Two-sample t tests or Wilcoxon rank-sum tests were used to compare respiratory values before and after iNO therapy. Statistical significance was defined as a 2-sided P value less than .05. All statistical analyses were performed by using SPSS, version 20, software (SPSS IBM).

Results

Survival Flight treated 139 patients with iNO at referring hospitals, initiating iNO in 114 patients (82%) and continuing therapy that had previously been started in 25 patients (18%). Baseline characteristics of the patients treated with iNO are shown in Table 1. The underlying pathophysiological condition requiring iNO during transport was ARDS in 79% of patients, cardiac failure in 16%, and other causes in 5%. A total of 74% of patients had severe ARDS (P:F ratio ≤ 100) (Table 2).

Figure 2 is the consort flow diagram of the patients included in the study, including outcomes.
before the arrival of the Survival Flight team). Among the responders to iNO, 2 died before transport, but the remaining 102 patients were transported to the tertiary care center successfully without complication.

Among the 102 patients, the mode of transport was helicopter in 66 (65%), ground in 33 (32%), and fixed-wing in 3 (3%). Mean iNO dose at transport was 33 (SD, 23) ppm. After arrival at the tertiary care center, 81 patients (79%) had treatment with iNO continued past the first day of admission. A total of 22 patients (22%) treated with iNO during transport required extracorporeal membrane oxygenation (ECMO) during admission at the tertiary care center; 9 of the 22 (41%) survived. Ultimately, 62 (60%) of the 102 patients treated with iNO during transport survived to discharge, including 67% of those who had cardiac failure and 60% of those who had ARDS.

Of the patients who had iNO therapy started by the Survival Flight team, 63 had a positive objective response (55%), 16 had a positive subjective response (14%), and 35 did not have a response (31%). Inhalation of nitric oxide was discontinued in the 35 nonresponders and continued in 104 patients (the 79 patients with an objective or subjective response plus the 25 patients treated with iNO before the arrival of the Survival Flight team). Among the responders to iNO, 2 died before transport, but the remaining 102 patients were transported to the tertiary care center successfully without complication.

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Table 2
Diagnosis or cause for transfer of 139 patients treated with inhaled nitric oxide

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute respiratory distress syndrome</td>
<td>110 (79)</td>
</tr>
<tr>
<td>Severe acute respiratory distress syndrome</td>
<td>103 (74)</td>
</tr>
<tr>
<td>Cardiac failure</td>
<td>22 (16)</td>
</tr>
<tr>
<td>Other</td>
<td>7 (5)</td>
</tr>
</tbody>
</table>

*a Ratio of PaO2 to fraction of inspired oxygen ≤ 100 mm Hg.

Figure 2: Consort diagram of patients treated with inhaled nitric oxide at referring hospitals by Survival Flight team. Abbreviations: ECMO, extracorporeal membrane oxygenation; iNO, inhaled nitric oxide.
Of the 35 patients who had iNO therapy discontinued, 18 were transferred without iNO treatment after further stabilization of their condition, and 17 could not be transferred at that time. A total of 2 of the 17 were subsequently transported with ECMO support; 3 others were transported at a later date after clinical improvement.

Changes in arterial blood gas measurements from before iNO therapy to after iNO therapy are shown in Figure 3. Oxygenation improved significantly after iNO therapy was started, with an increase in mean PaO₂ from 60.7 (SD, 20.2) mm Hg before to 72.3 (SD, 40.6) mm Hg after (P = .008) and a mean increase in the P:F ratio from 62.4 (SD, 26.1) before to 73.1 (SD, 42.6) after (P = .03). The P:F ratio continued to improve, with a mean of 109.7 (SD, 73.8) according to arterial blood gas analysis of blood obtained 6 to 8 hours after arrival at the tertiary care center (P < .001 relative to values before and after iNO therapy). No significant changes occurred in PaCO₂ or pH. Mean PaCO₂ was 52.2 (SD, 14.8) mm Hg before iNO therapy and 50.6 (SD, 14.4) mm Hg after therapy (P = .42), and mean pH was 7.32 (SD, 0.11) before and 7.34 (SD, 0.10) after (P = .14).

**Discussion**

Transport of critically ill patients with severe hypoxemia to a regional center for advanced care is complex and potentially life-threatening, and critical care transport teams face marked challenges to provide safe transport. Our results suggest that iNO therapy improves oxygenation, allowing for safe transport. We found significant increases in PaO₂ and the P:F ratio in patients treated with iNO. The increases persisted throughout transport to the tertiary care center. All patients who received iNO therapy during transport survived the transport, and some required ECMO or other rescue therapies for ongoing treatment of severe refractory hypoxemia.

Inhaled nitric oxide is a selective pulmonary vasodilator. It improves oxygenation via vasodilation of the ventilated part of the lungs, resulting in decreased shunting and improved ventilation-perfusion matching. Because iNO has no effect on the systemic circulation, it does not cause hypotension or increased perfusion to the shunted part of the lungs. However, iNO is also associated with increased renal dysfunction. Because of this association and the lack of a proven mortality benefit, iNO is not recommended as routine therapy for ARDS, rather it is considered a rescue therapy for severe refractory hypoxemia. When the P:F ratio cannot be maintained at more than 60 with other strategies for treatment of severe ARDs, then inhalation of nitric oxide is started by determining whether or not the patient responds to the inhaled gas.
responders, improved oxygenation facilitates more timely and safer transport to the ARDS referral center. Patients who are iNO nonresponders with a persistent P:F ratio less than 60 may ultimately not be able to be transported.

Our patients experienced no adverse events related to iNO use during transport, and all transported patients survived to arrival at the referral center. The importance of transporting critically ill patients to tertiary hospitals for advanced care has been well described. Gebremichael et al17 showed that critically ill patients can be transported safely and that transfer of patients with severe respiratory failure to tertiary care centers has a survival advantage. Ridley and Carter18 reported that patients have a predictable physiological response to transfer, independent of the severity of the underlying disease; that is, patients with higher critical illness scores did not have worse outcomes during transport. Ridley and Carter also showed that patients transferred from outside institutions had similar mortality to patients admitted directly to the tertiary center ICU, concluding that the risks of transport are generally lower than the risks of the underlying disease and that patients should be transferred if more advanced care is available at another medical center.

Use of specialized transport teams is beneficial in the transport of critically ill patients. Bellingan et al19 found that patients transported by specialized ICU teams had less hypotension, less acidosis, and lower mortality than did patients transported by traditional ambulance. The transport of patients with ARDS requires specialized teams, exemplified by the Acute Lung Rescue Team.20,21 Using advanced ventilator strategies and ECMO, the team has successfully transported patients with ARDS from the combat theater to military hospitals. Uusaro et al22 described a series of 66 patients, most of whom had ARDS, who were successfully transferred via ground to a tertiary ICU and concluded that transfers of even the most critically ill patients are safe.

Despite the benefit of iNO on oxygenation and the safety of transport, few data are available on transport of adult patients who receive iNO therapy during transport. Much of the existing literature23-25 is about iNO therapy in infants and children. In these patients, iNO therapy can improve oxygenation and allow stabilization of hypoxic newborns to facilitate transport. Although adult ARDS patients with severe hypoxemia have been successfully transported while receiving ECMO,26 this practice necessitates a substantially increased workload related to the equipment required and also requires a physician to perform cannulation.

We found no previous published reports of adult ARDS patients transported while receiving iNO therapy. Reily et al27 presented a case of a young adult with ARDS who was transported while receiving inhaled prostacyclin therapy, in part because the delivery system for inhalation of nitric oxide was too large for the helicopter. The delivery system we use is compact and fits in a helicopter, airplane, or ambulance, allowing consistent administration of iNO therapy during transport. Our findings indicate that use of a regionally based critical care transport team with equipment for iNO therapy for transport of adult critically ill patients with severe hypoxemia is feasible, safe, and associated with reasonable survival after transport.

The limitations of our study stem from its retrospective nature. We did not have data on the total number of ARDS patients who were evaluated for transport or who did not receive iNO therapy during transport. Also, the treatment algorithm is meant as a guide for treatment by the Survival Flight team; no clear criteria exist for progression to each next step in the algorithm, allowing flexibility but leading to variability in patient management. We also did not know the clinical course or outcome of the patients who were not transported to our institution.

Despite these limitations, our results support the use of iNO therapy as an additional tool in the management of severe hypoxemia in adult critically ill patients with cardiopulmonary failure who require transport to a regional referral center for advanced clinical care. A significant improvement in oxygenation, even if transient, makes iNO therapy valuable for the transport of critically ill patients, partly by mitigating the physiological challenges posed by transport of patients with severe hypoxemia. In our experience at the University of Michigan Medical System, use of iNO therapy allowed transport of critically ill adult patients who otherwise were not considered in stable enough condition for transport to our facility for advanced critical care.

Conclusions

Initiation of iNO therapy before transport improves oxygenation in critically ill patients with severe hypoxemia, allowing stabilization of the patients’ condition and safe transport. Although prospective randomized studies have indicated that iNO leads to improved oxygenation in patients with ARDS, no previous studies have shown the
effectiveness of iNO therapy for ARDS when initiated at referring hospitals by a nonphysician critical care transport team. We have demonstrated the role of iNO in our ARDS treatment algorithm for safe transport of these critically ill patients with severe hypoxemia. Specialized critical care transport teams can safely administer iNO therapy during transport to tertiary care centers for advanced ventilator strategies and rescue therapies for treatment of severe refractory hypoxemia.

FINANCIAL DISCLOSURES
None reported.

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Heart Rate Variability as a Predictor of Cardiac Dysrhythmias During Weaning From Mechanical Ventilation

By Muna H. Hammash, RN, PhD, Debra K. Moser, RN, DNsc, Susan K. Frazier, RN, PhD, Terry A. Lennie, RN, PhD, and Melanie Hardin-Pierce, RN, APRN, ACNP-BC, DNP

Background Weaning from mechanical ventilation to spontaneous breathing is associated with changes in the hemodynamic and autonomic nervous systems that are reflected by heart rate variability. Although cardiac dysrhythmias are an important manifestation of hemodynamic alterations, the impact of heart rate variability on the occurrence of dysrhythmias during weaning has not been specifically studied.

Objectives To describe differences in heart rate variability spectral power and occurrence of cardiac dysrhythmias at baseline and during the initial trial of weaning from mechanical ventilation and to evaluate the impact of heart rate variability during weaning on occurrence of dysrhythmias.

Method Continuous 3-lead electrocardiographic recordings were collected from 35 patients receiving mechanical ventilation for 24 hours at baseline and during the initial weaning trial. Heart rate variability was evaluated by using spectral power analysis.

Results Low-frequency power increased (P = .04) and high-frequency and very-low-frequency power did not change during weaning. The mean number of supraventricular ectopic beats per hour during weaning was higher than the mean at baseline (P < .001); the mean of ventricular ectopic beats did not change. Low-frequency power was a predictor of ventricular and supraventricular ectopic beats during weaning (P < .001). High-frequency power was predictive of ventricular and supraventricular (P = .02) ectopic beats during weaning. Very-low-frequency power was predictive of ventricular ectopic beats (P < .001) only.

Conclusion Heart rate variability power spectra during weaning were predictive of dysrhythmias. (American Journal of Critical Care. 2015;24:118-127)
Cardiac dysrhythmias are a common and important clinical problem in patients receiving or being weaned from mechanical ventilation. Cardiac dysrhythmias can induce myocardial ischemia, impair myocardial contractility, and decrease cardiac index, eventually leading to unsuccessful weaning. Unsuccessful weaning is associated with prolonged duration of mechanical ventilation and increased intensive care unit (ICU) mortality, complications, and costs.

Changes in intrathoracic pressure and lung volume during weaning may induce marked hemodynamic changes in right and left ventricular preload and afterload; and intrathoracic blood volume and flow. In response, the autonomic nervous system (ANS) is activated and induces alterations in ventricular afterload, contractility, and heart rate to maintain cardiac output and tissue perfusion. The balance between the 2 components of autonomic tone, sympathetic and parasympathetic innervation, can be evaluated by measuring heart rate variability (HRV).

HRV, the beat-to-beat variation in heart rate, is due primarily to ongoing changes in sympathetic and parasympathetic input to the sinoatrial node. During weaning, changes in the ANS with a shift to sympathovagal imbalance (ie, increased sympathetic and/or reduced vagal tone) may occur in patients who have underlying cardiovascular dysfunction and impaired compensatory mechanisms, resulting in decreased HRV. Sympathetic dominance is associated with decreased duration of myocardial action potential, and increased myocardial excitability, which may enhance abnormal automaticity, triggered activity, and reentry and produce cardiac dysrhythmias.

Numerous experimental and clinical studies have revealed a relationship between reduced HRV and the genesis of malignant ventricular dysrhythmias, paroxysmal atrial fibrillation, and atrial flutter, especially in patients with heart failure, myocardial ischemia, or myocardial infarction. Although dysrhythmias that develop during weaning are often clinically important and can lead to unsuccessful weaning, little research has been done on the relationship between HRV and occurrence of dysrhythmias during weaning. Therefore, the purpose of this study was to evaluate the impact of HRV as a noninvasive reflection of ANS tone during the initial weaning trial on occurrence of cardiac dysrhythmias. Clinically important cardiac dysrhythmias such as ventricular ectopy, ventricular tachycardia or fibrillation, atrial fibrillation or flutter, supraventricular tachycardia, and supraventricular beats were the focus of the study because of their potential adverse consequences in patients who are undergoing weaning trials. The specific aims of the study were to determine whether spectral power analysis indicated differences between HRV at baseline and during the initial weaning trial; determine whether occurrence of cardiac dysrhythmias at baseline and during the initial weaning trial differed; and determine the association between HRV measured during weaning and the occurrence of cardiac dysrhythmias, after controlling for baseline HRV measured during mechanical ventilation.

**Methods**

**Design, Sample, and Setting**
A descriptive correlational design was used to evaluate the impact of HRV during initial weaning from mechanical ventilation on the occurrence of cardiac dysrhythmias. Data were collected on cardiac dysrhythmias and HRV twice, at baseline (for 24 hours during mechanical ventilation) and during the initial weaning trial (up to 2 hours). A total of 35 adult patients from the medical, surgical, cardiac care, and trauma ICUs at the University of Kentucky Chandler Medical Center, Lexington, Kentucky, were enrolled in the study between 2008 and 2009. Patients were included in the study if they were 18 years or older and received mechanical ventilation for a minimum of 24 hours via an endotracheal tube. 

**About the Authors**
Muna H. Hammash is an assistant professor at the University of Louisville, Louisville, Kentucky. Debra K. Moser and Terry A. Lennie are professors, Susan K. Frazier is an associate professor, and Melanie Hardin-Pierce is an assistant professor at the University of Kentucky, Lexington, Kentucky.

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**Intrathoracic pressure and lung volume changes during weaning may induce hemodynamic alterations.**
Patients were excluded if they had experienced a myocardial infarction within the preceding 3 months or were admitted with a myocardial infarction, were undergoing cardiac surgery or had cardiac surgery within the previous 3 months, had neurological trauma or stroke within the previous 3 months or were admitted with neurological trauma or stroke, were in atrial fibrillation or had paroxysmal atrial fibrillation, had a pacemaker or implanted cardioverter defibrillator, or had a pulmonary artery catheter or central venous catheter that was not in the proper position as confirmed by radiography.

Measures

Sociodemographic Characteristics. Data on age, sex, marital status, ethnicity, and type of insurance were abstracted from the medical records at baseline when a patient was enrolled in the study.

Clinical Data. Clinical data on previous need for mechanical ventilation, history of cardiac diseases and dysrhythmias, score on the Acute Physiology and Chronic Health Evaluation (APACHE) IV, physiological status (temperature, score on the Glasgow Coma Scale, results of arterial blood gas analyses, electrolyte levels, complete blood cell count), pulmonary status (respiratory rate, tidal volume, minute volume, airway pressure and resistance), cardiovascular status (blood pressure, heart rate, central venous pressure), and intake and output were collected from the medical records twice, at baseline at the time of enrollment during mechanical ventilation and during the initial weaning trial.

Dysrhythmias. Three-lead electrocardiographic (ECG) Holter (Evo, Del Mar) recordings of cardiac electrical activity in leads I, II, and V1 were evaluated for cardiac dysrhythmias at baseline during mechanical ventilation and during the initial weaning trial. The Del Mar Holter Analysis System (CardioNavigator Plus version 3.05.0116, SpaceLabs Healthcare) was used to scan all Holter recordings, and all types of heart beats were confirmed by 2 of the investigators (M.H. and D.M.). Ventricular and supraventricular ectopic beats were identified, frequency determined, and calculated as beats per hour. Episodes of atrial fibrillation or flutter and ventricular tachycardia or fibrillation were evaluated and scored as present or not present.

Heart Rate Variability. HRV is the beat-to-beat alterations in heart rate produced by modulation by the ANS and is detected by variations in R-R intervals in the ECG. Frequency domain analysis of HRV was used to assess the autonomic modulation of sinus node activity during mechanical ventilation and the initial weaning trial. After confirmation of all normal R-R intervals obtained via Holter recordings, artifacts were filtered out and R-R tachograms (normal-to-normal R-R intervals) were generated. The software then used a fast Fourier transformation (FFT) to produce the frequency domain measures of the power spectrum. These variables are valid measures of the frequency bands that provide distinct indications of vagal, as well as sympathetic, modulation of the R-R intervals. This analytical technique provides quantification of the frequency bands in the power spectrum. The heart rate signal is dismantled into sine waves. The amplitude of each sine wave is then converted to power and plotted against the frequency of the sine wave to give the power spectrum. The FFT analysis separates the heart rate signal into its frequency components. These bands are quantified by their intensity, which is also known as power; thus, the greater the intensity of one band, the greater is the power in that band. The result is an evaluation of the power spectral density of the heart rate signal. High-frequency (HF), low-frequency (LF), very-low-frequency (VLF), and ultra-low-frequency (ULF) bands were included in the evaluation. The HF band (0.15-0.40 Hz) represents the vagal control to the heart, modulated by respiration. The LF band (0.04-0.15 Hz) has contributions from both vagal and sympathetic modulation of the heart. Although many investigators use the LF band as an index of sympathetic modulation, this practice is somewhat controversial because of the additional contribution of parasympathetic tone. VLF power (0.003-0.04 Hz) represents the sympathetic activity.

ECG recording periods were divided into consecutive, nonoverlapping 5-minute epochs by the HRV software (Del Mar). Artifacts, atrial fibrillation or flutter, and abnormal complexes along with the preceding and succeeding R-R intervals were excluded from the analysis, and linear interpolation was used to estimate the spectrum before applying an FFT. Segments in which more than 80% of the R-R intervals were not normal were excluded. The mean power spectra from the 5-minute epochs recorded during the 24-hour baseline period of mechanical ventilation and during the initial weaning trial were used in the data analysis.

Procedure

The study was approved by the University of Kentucky medical institutional review board. The...
appropriate surrogate for each patient provided informed consent. At baseline, upon enrollment in the study, demographic and baseline clinical data were abstracted from medical records. Electrodes for a 3-lead Holter monitor were positioned to record data from leads I, II, and V2, and ECG readings were continuously recorded for 24 hours during the baseline period.

Patients receiving mechanical ventilation were evaluated daily in the morning by respiratory therapists and an attending physician for readiness to wean. Readiness was determined by using the following criteria in the institution’s protocol: resolution of the reason for which the patient was intubated, adequate oxygenation (oxygen saturation by pulse oximeter ≥ 90% with positive end-expiratory pressure < 8 cm H2O, fraction of inspired oxygen 0.40), stable hemodynamic status without need for high-dose vasopressor treatment, pH greater than 7.35, body temperature less than 38.9ºC (102ºF), and minimal sedation or without need for sedation. Once the weaning trial was prescribed, the Holter monitor was placed and ECG values were continuously recorded during the initial weaning trial. Clinical data were then collected from the medical record for the weaning day.

Data Analysis

Data were evaluated for normality before statistical analyses were done. Frequency distributions were performed to detect errors, outliers, and missing data. Data transformation with log 10 was required for the HRV variables before statistical analysis; an inverse transformation was used to normalize distributions of beats per hour. Data were analyzed by using SPSS for Windows, version 20.0 (IBM SPSS). Descriptive statistics were used to characterize the sample. Repeated-measures analysis of variance was used to determine if mean values measured at baseline (during mechanical ventilation) differed from mean values measured during the initial weaning trial. Clinical data were then collected from the medical record for the weaning day.

Results

Sample Characteristics

The 35 patients in the study were primarily men (66%), and the mean age was 53.3 (SD, 14.6) years (Table 1). The mean duration of mechanical ventilation was 11.6 (SD, 8.4) days, and the mean length of stay in the ICU was 15.6 (SD, 9.2) days. A total of 31% of the sample had a history of chronic pulmonary disease, and 49% had a history of cardiovascular disease. Of those patients with previous

<table>
<thead>
<tr>
<th>Variable</th>
<th>Valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>53.3 (14.6)</td>
</tr>
<tr>
<td>Men</td>
<td>23 (66)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>34 (97)</td>
</tr>
<tr>
<td>African American</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>17 (49)</td>
</tr>
<tr>
<td>Single/divorced/widowed</td>
<td>18 (51)</td>
</tr>
<tr>
<td>Type of insurance</td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>23 (66)</td>
</tr>
<tr>
<td>Commercial/self</td>
<td>12 (34)</td>
</tr>
<tr>
<td>Score on Glasgow Coma Scale, mean (SD)</td>
<td>8.4 (2.6)</td>
</tr>
<tr>
<td>Score on Acute Physiology and Chronic Health Evaluation IV, mean (SD)</td>
<td>69.5 (24.8)</td>
</tr>
<tr>
<td>History of pulmonary diseases</td>
<td>11 (31)</td>
</tr>
<tr>
<td>History of cardiovascular disease</td>
<td>17 (49)</td>
</tr>
<tr>
<td>History of cardiac rhythm disturbances</td>
<td>5 (16)</td>
</tr>
<tr>
<td>Reason for current mechanical ventilation</td>
<td></td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>25 (71)</td>
</tr>
<tr>
<td>Neurological disorders</td>
<td>4 (11)</td>
</tr>
<tr>
<td>Surgical conditions</td>
<td>6 (17)</td>
</tr>
<tr>
<td>Outcomes of initial weaning trials (n = 30)</td>
<td></td>
</tr>
<tr>
<td>Success</td>
<td>7 (23)</td>
</tr>
<tr>
<td>Failure</td>
<td>23 (77)</td>
</tr>
<tr>
<td>Number of weaning trials (n = 30), mean (SD) [range]</td>
<td>2.8 (2.6) [0-11]</td>
</tr>
<tr>
<td>Duration of mechanical ventilation, mean (SD) [range], d</td>
<td>11.6 (8.4) [2-33]</td>
</tr>
</tbody>
</table>

a Values are number (%) of patients unless indicated otherwise. Because of rounding, not all percentages equal 100.

This technique maintained the statistical power to detect differences in HRV measures.32 Separate models were developed to test the impact of HRV during weaning in the frequency domain (HF, LF, and VLF frequencies) on each of the following outcomes: ventricular ectopic beats per hour, supraventricular ectopic beats per hour, episodes of atrial fibrillation, episodes of atrial flutter, episodes of ventricular fibrillation, and episodes of ventricular tachycardia.
using repeated-measures analysis (Table 2). The mean score on the Glasgow Coma Scale increased from 8.7 (SD, 2.3) to 10.3 (SD, 1.3) ($P = .001$), indicating an increase in consciousness and responsiveness. Serum levels of calcium and magnesium both increased significantly over time; mean calcium levels increased from 7.6 (SD, 0.8) mg/dL (to convert to millimoles per liter, multiply by 0.25) to 7.9 (SD, 0.8) mg/dL ($P = .02$), and mean magnesium levels increased from 1.8 (SD, 0.4) mg/dL to 2.0 (SD, 0.4) mg/dL ($P = .007$). However, values at both time points were within the reference range for these variables. Thus, although the increases are statistically significant, the changes are not clinically significant. Hemoglobin and hematocrit levels significantly decreased over time: hemoglobin, from 10.1 (SD, 1.7) g/L to 9.6 (SD, 0.9) g/L ($P = .05$); hematocrit, from 29.1% (SD, 4.8%) to 28.0% (SD, 2.6%) ($P = .05$). This change most likely reflects iatrogenic anemia, a common result of frequent blood sampling. Cumulative fluid balance increased by nearly 3 L over time: baseline, 12364.4 (SD, 10558.7) mL to 15340.1 (SD, 13764.5) mL ($P = .03$). No other differences in clinical variables occurred over time.

### Changes in Cardiac Rhythm

Data on cardiac rhythm were collected at baseline at the time of enrollment in the study for 24 hours and for 2 hours during the initial weaning trial. All patients experienced either ventricular or supraventricular ectopic beats or both during the ECG recording sessions (Table 3). When compared over time, the mean number of supraventricular ectopic beats per hour

### Table 2

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline during mechanical ventilation</th>
<th>Day of initial weaning trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score on Glasgow Coma Scale</td>
<td>8.7 (2.3) 3.0-11.0</td>
<td>10.3 (1.3) 6-14</td>
</tr>
<tr>
<td>Score on APACHE IV</td>
<td>69.8 (25.7) 26.0-125.0</td>
<td>61.0 (20.4) 16-111</td>
</tr>
<tr>
<td>Arterial blood gases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>7.4 (0.1) 7.2-7.6</td>
<td>7.4 (0.1) 7.3-7.6</td>
</tr>
<tr>
<td>$P_{ACO_2}$, mm Hg</td>
<td>97.3 (39.0) 34-243</td>
<td>109.5 (35.6) 34-179</td>
</tr>
<tr>
<td>$P_{CO_2}$, mm Hg</td>
<td>35.3 (10.1) 23-71</td>
<td>35.4 (10.3) 18-69</td>
</tr>
<tr>
<td>Serum sodium, mmol/L</td>
<td>139.0 (5.5) 127-150</td>
<td>139.0 (4.1) 131-148</td>
</tr>
<tr>
<td>Serum potassium, mmol/L</td>
<td>3.9 (0.6) 2.9-5.7</td>
<td>3.9 (0.7) 3.0-6.2</td>
</tr>
<tr>
<td>Serum calcium, mg/dL</td>
<td>7.6 (0.8) 5.3-9.3</td>
<td>7.9 (0.8) 5.3-9.3</td>
</tr>
<tr>
<td>Serum magnesium, mg/dL</td>
<td>1.8 (0.4) 1.3-3.6</td>
<td>2.0 (0.4) 1.4-3.1</td>
</tr>
<tr>
<td>Hemoglobin, g/L</td>
<td>29.1 (4.8) 20.3-41.5</td>
<td>28.0 (2.6) 24.0-33.2</td>
</tr>
<tr>
<td>Hematocrit, %</td>
<td>29.1 (4.8) 20.3-41.5</td>
<td>28.0 (2.6) 24.0-33.2</td>
</tr>
<tr>
<td>Cumulative fluid balance, mL</td>
<td>12364.4 (10558.7) -1431.4 to 42406.0</td>
<td>15340.1 (13764.5) -528.4 to 52804.0</td>
</tr>
</tbody>
</table>

Abbreviation: APACHE, Acute Physiology and Chronic Health Evaluation.

### Table 3

<table>
<thead>
<tr>
<th>Cardiac rhythm</th>
<th>Mean (SD) Baseline</th>
<th>Mean (SD) Weaning</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean supraventricular beats per hour</td>
<td>40 (82.2) 366 (1726.3)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Mean ventricular beats per hour</td>
<td>15 (37.4) 14 (27.2)</td>
<td>.68</td>
<td></td>
</tr>
</tbody>
</table>

* Supraventricular and ventricular beats per hour were inverse transformed before analysis.

Diagnosis of cardiovascular disease, 16% had a history of cardiac dysrhythmias (unspecified type). A total of 71% of the sample had mechanical ventilation for a pulmonary condition. Among the sample, the initial weaning trial was unsuccessful in 77%; the mean number of weaning trials before successful weaning was 2.8. During the study, 3 patients died before the weaning trial and 2 required tracheostomy; these 5 patients were excluded from the analyses. Of the 30 remaining patients, 3 self-extubated and received supplemental oxygen through either a partial rebreathing or a nonrebreathing mask. A total of 27 patients had a combination of pressure support (range, 8-15 cm H$_2$O) and continuous positive airway pressure of 5 cm H$_2$O during their initial weaning trial.

Baseline values were compared with values obtained on the day of the initial weaning trial by using repeated-measures analysis (Table 2). The mean score on the Glasgow Coma Scale increased from 8.7 (SD, 2.3) to 10.3 (SD, 1.3) ($P = .001$), indicating an increase in consciousness and responsiveness. Serum levels of calcium and magnesium both increased significantly over time; mean calcium levels increased from 7.6 (SD, 0.8) mg/dL (to convert to millimoles per liter, multiply by 0.25) to 7.9 (SD, 0.8) mg/dL ($P = .02$), and mean magnesium levels increased from 1.8 (SD, 0.4) mg/dL to 2.0 (SD, 0.4) mg/dL ($P = .007$). However, values at both time points were within the reference range for these variables. Thus, although the increases are statistically significant, the changes are not clinically significant. Hemoglobin and hematocrit levels significantly decreased over time: hemoglobin, from 10.1 (SD, 1.7) g/L to 9.6 (SD, 0.9) g/L ($P = .05$); hematocrit, from 29.1% (SD, 4.8%) to 28.0% (SD, 2.6%) ($P = .05$). This change most likely reflects iatrogenic anemia, a common result of frequent blood sampling. Cumulative fluid balance increased by nearly 3 L over time: baseline, 12364.4 (SD, 10558.7) mL to 15340.1 (SD, 13764.5) mL ($P = .03$). No other differences in clinical variables occurred over time.

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Data on cardiac rhythm were collected at baseline at the time of enrollment in the study for 24 hours and for 2 hours during the initial weaning trial. All patients experienced either ventricular or supraventricular ectopic beats or both during the ECG recording sessions (Table 3). When compared over time, the mean number of supraventricular ectopic beats per hour...
during weaning was significantly greater ($P<.001$) than the mean number per hour at baseline: weaning, 366 (SD, 1726.3) and baseline, 40 (SD, 82.2). Ventricular ectopic beats per hour were not different over time (Figure 1). Only 1 patient had a single episode of ventricular tachycardia during weaning; none of the patients had ventricular or atrial fibrillation.

Changes in HRV

HRV components at baseline (LF=82.9 ms$^2$, HF=78.8 ms$^2$, VLF=79.4 ms$^2$) were reduced compared with normalized values published by the Task Force of the European Society for Cardiology and the North American Society of Pacing and Electrophysiology. When baseline and weaning values were compared (Figure 2), LF power was significantly increased ($P=.04$) during weaning: baseline mean, 82.86 (SD, 126.43) ms$^2$; weaning mean, 202.62 (SD, 391.27) ms$^2$. No significant changes in HF or VLF power occurred during weaning (Table 4).

Relationship Between HRV During Weaning and Occurrence of Cardiac Dysrhythmias

HRV measures were entered into a linear regression with APACHE IV scores to control for the severity of illness, a confounding variable. In regression analyses, the LF power accounted for 41% of the variance in occurrence of ventricular ectopic beats ($\beta=0.60$; $P=.002$), and 36% of the variance in occurrence of supraventricular ectopic beats ($\beta=0.61$; $P=.002$) during weaning (Table 5). Although neither HF nor VLF power changed significantly during weaning, in the multiple linear regression analyses, HF power accounted for 68% of the variance in occurrence of ventricular ectopic beats ($\beta=0.79$; $P<.001$) and for 29% of the variance in occurrence of supraventricular ectopic beats during weaning ($\beta=0.53$; $P=.02$). The VLF power accounted for 63% of the variance in occurrence of ventricular ectopic beats ($\beta=0.78$; $P<.001$), but did not explain variance in supraventricular beats during weaning ($P=.53$).

Discussion

HRV in this small group of critically ill patients at baseline was lower than published normative values, indicating sympathetic dominance. We found a significant increase in supraventricular beats per hour during weaning in our patients: approximately 9 times as many supraventricular beats per hour during weaning as during the baseline measurement period. The number of ventricular beats per hour at baseline did not differ significantly from the number during weaning. HF and LF HRV were predictive of supraventricular ectopy during weaning, whereas all

![Figure 1](https://example.com/figure1.png)

**Figure 1** Comparison of frequency of dysrhythmias at baseline and at weaning ($n=25$). Supraventricular and ventricular beats per hour were inverse transformed before analysis.

![Figure 2](https://example.com/figure2.png)

**Figure 2** Comparison of the components of the power spectral analysis of heart rate variability ($n=25$). Two time points compared with independent $t$ tests. Values were transformed by using a log 10 transformation before analysis.

*Abbreviations: VLF, very low frequency; LF, low frequency; HF, high frequency.*

![Table 4](https://example.com/table4.png)

**Table 4** Comparison of the components of the power spectral analysis of heart rate variability measures at baseline and during the initial weaning trial ($n=25$)

<table>
<thead>
<tr>
<th>Variable$^a$</th>
<th>Mean (SD)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very low frequency, ms$^2$</td>
<td>79.4 (109.9)</td>
<td>.06</td>
</tr>
<tr>
<td>Low frequency, ms$^2$</td>
<td>82.9 (126.4)</td>
<td>.04</td>
</tr>
<tr>
<td>High frequency, ms$^2$</td>
<td>78.8 (109.0)</td>
<td>.18</td>
</tr>
</tbody>
</table>

$^a$ All variables were transformed by using log 10 before analysis.
3 components of HRV (HF, LF, and VLF) were predictive of ventricular ectopy.

Transition from mechanical ventilation to spontaneous breathing during weaning induces marked hemodynamic changes in intrathoracic vascular volume, preload, and afterload. The ANS responds to hemodynamic alterations by increasing the activity of the sympathetic nervous system, reducing the activity of the parasympathetic system, or doing both simultaneously to maintain adequate cardiac output and tissue oxygenation. The ANS response to hemodynamic changes is often altered in patients with impaired cardiac function. Altered ANS is primarily reflected by decreased HRV, with a shift toward sympathetic dominance, rather than the normal parasympathetic predominance. Using frequency domain measures of HRV in a group of 6 healthy anesthetized canines with normal ventricular function, Frazier et al. found a significant increase in activity of the sympathetic nervous system and a significant decrease in activity of the parasympathetic nervous system with exposure to a combination of pressure support 10 cm H2O and continuous positive airway pressure 10 cm H2O. In our study, almost half of our patients (49%) had a history of cardiac disease. We found that exposing patients to a combination

| Table 5 | Prediction of the relationship between heart rate variability and occurrence of cardiac dysrhythmias during weaning (n = 25)* |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Dependent variable | Model | Step | Variables | $R^2$ (adjusted $R^2$) | $R^2$ change | F score | $\beta$ | Standardized $\beta$ | P |
| Ventricular ectopic beats | 1 | 1 | APACHE IV score | 0.06 (0.01) | 0.06 | 1.13 | 0.32 | 0.24 | 0.30 |
| | 2 | 1 | APACHE IV score | 0.69 (0.65) | 0.63 | 19.49 | 0.29 | 0.21 | <0.001 |
| | | | HF power | 19.27 | 0.79 | | | | |
| | 2 | 1 | APACHE IV score | 0.06 (0.02) | 0.06 | 1.37 | 0.32 | 0.24 | 0.26 |
| | | | LF power | 2.03 | 0.60 | | | | |
| | 3 | 1 | APACHE IV score | 0.06 (0.02) | 0.06 | 1.37 | 0.32 | 0.24 | 0.26 |
| | | | VLF power | 1.90 | 0.78 | | | | |
| Supraventricular ectopic beats | | | APACHE IV score | 0.001 (-0.06) | 0.001 | 0.01 | -2.2 | -0.03 | 0.90 |
| | | | HF power | 822.28 | 0.53 | | | | |
| | | | LF power | | | | | | |
| | 5 | 1 | APACHE IV score | 0.001 (-0.05) | 0.001 | 0.015 | -2.2 | -0.03 | 0.90 |
| | | | VLF power | 130.17 | 0.61 | | | | |
| | | | VLF power | 22.19 | 0.14 | | | | |

Abbreviations: APACHE IV, Acute Physiology and Chronic Health Evaluation IV; HF, high frequency; LF, low frequency; VLF, very low frequency.

* Supraventricular and ventricular beats per hour were inverse transformed before analysis. Data on heart rate variability were transformed by using log 10 before analysis.
of pressure support (range, 8–15 cm H₂O) and continuous positive airway pressure of 5 cm H₂O during weaning led to an increase in sympathetic tone and a concomitant decrease in parasympathetic tone. Sympathetic dominance resulted in more rapid sinus node depolarization and a reduced R-R interval. Thus, HRV was reduced in response to weaning from mechanical ventilation in these patients.

Decreased HRV has been described as arrhythmogenic.16,17,36-40 In previous studies,16,17,36-38 increased sympathetic activity or decreased parasympathetic activity or both occurred before paroxysmal atrial fibrillation and atrial flutter in patients with underlying heart disease. Although our patients did not experience significant changes in VLF or HF power during weaning, VLF and HF power during weaning were predictive of the occurrence of supraventricular and ventricular dysrhythmias. We also found that at baseline, HRV spectral components were lower than published norms,16 indicating reduced HRV and sympathetic dominance. During weaning, HRV was further reduced; the consequence was a significant increase in supraventricular dysrhythmias. Consistent with previous researchers,16,17,36-40 we found that LF power and HF power were predictive of the occurrence of ventricular and supraventricular ectopic beats, whereas VLF power was predictive of only the occurrence of ventricular ectopic beats. Huikuri et al37 reported a significant decrease in HF power before the occurrence of ventricular tachycardia in patients with ischemic heart disease. Fei et al39 reported significant changes in HRV immediately before the occurrence of tachyarrhythmias in patients with congestive heart failure; these investigators39 later found a significant increase in the LF:HF ratio immediately before the occurrence of episodes of idiopathic ventricular tachycardia. Hayashi et al41 also reported an increase in the LF:HF ratio before the onset of ventricular tachycardia. Thus, our findings are consistent with, and add to the support for, the association between reduced HRV and serious dysrhythmias.

The prevalence of cardiac dysrhythmias during weaning from mechanical ventilation has only been described in a pilot study by Frazier et al,1 who reported that the number of supraventricular ectopic beats per hour during weaning was almost double the number at baseline and that the number of ventricular ectopic beats per hour decreased by nearly two-thirds in 39 patients exposed to a combination of pressure support of 10 cm H₂O and continuous positive airway pressure of 10 cm H₂O during weaning attempts. Our results are consistent with the observed change in supraventricular, but not ventricular, ectopic beats. We found no change in ventricular ectopic beats per hour during weaning. These findings may be attributed to the greater proportion of patients in our study with preexisting cardiac disease; half of our patients had a previous diagnosis of cardiovascular disease compared with only 21% in the study by Frazier et al.1 Thus, previous structural alterations may have influenced the effect of reduced HRV on the action potential and arrhythmogenesis, particularly for supraventricular dysrhythmias. We also studied patients whose severity of illness did not decrease between the baseline measure and the day of their initial weaning trial (APACHE IV score, 70 at baseline and 61 at weaning), whereas patients in the study by Frazier et al had significant reductions in their APACHE II score, from 26 at baseline to 14 the day of initial weaning.

In our study, supraventricular ectopic beats during weaning may have been induced by a mechanoelectrical feedback mechanism. We found 9 times more supraventricular ectopic beats during weaning than at baseline. During weaning, increased atrial and ventricular end-diastolic volume and afterload can be arrhythmogenic because of this feedback mechanism.42 Acute cardiac mechanical loading with greater blood volume, and distension of the atria and ventricles potentially induced mechanical changes that reduced duration of myocardial action potential and altered myocyte excitability. This mechanoelectrical feedback is mediated by cardiac myocyte stretch-activated channels and selective-ion channels.43-46 Because we found a mean cumulative fluid increase of nearly 3 L, we inferred that preload was also increased to some degree and may have stimulated the mechanoelectrical feedback mechanism. The result was a significant increase in supraventricular ectopic beats. This increase is consistent with findings in patients with chronic congestive heart failure.47

This study was the first investigation of the predictive power of HRV, characterized by using spectral power analysis, for dysrhythmias during weaning from mechanical ventilation. We found that the results of power spectral analysis of HRV explained 29% to 68% of the variance in the occurrence of supraventricular and ventricular ectopy. Our findings provide evidence that HRV measures may be useful as a clinical indicator of autonomic dysfunction in critically ill patients; interventions to address autonomic balance could
reduce the prevalence of cardiac dysrhythmias while patients are being weaned from mechanical ventilation. The use of HRV by clinicians could improve patients’ outcomes, because autonomic dysfunction and reduced HRV are predictive of greater morbidity, mortality, and complications in patients with a variety of health issues.48-52

Limitations

Our study has some limitations. First, the sample size was small. However, the percentages of baseline scores were used to maintain the power of the study to detect differences. Larger sample sizes are recommended for future studies. Second, we did not use other measures to collect data on autonomic activity, such as plasma catecholamine levels or baroreflex sensitivity. However, power spectral analysis of HRV is an accepted, valid, and reliable noninvasive indicator of ANs balance. Third, the majority of patients were male (67%) and white (97%), characteristics that reduce the generalizability of the study findings.

Conclusion, Clinical Implications, and Recommendation for Future Research

We found that HRV was significantly predictive of the occurrence of cardiac dysrhythmias during weaning from mechanical ventilation in a heterogeneous sample of critically ill patients. HRV was reduced at baseline and further decreased with weaning. Early detection of ANs changes and effective management of cardiac dysrhythmias during weaning are of paramount importance; these alterations can contribute to seriously unstable hemodynamic status, unsuccessful weaning, and the need for longer duration of mechanical ventilation. HRV analysis and clinical use could contribute to improved clinical decision making about readiness for weaning and subsequently lead to improved outcomes for patients.

FINANCIAL DISCLOSURES

Funding for this study was provided by the AACN-Philips Medical Research Award and the Southern Nursing Research Society.

eLetters

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Evidence-Based Review and Discussion Points

By Ronald L. Hickman, RN, PhD, ACNP-BC

Evidence-Based Review (EBR) is the journal club feature in the American Journal of Critical Care. In a journal club, attendees review and critique published research articles; an important first step toward integrating evidence-based practice into patient care. General and specific questions such as those outlined in the “Discussion Points” box aid journal club participants in probing the quality of the research study, the appropriateness of the study design and methods, the validity of the conclusions, and the implications of the article for clinical practice. When critically appraising this issue’s EBR article, found on pp 118-127, consider the questions and discussion points outlined in the “Discussion Points” box. Visit www.ajcconline.org to discuss the article online.

The transition from mechanical ventilation to spontaneous breathing can perpetuate hemodynamic alterations, resulting in dysrhythmias. During a weaning trial, the manifestation of cardiac dysrhythmias may contribute to myocardial ischemia, impaired myocardial contractility, and decreased cardiac index; which increase patient’s likelihood of failure to wean from mechanical ventilation.

This study describes the association between heart rate variability (HRV), the beat-to-beat variation in heart rate measured by the variation of the R to R intervals on an electrocardiogram, and the occurrence of cardiac dysrhythmias during the initial weaning trials of mechanically ventilated patients. A total of 35 critically ill adults who received a minimum of 24 hours of mechanical ventilation were recruited from medical, surgical, and trauma intensive care units (ICUs) to participate in this study. Participants had HRV and cardiac rhythm data collected at enrollment and during the initial weaning trial using a 3-lead Holter electrocardiogram.

This study confirmed that HRV was associated with the occurrence of cardiac dysrhythmias during the initial weaning trial of mechanically ventilated patients. Using spectral power analysis, the authors examined the influence of sympathetic and parasympathetic modulation of HRV stratified by the intensity of the heart rate signals. In this study, the authors used components of the very low frequency, low frequency, and high frequency power, to examine the effects of HRV on the incidence of cardiac dysrhythmias. The authors report that each of 3 components of the HRV power spectral analysis predicted the occurrence of cardiac dysrhythmia (eg, supraventricular or ventricular ectopy) and reductions in HRV during ventilatory weaning trials.

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The results of this study highlight the potential usefulness of capturing HRV as a measure of cardiovascular function and indicator of the patient’s likelihood to manifest cardiac dysrhythmias while weaning from mechanical ventilation.

Information From the Authors
Muna Hammash, RN, PhD, lead author on this article, provided additional information about the study. She comments that the study was designed to identify clinically useful evidence on the relationship between HRV and the occurrence of cardiac dysrhythmias among patients undergoing weaning from mechanical ventilation.

According to Hammash, the motivation for this study stems from her experience providing care to mechanically ventilated patients and their families. "Despite the life-sustaining benefits of mechanical ventilation, this therapy is associated with a variety of risks and complications, such as ventilator-associated pneumonia, cardiovascular compromise, and the need for a tracheostomy," she says.

Implications for Practice
Although HRV is not a commonly assessed in patients during weaning trials, the study findings link HRV with the occurrence of cardiac dysrhythmias that can contribute to cardiovascular compromise and prolonged mechanical ventilation. Hammash suspects that her research will contribute to the revision of existing weaning protocols to include the assessment of HRV and occurrence of cardiac dysrhythmia. "My work may help improve the outcomes of patients on mechanical ventilation, reduce length of mechanical ventilation, and thus prevent complications, such as ventilator-associated pneumonia," she comments.

Hammash encourages readers of the American Journal of Critical Care to assess for decrements in HRV and cardiac dysrhythmias in patients weaning from mechanical ventilation. Hammash and her coauthors comment that, “HRV analysis could contribute to improved clinical decision making about weaning readiness and lead to improved patient outcomes.”

Discussion Points
A. Description of the Study
- What is the purpose of this study?
- What is the importance of capturing heart rate variability (HRV)?

B. Literature Evaluation
- What has been cited in the literature about the relationship between HRV and cardiac dysrhythmias?
- What are the physiologic mechanisms that link weaning from mechanical ventilation with the genesis of cardiac dysrhythmias?

C. Sample
- What patients were eligible to participate in this study?
- Why did the investigators exclude patients with a history of an acute myocardial infarction and those who had undergone cardiac surgery?

D. Methods and Design
- How did the investigators capture HRV and assess occurrence of cardiac dysrhythmias?
- Explain how the investigators used spectral power analysis to evaluate HRV?

E. Results
- What were the main findings of this study?
- What is the significance of reduced HRV in this sample?

F. Clinical Significance
- What are the implications of this study for clinical practice?
- How can you use the study results in your clinical practice?
Mechanical ventilation is initiated in patients who are acutely ill and many have chronic underlying health problems. In those with cardiac disease, weaning from mechanical ventilation can place an added stressor on an already distressed system. For that reason, we monitor patients closely during weaning from mechanical ventilation. There are standard parameters that are monitored. For example, vital signs, tidal volume, and mental status changes are all important determinants of the success or failure of a weaning trial. However, as Hammash and colleagues found in their research, measuring heart rate variability can be a significant predictor of dysrhythmias during weaning. When risk can be predicted and measured, interventions can be planned and implemented before negative consequences, such as myocardial ischemia, impaired myocardial contractility, and a decrease in cardiac index, occur.

Here’s what you can do:

- Evaluate current weaning practices in your unit by surveying your staff or peers about their decision making during weaning.
- Collaborate with physicians and respiratory therapists to develop a common understanding of weaning criteria and goals.
- Understand the contributions comorbidities make to the success or failure of weaning.
- Consider developing a unit-based algorithm to determine expected weaning end points.
- Explain the process to the patient and family in language they can understand.
- Document decision making and communicate with colleagues to determine if patient goals should be continued or modified based on weaning outcomes.

Other helpful resources:

- AACN Adult Critical Care Assessment Pocket Reference. AACN Marketplace, product #400757.
- Burns SM, ed. AACN Protocols for Practice: Care of Mechanically Ventilated Patients. 2nd ed. Sudbury, MA: Jones and Bartlett Publishers; 2007.

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Hemodynamic Changes With Manual and Automated Lateral Turning in Patients Receiving Mechanical Ventilation

By Shannan K. Hamlin, RN, PhD, ACNP-BC, AGACNP-BC, CCRN, Sandra K. Hanneman, RN, PhD, Nikhil S. Padhye, PhD, and Robert F. Lodato, MD, PhD

Background Lateral turning of critical care patients receiving mechanical ventilation can adversely affect hemodynamic status.

Objective To study hemodynamic responses to lateral turning.

Method A time-series design with automated signal processing and ensemble averaging was used to evaluate changes in heart rate, mean arterial pressure, and pulse pressure due to lateral turning in 13 adult medical-surgical critical care patients receiving mechanical ventilation. Patients were randomly assigned to the manual-turn or the automated-turn protocol for up to 7 consecutive days. Heart rate and arterial pressure were measured every 6 seconds for more than 24 hours, and pulse pressure was computed.

Results A total of 6 manual-turn patients and 7 automated-turn patients completed the study. Statistically significant changes in heart rate, mean arterial pressure, and pulse pressure occurred with the manual turn. Return of the hemodynamic variables to baseline values required up to 45 minutes in the manual-turn patients (expected recovery time ≤ 5 minutes). However, clinically important changes dissipated within 15 minutes of the lateral turn. The steady-state heart rate response on the right side was slightly greater (3 beats per minute) than that on the back (P = .003). Automated turning resulted in no clinically important changes in any of the 3 variables.

Conclusions In medical-surgical critical care patients receiving mechanical ventilation, manual lateral turning was associated with changes in heart rate, mean arterial pressure, and pulse pressure that persisted up to 45 minutes. (American Journal of Critical Care. 2015;24:131-140)
Critically ill patients treated with mechanical ventilation are at high risk for preventable pulmonary complications. A standard of care to reduce complications is lateral turning every 2 hours. Lateral turning of intensive care patients receiving mechanical ventilation can adversely affect hemodynamic status. Although the adverse effects are typically transient, clinicians may be reluctant to laterally position critically ill patients who are receiving mechanical ventilation.

Clinicians may be reluctant to laterally turn critically ill patients treated with mechanical ventilation.

Positive-pressure ventilation can reduce venous return and cardiac output. Lateral turning may augment adverse hemodynamic effects in patients receiving mechanical ventilation. A decrease in blood pressure in the lateral position, compared with the back position, has been reported. Gawlinski and Dracup found that blood pressure returned to baseline values within 5 minutes of a turn, suggesting that lateral turning has a transient effect. Because factors that cause decreased venous return would be maintained throughout the time spent in the lateral position, transient effects on blood pressure suggest that the changes are either responses involved in hemodynamic compensation or responses to the physical act of turning and not to the lateral position per se.

Research on the hemodynamic effects of lateral turning has been limited by the use of discrete measurements (eg, ≤5 time points in each lateral position) and short study duration. The hemodynamic effects of automated turning have not been systematically evaluated. We conducted a randomized clinical trial as a pilot study to compare the efficacy for preventing and treating pulmonary complications and the safety of 2 turning interventions (www.ClinicalTrials.gov: NCT00542321): manual turning every 2 hours (standard of care and control group) and continuous automated turning with a kinetic therapy bed (experimental group).

As a component of the safety assessment, we examined turning-related hemodynamic responses, defined as changes in heart rate, mean arterial pressure (MAP), and pulse pressure.

Materials and Methods

A time-series design with automated signal processing and ensemble-averaging was used to measure heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), and MAP every 6 seconds for more than 24 hours. The research protocol was approved by the appropriate institutional review boards at the University of Texas Health Science Center at Houston and the 2 participating hospitals. The 13 eligible adult patients recruited for the study were assessed for hemodynamic response to manual or automated turning.

Interventions

The manual-turning protocol included a lateral turn of 45° or greater every 2 hours for a duration of 2 hours. Research nurses turned patients to the lateral position, ensuring that the patients’ proper body alignment was maintained with the lower leg in extension and the upper leg and upper limbs flexed. Pillows were placed between each patient’s thighs, shins, and arms for comfort. Adherence to the protocol was assessed every 10 minutes.

The Triadyne Proventa bed (ArjoHuntleigh) was used for automated turning. The automated-turning protocol included continuous rotation with lateral rotation to an angle of 40° or greater. Research nurses measured the maximum angle achieved and the direction of turn every hour.

Study Procedures

General study procedures, including random selection and assignment, have been reported elsewhere. Hemodynamic data were obtained with a

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physiological monitor (HP Component Monitoring System, Philips Medical Systems, or Solar 8000i, GE Healthcare) and an arterial catheter pressure transducer (Edwards Lifesciences, PX600F or PX284). Heart rate and blood pressure data from the HP system were directly transferred via an RS232 serial interface to a laptop computer by using a custom-written software application in the LabView programming environment (National Instruments). Heart rate, SBP, DBP, and MAP were downloaded every second with date and time stamp and were aggregated in sequential 6-second means. For the Solar monitor, BedMaster (version 1.3, Excel Medical Electronics) software was used to communicate with the hospital’s Unity Network (General Electric/Marquette) to obtain the data. Pulse pressure was calculated as SBP minus DBP.

In order to account for hydrostatic-pressure effects related to changes in the height of the pressure transducer with continuous rotation, a correction formula for MAP was applied, as reported elsewhere. The height-adjustment correction was not applied to pulse pressure because this variable is the difference between SBP and DBP, 2 quantities that are equally affected by the changes in height. Pulse pressure therefore reflects a difference that is independent of the height of the transducer.

Data Management and Analysis
SPSS (version 17.0, SPSS Inc) and TIBCO Spotfire S+ (version 8.1, TIBCO Software Inc) software programs were used for data management and analyses. Outliers, defined as data points 3 or more standard deviations from the mean, and missing data were replaced by using linear interpolation. Ensemble averaging, adjusted for autocorrelated data, was used to assess within-subject hemodynamic responses to turning. Heart rate, MAP, and pulse pressure were evaluated for graphical characteristics of increase or decrease with the manual turn and 95% CI overlap with the automated turn; statistical significance; clinical importance; and, in the automated turning, the ensemble average in each angle bin was computed according to a longitudinal mixed-effects model with random intercept for the turns and first-order autoregressive structure.

At the across-subjects level, 2-way analysis of variance was used to compare changes in heart rate, MAP, and pulse pressure between turn groups and back-to-right and back-to-left positions. Mean values were determined for each turn direction (manual-turn group) or angular bin (automated-turn group). In the automated-turn group, angle bins in the back position were combined and then compared separately with angle bins in the left and right positions. The 95% CI of the overall mean was an estimate of the variability.

Results
The study consisted of 6 patients (46%) randomly assigned to the manual-turn group and 7 patients (34%) randomly assigned to the automated-turn group. Patients’ demographic and clinical
characteristics did not differ significantly between the 2 groups (Table 1). Data collection time varied from 27.1 to 165.2 hours. Heart rate data were collected for all patients, and blood pressure data were collected for the 7 patients (54%) who had an arterial catheter placed for clinical purposes.

Standardized residuals were less than or equal to ±2 for all hemodynamic variables, suggesting normal distribution of the data.18 The length-of-time series data used in the analysis for each patient varied from 16247 to 99095 data points, representing a mean of 79.2 (sd, 51.3) hours for the manual-turn and 74.9 (sd, 55.7) hours for the automated-turn group (P=.88). Combined outlier and missing values represented 3.4% or less of the data. For the manual-turn group, turning was maintained for 94% of the time patients were on protocol, and mean turn angle was 50º (sd, 5º); for the automated-turn group, these values were 91% and 32º (sd, 3º), respectively. Mean turn angle differed significantly between groups (P=.003). Within-subject mean changes in heart rate, MAP, and pulse pressure across all turns for the manual- and automated-turn groups are presented in Figure 1. Postturn recovery time (manual-turn group only) is presented in Table 2.

### Ensemble Averages of the Manual-Turn Group

Manual lateral turning induced changes in heart rate, MAP, and pulse pressure. Figure 2 shows individual turn data and ensemble-averaged data for patient P001 as an example. Graphical displays of the data show hemodynamic responses to turning both in the individual turns (Figure 2, panels A, B, and C) and ensemble-averaged data (Figure 2, panels D, E, and F. Clinically important changes in heart rate were detected in 2 patients in the left position and in 2 patients in the right position. With the exception of 1 patient in the back-to-left position, all patients showed a prolonged, statistically significant recovery time in heart rate from 9 to 45 or more minutes after turning (Table 2); clinically important changes (heart rate, ±10 beats per minute) were transient and dissipated within 15 minutes of the turn. The same was true for MAP and pulse pressure recovery times.

Of the 4 manual-turn patients who had an arterial catheter, 2 had statistically and clinically significant increases in MAP with a change in position that varied from +13 to +22 mm Hg (Figure 1B). Magnitude of change did not differ between back-to-left (+22 mm Hg) and back-to-right (+21 mm Hg) lateral turning. Three patients had prolonged MAP recovery time that varied from 9 to 37 or more minutes (Table 2). A total of 4 patients had statistically significant changes in pulse pressure associated with manual turning: 3 had an increase and 1 had a decrease, but only 1 of the changes was a clinically important change, with the greatest magnitude of +23 mm Hg in the back-to-left position. Three patients had prolonged pulse pressure recovery time of up to 43 minutes (Table 2).

### Ensemble Averages for the Automated-Turn Group

Automated turning induced changes in heart rate, MAP, and pulse pressure (Figures 3A, 3B, and 3C). Among the 7 patients, 3 (43%) had a statistically significant heart rate response to left and right position.

---

**Table 1**  
**Patients’ demographic and clinical characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Manual turn (n = 6)</th>
<th>Automated turn (n = 7)</th>
<th>Pa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, range (mean [SD]), y</td>
<td>38-77 (54 [13.2])</td>
<td>45-75 (60 [10.7])</td>
<td>.38</td>
</tr>
<tr>
<td>Men, No. (%)</td>
<td>3 (50)</td>
<td>4 (57)</td>
<td>.76</td>
</tr>
<tr>
<td>Score on Acute Physiology and Chronic Health Evaluation II, range (mean [SD])</td>
<td>18-36 (29 [6.6])</td>
<td>15-29 (24 [5.4])</td>
<td>.19</td>
</tr>
<tr>
<td>Requirement of vasopressors, No. of patients (%)</td>
<td>4 (67)</td>
<td>2 (29)</td>
<td>.41</td>
</tr>
<tr>
<td>Positive end-expiratory pressure, range (mean [SD]), cm H2O</td>
<td>0-12 (5.3 [3.6])</td>
<td>0-12.5 (5.4 [3.0])</td>
<td>.94</td>
</tr>
<tr>
<td>Diagnosis or condition, No. (%) of patients</td>
<td></td>
<td></td>
<td>.32</td>
</tr>
<tr>
<td>Pneumonia/respiratory failure</td>
<td>3 (50)</td>
<td>2 (29)</td>
<td></td>
</tr>
<tr>
<td>Sepsis/shock</td>
<td>0 (0)</td>
<td>1 (14)</td>
<td></td>
</tr>
<tr>
<td>Neurological</td>
<td>1 (17)b</td>
<td>2 (29)c</td>
<td></td>
</tr>
<tr>
<td>Cardiopulmonary resuscitation</td>
<td>0 (0)</td>
<td>1 (14)</td>
<td></td>
</tr>
<tr>
<td>Liver failure</td>
<td>1 (17)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1 (17)d</td>
<td>1 (14)e</td>
<td></td>
</tr>
</tbody>
</table>

a Independent samples t test used for age, score on Acute Physiology and Chronic Health Evaluation II, and positive end-expiratory pressure; Pearson χ² test for use of vasopressors and diagnosis or condition.

b Meningitis.  
c Seizure, West Nile encephalitis.  
d Overdose.  
e Suicide attempt with insulin and ingestion of toilet bowl cleaner.
turning compared with the back position. However, the changes were not clinically important; the maximum response was a change in heart rate of 2 beats per minute compared with the back position. All 3 automated-turn group patients with an arterial catheter 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 mm Hg. With the height-adjusted model, MAP differences were 1 mm Hg or less. Two patients had a statistically significant change in pulse pressure in both the left and right positions compared with the back position. The changes were not clinically important; the maximum response was 5 mm Hg or less (Figure 3C). Because the patients were in constant motion, recovery time could not be calculated.

**Group Comparisons**

The change in heart rate for the manual-turn group was significantly greater in the right lateral than in the back position ($P = .003$); the mean change of +3 beats per minute was not clinically important. No other within-group differences in position or position by group interaction were significant. Between-group differences in heart rate, MAP, and pulse pressure were not significant.

**Power Computation**

Power calculations with $\alpha = .05$ showed that the study was adequately powered (>89%) to detect within- and between-group clinically important changes in heart rate and MAP and within-group changes in pulse pressure, but not clinically important changes in pulse pressure between turning-intervention groups.

**Discussion**

In this study of manual vs automated turning, statistically significant changes occurred in heart rate, MAP, and pulse pressure with manual turning. The heart rate and MAP changes were clinically important in 50% and 25% of patients, respectively, in this small study sample. These findings may reflect the higher mean scores on the Acute Physiology and Chronic Health Evaluation II and the greater percentage of patients with vasopressor support in the manual-turn group, despite random selection and assignment of patients. The times for the hemodynamic parameters to return to baseline values were highly variable: in some patients, heart rate did not recover to baseline within the observation period of 45 minutes after a turn. All patients with an arterial catheter in the automated-turn group had an arterial catheter.

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**Figure 1** Summary of within-subject ensemble-averaged mean change in heart rate (A), mean arterial pressure (B) and pulse pressure (C) with lateral turning in the manual-turn group ($n = 6$) and the automated-turn group ($n = 7$). Back position was compared with lateral position (left or right) in both groups. A total of 4 manual-turn and 3 automated-turn patients had an arterial catheter.

- Statistically significant, $P < .05$.
- Clinically significant, mean change $\pm 10$. 
had a statistically significant change in MAP and all but 1 had a significant change in pulse pressure in the lateral position. However, less than half of the automated-turn group had a statistically significant change in heart rate, and none of the hemodynamic changes was clinically important. Furthermore, the MAP differences were not statistically significant in the height-adjusted model. Thus, automated turning does not appear to adversely affect hemodynamic status and may be the preferred turning intervention when patients are at risk for unstable hemodynamic status.

The differences in hemodynamic responses we found between manual and automated turning may be due to the angle of turn, which was greater in the manual-turn group. On the basis of the literature, we expected to see a decrease in MAP with lateral turning. Bein et al observed an increased heart rate in the left and right positions and decreased MAP on the right side 15 minutes after a manual turn, whereas in our study, clinically important changes had abated in our study, clinically important changes had abated

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Our study differed from that of Bein et al in 4 ways. First, the mean score on the Acute Physiology and Chronic Health Evaluation II was higher in our patients (29 vs 20). Second, only 46% of our patients were receiving cardiac inotropic medications whereas all of the patients in the study by Bein et al were. Third, patients were turned to mean angles of 50º on our study and 62º in the other study. Fourth, we measured hemodynamic response to lateral turning continuously, whereas Bein et al obtained 1 measurement after patients had been in the lateral position for 15 minutes. Perhaps, in our study, turn angles were insufficiently steep to reduce venous return and cardiac output. Patients were laterally rotated to an angle of 62º in those studies16,17 in which differences between left and right positions were found. In our study, marked increases in heart rate and MAP with manual turns were reproducible and transient, suggesting that the physical turning maneuver produced an autonomic nervous system response that resolved with time in the lateral position.

All patients in our study tolerated lateral turning. The patient whose data are shown in Figure 1 (P001) was the worst-case scenario in the study sample, with the greatest magnitude of response to turning. Clinicians are apprehensive about turning patients who have dramatic responses to turning. If turning were aborted on the basis of these grounds, patients with dramatic responses could conceivably be in the back position for days, putting them at risk for a host of pathological sequelae. One patient enrolled in our study could not start the study protocol because SBP in the back position decreased to less than that specified in a rotation “stopping rule.” Of note, patients with unstable hemodynamic status, defined for our study as SBP less than 90 mm Hg in the back position in patients receiving vasopressors, were not eligible to participate in the trial. Thus, our findings do not apply to patients receiving mechanical ventilation whose hemodynamic status is unstable.

Even though our patients were randomly selected by using a scientifically valid method for generalizability,20,21 the small number of patients in the sample limits generalizability to adult patients treated with mechanical ventilation in a medical-surgical intensive care unit, particularly for the MAP and pulse pressure findings. Our findings provide an uncommon characterization of nearly continuous hemodynamic response to lateral rotation with manual and automated turning. Other investigators with comparable study objectives and populations of patients had far fewer data points than we did: 36 data points for heart rate22 and MAP with a sample size of 12. The nearly continuous characterization of hemodynamic changes increases the validity of our findings. Furthermore, the visual ensemble averages validate the statistical findings. Ensemble averaging offers advantages for characterizing such time-dependent data as heart rate, MAP, and pulse pressure; it improves precision and provides a graphical footprint to visually enhance interpretation.
Figure 2 Manual-turn responses of heart rate (A, D), mean arterial pressure (B, E), and pulse pressure (C, F) in patient P001. A, B, and C show the time series for 4 individual turns from back to left position. D, E, and F show the corresponding ensemble averages for a complete turn cycle (back to left, left to back, back to right, and right to back). Vertical lines indicate the times of the turns.
Conclusions and Implications

Lateral turning every 2 hours is a standard of care to minimize complications associated with immobility. Previous research has indicated adverse, albeit transient, hemodynamic effects with lateral turning. Clinicians are therefore often reluctant to turn patients, fearing adverse effects in patients who are already physiologically compromised.

Our findings suggest that patients receiving mechanical ventilation in a medical-surgical intensive care unit may experience changes in heart rate, MAP, and pulse pressure when manually turned to 45° or more, but clinically important changes are transient and related to the turning maneuver. No differences between left and right lateral turning should be anticipated with turn angles of 50° or less. Clinically important hemodynamic changes subside within 15 minutes after the turn; modest changes may persist for up to 45 minutes. In our patients, the magnitude of change in heart rate, MAP, and pulse pressure was tolerated clinically, and patients remained in the lateral position for the 2-hour turn period. Automated lateral turning in a specialty bed designed to turn to an angle of 40° or more appears to have no adverse hemodynamic effects and may be a safer turning method for patients whose hemodynamic status is unstable. Further research with a larger sample size is indicated to validate our findings, and future research should be conducted in patients with hemodynamic compromise to determine their ability to tolerate manual and automated lateral rotation.

ACKNOWLEDGMENTS
We thank Audrius Brazdeikis, PhD, research associate professor, University of Houston, Houston, Texas, for assistance with programming data acquisition. A special thanks to Mara Baun, RN, DNSc, FAAN, who served as member of the first author’s dissertation committee.

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SEE ALSO
For more about lateral turning, visit the Critical Care Nurse Web site, www.ccnonline.org, and read the article by Vollman, “Hemodynamic Instability: Is It Really a Barrier to Turning Critically Ill Patients?” (February 2012).

REFERENCES


To purchase electronic or print reprints, contact the American Association of Critical-Care Nurses, 101 Columbia, Aliso Viejo, CA 92656. Phone, (800) 899-1712 or (949) 362-2050 (ext 532); fax, (949) 362-2049; e-mail, reprints@aacn.org.
CNE Test  Test ID A152402: Hemodynamic Changes With Manual and Automated Lateral Turning in Patients Receiving Mechanical Ventilation

Learning objectives: 1. Identify hemodynamic changes that occur with manual repositioning. 2. Discuss hemodynamic changes that occur with continuous rotation. 3. Determine if use of manual or automatic turning is safe for medical-surgical patients receiving mechanical ventilation.

1. The dependent variables in this study include which of the following?
   a. Heart rate, mean arterial pressure (MAP), and pulse pressure
   b. Heart rate, blood pressure, and pulse rate
   c. Blood pressure, pulse oximetry, and heart rate
   d. Heart rate, cardiac rhythm, and MAP

2. Which of the following clinical characteristics of the study participants was statistically significant?
   a. Age
   b. Positive end-expiratory pressure (PEEP)
   c. Diagnosis
   d. None of the clinical characteristics proved to be statistically significant.

3. Exclusion criteria for the study included which of the following?
   a. Suspected or confirmed myocardial infarction
   b. Positive end-expiratory pressure (PEEP)
   c. Hemodynamic instability defined as systolic blood pressure < 90 mm Hg
   d. Patient receiving gastric feeding via nasogastric tube

4. Which of the following were limitations to the study identified by the researchers?
   a. The need to collect more data points
   b. Small sample size
   c. Study did not include hemodynamically stable patients
   d. Poor adherence to the turning protocol

5. A study of the back and lateral positions by Gawinski and Dracup found which of the following?
   a. Hemodynamic changes that occur with repositioning are constant.
   b. Turning from back to lateral positions increases venous return.
   c. There were no changes with hemodynamics related to position change from the back to lateral position.
   d. Hemodynamic changes that occur with repositioning are transient and return to baseline within 5 minutes.

6. Which of the following are independent variables in this study?
   a. Manual lateral turn to 45º angle or greater every 2 hours for a 2-hour time interval and continuous rotation with lateral rotation to 45º or greater
   b. Change in MAP when turned to the back position from the left or right position
   c. Decrease in MAP when turned to the left or right from the back position
   d. Heart rate, cardiac rhythm, and pulse rate

7. Which of the following was the sample size for this study?
   a. 7
   b. 10
   c. 13
   d. 45

8. Blood pressure measurement could only be captured on patients with an arterial line in situ. This data was available on which of the following percentages of participants?
   a. 54%
   b. 46%
   c. 22%
   d. 60%

9. In the automated turn group, which of the following changes were seen in MAP?
   a. Increase in MAP when turned to the left or right from the back position
   b. Increase in MAP when turned to the back position from the left or right position
   c. Decrease in MAP when turned to the left or right from the back position
   d. Decrease in MAP when turned to the back position from the left or right position

10. The patient population studied included which of the following?
    a. Hemodynamically stable burn patients requiring mechanical ventilation
    b. Hemodynamically stable trauma patients requiring mechanical ventilation
    c. Hemodynamically stable medical-surgical patients requiring mechanical ventilation
    d. Hemodynamically stable cardiovascular patients requiring mechanical ventilation

11. If a subject had missing data points, the researchers did which of the following?
    a. Removed the subject’s data from the analysis
    b. Used linear interpolation to replace the data
    c. Used ensemble averaging to replace the data
    d. Duplicated the previous data point into the missing data slot

12. Outlier and missing data represented which of the following percentages of the data collection?
    a. < 1%
    b. 35%
    c. 46%
    d. 3.4%

Test ID: A152402 Contact hours: 1.0  Pharma: 0.0  Form expires: March 1, 2018. Test Answers: Mark only one box for your answer to each question.

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A major postoperative problem for infants undergoing cardiopulmonary bypass surgery is hypothermia.

**Objective** To determine the safety and feasibility of a newly designed Heat Retention Head Wrap on infants during the rewarming period of cardiopulmonary bypass surgery.

**Methods** A sample of 10 infants was recruited into this descriptive pilot study. The health care providers completed ease-of-use questionnaires to describe the feasibility of the head wrap. Interval body temperatures were recorded to characterize temperature progression from onset of rewarming to arrival in the cardiac intensive care unit (ICU) and were compared with the temperature progression of a similar group of non-participants. Adverse events were recorded on the basis of perioperative body temperatures and skin assessments.

**Results** The head wrap was easily applied to the infant’s head and was removed without difficulty. A steady increase in median body temperature from (1) the onset of rewarming (28°C), to (2) removal of bypass cannulas (28.9°C), to (3) removal of the rectal temperature probe before transfer from the operating room to the cardiac ICU (34.5°C), and (4) upon arrival in the cardiac ICU (36.0°C) was observed. No skin lesions or temperature-related adverse events were observed.

**Conclusions** The newly designed Heat Retention Head Wrap was associated with a gradual normalization of temperature during rewarming and did not interfere with routine perioperative care of infants undergoing bypass surgery. This pilot study indicates that the head wrap is both safe and feasible for use in infants undergoing cardiopulmonary bypass surgery.

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Hypothermia can be a major postoperative problem for infants undergoing cardiopulmonary bypass (CPB) surgery. According to the World Health Organization, body temperature ranging from 36°C to 36.5°C is mild hypothermia, 32°C to 36°C is moderate hypothermia, and less than 32°C is severe hypothermia. During CPB, patients are cooled to decrease metabolism and protect the myocardium and brain from injury. When the repair is completed, the patient is rewarmed as the temperature of blood in the bypass pump is gradually increased. However, after separation from the CPB pump, infants consistently experience a temperature decrease of 2°C to 5°C.

Postoperative hypothermia can result in impaired clotting, acid-base disturbances, and cardiac arrhythmias. These disturbances are associated with a 2-fold to 5-fold increase in oxygen consumption, increased metabolic demand, increased carbon dioxide production, cutaneous vasoconstriction, and lactic acid production. Thus the postoperative return to normothermia is essential to prevent an increased metabolic demand, energy expenditure, and impaired oxygen delivery.

A meta-analysis of studies conducted in the past 20 years reports that older children and adult patients whose temperatures have been maintained at normal levels during the intraoperative period experience fewer adverse outcomes and lower hospital costs. These studies show that hypothermia, averaging 1.5°C less than normal, resulted in cumulative adverse outcomes adding between $2500 and $7000 per surgical hospital stay.

When heat is lost to the environment, it indirectly affects mortality rates, growth, and energy maintenance for newborn infants. Heat dissipates more quickly from the head than from any other body surface. As much as 60% of an infant’s body heat can dissipate through an uncovered head, leaving patients at high risk for complications associated with hypothermia. Adverse effects from inadvertent hypothermia include myocardial ischemia, impaired coagulation, prolonged healing, surgical wound infections, and decreased postoperative comfort. Despite these concerns, research examining the phenomenon of perioperative hypothermia, rewarming, and the use of head coverings is limited.

In a randomized controlled trial, investigators hypothesized that wearing a nonhazardous head covering would sharply decrease the risk of hypothermia for elders during major surgery. The head covering resulted in significant heat conservation, yielding positive outcomes for patients. In a study of 14 healthy infants 14 to 68 days old, significant increases in mean temperatures of the abdomen, forehead, and extremity were found when infants’ heads were covered with a head wrap made of thinsulate. Others found the use of a thermal ceiling in rooms in the intensive care unit (ICU) to be beneficial. Approximately 15 minutes after arrival in the ICU after cardiac surgery, shivering, oxygen uptake, carbon dioxide production, hypertension, and vasoconstriction were significantly reduced for adult patients exposed to the thermal ceiling.

Participation in the rewarming of patients during CPB surgery is a core nursing intervention. According to recommendations for perioperative registered nurses, the patient should be at or returning to normothermia at the conclusion of the immediate postoperative period. Current rewarming techniques include the administration of heated, humidified gases, warmed blood via the CPB machine, a water-heated mattress, forced air patient warming system (Bair Hugger, 3M Company), warm intravenous fluids, and warm irrigation solutions. These standards do not include a head covering for rewarming after CPB, and heat deficits can remain after CPB despite these interventions.

Hypothermia can be a major problem for infants after cardiopulmonary bypass surgery.

About the Authors
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A new head covering made of Mylar (biaxial-oriented polyethylene terephthalate), called the Heat Retention Head Wrap, was designed for infants to facilitate warming during the rewarming phase of CPB. The purpose of this descriptive pilot study was to determine safety and feasibility of the Heat Retention Head Wrap on a small sample of infants during the rewarming period following CPB. In addition, in this study, the interval body temperatures of the pilot sample were retrospectively compared with temperatures for a sample of nonparticipants cared for by the same clinical staff during the same time period.

The specific aims of this study were to

1. Describe the feasibility of placing a Heat Retention Head Wrap on the infant’s head from the time the rewarming process begins to the time the baby arrived in the cardiac ICU after transfer from the operating room.
2. Characterize the temperature progression from (a) the onset of rewarming, to (b) removal of bypass cannulas, to (c) removal of the rectal temperature probe immediately before transfer from the operating room to the cardiac ICU, and (d) upon arrival in the cardiac ICU.
3. Compare the rectal body temperatures of patients in this study who had the head wrap applied during the rewarming phase of surgery with temperatures in a sample of patients who did not have the head wrap applied.
4. Identify and describe adverse events observed with use of the Heat Retention Head Wrap.

Methods

Ethics

The Boston Children’s Hospital Committee for Clinical Investigation approved this study. Infant participants and their families did not receive compensation for participating. A Data and Safety Monitoring Board (DSMB) consisted of a cardiac nurse/skin specialist, cardiac surgeon, cardiac anesthesiologist, and an environmental/biomedical specialist. The DSMB reviewed all untoward or adverse events that occurred during the study period and was responsible for the final classification of event causation and seriousness.

Study Device

The Heat Retention Head Wrap was lined with Mylar. This material has been demonstrated to be effective for rewarming in several first aid and rescue situations. The head wrap was reinforced with a cotton outer lining to give the device more structure for application. The device was produced to accommodate differing head circumferences as follows: (1) 33-37 cm, (2) >37-40 cm, (3) >40-44 cm, and (4) >44-48 cm.

The device was 5-sided and laid on the operating room table beneath the infant’s head, allowing it to be wrapped around the head “turban” style with 2 resealable Velcro (hook and loop fastener) tabs to secure it in place (see Figure). This design allowed the wrap to be in an open or closed position, enabling easy access to the head as needed during or after surgery; it could be removed or reapplied easily as the infant’s body temperature fluctuated.

To meet regulatory requirements, Heat Retention Head Wraps were stored in a sealed plastic container in the operating room to maintain cleanliness, and a new head wrap was assigned to each study infant (1 time use). They were sequentially numbered according to the study ID numbers as they were assigned to each study patient. After use, the wraps were maintained in a separate sealed plastic container.

Sample, Setting, and Enrollment

The study team enrolled a convenience sample of 10 infants undergoing CPB surgery who met inclusion criteria (Table 1). Our sample came from a single, large 395-bed tertiary care children’s hospital with more than 17,000 admissions where care is provided for more than 800 patients undergoing CPB per year. The cardiac surgery scheduling office identified potential study participants. Signed informed consent was obtained from parents who agreed to participate. Every effort was made to include infants from non-English-speaking families so long as the parents could successfully communicate with...


Table 1

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tr>
<td>&gt; 37 weeks corrected gestational age undergoing CPB</td>
<td>Have a known or previously diagnosed neurological trauma, malignant hyperthermia, stroke,</td>
</tr>
<tr>
<td>age undergoing CPB</td>
<td>seizure, venticuloperitoneal shunt, evidence of scalp lesions, or other known comorbid condition</td>
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<tr>
<td>Weighs ≥ 3 and ≤ 10 kg</td>
<td>Have hair braided close to the scalp</td>
</tr>
<tr>
<td>Cooled to 24ºC-30ºC</td>
<td>Infants with known allergy or sensitivity to polyethylene terephthalate (known as Mylar)</td>
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<tr>
<td>Head circumference 33-48 cm</td>
<td></td>
</tr>
<tr>
<td>Scalp free of skin lesions such as reddened areas, ulcers, abrasions, burns, and hemangiomas</td>
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The wrap covered the infant’s ears, top of the forehead, and occiput, leaving the face exposed.

the research team using all available resources (interpreter services).

For the secondary aim, we retrospectively collected data on 27 nonparticipant infants undergoing CPB who had been cared for during the same time period as our study participants.

**Study Procedures**

After the informed consent process, study personnel obtained the infant’s head circumference and selected the appropriately sized Heat Retention Head Wrap. Before the operative procedure, but after all intravenous catheters were in place and when the infant was prepared for final positioning, the anesthesiologist (with assistance of the study staff) placed the head wrap under the head of the infant. After the operative procedure, when the attending surgeon indicated that it was time to re-warm the infant, the research team applied the wrap to the infant’s head (covering ears, top of the forehead, and occiput, leaving the face exposed). The head wrap was opened and closed as needed during the rewarming phase at the direction of the surgeon. If the baby became hyperthermic (defined as a body temperature of 37ºC or higher), the surgeon or anesthesiologist could ask the research team to completely remove the head wrap from underneath the infant to prevent adverse events associated with hyperthermia. After arrival in the cardiac ICU, the infant’s head was unwrapped and the research assistant or research nurse removed the wrap from underneath the infant’s head.

**Data Collection**

Medical history, infant weight, head circumference, and outcome measures were recorded on the demographic data collection tool. Data collection in the operating room was performed by a trained research nurse or research assistant who documented device use and patient temperatures (rectal and nasopharyngeal) at the predetermined time points during rewarming, including opening, closing and/or the removal of the device along with corresponding temperatures, if indicated, above and beyond the predetermined time points. Skin assessments were performed by nurses trained in skin assessment. Skin assessments were made before application of the head wrap, upon removal of the head wrap, and then at 6-hour increments 4 times, 12-hour increments twice, and at a 24-hour increment once (72 hours total). A member of the infant’s health care team that used the device during the procedure completed the ease-of-use tool by using a Likert rating scale. Data collection tools for each participant were maintained in separate folders bearing the study participants’ unique identification numbers.

For the secondary aim, the interval body temperatures of study participants were retrospectively compared with a similar sample of nonparticipants cared for by the same clinical staff during the same time period and using the same rewarming methods (ie, heated, humidified gases, warmed blood via the CPB machine, a water heated mattress, Bair Hugger forced air patient warming system, warm intravenous fluids, and warm irrigation solutions). Patients’ body temperatures were also obtained by using same methods in the operating room (nasal pharyngeal temperatures and rectal temperatures). Only rectal temperatures were recorded in the cardiac ICU for this sample. The comparison group was carefully selected to include patients with ages, weights, diagnoses, and cool-down temperatures similar to those of the participants in the pilot study.

**Staff Education**

Before the start of the study, the principal investigator trained data collection personnel on all aspects of the study protocol, assessment of patients, temperature maintenance parameters, and use of the data collection tools. Staff applying the Heat Retention Head Wrap received instruction on its application. They were informed that the device should be applied to the infant’s head, but that they should be able to fit 1 index finger between the wrap and the infant’s head so that it was fitted, but not tight.

At our institution, bedside nurses from the cardiac ICU and the cardiac step-down unit receive routine training by certified skin assessment nurses on how to conduct skin assessments. For this study, bedside nurses also received instruction on performing the scalp skin assessments (ie, examining scalp for skin

The wrap covered the infant’s ears, top of the forehead, and occiput, leaving the face exposed.
lesion, redness/erythema, rash, pressure sore or ulcer, lesion, burn) and on completing the skin assessment data collection tools via in-service training sessions held by the study investigators. The study staff maintained close contact with the nursing staff for the 72 hours following surgery to answer questions and to ensure that all data collection tools were completed in real time.

**Data Analysis**

Descriptive statistics (medians, frequencies) were used to describe the study population and to characterize the temperature progression. Characteristics between groups (pilot sample vs comparison group) and comparisons of postsurgery temperatures and temperature change between groups was accomplished by using the Mann-Whitney U test. Narrative data from the DSMB report were used to describe findings of reported events.

**Results**

The study sample included 10 infants of various sexes, ages, weights, and cardiac defects (Table 2). Health care providers were asked to complete a simple 5-question survey and rate the study device by using a Likert scale (rating scale: agree very strongly, agree strongly, agree, disagree, disagree strongly, and disagree very strongly). The health care providers reported that the Heat Retention Head Wrap was easily applied to the infant’s head (agree to agree very strongly), did not interfere with other medical devices or procedures (agree to agree very strongly) and was removed without difficulty upon arrival in the cardiac ICU (agree to agree very strongly; Table 3).

Median body temperature of participants steadily increased from (1) the onset of rewarming (28°C), to (2) removal of bypass cannulas (28.9°C), to (3) removal of the rectal temperature probe before transfer from the operating room to the cardiac ICU (34.5°C), and (4) upon arrival in the cardiac ICU (36.0°C; Table 4).

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**Table 2**

<table>
<thead>
<tr>
<th>Characteristics of the 10 patients in the sample</th>
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<tbody>
<tr>
<td>Characteristic</td>
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<tr>
<td>Sex, No. (%) of patients</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Race, No. (%) of patients</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Age at surgery, median (range), weeks</td>
</tr>
<tr>
<td>Weight at time of surgery, median (range), kg</td>
</tr>
<tr>
<td>Primary diagnoses 1 and 2, No. (%) of patients</td>
</tr>
<tr>
<td>Tetralogy of Fallot</td>
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<tr>
<td>Complete atrophic ventricular canal defect</td>
</tr>
<tr>
<td>Trisomy 21 and complete atrioventricular canal defect</td>
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<tr>
<td>Ventricular septal perforation and atrial septal defect</td>
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<tr>
<td>Ventricular septal defect</td>
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<tr>
<td>Ventricular septal defect and hydrocephaly</td>
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<tr>
<td>Hypoplastic right ventricle and tricuspid valve</td>
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**Table 3**

<table>
<thead>
<tr>
<th>Clinicians’ responses to ease-of-use tool</th>
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<tbody>
<tr>
<td>Heat Retention Head Wrap (N = 10)</td>
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<tr>
<td></td>
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<tr>
<td>Agree very strongly</td>
</tr>
<tr>
<td>Was easy to apply</td>
</tr>
<tr>
<td>Did not interfere with other medical devices</td>
</tr>
<tr>
<td>Did not interfere with any medical procedures</td>
</tr>
<tr>
<td>Was easy to remove</td>
</tr>
<tr>
<td>Comments</td>
</tr>
</tbody>
</table>

During the study, 2 events were reported to the DSMB by the investigators; neither was deemed to be an adverse event after review. The first was a reddened/irritated area on a participant’s occiput 6 hours after the procedure. This event of skin irritation was adjudicated by the DSMB and was deemed unrelated to device use, but rather a deviation from routine postoperative care (that required the use of a gel pillow). The second event occurred when the anesthesiologist ordered acetaminophen for a participant during the procedure because of an increase in body temperature (36.9ºC). The DSMB board deemed this to be a variation in practice by the anesthesiologist rather than a device-related adverse event.

No significant differences were detected in the retrospective comparisons between the pilot sample and comparison group (using an α of .05) for patients’ characteristics and interval body temperatures (Tables 5 and 6).
Discussion

The innovative use of the Heat Retention Head Wrap in a cohort of pediatric cardiac surgical patients was safe and feasible. Although the use of Mylar material and head coverings to promote heat retention are well documented, this is the first time a head wrap lined with Mylar has been used on infants undergoing CPB surgery. Several investigators have examined the use of head coverings in newborn infants following delivery of infants and in the newborn nursery. Also a variety of different materials have been used for head coverings in the newborn population: thinsulate hats, woolen hats lined with gangee (soft cotton), tubular stockinet hats, and clear plastic polyethylene caps.

In their research on the transparent polyethylene cap and bag, Besch et al12 studied 85 infants under various conditions. Results indicated that infants under radiant heaters who were swaddled in plastic bags with their heads covered with extensions of the same material had appreciably less heat loss than infants in any other group. Trevisanuto et al13 conducted a prospective, randomized, controlled trial in very preterm infants to evaluate if polyethylene caps prevent heat loss after delivery compared with a polyethylene occlusive wrap and conventional drying followed by the application of a warmed towel wrap. The polyethylene cap and polyethylene occlusive wrap were found superior at preventing heat loss compared with conventional drying and wrapping. Sennott Greer14 conducted a study to compare heat loss using 3 head treatment methods in conjunction with a radiant warmer: no head covering, stockinet hat, and a fabric-insulated bonnet. The stockinet was significantly less effective in preventing heat loss compared with the bonnet and no head covering methods. Chaput de Saintonge et al15 studied the efficacy of a woolen hat lined with a single layer of gangee versus stockinette hats in maintaining rectal temperatures of infants during the first 30 minutes after birth. They concluded that gangee-lined hats minimize heat loss in situations where heat loss is a concern.

We tested a soft muslin cotton head wrap lined with Mylar on a small sample of infants undergoing CPB surgery. The turban style design with Velcro tabs allowed the infant’s head to lie on the open wrap at the beginning of surgery, ensuring access to the infant during the surgical procedure. Once the rewarming phase began, the wrap was easily applied and removed at any given time without disruption of the surgical field. In addition to the turbanlike design, the materials used in the construction of the wrap were advantageous. The outside cotton lining made the wrap more durable and less prone to rips and tears. Additionally, the Mylar lining was developed by the National Aeronautics and Space Administration in the 1960s and has passive heating properties. It is a thin, flexible and thermal-reflective material that reflects heat, thereby assisting the body in conserving heat to stay warm. Blankets made of this material have been developed to help

Table 4
Temperature progression

<table>
<thead>
<tr>
<th>Timing of measurement</th>
<th>Temperature, median (range), °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cool-down temperature</td>
<td>28.0 (25.0-32.0)</td>
</tr>
<tr>
<td>Temperature of room during rewarming phase</td>
<td>18.0 (11.0-24.0)</td>
</tr>
<tr>
<td>Probe temperature when rewarming begins Nasopharyngeal</td>
<td>28.9 (25.3-31.6)</td>
</tr>
<tr>
<td>Rectal</td>
<td>28.5 (24.8-32.1)</td>
</tr>
<tr>
<td>Probe temperature when bypass cannulas removed Nasopharyngeal</td>
<td>34.5 (24.7-35.4)</td>
</tr>
<tr>
<td>Rectal</td>
<td>35.7 (34.1-37.0)</td>
</tr>
<tr>
<td>Last probe temperature in operating room when rectal probe removed Nasopharyngeal</td>
<td>35.9 (35.2-36.9)</td>
</tr>
<tr>
<td>Rectal</td>
<td>35.7 (34.9-37.4)</td>
</tr>
<tr>
<td>First temperatures upon admission to cardiac intensive care unit Nasopharyngeal</td>
<td>36.0 (34.6-36.9)</td>
</tr>
<tr>
<td>Rectal</td>
<td>36.1 (34.3-37.6)</td>
</tr>
</tbody>
</table>

Table 5
Comparison of patients’ characteristics: pilot group vs comparison group

<table>
<thead>
<tr>
<th>Character</th>
<th>No. of patients</th>
<th>Median</th>
<th>Pilot</th>
<th>Comparison</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, months</td>
<td>10</td>
<td>10</td>
<td></td>
<td>27</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Weight at time of surgery, kg</td>
<td>10</td>
<td>10</td>
<td>27</td>
<td>27</td>
<td>.85</td>
</tr>
<tr>
<td>Cool-down temperature, °C</td>
<td>10</td>
<td>10</td>
<td>27</td>
<td>27</td>
<td>.50</td>
</tr>
<tr>
<td>Transfer duration, min</td>
<td>9</td>
<td>9</td>
<td>23</td>
<td>23</td>
<td>.58</td>
</tr>
</tbody>
</table>

Table 6
Body temperatures: pilot group versus comparison group

<table>
<thead>
<tr>
<th>Outcome (rectal temperature)</th>
<th>No. of patients</th>
<th>Median</th>
<th>Pilot</th>
<th>Comparison</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last measurement in operating room, °C</td>
<td>10</td>
<td>10</td>
<td>26</td>
<td>26</td>
<td>.11</td>
</tr>
<tr>
<td>First measurement in cardiac intensive care unit, °C</td>
<td>10</td>
<td>10</td>
<td>27</td>
<td>27</td>
<td>.53</td>
</tr>
<tr>
<td>Temperature change during transfer, °C</td>
<td>10</td>
<td>10</td>
<td>26</td>
<td>26</td>
<td>.21</td>
</tr>
</tbody>
</table>
people stay warm, particularly in first-aid situations. The blanket forms a barrier between the user and the surrounding air, preventing moisture from escaping and carrying heat away. When someone is wrapped in a Mylar blanket, his own reflected infrared heat is reflected back toward the body, preventing or counteracting hypothermia.

In this study, the Heat Retention Head Wrap was applied to the heads of a small sample of infants undergoing CPB surgery. In addition to being deemed safe for use with this fragile population of patients, the head wrap was easy to apply and remove, and it did not interfere with the surgical procedure. We also observed steady increases in infants’ body temperatures over time, and none of the participants demonstrated heat loss upon arrival in the cardiac ICU. Additionally, we noted small increases in median body temperatures for the last temperature measured in the operating room (0.5°C) and the first temperature measured in the cardiac ICU (0.2°C) when we compared the pilot intervention sample against a similar group of infants. Although these differences were not statistically significant, they are clinically relevant to the goal of rewarming these infants.

This study had a number of limitations. First, because a variety of clinicians are responsible for the rewarming of CBP patients, we could not account for (1) practice differences among the nurses and anesthesiologists, (2) room temperature during rewarming, (3) administration of heated, humidified gases, (4) CPB machine regulation, (5) regulation of forced-air patient warming system (Bair Hugger), (6) warming of intravenous fluids, and (7) temperature of irrigation solutions in the operating room. These procedures are unregulated, and adjustments are left to the discretion of the experienced health care provider. Nevertheless, the clinicians caring for the study patients did not report any unusual changes in temperature. Second, our comparison group was retrospectively identified, thus we cannot be certain that there were no significant differences in patients’ characteristics using our limited inclusion criteria. Furthermore, although time to normalization of temperature did not differ between the 2 groups, a different result might have been found if collection of data for the comparison group had been prospective.

Conclusion

In this small pilot study, the Heat Retention Head Wrap was safe and feasible for use in infants during the rewarming phase of CPB surgery. Although additional investigations are needed to determine the effectiveness of the head wrap, this device demonstrates potential use for all patients (newborns, infants, children, and adults) during critical care procedures, patient transport, and first-aid/emergency situations.

ACKNOWLEDGMENTS

The investigators thank the departments of perioperative nursing, cardiac surgery, and cardiac anesthesia at Boston Children’s Hospital, as well as the Technology and Innovation Development Office and the Academy for Clinical Scholarship and Innovation in Pediatric Nursing. In addition, we acknowledge Dr Sandra Mott and Hillary Kuzdeba for their assistance in editing this document.

FINANCIAL DISCLOSURES

None reported.

eLetters

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A COMPUTER-BASED EDUCATION INTERVENTION TO ENHANCE SURROGATES’ INFORMED CONSENT FOR GENOMICS RESEARCH

By Ann K. Shelton, RN, PhD, Bradley D. Freeman, MD, Anne F. Fish, RN, PhD, Jean A. Bachman, RN, DSN, and Lloyd I. Richardson, PhD

**Background** Many research studies conducted today in critical care have a genomics component. Patients’ surrogates asked to authorize participation in genomics research for a loved one in the intensive care unit may not be prepared to make informed decisions about a patient’s participation in the research.

**Objectives** To examine the effectiveness of a new, computer-based education module on surrogates’ understanding of the process of informed consent for genomics research.

**Methods** A pilot study was conducted with visitors in the waiting rooms of 2 intensive care units in a Midwestern tertiary care medical center. Visitors were randomly assigned to the experimental (education module plus a sample genomics consent form; n = 65) or the control (sample genomics consent form only; n = 69) group. Participants later completed a test on informed genomics consent.

**Results** Understanding the process of informed consent was greater ($P = .001$) in the experimental group than in the control group. Specifically, compared with the control group, the experimental group had a greater understanding of 8 of 13 elements of informed consent: intended benefits of research ($P = .02$), definition of surrogate consentor ($P = .001$), withdrawal from the study ($P = .001$), explanation of risk ($P = .002$), purpose of the institutional review board ($P = .001$), definition of substituted judgment ($P = .03$), compensation for harm ($P = .001$), and alternative treatments ($P = .004$).

**Conclusions** Computer-based education modules may be an important addition to conventional approaches for obtaining informed consent in the intensive care unit. Preparing patients’ family members who may consider serving as surrogate consenters is critical to facilitating genomics research in critical care. (American Journal of Critical Care. 2015;24:148-155)
Patients in the intensive care unit (ICU) often are unable to give informed consent because of cognitive or physical impairments due to illness, trauma, or sedation. In such circumstances, a patient’s family member or proxy is asked to serve as a surrogate and provide informed consent on behalf of the patient. With increasing frequency, surrogates of ICU patients are being asked to provide consent for crucial genomics research. This type of research has an immediate aspect; any delay in consent for enrollment in the study may result in a missed opportunity to collect transient and perhaps vital clinical data. Furthermore, genomics research is complex and has inherent ethical, legal, and social implications. Without a basic understanding of the process of informed consent related to genomics research, surrogates may be poorly prepared to consent for their loved ones to participate in the studies.

The ICU environment is challenging for a patient’s surrogates because of the immediate need to react to changes in the patient’s condition. Because of these multiple stressors, surrogates giving consent in the ICU may benefit from a focused computer-based educational intervention as an addition to conventional consent forms. However, no studies have specifically examined the effectiveness of such interventions on surrogates’ understanding of informed consent for genomics research in the ICU. We found 9 high-quality studies in which investigators examined a computer-based educational intervention and the outcome (understanding of informed consent), but the researchers focused on procedures, a medical treatment, or non-ICU research and rarely used a surrogate. Computer-based educational interventions have been effective in enhancing understanding of the process of informed consent in procedural studies (cardiac catheterization, colonoscopy, endoscopy with parent as surrogate, and gastric banding surgery) and in a study on medical treatments (chemotherapy). Additionally, 4 studies focused on non-ICU research: 1 involved a cancer clinical trial, 1 had a sample composed of schizophrenic patients, 1 had patients’ parents as surrogates in high- and low-risk clinical trials, and 1 was a genetic tissue repository study. Results were mixed. The computer-based educational interventions used in the studies included video, CD-ROM, and slide presentations, yet no single approach has been more effective than another.

The purpose of this pilot study was to examine the effectiveness of a new, computer-based education module on the understanding of patients’ surrogates about the process of informed consent for genomics research in the ICU. The framework of the study was the Code of Federal Regulations and the principles of respect for persons, beneficence, and justice contained in the Belmont Report. Specifically, within the principle of respect for persons, we focused on the need to provide full disclosure of information to surrogates who were called on to give informed consent by using substituted judgment, and to make sure the surrogates understood the information disclosed. The term substituted judgment means that the surrogate chooses whether or not to allow a loved one to be entered into a research study on the basis of what the loved one would have wanted. The premise is that giving surrogates information is beneficial and that subsequently giving them a test on the information will clarify how much of the disclosed information they actually understood. The purpose of this pilot study was to examine the effectiveness of a new, computer-based education module on the understanding of patients’ surrogates about the process of informed consent for genomics research in the ICU. The framework of the study was the Code of Federal Regulations and the principles of respect for persons, beneficence, and justice contained in the Belmont Report. Specifically, within the principle of respect for persons, we focused on the need to provide full disclosure of information to surrogates who were called on to give informed consent by using substituted judgment, and to make sure the surrogates understood the information disclosed.

Methods
Design, Setting, and Sample
An experimental, posttest-only design with random assignment to group was used. The experimental group completed the computer-based education module, and the control group completed the usual consent form.
module and received a sample genomics consent form; the control group received the sample genomics consent form only. The setting was the waiting rooms of 2 ICUs (surgical-trauma and cardiac) in a Midwestern tertiary care medical center.

The participants in the study were adult visitors to the ICU waiting rooms. All of the visitors were considered potential surrogate consenters in the future and therefore were the surrogates for the purpose of this study. Persons were eligible for the study if they were visitors to the ICU waiting rooms, were 18 years or older, and were willing to participate in the study. Visitors were approached unless they appeared to be in crisis or actively grieving. A power analysis indicated that a total of 64 participants was needed per group to detect a 0.50 effect with a power of 0.80 and \( \alpha = .05 \).

During a 4-month period, 827 visitors were approached for the study; of these, 137 agreed to participate in the study. The Figure presents reasons for nonenrollment in the study. The sample included only those individuals who felt comfortable participating at that time.

**Computer-Based Education Module**

The education module was presented on a laptop computer and included a series of 36 slides. It was developed by a nurse researcher and was based on the Code of Federal Regulations and on related publications about the ethical, legal, and social implications for genomics research. An expert panel of 15 ICU physicians approved the content of the slides. The panel included 2 experts who were conducting research on informed consent. The information was written at or below the sixth grade level of reading comprehension. The brightly colored slides were designed to include persons of multicultural backgrounds. In addition, 4 slides had animated material to enhance interest.

The module included an introduction, educational content, and a summary. The educational content included information about the 13 essential elements of informed consent\(^{28,29}\) (Table 1), surrogate consent\(^{2,4}\) research in general,\(^{24,25}\) and genomics research.\(^{8,12}\) The slides specific to surrogate consent included information on the definition of a surrogate,\(^{1}\) definition of substituted judgment,\(^{31,33}\) and requirement that the researcher must provide all of the information that the surrogate needs to make an informed decision about participation in the research.\(^{1}\) The slides on research in general included information about research in the ICU, reasons for participating in research, role of the institutional review board, and who pays for research.\(^{14}\) The slides on genomics research included information on the definition of genomics,\(^{7}\) interactions between genes

![Figure](https://example.com/figure.png)

**Figure** Reasons for nonenrollment in the study given by visitors in the waiting rooms of the intensive care units. Top, Dealing with issues of uncertainty about their loved one. Bottom, Dealing with the environment in the waiting room. The percentages are greater than 100 because visitors had more than 1 reason for declining to participate.
and the environment, meaning and implications of DNA, and ownership of tissue specimens. Finally, 1 slide summarized the elements of informed consent. The module was pretested with 7 adults.

**Sample Genomics Consent Form**

The sample genomics consent form was a 7-page form printed on white paper. The information was written at or below the sixth grade level of reading comprehension. The consent form had been approved by the institutional review board, was about ventilator-associated pneumonia in the ICU, and had been used in a recent genomics study at the research site. In content detail, overall structure, and format, it was representative of a typical consent form for genomics research used at the study site. This consent form was used as a sample only, and participants were clearly instructed that their loved ones were not being recruited for a study on ventilator-associated pneumonia.

**Instrument**

The posttest instrument was a 13-item instrument with a 5-point Likert-type response format (1 = definitely false and 5 = definitely true). The posttest was used to measure surrogates’ understanding of the process of informed consent. Items on the instrument reflected essential elements of informed consent that the literature had indicated as necessary for surrogates to understand (Table 1). Higher scores indicated greater understanding of the process of informed consent. Content validity was established through the use of a content analysis table and examination by a panel of experts who evaluated the posttest according to the Code of Federal Regulations guidelines and publications on informed consent. The Cronbach $\alpha$ of the posttest was 0.73.

**Data Collection Procedures**

The study, approved by the appropriate institutional review board, was carried out in accordance with the ethical standards set forth in the Helsinki Declaration of 1975 and was conducted by 1 nurse researcher. The visitors were studied individually; visitors who were together with other family members were asked not to share information about the study. A private consultation room within the ICU waiting room was used to ensure a quiet space for the study. After entering the study room, visitors were randomly assigned to a group by using computer-generated random numbers. Participants read an information sheet written at or below the sixth grade level of reading comprehension, which explained the purpose of the study. Any questions participants had were answered. Participants in the experimental group were shown how to advance the slides on the laptop. The experimental group completed the computer-based education module and then read the sample genomics consent form. The control group read the sample genomics consent form only. Both groups completed the posttest, the demographic data form. A posttest key was given to all participants to check their answers. After each participant completed the posttest, the researcher again solicited and answered questions. Additionally, the researcher provided participants contact information in case they had further questions. Visits did not exceed 30 minutes. Visitors received no remuneration for their participation.

**Data Analysis**

Descriptive statistics, $\chi^2$ analysis, the Fisher exact test, and independent $t$ tests were used to summarize demographic data. According to the self-reports of the participants’ relationship to the ICU patients, the loved one was a spouse, fiancée, significant other, parent, sibling, child, friend, or other. Analysis of variance was used to analyze overall total posttest scores. Multivariate analysis of variance was used to determine between-group differences among the items. Top-box statistics were used to describe the percentage of participants who chose the most correct answers (probably true or definitely true) for each posttest item.

---

**Table 1**

<table>
<thead>
<tr>
<th>Essential elements of informed consent$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Intended benefit for future patients</td>
</tr>
<tr>
<td>2. Purpose of surrogate consenting</td>
</tr>
<tr>
<td>3. Study withdrawal</td>
</tr>
<tr>
<td>4. Purpose and length of the study</td>
</tr>
<tr>
<td>5. Overall research risks</td>
</tr>
<tr>
<td>6. Purpose of the institutional review board</td>
</tr>
<tr>
<td>7. Need for and purpose of researcher’s contact information</td>
</tr>
<tr>
<td>8. Sufficient information to make an informed decision</td>
</tr>
<tr>
<td>9. The voluntary nature of research</td>
</tr>
<tr>
<td>10. Substituted judgment</td>
</tr>
<tr>
<td>11. Confidentiality of information</td>
</tr>
<tr>
<td>12. Compensation for harm</td>
</tr>
<tr>
<td>13. Alternative treatment</td>
</tr>
</tbody>
</table>

$^a$ Based on the Code of Federal Regulations, the Belmont Report, and other published material.
Table 2
Demographic characteristics according to group

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. (%) of participants</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Experimental (n = 65)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control (n = 69)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>20 (31)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>45 (69)</td>
<td>.50</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>15 (23)</td>
<td>.76</td>
</tr>
<tr>
<td>White</td>
<td>50 (77)</td>
<td>.63</td>
</tr>
<tr>
<td>Hispanic</td>
<td>0 (0)</td>
<td>.68</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>2 (3)</td>
<td></td>
</tr>
<tr>
<td>High school graduate</td>
<td>15 (23)</td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>23 (35)</td>
<td></td>
</tr>
<tr>
<td>College graduate</td>
<td>22 (34)</td>
<td></td>
</tr>
<tr>
<td>Postgraduate college</td>
<td>3 (5)</td>
<td></td>
</tr>
<tr>
<td>Experience participating in a previous research project</td>
<td>5 (8)</td>
<td>.68</td>
</tr>
<tr>
<td>Relationship to patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spouse</td>
<td>10 (15)</td>
<td></td>
</tr>
<tr>
<td>Fiancée</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Significant other</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>Parent</td>
<td>13 (20)</td>
<td></td>
</tr>
<tr>
<td>Sibling</td>
<td>5 (8)</td>
<td></td>
</tr>
<tr>
<td>Child</td>
<td>12 (18)</td>
<td></td>
</tr>
<tr>
<td>Friend</td>
<td>2 (3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>22 (34)</td>
<td></td>
</tr>
</tbody>
</table>

*Because of rounding, not all percentages total 100.
*Because of low numbers in the relationship categories, no statistical tests were performed.

Results

Characteristics of the Sample

Of the 137 participants, 3 were called away during the session and did not complete the study, leaving a total of 134 visitors in the sample. A total of 65 participants in the experimental group and 69 in the control group completed the study. Participants were 19 to 82 years. The mean age was 49.4 (SD, 15.35) years for the experimental group and 45 (SD, 15.53) years for the control group. Demographic variables did not differ significantly between the 2 groups (Table 2).

Effectiveness of the Education Module

Overall, the experimental group had a greater (P = .001) understanding of the process of informed consent than did the control group. Age, sex, race, education, and previous experience participating in a research project did not significantly influence this finding.

Furthermore, according to the top-box statistic, the percentage of participants who picked the most correct responses (probably true and definitely true) was higher in the experimental than in the control group (Table 3). Specifically, compared with the control group, the experimental group had greater understanding of 8 of 13 elements of informed consent: intended benefits of research (P = .02), definition of surrogate consent (P = .001), study withdrawal (P = .001), explanation of risk (P = .002), purpose of the institutional review board (P = .001), definition of substituted judgment (P = .03), compensation for harm (P = .001), and alternative treatments (P = .004).

The 2 groups did not differ significantly for 4 posttest items: the right to know the purpose and duration of the study, the provision of researcher contact information in the event of questions, the voluntary nature of the research, and the confidentiality of information (Table 3). This finding indicates that, if the sample genomics consent form fully covered these items, additional information on these topics provided in the computer-based education module did not significantly improve posttest scores.

The final item that did not differ significantly between the 2 groups was the following: the researcher must give all information needed to make an informed decision about research (Table 3). Information about this item was explicitly stated in words in the computer-based education module but was not addressed in the sample genomics consent form. Both groups of participants had high mean scores on this item, indicating that those in the control group might have had this information as general knowledge or that the item sounded true, so the scores were high.

Discussion

Our study indicated that the computer-based education module was effective in improving surrogates’ understanding of the process of informed consent for genomics research in the ICU. Our findings are in general agreement with those of Bickmore et al., who used a computer-based education module and a sample research consent form on genetics research. Their study and ours differ, however: the study by Bickmore et al had a smaller sample size, was not conducted in an ICU, and did not include use of surrogates.

Care should be taken when approaching possible surrogates in the ICU waiting room for the purpose of obtaining informed consent. Although research participation is important to the researcher, a request to participate in a study may be perceived by surrogates as another demand on their time. An important premise emerged from our study: A balance must exist between the mandate to conduct...
genomics research and human research protections. The research mandate should not interfere with principles of respect for persons, beneficence, and justice; the inherent right of the surrogate to disclosure of all information needed and to an understanding of the information disclosed; and the opportunity of the surrogate to give voluntary and informed consent.

The computer-based education module was designed with basic features to enhance surrogates’ understanding of the process of informed consent, be comprehensive, and provide a single straightforward message: the importance of reviewing and understanding essential elements of informed consent before signing a consent form for a loved one to participate in genomics research in the ICU. A strength of the computer-based approach is that participants found the laptop easy to use; they had to master only a single skill: advancing the slides by using a button on the keyboard. Also, the quality of the education module was high, as judged initially by a panel of experts and then by the researcher collecting data, who noted that the module was used by participants without hesitation or questions.

With further testing, the computer-based education module might be tailored to a specific population of participants, such as those with low reading skills; be revised to include hyperlinks to provide additional information; and be produced in Spanish or other languages. Also the intervention might be used in a kiosk with new touch-pad technologies, permanently affixed in the ICU waiting room for convenient viewing by surrogates, to serve as an adjunct to brochures about the research that would also be available in the waiting room. Visitors could view the education module, read the research brochure, and then call the research nurse if they were interested in learning more about research participation.

Table 3

<table>
<thead>
<tr>
<th>Posttest Item</th>
<th>Experimental (n = 65)</th>
<th>Control (n = 69)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Top box %</td>
</tr>
<tr>
<td>1. Research is intended to benefit patients in the future. It may not help your loved one.</td>
<td>4.7</td>
<td>0.74</td>
<td>74</td>
</tr>
<tr>
<td>2. A loved one may be too ill to agree to participate in research. When that happens, you may be asked to give permission for your loved one.</td>
<td>4.8</td>
<td>0.53</td>
<td>68</td>
</tr>
<tr>
<td>3. If you agree to participate in research, you may not withdraw from the study until it is finished.</td>
<td>4.9</td>
<td>0.56</td>
<td>86</td>
</tr>
<tr>
<td>4. You have the right to know the purpose of the study and how long it will last.</td>
<td>4.7</td>
<td>0.76</td>
<td>95</td>
</tr>
<tr>
<td>5. Research risks your loved one might face must be explained to you.</td>
<td>4.9</td>
<td>0.27</td>
<td>85</td>
</tr>
<tr>
<td>6. The institutional review board approves research. Part of their job is to help protect research participants.</td>
<td>4.7</td>
<td>0.63</td>
<td>92</td>
</tr>
<tr>
<td>7. The researchers will make sure you know how to contact them if you wish to ask more questions.</td>
<td>4.9</td>
<td>0.45</td>
<td>80</td>
</tr>
<tr>
<td>8. The researcher must give you all the information you need to make an informed decision about research.</td>
<td>4.9</td>
<td>0.45</td>
<td>91</td>
</tr>
<tr>
<td>9. Participating in research is voluntary.</td>
<td>5.0</td>
<td>0.28</td>
<td>91</td>
</tr>
<tr>
<td>10. You should decide whether to allow a loved one to participate in research on the basis of what your loved one would want.</td>
<td>4.7</td>
<td>0.61</td>
<td>97</td>
</tr>
<tr>
<td>11. You have the right to know if the researcher plans to keep your loved one’s personal information confidential.</td>
<td>4.9</td>
<td>0.27</td>
<td>78</td>
</tr>
<tr>
<td>12. The process of informed consent includes providing information about compensation for harm that may come to your loved one during research.</td>
<td>4.6</td>
<td>0.89</td>
<td>92</td>
</tr>
<tr>
<td>13. Some research involves a treatment. You must be told if there are other treatments you may choose instead.</td>
<td>4.6</td>
<td>0.98</td>
<td>80</td>
</tr>
</tbody>
</table>

* Item 3 is reverse coded.
for their loved ones. However, before this approach is used clinically, additional research is needed to determine the feasibility and effectiveness of this type of kiosk in ICU waiting rooms.

A posttest-only experimental design was used because pretesting might have resulted in an unwanted sensitization effect in which the pretest itself influenced the posttest answers. Also a pretest would have taken additional time, and we purposely designed the study to limit the research visit to 30 minutes, so it would not be too much of a burden on the participants, who were already dealing with complex issues related to the illness of their loved one. A lack of a pretest might be a problem when the random assignment does not work and the 2 groups are not equivalent at baseline. A lack of a pretest also can become a problem when attrition is high. We did not expect and did not experience high attrition.

Other limitations also were identified. First, the use of only 2 ICU waiting rooms at a single medical center might limit the generalizability of the results. Second, we do not know the extent to which the presence of transitory personal factors of participants, such as fatigue, hunger, mood, fear, and anxiety, might have led to errors in measurement. Third, the number of participants in the relationship categories was too small to be correlated with understanding the process of informed consent. That analysis should be conducted in a larger study on informed consent of surrogates in the future. Finally, this study was the first time the posttest was used, although the test’s internal consistency reliability was acceptable for a new instrument.43

Conclusion

Computer-based education may be an important addition to conventional approaches for obtaining informed consent in the ICU. Preparing patients’ family members who may consider serving as surrogate consenters is critical. Further research is needed to examine the multiple challenges that researchers and surrogates face when considering informed consent for genomics research in the ICU.

ACKNOWLEDGMENTS

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FINANCIAL DISCLOSURES
None reported.

REFERENCES
Outcomes Associated With Postoperative Delirium After Cardiac Surgery

By Ralph Francis Mangusan, RN-BC, MSN, PCCN, CWCN, Vallire Hooper, RN, PhD, CPAN, Sheri A. Denslow, PhD, MPH, and Lucille Travis, RN, PhD, NE-BC

**Background** Delirium after surgery is a common condition that leads to poor outcomes. Few studies have examined the effect of postoperative delirium on outcomes after cardiac surgery.

**Objectives** To assess the relationship between delirium after cardiac surgery and the following outcomes: length of stay after surgery, prevalence of falls, discharge to a nursing facility, discharge to home with home health services, and use of inpatient physical therapy.

**Methods** Electronic medical records of 656 cardiac surgery patients were reviewed retrospectively.

**Results** Postoperative delirium occurred in 161 patients (24.5%). Patients with postoperative delirium had significantly longer stays ($P<.001$) and greater prevalence of falls ($P<.001$) than did patients without delirium. Patients with delirium also had a significantly greater likelihood for discharge to a nursing facility ($P<.001$) and need for home health services if discharged to home ($P<.001$) and a significantly higher need for inpatient physical therapy ($P<.001$). Compared with patients without postoperative delirium, patients who had this complication were more likely to have received zolpidem and benzodiazepines postoperatively and to have a history of arrhythmias, renal disease, and congestive heart failure.

**Conclusions** Patients who have delirium after cardiac surgery have poorer outcomes than do similar patients without this complication. Development and implementation of an extensive care plan to address postoperative delirium is necessary for cardiac surgery patients who are at risk for or have delirium after the surgery. (American Journal of Critical Care. 2015;24:156-163)
Postoperative delirium is a rapidly occurring acute condition characterized by fluctuating episodes of inattention, disorganized thinking, and altered level of consciousness. Diagnosis of delirium in general is based on the following criteria: disturbances in attention and cognition that are not better explained by another preexisting neurocognitive disorder or do not occur in the context of a severely reduced level of arousal and evidence that the disturbances are not direct physiological consequences of another medical condition. Postoperative delirium usually develops on postoperative days 1 through 3 and resolves within hours to days. The complication has various clinical manifestations and can be classified as hyperactive, hypoactive, and mixed delirium.

Postoperative delirium is common among patients who have undergone cardiac surgery. Studies indicate that postoperative delirium affects 20% to 25% of cardiac surgery patients and that the risk for it is higher in patients who have valve replacement than in patients who have bypass surgery. Numerous risk factors are associated with the development of postoperative delirium in cardiac surgery patients, including advanced age, high serum levels of cortisol, history of diabetes, use of perioperative analgesics and benzodiazepines, use of cardiac medications (eg, β-blockers, antiarrhythmics, antihypertensives, angiotensin-converting enzyme inhibitors, and calcium channel blockers), and antiemetics given during the postoperative period. Aspects of cardiac surgery associated with postoperative delirium include increased intubation time, increased surgery time, and the development of surgical complications.

In addition to being distressing for patients and their family members, postoperative delirium is also linked to further adverse outcomes. In noncardiac surgery patients, postoperative delirium has been associated with higher hospital costs, longer lengths of hospital stay, increased likelihood of institutionalization, increased risk for dementia, and increased morbidity and mortality. In a study of older surgical patients, postoperative delirium was also a strong predictor of functional and cognitive decline in the first year after discharge.

Limited studies in cardiac surgery patients have indicated similar outcomes, including higher risks for postoperative complications, prolonged duration of intensive care unit and hospital stay, increased number of readmissions, poorer cognitive and functional outcomes, and higher mortality rates. The purpose of this study was to examine the effect of postoperative delirium on 5 outcome measures in patients who had cardiovascular surgery with use of cardiopulmonary bypass: length of postoperative hospital stay, prevalence of falls, discharge to a nursing facility (skilled nursing facility, long-term acute care facility, rehabilitation center), discharge to home with home health services, and use of inpatient physical therapy. These outcome measures were chosen because of their influence on the recovery and postsurgical functional status of cardiac surgery patients.

Methods

Approval for this retrospective study was granted by the appropriate institutional review boards.

Data Collection

The electronic medical records of 656 patients who had undergone cardiac surgery during the period January 10, 2011, to October 30, 2011, were abstracted by the primary investigator (R.F.M.). The sample size was not predefined; all qualified patients within the set time period were included.

Cardiac procedures included coronary artery bypass grafting (CABG), valve replacement and/or valve repair, and CABG plus valve replacement and/or valve repair. In addition to their primary
procedure, patients may have also had other procedures, such as a maze procedure for treatment of atrial fibrillation, aortic aneurysm repair, and carotid endarterectomy. Patients who had surgery via the thoracotomy approach and without use of a cardiopulmonary bypass machine were excluded. Patients who used a wheelchair or were nonambulatory before surgery also were excluded. Three patients who were in the intensive care unit for more than a month after surgery were excluded. Patients who died during surgery or the postoperative hospital stay also were excluded.

In determining the development of postoperative delirium, the patient’s neurological status throughout the hospital stay was analyzed. Because standard screening tools for delirium were not being used at the facility during this time, assessment data from registered nurses, physicians, and midlevel care providers were reviewed. Assessments made while the patient was sedated and receiving mechanical ventilation or immediately after the patient had been weaned from mechanical ventilation and sedation were not used as a basis in determining the development of postoperative delirium because these assessments could lead to inaccurate results.

A patient was considered to have had postoperative delirium if at least one of the following indicators was noted in the records as a new-onset condition after surgery: encephalopathy, delirium, confusion, or altered mental status. The following cues from the nurses’ and medical staff’s documentation were also considered to help determine the development of postoperative delirium: agitation, altered level of consciousness, restlessness, disorientation, lethargy, hyperactivity, impulsiveness, poor or impaired judgment, and poor or impaired thought processes. Careful analysis and attention were given to the fluctuation of indicators as well as the patient’s baseline mental status to ensure accuracy in classification. Patients considered to have had postoperative delirium had changes in the neurological assessments between shifts or within a shift. For example, a patient was alert and oriented to person, place, time, and situation in the morning but was disoriented, confused, and agitated at night.

The data collection tool included patients’ demographic information. Ten comorbid conditions were also considered from the patient’s medical history: hypertension, hyperlipidemia, hypothyroidism, arrhythmias (atrial fibrillation, atrial flutter, supraventricular tachycardia, complete heart block, ventricular tachycardia), diabetes mellitus, renal disease (acute renal failure, renal insufficiency, chronic renal disease, end-stage renal disease), chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, and tobacco use within 6 months before surgery. Additionally, information was collected on the length of bypass time during the surgical procedure, estimated blood loss, and medications taken during the hospital stay. Outcomes assessed included falls and the use of physical therapy during the hospital stay, the hospital length of stay, and the discharge destination (home with home health services or nursing facility).

Data Analysis
The data were entered into a Microsoft Excel spreadsheet and were analyzed by using Minitab 16 (Minitab Inc) and SAS, version 9.3 (SAS Institute Inc), software. Demographic factors, medical characteristics, and outcomes were categorized according to postoperative delirium status and summarized by using frequency tables. Differences in frequencies between groups were determined by using $\chi^2$ analysis and the Fisher exact test. Differences in age, number of comorbid conditions, cardiopulmonary bypass time, estimated blood loss, and length of stay between the 2 groups (with and without postoperative delirium) were assessed by using $t$ tests and the Mann-Whitney test. Adjusted odds ratios were estimated by using logistic regression to assess the association between postoperative delirium and occurrence of an in-hospital fall, use of physical therapy services during the hospital stay, and type of discharge. Negative binomial regression was used to estimate the association of postoperative delirium with length of postsurgical hospital stay.

Results
Among the total study population of 656, postoperative delirium developed in 161 patients (24.5%). Patients ranged in age from 29 to 91 years (Table 1). The mean age (71.4 years) of patients with postoperative delirium was higher than that (64.9 years) for patients without postoperative delirium ($P<.001$). The percentage of women in the group with postoperative delirium (34.8%) did not differ significantly ($P=.70$) from the percentage in the group without such delirium (33.1%).

The most common comorbid conditions among the 656 patients in the sample were hypertension (77.4%), hyperlipidemia (73.0%), and diabetes mellitus (36.0%). Of the 10 assessed comorbid conditions...
conditions, differences between patients with and without postoperative delirium were significant for
arrhythmias ($P = .003$), renal disease ($P = .01$), and congestive heart failure ($P = .03$). The mean number of comorbid conditions was 4.0 for patients with postoperative delirium and 3.5 for patients without postoperative delirium ($P = .002$). Half of the 656 patients (50.2%) had an ejection fraction of 55% or greater, with no difference between patients with and without postoperative delirium.

A total of 60.1% of patients in the sample had had a CABG procedure; 23.8% had had valve surgery, and 16.2% had had both CABG and valve surgery (Table 2). Compared with patients without postoperative delirium, patients with postoperative delirium were less likely to have had a CABG procedure only ($P = .03$) and more likely to have had a combined CABG and valve procedure ($P < .001$). Mean cardiopulmonary bypass time was 117.3 minutes for patients with postoperative delirium and 106.5 minutes for patients without postoperative delirium ($P = .02$).

Patients with postoperative delirium also had higher mean estimated blood loss (213.7 mL) than did patients without delirium (192.7 mL) ($P = .03$).

---

**Table 1**

Demographic and medical characteristics of patients with and without postoperative delirium

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total sample (N = 656)</th>
<th>With delirium (n = 161)</th>
<th>Without delirium (n = 495)</th>
<th>$p^b$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>66.5 (10.8)</td>
<td>71.4 (9.0)</td>
<td>64.9 (10.8)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Women</td>
<td>220 (33.5)</td>
<td>56 (34.8)</td>
<td>164 (33.1)</td>
<td>.70</td>
</tr>
<tr>
<td>Medical history</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>508 (77.4)</td>
<td>131 (81.4)</td>
<td>377 (76.2)</td>
<td>.17</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>479 (73.0)</td>
<td>124 (77.0)</td>
<td>355 (71.7)</td>
<td>.19</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>93 (14.2)</td>
<td>30 (18.6)</td>
<td>63 (12.7)</td>
<td>.06</td>
</tr>
<tr>
<td>Arrhythmias</td>
<td>133 (20.3)</td>
<td>46 (28.6)</td>
<td>87 (17.6)</td>
<td>.003</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>236 (36.0)</td>
<td>62 (38.5)</td>
<td>174 (35.2)</td>
<td>.44</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>156 (23.8)</td>
<td>30 (18.6)</td>
<td>126 (25.5)</td>
<td>.08</td>
</tr>
<tr>
<td>Renal disease</td>
<td>86 (13.1)</td>
<td>31 (19.3)</td>
<td>55 (11.1)</td>
<td>.01</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>200 (30.5)</td>
<td>55 (34.2)</td>
<td>145 (29.3)</td>
<td>.24</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>100 (15.2)</td>
<td>31 (19.3)</td>
<td>69 (13.9)</td>
<td>.10</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>68 (10.4)</td>
<td>24 (14.9)</td>
<td>44 (8.9)</td>
<td>.03</td>
</tr>
<tr>
<td>Comorbid conditions, mean (SD)</td>
<td>3.7 (1.7)</td>
<td>4.0 (1.7)</td>
<td>3.5 (1.6)</td>
<td>.002</td>
</tr>
<tr>
<td>Ejection fraction ≥ 55%</td>
<td>329 (50.2)</td>
<td>82 (50.9)</td>
<td>247 (49.9)</td>
<td>.84</td>
</tr>
</tbody>
</table>

$^a$ All values are number (%) of patients unless otherwise indicated.

$^b$ According to $t$ test, Mann Whitney test, or $\chi^2$ analysis.

**Table 2**

Procedure and treatment characteristics of patients with and without postoperative delirium

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total sample (N = 656)</th>
<th>With delirium (n = 161)</th>
<th>Without delirium (n = 495)</th>
<th>$p^b$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary artery bypass grafting</td>
<td>394 (60.1)</td>
<td>85 (52.8)</td>
<td>309 (62.4)</td>
<td>.03</td>
</tr>
<tr>
<td>Valve</td>
<td>156 (23.8)</td>
<td>32 (19.9)</td>
<td>124 (25.1)</td>
<td>.20</td>
</tr>
<tr>
<td>Coronary artery bypass grafting and valve</td>
<td>106 (16.2)</td>
<td>44 (27.3)</td>
<td>62 (12.5)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Cardiopulmonary bypass time, mean (SD), min</td>
<td>109.1 (47.6)</td>
<td>117.3 (52.5)</td>
<td>106.5 (45.7)</td>
<td>.02</td>
</tr>
<tr>
<td>Estimated blood loss, mean (SD), mL</td>
<td>197.9 (114.5)</td>
<td>213.7 (126.5)</td>
<td>192.7 (110.0)</td>
<td>.03</td>
</tr>
</tbody>
</table>

$^a$ All values are number (%) of patients unless indicated otherwise.

$^b$ According to Mann Whitney test or $\chi^2$ analysis.
Table 3
Comparison of outcomes for patients with and without postoperative delirium

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Total sample (N = 656)</th>
<th>With delirium (n = 161)</th>
<th>Without delirium (n = 495)</th>
<th>p</th>
<th>Odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occurrence of fall</td>
<td>15 (2.3)</td>
<td>10 (6.2)</td>
<td>5 (1.0)</td>
<td>&lt;.001</td>
<td>3.95 (1.15-13.61)</td>
</tr>
<tr>
<td>Discharged to nursing facility</td>
<td>128 (19.5)</td>
<td>72 (44.7)</td>
<td>56 (11.3)</td>
<td>&lt;.001</td>
<td>4.31 (2.71-6.84)</td>
</tr>
<tr>
<td>Discharged to home with home health servicesa</td>
<td>104 (19.7)</td>
<td>36 (40.4)</td>
<td>68 (15.5)</td>
<td>&lt;.001</td>
<td>2.64 (1.56-4.47)</td>
</tr>
<tr>
<td>Used physical therapy</td>
<td>214 (32.6)</td>
<td>104 (64.6)</td>
<td>110 (22.2)</td>
<td>&lt;.001</td>
<td>3.35 (2.08-5.42)</td>
</tr>
<tr>
<td>Length of stay after surgery, mean (SD), d</td>
<td>6.2 (3.6)</td>
<td>8.3 (5.6)</td>
<td>5.5 (2.1)</td>
<td>&lt;.001</td>
<td>1.38 (1.27-1.49)</td>
</tr>
</tbody>
</table>

* All values are number (%) of patients unless otherwise indicated.
*a According to χ² analysis, Fisher exact test, or Mann Whitney test.
*A Adjusted for age, sex, dementia, use of zolpidem, use of lorazepam, use of intravenous morphine, total number of comorbid conditions, and length of stay after surgery.
*b Adjusted for age, dementia, falls, and total number of comorbid conditions.
*c Analysis restricted to those not discharged to a nursing facility (total, n=528; delirium, n=89; no delirium, n=439).
d Adjusted for age, dementia, falls, use of zolpidem, use of lorazepam, use of intravenous morphine, total number of comorbid conditions, and length of stay after surgery.
*f Risk ratio adjusted for age, falls, time on cardiopulmonary bypass, estimated blood loss, and total number of comorbid conditions.

Of the 4 assessed medications taken by patients after cardiac surgery, intravenous opioids were the most common (68.6%); next, in order, were intravenous ketorolac (43.8%), oral benzodiazepines (35.4%), and zolpidem (5.5%). Compared with patients without postoperative delirium, patients with postoperative delirium were more likely to have received benzodiazepines (P = .01) and zolpidem (P = .01) during the hospital stay. Patients without postoperative delirium were more likely to have received ketorolac (P = .01). Opioid use was similar for the 2 groups.

A total of 15 patients in the sample of 656 had in-hospital falls (Table 3). Among the 15 patients, 10 were in the group who had postoperative delirium (P < .001). After adjustments for age, sex, dementia, comorbid conditions, use of the 4 assessed medications, and total length of stay, patients with postoperative delirium were almost 4 times as likely to have a fall while hospitalized than were patients without postoperative delirium (odds ratio, 3.95; 95% CI, 1.15-13.61). The majority of patients in the sample (n = 424; 64.6%) were discharged home without home health services. A total of 128 patients (19.5%) were discharged to a nursing facility, and 104 (19.7%) were discharged home with home health services. Patients who had postoperative delirium were more likely than those without delirium to require skilled assistance at the time of discharge (discharged to a nursing facility or to home with home health services) (P < .001) and without postoperative delirium (95% CI, 2.71-6.84). Of those patients discharged home, after adjustments for age, dementia, comorbid conditions, and having a fall while hospitalized, patients with postoperative delirium were 2.64 times as likely as patients without postoperative delirium (5.5 days) (P < .001). Inpatient physical therapy was used by 214 patients (32.6%). Patients with postoperative delirium (64.6%) were more likely than patients without postoperative delirium (22.2%) to require this service (P < .01). After adjustments for age, dementia, comorbid conditions, use of medication, in-hospital falls, and postsurgical length of stay, patients with postoperative delirium were 3.35 times more likely than patients without postoperative delirium (22.2%) to use physical therapy (95% CI, 2.08-5.42).

Mean length of stay after surgery for the entire study population was 6.2 days. Patients with postoperative delirium had a longer postoperative length of stay (8.3 days) than did patients without postoperative delirium (5.5 days) (P < .001). After adjustments for age, comorbid conditions, in-hospital falls, time on cardiopulmonary bypass, and estimated blood loss, patients with postoperative delirium stayed 1.38 times as long as did patients without postoperative delirium (95% CI, 1.27-1.49).

Discussion
We found an association between postoperative delirium and 5 adverse outcome measures: prevalence of in-hospital falls, increased length of postsurgical hospital stay, discharge to a nursing facility, discharge to home with home health services, and use of...
inpatient physical therapy. Our findings also confirmed that postoperative delirium affects a substantial number of cardiac surgery patients.

Our results indicating that postoperative delirium is associated with an increased risk for in-hospital falls is supported by similar findings in a previous study. Patients with delirium are often agitated and restless, and because they are confused, they may not be able to cooperate with staff in implementing interventions to prevent falls. Or, patients with hypoactive delirium may have generalized weakness that puts them at higher risk for falls. Additionally, patients who have been treated with antipsychotic medications may manifest extrapyramidal signs and symptoms that can lead to an unstable gait and falls.

Patients with postoperative delirium were also more likely than those without such delirium to use inpatient physical therapy. Various studies have indicated that long-term functional abilities decline among patients in whom postoperative delirium develops after cardiac surgery. The cognitive and physical worsening due to postoperative delirium impairs patients’ abilities to function independently, a situation that may necessitate rehabilitative services.

Patients who had postoperative delirium were discharged later than were patients who did not have postoperative delirium. Previous studies have also indicated that patients with postoperative delirium have longer hospital stays. Additionally, because of the increased likelihood of impaired functionality in patients with postoperative delirium, patients with this complication are more likely than patients without delirium to be discharged to a skilled nursing facility, or, if discharged home, are more likely to need home health assistance. Our results indicating an association between postoperative delirium and the need for more care after discharge are supported by the findings of a previous study in which delirium among the elderly was associated with an increased rate of institutionalization. Postoperative delirium impairs a patient’s cognitive status and ability to perform activities of daily living independently. Hence, patients with this complication are more likely than those without delirium to be discharged to a nursing facility where they can be provided additional assistance. Patients with postoperative delirium also generally have slower postoperative progress than do those without delirium, thereby requiring extended skilled nursing care as well as rehabilitation for recovery from the surgical procedure.

Like other researchers, we found that patients with postoperative delirium generally were older and had more comorbid conditions than did patients without delirium. Additionally, certain factors associated with cardiac surgery procedures and outcomes were also associated with the development of postoperative delirium, including length of surgery time and time on cardiopulmonary bypass. Further, patients in whom postoperative delirium developed were more likely than patients who did not experience delirium to have had a combined CABG plus valve replacement procedure. This finding may be related to surgical time and time on cardiopulmonary bypass machine, a factor supported by previous studies showing that prolonged surgery time and extended cardiopulmonary bypass time are risk factors for postoperative delirium after cardiac surgery. Additionally, patients undergoing CABG procedures tend to be older than other surgical patients. Advanced age is a known risk factor for postoperative delirium and may also be a factor in linking CABG plus valve replacement procedures to the development of postoperative delirium.

We also found associations between the use of zolpidem and benzodiazepine medications during the hospital stay and the development of delirium after cardiac surgery. Interestingly though, the use of ketorolac during the hospital stay was more common in patients who did not experience postoperative delirium, whereas opioid use was similar in both groups. Sockalingam et al reported that benzodiazepines as well as opioid analgesics were associated with the development of postoperative delirium. A direct association between ketorolac and the development of postoperative delirium, or lack thereof, has not been found in previous studies. Ketorolac is commonly used as a component of a multimodal analgesic approach postoperatively and is also a common alternative to opioids in the management of pain in patients who have indications of delirium. Possibly, a multimodal analgesic approach incorporating ketorolac results in decreased overall dosage of opioids, leading to decreased postoperative delirium in cardiac surgery patients.

Limitations

At the time of the study, our facility was not using a standardized tool to detect delirium. This situation may have affected the identification of patients for the study. However, meticulous review of assessments done before and after surgery and of medical records was used to identify signs and symptoms of postoperative delirium. The overall
dosage of medications was also not collected; thus, the relationship of total medication dosage to development of postoperative delirium could not be analyzed. Additionally, a time line of events (occurring before or after onset of delirium) was not delineated, so drawing conclusions based on the timing of medications and falls in relation to the development of postoperative delirium is difficult.

Conclusions

Postoperative delirium affects a large number of cardiac surgery patients. Compared with patients who do not experience postoperative delirium, patients who do experience this complication have poorer outcomes and are more likely to stay in the hospital longer after surgery, have an in-hospital fall, require inpatient physical therapy, be discharged to a nursing facility, and, if discharged home, are more likely to require home health services.

In order to improve outcomes after cardiac surgery, patients should be carefully assessed and their modifiable risk factors for postoperative delirium should be addressed. Care planning for cardiac surgery patients should be individualized. Preventive interventions for postoperative delirium should be planned and implemented among patients who are at high risk for this condition. Use of medications linked to the development of postoperative delirium should be limited. Because of the important role of nursing staff in screening patients for delirium, health care facilities should continue to foster the education of nurses in recognizing the development of postoperative delirium.

FINANCIAL DISCLOSURES

None reported.

eLetters

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SEE ALSO

For more about managing delirium, visit the Critical Care Nurse Web site, www.ccnonline.org, and read the article by Balas et al, “Management of Delirium in Critically Ill Older Adults” (August 2012).

REFERENCES

CNE Test  Test ID A1524022: Outcomes Associated With Postoperative Delirium After Cardiac Surgery

Learning objectives: 1. Identify clinical indicators that may indicate delirium. 2. Describe 3 types of delirium. 3. Determine what medications to avoid after surgery to prevent delirium.

1. Postoperative delirium is an acute condition characterized by fluctuating episodes of inattention, disorganized thinking, and which of the following?
   a. Nausea  
   b. Hypotension  
   c. Hypertension  
   d. Altered level of consciousness

2. Postoperative delirium is highest in which of the following types of cardiac surgery patients?
   a. Valve replacement  
   b. Bypass  
   c. Valve repair  
   d. Maze procedure

3. How many patients were included in the study?
   a. 565  
   b. 356  
   c. 495  
   d. 656

4. Which of the following was the mean age of patients diagnosed with postoperative delirium?
   a. 74.1 years  
   b. 71.4 years  
   c. 69.4 years  
   d. 64.9 years

5. The most common comorbid condition noted among the patients in the sample was which of the following?
   a. Congestive heart failure  
   b. Diabetes mellitus  
   c. Hyperlipidemia  
   d. Hypertension

6. Out of the total population of patients in this study, how many developed postoperative delirium?
   a. 161  
   b. 656  
   c. 495  
   d. 329

7. Mean cardiopulmonary bypass time was how long in patients with postoperative delirium?
   a. 192.7 minutes  
   b. 213.7 minutes  
   c. 117.3 minutes  
   d. 106.5 minutes

8. Which of the following 2 medications were linked to the development of delirium after cardiac surgery in this study?
   a. Ketorolac and benzodiazepine  
   b. Benzodiazepine and opioids  
   c. Benzodiazepine and zolpidem  
   d. Zolpidem and ketorolac

9. After adjustments for age, comorbidities, in-hospital falls, estimated blood loss and cardiopulmonary bypass time, the patients with postoperative delirium had a longer postoperative length of stay by how many days?
   a. 1.38  
   b. 3.35  
   c. 5.53  
   d. 8.32

10. Patients with postoperative delirium were more likely than those without delirium to require skilled assistance at the time of discharge?
    a. True  
    b. False

11. According to Table 3, a total of 15 patients in the sample had in-hospital falls. Among the 15 patients who had a fall in hospital how many in the group had postoperative delirium?
    a. 5  
    b. 10  
    c. 15  
    d. 8

12. Postoperative delirium usually develops on which of the following postoperative days?
    a. 1 through 4  
    b. 1 through 3  
    c. 0 through 2  
    d. 3 through 4

Test ID: A1524022 Contact hours: 1.0; pharma 0.0 Form expires: March 1, 2018. Test Answers: Mark only one box for your answer to each question.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tr>
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<td>2. a</td>
</tr>
<tr>
<td>1b</td>
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<td>2b</td>
</tr>
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<td>1c</td>
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<td>2c</td>
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<td>1d</td>
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Fee: AACN members, $0; nonmembers, $10  Passing score: 9 correct (75%) Category: CERP A Test writer: Darlene Pileski

Test Answers: Mark only one box for your answer to each question.

<table>
<thead>
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<tbody>
<tr>
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The American Association of Critical-Care Nurses is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center’s Commission on Accreditation. AACN has been approved as a provider of continuing education in nursing by the State Boards of Nursing of Alabama (#ABNP0062), California (#CEP1036) and Louisiana (#LBN112). AACN programming meets the standards for most other states requiring mandatory continuing education credit for relicensure.
**Background** Delirium is the most common postoperative psychiatric condition in intensive care settings and can lead to increased complications and costs.

**Objectives** To evaluate the impact of multifaceted preoperative patient education on postoperative delirium, anxiety, and knowledge and to explore predictors of postoperative delirium, days of mechanical ventilation, and days in the intensive care unit (ICU) in patients undergoing pulmonary thromboendarterectomy.

**Method** A prospective, randomized controlled trial was conducted on consented patients from October 2011 to April 2013. Patients were randomized in a 1 to 1 ratio to receive either an individualized 45-minute multifaceted preoperative education (experimental group, n = 63) or standard education (control group, n = 66). Participants completed the State-Trait Anxiety Inventory and Knowledge Test before and after the education. Data on incidence of delirium, days of mechanical ventilation, ICU days, and cardiopulmonary parameters were collected.

**Results** The experimental group had significantly more knowledge about postoperative care ($P < .001$) and fewer days of mechanical ventilation ($P = .04$) than the control group. The 2 groups did not differ significantly in anxiety, incidence of delirium, or ICU days. In exploratory multivariate analyses, hearing impairment was a positive predictor for days of delirium ($P = .009$), days of mechanical ventilation ($P < .001$), and ICU days ($P = .049$), whereas the posttest knowledge was a negative predictor for days of mechanical ventilation ($P = .02$).

**Conclusion** The patient education appeared to be effective in improving knowledge and reducing days of mechanical ventilation. Hearing impairment was an unexpected predictor of adverse outcomes for patients but may be amenable to nursing intervention. (American Journal of Critical Care. 2015;24:164-171)
Delirium is the most common postoperative psychiatric condition, affecting up to 65% of all surgical patients and as many as 80% of patients in intensive care settings. Postoperative delirium can lead to increased complications, functional decline after discharge, decreased long-term cognition, and increased mortality. Delirium is also associated with an increased length of stay (LOS) and increased health care costs. Medicare spends $6.5 billion a year for delirium-related in-hospital complications and an additional $100 billion in posthospital delirium-related costs such as nursing home care, rehabilitation, and home health care.

Patients undergoing surgical procedures are also at increased risk for heightened anxiety, which is associated with a poorer postoperative recovery. Preoperative anxiety is a common occurrence leading up to procedures in a hospital setting, owing to fear of the unknown and loss of control, and may cause an array of detrimental physiological effects. Although the evidence identifying the risk factors for postoperative delirium and the effects of preoperative anxiety is substantial, little is known about the relationship between them.

Pulmonary thromboendarterectomy (PTE) is the only curative option for chronic thromboembolic pulmonary hypertension, which is caused by unresolved multiple pulmonary emboli that result in progressive right-sided heart failure. PTE is an open-heart surgery requiring cardiopulmonary bypass and complete circulatory arrest to access and remove adherent, unresolved pulmonary emboli from the lining of the pulmonary artery lumen. This surgery stops the progression of right-sided heart failure by reducing right ventricular afterload.

Studies suggest that patients with high preoperative anxiety have more favorable outcomes when preoperative education is provided in a general surgery setting, but the impact of preoperative patient education for patients undergoing PTE has not been studied. Although several modifiable risk factors for delirium have been identified, such as anticholinergic, sedative, and analgesic medications; age; dehydration; sleep deprivation; and mobility; preoperative anxiety has not been studied as a risk factor. Finally, the effects of preoperative patient education on patients’ outcomes, such as duration of mechanical ventilation and intensive care unit (ICU) LOS, have not been studied among PTE patients.

**Methods**

**Design and Consent**

A prospective, randomized, nonblinded, controlled trial was carried out during an 18-month period to test whether a multifaceted preoperative educational program would decrease the incidence of postoperative delirium. Preoperative anxiety and knowledge regarding postoperative care were assessed, as well as patient outcome measures such as duration of mechanical ventilation and ICU LOS. The appropriate institutional review boards approved the study. Informed consent was obtained from recruited patients admitted for a PTE procedure who met eligibility criteria and agreed to participate. Enrolled participants were randomly assigned in a 1 to 1 ratio to either the experimental or control group.

**Setting and Sample**

The study was carried out at a 12-bed combined medical-surgical cardiovascular ICU at Sulpizio Cardiovascular Center, University of California San Diego Health System, from October 2011 to April 2013. Participants were recruited upon admission, 1 day before their surgery. Inclusion criteria included the following: age 18 years or older, male or female, English literate, and no prior PTE. Exclusion criteria included history of Alzheimer disease, dementia, or inability to give consent.
**Instruments and Data Collection**

To evaluate the impact of multifaceted preoperative patient education, the following instruments were included: the State-Trait Anxiety Inventory, Confusion Assessment Method for Intensive Care Units, Knowledge Test, and a data collection form. All participants completed the State-Trait Anxiety Inventory and the Knowledge Test before and about an hour after receiving the preoperative education.

The State-Trait Anxiety Inventory comprises 2 scales, 1 that measures state anxiety and 1 that measures trait anxiety. The 20-item state anxiety scale is used to assess the amount of apprehension and worry the individual feels at the moment on a 4-point Likert scale, ranging from 1 (not at all) to 4 (very much so). The 20-item trait anxiety scale is used to measure longer term, enduring anxiety on a 4-point Likert scale, ranging from 1 (almost never) to 4 (almost always). The summation score for each scale ranges from 20 to 80, and a higher score indicates greater anxiety. Cronbach’s α for the internal consistency reliability was 0.92 for the state anxiety scale and 0.90 for the trait anxiety scale.

To assess delirium, the Confusion Assessment Method for Intensive Care Units was used. This tool has 4 components: (1) an acute onset of mental status change or a fluctuating course, (2) inattention, (3) disorganized thinking, and (4) an altered level of consciousness as measured by the Richmond Agitation and Sedation Scale. Delirium is present if both components 1 and 2 are positive in addition to either component 3 or component 4. The 10-item Knowledge Test was developed by the investigators to assess the participants’ knowledge about postoperative care. It includes questions on suctioning during mechanical ventilation, anticipated extubation, use of restraints, and prevention of pressure ulcers. Face validity of the question items was established with a panel of 7 experts in critical care.

The participants were interviewed to collect ethnicity, psychiatric and neurological history including anxiety or depression, vision status, and alcohol or illicit drug use. They were also asked about hearing impairment or use of hearing aid. The investigators also determined whether a support system (ie, family or friend) was present during the hospital admission. Additional demographic information, such as date of birth, sex, and other clinical variables were obtained from the participants’ electronic medical records.

The clinical variables included intraoperative and postoperative parameters up to the first 7 days after surgery or until ICU discharge.

**Intervention**

Participants in the experimental group received an individualized 45-minute multifaceted educational session that was led by one of the study educators. All educators were experienced ICU nurses who underwent education training. Consistency in educational technique was established by requiring return demonstration of all educators. The education was titled, “What to Expect of Your ICU Stay,” which included visual, tactile, kinesthetic, and auditory methods of teaching. The content of the education was focused on surgeries requiring a sternotomy and was not specific to the PTE procedure only. The nurse educators used a colorful handout written at a fifth-grade reading level that included multiple images. The educators described the sights, sounds, and nursing care to be anticipated postoperatively. Actual postoperative equipment was used for hands-on demonstrations during the educational session; that equipment included an endotracheal tube, a ventilator, restraints, venodynes, a Swan-Ganz catheter, and an incentive spirometer. The participants were also taken on a tour of the ICU.

The control group received the standard preoperative education, consisting of unstructured teaching by various members of the multidisciplinary team during preoperative clinic visits and after hospital admission. The content of the standard preoperative education was provider-dependent and was provided as a part of the informed consent process for the PTE surgery.

**Data Analysis**

SPSS software version 20.0 (SPSS Inc) was used for all data analyses. Descriptive statistics of mean, median, standard deviation, frequency, and percentage were calculated for demographic and clinical variables. To compare the experimental and control groups, independent t tests and Fisher exact tests were performed to compare the changes in pretest and posttest trait anxiety, state anxiety, and knowledge scores for the experimental and control groups. Intention-to-treat analyses were used to test the impact of the experimental and control groups.

To further explore the predictors of days of delirium, mechanical ventilation, and ICU stay, bivariate Pearson correlation analyses were initially performed between these 3 dependent variables and the independent demographic/clinical variables.
Dummy codes were assigned for categorical variables such as hearing impairment, history of alcoholism, anxiety, depression, posttraumatic stress disorder, and preoperative narcotics for chronic pain. The independent variables that had statistically significant correlations with 1 or more of the 3 dependent variables were selected as potential predictors. These statistically significant demographic and clinical variables were then entered simultaneously into multiple regression models. Two-sided statistical significance was set at .05 for all data analyses. Based on power analysis for 80% power and 2-sided significance level at .05, a total of 128 patients were needed to detect a 50% difference in delirium between the 2 groups.

Results

Sample Characteristics
Out of 215 patients undergoing PTE surgery during the study period, 143 patients were screened for the study. Eleven patients did not meet the inclusion criteria; the remaining 132 were randomized, 65 into the experimental group and 67 into the control group. Two patients from the experimental group and 1 from the control group were found to have a history of Alzheimer’s disease or dementia after randomization and were excluded from data analyses. The study flow diagram is shown in Figure 1.

Demographic characteristics of the experimental and control groups are shown in Table 1. The mean age was 54 years old and most participants were female and white. About 9% of the participants reported hearing impairment or hearing aid use. Forty-three percent of the participants had other surgical procedures performed concurrently with PTE. Fisher exact tests showed no significant differences between the experimental and control groups except for support system presence during the educational session. Preoperative mean pulmonary artery pressure did not differ significantly ($P = .83$) between the experimental group (43.1 mm Hg) and the control group (43.6 mm Hg).

Intraoperative and Postoperative Parameters
No statistically significant differences were observed in intraoperative parameters between the 2 groups (eg, total cardiopulmonary bypass time was 252 minutes for the experimental group and 254 minutes for the control group, $P = .74$). On postoperative day 1, the mean pulmonary artery pressure was lower for the experimental group than for the control group (20.4 mm Hg vs 22.8 mm Hg; $P = .04$), but the mean pulmonary artery pressure was not significantly different ($P > .05$) between the 2 groups on subsequent days.

Impact of Multifaceted Preoperative Patient Education
The incidence of delirium was 22.2% for the experimental group and 31.8% for the control group, which was not significantly different ($P = .24$). Figure 2 depicts the percentage of patients with delirium on each of the 7 postoperative days.

The internal consistency reliabilities of the scales on the State-Trait Anxiety Inventory as measured by Cronbach $\alpha$ were 0.94 for the state anxiety scale and 0.91 for the trait anxiety scale. Figure 3 shows the mean differences in pretest and posttest trait anxiety, state anxiety, and knowledge scores for the experimental and control groups. For trait anxiety and state anxiety scores, the posttest scores decreased numerically for both the experimental group and the control group, but the mean changes did not differ significantly between the 2 groups ($P = .97$ for trait anxiety, $P = .45$ for state anxiety). The mean changes in knowledge scores, however, were significantly different between the 2 groups: the experimental group achieved greater improvements in knowledge than the control group achieved ($P < .001$).

Days of Delirium, Mechanical Ventilation, and ICU Stay
The comparisons between the 2 groups are shown in Table 2. Mean days of delirium and mean days of ICU stay did not differ significantly between the
Predictors for Days of Delirium, Mechanical Ventilation, and ICU Stay

Among the independent demographic and clinical variables, white ethnicity, hearing impairment, support system presence, preoperative use of narcotics for chronic pain, preoperative use of psychiatric medications, preoperative mean pulmonary artery pressure, preoperative pulmonary vascular resistance, and medical history of anxiety, depression, and posttraumatic stress disorder had statistically significant \( (P<.05) \) correlations with 1 or more of the dependent variables. In addition, the posttest knowledge score had a statistically significant negative correlation with the days of mechanical ventilation \( (r=-0.26; P=.01) \), whereas the posttest state anxiety and posttest trait anxiety scores had no correlations with any of the dependent variables. All the significant variables were entered simultaneously into the multiple regression models to explore the predictors of days of delirium, days of mechanical ventilation, and days of ICU stay. Table 3 shows the results of the simultaneous regression models. Since the preoperative mean pulmonary artery pressure and pulmonary vascular resistance were collinear, preoperative pulmonary vascular resistance was not included as a potential predictor in the simultaneous multiple regression models. Model assumptions of normality, linearity, and homoscedasticity were met.\(^2\)

For days of delirium as the dependent variable, the potential predictors explained 17% of the variance \( (R^2=0.17) \). Among the predictors, white ethnicity \( (\beta=0.21; P=.02) \), hearing impairment \( (\beta=0.24; P=.009) \), and preoperative mean pulmonary artery pressure \( (\beta=0.21; P=.02) \) reached statistical significance. For the days of mechanical ventilation, the predictor variables explained 30% of the variance \( (R^2=0.30) \). White ethnicity \( (\beta=0.21; P=.01) \), hearing impairment \( (\beta=0.36; P<.001) \), preoperative mean pulmonary artery pressure \( (\beta=0.25; P=.003) \), and posttest knowledge \( (\beta=-0.20; P=.02) \) were the statistically significant predictors for days of mechanical ventilation. Finally, for the days of ICU stay as the dependent variable, the potential predictors explained 38.2% of the variance \( (R^2=0.38) \). Among predictor variables, hearing impairment \( (\beta=0.16; P=.049) \), preoperative mean pulmonary artery pressure \( (\beta=0.25; P=.002) \), posttraumatic stress disorder \( (\beta=0.40; P=.001) \), and depression \( (\beta=0.16; P=.048) \) reached statistical significance.

Table 1
Sample characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total sample (N = 129 )</th>
<th>Experimental (n = 63 )</th>
<th>Control (n = 66 )</th>
</tr>
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<tbody>
<tr>
<td>Age, mean (range), y</td>
<td>54 (22-84)</td>
<td>53 (25-84)</td>
<td>55 (22-78)</td>
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<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>71 (55)</td>
<td>33 (52)</td>
<td>38 (58)</td>
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<tr>
<td>Male</td>
<td>58 (45)</td>
<td>30 (48)</td>
<td>28 (42)</td>
</tr>
<tr>
<td>Ethnicity</td>
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<tr>
<td>White</td>
<td>87 (67)</td>
<td>47 (75)</td>
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<tr>
<td>Black</td>
<td>25 (19)</td>
<td>8 (13)</td>
<td>17 (26)</td>
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<tr>
<td>Hispanic</td>
<td>10 (8)</td>
<td>6 (10)</td>
<td>4 (6)</td>
</tr>
<tr>
<td>Asian</td>
<td>3 (2)</td>
<td>1 (2)</td>
<td>2 (3)</td>
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<tr>
<td>Other</td>
<td>4 (3)</td>
<td>1 (2)</td>
<td>3 (4)</td>
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<tr>
<td>Support system presence(^b)</td>
<td>121 (94)</td>
<td>62 (98)</td>
<td>59 (89)</td>
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<tr>
<td>Hearing impairment</td>
<td>11 (9)</td>
<td>5 (8)</td>
<td>6 (9)</td>
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<tr>
<td>History of alcohol use</td>
<td>49 (38)</td>
<td>26 (41)</td>
<td>23 (35)</td>
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<tr>
<td>Alcoholism</td>
<td>3 (2)</td>
<td>1 (2)</td>
<td>2 (3)</td>
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<tr>
<td>Anxiety</td>
<td>19 (15)</td>
<td>8 (13)</td>
<td>11 (17)</td>
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<tr>
<td>Depression</td>
<td>21 (16)</td>
<td>10 (16)</td>
<td>11 (17)</td>
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<tr>
<td>Posttraumatic stress disorder</td>
<td>5 (4)</td>
<td>3 (5)</td>
<td>2 (3)</td>
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<tr>
<td>Preoperative narcotics use for chronic pain</td>
<td>14 (11)</td>
<td>9 (14)</td>
<td>5 (8)</td>
</tr>
<tr>
<td>Preoperative use of anxiolytics</td>
<td>13 (10)</td>
<td>6 (10)</td>
<td>7 (11)</td>
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<tr>
<td>Preoperative use of psychiatric medications</td>
<td>14 (11)</td>
<td>6 (10)</td>
<td>8 (12)</td>
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<tr>
<td>Preoperative pulmonary artery pressure, mean (SD), mm Hg</td>
<td>43.4 (13.3)</td>
<td>43.1 (14.6)</td>
<td>43.6 (12.1)</td>
</tr>
<tr>
<td>Pulmonary thromboendarterectomy and additional surgical procedures (coronary artery bypass graft, valve repair, repair of atrial septal defect, and others)</td>
<td>55 (43)</td>
<td>28 (44)</td>
<td>27 (41)</td>
</tr>
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</table>

\( ^a \) Values are expressed as number (percentage) unless otherwise indicated. Percentages may not total 100 because of rounding.

\( ^b \) Fisher exact tests and independent t tests were used for categorical and continuous variables, respectively. The only characteristic that differed significantly \( (P=.04) \) between experimental and control groups was support system presence.

Figure 2 Percentage of patients with delirium during the first 7 postoperative days.
Discussion

In this randomized controlled trial, multifaceted preoperative patient education did not reduce the incidence of postoperative delirium or reduce preoperative anxiety among patients undergoing PTE. However, the education improved patients’ knowledge about postoperative care and decreased mechanical ventilation duration from 2.4 days for the control group to 1.6 days for the experimental group.

To identify potential predictors of patients’ outcomes, 3 exploratory multivariate analyses were performed. For duration of mechanical ventilation, patients’ knowledge of postoperative care before undergoing surgery was a significant predictor, with better knowledge scores predicting shorter ventilation days. It was surprising that hearing impairment was a significant predictor of all 3 outcome variables, increasing the duration of mechanical ventilation as well as ICU LOS and days of delirium. This finding highlights the importance of nurses prioritizing reestablishment of preoperative sensory baseline in the ICU. Nurses can help by ensuring that patients have their hearing aids properly placed and activated in the ICU during waking hours and before initiating the weaning process. This simple procedure should be a part of the standard nursing practice that could lead to improved outcomes for patients with hearing impairment. However, further research is needed to confirm the effects of hearing impairment on duration of mechanical ventilation and the generalizability of these findings to other ICU settings.

The current study supports the previous study findings that preoperative education increases knowledge.21 It is plausible that the knowledge gained through preoperative education allowed the participants to anticipate their postoperative environments and procedures, perhaps enabling better adaptation to postoperative stress. However, it is not clear which components of the multifaceted education were most beneficial in increasing participants’ knowledge. In addition, the educational sessions were time intensive and provision of additional ICU nursing staff resources was required for implementation.

Elevated preoperative mean pulmonary artery pressure was also a predictor of delirium, duration of mechanical ventilation, and ICU LOS. Mean pulmonary artery pressure is an expected contributor to these outcomes, as increased pulmonary artery pressures denotes an advanced disease process at baseline. Langer et al22 reported that patients undergoing PTE surgery with high baseline pulmonary pressures had an increased inflammatory response leading to prolonged ICU stay. Additionally, severe illness and inflammatory response are known risk

![Figure 3](image-url)

**Figure 3** Mean (SEM) scores on pretest and posttest (N = 129). Solid line indicates the experimental group and dashed line indicates the control group.

| Table 2 |

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Total sample (N = 129)</th>
<th>Experimental (n = 63)</th>
<th>Control (n = 66)</th>
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</thead>
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<tr>
<td>Days of delirium, mean (SD)</td>
<td>0.6 (1.3)</td>
<td>0.4 (1.1)</td>
<td>0.7 (1.4)</td>
<td>.16</td>
</tr>
<tr>
<td>Days of mechanical ventilation, mean (SD)</td>
<td>2.0 (2.3)</td>
<td>1.6 (1.7)</td>
<td>2.4 (2.6)</td>
<td>.04</td>
</tr>
<tr>
<td>Days in intensive care unit, mean (SD)</td>
<td>5.1 (6.9)</td>
<td>4.2 (2.9)</td>
<td>5.9 (9.2)</td>
<td>.17</td>
</tr>
</tbody>
</table>
factors of delirium. Previous research also demonstrated a statistically significant association between severity of preoperative pulmonary hypertension (mean pulmonary artery pressure and pulmonary vascular resistance) and the development of postoperative lung injury, which may lead to prolonged ventilation.

Operative time and pump time were not predictors of delirium—contrary to the common ICU belief associated with the term "pump brain." This result could be attributed to multiple factors including advances in mechanisms for preserving brain perfusion and in cardiac anesthesia and could be indicative of our center’s experience in caring for patients who require this level of care. Further research is needed on the impact of prolonged pump and operative time in patients undergoing PTE.

Numerous surgeries require mechanical ventilation postoperatively. Many of these patients receive postoperative ICU care and ventilation weaning similar to what was experienced by the participants in this study. They also are subject to many of the same postoperative complications. Although the multifaceted education did not affect the postoperative delirium, it may nevertheless provide an opportunity for nurses to influence other outcomes for surgical patients such as duration of mechanical ventilation. Further research is needed to explore the benefits of education on other surgical procedures to confirm the results of this study.

Limitations
The current study had several limitations. First, it was a single-center study, which may limit the generalizability of the results. In addition, although PTE surgeries parallel many aspects of general open-heart cardiac surgeries, their distinct characteristics may limit the generalizability of current study findings beyond PTE surgeries. Second, support system presence during the educational sessions differed significantly in the 2 randomized groups, potentially biasing the results. Third, the daily delirium assessments were performed by a large number of bedside nurses, and the interrater reliability of assessments had not been validated. Fourth, the lack of double-blinding may have introduced bias. Finally, because of the limited time between hospital admission and surgery the following morning, the participants may not have had adequate time to assimilate the preoperative education.

Conclusions
The multifaceted preoperative education did not affect postoperative delirium, but it appeared to improve postoperative knowledge and reduce the days of mechanical ventilation among patients who had undergone PTE. Hearing impairment was an unexpected predictor of postoperative delirium, prolonged mechanical ventilation, and longer ICU stay, and hearing impairment may be easily amenable to nursing intervention.

ACKNOWLEDGMENTS
We recognize and appreciate the valuable contributions to this study of the following people: Dr Larry Rankin, Professor Deana Noble, and Dr Jeanne Maiden, Toni Moseley, Sherry Carreau, Laura Martin, Carie Helm, Alex Whalen, Kelly Barber, and Lina Rossetti-Gruich.

FINANCIAL DISCLOSURES
None reported.

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REFERENCES


To purchase electronic or print reprints, contact the American Association of Critical-Care Nurses, 101 Columbia, Aliso Viejo, CA 92656. Phone, (800) 899-1712 or (949) 362-2050 (ext 532); fax, (949) 362-2049; e-mail, reprints@aacn.org.
Background Fluid responsiveness is a measure of preload dependence and is defined as an increase in cardiac output due to volume expansion. Recent publications have suggested that variation in amplitude of the pulse oximetry waveform may be predictive of fluid responsiveness. The pleth variability index (PVI) was developed as a noninvasive bedside measurement of this variation in the pulse oximetry waveform.

Objectives To measure the discriminatory value of PVI for predicting fluid responsiveness as measured by pulmonary artery catheter thermodilution in patients after cardiothoracic surgery.

Methods A prospective observational study of hemodynamically stable postoperative cardiac surgery patients with pulmonary artery catheters. A fingertip sensor was used to measure PVI. Vital signs, PVI, and cardiac index were measured before, during, and after passive leg raise. Fluid responsiveness was defined by increase in cardiac index of greater than 15% during passive leg raise. The discriminatory value of PVI was assessed by using the Wilcoxon method to measure the area under the receiver operating curve.

Results In 13 months, 47 patients (24 receiving mechanical ventilation, 23 spontaneously breathing) were enrolled. Fluid responsiveness was noted in 42% of intubated patients and 48% of spontaneously breathing patients. PVI was not adequate to discriminate fluid responsiveness in intubated patients (area under curve, 0.63; P = .16) or spontaneously breathing patients (area under curve, 0.41; P = .75).

Conclusions Among postoperative cardiac surgery patients, PVI is not reliable for predicting fluid responsiveness as measured by pulmonary artery catheter thermodilution, regardless of ventilatory status. (American Journal of Critical Care. 2015; 24:172-175)
Critically ill patients are frequently given crystalloid infusions to improve cardiac output and restore normal hemodynamics. Patients whose cardiac output increases after volume expansion are said to be fluid responsive. However, published reports suggest that only half of critically ill patients treated with fluid resuscitation will show improvement in cardiac output. Furthermore, a growing number of publications suggest that administering too much fluid may be associated with increased morbidity and mortality.

Many techniques exist to guide fluid resuscitation, such as the monitoring of central venous pressure (CVP) during goal-directed therapy for septic shock. However, numerous studies have demonstrated that CVP and other static measures are poor predictors of intravascular volume or fluid responsiveness. In contrast, dynamic measures of intravascular volume such as arterial pulse pressure variation, systolic pressure variation, and stroke volume variation are significantly better discriminatory predictors of fluid responsiveness. However, these techniques are invasive, technically challenging, and may be time-consuming to perform in critically ill patients. Furthermore, it has been suggested that these relationships are limited to patients receiving mechanical ventilation due to the relationship between cardiac preload, tidal volume depth, respiratory rate, and intrathoracic pressure during positive pressure ventilation.

The pleth variability index (PVI) was developed as a noninvasive means of predicting fluid responsiveness. This tool can be used to assess volume status by measuring variation in the amplitude of the pulse oximetry waveform during respiration. Recent publications have suggested that PVI may be a predictor of fluid responsiveness among patients receiving mechanical ventilation, but studies of PVI performance among spontaneously breathing patients have been limited by small sample size and variability in the reference standards used for comparison.

**Methods**

**Purpose**

Our goal was to measure the discriminatory ability of PVI in predicting fluid responsiveness as measured by using pulmonary artery catheter (PAC) thermodilution among patients after cardiac surgery. We hypothesized that PVI would be effective for predicting fluid responsiveness among intubated patients but not among spontaneously breathing patients.

**Study Design and Population**

This study was a prospective observational analysis of patients in the cardiothoracic surgical intensive care unit of Rhode Island Hospital, a tertiary academic medical center, from October 2011 to October 2012. Using prior estimates of expected correlation with an α of 0.05 and a β of 0.8, we calculated a sample size of 23 per group. Patients were enrolled by convenience sample. The study was approved by the hospital’s institutional review board. Verbal consent was obtained from each patient or from the patient’s family before data collection.

Patients more than 18 years old were eligible if they were undergoing routine postoperative PAC hemodynamic monitoring that included thermodilution as part of standard care. Patients were excluded if they had an irregular cardiac rhythm or if they had recent lower extremity trauma that would preclude a passive leg raise. A fingertip sensor was used to measure PVI (Radical-7 monitor, Masimo Corporation). While the patients were semirecumbent, PAC thermodilution was performed and hemodynamic data were measured, including heart rate, systemic
Fluid responsive, No. (%) of patients

Hemodynamic parameters, median (interquartile range)
Vasopressors, No. (%) of patients
Demographics

Passive leg raise, %
Change in cardiac index during
Cardiac indexa at rest
Pleth variability index
Central venous pressure, mm Hg
Diastolic blood pressure, mm Hg
Systolic blood pressure, mm Hg
Heart rate, beats per minute
Epinephrine
Norepinephrine
Other
Valve replacement
Coronary artery bypass graft
Female, No. (%) of patients
No. of patients

Cardiac indexb during passive leg raise
Change in cardiac index during
passive leg raise, %

Fluid responsive, No. (%) of patients

a Calculated as cardiac output in liters per minute divided by body surface area in square meters.

and pulmonary pressures, PVI, cardiac index, and stroke volume. Passive leg raise to 45° was performed, and hemodynamic data collection was repeated at 30 and 60 seconds.

Outcome Measures
The primary outcome was fluid responsiveness, which was defined a priori as an increase in cardiac index of 15% or greater during a passive leg raise.

Data Analysis
Categorical data were calculated as percentages. Continuous data were calculated as medians with interquartile range. Area under the receiver operating characteristic curve was calculated by using the Wilcoxon method.

Results
Forty-seven patients were enrolled. Patients’ age, procedure, PVI, and hemodynamic data are reported in the Table. Fluid responsiveness was noted in 42% of intubated and 48% of spontaneously breathing patients, respectively. Median (interquartile range) PVI before passive leg raise was 12 (8-15) among intubated patients and 19 (12-26) among spontaneously breathing patients.

Maximum predictive value was noted at a PVI threshold of 14%, with sensitivity and specificity of 67%. However, this discriminatory ability was not statistically significant among patients receiving mechanical ventilation (area under curve, 0.63; \( P = .16 \)). Predictive value also was poor among spontaneously breathing patients (area under curve, 0.41; \( P = .75 \)).

Discussion
This study examines the predictive value of PVI using thermodilution in both patients receiving mechanical ventilation and spontaneously breathing patients after cardiac surgery. PVI had insufficient discriminatory ability to be used to predict fluid responsiveness in either group. Our study is the second one with results indicating that PVI cannot be used to predict fluid responsiveness following cardiac surgery and is the first to do so by using a passive leg raise. PVI values measured during our study were similar to values reported in the past.4-6,9

Researchers in 2 other studies3,10 have examined PVI in patients following cardiac surgery. Fischer and colleagues4 analyzed 80 patients and concluded that PVI was not useful for predicting fluid responsiveness (area under curve, 0.6; \( P > .05 \)). Unlike our study, their protocol used colloid infusion rather than a passive leg raise and excluded patients with emergency or repeat surgery, low tidal volumes, or low thoracic compliance.

Haas et al1 studied adults receiving mechanical ventilation following cardiac surgery and reported that a PVI greater than 16% was predictive of fluid responsiveness (area under curve, 0.95). This finding is inconsistent with our results. Haas et al defined fluid responsiveness as an increase in cardiac index of greater than 10% (vs 15% in our study) and used colloid infusion rather than passive leg raise. These differences may partly explain the discordance, although colloid infusion and passive leg raise are generally considered interchangeable.11 Our data did not demonstrate significant discriminatory value at a confidence interval threshold of 10%.

Studies of PVI in patients receiving mechanical ventilation have produced mixed results. Cannesson et al10 examined patients before coronary artery bypass grafting and reported that a PVI greater than 14% was a predictor of fluid responsiveness (area under curve, 0.93; \( P < .001 \)). Broch et al11 concluded that a PVI greater than 13% was a predictor of fluid responsiveness among patients before coronary artery bypass graft (area under curve, 0.72; \( P = .01 \)), but only among patients with perfusion indices greater than 4%. However, these studies had substantial differences in
their samples of patients; Broch et al excluded patients with severe valvular disease or systolic impairment, whereas Cannesson et al excluded neither. Zimmermann et al reported that a PVI greater than 9.5% was predictive of fluid responsiveness in intubated adults before major abdominal surgery. In contrast, Wajima et al examined PVI in preoperative adults and reported no change in PVI or cardiac index after an infusion of 500 mL crystalloid. Pereira de Souza Neto et al noted similar negative findings among intubated children before surgery.

Past research has shown contradictory results regarding PVI use with vasopressors. Loupec et al examined ICU patients receiving norepinephrine infusions and concluded that a PVI threshold of 17% was predictive of fluid responsiveness (P < .05). In contrast, Bias et al concluded that PVI was non-predictive among patients receiving norepinephrine but that it performed well as a predictor of fluid responsiveness in the absence of vasopressors (area under the curve, 0.69 vs 0.93; P = .02).

Few studies have been done to measure the utility of PVI among spontaneously breathing patients. Among healthy volunteers, Keller et al reported that PVI was a weak but significant predictor of fluid responsiveness (area under the curve, 0.73). Our findings do not replicate those results.

Limitations

One limitation of our study is the impairment of myocardial contractility following cardiac surgery. This change could hypothetically alter the discriminatory ability of PVI monitoring in this population. However, contractility may be impaired in other critical illnesses such as severe sepsis, and consequently we believe that our findings may be generalized beyond cardiothoracic surgery. Second, our study was not designed to detect differences in the predictive value of PVI on the basis of patients’ comorbid conditions, surgical procedure, or vasopressor use. Prior research shows conflicting results regarding the utility of PVI during norepinephrine use. However, vasopressors remain an essential part of critical care resuscitation, and thus practical evaluation of PVI utility should occur in conditions of real-world clinical practice.

Conclusions

Among postoperative cardiothoracic surgery patients, PVI is not a reliable predictor of fluid responsiveness as measured by pulmonary artery catheter thermodilution, regardless of the patient’s ventilatory status.

FINANCIAL DISCLOSURES
None reported.

eLetters
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EAST MEETS WEST: EFFECTS OF MASSAGE ON THE EXPERIENCE OF CARDIAC SURGERY PATIENTS

By Margo A. Halm, RN, PhD, ACNS-BC

The way to health is a scented bath and an oiled massage every day.
—Hippocrates

In 2010, almost 400,000 patients underwent coronary artery bypass procedures in the United States.1 Despite advances in pain management, pain continues to be an important postoperative problem.2 Sources of pain include surgical positioning, incisions, retraction of chest wall tissues, dissection of major chest wall muscles, electrocautery, and insertion of catheters and drains—especially chest tubes. As a result, cardiac surgery patients often experience musculoskeletal pain in the neck, back, and shoulders.2,3 Yet the pathway to recovery presents more than physical challenges. Cardiac surgery patients face emotional distress, fear of death, uncertainty, and depressive symptoms.4

Healing after major surgery may be aided by the integration of the best that Eastern and Western medicine have to offer. Massage is a broad array of techniques that involve "manual soft-tissue manipulation that includes holding, causing movement, or applying pressure to the body."5(p59) With a long tradition, massage dates to ancient cultures in the time of Hippocrates (Father of Medicine, 460-370 BC). Florence Nightingale (1820-1910) later advocated that the role of nursing was to put the patient in the best possible condition for nature to act so that healing can occur.6 Historically part of practice, massage is used by nurses to promote circulation, sleep, and quality of life, as well as to relieve pain, anxiety, and depression.7 But massage has shifted to being considered complementary or alternative medicine (CAM), with the increased availability of drugs and complex medication regimes, advanced technology, and biomedical monitoring and the increased demands for documentation.3,7 Now, typically administered by massage therapists in 30- to 60-minute doses, different types of massage produce friction and/or pressure on cutaneous and subcutaneous tissues in the whole body or on specific regions such as the back, hands, or feet.7 The focused PICO (population, intervention, comparison, outcome) question for this evidence synopsis was, “What effect does massage have on symptoms that affect the experience of cardiac surgery patients?”

Method

The strategy included searching the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and MEDLINE. Key words included massage, cardiac surgery, major operation, pain, anxiety, and patient experience. The search was limited to original research in the past 10 years.

Results

Massage was provided by certified massage therapists (70%),3,15 researchers (20%),16,17 or physiotherapists (10%).18 Most massages were 20 minutes on multiple occasions (as opposed to single episodes) from the day of surgery to postoperative day (POD) 7. In 1 study,19 massage was performed 2 to 3 hours before sleep. Positioning was based on tolerance and changed as needed (ie, supine, prone, lateral recumbent position; sitting in chair or on bed). Effleurage, a technique that uses long sweeping strokes with varying degrees of pressure17 was used in 3 studies.5,15,17
In another study,16 Swedish techniques, kneading and stroking each hand and foot for 5 minutes, also were used. In remaining studies,11-13,14 the patient’s areas of maximal discomfort (usually the upper back, neck, and shoulders) were massaged. Techniques were individualized, incorporating Swedish, craniosacral, deep tissue, trigger point, myofascial release, acupressure, and reflexology using light to moderate pressure. In 1 study,14 researchers evaluated massage as 1 component of a CAM bundle that included music and guided imagery.

Table 1 outlines main findings of 10 retrieved studies. Researchers in most studies10-17 observed significant reductions or faster decline in pain intensity and unpleasantness with massage, reinforcing the gate control mechanism. By providing competing stimuli, pressure applied during massage “closes the gate,” blocking transmission of pain.10,13 Asadizaker et al16 reported that massage reduced use of sedatives, but others13,17 reported no effect of massage on opioid use. In another study,10 researchers found that opioids increased the day after massage, a finding attributed to soft-tissue release and increased mobility. Others reported that perceptions of sleep effectiveness improved the night after massage; fatigue also lessened on 2 postoperative days.18 Not only can massage close pain gates, it also can promote restorative sleep, reducing levels of substance P and somatostatin, both of which have been linked to pain.13 In addition to activating physiological mechanisms, some of the effect of massage may be attributed to interpersonal touch.13 These nonspecific effects have been reported in the CAM literature.

Anxiety or tension was lessened after massage in most studies that measured this aspect of patients’ experience.11-13,15 No effect was observed on mood or depression.12 Other researchers found that massage lessened muscular tension,11,13 providing theoretical support that manipulating and elongating the musculoskeletal system releases tension from muscle fibers and connective tissue. And despite subjective findings of relaxation,13 objective measures of the parasympathetic relaxation response induced by massage were observed in only 2 studies.5,10 Blood pressure and respiratory rate were significantly decreased after 20- to 30-minute massages on postoperative days 2 and 4.5,10 No effect was demonstrated on heart rhythm or length of stay.9

**Recommendations for Practice**

Most evidence for massage is level B evidence (Table 2). Massage was usually offered in short courses of multiple sessions, so the observed effects may be considered “single-dose effects,” because changes were transient and not enduring as one might expect after a series of sessions.17 Nevertheless, these physiological and psychological changes may affect cardiac surgery patients’ immediate experience. Multiple researchers have reported that the optimal dose—including the frequency, sequencing, and anatomic focus of massage after cardiac surgery—is yet unknown. Each one of these intervention aspects may influence outcomes, as could combination CAM interventions.3,8,14 Positioning tolerance during the early postoperative period may also limit full relaxation benefits.4

The Institute for Healthcare Improvement defines an “exceptional patient experience” as one that is safe, effective, patient-centered, timely, efficient, and equitable.21 In this review, massage was safe, with no adverse effects reported.12,14,15 Growing evidence exists for short-term effectiveness in reducing pain, anxiety, and muscular tension and improving sleep and relaxation in cardiac surgery patients. Beyond safety and effectiveness, improving the patient’s experience also requires an unmitting focus on patient-centeredness. Common dimensions of patient-centeredness include human interaction and touch, physical comfort, and respect for the patient’s values and preferences, including the incorporation of complementary therapies.21,22 Customizing care by offering options that promote healing during the postoperative period conveys respect for patients’ preferences. However, studies revealed that some patients may not be interested in massage, so assessment is essential. Common reasons patients gave for lack of interest included anxiety about surgery, postoperative symptoms (eg, nausea, diarrhea, pain), or lack of desire to be touched or bothered.12,13

Several studies demonstrated that patients were satisfied with massage.10,11,15 In 1 study,11 massage produced a greater level of patient satisfaction than rest time provided on postoperative days 3 and 4. Qualitatively, patients and staff members reported that massage improved pain relief, relaxation, and mobility.15 The reported massage interventions were feasible with few or no barriers.10,12,14 The major challenge was scheduling around rest/sleep periods and physical therapy.21 Ideally, massages would be available on request for patients. Thus, the timing of the intervention would be under control of the patient as much as possible.4,7

Institutions interested in offering massage as an option after cardiac surgery are advised to determine the return on investment.23 Most of the interventions provided in these studies were by certified massage therapists who are often part of a CAM bundle that includes music and guided imagery.
### Table 1

**Summary of evidence for effect of massage**

<table>
<thead>
<tr>
<th>Reference, year</th>
<th>Design and intervention</th>
<th>Effects of intervention*</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piotrowski et al, 2003</td>
<td>Randomized controlled trial; 10-min massage twice a day on POD 1-7 vs attention vs routine care; N=202 male patients who had major surgery (77% sternotomy)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kshettry et al, 2006</td>
<td>Randomized controlled trial, complementary and alternative medicine bundle (preoperative guided imagery/30-min massage, 20-min music on POD 1 and 2, 30-min massage POD 2); N=104 cardiac surgery patients</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mitchinson et al, 2007</td>
<td>Randomized controlled trial, 20-min daily back massages on POD 1-5 vs attention vs routine care; N=605 major surgery patients (64% sternotomy)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albert et al, 2009</td>
<td>Randomized controlled trial, 30-min massage on POD 2 or 3 and POD 4 or 5 vs usual care; N=252 cardiac surgery patients</td>
<td>0 (Atrial fibrillation)</td>
<td>+</td>
</tr>
<tr>
<td>Cutshall et al, 2010</td>
<td>Randomized controlled trial, 20-min massage between POD 2-5 vs routine care plus quiet time; N=58 cardiac surgery patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bauer et al, 2010</td>
<td>Randomized controlled trial, 20-min massage POD 2 and 4 vs relaxation POD 2 and 4; N=113 cardiac surgery patients</td>
<td>+ POD 2 and 4</td>
<td></td>
</tr>
<tr>
<td>Nerbass et al, 2010</td>
<td>Randomized controlled trial, massage on day of surgery through POD 2 vs control; N=57 coronary artery bypass patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asadizaker et al, 2011</td>
<td>Randomized controlled trial, 20-min hand and foot massage vs rest in bed; N=65 cardiac surgery patients</td>
<td></td>
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<tr>
<td>Dion et al, 2011</td>
<td>Observational, 20-min massage; N=160 thoracic surgery patients</td>
<td></td>
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</tr>
<tr>
<td>Braun et al, 2012</td>
<td>Randomized controlled trial, 20-min massage vs rest on POD 3 or 4 and POD 5 or 6; N=152 cardiac surgery patients</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Abbreviation: POD, postoperative day.

* Key: +, Beneficial effect of massage over control (P < .05); -, detrimental effect (P < .05); 0, no difference between groups (P > .05).

### Table 2

**American Association of Critical-Care Nurses evidence-leveling system**

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Meta-analysis of multiple controlled studies or metasynthesis of qualitative studies with results that consistently support a specific action, intervention, or treatment</td>
</tr>
<tr>
<td>B</td>
<td>Well-designed controlled studies, both randomized and nonrandomized, with results that consistently support a specific action, intervention, or treatment</td>
</tr>
<tr>
<td>C</td>
<td>Qualitative studies, descriptive or correlational studies, integrative reviews, systematic reviews, or randomized controlled trials with inconsistent results</td>
</tr>
<tr>
<td>D</td>
<td>Peer-reviewed professional organizational standards, with clinical studies to support recommendations</td>
</tr>
<tr>
<td>E</td>
<td>Theory-based evidence from expert opinion or multiple case reports</td>
</tr>
<tr>
<td>M</td>
<td>Manufacturer’s recommendation only</td>
</tr>
</tbody>
</table>

* From Armola et al, with permission.
therapists, so the observed clinical benefits may not occur if massage is delivered by nurses or other unlicensed therapists.4 As few payers cover the cost of CAM in the hospital setting, a business case could be developed to offer fee-for-service massage to patients.4 Another possibility is to demonstrate the worth that massage has on value-based purchasing specifically related to patient satisfaction measures or how its impact on patients' outcomes (eg, reductions in pain, anxiety, and poor sleep quality) affects postoperative recovery, discharge readiness, and length of stay. The gains in patients' experience and clinical outcomes could be used to offset the salaries of certified massage therapists in the hospital setting.

FINANCIAL DISCLOSURES
None reported.

REFERENCES

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PREHOSPITAL 12-LEAD ECGs AND DELIVERY OF CARE

By Salah S. Al-Zaiti, RN, PhD, CRNP, Teri M. Kozik, RN, PhD, CNS, CCRN, Michele M. Pelter, RN, PhD, and Mary G. Carey, RN, PhD, CNS

Scenario: This 12-lead electrocardiogram (ECG) was obtained during prehospital transport of a 72-year-old male with a history of coronary artery disease. He had called 911 to report chest pain. After the ECG, the patient experienced ventricular fibrillation and was resuscitated in the ambulance. At the hospital, the initial cardiac workup indicated myocardial infarction (MI), documented by a rise in cardiac troponin levels (>0.10 ng/mL). Twelve hours later, the patient was transferred to a nearby facility to undergo a coronary angiogram that revealed 100% occlusion of the left anterior descending artery and a coronary stent was placed. After a 9-day recovery, he was discharged home on an extensive cardiac rehabilitation program.

Interpretation Questions:

1. Is the ECG properly calibrated (10 mm) and are leads properly placed?  ☑ Yes ☐ No ☐ NA
2. Is this a sinus rhythm (one P wave preceding every QRS complex)?  ☑ Yes ☐ No ☐ NA
3. Is the heart rate (R-R interval) normal (60-100 beats/min)?  ☑ Yes ☐ No ☐ NA
4. Is the QRS complex narrow (duration <110 milliseconds [ms] in V1)?  ☑ Yes ☐ No ☐ NA
5. Is the ST segment deviated (>2 mm in V2-V3, or >1 mm in other leads)?  ☑ Yes ☐ No ☐ NA
6. Is the T wave inverted in relation to the QRS (>0.5 mV)?  ☑ Yes ☐ No ☐ NA
7. Is the QT interval lengthened (>450 ms [women] or >470 ms [men])?  ☑ Yes ☐ No ☐ NA
8. Is R- or S-wave amplitude enlarged (S wave V1 + R wave V5 >35 mm)?  ☑ Yes ☐ No ☐ NA

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By Salah S. Al-Zaiti, RN, PhD, CRNP, Teri M. Kozik, RN, PhD, CNS, CCRN, Michele M. Pelter, RN, PhD, and Mary G. Carey, RN, PhD, CNS

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Interpretation and Rationale

This ECG shows normal sinus rhythm with left ventricular hypertrophy (LVH), which is associated with secondary repolarization changes seen as inverted T-waves confounding interpretation of ST/T waveforms for acute coronary syndrome. Clinically, this non-ST elevation myocardial infarction (non-STEMI) has precipitated fatal, ischemia-induced ventricular tachyarrhythmia; hence urgent catheterization (< 2 hours) would be recommended according to guidelines.

Mechanism and Management

During prehospital triage, destination decisions and treatment decisions are made instantly. The prehospital 12-lead ECG is uniquely poised to support clinical decisions given that it is the only available diagnostic tool during prehospital care. In the absence of ST elevation, patients with non-STEMI are pooled with an undifferentiated patient group of nonspecific chest pain. Non-STEMI triage becomes, therefore, largely dependent on the clinical judgment of symptomatology (ie, angina-like pain), medical history (ie, coronary artery disease), and initial assessment (ie, hemodynamic instability and abnormal ECG). Of note, cardiac arrest is the first clinical presentation in nearly 50% of new-onset acute MIs.

In this example, advanced age, history of coronary artery disease, postcardiac arrest status, and the LVH on the ECG all suggest severe coronary artery disease, as was demonstrated by the angiogram. Proper triage would have redirected the ambulance to a hospital capable of performing immediate cardiac catheterization, which would have minimized time to revascularization, and consequently may have reduced the size of infarction and improved outcomes (ie, shorter hospital stay and less aggressive rehabilitation).

Current guidelines advocate building prehospital 12-lead ECG systems—with transmission capabilities—for real-time clinical decision support. Proper integration of ECGs in prehospital care systems could improve diagnostic accuracy by identifying high-risk patients who could be directed to the optimal site for delivery of care.
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Chicago

*Certiﬁcation in Legal Nurse Consulting (5-day Seminar and Online)*

*Date:* May 11-15, 2015 *Place:* Renaissance Chicago O’Hare Suites Hotel.  
*Address:* 5800 W Bryn Mawr Ave, Chicago, IL 60631.  
*Keynote Speaker:* Vickie L. Milazzo.  
*Sponsor:* Vickie Milazzo Institute.  
*Contact:* Vicki L. Milazzo.  
*Phone:* (800) 880-0944.  
*Fax:* (713) 942-8075.  
*Email:* mail@LegalNurse.com.  
*Fee:* Varies.  
*Credits:* 25.3 CEUs (5-day seminar); 40 CEUs (online).

Itasca

*Midwest Conference*

*Date:* March 23-24, 2015 *Place:* Eaglewood Resort and Spa.  
*Address:* 1401 Nordic Rd, Itasca, IL 60143.  
*Keynote Speakers:* TBA (Multiple speakers).  
*Sponsor:* Northwest Chicago Area Chapter of AACN.  
*Contact:* Jenny A. Zaker.  
*Phone:* (847) 309-0662.  
*Email:* zakerj46@gmail.com.  
*TBA.*  
*Credits:* TBD.

**PENNSYLVANIA**

Camp Hill

*Acute and Critical Care Issues Across the Lifespan*

*Date:* April 17, 2015 *Place:* Giant Community Room Trindle Rd.  
*Camp Hill, PA.*  
*Sponsor:* Susquehanna Valley Chapter of AACN.  
*Contact:* Lori Cox.  
*Email:* lorinlp@comcast.net.  
*Fee:* $20, members (fee refunded at door); $30, nonmembers.

**TENNESSEE**

Memphis

*Spring Seminar: Focus the Flame*

*Date:* April 10, 2015 *Place:* Baptist Memorial Hospital, Memphis  
*Seminar Room,* Memphis, TN.  
*Keynote Speaker:* Teri Lynn Kiss.  
*Sponsor:* Greater Memphis Area Chapter of AACN.  
*Contact:* Janet F. Mulroy.  
*Phone:* (901) 682-5478.  
*Fax:* (901) 344-2699.  
*Email:* jfmulroy@comcast.net.  
*TBA.*  
*Credits:* TBD.

**VIRGINIA**

Richmond

*Odyssey Symposium*

*Date:* March 16-17, 2015 *Place:* Preconference-Virginia Commonwealth University Alumni House; Conference-Richmond Convention Center.  
*Keynote Speakers:* Teri Lynn Kiss, Kathleen Volman.  
*Sponsor:* Greater Richmond Area Chapter of AACN.  
*Contact:* Marian Altman.  
*Phone:* (804) 370-8347.  
*Fax:* (804) 785-9076.  
*Email:* marian.altman@gmail.com.  
*Fee:* Varies.  
*Credits:* Pending.

**WASHINGTON**

Richland

*PCCN/CCRN Review*

*Date:* April 9-10, 2015 *Place:* Courtyard Marriott.  
*Address:* 480 Columbia Point Dr, Richland, WA 99352, (509) 942-9400.  
*Keynote Speaker:* Nicole Kupchick.  
*Sponsor:* Columbia Northwest Chapter of AACN.  
*Contact:* Lane Wilson.  
*Email:* lane.wilson@kadlecmed.org.  
*Fee:* $225-$300 dependent on registration time.  
*Credits:* Pending.

Spokane

*Spring Symposium 2015*

*Date:* March 16, 2015 *Place:* Washington State University Spokane Campus, Pharmacy and Biomedical Sciences Building.  
*Address:* 412 E Spokane Falls Blvd, Spokane, WA.  
*Keynote Speakers:* Kathryn Roberts, Nicole Kupchick.  
*Sponsor:* Inland Northwest Chapter of AACN.  
*Contact:* Sue Matthews.  
*Phone:* (509) 415-1135.  
*Email:* sjeanmatthews@ccomcast.net.  
*Fee:* Early Bird: $180/member, $225/nonmember, $74/student (not RN returning to school); Late fee-$205/member, $250/nonmember, $90/student (not RN returning to school).  
*One day fee:* $110/member, $135/nonmember, $40/student (not RN returning to school).  
*Credits:* TBD.

**WYOMING**

Jackson Hole

*Critical Care Summit*

*Date:* July 26-29, 2015 *Place:* Snow King Resort.  
*Sponsor:* Contemporary Forums.  
*Contact:* Kristine Mulholand.  
*Address:* 3478 Buskirk Ave, #242, Pleasant Hill, CA 94523.  
*Phone:* (800) 377-7707.  
*Fax:* (925) 828-1950.  
*Email:* info@cforums.com.  
*Fee:* $545.  
*Credits:* 17.75 CEUs.

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