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Nothing says more about the quality of a company — its products, services, and people — than the longevity of its customer relationships. In our 13 years in the cardiopulmonary market, Medical Graphics Corporation has established an enviable record of customer loyalty — ranging from the small clinic and physician’s office, to large research hospitals, and even to NASA, who will be relying on MedGraphics quality during many of its Space Shuttle missions.

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Over the years, we have worked closely with our customers to define the standards of quality. First and foremost, our systems answer the need for accuracy. Reliability, expandability, ease of use, and cost-effectiveness are also hallmarks of the MedGraphics name. These standards have guided the development of the MedGraphics Pulmonary Function Testing System 1070 and the Body Plethysmography System 1085 (shown here) which have come to be regarded worldwide as simply the best. Now, we are pleased to announce that both of these systems are available with our new generation of easier-than-ever-to-use software — BREEZE™. Also new — our Body Plethysmography System 1085D features complete lung function capabilities including diffusing capacity measurement.

The new MedGraphics BREEZE diagnostic software, with its colorful icons, makes testing a breeze!
In truly critical situations, physicians rely on the MedGraphics CCM Critical Care Management System for vital metabolic measurements that can help avoid ventilatory complications arising from inappropriate nutrition. In the ICU, the MedGraphics CCM assesses nutrition and the mechanics of breathing to dramatically decrease ventilator dependence and significantly improve patient outcome. Even neonates weighing as little as 500 grams can be accurately evaluated for ventilatory, metabolic and cardiac function, including cardiac output, with the MedGraphics Pediatric CARE™ System (shown here).

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SAFE & SIMPLE

A Breakthrough in Aerosol Heaters from Professional Medical Products, Inc.

PMP's Prefil' Adjustable Electronic Aerosol Heater can deliver aerosol at body temperature—even at a 28% FIO2 setting.

A Microprocessor Controls the Temperature of the Aerosol Stream

A sensor probe attached to the heater and to the circuit at the patient airway constantly monitors the proximal airway temperature and feeds that information back to a computer chip in the heater. The chip regulates the heat being generated by a large metal platen inside the heater. A LCD on the face of the heater shows the temperature of the aerosol going into the airway. The aerosol stream temperature cannot exceed 39°C or the power to the heater automatically shuts off — reducing the danger of tracheal burns.

Compact Size Means An Easy Fit

The aerosol heater is a compact unit that screws onto a Prefil Nebulizer. The prefilled bottle is a stable, low-profile bottle which helps eliminate spills. When assembled the entire unit fits easily into those restricted areas often found in ICU and ER.

For more information on this revolutionary concept in aerosol heaters, please contact your PMP representative or distributor. Or call us toll-free at 1-800-845-4571.
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Editor's Note: This issue's abstract citations include the articles published in the December 11, 1991 issue of JAMA, which focused on smoking cessation and tobacco advertising.


Transdermal Nicotine for Smoking Cessation: Six-Month Results from Two Multicenter Controlled Clinical Trials—Transdermal Nicotine Study Group. JAMA 1991;266:3133.

OBJECTIVE: To evaluate the efficacy of a new transdermal nicotine system for smoking cessation. DESIGN: Two 6-week, randomized, double-blind, placebo-controlled, parallel group trials were conducted. Successful abstainers from both trials enrolled in a third trial for blinded downtitration from medications (6 weeks) and subsequent off-drug follow-up (12 weeks). SETTING: Nine outpatient clinics specializing in the treatment of smoking cessation. PATIENTS: Healthy volunteers who smoked one or more packs of cigarettes daily and wanted to participate in a smoking cessation program. INTERVENTION: Patients were randomly assigned to a transdermal nicotine system delivering nicotine at rates of 21, 14, or 7 mg (in Trial 1 only) over 24 hours or to placebo. Group counseling sessions were provided to all participants. MAIN OUTCOME MEASURE: Rates of continuous smoking abstinence were determined during 6 weeks of full-dose treatment, a 6-week weaning period (through Week 12), and a 3-month follow-up receiving no therapy (through Week 24). Abstinence was defined by patient diary reports of no smoking during the designated periods, confirmed by expired-breath carbon monoxide levels of 8 ppm or lower. RESULTS: The centers enrolled 935 patients. Cessation rates during the last 4 weeks of the two 6-week trials (pooled data) were 61%, 48%, and 27% for 21- and 14-mg transdermal nicotine and placebo, respectively (p < 0.001 for each active
New!

Now Available!

SURVANTA®
beractant
intratracheal suspension

From Ross Laboratories—
Helping Premature Babies Survive™

Please see adjacent column for Brief Summary of prescribing information.
When all controlled studies were pooled, there was no difference in intracranial hemorrhage. However, in one of the single-dose resuscitation and one of the multi-dose prevention studies, the rate of intracranial hemorrhage was significantly higher in SURVANTA-treated than in control patients (22% vs 31%, P = 0.001; and 48%, 94%, vs 42%, P < 0.047, respectively). The rate in a treatment injury involving approximately 2400 infants was lower than in the controlled trials.

In the controlled clinical trials, there was no effect of SURVANTA on results of control laboratory tests: white blood cell count and serum sodium, potassium, bilirubin, creatinine.

More than 3700 pretreatment and post-treatment serum samples were tested by Western blot immunoassay for antibodies to surfactant-associated proteins SP-B and SP-C. No IgG or IgM antibodies were detected.

Several other complications are known to occur in premature infants. The following conditions were reported in the controlled clinical trials: The rates of the complications were not different in treated and control infants, and none of the complications were attributed to SURVANTA.

Respiratory: lung consolidation, blood from the endotracheal tube, deterioration after weaning, respiratory decompensation, subglottic stenosis, paralyzed diaphragm, respiratory failure.

Cardiovascular: hypotension, hypertension, tachycardia, ventricular tachycardia, aortic insufficiency, cardiac failure, respiratory arrest, increased epigastric pulse, persistent partial occlusion, air embolism, total anomalous pulmonary venous return.

Gastrointestinal: abdominal distention, hemorrhage, intussusception, bowel infarct, leading intolerance, hepatic failure, stress ulcer.

Renal: renal failure, hematuria.

Hematologic: coagulopathy, thrombocytopenia, disseminated intravascular coagulation.

Central Nervous System: seizures.

Endocrine: Metabolic: adrenal insufficiency, inappropriate ADH secretion, hyperphosphatemia.

Musculoskeletal: inguinal hernia.

Systemic: fever, dehydration.

Follow-Up Evaluations

Data on long-term complications or sequelae of SURVANTA therapy have been found.

Multiple-Dose Studies

Six-month, age-adjusted follow-up evaluations of 232 infants (115 treated) demonstrated no clinically important differences between treatment groups in pulmonary and neurologic sequelae, incidence or severity of respiratory morbidity, prematurity, rehospitalizations, growth, or allergic manifestations.

OVERDOSAGE

Overdose with SURVANTA has not been reported. Based on animal data, overdose might result in acute airway obstruction. Treatment should be symptomatic and supportive.

Rales and moist breath sounds can transiently occur after SURVANTA is given, and do not indicate overdose. Endotracheal suctioning or other remedial action is not required unless clear-cut signs of airway obstruction are present.

Since their original introduction, Wright and Haloscope Respirometers from Ferris Medical have set the industry standards in terms of absolute accuracy, reliability, and quality of workmanship.

A choice of ten models provides a version to suit every specific need while seven North American service centers assure the lowest repair cost and shortest service time of any monitoring spirometers available today.

For more than thirty years Ferris Medical has led the industry in providing the respiratory care practitioner with superior spirometers in their most compact and portable manifestions.

Wright and Haloscope Respirometers

Since their original introduction, Wright and Haloscope Respirometers from Ferris Medical have set the industry standards in terms of absolute accuracy, reliability, and quality of workmanship.

A choice of ten models provides a version to suit every specific need while seven North American service centers assure the lowest repair cost and shortest service time of any monitoring spirometers available today.

For more than thirty years Ferris Medical has led the industry in providing the respiratory care practitioner with superior spirometers in their most compact and portable manifestions.
ABSTRACTS


OBJECTIVES: To determine the percentage of smokers reporting that a physician had ever advised them to smoke less or to stop smoking, and the effect of time, demographics, medical history, and cigarette dependence on the likelihood that respondents would state that a physician had ever advised them to stop smoking. DESIGN & SETTING: Data were collected from the Stanford Five-City Project, a community-wide health education intervention program. The two treatment and three control cities were located in northern and central California. As there was no significant difference between treatment and control cities regarding cessation advice, data were pooled for these analyses. PARTICIPANTS: There were 5 cross-sectional, population-based Five-City-Project surveys (conducted in 1979-1980, 1981-1982, 1983-1984, 1985-1986, and 1989-1990); these surveys randomly sampled households and included all residents aged 12 to 74 years. MAIN OUTCOME MEASURES: Improved smoking advice rates over time in all towns was an a priori hypothesis. RESULTS: Of the 2,710 current smokers, 48.8% stated that their physicians had ever advised them to smoke less or stop smoking. Respondents were more likely to have been so advised if they smoked more cigarettes per day, were surveyed later in the decade, had more office visits in the last year, or were older. In 1979-1980, 44.1% of smokers stated that they had ever been advised to smoke less or to quit by a physician vs 49.8% of smokers in 1989-1990 (p < 0.07). Only 3.6% of 1,672 ex-smokers stated that their physicians had helped them quit. CONCLUSION: These findings suggest that physicians still need to increase smoking cessation counseling to all patients, particularly adolescents and other young smokers, minorities, and those without cigarette-related disease.


OBJECTIVE: Little is known about the influence of advertising on very young children. We, therefore, measured product logo recognition by subjects aged 3 to 6 years. DESIGN: Children were instructed to match logos with 1 of 12 products pictured on a game board. Twenty-two logos were tested, including those representing children’s products, adult products, and those for two popular cigarette brands (Camel and Marlboro). SETTING: Preschools in Augusta and Atlanta, Georgia. PARTICIPANTS: A convenience sample of 229 children attending preschool. RESULTS: The children demonstrated high rates of logo recognition. When analyzed by product category, the level of recognition of cigarette logos was intermediate between children’s and adult products. The recognition rates of The Disney Channel logo and Old Joe (the cartoon character promoting Camel cigarettes) were highest in their respective product categories. Recognition rates increased with age. Approximately 30% of 3-year-old children correctly matched Old Joe with a picture of a cigarette compared with 91.3% of 6-year-old children. CONCLUSION: Very young children see, understand, and remember advertising. Given the serious health consequences of smoking, the exposure of children to environmental tobacco advertising may represent an important health risk and should be studied further.


OBJECTIVES: To determine if RJR Nabisco's cartoon-theme advertising is more effective in promoting Camel cigarettes to children or to adults. To determine if children see, remember, and are influenced by cigarette advertising. DESIGN: Use of four standard marketing measures to compare the effects of Camel's Old Joe cartoon advertising on children and adults, SUBJECTS: High school students, Grades 9 through 12, from 5 regions of the United States, and adults, aged 21 years and over, from Massachusetts. OUTCOME MEASURES: Recognition of Camel’s Old Joe cartoon character, product and brand name recall, brand preference, appeal of advertising themes. RESULTS: Children were more likely to report prior exposure to the Old Joe cartoon character (97.7% vs 72.2%; p < 0.0001). Children were better able to identify the type of product being advertised (97.5% vs 67.0%; p < 0.0001) and the Camel

treatment vs placebo). Six-month abstinence rates for 21-mg transdermal nicotine and placebo were 26% and 12%, respectively (p < 0.001). All transdermal nicotine doses significantly decreased the severity of nicotine withdrawal symptoms and significantly reduced cigarette use by patients who did not stop smoking. Compliance was excellent, and no serious systemic adverse effects were reported. CONCLUSIONS: Transdermal nicotine systems show considerable promise as an aid to smoking cessation.
Twenty-eight years ago we declared germ warfare.
Meet our newest weapons.

Twenty-eight years ago, Johnson & Johnson Medical, Inc. revolutionized disinfection with the introduction of CIDEX* Activated Dialdehyde Solution. And now, we're offering two new additions to the CIDEX Solution Family of Products.

Introducing ENZOL* Enzymatic Detergent — it breaks down and removes tough, dried-on organic matter from instruments. Plus, easy rinsing means no clogging of scopes.

And, new CIDEX Solution Test Strips — developed exclusively for monitoring the effectiveness of CIDEX Solution. It's the easiest, most reliable way to detect unintentional dilution. Simply dip a test strip in CIDEX Solution, remove and read.

Depend on Johnson & Johnson Medical to lead the charge in asepsis and infection control. For additional product information, call 1-800-433-5009, or contact your Johnson & Johnson Medical sales representative.
cigarette brand name (93.6% vs 57.7%; p < 0.0001). Children also found the Camel cigarette advertisements more appealing (p < 0.0001). Camel’s share of the illegal children’s cigarette market segment has increased from 0.5% to 32.8%, representing sales estimated at $476 million per year. CONCLUSION: Old Joe Camel cartoon advertisements are far more successful at marketing Camel cigarettes to children than to adults. This finding is consistent with tobacco industry documents that indicate that a major function of tobacco advertising is to promote and maintain tobacco addiction among children.


OBJECTIVE: To evaluate whether tobacco advertising encourages teenagers younger than 18 years to start smoking. DESIGN: Comparison of 1990 California telephone survey data with data from a 1986 national telephone survey (both used a random-digit dialing system); 95% confidence intervals were calculated. To test our hypothesis, we considered whether the perception of advertising was related to age, whether the pattern of market share across age and sex groups followed the pattern of perceived advertising, and whether changes in market share paralleled changes in advertising as perceived by the youngest age group. PARTICIPANTS: There were 24,296 adults and 5,040 teenagers. RESULTS: The most advertised brands of cigarettes were Marlboro, according to 33.6% of adults and 41.8% of teenagers, and Camel, according to 13.7% of adults and 28.5% of teenagers—named most often by 12- to 13-year-olds (34.2%). The brands that were purchased most often were Marlboro and Camel. Together these were the brands of choice of 79.9% of males and 85% of females aged 12 through 17 years. Marlboro’s market share increased in youths and young adults up to age 24 years and then decreased gradually with age; Camel’s market share decreased abruptly with age: It was the brand of choice of 24.5% ± 5.8% of males aged 12 through 17 years but was chosen by only 12.7% ± 3.6% of males aged 18 through 24 years; for females, 21.7% ± 13.7% aged 12
through 17 years chose Camels, while only 5.5% ± 3.2% aged 18-24 years preferred this brand. Both Marlboro and Camel brands had a higher market share in California in 1990 compared with that for the United States in 1986. Of interest is that the market share for Camel increased among the younger smokers but was more evenly distributed for Marlboro. CONCLUSIONS: Perception of advertising is higher among young smokers; market-share patterns across age and sex groups follow the perceived advertising patterns; and changes in market share resulting from advertising occur mainly in younger smokers. Cigarette advertising encourages youth to smoke and should be banned.

RESULTS: Merchant sales rates in Woodridge decreased from a baseline of 70% before legislation to less than 5% in 1.5 years of compliance checking after legislation. Student surveys showed that the rates of cigarette experimentation and regular use of cigarettes by adolescents were reduced by over 50%. CONCLUSION: Cigarette control laws can be effective in significantly reducing the rate of cigarettes sold by merchants and rates of cigarette use by adolescents. Key elements of successful legislation implementation are consistent compliance checking and heightened community awareness of the problems and prevalence of adolescent smoking.


OBJECTIVE: To assess the prevalence, content, and growth of state and city laws restricting smoking in public places and workplaces in the United States and to identify factors associated with their passage. DESIGN: A mailed survey of city clerks in U.S. cities with a population of 25,000 or greater (n = 980) and review of existing data sources confirmed the status of smoking restrictions in 902 (92%) of the cities in the sample. State laws were identified by contacting each state’s Legislative Reference Bureau (100% response). Content of laws was coded using previously developed categories. MAIN OUTCOME MEASURES: Percentage of stores selling cigarettes to minors in Woodridge and percentage of students who had experimented with cigarettes or were regular smokers.

Through 17 years chose Camels, while only 5.5% ± 3.2% aged 18-24 years preferred this brand. Both Marlboro and Camel brands had a higher market share in California in 1990 compared with that for the United States in 1986. Of interest is that the market share for Camel increased among the younger smokers but was more evenly distributed for Marlboro. CONCLUSIONS: Perception of advertising is higher among young smokers; market-share patterns across age and sex groups follow the perceived advertising patterns; and changes in market share resulting from advertising occur mainly in younger smokers. Cigarette advertising encourages youth to smoke and should be banned.

The Effects of Combining Education and Enforcement To Reduce Tobacco Sales to Minors: A Study of Four Northern California Communities—E Feighery, DG Altman, G Shaffer. JAMA 1991;266:3168.

OBJECTIVE: To examine the effects of a community education and law enforcement intervention on illegal tobacco sales to minors. DESIGN: A 2-year, before-and-after trial with retail stores as the unit of analysis. SETTING: Implementation occurred in 4 suburban California commun-
HOW TO BUILD
AMERICA’S #1
PEAK FLOW METER
IN 10 EASY STEPS
1. **Nurture a drive to constantly be better**

   We started out competing against other peak flow meters. Now that we’re the leader, we compete against ourselves. In the last two years alone, we’ve made more than 10 separate product improvements...with more still on the drawing boards.

2. **Develop a patented design**

   ASSESS® and ASSESS Low Range use a unique flow-sampling technology that minimizes wear and delivers superior accuracy, reproducibility, and consistency. How consistent? After two years of simulated daily use, a recent independent research study found no more than 1% variability.¹

3. **Engineer it without compromise**

   Everything about ASSESS from its easy-to-use design...to its easy-to-read scale...to its transparent construction that encourages regular cleaning...to its virtually indestructible polycarbonate body—is designed to make it work better and last longer.

4. **Test every unit**

   Spot-checking is the norm in manufacturing quality control. Not at HealthScan. No unit leaves our plant without being tested at both the high and low ends of the scale. (Plus, every hour we select ten random samples for even more rigorous statistical quality control.)

5. **Put it to the test in the laboratory**

   Recently, researchers at Montefiore Medical Center measured ASSESS against our leading competitor. Their findings? The accuracy of the other product deteriorated after only two months of simulated use. But ASSESS kept on delivering consistently accurate readings.²

6. **Put it to the test in clinical practice**

   Lab results like this say a lot about ASSESS. Our clinical acceptance says even more. Nine out of every ten peak flow meters used in hospitals are ASSESS.³ Why? Read on.

7. **Support physicians**

   Physicians know they can count on us, not just for a superior product but for superior service—including extensive patient education materials, a dedicated professional services department, and the only comprehensive peak flow monitoring system.

8. **Support patients and their families**

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9. **Invite criticism**

   With all these efforts, you might think we’d hate to hear complaints about ASSESS. Just the opposite. Frank feedback from physicians and patients only helps us make ASSESS better. Which is why we encourage that feedback with a toll-free telephone hotline.

10. **Go back to step 1**

    We’re proud of our leadership...but we’re not satisfied. So we’ll keep on making improvements. We expect more of ASSESS. You should too.

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ABSTRACTS


OBJECTIVE: This paper reviews the evidence that exposure to environmental tobacco smoke (ETS) increases the risk of heart disease death among persons who have never smoked (never-smokers). The annual number of heart disease deaths in the United States attributable to ETS is estimated, as is the individual risk of heart disease death for exposed never-smokers. DATA SOURCES: Nine epidemiologic studies and numerous experimental studies are available to evaluate the association of ETS and heart disease. DATA SYNTHESIS: The relative risk for never-smokers living with current or former smokers, compared with never-smokers living with nonsmokers, has ranged from 0.9 to 3.0 in 9 studies. Seven studies were positive, one was positive for women but not men, and one was negative. Several studies have shown a dose-response relationship and have controlled for other risk factors. Evidence from experimental studies suggests that ETS can damage the cardiovascular system, via both short-term and long-term mechanisms. Assuming that the observed heart disease risk for those exposed to ETS is not an artifact of misclassification or confounding, approximately 35,000 to 40,000 deaths from ischemic heart disease among never-smokers and long-term former smokers are estimated to have occurred annually in the United States as a result of ETS exposure in the early 1980s. An individual male never-smoker living with a current or former smoker is estimated to have an approximately 9.6% chance of dying of ischemic heart disease by the age of 74 years, compared with a 7.4% chance for a male never-smoker living with a nonsmoker. The corresponding lifetime risks for women are 6.1% and 4.9%. CONCLUSIONS: The public health burden due to ETS exposure is likely to be much greater for heart disease than for lung cancer, which has been the focus of most debate to date. Individual lifetime excess risks of heart disease death due to ETS of one to three per 100 can be compared with much lower excess risks of one death per 100,000, which are often used in determining environmental limits for other toxins. Exposure to ETS is not currently regulated at the federal level, except for domestic air traffic.


We have previously shown that airway insufflation (AI) reduces dead space (Vb) and minute ventilation (Vl) in patients with respiratory failure, and when used chronically leads to lowered and more stable arterial Pco2. The present study was designed to measure the effect of increasing AI flowrate on Vb and other aspects of gas exchange in respiratory failure in order to examine the hypothesis that AI exerts its main physiologic effect by progressive reductions of Vb. Five patients with varying degrees of respiratory failure caused by either restrictive or obstructive lung disease were studied by means of the specialized techniques we developed to analyze gas exchange during AI. At 1 L/min (as in transtracheal oxygenation), at 5 L/min, and at 8 L/min, AI produced progressive reductions in Vb, tidal volume, and Vl. Contrary to our previous study, some of these patients accompanied the decrease in Vb with not only decreases in Vl but with slight rises in alveolar ventilation (Va) and decrements in arterial Pco2. The greatest percentile decreases in Vb and Vl occurred in those with the smallest initial control values for each of these parameters. In summary, AI exerts its main effects on gas exchange through the reductions in Vb that it produces, and the accompanying decreases in Vl and or slight increases in Va seem to stem from the latter.

120
More hope for infants with RDS*  
More proof of effectiveness  
More experience
The proven efficacy and impressive safety profile of the first protein-free, synthetic lung surfactant

Exosurf® NEONATAL™
(Colsosceril Palmitate, Cetyl Alcohol, Tyloxapol) For Intratracheal Suspension/10-mL vial

Controlled clinical trials with EXOSURF Neonatal showed “dramatic reductions” in morbidity and mortality of infants with RDS. Subsequent use under a year-long Treatment IND confirmed its efficacy and impressive safety profile. Since release for marketing in August 1990, widespread use in hospitals across the United States has further established its value in the treatment of RDS. The weight of clinical experience is in favor of EXOSURF Neonatal.

**Dramatic reductions in neonatal morbidity and mortality reported in clinical trials**

Improvement in clinical outcome after EXOSURF Neonatal has been significant in infants at risk of developing RDS as well as those with established RDS. Prophylactic as well as rescue treatment with EXOSURF Neonatal has dramatically reduced morbidity and mortality in infants weighing greater than 700 grams.

**SIGNIFICANT REDUCTIONS IN OVERALL MORTALITY FROM ANY CAUSE IN MIDDLE-SIZE AND LARGE INFANTS**

<table>
<thead>
<tr>
<th>Age</th>
<th>Prophylactic treatment</th>
<th>Rescue treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤10 Days</td>
<td>Single Dose 700-1100 grams (N=446)</td>
<td>One vs Three Doses 700-1100 grams (N=716)</td>
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<tr>
<td>≤28 Days</td>
<td>40%*</td>
<td>44%*</td>
</tr>
<tr>
<td>≤1 Year</td>
<td>44%*</td>
<td>41%*</td>
</tr>
</tbody>
</table>

*P<0.05. N=Number of infants enrolled in the clinical trials.

A single prophylactic dose of EXOSURF Neonatal reduced 1-year mortality by 44%. Two additional prophylactic doses provided an additional 41% reduction in 1-year mortality.

**SIGNIFICANT REDUCTIONS IN MORTALITY FROM RDS IN MIDDLE-SIZE AND LARGE INFANTS**

<table>
<thead>
<tr>
<th>Reducing in death from RDS</th>
<th>Prophylactic treatment</th>
<th>Rescue treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Single Dose 700-1100 grams (N=446)</td>
<td>Two Dose 700-1350 grams (N=419)</td>
</tr>
<tr>
<td></td>
<td>58%*</td>
<td>66%*</td>
</tr>
</tbody>
</table>

*P<0.01. N=Number of infants enrolled in the clinical trials.
Rapid onset of action documented in rescue use

Improvements in mean FiO₂ and mean alveolar-arterial PO₂ (A-a) gradient were present by 2 hours after dosing in middle-size babies (700-1350 grams). Improvements in mean airway pressures began sometime between 2 and 6 hours in middle-size babies. These improvements persisted for at least 7 days.
Efficacy and impressive safety profile of EXOSURF® Neonatal confirmed in continued widespread use.

In North American controlled clinical trials, more than 2600 premature infants received EXOSURF Neonatal. Under the year-long Treatment IND, over 11,400 infants received EXOSURF Neonatal. In the six months following its release for marketing, EXOSURF Neonatal has been given to 10,000 infants in more than 750 hospitals.

There are no known infectious or immunologic risks associated with EXOSURF Neonatal use. In controlled clinical trials, adverse events were comparable to those of placebo, with the exception of apnea and pulmonary bleeding. Infants receiving EXOSURF Neonatal required less ventilatory support, possibly contributing to an increased incidence of apnea. Pulmonary bleeding occurred in 1% of control infants and 2% of treated infants in controlled trials. In the treatment IND, pulmonary bleeding was reported in 4% and mucous plugging at a rate of 3/1000. Pulmonary bleeding appears to be preventable with early diagnosis and appropriate treatment of patent ductus arteriosus.

One-year follow-up evaluated developmental outcomes.

Double-blind 1-year follow-up of more than 1450 infants enrolled in randomized trials showed that mental and motor scores appeared to be higher in tiny infants (<750 grams) as well as middle-size infants (750-1249 grams) who received Exosurf Neonatal.

Economic data analysis showed cost savings.

Three separate studies evaluated the economic impact of a single prophylactic dose of EXOSURF Neonatal, two-dose rescue treatment in 700- to 1350-gram infants, and two-dose rescue treatment during the neonatal period in infants weighing over 1350 grams. Results indicate that both prophylactic treatment and rescue treatment are cost-effective. Mean hospital charges were $6451 less for large infants receiving two-dose rescue treatment versus air in the first 28 days of life.

As easy to use as it is effective.

- **Easy to store and use** EXOSURF Neonatal may be stored at room temperature. Reconstituted suspension may be maintained refrigerated or at room temperature for up to 12 hours. Key items needed for administration are supplied in one kit.

- **Easy to administer** Each EXOSURF Neonatal dose is administered in two 2.5-ml/kg half-doses without interrupting mechanical ventilation.

- **Easy on infant** To assist the distribution of EXOSURF Neonatal in the lungs, the infant is simply turned from midline position to the right after the first half-dose, and from midline position to the left after the second half-dose.

References:
Table 3. Safety Assessments—Prophylactic Treatment

| Number of Doses | Birth Weight Range | Single Dose | 500 to 749 grams | 750 to 1,500 grams | 1,500 grams and above
<table>
<thead>
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<tbody>
<tr>
<td>Treatment Group</td>
<td>Number of Infants</td>
<td>Exosurf</td>
<td>Exosurf</td>
<td>Exosurf</td>
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- **% of infants**
- **% of infants**

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<th>Prophylactic Treatment</th>
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<td>Exosurf</td>
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</table>

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<tr>
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</table>

Table 4. Safety Assessments—Rescue Treatment

| Number of Doses | Birth Weight Range | Single Dose | 500 to 749 grams | 750 to 1,500 grams | 1,500 grams and above
<table>
<thead>
<tr>
<th></th>
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<td>Number of Infants</td>
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- **% of infants**
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<th>2nd Dose (mL/kg)</th>
<th>3rd Dose (mL/kg)</th>
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Table 5. Events During the Open, Uncontrolled Study

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<th>Treatment Type Number of Infants</th>
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<td>Reflux of Exosurf</td>
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<tr>
<td>Droop in O₂ saturation (&gt; 20%)</td>
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<td>Reflux in O₂ saturation (&gt; 5%)</td>
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<td>30</td>
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<tr>
<td>Reflux in O₂ saturation (&gt; 0.1%)</td>
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<td>Reflux in O₂ saturation (&gt; 0.000000001%)</td>
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The decision to prescribe or withhold isoniazid (INH) preventive therapy for low-risk tuberculin reactors has been highly controversial, primarily due to isoniazid’s possible hepatotoxic effects. Previous analyses have explored the INH decision only from the perspective of patient age, recognizing that the risks of INH-induced hepatotoxicity are age related. Decision analyses presented in this paper assess the impact of gender and ethnic group, as well as age, on the INH decision. Results for low-risk patients favor prescribing INH preventive therapy for all 20-yr-olds, all 35-yr-olds except black women, and no 50-yr-olds, projecting life expectancy benefits that range from 3 to 19 days. A comparison set of analyses performed for high-risk patients favors prescribing INH for all groups except 50-yr-old black women. These findings suggest that ethnicity, gender, and age should be considered when making the decision to prescribe or withhold INH preventive therapy.


The effect of skin pigmentation on the reliability of noninvasive oximetry, especially during exercise and hypoxia, has not been thoroughly investigated. This is the first study, to our knowledge, that specifically addresses this question. Thirty-three young Black men performed multi-stage, steady-state cycle ergometry, breathing gas mixtures simulating different altitudes: 33 breathed gas simulating sea level (P_{O2} = 146 torr), 11 breathed gas simulating 2,300 m (P_{O2} = 110 torr), and 22 breathed gas simulating 4,000 m (P_{O2} = 85 torr). CO-oximeter S_{O2} determinations were performed in arterial blood samples obtained concurrently with ear oximetry that was measured using Hewlett-Packard 47201A (HP) and Biox II A oximeters. The mean error or bias for the [HP – S_{O2}^o] and for [Biox II A – S_{O2}^o] ± 95% CI were: at simulated sea level (S_{O2}^o > 96%): −0.4 ± 0.3% and 2.1 ± 0.3%; at simulated 2,300 m (range of S_{O2}^o: 89-94%): −0.8 ± 0.5% and 3.5 ± 0.9%; for simulated 4,000 m (range of S_{O2}^o: 75-84%): −4.8 ± 1.6% and 9.8 ± 1.8%, respectively. A better coefficient correlation was observed for all the pairs between S_{O2}^o versus HP (r = 0.94, p < 0.001, n = 279) than for the S_{O2}^o versus Binox IIA (r = 0.80, p < 0.001, n = 242). In conclusion, the HP oximeter appears to estimate S_{O2}^o more accurately than the Binox II A oximeter. The previously described overestimation for the Binox II A ear oximeter and the underestimation for the HP ear oximeter at low S_{O2}^o values in Whites is exaggerated in Blacks. Although noninvasive oximetry may be used to follow desaturation trends in Blacks, it would be unreliable to estimate absolute S_{O2}^o. The clinical utility of noninvasive oximetry in Blacks is unacceptable at values of S_{O2}^o ≤ 85% for the HP and < 90% for the Binox II A oximeters. The effect of skin pigmentation on the reliability of the many newer pulse oximeters requires further investigation.


Intermittent positive pressure ventilation administered nocturnally via a nasal mask has been associated with improvements in pulmonary function and symptoms in patients with restrictive ventilatory disorders. We hypothesized that nocturnal nasal ventilation (NNV) would bring about similar improvements in patients with severe chronic obstructive pulmonary disease (COPD). The study used a randomized, crossover design, with subjects undergoing NNV or “standard care” for sequential 3-month periods. Of 23 patients with obstructive lung disease and a FEV<sub>1</sub> < 1 L who were initially enrolled, 4 were excluded because of obstructive sleep apnea prior to randomization. Among the remaining 19 patients, 7 withdrew because of intolerance of the nose mask, 5 were withdrawn because of intercurrent illnesses, and 7 completed both arms of the protocol. These latter 7 patients used the ventilator for an average of 6.7 h/night, and 3 of the 7 had partial relief of dyspnea during ventilator use. However, in comparison with studies performed upon initiation or after the standard care arm of the study, studies performed after 3 months of NNV revealed no improvements in pulmonary function, respiratory muscle strength, gas exchange, exercise endurance, sleep efficiency, quality or oxygenation, or dyspnea ratings. The only improvements observed were in neuropsychological function, possibly related to a placebo effect or another unknown mechanism. Despite the small sample size, our study indicates that NNV is not well tolerated by and brings about minimal improvements in stable outpatients with severe COPD.

Treatment of Severe Cardiogenic Pulmonary Edema with Continu-

BACKGROUND: The nature of the toxic gases that cause death from smoke inhalation is not known. In addition to carbon monoxide, hydrogen cyanide may be responsible, but its role is uncertain, because blood cyanide concentrations are often measured only long after exposure. METHODS: We measured cyanide concentrations in blood samples obtained at the scene of residential fires from 109 fire victims before they received any treatment. We compared the results with those in 114 persons with drug intoxication (40 subjects), carbon monoxide intoxication (29 subjects), or trauma (45 subjects). The metabolic effect of smoke inhalation was assessed by measuring plasma lactate at the time of admission to the hospital in 39 patients who did not have severe burns. RESULTS: The mean (±SD) blood cyanide concentrations in the 66 surviving fire victims (21.6 ± 36.4 μmol/L, p < 0.001) and the 43 victims who died (116.4 ± 89.6 μmol/L, p < 0.001) were significantly higher than those in the 114 control subjects (5.0 ± 5.5 μmol/L). Among the 43 victims who died, the blood cyanide concentrations were above 40 μmol/L in 32 (74%), and above 100 μmol/L in 20 of these (46%). There was a significant correlation between blood cyanide and carbon monoxide concentrations in the fire victims (p < 0.001). Plasma lactate concentrations at the time of hospital admission correlated more closely with blood cyanide concentrations than with blood carbon monoxide concentrations. Plasma lactate concentrations above 10 mmol/L were a sensitive indicator of cyanide intoxication, as defined by the presence of a blood cyanide concentration above 40 μmol/L. CONCLUSIONS: Residential fires may cause cyanide poisoning. At the time of a patient’s hospital admission, an elevated plasma lactate concentration is a useful indicator of cyanide toxicity in fire victims who do not have severe burns.
Aerochamber®
The Ultimate Aerosol Delivery Solution

The Only Family of Aerosol Holding Chambers for Expanded Applications of MDI Aerosols

"Deposition of aerosol from an MDI with a spacer or holding chamber is similar to (and perhaps better than) deposition from a properly used MDI alone."
Aerosol Consensus Statement, Respiratory Care, Sept.'91, Vol. 36 No. 9

"In general, ... holding chamber) is the most convenient, versatile and cost-effective way to deliver aerosols."
Aerosol Consensus Statement, Respiratory Care, Sept.'91, Vol. 36 No. 9

"MDIs can be used effectively in children. However, because of the inability of many pediatric patients younger than 10 years of age to coordinate the actuation of the MDI, a holding chamber should always be used. A holding chamber with mask should be used in those less than 3 years of age."
Aerosol Consensus Statement, Respiratory Care, Sept.'91, Vol. 36 No. 9

"... a holding chamber should be used with inhaled steroids for pediatric patients of any age."
Aerosol Consensus Statement, Respiratory Care, Sept.'91, Vol. 36 No. 9
The Aerosol Consensus Statement of the AARC, the NIH expert panel and practitioners of respiratory care have established new *community standards* for the use of Metered Dose Inhaler aerosol treatments and therapy.

Monaghan Medical Corporation has been the industry pioneer of advancements in MDI aerosol therapy and today represents the ultimate MDI aerosol delivery solution. The Aerochamber® family of holding chambers is the most advanced and clinically proven MDI delivery system with a comprehensive range of aerosol holding chambers specifically designed to meet the individual needs of your patients.

Aerochamber® MDI aerosol delivery system is the most extensive and the only line of aerosol holding chambers available for adults, children, infants and ventilated patients or those with limited coordination.

"MDI holding chambers also eliminate the need to coordinate actuation and inhalation."  
Aerosol Consensus Statement, Respiratory Care, Sept.'91.  
Vol. 36 No. 9

"This study has demonstrated that a MDI plus aerosol holding chamber delivers a nearly fivefold greater dose of aerosolized drug to the lungs in comparison with a jet nebulizer in patients receiving mechanical ventilation."  
H.D. Fuller, M.B. Dolovich, G. Posmituck, W. Wong Pack, and M.T. Newhouse

"The Aerochamber and MDI appears to be a highly efficient method of budesonide delivery to ventilated infants."  
J. Grigg, et al Hammersmith Hospital, London, England
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  - Electrolyte/hematocrit

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Rugged and powered by 2 alkaline "C" cells, the MiniCAP III works well in a broad range of prehospital and clinical situations. Don't rely on breath sounds, chest rise, or disposable chemical-type detectors to verify proper tube placement. For more information on the MiniCAP III, call: 1-800-672-4678 Ext. 8826

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A Cart To Provide High Frequency Jet Ventilation during Transport of Neonates

John Scuderi RRT, Cecelia B Elton RRT, and Donald R Elton MD

We report the evaluation of a cart we created to provide high frequency jet ventilation (HFJV) to neonates during intrahospital or interhospital transport. DESCRIPTION: The cart carries a conventional ventilator, jet ventilator (JV), incubator, gas blender, 3 F cylinders of oxygen and 2 of air, uninterruptible electric power supply (UPS), 2 syringe infusion pumps, cardiac monitor, and oximeter. EVALUATION METHODS: To determine the available operating time of the ventilators, we ran tests with 60% and 100% oxygen, high and low ventilator settings, 2.5-mm and 3.5-mm endotracheal tubes, and lung simulator set for low and high time constants. With five different combinations of these variables, the system was run to exhaustion of its gas supply. To determine the operating time limit of the UPS, we used it to operate the JV until the low-battery alarm sounded. RESULTS: The UPS always provided electrical power for at least 2 hours. In no case did a single cylinder of oxygen fail to power the system for less than 20 min. Because the cart carries 3 cylinders of oxygen and 2 of air, under the conditions tested a minimum of 60 min of continuous operation, using 100% oxygen, should be available during those portions of transports when the system is away from hospital and ambulance bulk power sources and is dependent on its own UPS and E cylinders of gas. EXPERIENCE: We have used the cart on two occasions to transport a 30-week gestational age, 1-kg, HFJV-dependent infant, first from ICU to surgery, then to another hospital for cardiac catheterization. Total transport time was 3 hours; there were no problems. The cart has also been used to transport three patients between hospitals during ECMO, without HFJV. CONCLUSIONS: Our HFJV transport system is adequate to transport an HFJV-dependent infant during the 30 to 60 minutes that may elapse when the cart is away from ambulance or hospital sources of electricity and gas. Available operating time with an HFJV transport system should be estimated conservatively; when an infant is dependent on HFJV, it would be well to have aircraft backup in case of ambulance breakdown or other contingencies. (Respir Care 1992;37:129-136.)

Background

High frequency jet ventilation (HFJV) is used in neonates who are refractory to conventional ventilation, and it is also used for specific conditions, such as pulmonary interstitial emphysema, that might benefit from lower peak airway pressures than are normally associated with conventional ventilation.1,3

Patients being supported by HFJV may require transport within the hospital (internal transport) for surgery or cardiac catheterization, or transport to another medical facility (external transport) for services such as surgery or extracorporeal membrane oxygenation (ECMO). Because most patients on HFJV have failed on conventional ventilation, they might be harmed by a return to conventional ventilation during transport.2 For this reason, we constructed a transport cart that makes both conventional ventilation and HFJV available. This paper reports how this transport system is configured and the results of our testing of it.

Reprints: Donald Elton MD, 3207 Berkley Forest Dr, Columbia SC 29209-4111.
HFJV TRANSPORT CART

Description of Transport System

Basic Cart

The basis of the system is a stainless steel cart with two shelves, which was constructed in our hospital. Fully loaded, it weighs 475 lb (216 kg), and a hydraulic lifting device is needed to lift it into the ambulance. Most neonatal transport vans are equipped with such a lift, although weight-carrying capacities vary.

Equipment

Figures 1 and 2 show the front and back of the transport cart. Conventional ventilation is supplied by a Cavitron MVP-10 pressure-limited, time-cycled ventilator (CV), and HFJV is provided via a Bunnell Life Pulse high-frequency jet ventilator (JV). During HFJV, humidity is provided by a cartridge attached to the JV; no humidity is used with the CV during transport. The ventilators are configured to the patient’s airway as in Figure 3.

The cart also carries a transport incubator, an air-oxygen blender, a cardiac monitor, two syringe infusion pumps, a pulse oximeter, three E cylinders of oxygen, two E cylinders of air, and an unin-

---

*Suppliers of commercial products are identified in the Product Sources section at the end of the text.
Uninterruptible power supply (UPS) consisting of two 12-volt batteries, a DC-to-AC converter, and a built-in charger. This UPS provides 24 amperes of direct current that is converted to 117 volts of alternating current at up to 1,200 watts of power.

### Power Requirements

An infant transport can be visualized as having four segments: (1) stabilization at the referring nursery, (2) transport from the nursery to the ambulance, (3) transport in the ambulance, and (4) transport from the ambulance to the receiving intensive care unit (ICU). During Segment 1, the transport system can obtain electrical power and compressed gases from mainline sources in the hospital; and during Segment 3 it can obtain them from the cart’s UPS and H-size air and oxygen cylinders in the ambulance (additionally, electrical power can be obtained from a DC/AC inverter that runs off the main battery/alternator system of the ambulance, as well as from a gas-powered generator, if needed). However, during Segments 2 and 4, the transport system must be independent of outside sources of electricity and compressed gases. During these segments of a transport, the system depends entirely on the UPS and the E cylinders carried on the cart itself.

The E cylinders are attached to 50-psig output regulators connected to a manifold system that permits individual operation of each cylinder by virtue of the cylinder yoke on/off valve, as well as check valves in the high-pressure hoses connecting the cylinders to the blender (Fig. 4). Gas from the E cylinders is available, via the blender, to the ventilators. Each E cylinder contains approximately 622 liters of gas when full.4

The ambulance carries one H cylinder each of oxygen and air. The high-pressure hoses used with the E cylinders have standard DISS connections that are compatible with the H-cylinder regulators, making it simple during ambulance transport to use the larger cylinders and conserve the gas in the cart’s E cylinders for use during transport between the ambulance and hospitals. Each H cylinder contains approximately 6,900 liters of gas when full.4

### Cost

The cost of putting together the transport system is difficult to pin down because many of the parts were already available and internal labor was used for construction. We estimate that the materials for the empty cart cost about $400. The costs of the equipment can vary widely but would amount to several thousand dollars. It should be noted, however, that, except for the cart itself, the components

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**Abbreviations Used in this Paper**

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<thead>
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<th>Abbreviation</th>
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<td>AC</td>
<td>Alternating current</td>
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<tr>
<td>C</td>
<td>Compliance of the lung</td>
</tr>
<tr>
<td>CPAP</td>
<td>Continuous positive airway pressure</td>
</tr>
<tr>
<td>CV</td>
<td>Conventional ventilator</td>
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<tr>
<td>DC</td>
<td>Direct current</td>
</tr>
<tr>
<td>ECMO</td>
<td>Extracorporeal membrane oxygenation</td>
</tr>
<tr>
<td>ETT</td>
<td>Endotracheal tube</td>
</tr>
<tr>
<td>f</td>
<td>Frequency of breathing</td>
</tr>
<tr>
<td>HFJV</td>
<td>High frequency jet ventilation</td>
</tr>
<tr>
<td>IMV</td>
<td>Intermittent mandatory ventilation</td>
</tr>
<tr>
<td>J.V.</td>
<td>Intravenous</td>
</tr>
<tr>
<td>JV</td>
<td>Jet ventilator</td>
</tr>
<tr>
<td>P</td>
<td>Pressure</td>
</tr>
<tr>
<td>PEEP</td>
<td>Positive end-expiratory pressure</td>
</tr>
<tr>
<td>PIP</td>
<td>Peak inspiratory pressure</td>
</tr>
<tr>
<td>R</td>
<td>Resistance of the airway</td>
</tr>
<tr>
<td>TC</td>
<td>Time constant</td>
</tr>
<tr>
<td>ti</td>
<td>Inspiratory time</td>
</tr>
<tr>
<td>UPS</td>
<td>Uninterruptible power supply</td>
</tr>
</tbody>
</table>

---

![Fig. 4. Pneumatic diagram of transport system. JV—jet ventilator. CV—conventional ventilator. FIO2—air-oxygen blender.](image)
of the system do not have to be dedicated solely to use during transports.

Methods of Evaluation

While a successful HFJV transport has been reported, we felt a need to evaluate the safety and operating time capabilities of our transport system. The I.V. pumps, incubator, cardiac monitor, and oximeter all have their own independent batteries for power; these are rated for several hours of operation and are not ordinarily a factor in the available operating time of the system. The CV is gas powered, and the JV requires 117 volts AC. The primary indication of adequacy of the system is its ability to provide HFJV for the 30 to 60 minutes that the cart must be expected to operate away from the large supplies of electricity and gas available in hospitals and the ambulance.

The reliability of the equipment had already proven satisfactory in standard hospital usage, so the focus of our evaluation of the transport system was to learn how long it could provide ventilation under various conditions, including worst and best cases.

Evaluation Questions

We sought to discover what influences the following would have on the available operating time of the transport ventilators:

- 60% vs 100% oxygen supplied by the blender
- High ventilator settings (worst case) vs low settings (best case)
- Endotracheal tube (ETT) inner diameter of 2.5 vs 3.5 mm
- Lung simulator set for low time constant vs high time constant
- Back pressure against the CV circuit
- Capacity of the E cylinders of air and oxygen
- Capacity of the UPS

Test Setup

Both in our NICU and during transport, the CV and JV are set up as in Figure 3. To test the system, we used the same configuration, except that an infant lung simulator replaced the patient.

The ETT was mounted between the two ports of the lung simulator, with the proximal end of the ETT attached via its adapter, and the distal end attached via an adapter we created that simulates the position of the ETT in the trachea such that the distal end of the tube is not distorted, as it might be if another standard 9-mm tube adapter were used (Fig. 5).

![Fig. 5. Use of adapter for distal end of ETT to simulate ETT’s relationship to trachea. A—simulates glottis. B—end of ETT suspended inside trachea simulator.](image)

Ventilators

To test the gas requirements of the CV, we attached its oxygen inlet (which also supplies power to the ventilator’s fluidic control circuits) to a back pressure-compensated flowmeter set to flush, which was attached to a 50-psig oxygen source. By setting the flowmeter to flush, we allowed for a flow of 15 L/min or more, with pressurization up to 50 psig. The flow through the system can be read directly off the flowmeter supplying the ventilator in this manner. As long as the indicated flow was less than the flowmeter’s maximum flow (which is at least 15 L/min), we knew that the flowmeter was meeting the ventilator’s flow demands. We set a fixed flowrate of 4 L/min on the CV and varied the other settings to determine whether and to what extent they influenced the flow.
The high settings used for testing on the CV were PIP 40 cm H₂O, PEEP 3 cm H₂O, frequency (f) 5 breaths/min, inspiratory time (t₁) 0.45 s. On the JV, they were PIP 50 cm H₂O, f 660 breaths/min, t₁ 0.02 s.

The low settings on the CV were PIP 30 cm H₂O, PEEP 3 cm H₂O, f 5 breaths/min, t₁ 0.45 s. On the JV, they were PIP 35 cm H₂O, f 440 breaths/min, t₁ 0.02 s.

To assess the effect of back pressure on the CV, we measured the resistance of the jet injector ports of 2.5-, 3.0-, and 3.5-mm ETTs by attaching the proximal end of each ETT to a known gas flow of 5 L/min and measuring the back pressure upstream required to deliver the preset flow of oxygen through the tube.

The JV is time-cycled and pressure-limited; we theorized that its gas consumption would be related to (1) the amount of time spent in the inspiratory mode and (2) the servo pressure required to meet the settings of the ventilator.

Lung Simulator

Because lung mechanics might influence gas consumption, we tested the available operating time of the system with the lung simulator set to two settings representing different time constants (TC). For the low TC, compliance (C) was 1 mL/cm H₂O and resistance (R) was 50 cm H₂O · s · L⁻¹. For the high TC, C was 5 mL/cm H₂O and R was 500 cm H₂O · s · L⁻¹.

Mechanism of Failure of Gas Power

We conducted several tests that allowed the system to run to exhaustion of the gas supply so we could document the mechanism of failure and note any warning there might be of impending system failure.

We determined that an E cylinder’s realistic time of exhaustion should be when the cylinder’s manometer showed 200 psig, as only a few minutes of gas pressure remain at this point, and the operating characteristics of the ventilators were not predictable at the time of actual exhaustion. Actual gas utilization was estimated by calculating the pressure change from full to 200 psig and multiplying this by the volume factor for the E cylinder, which is 0.283 L/psig, assuming that a full cylinder at 2,200 psig holds about 622 L of gas. During the trials, we noted both the JV servo pressure and the minimum lung pressure (auto-PEEP level) as detected on the lung simulator manometer. Available operating time afforded by the cart’s gas supply was tested by running the system from full to 200 psig on the E cylinders. The four variables—high vs low ventilator settings, 100% vs 60% oxygen, high vs low TC, and 2.5-mm vs 3.5-mm ETTs—were each tested with the other three variables held constant. We theorized that the worst case from an operating time standpoint would be high ventilator settings, 100% oxygen, low TC, and the 3.5-mm ETT. This combination of conditions was used as the control for varying each of the four variables tested, which resulted in five trials of available operating time. One E cylinder of oxygen was used for each 100% oxygen test, and one E cylinder each of oxygen and air was used in the 60% oxygen test.

Mechanism of Failure of Electrical Power

The available operating time afforded by electrical power was measured by operating the JV from the UPS until the low-battery alarm sounded; the time elapsing between the alarm and ventilator failure was also noted.

Results

Exhaustion of Gas Supply

In tests of the available operating time afforded by the gas supply, the first indication of abnormal operation did not occur until the needle of the cylinder manometer was on the low stop. The first indication of low pressure was a gradual drop in peak pressure from the JV, which occurred approximately 1 to 2 min prior to absolute failure. The second finding was the sounding of the low-source-pressure alarm on the JV; it usually sounded after the PIP had fallen 5 to 10 cm H₂O from its set level. The third and final sign before complete failure was a failure to cycle or alteration in the set rate, of the CV; this finding was not consistent across trials.
Because the manometers on our cylinders had no markings below 200 psig, we chose the 200-psig level as the indication to change to another cylinder, as at 200 psig there were about 2 minutes worth of gas remaining, which gave adequate time to turn the valves without any danger of ventilator malfunction.

The studies of gas utilization revealed that low ventilator settings resulted in a 3.3% higher gas utilization than did high ventilator settings; using 60% oxygen resulted in a 12.2% higher gas utilization than did using 100% oxygen; a low time constant resulted in a 3.7% higher gas utilization than did a high time constant; and using a 3.5-mm ETT resulted in an 8% higher gas utilization than did using a 2.5-mm ETT. The available operating time varied from a low of 20.5 minutes (high ventilator settings, 100% oxygen, high TC, 3.5-mm ETT) to a high of 35.95 minutes (high ventilator settings, 60% oxygen, low TC, 3.5-mm ETT) (Table 1).

Exhaustion of Electrical Power Supply

In testing the UPS, we found that its low-power alarm sounded 2 minutes before total power failure. The available operating time based on the electrical power from the UPS varied from 2 to 3 hours and was dependent upon the time of charging prior to use, but this was not absolutely reproducible. In no instance did the UPS fail to operate for at least 2 hours, but this was after overnight charging.

**CV Flow Demand**

With the CV set to a flowrate of 4 L/min and in the CPAP mode (no cycling) and PIP at its minimum values, the CV drew 9 L/min from the source flowmeter, indicating that the fluidics drew 5 L/min as a minimum at a CV flow rate of 4 L/min. When the CV was set to an IMV rate, flow demand jumped to about 15 L/min during early inspiration and fell back to baseline during expiration. If inspiratory time was prolonged beyond 0.8 s, the flow requirement dropped from the initial 15 L/min to 12 L/min, suggesting an initial burst of flow required by the fluidics to change the mode from expiration to inspiration. Changing the PIP from its minimum to its maximum value added at most 2 L/min to the flow requirements.

Back pressure from ETTs did not significantly influence the CV's flow requirements. The resistances of the 2.5-, 3.0-, and 3.5-mm ETT injector ports were 840, 540, and 240 cm H₂O·s·L⁻¹, respectively, when measured at a constant flow of 5 L/min.

From these studies, one can surmise that total flow requirements for the CV derive from the set

<table>
<thead>
<tr>
<th>Trial No.</th>
<th>Ventilator Setting</th>
<th>Oxygen Setting</th>
<th>Time Constant</th>
<th>ETT Size (mm)</th>
<th>P (psig)</th>
<th>Gas Used (L)</th>
<th>Time (min)</th>
<th>Flowrate (L/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>High</td>
<td>100%</td>
<td>Low</td>
<td>3.5</td>
<td>1,850</td>
<td>524</td>
<td>21.32</td>
<td>24.6</td>
</tr>
<tr>
<td>2</td>
<td>High</td>
<td>100%</td>
<td>Low</td>
<td>2.5</td>
<td>1,950</td>
<td>552</td>
<td>24.43</td>
<td>22.6</td>
</tr>
<tr>
<td>3</td>
<td>High</td>
<td>100%</td>
<td>High</td>
<td>3.5</td>
<td>1,850</td>
<td>524</td>
<td>20.50</td>
<td>25.5</td>
</tr>
<tr>
<td>4</td>
<td>Low</td>
<td>100%</td>
<td>Low</td>
<td>3.5</td>
<td>2,000</td>
<td>566</td>
<td>22.30</td>
<td>25.4</td>
</tr>
<tr>
<td>5</td>
<td>High</td>
<td>60%</td>
<td>Low</td>
<td>3.5</td>
<td>3,900</td>
<td>1,104</td>
<td>35.95</td>
<td>30.7</td>
</tr>
</tbody>
</table>

*With one E cylinder of oxygen as source gas in the 100% oxygen trials, and one E cylinder of oxygen and one of air in the 60% oxygen trial.

Ventilator settings:
- High settings—3V: PIP 50 cm H₂O, f 60/60/min, t 0.02 s,
  - CV: PIP 40 cm H₂O, t 0.05 s, PEEP 3 cm H₂O.
- Low settings—3V: PIP 35 cm H₂O, f 440/440/min, t 0.02 s,
  - CV: PIP 30 cm H₂O, f 5/min, t 0.45 s, PEEP 3 cm H₂O.

Time constants:
- High: Resistance 500 cm H₂O·s·L⁻¹; compliance 5 mL/cm H₂O.
- Low: Resistance 50 cm H₂O·s·L⁻¹; compliance 1 mL/cm H₂O.
flow, plus a relatively fixed fluidic drain, plus the flow required during inspiration, which is directly related to inspiratory time multiplied by respiratory rate.

Effects of Lung Simulator Settings (Table 2)

As expected, the servo pressures were lower as R increased on the lung simulator; they were also lower with a smaller ETT. Interestingly, the change to a smaller ETT had a greater impact on lung pressure (auto-PEEP) than did changes in the R set on the lung simulator. Changes in C from 1 to 5 mL/cmH₂O did not significantly affect lung pressure or servo pressure.

Table 2. Effects of Lung Simulator on Servo and Lung Pressures

<table>
<thead>
<tr>
<th>Resistance (cm H₂O · s · L⁻¹)</th>
<th>50</th>
<th>100</th>
<th>200</th>
<th>500</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>With 3.5-mm ETT, high ventilator settings, compliance 1 mL/cm H₂O</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Servo pressure</td>
<td>8.4</td>
<td>6.4</td>
<td>5.6</td>
<td>4.9 psig</td>
</tr>
<tr>
<td>Lung pressure</td>
<td>20</td>
<td>15</td>
<td>13</td>
<td>14 cm H₂O</td>
</tr>
<tr>
<td><strong>With 2.5-mm ETT, low ventilator settings, compliance 1 mL/cm H₂O</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Servo pressure</td>
<td>7.4</td>
<td>5.8</td>
<td>5.1</td>
<td>4.1 psig</td>
</tr>
<tr>
<td>Lung pressure</td>
<td>32</td>
<td>26</td>
<td>23</td>
<td>20 cm H₂O</td>
</tr>
<tr>
<td><strong>With 3.5-mm ETT, high ventilator settings, compliance 5 mL/cm H₂O</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Servo pressure</td>
<td>8.3</td>
<td>6.1</td>
<td>5.4</td>
<td>4.7 psig</td>
</tr>
<tr>
<td>Lung pressure</td>
<td>20</td>
<td>16</td>
<td>14</td>
<td>15 cm H₂O</td>
</tr>
<tr>
<td><strong>With 2.5-mm ETT, high ventilator settings, compliance of 5 mL/cm H₂O</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Servo pressure</td>
<td>7.0</td>
<td>5.7</td>
<td>5.0</td>
<td>4.1 psig</td>
</tr>
<tr>
<td>Lung pressure</td>
<td>35</td>
<td>26</td>
<td>24</td>
<td>20 cm H₂O</td>
</tr>
</tbody>
</table>

Available Operating Time

In no case did a single E cylinder fail to power the transport system for less than 20 minutes. Since the cart carries three cylinders of oxygen and two cylinders of air, under the conditions tested it appears that a minimum of 60 minutes of continuous operation (using 100% oxygen) can be provided by the cart’s gas supply. If a lower oxygen concentration is used, the operating time will be increased. With electrical power from the UPS available for at least 2 hours, the cart met our requirement for 30 to 60 minutes of independent operating time.

Clinical Experience

We have used our HFJV transport cart on two separate occasions. Both transports involved a 30-week gestational age (estimated) infant who weighed 1 kg. The patient was placed on HFJV for refractory hypercarbia but required surgery. Because we were unable to wean him from HFJV, we decided to transport him to surgery with our cart. The ventilator settings were PIP 24 cm H₂O, t 420 breaths/min, t; 0.02 s, 60% oxygen by JV—and PIP 20 cm H₂O, PEEP 3 cm H₂O, t 10 breaths/min, t; 0.50 s, 60% oxygen by CV. During surgery, structural abnormalities were found; the patient was then referred to another institution for cardiac catheterization, and he was transported with the cart. Total time of the transport was 3 hours. The cart has also been used to transport three patients between hospitals during ECMO, without HFJV. No problems were experienced in connection with any of these transports.

Discussion

Not mentioned in our description of the system were the backup resources that we employ. In case of CV failure, we carry a manual resuscitator with a PEEP valve. In case of blender failure, we can supply the ventilators directly from the cylinders. If a regulator fails, any of the other four can be used (there is a regulator for each gas cylinder), and the system can be operated from a single cylinder of oxygen if necessary. In case of a patient-box failure, we carry a spare. We have no redundancy for the JV. and this means that careful consideration must be given to whether a given patient could survive without HFJV. If not, possibly the transport should not be attempted. While in more than 10,000 hours of HFJV time in our ICU we have had only one ventilator failure, that one failure shows that the risk is real.
Our method of determining gas utilization was based on measuring the time required to lower the pressure in a cylinder of gas from its ‘full’ value (generally 2,000-2,200 psig) to 200 psig. The manometers on the regulators are marked every 100 psig from 200 psig upward. We felt that we could judge cylinder pressure within 50 psig, which over a range of 2,000 psig would give an expected degree of precision of 2.5% if we made a 50-psig error in a reading of the gauge. Other potential sources of error include the possibility of inaccurate calibration of the cylinder pressure gauge at the factory, especially as they are seldom recalibrated in use. We have observed differences of as much as 150 psig between the readings of two regulators attached sequentially to the same cylinder. Yet another source of error could be inconsistent filling of cylinders; in our study, we noted that ‘full’ pressures varied from 2,050 to 2,200 psig. There may also be some wastage of gas during cylinder changes. Because of these sources of error, we feel that the calculated differences of oxygen utilization of less than 10% are probably not important. This would indicate that the changes in gas utilization caused by changes in ETT size, ventilator settings, and lung characteristics also are probably not important.

In Summary

While our study did not show important changes in gas utilization resulting from changes in ventilator settings, it should be noted that increases in the set flowrate, inspiratory time, and rate of conventional ventilation were not tested and could have important effects on the total gas requirements.

We recommend that available operating time be estimated conservatively and that H cylinders be available for use in the ambulance. It would also be a good idea to have aircraft backup in case of ambulance breakdown, traffic obstruction, and other contingencies.
Application Form Items as Predictors of Performance and Longevity among Respiratory Therapists: A Multiple Regression Analysis

Patti Gurza-Dully MS and Margaret Melaney MS RRT

BACKGROUND: Errors in employee selection and consequent high turnover rates are expensive and can result in poor staff morale and possible harm to patients and personnel. METHOD: We investigated the predictive validity of commonly used application blank items as measures of future performance, absenteeism, tardiness, and tenure (the criterion variables) among 100 hospital-employed respiratory therapists and looked at the relationships among the criterion variables. RESULTS: Regression analysis showed the most significant predictive variables to be grade point average in respiratory therapy school, college education in addition to respiratory therapy training (particularly an associate degree in health sciences or a baccalaureate degree), and, surprisingly, the neatness of the application form itself. No important differences were found among the types of respiratory therapy program attended or the length of previous respiratory therapy experience. CONCLUSION: The data offer cautious evidence for the validity of some application items to predict some employee behaviors. The relatively low correlations among the criterion variables (absenteeism, tardiness, tenure, and performance) suggest that these items may be assessing substantially different aspects of employee behavior. (Respir Care 1992;37:137-143.)

Background

The development of reliable employee selection devices has received attention from health care employers in recent years. Errors in selection, with a resulting loss of employees due to poor performance, and high turnover rates may have significant negative consequences for the organization. In addition, the high cost of recruiting and training health care workers makes selection errors particularly expensive.

In general, management literature tends to emphasize the financial consequences of selection error. Success has been expressed as the ratio of total cost of recruiting (TCOR) to the number of individuals hired (NH)—thus, gross cost per hire = TCOR/NH. Other criteria of success are reduction of time lost in recruiting and hiring and the fulfillment of legal requirements. However, the costs of selection errors in health care go beyond the financial considerations. Poor performance by an employee may result in physical harm to a patient, may put other workers at risk through careless technique, or may result in legal action against the organization. High turnover may lead to poor morale and inability to recruit qualified therapists. Lack of continuity due to high turnover may be most detrimental in departments, such as respiratory care, in which procedures, equipment, and job description may vary widely among hospitals. In addition, medical staff and patients may find lack of continuity among therapists to be an important negative consequence of poor selection.

The application blank has been found by some to be the selection device with the most predictive
validity. A number of studies have reported the development of weighted application blanks as predictors of turnover, absenteeism, rate of salary increase, and performance. The advantages of these selectors are (1) the ease of development, (2) low cost, (3) potentially high predictive validity, (4) accessibility of database, and (5) verifiability of accuracy of the information.

The primary purpose of our study was to investigate the predictive validity of commonly used application blank items as measures of future performance, absenteeism, tardiness, and tenure (the criterion variables) among hospital-employed respiratory therapists and to study the relationship among the criterion variables to determine the extent to which they reflect separately predictable employee behaviors. Unlike a retrospective study, in which past behaviors are inferred from currently measured behaviors (opinions, reminiscences), a predictive analysis uses data generated both before and after the event. In this study, the data are the predictor and criterion values, and the event is the start of employment.

**Method**

**Subjects**

Subjects consisted of 100 respiratory therapists currently or previously employed in a hospital setting and hired before November 1987. The only other requirements were that the employee had been hired from outside Stanford University Hospital and had worked long enough to have received a performance evaluation (about 6 months). All data were recorded by code number known only to authorized personnel in order to protect employee confidentiality. An approximation of a simple random sampling model was used, in which subjects were drawn from an alphabetic file of employee records. Because of the large number of records, every second file drawer (containing about 30 records) was used. Subjects were accepted into the study if they met the inclusion criteria. Selection continued until 100 subjects had been identified.

**Prediction Data**

Items selected for inclusion as predictors were taken from the subject’s employment application: (1) sex, (2) previous employment in the hospital, (3) type of respiratory therapy (RT) program (1-year, 2-year, job-training, baccalaureate, technician, or accelerated), (4) reported RT program grade point average (GPA), (5) length of previous experience in RT, (6) reason for leaving previous job (coded as positive, negative, or medical), (7) gap in employment after last job, (8) appearance of application (coded as typed, neat, or sloppy), (9) other education (high school, associate degree in health science [AA-HS], other associate degree [AA], baccalaureate in any discipline [BA], master’s degree [MA/MS], some college, or doctor of medicine [MD]).

These items are similar to items used in other studies of employee performance. They were selected because they could be assigned a score, and they appeared on all applications. Reason for leaving previous job was coded “negative” for any indication of employee dissatisfaction. Application was coded “sloppy” for more than one misspelling or crossout or more than three items missing and not covered by a résumé. All predictor scores were assigned independent of any knowledge of criteria ratings. Table 1 summarizes the sample demographics.

**Criteria Measures**

The items selected as criterion variables (the variables to be predicted) were (1) absenteeism rating, (2) tardiness rating, (3) employee performance rating, and (4) length of employment (tenure) in years. These items were selected on the basis of research that suggests that they are reliable indicators of desired behavior. In addition, little correlation between performance and turnover and between absenteeism and turnover has been reported, making them fairly independent measures. Each of the items was coded in real numbers, with length of employment expressed in years. The range of possible scores for absenteeism and tardiness was 0 to 20, with 20 being the most favorable rating. The performance rating was independent of absenteeism and tardiness, with a maximum possible score of 470. The forms used for ratings were those routinely used for employee evaluation.
APPLICATIONS AS PREDICTORS

Table 1. Demographics of 100 Subjects Comprising Study Group To Determine Performance and Longevity

<table>
<thead>
<tr>
<th>Variable</th>
<th>Count</th>
<th>Percent</th>
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</thead>
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<td></td>
</tr>
<tr>
<td>1-year</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>2-year</td>
<td>62</td>
<td>62</td>
</tr>
<tr>
<td>OJT*</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Baccalaureate</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Technician</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Accelerated</td>
<td>9</td>
<td>9</td>
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<tr>
<td>Highest educational level attained</td>
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<td></td>
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<td>MD</td>
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<td>65</td>
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<tr>
<td>Male</td>
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<td>35</td>
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<tr>
<td>GPA</td>
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<tr>
<td>Mean</td>
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</tr>
<tr>
<td>SD</td>
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</tr>
<tr>
<td>Range</td>
<td>2.4</td>
<td></td>
</tr>
<tr>
<td>Experience (years)</td>
<td>1.43</td>
<td></td>
</tr>
</tbody>
</table>

*OJT = on-job training.

Table 2. Mean, Standard Deviation, and Range for the Four Criterion Variables

<table>
<thead>
<tr>
<th>Element</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absence*</td>
<td>15.3</td>
<td>4.5</td>
<td>4-20</td>
</tr>
<tr>
<td>Tardiness*</td>
<td>18.0</td>
<td>3.7</td>
<td>4-20</td>
</tr>
<tr>
<td>Performance†</td>
<td>378</td>
<td>31</td>
<td>251-425</td>
</tr>
<tr>
<td>Tenure (years)</td>
<td>5.1</td>
<td>3.8</td>
<td>0.2-14</td>
</tr>
</tbody>
</table>

* Scored on a scale from 0-20, with 20 being most favorable.
† Scored on the basis of a scale from 0-430, with 430 being most favorable.

minimization for those predictors entered into the regression equation for each criterion variable. In cases in which it didn’t make sense to combine two variables (such as education), they were entered individually in simple regression equations.

The strongest relationship was between absenteeism and GPA (p < 0.01) (a higher GPA predicted fewer absences). GPA also showed up in the multiple regression equation on performance, in combination with the surprise predictor of the study, neatness of the application form (p < 0.05). Neatness alone was the strongest predictor of future performance (p < 0.01).

Because performance ratings tended to be grouped towards the high end of the rating scale, this variable showed a marked negative log-normal distribution (Fig. 1). A rotation using log (x + 1) to correct for skewness showed no appreciable difference in the F values obtained. In addition, the relatively low ratio of standard deviation to mean (0.08) for performance ratings suggests that such a transformation may not add much to the accuracy of the test.

Table 3. Correlation Matrix for the Four Criterion Variables

<table>
<thead>
<tr>
<th></th>
<th>Absence</th>
<th>Tardiness</th>
<th>Tenure</th>
<th>Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absence</td>
<td>1.0</td>
<td>0.419</td>
<td>1.0</td>
<td>-0.140</td>
</tr>
<tr>
<td>Tardiness</td>
<td>0.419</td>
<td>1.0</td>
<td>0.123</td>
<td>0.007</td>
</tr>
<tr>
<td>Tenure</td>
<td>-0.140</td>
<td>0.123</td>
<td>1.0</td>
<td>0.315</td>
</tr>
<tr>
<td>Performance</td>
<td>0.007</td>
<td>0.440</td>
<td>0.315</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Discussion

The results were surprising. We found fewer variables to be significant in predicting the criteria than we had expected from our own experience. In
### Table 4. Results of Simple and Multiple Regression Analysis for Criteria Ratings (Absence, Tenure, and Performance)

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Predictor Variable</th>
<th>$r^2$ *</th>
<th>p †</th>
<th>$\beta$ coefficient ‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absence</td>
<td>1-year</td>
<td>0.050</td>
<td>0.0262</td>
<td>-2.905</td>
</tr>
<tr>
<td></td>
<td>2-year</td>
<td>0.017</td>
<td>0.2038</td>
<td>1.209</td>
</tr>
<tr>
<td></td>
<td>BA</td>
<td>0.012</td>
<td>0.2857</td>
<td>1.800</td>
</tr>
<tr>
<td></td>
<td>Technician</td>
<td>0.039</td>
<td>0.0504</td>
<td>-4.532</td>
</tr>
<tr>
<td></td>
<td>Accelerated</td>
<td>0.002</td>
<td>0.6536</td>
<td>0.719</td>
</tr>
<tr>
<td></td>
<td>GPA</td>
<td>0.082</td>
<td>0.0078</td>
<td>2.796</td>
</tr>
<tr>
<td></td>
<td>Experience</td>
<td>0.004</td>
<td>0.5267</td>
<td>-0.146</td>
</tr>
<tr>
<td></td>
<td>Neatness</td>
<td>&lt; 0.001</td>
<td>0.9610</td>
<td>-0.088</td>
</tr>
<tr>
<td></td>
<td>AA-health</td>
<td>0.013</td>
<td>0.2652</td>
<td>-2.145</td>
</tr>
<tr>
<td></td>
<td>AA-other</td>
<td>0.008</td>
<td>0.3807</td>
<td>-1.841</td>
</tr>
<tr>
<td></td>
<td>BA-other</td>
<td>&lt; 0.001</td>
<td>0.6500</td>
<td>0.229</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
<td>0.002</td>
<td>0.6500</td>
<td>0.441</td>
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<td></td>
<td>GPA/experience§</td>
<td>0.093</td>
<td>0.0184</td>
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</tr>
<tr>
<td>Tenure</td>
<td>1-year</td>
<td>0.007</td>
<td>0.1986</td>
<td>1.421</td>
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<tr>
<td></td>
<td>2-year</td>
<td>0.006</td>
<td>0.4608</td>
<td>-0.584</td>
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<td>BA</td>
<td>0.027</td>
<td>0.0998</td>
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<td></td>
<td>Technician</td>
<td>0.053</td>
<td>0.0212</td>
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<td></td>
<td>Accelerated</td>
<td>0.010</td>
<td>0.3120</td>
<td>-1.357</td>
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<td></td>
<td>GPA</td>
<td>0.003</td>
<td>0.6276</td>
<td>0.440</td>
</tr>
<tr>
<td></td>
<td>Experience</td>
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<td>0.4610</td>
<td>-0.142</td>
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<tr>
<td></td>
<td>Neatness</td>
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<td>1.144</td>
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<td></td>
<td>AA-health</td>
<td>0.042</td>
<td>0.0400</td>
<td>3.296</td>
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<td></td>
<td>AA-other</td>
<td>0.024</td>
<td>0.1199</td>
<td>-2.732</td>
</tr>
<tr>
<td></td>
<td>BA-other</td>
<td>0.040</td>
<td>0.0480</td>
<td>2.006</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
<td>0.001</td>
<td>0.7844</td>
<td>0.221</td>
</tr>
<tr>
<td>Performance</td>
<td>1-year</td>
<td>0.004</td>
<td>0.5178</td>
<td>-5.929</td>
</tr>
<tr>
<td></td>
<td>2-year</td>
<td>&lt; 0.001</td>
<td>0.9516</td>
<td>-0.407</td>
</tr>
<tr>
<td></td>
<td>BA</td>
<td>&lt; 0.001</td>
<td>0.8573</td>
<td>2.108</td>
</tr>
<tr>
<td></td>
<td>Technician</td>
<td>0.001</td>
<td>0.745</td>
<td>5.277</td>
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<tr>
<td></td>
<td>Accelerated</td>
<td>0.001</td>
<td>0.8211</td>
<td>2.514</td>
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<tr>
<td></td>
<td>GPA</td>
<td>0.028</td>
<td>0.1245</td>
<td>12.036</td>
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<tr>
<td></td>
<td>Experience</td>
<td>0.005</td>
<td>0.4899</td>
<td>-1.105</td>
</tr>
<tr>
<td></td>
<td>Neatness</td>
<td>0.075</td>
<td>0.0075</td>
<td>32.703</td>
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<tr>
<td></td>
<td>AA-health</td>
<td>0.005</td>
<td>0.4954</td>
<td>9.120</td>
</tr>
<tr>
<td></td>
<td>AA-other</td>
<td>&lt; 0.001</td>
<td>0.9805</td>
<td>-0.357</td>
</tr>
<tr>
<td></td>
<td>BA-other</td>
<td>0.018</td>
<td>0.1902</td>
<td>11.090</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
<td>0.009</td>
<td>0.3632</td>
<td>6.121</td>
</tr>
<tr>
<td></td>
<td>GPA/neatness</td>
<td>0.095</td>
<td>0.0170</td>
<td></td>
</tr>
</tbody>
</table>

* $r^2$ = coefficient of determination.
† $p = < 0.05, p < 0.01$.
‡ Beta coefficient represents the slope of the regression equation. A negative number indicates an inverse relationship between the two variables.
§ Multiple regression with two variables (no $\beta$ coefficient).

In particular, we found no single, unifying factor that could account for variation among the predictors. None of the other studies reviewed found GPA to be a significant predictor.  

We had expected the type of RT program to be a factor in predicting performance. This was in part based on a study of nursing performance that shows a significant difference between diploma and baccalaureate school graduates in later performance ratings. We found no differences in performance among the graduates of technician, AA, baccalaureate, or accelerated programs. There was
APPLICATIONS AS PREDICTORS

Fig. 1. Frequency distribution of performance ratings.

a tendency (p < 0.05) for graduates of technician programs to score higher on tenure. Two other variables, AA-HS (p < 0.05) and BA (p < 0.05), were also significant in predicting tenure.

In summary, the regression data in Table 4 offer cautious evidence for the validity of some application items to predict some employee behaviors. Type of school is a better predictor of time an employee will stay in a job than it is of an employee’s performance. No one factor appeared in all four regression equations. In addition, the relatively low correlations among the criteria (Table 4) suggest that these items may be assessing substantially different aspects of employee behavior.

Selection Devices

Among the selection devices reviewed in the literature, standardized tests, work samples, interviews, written recommendations, weighted application blanks, and biographical inventories. Of these, interviews and application blanks are probably the most commonly used devices in respiratory care departments. Work samples are almost impossible to set up and control. The registry and certification exams are standardized tests, and for many departments a cutoff score (passing score) is required for employment. However, not all applicants may have taken credentialing examinations, and, further, the individual scores are generally not compared among applicants.

Interviews play a large part in employee selection in most departments. They perform several functions, the most important of which may be (1) allowing the applicant to ask questions and clarify responses, and (2) allowing assessment of the applicant’s communication skills. However, recent management literature describes the “track record” of employment interviews as “dismal” in predicting job performance.

There are probably as many interview techniques as there are employers who interview. Consequently, the reliability and validity of the interview varies widely among different interviewers, applicants, and job situations. When the interview is used as a basis for selection decisions, these issues must, legally, be addressed.

The issue of falsification is important in considering the use of application form items as predictors. In general, applicants tend not to falsify biographical data. The responses can be easily checked, and the risks seldom justify the deception. Although research into the rate of item falsification shows that such cases are rare, most employers prefer the use of verifiable, historical, and specific responses in order to obtain complete accuracy. This would preclude asking questions about future behavior, hypothetical situations, or general opinions. However, such questions are by no means useless because they may be found to have considerable discriminant validity in candidate selection.

Statistical Method

Simple and multiple regression were the statistical methods primarily used in this study. These differ from pure inferential statistics (such as Student’s t test or ANOVA) in that a null hypothesis is neither generated nor rejected, although significance of relationship is still calculated. Instead, the coefficient of determination (r²) reflects the percentage of variation in the criterion that is accounted for by the predictor, and, thus, the strength of the relationship. Multiple regression allows several predictors to be combined at once to produce an even stronger relationship. A perfect relationship is indicated by an r² of 1 and is represented by a straight line. In this study, an r² as small as 0.075 is significant at 0.007. We would probably not have found this with a smaller sample size.
Implications

Some tentative implications for employee hiring criteria can be identified from these data. First, it appears that it is hard to identify who will be a 'perfect' employee. Good performance is not always associated with longevity or a good attendance record. Although a moderate positive correlation exists between tenure and performance (r = 0.315), due either to improvement or halo effect, those whom we would like to have stay don't always do so, for whatever reason.

The present data also suggest that the best predictors of employee behavior are not the ones we would intuitively expect. When we talked with managers of RT departments, we found an overwhelming emphasis on interviews, education, and job experience in choosing among candidates. In addition, many departments have policies of not hiring new graduates or graduates of less than 2-year programs. As well as showing no relation between experience and performance, our data showed no difference on any of the predictors when the sample was divided into new graduates and those with experience (Fig. 2).

![Graph showing comparison of mean scores for new and old graduates on the four criterion variables (performance, absenteeism, tardiness, and tenure).](image)

Fig. 2. Comparison of mean scores for new and old graduates on the four criterion variables (performance, absenteeism, tardiness, and tenure).

Education, however, does influence behavior. We found that not just RT credentials but any degree above the high school level tends to predict tenure on the job. In particular, baccalaureates in any field and associates in other health sciences tended to stay longer. Our sample did not include enough subjects with master’s or doctoral degrees to reach significance for these levels.

Two of our findings were unexpected. We have no explanation for the relationship between graduation from a 1-year, or technician, program and a higher rate of absenteeism. We also suspect that a neat application is not a direct predictor of performance, but that there is a modifier variable at work here. It must be noted here that we are measuring a supervisor's evaluation of performance, which may be biased toward (or against) characteristics not related to 'true' performance.

As with any study, it must be remembered that significance levels are indicative of probabilities, not of proven relationships. Other studies, using different groups of subjects, would be necessary in order to draw widespread conclusions from these results. In addition, we have made no attempt to make cause and effect judgments about our data. In dealing with employees, a research design using control and experimental groups is generally impossible. The fact that education predicts tenure in no way implies that education causes tenure. We cannot take a group of employees, randomly select half of them to be educated, and then measure the results. We must be content with noting the relationship and recognize its value in predicting tenure without assuming we know the reason for the relationship. Although sometimes good guesses are possible, they remain guesses.

Many studies have attempted to look at causality, particularly in relation to attrition, and have provided useful guidelines for addressing unsatisfactory job situations that may lead to an employee’s desire to quit. Two caveats are in order here. The first is that employees’ stated perception of a situation (eg, desire to quit or dissatisfaction with the job) can never take the place of actual employee behavior (eg, quitting or absenteeism). The other is that retrospective analyses, such as exit interviews, which form the bulk of the research (“Why did the employee do that?”) are not substitutes for predictive analyses (“Will the employee do that?”). The two must complement each other, and the researcher must be alert for disparities in reported and observed behavior caused by the individual’s tendency to rationalize and report selectively.

In Conclusion

Further research on the subject of employee selection is needed. In particular, we would like to
see an evaluation of other predictor variables that have been developed by departments for the screening process. Among these would certainly be a weighted standardized interview checklist, with the ability to differentiate numerically among candidates on several variables. Such a device would have the advantage of an established content validity and could be a useful tool in a study of predictive validity.

REFERENCES


ADDITIONAL BIBLIOGRAPHY

Symposium Papers

New Horizons VII: What's New in the ICU?

David J Pierson MD

Last year, in introducing the five articles developed from the 6th annual New Horizons in Respiratory Care Symposium (presented in New Orleans at the 1990 AARC Annual Meeting), I discussed one of the most important, most difficult challenges facing those working in respiratory care: how to assess new developments in this exciting and fast-moving field. I pointed out that new machines and techniques are inevitably touted as important breakthroughs, and that clinicians tend to gain access to them before their efficacy, safety, and cost-effectiveness can be formally evaluated. Yet in most cases the so-called breakthrough proves ultimately to be not much different (although often more expensive) from what we had before—or even proves to be dangerous.

Respiratory care is about new devices and improvements in therapy. To restrict practitioners' access to these new devices and improvements would take a lot of the excitement out of the field. New devices and techniques continue to be presented to the clinician, who must decide somehow whether to buy them or try them on patients. At stake are the possibility of improved patient care but also money, personnel costs, patient safety, and the possibility of legal liability. The available database for making an informed decision tends to be pretty incomplete.

A main purpose of the "New Horizons" series is to help clinicians with such decisions. Realizing that it usually takes years for research on new devices and procedures to appear in print, and that most practitioners cannot subject such things to formal study in the course of their daily work, the originators of this series have attempted to provide the clinician-reader with articles to serve as more complete, objective sources of information than word of mouth, manufacturers' brochures, and initial anecdotal publications or research abstracts. The five review articles that follow are the latest installments in this continuing saga, the result of the 7th annual "New Horizons" symposium, held in Atlanta in December 1991. Once again, five leaders in the profession and some of their colleagues have been challenged to examine a series of cutting-edge developments in ICU care, to eschew the biases that come with advocacy, and to present the clinician with an objective basis for assessing them.

As with the topics of previous symposia, the objects of these reviews are of much current interest at the bedside, but no one knows whether they will turn out to be true breakthroughs in assessment and management. Considered under the overall title of "What's New in the ICU?" are the following topics: the IVOX implantable intravenous oxygenator; monitoring mixed venous oxygenation; in vivo monitoring of arterial blood gases and pH; computerized ICU data collection, storage, and display; and "high tech" ICU beds for the prevention and treatment of a variety of diseases and complications.

Although very little has appeared in print about the IVOX, it was one of the hottest topics at this year's Annual Meeting—at least by my assessment of hallway and cocktail party conversation. The idea is exciting: being able to insert a device directly into the central circulation and administer oxygen directly into the blood of the patient with life-threatening hypoxia whose arterial blood cannot be adequately oxygenated with a high inspired oxygen fraction and positive end-expiratory pressure. This is different from extracorporeal membr-
brane oxygenation (ECMO), in which blood is removed from the patient, passed through an artificial lung, and then pumped back into the patient. The use of ECMO in adult respiratory failure was largely abandoned after a multicenter study showed it to be ineffective in improving survival among patients with severe respiratory failure.\(^2\) In neonatology, ECMO has attained greater popularity and utility,\(^3,4\) and even in adults a less extreme version of ECMO has reappeared in recent years.\(^5,6\)

The IVOX, however, is simpler and less invasive, at least in concept, than ECMO. In his article, "Intravenous Oxygenation and CO\(_2\) Removal Device: IVOX," Charles G Durbin Jr describes this device and what it is supposed to do, and summarizes the clinical data to date on its effectiveness.

The second paper in this year’s symposium series, “Monitoring Mixed Venous Oxygen,” by Loren D Nelson and Edmund J Rutherford,\(^8\) discusses the physiology of venous (as opposed to arterial) oxygenation, describes the various techniques now available for monitoring it, and points out the clinical advantages and disadvantages of each. While not exactly new, in the sense that it has been used by some clinicians ever since introduction of the pulmonary artery catheter, the monitoring of mixed venous oxygen tension, saturation, and content has become much more popular with the advent of new technology. With this technology has come the potential for better understanding and manipulation of oxygen delivery and utilization in critically ill patients, but also the opportunity for erroneous data collection, incorrect interpretation, and unnecessary increases in cost. Nelson and Rutherford describe the most common technical pitfalls and errors in interpretation in mixed venous oxygenation monitoring, and also provide practical guidelines for its application in the most clinically appropriate, cost-effective manner.

Pulse oximetry, transcutaneous PO\(_2\) and PCO\(_2\) monitoring, and the measurement of end-tidal gases all provide an assessment of oxygenation and/or ventilation, but each has technical and/or clinical limitations that prevent the accurate and continuous assessment of arterial blood gas (ABG) status. This is especially true in the management of critically ill adults. The gold standards remain the laboratory measurement of ABGs and pH, which can only be carried out intermittently and can be very expensive when performed often. Although prototype in-vivo ABG monitors were tested in the 1970s, they proved impractical and unreliable, and only now are systems becoming available that may fulfill the potential of this type of monitoring. In his review, “In-Vivo Monitoring of Arterial Blood Gases and pH,” Barry A Shapiro reviews the theoretical advantages, technical aspects, and initial experience with soon-to-be-available optode-based blood gas monitors. Dr Shapiro points out that a reliable in-vivo ABG monitor, in conjunction with currently available noninvasive monitors, could present several important advances, including continuous assessment of gas exchange across the physiologic ranges of ABG values, decreased blood loss for patients, reduced risks of nosocomial infection for patients and of blood exposure for caregivers, and decreased costs as compared with present-day monitoring.

In the fourth paper, Thomas D East discusses the pros and cons of computerized data collection, storage, and display in critical care: “Computers in the ICU: Panacea or Plague?”\(^10\) Here again, the concept is not new (computers having been utilized in ICUs since introduction of the latter in the 1960s), but practical, commercial systems applicable to any ICU setting have only recently become available. Documentation of the practical value of these systems in patient management—as opposed to their use in the research setting—remains scarce. As Dr East points out, for computers to be embraced in the ICU environment, commercial systems must go beyond the mere gathering and display of information; they must help the clinician to wade through today’s vast flood of ICU data and aid in clinical decision making. However, ICU computers are probably here to stay, and, if appropriately wedded to the human aspects of critical care, they hold promise for improving patient care and perhaps even making the clinician’s work easier.

Microprocessor ventilators are not the only high-tech machines at the bedside in today’s ICU. In fact, in an increasing number of units the beds themselves would hardly be recognizable to a clinician time-transported from a 1970s-era ICU. In the 1990s, sophisticated electronic beds—some of them microprocessor-controlled and as expensive as top-of-the-line ventilators—seek to provide
much more than just a place for patients to lie.\textsuperscript{11} Offering a variety of motions, supports, and skin contacts, these beds are claimed by their manufacturers to prevent pneumonia, pulmonary embolism, and other complications of immobility, and to facilitate wound care and hasten healing. Can they really do all these things, and are they worth their substantial addition to the daily cost of ICU care? Dean Hess addresses these issues in “Positioning, Lung Function, and Kinetic Bed Therapy.”\textsuperscript{12}

Clinicians in ICUs everywhere are likely to be confronted soon by the topics of these five reviews (if this has not already occurred). These papers provide valuable background information, and the personal perspectives of their distinguished authors, for use in evaluating these important developments. Future “New Horizons” symposia will grapple with other controversial new devices and techniques, and will produce other papers for publication in these pages. In the meantime, these reviews and the principles used by their authors in approaching their subjects\textsuperscript{1} can guide the clinician in assessing these and other emerging issues in respiratory care.

REFERENCES

Intravenous Oxygenation and CO\textsubscript{2} Removal Device: IVOX

Charles G Durbin Jr MD

Introduction

Respiratory Distress Syndrome

The adult respiratory distress syndrome (ARDS) continues to be a prominent cause of death and disability in critically ill patients. The reported incidence of ARDS in critically ill patients depends upon the underlying clinical condition. Those with the highest risks include patients who have the septic syndrome or have experienced aspiration of gastric contents, multiple transfusions, or pulmonary contusion.\textsuperscript{1,2} The incidence within an intensive care unit varies from 5-45\% depending on patient mix and diagnostic criteria. The estimated annual incidence of ARDS is 1.5-3.5/100,000.\textsuperscript{3} Most studies suggest that the mortality from ARDS approaches 70\% and has not changed significantly in the past 20 years as shown in Table 1.\textsuperscript{1-11} In contrast to the original extracorporeal membrane oxygenation trial (ECMO) of the mid-1970s,\textsuperscript{12} which reported a survival of 11\% in both control and study patients, current application of intensive pulmonary care (without ECMO) has raised the survival rate to approximately 40-45\% in patients with the same severity of illness as that present in the ECMO study patients.\textsuperscript{13}

Despite this evidence of improved survival in some groups with ARDS, the mortality remains high. Occasional patients die of refractory hypoxemia and hypercapnia; however, the more usual cause of death is multiple system organ failure (MSOF).\textsuperscript{8} Current understanding of ARDS is that it often is one manifestation of the systemic problem of MSOF. Progression to irreversible pulmonary failure in some patients may be due to the toxic effects of the therapy used to treat hypoxemia.

<table>
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<td>Kaplan et al\textsuperscript{4}</td>
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<td>Gallagher &amp; Civetta\textsuperscript{6}</td>
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<tr>
<td>Laghi et al\textsuperscript{11}</td>
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Treatment Goals and Ways To Achieve Them

Complicating the management of patients with severe ARDS are the deleterious effects of high concentrations of inspired oxygen (F\textsubscript{I\textsubscript{O}_2}) and high airway pressure. High concentrations of oxygen may directly contribute to poor outcome due to the toxic effects of oxygen on the lung parenchyma.\textsuperscript{14-16} High airway pressures may increase barotrauma, augment the effects of high inspired F\textsubscript{I\textsubscript{O}_2}, and decrease survival.\textsuperscript{17-19} Current conventional ventilator management techniques involve minimizing peak airway pressure while providing appropriate mean airway pressure to reduce F\textsubscript{I\textsubscript{O}_2} and, thus, avoid these complications. Despite the efficacy of this ap-
proach in most patients, some die of hypoxemic and hypercapnic respiratory failure.

Similarities between adult ARDS and infant respiratory distress syndrome (IRDS) have been noted and, in fact, many of the milestones in treatment of adults were first established as effective in children. Survival rates for children with IRDS are much better than for adults with the same degree of respiratory dysfunction; this is presumably due to the fact that the immature lung can continue to grow and develop to overcome the initial disease and the consequences of therapy.

Although not routinely applied or generally believed to be helpful in adults, ECMO has been used in infants with some regularity. ECMO allows the lung to 'rest' thus avoiding the use of high FiO\textsubscript{2} and airway pressure. The most common method of applying ECMO (in infants) is by venoarterial bypass with cannulation of the right internal jugular vein and the right common carotid artery. Venous blood is drained from the right atrium and oxygenated blood is returned through the carotid artery. Patients managed with ECMO usually have their airway pressures reduced (although not to ambient pressure). Mechanical ventilation frequency, tidal volume, and FiO\textsubscript{2} also decrease. ECMO can provide total ventilatory gas exchange, but the ideal lung ventilation pattern during ECMO has not been established.

Originally, ECMO was proposed as a rescue treatment for dying infants; however, currently it appears to have a higher success rate than conventional therapy.\textsuperscript{20} Used in this fashion, a survival rate in neonates with ECMO is estimated at around 80\%.\textsuperscript{21} Use in infants with unilateral lung disease such as congenital diaphragmatic hernia is especially encouraging.\textsuperscript{22,23}

In light of the improved outcome with ECMO in infants, a renewed interest in its use in adults has occurred. A recent uncontrolled study by Gattinoni et al\textsuperscript{24} reported a 90\% survival rate in 43 adults with ARDS using a modified ECMO procedure. In their series, veno-venous bypass rather than venoarterial bypass was used. The system was primarily designed to remove carbon dioxide (CO\textsubscript{2}) (prolonged extracorporeal CO\textsubscript{2} removal, ECCO\textsubscript{2}R) and to allow a reduction in the level of mechanical ventilation.\textsuperscript{25,26} This form of partial lung bypass has been effective in removal of CO\textsubscript{2}. Improvement of oxygenation with this technique has not been as dramatic; however, complications associated with the original ECMO study have been markedly reduced using a veno-venous system.\textsuperscript{27,28}

### The IVOX Device

With the success of partial lung-bypass procedures in adults, a renewed interest in implantable devices capable of providing support of oxygenation and CO\textsubscript{2} removal has been seen. An intravascular (venous) blood gas exchange device (IVOX) (CardioPulmonics Inc. Salt Lake City UT) has been developed and tested in animals and humans to partially support a failing respiratory system.

The IVOX consists of a series of elongated siloxane-coated hollow fibers with walls that are 20 µ thick and an external diameter of 230 µ (internal lumen is 190 µ). These are of very thin plastic, are semipermeable, and allow oxygen and CO\textsubscript{2} to diffuse across them. The device is implanted in the vena cava, and 100\% oxygen is drawn through the fibers by a vacuum system. The fibers are cramped and furled so that they can be placed through a small venotomy (cutdown) and then untwisted and unfolded once in place in the inferior vena cava. The twisted and cramped shape of the fibers produces disordered blood flow around them and improves contact with the oxygenator (increasing efficiency). The device is produced in several sizes (diameters in the furled configuration). The largest (10 mm) is capable of delivering up to 170 mL of oxygen and of removing up to 140 mL of CO\textsubscript{2}/min.

The IVOX is essentially a mechanical hollow-fiber membrane oxygenator. Instead of taking the blood from the patient to the extracorporeal system and perfusing the oxygenator with gas, the IVOX accomplishes its tasks by having the patient’s venous blood circulate around the fibers that form the oxygenator. As a foreign body, the IVOX raises several safety and efficacy concerns that differ from those of traditional extracorporeal blood-oxygenator systems. The size of the gas transfer area (and effectiveness of blood contact) is a limiting factor in the ability of the device to exchange O\textsubscript{2} and CO\textsubscript{2}. The largest device available is about one third as efficient as the simplest extracorporeal membrane oxygenator.
Because contact of blood and clotting factors with the exchange membrane occurs continuously, systemic anticoagulation is required to prevent thrombosis and to improve efficiency. With current fiber technology (coating), there seems to be less problem with clot formation than in earlier models and certainly less than with ECMO. A schematic of the device is shown in Figure 1. The largest device that will fit through the selected peripheral vessel should be chosen to maximize gas exchange. The effectiveness of the currently tested devices is shown in Table 2. The chosen device may be inserted through the right femoral vein as illustrated in Figure 2 or the right internal jugular vein from the superior route. To optimize function the device will lie within the superior and inferior venae cavae and the right atrium. Hemodynamic compromise has not been seen in animals or humans with the device so placed.

A comparison of ECMO and IVOX concerns is shown in Table 3. The major benefits of IVOX appear to be ease of insertion and simplicity of use after placement. Reduced cost in terms of personnel and equipment also favor IVOX. Both techniques require careful anticoagulation, with an activated clotting (ACT) time of 180-200 seconds recommended. The problem of gas embolism is negligible with IVOX, due to the vacuum system 'pulling' the gas through the oxygenator. Another advantage of the IVOX is the absence of need for a heat exchanger as is necessary to warm the blood with ECMO. However, clinical experience is minimal, the device is in Phase-II testing, and more information about performance should soon be available.

**Animal Studies**

Experiments in dogs and sheep have demonstrated that the IVOX can achieve effective gas transfer.²⁰,²¹ The larger the surface area available for gas exchange the greater is gas transfer. Surface areas of prototype models varied from 0.2 to 0.5 m². As expected, CO₂ removal was more efficient than O₂ delivery partially due to the greater fiber permeability to CO₂. In heparinized animals, there have been no problems with caval thrombosis or evidence of pulmonary embolism clinically or on autopsy examination. Although more than 300 animals have had these devices implanted, only a few studies have reached publication.

---

**Fig. 1.** A—Schematic representation of the IVOX device. The fibers are crimped to increase length and surface area and create disturbed blood flow in the vena cava. Oxygen is sucked through the fibers to effect gas exchange. B—Fiber in cross-section.
Table 2. Oxygen and Carbon Dioxide Exchange Data for the Various Sizes of IVOX Devices Currently Being Studied, with a Total of 18 Datapoints in Humans

<table>
<thead>
<tr>
<th>Size</th>
<th>Length (cm)</th>
<th>Number of Fibers/</th>
<th>Oxygen Exchange (mL/min)</th>
<th>Carbon Dioxide (mL/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mean</td>
<td>Range</td>
</tr>
<tr>
<td>7</td>
<td>380/55</td>
<td>52.4</td>
<td>18-128</td>
<td>48.2</td>
</tr>
<tr>
<td>8</td>
<td>520/55</td>
<td>66.3</td>
<td>42-84</td>
<td>70.5</td>
</tr>
<tr>
<td>9</td>
<td>800/60</td>
<td>73.2</td>
<td>56-84</td>
<td>72.8</td>
</tr>
<tr>
<td>10</td>
<td>1200/65</td>
<td>104.7</td>
<td>66-142</td>
<td>74.3</td>
</tr>
</tbody>
</table>

**Human Studies: Safety**

Phase-I studies, or safety trials, in humans, have been completed but not published. Phase-II, or efficacy studies, began at 18 investigative centers in the United States and Europe. The first 36 patients who were dying in respiratory failure in whom the device was used were presented by Mortensen, Gaykowski, and Schaap at the International Society of Artificial Organs meeting in Montreal (August 20, 1991). A list of institutions and the principle investigators contributing to these early trials appears in the Appendix at the end of this paper. The information presented forms the basis for the human data. A total of 56 IVOX implants had been carried out; however, only 36 had been adequately analyzed at the time of presentation. This group of 36 included patients from both Phase-I and Phase-II studies. In the 14 patients who had postmortem examinations there was no evidence of clot formation in the venae cavae, in the heart, or in the pulmonary circulation. Removed devices and those examined at necropsy showed minimal signs of thrombus accumulation on the device after an average of 6.5 days of implantation (maximum 18 days).

No changes in hemoglobin, hematocrit, white blood cell count, fibrinogen, or fibrin-split products (indicating ongoing clot lysis) were associated with IVOX placement. Half of the patients experienced a mild-to-moderate decline in platelet count, but this decline was clinically significant in only 2 patients. Unilateral leg edema related to IVOX insertion site was noted in 3 patients, but responded to conservative measures (compression stockings). Five cases of femoral vein thrombosis were identified at necropsy.

Table 3. Comparison of Characteristics of ECMO and IVOX Applications

<table>
<thead>
<tr>
<th>Concern</th>
<th>ECMO/ECCO-R</th>
<th>IVOX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas exchange</td>
<td>Full*</td>
<td>Partial</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>Partial</td>
<td>Partial</td>
</tr>
<tr>
<td>Length of use</td>
<td>Days to weeks</td>
<td>Days (19 max)</td>
</tr>
<tr>
<td>Hemodynamic effects</td>
<td>Important</td>
<td>Minimal</td>
</tr>
<tr>
<td>Initiation</td>
<td>Complicated</td>
<td>Simple</td>
</tr>
<tr>
<td>Equipment used</td>
<td>Complicated</td>
<td>Simple</td>
</tr>
<tr>
<td>Body temperature effects</td>
<td>Marked</td>
<td>None</td>
</tr>
<tr>
<td>Personnel required</td>
<td>Highly trained</td>
<td>Routine ICU</td>
</tr>
<tr>
<td>Equipment repair</td>
<td>Membrane change</td>
<td>Device change</td>
</tr>
<tr>
<td>Cost</td>
<td>Considerable</td>
<td>Less</td>
</tr>
<tr>
<td>Clinical experience</td>
<td>Considerable</td>
<td>Minimal</td>
</tr>
</tbody>
</table>

*Veno-venous ECMO only.

Fig. 2. The IVOX in place in the venous system. It may be placed by direct vessel cutdown from the right femoral vein (1) or the right internal jugular vein (2).
Table 4. Bleeding Problems Related to IVOX Use in 36 Patients

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No problems with bleeding</td>
<td>22</td>
<td>61</td>
</tr>
<tr>
<td>Insertion/removal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 100 mL</td>
<td>31</td>
<td>86</td>
</tr>
<tr>
<td>&gt; 100 mL</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>Bleeding at site</td>
<td></td>
<td></td>
</tr>
<tr>
<td>minimal*</td>
<td>6</td>
<td>17</td>
</tr>
<tr>
<td>severe†</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Bleeding at remote site</td>
<td></td>
<td></td>
</tr>
<tr>
<td>minimal‡</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>severe§</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*2 patients required transfusion.
†5 patients required transfusion and intervention.
‡3 patients required transfusion.

A concern over the possibility of bleeding in patients exists with this device because they are maintained on heparin. The bleeding complications in the 36 patients studied were minor and rare as shown in Table 4. Most patients had minor or no problems with bleeding.

Human Studies: Efficacy

Eleven of the 36 patients survived; 85% of them demonstrated a clinical improvement in respiratory gas exchange immediately after placement of the IVOX device. Averages of 66.4 mL/min of O₂ and 74 mL/min of CO₂ were transferred. No decline in gas exchange efficacy occurred over time. The desired goal in using partial respiratory support is to allow ventilatory support to be reduced (airway pressure, tidal volume, frequency, or delivered oxygen concentration). This was achieved in most patients, and after removal of the IVOX, the patient was able to be weaned completely and the trachea extubated. Some patients showed no improvement and proceeded to die a respiratory death.

Efficacy for the IVOX is defined as delivering clinically important quantities of O₂ and removing clinically important quantities of CO₂. These preliminary data suggest reasonable safety and efficacy by this standard. Any improvement in patient outcome can only be determined by randomized, prospective trials comparing patients of the same severity of illness treated with ‘conventional’ therapy or IVOX. Use of IVOX early in the course of reversible respiratory failure, although logical, must be weighed against the likelihood of successful management and good outcome without it. Because the ECMO trials in neonates have shown improvement over conventional techniques, IVOX in adults holds significant promise. Unlike in the neonate, important other ‘irreversible’ illness often accompanies ARDS in adults. The causes of death in the first 14 patients who died after IVOX placement are shown in Table 5. As expected, respiratory failure was only a small contributor.

Table 5. Causes of Death in 14 Patients after Use of IVOX

<table>
<thead>
<tr>
<th>Primary Cause</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sepsis, shock</td>
<td>7</td>
<td>50</td>
</tr>
<tr>
<td>MSOF*</td>
<td>5</td>
<td>35.7</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>5</td>
<td>35.7</td>
</tr>
<tr>
<td>Hepatic failure</td>
<td>1</td>
<td>7.1</td>
</tr>
<tr>
<td>Ruptured cerebral aneurysm</td>
<td>1</td>
<td>7.1</td>
</tr>
<tr>
<td>Renal failure</td>
<td>1</td>
<td>7.1</td>
</tr>
</tbody>
</table>

* MSOF = multiple system organ failure.

If the safety of IVOX is borne out, possible applications are in patients with acute reversible lung disease receiving maximum ventilatory support but in whom gas exchange is still inadequate; in patients with moderate acute respiratory failure in whom ventilatory pressures and/or FIO₂ are causing complications such as bronchopleural fistula or other forms of barotrauma; and selected postoperative patients in whom avoidance of airway pressure is desirable, such as lung transplant or pulmonary resections, but in whom gas exchange is marginal. Another possible use is for salvaging dying patients with irreversible pulmonary failure in preparation for lung transplantation.

There are currently 12 centers in the United States enrolling patients in Phase-II studies: University of Texas Medical Branch (Galveston), Pennsylvania State University, University of Michigan, University of Southern California (Los Angeles), Louisiana State University, Northwestern University, Cleveland Clinic Foundation, Saint Louis University Medical Center, University of Washington, Duke University Medical Center,
New England Deaconess Hospital, and the Mayo Clinic. Entry criteria for this study are listed in Table 6; these objective indications in the light of reversible acute respiratory failure will be guides to IVOX use in the future. The medical contraindications to IVOX use are advanced MSOF, uncontrolled infection, bleeding diathesis, contraindications to systemic anticoagulation (such as recently ruptured cerebral aneurysm), and irreversible lung failure (without the possibility of lung transplant).

Table 6. Patient-Entry Criteria for Phase-II IVOX Testing

| Ventilation | Positive pressure ventilation with minute ventilation > 150 mL · kg⁻¹ · min⁻¹ and positive end-expiratory pressure > 10 cm H₂O  
or peak inspiratory pressure > 45 cm H₂O  
or mean airway pressure > 30 cm H₂O |
|-------------|----------------------------------------------------------------------------------|
| Gas Exchange | FIO₂ > 0.5 with P₅O₂ < 8.0 kPa (60 torr)  
and P₅CO₂ > 5.3 kPa (40 torr) |
| Duration | Must be 3 separate occasions at least 1 hour apart |

Conclusions

The safety and efficacy of an implantable venous oxygenator is being evaluated. Very few significant problems have been seen so far. Bleeding complications are the most notable and occur in 10-15% of patients (severe in 3%). No severe thrombotic problems have been seen. Gas transfer has been as predicted, although insufficient to totally replace pulmonary function. Phase I and II studies in humans have supported study of the use of IVOX earlier in the course of ARDS. It is too early to predict the place this technology will have in treating respiratory failure.

ACKNOWLEDGMENTS

Thanks and appreciation are offered to CardioPulmonics Inc for assistance in preparing this presentation. Special thanks to Robert N Schnap MD for editorial suggestions and for supplying some of the illustrations.

REFERENCES

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tion: role of PEEP, peak airway pressure, and distending volume. Respir Care 1988;33:472-486.


APPENDIX

Institutions and Principal Investigators Contributing to the First 36 IVOX Implantations

<table>
<thead>
<tr>
<th>Institution</th>
<th>Principal Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belin Heart Institute</td>
<td>N Friedel/Hetzer</td>
</tr>
<tr>
<td>Cleveland Clinic</td>
<td>T Kirby</td>
</tr>
<tr>
<td>Gutenberg University Hospital</td>
<td>B Shaprio</td>
</tr>
<tr>
<td>Harborview, University of</td>
<td>D Figuera</td>
</tr>
<tr>
<td>Washington</td>
<td>Royal London Hospital</td>
</tr>
<tr>
<td>Hershey Medical Center</td>
<td>A Woods/T Lewis</td>
</tr>
<tr>
<td>LAC, University of Southern</td>
<td>D Bennett</td>
</tr>
<tr>
<td>California</td>
<td>W Binder</td>
</tr>
<tr>
<td>Latter Day Saints’ Hospital</td>
<td>G Kreymann</td>
</tr>
<tr>
<td>Louisana State University</td>
<td>C Aren</td>
</tr>
<tr>
<td>Medical Hochschule, Hannover</td>
<td>R Bartlett</td>
</tr>
<tr>
<td></td>
<td>J Zwischenberger</td>
</tr>
<tr>
<td>Northwestern University</td>
<td></td>
</tr>
<tr>
<td>Puerta de Hiero Hospital, Madrid</td>
<td></td>
</tr>
<tr>
<td>Royal London Hospital</td>
<td></td>
</tr>
<tr>
<td>St George’s Hospital, London</td>
<td></td>
</tr>
<tr>
<td>University Hospital, Augsburg</td>
<td></td>
</tr>
<tr>
<td>University Hospital, Hamburg</td>
<td></td>
</tr>
<tr>
<td>University Hospital, Linkoping, Sweden</td>
<td></td>
</tr>
<tr>
<td>University of Michigan Hospital</td>
<td></td>
</tr>
<tr>
<td>University of Texas, Galveston</td>
<td></td>
</tr>
</tbody>
</table>

RESPIRATORY CARE • FEBRUARY ’92 Vol 37 No 2 153
Monitoring Mixed Venous Oxygen

Loren D Nelson MD and Edmund J Rutherford MD

Introduction

Monitoring of mixed venous oxygenation has become increasingly popular over the past ten years. Technology is now available that allows the continuous measurement of mixed venous oxygen saturation ($S_{\text{vO}_2}$) in the intensive care unit and the operating room. With the new technology comes increased cost and the risk of misinterpretation of vast amounts of data.

Our purpose is to review the physiology of mixed venous oxygenation and the technology currently available for its assessment. Specifically, we look at the accuracy, efficacy, clinical value, and cost-effectiveness of monitoring venous oxygenation, and review the lessons we have learned in the past, the current state-of-the-art of venous oxygenation measurements, and the future for these measurements.

Assessment of venous oxygenation has been performed for a variety of reasons. One compelling reason to monitor venous oxygenation is to better understand oxygenation at the tissue level. It has long been known that arterial saturation and even oxygen delivery [$D_{\text{o}_2} = \text{cardiac output, or C.O.}$] (arterial oxygen content, or $C_{\text{aO}_2}$) give little information regarding oxygenation at the cellular level. Mixed venous oxygen tension ($P_{\text{vO}_2}$) has long been measured as an indicator of "tissue oxygenation" (Table 1). $P_{\text{vO}_2}$ correlates with the development of lactic acidosis and mortality in critically ill patients. Unfortunately, venous $P_{\text{O}_2}$ correlates with tissue $P_{\text{O}_2}$ only when very specific vascular beds are investigated. The $P_{\text{O}_2}$ (measured in the pulmonary artery) does not correlate well with tissue $P_{\text{O}_2}$ of any individual vascular bed.

Venous oxygenation has also been used to determine total body oxygen consumption and the relative relationship between oxygen delivery ($D_{\text{o}_2}$) and oxygen consumption ($\dot{V}_{\text{O}_2}$). The physiologic basis for this seems to be well founded.

Finally, continuous assessment of $S_{\text{vO}_2}$ has been suggested as an indicator of changes in C.O. Results of studies showing the correlation between $S_{\text{vO}_2}$ and C.O. have been contradictory and often inconclusive. The reason for the contradictory results seems to be the patient populations and conditions under which the studies have been performed.

Physiology

The physiology of venous oxygenation is based upon our understanding of the Fick equation, which relates the $\dot{V}_{\text{O}_2}$ in the tissue to C.O. and extraction of oxygen. Based upon the law of conservation of mass, the Fick equation states that the volume of oxygen consumed is equal to the volume of oxygen delivered to the tissue minus the volume of oxygen returned from the tissue. The volume of oxygen delivered to the tissue is equal to the product of C.O. and $C_{\text{aO}_2}$ (Table 2). A normal oxygen delivery is approximately 600 L · m⁻² · min⁻¹. The volume of oxygen returned to the heart is equal to
Table 1. Clinically Important Oxygen Variables, Symbols, Definition or Calculation, and Normal Ranges*

<table>
<thead>
<tr>
<th>Term</th>
<th>Symbol</th>
<th>Definition/Calculation</th>
<th>Normal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial tension</td>
<td>P_aO_2</td>
<td>Partial pressure</td>
<td>&gt; 60 torr, varies with FIO_2</td>
</tr>
<tr>
<td>Arterial saturation</td>
<td>S_aO_2</td>
<td>Oxyhemoglobin saturation</td>
<td>0.90-1.0, varies with FIO_2</td>
</tr>
<tr>
<td>Arterial content</td>
<td>C_aO_2</td>
<td>Volume of gaseous oxygen ( C_aO_2 = \left( Hb \times 1.34 \times S_aO_2 \right) + \left( 0.0031 \times P_aO_2 \right) )</td>
<td>16-22 mL/dL</td>
</tr>
<tr>
<td>Venous tension</td>
<td>P_vO_2</td>
<td>Partial pressure</td>
<td>35-42 torr</td>
</tr>
<tr>
<td>Venous saturation</td>
<td>S_vO_2</td>
<td>Oxyhemoglobin saturation</td>
<td>0.68-0.77</td>
</tr>
<tr>
<td>Venous content</td>
<td>C_vO_2</td>
<td>Volume of gaseous oxygen ( C_vO_2 = \left( Hb \times 1.34 \times S_vO_2 \right) + \left( 0.0031 \times P_vO_2 \right) )</td>
<td>12-16 mL/dL</td>
</tr>
<tr>
<td></td>
<td>P_50</td>
<td>Partial pressure of oxygen that results in saturation of 0.50</td>
<td>26.6 torr</td>
</tr>
</tbody>
</table>

*Hb = hemoglobin concentration (g/dL).

the product of venous blood return (which must be equal to C.O.) and C_vO_2. The normal venous oxygen return is approximately 450-460 L \( \cdot \) m\(^2\) \( \cdot \) min\(^{-1}\) making the volume of oxygen consumed approximately 140-150 L \( \cdot \) m\(^2\) \( \cdot \) min\(^{-1}\).

Because oxygen levels are quite low in venous blood, nearly all of the oxygen (> 99%) is bound to hemoglobin. Less than 1% of venous oxygen is dissolved in the plasma. This means that virtually the entire oxygen content in venous blood is determined by the venous oxygen saturation (S_vO_2) and the tension (P_vO_2) contributes almost nothing to venous oxygen content. Because the oxygen content of venous blood is determined by the variables in the Fick equation and because virtually all of the oxygen content in venous blood is bound to hemoglobin, the saturation of the hemoglobin must be determined by the variables in the Fick equation. This means that venous blood is unique in that the oxyhemoglobin saturation determines the oxygen tension rather than the tension determining the saturation as is the case in arterial blood.

The most important variable in assessing venous oxygenation is obviously the content of gaseous oxygen present in the venous blood. The direct measurement of venous (or for that matter arterial) oxygen content has been all but abandoned clinically with the possible exception of a few cardiac

Table 2. Terms, Symbols, Definitions, and Calculations Used To Describe Oxygen Transport in Critically Ill Patients*

<table>
<thead>
<tr>
<th>Term</th>
<th>Symbol or Term</th>
<th>Definition/Calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport</td>
<td>—</td>
<td>Balance between supply and demand</td>
</tr>
<tr>
<td>Delivery</td>
<td>D_O_2</td>
<td>O(_2) volume ejected from left ventricle, ( D_O_2 = CI \times C_aO_2 \times 10 )</td>
</tr>
<tr>
<td>Consumption</td>
<td>( \dot{V}_O_2 )</td>
<td>( O_2 ) volume used by tissue, ( \dot{V}<em>O_2 = CI \times C</em>{a-O_2} \times 10 )</td>
</tr>
<tr>
<td>Upake</td>
<td>—</td>
<td>( O_2 ) volume taken up by lungs</td>
</tr>
<tr>
<td>Demand</td>
<td>—</td>
<td>( O_2 ) volume needed by tissues</td>
</tr>
<tr>
<td>Utilization</td>
<td>OUC</td>
<td>Fraction of delivered ( O_2 ) consumed, ( OUC = \dot{V}_O_2/D_O_2 )</td>
</tr>
</tbody>
</table>

*CI = cardiac index (L \( \cdot \) m\(^2\) \( \cdot \) min\(^{-1}\)); C_aO_2 = arterial oxygen content (mL/dL); C_{a-O_2} = arterial-venous oxygen content difference (mL/dL).
catheterization and unique research laboratories. The content more commonly is calculated from the \( S_{O_2} \) (Table 1), which is easily and reliably measured in the clinical laboratory.

Measurement of \( P_{O_2} \) has also been all but abandoned except in unusual circumstances. Because saturation and content are closely related and because dissolved oxygen contributes almost nothing to venous content, \( P_{O_2} \) yields little to our understanding of venous oxygenation. \( P_{O_2} \) may be of value in determining the approximate in-vivo \( P_{O_2} \) (tension associated with 50% saturation) when tonometry is unavailable (Table 1). Because \( P_{O_2} \) and \( S_{O_2} \) are much closer to values associated with a normal \( P_{O_2} \) than are \( P_{aO_2} \) and \( S_{aO_2} \), these values may be used in the Hill equation to solve for an approximate \( P_{O_2} \).

Theoretically, \( P_{O_2} \) represents the driving force for the diffusion of oxygen from the most distal capillaries to the cells and mitochondria. Although the driving pressure is important, the actual driving pressure necessary for mitochondrial function is so low (approximately 6 torr) that \( P_{O_2} \) is of only theoretic importance in estimating driving pressure for diffusion.

\( S_{O_2} \) is directly determined by the variables in the Fick equation. The classic Fick equation relates oxygen consumption to the product of C.O. and the arterial-venous oxygen content difference, \( C_{a-v}O_2 \). Thus, the following equations can be derived:

\[ \dot{V}_O_2 = C.O. \times C_{a-v}O_2 \]  
(Fick equation)

\[ \dot{V}_O_2/C.O. = C_{a-v}O_2 \]  
(Divide by C.O.)

\[ \dot{V}_O_2/C.O. = C_{aO_2} - C_{vO_2} \]  
(Definition of \( C_{a-v}O_2 \))

\[ \dot{V}_O_2/C.O. - C_{aO_2} = -C_{vO_2} \]  
(Subtract \( C_{aO_2} \))

\[ C_{vO_2} = C_{aO_2} - (\dot{V}_O_2/C.O.) \]  
(Multiply by -1)

\[ C_{vO_2}/C_{aO_2} = 1 - (\dot{V}_O_2/C.O. \times C_{aO_2}) \]  
(Defined by \( C_{aO_2} \))

\[ C_{vO_2}/C_{aO_2} = 1 - \dot{V}_O_2/D_O_2 \]  
(Definition of \( D_O_2 \))

(If \( S_{aO_2} = 1 \), then \( S_{vO_2} = C_{vO_2}/C_{aO_2} \)

\[ S_{vO_2} = 1 - \dot{V}_O_2/D_O_2 \]  
(Substitute \( S_{vO_2} \))

It is therefore mathematically ordained that \( S_{vO_2} \) is equal to 1 minus the fraction of delivered oxygen that is consumed. This relationship (\( \dot{V}_O_2/D_O_2 \)) is also known as the oxygen utilization coefficient (OUC) or the oxygen extraction ratio (OER). When \( S_{vO_2} \) is maintained at relatively high levels, mixed venous oxygenation is determined by the relative balance between oxygen consumption and delivery.

It is important to recognize that the \( S_{O_2} \) is a flow-weighted average of the effluents from all perfused vascular beds. Therefore, while \( S_{O_2} \) gives an accurate indication of the total body balance between the \( V_O_2 \) and \( D_O_2 \), it does not give information regarding any specific vascular bed or organ.

Four variables determine \( S_{O_2} \): \( V_O_2 \), C.O., hemoglobin concentration, and \( S_{aO_2} \). In critically ill patients, each of these variables may change with little or no compensatory change in the other variables. Uncompensated increases in \( V_O_2 \) or decreases in any of the three components of \( D_O_2 \) result in a decrease in \( S_{O_2} \). In normal healthy subjects, an increase in \( V_O_2 \) is matched by an increase in \( D_O_2 \), keeping \( S_{O_2} \) normal. Also, in subjects with compensatory mechanisms in place, a decrease in hemoglobin concentration or \( S_{aO_2} \) is matched by an increase in C.O. to normalize \( S_{O_2} \).

The ability of critically ill patients to compensate for physiologic derangements is often severely impaired. For this reason, the relationship between \( S_{O_2} \) and any of the four determinants of \( S_{O_2} \) is nonexistent or poor. There is virtually no correlation between \( S_{O_2} \) and either \( P_{O_2} \) or \( S_{aO_2} \) (Figs. 1A & 1B). Similarly, there is no statistical correlation with hemoglobin concentration or \( V_O_2 \) (Fig. 2C). Statistically significant correlations exist between \( S_{O_2} \) and both C.O. and \( D_O_2 \) (Figs. 2A & 2B), but the correlations are sufficiently weak (\( r^2 = 0.16 \) and 0.24) to be of little clinical value. However, the relationship between \( S_{O_2} \) and the OUC (Fig. 2D) is consistent. Therefore, even in critically ill patients \( S_{O_2} \) gives an indication of the relative balance between the consumption and delivery of oxygen in perfused vascular beds.

Technology

Mixed venous oxygenation may be clinically assessed by looking at \( P_{O_2} \), \( S_{O_2} \), or \( C_{O_2} \). The most important of these is the \( C_{vO_2} \). Unfortunately, oxygen content is rarely measured directly in the clinical situation. Oxygen tension gives very little information regarding content and therefore has
MONITORING VENOUS OXYGENATION

Fig. 1. No statistical correlation exists between $SvO_2$ and either $P_aO_2$ or $SvO_2$. (Reprinted, with permission, from Reference 11.)

lost favor to the direct measurement of venous oxygen saturation.

**Sampling Site**

Venous oxygen saturation has been measured at several locations. Obviously, peripheral venous oxygen saturation measurements give little information regarding oxygen supply-demand balance of vital organs and rather reflect only the relationship of the local skin and muscle vascular beds. For this reason, venous oxygen saturation measurements must be made at a more central location.

A great deal of debate has raged between those advocating the simple measurement of venous oxygen saturation in the vicinity of the superior vena cava or right atrium versus the more complex technology required for measurements in the pulmonary artery. Although a number of studies have shown that central venous oxygen saturation correlates with $SvO_2$ (i.e. from the pulmonary artery), there is also a wide degree of scatter in the measurements. The variability seems to be due to the positioning of the central venous catheter (CVC). In the normal patient, oxygen saturation in the inferior vena cava is slightly higher than in the superior vena cava because of the relative low levels of extraction relative to perfusion that occur in the renal vasculature and, in some situations, in the mesenteric vasculature. However, when the patient is under stress, such as that induced by hypovolemia, shock, or vigorous exercise, a decrease in renal and splanchnic blood flow causes a prompt fall in the venous saturation in the inferior vena cava. This reduction in saturation is in excess of the change that occurs in the superior vena cava so that saturation measured in the superior vena cava may actually become higher than that from the inferior vena cava (Fig. 3). Because of these potentially dramatic shifts in the relative oxygen supply-demand balance in vascular beds served by the two divisions of the vena cava, precise positioning of a CVC must be assured to interpret properly the changes in the oxygen saturation values. That is, a catheter that is positioned slightly too high in the superior vena cava will miss the wide swings in saturations seen by a catheter positioned lower than the atrium and sampling blood primarily from the inferior vena cava.

True mixed venous blood is available only after complete mixing as the blood passes through the chambers of the heart. The venous blood is reasonably well mixed by the time it reaches the right ventricle, but catheters placed in the right ventricle may irritate the endocardium and predispose the patient to cardiac dysrhythmias. For this reason, blood is usually sampled past the pulmonic valve in the pulmonary artery. This blood pool represents true mixed venous blood.

**Intermittent Sampling**

Venous oxygenation has typically been assessed by either intermittent sampling of blood from the central venous system or from the pulmonary artery or by continuous monitoring using an in-vivo fiberoptic technique. When intermittent sampling is performed, the gas analysis has been done either on a blood gas machine by which tension is measured and saturation is calculated or by CO-oximetry in which saturation is measured.
Monitors and oxygenation, 16 14 H D 12 a. O Q CC < u R = 40 P < .025

Cardiac output vs. oximetry S\textsubscript{vO\textsubscript{2}}

Oxygen delivery vs. oximetry S\textsubscript{vO\textsubscript{2}}

Oxygen consumption vs. oximetry S\textsubscript{vO\textsubscript{2}}

O\textsubscript{2} utilization ratio vs. oximetry S\textsubscript{vO\textsubscript{2}}

Fig. 2. The relationship between mixed venous oxygen saturation (S\textsubscript{vO\textsubscript{2}}) and cardiac output (C.O.), oxygen delivery (D\textsubscript{O\textsubscript{2}}), oxygen consumption (V\textsubscript{O\textsubscript{2}}), and oxygen utilization coefficient (OUC). (Reprinted, with permission, from Reference 11.)

directly. A number of studies have indicated that wide changes in P\textsubscript{50} occur in critically ill patients.\textsuperscript{22} These changes in P\textsubscript{50} make the saturation calculated from the tension highly unreliable on this very steep area of the oxyhemoglobin saturation curve.\textsuperscript{23} For this reason, it is strongly recommended today that venous saturation be measured directly by CO-oximetry rather than calculated.

Intermittent sampling of venous blood produces a ‘snapshot’ of the oxygen supply-demand balance at the particular point in time in which the blood was sampled. Although this may be quite helpful, it is obvious that the time of the sampling will have a major effect on the result in a patient who is unstable. We have learned through the use of pulse oximetry that intermittent sampling of arterial blood gases gives us a very imprecise picture of the actual fluctuations in arterial saturation that occur on a minute-to-minute basis. Furthermore, the clinical picture suggesting that arterial blood gas analysis may be needed is usually less subtle than the changes commonly associated with variation in venous oxygenation. Therefore, our clinical judgment may not be as helpful in suggesting when venous blood oxygenation should be assessed.

Fig. 3. The relative changes in venous oxygen saturation measures in the superior vena cava, inferior vena cava, and pulmonary artery before and after induction of shock. (Reprinted, with permission, from Reference 10.)
Continuous Monitoring

In the early 1980s, technology became available for the continuous analysis of \( S_O_2 \) using a fiberoptic technique combined with a flow-directed pulmonary artery catheter (PAC).\(^{18,19,24}\) The catheter design was improved in the early 1980s making the handling characteristics of this catheter indistinguishable from those of traditional non-fiberoptic PACs.\(^{25}\) The original commercially available monitor used three wavelengths of light for the determination of \( S_O_2 \). The relative reflectances of light in the infrared and red ranges allowed the accurate determination of the oxyhemoglobin saturation of blood flowing past the tip of the catheter. The third wavelength of white light was used to automatically adjust the system for changes in light reflectance due to changes in hemoglobin concentration or fibrin deposition over the fiberoptics.\(^{26}\) The system uses the concept of reflectance spectrophotometry, meaning that light is transmitted at specific wavelengths, and the reflected signal bouncing off of the red cells flowing past the tip of the catheter gives the information necessary to calculate the saturation. This is somewhat different from the transmission or absorbance spectrophotometry used in most laboratory CO-oximeters in which the red cells are lysed, and narrow wavelengths of light are transmitted through the suspension of hemoglobin to determine the oxygen saturation. Although the techniques differ, the results of measurements by the two techniques correlate well (Fig. 4).

More recently, new systems have been introduced that use two wavelengths of light, eliminating the white light used for calibrating the overall light intensity. Although this 2-wavelength approach is capable of accurate measurement of venous oxygen saturation, it has been demonstrated to have more drift and require more frequent calibration than the 3-wavelength system.\(^{27}\)

Pitfalls

Technical Errors

The major pitfalls in the utilization of venous oxygenation measurements fall into two categories: technical errors and interpretation errors. The major technical errors in the assessment of venous oxygenation that occur with intermittent sampling techniques are associated with malpositioning of the catheter and inappropriate sampling techniques. As stated previously, malpositioning of a CVC can lead to erroneously high or low estimates of \( S_O_2 \).

Another major technical error must be considered when drawing mixed venous blood samples from the distal port of a PAC. If the catheter is positioned in a relatively distal branch of the pulmonary artery, rapid aspiration of blood through the catheter may ‘contaminate’ the sample of mixed venous blood with pulmonary capillary blood. This will lead to a false increase in the observed oxygen tension or saturation.\(^{28,29}\) Proper positioning of the PAC in a very proximal location will nearly eliminate this possibility. When the position of the tip of the PAC cannot be precisely identified, it is recommended that blood drawn from the pulmonary artery be aspirated at a rate of no greater than 1 mL every 30 seconds. This should give plenty of time for refill of the distal pulmonary arterial circulation so that contamination with capillary blood does not occur.

The major technical errors associated with the continuous in vivo measurement of \( S_O_2 \) are primarily related to the calibration of the instrument and the stability of the light intensity signal. The drift of 3-wavelength monitoring systems is relatively low and generally is less than 1% every 24 hours.\(^{11,18,20}\) For this reason, calibration of the instrument every 24 hours would seem to be sufficient to assure an accurate measurement. The

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Fig. 4. A strong correlation \((r = 0.88, p < 0.001)\) exists between venous saturation measured by in-vivo continuous reflectance oximetry (Oximetrax) and in-vitro transmission oximetry (CO-oximetry). (Reprinted, with permission, from Reference 11.)

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blood sample drawn for calibration of the instrument is subject to the same pitfalls as any other intermittent sampling of mixed venous blood. If an inadequate sample is drawn and the erroneous value is entered into the memory of the oximetry computer, it is obvious that errors result. Similarly, fibrin deposition on the tip of the optic fibers over time occurs. This may become sufficient to interfere with the accurate calculation of venous oxygen saturation. Abnormal light intensity signals should be corrected before calibration of the instrument and before clinical actions are taken based on changes noted in the venous oxygen saturation.9,26

The light intensity signal is also a useful indicator of malpositioning of the tip of the PAC. Distal migration of the catheter to a small vessel or movement of the catheter tip against a vessel wall or bifurcation usually results in a significant change in light intensity. This change alerts the patient care team to the need either to reposition the catheter or to recalibrate the light intensity.

**Interpretation Errors**

Errors in the interpretation of changes in mixed venous oxygenation are much more common than the technical errors described previously. One major class of interpretation errors that has been frequently discussed in the literature is the correlation between \( S_{\text{O}_2} \) and C.O. Numerous studies have now demonstrated that there is insufficient correlation between \( S_{\text{O}_2} \) and C.O. to allow for the venous oxygenation measurements to replace measurements of C.O.11,10,31 Although some studies do show a statistically significant correlation, the correlation is rarely of clinical value.

Another major pitfall in the interpretation of mixed venous oxygen measurements is the assumption that a normal value equates to normal values for all organs. The \( S_{\text{O}_2} \) is a flow-weighted average of the effluents from all perfused vascular beds and in no way gives assurance of normal venous oxygen saturation in any individual vascular bed. High blood flow, low-oxygen-extraction organs (such as the kidneys) have a much greater effect on \( S_{\text{O}_2} \) than do low-flow, high-extraction organs (such as the heart).10

The final major pitfall in the interpretation of mixed venous oxygen measurements has to do with high values. High values imply that the total body \( D_{\text{O}_2} \) exceeds the total body \( V_{\text{O}_2} \). This is commonly seen in states of systemic infection in which either the tissue’s ability to utilize oxygen is impaired or the ability to vasoregulate blood flow to areas of high oxygen demand is abnormal.32 In this situation, a high or increasing \( S_{\text{O}_2} \) may be a bad clinical sign implying worsening of the septic state. On the other hand, a decrease in \( S_{\text{O}_2} \) may be a good sign that the sepsis is coming under control or a bad sign that \( D_{\text{O}_2} \) is not keeping up with an increasing level of consumption. The interpretation of high values of venous oxygen saturation should be done with extreme caution and in light of the entire clinical picture of the patient.

**Clinical Utility**

The assessment of mixed venous oxygenation has become a critical part of the management of patients with severe cardiopulmonary disease. As indicated in the previous sections, the assessment of \( S_{\text{O}_2} \) plays a key role in the assessment of \( C_{\text{O}_2} \). Its measurement is critical for the calculation and interpretation of data to answer three primary questions in the care of critically ill patients.

The first question that is asked in patients with severe cardiopulmonary disease is whether the \( D_{\text{O}_2} \) is satisfactory to maintain the consumption of oxygen at the tissue level. It is generally recognized today that maintenance of maximal levels of oxygen consumption improves the outcome in some groups of critically ill patients.33,34 \( V_{\text{O}_2} \) must increase to meet the demand for oxygen that is created at the tissue level. If the \( D_{\text{O}_2} \) to the tissue is markedly compromised, consumption may decrease to a level that it becomes flow dependent.35-40 A stable and normal value for \( S_{\text{O}_2} \) indicates that the \( D_{\text{O}_2} \) is adequate for the level of consumption at the tissue level.

The second question that is asked is whether C.O. is adequate for the current level of \( V_{\text{O}_2} \). The Fick equation relates C.O., \( V_{\text{O}_2} \), and oxygen extraction as defined by the \( C_{\text{a},\text{\%}} \). Because of this relationship, the \( C_{\text{a},\text{\%}} \) gives an indication of the adequacy of C.O. in relationship to \( V_{\text{O}_2} \). Because \( S_{\text{O}_2} \) is necessary for the calculation of the \( C_{\text{a},\text{\%}} \), the utility of this measurement should be clear.
The third question that is often asked in critically ill patients is whether the \( \dot{V}_{\text{O}_2} \) (that volume of oxygen that is actually used by the tissue) has increased to meet the actual demand for oxygen (that volume of oxygen that is needed by the tissues to function aerobically). Whenever the demand for oxygen exceeds the actual \( \dot{V}_{\text{O}_2} \), anaerobic metabolism must occur. In these states, lactic acid often accumulates and is manifested as a lactic acidosis. An elevated lactic acid concentration implies either decreased metabolism of lactic acid or increased production. When one is trying to sort this out at the patient's bedside, the finding of a normal and adequate \( S_{\text{O}_2} \) implies that oxygen transport, in fact, is well balanced and an increased lactic acid usually implies peripheral washout of lactate that has accumulated or decreased lactate metabolism rather than ongoing increased production.

\( S_{\text{O}_2} \) is a crucial value used also for the calculation of right-to-left intrapulmonary shunting. The calculation of intrapulmonary shunt is an accurate indicator of the magnitude of lung oxygenation dysfunction. Because the calculation of shunt requires the measurement of \( S_{\text{O}_2} \), this value is useful in the assessment of patients with acute respiratory failure.

While the assessment of \( S_{\text{O}_2} \) has apparent clinical utility, the continuous measurement of \( S_{\text{O}_2} \) provides data for the calculation of all the previously described oxygen transport parameters and serves as a monitor for acute changes in the value. Continuous monitoring of \( S_{\text{O}_2} \) has been advocated in three clinical situations. The first situation is to assure that oxygen transport is, in fact, in balance. A normal value of \( S_{\text{O}_2} \) implies that the relative balance between oxygen supply and demand is being maintained.

An acute change in \( S_{\text{O}_2} \) indicates a disruption in the balance between the \( D_{\text{O}_2} \) and \( \dot{V}_{\text{O}_2} \). This acute change should alert the clinical team that more information is needed. Because \( S_{\text{O}_2} \) monitoring provides sensitive but not specific information regarding oxygen transport balance, data may be needed that include C.O., hemoglobin concentration, \( S_{\text{A}_\text{O}_2} \), and lactic acid. In this regard, \( S_{\text{O}_2} \) may serve as an early warning of potential untoward events.

In patients with inadequate oxygen transport, \( S_{\text{O}_2} \) monitoring can be used to titrate therapy to optimize \( D_{\text{O}_2} \) in relationship to \( \dot{V}_{\text{O}_2} \). The continuous device can provide minute-to-minute assessment of the oxygen transport balance during the titration of vasoactive drugs or administration of blood products or fluid. Steady improvement in \( S_{\text{O}_2} \) may be viewed as a sign of adequate resuscitation and worsening of \( S_{\text{O}_2} \) or failure to improve the value should be viewed as a sign that further information is needed because the patient is not making therapeutic progress. Therefore, a low or decreasing \( S_{\text{O}_2} \) should be an indication that the patient is in trouble and more information is necessary.

A high \( S_{\text{O}_2} \), as stated previously, is difficult to interpret. In patients with sepsis, cirrhosis, or other hyperdynamic states, the interpretation of changes in \( S_{\text{O}_2} \) is particularly difficult. Further clinical information is almost always necessary prior to treatment when \( S_{\text{O}_2} \) is above the normal range. However, a low \( S_{\text{O}_2} \) in patients with a presumed hyperdynamic state should be viewed as an ominous clinical sign and an indication for prompt oxygen transport resuscitation.

**Cost Efficiency**

Cost efficiency of continuous \( S_{\text{O}_2} \) monitoring is a subject of great debate. Studies have indicated tremendous cost savings using a continuously monitored value, but other studies have shown cost increase in all patients or in subsets of patients when the more expensive venous oximetry catheter is used. The incorporation of fiberoptics into the flow-directed PAC adds approximately $100-$120 to the cost of the catheter. For this monitoring technique to be cost-efficient, savings must be obtained by reducing the frequency of blood gas analyses, hemodynamic measurements, or calculation of derived parameters. This question has been evaluated in the literature and again conflicting results have been reported. It seems apparent at this time that when the \( S_{\text{O}_2} \) values obtained by the continuous monitoring technique are used in clinical decision making in critically ill patients, the technique is cost-effective. When changes in \( S_{\text{O}_2} \) merely trigger the reaction of remeasuring all val-
ues and confirming the calibration of the monitoring device, costs are actually increased above those incurred by routine PAC monitoring.\textsuperscript{38,49}

To this date, the appropriate studies have not been performed to determine whether $S\textsubscript{O}_2$ monitoring, in fact, improves patient outcome. The design of these studies is obviously difficult but, yet, is essential for continued use of this expensive monitoring technology.

**Future Applications**

Continuous monitoring of $S\textsubscript{O}_2$ is being incorporated into a variety of new-generation oxygen transport monitors. These monitors in general have used pulse oximetry as a means of assessing arterial saturation and a microcomputer to perform calculations yielding derived oxygen transport variables.

The first of these monitoring techniques was called dual oximetry. Arterial and venous saturation signals were fed into the bedside computer system so that a continuous display of the OUC and an index of right-to-left intrapulmonary shunting could be displayed.\textsuperscript{50,51} This system was demonstrated to have clinical utility in the hands of the original investigators.\textsuperscript{50-52} It is very likely that this system will become commercially available within the next year.

Even if a commercially available system incorporating arterial and venous saturation signals is not available, the utility of the availability of these two signals simultaneously is obvious. In patients with decreased $S\textsubscript{O}_2$, a convergence between $S\textsubscript{O}_2$ and venous saturation implies a worsening of the right-to-left intrapulmonary shunting. On the other hand, a divergence of venous saturation away from the $S\textsubscript{O}_2$ implies increased peripheral utilization of oxygen and decreased shunting. Clinical observation of these two variables seems to be clinically useful.

The other monitoring technique that has been evaluated using continuous venous oximetry combines both pulse oximetry and inspired and expired gas analysis to give continuous $V\textsubscript{O}_2$ calculations. Because the oximetry devices can give an approximation of $C\textsubscript{a}\textsubscript{O}_2$, C.O. can be calculated continuously using the Fick equation. Although this particular continuous C.O. monitoring technique is not available commercially at this time, it is being actively investigated in a number of centers.\textsuperscript{53-55}

**Conclusions**

The evaluation of mixed venous oxygenation has become commonplace in many ICUs today. Patient populations in whom this monitoring technique is cost-effective and in whom it is beneficial for patient care have not been precisely determined. The continuous assessment of $S\textsubscript{O}_2$ seems to have significant clinical utility when properly applied. Overuse of this monitoring technique and improper patient selection may cause further increases in hospital costs without significant benefit in patient care.\textsuperscript{56}

**ACKNOWLEDGMENTS**

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MONITORING VENOUS OXYGENATION


In-Vivo Monitoring of Arterial Blood Gases and pH

Barry A Shapiro MD

Introduction

In-vitro methods for analysis of blood oxygen, carbon dioxide, and hydrogen ion concentration were developed more than 100 years ago but were limited to the research laboratory because they required several hours of technician time to achieve a single set of measurements.1 Electrochemical techniques requiring only a few minutes to measure arterial pH, PCO2, and PO2 (the “blood gases”) were introduced in 1956,2 but two decades passed before 24-hour availability of blood gas measurements was a reality in most hospitals.3

A clinical analyzer is a device that requires removal of body fluid or tissue to perform a measurement, and it allows a single device to serve multiple patients. The major disadvantages of blood gas analyzers are that (1) they provide intermittent data with significant delay secondary to transportation of the sample and transmission of the results, (2) the frequency of measurement is limited because blood samples must be permanently removed from the patient, and (3) the blood sample is subject to pre-analytic error.4 Modern blood gas machines combine electrochemical sensors with microprocessor technology, resulting in automated analyzers that routinely check calibration and minimize technician time. The availability of these sophisticated electrochemical analyzers has culminated in arterial blood gases becoming a cornerstone in guiding cardiopulmonary supportive care in the operating room (OR) and the intensive care unit (ICU). In fact, arterial blood gases are presently the most frequently ordered laboratory examination in the OR and ICU.5

A clinical monitor is a device dedicated to a single patient that measures biomedical data as frequently as is considered necessary, without removing body fluid or tissue. Table 1 classifies clinical monitors in a descending order of desirability. Because electrochemical techniques are not readily adapted to in-vivo use, other techniques are required to make patient-dedicated blood gas monitors possible.6

Table 1. Classification of Clinical Monitors

<table>
<thead>
<tr>
<th>Classification</th>
<th>Examples</th>
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<tbody>
<tr>
<td>Noninvasive, continuous</td>
<td>ECG, pulse oximeter</td>
</tr>
<tr>
<td>Noninvasive, intermittent</td>
<td>Sphygmomanometer</td>
</tr>
<tr>
<td>Invasive, continuous</td>
<td>Transduced blood pressure</td>
</tr>
<tr>
<td>Invasive, intermittent</td>
<td>Thermal-dilution cardiac output</td>
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Optode Microsensing

A sensor that operates via electrochemical properties is an “electrode”; a sensor that operates via optical detection of altered light is an “optode.”7 Advances in fiber optic and microprocessor technology, combined with optical techniques that alter light without consuming reagents, led to the development of miniaturized optodes with great potential for biomedical applications.8 Either transmission-based or fluorescence-based chemistries can be used as indicators for optode microprocessing.

Transmission Optodes

Transmission optodes require two optic paths. One optic path carries a light of known intensity to
an indicator. Changes in concentration of an analyte within the indicator cause attenuation of the light by absorption, scattering, reflection outside the fiber, or reflection at the fiber surface. A second optic path carries the attenuated light. An absorbance-based optode has been described for in-vivo pH measurement.9

**Fluorescent Optodes**

A fluorescent optode is essentially an optic fiber with a fluorescent dye at one end. A fluorescence chemical contains components that are activated when exposed to an appropriate light intensity. When the light exposure ends, the electrons return to basal activity and in that process emit a light (fluorescence) of lower frequency, or intensity, than that of the excitation light source. A fluorescent dye will either augment or quench fluorescence as the concentration of a specific analyte changes within the dye. Fluorescence-based optodes have been described for patient-dedicated measurement of pH, P<sub>CO<sub>2</sub></sub>, and P<sub>O<sub>2</sub></sub>.10,11

A limitation of fluorescent optodes is the relatively small number of substances that fluoresce. Energy-transfer optodes combine a colorimetric reagent with a fluorescent indicator, greatly increasing the range of substances that can be measured with fluorescent optodes. Optic probes that measure sodium ion and pH using energy-transfer techniques have been described.12

**Clinical Feasibility of Optode Blood Gas Monitors**

To justify its routine clinical use in the OR and ICU, a patient-dedicated blood gas monitor must fulfill at least the nine requirements listed in Table 2. Our group at Northwestern University recently reported an evaluation of a fluorescent optode intravascular blood gas system intended to continuously measure arterial pH, P<sub>CO<sub>2</sub></sub>, and P<sub>O<sub>2</sub></sub> (CDI System 1000, CDI-3M Healthcare, Irvine CA).13 Animal studies comparing the optode-system values to arterial-sample values revealed excellent correlation (r<sup>2</sup> = 0.94 for pH, 0.90 for P<sub>CO<sub>2</sub></sub>, 0.92 for P<sub>O<sub>2</sub></sub>)—with pH ranging from 7.05 to 7.57, P<sub>CO<sub>2</sub></sub> ranging from 18 to 92 torr, and P<sub>O<sub>2</sub></sub> ranging from 27 to 313 torr. A clinical study was designed to evaluate the performance of the optode system in the OR and ICU when all patient-interface conditions known to alter the optode system’s function were absent. Of 23 carefully selected patients, 12 met the criteria for more than 24 hours. These highly selective patient data confirmed the excellent correlations of the animal data—with the clinical correlations being r<sup>2</sup> = 0.94 for pH, 0.92 for P<sub>CO<sub>2</sub></sub>, and 0.98 for P<sub>O<sub>2</sub></sub>—and they demonstrated bias (mean difference between optode and arterial values) and precision (SD of differences) of 0.002 and 0.02 for pH in the range of 7.30-7.62; 0.44 and 2.97 for P<sub>CO<sub>2</sub></sub> in the range of 24-67 torr; and 1.33 and 6.49 for P<sub>O<sub>2</sub></sub> in the range of 34-99 torr. These findings confirm that the clinical performance of this device is within 95% confidence limits that imply that the system could have replaced conventional blood gas analysis in these patients. However, because of the major patient-interface problems encountered with the CDI System 1000, only the first three requirements in Table 2 were met.14

**Table 2. Minimal Requirements for a Blood Gas Monitor in Conjunction with Arterial Catheters**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
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<tbody>
<tr>
<td>1. Must accurately measure pH, P&lt;sub&gt;CO&lt;sub&gt;2&lt;/sub&gt;&lt;/sub&gt;, and temperature, with rapid response time.</td>
<td></td>
</tr>
<tr>
<td>2. Must be operable with a 20-gauge arterial catheter and not negatively affect (1) continuous pressure measurement, (2) obtaining of blood samples, or (3) routine function of the arterial catheter system.</td>
<td></td>
</tr>
<tr>
<td>3. Must be biocompatible and nonthrombogenic, so that the arterial catheter’s longevity, reliability, and rate of complications are not negatively affected.</td>
<td></td>
</tr>
<tr>
<td>4. Must be simple to operate and maintain.</td>
<td></td>
</tr>
<tr>
<td>5. Must be able to withstand the abuse and rigors of clinical conditions common to the OR and ICU.</td>
<td></td>
</tr>
<tr>
<td>6. Must be stable and consistent for at least 72 hours.</td>
<td></td>
</tr>
<tr>
<td>7. Must not be adversely affected by reduction in local blood flow or temperature.</td>
<td></td>
</tr>
<tr>
<td>8. Must not be adversely affected by the hemodynamic changes often encountered in critically ill patients.</td>
<td></td>
</tr>
<tr>
<td>9. Must be cost-effective.</td>
<td></td>
</tr>
</tbody>
</table>

**Blood Gas Monitors Currently in Clinical Trials**

The PB 3300 Intra-Arterial Blood Gas Monitor (Puritan-Bennett Corp, Los Angeles CA) has three fluorescent optodes with significant design improvements that appear to provide accuracy, stability, and dependability over at least 72 hours.
Another important feature is that the microsensors are transportable between instruments, allowing for easy patient transfer from OR to ICU. The Optex BioSentry Optode System (Optex Biomedical Inc. The Woodlands TX) incorporates both transmission and fluorescent optodes with a unique side-window sample-chamber configuration that appears to lend stability and precision. Both of these continuous blood gas monitors have sophisticated microprocessor systems that provide trend data and alarms. Preliminary data from clinical trials suggest that these products meet at least the first six requirements in Table 2: how well they meet the final three requirements has yet to be determined, but there is ample justification for optimism.

A rapid on-demand fluorescent optode blood gas monitor in which the fluorescent optodes are attached directly to the arterial catheter is currently being studied in multicenter clinical trials (CDI System 2000, CDI-3M Healthcare, Irvine CA). When blood gas values are desired, blood is drawn back from the arterial catheter into a chamber that is in contact with the optodes, and the values are displayed in approximately 90 seconds. The line is then flushed as if a routine blood sample had been drawn. No blood is removed from the patient, and there is no break in the sterile fluid path of the arterial catheter system. Blood gas measurement can be performed as frequently as desired, and the system could readily be automated to obtain blood gas values at intervals desired by the therapist, nurse, or physician. Although this on-demand system does not provide continuous values, it avoids the interface problems encountered with intravascular optode placement. Our preliminary experience with this device suggests that it may meet all nine requirements listed in Table 2.

Advantages of Blood Gas Monitors (Table 3)

Arterial catheters are routinely placed in OR and ICU patients when the need for continuous blood pressure monitoring or frequent blood gas measurement is anticipated. For such patients, the appropriateness of blood gas monitors is obvious as long as there is no requirement to alter the size, location, or placement of the arterial catheter, and the routine use and maintenance of the arterial catheter system is unaffected.

Table 3. Advantages of Blood Gas Monitors in Conjunction with Arterial Catheters

<table>
<thead>
<tr>
<th>Advantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. They provide a proactive monitor with alarms for early warning of significant changes, perhaps leading to therapeutic intervention prior to significant physiologic disruption.</td>
</tr>
<tr>
<td>2. They furnish immediate and continuing blood gas trends, allowing for more rapid and precise changes in respiratory supportive therapy such as supportive ventilation, PEEP, and oxygen.</td>
</tr>
<tr>
<td>3. They reduce blood loss incident to obtaining data.</td>
</tr>
<tr>
<td>4. They reduce the risks of nosocomial infection.</td>
</tr>
<tr>
<td>5. They reduce the exposure of personnel to patients’ blood.</td>
</tr>
</tbody>
</table>

Continuous blood gas monitors should permit proactive therapeutic intervention because alterations in respiratory homeostasis may be detected prior to changes of clinical signs. Both continuous and on-demand blood gas monitors should significantly reduce therapeutic decision time (the interval between ordering a test and initiating therapeutic action based on the test results). Reducing therapeutic decision time to a few minutes would permit rapid and dependable titration of common therapeutic modalities such as oxygen administration, positive-pressure ventilation, positive end-expiratory pressure, and alkali therapy.

Because the two major reasons for limiting the frequency of in-vitro blood gas measurements are blood loss and cost, with blood gas monitors the blood gas values would be available as frequently as deemed necessary without increased cost, while a major portion of blood removal for laboratory testing would be eliminated. Further, the risk of nosocomial infection from contaminated arterial catheters should be reduced because the integrity of the arterial line system is not interrupted to obtain blood gas values. Coincidentally, the frequency of exposure of personnel to the patient’s blood would be markedly reduced.

Potential Impact of Blood Gas Monitors

Assuming an acceptable cost for patient-dedicated blood gas monitors, the advantages listed in Table 3 would be reason enough for enthusiasm.
Such enthusiasm notwithstanding, I believe that these factors represent the ‘tip of the iceberg’ regarding the impact that blood gas monitors will have on patient care in the OR and ICU. I submit that capnographs and transcutaneous oxygen electrodes, in conjunction with blood gas monitors, have the potential to reliably trend cardiac output and quantify the shunt fraction in the majority of OR and ICU patients. No direct data confirming this has yet been published because blood gas monitors have not been available for prolonged study. However, the information referenced below suggests that these concepts will prove clinically useful.

Arterial CO₂ to End-Tidal CO₂ Gradient

The difference between arterial and end-tidal CO₂ (ie, the gradient, PₐCO₂ - PₑCO₂) is a function of dead-space ventilation. The two major pathologic factors that alter this gradient are lung disease and changes in cardiac output. As is illustrated in Figure 1, an acute change in the PₑCO₂ without simultaneous change in capnographic configuration should indicate a change in cardiac output. This concept offers the ability to trend cardiac output changes occurring in response to interventions such as intravenous fluid therapy, inotropic therapy, or diuretic therapy.

Arterial P₀₂ to Transcutaneous P₀₂ Gradient

The transcutaneous oxygen tension (PₑCO₂) is determined by both the arterial P₀₂ and skin perfusion. Simultaneous consideration of PₐO₂ and PₑCO₂ makes it possible to derive the PₑCO₂ index [PₑCO₂/PₐO₂], which has been shown to correlate with cardiac output and perfusion. When post-resuscitation fluid administration is not sufficient, the PₑCO₂ index is low despite normal blood pressure, and persistently low PₑCO₂ indices often precede cardiac arrest by 45 to 60 minutes. The PₑCO₂ index should provide an early detection of global perfusion deficit because skin is normally the first organ system to sustain decreases in blood flow in the presence of such deficit. It is reasonable to assume that in the absence of sepsis and drugs that alter skin perfusion, an acceptable PₑCO₂ index reflects an adequate global perfusion status.

Estimating Intrapulmonary Shunt Fraction

Although far from ideal, calculation of the intrapulmonary shunt fraction is the most reliable way to quantify disruption of pulmonary oxygen transfer. Because calculation of the shunt fraction requires determination of both arterial and mixed-venous oxygen content, numerous tension-based indices [Pₑ(Pa-O₂)/PₑCO₂, PₑCO₂/PₑO₂, PₑCO₂/PₑO₃, Pₑ(Pa-O₂)/PₑCO₂] have been proposed to reflect the shunt fraction when mixed-venous blood is not available. However, oxygen tension indices correlate poorly with the shunt fraction in critically ill patients, which is a predictable finding, as a non-linear relationship exists between oxygen content and oxygen tension when hemoglobin is < 95% saturated.

Oxygen content indices should reliably reflect the shunt fraction. The estimated shunt is the clinical shunt equation with an assumed Cₒ₂ of 3.5 mL/dL, and it has been demonstrated to be superior to tension-based indices in reflecting the intrapulmonary shunt fraction. An acceptable PₑCO₂...
index should validate the assumption that the $C_{(a-v)O_2}$ is 3 to 4 mL/dL, thereby confirming the reliability of the estimated shunt to quantify changes in the shunt fraction.

**Summary**

Despite technologic sophistication, electrochemical analyzers cannot provide the frequency or response times available from optode blood gas monitors. Optode microsensing has developed to the point where three companies are currently engaged in multicenter clinical trials of blood gas monitors. The continuous or rapid on-demand availability of blood gases promises to have far-reaching impact in the OR and ICU, especially in the reduction of therapeutic decision time to essentially that of the practitioner’s response time. Using this new technology in combination with currently available noninvasive monitors, it should be possible to trend cardiac output and reflect changes in the intrapulmonary shunt fraction in many patients with nothing more invasive than a 20-gauge radial artery catheter. Blood gas analyzers have had an astounding influence on the growth and expansion of the respiratory care profession. In my opinion, the translocation of blood gas measurement from the clinical laboratory to patient-dedicated monitors will have as significant an effect on OR and ICU practice as did the introduction of blood gas analyzers more than 30 years ago.

**REFERENCES**

Computers in the ICU: Panacea or Plague?

Thomas D East PhD

The introduction of the intensive care unit (ICU) in the 1960s with its demands for management of large volumes of patient data drove the initial introduction of computers into the ICU. Since the mid-1960s computer systems for the ICU have evolved into the highly sophisticated bedside workstations commercially available today. Despite all of the technologic advances in computers, their application in ICUs in the United States continues to spread very slowly. One of the largest problems is justifying the cost of systems primarily designed to automate data charting and generation of care plans. Although the existing commercial systems do an excellent job, few conclusive studies prove that these systems have a favorable cost-to-benefit ratio. Research systems have demonstrated that if one extends these systems to incorporate a fully integrated database, decision-support tools, automation of data acquisition, and more sophisticated display and user-interface technology, then these ICU computer systems can have a significant impact on improving the quality and reducing the costs of patient care. For computers to be embraced in the ICU environment, commercial systems of the future must move beyond merely gathering and displaying information. They must help the clinician at the bedside assimilate the vast array of ICU data and help him to make more effective decisions. (Respir Care 1992;37:170-180.)

History of Computers in the ICU

The intensive care unit (ICU), introduced widely during the 1960s, created an environment that dictated that large amounts of information be gathered at frequent intervals. This drove the development of the flow sheets typically used in ICU charting today. The flow sheets not only provide a place to conveniently record information in a way that makes it easy to see the temporal sequence of events but also by their design act as a guide for patient assessment.

Because computers easily shuffle large amounts of data in a very rapid, reliable, and repeatable manner, it seems only logical that the large data demands of the ICU would attract computer applications. Computers were first used in intensive care during the 1960s. These systems were all research systems developed at university hospitals on the primitive mainframe computers that constituted the state of the art at the time. Much of the programming was done using punch cards, and the user interacted either through printed reports or by manipulating toggle switches on the front panel of the computer.

The introduction of the minicomputer and the microcomputer in the 1970s dramatically increased the availability of computers, and it was during this era that computers first began to be used routinely in hospitals and ICUs. These systems typically used teletype and primitive video terminal-user interfaces. The proliferation of the early IBM PC (and clones) in the early 1980s greatly enhanced the spread of computers in medicine in general.

Dr East is associated with the Pulmonary Division, LDS Hospital, and the Medical Informatics Dept, University of Utah—Salt Lake City, Utah.

The research material on the computer protocols developed using the HELP system was supported by NIH Grant HL36787 "Extracorporeal CO\textsubscript{2} Removal for ARDS," the Deseret Foundation (LDS Hospital), and the Respiratory Distress Syndrome Foundation.

A version of this paper was presented by Dr East during the LifeCare Symposium "New Horizons in Respiratory Care: What's New in the ICU?" during the 1991 Annual Meeting of the AARC in Atlanta, Georgia.

Reprints: Thomas D East PhD, Pulmonary Division, LDS Hospital, 8th Ave and C Street, Salt Lake City UT 84143.
During the late 1970s and early 1980s, several different types of hospital information systems (HIS) were introduced. HIS were designed primarily to deal with the problem of moving data rapidly through a complex institution, and were run on large mainframe systems. They primarily provided support for admission, discharge, and transfer (ADT), order entry, some result reporting, charge capture, and billing. Departmental support systems were focused on satisfying the needs of the ancillary support departments such as the clinical laboratory. These systems typically were stand-alone systems that only performed functions specific to the particular department (eg, specifically for laboratory results reporting) and did not communicate with the HIS. The third type of system was clinical information systems (CIS), targeted at certain ambulatory clinics and subspecialty areas. CIS were typically implemented on mini- and microcomputers. Both HIS and CIS were used in the ICU. During this era a new term was introduced for CIS: patient data management systems (PDMS). The PDMS were basically an extension of the monitoring systems already used in the ICU and was oriented at automating the flow sheet. About 250 PDMS were installed in ICUs from the mid-1970s to about 1985. Of these systems, only 15-25 (6-10%) were actually routinely used to chart patient data. The remaining installations were primarily used to view vital signs and as remote monitoring stations. The primary reasons that these systems failed to achieve routine clinical use were (1) degraded performance under peak load, (2) poor response time, (3) primitive user interface, (4) lack of development and research tools, (5) poor adaptability with few configuration options, (6) high cost to upgrade, (7) lack of reliability/excessive down time, (8) inability to interface to other devices and other HIS, and (9) absence of an integrated patient database.

Many of these weaknesses were the result of hardware and software limitations of the late 1970s and early 1980s. Certain institutions that had a strong commitment to computerization and good local development staff extended these early PDMS and made them very successful. Some notable installations were at Cedar-Sinai Hospital (Los Angeles CA), University of Alabama (Birmingham AL), and the University of Miami/Jackson Memorial Hospital Burn Center (Miami FL).

The evolution of the computer industry in the mid-to-late 1980s blurred many of the previous distinctions between mini-, micro-, and mainframe computers. It rapidly became possible to have what had been considered mainframe computing power in a single chip the size of a postage stamp. Networking allowed these high power microcomputers to communicate and share resources, such as disks and printers. In addition, software and database management systems evolved to a new level at which it was possible to have a networked group of computers with local disk drives that could be viewed as an integrated, centralized patient database composed of many smaller modular elements. New display technology allowed relatively inexpensive, high-resolution color displays. Xerox and then Apple introduced the concepts of the graphical user interface and the use of alternate input devices (eg, mouse and track ball). The graphical user interface consists of icons or symbols (pictures), menus, buttons, slide bars, and a “what you see is what you get” (WYSIWYG) working environment. The whole idea was to try to make the user interface “intuitive” without a lot of training. For example, to delete a file, one would use the mouse to drag the picture of the file into the picture of a trash can.

Commercially Available Systems Today

New developments in the computer industry in the 1980s helped to create the new generation of CIS for the ICU. A variety of sophisticated ICU CIS are available to run either on one of several different networked workstations or in a more traditional centralized minicomputer interfaced to intelligent terminals at the bedside. Almost all systems provide the features shown in Table 1. Table 2 lists the currently marketed computer systems for use in the ICU.

In considering the purchase of such systems, it would be wise to carefully review, and fully itemize, your institution’s needs. Review Table 1 and consider, for each of these elements, exactly what your institution requires. Consulting firms can be hired to do an in-depth analysis of your needs and to make suggestions based on current market products. In general, many of the products are similar in the features that they offer. The features that appear to differentiate among the various products are shown in Table 3.
Table 1. Common Features of ICU Computers Systems in 1991-92

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Communications</strong></td>
<td>Interface to HIS/ADT*</td>
</tr>
<tr>
<td></td>
<td>Interface to laboratories</td>
</tr>
<tr>
<td></td>
<td>Interface to monitors and ventilators</td>
</tr>
<tr>
<td></td>
<td>Interface to accounting and billing systems</td>
</tr>
<tr>
<td></td>
<td>Interface to pharmacy for drug orders and billing</td>
</tr>
<tr>
<td><strong>Charting</strong></td>
<td>Flow sheet</td>
</tr>
<tr>
<td></td>
<td>Fluid intake and output</td>
</tr>
<tr>
<td></td>
<td>Medications</td>
</tr>
<tr>
<td></td>
<td>Laboratory reporting</td>
</tr>
<tr>
<td></td>
<td>Physical exam/patient assessment</td>
</tr>
<tr>
<td></td>
<td>Nutrition</td>
</tr>
<tr>
<td></td>
<td>Notes</td>
</tr>
<tr>
<td></td>
<td>Audit trail on all entries and edits</td>
</tr>
<tr>
<td></td>
<td>Copy forward and default values possible for all fields</td>
</tr>
<tr>
<td><strong>Task management</strong></td>
<td>Patient-specific task list for each shift</td>
</tr>
<tr>
<td></td>
<td>Medication schedule and management</td>
</tr>
<tr>
<td></td>
<td>Kardex</td>
</tr>
<tr>
<td><strong>Planning</strong></td>
<td>Physicians’ orders</td>
</tr>
<tr>
<td></td>
<td>Nurses’ care plans</td>
</tr>
<tr>
<td></td>
<td>Automated care plans based on definitions of problem-oriented charting</td>
</tr>
<tr>
<td></td>
<td>Audit trail of care plan changes</td>
</tr>
<tr>
<td><strong>Review and analysis</strong></td>
<td>Research</td>
</tr>
<tr>
<td></td>
<td>Quality assurance</td>
</tr>
<tr>
<td></td>
<td>Administration</td>
</tr>
<tr>
<td></td>
<td>Graphical display of multiple data items versus time</td>
</tr>
<tr>
<td></td>
<td>X-Y plots of any combination of variables</td>
</tr>
<tr>
<td></td>
<td>Scoring (eg. APACHE) and its use to plan ICU resource allocation</td>
</tr>
<tr>
<td><strong>General issues</strong></td>
<td>User configurability of all charting, care plans, and reports</td>
</tr>
<tr>
<td></td>
<td>Data entry can be made for any patient from any workstation</td>
</tr>
<tr>
<td></td>
<td>Reference library and on-line, context-sensitive help</td>
</tr>
</tbody>
</table>

*HIS = hospital information system; ADT = admission, discharge, and transfer.

Despite all of the vast technologic improvements in ICU computer systems, only about 20 new systems were installed in 1991. With about 5,000 ICUs in the United States, one would expect far more sales per year if these systems are truly as beneficial as their sales staff would have us believe. Why is it such a slow market? Much of the answer probably lies in cost-justification. These systems are typically cost-justified based on the data in Table 4. The only hard data justifying these systems comes from reduced number of positions (FTE, or full-time equivalents) for nursing; however, even this varies widely from study to study. Hammond et al.\(^6\) have demonstrated that an ICU PDMS can significantly reduce the number of errors found in paper flow charts and improve the quality, accuracy, and timely capture and retrieval of data. They did not show a reduction in the required nursing FTEs.\(^7\) Bradshaw et al.\(^8\) showed less nursing time spent on direct patient care (a reduction from 49.1% to 43.2%) and an increase in time spent on clinical data entry (18.2% to 24.2%). Many anecdotal reports address the impact of such systems on the quality of patient care; however, few conclusive studies clearly demonstrate improvement in the quality of patient care. One would assume that the improvements in the quality of the patient chart would impact the quality of patient care; however, some have estimated that it would require a study of at least 6,000 patients to be able to statistically detect any impact on patient outcome (assuming a reduction in mortality from 16% to 14.4%).\(^9\) It may be possible to observe an impact on the quality of patient care by looking at other intermediate indicators such as the length of stay or incidence of medication mistakes. It is essential that carefully designed studies be performed to evaluate the impact of these systems in the ICU.

**Future Commercial ICU Computer Systems**

The main problem with demonstrating efficacy of computers in the ICU may be that the current systems, which focus on automating the charting process, do not really address the needs of the clinician in the ICU environment. What are the real needs of the clinician—physician, nurse, or respiratory care practitioner—at the bedside? We recently went to the bedside of a critically ill patient and counted the current information categories (not repeated measures) that were reviewed for clinical decision making. The total was in excess of 236! Eddy summarized it best: "It is simply unrealistic to think that individuals can synthesize in their head scores of pieces of evidence, accurately estimate the outcomes of different
Table 2. Survey of Commercial Computer Systems Used in Intensive Care Units

<table>
<thead>
<tr>
<th>Company</th>
<th>Location &amp; Contact</th>
<th>Phone</th>
<th>No. of Hospitals</th>
<th>No. of Beds</th>
<th>Hardware</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT-PC</td>
<td>Madison WI</td>
<td>608-273-8860</td>
<td>6</td>
<td>80</td>
<td>286 &amp; 386 PC</td>
<td>CIS/Distributed*</td>
</tr>
<tr>
<td>(Argus 2000)</td>
<td>Joel Gechburg</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMTEK</td>
<td>Tempe AZ</td>
<td>800-633-6835</td>
<td>14</td>
<td>160</td>
<td>Sun SPARC station</td>
<td>CIS/Distributed</td>
</tr>
<tr>
<td>(System 2000)</td>
<td>Harry Comanchero</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hewlett-Packard</td>
<td>Andover MA</td>
<td>617-890-6300</td>
<td>20</td>
<td>100</td>
<td>HP</td>
<td>CIS/Distributed</td>
</tr>
<tr>
<td>(HP CareVue 9000)</td>
<td>John Mitchell</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SpaceLabs</td>
<td>Redmond WA</td>
<td>800-882-3700</td>
<td>32</td>
<td>124</td>
<td>Platform Independent</td>
<td>CIS/Distributed</td>
</tr>
<tr>
<td>(PC Chartmaster)</td>
<td>Dun Soule</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinicom</td>
<td>Boulder CO</td>
<td>619-456-0361</td>
<td>13</td>
<td>2000</td>
<td>IBM Sequent</td>
<td>CIS/Centralized</td>
</tr>
<tr>
<td>(CliniCare)</td>
<td>Chris Houdenschild</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oceania</td>
<td>Palo Alto CA</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>NEXT workstation</td>
<td>CIS/Distributed</td>
</tr>
<tr>
<td></td>
<td>Dick Peters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3M (HELP)</td>
<td>Salt Lake UT</td>
<td>—</td>
<td>3</td>
<td>700</td>
<td>Tandem</td>
<td>HIS/Centralized</td>
</tr>
<tr>
<td>HDS (Ulticare)</td>
<td>San Bernadino CA</td>
<td>—</td>
<td>11</td>
<td>1100</td>
<td>Data General</td>
<td>HIS/Centralized</td>
</tr>
<tr>
<td>SMS (Invision)</td>
<td>Malvern PA</td>
<td>—</td>
<td>9</td>
<td>331</td>
<td>IBM 7690</td>
<td>HIS/Centralized</td>
</tr>
<tr>
<td>TDS (7000 Series)</td>
<td>Atlanta GA</td>
<td>—</td>
<td>5</td>
<td>70</td>
<td>TDS 4270B</td>
<td>HIS/Centralized</td>
</tr>
</tbody>
</table>

*CIS = clinical information system; HIS = hospital information system.

options, and accurately judge the desirability of those outcomes for patients. . . . All confirm what would be expected from common sense: The complexity of modern medicine exceeds the inherent limitations of the unaided human mind." 20 The next generation of computers for the ICU must help the clinician assimilate the myriads of data and to make fast and effective decisions. It is not enough to merely display the data in a large spreadsheet or on a complex colorful graph versus time. New data-display concepts and expert systems need to be included in the commercial products. Few computer systems for the ICU currently provide any tools for decision support.

I believe that the next generation of ICU computer systems must include the following features if they are to have a significant impact on the quality of patient care.

Fully Integrated Database

The system will have to have interfaces for or will already include data from far more than just the ICU, including the ADT, clinical and diagnostic laboratories, radiology, operating room and surgery records, and outpatient clinics. The introduction of prospective reimbursement has caused a shift to performing as many tests as possible on an outpatient basis before hospitalization. It is essential that records and results from these outpatient visits be available and integrated with the ICU data. 21 If the integrated database is handled by interfacing to other systems, the interface must guarantee accurate and timely data (response in < 1 minute) and avoid the pitfalls of a duplicated copy of a remote database. The risk is that some interface techniques might download data periodically
from a remote system. This does not guarantee ‘timely’ access to data and may not guarantee that if data are edited at the original laboratory, changes will be communicated down to the ICU computer system. There is a movement toward the establishment of local, regional, national, and international databases that would track all information on a patient from birth to death.\textsuperscript{21,22} It is obvious that access to such systems would facilitate medical care in our highly mobile society. The integrated database must not only be available in the ICU, but it must also be made accessible to other departments and divisions as needed to complete their own integration. This also applies to billing and accounting, with all procedures charted in the ICU billed separately—thus improving charge capture and reducing lost charges to third-party payers.

\textbf{Tools for Decision Support}

These tools must provide decision support on several levels: (1) seamless access to information
systems such as bibliographies (eg, Medline or BRS Colleague) and on-line reference materials, (2) user-definable alarms and alerts, and (3) user-definable knowledge bases and expert systems.

**Automation of Data Entry**

As much data as possible must be captured automatically to reduce the work load for documentation and to improve the accuracy and timeliness of the charted data. The future of this automation heavily depends on the establishment of an industry standard for communication between medical devices such as the Medical Information Bus (MIB).\(^{15,23-28}\) It is essential that the critical care community become actively involved in the generation of these standards. If it does not, then the commercial vendors will determine what data are important for clinical care, how often they should be collected, and in what format.

**Table 4. Cost-Justification of Commercial ICU Computer Systems**

<table>
<thead>
<tr>
<th>Category</th>
<th>Impact of Computer Systems</th>
<th>Documented Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staffing</td>
<td>Reduced charting time</td>
<td>Reduced FTEs*</td>
</tr>
<tr>
<td>Personnel retention</td>
<td>Reduced documentation burden</td>
<td>Increased nursing satisfaction, Lower turnover, Less training costs</td>
</tr>
<tr>
<td>Record management</td>
<td>Complete, detailed, and legible record that is easily searched</td>
<td>Less time spent on QA(^+), Better risk management, Better insurance audits (fewer lost charges), More complete billing information, DRG management(^\d), Automated assignment of diagnosis</td>
</tr>
<tr>
<td>Supply and resource waste</td>
<td>Elimination of paper record and reduction in errors in medication calculations and duplication of laboratory test orders</td>
<td>Less cost for paper forms, Less wasted medication, Fewer duplicate lab tests</td>
</tr>
<tr>
<td>Improved quality of care</td>
<td>Better quality charts, Automated data entry, Automated calculations, Extensive error checking</td>
<td>Impact on length of stay, Questionable outcome, Questionable morbidity, Questionable quality of care</td>
</tr>
</tbody>
</table>

\(^*\)FTE = full-time equivalents (re, staff positions).
\(^+\)QA = quality assurance.
\(^\d\)DRG = diagnosis-related groups.

**New Display and User-Interface Technology**

There is need for new techniques for graphically presenting data as icons and other strategies designed to take advantage of the human mind’s ability to assimilate pictures and shapes more quickly than numbers and text. Although such techniques are of lesser importance than integration, decision support, and automated data entry, they are important in the drive to help the clinician interpret vast amounts of information and make decisions more effectively. For example, rather than displaying an alert message such as “Warning—The patient is threateningly hypoxic with a PaO\(_2\) = 45 mm Hg.” This concept might be much more quickly interpreted if a small icon of the patient were always displayed color-coded for oxygenation status. A quick glance at the monitor showing a dark blue icon of the patient would clearly indicate the hazardous situation. The user could always...
click on the icon and get more detailed information in a traditional text and quantitative fashion.

Research Examples of the ICU Computer Systems of the Future

Fortunately, several research systems provide examples of many of the features desirable in commercial ICU systems of the future.

Fully Integrated Database

The HELP system, which stands for Health Evaluation through Logical Processing, at my institution (the LDS Hospital, Salt Lake City UT),8,26,29,30 is a comprehensive, hospital-wide, integrated data and decision-support system (Fig. 1) that has evolved over the last 30 years. The integrated database is also used to generate many of the charges. Patients are charged for the room (as in a hotel) and then each charted procedure is billed separately based on the integrated database. The HELP system database includes both inpatient and outpatient data. Intermountain Health Care (IHC), which owns LDS Hospital, is establishing a regional network of IHC facilities that use the HELP system and share a regional integrated database.

![Graph](image)

**Fig. 1.** The number and percentage of the total protocol instructions (from paper-based flow diagrams and from computerized protocols) followed clinically.

Tools for Decision Support

Seamless access to reference materials. The National Library of Medicine31 and several other integrated academic information system (IAMS) research sites are working to integrate reference material such as Medline (accessed through tools such as Grateful Med) and even full text references into the everyday work environment of the hospital. It has been suggested that eventually context sensitive searches will be issued automatically by information systems. For example, if the clinician is currently examining pathology laboratory data, the computer could issue a query for current references explaining the interpretation of tests done on the patient. If the clinician needs help at any point, he could push a button and receive both text and graphic information.

User-definable alarms and alerts. Both the HELP system at the LDS Hospital14,32,34 and the PDMS at Cedar-Sinai Hospital provide alarms and alerts.14 Automated alarms and alerts, which are generated on a variety of data types, can help to direct decision making. At LDS Hospital, alerts and critiques are generated on drug interactions or incompatibilities, drug-allergy situations, drug selection and dosing,15 blood ordering,16 organ dysfunction, or critical changes in laboratory or physiologic parameters.8,32,34 Alerts are automatically generated every time a new piece of information that meets the alert criteria is entered into the system. It is essential to have an integrated database that includes more than just ICU data to adequately perform these functions. For example, a respiratory care manager’s alert is generated when nosocomial infections are noted in patients served by the same respiratory therapist.37,38 The respiratory care department manager can then review proper policy and procedures with the therapist in the hope of reducing nosocomial infections in the future. This particular example requires data from respiratory care charting and laboratory data from microbiology. There is a high benefit-to-cost ratio for such alerting systems.35,36,39

User-definable knowledge bases and expert systems. In the ICUs at the LDS Hospital, decision-support tools are available for antibiotic therapy,8,34 nutritional management,40 and management of mechanical ventilation. Computer protocols for the management of mechanical ventilation (respiratory evaluation, ventilation, oxygenation, weaning and extubation) in patients with adult respiratory distress syndrome (ARDS) have already been developed and clinically validated at the LDS Hospital.37,41-45
The protocols were originally designed to control the treatment in both groups in our clinical trial of extracorporeal CO2 removal for ARDS (ECCO,R, NIH Grant HL-36787). These protocols had to be designed to be followed by the clinical-care staff around the clock at the bedside. A key element of the whole protocol-development process was a driving desire to integrate the clinical environment into the logic-generation process. It was felt that this was the only way to generate a successful protocol that would handle the majority of circumstances encountered and be acceptable to the clinical-care staff. A therapy consensus committee of 14 physicians, 3 nurses, 1 respiratory therapist, and 1 PhD was formed to further develop and refine protocol logic. The committee members came from the Departments of Pulmonary Medicine, Respiratory Care, Critical Care Medicine, and Anesthesia at LDS Hospital and the University of Utah and included two research-associate physicians from the University of Milan (Dr Gattinoni's group). A fundamental philosophy of this committee was to enforce the KIS principle (Keep It Simple). The committee focused on defining the minimum data set and the simplest logic necessary to make decisions. The fundamental belief was that if the logic was too constrained, the limitations would become rapidly evident during testing at the bedside. If persistent problems were encountered at the bedside, the logic could always be made more complex to deal with them. This philosophy resulted in simple logic that focused on just a handful of the myriad of variables present at the bedside. Despite their simplicity, these protocols have been found to work in most situations and have been accepted by practicing physicians.

The protocols (in paper flow-diagram and computerized form) have been used for over 40,000 hours in more than 125 ARDS patients. Figure 1 illustrates the protocol performance for the first 101 patients. The protocols (in both paper and computer forms) controlled care 94% of the time. During the remainder of the time, patient care was not protocol controlled because the patient was in a state not covered by current protocol logic (eg, hemodynamic instability or transport for radiologic studies). The computerized version of the protocols has been used for over 30,000 hours in more than 95 ARDS patients. A total of 19,802 computer protocol instructions were generated. Of the 19,802 computer decisions, 17,670 (90%) were actually followed clinically. Figure 1 illustrates that the computer performance has improved dramatically over time. Performance has been improved by reduction of incomplete, erroneous, and unrepresentative patient data; improvement of the protocol logic and its interpretation; and elimination of software errors.

Fifty-two of these ARDS patients met extracorporeal membrane oxygenation (ECMO) criteria. The survival of the ARDS patients who met ECMO criteria was 41%, four times that expected from historical data (9%) (P < 0.0002). The explanation is unclear for the increased survival seen in patients cared for during the time of protocol application at the LDS Hospital. One possible explanation is the importance of standardization of care. The routine application of around-the-clock rules that minimize the side effects of the therapy may be responsible for improved outcome. It may also be that the decision-support system helps to avoid mistakes that might detrimentally affect patient outcome. These are unproven concepts at the present time; however, it does seem clear that the success of these computer protocols and their acceptance by the clinical staff clearly establish the feasibility of controlling the therapy of severely ill patients.

In the future, we will be working on new critical care protocols for oxygenation and ventilation for a wide variety of ventilatory modes, hemodynamics, acid-base balance, coagulation therapy, sedation, and paralysis. We will be transferring the protocols to a portable system to allow a prospective randomized trial to assess the efficacy of computer decision support at a hospital that does not have the HELP system.

**Automation of Data Entry.**

A pilot version of the Medical Information Bus (MIB) has been installed at the LDS Hospital (Fig. 2), to allow us to learn what problems are likely to be encountered once the devices are interconnected and one tries to obtain reliable, accurate, and representative data. One of the immediate observations is the literal flood of digital data coming from devices. It is impossible to collect all of this data. Filters and data-selection algorithms must
be developed to select only representative data that are important to clinical care. The problem lies in defining "representative" and "important" for a wide variety of data.

New Display Technology.

Commercial computer systems for the ICU are already using icon-based displays and the graphical user interface. What is missing is the use of these concepts to help in the display of data. Some research systems have been developed in the media laboratory at the Massachusetts Institute of Technology. Perhaps, in the distant future, three-dimensional "virtual reality" systems will help in the interpretation of data. The data could be represented as a variety of radii in a spherical coordinate system. The amplitude would be coded not only by position but also by color. The user would look through a stereoscopic display and put his hand in a sensor glove. From the user's perspective, the data may be in the shape of a solid three-dimensional object that can be grabbed by the glove and manipulated in real time to investigate different aspects of data relations. Perhaps the glove would even receive feedback about the "feel" of the surface (ie, smooth or rough).

Summary

Webster's Dictionary defines panacea as "a remedy for all diseases; a universal medicine or remedy," and plague as "That which smites or troubles; any afflictive evil; a scourge; an infestation."

It is clear that the current level of computer technology threatens to pervade all aspects of our life, including the ICU. The current ICU systems may be considered by some to be a plague in the sense that we have not really proven that these systems provide more good than evil, and, yet, they continue to proliferate because of pressures on administration to have an ICU that is considered "modern." I feel that the existing systems are excellent, as far as they go. The only problem is that they have not advanced to the point of being a true asset to the clinician at the bedside. Evidence from research systems suggests that if future commercial ICU systems include essential features—integrated database, decision-support tools, automated data capture, and new display technology and user interfaces—they may indeed become a panacea. The ICU computer system of the future will help us not only to improve the quality of patient care but also to reduce costs—a winning and badly needed combination.

REFERENCES

10. Shabot MM, LoBue M, Leyerle BJ. Use of automatic computerized intensity intervention scores to measure the appropriateness of ICU utilization. In: Proceedings


Positioning, Lung Function, and Kinetic Bed Therapy

Dean Hess MEd RRT, Nikhileshwer N Agarwal MD, and Collin L Myers MD

Positioning, Lung Function, and Kinetic Bed Therapy

Bed rest is commonly used in the care of the ill patient. Patients admitted to the hospital are assigned a bed, and spend most of their time in that bed. In spite of recent interest in early ambulation, particularly in the postoperative period, patients inevitably spend a large fraction of their hospital stay reclining in bed. The deleterious effects of prolonged bed rest have been known for many years (Table 1).\(^1\)\(^-\)\(^7\) Pulmonary effects associated with bed rest include atelectasis, hypoxemia, pneumonia, and pulmonary embolism. It has even been suggested that the changes that occur with prolonged physical inactivity (eg, bed rest) are similar to those changes commonly attributed to the process of aging.\(^8\) In this paper, we review the literature related to changes in lung function with changes in body position, the pulmonary effects of changes in body position with unilateral lung disease, and the use of kinetic bed therapy.

Lung Function with Changes in Body Position

Physiologic Aspects

The changes in lung volume and distribution of ventilation that occur with changes in body posi-

Table 1. Complications of Bed Rest*

<table>
<thead>
<tr>
<th>Respiratory</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Atelectasis</td>
<td></td>
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<tr>
<td>Hypoxemia</td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td></td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td></td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Decreased cardiac output</td>
</tr>
<tr>
<td></td>
<td>Decreased aerobic capacity</td>
</tr>
<tr>
<td></td>
<td>Orthostatic intolerance</td>
</tr>
<tr>
<td></td>
<td>Venous thrombophlebitis</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>Muscle atrophy and loss of strength</td>
</tr>
<tr>
<td></td>
<td>Decreased muscle oxidative capacity</td>
</tr>
<tr>
<td></td>
<td>Bone loss (osteoporosis)</td>
</tr>
<tr>
<td></td>
<td>Joint contractures</td>
</tr>
<tr>
<td></td>
<td>Osteoarthritis</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Constipation</td>
</tr>
<tr>
<td>Genitourinary</td>
<td>Incontinence</td>
</tr>
<tr>
<td></td>
<td>Renal calculi</td>
</tr>
<tr>
<td>Skin</td>
<td>Pressure sores</td>
</tr>
<tr>
<td></td>
<td>Functional</td>
</tr>
<tr>
<td></td>
<td>Impaired ambulation</td>
</tr>
<tr>
<td></td>
<td>Psychological</td>
</tr>
<tr>
<td></td>
<td>Sensory deprivation</td>
</tr>
</tbody>
</table>

*Adapted, with permission, from Reference 1.

Mr Hess is Assistant Director, Department of Research, York Hospital. Dr Agarwal is Director of Trauma Services and the Trauma/Surgical ICU, York Hospital, and Dr Myers is a Resident, Department of Surgery, York Hospital—York, Pennsylvania.

A version of this paper was presented by Mr Hess during the Lifecare Symposium “New Horizons in Respiratory Care: What’s New in the ICU?" during the 1991 Annual Meeting of the AARC in Atlanta, Georgia.

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In a lateral position (in an individual with normal lung function), the FRC is greater in the non-dependent lung. In the supine position, the drop in FRC is greater with paralysis. It is interesting to note that the drop in FRC in the change from the erect to the prone position is not as great as that which occurs in the change to the supine position.

With normal lung function, ventilation is greater in the dependent lung zones. This is due to the pleural pressure gradient (pleural pressure is more negative at the top of the lungs than at the bottom of the lungs), which places alveoli near the bottom of the lungs on a more compliant part of the volume-pressure curve (Fig. 2). Blood flow is also greater to the dependent lung zones (due to gravity). However, the increase in blood flow from the top to the bottom of the lungs is greater than the increase in ventilation (Fig. 3). Therefore, the ventilation/perfusion (V/Q) ratio is greater at the top of the lungs than at the bottom (Figs. 3 & 4).

Changes in body position affect arterial oxygenation because of changes in FRC relative to closing volume (CV), which is the lung volume at which dependent airways and alveoli close. When CV becomes greater than FRC, small airways and alveoli close during tidal breathing. Young persons with healthy lungs have a CV less than FRC. Thus, dependent airways and alveoli do not close during tidal volume breathing, and, subsequently, ventilation is greater to dependent lung fields (Fig. 2). CV increases with age, and becomes greater than

![Diagram](image)

**Fig. 1.** In the supine position, the abdominal contents produce a hydrostatic column exerting a pressure of 20 cm H₂O at the lowermost point. The mechanical consequences of this are lower pressure gradients in the dependent portions, leading to reduced inflation during inhalation. (Reprinted, with permission, from Reference 18.)

**Fig. 2.** Volume-pressure curve of the lungs. Because of the pleural pressure gradient, alveoli at the bottom of the lungs are normally on a more compliant part of this curve than alveoli near the top of the lungs.

**Fig. 3.** Relative blood flow, ventilation, and V/Q gradients from the top of the lungs to the bottom of the lungs. (Adapted, with permission, from Reference 17.)
FRC even in erect individuals with normal lungs who are older than 65 years. In the supine position, CV exceeds the FRC at approximately 44 years in individuals with normal lung function. Due to the pleural pressure gradient, CV exceeds FRC first in dependent lung regions and results in hypoxemia. With a decrease in FRC, as occurs with acute respiratory failure, dependent alveoli and airways close if FRC becomes less than CV (Fig. 5), resulting in preferential ventilation of nondependent lung regions, decreased V/Q in dependent lung regions (which have the greater blood flow), and hypoxemia. These effects are further aggravated by the supine position.

Clinical Studies

Theoretically, oxygenation should be better in the sitting position than in the supine position. Although this has been found to be the case in several studies, it has not been a universal finding (Table 3). In a group of normal subjects and another group of subjects with COPD, Marti and Ulmer found a higher Po2 in the sitting position than the supine position in the 34- to 54-year-old subjects in each group. In postoperative patients after upper-abdominal surgery, Güi et al found no difference in Po2 between the supine and sitting position. Dalrymple et al and Russell found a lower Po2 in the sitting position than the supine position in intraoperative and postoperative patients. Thus, not all patients necessarily benefit from the sitting position, and the choice of a sitting versus a supine position should be individually determined.
Table 3. Studies Evaluating the Effects of Sitting versus Supine Position on Oxygenation

<table>
<thead>
<tr>
<th>Investigators</th>
<th>n</th>
<th>Subjects</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marti &amp; Ulmer</td>
<td>46</td>
<td>Normal</td>
<td>$P_aO_2$ higher in sitting position than supine position</td>
</tr>
<tr>
<td></td>
<td>27</td>
<td>COPD</td>
<td>$P_aO_2$ higher in sitting position than supine position</td>
</tr>
<tr>
<td>Gui et al</td>
<td>9</td>
<td>Postoperative</td>
<td>No difference in $P_aO_2$ between sitting position and supine position</td>
</tr>
<tr>
<td>Dalrymple et al</td>
<td>6</td>
<td>Intra-operative</td>
<td>$P_aO_2$ higher in supine position than sitting position</td>
</tr>
<tr>
<td>Russell</td>
<td>19</td>
<td>Postoperative</td>
<td>$P_aO_2$ higher in supine position than sitting position</td>
</tr>
<tr>
<td>Marini et al</td>
<td>25</td>
<td>Normal</td>
<td>A small, but significant, decrease in arterial oxygen saturation when changing from sitting to supine to head-down positions</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>Advanced COPD</td>
<td>No difference in arterial oxygen saturation between sitting, supine, and head-down positions</td>
</tr>
<tr>
<td>Biddle et al</td>
<td>60</td>
<td>Postoperative</td>
<td>Arterial oxygen saturation best with head of bed elevated 45° and patients coached to deep breathe during transport from operating room to recovery room</td>
</tr>
</tbody>
</table>

Marini et al\textsuperscript{29} evaluated the effect of head-dependent positions on lung volume and oxygen saturation in normal subjects and subjects with COPD. In that study, subjects were evaluated in sitting, supine, lateral decubitus, and head-down positions. In normal subjects, a marked decrease in FRC occurred with the change from the sitting to supine position, but fell little more in a head-down position. In contrast to the supine position, the fall in lung volume was less in the lateral decubitus position. Unlike the normal subjects, COPD patients had little change in FRC with changes in body position. In the normal subjects, there was a small, but significant, fall in arterial oxygen saturation in the supine and head-down positions. However, no change in arterial oxygen saturation occurred with changes in body position in the COPD patients.

Several studies have evaluated the effects of supine versus lateral positions on oxygenation (Table 4\textsuperscript{31-33}). Clauss et al\textsuperscript{31} reported higher $P_aO_2$ values in the lateral position than the supine position in subjects with normal lungs, subjects with chronic lung disease, and subjects following thoracotomy. Zack et al\textsuperscript{32} found higher $P_aO_2$ values with the good lung dependent in patients with unilateral lung disease, higher $P_aO_2$ values with the right lung down in patients with bilateral lung disease, and no change in $P_aO_2$ in either lateral position in patients with normal lung function.

Table 4. Studies Evaluating the Effects of Lateral versus Supine Position on Oxygenation

<table>
<thead>
<tr>
<th>Investigators</th>
<th>n</th>
<th>Subjects</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clauss et al</td>
<td>15</td>
<td>Normal lung function</td>
<td>$P_aO_2$ higher in lateral position than supine position</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>Chronic lung disease</td>
<td>$P_aO_2$ higher in lateral position than supine position</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>Thoracotomy</td>
<td>$P_aO_2$ higher in lateral position than supine position</td>
</tr>
<tr>
<td>Zack et al</td>
<td>7</td>
<td>Normal lung function</td>
<td>No change in $P_aO_2$ with change in body position</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>Bilateral disease</td>
<td>$P_aO_2$ higher when lying on right side</td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>Unilateral disease</td>
<td>$P_aO_2$ higher with healthy lung down</td>
</tr>
<tr>
<td>Bozynski et al</td>
<td>18</td>
<td>Stable mechanically ventilated newborns</td>
<td>No difference in transcutaneous $P_O_2$ in supine and lateral positions</td>
</tr>
</tbody>
</table>
Table 5. Studies Evaluating the Effects of Prone versus Supine Positions on Oxygenation

<table>
<thead>
<tr>
<th>Investigators</th>
<th>n</th>
<th>Subjects</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Douglas et al34</td>
<td>6</td>
<td>Acute respiratory failure; mechanical ventilation</td>
<td>( P_{aO_2} ) higher in prone position than supine; initial response better than subsequent response; arbitrary limit of 4 h used for the prone position</td>
</tr>
<tr>
<td>Piehl &amp; Brown35</td>
<td>5</td>
<td>ARDS; mechanical ventilation</td>
<td>( P_{aO_2} ) increased a mean (SD) of 47 (16) torr when patients changed from supine to prone position; after 4-6 h in the prone position, ( P_{aO_2} ) values gradually fell</td>
</tr>
<tr>
<td>Langer et al36</td>
<td>13</td>
<td>ARDS</td>
<td>( P_{aO_2} ) improvement of at least 10 torr after 30 min of prone position in 8/13 patients</td>
</tr>
<tr>
<td>Martin et al37</td>
<td>16</td>
<td>Preterm infants</td>
<td>Transcutaneous ( P_{O_2} ) increased a mean of 7.4 torr (15%) when the infants were prone</td>
</tr>
<tr>
<td>Wagaman et al38</td>
<td>14</td>
<td>Intubated infants</td>
<td>Mean (SD) ( P_{aO_2} ) 70.4 (2.5) torr in supine position and 81.1 (4.4) torr in prone position</td>
</tr>
</tbody>
</table>

Differences in \( P_{aO_2} \) between the supine and the prone positions have also been evaluated (Table 5). In 6 mechanically ventilated patients with acute respiratory failure, Douglas et al34 found that \( P_{aO_2} \) increased by a mean of 69 torr in the prone position. Although the increase in \( P_{aO_2} \) when changing from the supine to prone position was less following subsequent turns, it was nonetheless a modest increase of 35 torr (Fig. 6). Piehl and Brown35 evaluated the prone position in 5 mechanically ventilated patients with ARDS. They found a mean (SD) increase in \( P_{aO_2} \) of 47 (16) torr after turning the patients from the supine to the prone position. However, they also noted that after 4-8 hours in the prone position, the \( P_{aO_2} \) values gradually fell. Langer et al reported an improvement in \( P_{aO_2} \) \( \geq 10 \) torr after 30 minutes in the prone position in 8/13 ARDS patients.36 Martin et al37 evaluated changes in transcutaneous \( P_{O_2} \) (\( P_{tcO_2} \)) after turning premature infants from the supine to the prone position, and reported a modest mean increase in \( P_{tcO_2} \) of 7.4 torr (15%) (Fig. 7). Similarly, Wagaman et al38 reported a mean increase in \( P_{aO_2} \) of 11 torr in intubated infants turned from a supine to a prone position. The results of these studies indicate that the prone position may improve oxygenation in some patients. Unfortunately, use of the prone position is not very practical, particularly in intubated mechanically ventilated patients, postoperative patients, and patients who have sustained multiple trauma.

The reasons for the improvements in \( P_{aO_2} \) that occur when acutely ill patients are turned from a supine to a prone position are unclear. Animal studies, however, suggest that gravitational influences on pulmonary blood flow are a minor determinant of this effect.39-41

![Fig. 6. Changes in \( P_{aO_2} \) with changes in body position between the supine and prone positions. (Reprinted, with permission, from Reference 34.)](image-url)
Changes in Body Position with Unilateral Lung Disease

A number of studies have evaluated the effects of changes in body position in patients with unilateral lung disease (Table 6). In adult patients, the results of these studies are very similar.\textsuperscript{42-51} Positioning of patients with the good lung down results in a higher $P_{a02}$ (Figs. 8 & 9). Because gravity causes greater blood flow to dependent lung zones, positioning the good lung down presumably improves V/Q by placing the more ventilated lung in the area of greatest blood flow. Although there are many approaches to the management of adult patients with unilateral lung disease,\textsuperscript{52} positioning of the patient with the good lung down may be the easiest and most effective in many cases.
Table 6. Studies Evaluating Effects of Body Position in Patients with Unilateral Lung Disease

<table>
<thead>
<tr>
<th>Investigators</th>
<th>n</th>
<th>Subjects</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Katz &amp; Barash⁴¹</td>
<td>1</td>
<td>Multiple trauma</td>
<td>(P_{\text{AO2}}) best with good lung down</td>
</tr>
<tr>
<td>Seaton et al⁴⁵</td>
<td>12</td>
<td>Post-thoracotomy</td>
<td>In 9 subjects, (P_{\text{AO2}}) greater with unoperated lung (good lung) dependent and lower with operated lung (sick lung) dependent; the opposite effect occurred in 3 subjects</td>
</tr>
<tr>
<td>Dhainaut et al⁴⁶</td>
<td>4</td>
<td>Unilateral pneumonia</td>
<td>(P_{\text{AO2}}) better with good lung down than in supine position</td>
</tr>
<tr>
<td>Remolina et al⁴⁷</td>
<td>9</td>
<td>Unilateral lung disease</td>
<td>(P_{\text{AO2}}) significantly better with good lung down as compared to supine position or sick lung down</td>
</tr>
<tr>
<td>Ibanez et al⁴⁸</td>
<td>10</td>
<td>Unilateral lung disease</td>
<td>(P_{\text{AO2}}) best with good lung down</td>
</tr>
<tr>
<td>Sonnenblick et al⁴⁹</td>
<td>8</td>
<td>Unilateral pleural effusion</td>
<td>(P_{\text{AO2}}) better in the lateral decubitus position with the pleural fluid uppermost</td>
</tr>
<tr>
<td>Rivara et al⁵⁰</td>
<td>8</td>
<td>Ventilated adults with unilateral lung disease</td>
<td>(P_{\text{AO2}}) better with good lung down</td>
</tr>
<tr>
<td>Syracuse et al⁵¹</td>
<td>9</td>
<td>Unilateral consolidation</td>
<td>(P_{\text{AO2}}) best with good lung down</td>
</tr>
<tr>
<td>Heaf et al⁵³</td>
<td>10</td>
<td>Infants with unilateral lung disease</td>
<td>Transcutaneous (P_{\text{O2}}) greater with the good lung uppermost than in supine position or with good lung dependent</td>
</tr>
</tbody>
</table>

In contrast to adults, Heaf et al⁵³ found a higher \(P_{\text{ICO2}}\) in infants with unilateral lung disease when they were placed with the good lung up. Mean (SD) \(P_{\text{ICO2}}\) was 82 (7.6) torr with the good lung up, 73 (7) torr with the good lung down, and 78 (7) torr in the supine position. Krypton lung scans (Fig. 10) and changes in thoracic gas volumes showed that the proportion of ventilation to the good lung was greater with the good lung up.

Many studies have also evaluated the effects of positive end-expiratory pressure (PEEP) in patients with unilateral lung disease.⁵⁴-⁶² These studies consistently show that PEEP may adversely affect arterial oxygenation in patients with unilateral lung disease. In patients with unilateral lung disease, application of PEEP may shunt pulmonary blood flow away from the healthy lung to the diseased lung.

![Fig. 10. Krypton ventilation scans in a normal 31-year-old man and a 2-month-old girl. In the adult, ventilation is greater to the dependent lung. In the infant, however, ventilation is greater to the uppermost lung. (Reprinted, with permission, from Reference 53.)](image-url)
lung, thus increasing right-to-left shunt and decreasing \( P_{aO_2} \). Thus, PEEP should be used judiciously in patients with unilateral lung disease.

**Kinetic Bed Therapy**

It has long been appreciated that patient turning can decrease the frequency of pulmonary complications in patients confined to bed. In fact, side-to-side turning at 2-hour intervals is considered standard nursing care for immobilized patients. It was shown many years ago that prolonged positioning on one side resulted in consolidation of the dependent lung.\(^{62,63}\) Chulay et al\(^{64}\) studied the effects of turning every 2 hours in patients for the first 24 hours following coronary artery bypass surgery and found that there was less postoperative fever and a shorter duration of ICU stay in patients who were turned in comparison to a control group of patients who remained in the supine position. Because normal persons during sleep make one gross postural change every 11.6 minutes, it has been suggested that this is the minimal physiologic mobility requirement for patients supported on a soft surface.\(^{65}\) Because frequent turning is labor-intensive, there has been increasing interest in recent years in the use of beds that automatically turn the patient. Kinetic therapy is the use of a bed that automatically and continuously turns a patient from side to side.

**Technical Aspects**

The Stryker Wedge Turning Frame and Stryker Circ-O-Lectic Bed (Stryker Medical, Kalamazoo MI) are designed to allow spinal-cord injured patients to be turned from supine to prone position (Figs. 11 & 12). Although it appears that these beds are less commonly used since kinetic beds became popular in the early 1980s, they continue to be used in some spinal-cord injury centers. These beds do not represent true kinetic therapy because they do not automatically and continuously turn the patient. Although the currently available Stryker beds are easier to use than previous models, they do require considerable nursing staff time to position the patient. Care must be taken to avoid injury when positioning patients on the Wedge Turning Frame and Circ-O-Lectic Beds because complications and death have been associated with these beds.\(^{66-68}\)

Fig. 11. Stryker Wedge Turning Frame (photograph courtesy of Stryker Medical, Kalamazoo MI).

Fig. 12. Stryker Circ-O-Lectic Beds (photograph courtesy of Stryker Medical, Kalamazoo MI).

The Roto-Rest Bed (Kinetic Concepts Inc. San Antonio TX) (Figs. 13 & 14) rotates continuously on its long axis, through an arc of 124° (62° from a level plane), approximately every 3.5 minutes (1° every 1.7 seconds). Trendelenburg and reverse Trendelenburg positions (maximal 13° in either direction) can be used. Patient position can be locked at a variety of positions along the arc of rotation of the bed. Hatches in the occipital, thoracic, rectal, and extremity areas allow for patient
KINETIC BED THERAPY

Fig. 13. Roto-Rest Bed (photograph courtesy of Kinetic Concepts, San Antonio TX).

Fig. 14. Schematic drawing illustrating the continuous rotation of the Roto-Rest Bed along its rotational axis. (Reprinted, with permission, from Reference 80.)

Fig. 15. BioDyne air-filled bed (photograph courtesy of Kinetic Concepts, San Antonio TX).

care and evaluation. For chest physiotherapy, the patient is positioned and the thoracic hatch opened to provide chest percussion. Variable rotation allows precise unilateral rotation for patients with unilateral lung disease. The Roto-Rest Bed can be used in patients with spinal-cord injury because its design provides for almost complete axial immobilization of the patient. Also, the Roto-Rest Bed will accommodate equipment for skeletal traction.

Another form of kinetic therapy involves the use of air-suspension (fluid-air, air-loss) beds. These are intended to reduce skin breakdown by providing an air support surface. They also provide continuous side-to-side rotation (up to 45°). These include air-filled beds (eg, BioDyne, Kinetic Concepts, San Antonio TX) (Fig. 15) and beds filled with fluidized silicon-coated microspheres (eg, FluidAir, Kinetic Concepts, San Antonio TX). Unlike the Roto-Rest Bed, these beds should not be used in patients with an unstable spine or those with spinal traction. Virtually nothing has been
reported on air-suspension beds in the scientific literature.

Clinical Studies

Anecdotal reports,69-72 retrospective studies,73,74 prospective controlled clinical trials,75-81 and a literature review82 of kinetic therapy (in each case, the Roto-Rest Bed) have been published (Table 7). Kinetic bed therapy has been evaluated in stroke patients, medical patients, and patients with multiple trauma. Use of kinetic bed therapy has been reported to prevent deep-vein thrombosis, atelectasis, and pneumonia. Although the cost of a kinetic bed is greater than that of a conventional bed, kinetic bed therapy may reduce the patient’s length of stay in the ICU such that the total patient cost may be similar for a kinetic bed or a conventional bed.80,81

The studies that have evaluated kinetic bed therapy suffer from a variety of methodologic flaws. These include retrospective designs,73,74 lack of control groups,72,73 and small sample sizes. We believe that three of the studies are of acceptable scientific rigor.76,79,81 The data from these studies (Table 8) show a clinically important decrease in pneumonia in patients treated on a kinetic bed. The decrease is not statistically significant in two of these studies due to small sample sizes (β > 0.5, power < 0.5). However, pooling of the results from the three studies results in a highly significant difference in pneumonia rates between the Roto-Rest group (18%) and the conventional bed group (41%) (p < 0.001).

All of the published studies on the use of kinetic bed therapy have a sample size too small to adequately evaluate some important outcome variables. These studies lack statistical power (that is, they lack the ability to detect a real difference if one exists, or there is a high probability of a beta error).83 For example, it would be clinically important to show a decrease in ICU stay from a mean (SD) of 10 (3) days to 8 (3) days due to the use of kinetic bed therapy. This would require nearly 150 patients—a minimum of 71 patients in the treatment group (kinetic bed) and 71 patients in the control group (conventional hospital bed) to detect a significant difference (p < 0.05) with acceptable statistical power (power > 0.80, β < 0.20).

Risk of beta error is a particular problem when one is evaluating mortality. In each of three randomized clinical trials evaluating kinetic bed therapy, the mortality was greater in the treatment group (Roto-Rest) than the control group (conventional bed). This may be because patients placed into Roto-Rest Beds were more critically ill (eg, serious head injury, multisystem failure). However, neither of these studies had sample sizes sufficiently large enough to produce an acceptable statistical power (β > 0.50 in each case). When the data from these studies are pooled (Table 9), it can be seen that mortality rate is greater in the Roto-Rest groups (24%) than in the conventional groups (16%). Even with pooling of data, however, the total samples sizes are too small to produce statistical significance; 390 patients per group (total of nearly 800 patients) would be required to show statistical significance between 24% and 16% at p < 0.05 and β < 0.20. Because mortality may have been the result of many factors in these studies, the greater mortality in the patients treated with Roto-Rest Beds than in patients treated on conventional beds may be real or may be due to sampling error. A large study (probably multi-institutional) will be required to adequately address this issue.

Indications

Indications for kinetic bed therapy are listed in Table 10. Generally, kinetic bed therapy should only be considered in patients who are immobile and who are expected to be immobile for a prolonged period of time. Kinetic bed therapy may also be considered for patients with limited mobility (eg, obese patients), who require turning for therapeutic procedures (eg, chest physiotherapy). Kinetic therapy may also be useful in some patients with unilateral lung disease, who have a postural improvement in pulmonary shunt (the kinetic bed can be programmed to favor positioning to one side). Because of the cost associated with this therapy, the decision to use kinetic therapy should be carefully considered and individualized to the specific patient; kinetic therapy should never be considered routine for any group of patients.

Although kinetic therapy is designed to provide continuous rotation, this often does not occur in critically ill patients. In these patients, bed rotation
Studies pulmonary, ironic is Comments

Prospective; often circumstances patients

105 the 191 Subjects most

Table 7. Studies Evaluating Kinetic Bed Therapy

<table>
<thead>
<tr>
<th>Investigators</th>
<th>n</th>
<th>Study Design</th>
<th>Subjects</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keane39,70</td>
<td>—</td>
<td>Descriptive; anecdotal</td>
<td>—</td>
<td>Descriptive reports by the inventor of the Roto-Rest Bed; no data provided to support claims</td>
</tr>
<tr>
<td>Schimmel et al71</td>
<td>1</td>
<td>Case report</td>
<td>Shotgun wound</td>
<td>Resolution of unilateral contusion attributed to use of Roto-Rest Bed</td>
</tr>
<tr>
<td>Green et al72</td>
<td>105</td>
<td>Retrospective; anecdotal; no control group</td>
<td>Acute spinal-cord injury</td>
<td>Reduction in complications in pulmonary, cardiovascular, skin, musculoskeletal, nervous, gastrointestinal, and genitourinary systems, attributed to Roto-Rest Bed</td>
</tr>
<tr>
<td>Brouwers73</td>
<td>5</td>
<td>Case series</td>
<td>Unilateral lung disease</td>
<td>Arterial oxygenation decreased when bed was rotated such that diseased lung was dependent</td>
</tr>
<tr>
<td>Brackett &amp; Condon74</td>
<td>31</td>
<td>Retrospective</td>
<td>Acute spinal-cord injury</td>
<td>Compared Roto-Rest Bed to Stryker frame; mortality and pulmonary complications less with Roto-Rest; ICU stay less with Roto-Rest</td>
</tr>
<tr>
<td>Reines &amp; Harris75</td>
<td>20</td>
<td>Retrospective; no control group</td>
<td>Acute spinal-cord injury</td>
<td>Suggested that pulmonary complications are reduced in patients using the Roto-Rest Bed</td>
</tr>
<tr>
<td>Becker et al76</td>
<td>15</td>
<td>Prospective; randomized</td>
<td>Acute spinal-cord injury</td>
<td>Incidence of deep vein thrombosis less common in patients on Roto-Rest Bed</td>
</tr>
<tr>
<td>Gentilello et al77</td>
<td>65</td>
<td>Prospective; randomized</td>
<td>Critically ill</td>
<td>Incidence of atelectasis and pneumonia less in patients on Roto-Rest Bed as compared to conventional bed; mortality and incidence of decubitus ulcers similar in both groups</td>
</tr>
<tr>
<td>Demarest et al78</td>
<td>30</td>
<td>Prospective; randomized</td>
<td>Multiple trauma</td>
<td>Less atelectasis and pneumonia developed in patients who entered study with clear lungs and were treated with Roto-Rest; no difference between conventional bed and Roto-Rest in patients who entered study with abnormalities in their lungs</td>
</tr>
<tr>
<td>Summer et al79</td>
<td>86</td>
<td>Prospective; randomized</td>
<td>Medical ICU</td>
<td>Benefit from Roto-Rest Bed in some, but not all, diagnostic groups; patients on Roto-Rest Bed with sepsis and pneumonia had a 3.48 day shorter length of ICU stay; COPD patients on Roto-Rest had 6.84 fewer ICU days and 4.6 days less of mechanical ventilation</td>
</tr>
<tr>
<td>Kelly et al80</td>
<td>43</td>
<td>Prospective; randomized</td>
<td>Acute stroke</td>
<td>Incidence of infection less in patients treated on Roto-Rest Bed; all patients who died of transtentorial herniation were in the Roto-Rest Bed</td>
</tr>
<tr>
<td>Kelly et al81</td>
<td>43</td>
<td>Prospective; randomized</td>
<td>Acute stroke</td>
<td>Concluded that use of Roto-Rest was cost-effective</td>
</tr>
<tr>
<td>Fink et al82</td>
<td>106</td>
<td>Prospective; randomized</td>
<td>Blunt trauma</td>
<td>Risk of pulmonary sepsis less in patients on Roto-Rest Bed; costs similar in patients on Roto-Rest and conventional beds</td>
</tr>
</tbody>
</table>

is often interrupted for therapeutic and diagnostic procedures. It is ironic that the amount of rotation time is most limited when the patient is the most ill—the circumstances under which continuous rotation may be most beneficial. At this time, there has been no scientific evaluation of the minimal amount of rotation time needed each day for benefit.
Hazards, Complications, and Contraindications

Hazards and complications of kinetic therapy are listed in Table 11.8485 Some of these are potentially life-threatening (e.g., ventilator disconnection, intravascular catheter disconnection). The complication rate associated with the use of kinetic beds is unknown and probably under-reported. For example, frequent ventilator disconnections that are promptly recognized and corrected are likely not to be reported, but, nonetheless, are frustrating and time-consuming for those caring for the patient. Ventilator tubing and vascular lines must be long enough to allow patient rotation; satisfactory length must be determined before rotation is begun. Care must be taken to be certain that all lines (including electrical cords) are free of the bed. Rotation of the bed can result in stretching and, ultimately, breakage of lines and cords (in the case of an electrical cord, this could result in electrical shock to patient or clinicians). Care must also be taken to be certain that objects such as chairs are away from the bed; rotation of the bed onto objects such as these could result in lifting of the bed, followed by a sudden drop, with the potential for patient injury.

Kinetic therapy interferes with patient assessment in several ways. First, physical assessment of the posterior of the patient is limited, particularly if an air-suspension bed is used. Second, the quality of the chest radiograph is diminished (Fig. 16). Although the Roto-Rest Bed has a radiolucent surface, artifact (lines and shadows) appears on the chest x-ray that can make interpretation difficult. Also, the chest x-ray taken on a Roto-Rest Bed places the heart farther from the x-ray film, resulting in magnification.

We have seen cases of decubitus ulcer formation (occipital and sacral) in patients placed on Roto-Rest Beds. We believe that this results from the fact that kinetic therapy has a lesser effect on skin blood flow in regions close to the axis of rotation, as compared to areas farther from the axis of rotation. One might suspect that the effects of kinetic
bed therapy on pulmonary blood flow may also be greater in the peripheral lung fields than the hilar regions because the hilar regions are along the axis of rotation.

It has been our clinical impression that febrile patients are more difficult to cool when they are in a kinetic bed. Current designs of kinetic beds act as heat traps due to the packing that is used to secure the patient to the bed. It is also difficult to use a cooling blanket effectively in patients on kinetic beds.

Table 11. Hazards and Complications of Kinetic Therapy

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilator disconnection, inadvertent extubation, accidental</td>
<td>aspiration of ventilator circuit condensate</td>
</tr>
<tr>
<td>Disconnection of intravenous, intra-arterial, and urinary catheters</td>
<td></td>
</tr>
<tr>
<td>Stretching and breakage of lines and cords</td>
<td></td>
</tr>
<tr>
<td>Axial decubitus ulcer formation (occipital, sacral)</td>
<td></td>
</tr>
<tr>
<td>Arrhythmias</td>
<td></td>
</tr>
<tr>
<td>Patient intolerance (agitated, combative patients)</td>
<td></td>
</tr>
<tr>
<td>Problems with heat loss in febrile states</td>
<td></td>
</tr>
<tr>
<td>Increased intracranial pressure</td>
<td></td>
</tr>
<tr>
<td>Worsening dyspnea and hypoxemia</td>
<td></td>
</tr>
<tr>
<td>Difficult examination of the posterior</td>
<td></td>
</tr>
<tr>
<td>Chest x-ray artifact</td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td></td>
</tr>
</tbody>
</table>

Positioning has been shown to result in intracranial pressure changes in head-injured patients, of particular concern in kinetic therapy because these beds are commonly used in head-injured acute trauma patients. However, in one study that evaluated this, it was found that kinetic therapy did not adversely affect intracranial pressure in comatose neurosurgical patients. We have found that effective elevation of the head is difficult in patients on kinetic beds; this can be a problem in some patients with elevated intracranial pressure and in some patients with pulmonary problems.

The cost of these beds is a concern. The rental cost of the Roto-Rest Bed is $88.45/day at our hospital, and the rental cost of the BioDyne bed is $135.00/day. The potential benefits of these beds must be weighed against their associated rental costs.

Contraindications for kinetic therapy are listed in Table 12. The only absolute contraindications

Table 12. Contraindications for Kinetic Therapy*

<table>
<thead>
<tr>
<th>Contraindication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute</td>
</tr>
<tr>
<td>Unstable spinal injuries</td>
</tr>
<tr>
<td>Traction of the arm abductors</td>
</tr>
<tr>
<td>Relative</td>
</tr>
<tr>
<td>Marked agitation</td>
</tr>
<tr>
<td>Severe diarrhea</td>
</tr>
<tr>
<td>A rise in intracranial pressure</td>
</tr>
<tr>
<td>Greater than 10% decrease in blood pressure</td>
</tr>
<tr>
<td>Worsening dyspnea and hypoxia</td>
</tr>
<tr>
<td>Cardiac arrhythmias</td>
</tr>
</tbody>
</table>

*Adapted, with permission, from Reference 84.
are unstable spinal-cord injuries and traction of the arm abductors.

**Criteria for Discontinuation**

Criteria for discontinuation of kinetic therapy are listed in Table 13. The principal reason for discontinuation is return of the patient’s spontaneous mobility. Kinetic therapy should also be discontinued if the patient has an adverse response to this therapy.

Table 13. Criteria for Discontinuation of Kinetic Bed Therapy

<table>
<thead>
<tr>
<th>Occurrence of a complication associated with notation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(eg. arrhythmia, increased intracranial pressure, hemodynamic instability)</td>
<td></td>
</tr>
<tr>
<td>Increased spontaneous mobility</td>
<td></td>
</tr>
</tbody>
</table>

**Summary**

Body position affects lung function. Compared to the upright position, the supine position results in a decreased FRC and hypoxemia in some patients. Although technically difficult, periodic positioning in the prone position produces an increase in P\(_{aO_2}\) in acutely ill patients. With unilateral disease, placing the good lung down increases the P\(_{aO_2}\) in adults but not in infants.

Kinetic bed therapy is useful in some patients. However, very few appropriately designed studies have evaluated this therapy. Pneumonia rates seem to be lower in immobilized patients treated with kinetic bed therapy, but its effect on other outcome variables (such as survival, ventilator days, ICU days, hospital days) is unclear. Further work is needed to evaluate this therapy, and it should be used judiciously until appropriately designed studies are reported (ie, controlled clinical trials with a sample size large enough to produce an appropriate statistical power).

**ACKNOWLEDGMENTS**

We thank Ann Ropp for her help with the preparation of the manuscript, the staff of the Philip A Hoover MD Library for their help with the literature search, and the York Hospital Media Services Department for their production of the illustrations.

**REFERENCES**

KINETIC BED THERAPY


Radiographic Findings following Feeding-Tube Placement

Joan Kohr BA and Frederick W Clevenger MD

A 23-year-old Hispanic man was admitted to the Regional Burn Center, with burns over 55% of his total body-surface area following a house fire. His initial hospital course was complicated by inhalation injury and burn-wound sepsis requiring emergency wound debridement and invasive hemodynamic monitoring. Because of a severe gastrointestinal ileus associated with his burn wound and septic state, the patient was placed on total parenteral nutrition for the first 3 weeks of hospitalization. Shortly after completion of excisional debridement and split-thickness skin grafting to all affected burn areas, the patient was deemed a candidate for enteral feedings and a 12-Fr 109-cm tungsten-weighted enteral feeding tube was passed transnasally a length of 80 cm without difficulty. According to Burn Unit protocol, a portable anteroposterior chest radiograph was taken prior to initiation of feedings (Fig. 1). Because of the obvious malplacement of the feeding tube in the left hemithorax, the tube was gently removed: 10 minutes later, acute respiratory distress developed with elevation in respiratory rate from a baseline of 24 breaths/min to 60 breaths/min. Blood pressure was noted at the onset of acute respiratory distress to drop from 120 mm Hg systolic to 80 mm Hg systolic. The patient became profoundly tachycardic, and physical examination revealed decreased breath sounds on the left side, with a hyper-

tympanic resonant tone to percussion. The anteroposterior portable chest radiograph taken at the time of respiratory distress is shown in Figure 2.

Questions

Radiographic Finding: What radiographic abnormality is present in Figure 1? What pathologic process could explain this finding?
TEST YOUR RADIOLOGIC SKILL

Fig. 2. Portable AP chest radiograph taken when the patient became tachypneic and hemodynamically unstable.

Diagnostic Confirmation: What methods are necessary to establish a diagnosis for the condition depicted in Figure 2?

Corrective Action: What corrective action is indicated?

Answers and Discussion on Next Page

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**Answers**

**Radiographic Finding:** The chest radiograph (Fig. 1) demonstrates misplacement of the feeding tube in the left hemithorax. A feeding tube could be passed into the left chest by passing through the esophagus and mediastinal tissues or as a consequence of being passed down the trachea and left main-stem bronchus, and out through the pulmonary parenchyma. The mechanism in this patient is evident by the follow-up radiograph (Fig. 2) demonstrating a pneumothorax.

**Diagnostic Confirmation:** The diagnosis of tension pneumothorax is clinical and does not require radiographic documentation prior to treatment. In this patient, absence of breath sounds with unilateral hyptertympany and hemodynamic instability was consistent with a tension pneumothorax and justified rapid decompression. Radiographic documentation prior to intervention was not necessary.

**Corrective Action:** Evidence of tension pneumothorax is an indication for emergency needle decompression performed by passing a large-bore intravenous catheter through the second intercostal space at the midclavicular line until a rush of air is encountered. Following decompression of the tension pneumothorax and return of vital signs towards normal, a thoracostomy tube was inserted as is evident in Figure 3.

**Discussion**

Tracheobronchial perforation is a common and potentially lethal complication of feeding-tube placement. Although Cataldi-Betcher and colleagues described 253 tube placements with no pulmonary complications,1 in a prospective study most series report a complication rate of 0.2 to 2%.2-7 Feeding-tube misplacement occurs about equally in men and women,2,8,9 and no particular style or brand of tube appears to be free of the potential for pleuropulmonary trauma. The frequency of a specific product’s causing injuries is proportional to that tube’s popularity on the market.5

When a feeding tube is mistakenly passed intratracheally, it preferentially enters the right main-stem bronchus about 60% of the time because the left main-stem bronchus joins the trachea at a more acute angle.9 McWey et al2 reported a 73% rate of right-side intubations, and 2 patients developed bilateral pneumothoraces after repeated intubation attempts.2

Pleuropulmonary complications of misplacement include bronchial perforation,10 pneumothorax,2,11 bronchopleural fistula,12 and pulmonary hemorrhage.13 Our patient experienced respiratory distress and tachycardia after removal of the misplaced feeding tube. Tube removal from the lung presumably opens the bronchial tear and allows pneumothorax to develop.2 Odocha et al reported that 11 of 18 patients on mechanical ventilation at the time of feeding-tube misplacement deteriorated immediately when the tube was removed.7 Because positive-pressure ventilation increases the risk of tension pneumothorax, some authors recommend consideration of prophylactic chest-tube placement before removal of a misplaced feeding tube in such patients.9

There is often a delay of minutes to days before feeding-tube misplacement is recognized.5 Odocha et al have reported that 64% of misplaced tubes are not detected until 6 hours or more after insertion.9 Delay is often due to misleading results from bedside techniques used to verify tube position or failure to review a postprocedure roentgenogram.9 During the delay, further injury often results from the introduction of formula9 or from connecting the tube to suction.13
Odocha et al. found that 58% of patients suffered sequelae from tube malplacement including death, sepsis, respiratory failure, empyema, and bronchopleural or pleuropulmonary fistulae. In their series, the deaths of 13 patients (16%) were directly attributed to injuries and complications from malpositioning of the feeding tube. In 111 reports of feeding-tube malplacement published through 1988 and reviewed by Roubenoff and Ravich, 84 described the patient outcome: pneumothorax (64%), intrapulmonary feeding (13%), abscess or empyema (5%), death (4%), and no complication (14%).

Tracheal intubation (or tracheostomy) and diminished mental status are the two major risk factors for feeding-tube misplacement. Less common risk factors include upper-airway denervation and poor cooperation. Only 1% of cases in the literature have no identifiable risk factor. Table 1 outlines the relative frequency of clinical risk factors with tube malplacement. It is unfortunate that endotracheal tube cuffs do not act as barriers to small-bore feeding tubes. Because the cuffs function at low pressures, it is easy for a feeding tube to slip by. Furthermore, glottic function is eliminated with intubation, adding to the risk of tracheal feeding-tube placement. Finally, mechanically ventilated patients are usually sedated, making it difficult to separate the risk of being intubated from the risk of decreased level of consciousness. Patients with impaired consciousness cannot cooperate and have impaired gag and cough reflexes that mask the manifestations of laryngeal, glottic, or bronchial irritation. Even alert patients have diminished laryngeal sensation for at least 8 hours following extubation and present a similar problem.

Symptoms of pneumothorax may not occur immediately. Katelaris described 3 patients who expressed sensations of chest pain and dyspnea more than 1.5 hours after pleuropulmonary placement of a feeding tube. When symptoms are delayed, they may be ignored and not associated with tube insertion.

Although the patient in this report was not being mechanically ventilated, he did exhibit altered mental status. No other risk factors could be identified.

Roubenoff and Ravich suggest a two-step technique for nasoenteric intubation of high-risk patients. The tube is inserted nasally a predetermined length that corresponds to a position in the esophagus just below the level of the carina. This length is approximated by draping the feeding tube between the patient's xiphoid process and the tip of his ear lobe. After insertion, the tube is taped in place and a portable chest x-ray is obtained. If the tube is seen to be straight and positioned below the carina, it is in the esophagus and can be advanced to the stomach. The final position is confirmed with a second chest x-ray. If the tube is seen to curve laterally, it rests in a main-stem bronchus and must be removed. Intubation of a proximal bronchus has not been shown to cause pneumothorax or bronchopleural fistula. In the 6 months following the institution of this protocol for high-risk patients, no pulmonary complications were observed in 607 patients. Patients who are not at increased risk for pulmonary complications can undergo tube insertion in the standard fashion with confirmation of proper placement by chest x-ray immediately after the procedure. Immediate chest roentgenography minimizes delay in detecting tube malplacement and the resultant complications in all cases.

Woodall et al have suggested placement of larger diameter tubes (4.3 mm vs 2.7 mm) as a means of preventing transpleural passage of misplaced feeding devices. Although this approach does not eliminate the possibility of intrapleural tube placement, it does appear to greatly reduce if not eliminate the possibility of pneumothorax or hydro pneumothorax. In our patient's case, the inserted tube was 8-Fr, which does correspond to a 2.7-mm diameter. Clearly, the smaller tube is more comfortable for the patient but increases the risk of the complication seen in this case and is probably associated with higher occlusion rates.

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Frequency of Association with Malplacement</th>
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<tbody>
<tr>
<td>Mechanical ventilation</td>
<td>45</td>
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<tr>
<td>Mental status changes</td>
<td>29</td>
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<tr>
<td>Loss of swallow or cough reflexes after head-and-neck dissection</td>
<td>2</td>
</tr>
<tr>
<td>Uncooperative patient</td>
<td>1</td>
</tr>
<tr>
<td>No apparent risk factors</td>
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</table>
There are four aspects to consider when one chooses a method of providing nutritional support to patients: complications, benefits, adequacy of nutrition, and cost. For enteral nutrition, the risk of pneumothorax ranges from 0.2 to 2%.2,8 This compares to a 1.1 to 1.7% risk associated with catheter insertion for total parenteral nutrition (TPN).18,19

Enteral feeding has several benefits over parenteral feeding including prevention of intestinal mucosal atrophy,20 prevention of stress ulcers,21 and reduction of septic morbidity.22 By helping to maintain the gut’s mucosal integrity, which TPN cannot, tube feedings may prevent bacterial translocation and increase the host’s ability to control a septic challenge.23,24 When enteral and parenteral nutrition have been compared prospectively in patients who can receive either, the differences in nutritional status have been small.25 The equipment and solutions used for TPN are 2.8 times more expensive than those used for enteral nutrition.25 Thus, when pleuropulmonary complications of feeding-tube insertion are minimized by using the methods described above, enteral nutrition is the method of choice for nutritional support in patients who can tolerate it.

REFERENCES

Notices of competitions, scholarships, fellowships, examination dates, new educational programs, and the like will be listed here free of charge. Items for the Notices section must reach the Journal 60 days before the desired month of publication (January 1 for the March issue, February 1 for the April issue, etc). Include all pertinent information and mail notices to RESPIRATORY CARE Notices Dept., 11030 Ables Lane, Dallas TX 75229-4593.

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The Registry, Naples, Florida, July 24-26, 1992

AARC ANNUAL CONVENTION SITES & DATES
1992—San Antonio, Texas, December 12-15
1993—Nashville, Tennessee, December 11-14
1994—Las Vegas, Nevada, December 12-15
1995—Orlando, Florida, December 2-5
1996—San Diego, California, November 2-5

PUBLICATION OF INTEREST
"Guidelines for the Diagnosis and Management of Asthma," an expert panel report of the National Asthma Education Program, was released in August 1991 (Publication No. 91-3042).
A complete listing of resources for individual or group education materials can be obtained from:
National Asthma Education Program
Office of Prevention, Education, and Control
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda MD 20892

THE NATIONAL BOARD FOR RESPIRATORY CARE—1992 Examination and Fee Schedule

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<tr>
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<td>JANUARY 1, 1992</td>
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<tr>
<td>EXAMINATION DATE: JULY 18, 1992</td>
<td>APPLICATION DEADLINE: MAY 1, 1992</td>
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April 29-May 1 in Osage Beach, Missouri. The MSRC presents its 21st Annual Educational Seminar at the Tan-Tar-A Marriott. Topics cover a wide range of subjects, including care of the caregiver, CPQI, and respiratory protocols. Contact Wilma Alexander (816) 276-4222.

May 28-29 in Laurel, Maryland. The MD/DC Society for Respiratory Care holds its 2nd Annual “Conference by the Tee” at Patuxent Greens Country Club. Topics include PC/IRV, ACLS and the RCP, CLIA validation protocols, continuous-flow ventilation, trends in mechanical ventilation, and more. Contact Joe Lynott (202) 877-1064.

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May 3-5 in Bellevue, Washington. The 19th Annual Pacific Northwest Regional Respiratory Care Conference is slated for at the Bellevue Red Lion Inn. Topics cover pediatric, management, and critical care issues. A special guest speaker will address the establishment of a four-year respiratory care program in Washington state. Call Richard Larson (206) 880-4585.

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1992 Call for Abstracts

The American Association for Respiratory Care and its science journal, Respiratory Care, invite submission of brief abstracts related to any aspect of cardiopulmonary care. The abstracts will be reviewed, and selected authors will be invited to present papers at the OPEN FORUM during the AARC Annual Meeting in San Antonio, Texas, December 12-15, 1992. Accepted abstracts will be published in the November 1992 issue of Respiratory Care. Membership in the AARC is not necessary for participation.

Specifications—READ CAREFULLY!

An abstract may report (1) an original study, (2) the evaluation of a method or device, or (3) a case or case series. Topics may be aspects of adult acute care, continuing care/rehabilitation, perinatology/pediatrics, cardiopulmonary technology, health occupations education, or management of personnel and health-care delivery. The abstract may have been presented previously at a local or regional—but not national—meeting and should not have been published previously in a national journal. The abstract will be the only evidence by which the reviewers can decide whether the author should be invited to present a paper at the OPEN FORUM. Therefore, the abstract must provide all important data, findings, and conclusions. Give specific information. Do not write such general statements as "Results will be presented" or "Significance will be discussed."

Essential Content Elements

An original study abstract must include (1) Introduction: statement of research problem, question, or hypothesis; (2) Method: description of research design and conduct in sufficient detail to permit judgment of validity; (3) Results: statement of research findings with quantitative data and statistical analysis; (4) Conclusions: interpretation of the meaning of the results. A method/device evaluation abstract must include (1) Introduction: identification of the method or device and its intended function; (2) Method: description of the evaluation in sufficient detail to permit judgment of its objectivity and validity; (3) Results: findings of the evaluation; (4) Experience: summary of the author's practical experience or a notation of lack of experience; (5) Conclusions: interpretation of the evaluation and experience. Cost comparisons should be included where possible and appropriate. A case report abstract must report a case that is uncommon or of exceptional teaching/learning value and must include (1) case summary and (2) significance of case. Content should reflect results of literature review. The author(s) should have been actively involved in the case and a case-managing physician must be a co-author or must approve the report.

Abstract Format and Typing Instructions

An optical scanner will be used to process abstracts. First line of abstract should be the title. Title should explain content. Type or electronically print the abstract double-spaced on plain white bond paper, on one page only (copier bond is excellent). Do not underline or boldface and insert only one letter space between sentences. Provide a 1-inch margin top and bottom, a 1/2-inch left margin, and an approximate 1/2-inch ragged-right margin. Text submission on diskette is encouraged but must be accompanied by a hard copy. No identification of authors or institutions is to appear on the abstract sheet or within the abstract itself. Make the abstract all one paragraph. Data may be submitted in table form provided the table width is limited to 55 letter spaces (ie, letters or numbers plus necessary blank spaces = 55). No figures or illustrations are to be attached to the abstract. Type all information required to complete the author information form on the other side of this page. A photocopy of good quality may be used. Standard abbreviations may be employed without explanation. A new or infrequently used abbreviation should be preceded by the spelled-out term the first time it is used. Any recurring phrase or expression may be abbreviated if it is first explained. Check the abstract for (1) errors in spelling, grammar, facts, and figures; (2) clarity of language; and (3) conformance to these specifications. An abstract not prepared as requested may not be reviewed. Questions about abstract preparation may be telephoned to the editorial staff of Respiratory Care at (214) 243-2272.

Deadlines

The mandatory Final Deadline is June 6 (postmark). Authors will be notified of acceptance or rejection by letter only—to be mailed by August 15. Authors may choose to submit abstracts early. Abstracts received by March 18 will be reviewed and the authors notified by April 24. Rejected abstracts will be accompanied by a written critique that should in many cases enable authors to revise their abstracts and resubmit them by the final deadline (June 6).

Mailing Instructions

Mail (Do not fax!) 1 copy of the abstract, 1 author information sheet, and a stamped, self-addressed postcard (for notice of receipt) to:

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