Low Levels of Protein Related to Poor Outcome in ARDS

Low levels of a calcium-dependent protein that binds to a substance called actin, which itself is leaked from damaged and dying cells, could be an early prognostic marker for the development of acute respiratory distress syndrome (ARDS). In a study conducted among patients in a trauma intensive care unit and hospital, the lowest levels of the protein called gelsolin were associated with prolonged, complicated, and often fatal outcomes. Researchers suggest that local applications or infusions of recombinant human gelsolin might prevent ARDS from developing as a result of blunt trauma or sepsis. (American Journal of Respiratory and Critical Care Medicine, 11/99)

Respiratory Disease Product Patent Granted to Milkhaus Labs

Milkhaus Laboratory, Inc., a clinical-stage biopharmaceutical company, has been granted a U.S. patent for a product to treat respiratory diseases such as cystic fibrosis, bronchitis, and chronic obstructive pulmonary disease (COPD).

Says Dr. John McMichael, president and CEO of Milkhaus, “Earlier this year we reported that our product, HP-3, had been successful in two Phase II trials, one for chronic bronchitis and another for COPD. In those trials, HP-3 improved both pulmonary function and physical endurance. The company expects to report on the outcome of a third Phase II study, one dealing with cystic fibrosis patients, before the end of the year.”

Milkhaus Laboratory, Inc. is a privately held biopharmaceutical company focused on the development of therapeutic agents for chronic diseases in man and animals. The company’s business strategy is to conduct early stage clinical trials and then license out its products for further development. Milkhaus has also completed successful Phase II trials for HP-4, a product for the treatment of benign prostatic hyperplasia and myelodysplastic syndrome.

Over 44 Million Americans Face Increased Health Risks Due to Reduced Access to Health Care

A lack of health insurance is a health risk warranting as great a level of concern and urgency as other known hazards, including smoking, alcohol abuse, or not wearing a seat belt, say researchers who conducted a study for the American College of Physicians-American Society of Internal Medicine (ACP-ASIM).

According to the report, an increasing number of men, women, and children are unable to receive the health care they need, endangering their health and lives. The study refutes the myth that those without insurance merely face inconveniences in receiving care by citing the cumulative evidence of over 100 well-designed studies that link the lack of health care coverage with an amplified risk of poor health.

“Health Risks” continued on page 2
Reducing Needlestick Injuries to Health Care Workers

Every year, between 800,000 and one million health care workers in the United States are injured by needles and other sharp medical implements. Exposure to contaminated sharps puts workers at risk for contracting such blood-borne diseases as HIV and hepatitis B and C.

In a recent study, a team of researchers found that introducing a comprehensive safety and education program at a community hospital led to a significant and sustained decrease in the overall injury rate of its personnel. According to lead author Robyn R. M. Gershon, DrPH, associate scientist in environmental health sciences at the Johns Hopkins School of Public Health, “A multifaceted approach incorporating training as well as safety devices such as anti-needlestick devices was found to be beneficial in reducing the overall number of injuries from sharps. The training component is extremely important since it sends a message to employees that management is serious about their safety and health. Importantly, health care workers are more likely to adopt safe work practices if they perceive a strong organizational commitment to safety.”

Injury data were collected over a nine-year period, from 1990 to 1998, at a mid-sized, acute-care community hospital. In 1991, the hospital’s senior administrators created an Anti-Needlestick and Sharp Injuries Task Force to develop and implement a comprehensive intervention program. The program included the introduction of a needleless intravenous catheter and a new comprehensive sharps disposal system, along with extensive safety training for all hospital employees. All workers experiencing sharps injuries were asked to complete a detailed exposure questionnaire as soon as possible following an incident.

The researchers evaluated the program’s effectiveness by analyzing the pre- and post-intervention injury rates. They found that the overall rate of sharps injuries decreased by 70% from 1990, when the program was first implemented, to 1998. Data were obtained on a total of 633 injuries for an average population of 2,300 employees. Injuries were most frequently reported by registered nurses and licensed practical nurses, followed by technicians and support staff.

For health care workers, the risk of contracting HIV through a contaminated needle has been estimated at 0.3-0.4%; hepatitis B at 10-35%; and hepatitis C at 1.2-10%. The study was funded by the Centers for Disease Control and Prevention (Infection Control and Hospital Epidemiology, 12/99).
Not Enough Decision-Making Dialogue Between Doctors and Patients

Surgeons and primary care physicians are failing to have complete discussions of clinical decisions with their patients. Clarence H. Braddock III, MD, MPH, from the University of Washington in Seattle, and colleagues, studied audio tapes from 1,057 physician visits to characterize the nature and completeness of informed decision-making during routine office visits to primary care physicians and surgeons. The study involved 59 primary care physicians (general internists and family practitioners) and 65 general and orthopedic surgeons. The 1,057 taped visits contained 3,552 clinical decisions.

According to background material cited in the study, there have been calls for a shift toward a view of informed consent in which the emphasis is on a meaningful dialogue between physicians and patients instead of an unidirectional physician’s description of alternatives, risks, and benefits. The new dialogue version of informed consent is termed “informed decision-making.”

The researchers report that 9% of decisions met the researchers’ criteria of completeness for informed consent. Approximately 17% of basic decisions were completely informed, but none of the intermediate decisions were completely informed and only 0.5% of the complex decisions were completely informed. “Among the elements of informed decision-making, discussion of the nature of the intervention occurred most frequently (71%) and assessment of patient understanding least frequently (1.5%),” write the authors.

The criteria for informed decision-making used in this study included discussion of:

- The patient’s role in decision-making.
- The nature of the decision.
- Alternatives
- Benefits and risks of the alternatives.
- Uncertainties associated with the decision.
- The patient’s understanding of the decision.
- The patient’s preferences.

The researchers found that, in general, surgeons demonstrated more complete informed decision-making than primary care physicians, possibly because surgeons are experienced with obtaining written consent for surgery and may be more accustomed to discussing other decisions with patients as a result.

The researchers write that “this low level of informed decision-making suggests that physicians’ typical practice is out of step with ethical ideals. There are practical implications of this missing practice. Inadequate efforts to foster patient involvement in decision-making may impair the patient-physician relationship. Furthermore, there are quality-of-care concerns, since there is mounting evidence that inadequate patient involvement may interfere with patient acceptance of treatment and adherence with medical regimens.”

The researchers conclude that this new concept of informed decision-making can assist in evaluating the adequacy of current practice. It can also aid in developing behaviors and skills that will enhance communication and strengthen trust, thereby improving the patient-physician relationship.

In an accompanying editorial, Michael J. Barry, MD, from the Massachusetts General Hospital in Boston, recommends that physicians use communications materials to enhance information about therapies and procedures and to address the possible outcomes of different management options. Educational materials such as pamphlets and videotapes can allow physicians to spend their time tailoring management options to the patient’s preferences.

“Most physicians would accept the importance of informed consent to patient management as something more than just a medical-legal necessity,” concludes Dr. Barry. “If that is the case, we, as physicians, must do a better job of practicing what we preach. Physician time will be a major impediment, and new strategies, including more effective and efficient use of educational materials and decision aids in office practice, will need to be developed and tested as part of the solution.” (JAMA, December 22/29, 1999).

Sleep-Related Breathing Disorder Is Risk Factor for Hypertension

Individuals with sleep-related breathing disorder (SRBD) are at greater risk for high blood pressure and increased resting heart rate independent of such factors as body mass index, age, and cholesterol level, according to a Swedish study. Ludger Grote, MD, of the department of clinical pharmacology and sleep disorders clinic at Sahlgrenska University Hospital in Gothenburg, along with five associates, studied 1,087 men and 103 women referred for clinical symptoms of SRBD. The investigators’ results showed a relationship between SRBD severity and systolic/diastolic blood pressure, as well as heart rate.

During the study, the researchers recorded patient age, sex, race, and body mass index. Each participant completed a questionnaire and had a standard medical interview which included questions about SRBD-related symptoms such as snoring, witnessed apneas, excessive daytime sleepiness, insomnia, and falling asleep while driving a car. Smoking habits and current alcohol consumption were recorded. Blood samples were analyzed to determine total cholesterol, and blood gas samples were studied. Blood pressure readings were performed, along with heart rate determinations.

All patients also underwent unattended home monitoring of nocturnal breathing on two consecutive nights to measure oxygen saturation, snoring, beat-to-beat heart rate, and body position. Experienced sleep technicians evaluated all events recorded during sleep and devised a respiratory disturbance index (RDI) based on estimated sleep duration. An RDI of less than five, which indicated no SRBD, was found in 400 patients. They assigned an elevated RDI (more than five) to 790 individuals. After the allocation of patients into different RDI classes, researchers saw an obvious step-like increase in blood pressure and heart rate. “In particular, SRBD, had a highly significant influence on daytime resting heart rate,” say the authors.

The researchers also found that the risk of hypertension associated with SRBD was greater for younger patients and that the RDI showed an independent influence on resting heart rate larger than that found for blood pressure. In fact, during future studies, the researchers believe that resting heart rate will be considered an important predictor for cardiovascular illness and mortality in SRBD patients. Finally, the investigators found that daytime blood gas levels independently influenced blood pressure and resting heart rate. (American Journal of Respiratory and Critical Care Medicine, 12/99)
Small Airway Tests Signal Acute Respiratory Distress Syndrome Risk

Researchers have shown that concentrations of surfactant-associated proteins (SP-A and SP-D) in washings from the smaller airways during bronchoalveolar lavage (BAL) can classify patients with sepsis or trauma who are at high risk for acute respiratory distress syndrome (ARDS) and at high risk of dying after disease onset.

Thomas R. Martin, MD, from the pulmonary research labs at the Seattle Veterans Affairs Medical Center in Washington, along with 12 associates, examined 22 patients at risk for ARDS and 41 patients with ARDS. They found that higher SP-A concentrations were useful in identifying patients who were at low risk of developing ARDS. In addition, they discovered that patients with ARDS who later died had the lowest concentrations of SP-D in BAL and were 3.2 times more likely to have low SP-D on their first day with ARDS.

These findings suggest that a low BAL SP-D concentration identifies patients with the most severe epithelial injury in the lungs, as well as those with the worst overall lung injury, he writes.

The researchers believe that strategies to increase these surfactant proteins in the lungs of patients with ARDS could be a useful way either to modify the onset of the disease or to change its course. (American Journal of Respiratory and Critical Care Medicine, 12/99)

Moldy Buildings Cause Respiratory Reactions

Microbes from moldy buildings can cause adverse respiratory health effects, according to a study by Finnish biomedical researchers. Maija-Riitta Hirvonen, MD, of the division of environmental health of the National Public Health Institute in Kuopio, along with eight associates, detected inflammatory substances in the fluid from nasal washings of 32 subjects who worked in a moldy school building. At the end of a five-month spring term, the researchers found that levels of tumor necrosis factor alpha (TNF-a), interleukin 6 (IL-6), and nitric oxide (NO) were significantly higher in the school workers than in eight normal controls. Following a 2 1/2 month summer vacation, the levels of the three markers were the same in the workers as in the normal controls. During the school session, the subjects had reported cough, phlegm, rhinitis, eye irritation, and fatigue as levels of the inflammatory markers increased.

The 32 school employees included 22 teachers, four kitchen workers, three cleaning personnel, a nurse, a janitor, and a secretary. Researchers contacted them three times: after the spring term, following summer vacation, and at the end of the five-month fall term. An engineer recorded visible signs of mold growth and performed microbiological analysis of indoor air, surfaces, and building materials. The employees answered a questionnaire on current health, with emphasis on any respiratory symptoms. An investigator performed nasal lavage.

The levels of NO and IL-6 were significantly higher at the end of the spring and fall terms. However, the value of TNF-a was not significantly different at the end of the fall term, but was similar to levels detected at the end of vacation. The researchers believe that the differences in the profiles in the nasal lavage fluid may have been due to the different total exposure leading to activation of different cell types in the airways.

The present data clearly indicate that occupational exposure to mold growth leads to an increased production of pro-inflammatory mediators in the nasal lavage fluid of the exposed individuals, says Dr. Hirvonen. The results indicate an association between exposure to mold, the symptoms, and the pro-inflammatory mediators detected.

The investigators conducted their study because they believed there was a serious lack of research data showing a biochemical link between the biomarkers, mold exposure, and patient symptoms. (American Journal of Respiratory and Critical Care Medicine, 12/99)