DR. R. M. Flores (left) transsects the main pulmonary artery of a mesothelioma patient with the assistance of a thoracic fellow.

Mesothelioma Surgery Choice Is Complex

BY MARK S. LESNEY
Elsevier Global Medical News

Surgery for malignant pleural mesothelioma remains a complicated and controversial issue. Thus far, the benefits of surgery vs. nonsurgical treatment have yet to be demonstrated.

Complete resection with surgery alone (R0) appears theoretically unattainable since it is impossible to eradicate residual microscopic disease, regardless of the surgical method used. Hence, most surgical treatment today is coupled with various adjuvant treatments, primarily a trimodality mode with radiotherapy and chemotherapy, according to Dr. R. M. Flores, FCCP, professor and chief of thoracic surgery, Mount Sinai School of Medicine, New York.

A “curative” surgical procedure remains an elusive goal, and thus the focus of lung surgery for malignant pleural mesothelioma (MPM) has shifted to R1 surgical resection for cytoreduction in the hope of prolonging life, relieving symptoms, and enhancing the effectiveness of adjuvant therapies. This approach has often meant a shift from the more radical extrapleural pneumonectomy (EPP), when possible, to the more lung-sparing pleurectomy/decortication (PD) procedure, according to Dr. Flores (Sem. Thorac. Cardiovasc. Surg. 2009;21:149-53).

EPP involves a radical en bloc resection of the lung, pleura, diaphragm, and pericardium. PD involves resection of the parietal and visceral pleurae, pericardium, and — when necessary — the diaphragm, but it spares the entire lung. Both operations are technically complex and require extensive surgical expertise.

The operative mortality rate of EPP in the literature ranges from 4% to 15%, compared with 1%-5% for PD. In addition, PD has lower morbidity than does EPP. But the two techniques are not interchangeable, according to Dr. Flores. The choice of surgical technique depends on multiple factors.

See Mesothelioma • page 6

AHA: ‘Smokeless’ Tobacco Not a Safe Alternative

BY LORINDA BULLOCK
Elsevier Global Medical News

Smokeless tobacco products are not safer alternatives to cigarette smoking and do not help smokers quit; in addition, their long-term use can increase the risk of fatal heart attack, fatal stroke, and cancer, the American Heart Association warned in a scientific statement.

The researchers, led by Marianne R. Piano, Ph.D., examined several international studies to compare smokeless tobacco use and its health risks. Meta-analysis data involving male Swedish smokers in 1976-2002 showed a significant decrease in cigarette smoking that corresponded with an increase in use of smokeless tobacco products, the investigators wrote (Circulation 2010 Sept. 13 [doi:10.1161/CIR.0b013e3181f432c3]).

Despite the decline in cigarette use, concern is warranted. “Smokeless tobacco products are harmful and addictive — that does not translate to a better alternative,” Dr. Piano, professor of behavioral science at the University of Illinois at Chicago, said in a written statement released by the American Heart Association (AHA).

“Scientists and policy makers need to assess the effect of reduced risk messages related to smokeless tobacco use on public perception, especially among smokers who might be trying to quit,” Dr. Piano and her colleagues wrote.

Citing “inadequate evidence of smoking cessation efficacy and safety,” the researchers deemed as inappropriate the promotion of smokeless tobacco as a way of reducing smoking-related diseases.

See AHA • page 3

Rivaroxaban Scores High Marks for DVT

BY BRUCE JANCIN
Elsevier Global Medical News

STOCKHOLM — Fixed-dose rivaroxaban is at least as effective as current standard treatment for acute deep vein thrombosis — and far simpler to use, according to the large phase III EINSTEIN-DVT trial presented in a hotline session at the annual congress of the European Society of Cardiology.

“Results from EINSTEIN-DVT could transform the way physicians treat deep vein thrombosis,” Dr. Harry R. Buller predicted in presenting the data.

Congress program chair Dr. Fausto Pinto of Lisbon University agreed. Indeed, in a wrap-up session at the close of the conference, he singled out EINSTEIN-DVT as one of the meeting’s highlights, citing the trial’s likely practice-changing impact on the treatment of a problem that affects 2-3/1,000 adults every year in the Western world.

EINSTEIN-DVT was an open-label study involving 3,449 patients at 253 centers in 12 countries.

See Rivaroxaban • page 7
Decline in Smoking Stalled; Secondhand Smoke Down

By Robert Finn

Smoking rates, which declined precipitously in the United States from 1964 to 2004, have remained virtually unchanged since then, according to data from the 2009 National Health Interview Survey. In 2009, 20.6% of adult Americans smoked cigarettes, compared with 26.9% of Americans in 2005, a difference that was not statistically significant.

On the other hand, data from the 2007-2008 National Health and Nutrition Examination Survey (NHANES) demonstrated that smoking rates in the proportion of nonsmoking Americans aged 3 years and above with detectable levels of serum cotinine, an indication of exposure to secondhand smoke. That rate fell from 52.5% in the 1999-2000 survey to 40.1% in the 2007-2008 survey.


In announcing the results at a press briefing, Dr. Thomas R. Frieden, director of the CDC, said that both the tobacco industry and federal, state, and local governments bear the blame for the failure of smoking rates to decline. "The industry has gotten even better at side-stepping laws designed to get people to stop smoking," he said. "They ensure that every cigarette they sell delivers nicotine quickly and efficiently to people addicted."

In addition, the industry has found ways to sidestep regulations banning the sale of flavored cigarettes, which can encourage children to start smoking. Dr. Frieden said. And while tobacco companies are not permitted to market their products as having lower levels of tar and nicotine, "they continue to deceive smokers with color coding and other subtle and not-so-subtle ways of sending the message that some cigarettes are less deadly than others, when in fact all cigarettes kill equally," he said.

Furthermore, "government is also not doing what it needs to reduce smoking," he charged. "Comprehensive, evidence-based programs are not being widely implemented. Last year, states took in about $25 billion from tobacco taxes and the

THE INDUSTRY ENSURES THAT ‘EVERY CIGARETTE THEY SELL DELIVERS NICOTINE QUICKLY AND EFFICIENTLY TO KEEP PEOPLE ADDICTED.’

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Smokeless Tobacco Assessed

The AHA does recommend nicotine-replacement therapy (nicotine gum or a nicotine-releasing patch placed on the skin) as a safe option for cigarette smokers who want to quit. “Clinical studies have found no increased risk of heart attack or stroke with either type of nicotine replacement therapy,” the AHA said in the written statement.

Meta-analysis data in the AHA scientific statement indicated that smokeless tobacco use was associated with an increased risk of heart disease (relative risk 1.12) (Int. J Epidemiol. 2007;36:789-804). In addition, a subanalysis of INTERHEART (a study of 15,152 cases of first myocardial infarction in 52 countries) showed that tobacco chewers had a significantly increased risk of first myocardial infarction (odds ratio 2.23), compared with those who never used tobacco. Two other meta-analyses indicated that smokeless tobacco use was also associated with an increased risk of fatal stroke (RR 1.42 and 1.40).

The researchers explained that, like cigarettes, smokeless tobacco (ST) products still contain nicotine of varying concentrations, as well as a number of carcinogens that are just as harmful. Cigarettes and oral snuff have similar amounts of nicotine, while chewing tobacco appears to have “somewhat lower” amounts compared with cigarettes.

Dr. Piano and her colleagues wrote: “Even though certain manufacturing techniques are used to reduce the level of these compounds in some products, they remain present in substantial concentrations in ST products, including Swedish snus,” they said.

In a comparison of nicotine concentration between three types of smokeless tobacco products (chewing tobacco, dry snuff, and moist snuff) and cigarettes sold in the United States, all of the smokeless tobacco products had nicotine concentrations that were similar to cigarettes with the highest concentrations.

Nicotine Concentrations in Smokeless Tobacco Products and Cigarettes Sold in the United States

<table>
<thead>
<tr>
<th>Nicotine Concentrations (mean range)</th>
<th>Chewing tobacco*</th>
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*Nicotine products sold in Massachusetts in 2003. Source: Circulation.

COPD With Frequent Exacerbations a Distinct Phenotype

It appears that chronic obstructive pulmonary disease (COPD) with frequent exacerbations constitutes a distinct phenotype of the disease that can occur at mild, moderate, or severe levels of illness, according to results from a data analysis.

The frequency of COPD exacerbations appears to be relatively stable over time, and a distinct subgroup of patients appears to be prone to frequent (two or more times per year) exacerbations year after year, said Dr. John B. Hurst of University College London Medical School and his associates.

“Despite the importance of exacerbations, we know relatively little about their incidence, their determinants, and their effects in patients with COPD at various levels of severity,” the investigators noted. They used data from a large observational study – the Evaluation of COPD with the Use of Clinical Heterogeneity Computed (ECLIPSE) – to examine exacerbation frequency.

The international ECLIPSE study included 2,188 patients aged 40-75 years with a history of 10 or more pack-years of smoking, a forced expiratory volume in 1 second (FEV) of less than 80% of predicted value, and an FEV1-to-forced vital capacity ratio of 0.7 or less after use of a bronchodilator.

The participants had a wide range of COPD severity, and were evaluated at baseline, 3 months, and 6 months, and at 6-month intervals thereafter for 3 years.

Although exacerbations tend to increase with increasing disease severity, patients also tended to fall into and remain in one of two groups: those with infrequent exacerbations (0 or 1 per year) or those with more frequent exacerbations.

For example, 1,187 patients had infrequent exacerbations in the first year of the study, and 987 (83%) of them also had infrequent exacerbations in the second year. Another 492 patients had frequent exacerbations in year 1, and 296 of them (60%) had frequent exacerbations in year 2.

Thus, exacerbation frequency in the first year had a sensitivity of 60% and a specificity of 83% for predicting the frequency in the second year, Dr. Hurst and his colleagues said (N. Engl. J. Med. 2010;363:1128-38).

Similarly, 694 (84%) of the 1,187 patients with infrequent exacerbations also had infrequent exacerbations during the third study year, while 276 (36%) of the 496 with frequent exacerbations also had frequent exacerbations during the third study year.

And 210 (71%) of those with frequent exacerbations during years 1 and 2 went on to have frequent exacerbations in year 3, while 388 (74%) of those who had no exacerbations during years 1 and 2 also had no exacerbations in year 3.

The easiest and most accurate way of predicting a patient’s susceptibility to exacerbations was simply to ask that patient how many exacerbations they had in the preceding year, the researchers said.

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A full 22% of the patients with moderate COPD were found to have frequent exacerbations, which is an important observation, considering that such patients had relatively mild disease according to FEV1 criteria, they noted.

Conversely, 29% of the subjects who had very severe COPD appeared to have some resistance to exacerbations, since they experienced none or very few exacerbations during the study.

The ECLIPSE study was funded by GlaxoSmithKline. Dr. Hurst and his associates report ties to numerous pharmaceutical companies.

**Dr. Philip Marcus, FCCP:** Tobacco is a toxic drug that can be addictive. Effective smoking cessation products exist and can be given to patients. The use of nicotine replacement therapy, bupropion, and varenicline. The use of smokeless tobacco has not been found to be effective or protective against the other known adverse effects of tobacco. In addition, the use of electronic cigarettes has not been shown to be effective as a smoking cessation aid for smokers trying to quit.

**Dr. Nicola Hanania, FCCP:** This study sheds light on yet another important phenotype of COPD. For many years we focused only on the “pink puffers” and the “blue blowers” of this disease. We now realize that these two “classic” phenotypes are not the only ones that exist, and we need to become aware of other clinically important faces of COPD. The current study results reveal that an “exacerbator” phenotype can indeed be identified that is independent of disease severity. The observation that one or more exacerbations in the preceding year increases the risk of subsequent exacerbations has significant therapeutic implications, as it leads us to target patients belonging to this phenotype with pharmacologic and nonpharmacologic interventions. However, many patients fail to recognize exacerbations when they occur and therefore underreport them. It is thus imperative that clinicians educate patients with COPD about the signs and symptoms of such episodes so that they recognize them and report them if they occur.
Quick Test Identified Rifampin-Resistant TB

BY MARY ANN MOON
Elsevier Global Medical News

An automated assay designed for use in Third World regions rapidly and accurately detected Mycobacterium tuberculosis infection and resistance to rifampin, according to a report published online.

In a multicenter, prospective trial in South Africa, Peru, India, and Azerbaijan involving 1,780 patients suspected of having TB, the Xpert Mtb/Rif device, which delivers test results within 2 hours. Relatively unskilled health care workers at all the study locations became proficient in the assay’s use after brief training. Data from a separate study confirm that the assay generates no infectious aerosols, which obviates the need for laboratories equipped for advanced biosafety.

Because of the wide variability across influenza seasons in which it was not,” the authors reported. “The average annual number of influenza-associated deaths during influenza A(H3N2) prominent seasons was 7,722 for pneumonia and influenza causes and 28,909 for respiratory and circulatory causes, compared with 2,856 deaths for pneumonia and influenza causes and 10,648 deaths for respiratory and circulatory causes in seasons in which it was not.”

The findings represented in the revised model are limited by several factors, including the failure to account for co-circulating pathogens such as respiratory syncytial virus; the possibility that changing virus surveillance data may reduce the relevance of comparing estimates over time; and the possibility that the increase in the number of adults older than age 65 years during the study period could have contributed to an increase in influenza-associated mortality, according to the authors. Also, because the models rely on national death certificate data through 2007, preliminary estimates for 2009 influenza A(H1N1)-associated deaths are not comparable, they wrote.

Influenza Mortality Still Varies Widely Across Seasons

Range of 1.4-1.67 deaths per 100,000 persons seen.

BY DIANA MAHONEY
Elsevier Global Medical News

Annual estimates of influenza-associated deaths from 1976 to 2007 varied substantially by season, influenza virus type, underlying cause of death, and age group, according to revised statistical models, the Centers for Disease Control and Prevention reported in its Morbidity and Mortality Weekly Report.

The “incremental variation” indicates that using a single, average estimate insuffi- ciently communicates the mortality burden of influenza, Dr. David Shay, medical officer with the CDC’s National Center for Immunization and Respiratory Diseases, said in a media briefing.

With a low of 3,349 estimated deaths in 1986-1987 and a high of 6,194 deaths in 2001-2003, the estimated annual rate of influenza-associated deaths in the United States from 1976 to 2007 ranged from 1.4 to 1.67 deaths per 100,000 persons, according to the new models, which update the CDC’s previously published estimates for 1976-2003 and include new data from 2006-2007.

Because of the wide variability across influenza seasons, it is relatively meaningless to try to summarize [influenza burden] with one number,” Dr. Shay stressed.

For this reason, the CDC advises quantifying influenza-associated deaths in the context of circulating virus strains and underly- ing causes of death among age groups. Toward this end, the influenza-associated mortality estimates in the CDC’s revised models are provided for three age groups (younger than 19 years, 19-64 years and 65 years or older) and for two cate- gories of underlying cause of death codes: pneumonia and influenza causes and respi- ratory and circulatory causes.

For pneumonia and influenza causes, the respective estimated annual average of influenza-associated deaths and the rate of influenza-associated deaths per 100,000 people were 6,309 and 2.4 for the U.S. pop- ulation overall; 97 and 0.1 for persons younger than 19 years; 666 and 0.4 for adults age 19-64 years; and 5,546 and 17.0 for adults 65 years and older, the report states.

For deaths with underlying respiratory and circulatory causes, the respective esti- mated number and rate of influenza-associated deaths per 100,000 were 23,607 and 9.0 for the United States overall; 124 and 0.2 for people younger than 19 years; 2,385 and 1.5 among adults age 19-64 years; and 21,049 and 66.1 among adults age 65 years and older (MMWR 2010;59:1037-62).

For both causes, “the average mortality rates for the 22 seasons during which in- fluenza A(H1N2) was a prominent strain were 2.7 times higher than for the nine seasons that it was not,” the authors re- ported. “The average annual number of influenza-associated deaths during in- fluenza A(H1N2) prominent seasons was 7,722 for pneumonia and influenza causes and 28,909 for respiratory and circula- tory causes, compared with 2,856 deaths for pneumonia and influenza causes and 10,648 deaths for respiratory and circula- tory causes in seasons in which it was not.”

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FDA: Tigecycline Not Advised For Serious Infections

Alteratives to tigecycline “should be considered” when treating patients with serious infections because the intra- venous antibiotic has been associated with increased mortality in this population, ac- cording to a safety alert issued last month by the Food and Drug Administration.

In a pooled analysis of 13 clinical trials, treatment with tigecycline (Tygacil) was associated with increased mortality when compared with other antibiotics, according to the FDA.

The higher risk was seen “most clearly” in patients with ventilator-associated pneu- monia (VAP): 19.1% of those treated with tigecycline died, vs. 12.3% of those treat- ed with other antibiotics. Tigecycline is not approved for this condition.

Morbidity was also increased in patients treated with tigecycline for complicated skin and skin structure infections (cSSSI) and complicated intra-abdominal infec- tions (cIAI) – both approved indications – and diabetic foot infections – an unap- proved indication – compared with other antibiotics.

In patients with cSSSI, 1.4% of those treated with tigecycline died, vs. 0.7% of those who received antibiotics. For cIAI, the mortality rates were 3.0% and 2.2%, respectively; and for diabetic foot infec- tions, the mortality rates were 1.3% and 0.6%, respectively.

The notice is available at www.fda.gov/ Drugs/DrugSafety/ucm224370.htm.

—Elizabeth Mechatie
This Month in CHEST: Editor’s Picks

BY DR RICHARD S. IRWIN
MASTER FCCP
Editor in Chief, CHEST

- Respiratory Viruses in Adults With Community-Acquired Pneumonia. By Dr D. Lieberman, et al.
- Safety of Uninterrupted Anticoagulation in Patients Requiring Elective Coronary Angiography With or Without Percutaneous Coronary Intervention. By Dr E. Janula, et al.

POINT/COUNTERPOINT

Product of the Month

ACCP/AAP Pediatric Pulmonary Medicine Board Review 2010

New! Straight from the ACCP/AAP Pediatric Pulmonary Medicine Board Review 2010 course, this text covers every topic in a concise, easy-to-use format.


October Lessons

- Pain Management in the ICU: Essentials for the Intensivist. By Dr C. Spencer Yost; and Dr Michael A. Gropper, FCCP
- Approaching Glucose Management in the ICU. By Dr Shyoko Honiden, MSc

SLEEP Medicine 2011

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Transplant, Script Theory, Bronchoscopy

**Transplant**

The Transplant NetWork has been involved in several projects over the last few years that are currently in different stages. The survey on Barriers to Palliative Care has been sent to the membership of the Transplant NetWork and the Pulmonary Council of the International Society for Heart and Lung Transplantation. The chair of this project, Dr Liane Singer, is in the process of analyzing the data and compiling the results. The second project is the “Consensus Statement on the Management of the Organ Donor.” This effort has been done in collaboration with many other societies, and it is in the final stages of preparation for publication in Critical Care Medicine. Many members of the NetWork have participated in the project. The third project deals with medical complications (noninfectious and nonrejection) after lung transplantation. It has been approved and is being circulated to the steering committee (and then to the NetWork membership) for further ideas in order to reach its final form. A consensus statement is being considered. Another project being considered is the creation of a working group to study variations on the diagnosis of bronchiolitis obliterans syndrome (BOS). There are definitions for its diagnosis.

**Pulmonary, Critical Care, Sleep Medicine Physician**

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**NEWS FROM THE COLLEGE**

**DISCLAIMER**

Dr. William Kelly, MC, USA, FCCP

**Chair**

Interventional Chest/Diagnostic Procedures

Bronchoscopy is one of the most common procedures performed by chest physicians. The procedure may be uncomfortable, with most patients expressing fear of pain or discomfort and anxiety about complications. There are many examples of the lack of standardization in our daily practice. A pulmonologist at a university hospital routinely gives atropine before bronchoscopy to decrease secretions and dilate the airway, while a colleague at the VA believes that anti-cholinergic agents are ineffective. Another performs a bronchoscopy on the inpatient ward with topical lidocaine only, while a colleague in another hospital performs bronchoscopy under deep sedation with propofol. Similarly, while one physician prefers nebulized lidocaine 4% for topical anesthesia, another utilizes an atomized solution of tetracaine 1%

The ACCP Interventional Chest/Diagnostic Procedures Network has embarked on the development of a consensus statement (CS) on the use of topical anesthesia, analgesia, and sedation during flexible bronchoscopy based on the best current available data. This CS addresses issues such as performing bronchoscopy with or without sedation, using anti-cholinergic agents prebronchoscopy, and choosing among various agents and modalities for topical anesthesia, sedation, and analgesia. It is important to realize that this CS represents the collective opinions of a convened expert panel derived by a systematic approach with a traditional literature review as outlined by the ACCP Health and Science Policy Committee recommendations. A CS is not the equivalent of evidence-based practice guidelines and should not be used for performance measurements but rather as a summary of current knowledge and a forum for discussion.

Dr. Momen M. Waduhi, MBA, FCCP

**Vice Chair**

**Affiliate**

CHEST 2010: The Right PreCRIPTion for Learning

Script theory postulates that physicians in clinical practice apply presupposed knowledge edge sets (or “scripts”) to understand a situation and then either accept or reject their hypothesis when presented with additional information (Charlin et al. Teach Learn Med. 2000;12[4]:189). The scripts of experienced clinicians vary to a degree, but essential elements are similar, and students (including residents, fellows) can be measured against this standard (Fourmir et al. BMC Med Inform Decis Mak 2008;8[May 6]:18). A script concordance test measures how well your answer agrees, or is in concordance with, a group of experts.

Vignette: You are called to see a 57-year-old critically ill patient with sudden onset respiratory distress and hypoxia. You suspect pulmonary embolism (=hypothesis), and then the pictured radiograph becomes available (=new information). Is your diagnosis more likely, less likely, or unchanged? (See answer at end.)

The CHEST 2010 meeting’s core learning program, essential updates, and other resources will help you build and refine your personal bank of scripts. Some proudly sponsored by the Affiliate NetWork include:

Monday – Wednesday, 8:00 AM: CHEST Challenge Play-offs. Test yourself as you cheer for fellows from around the country as they compete in this “Jeopardy”-game-show-style competition of pulmonary/critical care/sleep knowledge. Monday: “CHEST CT for the Pulmonologist – Anatomic Correlation, Interpretation, and Case Review”

Tuesday: “Lung Histopathology Review: Preparation for Boards, Preparation for Practice”

Wednesday: “Critical Care Radiology: Indications, Interpretation, and Case Review for the Intensivist” and “Academic vs Private Practice: Which To Choose and What To Look for in the Contract”

With all of this script enhancement going on, don’t forget your lunch.
Mandatory Flu Shots Urged for Health Workers

Dr. Fishman reported having no conflicts of interest. The authors of SHEA's position paper reported having served as consultants for or having received honoraria from various pharmaceutical companies, influenza diagnostics, and pharmacueticals.

'The flu is very contagious, and getting vaccinated is one of the best ways to protect yourself and others from getting sick,' Dr. Fishman said. 'The flu affects millions of people each year in the United States, and it is the leading cause of preventable death.'

Dr. Fishman said that this year’s flu season is expected to be severe, with influenza activity expected to peak in early January or February. He urged healthcare workers to get vaccinated as soon as possible.

‘Healthcare providers and their patients should be aware of the risks of influenza, and take the necessary precautions to prevent its spread,’ Dr. Fishman said. ‘This is especially important for healthcare workers, who are at high risk of contracting and spreading influenza to their patients.’

Influenza vaccination of healthcare providers is a professional and ethical obligation.'

Dr. Fishman said that the flu vaccine is safe and effective, and it is important for healthcare workers to get vaccinated to protect themselves and their patients.

‘The flu vaccine is the best way to reduce the severity of influenza,’ Dr. Fishman said. ‘It is also effective in preventing hospitalization and death from influenza.’

Dr. Fishman said that healthcare workers who are vaccinated have a lower risk of complications and hospitalization from influenza, compared to those who are not vaccinated.

‘The flu vaccine is an important tool in preventing the spread of influenza,’ Dr. Fishman said. ‘It is especially important for healthcare workers who are in close contact with vulnerable populations, such as the elderly and those with underlying medical conditions.’

Dr. Fishman said that healthcare workers should get vaccinated annually, and that it is important to get vaccinated early in the season.

‘Getting vaccinated early in the season is important because it takes time for the vaccine to become effective,’ Dr. Fishman said. ‘It is important to get vaccinated by the end of October.’

Dr. Fishman said that healthcare workers should also take other measures to prevent the spread of influenza, such as washing their hands regularly and avoiding close contact with sick individuals.

‘Healthcare workers should also take other measures to prevent the spread of influenza, such as avoiding close contact with sick individuals,’ Dr. Fishman said. ‘It is also important to practice good hygiene, such as washing their hands regularly.’

Dr. Fishman said that healthcare workers should also keep their workplace clean and well-ventilated, and that it is important to stay home when sick.

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**TYGACIL does not cover Pseudomonas aeruginosa.**

**TYGACIL is indicated for the treatment of adults with:**

- Complicated skin and skin structure infections caused by *Enterococcus faecalis* (vancomycin-susceptible isolates), *Staphylococcus aureus* (methicillin-resistant and -sensitive isolates), *Enterobacter cloacae*, *Klebsiella pneumoniae*, and *Bacteroides fragilis*.
- Community-acquired bacterial pneumonia caused by *Streptococcus pneumoniae* (penicillin-susceptible isolates), including cases with concurrent bacteremia, *Haemophilus influenzae*, (beta-lactamase negative isolates), and *Legionella pneumophila*.

**Important Safety Information**

- **TYGACIL** may cause any one of the following side effects when administered to a pregnant woman:
  - Anaphylaxis/anaphylactoid reactions have been reported with nearly all antibacterial agents, including tigecycline, and may be life-threatening. **TYGACIL should be administered with caution in patients with known hypersensitivity to tetracycline-class antibiotics.**
  - Isolated cases of significant hepatic dysfunction and hepatic failure have been reported in patients being treated with tigecycline. Some of these patients were receiving multiple concomitant medications. Patients who develop abnormal liver function tests during tigecycline therapy should be monitored for evidence of worsening hepatic function. Adverse events may occur after the drug has been discontinued.
  - The safety and efficacy of **TYGACIL** in patients with hospital-acquired pneumonia have not been established.
  - An increase in all-cause mortality has been observed across phase 3 and 4 clinical studies in **TYGACIL**-treated patients versus comparator-treated patients. The cause of this increase has not been established. This increase in all-cause mortality should be considered when selecting among treatment options.

- **TYGACIL** may cause fetal harm when administered to a pregnant woman:
  - The use of **TYGACIL** during tooth development may cause permanent discoloration of the teeth. **TYGACIL** should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated.
  - Acute pancreatitis, including fatal cases, has occurred in association with tigecycline treatment. Consideration should be given to the cessation of the treatment with tigecycline in cases suspected of having developed pancreatitis.
  - **Candida difficile-associated diarrhea (CDAD)** has been reported with use of nearly all antibacterial agents, including **TYGACIL**, and may range in severity from mild diarrhea to fatal colitis.
  - Monotherapy should be used with caution in patients with clinically apparent intestinal perforation.
  - **TYGACIL** is structurally similar to tetracycline-class antibiotics and may have similar adverse effects. Such effects may include: photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acidosis, and hyperphosphatemia). As with tetracyclines, pancreatitis has been reported with the use of **TYGACIL**.
  - To reduce the development of drug-resistant bacteria and maintain the effectiveness of **TYGACIL** and other antibacterial drugs, **TYGACIL** should be used only to treat infections proven or strongly suspected to be caused by susceptible bacteria. As with other antibacterial drugs, use of **TYGACIL** may result in overgrowth of non-susceptible organisms, including fungi.
  - The most common adverse reactions (incidence >5%) are nausea, vomiting, diarrhea, abdominal pain, headache, and increased SGPT.
  - Prothrombin time or other suitable anticoagulant test should be monitored if **TYGACIL** is administered with warfarin.
  - Concurrent use of antibacterial drugs with oral contraceptives may render oral contraceptives less effective.
  - The safety and effectiveness of **TYGACIL** in patients below age 18 and lactating women have not been established.

**References:**
3. **TYGACIL** (tigecycline) Prescribing Information, Wyeth Pharmaceuticals Inc.
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*Society of Thoracic Surgeons National Database, for high complexity, high volume centers.
Choosing Appropriate Treatment

Mesothelioma • from page 1

Factors, and the decision is often made at the time of surgery because the preoperative imaging may have underestimated the amount of disease present.

Staging is critical in determining the appropriate procedure, and the merits of each surgical approach have been debated in several recent clinical and registry trials examining individual mortality and morbidity of these procedures at different stages, coupled with the use of a variety of adjuvant therapies. However, many decisions are based on surgical conjecture and bias rather than scientific data.

Evidence shows that PD provides a survival advantage for patients with stage I MPM, which may be accounted for by “lower mortality, lower postoperative adverse events, and greater lung capacity when relapse occurs,” according to Dr. Flores. However, he explained, most patients with mesothelioma will present at a stage that requires EPP to eradicate all gross disease. PD can provide an R1 resection in early-stage disease, but as the tumor enlarges and invades the lung, fissures, and costophrenic sulcus, a PD is suboptimal regardless of resection of the pericardium and diaphragm.

There is, however, a critical balance between optimal cytoreduction and morbidity that varies across stages for these two procedures. For stage II disease, there is a “trend toward improved survival for EPP despite an inherently higher tumor stage than PD,” Dr. Flores said.

Stage III disease proved more complex, with similar survival data seen for both EPP and PD. Ultimately, “one should focus on obtaining a complete macroscopic resection based on the extent of tumor” for this stage of disease, choosing the best procedure accordingly, he advised.

For more advanced (stage IV) disease characterized by diffuse chest wall invasion and extensions through the diaphragm to the underlying peritoneum, the situation is much different.

“The tumor may be amenable to EPP, but there will be gross residual tumor left behind in the hemithorax. Because one of the most likely sites of recurrence is the contralateral pleura, the patient is better served by preserving lung function,” Dr. Flores explained.

In stage IV disease, PD trended toward better survival, presumably because “when disease spreads to the contralateral lung, PD or debulked patients will be less symptomatic and better functionally able to tolerate systemic therapy because of their greater pulmonary reserve,” he said.

“The goal is to remove all gross tumor while preserving as much of the lung as possible. Every patient and clinical situation is unique; therefore, treatment is difficult to generalize. Find an experienced mesothelioma surgeon you trust and leave it in their hands,” Dr. Flores said in an interview.

Ultimately, the situation remains complex. Dr. Heyman Luckraz of the New Cross Hospital, Wolverhampton, England, and his colleagues recently reported results with 139 patients. EPP was chosen for clinically fit patients with stage I disease, while patients with advanced disease or who were unfit for EPP underwent PD. “EPP may only have a limited role in diffuse MPM, particularly as neither operative procedure is curative. Ultimately, the place of EPP will only be determined by randomized trial in comparison to PD in stage I disease with both groups receiving adjuvant therapy,” the investigators concluded (Eur J Cardiotorac Surg. 2010;37:552-6).

Whether such trials will ever be performed is an open question. Despite the recent Mesothelioma and Radical Surgery (MARS) trial, which demonstrated the possibility of randomizing patients to surgical vs. nonsurgical treatment, there will likely never be a randomized clinical trial powered enough to completely solve the puzzle, according to Dr. Tom Treasure of the University College of London (Eur. J. Cardiothorac. Surg. 2010;38:245-53).

None of the authors mentioned in this article had disclosures deemed relevant to their reported research.
Hospitalized patients continue to be harmed by adverse events and medical errors (Leape. Clin Chim Acta. 2009;404[1-2]). The contribution to errors by preventable diagnostic errors is underappreciated (Newman-Toker et al. JAMA. 2009;301[10]:1060). Studies suggest that the ICU is a particularly high-risk place for diagnostic errors (Shojania et al. JAMA. 2003;289[21]:2849), given the ICU’s high stress, fast pace, and intense environment.

What Constitutes a Diagnostic Error?
Diagnostic errors occur when diagnoses are wrong, delayed, or missed (Combes et al. Arch Intern Med. 2004;164[4]:389; Roosen et al. Mayo Clin Proc. 2000;75[6]:562; Pastores et al. Crit Care. 2007;11[2]:R48), when it is too late to effect therapy. Life-threatening diseases that go unrecognized and, therefore, untreated, are perhaps the most concerning of these possibilities. However, incorrect diagnoses resulting in unnecessary testing or inappropriate therapy that confers risk, but little or no benefit, may be more ubiquitous (Newman-Toker et al. JAMA. 2009;301[10]:1060). Missdiagnoses are usually classified based on their clinical relevance and potential for therapy to have prevented harm. The Goldman (Goldman et al. N Engl J Med. 1983;308[17]:1000) or Battle-Battle (JAMA. 1987;258[3]:339) classification systems are typically used when autopsy recognizes the misdiagnosis. Goldman class I errors are major diagnostic errors in which recognition of the underlying condition before death may have led to different therapeutic options and prolonged survival. Goldman class II errors are major diagnostic errors in which treatment antemortem may not have prolonged survival.

Class I errors have been described in as many as 9% of autopsies in hospitalized patients (9% were considered lethal) (Shojania et al. JAMA. 2003;289[21]:2849) and in 6% to 17.5% of ICU patients undergoing postmortem examinations (Marsi et al. Virchows Arch. 2007;450[3]:329; Pastores et al. Crit Care. 2007;11[2]:R48).

Class II errors range from 8% to 11% in the ICU. After adjusting for diagnostic improvements over time and declining autopsy rates, analysis suggests that 10% of all hospital deaths involve a major diagnostic error, and in 20 hospital deaths involve potentially preventable class I errors, while as many as 1 in 10 ICU deaths has such an error (Shojania et al. JAMA. 2003;289[21]:2849).

Discrepancies found at autopsy create a record of these errors; however, without a definitive test that shows diagnostic errors during life, both lethal and nonlethal diagnostic errors get “lost in the chart.” Nonlethal diagnostic errors in the ICU may also affect long-term outcomes, yet this group remains largely undefined and unexplored. An example would be the failure to recognize subtle clinical status epilepticus that may leave the patient alive but in a persistent vegetative state (Drislane et al. J Clin Neuropsychol. 2008;25[4]:181).

Of course, some diagnostic errors may be completely harmless and others may be caught before harm occurs. However, just because a diagnostic error did not cause harm does not mean that it is acceptable or unimportant. To date, almost nothing is known about these incidental errors, but the process by which they occur could provide us with valuable clues on how to implement system strategies that may identify and reduce the harmful ones. Misdiagnosis, less described causal analyses, such as morbidity and mortality conference reports or root cause analysis investigations, rarely address near misses.

A Systems-Based Approach
Can we prevent ICU diagnostic errors and their resultant harm? This is a great challenge because we do not yet have a full perspective on the scope of the problem. With that said, we know what does not work. The culture of the ABCDs (acuse, blame, criticize, deny) that commonly surfaces when diagnostic errors occur is often counterproductive, reinforces a culture of “defensive medicine,” and fails to address the root causes of the errors and the inherent fallibility in the system. We suggest using systems-based solutions for recognizing and reducing diagnostic errors. While diagnostic errors may result from “thought process” breakdowns in providers, other system-oriented factors, such as data and information management, presentation, integration, and communication, may be vastly more important and are ripe for targeting by systems-based principles.

Systems-based approaches include implementation of comprehensive unit safety programs (CUSPs) to effect culture change and adherence to the principles of safe design—standardization, creation of independent checks (tools such as checklists and staff empowerment encourage staff to speak up when something is not right), and learning from defects when things go wrong. CUSPs involve all stakeholders (nurses, doctors, administrators, and others) at a local unit level who work proactively to identify risk for patient harm. Such systems interventions have been shown to be very effective at eliminating some adverse events once considered inherent in patients in the ICU (Pronovost et al. Crit Care Med. 2008;36[2]:207; Berenholtz et al. Crit Care Med. 2004;32[10]:1014).

“Learning from defect” (LFD) strategies, a second systems-based approach, may also be useful in preventing diagnostic errors. LFD is a proactive root cause analysis–like strategy that emphasizes not only causal system factors for adverse events but additionally seeks to uncover mitigating factors that may be capitalized upon to improve the system itself and reduce future harm. This strategy is local and streamlined to allow individual units to address their local problems (Pronovost et al. Jt Comm J Qual Patient Saf. 2006;32:102).

Creating a Framework for Improvement
What are the root causes of ICU diagnostic errors? We do know that during off hours, the risk of misdiagnosis goes up (Kollel. Crit Care Med. 1991;19[7]:796; Okello et al. Injury. 2007;38[1]:112). However, we need to ask whose contributions remain ill-defined, exist. These may include high-complexity illnesses, alarm fatigue, stress, excessive workload (Donchin et al. Curr Opin Crit Care. 2007;4[4]:316), inappropriate staff-to-patient ratios, questionable qualifications of ICU staff physicians (Pronovost et al. JAMA. 2002;288[17]:2151). Others, however, will need to be specific to a particular clinical context, such as standardization with structured diagnostic algorithms and checklists to ensure cognitive consistency and thoroughness for a particular clinical diagnosis (eg, unexplained hypotension). Additionally, technological solutions to bring order to the chaos of data presentation, integration, and decision analysis in the ICU environment will need to be developed.

Diagnostic errors clearly exist in the ICU, despite the aggressive and organized care that we provide. Diagnostic error type and incidence may vary, but they undoubtedly lead to some level of harm, and all harm should be viewed as a “never happen event.” However, the incidence and harm of ICU misdiagnosis are difficult to quantify and must be addressed more scientifically. To date, misdiagnosis has received too little attention. It’s time to more fully define this problem and better diagnose and treat diagnostic errors.

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November marks my 1-year anniversary as Executive Vice President and CEO of the ACCP. It has been an exciting 12 months, filled with many changes—big and small—as we work to propel the ACCP “to the next level.” Immediately upon arriving at the ACCP in late October 2009, I was struck by the profound dedication and “can do” spirit of College leaders and staff and their passion for delivering world-class clinical education for chest medicine. The results of a member survey conducted by an outside firm in March suggested that this passion is our greatest strength as an organization. At its strategic planning session in April, the Board determined that, going forward, the College would focus on providing the best clinical education in chest medicine and leveraging appropriate technologies to deliver this content globally to physicians and allied health professionals. We developed the ACCP Strategic Plan 2010 – 2011 to reflect this focus, including the following updated ACCP mission and vision:

Our Mission: To promote the prevention, diagnosis, and treatment of chest diseases through education, communication, and research.

Our Vision: The ACCP is the global leader in providing education in cardiovascular, critical care, and sleep medicine to optimize health and advance patient care.

Since the Board approved the strategic plan in June, what has the ACCP done to realize its updated mission and vision and what will this renewed focus on delivering education content in the “information age” mean? With a realigned staff, we initiated a major overhaul of our information technology infrastructure and Web presence, including the development of content and learning management systems, to better serve our members. When this process, which typically takes 18 to 24 months, is complete, the resulting new systems will revolutionize the way that we do business.

We launched the ACCP Board Review e-books on the CHEST journal platform to create the www.chestpubs.org site and the first ACCP iPhone®/iPod® Touch app for ACCP-SEEK. A CHEST app also is in development. Innovations like these have not come at the expense of, but rather go hand-in-hand with, providing exceptional content. This summer, CHEST reached its highest impact factor (6.36) – a measure of the average number of citations to articles published in science and social science journals – and ranking (3rd out of 43 respiratory journals) in its 75-year history. Another highlight was the creation of the COPD Alliance, with the American Academy of Nurse Practitioners, American Academy of Physician Assistants, American College of Osteopathic Family Physicians, American College of Osteopathic Internists, and American Osteopathic Association as participating partners. One of the first action items of this multiyear, multimillion-dollar project will be the development of COPD.org, a shared resource designed to house content on COPD awareness and management.

The Alliance was recently featured in the ACCP Leadership Update, one of two e-newsletters launched this summer, as part of our efforts to enhance communication and transparency.

ACCP NewsBrief is a weekly newsletter sent to all ACCP members and includes ACCP/Foundation news and news from the health-care industry.

As I previously noted here, The CHEST Foundation, in consultation with an outside agency, created a strategic architecture, based on the attributes of The Foundation, in the areas of education, care, and community, a microscope to establish a public face that leverages ACCP and Foundation assets related to patient education about the prevention of chest diseases; and a branding tag line, OneBreath™. The College and The Foundation will work in concert to implement their intersecting strategic plans.

As we take stock of all of the products and services that the College offers, this fall, we turn our attention to the future roles of the Networks, advocacy, and global education. After that? Our aspiration is to transform the ACCP into a virtual medical society, where members go online to view a customized dashboard of unsurpassed clinical content in chest medicine.

Mr. Markowski is Executive Vice President and Chief Executive Officer of the American College of Chest Physicians.
‘New Era’ of Antithrombotic Tx

Rivaroxaban • from page 1

Congestion Does Not Predict Heart Failure Outcomes

BY BRUCE JANCIN
Elsevier Global Medical News

STOCKHOLM—The absence of signs and symptoms of congestion at discharge in patients hospitalized for acute decompensated heart failure does not predict a favorable prognosis, contrary to the conventional wisdom.

A new rivaroxaban arm of the international EVEREST trial provides an important lesson in the everyday management of acute heart failure: “The fact that a patient improves in-hospital with diuretics and other medications is not sufficient. It’s not ‘mission accomplished,’” Dr. Mihai Gheorghiade said at the annual congress of the European Society of Cardiology.

“There is a dissociation between signs and symptoms of congestion at discharge and outcomes. In spite of having a very low congestion score, the event rate in EVEREST during 10 months of follow-up was astronomical,” Dr. Gheorghiade, professor of medicine and surgery and associate chief of cardiology at Northwestern University, Chicago.

EVEREST (Efficacy of Vapaspessin Antagonism in Heart Failure Outcome Study With Tolvaptan) was a double-blind study that randomized 4,133 patients with worsening heart failure and a left ventricular ejection fraction of 40% or less to oral vasopressin V2 receptor blocker tolvaptan or placebo within 48 hours of hospitalization.

Standard background therapy in both study arms included diuretics, ACE inhibitor or angiotensin II receptor block-er therapy, a beta-blocker, and an aldosterone antagonist. In the previous-ly reported primary results, tolvaptan proved to have no benefit over placebo during a mean follow-up of 9.9 months (JAMA 2007;297:1319-31).

Dr. Gheorghiade presented a sec-ondary analysis that focused on the 2,061 patients in the placebo group. When these patients were randomized following initial treatment with diuretics, they had a mean congestion score of 4 points based upon their degree of jugular vein distention, rales, and peripheral edema.

At discharge, patients had lost a mean 2.8 kg of body weight, and 72% had a congestion score of 0 or 1.

Although that appears to be a high rate of short-term treatment success, this large subgroup of patients with minimal or no signs or symptoms of congestion at discharge had a 15% all-cause mortality and a 29% rate of rehospitalization for heart failure during the next 9.9 months.

The adverse event rate was even greater in those with a higher congestion score at discharge. In the overall placebo group, all-cause mortality was 26%, with a 40% rate of rehospitalization for heart failure during follow-up. That is a particularly sobering statistic given that heart failure is the No. 1 reason for hospital admission in the Medicare population.

“We’re dealing with a disorder that has an event rate as high as 50%. There is no other medical condition for which patients are hospitalized and are improving with therapy that has a comparable event rate,” the cardiologist observed.

The new EVEREST analysis contains an important message for clinical trial-ists: Using the signs and symptoms of congestion as a key target for treatment during hospitalization as well as the standard end point in acute heart failure studies, as has been common until now, is a recipe for a negative trial result.

“It’s very difficult to beat placebo, because placebo plus standard therapy has a tremendous effect on congestion,” Dr. Gheorghiade said.

“Looking for new therapies that im-prove signs and symptoms of congestion in the whole population is a waste of time unless you’re dealing with special populations who don’t respond to stan-dard therapies, such as patients with low blood pressure,” he noted.

Surrogate markers that are better than congestion are needed to guide therapy. One possibility is B-type natriuretic peptide (BNP). The mean BNP at admission in the placebo group of EVEREST was 1,375 pg/mL. At discharge, BNP was still markedly elevated at 948 pg/mL.

The lesson here is that by treating the signs and symptoms of congestion, you can make patients feel much better, but even though they are now able to walk up a flight of stairs, inside, in terms of renal function and BNP, they are still very sick,” he said.

Until better treatments for acute heart failure are found, the best thing physi-cians can do for affected patients is to identify specific targets amenable to cur-rent pulmonary embolism therapy, such as renal dysfunction or myocardial ischemia, Dr. Gheorghiade concluded.

The EVEREST trial was sponsored by Otsuka. Dr. Gheorghiade has received research grants and serves as a consultant to Otsuka and numerous other pharmaceutical companies.
A new law requiring New York physicians to discuss palliative care and end-of-life options with terminally ill patients is well intentioned, but may not do much to change clinical practice or institutional culture, according to some observers in the state.

The New York Palliative Care Information Act was signed into law by Gov. David Paterson (D) in August. Perhaps as a sign that palliative care is being embraced more readily and becoming better understood, it took just 14 months from the time of the bill’s introduction in the state Senate (S. 4498 and A. 7617) to its signing.

Even so, “whether or not it will change behavior is a bit of a black box,” said Dr. Bradley Flansbaum, director of hospitalist services at Lenox Hill Hospital in New York. “It’s a nice thought, but I don’t know how they’re going to put it into effect,” he said.

Under the law, physicians and nurse practitioners are required to provide a patient who has less than 6 months to live with information and counseling on palliative care and end-of-life options, which would include “the range of options appropriate to the patient, the prognosis, risks and benefits of the various options, and the patient’s legal rights to comprehensive pain and symptom management at the end of life.”

The physician or nurse practitioner can refer the patient to another provider who is willing to meet the legal statute or who is “professionally qualified” to offer the services.

There is no reimbursement offered for the required services. Because it is an amendment to the state’s public health law, violations of the new law could result in penalties or fines. It’s not clear how it will be enforced or what might trigger the penalties; the health department has until the law’s effective date (February 2011) to devise regulations, said David Leven, executive director of Compassion and Choices of New York.

That advocacy group helped devise the legislation and even with increased training on end-of-life issues, too few physicians are having conversations with their dying patients, according to Mr. Leven.

That means patients’ wishes are not being respected, to the detriment of both patients and the practice of medicine.

The organization also hoped that the law would be a catalyst to improving education in the field of end-of-life care in medical school and at the professional level, he said.

Dr. Wendy Edwards, director of the palliative medicine program at Lenox Hill, said that education would be a key component, but there appeared to be no such formal requirements in the law. About 15 years ago, she was part of a group that attempted to get a bill passed to mandate the teaching of palliative care in medical schools, but it did not get anywhere.

She said she wasn’t sure that the new law was the way to increase attention to palliative care, but that it likely came about as a result of frustration and impatience on the part of palliative specialists.

The law will be positive, however, she said. Palliative care won’t just be the standard of care, but will be the law, which gives some backing to hospitals that seek to implement and strengthen their quality of care, and end-of-life care in particular.

But it still will not make it easier for physicians who do not have experience in palliative care, Dr. Edwards said.

“It’s a very hard discussion to have; it’s not something doctors are trained to do,” she noted.

A recent study in non–small cell lung cancer patients found that those who were given palliative care at the time of diagnosis had a better quality of life than did those in standard care (N. Engl. J. Med. 2010;363:733-42). This study may do more to advance the field than does the New York law, Dr. Edwards noted.

Although the Hospice and Palliative Care Association of New York State supported the law, the Medical Society of the State of New York did not. The medical society, which represents a total of 25,000 physicians, opposed the law because of concerns that it would interfere with the way each and every doctor navigates through end-of-life situations with each individual patient, said Elizabeth C. Dears, the society’s senior vice president for legislative and regulatory affairs.

Mandating that information be given on palliative care “may undermine the patient’s belief and conviction in prevailing against their disease and undercut the confidence in their treating physician,” Ms. Dears said.

The medical society also said that physicians are not licensed to provide legal advice in areas such as pain or symptom management. In addition, physicians may not know what they are supposed to be communicating to patients under certain provisions, while still being subject to penalties.

Although the medical society might object to requiring any such talk, both Dr. Flansbaum and Dr. Edwards said that, realistically, the law should be requiring palliative care to be offered sooner in the disease process. In addition, palliative care should be offered to a broader group of patients, such as those who have chronic life-limiting conditions like heart failure.

“By the time you’re invoking palliative care in terminal patients, you’re behind the curve,” Dr. Flansbaum said.

Dr. Paul Selecky, FCCP, comments: Like many other well-intended laws, the impact on the delivery of health care may be minimal. Regardless, ACCP members can and should become champions for palliative care in their practice settings, both inpatient and outpatient. We are uniquely qualified because of our training and experience in critical care and the chronic care of lung disease. Invite your colleagues to join you — “build it and they will come.” The Palliative and EOL Care NetWork welcomes your involvement in their work to improve the care of our patients. Check the ACCP Web site at www.chestnet.org/accpp/networks.
Some patients have ZYVOX written all over them

ZYVOX is indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms:

Nosocomial pneumonia caused by Staphylococcus aureus (methicillin-susceptible and -resistant strains) or Streptococcus pneumoniae (including multiresistant strains [MDRSP]).

Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, caused by Staphylococcus aureus (methicillin-susceptible and -resistant strains), Streptococcus pyogenes, or Streptococcus agalactiae. ZYVOX has not been studied in the treatment of decubitus ulcers.

ZYVOX use is contraindicated in patients with known hypersensitivity to linezolid or any of the other product components.

ZYVOX should not be used in patients taking any medicinal product which inhibits monoamine oxidases A or B (e.g. phenelzine, isocarboxazid) or within 2 weeks of taking any such product.

Unless patients are monitored for potential increases in blood pressure, ZYVOX should not be administered to patients with uncontrolled hypertension, pheochromocytoma, thyrotoxicosis and/or patients taking any of the following: directly and indirectly acting sympathomimetic, vasoactive, and dopaminergic agents.

Unless patients are carefully observed for signs and symptoms of serotonin syndrome, ZYVOX should not be administered to patients with carcinoid syndrome and/or patients taking any of the following medications: serotonin reuptake inhibitors, tricyclic antidepressants, serotonin 5-HT1 receptor agonists, meperidine, or buspirone.

Spontaneous reports of serotonin syndrome have been reported with the coadministration of ZYVOX and serotonergic agents. If signs or symptoms of serotonin syndrome, such as cognitive dysfunction, hyperpyrexia, hyperreflexia, and incoordination occur, discontinuation of one or both agents should be considered.

Myelosuppression (including anemia, leukopenia, pancytopenia, and thrombocytopenia) has been reported in patients receiving ZYVOX. In cases where the outcome is known, when ZYVOX was discontinued, the affected hematologic parameters returned to pretreatment levels. Complete blood counts should be monitored weekly, particularly in patients who receive ZYVOX for longer than 2 weeks.

ZYVOX is not approved and should not be used for the treatment of patients with catheter-related bloodstream infections or catheter-site infections.

ZYVOX has no clinical activity against Gram-negative pathogens and is not indicated for the treatment of Gram-negative infections. It is critical that specific Gram-negative therapy be initiated immediately if a concomitant Gram-negative pathogen is documented or suspected.

Clostridium difficile-associated diarrhea has been reported with use of nearly all antibacterial agents, including ZYVOX, and may range in severity from mild diarrhea to fatal colitis.

Lactic acidosis has been reported with the use of ZYVOX. Patients receiving ZYVOX who develop recurrent nausea, vomiting, unexplained acidosis, or a low bicarbonate level should receive immediate medical evaluation.

Peripheral and optic neuropathy have been reported primarily in patients treated with ZYVOX for longer than the maximum recommended duration of 28 days. If patients experience symptoms of visual impairment, prompt ophthalmic evaluation is recommended.

Convulsions have been reported in patients treated with ZYVOX. In some of these cases, history of seizures or risk factors for seizures was reported.

The most commonly reported adverse events in adults across phase 3 clinical trials were diarrhea, nausea, and headache.

References:

Please see www.zyvox.com for further information.
PEDIATRIC CHEST MEDICINE

Asthma Admissions Drop After Smoking Ban

BY MARY ANN MOON

Elsevier Global Medical News

Dr. Burt Lessnick, FCCP, comments: This study adds evidence that smoking restrictions in public areas improve health of nonsmokers. If a clinically significant reduction in pediatric asthma hospitalizations can be achieved with tobacco smoke reductions in public areas, imagine the possible effects if exposure were reduced in homes.
Bronchodilators Not Needed With 3% Saline?

MINNEAPOLIS – OCTOBER 2010 • CHEST PHYSICIAN BY PATRICE WENDLING

Hypertonic 3% saline has emerged as a popular therapy for inpatient pediatric bronchiolitis, but is typically coadministered with bronchodilators because of a perceived risk of bronchospasm, Dr. Shawn Ralston, lead author, said in an interview.

There is no evidence to show that 3% saline-induced bronchospasm in infants is no different from that with bronchodilators or that it is safe when used in the absence of adjunctive bronchodilators.

Studies in asthmatics, however, have shown bronchodilators with the use of hypertonic saline at higher concentrations ranging from 4.5% to 7% with volumes as high as 10-15 cc, she said. All doses of 3% saline in the current study were 4 ml in volume and nebulized at a 6-L/m flow of oxygen.

There were 644 total doses of 3% saline given to 154 patients aged less than 2 years, hospitalized with acute viral bronchiolitis; 377 doses were given without bronchodilators either 4 hours before or after the saline dose, and 67 doses were given with concomitant bronchodilators.

Four adverse events occurred in the 377 doses, for an adverse event rate of 1%. Dr. Ralston, a pediatric hospitalist at the University of Texas Health Science Center in San Antonio, reported in a poster at the meeting.

One episode of bronchospasm was reported (0.3% of doses given) in a 6-week-old boy who had received 4 cc of 3% saline. He was treated with racemic epinephrine and received a further dose of saline and scheduled albuterol without improvement before transfer to the ICU.

One child experienced coughing during nebulization that resulted in discontinuation of therapy (0.5% of doses given), and two children had excessive coughing that required no intervention. For comparison, one adverse event each was reported with racemic epinephrine nebulization (3.8% doses given) and with albuterol administration (0.3% of doses given), Dr. Ralston noted.

Children who received 3% saline were as likely as those who did not to be given antibiotics (31% vs. 42%) or steroids (6% vs. 15%), and to be transferred to higher levels of care (2.3% vs. 2.5%) or readmitted within 72 hours (1.5% vs. 1.2%).

Dr. Ralston studied 3% saline without bronchodilators to clarify the questions that remain about its utility, mainly because I believe bronchodilator usage in routine bronchiolitis to be unnecessary and wasteful,” she said.

She stressed that the current data cannot be applied to the efficacy of 3% saline and that further trials are needed to evaluate its effectiveness without adjunct bronchodilators.

“My personal strategy … is not to routinely use any nebulized therapy in the majority of my patients,” she said.

Statistical analysis is underway for a large double-blind, randomized trial of nebulized 3% saline vs. normal saline in roughly 700 children up to 24 months of age with viral bronchiolitis, principal investigator Dr. Susan Wu of Children’s Hospital Los Angeles, said in an interview.

The primary end points are adverse events occurred in the majority of patients, she said.
CPR – 50 Years On: Part 1

A t Johns Hopkins Hospital 50 years ago, Kouwenhoven and colleagues synthesized nearly a century of clinical and animal investigation and published the first report of treatment of human cardiac arrest with closed chest massage. This technique is now known as cardiopulmonary resuscitation (CPR). Kouwenhoven and colleagues reported 20 cases; all were successfully resuscitated, with 70% leaving the hospital alive. “Anyone anywhere can now initiate cardiac resuscitative procedures. All that is needed are two hands,” the authors stated. They described five patients: four with intraoperative events and one with peri-infarction ventricular fibrillation (Kouwenhoven et al. JAMA. 1960;173[10]:1064).

The CPR concept promoted by the American Heart Association is the chain of survival consisting of early activation of emergency response, early CPR, early defibrillation when appropriate, and advanced care, primarily advanced cardiac life support (ACLS). Among the more important resuscitation outcomes are return of spontaneous circulation (ROSC), defined as recovery of a palpable pulse any time during CPR, and survival to hospital discharge (STD), particularly neurologically intact survival (Cummins et al. Circulation. 1991;84[2]:960).

Epidemiology

Sudden cardiac arrest occurs as many as 500,000 times in the United States annually. Two-thirds of these events occur outside the hospital (OHCA) at a rate of 0.04% to 0.19% per year. More than 60% of these arrests are due to coronary artery disease. About one-quarter of these arrests involve shockable rhythms—ventricular fibrillation or ventricular tachycardia (Lloyd-Jones et al. Circulation. 2010;121[7]:e46). The proportion of shockable rhythms has decreased substantially through 4 decades of CPR with recent stabilization (Polentini et al. Prehosp Emerg Care. 2006;10[1]:32). Bystanders frequently attempt CPR, but few of these arrests are witnessed. Beware, almost 80% of in-hospital cardiac arrests (IHCA) are witnessed. Almost half occur in ICU areas. Again, approximately one-quarter of these events involve a shockable rhythm, but only a small fraction result from coronary artery disease (Meaney et al. Crit Care Med. 2010;38[1]:101).

Pathophysiology

When effective cardiac action is lost, blood pressure falls precipitously, ultimately decreasing exponentially to a mean static pressure of about 7 mm Hg over 6 to 7 minutes. Coronary artery flow falls faster than arterial blood flow. Sluggish forward flow dilates the rightventricle (Stein et al. Resuscitation. 2003;58[3]:249). The dilated right ventricle presents a significant obstacle to successful resuscitation. Leftward motion of the interventricular septum impairs left ventricular preload and decreases cardiac myocyte length to an ineffective portion of the Frank-Starling curve. Relative equalization of right and left ventricular pressures decreases the gradient for coronary perfusion pressure and flow (Berg et al. Circulation. 2005;111[9]:1136).

The immediate goal in CPR is restoration of coronary and cerebral perfusion. Chest compression helps empty the right ventricle into the pulmonary circulation, providing preload to the left ventricle, augmenting the gradient for coronary perfusion. Emptying the left ventricle improves systemic and cerebral perfusion. Effective coronary flow generally requires a perfusion pressure over 20 mm Hg. At this level of coronary perfusion pressure, peak systolic blood pressure is 60 to 80 mm Hg, cardiac output is 25% to 40% of baseline, and there is sufficient cerebral blood flow to avoid anoxic injury (Andreka et al. Curr Opin Crit Care. 2006;12[3]:198).

Failure to achieve adequate coronary perfusion pressure will result in pulseless electrical activity (PEA) or asystole, even if a shockable rhythm was initially present. Although oxygenation is ultimately necessary for successful resuscitation, the application of positive pressure ventilation by rescuers may compromise the ability to generate adequate coronary perfusion. Increased intrathoracic pressure, especially with rapid ventilation rates, has been shown to increase right-sided pressures and decrease coronary perfusion pressure.


Arrest Outcomes

Now, 50 years after Kouwenhoven and colleagues, there has been improvement in the rates of ROSC for out-of-hospital and in-hospital resuscitations, without improvement in survival to discharge. Survival from OHCA is poor (median STD of 4% for all arrests, 8% with attempted resuscitation). Survival varies considerably by geographic location (range, 3% to 16%). Four factors have been identified as important determinants of OHCA survival: witnessed arrest, bystander CPR, a shockable rhythm, and successful ROSC in the field (Sasson et al. Circ Cardiovasc Qual Outcomes. 2010;3[1]:63).

In IHCA, there is considerable interhospital variability in the rates of ROSC and STD. Average IHCA ROSC rates approach 50%, with STD approximately 18%. For IHCA, rhythm is more important in determining survival than arrest location (critical or noncritical care setting). Survival of IHCA is lower when the arrest occurs at night or on weekends (Peberdy et al. JAMA. 2008;299[7]:778). African Americans have been reported to have lower survival rates than Caucasians, attributed to disproportionate care in poorly performing hospitals (Chan et al. JAMA. 2009;302[11]:1195). The proportion of successful IHCA resuscitations resulting in a ROSC has decreased over the past 50 years. For both arrest locations, approximately one-third of patients with successful ROSC leave the hospital alive.

The ultimate goal in CPR is to maximize the number of patients leaving the hospital alive and neurologically intact. Improved survival could be achieved by a reduction in the number of coronary arrests, improving the ROSC rate, and optimization of postarrest care. Variability in ROSC outcomes suggests a potential for improvement in CPR technique. The relatively unchanged percentage of survivors to discharge in both arrest scenarios points to the need for systematic improvements in post–cardiac arrest care.

Prevention

Within a year of the initial description of CPR, as less-favorable outcomes accumulated, the original Johns Hopkins authors recognized that “not all dying patients should have cardiopulmonary resuscitation attempted. Some evaluation should be made before proceeding. The cardiac arrest should be sudden and unexpected. The patient should not be in the terminal stages of disease, and there should be some possibility of a return to a functional existence” (Jude et al. JAMA. 1961;178[11]:1063).

Today, without advance directives, in-hospital CPR is nearly universal. Methods to reliably predict successful resuscitation and individual survival potential are lacking. Even if these were available, selective application of CPR would only improve percentages of ROSC and STD without increasing the actual number of survivors.

End-tidal carbon dioxide (CO₂) reflects the presence of cellular metabolism and sufficient circulation to deliver carbon dioxide to the lungs. End-tidal CO₂ has shown some promise in monitoring the effectiveness of CPR and as a criterion for termination of resuscitative efforts, where one study found that an initial end-tidal CO₂ of less than 10 mm Hg predicted ROSC failure (Grunec et al. Resuscitation. 2007;72[3]:404). However, further research is needed before valid decisions can be made based on this measurement.

Out-of-hospital arrests could be reduced by improved primary and secondary prophylaxis of coronary artery disease. Wider use of beta-adrenergic blockers and implantable defibrillators may have reduced the number of OHCA events but has unintentionally decreased the proportion of shockable rhythms, making successful resuscitation more difficult to achieve (Agarwal et al. Resuscitation. 2009;80[11]:1251).

Medical Emergency Teams

Many in-hospital arrests have been associated with 6.5 (median) of physiologic instability before the arrest event. To effectively treat unstable patients before an arrest occurred, emergency detection and response systems featuring multidisciplinary teams (ie, rapid response teams, medical emergency teams, and intensive care outreach) were developed and deployed. Early studies suggested effectiveness in reducing in-hospital code events with improved mortality outcomes.

The rapid response concept was enthusiastically embraced by The Joint Commission and the Institute for Healthcare Improvement. Subsequent studies report less consistent success. A meta-analysis of the rapid response literature (17 studies and nearly 1.3 million hospital admissions) documents a 33% reduction in arrest events outside of critical care areas without a decrease in hospital mortality. The authors suggested that the lack of mortality benefit may be due to increasing use of do-not-resuscitate orders or a shift of arrest events from hospital floors to critical care areas (Chan et al. Arch Intern Med. 2010;170[1]:18).

The weakest link in the rapid response system may be the afferent arm: the ability to recognize and promptly initiate effective treatment of a potential crisis.

A recent expert consensus conference

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Optimum outcomes through a team approach

Today, the incidence of asthma and complicated airway diseases in America is rising faster than nearly any other chronic disease. Tackling diseases that so significantly impact public health requires the most innovative clinical thinking; and a dedication to discovering its underlying causes.

In addition to providing state-of-the-art clinical care, Yale-New Haven Hospital has teamed with Yale School of Medicine to create a research hub where industry-sponsored and investigator-initiated studies are continually underway. Our physicians in the Yale Center for Asthma and Airways Disease are at the forefront of groundbreaking research, such as studies that highlight the potential role of the chitinase-like protein YKL-40 as novel biomarkers in asthma. This research suggests that this protein could be useful to identify asthmatics or to characterize disease severity.

Other studies have focused on the pathogenesis of refractory asthma, the vascular basis of asthma and the natural history of asthma.

With their research as the backbone for providing exceptional treatments, our physicians are making life better for our patients with complex airway diseases, and for patients everywhere.

Yale-New Haven Hospital is the primary teaching hospital of Yale School of Medicine. Pulmonology services at Yale-New Haven were ranked 20th by U.S. News & World Report in 2010.
A Successful G-I-N Conference 2010 in Chicago

The American College of Chest Physicians hosted the first US conference for the Guidelines International Network (G-I-N) in August in Chicago. Final attendance broke all previous G-I-N records, with 435 registrants from 30 countries representing North and South America, Europe, Asia, and Oceania. Roughly 40% of the registrants were from the United States.

The conference theme of “Integrating Methods. Improving Outcomes.” brought professionals from across the spectrum of evidence-based medicine. The goal was to learn how to integrate collective knowledge into evidence-based practices that can translate clinical research into interventions to improve patient care and outcomes. Attendees ranged from health technology appraisers and evidence reviewers to guideline developers and implementers, as well as those in quality improvement, medical education, and health-care policy.

The 270 submitted abstracts topped previous achievements for both quantity and quality. Dr Dan Ouellette, FCCP, remarked: “I have seldom attended a medical conference with such excellent speakers, such a diverse group of participants, and such well-organized activities and venues.”

Five plenary panels composed of 15 invited speakers from around the globe covered the following topics:

- Politics, Media, and Guidelines: A Dangerous Mix?
- Implementation: Bridging the Gap Between Evidence and Action
- Challenges in Managing Conflict of Interest in Guideline Development
- A Seat at the Table: The Effects of Consumer Engagement in Guideline Development
- Rationing or Rationality? Health Economics in National Guidance

There were 14 interactive workshops, 125 presentations over 26 moderated concurrent sessions, and nearly 100 posters. The ACCP Health and Science Policy Committee taught a full-day course on the ACCP guideline methodology, which was attended by 98 guideline developers, varying from novice to very experienced. Another 32 individuals attended a course on using evidence-trained consumers in guideline development. Eleven nonindustry exhibitors and supporters showcased their products and services, including the Agency for Healthcare Research and Quality, The Cochrane Collaboration, New York Academy of Medicine, several medical specialty societies, registry developers, medical journal publishers, and clinical decision support vendors.

Networking opportunities are very important when G-I-N attendees convene. The social events included a gala on the last night of the conference. Attendees cruised Lake Michigan’s Chicago shores on the Odyssey II yacht, topping off a conference that will set the bar high for future G-I-N conferences, including the 2011 meeting in Seoul, South Korea.