FDA Panels: ‘No’ to LABA Monotherapy, ‘Yes’ to Combo Tx

Use of LABAs for asthma debated.

BY ELIZABETH MECHCATIE
Elsevier Global Medical News

NEW ORLEANS — Obstructive sleep apnea is common in patients who have recently had a myocardial infarction and is closely linked to the presence of complex ventricular arrhythmias. These findings from an Italian observational study have two important implications worthy of further investigation, Dr. Stefano Fumagalli said at the annual scientific sessions of the American Heart Association.

One possibility raised by the committee members was that a patient with sleep apnea might prove useful in deciding whether to place an implantable cardioverter-defibrillator in a patient with a reduced left ventricular ejection fraction post MI, according to Dr. Fumagalli of the University of Florence (Italy). He reported on 107 consecutive patients who underwent sleep studies 1 month following acute MIs. Seventy-six percent of patients had primary percutaneous coronary intervention for their MI, which was an ST-elevation MI in more than two-thirds of study participants. Men composed 83% of the consecutive patient series. Participants’ mean body weight was 78 kg.

OSA Is Common in Post-MI Patients

BY BRUCE JANCIN
Elsevier Global Medical News

New Orleans — Obstructive sleep apnea is common in patients who have recently had a myocardial infarction and is closely linked to the presence of complex ventricular arrhythmias. These findings from an Italian observational study have two important implications worthy of further investigation, Dr. Stefano Fumagalli said at the annual scientific sessions of the American Heart Association.

One possibility raised by the study is that continuous positive airway pressure for the treatment of obstructive sleep apnea (OSA) in affected patients post MI might improve cardiovascular outcomes. The other potential implication is that an evaluation for OSA might prove useful in deciding whether to place an implantable cardioverter-defibrillator in a patient with a reduced left ventricular ejection fraction post MI, according to Dr. Fumagalli of the University of Florence (Italy). He reported on 107 consecutive patients who underwent sleep studies 1 month following acute MIs. Seventy-six percent of patients had primary percutaneous coronary intervention for their MI, which was an ST-elevation MI in more than two-thirds of study participants. Men composed 83% of the consecutive patient series. Participants’ mean body weight was 78 kg.
New Editor in Chief

► Dr. Paul A. Selecky, FCCP, has assumed the position of editor in chief. Dr. Selecky served as deputy editor and is a 2-year veteran of the newspaper’s editorial advisory board. He is clinical professor of medicine at UCLA, and medical director of the Pulmonary Department, Sleep Disorders Center, and Palisades Medicine Service, Hoag Hospital, Newport Beach, Calif. Dr. Selecky is a past chair of the ACCP Continuing Education Committee and a past president of NAMDRC. He has participated in ACCP committees, including Ethics, Government Relations, and Health and Science Policy. He is a past chair of the Respiratory Care Network.

CHEST PHYSICIAN Adds to Its Editorial Team

New Section Editors

► Dr. Neil Halpern, FCCP, has assumed the position of section editor for Critical Care Commentary. Dr. Halpern is currently chief of critical care medicine and medical director of respiratory therapy at the Memorial Sloan Kettering Cancer Center, New York, and is professor of medicine and anesthesiology at the Weill Medical College of Cornell University. He is a fellow of the ACCP. Dr. Halpern is a prolific author and noted speaker, specializing in the cost and use of critical care in America, technology introduction in critical care, and innovations in ICU design.

► Dr. James Parish, FCCP, has assumed the position of section editor for Sleep Strategies. Dr. Parish is currently chair of the Division of Pulmonary Medicine and associate professor of medicine at Mayo Clinic College of Medicine in Scottsdale, Ariz. He is board-certified in internal medicine, pulmonary medicine, and sleep medicine. He serves the ACCP as vice-chair of the Sleep Medicine Network and as section editor for Sleep. Dr. Parish has served as chair of the ACCP Government Relations Committee and ACCP Governor for Arizona.

New Editorial Advisory Board Members

► Dr. Richard Fischel, FCCP, is currently the director of thoracic oncology at Hoag Hospital in Newport Beach, Calif. He is chief of surgery and director of the Lung Center at Chapman Medical Center, a Medicare-approved lung volume reduction surgery site. He is a board-certified general thoracic surgeon specializing in minimally invasive thoracic surgery. Dr. Fischel also serves as the president of the Orange County Board of the American Lung Association. He received a PhD in surgery and immunology at the University of Minnesota for his work in the field of xenotransplantation.

► Dr. Burt Lesnick, FCCP, is a practicing pediatric pulmonologist in private practice in Atlanta. He is practicing pediatric pulmonologist in private practice in Atlanta. He is a fellow of the ACCP and serves the ACCP as vice-chair of the Pediatric Chest Medicine Network, steering committee member of the Private Practice Network, and member of the Practice Management Committee. He is an alternate ACCP representative to the AMA RUC (RBRRS Update Committee).

Sleep Apnea

The mean apnea-hypopnea index (AHI) was 14.3 events/hr. A normal AHI—that is, a value less than 5—was present in only 26% of patients. Some 40% percent of participants had an AHI greater than 15, indicative of OSA of at least moderate severity.

Fifty-two patients had complex ventricular arrhythmias on 24-hour Holter monitoring. Their mean AHI was 16.8, significantly greater than the AHI of 12.2 in patients without complex ventricular arrhythmias. In a multivariate regression analysis, the strongest predictor of OSA was the presence of complex ventricular arrhythmias, which conferred a 5.8-fold increased risk. Other independent predictors of OSA were an increase in serum creatinine, the presence of aortic insufficiency, and greater body weight.

Dr. Fumagalli noted that, although OSA previously has been linked to hypertension, atrial fibrillation, and heart failure, there have been few prior studies investigating a possible association with ischemic heart disease.

► Dr. Stephen A. Geraci, FCCP, comments: Scientifically, I would bet that many—if not most—patients had heart failure before and/or after SA. Some percentage of sudden death is likely from infarction, though a concept exceedingly difficult to prove. In a perfect world, we would pick up the OSA before their MI, as it is no great stretch to see a relationship between the sympathetic activation causing plaque destabilization and MI. It is likely that nobody’s algorithm has “sleep study” on the post-MI order set. This doesn’t say that we should, but it alerts people to the possibility.
Respiratory Illnesses Tied to Later Asthma

BY SUSAN LONDON
Elsevier Global Medical News

SEATTLE — Children prone to atopy are more likely to develop asthma if they frequently have moderate to severe respiratory illnesses in the first years of life, according to results of a prospective cohort study. Moreover, these illnesses do not protect against other atopic conditions.

Childhood respiratory illnesses cause considerable morbidity, contribute to parental absence from work, and are one of the most common causes of health care visits among the pediatric population, lead author Dr. Christine Virnig reported.

“We sought to further understand the risk factors for and atopic consequences of having frequent respiratory illnesses during the first 3 years of life,” she said.

The investigators analyzed data from 277 children in the Childhood Origins of Asthma (COAST) study, which enrolled a birth cohort of infants who were at high risk for atopic conditions because at least one parent had allergies, asthma, or both.

During the children’s first 3 years of life, parents completed a scorecard when their child had a respiratory illness to document the frequency and severity of these illnesses, said Dr. Virnig, an allergy and immunology fellow at the University of Wisconsin, Madison.

The children’s personal, family, and environmental characteristics were assessed between birth and age 6 years. Total IgE levels, eosinophil counts, levels of antigen-specific IgE to food and airborne allergens, and presence of atopic dermatitis were assessed at 1, 3, and 6 years, and the presence of asthma was assessed at 6 years.

Scorecard results indicated that 8% of the children did not have any moderate to severe respiratory illnesses (MSIs) during the first 3 years of life, whereas 9% had frequent MSIs (12 or more), Dr. Virnig reported.

Not unexpectedly, she said, children who had frequent MSIs were significantly more likely to have attended day care in their first 6 months of life, compared with their counterparts who did not have any MSIs during those months (66% vs. 58%).

But in a surprising finding, children with frequent MSIs also were significantly more likely to have been exclusively breastfed for the first 6 months of life (54% vs. 18%).

This association remained significant even after adjusting for multiple variables, including sex, birth weight, socioeconomic status, maternal education, and the presence of other atopic conditions.

Children who had frequent MSIs also were marginally more likely to have atopy, and 60% of the children who had frequent MSIs also had atopy, compared with 50% of the children who did not have any MSIs.

Children with frequent MSIs also were significantly more likely to have asthma, with an odds ratio of 1.8 (95% CI: 1.4 to 2.2).

The findings suggest that drug interventions aimed at reducing respiratory illnesses, with agents such as calcium-channel blockers or phosphodiesterase-4 inhibitors such as sildenafil, may help reduce risk of asthma.

Before a study is done to test the efficacy of treatments aimed at lowering respiratory illnesses, however, the prognostic role of elevated PASP must be explored in additional studies in different populations, Dr. Virnig cautioned.
Hospitals Test Blood Programs

Blood Costs • from page 1

CRITICAL CARE MEDICINE

JANUARY 2009 • CHEST PHYSICIAN

Voluntary—for Now

These devices measure blood parameters with a very small volume of blood, and the turnaround is 30 seconds. This allows you to strategize how to transfuse the patient,” Dr. Waters said.

With the old 1-hour turnaround time for these tests, “if someone was bleeding, you just gave them everything you had,” he said. “Since we’ve turned to point-of-care testing, we’ve had a 70% decrease in blood use.”

That kind of reduction soon pays for any investment in transfusion-minimizing equipment, Dr. Waters pointed out.

A 2007 study concluded that the intraoperative blood cell salvage service at the Cleveland Clinic, which initially cost $103,500, paid for itself with 2 months’ worth of reduced blood costs (Anesth. Analg. 2007;104:869-75).

Voluntary—for Now

Hospital blood management programs are a growing phenomenon, but by no means a universal one. Accreditation is based on voluntary compliance with standards set forth by the American Association of Blood Banks, but that may change in the future, Dr. Waters said.

“Two years ago, the Joint Commission formed a committee with representatives from interested parties on the provider side to determine if the commission should develop evidence-based blood management performance measures, which everyone thought was a good idea,” Dr. Waters noted.

The committee came up with 19 possible measures, ranging from administrative to clinical, and posted them on the Internet for public comment. That comment period is now over, and the committee is about to winnow the measures down to the most pertinent ones.

Funding could throw a wrench in the process, though, said Linda Hanold, the Joint Commission’s director of quality assessment. Bayer Healthcare Pharmaceuticals funded the initial phase of the project with an unrestricted educational grant. But the money has run out, and Ms. Hanold isn’t sure where the next grant might come from.

“Developing these measures usually takes about 27 months and costs around $600,000,” she said.

If funding is secured, the measures will go through a testing process before publication in 2010. If not, the Joint Commission will publish the prospective performance measures and evidence as a monograph, probably sometime in 2009. Either way, the measures will reside in the Joint Commission’s Measure Reserve Library, ready for implementation if a national mandate is handed down.

Until then, organizations can still make free use of the performance measures, Ms. Hanold said. “They can be used at the organizational level, adapted by individual organizations, or promoted for use by professional societies.”

But implementation of any performance measures will remain primarily local until and unless legislative action makes measurement of blood management a nationally supported priority.

“These measures won’t be used for accreditation until they are endorsed at the national level,” Ms. Hanold said. “I can’t predict when that will be, but it is an issue receiving growing attention.”

Dr. Philip Marcus, MPH, comments:

Things have changed for granted now deserve a second look. We previously used transfusions without thinking twice: A low hematocrit meant a transfusion was going to be ordered. We have learned a lot since those days, and now—with a looming blood shortage and the economics of blood donation, storage, and transfusion—we have re-evaluated how we use this precious commodity. Old blood has already been shown to result in poorer outcomes for those receiving it.
Panels Debate LABAs for Asthma

The FDA and the manufacturers agreed that a LABA should never be used with an ICS for treating asthma, although evidence that ICS use with a LABA “nullifies LABA-related risks is lacking.” Dr. Andrew Mosholder, chief medical officer at the FDA’s Office of Surveillance and Epidemiology (OSE), said at the meeting. There was no disagreement that the risk associated with LABAs and ICS should be removed for all age groups. The Division of Pulmonary and Allergy Drug Products, however, recommended that the LABAs remain on the market for asthma with stronger labeling that addressed their safety risks.

“There’s no doubt” that LABAs have improved the lives of children with asthma, and it would be “irresponsible” to withdraw them from the market, said panelist Dr. Fernando Martinez, director of the Arizona Respiratory Center at the University of Arizona, Tucson. He said he has not prescribed monotherapy with a LABA alone for at least 5 years. “I don’t consider the benefits trivial at all,” said Dr. Jesse Joa, another pediatric pulmonologist on the panel, who described the advent of the drugs as a “revolution” in treating pediatric asthma.

However, the single-ingredient products should not be used for asthma, said Dr. Joa, professor and vice chair of pediatrics at the University of California, Davis. The availability of Advair in three ICS strengths provides dosing flexibility, she noted.

The meeting was held nearly 6 years after the Salmeterol Multicenter Asthma Research (SMART) trial. SMART, a randomized, double-blind study comparing salmeterol inhalation aerosol with placebo in about 26,000 people with asthma who were at least 12 years old (about 12% were 12-18 years old). SMART stopped early, in January 2003, because of recruitment problems.

The study results showed a small but significant increase in asthma-related deaths after 28 weeks among patients using salmeterol, compared with patients on placebo (13 deaths vs. 3 deaths, a relative risk of 4.43), the risk appeared to be higher among black patients. A paradoxical finding was that although some severe events increased with treatment, immediate symptoms improved with treatment. At the December meeting, the FDA presented a new meta-analysis of previously available data obtained from the manufacturers. The data were drawn from 110 trials of Advair, Serevent, Foradil, and Symbicort in about 61,000 people aged 4-100 years (median age 37 years). The median treatment time was about 6 months. About half of patients reported using an ICS at baseline. LABA treatment was associated with an increased risk of asthma-related events, compared with treatment that did not include a LABA (such as an ICS, short-acting β-agonist, or other non-LABA treatment), as measured by a composite endpoint of asthma-related deaths, asthma-related intubations, and asthma-related hospitalizations. There were 20 asthma-related deaths (16 in the LABA group [all in Serevent-treated patients] and 4 in the non-LABA group).

The increased risk associated with LABAs, as measured by the composite endpoint, was higher among blacks, according to the FDA. Children ages 4-11 years appeared to be at the greatest risk, compared with other age groups. In addition, black patients were at a greater risk than other races, and women were at a greater risk than men.

The three FDA advisory committees’ exact vote tallies were as follows: For Advair, the panels voted 26-0 in favor of the benefit-risk profile for adults 18 years and older, and 23-3 with 1 abstention for adolescents 12-17 years. For Symbicort, for which there are far fewer data than for Advair, the panel voted 26-0 with 1 abstention in favor of the benefit-risk profile in adults 18 years and older, and 20-5 with 2 abstentions for adolescents 12-17 years. By a vote of 17-10, the panels agreed that the benefits of Serevent did not outweigh its risks for maintenance treatment of asthma in adults. They reached the same conclusion regarding its use in adolescents (21-6 vote) and in children ages 4-11 years (unanimous vote). For Foradil, the panels agreed that the benefits did not outweigh its risks in adults by a vote of 18-9, and for children by a vote of 21-6. The panels also unanimously agreed that the benefits of Foradil did not outweigh its risks in younger patients.

FDA Committees’ Ruling on Safety of LABAs: What It Means for Clinicians

The Dec. 11, 2008, joint ruling by three of the U.S. Food and Drug Administration’s advisory committees should make clinicians stop and consider the risks and benefits of long-acting β-agonist use in patients with asthma.

Fortunately, the joint panel voted unanimously that both salmeterol and formoterol (which are approved for asthma in children and young adults) should not be taken off the market. Combined with inhaled corticosteroids (ICS), they have dramatically improved the quality of life and the safety of patients, compared with the era in which theophylline was second-line therapy for moderately severe asthma.

The concern stems from the fact that these agents (LABAs) have clearly been shown to increase the risks for the composite endpoint of asthma exacerbations that were taken off the market. Combined with inhaled corticosteroids (ICS), they have dramatically improved the quality of life and the safety of patients, compared with the era in which theophylline was second-line therapy for moderately severe asthma.

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In adult patients, there is little doubt that the combined use of ICS and LABAs has resulted in significant improvement in the quality of life and an overall reduction in asthma exacerbations. The question remains as to what the risks of LABAs are, and whether and whenever they are completely ameliorated by the combined use of ICS.

The main concern regarding the risk of LABAs comes from the 2006 SMART study, in which there were 3 deaths out of 13,000 patients in the placebo group and 11 deaths out of 13,000 patients in the active treatment arm.2 This study also raised concerns that the increased risk of mortality was higher in African Americans. However, only half of patients in the SMART study were using ICS, and documentation of ICS use was not obtained throughout the trial.

The recent FDA analysis of 110 trials of Advair, Serevent, Foradil, and Symbicort should be both a comfort and a warning to physicians. It supports the concept that the combination of ICS/LABA has a very favorable benefit-risk ratio. In this analysis, ICS/LABA (Advair) demonstrated no increased risk of the combined end points (asthma-related deaths, intubations, or hospitalizations); and, importantly, all the LABA deaths were in patients treated with LABA alone. It should also serve as a warning that when LABAs and ICS are written as separate prescriptions (which often occurs for reasons of cost/insurance plans), poorly compliant patients who fill only one medication and rely on their long-acting bronchodilator place themselves at increased risk for severe exacerbation or death.

Overall, I think clinicians should rely on the National Asthma Education and Prevention Program’s Expert Panel guidelines that considered these issues in depth when they wrote the 2007 EPR-3: Guidelines for the Diagnosis and Management of Asthma.3 The combination of ICS/LABA should not be used in patients with mild asthma, and step-down therapy should be considered in every asthmatic patient who has been stable for 3-6 months. Physicians should reserve the use of ICS/LABA as preferred therapy for persistent asthma only when indicated (step 3 therapy in children 5-11 years of age, and in children 12 years of age or older/adult; step 4 therapy in children 0-4 years of age).

There is no doubt that LABAs should not be used as monotherapy for asthma management in either children or adults and that physicians should assess the benefits and risks in patients at high risk for severe exacerbation and in poorly compliant patients.

References
New Medicare Fee Schedule Payments Compared With 2008

The Centers for Medicare & Medicaid Services (CMS) reported the 2009 Medicare conversion factor of $36.0666 as a 1.1% increase over 2008. This conversion factor is actually $2.02 lower than the 2008 Medicare conversion factor of $38.09.

However, Dr. Scott Manaker, FCCP, the ACCP advisor to the AMA Relative Value Scale (RUC) Update Committee (RUC) says, “While the conversion factor is lower, there is actually an increase in overall payment for physician services.”

The overall impact for this year for pulmonary medicine is reported by CMS as a positive 3%. Last year, there was a reduction in physician work relative values as a result of budget neutrality, which was meant to offset increases to the evaluation and management codes, including critical care services, determined through the RUC’s third Five-Year Review.

Organized medicine questioned CMS about this and, in 2009, it has been corrected. “This results in a lowering of the conversion factor but an increase in value for most of the work we do, resulting in higher payments for evaluation and management services; however, there is a lower value for technical and procedural services,” said Dr. Michael Nelson, FCCP, Chair, ACCP’s Practice Management Committee.

The accompanying table of selective pulmonary services and procedures provides some examples of the changes and represents nationalized payment rates. A physician’s individual rate is affected by a geographic practice cost index factor based on where your practice is located.

The final rule can be reviewed at www.access.gpo.gov/su_docs/fedreg/081119c.html. Visit the expanded and continually updated ACCP Practice Management Web page at www.chestnet.org/practice/pm/index.php.

### Medicare Physician Fee Schedule Nationalized Payments (Subject to Geographic Adjustments)

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Meet New Ambassadors Group Chair

Born and raised in Richmond, Virginia, Susan Mathers is delighted to serve as the Ambassadors Group Chair for 2008-2009. Susan is the wife of Dr. James L. Mathers, Jr., FCCP, the ACCP President for 2008-2009. She has two older brothers, a younger sister, and a father who is doing great at 85. She quit work to help her dad take care of her mother who had Alzheimer disease for 14 years and says it taught her a lot about life and what is really important. Susan has one son, Matthew, 28, who recently got engaged.

Susan went to Stratford College in Danville, VA, and majored in art history (and having fun). She loves to walk outside on walks (weather permitting) and, in addition, enjoys decorating, hiking for unusual bargains, and kayaking. Her greatest joy is doing things for and with her husband, Jim, their families, and friends.

As Ambassadors Group Chair, she would like to continue the presentations at the Chest Meeting and meetings from international members of the Ambassadors Group. The presentations on India at CHEST 2008 by Anita and Pratima Mathur and Sabha Raos were particularly enjoyed by all. She noted that being an Ambassadors Group member has afforded her the opportunity to make many new friends from all over the United States and the world. She would like to present the Lung Lessons program, developed by The CHEST Foundation, in schools, similar to what Susan Raole does when accompanying her husband on ACCP trips. She invites other members to help present these lessons, as well.

As Chair, she welcomes new ideas or worthwhile projects that will help further the work of The CHEST Foundation. One area she would like to focus on is the damage secondhand smoke causes to children and, in particular, those with asthma. “We need to educate parents and other family members who smoke that secondhand smoke affects the lungs of their children and exacerbates asthma,” she said. “The result is not only frequent physician and emergency room visits but possible long-term lung damage.”

Stereolâ® Talc Powder provides uniform, consistent and clean administration.

STERILE TALC POWDER™

Infection: Complications reported include enuresis.
Respiratory: Genotoxicity was tested in cultures of rat pleural mesothelial cells (RPMC) as unscheduled DNA synthesis (UDS) and sister chromatid exchanges (SCEs). None of the talc samples (which were asbestos-free) produced any evidence of SCEs. None of the talc samples produced any evidence of UDS.

CLINICAL PHARMACOLOGY
Mechanisms of Action
The therapeutic action of talc instilled into the pleural cavity is believed to result from induction of pleurodesis, a non-specific desquamative inflammation of the pleura. The resulting pleural adhesion prevents reaccumulation of pleural fluid. This allows the possibility of talc administration to mice at 20 mg/kg. Approximately 5 days after talc instillation, 50% of the talc was still present in the pleural cavity. Talc has not been shown to cause pleurodesis. The most often reported adverse effects are in patients who had previous pleurodesis.

INDICATIONS AND USAGE
The talc powder, administered via the chest tube, is indicated as a sclerosing agent to decrease the recurrence of malignant pleural effusions in symptomatic patients.

CONTRAINDICATIONS
None known.

WARNINGS
None.

PRECAUTIONS
1. Future procedures: The possibility of the future diagnostic and therapeutic procedures involving the thorax to be treated must be considered prior to administering Sterile Talc Powder. The pleural spaces may preclude subsequent diagnostic or therapeutic pleural procedures or instrumentation, including percutaneous procedures, thoracentesis, thoracoscopy, and transbronchial lung biopsies.

2. Talc In Potentia Curative Disease: Talc has not been shown to cause pleurodesis. Talc should not be used for the potential curative pleurodesis in patients with a life expectancy of less than 3 months.

3. Pulmonary complications: Acute pneumonitis and Acute Respiratory Distress Syndrome (ARDS) may occur. ARDS was reported in one patient who was treated with talc. The ARDS reports of ARDS have occurred after treatment with a relatively large talc dose (20 to 50 g administered at the chest tube sites). One patient died one month after talc was administered for pleurodesis.

DRUG INTERACTIONS
Talc administration is the administration of a second sclerosing agent after prior talc pleurodesis may be diminished by the appearance of the antitryptic activity of talc.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies on the carcinogenicity of talc have been performed using standard doses which prevent tumor induction in the animal. Talc has no known mechanism for animal carcinogenesis. In a 3-yr. carcinogenicity study in Sprague-Dawley rats, talc had no effect on the incidence of tumors and no increase in any of the tissues examined.

Pregnancy Category B: An oral administration study has been performed in the rabbit at 20 mg/kg. Approximately 1/10th higher than a human dose in rodent species. No evidence of teratogenic activity due to talc. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should not be used during pregnancy unless the benefit outweighs the risk.

Pediatric Use: The safety and efficacy of Sterile Talc Powder in pediatric patients have not been established.

Geriatric use: The estimated mean and median ages of patients treated with talc from clinical studies (single arm or randomized) were 60 and 50 years, respectively. No analyses to specifically evaluate the safety and efficacy in the geriatric population have been reported.

ADVERSE REACTIONS
Intrathoracic administration of talc has been described in medical literature reports involving more than 1000 patients. Patients with malignant pleural effusions were treated with talc instillation through a chest tube. At times, a chest tube was replaced to continue talc administration. The effects of talc are believed to be the direct result of the talc administered along with its administration. The most often reported adverse reactions are intercostal pleural and/or subpleural.

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NEWS FROM THE COLLEGE

January 2009 • CHEST PHYSICIAN

Stereolâ® Talc Powder is supplied in a 100 mL brown glass bottle containing 5 g of talc. The bottle is closed with a gray stopper and covered with a flip-off seal.

Stor age: Store at Room Temperature (15-25°C). Protect against sunlight.

DISTRIBUTED BY: Bryan Corporation, Woburn, MA 01801

HOW SUPPLIED
NDC 61236-208-05: Sterile Talc Powder is supplied in a 100 mL brown glass bottle containing 5 g of talc. The bottle is closed with a gray stopper and covered with a flip-off seal.

Storage: Store at Room Temperature (15-25°C). Protect against sunlight.
The topic of sleep apnea (OSA) treatment has been controversial since the early 2000s. In 2001, there was a systematic review sponsored by the ACCP to review the utility, cost effectiveness, and limitations of portable equipment, but there was not support of the use of PM in the unattended setting for the diagnosis of OSA. The American Academy of Sleep Medicine, and the American Thoracic Society, found that the evidence in the literature at that time did not support the use of PM.

In 2003, as a result of this review, CMS determined that only polysomnography in a facility-based sleep laboratory should be used to identify patients with OSA. CMS then received a request to modify this decision to include the use of portable multichannel HSAT devices as an alternative to facility-based polysomnography in the evaluation of OSA. Despite this, CMS reported their final decision in April 2005.

CMS found that the evidence at that time was not adequate to support and, hence, reimburse for the use of unattended portable multichannel sleep testing adequate for the diagnosis of OSA and the prescription of CPAP.

Just a few years later, in March 2007, at the request of the American Academy of Otolaryngology-Head and Neck Surgery, CMS agreed to open up on the issue and review it again. Some observers noted that the rapid rise in Medicare reimbursements for sleep studies—$62 million in 2001 to $215 million in 2005—was a concern. It was also recognized that several large organizations, such as Kaiser Permanente and some Veterans Administration hospitals, reported using PM successfully in the diagnosis of OSA and treatment with CPAP.

A long review process followed, involving expert review of the medical literature and written public opinion. The ACCP provided written comments based on feedback from members of the ACCP Sleep Institute and Sleep Medicine Network. Additionally, an open public hearing was held by an expert panel at CMS headquarters in Baltimore, MD, on September 12, 2007.

On March 13, 2008, a decision memo was issued by CMS (CAG-068932) that, for the first time, allowed CPAP coverage based on the results of an HSAT. After receiving commentary from the ACCP and many other national organizations, the final national coverage determination (NCD) memo was posted in October and contained several specific provisions for reimbursement that will change the practice of sleep medicine (www.cms.hhs.gov/transmittals/downloads/R96NCD.pdf).

The NCD placed an emphasis on providing quality service to the patient before and after the sleep study in the treatment of OSA and not just on interpretation of the sleep study. This NCD dictated several new stipulations that determined the rules for CPAP reimbursement from the four durable medical equipment Medicare administrative carriers (DME MACs). The good news is that the regulations from all four are exactly the same.

There are some key features of which physicians who care for patients with OSA should be aware:
OSA should be aware. Initially, the patient must have a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for OSA. This evaluation needs to include the following elements:

- Symptoms and signs of sleep-disordered breathing, including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, and witnessed pauses in breathing
- Duration of symptoms
- Validated sleep hygiene inventory, such as the Epworth sleepiness scale

Continued from previous page

Career Initiative Unveiled at CHEST 2008

In a new education initiative aimed at promoting careers in pulmonary, critical care, and/or sleep medicine, the American College of Chest Physicians invited medical students and residents in the northeast region of the county to attend CHEST 2008 in Philadelphia. The ACCP’s primary goal was to provide students and residents an opportunity to attend the ACCP annual meeting and benefit from leading experts in these fields. Students and residents enjoyed complimentary registration and were able to participate in a rich educational day of programming, consisting of an overview and orientation to pulmonary, critical care, and sleep medicine career opportunities; scientific abstract presentation sessions; complimentary lunch in the exhibit hall; poster grand rounds; and hands-on clinical education in the Simulation Center. Students were also invited to attend the CHEST Challenge Championship and Awards Reception as an educational and networking opportunity.

Based on the success of this year’s program, medical students and residents on the West coast will be invited to attend a similar program at CHEST 2009 in San Diego, CA.
BROVANA is indicated for the long-term, twice-daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. BROVANA is for use by nebulization only.

Important Safety Information

Long-acting beta2-adrenergic agonists may increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta2-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol may apply to arformoterol (a long-acting beta2-adrenergic agonist), the active ingredient in BROVANA.

BROVANA is not indicated for the treatment of acute episodes of bronchospasm, i.e., rescue therapy, and does not replace fast-acting rescue inhalers.

BROVANA should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition.

BROVANA should not be used in conjunction with other inhaled, long-acting beta2-agonists. BROVANA should not be used with other medications containing long-acting beta2-agonists. Patients who have been taking inhaled short-acting beta2-agonists on a regular basis should be instructed to discontinue their regular use and to use them only for symptomatic relief for acute respiratory symptoms.

As with other inhaled beta2-agonists, BROVANA can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, BROVANA should be discontinued immediately and alternative therapy instituted.

BROVANA, like other beta2-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, blood pressure, and/or symptoms.

BROVANA, as with other beta2-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval because the action of adrenergic agonists on the cardiovascular system may be potentiated by these agents.

The most common adverse events reported in patients taking BROVANA, and occurring more frequently than in patients taking placebo, were pain (8% vs 5%), chest pain (7% vs 6%), back pain (6% vs 2%), diarrhea (6% vs 4%), and sinusitis (5% vs 4%).

References:
3. Data on file, Sepracor Inc. CSR-091-050, Table 14.2.11.

Not an actual patient.

* BROVANA has not been demonstrated to have an impact on progression of disease or survival of patients with COPD.
1 Clinical trial A was one of two identical 12-week, double-blind, placebo- and active-controlled, randomized, multicenter, parallel-group studies that included a comparison of BROVANA 15 mcg twice daily with placebo.

The results from clinical trial B were similar to clinical trial A.
better, living better*

with BROVANA just twice a day

Sustained relief and twice-daily dosing help COPD patients get back to daily living

**Sustained effective relief for a full 12 hours**

Mean change in FEV1 over time at 12 weeks: clinical trial A\(^2,3\)

<table>
<thead>
<tr>
<th>Hours Postdose</th>
<th>FEV1 Mean Change From Baseline (mL)</th>
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<tr>
<td>0</td>
<td>-100</td>
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<tr>
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<td>-50</td>
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**BROVANA** 15 mcg twice daily (ITT, n=141); baseline FEV1=1.15 L vs placebo (ITT, n=143); baseline FEV1=1.20 L

160 mL difference vs placebo\(^6\)

\(^1\)100-mL increase from study baseline in mean FEV1 at 12 hours (Week 12), while the placebo group had a 60-mL decrease.\(^1\) Overall efficacy was maintained throughout the 12-week trial. Some tolerance to the bronchodilator effect of BROVANA was observed after 6 weeks of dosing (at the end of the dosing interval), although the FEV1 improvement remained statistically significant. This was not accompanied by other clinical manifestations of tolerance.\(^2\)

**Relief that works within minutes**

**6.7-minute median time to onset** (15% increase in FEV1)\(^1\)

- BROVANA is not indicated for the treatment of acute episodes of bronchospasm.
- Patients on BROVANA should always have access to rescue therapy

**Well tolerated**

- Patients receiving BROVANA 15 mcg twice daily experienced an incidence of adverse events (AEs) comparable with placebo\(^1\)
- Most common AEs were pain, chest pain, back pain, diarrhea, and sinusitis

**Nebulized bronchodilator therapy**

for patients with COPD

**Have your patients experience BROVANA**

For samples, ask your Sepracor representative

![BROVANA](image)

Get them back into daily living
BROVANA® (arformoterol tartrate) Inhalation Solution 15 mcg/2 ml: *potency expressed as arformoterol for ORAL INHALATION ONLY BRIEF SUMMARY

WARNINGS: Long-acting beta, adrenergic agonists may increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta, adrenergic agonist (LABA) monotherapy to LABA plus inhaled corticosteroid (ICS) therapy demonstrated an increased risk of asthma-related death in patients receiving the LABA alone (5 mg/m2 dose in adults on a mg/m2 basis).

INDICATIONS AND USAGE: BROVANA (arformoterol tartrate) Inhalation Solution is indicated for the long-term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. BROVANA is for use by nebulization only. BROVANA should be used in adults only. BROVANA is not indicated for the treatment of acute COPD exacerbations.

DOSAGE AND ADMINISTRATION: Adverse events for which the rates in the BROVANA 15-mcg twice-daily group was equal to or greater than 2% and greater than that for the placebo group were (BROVANA and placebo rates, respectively) pain (8%, 5%), chest pain (7%, 6%), back pain (6%, 2%), diarrhea (6%, 4%), sinusitis (5%, 4%), leg cramps (3%, 2%), and arthralgia (3%, 2%).

Parameters should be given the following information: Patients should be instructed to use BROVANA appropriately and how it should be used in relation to other medications to treat COPD they are taking.

PRECAUTIONS, General: Wolff-Parkinson-White syndrome. If patients have Wolff-Parkinson-White Syndrome, the use of beta blocking agents is contraindicated. If Wolff-Parkinson-White Syndrome is present, the use of BROVANA should be restricted to patients in whom the benefit of the medication outweighs the potential risk.

CLINICAL PHARMACOLOGY: Other long-acting beta-agonists have been associated with an increased risk of asthma-related death. BROVANA is not indicated to relieve acute respiratory symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting, beta-agonist (and/or inhaled corticosteroids). Asthma patients should be instructed to seek medical attention if their symptoms become persistent or at night. Patients should be instructed that if severe hypotension occurs, the patient should be instructed to use BROVANA by nebulizer only and not to inject or swallow this inhalation solution. Patients should protect BROVANA from moisture and/or diastolic blood pressure, pulse rate and electrocardiograms have been seen infrequently in individual patients in controlled clinical studies with arformoterol. Doses of the related beta2-agonist albuterol, inhaled or nebulized, have been greater than 15 mg per day (as salbutamol sulfate) have been used in controlled clinical studies with arformoterol.

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glucocorticoids (Reid et al. Allergy Clin Immunol 1993; 92:6) are not suitable for immunotherapy, as they are at risk for severe bronchospsasm. Evaluation of sensitization is a prerequisite.

While subcutaneous immunotherapy is the established treatment, sublingual immunotherapy is a viable alternative, since no serious reactions have been reported, and self-administration obviates frequent physician visits for injections (Mungan et al. Ann Allergy Asthma Immunol 1999; 82:485).

**Bronchial Thermoplasty**

Increased airway smooth-muscle mass is observed in patients with severe or fatal asthma (Carroll et al. Am Rev Respir Dis 1993; 147:405). Bronchial thermoplasty (BT) delivers radiofrequency energy to the bronchial wall through a catheter with expandable four-arm-basket via bronchoscopy. While airway cells are susceptible to heat injury, complete anatomic reconstruction occurs except for smooth muscle (Cox et al. Eur Respir J 2004; 24:659).

In the Asthma the Intervention Trial (Cox et al. N Engl J Med 2007; 356:1327), where 110 moderate to severe persistent asthmatics were randomized to standard medical care with and without BT, those who received BT had fewer exacerbations; improved peak flow rates; more symptom-free days; and better symptom scores, quality of life, and asthma control questionnaire responses. As the study was not blinded, improved subjective outcomes with BT that did not correspond to objective measurements (FEV1, BHR) are a concern, and results comparing BT with sham bronchoscopy are eagerly awaited.

Asthma treatment is evolving beyond steroids and bronchodilation and into disease-modifying interventions with immunotherapy and BT.

**Critical Care**

CHEST 2008 provided an excellent opportunity for the Critical Care NetWork to reflect on a very successful year. The NetWork meeting was highlighted by a presentation by Dr. Kay Guentupalli, FCCP, ACCP President-Elect and recipient of the 2007-2008 Distinguished Scholar Award, for her project, “Development and Validation of the Educational Materials for Use by the Critical Care Health-care Team and Patient/Family for Use in the Critical Care Units.”

The NetWork also sponsored a wide variety of outstanding educational offerings.

The ACCP is sponsoring several critical care courses at its Simulation Center for Advanced Clinical Education in Northbrook, IL, in early 2009. For more information or to register, visit www.chestnet.org/simulation/index.php.

We would like to invite interested members to join one of the six subcommittees that are responsible for the majority of our NetWork activities. Please visit www.chestnet.org/networks/critical_care/index.php for more information.

We are working very hard to increase your resources on the Critical Care NetWork Web page, and we need your help!

We are looking for individuals who are interested in submitting clinical vignettes, images, and tracings for the NetWork Online Puzzler.

Submissions should be under 800 words and include a summary of relevant clinical information and a brief discussion of one to two key points with up to five references. Contact me at alexander.niven@us.army.mil with submissions or questions.

**Critical Training in Critical Care**

**Ultrasoundography:**

**Fundamentals in Critical Care**

**April 24-26, 2009**

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**Ft. Lauderdale, FL**

Don’t miss this robust educational experience in ultrasound training, featuring hands-on skill-building opportunities with live patient models. The three critical components of ultrasound—knowledge base, image interpretation, and image acquisition—will be covered in depth, so you develop proficiency in this emerging field.

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Well-established, busy 11-physician single-specialty Pulmonary practice in suburban Atlanta, Georgia, looking for one or more BC/BE Pulmonary/Critical Care physicians. Sleep certification is a plus. Practice includes all aspects of pulmonary medicine, including critical care, sleep medicine, out-patient clinic, pulmonary rehab and clinical research. Practice located at two large acute-care hospitals, with one being the busiest ER in Georgia, and also rounds at a nearby long term acute care hospital. Competitive salary with bonus potential, generous benefits package and malpractice coverage. Fax CV to: 770-792-1738.

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for Pulmonary Group

Pulmonary/Sleep Medicine/Critical Care. Sixth physician for Pulmonary Group. Eastern Connecticut. One hospital coverage and Sleep Center. Near to shore. Easy access to New York and Boston. Many cultural and recreational activities. Partnership available. Send CV to Chest #95, P.O. Box 996, Abingdon, MD 21009.

Intensivist
NEW YORK – Desirable Coastal Long Island Community. Intensivist needed for new program at state of the art community hospital. Just a short drive or train ride to metropolitan area. Excellent schools and beautiful homes. Excellent salary and earning potential and full benefits. Submit CV to flidcomd@hotmail.com

Pulmonary Critical Care Opportunity
Northern California

Sutter Medical Group (SMG) is seeking a BE/BC Pulmonary Critical Care physician in Auburn, CA. Good call schedule. Option for hospitalist work if desired.

SMG offers an income guarantee with shareholder track, generous compensation, benefits, and retirement package.

Sutter Auburn Faith Hospital is a medium sized hospital with a 24/7 hospitalist program, open ICU, high resolution CT scan, cardiac cath lab, full nuclear medicine department, bronchoscopy suites and a pulmonary function laboratory.

Auburn is centrally located in the Sierra Nevada foothills between Sacramento and Lake Tahoe. Auburn is close to shopping and restaurants, and offers a variety of outdoor activities.
Roughly two-thirds of non-atopic children with persistent asthma also have gastroesophageal reflux disease (GERD), and that disease appears to exacerbate the asthma, Dr. Aaron Kobernick said at the annual meeting of the American College of Allergy, Asthma, and Immunology. Studies of GERD treatment in this context have focused on asthma medication use and have been relatively short.

“We know that with asthma, short-term studies are just not as reliable,” Dr. Kobernick said. “Because asthma is a disease of exacerbation attainment also has the longer we look at asthma and outcomes in asthma, the better off we are going to be.”

In a prospective 2-year study, Dr. Kobernick and his colleagues enrolled 62 children between the ages of 6 and 11 years who had moderate persistent asthma but did not have atopy or risk factors for wheezing. At baseline, all of the children were asymptomatic and extended esophageal pH monitoring. The latter testing revealed that the majority of the children also had GERD. Of the children with asthma and GERD, 32 were treated with medical therapy for GERD consisting of proton pump inhibitors and prokinetic agents and 12 underwent surgical fundoplication; they also received asthma therapy.

The 18 children who did not have co-morbid GERD received asthma therapy alone (2.9), Dr. Kobernick reported. The difference between the medically and surgically treated groups was not significant.

The percentage of children who had an improvement in forced expiratory volume in 1 second (FEV1) by more than 20% from baseline was significantly greater in the groups given medical treatment (47%) and surgical treatment (58%), compared with the group given asthma therapy alone (28%).

Similarly, the percentage of children having an improvement in forced expiratory volume in 1 second (FEV1) by more than 20% from baseline was significantly greater with added medical treatment (22%) and surgical treatment (23%), compared with asthma therapy alone (11%).

Dr. Kobernick concluded that the results may underestimate the benefit of anti-GERD treatment, because many children had been previously treated for asthma.

Dr. Kobernick reported that he had no conflicts of interest in association with the study.

TREATING GERD IN ASTHMA IMPROVED LUNG FUNCTION

By Susan London

In a prospective 2-year study, Dr. Kobernick and his colleagues enrolled 62 children between the ages of 6 and 11 years who had moderate persistent asthma but did not have atopy or risk factors for wheezing. At baseline, all of the children were asymptomatic and extended esophageal pH monitoring. The latter testing revealed that the majority of the children also had GERD. Of the children with asthma and GERD, 32 were treated with medical therapy for GERD consisting of proton pump inhibitors and prokinetic agents and 12 underwent surgical fundoplication; they also received asthma therapy.

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"The treatment of GERD in asthma, the better off we are going to be."
In treatment of gram-negative infections caused by susceptible gram-negative microorganisms

AZACTAM is indicated for

• Complicated and uncomplicated urinary tract infections, lower respiratory tract infections, septicemia, skin and skin-structure infections, intra-abdominal infections, and gynecologic infections

• Adjunctive therapy to surgery in the management of infections caused by susceptible organisms. Effective against most commonly encountered gram-negative aerobic pathogens seen in general surgery

Important Safety Information: AZACTAM is contraindicated in patients with known hypersensitivity to aztreonam or any other component in the formulation.

While cross reactivity of aztreonam with other beta-lactam antibiotics is rare, this drug should be administered with caution to any patient with a history of hypersensitivity to beta-lactams.

Clostridium difficile-associated diarrhea (CDAD) occurs with use of nearly all antibacterial agents, including AZACTAM, and severity ranges from mild diarrhea to fatal colitis. Antibacterial agent use alters the normal flora of the colon leading to overgrowth of C difficile. Consider CDAD in all patients presenting with diarrhea following antibiotic use. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C difficile may need to be discontinued.

In patients with impaired hepatic or renal function, appropriate monitoring is recommended during therapy.

Please see brief summary of prescribing information on adjacent page.

think negative.